

An aerial photograph of Chicago, Illinois, showing the city skyline in the background, a large park with green lawns and trees in the middle ground, and a multi-lane highway with traffic in the foreground. The image is taken from a high angle, looking down at the city and park.

# Virtual Meeting

SEPTEMBER 23-26, 2020

# We're Back On...line!

An engaging, relevant, and fun virtual meeting awaits you

Nothing replaces meeting face-to-face. Science meetings are all about side conversations, spontaneous session questions, connections with old colleagues and meeting new people.

I miss seeing you, and look forward to when we can do all that again.

In the meantime, we've built a virtual group meeting that we hope will be engaging, relevant, and fun. We've asked committee chairs to keep sessions succinct and strategy-focused, and to encourage participation from as many members as possible. The agenda book is back, and features a list of committee news and trials we activated since we last met in Chicago. The spread is meant to provide a fast and easy update to get you up to speed on SWOG.

While we had to toss some sessions for practical reasons, we're sticking to tradition on a few fronts. For example, you'll get a one-hour plenary update from me – welcomes, goodbyes, and news. (No joke though; I couldn't stand

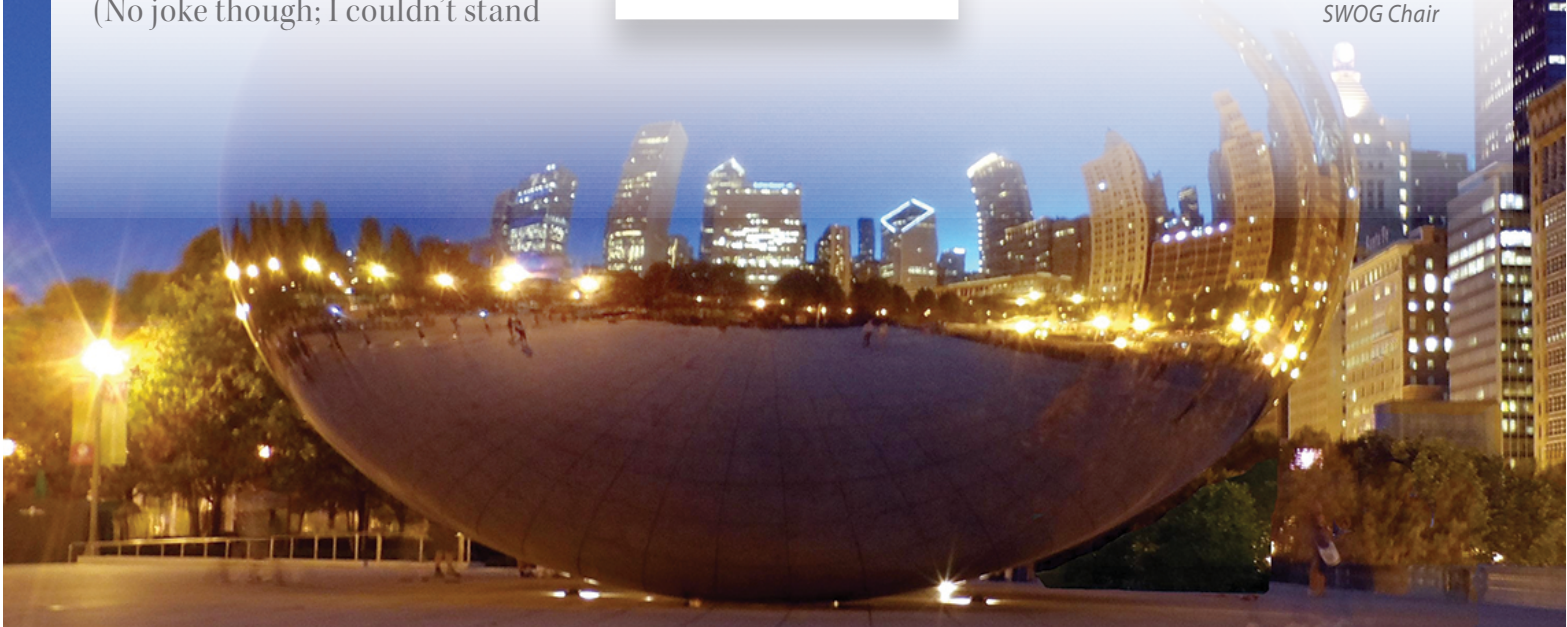
not hearing the usual uproarious laughter). We're also adapting. We're resurrecting the fun run and walk, now a virtual event, and The Hope Foundation for Cancer Research is hosting a panel discussion aimed at helping our researchers, whose science and clinical research can be suffering during the pandemic. Nothing is more important than supporting our members at this time.

These last seven months have been challenging ones for us, as physicians, researchers, parents, neighbors, and friends. The coronavirus has taken a heavy toll. But being part of a team, with a common purpose of healing, brightens and lightens us. I am grateful for being part of SWOG Cancer Research Network, and being part of this online meeting.

You'll be seeing me at the plenary!



Charles D. Blanke, MD  
SWOG Chair



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# What's New For Our Meeting

## 3 THINGS TO KNOW:

**1** We've got a special **website** that will be your group meeting home base. It's where you can log into every session, see agendas, get meeting highlights, and more. Registrants will get a link to the site by email, and the link will be also posted on [SWOG.org](http://SWOG.org).

**2** We've a got a **bonus feature** at the back of this agenda book. Turn to **Page 61**, and get an update from just about every SWOG committee chair. It's a fast way to get up to speed on new concepts in development and new projects and people.

**3** Don't forget! We're on Chicago time. **So all session times listed on the meeting website and in the agenda book are Central Time.** Please mark your calendars accordingly!



## CRUCIAL CONVERSATIONS A PANEL SERIES

Topic 1: Balancing Act | Live event: September 16, 12-1 pm CT



**Dr. Dawn Hershman**  
SWOG Vice Chair  
Session Moderator

*Join a panel of SWOG member investigators for our first session in the series, focused on the enduring impact of the COVID-19 environment on a generation of our members.*

- **How** are early career investigators juggling the new reality of uncertainty – online school, childcare, and telehealth for patients?
- **What** are the longer-term impacts for careers, given hiring freezes and changes in research funding – and where does SWOG fit in?
- **What** coping strategies have emerged, and which have been successful?
- **How** do organizations like The Hope Foundation stand poised to help?

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# What Pandemic?

**We've launched 10 new trials this year.**

As you can see from the activation dates below, the coronavirus slowed us down for a few months. But we're back on track — and have several more trials to launch by the end of the year.

**Thanks team — especially the lung committee leading this pack!**

**Trial:** S1827 “MRI Brain Surveillance Alone Versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer (MAVERICK)”

**Study Chair:** Chad Rusthoven, MD

**Committee:** Lung

**Activation Date:** 1/10/20

**Trial:** S1900C “A Phase II Study of Talazoparib plus Avelumab in Patients with Stage IV or Recurrent Non-Squamous Non-Small Cell Lung Cancer Bearing Pathogenic STK11 Genomic Alterations (Lung-MAP Sub-Study)”

**Study Chairs:** Ferdinandos Skoulidis, MD, PhD, MRCP, Jennifer Marie Suga, MD, MPH

**Committee:** Lung

**Activation Date:** 1/16/20

**Trial:** 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)”

**Study Chairs:** Jhanelle E. Gray, MD, Yasir Elamin, MD

**Committee:** Lung

**Activation Date:** 2/10/20

**Trial:** S1914 “A Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT Versus SBRT Alone in High Risk, Early Stage NSCLC”

**Study Chairs:** Megan Daly, MD and Charles Simone, MD

**Committee:** Lung

**Activation Date:** 3/25/20

**Trial:** S1823 “A Prospective Observational Cohort Study to Assess miRNA 371 for Outcome Prediction in Patients with Newly Diagnosed Germ Cell Tumors”

**Study Chairs:** Craig Nichols, MD and Luccia Nappi, MD

**Committee:** Prevention

**Activation Date:** 6/1/20

**Trial:** S1933 “A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status”

**Study Chair:** Raid Aljumaily, MD

**Committee:** Lung

**Activation Date:** 6/15/20

**Trial:** S1929 “Phase II Randomized Study of Maintenance Atezolizumab Versus Atezolizumab in Combination with Talazoparib in Patients with SLFN11 Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC)”

**Study Chairs:** Nagla Abdel Karim, MD, PhD and Karen Lynn Reckamp, MD

**Committee:** Lung

**Activation Date:** 6/15/20

**Trial:** S1905 “A Phase I/II Study of AKR1C3-Activated PRODRUG OBI-3424 (OBI-3424) in Patients With Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL) / T-Cell Lymphoblastic Lymphoma (T-LBL)”

**Study Chairs:** Anjali S. Advani, MD and Nikolaos Papadantonakis, MD, Msc, PhD

**Committee:** Leukemia

**Activation Date:** 8/17/20

**Trial:** 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”

**Study Chair:** Katherine D. Crew, MD

**Committee:** Prevention and Epidemiology

**Activation Date:** 9/1/20

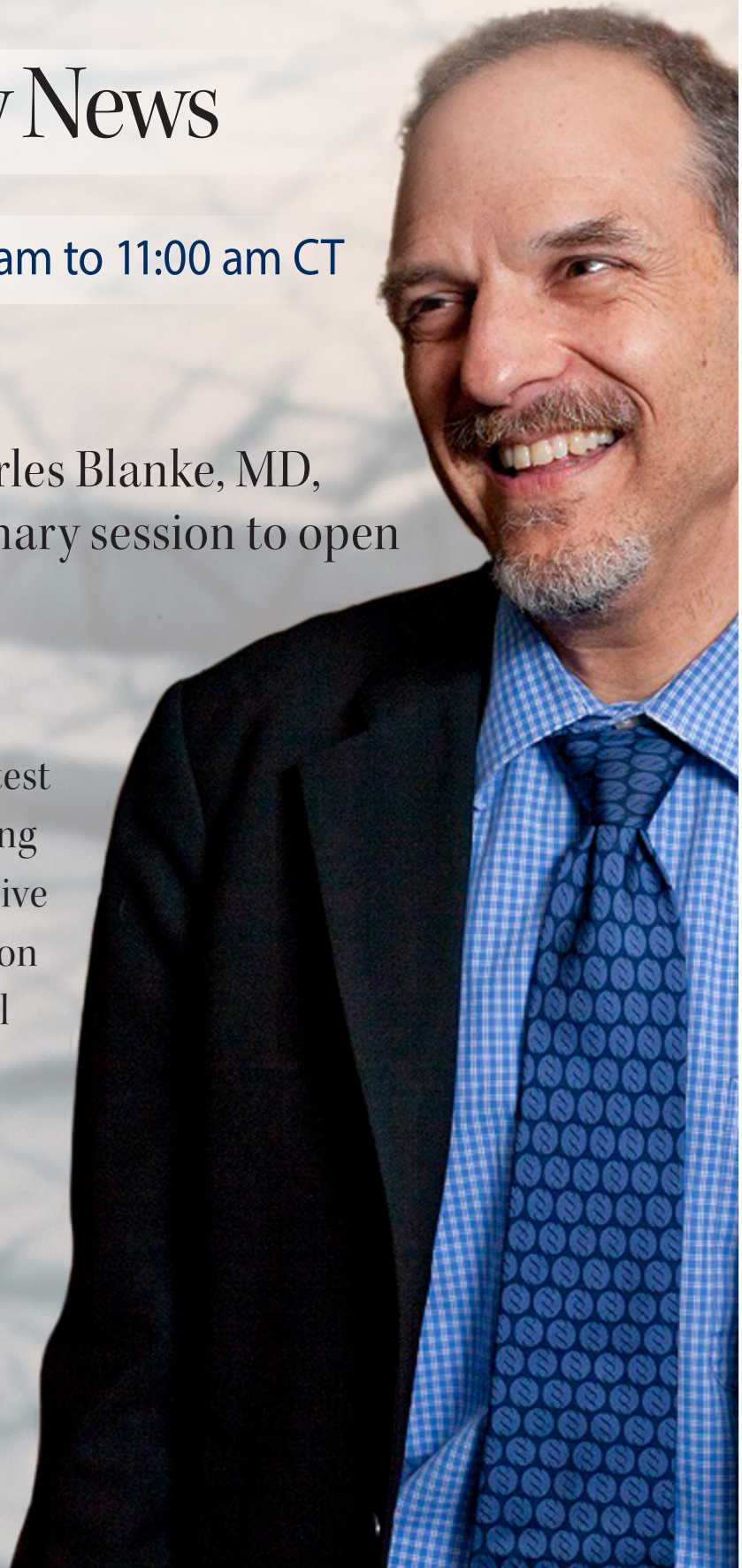
# Get your Plenary News

Thursday, Sept. 24 from 10:00 am to 11:00 am CT

SWOG Group Chair Dr. Charles Blanke, MD, hosts a special one-hour plenary session to open the virtual fall meeting.

