

# Chicago

 **SWOG** | CANCER  
RESEARCH  
NETWORK

OCTOBER 2-5, 2019  
CHICAGO, ILLINOIS



# Let's Get Digital!

If there's a watchword for our meeting here in Chicago, it's "digital."

We've got general plenary speakers talking about digital therapeutics – evidence-based, software-driven therapies used in disease prevention, management, and treatment. Digital therapeutics are often used alongside traditional drugs, and can be used to influence behavior, urging patients to exercise more, eat healthier, or remind them to take their medication. SWOG will be the first to test an innovative digital medicine system in a clinical trial. We will run a pilot involving use of an ingestible sensor, wearable sensor patch, and a physician web portal to track adherence to cancer analgesics.

Of course, this all involves regulatory review and approval. So, here's our chance to learn more about the processes. At the plenary, we'll have speakers discuss the implications of digital therapeutics for cancer clinical trials. They'll also discuss efforts the U.S. Food and Drug Administration is making to regulate these new



treatments and therapies. Last year, FDA approved the first digital therapeutics, including a 12-week cognitive behavior program used to treat substance abuse and an inhaler with built-in sensors that can help prevent and better treat asthma and COPD.

Here in Chicago, we'll also offer our first member-wide Twitter training. It's a product of our digital engagement committee, and a part of their strategic plan. It is open to all SWOG members interested in learning about the benefits and pitfalls of Twitter for cancer researchers, and in getting the basics of joining the platform, which has more than 320 million users worldwide. More than 7,000 people follow our SWOG feed!

Our meeting also features some great clinical trial kick-off meetings, and our SWOG NCORP Research Base Clinical Trials Workshop.

Have a wonderful time with your colleagues here in one of my favorite places.

A handwritten signature in black ink that reads "Charles D. Blanke MD".

**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 present.

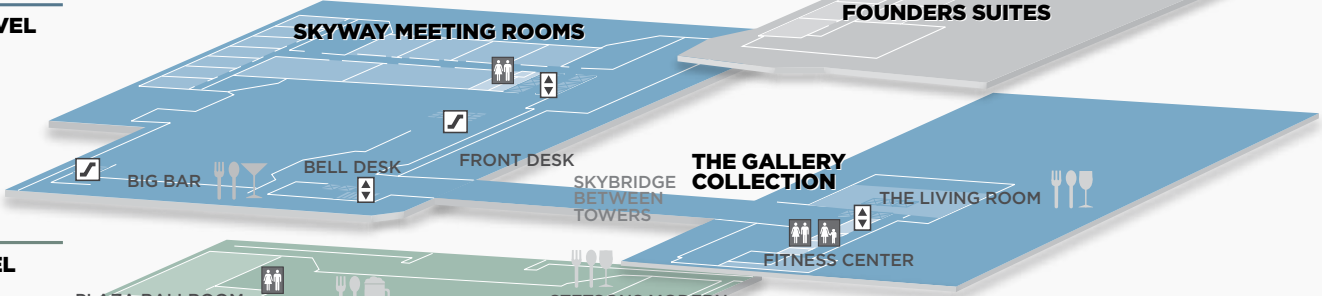
**CROSSING BETWEEN TOWERS:** Cross between towers via the Skybridge or the Concourse. You may also cross from the lobby level via the crosswalk on Stetson Drive.

- 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 Level
- STETSONS 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

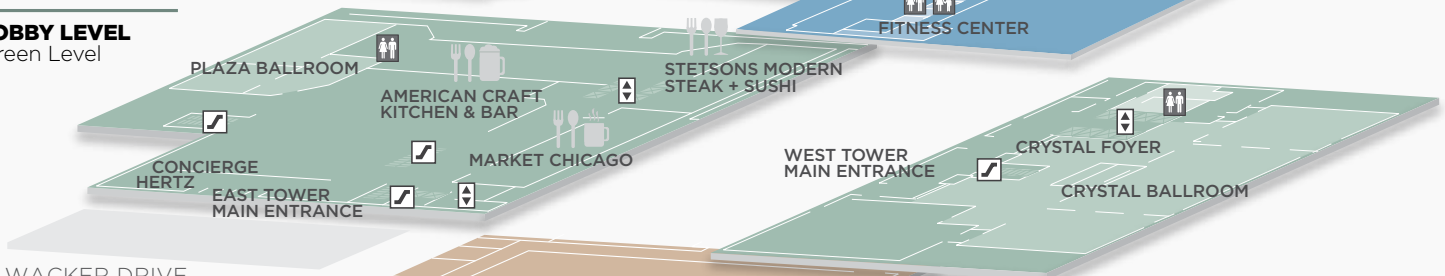
# EAST TOWER

# WEST TOWER

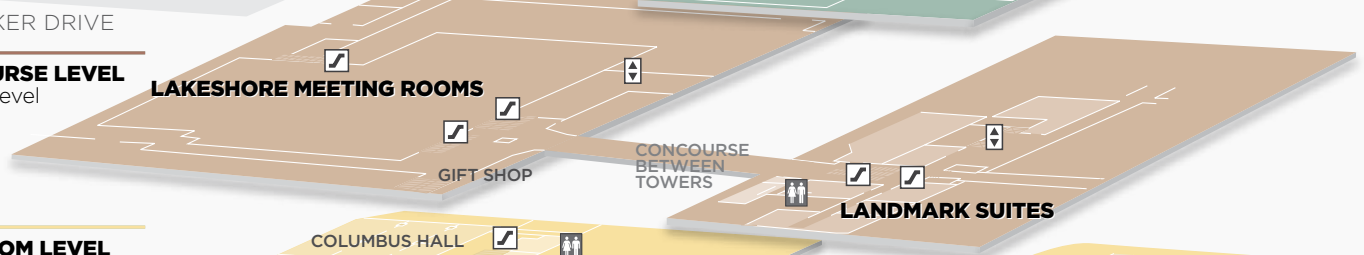
## SKYWAY LEVEL Blue Level



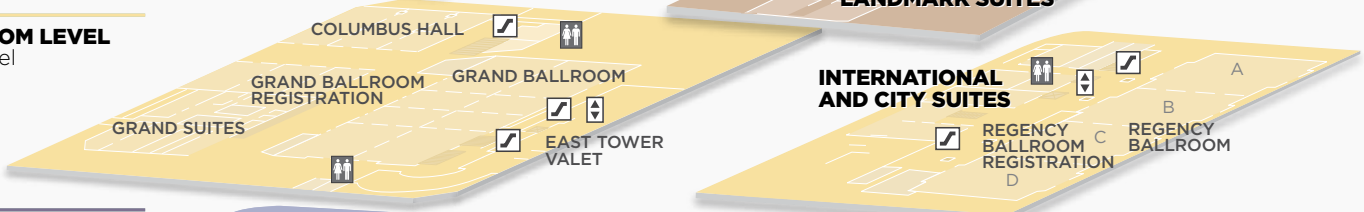
## LOBBY LEVEL Green Level



## CONCOURSE LEVEL Bronze Level



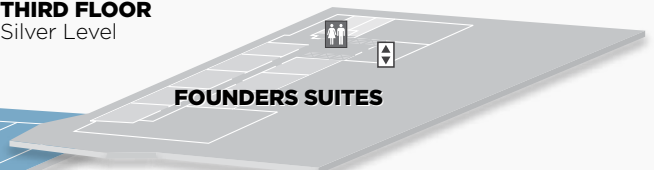
## BALLROOM LEVEL Gold Level



## RIVERSIDE EXHIBIT LEVEL Purple Level



## THIRD FLOOR Silver Level



- ELEVATORS
- ESCALATORS AND STAIRS
- RESTROOMS
- MOTHER'S ROOM

# 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 3, 3:30 – 5:00 pm. Speakers and topics will include:

Welcome and Introduction

**Lee Ellis, MD, FASCO**

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



Biomarker Studies in S1314:  
The "CoXEN" Trial

**David J. McConkey, PhD**

Director, Johns Hopkins Greenberg  
Bladder Cancer Institute  
The Erwin and Stephanie Greenberg  
Professor of Urology, Brady Urological Institute  
The Johns Hopkins University School of Medicine



Accessing Biospecimens for Translational Studies

**Elise C. Kohn, MD**

Head, Gynecologic Cancer Therapeutics  
Head, Gastrointestinal Neuroendocrine  
Cancer Therapeutics Lead,  
NCTN Core Correlative Sciences Committee  
National Cancer Institute



Inhibiting KRAS in the Clinic: Are We There Yet?

**Alex A. Adjei, MD, PhD**

Professor, Oncology and Pharmacology  
Consultant, Division of Medical Oncology  
Director, Early Cancer Therapeutics Program  
Leader, Lung Cancer Program  
Mayo Clinic, Rochester, MN



## Plenary Part II

Regency A-C (Ballroom Level, West Tower)

The fall meeting's general plenary will take place Friday, October 4, 12:00 – 2:00 pm. Speakers and topics will include:

Chair's Welcome and Update

**Charles D. Blanke, MD, FASCO**

SWOG Cancer Research Network Chair  
Oregon Health & Science University



Digital Health Evolution and Evidence:  
From Social Media to Digital Drugs

**Don Dizon, MD, FACP, FASCO**

Professor  
Brown University  
Director of Women's Cancers  
Lifespan Cancer Institute  
Director of Medical Oncology  
Rhode Island Hospital  
Chair, Digital Engagement Committee  
SWOG Cancer Research Network



The Second Coming of the Gutenberg Press: Digital  
Dissemination of Information to Patients and Physicians

**Mark A. Lewis, MD**

Director of Gastrointestinal Oncology  
Intermountain Healthcare  
Chair, Adolescent and Young Adult Committee  
Member, Digital Engagement Committee  
SWOG Cancer Research Network



Digital Transformation of Trials and Treatments:  
It's Not (All) About the Technology

**Bonnie J. Spring, PhD**

Director, Institute for Public Health and Medicine  
Chief of Behavioral Medicine,  
Department of Preventive Medicine  
Professor of Preventive Medicine,  
Psychiatry and Behavioral Sciences  
Northwestern University Feinberg School of Medicine



Harry E. Hynes Memorial Lecture:  
Genomic Testing for Population Risk Stratification

**Olufunmilayo Olopade, MD, FACP**

Walter L. Palmer Distinguished Service Professor  
of Medicine and Human Genetics  
Director, Center for Clinical Cancer Genetics  
& Global Health  
The University of Chicago  
Pritzker School of Medicine





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MISSION  
AND VALUES

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# What We Do

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

# What We Believe

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

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**Sumanta (Monty) Kumar Pal, MD**

Associate Professor,

Department of Medical Oncology & Therapeutics Research

City of Hope, Duarte, CA

# SWOG NCORP Research Base Clinical Trials Workshop

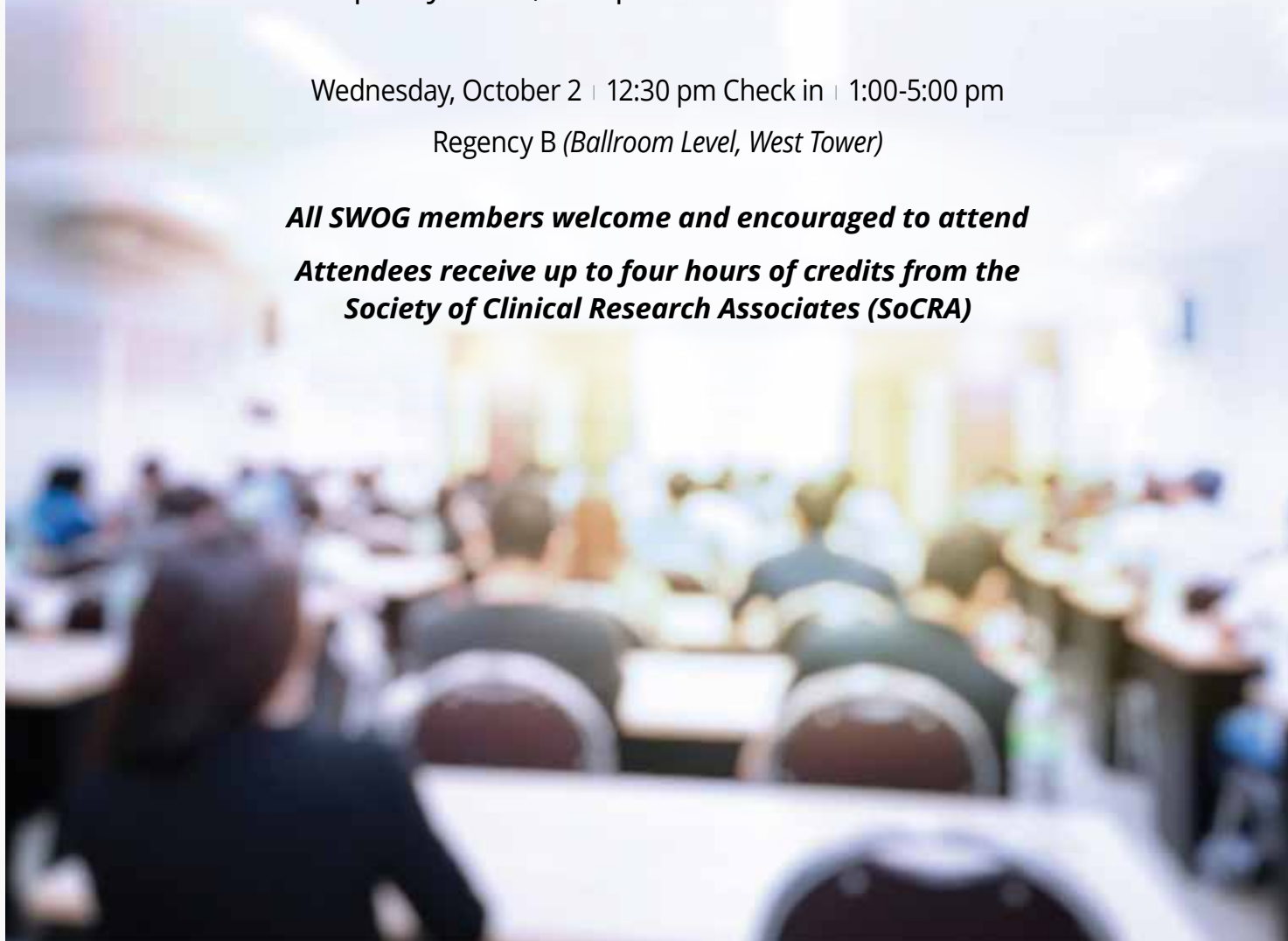
An in-depth session on clinical trials in these areas — cancer care delivery, cancer survivorship, prevention and epidemiology, symptom control and quality of life, and palliative and end of life care.

Wednesday, October 2 | 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 administering studies in the NCI's Community Oncology Research Program (NCORP) areas. NCORP leaders will present on the NCORP research areas with talks on topics such as current SWOG NCORP clinical trials, trial recruitment and retention, cancer disparities, and more.

***Participants will also take part and share information in breakout sessions on a variety of topics.***

# Jeri and Noboru Oishi Symposium

A Special Session Organized by the Oncology Research Professionals Committee

Thursday, October 3 | 8:00 am – 11:30 am | Regency AB

7:30 – 8:00	<b>Registration</b>	9:25 – 9:55	<b>The Challenges and Experience of Re-Engaging in Clinical Trials</b> <i>Dana Little, MA</i> Clinical Research Supervisor UC Davis Health <i>Ofilio Vigil, MS</i> Senior Regulatory Affairs Coordinator UC Davis Health
8:00 – 8:10	<b>Welcome &amp; Introductions</b> <i>Connie Szczepanek, RN, BSN, CCRP</i> Chair, Oncology Research Professionals Committee	9:55 – 10:15	<i>Break</i>
8:10 – 8:30	<b>SWOG Statistics and Data Management Center</b> <i>Center Update</i> <i>Rodney Sutter, CCRP</i> Program Director, Therapeutics Data Management SWOG Statistics and Data Management Center <i>Central Monitoring</i> <i>Jourdain Hayward</i> Clinical Research Data Coordinator SWOG Statistics and Data Management Center	10:15-10:35	<b>CTSU Updates</b> <i>Jenny R. Hopkins, BA, BSN</i> Assistant Project Director Cancer Trials Support Unit National Cancer Institute
8:30 – 9:05	<b>RUSTIC (S1919)</b> <i>Trial Design &amp; Statistical Issues</i> <i>William Barlow, PhD</i> Biostatistician SWOG Statistics and Data Management Center <i>Logistical Details</i> <i>Jacqueline Scurlock</i> Clinical Research Data Coordinator SWOG Statistics and Data Management Center RAVE Instant Differences <i>Katie Minichiello, MS</i> Statistical Research Associate SWOG Statistics and Data Management Center	10:35 – 11:00	<b>Common Mistakes in Clinical Trials: Real Life Stories</b> <i>Christa Braun-Inglis, NP, MS</i> Nurse Practitioner, Assistant Researcher University of Hawaii Cancer Center <i>Stephanie Smith, RN, OCN</i> Clinical Research Manager St. Joseph's/Candler
9:05 – 9:25	<b>CDASH Training for CRAs</b> <i>Dani Weatherbee</i> Applications Development Project Manager SWOG Statistics and Data Management Center	11:00 – 11:30	<b>A Multi-Disciplinary Approach to Getting A Protocol Approved and Enrolling Patients Efficiently</b> <i>Scott Delacroix, Jr., MD</i> Director, Urologic Oncology Director, Cancer Pathology Associate Professor, Department of Urology Louisiana State University School of Medicine
		11:30	<b>Closing</b>

## S1803 Kick-Off Meeting

Thursday, October 3 | 5:00 pm – 6:00 pm | Acapulco  
**Open to All SWOG Members; Suggested for Site Staff**

### **Phase III Study of Daratumumab + Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma Using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC Study)**

S1803 is a new SWOG trial supported by the myeloma committee that activated in June.

The trial will shed light on whether adding the targeted monoclonal antibody daratumumab to maintenance therapy with Lenalidomide will improve patient survival. S1803 will also determine if testing for minimal residual disease (MRD) – a very small number of cancer cells that remain in the body during or after treatment – can be used to guide treatment.

If the study finds that a shorter course of maintenance can provide comparable or better results to the current standard of indefinite maintenance therapy it may spare patients the cost and toxicities of long term maintenance.

Hear from study co-chairs Amrita Y. Krishnan, MD from City of Hope and Parameswaran Hari, MD, MRCP from the Medical College of Wisconsin as they give an overview of the protocol, accrual, data submission, and more.

SWOG myeloma patient advocate Jack Aiello will provide a patient's view of S1803. Additionally, Allison Jacob from Adaptive Biotechnologies Corporation, the laboratory performing the MRD testing, will explain the test ordering process.

***The group will also take questions from attendees.***

***Staff is encouraged to attend.***

## S1820 Kick-Off Meeting

Friday, October 4 | 9:30 am – 11:30 am | Crystal C  
**Open to All SWOG Members; Suggested for Site Staff**

### **A Randomized Trial of the Altering Intake, Managing Symptoms Intervention for Bowel Dysfunction in Rectal Cancer Survivors compared to a Healthy Living Education Control: A Feasibility and Preliminary Efficacy Study (AIMS-RC)**

Come hear about S1820, a unique trial supported by the SWOG palliative and end of life care committee. This study will focus on rectal cancer survivors, and determine if an intervention that uses a health coach to manage symptoms by altering dietary intake can significantly improve bowel function. Rectal cancer survivors often experience persistent, long-term effects from their cancer treatment, yet there is a lack of evidence-based interventions to improve their quality of life.

S1820 is a six-month randomized intervention that will split participants into two arms. One will receive the intervention - telephone calls and texts from trained health coaches on diet behavior change for bowel symptom control - and the other will receive telephone calls and texts on healthy living information. The protocol is expected to activate in October 2019.

In this session, SWOG study chair Virginia Sun, RN, PhD and the core research team will give an overview of the study, explain eligibility criteria, and provide other details about the trial.

# S1919 (RUSTIC) Training Session + Kick-Off Meeting

Friday, October 4 | 8:00 am - 9:00 am | Wrigley

**Open to All SWOG Members; Suggested for Site Staff | Light refreshments will be provided**

**Learn about S1919, or RUSTIC**, an upcoming trial for metastatic breast cancer patients being conducted through Clinical Trials Partnerships (CTP), SWOG's platform for industry supported trials.

**Dr. Kathy Albain**, SWOG vice chair for Clinical Trials Partnerships, will briefly describe the initiative, then study chairs and breast cancer committee leaders **Dr. Lajos Pusztai** from Yale Cancer Center and **Dr. Priyanka Sharma** of University of Kansas Medical Center will walk through the details of RUSTIC, a partnership with AstraZeneca.

**The trial** will combine the anti-PDL1 antibody durvalumab with other immune- or biologically-targeted agents and test the hypothesis that simultaneously inhibiting multiple immune evasion and

immunosuppressive pathways will increase the anti-tumor activity of durvalumab. RUSTIC will open with five treatment arms for hormone receptor positive (HR+) breast cancer patients and three treatment arms for hormone receptor negative (HR-) breast cancer patients. The trial will activate in early 2020.

**Finally, Dani Weatherbee**, an applications development project specialist in SWOG's statistics and data management center, will provide a detailed explanation of the new Rave EDC, the data capture and management tool that RUSTIC will be built on, including an explanation of how the system differs from the classic Rave system currently used in SWOG trials.

## Radiation Oncology Committee

### Strategic Planning Symposium for Radiation Research in SWOG

*"The Promise of Incorporating Advanced Radiation Therapy into the Management of Oligometastatic Disease"*

Saturday, October 5 | 9:15 am – 12:00 pm | Acapulco, Ballroom Level | **Open to all SWOG Attendees**

09:15 AM-9:20 AM **Opening Remarks and Moderator**

**Steven Finkelstein, MD, FACRO** | Florida Cancer Affiliates & The U.S. Oncology Network

9:20 AM-9:45 AM **Quantifying Cell Death Using a cfDNA Biomarker: Aid in Estimating Tumor and Normal Tissue Response**

**Paul Okunieff, MD** | University of Florida

9:45AM-10:10AM **SBRT for Oligometastases: Present and Future**

**Michael Milano, MD, PhD** | University of Rochester

10:10 AM-10:35 PM **NCI Support for Targeted Radionuclide Therapy Research**

**Jacek Capala, PhD, DSc** | National Cancer Institute Radiation Research Program

10:35 AM-10:40 AM **Break**

10:40 AM-11:05 AM **Is Radiotherapy the Principal Curative Treatment with Immunotherapy? Or Is Radiotherapy Employed to Activate Immunotherapy?**

**Ralph Weichselbaum, MD** | University of Chicago

11:05 AM-11:30 AM **Answering Clinical Questions in Oligometastatic Disease**

**Roy Decker, MD, PhD** | Yale University

11:30 AM-12 PM **White Paper Discussion**

12 PM **Lunch and Social**

# Genitourinary Cancers Special Symposium: Radiomics in Urologic Oncology

Friday, October 4 | 9:30 am - 11:30 am | Crystal B

**All SWOG Members Welcome**

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Clinical Perspective of Imaging for Staging, Treatment Monitoring, and Response in Urologic Oncology

**Seth Lerner, MD, FACS**

Professor of Urology  
Beth and Dave Swalm Chair in Urologic Oncology  
Director of Urologic Oncology  
Director of the Multidisciplinary Bladder Cancer Program  
Baylor College of Medicine

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Case Study: Radiomic Surrogates for Tumor Infiltrating Lymphocytes in ccRCC

**Haris Zahoor, MD, MS**

Assistant Professor of Clinical Medicine  
Keck School of Medicine of USC  
Medical Oncologist  
USC Cancer Center

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Primer on Radiomics

**Vinay Duddalwar, MD**

Professor of Clinical Radiology  
Keck School of Medicine of USC  
Medical Director of Imaging Services  
USC Cancer Center

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Case Study: UC Radiogenomic Evaluation of TCGA Cohort

**Seth Lerner, MD, FACS**

Professor of Urology  
Beth and Dave Swalm Chair in Urologic Oncology  
Director of Urologic Oncology  
Director of the Multidisciplinary Bladder Cancer Program  
Baylor College of Medicine

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Case Study: Renal Mass Evaluation Using Radiomics

**Felix Yap, MD**

Body Imaging and Intervention Fellow  
Keck School of Medicine of USC

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Developing an Imaging Repository for Multisite Trials

**Steven Cen, PhD**

Associate Professor of Research Neurology  
Keck School of Medicine of USC

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Case Study: ccRCC Multiomics – Developing a Predictive Model for Identifying Aggressive ccRCC Using Integration of Epigenomics and Radiomics

**Vinay Duddalwar, MD**

Professor of Clinical Radiology  
Keck School of Medicine of USC  
Medical Director of Imaging Services  
USC Cancer Center

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Imaging Variability in Multisite Trials: Problems and Solutions

**Vinay Duddalwar, MD**

Professor of Clinical Radiology  
Keck School of Medicine of USC  
Medical Director of Imaging Services  
USC Cancer Center

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Open Forum | Wrap Up

**Seth Lerner, MD and Vinay Duddalwar, MD**

# SWOG Surgery Committee Meeting Fall 2019

Friday, October 4 | 2:00 pm – 4:00 pm | Acapulco

## *Invited Lecture*

Development of Liquid Biomarkers to Guide Therapy in Patients with Clinically Localized PDAC

**Christopher L. Wolfgang, MD, PhD, FACS**  
**Paul K. Neumann Chair of Pancreatic Cancer Research**  
**Chief, Hepatobiliary and Pancreatic Surgery**  
**Associate Professor of Surgery, Pathology, and Oncology**  
**Johns Hopkins University**

How Can We Access the SWOG Databases For Secondary Analysis?