You'll get a list of outgoing leaders, incoming luminaries, and all the latest on recently completed and upcoming trials, programs, and projects. The live session will also include an update on our NCTN and NCORP trial accrual – which has been recovering nicely.

## See you there!





# Get off the Couch and Crush the Crab!

Warm up for the group meeting and help raise funds for The Hope Foundation for Cancer Research

We usually lace up and hit the Embarcadero each spring in San Francisco for our traditional “**Crush the Crab**” fun run and walk. (The crab, of course, is cancer). Since we missed the event this spring, we’re bringing it back this fall in a virtual version.

**The goal:** Get members outside, create some online togetherness, and raise money for the charity that supports our cancer clinical trials in good times and in bad.

## Here’s how the 2020 Crush the Crab works:

- **Register** at <https://runsignup.com/crushthecrab2020> any time before Sept. 19
- **It’s free**, but donations and team fundraising are encouraged!
- **Run or walk** a 5K any time between Sept. 12-Sept. 19
- **Record and post** a video here <https://www.tribute.co/crush-the-crab/>

Video tributes will be played during the group meeting proceedings. Tell us about who and what inspires you!



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## 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

### **Immunotherapeutics**

Siwen Hu-Lieskovan, MD, PhD

Katerina Politi, PhD

### **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**

Allison Caban-Holt, PhD

### **Surgery**

Syed A. Ahmad, MD

## Future Meeting Dates

### 2021

#### Spring

April 21-24  
San Francisco, CA

#### Fall

October 13-16  
Chicago, IL

### 2022

#### Spring

April 6-9  
Seattle, WA

#### Fall

October 19-22  
Chicago, IL

### 2023

#### Spring

April 26-29  
San Francisco, CA

#### Fall

October 11-14  
Chicago, IL

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**tomorrow.**



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# 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: Adolescent and Young Adult Committee, 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 Session; Leukemia Committee; Breast Committee; Gastrointestinal

Committee; Lung Committee; Lymphoma Committee; Immunotherapeutics Committee; Digital Engagement Committee; and Bone Marrow & Stem Cell Transplantation Committee

## Continuing Medical Education Credit

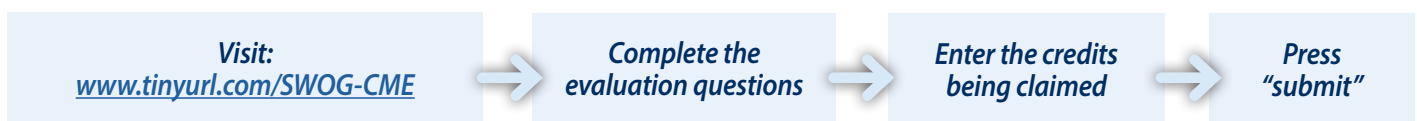
The Hope Foundation is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Hope Foundation designates this live activity for a maximum of 18.5 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. Best attempts will also be made to provide up to date information on introductory slides at each CME session.

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



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 on the next page.

# Track Your CME Credits

Time	Session Title	Credits	
		Available	Actual
<b>WEDNESDAY, SEPTEMBER 23, 2020</b>			
10:00 am – 12:00 pm	Radiation Oncology Committee	2.0	_____
12:30 pm – 2:30 pm	Immunotherapeutics Committee	2.0	_____
1:00 pm – 2:00 pm	Adolescent and Young Adult (AYA) Committee	1.0	_____
2:00 pm – 4:00 pm	Surgery Committee	2.0	_____
2:30 pm – 4:00 pm	Digital Engagement Committee	1.5	_____
<b>THURSDAY, SEPTEMBER 24, 2020</b>			
10:00 am – 11:00 am	Plenary Session	1.0	_____
11:15 am – 12:15 pm	Cancer Care Delivery Committee	1.0	_____
11:15 am – 2:15 pm	Early Therapeutics and Rare Cancers Committee	3.0	_____
11:30 am – 1:00 pm	Bone Marrow & Stem Cell Transplantation Committee	1.5	_____
12:30 pm – 2:30 pm	Prevention and Epidemiology Committee	2.0	_____
1:15 pm – 3:45 pm	Lymphoma Committee	2.5	_____
1:30 pm – 3:30 pm	GI Committee	2.0	_____
2:45 pm – 4:45 pm	Palliative and End of Life Care Committee	2.0	_____
<b>FRIDAY, SEPTEMBER 25, 2020</b>			
10:00 am – 12:00 pm	Cancer Survivorship Committee	2.0	_____
10:00 am – 12:00 pm	Barlogie-Salmon Myeloma Committee	2.0	_____
10:00 am – 12:00 pm	Melanoma Committee	2.0	_____
10:00 am – 2:00 pm	Lung Committee	4.0	_____
12:00 pm – 4:00 pm	Breast Committee	3.75	_____
12:30 pm – 2:30 pm	Leukemia Committee	2.0	_____
12:30 pm – 4:30 pm	GU Committee	4.0	_____
3:30 pm – 4:30 pm	Symptom Control and Quality of Life Committee	1.0	_____
<b>Total Possible Credits</b>		<b>18.5</b>	<b>_____</b>

**I confirm that I attended the sessions indicated above.**

PRINTED Name: \_\_\_\_\_

Degree(s) (MD, DO, PhD, PA, etc.) \_\_\_\_\_

Signature: \_\_\_\_\_

E-mail: \_\_\_\_\_

# Schedule of Events

## WEDNESDAY, SEPTEMBER 23, 2020

<a href="#">10:00 AM – 11:00 AM</a>	Nursing Research Subcommittee (Invitation Only)
<a href="#">10:00 AM – 12:00 PM</a>	Recruitment and Retention Committee
<a href="#">10:00 AM – 12:00 PM</a>	Radiation Oncology Committee
<a href="#">12:00 PM – 2:00 PM</a>	SWOG NCORP Research Base Clinical Trials Workshop
<a href="#">12:15 PM – 2:15 PM</a>	Advocates Committee Meeting (Invitation Only)
<a href="#">12:30 PM – 2:30 PM</a>	Immunotherapeutics Committee
<a href="#">1:00 PM – 2:00 PM</a>	Adolescent and Young Adult (AYA) Committee
<a href="#">1:00 PM – 2:00 PM</a>	SWOG Tissue Banking Meeting (Invitation Only)
<a href="#">2:00 PM – 4:00 PM</a>	Pharmaceutical Sciences & Drug Information Subcommittee
<a href="#">2:00 PM – 4:00 PM</a>	Surgery Committee
<a href="#">2:30 PM – 3:30 PM</a>	SWOG-CTP Scientific Advisory Board meeting (Invitation Only)
<a href="#">2:30 PM – 4:00 PM</a>	Digital Engagement Committee
<a href="#">2:30 PM – 4:30 PM</a>	Hope Foundation Board Meeting (Invitation Only)
<a href="#">3:30 PM – 5:00 PM</a>	Site Operations
<a href="#">4:00 PM – 5:00 PM</a>	NCORP/MU-NCORP Site PI Meeting

## THURSDAY, SEPTEMBER 24, 2020

<a href="#">10:00 AM – 11:00 AM</a>	Plenary Session
<a href="#">11:15 AM – 12:15 PM</a>	Cancer Care Delivery Committee
<a href="#">11:15 AM – 2:15 PM</a>	Early Therapeutics and Rare Cancers Committee
<a href="#">11:30 AM – 1:00 PM</a>	Professional Review Committee (Invitation Only)
<a href="#">11:30 AM – 1:00 PM</a>	Bone Marrow & Stem Cell Transplantation Committee

<a href="#">11:30 AM – 1:30 PM</a>	Quality Initiative Meeting (Invitation Only)
<a href="#">12:30 PM – 2:30 PM</a>	Prevention and Epidemiology Committee
<a href="#">1:00 PM – 2:00 PM</a>	Jeri & Noboru Oishi Symposium
<a href="#">1:15 PM – 3:45 PM</a>	Lymphoma Committee
<a href="#">1:30 PM – 3:30 PM</a>	GI Committee
<a href="#">2:00 PM – 4:00 PM</a>	Conflict Management Committee (Invitation Only)
<a href="#">2:15 PM – 3:15 PM</a>	ORP Open Forum
<a href="#">2:45 PM – 4:45 PM</a>	Palliative and End of Life Care Committee
<a href="#">4:00 PM – 5:00 PM</a>	GI Translational Medicine Subcommittee (Invitation Only)
<a href="#">5:00 PM – 6:00 PM</a>	SLAI Latin America Symposium

## FRIDAY, SEPTEMBER 25, 2020

<a href="#">10:00 AM – 12:00 PM</a>	Cancer Survivorship Committee
<a href="#">10:00 AM – 12:00 PM</a>	VA Working Group
<a href="#">10:00 AM – 12:00 PM</a>	Barlogie-Salmon Myeloma Committee
<a href="#">10:00 AM – 12:00 PM</a>	Imaging Committee (Invitation Only)
<a href="#">10:00 AM – 12:00 PM</a>	Melanoma Committee
<a href="#">10:00 AM – 2:00 PM</a>	Lung Committee
<a href="#">11:00 AM – 11:30 AM</a>	Publications Committee (Invitation Only)
<a href="#">12:00 PM – 4:00 PM</a>	Breast Committee
<a href="#">12:30 PM – 2:30 PM</a>	Leukemia Committee
<a href="#">12:30 PM – 4:30 PM</a>	GU Committee
<a href="#">3:30 PM – 4:30 PM</a>	Symptom Control and Quality of Life Committee

## SATURDAY, SEPTEMBER 26, 2020

<a href="#">10:00 AM – 11:00 AM</a>	Board of Governors (Invitation Only)
-------------------------------------	--------------------------------------

# Jeri and Noboru Oishi Symposium

September 24, 2020 | 1-2 pm CT

1:00 – 1:05

## Welcome & Introductions

**Kristine Abueg, CRN**  
Oishi Symposium Chair

1:07 – 1:30

## The impact of SWOG Studies on Advances in Cancer

**Joseph Unger, PhD**  
Assistant Member, Public Health Sciences  
Biostatistician and Health Services  
Researcher at the SWOG Statistical Center  
Fred Hutchinson Cancer Research Center

1:35 – 2:00

## Adaptations in the COVID era – Real Life Stories (Panel Discussion)

**Diana B. Lin**  
Kaiser Permanente NCORP

**Christa Varnadoe**  
Tisch Cancer Institute

**Alexandra Annis**  
University of Arkansas for Medical Sciences

**Stephanie Couch**  
Michigan Cancer Research Consortium

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## ROBERT B. LIVINGSTON LECTURE

# Progress in Endocrine Therapy: Next Steps

**2020 Speaker: Gabriel N. Hortobagyi, MD**

*Can't make the breast meeting? No problem.*

*This session has been pre-recorded and the talk is posted on the SWOG meeting site.*

Dr. Robert Boyd Livingston was a clinician and researcher who made a major impact on the field of cancer research through a sweeping career at multiple institutions, including the University of Texas Health Science Center, the Cleveland Clinic, the Fred Hutchinson Cancer Research Center and University of Washington, and the University of Arizona. Established in 2017 by The Hope Foundation for Cancer Research, this lectureship brings a special guest speaker to each spring SWOG group meeting. Speakers will discuss advances in translational medicine breast cancers in one year, then lung cancers the next year. Livingston chaired both SWOG committees between 1974 and 2008.