**Michael LeBlanc, PhD**  
**Director**  
**SWOG Statistics and Data Management Center**

## *Trials in Development and Ongoing Trials*

**Randomized Perioperative Study of Nivolumab versus Nivolumab plus Ipilimumab Versus Surgery Alone For Patients With Resectable HCC** (Ahmad Kaseb MD, Associate Professor of Medicine, MD Anderson Cancer Center)

**Is There a Role for Adjuvant Treatment in Pancreatic Neuroendocrine Tumors?** (Heloisa P. Soares, MD, Assistant Professor of Medicine, University of New Mexico Comprehensive Cancer Center)

**S1512: A Phase II And Pilot Trial Of PD-1 Blockade With Pembrolizumab In Patients With Resectable Or Unresectable Desmoplastic Melanoma** (Kari Kendra, MD, Professor Of Internal Medicine, Ohio State University Wexner Medical Center)

**Melanoma Margins Trial (MELMART) A Phase III, Multi-National Randomized Control Trial Investigating 1 cm versus 2 cm Wide Excision Margins For Primary Cutaneous Melanoma** (Joshua M.V. Mammen, MD, PhD, Associate Professor of Surgery, University of Kansas)

**EA 2185: Comparing The Clinical Impact Of Pancreatic Cyst Surveillance Programs** (Flavio Rocha, MD, Staff Surgeon and Associate Medical Director Virginia Mason Medical Center)

## *Update From The Subcommittees*

**Update from the GI Committee** (Kaitlyn Kelly, MD, Assistant Professor of Surgery, UCSD Moores Cancer Center)

**Update from the Melanoma Committee** (Jeffrey J. Sussman, MD, Professor of Surgery, The University of Cincinnati Medical Center)

# Procedures for CME Credit

## Group Meeting Target Audience and Educational Objectives

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

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

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

## Continuing Medical Education Credit

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

The Hope Foundation designates this live activity for a maximum of 24.25 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

## Speaker and Planner CME Disclosure Information

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

## SWOG gratefully acknowledges our CME Commercial Supporters



**Celgene**



**AbbVie**



**Lilly**



**Genomic Health**



**AstraZeneca**



# New Procedures for CME Credit

Time	Session Title	Credits	
		Available	Actual
<b>THURSDAY, OCTOBER 3, 2019</b>			
8:00 am – 10:00 am	Cancer Care Delivery Committee	2.0	_____
10:00 am – 2:15 pm	Early Therapeutics and Rare Cancers Committee	2.25	_____
10:15 am – 12:15 pm	Palliative and End of Life Care Committee	2.0	_____
1:00 pm – 3:00 pm	Symptom Control and Quality of Life Committee	2.0	_____
3:30 pm – 5:00 pm	Plenary I (Translational Medicine)	1.5	_____
5:00 pm – 7:00 pm	Prevention and Epidemiology Committee	2.0	_____
<b>FRIDAY, OCTOBER 4, 2019</b>			
7:00 am – 9:00 am	Cancer Survivorship Committee	2.0	_____
7:30 am – 9:30 am	Barlogie-Salmon Myeloma Committee	2.0	_____
9:30 am – 11:30 am	Melanoma Committee	2.0	_____
12:00 pm – 2:00 pm	Plenary II (General)	2.0	_____
2:00 pm – 4:00 pm	Surgery Committee	2.0	_____
2:30 pm – 6:15 pm	GU Committee Part I	3.75	_____
4:00 pm – 6:00 pm	GI Committee	2.0	_____
4:00 pm – 7:00 pm	Lung Committee	3.0	_____
4:30 pm – 6:30 pm	Leukemia Committee	2.0	_____
<b>SATURDAY, OCTOBER 5, 2019</b>			
9:30 am – 11:30 am	Radiation Oncology Committee	2.0	_____
9:30 am – 12:30 pm	Lymphoma Committee	3.0	_____
9:30 am – 12:30 pm	Breast Committee	3.0	_____
9:30 am – 12:30 pm	GU Committee Part II	3.0	_____
<b>Total Possible Credits</b>		<b>24.25</b>	

## We've gone paperless!

**SWOG no longer requires members to submit paper forms to obtain CME credits. Getting your credits online is easy:**

- Visit: <https://tinyurl.com/SWOG-CME>
- Complete the evaluation questions
- Enter the credits being claimed
- Press "submit"

Your certificate will automatically be emailed to you.

Problems or questions? Contact Courtney Wille in the SWOG operations office at [cwille@swog.org](mailto:cwille@swog.org).

To keep track of your credits during the meeting, use the form above.



## 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

### **Adolescent and Young Adult**

*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**

*Connie Szczepanek, RN, BSN, CCRP*

### **Patient Advocates**

*Rick Bangs, MBA*

### **Pharmaceutical Sciences**

*Siu-Fun Wong, PharmD*

### **Radiation Oncology**

*Roy Decker, MD, PhD*

### **Recruitment and Retention**

*Elise D. Cook, MD*

### **Surgery**

*Syed A. Ahmad, MD*

## Future Meeting Dates

### **Spring 2020**

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

### **Fall 2020**

September 23-26, 2020  
Hyatt Regency  
Chicago  
Chicago, IL

### **Spring 2021**

April 21-24, 2020  
Hyatt Regency  
San Francisco  
San Francisco, CA



Jack Aiello, MS, EE  
*Myeloma*



Rick Bangs, MBA, PMP  
*Genitourinary*



Christabel Cheung, PhD, MSW  
*Adolescent and Young Adult*



Tony Crispino  
*Genitourinary*



Hildy Dillon, MPH  
*Lymphoma*



Valerie Fraser  
*Palliative and End of Life Care*



Amy Geschwender, PhD  
*Symptom Control + Quality of Life*



Valerie Guild, MBA, CPA  
*Melanoma*

# Patient Advocates

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



Sandra Hamilton, RN, BSN, MEd  
*Recruitment + Retention*



Marcia K. Horn, JD  
*Early Therapeutics and Rare Cancers*



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, MEd  
*Genitourinary*

PLEASE READ THE SWOG ADVOCATES BIOS AT [WWW.SWOG.ORG/SWOG-NETWORK/OUR-ADVOCATES](http://WWW.SWOG.ORG/SWOG-NETWORK/OUR-ADVOCATES)

# guidebook

## Plan Your Meeting. Check Into Sessions. Connect With Members. **There's An App For That**



The Guidebook app helps you hack your SWOG group meeting - for free.

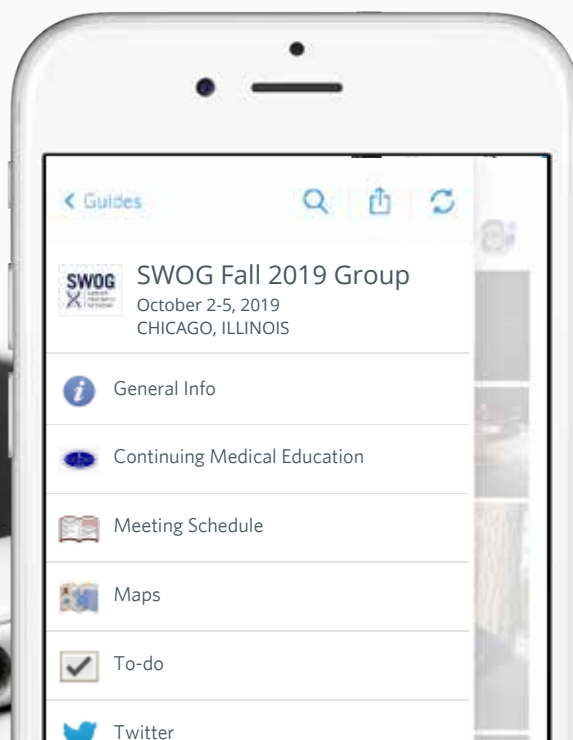
Download Guidebook and create an account using just your name and email, then:

- **Create** a meeting schedule
- **See** who's at the meeting — and send them direct messages
- **Access** Twitter and tweet the meeting
- **Find** continuing medical education info
- **Get** hotel maps
- **View** the featured speakers

When you create an app account, you can build a meeting schedule. SWOG leadership will use this scheduling information to gauge interest in sessions, to build better meetings, and engage with members after the meeting.

### Downloading is easy!

- **Plug in** this URL on your mobile device <https://bit.ly/2uaYznP> or **scan** the unique QR code above
- **Tap** the download button to get Guidebook
- **Open** and look for SWOG Fall 2019 Group Meeting
- **Create** an account using your name and email address



*Have questions?  
Need help?  
Ask SWOG staff at the  
registration desk.*

# Tweeting, Following, Liking:

## SWOG Digital Engagement Training on Twitter Basics

Friday, October 4 | 11:00 am – 12:00 pm | Comiskey | All Members Welcome

### Tempted by Twitter?

**This session will show you** how to use this popular social media platform for your cancer research work.

**It's the first annual workshop** created and delivered by SWOG's digital engagement committee.

**At each fall meeting,** members of the digital engagement committee will offer this training session to:



**Share statistics** and research on the use of Twitter in the cancer research community



**Offer examples** from a variety of SWOG members about Twitter's professional value



**Explain the risks** and benefits of using the platform, and provide tips for using it ethically and legally



**Share examples** of how to make Twitter effective – what works and why



**Provide basic** information on how to create a Twitter profile and begin using the platform

Everyone from @ASCO to @ASTRO is on Twitter.  
And over 7,000 people follow @SWOG.

So Join the Party.  
It's What's Happening.

# Schedule of Events

## WEDNESDAY, October 2, 2019

**Group Meeting Registration & Information Desk**  
1:00 p.m. - 5:00 p.m. - Regency Foyer, Ballroom Level,  
West Tower

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

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

**Soldier Field, Concourse Level**      ORP Executive Committee (Cmte Members Only)

11:30 A.M. - 2:00 P.M.

**Acapulco, Ballroom Level**      Core Office Staff Meeting (Invitation Only)

12:00 P.M. - 1:45 P.M.

**Haymarket, Concourse Level**      Nursing Research Subcommittee

12:30 P.M. - 1:00 P.M.

**Regency Foyer, Ballroom Level**      NCORP Workshop Check-In

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

**Regency B, Ballroom Level**      SWOG NCORP Research Base Clinical Trials Workshop

2:00 P.M. - 3:30 P.M.

**Comiskey, Concourse Level**      SWOG Tissue Banking Meeting (Invitation Only)

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

**Haymarket, Concourse Level**      Hope Foundation Board Meeting (Board Members Only)

4:30 P.M. - 5:30 P.M.

**Soldier Field, Concourse Level**      ORP Liaison Subcommittee

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

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

5:30 P.M. - 8:00 P.M.

**Regency C, Ballroom Level**      NCORP Research Base Executive Committee Meeting (Cmte Members Only)

## THURSDAY, October 3, 2019

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

**Hope Foundation Information Desk**  
8:00 a.m. - 5:00 p.m. - Regency Foyer, Ballroom Level,  
West Tower

**Exhibits & Complimentary Coffee Service**  
7:00 a.m. - 4:00 p.m. - Toronto, Ballroom Level, West Tower

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

6:30 A.M. - 8:00 A.M.

**Wrigley, Concourse Level**      Advocates Committee Meeting (Cmte Members Only)

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

**Regency Foyer, Ballroom Level**      Jeri & Noboru Oishi Symposium Check-In

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

**Regency AB, Ballroom Level**      Jeri & Noboru Oishi Symposium (Open Session)

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

**Haymarket, Concourse Level**      Survivorship Liaison Breakfast Meeting (Invitation Only)

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

**Regency D, Ballroom Level**      CANCER CARE DELIVERY COMMITTEE

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

**Comiskey, Concourse Level**      Digital Engagement Committee (Cmte Members Only)

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

**Wrigley, Concourse Level**      Quality Initiative Meeting (Cmte Members Only)

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

**Crystal B, Lobby Level**      EARLY THERAPEUTICS AND RARE CANCERS COMMITTEE

# Schedule of Events

10:15 A.M. – 12:15 P.M.

**Regency D, Ballroom Level**

PALLIATIVE AND END OF LIFE CARE  
COMMITTEE IN DEVELOPMENT

3:00 P.M. – 4:30 P.M.

**Wrigley, Concourse Level**

Advocates Committee Meeting  
(Cmte Members Only)

12:00 P.M. – 2:00 P.M.

**Gold Coast, Concourse Level**

Lung-MAP Site Coordinators  
Committee (Cmte Members Only)

3:30 P.M. – 5:00 P.M.

**Regency A-C, Ballroom Level**

PLENARY I (TRANSLATIONAL  
MEDICINE)

12:30 P.M. – 2:00 P.M.

**Crystal C, Lobby Level**

ORP Open Forum

5:00 P.M. – 6:00 P.M.

**Acapulco, Ballroom Level**

S1803 Kick-Off Meeting

12:30 P.M. – 2:30 P.M.

**Acapulco, Ballroom Level**

Adolescent and Young Adult (AYA)  
Committee

5:00 P.M. – 7:00 P.M.

**Regency D, Ballroom Level**

PREVENTION AND EPIDEMIOLOGY  
COMMITTEE

12:30 P.M. – 3:30 P.M.

**Regency D, Ballroom Level**

GI Working Group (Working  
Group Members Only)

5:00 P.M. – 7:00 P.M.

**Comiskey, Concourse Level**

Leukemia Working Group Meeting  
(Working Group Members Only)

12:30 P.M. – 3:30 P.M.

**Comiskey, Concourse Level**

Myeloma Working Group  
(Working Group Members Only)

5:00 P.M. – 7:00 P.M.

**Roosevelt 3AB, Lobby Level  
East Tower**

Lung Working Group (Working  
Group Members Only)

1:00 P.M. – 2:00 P.M.

**Wrigley, Concourse Level**

Lung Executive Subcommittee  
(Cmte Members Only)

5:00 P.M. – 7:00 P.M.

**Columbian, Concourse Level**

Conflict Management Committee  
(Cmte Members Only)

1:00 P.M. – 3:00 P.M.

**Crystal B, Lobby Level**

SYMPTOM CONTROL AND  
QUALITY OF LIFE COMMITTEE

6:00 P.M. – 9:00 P.M.

**Wrigley, Concourse Level**

Latin American Symposium  
(Invitation Only)

1:00 P.M. – 3:00 P.M.

**Water Tower, Concourse Level**

Immunotherapeutics Committee  
(Cmte Members Only)

7:00 P.M. – 9:00 P.M.

**San Francisco, Ballroom Level**

Early Therapeutics Working Group  
Dinner (Invitation Only)

2:30 P.M. – 3:30 P.M.

**Regency Foyer, Ballroom Level**

Plenary Reception (Light Hors  
D'oeuvres)

2:30 P.M. – 3:30 P.M.

**Gold Coast, Concourse Level**

S1316 Protocol Meeting

2:30 P.M. – 3:30 P.M.

**New Orleans, Ballroom Level**

Breast Committee Leadership  
Meeting (Invitation Only)

# Schedule of Events

## FRIDAY, October 4, 2019

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

**Hope Foundation Information Desk**  
8:00 a.m. - 5:00 p.m. - Regency Foyer, Ballroom Level,  
West Tower

**Exhibits & Complimentary Coffee Service**  
7:00 a.m. - 4:00 p.m. - Toronto, Ballroom Level, West Tower

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

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

**Regency D, Ballroom Level**

**CANCER SURVIVORSHIP  
COMMITTEE**

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

**Gold Coast, Concourse Level**

**Drug Information Subcommittee  
and Working Group (Working  
Group Members Only)**

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

**Acapulco, Ballroom Level**

**Melanoma Working Group  
(Working Group Members Only)**

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

**Crystal B, Lobby Level**

**BARLOGIE-SALMON MYELOMA  
COMMITTEE**

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

**San Francisco, Ballroom Level**

**Imaging Committee (Cmte  
Members Only)**

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

**Comiskey, Concourse Level**

**Lung-MAP Administrative Meeting  
(Invitation Only)**

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

**Haymarket, Concourse Level**

**SWOG Data and Safety Monitoring  
Committee (Cmte Members Only)**

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

**Wrigley, Concourse Level**

**S1919 (RUSTIC) Training Session**

8:00 A.M. - 9:30 A.M.

**Picasso, Concourse Level**

**Professional Review Committee  
(Cmte Members Only)**

8:30 A.M. - 9:30 A.M.

**New Orleans, Ballroom Level**

**Lung Surgery Subcommittee  
(Cmte Members Only)**

8:30 A.M. - 10:00 A.M.

**Gold Coast, Concourse Level**

**Pharmaceutical Sciences  
Committee**

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

**Soldier Field, Concourse Level**

**Cardiotoxicity Panel**

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

**Plaza Ballroom, Lobby Level  
East Tower**

**Breast Working Group Meeting  
(Working Group Members Only)**

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

**New Orleans, Ballroom Level**

**Lung Radiation Subcommittee  
(Cmte Members Only)**

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

**Crystal B, Lobby Level**

**GU Cancers Special Symposium:  
Radiomics in Urologic Oncology**

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

**Regency D, Ballroom Level**

**MELANOMA COMMITTEE**

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

**Crystal C, Lobby Level**

**S1820 Kick-Off Meeting**

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

**Haymarket, Concourse Level**

**Lung Community Engagement  
Meeting (Working Group Members  
Only)**

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

**Columbian, Concourse Level  
Meeting**

**Quality Assurance Committee  
(Cmte Members Only)**

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

**Water Tower, Concourse Level**

**VA Working Group**



# Schedule of Events

10:30 A.M. – 11:30 A.M.

**New Orleans, Ballroom Level**

Lung TM Subcommittee  
(Cmte Members Only)

2:30 P.M. – 6:15 P.M.

**Regency D, Ballroom Level**

GU COMMITTEE PART I: Prostate  
Cancer Organ Site (2:30-4:15); TM  
Organ Site (4:15-5:30); Cancer  
Control (5:30-6:15)

10:30 A.M. – 12:00 P.M.

**Crystal A, Lobby Level**

Bone Marrow & Stem Cell  
Transplantation Committee

3:30 P.M. – 5:30 P.M.

**San Francisco, Ballroom Level**

ORP Planning Meeting (Cmte  
Members Only)

11:00 A.M. – 12:00 P.M.

**Comiskey, Concourse Level**

Tweeting, Following, Liking: SWOG  
DE Training on Twitter

4:00 P.M. – 5:00 P.M.

**Comiskey, Concourse Level**

S1714 Protocol Training

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

**Gold Coast, Concourse Level**

GI Translational Medicine Working  
Group (Working Group Members  
Only)

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

**Picasso, Concourse Level**

Recruitment and Retention  
Committee Meeting

11:00 A.M. – 12:00 P.M.

**Picasso, Concourse Level**

Publications Committee  
(Cmte Members Only)

4:00 P.M. – 6:00 P.M.

**Regency C, Ballroom Level**

GI COMMITTEE

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

**Regency Foyer, Ballroom Level**

Plenary Reception (Light Hors  
D'oeuvres)

4:00 P.M. – 7:00 P.M.

**Regency A, Ballroom Level**

LUNG COMMITTEE

12:00 P.M. – 2:00 P.M.

**Regency A-C, Ballroom Level**

PLENARY II (GENERAL)

4:30 P.M. – 6:30 P.M.

**Regency B, Ballroom Level**

LEUKEMIA COMMITTEE

2:00 P.M. – 4:00 P.M.

**Acapulco, Ballroom Level**

SURGERY COMMITTEE

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

Executive Reception (Invitation  
Only)

2:15 P.M. – 3:15 P.M.

**Crystal A, Lobby Level**

NCORP/MU-NCORP Site PI Meeting

6:45 P.M. – 8:30 P.M.

**Crystal BC, Lobby Level**

Reception

2:15 P.M. – 4:15 P.M.

**Water Tower, Concourse Level**

Lymphoma Working Group  
(Working Group Members Only)

2:15 P.M. – 5:15 P.M.

**Plaza Ballroom, Lobby Level  
East Tower**

Breast Translational Medicine  
Working Group (Working Group  
Members Only)

2:30 P.M. – 4:00 P.M.

**Crystal BC, Lobby Level**

Lung-MAP Update Meeting

# Schedule of Events

## SATURDAY, October 5, 2019

### Group Meeting Registration & Information Desk

7:00 a.m. - 11:00 a.m. - Regency Foyer, Ballroom Level,  
West Tower

### Hope Foundation Information Desk

8:00 a.m. - 11:00 a.m. - Regency Foyer, Ballroom Level,  
West Tower

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

7:15 A.M. – 8:00 A.M.

**Regency B, Ballroom Level**

Board of Governors  
(Board Members Only)

8:15 A.M. – 9:15 A.M.

**Regency B, Ballroom Level**

Committee Chairs  
(Committee Chairs Only)

9:15 A.M. – 12:00 P.M.

**Acapulco, Ballroom Level**

RADIATION ONCOLOGY  
SYMPOSIUM

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

**Regency A, Ballroom Level**

LYMPHOMA COMMITTEE

9:30 A.M. – 12:30 P.M.

**Regency C, Ballroom Level**

BREAST COMMITTEE

9:30 A.M. – 12:30 P.M.

**Regency D, Ballroom Level**

GU COMMITTEE PART II: Bladder  
Cancer Organ Site (9:30-11:00);  
Renal Cancer Organ Site (11:00-  
12:30)

**THE HOPE**  
**FOUNDATION**  
FOR CANCER RESEARCH

# New Procedure for Submitting Grant Applications!

Three Hope programs now require a Letter of Intent as the first step in the application process



## Dr. Charles A. Coltman, Jr. Fellowship Program

(JANUARY 15)

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## SWOG Career Engagement Award Program

(JANUARY 15)

## SWOG/Hope Foundation Impact Award Program

(JANUARY 15-SPRING ROUND)

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*Learn more at [thehopefoundation.org/research-funding](https://thehopefoundation.org/research-funding)  
Contact Morgan Cox ([morgan@thehopefoundation.org](mailto:morgan@thehopefoundation.org)) with questions*



*Thanks To*

# Our Top Accruers

Patient volunteers power our trials — and SWOG members are the ones to connect us to them.

In 2018, these members topped the charts for SWOG-credited registrations to SWOG managed trials.

We appreciate their hard work, and their confidence in our research.

## SWOG NCORP Sites

- 1 Michigan CRC NCORP
- 2 Heartland NCORP Illinois
- 3 New Mexico MU-NCORP
- 4 Wisconsin NCORP
- 5 Kaiser Permanente NCORP California

## SWOG Lead Academic Partner and Member Sites

- 1 MD Anderson Cancer Center
- 2 University of Kansas Cancer Center
- 3 Huntsman Cancer Institute at University of Utah
- 4 Yale Cancer Center
- 5 University of Michigan Rogel Cancer Center



A program of the National Cancer Institute of the National Institutes of Health



a National Cancer Institute program

# Barlogie-Salmon Myeloma Committee

## Leadership

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

## Scientific Leadership

Translational Medicine: ..... Brian A. Walker, B.Sc., Ph.D.  
 Radiation: ..... Chelsea Camille Pinnix, M.D., Ph.D.  
 Surgery: ..... J. Sybil Biermann, M.D.  
 Imaging: ..... Saad Z. Usmani, M.D.  
 ..... Eric M. Rohren, M.D., Ph.D.  
 Pathology: ..... Robert B. Lorschach, M.D., Ph.D.  
 Early Therapeutics: ..... Frits van Rhee, M.D., Ph.D.

## Designates

Digital Engagement: ..... Saad Z. Usmani, M.D.  
 NCORP Representative: ..... Charles S. Kuzman, M.D.  
 Data Coordinators: ..... Sean O'Bryan  
 Oncology Research Professionals:  
 CRA: ..... TBD  
 Nurses: ..... Deborah A. Shaw, R.N.  
 ..... Teresa Witcher, B.S.N., R.N.  
 Patient Advocate: ..... Jack Aiello, M.S.  
 Pharmaceutical Science: ..... Lara M. Au, Pharm.D.  
 ..... Craig Elg, Pharm.D.  
 Protocol Coordinator: ..... Cynthia Smith  
 Clinical Trials Project Manager: ..... Sandi Hita, J.D.

## Time/Location

Friday, October 4, 2019 7:30 a.m. - 9:30 a.m.  
 Room: Crystal B (Lobby Level, West Tower)

## Active Studies

S1702, "A Phase II Study of Isatuximab (SAR650984) for Patients with Previously Treated AL Amyloidosis." Drs. Parker and Sanchorawala. Activated 3/8/18.

S1803, "Phase III Study of Daratumumab/rHuPH20 (NSC- 810307) + 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, and Hari. Activated: 6/27/19.

## Closed Studies

S0777 "A Randomized Phase III Trial of CC-5013 (Lenalidomide, NSC-703813) and Low Dose Dexamethasone (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 Immediate Autologous Stem Cell Transplant." Drs. Durie and Barlogie. Activated: 4/1/08; Closed: 2/1/12.

S1211, "A Randomized Phase I/II Study of Optimal Induction Therapy of Bortezomib, Dexamethasone and Lenalidomide with or Without Elotuzumab (NSC-764479) for Newly Diagnosed High Risk Multiple Myeloma (HRMM)." Drs. Usmani, Ailawadhi, and Lipe. Activated: 10/12/12; Closed: 5/15/18.