**Gabriel N. Hortobagyi, MD**



*Thanks To*

# Our Top Accruers

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

In 2019, these members topped the charts for SWOG-credited registrations to SWOG managed trials.

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

## Main Member / LAPS

University of Texas  
MD Anderson Cancer Center

City of Hope

University of Michigan  
Rogel Cancer Center

University of Utah  
Huntsman Cancer Institute

Moffitt Cancer Center

## NCORP

Heartland Cancer Research NCORP

New Mexico Minority  
Underserved NCORP

Michigan Cancer Research  
Consortium NCORP

Gulf South Minority Underserved  
NCORP

Cancer Research Consortium  
of West Michigan NCORP



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



a National Cancer Institute program

# Barlogie-Salmon Myeloma Committee

## Committee Leadership

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

## Scientific Leadership

Translational Medicine: ..... Brian A. Walker, BSc, PhD  
Radiation: .....Chelsea Camille Pinnix, MD, PhD  
Surgery: ..... J. Sybil Biermann, MD  
Imaging: ..... Saad Z. Usmani, MD  
..... Eric M. Rohren, MD, PhD  
Pathology: ..... TBD  
Early Therapeutics: ..... Frits van Rhee, MD, PhD  
Designates  
Digital Engagement: ..... Saad Z. Usmani, MD  
NCORP Representative: .....Charles S. Kuzma, MD  
Data Coordinators: .....Sean O'Bryan  
..... Hannah Hale  
Oncology Research Professionals:  
CRA: .....Erik Bailey, BA  
Nurses: ..... Deborah A. Shaw, RN  
..... Teresa Witcher, BSN, RN  
Patient Advocate: ..... Jack Aiello, MS  
Pharmaceutical Science: ..... Craig Elg, PharmD  
.....Ila M. Saunders, PharmD  
Protocol Coordinator: ..... TBD  
Clinical Trials Project Manager: .....Sandi Hita, JD

## Agenda

Friday, September 25, 2020  
10:00 am- 12:00 pm

## Active Studies

**S1803**, "Phase III Study of Daratumumab/rHuPH20 (NSC- 810307) + Lenalidomide or Lenalidomide 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

**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.

**S1702**, "A Phase II Study of Isatuximab (SAR650984) (NSC-795145) for Patients with Previously Treated AL Amyloidosis." Drs. Parker and Sanchorawala. Activated: 3/8/18; Closed: 9/30/19.

## Proposed Studies

**S2005**, "A Phase II Randomized Study of Venetoclax with Ibrutinib and Rituximab in Previously Untreated Waldenström's Macroglobulinemia." Drs. Ailawadhi and Bhutani.

**S2105**, "A Phase III Randomized Trial for Newly Diagnosed Multiple Myeloma (NDMM) Patients Considered Frail or Ineligible for Stem Cell Transplant Comparing Upfront Bortezomib- Lenalidomide- Dexamethasone-Lite (VRd-Lite) with Daratumumab-Lenalidomide- Dexamethasone (DRd)." Drs. Ailawadhi, Ye, and Gowin.



## Barlogie-Salmon Myeloma Committee

## Cumulative Accrual by Institution and Study

Includes accrual through 7/10/2020. Includes studies that are currently open or that closed since 1/1/19.

	S1702	S1803	A061202	E1A11	EAA173
Arizona CC, Univ of	-	4	-	-	-
Arkansas, U of	-	-	-	3	-
Baylor College	-	-	-	9	-
Beaumont NCORP	-	-	-	6	-
Boston Medical Ctr	6	1	-	-	-
CORA NCORP	2	-	-	1	-
City of Hope Med Ctr	-	33	-	-	-
Cleveland Clinic OH	-	2	-	-	-
Columbia MU-NCORP	2	-	-	-	-
Columbus NCORP	-	2	-	-	-
Cotton O'Neil CC	-	-	-	3	-
Davis, U of CA	1	1	-	26	-
Dayton NCORP	-	1	-	2	-
Duke Univ Med Ctr	-	1	-	-	-
Fred Hutchinson CRC	-	-	-	-	1
Georgia NCORP	-	3	-	-	-
Hawaii MU-NCORP	-	-	-	1	-
Heartland NCORP	1	5	-	-	-
Henry Ford Hospital	-	-	1	15	-
Irvine, U of CA	1	-	-	6	-
Kaiser Perm NCORP	-	4	-	40	-
Kansas City NCORP	-	-	-	2	-
Kansas MU-NCORP	-	3	-	-	-
Lahey Hosp & Med Ctr	-	1	-	-	-
Loyola University	3	3	-	13	-
MUSC MU-NCORP	1	1	-	-	1
Michigan, U of	-	-	-	10	-
Montana NCORP	-	2	-	3	-
Nevada CRF NCORP	-	-	-	1	-
New Mexico MU-NCORP	-	4	-	-	-
Ohio State Univ	-	6	-	-	-
Oregon Hlth Sci Univ	2	2	-	4	2
Ozarks NCORP	-	-	-	6	-
PCRC NCORP	-	2	-	-	-
Providence Hosp	-	-	1	11	-
Rochester, Univ of	-	5	-	-	-
San Antonio, U of TX	-	10	-	9	-
San Diego, U of CA	-	-	-	1	-
Southeast COR NCORP	-	-	-	10	-
Sutter Cancer RC	-	-	-	6	-
Upstate NCORP	-	2	-	-	-
Utah, U of	-	3	-	-	1
VAMC Kansas City	-	-	-	6	-
Wayne State Univ	1	1	-	13	-
Wisconsin NCORP	-	4	-	-	-
Yale University	4	-	-	52	1
Alliance	3	25	-	-	-
ECOG-ACRIN	14	11	-	-	-
NRG	2	16	-	-	-
<b>Total</b>	<b>43</b>	<b>158</b>	<b>2</b>	<b>259</b>	<b>6</b>

# Breast Committee

## Committee Leadership

Chair: ..... Lajos Pusztai, MD, PhD  
Vice-Chair: .....Priyanka Sharma, MD  
Executive Officer:..... Julie R. Gralow, MD  
Statisticians: .....William E. Barlow, PhD  
..... Danika Lew, MA  
..... Jieling Miao, MS

## Scientific Leadership

Translational Medicine: ..... Alastair M. Thompson, MD  
..... Andrew K. Godwin, PhD  
Radiation Oncology:..... Reshma Jagsi, MD  
Surgery: ..... Anees B. Chagpar, MD  
Imaging:..... Joanne E. Mortimer, MD  
..... Wei Tse Yang, MBBS  
Pathology:..... David L. Rimm, MD, PhD  
Early Therapeutics:..... George Somlo, MD

## Designates

Cancer Control Liaisons: ..... Melinda L. Irwin, PhD, MPH (Survivorship)  
..... Dawn L. Hershman, MD (Cancer Care Delivery)  
..... Banu Arun, MD (Prevention)  
..... Helen K. Chew, MD (Symptom Control & QOL)  
Digital Engagement:..... Sarah S. Mougalian, MD  
NCORP Representative:..... Philip E. Lammers, MD  
Data Coordinators:..... Iris Syquia  
..... Larry Kaye  
..... Jacqueline Scurlock  
..... Gabi Herbert  
Oncology Research Professionals:  
CRAs:..... Karyn N. Hart, CCRP  
..... Avidanka Baftirovska, BS, CCRP  
Nurse: ..... TBD  
Patient Advocates:..... Ginny Mason, RN, BSN  
..... Elda Railey  
Pharmaceutical Science:..... Jessie Modlin, PharmD  
..... Jorge G. Avila, PharmD  
Protocol Coordinator:..... Cara Laubach, MIIM  
Clinical Trials Project Manager:..... Vanessa Benavidez, BS, CCRC

## Agenda

Friday, September 25, 2020  
12:00 pm- 4:00 pm

**12:00 – 12:05 pm** Welcome and Introductions  
Lajos Pusztai, MD, DPhil and Priyanka Sharma, MD

**12:05 – 12:10 pm** Robert Livingston lecture introduction “Progress in Endocrine Therapy: Next Steps” by Dr. Gabriel Hortobagyi - Pre-recorded lecture available on the SWOG Fall Virtual Meeting website

## Breast Committee Mini-Symposium (12:10 - 1:10 pm)

**12:10 - 12:30 pm** “CtDNA testing platforms, results and clinical utility in breast cancer” – Minetta Liu MD, Mayo Clinic

**12:30 - 12:50 pm** “Oncology Applications on the GeneXpert” – Michael Bates, Cepheid

**12:50 - 1:10 pm** Panel discussion, Q&A

**1:10 – 1:20 pm** Update on previously discussed Concepts  
– S2103 (NeoTACT) (Moulder)  
– S2007 (Brenner)

**1:20 – 2:20 pm** Review of new Concepts

**2:20 – 2:30 pm** BREAK

**2:30 – 2:40 pm** Patient Advocate update – Ginny Mason and Elda Railey

**2:40 – 2:45 pm** Publications update – William Barlow, PhD

**2:45 – 2:55 pm** How to use online SWOG statistical tool – William Barlow, PhD

**2:55 – 3:35 pm** Translational Medicine Sub-Committee Update  
Alastair Thompson, MD and Andrew K. Godwin, PhD

**3:35 – 3:55 pm** Review of open CTSU trials

**3:55 pm** Closing Comments and Adjournal

## 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.

**CTSU/A011202**, “A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3

# Breast Committee

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/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 EA1181, "(CompassHER2-pCR): Preoperative THP and Postoperative HP in Patients Who Achieve a Pathologic Complete Response Part 1 Component of: The CompassHER2 Trials (COMprehensive Use of Pathologic Response ASSESSment to Optimize Therapy in HER2-Positive Breast Cancer)" Dr. Tung. SWOG Champion: Dr. Tang. Activated: 2/11/20.

CTSU/EA1183, "FDG PET to Assess Therapeutic Response in Patients with Bone-dominant Metastatic Breast Cancer, FEATURE." Dr. Specht. SWOG Champion: Dr. Linden. Activated: 4/2/20.

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. Temporarily Closed to Accrual: 9/13/19.

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

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. Temporarily Closed to Accrual: 5/20/20.

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.

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 – Making Informed Choices on Incorporating Chemoprevention into Care (MiCHOICE)." Dr. Crew. In Development.

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.

## Breast Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/10/2020. Includes studies that are currently open or that closed since 1/1/19.

	S1207	S1416	S1418	S1706	A011106	A011401	A011502	B51	B55	EA1131	EA1181	MA39	NRGBR002	NRGBR003	NRGBR004	NRGBR005
Arizona CC, Univ of	14	-	4	-	33	7	-	-	-	-	-	-	-	-	-	-
Arkansas, U of	16	-	15	1	2	3	8	-	-	-	-	-	-	-	-	-
Baptist MU-NCORP	5	1	6	2	12	7	-	-	-	-	-	-	-	1	-	-
Bay Area NCORP	1	-	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Baylor Univ Med Ctr	2	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-
Beaumont NCORP	8	2	1	-	-	5	2	1	-	-	-	-	1	-	-	-
Boston Medical Ctr	3	-	-	-	-	3	-	-	-	-	-	-	-	-	-	-
CORA NCORP	22	3	14	1	1	-	-	2	-	-	-	-	-	-	-	-
CRC West MI NCORP	10	3	17	-	-	1	-	-	-	-	-	-	-	-	-	-
Carle CC NCORP	12	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Cedars-Sinai Med Ctr	9	-	-	-	-	-	-	-	6	-	-	-	-	-	-	-
Cincinnati MC, U of	10	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
City of Hope Med Ctr	21	-	9	-	-	-	-	-	-	-	-	-	-	-	-	-
Cleveland Clinic OH	12	8	7	-	-	1	-	5	2	-	-	1	-	8	-	-
Colorado, U of	18	7	9	1	16	23	7	3	2	-	-	-	-	-	-	2
Columbia MU-NCORP	7	-	5	-	-	-	-	-	-	-	-	-	-	-	-	-
Columbus NCORP	17	14	8	-	-	-	-	-	-	-	-	-	-	-	-	-
Cotton O'Neil CC	2	-	-	-	-	1	-	-	-	-	-	-	-	1	-	-
Davis, U of CA	7	12	7	2	-	3	15	-	-	-	-	-	-	-	-	-
Dayton NCORP	8	4	1	-	3	1	-	-	-	-	-	-	-	-	-	-
Desert Hospital	1	-	1	-	-	4	-	4	-	-	-	-	-	-	-	-
Essentia Hlth NCORP	3	-	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson CRC	22	13	8	-	-	11	8	-	3	-	-	-	-	-	-	-
Georgia NCORP	2	-	14	-	-	2	-	-	-	-	-	-	-	-	-	-
Greenville NCORP	-	2	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Gulf South MU-NCORP	23	-	4	-	-	-	-	-	-	-	-	-	-	3	-	-
H Lee Moffitt CC	5	-	-	-	-	3	2	-	-	-	-	-	-	-	-	-
Harrington CC	3	-	5	1	-	7	-	1	-	-	-	-	-	-	-	-
Hawaii MU-NCORP	13	-	4	-	-	-	-	-	-	-	-	-	-	-	-	-
Heartland NCORP	30	6	16	1	-	-	1	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	6	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Houston Methodist	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	1
Irvine, U of CA	11	-	5	-	3	2	-	-	-	-	-	-	-	1	-	-
Kaiser Perm NCORP	50	15	39	-	-	52	18	-	6	-	-	-	-	24	1	-
Kansas City NCORP	9	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Kansas MU-NCORP	54	-	18	2	-	21	9	-	2	-	-	-	-	-	-	1
Kentucky, U of	-	-	-	-	-	-	3	1	-	-	-	-	-	-	-	-
Lahey Hosp & Med Ctr	4	-	3	-	-	9	4	-	-	1	-	-	-	-	-	-
Loma Linda Univ	10	-	-	-	1	-	-	3	-	-	-	-	-	-	-	-
Loyola University	16	2	3	-	-	5	7	1	-	1	-	-	-	-	-	-
MAVERIC	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-

## Breast Committee, cont.

### Cumulative Accrual by Institution and Study

Includes accrual through 7/10/2020. Includes studies that are currently open or that closed since 1/1/19.

	S1207	S1416	S1418	S1706	A011106	A011401	A011502	B51	B55	E01131	E01181	MA39	NRGBR002	NRGBR003	NRGBR004	NRGBR005
MD Anderson CC	89	-	12	-	-	-	-	-	-	-	-	-	-	-	-	3
MUSC MU-NCORP	14	9	9	-	1	-	-	-	-	-	-	-	-	-	-	-
Memorial Hermann	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Michigan CRC NCORP	25	15	15	-	-	-	-	-	-	-	-	-	-	-	-	-
Michigan, U of	23	9	12	2	-	11	8	-	1	-	-	1	-	3	-	-
Montana NCORP	12	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Nevada CRF NCORP	3	-	9	-	-	-	-	-	-	-	-	-	-	-	-	-
New Mexico MU-NCORP	29	15	15	1	2	-	-	-	-	-	-	-	-	-	-	-
Northwest NCORP	9	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Northwestern Univ	23	-	2	-	-	-	-	-	-	-	-	-	-	1	-	-
Ohio State Univ	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Oklahoma, Univ of	9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Orange Reg Med Ctr	-	-	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Oregon Hlth Sci Univ	18	3	13	-	-	-	-	1	-	-	-	-	-	2	-	-
Ozarks NCORP	15	7	5	1	-	-	-	-	-	-	-	-	-	3	-	-
PCRC NCORP	21	5	12	-	-	3	-	-	-	-	-	-	-	1	-	-
Providence Hosp	10	2	3	2	1	9	8	6	1	-	1	-	-	3	1	-
Rochester, Univ of	10	-	2	1	1	-	15	-	1	7	1	-	-	9	-	-
Salem Hospital	13	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
San Antonio, U of TX	24	-	6	-	1	1	2	3	2	4	-	-	-	5	-	-
San Diego, U of CA	-	-	-	-	-	2	2	-	-	-	-	-	-	1	-	-
Scott & White Mem	-	-	-	-	-	4	-	-	-	-	-	-	-	-	-	-
So Calif, U of	19	-	2	-	-	-	-	-	2	-	-	-	-	-	-	-
Southeast COR NCORP	38	5	40	-	-	1	6	-	-	-	-	-	-	-	-	-
St Louis University	1	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Sutter Cancer RC	10	1	-	-	4	8	2	2	-	1	-	-	-	3	-	-
Tennessee, U of	8	-	-	-	-	-	-	4	-	-	-	-	-	-	-	-
Tulane University	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Upstate NCORP	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Utah, U of	-	3	3	2	-	4	-	-	-	-	-	-	-	-	-	-
Virginia Mason MC	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Wayne State Univ	17	-	2	-	-	12	9	-	3	4	-	-	-	6	-	-
Western States NCORP	1	-	2	-	-	1	-	-	1	-	-	-	-	-	-	-
Wichita NCORP	30	3	11	-	-	-	-	-	-	-	-	-	-	-	-	-
Wisconsin NCORP	2	5	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Yale University	52	-	7	-	12	78	30	-	2	6	-	-	-	9	-	-
Alliance	276	62	91	6	-	-	-	-	-	-	-	-	-	-	-	-
CCTG	-	-	8	-	-	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	253	36	97	3	-	-	-	-	-	-	-	-	-	-	-	-
NRG	414	66	208	18	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total</b>	<b>1,939</b>	<b>344</b>	<b>826</b>	<b>48</b>	<b>94</b>	<b>305</b>	<b>167</b>	<b>42</b>	<b>34</b>	<b>25</b>	<b>2</b>	<b>2</b>	<b>1</b>	<b>84</b>	<b>2</b>	<b>7</b>

# Breast Committee

## 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.

## 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.

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, and 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/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. Closed: 12/31/19.

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

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. Closed: 4/15/20.

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

S2007, "A Phase II Trial of Sacituzumab Govitecan for Patients with HER2-Negative Breast Cancer and Brain Metastases." Dr. Brenner.

S2103, "A Phase II Single-Arm Trial of Tumor Immune Lymphocyte Adapted Neoadjuvant Chemotherapy De-escalation in Triple Negative Breast

# WELCOME PATIENT ADVOCATES

We've got two new research advocates and five new community advocates. Research advocates serve on committees that produce SWOG protocols, and bring patient voices to our trials. Community advocates work across SWOG committees to deliver that patient view or to help connect trial teams to the communities, such as African Americans or military veterans, that they represent.



**Janice Choe**  
**Community Advocate**  
Asian-Pacific Islander  
Community



**Allison Rosen**  
**Community Advocate**  
Adolescent and Young  
Adult Community



**Samantha Guild**  
**Research Advocate**  
Melanoma Committee



**Robert E. Taylor**  
**Community Advocate**  
African American Community



**Howard Krongard**  
**Community Advocate**  
Older Adult Cancer  
Community



**Desirée A. H. Walker**  
**Research Advocate**  
Recruitment and Retention  
Committee

With these additions, the number of SWOG advocates rises to 29 — nearly three times the number just five years ago. This means our network features the largest, and most diverse, group of advocates in the National Clinical Trial Network. **Congratulations, team!**



**Bruce A. Wright**  
**Community Advocate**  
Military Veterans

# Cancer Control & Prevention Committee

## Committee Leadership

Vice-Chair NCORP: ..... Dawn L. Hershman, MD, MS  
Cancer Care Delivery Co-Chairs: ..... Dawn L. Hershman, MD, MS  
..... Scott D. Ramsey, MD, PhD  
Cancer Survivorship Co-Chairs: ..... Halle C.F. Moore, MD  
..... Melinda L. Irwin, PhD, MPH  
Palliative & End of Life Co-Chairs: ..... Robert S. Krouse, MD, FACS  
..... Mark A. O'Rourke, MD  
..... Marie Bakitas, DNSc, CRNP  
Prevention and Epidemiology Co-Chairs: ..... Banu Arun, MD  
..... Marian L. Neuhouser, PhD, RD  
Symptom Control & QOL Co-Chairs: ..... Michael J. Fisch, MD, MPH  
..... Norah Lynn Henry, MD, PhD  
Executive Officers: ..... Katherine D. Crew, MD (Palliative, Prevention,  
..... Survivorship)  
..... Gary H. Lyman, MD (CCD, Symptom Control & QOL)  
Senior Advisor: ..... Frank L. Meyskens, Jr, MD  
Statisticians: ..... Garnet Anderson, PhD  
..... William E. Barlow, PhD  
..... Katherine Guthrie, PhD  
..... Cathy Tangen, DrPH  
..... Joseph M. Unger, PhD  
..... Riha Vaidya, PhD  
..... Kathryn B. Arnold, MS  
..... Amy K. Darke, MS  
..... Mai Doung, MS  
..... Phyllis J. Goodman, MS  
..... Danika Lew, MA  
..... Hongli Li, MS  
..... Anna Moseley, MS  
..... Eddie Mayerson, MS  
Administrative Lead Statistics & Data Mgt Center: ..... Monica Yee, CCRP  
NCORP Representative: ..... Mark A. O'Rourke, MD  
Radiation Oncology Committee: ..... Louis "Sandy" Constine, MD  
Surgery Committee: ..... Robert S. Krouse, MD, FACS  
Translational Medicine: ..... James (Jimmy) Rae, PhD  
Liaisons:  
Barlogie-Salmon Myeloma Committee: ..... Charles S. Kuzma, MD  
Breast Committee: ..... Melinda L. Irwin, PhD, MPH (Survivorship)  
..... Helen K. Chew, MD (Symptom Control & QOL)  
..... Dawn Hershman, MD, MS (CCD)  
..... Banu Arun, MD (Prevention)  
Early Therapeutics & Rare Cancers: ..... Jason M. Prosek, MD  
Gastrointestinal Committee: ..... Jason A. Zell, DO (Prevention)  
..... Afsaneh Barzi, MD (CCD)