S1304, "A Phase II Randomized Study Comparing Two Doses of Carfilzomib (NSC-756640) with Dexamethasone for Multiple Myeloma Patients with Relapsed or Refractory Disease." Drs. Ailawadhi, Abidi, S. Lentzsch, et al. Activated: 10/18/13; Closed: 11/6/16.

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: 7/14/17.

**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: 11/13/13; Closed: 1/29/19.

**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 Therapy.” Dr. Manasanch. Activated: 12/23/15; Closed: 8/15/19.

#### Proposed Studies

**S1611**, “A Phase II Non-Randomized Study of 11-1F4 Chimeric Monoclonal Ab Added to Standard Induction Therapy in Untreated Subjects with Light Chain (AL) Amyloidosis.” Dr. Bhutani.

**S1911**, “Phase III Study of Optimal Induction/Maintenance Therapy for Newly Diagnosed High Risk Multiple Myeloma (HRMM).” Drs. Lipe and Usmani.

#### Open Forum Discussion

MRD testing & new response criteria in SWOG

#### 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 7/12/2019. Includes studies that are currently open or that closed since 1/1/2018.

	S1211	S1702	E1A11
Arkansas, U of	—	—	3
Baylor College	—	—	9
Beaumont NCORP	—	—	6
Boston Medical Ctr	—	5	—
CORA NCORP	—	1	1
CRC West MI NCORP	1	—	—
City of Hope Med Ctr	7	—	—
Cleveland Clinic OH	10	—	—
Columbia MU-NCORP	—	2	—
Columbus NCORP	4	—	—
Davis, U of CA	—	—	26
Dayton NCORP	1	—	2
Essentia Hlth NCORP	1	—	—
Hawaii MU-NCORP	—	—	1
Heartland NCORP	3	1	—
Henry Ford Hospital	—	—	15
Irvine, U of CA	—	1	6
Kaiser Perm NCORP	—	—	40
Kansas City NCORP	1	—	2
Kansas, U of	13	—	3
Loyola University	3	2	13
MD Anderson CC	10	—	—
Michigan CRC NCORP	5	—	—
Michigan, U of	—	—	10
Montana NCORP	—	—	3
Nevada CRF NCORP	—	—	1
Oklahoma, Univ of	1	—	—
Oregon Hlth Sci Univ	—	2	4
Ozarks NCORP	2	—	6
Providence Hosp	4	—	11
Rochester, Univ of	7	—	—
San Antonio, U of TX	15	—	9
San Diego, U of CA	—	—	1
So Calif, U of	2	—	—
Southeast COR NCORP	4	—	10
Sutter Cancer RC	—	—	6
Tulane University	1	—	—
VAMC Kansas City	—	—	6
Wayne State Univ	3	1	13
Yale University	—	2	52
Alliance	10	1	—
ECOG-ACRIN	31	9	—
NRG	3	2	—
<b>Total</b>	<b>142</b>	<b>29</b>	<b>259</b>

# Breast Committee

## 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.  
 Surgery: ..... Christine Lee, M.D.  
 Imaging: ..... Joanne E. Mortimer, M.D.  
 ..... Wei Tse Yang, M.B.B.S.  
 Pathology: ..... David L. Rimm, M.D., Ph.D.  
 Early Therapeutics: ..... George Somlo, M.D.

## Designates

Cancer Control Liaisons: ..... Melinda L. Irwin, Ph.D., M.P.H. (Survivorship)  
 ..... Dawn L. Hershman, M.D. (Cancer Care Delivery)  
 ..... Banu Arun, M.D. (Prevention)  
 ..... Helen K. Chew, M.D. (Symptom Control & QOL)  
 Digital Engagement: ..... Sarah S. Mougalian, M.D.  
 NCORP Representative: ..... Philip Lammers, M.D.  
 Data Coordinators: ..... Iris Syquia  
 ..... Larry Kaye  
 ..... Jacqueline Scurlock  
 Oncology Research Professionals:  
 CRA: ..... Karyn N. Hart, C.C.R.P.  
 Nurse: ..... Dorothy Coleman, R.N., M.S.N.  
 Patient Advocate: ..... Ginny Mason, R.N., B.S.N.  
 ..... Elda Railey  
 Pharmaceutical Science: ..... Jessie Modlin, Pharm.D.  
 Protocol Coordinator: ..... Cara Laubach, M.I.I.M.  
 Clinical Trials Project Manager: ..... Vanessa Benavidez, B.S., C.C.R.C.

## Time/Location

Saturday, October 5, 2019 9:30 a.m. - 12:30 p.m.  
 Room: Regency C (Ballroom Level, West Tower)

**9:30 – 9:35 a.m.** Welcome and Introductions – Lajos Pusztai, M.D. D.Phil and Priyanka Sharma, M.D.

## Breast Committee Mini-Symposium: Targeting of PI3K/AKT pathway for treatment of breast cancer

**9:35 - 10:05 a.m.** Therapeutic implications of PIK3CA/ATK alterations and biomarkers of response – Dejan Juric, M.D.

**10:05 - 10:35 a.m.** Combinatorial approaches and current clinical investigation landscape – Reva Basho, M.D.

**10:35 – 10:50 a.m.** Publications update – Bill Barlow, Ph.D.

**10:50 – 11:30 a.m.** Update of open SWOG and SWOG-Championed CTSU trials – All

**11:30 – 12:00 p.m.** Studies in Development – All

**12:00 – 12:15 p.m.** 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)  
 Philip Lammers, M.D.

**12:15 – 12:20 p.m.** Translational Medicine Sub-Committee Update – Alastair Thompson, M.D. and Andrew K. Godwin, Ph.D.

**12:20 – 12:25 p.m.** New Business – All

**12:25 p.m.** Closing Comments and Adjourn

## Active Studies

**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  $\geq 1$  cm Residual Invasive Cancer or Positive Lymph Nodes (ypN+) After Neoadjuvant Chemotherapy.” Drs. Pusztai and Mammen. Activated: 11/15/16.

**S1706**, “A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy Alone for Inflammatory Breast Cancer.” Dr. Jagsi. Activated: 9/12/18.

# Breast Committee

**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; Temporarily closed to accrual: 4/18/19.

**CTSU/A011502**, "A Randomized Phase III Double Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for Node Positive HER2 Negative Breast Cancer: The ABC Trial." Dr. Chen. SWOG Champion: Dr. Symington. Activated: 12/8/16.

**CTSU/A221405**, "A Study Evaluating the Pregnancy Outcomes and Safety of Interrupting Endocrine Therapy for Young Women with Endocrine Responsive Breast Cancer who Desire Pregnancy." Dr. Pagani. SWOG champion Dr. 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: Dr. Arun. Activated: 7/6/17.

**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- BR004**, "A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer." Dr. Geyer. SWOG Champion: Dr. Cobain. Activated: 3/12/19.

**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; Temporarily closed to accrual: 7/2/19.

**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: 8/22/13.

**CTSU/CCTG MA.39**, "Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer." Dr. Whelan. SWOG Champion: Dr. Jagsi. Activated: 5/30/18.

## 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.

**S1501**, "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.

**S1614**, "Randomized Trial of Prophylactic Antiviral Therapy in Patients with Current or Past Hepatitis B Virus (HBV) Infection Receiving Cytotoxic Therapy for Solid Tumors." Dr. Hwang. Activated: 2/21/19.

**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. Accordino. Activated: 7/16/18.

**S1714**, "A Prospective Observational Cohort Study to Develop a Predictive Model of Taxane-Induced Peripheral Neuropathy in Cancer Patients." Dr. Trivedi. Activated 3/1/19.

**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.

## Rare Cancers Active Studies

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

**CTSU/EAY131**, "Molecular Analysis for Therapy Choice (MATCH)". Dr. Villalobos. Activated: 7/15/15.



# Breast Committee

## Closed Studies

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

**S1204**, "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; Closed: 2/15/17.

**S1207**, "Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer." Drs. Chavez-MacGregor, Rastogi, Pusztai. Activated: 9/3/13; Closed: 4/15/19.

**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; Closed: 6/15/19.

**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. Arm 2 and Arm 3 were Permanently Closed to Accrual, Effective 11/30/18; Closed: 7/15/19.

**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; Closed: 10/17/18.

**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; Closed: 4/29/19.

## 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.

**CTSU/E1Z11**, "A Cohort Study to Evaluate Genetic Predictors for Aromatase Inhibitor Musculoskeletal Symptoms (AIMSS)." Dr. Stearns. Activated: 5/21/13; Closed: 10/22/18.

## Studies in Development

**S1919**, "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.

**S1930**, "Phase II Randomized Trial to Evaluate the Safety and Efficacy of Pertuzumab and Trastuzumab plus Abemaciclib and Anti-estrogen therapy as treatment for HER2-positive and HR-positive Metastatic Breast Cancer (PETRA)." Drs. Giordano and Lu.

**S1938**, "Randomized Phase III trial of continuation of checkpoint inhibitors with chemotherapy after progression of checkpoint inhibitor and chemotherapy received as first line therapy for metastatic triple negative breast cancer (TNBC)." Drs. Litton and Mitri.

**SXXXX**, "A Phase II Single-Arm Trial of Tumor Immune Lymphocyte Adapted Neoadjuvant Chemotherapy De-escalation in Triple Negative Breast Cancer (TACT)." Drs. Moulder, Kang, and Sharma.

## Breast Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/12/2019. Includes studies that are currently open or that closed since 1/1/2018.

	S1207	S1416	S1418	S1706	A011106	A011202	A011401	A011502	A221405	B51	B55	E1Z11	E2112	E41131	E41151	NRGBR002	NRGBR003	NRGBR005
Arizona CC, Univ of	14	—	1	—	33	1	1	—	—	—	—	—	—	—	9	—	—	—
Arkansas, U of	16	—	7	1	2	—	2	—	—	—	—	—	—	—	—	—	—	—
Baptist MU-NCORP	5	1	3	1	12	1	7	—	—	—	—	1	1	—	—	—	1	—
Bay Area NCORP	1	—	3	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Baylor Univ Med Ctr	2	—	—	—	—	1	—	—	—	2	—	—	—	—	—	—	—	—
Beaumont NCORP	8	2	1	—	—	6	5	2	—	1	—	3	—	—	—	1	—	—
Boston Medical Ctr	3	—	—	—	—	—	2	—	—	—	—	—	—	—	—	—	—	—
Brooke Army Med Ctr	—	—	2	—	—	—	—	1	—	—	1	—	—	3	—	—	1	—
CORA NCORP	22	3	8	—	1	—	—	—	—	2	—	1	3	—	—	—	—	—
CRC West MI NCORP	10	3	13	—	—	—	1	—	—	—	—	2	—	—	—	—	—	—
Carle CC NCORP	12	2	2	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Cedars-Sinai Med Ctr	9	—	—	—	—	—	—	—	—	—	6	—	—	—	—	—	—	—
Cincinnati MC, U of	10	—	—	—	—	—	—	—	—	1	—	4	—	—	—	—	—	—
City of Hope Med Ctr	21	—	3	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Cleveland Clinic OH	12	8	4	—	—	—	—	—	—	2	2	—	18	—	—	—	7	—
Colorado CRP NCORP	1	—	1	—	—	—	1	—	—	—	—	—	—	—	—	—	—	—
Colorado, U of	18	7	8	—	16	33	20	6	10	3	2	2	—	—	2	—	—	2
Columbia MU-NCORP	7	—	3	—	—	—	—	—	—	—	—	17	2	—	—	—	—	—
Columbus NCORP	17	14	5	—	—	—	—	—	—	—	—	2	—	—	—	—	—	—
Davis, U of CA	7	12	4	—	—	2	1	13	—	—	—	1	—	—	—	—	—	—
Dayton NCORP	8	4	1	—	3	—	1	—	—	—	—	2	—	—	—	—	—	—
Desert Hospital	1	—	1	—	—	5	2	—	—	4	—	—	—	—	—	—	—	—
Essentia Hlth NCORP	3	—	1	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Fred Hutchinson CRC	22	13	6	—	—	—	7	3	2	—	3	—	4	—	—	—	—	—
Georgia NCORP	2	—	9	—	—	—	2	—	—	—	—	8	—	—	—	—	—	—
Greenville NCORP	—	2	1	—	—	—	—	—	—	—	—	12	—	—	—	—	—	—
Gulf South MU-NCORP	23	—	3	—	—	—	—	—	—	—	—	5	—	—	—	—	3	—
H Lee Moffitt CC	5	—	—	—	—	1	3	2	—	—	—	—	—	—	—	—	—	—
Harrington CC	3	—	2	—	—	10	5	—	—	—	—	—	—	—	—	—	—	—
Hawaii MU-NCORP	13	—	—	—	—	—	—	—	—	—	—	23	—	—	—	—	—	—
Heartland NCORP	30	6	11	—	—	—	—	1	—	—	—	—	—	—	—	—	—	—
Henry Ford Hospital	6	1	—	—	—	—	—	—	—	—	—	—	1	1	—	—	—	—
Irvine, U of CA	11	—	1	—	3	3	2	—	—	—	—	—	—	—	—	—	—	—
Kaiser Perm NCORP	50	15	31	—	—	1	34	9	—	—	6	34	—	—	—	—	21	—
Kansas City NCORP	9	—	1	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Kansas, U of	56	—	15	2	—	5	17	5	—	—	2	—	9	—	—	—	1	1
Kentucky, U of	—	—	—	—	—	—	—	2	—	—	—	—	—	—	—	—	—	—
Lahey Hosp & Med Ctr	4	—	2	—	—	—	7	4	—	—	—	—	—	—	—	—	—	—
Loma Linda Univ	10	—	—	—	1	2	—	—	—	3	—	—	—	—	—	—	—	—
Loyola University	16	2	3	—	—	—	4	2	—	1	—	—	—	1	—	—	—	—

## Breast Committee, cont.

## Cumulative Accrual by Institution and Study

Includes accrual through 7/12/2019. Includes studies that are currently open or that closed since 1/1/2018.

	S1207	S1416	S1418	S1706	A011106	A011202	A011401	A011502	A221405	B51	B55	E1Z11	E2112	EA1131	EA1151	NRGBR002	NRGBR003	NRGBR005
MAVERIC	—	—	—	—	—	—	—	1	—	—	—	—	—	—	—	—	—	—
MD Anderson CC	89	—	6	—	—	—	—	—	—	—	—	—	—	—	—	—	—	3
MUSC MU-NCORP	14	9	8	—	1	—	—	—	—	—	—	5	—	—	—	—	—	—
Memorial Hermann	3	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Methodist Hospital	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	1
Michigan CRC NCORP	25	15	11	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Michigan, U of	23	9	8	—	—	—	8	5	—	—	1	11	—	—	—	—	—	3
Montana NCORP	12	3	—	—	—	—	—	—	—	—	—	4	—	—	—	—	—	—
Nevada CRF NCORP	3	—	5	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
New Mexico MU-NCORP	29	15	10	—	2	—	—	—	—	—	—	—	—	—	—	—	—	—
Northwest NCORP	9	—	1	—	—	—	—	—	—	—	1	—	—	—	—	—	—	—
Northwestern Univ	23	—	1	—	—	—	—	—	1	—	—	—	2	—	—	—	—	1
Oklahoma, Univ of	9	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Orange Reg Med Ctr	—	—	3	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Oregon Hlth Sci Univ	18	3	5	—	—	—	—	—	—	1	—	—	1	—	—	—	—	2
Ozarks NCORP	15	7	2	—	—	—	—	—	—	—	—	9	—	—	—	—	—	3
PCRC NCORP	21	5	6	—	—	—	2	—	—	—	—	6	—	—	—	—	—	1
Providence Hosp	10	2	2	—	1	4	9	6	—	6	1	2	—	—	—	—	—	3
Rochester, Univ of	10	—	—	—	1	—	—	5	—	—	1	—	5	4	142	—	—	5
Salem Hospital	13	—	—	—	—	4	—	—	—	—	—	—	—	—	—	—	—	—
San Antonio, U of TX	24	—	4	—	1	1	1	—	—	3	1	—	4	—	—	—	—	4
San Diego, U of CA	—	—	—	—	—	—	2	1	—	—	—	—	—	—	—	—	—	1
Scott & White Mem	—	—	—	—	—	—	3	—	—	—	—	—	—	—	—	—	—	—
So Calif, U of	19	—	2	—	—	3	—	—	—	—	2	—	—	—	—	—	—	—
Southeast COR NCORP	38	5	23	—	—	—	1	6	—	—	—	—	—	—	—	358	—	—
St Louis University	1	—	—	—	1	—	—	—	—	—	—	—	—	—	—	—	—	—
Sutter Cancer RC	10	1	—	—	4	—	6	2	—	2	—	—	—	—	—	—	—	3
Tennessee, U of	8	—	—	—	—	6	—	—	—	4	—	—	—	—	—	—	—	—
Tulane University	2	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Univ of Louisville	—	—	—	—	—	2	—	—	—	—	—	—	—	—	—	—	—	—
Utah, U of	—	3	—	—	—	—	2	—	—	—	—	—	—	—	—	—	—	—
Wayne State Univ	17	—	—	—	—	11	12	9	—	—	3	—	3	3	—	—	—	6
Wichita NCORP	30	3	11	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Wisconsin NCORP	2	5	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Yale University	52	—	5	—	12	—	77	28	5	—	2	2	7	4	—	—	—	8
Alliance	276	62	51	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
ECOG-ACRIN	253	36	57	2	—	—	—	—	—	—	—	—	—	—	—	—	—	—
NRG	414	66	129	5	—	—	—	—	—	—	—	—	—	—	—	—	—	—
<b>Total</b>	<b>1,939</b>	<b>344</b>	<b>506</b>	<b>11</b>	<b>94</b>	<b>102</b>	<b>247</b>	<b>113</b>	<b>18</b>	<b>35</b>	<b>34</b>	<b>156</b>	<b>60</b>	<b>16</b>	<b>511</b>	<b>1</b>	<b>74</b>	<b>7</b>

# 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.  
 ..... Mark A. O'Rourke, M.D.  
 ..... Marie Bakitas, D.N.Sc., C.R.N.P.  
 Prevention and Epidemiology Cmte Co-Chairs: ..... Banu Arun, M.D.  
 ..... Marian Neuhouser, Ph.D., R.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: ..... Garnet Anderson, Ph.D.  
 ..... William E. Barlow, Ph.D.  
 ..... Katherine Guthrie, Ph.D.  
 ..... Cathy Tangen, Dr.P.H.  
 ..... Joseph M. Unger, Ph.D.  
 ..... Riha Vaidya, Ph.D.  
 ..... Kathryn B. Arnold, M.S.  
 ..... Amy K. Darke, M.S.  
 ..... Phyllis J. Goodman, M.S.  
 ..... Danika Lew, M.A.  
 ..... Anna Moseley, M.S.  
 ..... Eddie Mayerson, M.S.

## Administrative Lead

Statistics & Data Management Center (SDMC): ..... Monica Yee, C.C.R.P.

## Scientific Leadership

NCORP Representative: ..... Mark A. O'Rourke, M.D.  
 Radiation Oncology Committee: ..... Louis "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: ..... Afsaneh Barzi, M.D. (GI)  
 Early Therapeutics & Rare Cancers: ..... Jason M. Prosek, M.D.  
 Gastrointestinal Committee Colon: ..... Jason, Zell, D.O. (Prevention)  
 ..... Afsaneh Barzi, M.D. (CCD)

Genitourinary Committee: ..... Peter J. Van Veldhuizen, Jr., M.D.  
 International Liaison: ..... Kathy S. Albain, M.D.  
 Leukemia Committee: ..... Stephanie B. Tsai, M.D.  
 Lung Committee: ..... Gary E. Goodman, M.D.  
 Melanoma Committee: ..... Sancy Leachman, M.D., Ph.D.  
 ..... Thach-Giao Truong, M.D. (Survivorship)  
 Recruitment and Retention Committee: ..... Elise Cook, M.D.  
 Digital Engagement: ..... Jennifer R. Klemp, Ph.D. (Survivorship)  
 ..... Krishna Soujanya Gunturu, M.D. (Survivorship)  
 ..... Mina S. Sedrak, M.D. (CCD)  
 ..... Katherine D. Crew, M.D. (Prevention)  
 ..... Michael J. Fisch, M.D. (Symptom Control & QOL)

## Designates

### Oncology Research Professionals

Clinical Research Associates: ..... Amanda R. Dinsdale, M.H.A., C.C.R.C.  
 Nurses: ..... Joan Long, R.N., O.C.N.  
 ..... Connie Szczepanek, R.N., B.S.N.  
 ..... Joyce N. Tull, R.N., M.S.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)  
 ..... Amy Geschwender, Ph.D. (Symptom Control & QOL)  
 ..... Hartley "Lee" M. Jones, M.B.A. (Survivorship)  
 ..... Sandra Jean Hamilton, R.N., M.E.D. (Recruitment &  
 ..... Retention)  
 ..... Cheryl Jernigan, CPA (Prevention & Epidemiology)  
 ..... Valerie Fraser (Palliative & End of Life Care)  
 Protocol Coordinator (Cancer Care Delivery;  
 Prevention and Epidemiology Committees): ..... Patricia O'Kane  
 Protocol Coordinator (Cancer Survivorship  
 Committee): ..... Veronica Garcia  
 Protocol Coordinator (Symptom Control and  
 Quality of Life Committee): ..... TBD  
 Clinical Trials Project Manager (Palliative Care): ..... Vanessa Benavidez, B.S.,  
 ..... C.C.R.C.  
 Clinical Trials Project Manager (CCD; Prevention;  
 Survivorship): ..... Sandi Hita, J.D.  
 Clinical Trials Project Manager (Symptom Control): ..... Crystal Miwa

# 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 3, 2019 8:00 a.m. - 10:00 a.m.

Room: Regency D (Ballroom Level, West Tower)

## Presentations

Why is Implementation Science Important for Intervention Design? Rita Kukafka, Dr.PH., M.A., Columbia University Irving Medical Center

Tackling Financial Toxicity and Uncompensated Care with a Novel Technological Platform, Srulik Dvorsky, TailorMed

Financial Toxicity of Cancer: Advancing Assessment and Intervention, Grace Smith, M.D., Ph.D., M.P.H., MD Anderson

## \*\*Group panel discussion\*\*

## New Study Ideas

"Feasibility and Efficacy Study of the Implementation of an Educationally Enhanced Genomic Tumor Board (GTB) at NCORP Sites to Improve Understanding and Application of Genomic Tumor Testing (GTT)." Jens Rueter, M.D., Maine Cancer Genomics Initiative

"Quasi-Experimental Pilot Study of PEPID to Improve DDI Screening for SWOG Clinical Trial Enrollment." Dan Hertz, PharmD, Ph.D., University of Michigan

"A Multidimensional Study of Financial Burden in Cancer Care in the United States." Maryam Lustberg, M.D., M.P.H., Ohio State University

## Active 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, et al. Activated: 10/7/16.

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. Accordini. Activated: 7/16/18.

S1916, "Feasibility of a Digital Health Offering in Optimizing Opioid Pain Control in Cancer Patients." Drs. Hershman and Shen. Columbia University Irving Medical Center. (Pilot study sponsored by Proteus).

## Closed Studies

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. Ramsey, Loomba, Chugh, et al. Activated: 8/29/13; Closed: 2/15/17.

S1400 (Genomics), "Ancillary Study to Evaluate Patient & Physician Knowledge, Attitudes, and Preferences Related to Return of Genomic Results in SWOG 1400 (Lung-MAP)." Dr. J. Roth. Activated: 2/5/18; Closed: 6/30/19.

S1417CD, "Implementation of a Prospective Financial Impact Assessment Tool in Patients with Metastatic Colorectal Cancer." Dr. V. Shankaran. Activated: 4/15/16; Closed: 2/1/19.

S1105, "Text Messaging Intervention to Reduce Early Discontinuation of AI Therapy in Women with Early Stage Breast Cancer," Dr. A. Neugut. Activated: 3/27/12; Closed: 9/15/13. (Results to be presented at ASCO).

## Concepts in Development

S1912, "Randomized Trial of a Proactive Financial Navigation Intervention for Cancer Patients and Caregivers," Veena Shankaran, M.D., University of Washington

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

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

S1007, "Update on Quality of Life and Economic Analysis Sub-study of Breast protocol S1007." Bill Barlow, Ph.D.

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

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

# Cancer Care Delivery (CCD) Committee

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

## Database/Grant Funded Projects

### Published

Survival by Hispanic ethnicity among patients with cancer participating in SWOG clinical trials. Mariana Chavez-MacGregor, M.D. Published in Cancer, April 2018.

Osteoporosis in Patients with Colorectal Cancer Enrolled on SWOG Trials. Afsaneh Barzi, M.D. Published in Arch Osteoperos, July 2019

Geographic Distribution and Survival Outcomes for Rural Patients With Cancer Treated in Clinical Trials. Joseph Unger, Ph.D. Published in JAMA Network Open, August 2018.

Long-term Consequences of Finasteride vs Placebo in the Prostate Cancer Prevention Trial. Joseph Unger, Ph.D. Published in JNCI, August 2016.

Association between Body Mass Index and Response to Duloxetine for Aromatase Inhibitor- Associated Musculoskeletal Symptoms in SWOG S1202. Lynn Henry, M.D. Published in Cancer, June 2019.

### Ongoing

Sex Differences in Adverse Event Reporting in SWOG Chemotherapy, Biologic/Immunotherapy and Targeted Agent Cancer Clinical Trials. Joseph Unger, Ph.D.

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

Positive Clinical Trial Treatment Effects within Demographic and Insurance Status Subsets. Joseph Unger, Ph.D.