Genitourinary Committee: ..... Peter J. Van Veldhuizen, Jr, MD  
International Liaison: ..... Kathy S. Albain, MD  
Leukemia Committee: ..... Stephanie B. Tsai, MD  
Lung Committee: ..... Gary E. Goodman, MD  
Lymphoma Committee: ..... Hayder Saeed, MD  
Melanoma Committee: ..... Sancy Leachman, MD, PhD  
..... Thach-Giao Truong, MD (Survivorship)  
Recruitment and Retention Committee: ..... Allison M. Caban-Holt, PhD  
Digital Engagement: ..... Jennifer R. Klemp, PhD (Survivorship)  
..... Krishna Soujanya Gunturu, MD (Survivorship)  
..... Mina S. Sedrak, MD (CCD)  
..... Katherine D. Crew, MD (Prevention)  
..... Michael J. Fisch, MD (Symptom Control & QOL)  
Oncology Research Professionals  
Clinical Research Associates: ..... Amanda R. Dinsdale, MHA, CCRC  
Nurses: ..... Connie Szczepanek, RN, BSN  
..... Joyce N. Tull, RN, MSN  
..... Melyssa W. Foust, MSN, RN  
Pharmaceutical Sciences Committee: ..... Kimberly McConnell, PharmD  
..... Siu-Fun Wong, PharmD  
..... Sun "Coco" Yang, PharmD, PhD  
SDMC Data Coordinators: ..... Kimberly Carvalho  
..... Sam Dzingle  
..... Matthew Eng, PharmD  
..... Diane Liggett, CCRP  
..... Roxanne Topacio, CCRP  
..... Monica Yee, CCRP  
Recruitment and Retention Specialist: ..... Jennifer Maeser, MS  
Patient Advocates: ..... Barbara Segarra-Vazquez, DHSc (CCD)  
..... Amy Geschwender, PhD (Symptom Control & QOL)  
..... Hartley "Lee" M. Jones, MBA (Survivorship)  
..... Cheryl L. 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): ..... Sonali Tinsley  
Protocol Coordinator (Palliative Care): ..... Christy Klepetko  
Clinical Trials Project Manager (Palliative Care): .....  
..... Vanessa Benavidez, BS, CCRC  
Clinical Trials Project Manager (CCD; Prevention;  
Survivorship): ..... Sandi Hita, JD  
Clinical Trials Project Manager (Symptom Control): ..... Crystal Miwa



# Cancer Care Delivery (CCD) Committee

## Committee Leadership

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

## Agenda

Thursday, September 24, 2020  
11:15 am- 12:15 pm

## Presentations

Overview of CCDR Priorities – Dawn Hershman, MD, MS and  
Scott Ramsey, MD, PhD

## New Study Idea Updates

Examining Clinical Work Intensity Among Medical Oncologists, Matt  
Hudson, PhD, MPH, Prisma Health

Managing Oral Anti-Cancer Agents in Community Oncology Practices:  
Implementation and Impact, Karen B. Farris, PhD, Emily Mackler, PharmD,  
University of Michigan

## Up-and-Coming Studies

S1912CD, "Randomized Trial of a Proactive Financial Navigation  
Intervention for Cancer Patients and Caregivers." Veena Shankaran, MD,  
University of Washington

S2100CD, "Randomized Comparison of an Educationally Enhanced  
Genomic Tumor Board (eGTB) Intervention to Usual Practice of  
Incorporating Genomic Test Results into Clinical Care." Jens Rueter,  
MD, Maine Cancer Genomics Initiative; Meghna Trivedi, MD, Columbia  
University

## Active Studies

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.

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

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.

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

## 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, PhD

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." Drs. Vaidya and Unger

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

## Database/Grant Funded Projects

### Published

Representativeness of Black Patients in Cancer Clinical Trials Sponsored  
by the National Cancer Institute Compared With Pharmaceutical  
Companies. Unger, Hershman, Raghav. JNCI Cancer Spectrum, 2020.

Healthcare utilization and cost of care in elderly breast cancer patients  
enrolled in SWOG clinical trials. Dawn Hershman, MD

Association of the Coronavirus Disease 2019 (COVID-19) Outbreak With  
Enrollment in Cancer Clinical Trials. Unger, Blanke, Hershman. JAMA  
Network Open, 2020.

## Cancer Care Delivery (CCD) Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/10/2020. Includes studies that are currently open or that closed since 1/1/19.

	S1415CD	S1417CD	S1703	S1916	A011104	A191402C	A231602C	ACC16N1	EA1151	EAQ162CD	EAQ171CD	NHLBIMDS
Arizona CC, Univ of	-	-	-	-	-	-	-	-	47	-	-	-
Arkansas, U of	-	-	3	-	-	-	-	-	160	-	-	-
Baptist MU-NCORP	149	-	-	-	1	-	-	-	-	-	-	-
Bay Area NCORP	36	2	-	-	-	-	-	-	-	-	-	-
Beaumont NCORP	7	-	-	-	-	5	-	-	-	-	-	2
Brooke Army Med Ctr	-	-	-	-	2	-	-	-	-	-	-	-
CORA NCORP	60	18	5	-	-	-	-	-	-	-	-	-
CRC West MI NCORP	60	20	-	-	-	-	-	3	-	-	-	-
Carle CC NCORP	60	1	3	1	-	-	-	-	-	-	-	-
Cleveland Clinic OH	-	-	1	-	-	-	-	-	-	-	-	4
Colorado, U of	-	-	-	-	-	-	-	-	2	-	-	-
Columbia MU-NCORP	118	11	6	-	-	1	-	-	-	-	-	3
Columbus NCORP	26	26	2	-	-	-	-	-	-	-	-	-
Cotton O'Neil CC	-	-	1	-	-	-	-	-	-	-	-	-
Dayton NCORP	32	4	2	-	-	-	-	-	-	2	-	-
Essentia Hlth NCORP	96	-	-	-	-	-	-	-	2	-	-	-
Fred Hutchinson CRC	-	-	-	-	-	-	-	-	-	-	-	10
GACARES MU-NCORP	56	-	-	-	-	-	-	-	-	-	-	-
Georgia NCORP	64	9	-	-	-	-	-	17	-	-	-	-
Greenville NCORP	61	20	4	-	-	-	-	-	16	-	-	1
Gulf South MU-NCORP	102	12	2	-	-	-	-	-	-	4	-	-
H Lee Moffitt CC	-	-	-	-	-	-	-	-	-	-	-	8
Hawaii MU-NCORP	73	9	3	-	-	-	-	-	-	10	-	5
Heartland NCORP	328	37	6	1	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	-	-	-	-	-	95	-	-	-
Irvine, U of CA	-	-	-	-	-	-	-	-	-	-	-	2
Kaiser Perm NCORP	-	41	1	-	-	13	-	34	-	11	-	4
Kansas City NCORP	6	1	-	-	-	-	-	-	-	-	-	2

## Cancer Care Delivery (CCD) Committee

Association of Patient Demographic Characteristics and Insurance Status  
 With Survival in Cancer Randomized Clinical Trials With Positive Findings.  
 Unger, Hershman. JAMA Network Open, 2020.

### Ongoing

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

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

## Cancer Care Delivery (CCD) Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/10/2020. Includes studies that are currently open or that closed since 1/1/19.

	S1415CD	S1417CD	S1703	S1916	A011104	A191402C	A231602C	ACC116N1	E41151	EAQ162CD	EAQ171CD	NHLBIMDS
Kansas MU-NCORP	-	-	-	-	-	-	4	-	-	-	-	-
Lahey Hosp & Med Ctr	-	-	4	-	-	-	-	-	-	-	-	-
MAVERIC	-	-	-	-	-	-	-	-	-	-	-	10
MUSC MU-NCORP	-	-	-	-	-	-	-	-	-	-	-	1
Memorial Hermann	-	-	-	-	-	-	-	-	8	-	-	-
Michigan CRC NCORP	276	13	2	-	-	-	-	-	-	-	-	-
Montana NCORP	126	1	2	-	-	-	-	-	-	-	-	-
Nevada CRF NCORP	-	1	-	-	-	-	-	-	-	1	-	-
New Mexico MU-NCORP	250	6	-	-	-	-	-	-	-	-	-	-
Northwest NCORP	104	3	-	-	-	-	-	-	-	-	-	-
Oregon Hlth Sci Univ	-	-	-	-	-	-	-	-	-	-	-	3
Ozarks NCORP	114	3	-	-	-	-	-	-	-	-	-	-
PCRC NCORP	186	8	4	-	-	-	-	-	-	4	-	-
Providence Hosp	-	-	-	-	13	-	-	-	-	-	-	1
Rochester, Univ of	-	-	4	-	-	-	-	-	198	-	-	-
San Diego, U of CA	-	-	-	-	-	-	-	-	-	-	-	10
Southeast COR NCORP	120	16	-	-	2	-	-	-	389	11	-	-
Upstate NCORP	-	-	-	-	-	-	-	-	227	1	-	-
VAMC Kansas City	-	-	-	-	-	-	-	-	-	-	-	4
Wayne State Univ	-	-	-	-	1	-	-	-	-	-	-	-
Western States NCORP	-	-	-	-	-	-	-	-	30	-	1	-
Wichita NCORP	60	8	-	-	-	-	-	-	-	-	-	-
Wisconsin NCORP	163	2	1	-	-	-	-	-	-	-	-	-
Yale University	-	-	9	-	4	-	-	-	-	-	-	7
Alliance	360	23	2	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	394	65	8	-	-	-	-	-	-	-	-	-
NRG	178	20	6	-	-	-	-	-	-	-	-	-
<b>Total</b>	<b>3,665</b>	<b>380</b>	<b>81</b>	<b>2</b>	<b>23</b>	<b>19</b>	<b>4</b>	<b>54</b>	<b>1,174</b>	<b>44</b>	<b>1</b>	<b>77</b>

# We've got a great following

@SWOG has over 9,000 Twitter followers. Help us get to 10,000!  
 Tweet the virtual meeting with the hashtag #SWOGonc and tag your @SWOG friends.



## And keep talking on Twitter!

It's a critical place for SWOG, and the entire cancer research community, to come together during the COVID-19 pandemic to share information and inspiration.