Association of BMI categories and healthcare utilization and costs among patients with the four most common cancers. Mariana Chavez-MacGregor, M.D.

Long-term Complications of Treatment for Prostate Cancer. Joseph Unger, Ph.D.

The Association of Baseline Cardiovascular Risk Factors and Healthcare Utilization and Costs in Elderly Breast Cancer Patients Enrolled in SWOG Clinical Trials. Dawn Hershman, M.D.

## Cancer Care Delivery Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/12/2019. Includes studies that are currently open or that closed since 1/1/2018.

	S1415CD	S1417CD	S1703	A011104	A191402CO	ACCL16N1	EAQ162CO	NHLBI/MDS
Arkansas, U of	—	—	1	—	—	—	—	—
Baptist MU-NCORP	123	—	—	1	—	—	—	—
Bay Area NCORP	31	2	—	—	—	—	—	—
Beaumont NCORP	7	—	—	—	5	—	—	2
Brooke Army Med Ctr	—	—	—	2	—	—	—	—
CORA NCORP	60	18	1	—	—	—	—	—
CRC West MI NCORP	59	20	—	—	—	—	—	—
Carle CC NCORP	60	1	2	—	—	—	—	—
Cleveland Clinic OH	—	—	—	—	—	—	—	3
Columbia MU-NCORP	102	11	1	—	1	—	—	—
Columbus NCORP	25	26	2	—	—	—	—	—
Dayton NCORP	29	4	1	—	—	—	2	—
Essentia Hlth NCORP	88	—	—	—	—	—	—	—
Fred Hutchinson CRC	—	—	—	—	—	—	—	3
GRU MU-NCORP	36	—	—	—	—	—	—	—
Georgia NCORP	57	9	—	—	—	—	—	—
Greenville NCORP	61	20	2	—	—	—	—	1
Gulf South MU-NCORP	82	12	—	—	—	—	—	—
H Lee Moffitt CC	—	—	—	—	—	—	—	8
Hawaii MU-NCORP	64	9	—	—	—	—	7	5
Heartland NCORP	280	37	3	—	—	—	—	—
Kaiser Perm NCORP	—	41	—	—	13	34	7	4
Kansas City NCORP	6	1	—	—	—	—	—	2
Lahey Hosp & Med Ctr	—	—	1	—	—	—	—	—
MAVERIC	—	—	—	—	—	—	—	5
Michigan CRC NCORP	236	13	1	—	—	—	—	—
Montana NCORP	107	1	—	—	—	—	—	—
Nevada CRF NCORP	—	1	—	—	—	—	—	—
New Mexico MU-NCORP	212	6	—	—	—	—	—	—
Northwest NCORP	99	3	—	—	—	—	—	—
Oregon Hlth Sci Univ	—	—	—	—	—	—	—	3
Ozarks NCORP	113	3	—	—	—	—	—	—
PCRC NCORP	176	8	2	—	—	—	4	—
Providence Hosp	—	—	—	12	—	—	—	—
Rochester, Univ of	—	—	3	—	—	—	—	—
San Diego, U of CA	—	—	—	—	—	—	—	7
Southeast COR NCORP	120	16	—	2	—	—	9	—
VAMC Kansas City	—	—	—	—	—	—	—	2
Wayne State Univ	—	—	—	1	—	—	—	—
Wichita NCORP	60	8	—	—	—	—	—	—
Wisconsin NCORP	151	2	—	—	—	—	—	—
Yale University	—	—	4	4	—	—	—	4
Alliance	284	23	—	—	—	—	—	—
ECOG-ACRIN	331	65	2	—	—	—	—	—
NRG	145	20	—	—	—	—	—	—
<b>Total</b>	<b>3,204</b>	<b>380</b>	<b>26</b>	<b>22</b>	<b>19</b>	<b>34</b>	<b>29</b>	<b>49</b>

# Cancer Survivorship Committee

## Leadership

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

## Time/Location

Friday, October 4, 2019 7:00 a.m. - 9:00 a.m.  
 Room: Regency D (Ballroom Level, West Tower)

**Welcome and Introduction:** Melinda Irwin and Halle Moore

**Update from committee liaison mini-retreat**

**Survivorship Presentation: Onco-Fertility:** Clarisa Gracia M.D., Chief, Division of Reproductive Endocrinology and Infertility Hospital of the University of Pennsylvania

## Onco-fertility Concepts

“GnRH agonists for ovarian function protection during chemotherapy treatment of non-breast AYA malignancies.” Jennifer Levine, M.D.

“Impact of Immune Checkpoint Inhibition on Gonadal Reserve: A Longitudinal Analysis of Biospecimens from S1404” Katy Tsai, M.D.

## Other New Ideas

“Modeling thrombosis risk in patients treated with modern myeloma therapy” Raj Chakraborty M.D.

“Reducing health disparities through lifestyle interventions in colorectal survivors” Heather Greenlee, Ph.D.

**Patient Advocate Update:** Lee Jones

## Other Liaison Updates

## Active Study

**S1501.** “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.

## Cardiac Advisory Panel Update

## Previously Presented Concepts in Development

**S1926.** “Tele-psychiatry for Women with Breast Cancer and Major Depression.” John Markowitz, M.D., David Hellerstein, M.D., and Jon Levenson, M.D.

## SWOG Endorsed Survivorship Studies

**UPBEAT Study,** looking at risk factors for cardiac toxicity in patients with early stage Breast Cancer which has been activated in ECOG. The study involves getting a cardiac MRI(s).

# Cancer Survivorship Committee

## Cumulative Accrual by Institution and Study

Includes accrual through 7/12/2019. Includes studies that are currently open or that closed since 1/1/2018.

	S1316	S1501	E1Q11	EA9131
Arizona CC, Univ of	10	—	—	—
Arkansas, U of	6	—	—	—
Bay Area NCORP	—	2	—	—
Baylor College	1	—	—	—
CORA NCORP	—	1	—	—
City of Hope Med Ctr	5	18	—	—
Cleveland Clinic OH	—	4	—	—
Columbia MU-NCORP	1	2	—	—
Davis, U of CA	—	1	—	—
Essentia Hlth NCORP	1	—	—	—
Georgia NCORP	—	5	—	—
Greenville NCORP	—	1	—	—
H Lee Moffitt CC	3	4	—	—
Hawaii MU-NCORP	—	—	20	—
Heartland NCORP	—	10	—	—
INCan	5	—	—	—
INEN	5	—	—	—
Kaiser Perm NCORP	—	—	—	28
Kansas, U of	18	4	—	—
Lahey Hosp & Med Ctr	—	5	—	—
Loma Linda Univ	1	—	—	—
Loyola University	—	8	—	—
MD Anderson CC	2	—	—	—
MUSC MU-NCORP	5	1	—	—
Michigan, U of	8	3	—	—
New Mexico MU-NCORP	1	—	1	—
Oklahoma, Univ of	2	—	—	—
Ozarks NCORP	—	3	—	—
Providence Hosp	—	1	—	—
San Antonio, U of TX	5	—	—	—
Southeast COR NCORP	—	—	1	—
Tennessee, U of	36	—	—	—
Wayne State Univ	—	3	—	—
Alliance	25	11	—	—
ECOG-ACRIN	2	16	—	—
NRG	57	11	—	—
<b>Total</b>	<b>199</b>	<b>114</b>	<b>22</b>	<b>28</b>

## Other Updates and Additional Business: Group

**POSITIVE Study,** Interrupting endocrine therapy for pregnancy attempt.  
 No longer enrolling new sites



# Palliative and End of Life Care Committee

## Leadership

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

## Time/Location

Thursday, October 3, 2019 10:15 a.m. - 12:15 p.m.  
 Room: Regency D (Ballroom Level, West Tower)

## Agenda

10:15 – 10:25 a.m.	Welcome and Introductions – Co-Chairs
10:25 – 10:35 a.m.	Committee Liaison Updates
	Patient Advocates
	NCORP Representatives
10:35 – 10:55 a.m.	Plenary
	Dr. Justin Sanders & Dr. Bob Arnold
10:55 – 11:55 a.m.	Proposed Concepts Discussion
11:55 – 12:10 p.m.	Active Study Updates
12:10 – 12:15 p.m.	New Business
12:15 p.m.	Closing Comments and Adjourn

## Active Studies

**S1316**, “Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction.” Dr. Krouse. Activated: 3/9/15.

**S1820**, “A Randomized Phase II Trial of the Altering Intake, Managing Symptoms Intervention for Bowel Dysfunction in Rectal Cancer Survivors (AIMS-RC). Dr. V. Sun. Activation: anticipated October 2019

“Hopefulness for Providers and Patients, Survey.” Drs. Corn & Feldman. Activated: July 2019

## Proposed Concepts

“Advanced Cancer Communication and Advance Care Planning Trial (ACCEPT)” Drs. Sanders & Arnold

“Randomized Phase III Trial of a Primary Palliative Care Intervention in Pancreatic Cancer.” Drs. Chung & Sun

“Exploring intimacy for patients in palliative care.” Drs. Yung & Dizon.

“Symptom Management of Treatment-Related Toxicities from Oral Targeted Agents in Metastatic Renal Cell Carcinoma Patients.” Drs. Reding & Fung

“Whole Cannabis Plant extract RCT PhI/II Proposal.” Drs. Hernandez-Suarez & Krouse

“Depression screening and treatment in patients requesting Medical Aid In Dying (MAID).” Drs. Salman & Blanke

# Prevention & Epidemiology Committee

## Leadership

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

## Time/Location

Thursday, October 3, 2019 5:00 p.m. - 7:00 p.m.  
 Room: Regency D (Ballroom Level, West Tower)

## Introduction

**Welcome and Opening Comments:** Marian Neuhouser and Banu Arun

**Presentation:** "Collaborating on prostate cancer and other men's health research leveraging the resources of PCPT and SELECT: tissue biomarkers and embedded study design". Dr. Elizabeth Platz, Martin D Abeloff, MD Scholar in Cancer Prevention, Deputy Chair Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health.

## 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. D. Hill, MPH, Ph.D. and Cecilia Arana Yi, M.D. Study Champions. Activated: 4/5/16.

## Protocols Pending DCP Approval

**S1904**, "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.

**S1823**, "A Prospective Observational Cohort Study to Assess miRNA 371 for Outcome Prediction in Patients with Newly Diagnosed Germ Cell Tumors". Drs. Nappi and Nichols.

## Pending CTEP Approval

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

## Concept pending R01 funding

**S1906**, "A Randomized Double-Blind Placebo-Controlled Biomarker Study of Aspirin in Addition to Non-Steroidal Aromatase Inhibitors in Women of High BMI ( $\geq 30$  kg/m<sup>2</sup>) with Breast Cancer". Andrew Brenner, M.D., Ph.D.

## Other Proposals in Development

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

Effects of Chemoprevention and Adjuvant Endocrine Therapy on a Convolutional Neural Network (CNN)-Based Breast Cancer Risk Model Using Breast Imaging Datasets. Drs. K. Crew, K. Kalinsky, R. Ha.

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

Melanoma Chemoprevention. Sancy Leachman, M.D.

## New Business/Open Discussion

Save the date for the  
 Spring 2020 meeting

April 22-25 | San Francisco, CA



## Prevention & Epidemiology Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/12/2019. Includes studies that are currently open or that closed since 1/1/2018.

	50820	A211102	A211401	A211601
Baptist MU-NCORP	3	—	—	—
Bay Area NCORP	1	—	—	—
Brooke Army Med Ctr	3	—	—	—
CORA NCORP	3	—	—	—
CRC West MI NCORP	1	—	—	—
City of Hope Med Ctr	1	2	—	—
Colorado, U of	5	—	—	—
Columbia MU-NCORP	1	1	—	—
Columbus NCORP	5	—	—	—
Dayton NCORP	1	—	—	—
Essentia Hlth NCORP	4	—	—	—
Georgia NCORP	2	—	—	—
Hawaii MU-NCORP	10	—	—	—
Heartland NCORP	2	—	—	—
Irvine, U of CA	21	—	—	—
Kaiser Perm NCORP	30	—	—	—
Kansas, U of	3	—	—	—
Loma Linda Univ	2	—	—	—
Loyola University	2	—	—	—
MAVERIC	3	—	2	—
MD Anderson CC	10	—	—	—
Michigan CRC NCORP	6	—	—	—
Mississippi, Univ of	1	—	—	—
Nevada CRF NCORP	1	—	—	—
New Mexico MU-NCORP	1	—	—	—
Northwest NCORP	9	—	—	—
Oklahoma, Univ of	1	—	—	—
PCRC NCORP	1	—	—	—
Providence Hosp	1	—	—	1
San Antonio, U of TX	8	—	—	—
So Calif, U of	5	—	—	—
Southeast COR NCORP	2	—	—	—
Wayne State Univ	2	—	—	—
Wichita NCORP	13	—	—	—
Wisconsin NCORP	1	—	—	—
Yale University	14	—	—	—
Alliance	24	—	—	—
ECOG-ACRIN	17	—	—	—
NRG	27	—	—	—
<b>Total</b>	<b>247</b>	<b>3</b>	<b>2</b>	<b>1</b>

# 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 3, 2019 1:00 p.m. - 3:00 p.m.  
 Room: Crystal B (Lobby Level, West Tower)

## Feature Presentation (50 minutes)

"Oncology Acupuncture for Symptom Management: Precision Medicine meets Patient-Centered Care" Jun J. Mao, MD, MSCE. Chair, Integrative Medicine, Memorial Sloan Kettering Cancer Center

## Active Trials (15 min)

S1600, "Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes." Drs. Hamilton-Reeves and Holzbeierlein. Activated 2/21/19.

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. Activated 2/21/19.

S1714, "A Prospective Observational Cohort Study to Develop a Predictive Model of Taxane-Induced Peripheral Neuropathy in Cancer Patients." Drs. Trivedi, Hershman, Brannagan, et al. Activated 3/1/19.

## Other Concepts in Development (30 min)

"Immunotherapy Adverse Events Observational Study". Drs. Gunturu and Kuderer

"mHealth Mindfulness to Improve Quality of Life in Castration-Resistant Metastatic Prostate Cancer Patients and their Partners." Drs. Kubo and Greyz.

"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

## Other Discussion Topics (20 minutes)

Advocates update – Dr. Amy Geschwender

Stats update – Dr. Joe Unger

## 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.

S1202, "A Randomized Placebo-Controlled Phase III Study of Duloxetine for Treatment of Aromatase Inhibitor(AI)-Associated Musculoskeletal Symptoms in Women with Early Stage Breast Cancer." Drs. Henry and Schott. Activated: 5/15/13. Closed to accrual 10/1/15.

## Other SWOG 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<sup>3</sup> 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. Puztai Mammen, Henry, et al. Activated: 11/15/16.

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

S1807, "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

S1802, "Phase III Randomized Trial of Standard Systemic Therapy (SST) Versus Standard Systemic Therapy plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer." Dr. Chapin. Activated 9/17/18

S-N1806, "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. Temporarily Closed to accrual 10/22/2018.

# Symptom Control & Quality of Life Committee

## 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.

**S1400GEN**, "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.

**S1827**, "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

**S1803**, "Phase III Study of Daratumumab (NSC-791647) + Lenalidomide (LD) or Lenalidomide (L) as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) Using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC Study)." Drs. 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: 12/9/2013. 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: 3/15/2008. 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 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.

# Symptom Control & Quality of Life Committee

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

## Symptom Control & Quality of Life Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/12/2019. Includes studies that are currently open or that closed since 1/1/2018.

	S1600	S1714	A221101	A221504	A221505	NRGGU003
Arkansas, U of	—	—	1	—	—	—
CRC West MI NCORP	—	3	—	—	—	—
Cleveland Clinic OH	—	—	—	—	1	3
Colorado, U of	—	—	—	—	8	—
Columbia MU-NCORP	—	3	—	—	—	—
Dayton NCORP	—	—	—	1	—	—
Irvine, U of CA	—	—	8	—	1	—
Kansas, U of	8	—	2	—	—	—
Kentucky, U of	—	—	1	—	—	—
Loma Linda Univ	—	—	2	—	—	—
Northwest NCORP	—	—	1	—	—	—
Ozarks NCORP	—	1	—	—	—	—
Providence Hosp	—	—	3	—	—	—
Rochester, Univ of	—	—	—	1	—	—
San Antonio, U of TX	—	—	1	—	—	—
So Calif, U of	—	—	—	1	—	—
Southeast COR NCORP	—	7	—	—	—	—
Sutter Cancer RC	—	—	1	—	—	—
Upstate Carolina	—	—	1	—	—	—
VAMC Kansas City	—	—	—	1	—	3
<b>Total</b>	<b>8</b>	<b>14</b>	<b>21</b>	<b>4</b>	<b>10</b>	<b>6</b>

**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: 7/8/2011. Closed: 12/18/2015.

**CTSU/R0848**, "A Phase II-R and a Phase III Trial Evaluating Both Erlotinib (Ph II-R) and Chemoradiation (Ph III) as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma." Dr. 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  
 ..... Sewan Gurung  
 Digital Engagement: ..... Kanwal Raghav, M.D., M.B.B.S.  
 Oncology Research Professionals:  
 CRA: ..... Corrine Turrell, C.C.R.P.  
 ..... Yarden Ginsburg  
 Nurse: ..... TBD  
 Pharmaceutical Science: ..... Craig Elg, PharmD  
 ..... Sun "Coco" Yang, PharmD  
 Patient Advocate: ..... Marcia K. Horn, J.D.  
 Protocol Coordinator: ..... Cara Laubach, M.I.I.M. (Interim Coordinator)  
 Clinical Trials Project Manager: ..... Crystal Miwa

## Early Therapeutics Liaisons

Breast Committee Liaison: ..... George Somlo, M.D.  
 Cancer Control Liaison: ..... Jason M. Prosek, M.D.  
 Genitourinary Committee Liaison: ..... Neeraj Agarwal, M.D.  
 Imaging: ..... 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 3, 2019 10:00 a.m. - 12:15 p.m.  
 Room: Crystal B (Lobby Level, West Tower)

## Introduction

**10:00 a.m. - 10:05 a.m.:** Razelle Kurzrock, M.D., Director, Center for Personalized Cancer Therapy, UCSD Moores Comprehensive Cancer Center, San Diego, CA; Chair, Early Therapeutics and Rare Cancer Committee (SWOG)

## Presentations

**10:05 a.m. - 10:40 a.m.:** "Early Therapeutic Overview: The Cutting Edge?"  
 Monica Mita, M.D., Associate Professor, Department of Medicine;  
 Co-Director, Experimental Therapeutics Program, Samuel Oschin  
 Comprehensive Cancer Institute, Cedars-Sinai Medical Center.

**10:40 a.m. - 11:05 a.m.:** "Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors (DART)." Sandip Pa-tel M.D., Associate Professor, Deputy Director, San Diego Center for Precision Immunotherapy, UC San Diego Moores Comprehensive Cancer Center, San Diego, CA.

**11:05 a.m. - 11:30 a.m.:** "DART Translational Initiative." Young Kwang Chae, M.D., Associate Professor, Co-Director, Early Therapeutics, Northwestern University, Robert H. Lurie Comprehensive Cancer Center.

**11:30 a.m. - 11:50 a.m.:** "Angiosarcoma: Rationale for a DART Cohort."  
 Michael Wagner, M.D., Assistant Professor, Division of Medical Oncology, University of Washington, Fred Hutchinson Cancer Research Center,

**11:50 a.m. - 12:05 p.m.:** "PDL1 Amplification and Immunotherapy." Razelle Kurzrock, M.D., Director, Center for Personalized Cancer Therapy, UCSD Moores Comprehensive Cancer Center, San Diego, CA; Chair, Early Therapeutics and Rare Cancer Committee (SWOG)

**12:05 p.m. - 12:15 p.m.:** Wrap Up and Open Discussion. Razelle Kurzrock, M.D., Director, Center for Personalized Cancer Therapy, UCSD Moores Comprehensive Cancer Center, San Diego, CA; Chair, Early Therapeutics and Rare Cancer Committee (SWOG)

## Active Studies

**S1609,** "DART: Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors." Drs. P. Patel, Y. Chae, F. Giles, and R. Kurzrock. Activated: 1/13/17.

**CTSU/A071401,** "Phase II Trial of SMO/AKT/NF2 Inhibitors in Progressive Meningiomas with SMO/AKT/ NF2 Mutations." Dr. D.E. Piccioni. Activated by Alliance 8/28/15. Activated by SWOG: 1/1/16. Temporarily Closed to Accrual 2/15/18.

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

**CTSU/EAE161,** "Perfusion CT to Predict Progression-free Survival and Response Rate in Bevacizumab and Paclitaxel Treatment of Platinum-Resistant Persistent or Recurrent Epithelial Ovarian, Fallopian Tube, or Peritoneal Carcinoma." Dr. D. Dizon. Activated by ECOG-ACRIN 2/14/18, activated by SWOG 3/1/19. Temporarily closed to accrual effective 3/20/19.

## Recently Closed Studies

**CTSU/ARST1321,** "Pazopanib Neoadjuvant Trial in Non-Rhabdomyosarcoma Soft Tissue Sarcomas (PAZNTIS): A Phase II/III Randomized Trial of Preoperative Chemoradiation or Preoperative Radiation Plus or Minus Pazopanib (NSC# 737754, IND# 118613)." Dr. V.M. Villalobos. Activated by COG 1/27/14. Activated by SWOG: 3/15/16. Permanently closed to accrual: 1/22/19.

# Early Therapeutics & Rare Cancers Committee

**CTSU/A071102**, "A Phase II/III Randomized Trial of Veliparib or Placebo in Combination with Adjuvant Temozolomide in Newly Diagnosed Glioblastoma with MGMT Promoter Hypermethylation." Dr. D.E. Piccioni. Activated by Alliance 12/15/14. Activated by SWOG: 4/1/15. Permanently closed to accrual (Step 1): 10/15/18.

## Proposed Studies

**SXXXX**, "A Phase II Trial of Dostarlimab plus Cisplatin/Bevacizumab for Advanced, Recur-rent/Metastatic Carcinoma of the Cervix." Dr. W.R. Robinson.

**SXXXX**, "Randomized Phase 2 Trial of First Line Platinum/Etoposide With or Without Atezolizumab in Patients with Poorly Differentiated Non-Pulmonary Small Cell Neuroendocrine Carcinomas (NEC)" Dr. D.B. Zhen.

# Early Therapeutics & Rare Cancers Committee

## Cumulative Accrual by Institution and Study

Includes accrual through 7/12/2019. Includes studies that are currently open or that closed since 1/1/2018.

	S1609	A071102	A071401	ARST1321	EAY131		S1609	A071102	A071401	ARST1321	EAY131
Arizona CC, Univ of	3	—	—	—	8	MD Anderson CC	17	—	—	—	—
Arkansas, U of	3	—	—	—	3	MUSC MU-NCORP	4	—	—	—	—
Baptist MU-NCORP	2	—	—	—	—	Methodist Hospital	—	—	—	—	1
Baylor College	—	2	—	—	3	Michigan CRC NCORP	15	—	—	—	—
Brooke Army Med Ctr	—	2	—	—	—	Michigan, U of	25	—	—	—	21
CORA NCORP	5	1	1	—	1	Mississippi, Univ of	3	1	—	—	—
Carle CC NCORP	2	—	—	—	—	Montana NCORP	10	—	—	—	—
Cedars-Sinai Med Ctr	5	—	—	—	6	Nevada CRF NCORP	16	—	—	—	—
City of Hope Med Ctr	—	—	—	—	6	New Mexico MU-NCORP	14	—	—	—	—
Cleveland Clinic OH	—	—	—	—	7	Northwest NCORP	2	—	—	—	—
Colorado, U of	6	3	1	—	9	Northwestern Univ	9	1	—	1	—
Columbus NCORP	3	—	—	—	—	Oklahoma, Univ of	1	—	—	—	—
Davis, U of CA	9	—	—	—	7	Oregon Hlth Sci Univ	3	—	—	4	—
Dayton NCORP	2	—	—	—	1	Ozarks NCORP	1	2	—	—	—
Essentia Hlth NCORP	3	—	—	—	—	PCRC NCORP	9	3	—	—	—
Fred Hutchinson CRC	6	—	—	—	2	Providence Hosp	1	1	—	—	2
Georgia NCORP	4	—	—	—	—	Rochester, Univ of	2	13	—	—	—
Gulf South MU-NCORP	2	—	—	—	—	San Antonio, U of TX	5	—	—	3	6
H Lee Moffitt CC	17	—	—	—	—	San Diego, U of CA	18	7	2	—	—
Hawaii MU-NCORP	3	—	—	—	1	So Calif, U of	1	—	—	—	—
Heartland NCORP	14	—	—	—	1	Southeast COR NCORP	4	—	—	—	8
Henry Ford Hospital	15	—	—	—	11	Sutter Cancer RC	2	—	—	—	4
Irvine, U of CA	8	2	1	—	10	Tulane University	—	—	—	—	1
Kaiser Perm NCORP	24	5	—	—	5	Utah, U of	3	—	—	—	—
Kansas City NCORP	—	—	—	—	1	Wayne State Univ	—	—	—	—	3
Kansas, U of	27	—	—	1	5	Wisconsin NCORP	8	—	—	—	—
Kentucky, U of	—	—	—	—	13	Yale University	5	3	—	—	9
Lahey Hosp & Med Ctr	—	3	—	—	—	Alliance	73	—	—	—	—
Loma Linda Univ	2	—	—	—	1	ECOG-ACRIN	68	—	—	—	—
Loyola University	2	—	—	—	—	NRG	93	—	—	—	—
MAVERIC	3	—	—	—	—	<b>Total</b>	<b>582</b>	<b>49</b>	<b>5</b>	<b>9</b>	<b>156</b>



# Gastrointestinal Committee

## Leadership

Chair: ..... Philip A. Philip, M.D., Ph.D.  
 Vice-Chair: ..... Cathy Eng, M.D.  
 Executive Officer: ..... Christopher W. Ryan, M.D.  
 Statisticians: ..... Katherine A. Guthrie, Ph.D.  
 ..... Danika Lew, M.A.  
 ..... Mai Duong, M.S.