# #StayConnected

# Cancer Survivorship Committee

## Leadership

Co-Chairs: ..... Halle C.F. Moore, MD  
 ..... Melinda L. Irwin, PhD, MPH  
 Statistician: ..... Katherine Guthrie, PhD  
 Executive Officer: ..... Katherine Crew, MD, MS  
 Patient Advocate: ..... Lee Jones

## Agenda

Friday, September 25, 2020  
 10:00 am- 12:00 pm

- Welcome and Introduction: Melinda Irwin and Halle Moore
- Survivorship Presentation: Cancer Health Disparities, Tiffany Wallace, PhD, Program Director, Center to Reduce Cancer Health Disparities, National Cancer Institute
- Discussion of Concepts Related to Health Disparities
- Patient Advocate Update
- Other Liaison Updates
- Cardiac Advisory Panel Update
- Update on Sarcopenia Analysis Working Group

## Active Study

**S1501**, "Prospective Evaluation of Carvedilol in Prevention of Cardiac Toxicity in Patients with Metastatic HER-2+ Breast Cancer." Drs. Floyd and Leja. Activated: 9/15/17.

## Study and Concepts in Development

- "Tele-psychiatry for Women with Breast Cancer and Major Depression." Drs. Markowitz, Hellerstein and Levenson.
- "Loss of muscle and fat mass induced by inflammation, disease progression and treatment toxicity in S0816." Dr. Baracos.
- "Modeling thrombosis risk in patients treated with modern myeloma therapy." Dr. Chakraborty.
- "Impact of Immune Checkpoint Inhibition on Gonadal Reserve: A Longitudinal Analysis of Biospecimens from S1404." Dr. Tsai.
- "Secondary analysis of S1404, immunotherapy toxicity." Dr. Gunturu.
- "GnRH agonists for ovarian function protection during chemotherapy treatment of non-breast AYA malignancies." Dr. Moore.

## Cancer Survivorship Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/10/2020.  
 Includes studies that are currently open or that closed since 1/1/19.

	S1501	A221405	E1011	EA9131
Baptist MU-NCORP	3	-	-	-
Bay Area NCORP	2	-	-	-
CORA NCORP	1	-	-	-
City of Hope Med Ctr	35	-	-	-
Cleveland Clinic OH	10	-	-	-
Colorado, U of	-	12	-	-
Columbia MU-NCORP	2	-	-	-
Davis, U of CA	2	-	-	-
Fred Hutchinson CRC	3	2	-	-
Georgia NCORP	7	-	-	-
Greenville NCORP	2	-	-	-
Gulf South MU-NCORP	3	-	-	-
H Lee Moffitt CC	9	-	-	-
Hawaii MU-NCORP	-	-	21	-
Heartland NCORP	14	-	-	-
Kaiser Perm NCORP	-	-	-	42
Kansas MU-NCORP	5	-	-	-
King Faisal Spec Hos	3	-	-	-
Lahey Hosp & Med Ctr	6	-	-	-
Loyola University	8	-	-	-
MUSC MU-NCORP	1	-	-	-
Michigan, U of	6	-	-	-
Montana NCORP	1	-	-	-
New Mexico MU-NCORP	-	-	1	-
Northwestern Univ	-	1	-	-
Oregon Hlth Sci Univ	1	-	-	-
Ozarks NCORP	6	-	-	-
Providence Hosp	1	-	-	-
So Calif, U of	1	-	-	-
Southeast COR NCORP	-	-	1	-
Wayne State Univ	5	-	-	-
Yale University	-	5	-	-
Alliance	17	-	-	-
ECOG-ACRIN	28	-	-	-
NRG	15	-	-	-
<b>Total</b>	<b>197</b>	<b>20</b>	<b>23</b>	<b>42</b>

# Palliative and End of Life Care Committee

## Committee Leadership

Co-Chairs: ..... Robert S. Krouse, MD  
 ..... Mark A. O'Rourke, MD  
 ..... Marie A. Bakitas, DNSc, NP-C, FAAN  
 Executive Officer: ..... Katherine Crew, MD, MS  
 Statisticians: ..... Katherine Guthrie, PhD  
 ..... Garnet Anderson, PhD  
 ..... Kathryn B. Arnold MS  
 ..... Danika Lew, MA  
 Designates  
 Senior Advisor: ..... Frank Meyskens, MD  
 NCORP Representative: ..... Bernard Parker, MD  
 ..... Kate Castro, MS, RN  
 Pharmaceutical Sciences Committee: ..... Kimberly McConnel, PharmD  
 ..... Sun "Coco" Yang, PharmD, PhD  
 ..... Siu-Fun Wong, PharmD, FASHP, FCSHP  
 Data Coordinators: ..... Roxanne Topacio  
 ..... Monica Yee  
 Oncology Research Professionals:  
 CRA: ..... Amanda R. Dinsdale, MHA, CCRC  
 Nurse: ..... Joan Long, RN, OCN  
 ..... Connie Szczepanek, RN, BSN  
 ..... Joyce N. Tull, RN, MSN  
 Patient Advocates: ..... Lee Jones  
 ..... Carol Seigel  
 ..... Valerie Fraser  
 ..... Michelle Denault  
 Protocol Coordinator: ..... Christy Klepetko  
 Clinical Trial Project Manager: ..... Vanessa Benavidez, BS, CCRC, ACRP-PM

## Agenda

Thursday, September 24, 2020  
 2:45 pm- 4:45 pm

2:45 - 2:50 pm: Welcome and Introductions – Co-Chairs  
 2:50 - 2:55 pm: Committee Liaison Updates (Patient Advocates/  
 Nursing)  
 2:55 - 3:10 pm: Committee Member Discussion Syndemic of COVID 19  
 and social Injustice - Impact at an Institutional/Personal  
 level - Marie A. Bakitas, DNSc, NP-C, FAAN  
 3:10 - 3:35 pm: Plenary: "Assessing the Older Adult with Cancer:  
 Predicting Treatment Tolerability and Outcomes" by  
 Grant Williams, MD  
 3:35 - 4:05 pm: Proposed Concepts Discussion  
 4:05 - 4:20 pm: Active Study Updates  
 4:20 - 4:30 pm: Secondary Analysis  
 4:30 - 4:40 pm: New Business  
 4:40 - 4:45 pm: Closing Comments and Adjourn

# Palliative and End of Life Care Committee

## Active Studies

S1820, "A Randomized Phase II Trial of the Altering Intake, Managing Symptoms Intervention for Bowel Dysfunction in Rectal Cancer Survivors (AIMS-RC)." Dr. Sun. Activated: 12/9/19.

"Hopefulness for Providers and Patients, Survey." Drs. Corn and Feldman. Activated: July 2019.

## Developing Studies

S2016, "Randomized Phase III Trial of a Primary Palliative Care Intervention in Pancreatic Cancer." Drs. Chung and Sun.

SXXXX, "Depression screening and treatment in patients requesting Medical Aid in Dying (MAID)." Drs. Salman and Blanke.

## Secondary Analysis

"Fatigue secondary analyses." Julia Mo.

"Quality of Life and Survival/Toxicity in Cancer Treatment Trials." Dr. Hui.

## Proposed Concepts:

"Palliative & geriatric assessment plus PRO package to be made available for treatment trials for advanced cancer." Dr. Agarwal

"Online Hope Workshops for Patients/Caregivers/Providers." Drs. Feldman and Corn.

"Symptom Management of Treatment-Related Toxicities from Oral Targeted Agents in Metastatic Renal Cell Carcinoma Patients." Drs. Reding and C. Fung.

"Whole Cannabis Plant extract RCT PhI/II Proposal." Drs. Krouse and Rodriguez.

"Feasibility of oncology providers completing an on-line communication curriculum and measuring provider confidence following course completion" Drs. Subbiah, Feldman, Hudson and Corn.

"Study of an on-line illness communication and advance care planning curriculum for oncology providers." Drs. O'Rourke and Corn.

## Closed Studies

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

## Palliative and End of Life Care Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/10/2020.

Includes studies that are currently open or that closed since 1/1/19.

	S1316	S1820
Arizona CC, Univ of	11	-
Arkansas, U of	6	-
Baylor College	1	-
City of Hope Med Ctr	5	1
Columbia MU-NCORP	1	-
Essentia Hlth NCORP	1	-
Greenville NCORP	-	3
H Lee Moffitt CC	3	-
INC, Bogota	1	-
INCan	8	-
INEN	7	-
Irvine, U of CA	-	2
Kansas MU-NCORP	18	-
Loma Linda Univ	1	-
MD Anderson CC	2	-
MUSC MU-NCORP	5	-
Michigan CRC NCORP	-	1
Michigan, U of	8	-
New Mexico MU-NCORP	1	-
Oklahoma, Univ of	2	-
San Antonio, U of TX	7	-
Tennessee, U of	42	-
Alliance	27	-
ECOG-ACRIN	2	-
NRG	62	2
<b>Total</b>	<b>221</b>	<b>9</b>

SWOG Provider Hope and Burnout Survey with manuscript in preparation

# Prevention & Epidemiology Committee

## Committee Leadership

Co-Chairs: ..... Banu Arun, MD  
..... Marian L. Neuhouser, PhD, RD

## Agenda

Thursday, September 24, 2020 | 12:30 pm- 2:30 pm

## Introduction

Welcome and Opening Comments Marian Neuhouser and Banu Arun

## Cancer Prevention Presentation

### 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.

**S1823**, "A Prospective Observational Cohort Study to Assess miRNA 371 for Outcome Prediction in Patients with Newly Diagnosed Germ Cell Tumors". Drs. Nichols and Nappi. Activated: 6/1/20.

**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. Activated: 9/1/20.

**NHLBI-MDS**, "The National Myelodysplastic Syndromes Natural History Study." Drs. Hill and Arana Yi, Study Champions. Activated: 4/5/16.

### Pending CTEP Approval

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

### Concept to be submitted to Cancer Prevention Steering Committee:

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

### Concept pending R01 funding

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

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

## Melanoma Update

Melanoma Chemoprevention. Sancy Leachman, MD

## New Business/Open Discussion

## Prevention & Epidemiology Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/10/2020.  
Includes studies that are currently open or that closed since 1/1/19.

	S0820	A211102	A211401	A211601
Baptist MU-NCORP	5	-	-	-
Bay Area NCORP	1	-	-	-
Baylor Univ Med Ctr	-	-	2	-
Brooke Army Med Ctr	3	-	-	-
CORA NCORP	4	-	-	-
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	26	-	-	-
Kaiser Perm NCORP	34	-	-	-
Kansas MU-NCORP	3	-	-	-
Loma Linda Univ	2	-	-	-
Loyola University	2	-	-	-
MAVERIC	3	-	2	-
MD Anderson CC	12	-	-	-
Michigan CRC NCORP	7	-	-	-
Mississippi, Univ of	1	-	4	-
Nevada CRF NCORP	1	-	-	-
New Mexico MU-NCORP	1	-	-	-
Northwest NCORP	10	-	-	-
Oklahoma, Univ of	1	-	-	-
PCRC NCORP	2	-	-	-
Providence Hosp	1	-	-	2
Rochester, Univ of	-	-	2	-
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	16	-	-	-
Alliance	29	-	-	-
ECOG-ACRIN	20	-	-	-
NRG	31	-	-	-
<b>Total</b>	<b>278</b>	<b>3</b>	<b>10</b>	<b>2</b>

# Symptom Control & Quality of Life Committee

## Leadership

Co-Chairs: ..... Michael J. Fisch, MD, MPH  
..... Norah Lynn Henry, MD, PhD

## Agenda

Friday, September 25, 2020 | 3:30 pm- 4:30 pm

**3:35 - 4:05 pm:** Keynote – Claire Snyder, PhD, PROTEUS (Patient-Reported Outcomes Tools: Engaging Users & Stakeholders)

**4:05 - 4:15 pm:** S1614 updates : Jessica Hwang, MD

**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.

## Additional Active Trials

**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.

**S2013**, “Immune Checkpoint Inhibitor Toxicity (I-CHECKIT): A Prospective Observational Study.” Drs. Gunturu, Hershman, and Kuderer.

## Other Concepts in Development

**S2014**, “mHealth Mindfulness to Improve Quality of Life in Castration-Resistant Metastatic Prostate Cancer Patients and their Partners.” Drs. Kubo and Greyz.

**S2010**, “Improving Endocrine Therapy-Emergent Symptoms in Young Women with Breast Cancer using Active Symptom Monitoring.” Dr. Henry

**4:15 - 4:20 pm:** Advocate updates – Amy Geschwender, PhD

**4:20 - 4:30 pm:** Other Discussion Topics (10 minutes)

## New Committee Members

- Javier Retamales MD : Chilean Cooperative Group for Oncologic Research, accepted to the upcoming SWOG YITC
- Evan Hall MD, MPhil : University of Washington
- Stephanie Smith, MSN, RN, OCN : St. Joseph's/Candler Health System
- Michelle Loch, MD: Louisiana State University Health Sciences Center in New Orleans

## 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.

**S1600**, “Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes.” Drs. Hamilton-Reeves and Holzbeierlein. Activated: 2/21/19. Temporarily Closed.

**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. Temporarily Closed.

## 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^3 Breast Cancer Study Evaluating Everolimus with Endocrine Therapy.” Dr. Chavez-MacGregor. Activated: 9/3/13.

**S1418**, “A Randomized Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with  $\geq 1$  cm Residual Invasive Cancer or Positive Lymph Nodes (ypN+) After Neoadjuvant Chemotherapy.” Drs. Pusztai 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. Jagasi.

**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.



# Symptom Control & Quality of Life Committee

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.

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.

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.

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.

# Symptom Control & Quality of Life Committee

## Symptom Control & Quality of Life Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/10/2020. Includes studies that are currently open or that closed since 1/1/19.

	S1600	S1614	S1714	A171601	A221101	A221504	A221505	A221602	A221702
Arkansas, U of	-	-	30	-	1	-	-	-	-
CORA NCORP	-	-	29	-	-	-	-	-	-
CRC West MI NCORP	-	-	73	-	-	-	-	-	-
Carle CC NCORP	-	-	3	-	-	-	-	-	-
Cleveland Clinic OH	-	-	-	-	-	-	2	-	-
Colorado, U of	2	-	-	-	-	-	14	-	-
Columbia MU-NCORP	-	-	18	-	-	-	-	-	-
Cotton O'Neil CC	-	-	-	-	2	-	-	-	-
Davis, U of CA	-	-	-	1	-	-	-	-	-
Dayton NCORP	-	-	-	-	-	1	-	-	-
Georgia NCORP	-	-	4	-	-	-	-	-	-
Greenville NCORP	-	-	4	-	-	-	-	-	-
Gulf South MU-NCORP	-	-	2	-	-	-	1	-	-
Hawaii MU-NCORP	-	-	34	-	-	-	-	-	-
Heartland NCORP	-	-	9	-	-	-	-	-	-
Irvine, U of CA	-	-	-	-	8	-	1	3	-
Kaiser Perm NCORP	-	1	-	-	-	-	-	-	-
Kansas MU-NCORP	11	-	3	-	-	-	-	-	-
Kentucky, U of	-	-	-	-	1	-	-	5	-
Lahey Hosp & Med Ctr	-	-	8	-	-	-	-	-	-
Loma Linda Univ	-	-	-	-	2	-	-	-	-
Loyola University	-	-	2	-	-	1	-	-	-
Northwest NCORP	-	-	-	-	1	-	-	-	-
Ozarks NCORP	-	-	3	-	-	-	-	-	-
PCRC NCORP	-	-	2	-	-	-	-	-	-
Providence Hosp	-	-	-	-	3	-	-	-	-
Rochester, Univ of	-	-	-	-	-	1	-	-	14
San Antonio, U of TX	-	-	1	-	1	-	-	-	-
So Calif, U of	-	-	-	-	-	1	-	-	-
Southeast COR NCORP	-	-	59	-	-	-	-	-	-
Sutter Cancer RC	-	-	-	-	1	-	-	-	-
Upstate NCORP	-	-	41	-	1	-	1	-	-
Utah, U of	-	-	-	-	-	-	-	5	-
VAMC Kansas City	-	-	-	-	-	2	-	-	-
Wayne State Univ	-	-	-	1	-	-	-	-	1
Wichita NCORP	-	-	1	-	-	-	-	-	-
Alliance	1	-	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	1	-	-	-	-	-	-
NRG	1	1	12	-	-	-	-	-	-
<b>Total</b>	<b>15</b>	<b>2</b>	<b>339</b>	<b>2</b>	<b>21</b>	<b>6</b>	<b>19</b>	<b>13</b>	<b>15</b>

# Early Therapeutics & Rare Cancers Committee

## Committee Leadership

Chair: ..... Razelle Kurzrock, MD  
Vice-Chair: ..... Young Kwang Chae, MD, MPH  
Executive Officer: ..... Christopher W. Ryan, MD  
Statisticians: ..... Megan Othus, PhD  
..... Melissa Plets, MS  
..... Edward Mayerson, MS

## Designates

Data Coordinators: ..... Christine McLeod  
..... Sewan Gurung  
Digital Engagement: ..... Kanwal Raghav, MD, MBBS  
Oncology Research Professionals:  
CRAs: ..... Corrine Turrell, CCRP  
Nurse: ..... TBD  
Pharmaceutical Science: ..... Craig Elg, PharmD  
..... Sun "Coco" Yang, PharmD, PhD  
Patient Advocate: ..... Marcia K. Horn, JD  
Protocol Coordinator: ..... Christy Klepetko  
Clinical Trials Project Manager: ..... Vanessa Benavidez, BS, CCRC

## Early Therapeutics Liaisons

Breast Committee Liaison: ..... George Somlo, MD  
Cancer Control Liaison: ..... Jason M. Prosek, MD  
Genitourinary Committee Liaison: ..... Neeraj Agarwal, MD  
Imaging: ..... TBD  
Lung Committee Liaison: ..... Shirish M. Gadgeel, MD  
Lymphoma Committee Liaison: ..... Daruka Mahadevan, MD, PhD  
Melanoma Committee Liaison: ..... Jeffrey A. Sosman, MD  
Myeloma Committee Liaison: ..... Frits van Rhee, MD, PhD

## Agenda

Thursday, September 24, 2020  
11:15 am- 2:15 pm

## Introduction

**11:15 – 11:20 am** Razelle Kurzrock, MD, Director, Center for Personalized Cancer Therapy, UCSD Moores Comprehensive Cancer Center, San Diego, CA; Chair, Early Therapeutics and Rare Cancer Committee (SWOG)

## Presentations

**11:20 – 12:00 pm** "Novel Therapeutics in Development" Monica Mita, MD, Associate Professor, Department of Medicine; Co-Director, Experimental Therapeutics Program, Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center.

**12:00 – 12:25 pm** "Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare

Tumors (DART)." Sandip Patel MD, Associate Professor, Deputy Director, San Diego Center for Precision Immunotherapy, UC San Diego Moores Comprehensive Cancer Center, San Diego, CA.

**12:25 – 12:50 pm** "DART Translational Initiative." Young Kwang Chae, MD, Associate Professor, Co-Director, Early Therapeutics, Northwestern University, Robert H. Lurie Comprehensive Cancer Center.

**12:50 – 1:10 pm** "iMATCH Update" Siwen Hu-Lieskovan, MD, PhD, Assistant Professor, Division of Oncology Director, Solid Tumor Immunotherapy Huntsman Cancer Institute, University of Utah

**1:10 – 1:30 pm** "Biomarker Stratified CaboZantinib and Nivolumab (BiCaZO) - A phase II study of combining cabozantinib and nivolumab in patients with advanced melanoma and head and neck cancer, Paul Swiecicki, MD, University of Michigan, Assistant Professor, Division of Hematology/Oncology Head and Neck Oncology Program.

**1:30 – 1:55 pm** "Role of Immunotherapy in Anaplastic Thyroid Cancer" Young Kwang Chae, MD, Northwestern University, Robert H. Lurie Comprehensive Cancer Center, Associate Professor Co-Director, Early Therapeutics, Vice Chair, Early Therapeutics and Rare Cancers (SWOG)

**1:55 – 2:15 pm** Wrap Up and Open Discussion. Razelle Kurzrock, MD, 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. Patel, Chae, Giles, and Kurzrock. Activated: 1/13/17.

**NCI COVID Study**, "NCI COVID-19 in Cancer Patients Study (N-CCaPS): A Longitudinal Natural History Study." Nagla Abdel Karim, MD.

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

**CTSU/EAY131**, "Molecular Analysis for Therapy Choice (MATCH)." Dr. 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. Dizon. Activated by ECOG-ACRIN: 2/14/18; Activated by SWOG: 3/1/19. Closed to accrual: 1/9/20.

# Early Therapeutics & Rare Cancers Committee

**EA3163**, "Phase II Randomized Trial of Neo-Adjuvant Chemotherapy

Followed by Surgery and Post-Operative Radiation Versus Surgery and Post-Operative Radiation for Organ Preservation of T3 and T4a Nasal and Paranasal Sinus Squamous Cell Carcinoma (NPNSCC)" January 17, 2019: Dr. Swiecicki is champion. Activated: 2/21/20.

**A071601**, "Phase II Trial of BRAF/MEK Inhibitors in Papillary Craniopharyngiomas." Dr. Ahluwalia. Activated: 2/9/18.

**NRG-GY009**: "A Randomized, phase ii/iii study of pegylated liposomal doxorubicin and CTEP-Supplied atezolizumab versus pegylated liposomal doxorubicin/bevacizumab and CTEP-SUPPLIED atezolizumab versus pegylated liposomal doxorubicin/bevacizumab in platinum resistant ovarian cancer." Dr. Robinson. Activated: 2/2/18; Temporarily closed to accrual: 5/9/19.

**NRG GY006**, "A Randomized Phase II Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, or Stage II-IVA Vaginal Cancer." Dr. Robinson. Activated: 2/16/18.

**NRG-GY016**, "A Phase II Study of MK-3475 (Pembrolizumab) + epacadostat in Recurrent Clear Cell Carincoma of the Ovary." Dr. Robinson. Activated: 11/8/18; Temporarily Closed to Accrual: 4/10/19.

## Proposed Study

**S2012**, "Randomized Phase 2/3 Trial of First Line Platinum/Etoposide With or Without Atezolizumab in Patients with Poorly Differentiated Extrapulmonary Small Cell Neuroendocrine Carcinomas (NEC)" Dr. Zhen.