## Scientific Leadership

Phase I Studies: ..... Sandip P. Patel, M.D.  
 Gastroesophageal: ..... Syma Iqbal, M.D.  
 ..... Zev A. Wainberg, M.D.  
 Pancreatic: ..... Elena Gabriela Chiorean, M.D.  
 ..... Andrew M. Lowy, M.D. (Surgical representative)  
 Hepatobiliary: ..... Anthony B. El-Khoueiry, M.D.  
 ..... Milind Javle, M.D.  
 ..... Syed Ahmad, M.D. (Surgical representative)  
 Colon: ..... Philip J. Gold, M.D.  
 ..... Wells A. Messersmith, M.D.  
 Neuroendocrine Tumors: ..... Nageshwara Arvind Dasari, M.D.  
 ..... Jonathan R. Strosberg, M.D.  
 Rectal: ..... Lisa A. Kachnic, M.D.  
 ..... Hagen F. Kennecke, M.D.  
 Translational Medicine: ..... Heinz-Josef Lenz, M.D.  
 ..... Christopher H. Lieu, M.D.  
 Drug Development: ..... TBD  
 Imaging: ..... Anthony F. Shields, M.D., Ph.D.  
 Radiation Oncology: ..... Lisa A. Kachnic, M.D.

## Designates

Cancer Control Liaison: ..... Jason A. Zell, D.O.  
 Digital Engagement: ..... Heloisa Soares, M.D., Ph.D.  
 Data Coordinators: ..... Christine McLeod  
 ..... Jacqueline Scurlock  
 ..... Brian Zeller  
 ..... Sewan Gurung  
 Oncology Research Professionals:  
 CRA: ..... Sandy Annis, C.C.R.P.  
 Nurses: ..... Rita Kaul, R.N., B.S.N.  
 Patient Advocate (Pancreatic): ..... Carole Seigel, M.B.A.  
 Patient Advocate (Colon): ..... Florence Kurttila, M.S.  
 Pharmaceutical Science: ..... Jane E. Rogers, Pharm.D.  
 Protocol Coordinator: ..... Danae Campos, M.B.A.  
 Clinical Trials Project Manager: ..... Vanessa Benavidez, B.S., C.C.R.C.

## Time/Location

Friday, October 4, 2019 4:00 p.m. - 6:00 p.m.  
 Room: Regency C (Ballroom Level, West Tower)

**Introduction:** Philip A. Philip, M.D. & Cathy Eng, M.D.

## Featured Trial

**S1922**, "Randomized Phase II Study of Ramucirumab and Paclitaxel versus FOLFIRI in Refractory Small Bowel Adenocarcinoma". Dr. Michael Overman.

## Gastroesophageal

### Active Studies

**EA2174**, "A Phase II/III Study of Peri-operative Nivolumab and Ipilimumab in Patients with Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma." Dr. Kaitlyn Kelly. Activated 1/17/19.

## Pancreatic

### Proposed Studies

**S2001**, "Parallel Randomized Phase II Clinical Trials of Olaparib + Pembrolizumab vs. Olaparib as Maintenance Therapy in Two Cohorts of Metastatic Pancreatic Cancer Patients with DNA Damage Repair Defects". Dr. Vincent Chung.

### 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

### Closed Studies

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

**S1513**, "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.

**S1505**, "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 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 6/01/18.

# Gastrointestinal Committee

## Neuroendocrine

**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.

**EA2161**, "A Phase II Study of MLN0128 (TAK-228) in Rapalog-Resistant Advanced Pancreatic Neuroendocrine Tumors (PNET)." NCTN activated: 11/5/18

## Hepatobiliary

### Active Studies

**S1815**, Gemcitabine, cisplatin, and nab-paclitaxel versus gemcitabine and cisplatin in advanced biliary cancers: a randomized Phase II/III study. Dr. Rachna Shroff. Activated: 12/3/18

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

## Colon

### Active Studies

**A021502**, "Randomized Trial of Standard Chemotherapy Alone or Combined with Atezolizumab as Adjuvant Therapy for Patients with Stage III Colon Cancer and Deficient DNA Mismatch Repair."

**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." Dr. Zell. Activated: 3/1/13.

**S1417CD**, "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

**CTSU/NRG-GI004/S1610**, "Colorectal Cancer Metastatic MSI-High Immuno-Therapy (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 Microsatellite Instability-High (MSI-H) Metastatic Colorectal Cancer" Overman. Activated: 11/7/17.

## Rectal

### Active Studies

**CTSU/NRG-GI002**, "A Phase II Clinical Trial Platform of Sensitization Utilizing Total Neoadjuvant Therapy (TNT) in Rectal Cancer." Dr. Kachnic. Activated: 10/12/2016.

### Closed Studies

**CTSU/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.

## Anal

### Active Studies

**EA2165**, "A Randomized Phase II Study of Nivolumab After Combined Modality Therapy (CMT) in High Risk Anal Cancer." NCTN activated: 04/13/2018

**EA2182**, "A Randomized Phase II Study of De-Intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE). Dr. Dorth.

### Pending approval:

**EA2176**, "Immune checkpoint inhibition with chemotherapy in treatment-naïve metastatic anal cancer patients. Drs. Eng and Van Morris.

### Closed

**InterAACT EA2133**, "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.

# Gastrointestinal Committee

## Other

### Proposed Studies

S1922, "Randomized Phase II Study of Ramucirumab and Paclitaxel versus FOLFIRI in Refractory Small Bowel Adenocarcinoma". Dr. Michael Overman.

### Active Studies

S1316, "Prospective Comparative Effectiveness Trial For Malignant Bowel Obstruction." Dr. Krouse. Activated: 3/9/15.

S1609, "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

S1204, "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.

## Gastrointestinal Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/12/2019. Includes studies that are currently open or that closed since 1/1/2018.

	S1505	S1613	S1815	A021501	A021502	A021602	EA2142	EA2161	EA2165	N1048	NRGG1002	NRGG1004	R0848
Arizona CC, Univ of	1	—	1	—	—	—	—	—	—	4	—	—	—
Arkansas, U of	—	—	—	—	—	—	—	—	1	—	—	—	—
Baptist MU-NCORP	1	—	—	—	—	—	—	—	—	—	—	—	—
Baylor College	—	—	—	—	—	—	—	—	—	25	2	—	—
Beaumont NCORP	—	—	—	—	1	—	—	—	—	—	—	—	—
Boston Medical Ctr	—	—	—	—	1	1	—	—	1	4	—	—	—
CORA NCORP	—	—	—	—	—	—	—	—	—	2	—	—	—
Carle CC NCORP	2	—	—	—	—	—	—	—	—	—	—	—	—
Cincinnati MC, U of	2	—	—	2	—	—	—	—	—	—	—	—	—
City of Hope Med Ctr	—	—	3	—	—	—	—	—	—	—	—	—	—
Cleveland Clinic OH	6	—	—	—	—	—	—	—	—	—	—	—	—
Colorado, U of	—	1	—	—	1	—	—	—	—	1	—	—	—
Columbia MU-NCORP	—	—	—	—	—	—	—	—	—	—	—	—	2
Columbia University	—	—	—	—	—	—	—	—	—	—	—	—	1
Columbus NCORP	1	—	1	—	—	—	—	—	—	—	—	—	—
Davis, U of CA	—	—	3	—	3	—	—	—	1	2	—	—	—
Dayton NCORP	3	—	—	—	1	—	—	—	—	2	2	—	—
Fred Hutchinson CRC	—	—	—	—	—	—	—	—	1	17	4	—	—
Greenville NCORP	4	—	1	—	—	—	—	—	—	—	—	—	1
Gulf South MU-NCORP	—	—	1	—	—	—	—	—	—	—	—	—	—
Hawaii MU-NCORP	—	—	4	—	—	—	—	—	—	—	—	—	1
Heartland NCORP	7	1	—	—	—	—	—	—	—	—	—	—	—
Irvine, U of CA	—	—	—	3	—	—	—	—	—	19	1	—	6
Kaiser Perm NCORP	5	—	—	1	5	—	1	—	2	22	—	—	—
Kansas, U of	3	1	—	—	—	—	—	—	—	1	1	—	1
Kentucky, U of	3	—	—	1	—	—	—	—	—	—	—	—	—
Lahey Hosp & Med Ctr	—	—	—	—	—	—	—	—	—	12	—	—	—
Loyola University	—	1	—	—	—	—	—	—	—	—	—	—	4
MD Anderson CC	—	10	—	—	—	—	—	—	—	—	—	8	—



# Since 1956,

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1,400 cancer clinical trials.

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or better, for thousands of people.

## Gastrointestinal Committee, cont.

### Cumulative Accrual by Institution and Study

Includes accrual through 7/12/2019. Includes studies that are currently open or that closed since 1/1/2018.

	S1505	S1613	S1815	A021501	A021502	A021602	EA2142	EA2161	EA2165	N1048	NRGG1002	NRGG1004	R0848
MUSC MU-NCORP	3	—	—	—	—	—	—	—	—	—	—	—	—
Methodist Hospital	—	—	—	—	—	—	—	—	—	12	—	—	—
Michigan CRC NCORP	2	—	—	—	—	—	—	—	—	—	—	—	—
Michigan, U of	6	1	—	6	—	—	3	1	—	5	—	—	—
New Mexico MU-NCORP	1	—	1	—	—	—	—	—	—	2	—	—	—
Northwest NCORP	—	—	—	—	—	—	—	—	—	1	1	—	3
Northwestern Univ	—	—	—	—	—	—	—	—	—	1	—	—	—
Oklahoma, Univ of	1	—	—	—	—	—	—	—	—	—	—	—	—
Orange Reg Med Ctr	—	—	—	—	—	—	—	—	—	—	1	—	—
Ozarks NCORP	2	—	1	—	—	—	—	—	—	1	—	—	—
PCRC NCORP	5	2	—	—	—	—	—	—	—	1	—	—	—
Rochester, Univ of	4	—	—	1	2	—	—	—	—	22	—	1	—
Salem Hospital	1	—	—	—	—	—	—	—	—	—	—	—	—
San Antonio, U of TX	1	—	—	—	—	—	—	—	—	—	—	—	—
San Diego, U of CA	6	—	—	—	—	—	—	—	—	4	—	—	—
Scott & White Mem	—	—	—	—	—	—	—	—	—	1	—	—	—
So Calif, U of	—	1	1	—	—	—	—	—	—	4	2	—	—
Southeast COR NCORP	3	—	—	—	—	—	—	—	—	—	—	—	—
Sutter Cancer RC	—	—	—	1	2	—	—	—	—	—	—	—	—
Utah, U of	—	—	—	—	—	—	—	—	—	4	—	—	—
Wayne State Univ	—	—	1	1	—	—	—	—	3	—	3	—	—
Wichita NCORP	—	—	—	—	—	—	—	—	—	—	—	—	1
Wisconsin NCORP	3	—	—	—	—	—	—	—	—	—	—	—	—
Yale University	—	—	—	—	—	—	—	—	—	1	3	—	—
Alliance	18	3	15	—	—	—	—	—	—	—	—	—	—
ECOG-ACRIN	32	2	11	—	—	—	—	—	—	—	—	—	—
NRG	21	—	3	—	—	—	—	—	—	—	—	—	—
<b>Total</b>	<b>147</b>	<b>23</b>	<b>47</b>	<b>16</b>	<b>16</b>	<b>1</b>	<b>4</b>	<b>1</b>	<b>9</b>	<b>170</b>	<b>20</b>	<b>9</b>	<b>20</b>

# Thanks, team!



# Genitourinary Committee

## Leadership

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

## Scientific Leadership

Translational Medicine: ..... David J. McConkey, Ph.D. (GU Chair)  
 ..... Joshua J. Meeks, M.D., Ph.D. (Bladder)  
 ..... Amir Goldkorn, M.D. (Prostate)  
 ..... Sumanta "Monty" K. Pal, M.D. (Renal)  
 Radiation Oncology: ..... James B. Yu, M.D.  
 ..... Jing Zeng, M.D.  
 Imaging: ..... Daniel W. Lin, M.D.  
 ..... Hiram Shaish, M.D.  
 ..... John D. Hazle, Ph.D.  
 Pathology: ..... M. Scott Lucia, M.D.  
 Liaison to the SPORES: ..... Colin P.N. Dinney, M.D.  
 Early Therapeutics: ..... Neeraj Agarwal, M.D.  
 Bladder Organ Site Chairs: ..... Seth P. Lerner, M.D. (Localized)  
 ..... Daniel P. Petrylak, M.D. (Advanced)  
 Prostate Organ Site Chairs: ..... Daniel W. Lin, M.D. (Localized)  
 ..... David I. Quinn, M.D., Ph.D. (Advanced)  
 Renal Organ Site Chairs: ..... Brian Shuch, M.D. (Localized)  
 ..... Ulka N. Vaishampayan, M.D. (Advanced)

## Designates

Cancer Control: ..... Peter J. Van Veldhuizen, Jr., M.D.  
 Digital Engagement: ..... Neema Navai, M.D.  
 Data Coordinators: ..... Sean O'Bryan  
 ..... Joseph Sanchez  
 Oncology Research Professionals:  
 CRA: ..... TBD  
 Nurses: ..... Deborah A. Shaw, R.N.  
 ..... Cheryl Kefauver, R.N.  
 Patient Advocates: ..... Rick Bangs, M.B.A. (Bladder)  
 ..... Tony Crispino (Prostate)  
 ..... Margaret "Peggy" Zuckerman, M.Ed. (Renal)  
 Pharmaceutical Science: ..... Joyce Lee, Pharm.D.  
 ..... Jason M. Reed, Pharm.D., R.Ph.  
 Protocol Coordinator: ..... Veronica Garcia, M.S.  
 Clinical Trials Project Manager: ..... Sandi Hita, J.D.

## Time/Location

GU Committee Part I: Friday, October 4, 2019 2:30 p.m. - 6:15 p.m.  
 Room: Regency D (Ballroom Level, West Tower)

## Time/Location

GU Committee Part II: Saturday, October 5, 2019 9:30 a.m. - 12:30 p.m.  
 Room: Regency D (Ballroom Level, West Tower)

## Agenda

**GU Committee, Part I: Friday, October 4, 2:30 p.m. – 6:15 p.m.**

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

## Prostate

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

## Priority Study

**S1802**, "Phase III Randomized Trial of Standard Systemic Therapy (SST) versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer." Dr. Chapin and Dr. Aparicio. Activated: 09/17/18

## Active Studies

**CTSU/A031102**, "A Randomized Phase III Trial Comparing Conventional-Dose Chemotherapy Using 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: 07/01/15.

**CTSU/EA8153**, "Cabazitaxel with Abiraterone Versus Abiraterone Alone Randomized Trial for Extensive Disease Following Docetaxel: The CHARTED2 Trial." Dr. Corn. Activated: 02/08/18.

**CTSU/EA8171**, "Multiparametric MRI (mpMRI) for Preoperative Staging and Treatment Planning for Newly-Diagnosed Prostate Cancer." Dr. Liss. Activated: 07/09/18.

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

**CTSU/NRG-GU005**, "Phase III IGRT and SBRT Vs IGRT and Hypofractionated IMRT for Localized Intermediate Risk Prostate Cancer." Dr. Yu. Activated: 11/16/17.

# Genitourinary Committee

**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: 04/27/18.

## Closed Studies

**S1216**, "A Phase III Randomized Trial Comparing Androgen Deprivation Therapy + TAK-700 with Androgen Deprivation Therapy + Bicalutamide in Patients with Newly Diagnosed Metastatic Hormone Sensitive Prostate Cancer." Dr. Agarwal, Dr. Goldkorn, Dr. Gupta, et al. Activated: 03/01/13. Closed: 07/15/17.

**CTSU/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: 07/07/11. Closed: 06/24/19.

## 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 Studies

**S1316**, "Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction." Dr. Krouse, Dr. Denevee, and Dr. Sun. Activated: 03/09/15.

**S1600**, "A Randomized Phase III Double-Blind Clinical Trial Evaluating the Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes." Dr. Hamilton-Reeves and Dr. Holzbeierlein. Activated: 02/21/19.

## Diverse Studies of Interest

**S1609**, "DART: Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors." Dr. Patel, Dr. Chae, Dr. Kurzrock, et al. Activated: 01/13/17.

**CTSU/EAY 131**, "Molecular Analysis for Therapy Choice (MATCH)." Dr. Villalobos. Activated: 08/12/15.

## GU Committee, Part II: Saturday, October 5, 9:30 – 12:30

### Bladder

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

### Priority Study

**S1806**, "Phase III Randomized Trial of Concurrent Chemoradiotherapy with or Without Atezolizumab in Localized Muscle Invasive Bladder Cancer." Dr. Singh, Dr. Lerner, Dr. Efstathiou, et al. Activated: 04/19/19

### Active Study

**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." Dr. Svatek. Activated: 02/07/17.

**CTSU/A031701**, "A Phase II Study of Dose-Dense Gemcitabine Plus Cisplatin (ddGC) in Patients with Muscle-Invasive Bladder Cancer with Bladder Preservation for Those Patients Whose Tumors Harbor Deleterious DNA Damage Response (DDR) Gene Alterations." Dr. A. Gupta and Dr. S. Gupta. Activated: 08/01/18.

### Closed Studies

**S1011**, "A Phase III Surgical Trial to Evaluate the Benefit of a Standard Versus an Extended Pelvic Lymphadenectomy Performed at Time of Radical Cystectomy for Muscle Invasive Urothelial Cancer." Dr. Lerner, Dr. Alva, Dr. Koppie, et al. Activated: 08/01/11. Closed: 04/15/17.

**S1314**, "A Randomized Phase II Study of CO-eXpression Extrapolation (COXEN) Directed Neo-adjuvant Chemotherapy for Localized, Muscle-Invasive Bladder Cancer." Dr. Flaig, Dr. Alva, Dr. Daneshmand, et al. Activated: 07/09/14. Closed 12/01/17.

**S1605**, "Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer." Dr. Black and Dr. Singh. Activated: 02/07/17. Closed: 07/05/19.

**CTSU/EA8141**, "A Prospective Phase II Trial of Neoadjuvant Systemic Chemotherapy Followed by Extirpative Surgery for Patients with High Grade Upper Tract Urothelial Carcinoma." Dr. Go-doy and Dr. Alva. Activated 04/10/15. Closed 01/05/18.

# Genitourinary Committee

## Renal

Organ Site Chairs: Dr. Ulka Vaishampayan (Advanced) and Dr. Brian Shuch (Local).

### Active Studies

**S1500**, "A Randomized, Phase II Efficacy Assessment of Multiple MET Kinase Inhibitors (Cabozantinib [NSC #761968], Crizotinib [NSC #749005], Savolitinib [NSC #785348], and Sunitinib [NSC #736511]) in Metastatic Papillary Renal Carcinoma (PAPMET)." Dr. Pal, Dr. Lara, and Dr. Shuch. Activated: 04/05/16.

**CTSU/AREN-1721**, "A Randomized Phase 2 Trial of Axitinib/Nivolumab Combination Therapy vs. Single Agent Axitinib or Nivolumab for the Treatment of TFE/Translocation Renal Cell Carcinoma (tRCC) Across All Age Groups." Dr. Parikh. Activated: 10/09/18

**CTSU/A031501**, "Phase III Randomized Adjuvant study of MK-3475 (Pembrolizumab) in muScle invaSive and locAlly aDvanced urOthelial caRcinoma (AMBASSADOR) Versus Observation." Dr. Sonpavde. Activated: 09/21/17.

# Genitourinary Committee

## Cumulative Accrual by Institution and Study

Includes accrual through 7/12/2019. Includes studies that are currently open or that closed since 1/1/2018.

	S1500	S1602	S1605	S1802	S1806	A031102	A031501	A031701	EA8134	EA8141	EA8143	EA8153	EA8171	NRGGU002	NRGGU005	NRGGU006	R0924
Arizona CC, Univ of	—	—	—	1	—	—	—	—	—	—	3	—	—	—	—	—	—
Arkansas, U of	1	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Baylor College	—	12	3	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Beaumont NCORP	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	2
Birmingham, U of AL	—	—	—	—	—	—	—	—	—	1	—	—	—	—	—	—	—
CORA NCORP	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	1
CRC West MI NCORP	1	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Cedars-Sinai Med Ctr	1	—	—	—	—	—	—	—	—	—	4	—	—	—	—	—	—
City of Hope Med Ctr	20	1	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Cleveland Clinic OH	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	4
Colorado, U of	—	12	5	—	—	—	7	—	—	5	1	—	—	1	1	—	—
Columbus NCORP	1	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Davis, U of CA	2	—	1	—	—	—	1	1	—	—	1	—	—	—	—	—	—
Dayton NCORP	—	1	1	1	—	—	—	—	—	—	1	—	—	—	—	—	—
Desert Hospital	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	8
Essentia Hlth NCORP	—	—	1	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Greenville NCORP	1	1	1	2	—	—	—	—	—	—	—	—	—	—	—	—	—
Gulf South MU-NCORP	1	54	3	23	1	—	1	—	—	—	—	—	—	—	—	—	—
H Lee Moffitt CC	—	13	—	—	—	—	—	—	—	—	1	—	—	—	—	—	—
Hawaii MU-NCORP	—	2	3	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Heartland NCORP	4	4	6	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Henry Ford Hospital	—	1	—	1	—	—	—	—	—	—	—	—	—	—	—	—	—
Irvine, U of CA	—	—	—	—	—	—	—	—	—	—	1	—	—	—	—	—	—
Kaiser Perm NCORP	—	9	—	—	—	—	7	—	—	—	12	—	—	—	—	—	—
Kansas, U of	—	11	8	4	—	—	2	—	—	1	1	—	—	—	—	—	6
Kentucky, U of	—	—	3	—	—	—	—	—	—	—	6	—	—	—	—	—	—
Lahey Hosp & Med Ctr	—	—	—	—	—	—	—	—	—	—	2	—	—	—	—	—	—
Los Angeles, U of CA	—	—	—	—	—	—	—	—	—	—	2	—	—	—	—	—	—
Loyola University	—	3	2	—	—	—	—	—	—	—	—	—	—	—	—	—	—



**CTSU/EA8143**, “A Phase 3 Randomized Study Comparing Perioperative Nivolumab vs. Observation in Patients with Localized Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC).” Dr. Lara and Dr. Shuch. Activated: 02/02/17.

**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 08/08/12. Closed 07/25/17.

**Closed Studies**

**S0931**, “EVEREST: VErolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study.” Dr. Ryan, Dr. Heath, Dr. Lara, et al. Activated: 04/01/11. Closed: 09/15/16.

## Genitourinary Committee, cont.

### Cumulative Accrual by Institution and Study

Includes accrual through 7/12/2019. Includes studies that are currently open or that closed since 1/1/2018.

	S1500	S1602	S1605	S1802	S1806	A031102	A031501	A031701	EA8134	EA8141	EA8143	EA8153	EA8171	NRGGU002	NRGGU005	NRGGU006	R0924
MD Anderson CC	—	19	—	22	—	—	—	—	—	1	—	1	—	—	—	—	—
MUSC MU-NCORP	1	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	2
Michigan CRC NCORP	1	—	—	1	—	—	—	—	—	—	—	—	—	—	—	—	—
Michigan, U of	5	18	—	—	—	—	8	—	—	—	—	—	—	—	—	—	—
Mississippi, Univ of	—	—	—	1	—	—	—	—	—	—	1	1	—	1	—	—	—
Montana NCORP	1	1	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Nevada CRF NCORP	4	—	1	—	—	—	—	—	—	—	1	—	—	—	—	—	—
Northwestern Univ	—	19	1	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Ohio State Univ	—	1	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Oklahoma, Univ of	2	14	5	7	—	—	—	—	—	—	—	—	—	—	—	—	—
Oregon Hlth Sci Univ	3	3	3	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Ozarks NCORP	2	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
PCRC NCORP	2	14	2	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Rochester, Univ of	—	1	1	—	—	—	—	—	—	—	—	—	—	—	—	—	26
San Antonio, U of TX	—	32	5	—	—	—	—	—	—	—	4	—	6	—	—	2	—
San Diego, U of CA	—	—	5	—	—	—	—	—	—	—	2	—	—	—	—	—	—
So Calif, U of	2	10	—	—	—	5	4	—	1	—	—	—	—	—	—	—	—
Sutter Cancer RC	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	2
Utah, U of	2	42	9	1	—	—	3	—	—	—	1	5	—	—	—	—	—
VAMC Kansas City	—	—	1	—	—	—	—	—	—	—	—	—	—	—	—	—	42
Wayne State Univ	4	—	—	—	—	—	—	—	—	—	—	—	—	1	—	—	—
Wichita NCORP	1	—	2	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Wisconsin NCORP	1	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Yale University	—	3	3	—	—	—	4	—	—	—	1	—	—	—	—	—	—
Alliance	19	60	41	8	—	—	—	—	—	—	—	—	—	—	—	—	—
CCTG	21	—	9	—	—	—	—	—	—	—	—	—	—	—	—	—	—
ECOG-ACRIN	17	36	27	—	—	—	—	—	—	—	—	—	—	—	—	—	—
NRG	11	37	20	3	—	—	—	—	—	—	—	—	—	—	—	—	—
<b>Total</b>	<b>131</b>	<b>434</b>	<b>172</b>	<b>75</b>	<b>1</b>	<b>5</b>	<b>37</b>	<b>1</b>	<b>1</b>	<b>8</b>	<b>45</b>	<b>7</b>	<b>6</b>	<b>3</b>	<b>1</b>	<b>2</b>	<b>93</b>

# Leukemia Committee

## Leadership

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

## Scientific Leadership

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

## Designates

Cancer Control: ..... Stephanie B. Tsai, M.D.  
 Data Coordinators: ..... Louise Highleyman  
 ..... Tracy Maher, C.C.R.P.  
 ..... Laura Kingsbury  
 Oncology Research Professionals:  
 CRA: ..... TBD  
 Nurse: ..... TBD  
 Patient Advocate: ..... Gail Sperling, M.P.H.  
 Pharmaceutical Science: ..... Mai T. Nguyen, Pharm.D.  
 ..... Holly O. Chan, Pharm.D.  
 Protocol Coordinator: ..... Cynthia Smith  
 Clinical Trials Project Manager: ..... Sandi Hita, J.D.

## Time/Location

Friday, October 4, 2019 4:30 p.m. - 6:30 p.m.  
 Room: Regency B (Ballroom Level, West Tower)

## Introduction

**Leukemia Committee Updates** – Dr. Harry Erba

### AML/MDS Studies

## Active Studies

**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.” Drs. Michaelis, Walter, Assouline, Hay, Im, and Foran. Activation: 12/22/17; Temporary closure: 10/22/18.

**A041701**, “Randomized Phase II/III Study of Conventional Chemotherapy +/- Uproleselan (GMI-1271) in Older Adults with Acute Myeloid Leukemia Receiving Intensive Induction Chemotherapy.” Dr. Liesveld. Activation: 01/16/19.

## 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, Relapsed/Refractory Philadelphia-Chromosome Positive (Ph+) ALL, and Philadelphia-Chromosome-Like Signature (Ph-Like) ALL (Newly Diagnosed or Relapsed/Refractory) with Known or Presumed Activating Dasatinib-Sensitive Mutations or Kinase Fusions (DSMKF).” Drs. Advani, O'Dwyer, and Wood. Activation: 1/12/2015; Permanent closure of Cohort 1: 9/15/17; Temporary closure of Cohort 2: 4/15/17.

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

**CTSU/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 18-39 years) with Newly Diagnosed Precursor B-Cell ALL.” Dr. Advani. Activation: 6/1/17.

### Closed Studies

**S1312**, “A Phase I Study of Inotuzumab Ozogamicin (NSC-772518) in Combination with CVP (Cyclophosphamide, Vincristine, Prednisone) for Patients with Relapsed/Refractory CD22-Positive Acute Leukemia (Including B-ALL, Mixed Phenotypic Leukemia and Burkitt's Leukemia).” Drs. Advani and Liedtke. Activation: 4/1/14; Closed: 8/02/19.

### Proposed Studies

**S1902**, “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 II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL).” Drs. Advani, Papadantonakis, and Yeung.

**CTSU/EA9181**, “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.

# Leukemia Committee

## CLL Studies

### Active Studies

**CTSU/EA9161**, "A Randomized Phase III Study of the Addition of Venetoclax to Ibrutinib and Obinutuzumab versus Ibrutinib and Obinutuzumab in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL)." Dr. Shadman. Activation: 1/3/19.

**CTSU/A041702**, "A Randomized Phase III Study of Ibrutinib plus Obinutuzumab Versus Ibrutinib plus Venetoclax and Obinutuzumab in Untreated Older Patients ( $\geq 70$  Years of Age) with Chronic Lymphocytic Leukemia (CLL)." Dr. Hill. Activation: 1/4/19.

## Proposed Studies

**S1925**, "Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab versus Delayed Therapy with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia (CLL): EVOLVE CLL Study." Dr. Stephens, Hill, Pagel, and Danilov.

## CML Studies

### Active Studies

**S1712**, "A Randomized Phase II Study of Ruxolitinib (NSC-752295) in Combination with BCR-ABL Tyrosine Kinase Inhibitors in Chronic Myeloid Leukemia (CML) Patients with Molecular Evidence of Disease." Drs. Sweet and Radich. Activation: 7/20/18.

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## Leukemia Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/12/2019. Includes studies that are currently open or that closed since 1/1/2018.

	S1312	S1612	S1712	A041501	A041701	A041702	E1910	E2906	EA9161
Arizona CC, Univ of	—	1	—	—	—	—	4	7	—
Arkansas, U of	—	—	—	—	—	—	3	—	—
Baylor College	7	—	—	—	—	—	—	—	—
Birmingham, U of AL	—	—	—	—	—	—	10	—	2
CRC West MI NCORP	—	—	—	—	—	—	—	4	—
Carle CC NCORP	—	1	—	—	—	—	—	—	—
Cincinnati MC, U of	—	—	—	—	—	—	—	3	—
City of Hope Med Ctr	18	—	—	—	—	—	—	—	—
Cleveland Clinic OH	11	—	—	—	—	—	9	—	—
Columbia MU-NCORP	—	—	—	—	—	—	—	3	—
Davis, U of CA	—	1	—	—	—	—	—	—	—
Dayton NCORP	—	—	—	—	—	1	1	5	—
Georgia NCORP	—	1	—	—	—	—	—	—	—
Greenville NCORP	—	2	—	—	—	—	1	—	—
H Lee Moffitt CC	—	3	1	—	—	—	—	—	—
Hawaii MU-NCORP	—	—	1	—	—	—	—	—	—
Heartland NCORP	—	6	2	—	—	—	—	—	—
Henry Ford Hospital	—	—	—	—	—	—	4	—	—
Irvine, U of CA	—	—	—	—	—	—	10	—	—
Kaiser Perm NCORP	—	9	—	—	—	—	—	—	5
Kansas City NCORP	—	—	—	—	—	—	1	—	—
Kansas, U of	—	—	—	—	—	—	10	—	—
Kentucky, U of	—	—	—	—	—	—	—	7	—
Loyola University	—	1	—	—	—	—	2	9	—
Michigan CRC NCORP	—	2	—	—	—	—	—	—	—
Mississippi, Univ of	—	—	—	—	—	—	—	1	—
Montana NCORP	—	3	—	—	—	—	—	—	—
Nevada CRF NCORP	—	—	—	—	—	—	—	—	1
New Mexico MU-NCORP	—	3	—	—	—	—	—	1	—
Northwest NCORP	—	—	—	—	—	—	9	—	—
Northwestern Univ	—	—	—	—	—	—	1	—	—
Oregon Hlth Sci Univ	—	—	—	—	—	—	—	—	3
PCRC NCORP	—	2	—	—	—	—	—	—	—
Rochester, Univ of	12	3	—	1	2	—	10	27	—
San Diego, U of CA	—	—	—	—	—	—	3	—	—
Southeast COR NCORP	—	1	—	—	—	—	—	—	2
Stanford University	2	—	—	—	—	4	12	—	12
Upstate Carolina	—	—	—	—	—	—	—	3	—
Utah, U of	—	—	1	—	—	—	—	—	4
Wayne State Univ	—	2	—	—	—	—	6	—	—
Yale University	—	—	—	—	—	—	19	5	—
Alliance	—	23	1	—	—	—	—	—	—
ECOG-ACRIN	—	2	—	—	—	—	—	—	—
NRG	—	12	1	—	—	—	—	—	—
<b>Total</b>	<b>50</b>	<b>78</b>	<b>7</b>	<b>1</b>	<b>2</b>	<b>5</b>	<b>115</b>	<b>75</b>	<b>29</b>

# Lung Committee

## Leadership

Chair: ..... Karen Kelly, M.D.  
 Vice-Chair: ..... Roy S. Herbst, M.D., Ph.D.  
 Executive Officer: ..... Julie R. Gralow, M.D.  
 Statisticians: ..... Mary Redman, Ph.D.  
 ..... Yingqi Zhao, Ph.D.  
 ..... Katherine Minichiello, M.S.  
 ..... Jieling Miao, M.S.  
 ..... James Moon, M.S.  
 ..... Lu Qian, M.S.

## Scientific Leadership

### Translational Medicine:

Biology/Pathology: ..... Philip C. Mack, Ph.D.  
 ..... Fred R. Hirsch, M.D., Ph.D.  
 ..... Ignacio I. Wistuba M.D.  
 Imaging: ..... Chadwick L. Wright M.D., Ph.D.  
 ..... Myrna C. Godoy, M.D., Ph.D.  
 Radiation Oncology: ..... Roy H. Decker, M.D., Ph.D.  
 Surgery: ..... Wayne L. Hofstetter, M.D.

### Subcommittee Chairs:

Early Stage Disease: ..... Wayne L. Hofstetter, M.D.  
 ..... Raymond Osarogiagbon, M.D.  
 Locally Advanced Disease: ..... Roy H. Decker, M.D., Ph.D.  
 ..... Shirish Gadgeel, M.D. (Early Therapeutics)  
 Metastatic Disease: ..... Ross Camidge, M.D.  
 ..... Karen Reckamp, M.D.  
 Community Engagement: ..... Paul J. Hesketh, M.D.  
 ..... Suzanne Cole, M.D.  
 ..... Alex R. Menter, M.D.

## Designates

Cancer Control Liaison: ..... Gary E. Goodman, M.D.  
 Data Coordinators: ..... Leah Everhart  
 ..... Joni Harris  
 ..... Louise Highleyman  
 ..... Larry Kaye  
 Clinical Research Project Manager: ..... Sarah Basse  
 Oncology Research Professionals:  
 CRAs: ..... Courtney L. Williamson  
 ..... Ginny M. Keeling, M.S.  
 Nurses: ..... Kimberly M. Belzer, M.S., P.A.C  
 ..... Rosalie Zablocki, R.N.  
 Patient Advocate: ..... Judy Johnson, M.B.A.  
 Pharmaceutical Science: ..... Joyce Lee, Pharm.D.  
 ..... Kimberly McConnell, Pharm.D.

Protocol Coordinators: ..... Gretchen Goetz, M.B.A.  
 ..... Mariah Norman, M.S. (Lung-MAP)  
 Clinical Trials Project Manager: ..... Crystal Miwa

## Time/Location

Friday, October 4, 2019 4:00 p.m. - 7:00 p.m.

Room: Regency A (Ballroom Level, West Tower)

## Agenda

- 4:00 p.m. Opening Remarks and General Update – Dr. Kelly
- 4:15 p.m. Translational Medicine Session – Biology/Pathology – Dr. Mack  
 Scientific Presentation: “Immunology Lung Cancer Atlas”  
 Miriam Merad, M.D., Ph.D., Professor of Oncologic Science,  
 Medicine (Hematology On-cology Division) and Immunology,  
 Mount Sinai Icahn School of Medicine  
 Translational Medicine Imaging Session – Dr. Wright  
 Trial Updates
- 4:45 p.m. Thoracic Surgery Session – Dr. Hofstetter  
 Trial updates
- 5:00 p.m. Thoracic Radiation Session – Dr. Decker  
 Scientific Presentation: “Applications of Machine Learning in  
 Thoracic Oncology” Sanjay Aneja, M.D., Assistant Professor of  
 Therapeutic Radiology, Yale School of Medicine  
 Trial updates
- 5:45 p.m. Community Engagement Core – Dr. Hesketh
- 6:00 p.m. Thoracic Oncology Session – Lung Cancer  
 Scientific Presentation: “Highlights from WCLC/ESMO-  
 Targeted Therapies” Shirish Gadgeel, M.D., Professor,  
 Department of Internal Medicine, Division of Hematology  
 Oncology, University of Michigan  
 Scientific Presentation: “Highlights from WCLC/ESMO –  
 Molecular Therapies” Karen Reckamp, M.D., Professor,  
 Department of Medical Oncology and Therapeutics  
 Research, City of Hope  
 Trial updates
- 6:45 p.m. Thoracic Oncology – Mesothelioma/Thymic Malignancies  
 Trial updates

# Lung Committee

## Active Studies

**LUNGMAP**, "A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study)." Drs. Papadimitrakopoulou, Herbst, Gandara, et al. Activation: 1/28/19.

**S1800A**, "A Phase II Randomized Study of Ramucirumab plus MK3475 (Pembrolizumab) versus Standard of Care for Patients Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Non-Match Sub-Study)." Drs. Reckamp and Dragnev. Activation: 5/17/19.

**S1900A**, "A Phase II Study of Rucaparib in Patients with Genomic LOH High and/or Deleterious BRCA1/2 Mutation Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)." Drs. Riess and Wheatley-Price. Activation: 1/28/19.

**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. Activation: 10/2/17.

**S1701**, "A Randomized Phase II Trial of Carboplatin-Paclitaxel with or without Ramucirumab in Patients with Unresectable Locally Advanced, Recurrent, or Metastatic Thymic Carcinoma." Drs. Tsao and Koczywas. Activation: 8/9/18.

**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. Activation: 11/3/17.

**CTSU/S1709/EA5163**, "INSIGNA: 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. Activation: 2/28/19.

**CTSU/A221504**, "A Randomized, Double-Blind, Placebo-Controlled Pilot Study of an Oral, Selective Peripheral Opioid Receptor Antagonist in Advanced Non-Small Cell Lung Cancer." Dr. Menter. Activation: 10/13/17.

**CTSU/NRG-LU002**, "Maintenance Systemic Therapy Versus Local Consolidative Therapy (LCT) plus Maintenance Systemic Therapy for Limited Metastatic Non-Small Cell Lung Cancer (NSCLC): A Randomized Phase II/III Trial." Dr. Gomez. Activation: 4/7/17.

**CTSU/NRG-CC003**, "Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hip-pocampal Avoidance for Small Cell Lung Cancer." Dr. Gaspar. Activation: 12/7/2015.

**CTSU/A151216**, "Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHE-MIST)." Dr. Gandara. Activation: 8/18/14.

**CTSU/A081105**, "Randomized Study of Erlotinib versus Observation in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC)." Dr. Kelly. Activation: 8/18/14.

**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 Kinase (ALK) Fusion Protein." Dr. Li. Activation: 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. Activation: 3/15/08.

## Closed Studies

**S1400**, "A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer." Drs. Papadimitrakopoulou, Hirsch, Herbst, et al. Activation: 6/16/14; Closure: 1/28/19.

## NCI Approved Concepts

**S1900B**, "A Phase II Study of LOXO-292 in Patients with RET Fusion-Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)." Drs. Elamin and Gray.

**S1900C**, "A Phase II Study of Talazoparib plus Avelumab in Patients with STK11-Positive Stage IV or Recurrent Non-Squamous Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)." Drs. Skoulidis and Suga.

# Lung Committee

**S1900D**, "A Randomized Phase II Study of Sapanisertib (TAK-228, MLN0128) plus Docetaxel versus Standard of Care in Patients with Previously-Treated NFE2L2 or KEAP1-Positive Stage IV or Recurrent Squamous Cell Lung Cancer (ECOG-ACRIN Lung-MAP Sub-Study)." Drs. Paik and Edelman.

**S1827**, "A Randomized Phase III Trial of MRI Surveillance with or without Prophylactic Cranial Irradiation (PCI) in Small-Cell Lung Cancer." Drs. Rusthoven, Brown, and Wefel.

**S1914**, "A Randomized Phase III Trial of Induction/Consolidation Atezolizumab + SBRT versus SBRT Alone in High Risk, Early Stage NSCLC." Drs. Daly and Simone.

**S1929**, "Phase II Study of Maintenance Atezolizumab versus Atezolizumab in Combination with Talazoparib in Patients with SLFN11 Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC)." Drs. Karim and Reckamp.

**S1933**, "A Phase II Feasibility Trial of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status." Dr. Aljumaily.

## Concepts in Development

**S1800B**, "A Phase II Selection Design Of TSR-022 (Anti-TIM-3) And TSR-042 (Anti-Pd-1) Or Tsr-022 (Anti-Tim-3), Tsr-042 (Anti-Pd-1), And Niraparib In Patients with Previously Treated Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Non-Match Sub-Study)." Drs. Pacheco and Patel.

**S1700**, "Strategies to Improve Lymph Node Examination of Non-Small Cell Lung Tumors (SILENT)." Dr. Osarogiagbon.

**S1934**, "Trimodality + Immunotherapy in Resectable and Marginally Unresectable Superior Sulcus Tumors." Dr. Osarogiagbon.

## 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 Chair

## Lung Committee

## Cumulative Accrual by Institution and Study

Includes accrual through 7/12/2019. Includes studies that are currently open or that closed since 1/1/2018.

	LUNGMAP	S1400	S1400F	S1400G	S1400I	S1400K	S1403	S1507	S1619	S1701	S1800A	S1900A	A081105	A151216	C30610	E4512	EA5142	EA5161	EA5163	NRGCC003
Arizona CC, Univ of	—	1	—	—	—	—	—	—	—	—	—	—	—	4	—	1	—	—	—	—
Arkansas, U of	—	5	—	—	—	—	—	—	—	—	—	—	—	2	2	—	1	3	—	—
Baptist MU-NCORP	11	16	—	—	5	1	2	1	—	—	—	1	—	18	3	—	—	—	—	—
Baylor College	—	1	—	—	1	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Beaumont NCORP	—	2	—	—	—	—	—	—	—	—	—	—	—	2	—	—	1	—	—	—
Boston Medical Ctr	—	5	—	—	2	—	—	—	—	—	—	—	—	3	—	—	—	—	—	—
Brooke Army Med Ctr	—	6	—	—	2	—	—	—	—	—	—	—	—	8	—	—	—	—	—	—
CORA NCORP	3	15	—	1	3	—	—	—	—	—	—	—	—	2	—	—	—	—	—	—
CRC West MI NCORP	—	11	—	—	1	—	2	—	—	—	—	—	—	1	—	—	—	—	—	—
Carle CC NCORP	—	4	—	—	3	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Cincinnati MC, U of	—	6	—	—	2	—	—	—	—	—	—	—	1	15	3	1	3	—	—	—
City of Hope Med Ctr	—	16	—	—	2	—	—	—	—	—	—	—	1	4	—	—	2	—	—	—
Cleveland Clinic OH	—	10	—	—	1	—	—	1	—	—	—	—	4	39	—	—	11	—	1	—
Colorado, U of	2	3	1	—	1	—	—	—	—	—	—	—	7	41	—	2	3	—	—	—
Columbia MU-NCORP	2	2	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Columbus NCORP	3	15	—	—	1	—	3	2	—	—	—	—	—	—	1	—	—	—	—	—
Davis, U of CA	2	21	—	3	3	—	4	2	—	1	—	1	2	36	13	1	3	—	1	—
Dayton NCORP	2	6	—	—	1	—	2	—	—	—	—	—	—	5	—	—	2	—	—	—
Essentia Hlth NCORP	3	9	—	1	2	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Fred Hutchinson CRC	—	20	—	1	4	1	—	—	1	—	—	—	1	15	—	—	1	—	—	—
Georgia NCORP	10	33	5	1	5	4	—	1	—	—	—	—	—	—	1	—	—	—	—	—
Greenville NCORP	2	16	—	1	6	—	2	—	—	—	—	—	—	1	—	—	—	—	—	—
Gulf South MU-NCORP	2	6	—	1	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
H Lee Moffitt CC	—	10	—	—	1	—	—	—	—	—	—	—	3	83	—	1	12	1	—	—
Harrington CC	—	9	1	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Hawaii MU-NCORP	—	7	—	—	1	1	7	1	—	—	—	—	—	—	—	—	—	—	—	—
Heartland NCORP	35	61	6	—	8	1	2	7	—	—	1	3	—	—	7	—	—	—	—	—
Henry Ford Hospital	1	9	—	—	—	1	—	—	—	—	—	1	1	22	—	—	4	—	—	—
Irvine, U of CA	1	9	2	—	2	—	—	1	—	—	—	—	2	8	—	—	3	—	—	—
Kaiser Perm NCORP	4	53	—	1	6	—	28	—	—	—	—	—	18	169	3	2	15	1	—	—
Kansas City NCORP	—	1	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Kansas, U of	7	44	—	—	12	1	2	—	—	—	1	1	1	25	1	—	7	—	—	—
Kentucky, U of	5	8	2	—	4	—	—	—	—	—	—	—	1	4	—	—	1	—	—	—
Lahey Hosp & Med Ctr	5	13	—	1	1	—	3	1	—	—	1	—	—	23	—	—	4	1	1	—
Loma Linda Univ	—	7	—	1	1	—	—	1	—	—	—	—	2	3	—	—	1	—	—	—
Loyola University	1	12	—	—	4	—	—	—	—	—	—	—	—	16	—	—	5	1	—	—
MAVERIC	3	19	2	—	9	1	—	—	—	—	1	—	—	7	—	—	3	—	—	—
MD Anderson CC	1	24	1	—	1	—	—	—	12	—	—	—	—	2	—	—	—	—	—	—



# Lung Committee

## Cumulative Accrual by Institution and Study

Includes accrual through 7/12/2019. Includes studies that are currently open or that closed since 1/1/2018.

	LUNGMAP	S1400	S1400F	S1400G	S1400I	S1400K	S1403	S1507	S1619	S1701	S1800A	S1900A	A081105	A151216	C30610	E4512	E45142	E45161	E45163	NRGCC003
MUSC MU-NCORP	—	1	—	—	—	—	—	2	3	—	—	—	—	—	1	—	—	—	—	—
Methodist Hospital	—	5	—	—	—	—	—	—	—	—	—	—	1	4	—	—	—	—	—	—
Michigan CRC NCORP	12	38	1	3	4	1	7	4	—	—	—	1	—	—	—	—	—	—	—	—
Michigan, U of	—	13	1	—	4	—	3	1	—	—	—	—	—	57	1	—	1	—	—	—
Mississippi, Univ of	—	6	—	—	3	—	—	—	—	—	—	—	2	22	1	—	4	—	—	—
Montana NCORP	11	15	—	—	2	—	2	1	—	—	—	—	—	—	—	—	—	—	—	—
Mt Sinai Med Ctr	—	4	—	—	—	1	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Nevada CRF NCORP	1	5	—	—	3	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
New Mexico MU-NCORP	9	14	3	—	—	—	1	—	—	—	—	—	—	—	—	—	—	—	—	—
Northwest NCORP	—	6	—	—	—	1	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Northwestern Univ	—	2	—	—	1	—	—	3	—	—	—	—	—	—	—	—	—	—	—	—
Oklahoma, Univ of	9	10	1	1	2	—	4	—	—	—	—	—	—	—	—	—	—	—	—	—
Oregon Hlth Sci Univ	—	9	1	1	4	—	—	—	—	—	—	—	1	4	—	—	1	—	—	—
Ozarks NCORP	14	16	—	—	2	—	3	1	—	—	—	—	1	1	—	—	—	—	—	—
PCRC NCORP	7	18	—	—	—	—	—	—	—	—	—	—	—	4	—	—	—	—	—	—
Providence Hosp	7	15	1	—	—	—	—	—	—	—	—	—	—	12	2	1	3	2	—	—
Rochester, Univ of	8	22	1	1	1	—	2	1	—	—	—	1	—	—	—	—	—	4	—	4
Salem Hospital	—	6	—	2	3	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
San Antonio, U of TX	—	13	—	—	3	—	5	—	—	—	—	—	—	—	3	—	—	—	—	—
San Diego, U of CA	4	16	1	—	1	—	7	—	—	—	—	—	1	5	—	—	—	—	—	—
So Calif, U of	—	—	—	—	—	—	—	—	—	—	—	—	1	10	—	—	—	—	—	—
Southeast COR NCORP	16	75	6	3	14	2	2	—	—	—	—	—	—	—	—	—	—	4	—	—
Sutter Cancer RC	4	4	—	—	1	—	—	—	—	—	—	—	1	5	—	—	4	—	—	—
Tulane Univ MBCCOP	—	3	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Univ of Louisville	—	—	—	—	—	—	—	—	—	—	—	—	—	5	—	—	—	—	—	—
Upstate Carolina	—	2	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Utah, U of	—	1	—	—	—	—	—	4	—	—	—	—	—	—	—	—	—	—	—	—
VAMC Kansas City	—	9	1	—	1	—	—	—	—	—	—	—	—	—	1	—	—	—	—	—
Wayne State Univ	—	15	1	2	—	—	2	1	—	—	—	—	—	1	1	—	—	2	—	—
Wichita NCORP	1	24	1	1	3	1	8	—	—	—	—	—	—	—	13	—	—	—	—	—
Wisconsin NCORP	14	9	—	—	—	1	1	—	—	—	1	1	—	—	—	—	—	—	—	—
Yale University	—	27	1	1	4	—	24	—	—	—	—	—	3	45	—	3	16	—	—	—
Alliance	65	399	11	12	39	5	24	9	—	—	—	—	—	—	—	—	—	—	—	—
CCTG	—	18	—	1	3	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
ECOG-ACRIN	42	326	6	9	58	1	9	9	1	—	—	—	—	—	—	—	—	—	—	—
NRG	27	203	7	2	24	4	13	6	—	—	—	1	—	—	—	—	—	—	—	—
<b>Total</b>	<b>356</b>	<b>1,864</b>	<b>64</b>	<b>51</b>	<b>275</b>	<b>28</b>	<b>174</b>	<b>60</b>	<b>17</b>	<b>1</b>	<b>5</b>	<b>11</b>	<b>55</b>	<b>733</b>	<b>57</b>	<b>12</b>	<b>111</b>	<b>19</b>	<b>3</b>	<b>4</b>

# Lymphoma Committee

## Leadership

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

## Scientific Leadership

Translational Medicine: ..... 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  
 Digital Engagement: ..... Mazyar Shadman, M.D.  
 Data Coordinators: ..... 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, M.I.I.M.  
 Clinical Trials Project Manager: .....Vanessa Benavidez, B.S., C.C.R.C.

## Time/Location

Saturday, October 5, 2019 9:30 a.m. - 12:30 p.m.  
 Room: Regency A (Ballroom Level, West Tower)

## Agenda

**Welcome:** Drs. Jonathan Friedberg and Sonali Smith

**Mature results of S1001 in Early Stage DLBCL:** Dr. Persky

**Presentation:** Dr. Justin Kline, Associate Professor of Medicine, Hematology and Oncology, University of Chicago Medicine: "Immune Landscape of Diffuse Large B-cell Lymphoma."

## Updates on Open Studies:

- a. S1826: Dr. Herrera
- b. S1608: Dr. Barr
- c. A051301: Dr. Stiff
- d. EA4151: Dr. Till
- e. E4412: Dr. Amengual

- f. A051301: Dr. Smith
- g. A041702: Dr. Stephens
- h. EA9161: Dr. Stephens

## Studies in Development

- a. S1918: Dr. E. Brem
- b. S1925 (CLL): Dr. Stephens
- c. CTSU/EA4181 (untreated mantle cell): Dr. Spurgeon
- d. CTSU/ANHL1931 (COG primary mediastinal): Dr. Kamdar
- e. Alliance- T cell lymphoma: Dr. Amengual
- f. AHOD1931: COG AVD-BV Early Stage: Dr. Persky

## Other Business

## Adjourn

## Open Studies

**S1826**, "Nivolumab (Opdivo) or Brentuximab Vedotin (Adcetris) Plus AVD in Patients with Newly Diag-nosed Advanced Stage Classical Hodgkin Lymphoma." Drs. Herrera and Friedberg. Activated: 07/19/19.

**S1608**, "Randomized Phase II Trial in High-Risk Relapsed Refractory Follicular Lymphoma." Dr. Barr. Activated: 8/10/2017.

**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." Drs. Andreadis, Fenske, Shea, His, Kelley, and Richards. Activated: 7/6/2016. SWOG Champion: Dr. Stiff.

**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: 8/29/2017. SWOG Champion: Dr. Till.

**CTSU/E4412**, "A Phase I Study with an Expansion Cohort/Randomized Phase II Study of the Combinations of Ipilimumab, Nivolumab and Brentuximab Vedotin in Patients with Relapsed/Refractory Hodgkin Lymphoma." Drs. Diefenbach, Ansell, and Kostakoglu. Activated 11/15/18. SWOG Champion: Dr. Amengual.

**CTSU/A051701**, "Randomized Phase II/III Study of Venetoclax (ABT199) Plus Chemoimmunotherapy for MYC/BCL2 Double-Hit and Double Expressing Lymphomas." Dr. Abramson. Activated: 08/07/19. SWOG Champion: Dr. Smith. Temporarily Closed to Accrual: 08/13/19.

**CTSU/EAY131**, "Molecular Analysis for Therapy Choice (MATCH)." Drs. Chen, Flaherty, Conley, et al. Activated: 8/12/2015.

### Developing Studies

**S1918**, "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.

**CTSU/ ANHL1931**, "A Randomized Phase 3 trial of Pembrolizumab in Combination with Chemo immunotherapy for the Treatment of Newly Diagnosed Primary Mediastinal B cell Lymphoma." Dr. Kamdar.

**CTSU/ EA4181**, "A Randomized 3-Arm Phase II Study Comparing 1.) Bendamustine, Rituximab and High Dose Cytarabine (BRC) 2.) Bendamustine, Rituximab, High Dose Cytarabine and Acalabrutinib (BRCA), and 3.) Bendamustine, Rituximab and Acalabrutinib (BRA) in Patients  $\leq$  70 years Old with Untreated Mantle Cell Lymphoma." Dr. Spurgeon.

### Open Leukemia Studies

**A041702**, "A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib Plus Veneto-clax and Obinutuzumab in Untreated Older Patients ( $\geq$  70 Years of Age) with Chronic Lymphocytic Leukemia (CLL)." Dr. Woyach. Activated: 01/04/2019. SWOG Champion: Dr. Hill. Presented by Dr. Stephens.

**EA9161**, "A Randomized Phase III Study of the Addition of Venetoclax to Ibrutinib and Obinutuzumab Versus Ibrutinib and Obinutuzumab in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL)." Drs. Shanafelt and Kay. Activated: 01/03/2019. SWOG Champion: Dr. Shadman. Presented by: Dr. Stephens.

### Developing Leukemia Study

**S1925**, "A Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab versus Delayed Therapy with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia (CLL): EVOLVE CLL Study. Dr. Stephens.

## Lymphoma Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/12/2019. Includes studies that are currently open or that closed since 1/1/2018.

	S1608	A051301	E4412	EA4151
Arizona CC, Univ of	1	—	—	—
Baylor College	—	1	—	—
Birmingham, U of AL	—	—	1	—
CRC West MI NCORP	2	—	—	—
City of Hope Med Ctr	2	1	—	7
Colorado, U of	—	1	—	—
Columbus NCORP	1	—	—	—
Fred Hutchinson CRC	—	—	—	2
Heartland NCORP	1	—	—	—
Kaiser Perm NCORP	—	—	2	—
King Faisal Spec Hos	—	1	—	—
Michigan CRC NCORP	1	—	—	—
Nevada CRF NCORP	—	—	1	—
Oregon Hlth Sci Univ	—	—	—	1
Rochester, Univ of	7	2	—	—
San Antonio, U of TX	—	—	—	4
San Diego, U of CA	—	—	—	1
Utah, U of	1	—	—	4
Alliance	5	—	—	—
ECOG-ACRIN	3	—	—	—
NRG	4	—	—	—
<b>Total</b>	<b>28</b>	<b>6</b>	<b>4</b>	<b>19</b>

### Recently Closed Studies (Cancer Care Delivery)

**S1204**, "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: 8/29/2013. Closed: 2/16/17.

# Melanoma Committee

## Leadership

Chair: ..... Kenneth F. Grossmann, M.D., Ph.D.  
 Vice-Chair: ..... Hussein A. Tawbi, M.D., Ph.D.  
 Executive Officer: ..... Christopher W. Ryan, M.D.  
 Statisticians: ..... Michael Wu, Ph.D.  
 ..... Megan Othus, Ph.D.  
 ..... James Moon, M.S.  
 ..... Hongli Li, M.S.  
 ..... Lu Qian, M.S.

## Scientific Leadership

Translational Medicine: ..... William E. Carson, III, M.D.  
 Radiation Oncology: ..... Evan J. Wuthrick, M.D.  
 Surgery: ..... John Robert Hyngstrom, M.D.  
 Dermatology: ..... TBD  
 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.  
 ECOG's SWOG Liaisons: ..... David H. Lawson, M.D.  
 ..... Andrew Poklepovic, M.D.  
 Digital Engagement: ..... Zeynep Eroglu, M.D.

## Designates

Cancer Control Liaison: ..... Sancy Leachman, M.D., Ph.D.  
 ..... Thach-Giao Truong, M.D. (Survivorship)  
 Data Coordinator: ..... Manni Shi  
 ..... Joseph Sanchez  
 ..... Laura Kingsbury, M.R.T.  
 Oncology Research Professionals:  
 CRA: ..... Kacie L. 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: ..... Sun "Coco" Yang, Pharm.D., Ph.D.  
 ..... Mai T. Nguyen, Pharm.D.  
 Protocol Coordinator: ..... Danae Campos, M.B.A.  
 Clinical Trials Project Manager: ..... Vanessa Benavidez, B.S., C.C.R.C.

## Time/Location

Friday, October 4, 2019 9:30 a.m. - 11:30 a.m.  
 Room: Regency D (Ballroom Level, West Tower)

## Agenda

**9:30-11:30 am: Presentation of ongoing SWOG melanoma committee clinical trials**

**Welcome:** Antoni Ribas MD, PhD and Kenneth Grossmann MD, PhD (5 min)

**Presentation:** New approaches to patients with melanoma brain metastasis (20 min, 9:35-9:45), Hussein Tawbi MD, PhD

**Active Studies (1 hr, 9:45-10:45, each talk capped to 10 min,)**

**S1512**, "A Phase II Study of PD-1 Blockade with Pembrolizumab in Patients with Locally Advanced and Metastatic Desmoplastic Melanoma (DM)." Drs. K. Kendra and S. 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-L1 Agent." Drs. A. VanderWalde and A. Ribas. Activated 7/17/17.

**S1607**, "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 and A. Ribas. Activated 10/02/17

**S1801**, "A Phase II Randomized Study of Adjuvant Versus Neo-Adjuvant MK-3475 for Clinically Detectable Stage III-IV High Risk Melanoma. Dr. S. Patel and K. Grossmann. Activated 12/06/18.

**CTSU/EA6134**, "A Randomized Phase III Trial of Dabrafenib + Trametinib Followed by Ipilimumab + Nivolumab at Progression vs. Ipilimumab + Nivolumab followed by Dabrafenib + Trametinib at Progression in Patients with Advanced BRAFV600 Mutant Melanoma". Dr. B. Chmielowski. Activated: 7/13/15.

**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. K. Kim. Activated: 9/10/15. Temporarily closed: 6/23/17.

**EA6174**, "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. K. Kim.

# Melanoma Committee

## Upcoming Studies

S1935, "Randomized Phase 3 Study of Adjuvant Pembrolizumab in combination with Dabrafenib and Trametinib vs Physician's Choice in Patients with High-Risk Resected Melanoma. Dr. H. Tawbi.

S2000, "A Randomized Phase 2 trial of encorafenib + binimetinib + nivolumab vs nivolumab + ipilimumab in BRAFV600-mutant melanoma brain metastases. Dr. Z. Eroglu.

## 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. K. Grossmann and S. Patel. Activated 10/15/15. Closed: 8/15/17.

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. A. Algazi. Activated: 7/22/14. Closed: 07/15/2019.

E3612, "A Randomized Phase II Trial of Ipilimumab with or without Bevacizumab in Patients with Unresectable Stage III or Stage IV Melanoma.

**ECOG/SWOG liaisons report (10 min - 11:20-11:30):** David Lawson/Andrew Poklepovich

## Melanoma Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/12/2019. Includes studies that are currently open or that closed since 1/1/2018.

	S1320	S1512	S1607	S1616	S1801	EA613A	EA614I	EA617A
Arizona CC, Univ of	2	—	—	—	2	—	—	—
Arkansas, U of	7	—	—	—	—	1	—	—
Bay Area NCORP	1	—	—	—	—	—	—	—
Boston Medical Ctr	1	—	—	—	—	—	—	—
CORA NCORP	1	—	—	—	—	—	—	—
CRC West MI NCORP	2	—	—	3	4	—	—	—
City of Hope Med Ctr	—	—	—	—	—	2	3	—
Cleveland Clinic OH	—	—	—	—	—	5	—	—
Colorado, U of	2	—	—	—	—	1	—	—
Columbus NCORP	3	—	—	—	—	—	—	—
Dayton NCORP	1	—	—	1	—	—	—	—
Georgia NCORP	—	1	—	—	—	—	—	—
H Lee Moffitt CC	—	10	—	2	—	—	—	—
Harrington CC	—	—	—	—	1	—	—	—
Hawaii MU-NCORP	1	—	—	—	—	—	—	—
Heartland NCORP	6	—	—	—	2	—	—	—
Kaiser Perm NCORP	33	—	—	1	4	15	20	—
Kansas City NCORP	—	—	—	—	—	—	1	—
Kansas, U of	17	2	—	1	—	2	—	—
Lahey Hosp & Med Ctr	1	—	—	—	—	—	—	—
Los Angeles, U of CA	4	3	8	5	—	6	—	—
Loyola University	8	—	—	—	—	—	—	—
Michigan CRC NCORP	—	—	—	—	1	—	—	—
Michigan, U of	7	—	—	—	1	—	—	—
Montana NCORP	—	—	—	—	1	—	—	—
Nevada CRF NCORP	4	—	—	—	—	—	—	1
New Mexico MU-NCORP	—	—	—	2	—	—	—	—
Northwestern Univ	—	1	—	5	3	—	—	—
Ohio State Univ	17	4	2	3	—	2	—	—
Ozarks NCORP	2	—	—	—	—	—	—	—
PCRC NCORP	2	—	—	—	—	—	—	—
Rochester, Univ of	4	—	—	1	—	2	—	—
San Antonio, U of TX	—	—	—	—	—	—	1	—
San Diego, U of CA	—	—	—	1	—	—	—	—
San Francisco, U-CA	8	—	—	—	—	—	—	—
So Calif, U of	—	2	3	—	1	—	—	—
Southeast COR NCORP	8	1	—	—	—	—	—	—
Sutter Cancer RC	—	—	—	—	—	2	5	—
Tennessee, U of	—	—	—	5	—	—	—	—
Utah, U of	12	2	3	—	2	—	—	—
Wayne State Univ	—	—	—	—	—	2	—	—
Wichita NCORP	8	—	—	—	—	—	—	—
Wisconsin NCORP	1	—	—	—	3	—	—	—
Yale University	—	—	—	—	—	—	6	—
Alliance	15	—	—	4	3	—	—	—
ECOG-ACRIN	49	—	3	3	3	—	—	—
NRG	22	—	1	8	2	—	—	—
<b>Total</b>	<b>249</b>	<b>26</b>	<b>20</b>	<b>45</b>	<b>33</b>	<b>40</b>	<b>36</b>	<b>1</b>

# Publication List by Committee

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 2019 Group Meeting. Conference abstracts are not included.

## ADOLESCENT AND YOUNG ADULT (AYA) COMMITTEE

No publication information for this cycle.

## BARLOGIE-SALMON MYELOMA COMMITTEE

### Published/Accepted Manuscripts

**Multiple Studies\*** Du Z, Weinhold N, Song C, Rand K, Van Den Berg D, Hwang A, Sheng X, Hom V, Ailawadhi S, Goodman P, Klein E, Zonder J, Orlowski R, Conti D, Haiman C, Cozen W. A Meta-Analysis of Genome-Wide Association Studies of Multiple Myeloma among African Americans. *Blood Advances*, accepted 2019. [\*S0000, S9217, Other Studies] [see also Prevention & Epidemiology Cmte]

### Submitted Manuscripts

**S1304** Low-dose versus High-dose Carfilzomib with Dexamethasone (S1304) in Patients with Relapsed-Refractory Multiple Myeloma. Ailawadhi S, Sexton R, Lentzsch S, Abidi M, Voorhees P, Cohen AD, Rohren E, Heitner S, Kelly KR, Mackler N, Baer DM, Hoering A, Durie BGM, Orlowski. *Clinical Cancer Research*, under revision for resubmission 2019.

## BREAST COMMITTEE

### Published/Accepted Manuscripts

**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. Mehta R, Barlow W, Albain K, Vandenberg T, Dakhil S, Tirumali N, Lew DL, Hayes D, Gralow J, Linden H, Livingston R. *New England Journal of Medicine* Mar 28;380(13):1226-1234, 2019. <https://www.ncbi.nlm.nih.gov/pubmed/30917258>

**S0500** Circulating Tumor Cell Clusters in Metastatic Breast Cancer Patients: a SWOG S0500 Translational Medicine Study. Paoletti C, Miao J, Dolce E, Darga E, Repollet M, Doyle G, Gralow J, Hortobagyi G, Smerage J, Barlow W, Hayes D. *Clinical Cancer Research* Jul 29 [Epub ahead of print], 2019. <https://www.ncbi.nlm.nih.gov/pubmed/31358544>

**S0800** Immune profiling of pre- and post-treatment breast cancer tissues from the SWOG S0800 neoadjuvant trial. Li X, Warren S, Pelekanou V, Wali V, Cesano A, Liu M, Danaher P, Elliott N, Nahleh Z, Hayes D, Hortobagyi G, Barlow W, Hatzis C, Pusztai L. *Journal for ImmunoTherapy of Cancer* Apr 10;7(1):88, 2019. <https://www.ncbi.nlm.nih.gov/pubmed/30967156>

**S8897** Germline Genetic Variants in GATA3 and Breast Cancer Treatment Outcomes in SWOG S8897 Trial and the Pathways Study. Larsen V, Barlow W, Yang JJ, Zhu Q, Liu S, Kwan M, Ergas I, Roh J, Hutchins L, Kadlubar S, Albain K, Rae J, Yeh I-T, Ravdin P, Martino S, Lyss A, Osborne CK, Hortobagyi G, Kushi L, Hayes D, Ambrosone C, Yao S. *Clinical Breast Cancer* Aug;19(4):225-235, 2019. <https://www.ncbi.nlm.nih.gov/pubmed/30928413>

**PACCT-1/E-A** Clinical and Genomic Risk to Guide the Use of Adjuvant Therapy for Breast Cancer. Sparano J, Gray RJ, Makower DF, Pritchard K, Albain K, Hayes D, Geyer CE, Dees E, Goetz M, Olson J, Jr, Abrams J, Lively T, Badve S, Saphner TJ, Wagner L, Whelan TJ, Ellis MJ, Paik S, Wood WC, Ravdin PM, Keane MM, Gomez Moreno H, Reddy PS, Goggins TF, Mayer IA, Brufsky A, Toppmeyer D, Kaklamani V, Berenberg JL, Sledge G. *New England Journal of Medicine*, Jun 20;380(25):2395-2405, 2019. <https://www.ncbi.nlm.nih.gov/pubmed/31157962>

### Submitted Manuscripts

**S0221** Vitamin supplement use during chemotherapy and survival outcomes of breast cancer patients enrolled in a cooperative group clinical trial (SWOG S0221). Ambrosone C, Zirpoli G, Hutson A, McCann S, Barlow W, Kelly KM, Cannioto R, McCann W, Hershman D, Unger J, Moore HCF, Stewart JA, Isaacs C, Hobday TJ, Salim M, Hortobagyi G, Gralow JR, Budd GT, Albain KS. *Journal of Clinical Oncology*, under revision for resubmission 2019. [see also Cancer Survivorship Cmte]

**S0221** Cannioto RA, Hutson A, Dighe S, McCann W, McCann S, Zirpoli G, Barlow W, Kelly KM, DeNysschen CA, Hershman DL, Unger JM, Moore HCF, Stewart JA, Isaacs C, Hobday T, Salim M, Hortobagyi GN, Gralow J, Albain K, Budd GT, Ambrosone C. Exercise before, during and after chemotherapy for high-risk breast cancer in a therapeutic trial (S0221); relationships with recurrence and survival. *JAMA Oncology*, submitted 2019. [see also Cancer Survivorship Cmte]

**S0307** Phase III trial of bisphosphonates as adjuvant therapy in primary breast cancer: SWOG/ Alliance/Canadian Cancer Trials Group (CCTG)/ ECOG-ACRIN/NRG Oncology study S0307. Gralow JR, Barlow W, Paterson A, Miao J, Lew D, Stopeck A, Hayes D, Hershman D, Schubert M, Clemons M, Van Poznak C, Dees E, Ingle J, Falkson CI, Elias A, Messino M, Margolis J, Dakhil S, Chew H, Dammann K, Abrams J, Livingston R, Hortobagyi G. *Journal of the National Cancer Institute*, submitted 2019.

# Publication List by Committee

**S8814** The 21-gene recurrence score and locoregional recurrence rates in patients with node-positive breast cancer treated on SWOG S8814. Woodward WA, Barlow WE, Jagsi R, Buchholz TA, Shak S, Baehner F, Yoshizawa CN, Whelan TJ, Davidson NE, Ingle JN, King TN, Ravdin PM, K. Osborne CK, Tripathy D, Livingston RB, Gralow JR, Hortobagyi GN, Hayes DF, Albain KS. *JAMA Oncology*, under revision for resubmission, 2019.

**S9313** Validation of the DNA Damage Immune Response (DDIR) Signature in Triple-Negative Breast Cancer (TNBC) Patients from the SWOG 9313c Trial. Sharma P, Barlow W, Godwin A, Parkes E, Knight L, Walker SM, Kennedy RD, Harkin D, Logan G, Steele CJ, Lambe S, Badve S, Gokmen-Polar Y, Pathak H, Isakova K, Linden HM, Porter P, Puzstai L, Thompson AM, Tripathy D, Hortobagyi G, Hayes D. *Journal of Clinical Oncology*, revised/resubmitted 2019.

**B47** NSABP B-47 / NRG Oncology Phase III Randomized Trial Comparing Adjuvant Chemotherapy with or without Trastuzumab in High-risk Invasive Breast Cancer Negative for HER2 by ISH and with IHC 1+ or 2+ (HER2-low). Fehrenbacher L, Cecchini R, Geyer CE, Rastogi P, Costantino J, Atkins JN, Crown JP, Polikoff J, Boileau J-F, Provencher L, Stokoe C, Moore TD, Robidoux A, Flynn PJ, Borges VF, Albain KS, Swain SM, Paik S, Mamounas EP, Wolmark N. *Journal of Clinical Oncology*, submitted 2019.

## CANCER CONTROL AND PREVENTION COMMITTEES

### CANCER CARE DELIVERY COMMITTEE

#### Published/Accepted Manuscripts

**S1415CD** Effective Stakeholder Engagement: Design and Implementation of a Clinical Trial (SWOG S1415CD) to Improve Cancer Care. Barger S, Bell-Brown A, Bott B, Ciccarella AM, Golenski J, Gorman M, Johnson J, Kreizenbeck K, Kurttila F, Mason G, Myers J, Seigel C, Wade JL, III, Walia G, Watabayashi K, Lyman GH, Sullivan SD, Ramsey SD. *BMC Medical Research Methodology* Jun 11;19(1):119, 2019. <https://www.ncbi.nlm.nih.gov/pubmed/?term=barger+s+stakeholder>

**Multiple Studies\*** The Association of NCI-Sponsored Network Group Clinical Trials and Guideline Care and New Drug Indications. Unger JM, Nghiem VT, Hershman DL, Vaidya R, LeBlanc M, Blanke CD. [\*multiple SWOG and other NCTN-led trials]. *JAMA Open Network*, accepted 2019.

**Multiple Studies\*** Osteoporosis in Colorectal Cancer Survivors: Analysis of the Linkage between SWOG Trial Enrollees and Medicare Claims. Barz A, Hershman D, Till C, Barlow W, Ramsey S, Lenz H-J, Hochster H, Unger J. *Archives of Osteoporosis* Jul 28;14(1):83, 2019. [\*S9304, S9415, S9420]; [see also GI Cmte] <https://www.ncbi.nlm.nih.gov/pubmed/31352608>

Reimbursing Patients for Participating in Cancer Clinical Trials [Viewpoint]. Unger JM, Fleury ME. *JAMA Oncology* Jul 1;5(7):932-934, 2019. <https://www.ncbi.nlm.nih.gov/pubmed/?term=unger+jm+reimbursing>

#### Submitted Manuscripts

**S1105** Randomized Trial of Text-Messaging to Reduce Early Discontinuation of Adjuvant Aromatase Inhibitor Therapy in Women with Early Stage Breast Cancer: SWOG S1105. Hershman DL, Unger JM, Clarke Hillyer G, Moseley A, Arnold K, Dakhil S, Esparaz B, Kuan M, Graham ML, Lackowski D, Edenfield W, Dayao Z, Henry NL, Gralow J, Ramsey S, Neugut A. *JAMA*, submitted 2019.

**Multiple Studies\*** Influence of Modeling Choices on Value of Information Analysis: An Empirical Analysis from a Real-world Experiment. Kim DD, Guzauskas G, Bennette C, Basu A, Veenstra D, Ramsey S, Carlson J. *PharmacoEconomics*, under revision for resubmission, 2019. [\*S1418, S1513]

**Multiple Studies\*** Economic evaluations in NCI-sponsored network cancer clinical trials. Nghiem VT, Vaidya R, Lyman GH, Hershman DL, Ramsey SD, Unger JM. *Journal of Oncology Practice*, submitted 2019. [\*E2100, E4494, IBCSG25, JMA17, N9741, N9831, S8494, S8710, S8794, S8797, S9031, S9412, S9509]

### CANCER SURVIVORSHIP COMMITTEE

#### Published/Accepted Manuscripts

No publication information for this cycle.

#### Submitted Manuscripts

**S0221** Vitamin supplement use during chemotherapy and survival outcomes of breast cancer patients enrolled in a cooperative group clinical trial (SWOG S0221). Ambrosone C, Zirpoli G, Hutson A, McCann S, Barlow W, Kelly KM, Cannioto R, McCann W, Hershman D, Unger J, Moore HCF, Stewart JA, Isaacs C, Hobday TJ, Salim M, Hortobagyi G, Gralow JR, Budd GT, Albain KS. *Journal of Clinical Oncology*, under revision for resubmission 2019. [see also Breast Cmte]

**S0221** Cannioto RA, Hutson A, Dighe S, McCann W, McCann S, Zirpoli G, Barlow W, Kelly KM, DeNysschen CA, Hershman DL, Unger JM, Moore HCF, Stewart JA, Isaacs C, Hobday T, Salim M, Hortobagyi GN, Gralow J, Albain K, Budd GT, Ambrosone C. Exercise before, during and after chemotherapy for high-risk breast cancer in a therapeutic trial (S0221); relationships with recurrence and survival. *JAMA Oncology*, submitted 2019. [see also Breast Cmte]



# Publication List by Committee

## PALLIATIVE AND END OF LIFE CARE COMMITTEE

### Published/Accepted Manuscripts

**S1316** Intellectual Equipoise and Challenges: Accruing Patients with Advanced Cancer to a Trial Randomizing to Surgical or Non-Surgical Management (SWOG S1316). Deutsch G, Deneve J, Al-Kasspooles M, Nfonsam V, Gunderson C, Alvarez Secord A, Rodgers P, Hendren S, Silberfein E, Grant ML, Sloan J, Sun V, Arnold K, Anderson G, Krouse R. American Journal of Hospice & Palliative Medicine May 23 [Epub ahead of print], 2019. <https://www.ncbi.nlm.nih.gov/pubmed/?term=krouse+r+intellectual>

Trends in Medical Aid in Dying in Oregon and Washington. Al Rabadi L, LeBlanc M, Bucy T, Ellis LM, Hershman DL, Meyskens FL, Jr, Taylor L, Blanke CD. JAMA Network Open, in press 2019.

### Submitted Manuscripts

**PILOT (S1820)** Altering Intake and Managing Symptoms in Rectal Cancer (AIMS-RC): Feasibility of a Diet Modification Intervention for Post-Treatment Bowel Dysfunction [pilot for S1820]. Sun V, Crane T, Wright S, Chanson D, Slack S, Yung A, Sentovich S, Melstrom K, Fakih M, Krouse R, Thomson CA. Nutrition and Cancer, submitted 2019.

## PREVENTION AND EPIDEMIOLOGY COMMITTEE

### Published/Accepted Manuscripts

**S0812** Randomized Double-Blind Placebo-Controlled Biomarker Modulation Study of Vitamin D in Premenopausal Women at High Risk for Breast Cancer (SWOG S0812). Crew K, Anderson G, Hershman D, Terry M, Tehranifar P, Lew DL, Yee M, Brown E, Kairouz S, Kuwajerwala N, Bevers T, Doster J, Zarwan C, Kruper L, Minasian L, Ford L, Arun B, Neuhaus M, Goodman G, Brown P. Cancer Prevention Research Jul;12(7):481-490, 2019. <https://www.ncbi.nlm.nih.gov/pubmed/?term=crew+k+s0812>

**S9217** Association of treatment with 5a-reductase inhibitors with time to diagnosis and mortality in prostate cancer. Thompson IM, Tangen CM, Kramer B. Letter to the Editor re: Sarkar RR, Parsons JK, Bryant AK, et al. JAMA Internal Medicine, accepted 2019.

**S9217** More on Long-Term Effects of Finasteride on Prostate Cancer Mortality. Reply. Goodman PJ Tangen CM, Thompson IM Jr. New England Journal of Medicine May 16;380(20):e38. doi: 10.1056/NEJMc1902700, 2019. <https://www.ncbi.nlm.nih.gov/pubmed/31091400>

**Multiple Studies\*** Meta-analysis of 16 studies of the association of alcohol with colorectal cancer. McNabb S, Harrison TA, Albanes D,

Berndt SI, Brenner H, Caan BJ, Campbell PT, Cao Y, Chang-Claude J, Chan A, Chen Z, English DR, Giles GG, Giovannucci EL, Goodman PJ, Hayes RB, Hoffmeister M, Jacobs EJ, Joshi AD, Larsson SC, Le Marchand L, Li L, Lin Y, Männistö S, Milne RL, Nan H, Chri Newton C, Ogino S, Parfrey PS, Petersen PS, Potter JD, Schoen RE, Slattery ML, Su Y-R, Tangen CM, Tucker TC, Weinstein SJ, White E, Wolk A, Woods MO, Phipps AI, Peters U. International Journal of Cancer, Apr 29 [Epub ahead of print], 2019. [\*S0000, multiple other] <https://www.ncbi.nlm.nih.gov/pubmed/31037736>

**Multiple Studies\*** Prediagnostic circulating markers of inflammation and risk of esophageal adenocarcinoma: a study within the National Cancer Institute Cohort Consortium. Cook MB, Barnett M, Bock C, Cross A, Goodman P, Goodman G, Haiman C, Khaw K-T, McCullough ML, Newton CC, Boutron-Ruault M-C, Lund E, Rutegard M, Thornquist M, Spriggs M, Giffen C, Freedman ND, Kemp T, Kroenke CH, Le Marchand L, Park JY, Simon M, Wilkens L, Pinto L, Hildesheim A, Campbell P. Gut Jun;68(6):960-968, 2019. [\*S0000, S9217, multiple other] <https://www.ncbi.nlm.nih.gov/pubmed/30121626>

**Multiple Studies\*** Du Z, Weinhold N, Song C, Rand K, Van Den Berg D, Hwang A, Sheng X, Hom V, Ailawadhi S, Goodman P, Klein E, Zonder J, Orłowski R, Conti D, Haiman C, Cozen W. A Meta-Analysis of Genome-Wide Association Studies of Multiple Myeloma among African Americans. Blood Advances, accepted 2019. [\*S0000, S9217, Other Studies] [see also Myeloma Cmte]

### Submitted Manuscripts

**S0000/S9217** Prostate Cancer Prevention: A Perspective. Thompson IM, Tangen C. Science, submitted 2019.

**S0000B** Age-related Macular Degeneration in a Randomized Trial of Selenium and Vitamin E in Men: The SELECT Eye Endpoints (SEE) Study (SWOG S0000B). Christen W, Darke A, Gaziano JM, Glynn RJ, Goodman P, Crowley J, Lippman SM, Lad TE, Bearden JD, Goodman GE, Minasian LM, Thompson IM, Blanke CD, Klein EA. JAMA Network Open, under review 2019.

**S0820/other** Effect of Increasing Trust in Medical Researchers on Minority Recruitment: The RECRUIT Randomized Clinical Trial. Tilley BC, Mainous AG, Amorrortu RP, McKee MD, Smith DW, Li R, DeSantis SM, Vernon SW, Alvidrez J and additional RECRUIT Trial Center and Parent Trials' investigators [including Zell J, Yee M and Unger JJ], Clinical Trials, submitted 2019.

# Publication List by Committee

**Multiple Studies\*** Young-onset colorectal cancer shows higher susceptibility to common genetic risk factors. Archambault A, Su Y-R, Jeon J, Minta T, Lin Y, Conti D, Albanes D, Goodman P, Platz E, Tangen C, Lenz H-J, Corley D, Hsu L, Peters U. Lancet, submitted 2019. [\*S0000, MULTIPLE OTHER]

**Multiple Studies\*** Dysregulated super-enhancers in colorectal cancer are beacons for discovering genetic risk loci. Bien S, Harrison T, Huyghe J, Lu Y, Wang H, Shcherbina A, Albanes D, Goodman P, Platz E, Tangen C, Le Marchand L, Zheng W, Gruber S, Hsu L, Schacheri P, Peters U. Nature Communications, under review 2019. [\*S0000, MULTIPLE OTHER]

**Multiple Studies\*** Measures of Body Fatness and Height Across the Adult Lifecourse and Risk of Prostate Cancer Incidence and Mortality in the Pooling Project of Prospective Studies of Diet and Cancer. Genkinger JM, Wu K, Wang M, Albanes D, Black A, van den Brandt P, Cook MB, Gapstur SM, Giles GG, Giovannucci E, Goodman G, Goodman P, Hakansson N, Key T, Mannisto S, Le Marchand L, Liao L, MacInnis R, Neuhauser M, Platz E, Sawada N, Schenk Kisser J, Stevens VL, Travis RC, Tsugane S, Visvanathan K, Wilkens RL, Wolk A, Smith-Warner SA. Annals of Oncology, revised/resubmitted 2019. [\*S9217, multiple other]

**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. Srinivasan S, Kryza T, Bock N, Stephens C, Dong Y, Panchadsaram J, Moya L, Rohl J, Perry-Keene J, Buzacott K, Gago M, Schleutker J, Maier C, Muir K, Tangen C, Gronberg H, Pashayan N, Albanes D, Wolk A, Eles R, Clements J, Batra J. Nature Genetics, under review 2019. [\*S0000, S9217]

## SYMPTOM CONTROL AND QUALITY OF LIFE COMMITTEE

### Published/Accepted Manuscripts

No publication information for this cycle.

### Submitted Manuscripts

**N0147** 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). Mahoney MR, Sloan JA, Hubbard JM, Tan AD, Liu H, Goldberg RM, Nair SG, Shields AF, Gill S, Jahagirdar B, Benson A, Sargent DJ, Alberts SR. Journal of Patient Reported Outcomes, submitted 2019. [see also GI Committee]

## DIGITAL ENGAGEMENT COMMITTEE

### Published/Accepted Manuscripts

No publication information for this cycle.

### Submitted Manuscripts

Clinical Trials in the Era of Digital Engagement: Key Stakeholder Roles and Responsibilities. Gunturu K, Dizon D, Klemp J. The BMJ, submitted 2019.

## EARLY THERAPEUTICS AND RARE CANCERS COMMITTEE

### Published/Accepted Manuscripts

No publication information for this cycle.

### Submitted Manuscripts

**S1609** DART (SWOG S1609): Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Neuroendocrine Tumors (NCT#02834013). Patel S, Othous M, Chae Y, Giles F, Hansel D, Singh P, Fontaine A, Shah M, Kasi A, Al Baghdadi T, Vasireddy S, Mayerson E, Ryan CW, Plets Melissa, Blanke CD, Kurzrock R. Cancer Immunology Research, submitted 2019.

## EXECUTIVE COMMITTEE

No publication information for this cycle.

## GASTROINTESTINAL COMMITTEE

### Published/Accepted Manuscripts

**C/S80405** Impact of Consensus Molecular Subtype (CMS) on Survival in Patients With Metastatic Colorectal Cancer: Results From CALGB/SWOG 80405 (Alliance). Lenz H-J, Ou F-S, Venook AP, Hochster HS, Niedzwiecki D, Goldberg RM, Mayer RJ, Bertagnolli MM, Blanke CD, Zemla T, Qu X, Wirapati P, Tejpar S, Innocenti F, Kabbarah O. Journal of Clinical Oncology Aug 1;37(22):1876-1885, 2019. <https://www.ncbi.nlm.nih.gov/pubmed/?term=lenz+h+impact+of+consensus>

**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. Archives of Osteoporosis Jul 28;14(1):83, 2019. [\*S9304, S9415, S9420]; [see also CCD Cmte] <https://www.ncbi.nlm.nih.gov/pubmed/31352608>

### Submitted Manuscripts

**S1201** A Randomized Phase II Pilot Study Prospectively Evaluating Treatment for Patients with Advanced/Metastatic Esophageal, Gastric or Gastroesophageal Junction Cancer Based on Gene Expression of ERCC1: SWOG S1201. Iqbal S, McDonough S, Lenz H-J, Ilson D, Burtneess B, Nangia

# Publication List by Committee

C, Barzi A, Schneider CJ, Liu J, Dotan E, Guthrie K, Hochster H. Journal of Clinical Oncology, under revision for resubmission, 2019.

**S1310** Randomized Phase II Trial (SWOG S1310) of Single Agent MEK Inhibitor Trametinib vs 5-Fluorouracil or Capecitabine in Refractory Advanced Biliary Cancer. Kim R, McDonough S, El-Khoueiry A, Bekaii-Saab T, Stein S, Sahai V, Keogh G, Kim E, Baron A, Siegel A, Barzi A, Guthrie K, Javle M, Hochster H. European Journal of Cancer, under review, 2019.

**C/S80405** Diabetes and Clinical Outcome in Patients with Metastatic Colorectal Cancer: CALGB 80405 (Alliance). Brown JC, Zhang S, Ou F-S, Venook A, Niedzwiecki D, Lenz H-J, Innocenti F, O'Neil BH, Shaw JE, Polite B, Hochster H, Atkins JN, Goldberg RM, Ng K, Meyer RJ, Blanke CD, O'Reilly E, Fuchs CS, Meyerhardt JA. JAMA, submitted 2019.

**C/S80405** Plasma 25-Hydroxyvitamin D Levels and Survival in Patients with Advanced or Metastatic Colorectal Cancer: Findings from CALGB/SWOG 80405 (Alliance). Yuan C, Sato K, Hollis B, Zhang S, Niedzwiecki D, Ou F-S, Chang I-W, O'Neil BH, Innocenti F, Lenz H-J, Blanke C, Venook A, Mayer R, Fuchs C, Meyerhardt J, Ng K. Clinical Cancer Research, under review 2019.

**N0147** 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). Mahoney MR, Sloan JA, Hubbard JM, Tan AD, Liu H, Goldberg RM, Nair SG, Shields AF, Gill S, Jahagirdar B, Benson A, Sargent DJ, Alberts SR. Journal of Patient Reported Outcomes, submitted 2019. [see also SCQOL Cmte]

## GENITOURINARY COMMITTEE

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

### Published/Accepted Manuscripts

**S0931** Everolimus Exposure as a Predictor of Toxicity in Renal Cell Cancer Patients in the Adjuvant Setting: Results of a Pharmacokinetic Analysis for SWOG S0931 (EVEREST), a Phase III Study (NCT01120249). Synold T, Plets M, Tangen C, Heath E, Palapattu G, Mack P, Stein M, Meng M, Lara P, Vogelzang N, Thompson IM, Ryan CR. Kidney Cancer, accepted 2019.

**S1314** ERCC2 Mutation: The Marker for Chemosensitivity in Primary and Secondary Muscle-invasive Bladder Cancers. Choi W, McConkey DJ. European Urology Feb;75(2):240-241, 2019. <https://www.ncbi.nlm.nih.gov/pubmed/30366635>

**S8795** Predicting Response to Intravesical Bacillus Calmette-Guérin Immunotherapy: Are We There Yet? A Systematic Review. Kamat AM, Li R, O'Donnell MA, Black PC, Roupert M, Catto JW, Comperat E, Ingersoll MA, Witjes WP, McConkey DJ, Witjes JA. European Urology May;73(5):738-748, 2018. <https://www.ncbi.nlm.nih.gov/pubmed/29055653>

**S8949** Considerations for the Next Clinical Trial Evaluating the Role of Cytoreductive Nephrectomy for Metastatic Renal Cell Carcinoma. Kim HL, Mayerson E, Lara PN, Messing E, Tangen C, Shuch BM, Vaishampayan U. Eur Urol Focus. 2019 May 15 [Epub ahead of print]. <https://www.ncbi.nlm.nih.gov/pubmed/31103605>

**C70807** The Men's Eating and Living (MEAL) Study (CALGB 70807 [Alliance]): A Randomized Clinical Trial of a Diet Intervention in Men on Active Surveillance for Prostate Cancer. Parsons JK, Zariah D, Mohler J, Paskett E, Hansel D, Kibel A, Liu H, Seisler D, Natarajan L, Hahn O, Taylor J, Small E, Van Veldhuizen P, Morris MJ, Bertagnolli M, Stroup S, Pierce JP, Marshall J. JAMA, revisions under review, 2019.

**EA8143** The future of perioperative therapy in advanced renal cell carcinoma: how can we PROSPER? Patel HD, Puligandla M, Shuch BM, Leibovich BC, Kapoor A, Master VA, Drake CG, Heng DY, Lara PN, Choueiri TK, Maskens D, Singer EA, Eggener SE, Svatek RS, Stadler WM, Cole S, Signoretti S, Gupta RT, Michaelson MD, McDermott DF, Cella D, Wagner LI, Haas NB, Carducci MA, Harshman LC, Allaf ME. Future Oncology May;15(15):1683-1695, 2019. <https://www.ncbi.nlm.nih.gov/pubmed/?term=PATEL+HD+PROSPER>

Development of a translational medicine protocol for an NCTN genitourinary clinical trial: Critical steps, common pitfalls and a basic guide to translational clinical research. Meeks JJ, Goldkorn A, Aparicio AM, McConkey DJ. Urologic Oncology May;37(5):313-317, 2019. <https://www.ncbi.nlm.nih.gov/pubmed/30115512>

### Submitted Manuscripts

No publication information for this cycle.

## LEUKEMIA COMMITTEE

### Published/Accepted Manuscripts

No publication information for this cycle.

### Submitted Manuscripts

**S1203** Standard versus high-dose cytarabine with or without vorinostat for AML. Garcia-Manero G, Othus M, Pagel J, Radich J, Fang M, Rizzieri D, Marcucci G, Strickland SA, Litzow MR, Savoie M, Medeiros B, Sekeres M, Lin TL, Uy G, Powell BL, Kolitz JE, Larson RA, Stone RM, Claxton D, Essell J,

# Publication List by Committee

Luger S, Mohan S, Moseley A, Appelbaum F, Erba HP. Journal of Clinical Oncology, submitted 2019.

**S1203** Rapid Donor Identification Improves Survival in High Risk First Remission AML Patients. Pagel J, Othus M, Garcia-Manero G, Fang M, Radich J, Rizzieri D, Marcucci G, Strickland S, Litzow M, Savoie ML, Spellman S, Confer D, Chell J, Brown M, Medeiros B, Lin T, Uy G, Powell B, Bayer R, Larson RA, Stone RM, Claxton D, Essell J, Luger S, Mohan S, Moseley A, Erba H, Appelbaum F. Journal of Oncology Practice, under revision for resubmission 2019.

**Multiple Studies\*** Development and Performance of Risk Stratification Models in AML Patients Utilizing ELN-2017 Guidelines and Additional Prognostic Factors: A SWOG Report. Era L, Pogossova-Agadjanyan EL, Moseley A, Othus M, Appelbaum FR, Chauncey TR, Chen I-M L, Erba HP, Godwin JE, Jenkins IC, Fang M, Huyhn M, Kopecky KJ, List AF, Naru J, Pogosov GL, Radich JP, Stevens E, Willborg B, Willman CL, Wood BL, Zhang Q, Meshinchi S, Stirewalt DL. Leukemia, submitted 2019. [\*S0106, S0112, S9031, S9333]

**Multiple Studies\*** Associations Between Complete Remission and 2-3 Year Survival Following 7+3 Induction for Acute Myeloid Leukemia. Othus M, Garcia-Manero G, Godwin J, Weick J, Stirewalt D, Appelbaum F, Erba H, Estey E. Blood Advances, 2019. [\*S0106, S1203, S8600, S9031, S9333]

**Multiple Studies\*** Karyotype gender comparison: a novel method of identifying transgender patients in large cohorts of patients with leukemia. Alpert A, Othus M, Erba H. Blood Advances, submitted 2019. [\*S0106, S0432, S0703, S1117, S1203]

## LUNG COMMITTEE

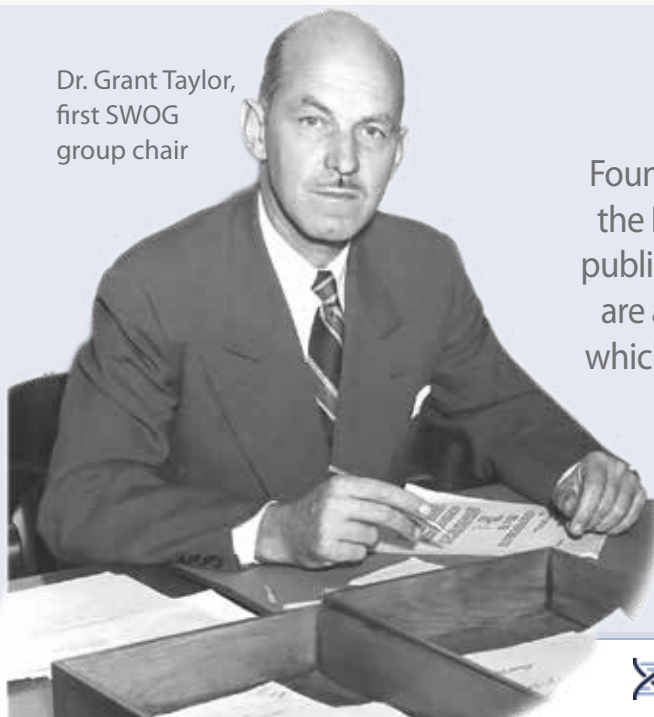
### Published/Accepted Manuscripts

**S0905** Phase II Trial of Cediranib in combination with cisplatin and pemetrexed in chemo naive patients with unresectable malignant pleural mesothelioma (SWOG S0905). Tsao A, Miao J, Wistuba I, Vogelzang N, Heymach J, Fossella F, Lu C, Velasco M, Box-Noriega B, Hueftle J, Gadgeel S, Redman M, Gandara D, Kelly K. Journal of Clinical Oncology, Aug 6 [Epub ahead of print]. <https://www.ncbi.nlm.nih.gov/pubmed/31386610>.

**S1400B** Brief Report: SWOG S1400B (NCT02785913), A Phase II Study of GDC-0032 (Taselisib) for Previously Treated PI3K-Positive Patients with Stage IV Squamous Cell Lung Cancer (Lung-MAP Sub-Study). Langer C, Redman M, Wade JL, III, Aggarwal C, Bradley J, Crawford J, Stella P, Knapp MH; Miao J, Minichiello K, Herbst RS, Kelly K, Gandara DR, Papadimitrakopoulou V. Journal of Thoracic Oncology May 31 [Epub ahead of print], 2019. <https://www.ncbi.nlm.nih.gov/pubmed/?term=langer+c+S1400b>

**S1400C** Brief Report: SWOG S1400C (NCT02154490)-A Phase II Study of Palbociclib for Previously Treated Cell Cycle Gene Alteration Positive Patients with Stage IV Squamous Cell Lung Cancer (Lung-MAP Sub-study). Edelman MJ, Redman M, Albain KS, McGary EC, Rafique NM, Petro D, Waqar S, Minichiello K, Miao J, Papadimitrakopoulou V, Kelly K, Gandara DR, Herbst RS. Journal of Thoracic Oncology Jul 11 [Epub ahead of print] 2019. <https://www.ncbi.nlm.nih.gov/pubmed/31302234>

Dr. Grant Taylor,  
first SWOG  
group chair



## 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.



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# Publication List by Committee

**S1400D** Brief Report: SWOG S1400D (NCT02965378), a Phase II Study of the Fibroblast Growth Factor Receptor Inhibitor AZD4547 in Previously-treated Patients with Fibroblast Growth Factor Pathway-Activated Stage IV Squamous Cell Lung Cancer (Lung-MAP Sub-Study). Aggarwal C, Redman M, Lara PN, Jr., Borghaei H, Hoffman P, Bradley JD, Newman AJ, III, Feldman MJ, Minichiello K, Miao J, Mack PC, Papadimitrakopoulou V, Herbst RS, Kelly K, Gandara DR. *Journal of Thoracic Oncology* May 31 [Epub ahead of print], 2019. <https://www.ncbi.nlm.nih.gov/pubmed/31195180>

## Submitted Manuscripts

No publication information for this cycle.

### LYMPHOMA COMMITTEE

#### Published/Accepted Manuscripts

**S0816** Long-term Follow-up of SWOG S0816: Response-Adapted Therapy for Stage III/IV Hodgkin Lymphoma Demonstrates Limitations of PET-adapted Approach. Stephens DM, Li H, Schoder H, Straus DJ, Moskowitz CH, LeBlanc M, Rimsza LM, Bartlett NL, Evens AM, LaCasce AS, Barr PM, Knopp MV, Hsi ED, Leonard JP, Kahl B, Smith SM, Friedberg JW. *Blood* 2019 Jul 22 [Epub ahead of print]. <https://www.ncbi.nlm.nih.gov/pubmed/31331918>

**C50303** Dose-Adjusted EPOCH-R Compared with R-CHOP as Frontline Therapy for Diffuse Large B-Cell Lymphoma: Clinical Outcomes of the Phase 3 Intergroup Trial Alliance/CALGB 50303. Bartlett N, Wilson WH, Yung S, Hsi E, Maurer MJ, Pederson L, Polley M-Y, Pitcher B, Cheson B, Kahl B, Friedberg J, Staudt L, Wagner Johnston N, Blum KA, Abramson

JS, Reddy N, Winter J, Chang JE, Gopal A, Chadburn A, Mathew S, Fisher RI, Richards KL, Schoder H, Zelenetz A, Leonard JP. *Journal of Clinical Oncology* Jul 20;37(21):1790-1799, 2019. <https://www.ncbi.nlm.nih.gov/pubmed/30939090>

## Submitted Manuscripts

**S1106** Five-Year Outcomes of SWOG S1106: A Randomized Phase II US Intergroup Study of R-HCVAD Vs. R-Bendamustine Followed By Autologous Stem Cell Transplant for Patients with Mantle Cell Lymphoma. Kamdar M, Li H, Chen RW, Rimsza LM, Leblanc M, Fenske TS, Shea TC, Barr P, Phillips TJ, Leonard JP, Kahl BS, Friedberg JW, Smith SM. *Blood Advances*, submitted 2019.

### MELANOMA COMMITTEE

#### Published/Accepted Manuscripts

No publication information for this cycle.

## Submitted Manuscripts

**S0826** SWOG S0826: A phase II trial of SCH 727965 (NSC 727135, dinaciclib) in patients with stage IV melanoma. Lao CD, Moon J, Fruehauf JP, Flaherty LE, Bury MJ, Ribas A, Sondak VK. *Cancer*, submitted 2019.

### PHARMACEUTICAL SCIENCES COMMITTEE

No publication information for this cycle.

### RADIATION ONCOLOGY COMMITTEE

No publication information for this cycle.

## Our clinical trials have:

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times

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million years of human life

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