**SXXXX**, "A Phase I/II Study of Nivolumab and Low-dose Ipilimumab in Combination with Recombinant Interleukin-12 in Patients with Advanced or Metastatic Solid Tumors." Drs. Mahdi and Tarhini.

## Early Therapeutics & Rare Cancers Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/10/2020. Includes studies that are currently open or that closed since 1/1/19.

	S1609	ARST1321	EAY131		S1609	ARST1321	EAY131
Arizona CC, Univ of	7	-	8	MD Anderson CC	19	-	-
Arkansas, U of	4	-	3	MUSC MU-NCORP	4	-	1
Baptist MU-NCORP	2	-	-	Michigan CRC NCORP	16	-	-
Baylor College	-	-	3	Michigan, U of	32	-	23
CORA NCORP	8	-	1	Mississippi, Univ of	5	-	-
Carle CC NCORP	3	-	-	Montana NCORP	11	-	-
Cedars-Sinai Med Ctr	7	-	6	Nevada CRF NCORP	17	-	-
City of Hope Med Ctr	2	-	6	New Mexico MU-NCORP	15	-	-
Cleveland Clinic OH	4	-	8	Northwest NCORP	2	-	-
Colorado, U of	6	-	9	Northwestern Univ	14	1	-
Columbus NCORP	3	-	-	Oklahoma, Univ of	1	-	-
Davis, U of CA	11	-	8	Oregon Hlth Sci Univ	9	4	-
Dayton NCORP	2	-	1	Ozarks NCORP	1	-	-
Essentia Hlth NCORP	4	-	-	PCRC NCORP	11	-	-
Fred Hutchinson CRC	8	-	2	Providence Hosp	1	-	3
Georgia NCORP	4	-	-	Rochester, Univ of	5	-	-
Gulf South MU-NCORP	2	-	-	San Antonio, U of TX	6	3	6
H Lee Moffitt CC	22	-	-	San Diego, U of CA	25	-	-
Hawaii MU-NCORP	3	-	1	So Calif, U of	4	-	-
Heartland NCORP	15	-	1	Southeast COR NCORP	4	-	8
Henry Ford Hospital	17	-	11	Sutter Cancer RC	2	-	4
Houston Methodist	-	-	1	Tulane University	-	-	1
Irvine, U of CA	8	-	18	Utah, U of	3	-	-
Kaiser Perm NCORP	26	-	6	Wayne State Univ	-	-	3
Kansas City NCORP	-	-	1	Western States NCORP	1	-	-
Kansas MU-NCORP	33	1	5	Wisconsin NCORP	12	-	-
Kentucky, U of	-	-	13	Yale University	7	-	12
Loma Linda Univ	6	-	1	Alliance	97	-	-
Loyola University	4	-	-	ECOG-ACRIN	75	-	-
MAVERIC	5	-	-	NRG	124	-	-
				<b>Total</b>	<b>739</b>	<b>9</b>	<b>174</b>

# Gastrointestinal Committee

## Committee Leadership

Chair: ..... Philip A. Philip, MD, PhD  
Vice-Chair: ..... Cathy Eng, MD  
Executive Officer: ..... Christopher W. Ryan, MD  
Statisticians: ..... Katherine A. Guthrie, PhD  
..... Mai Duong, MS

## Scientific Leadership

Phase I Studies: ..... Sandip P. Patel, MD  
Gastroesophageal: ..... Syma Iqbal, MD  
..... Zev A. Wainberg, MD  
Pancreatic: ..... Elena Gabriela Chiorean, MD  
..... Andrew M. Lowy, MD (Surgical representative)  
Hepatobiliary: ..... Anthony B. El-Khoueiry, MD  
..... Rachna T. Shroff, MD  
..... Syed Ahmad, MD (Surgical representative)  
Colon: ..... Philip J. Gold, MD  
..... Wells A. Messersmith, MD  
Neuroendocrine Tumors: ..... Nageshwara Arvind Dasari, MD  
..... Jonathan R. Strosberg, MD  
Ano-Rectal: ..... Lisa A. Kachnic, MD  
..... Hagen F. Kennecke, MD  
Translational Medicine: ..... Heinz-Josef Lenz, MD  
..... Christopher H. Lieu, MD  
..... Daniel Catenacci, MD  
Imaging: ..... Anthony F. Shields, MD, PhD  
Pathology: ..... Mary Kay Washington, MD, PhD  
Radiation Oncology: ..... Lisa A. Kachnic, MD

## Designates

Cancer Control Liaisons: ..... Jason A. Zell, DO (Prevention)  
..... Afsaneh Barzi, MD (CCD)  
Community Liaisons: ..... Gary L. Buchsacher, MD, PhD  
..... (Medical Oncology)  
..... Mohamed E. Salem, MD (Medical Oncology)  
..... Jeremiah Lee Deneve, DO (Surgical)  
..... Flavio Rocha, MD (Surgical)  
Digital Engagement: ..... Heloisa Soares, MD, PhD  
Data Coordinators: ..... Christine Magner  
..... Jacqueline Scurlock  
..... Brian Zeller  
..... Sewan Gurung  
Oncology Research Professionals:  
CRA: ..... Sandy Annis, CCRP  
Nurse: ..... TBD  
Patient Advocate (Pancreatic): ..... Carole Seigel, MBA

Patient Advocate (Colon): ..... Florence Kurttila, MS  
Pharmaceutical Science: ..... Jane E. Rogers, PharmD  
..... Jason M. Reed, PharmD  
Protocol Coordinator: ..... Danae Campos, MBA  
Clinical Trials Project Manager: ..... Vanessa Benavidez, BS, CCRC

## Agenda

Thursday, September 24, 2020  
1:30 pm- 3:30 pm

- I. Introduction. Philip A. Philip, MD & Cathy Eng, MD
- II. SWOG Clinical Trials Management Initiative: Cathy Eng, MD
- III. Patient Advocate Update: Carole Seigel, MBA & Florence Kurttila, MS
- IV. Updates from the Subcommittee:
  - a. Gastroesophageal: Syma Iqbal, MD & Zev A. Wainberg, MD
  - b. Hepatobiliary
  - c. Pancreatic
  - d. Colon
  - e. Anorectal
  - f. Neuroendocrine
- V. Concluding remarks/Adjourn

## Gastroesophageal

### Proposed Studies

**S2009**, "Phase II/III Randomized Study of Pembrolizumab with or without Cabozantinib for Third Line Treatment of Patients with Advanced PD-L1+ Gastric and Gastroesophageal (GE) Junction Adenocarcinomas". Dr. Saeed.

### 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**, "Randomized Phase II Clinical Trials of Olaparib + Pembrolizumab vs. Olaparib Alone as Maintenance Therapy in Metastatic Pancreatic Cancer Patients with Germline BRCA1 or BRCA2 Mutations". Dr. Chung.

## Gastrointestinal Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/10/2020. Includes studies that are currently open or that closed since 1/1/19.

	S1613	S1815	S1922	A021501	A021502	A021602	A021703	EA2142	EA2161	EA2165	NRGG1004	NRGG1005
Arizona CC, Univ of	-	7	-	-	1	-	-	-	-	-	-	-
Arkansas, U of	-	1	-	-	-	-	-	-	-	5	-	-
Baylor College	-	2	-	-	-	-	-	-	-	-	-	-
Beaumont NCORP	-	-	-	-	1	-	-	-	-	-	-	-
Boston Medical Ctr	-	-	-	-	1	1	-	-	-	1	-	-
CORA NCORP	-	3	-	-	-	-	-	-	-	-	-	-
CRC West MI NCORP	-	2	-	-	-	-	-	-	-	-	-	-
Cincinnati MC, U of	-	1	-	2	-	-	2	-	-	2	-	-
City of Hope Med Ctr	-	4	-	-	-	1	-	-	-	-	-	-
Cleveland Clinic OH	-	-	-	-	2	-	-	-	-	-	-	-
Colorado, U of	1	-	-	-	2	-	-	-	-	-	-	-
Columbus NCORP	-	3	-	-	-	-	-	-	-	-	-	-
Davis, U of CA	1	4	-	-	4	-	-	-	-	4	-	1
Dayton NCORP	-	2	-	-	2	-	-	-	-	-	-	-
Fred Hutchinson CRC	-	-	-	-	-	-	-	-	-	3	-	-
Greenville NCORP	-	9	-	-	-	-	-	-	-	-	-	-
Gulf South MU-NCORP	-	3	-	-	-	-	-	-	-	-	-	-
H Lee Moffitt CC	-	-	-	-	-	4	-	-	-	-	-	-
Hawaii MU-NCORP	-	7	-	-	-	-	-	-	-	-	-	-
Heartland NCORP	1	5	-	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	2	-	-	-	-	-	-	-	-	-	-
Houston Methodist	-	-	-	-	-	-	-	-	-	-	1	-
Irvine, U of CA	-	-	-	3	-	-	-	-	-	-	-	-
Kaiser Perm NCORP	-	-	-	1	8	-	-	2	-	3	-	-
Kansas MU-NCORP	3	-	-	-	1	-	1	-	-	-	-	-
Kentucky, U of	-	-	-	1	-	-	-	-	-	-	-	-
Lahey Hosp & Med Ctr	1	-	-	-	-	-	-	-	-	-	-	-
Loyola University	1	-	-	-	-	-	-	-	-	-	-	-
MD Anderson CC	11	12	1	-	-	-	-	-	-	-	12	-
Michigan, U of	1	3	-	6	-	-	-	3	1	-	-	-
Montana NCORP	-	3	-	-	-	-	-	-	-	-	-	-
New Mexico MU-NCORP	-	5	-	-	-	-	-	-	-	-	-	-
Northwestern Univ	-	10	-	-	-	-	1	-	-	-	-	-
Oregon Hlth Sci Univ	-	3	-	-	-	-	-	-	-	2	-	-
Ozarks NCORP	-	3	-	-	-	-	-	-	-	-	-	-
PCRC NCORP	3	6	-	-	-	-	-	-	-	-	-	-
Rochester, Univ of	-	3	-	1	2	2	-	-	-	-	1	-
San Antonio, U of TX	-	1	-	-	-	-	-	-	-	-	-	-
So Calif, U of	1	6	-	-	-	-	-	-	-	-	-	-
Southeast COR NCORP	1	-	-	-	-	-	-	-	-	-	-	-
Sutter Cancer RC	-	-	-	1	3	-	-	-	-	-	-	-
Utah, U of	-	3	-	-	-	-	-	-	-	-	-	-
Virginia Mason MC	-	-	-	-	1	-	-	-	-	-	-	-
Wayne State Univ	-	2	-	1	-	-	-	-	-	3	-	-
Wichita NCORP	-	1	-	-	-	-	-	-	-	-	-	-
Yale University	-	8	-	-	-	-	-	-	-	-	-	-
Alliance	4	72	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	3	55	-	-	-	-	-	-	-	-	-	-
NRG	1	25	-	-	-	-	-	-	-	-	-	-
<b>Total</b>	<b>33</b>	<b>276</b>	<b>1</b>	<b>16</b>	<b>28</b>	<b>8</b>	<b>4</b>	<b>5</b>	<b>1</b>	<b>23</b>	<b>14</b>	<b>1</b>

# Gastrointestinal Committee

## 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: 6/1/18.

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: 5/31/19.

## Neuroendocrine

### Proposed Studies

S2104, "A Phase II Randomized Trial of Postoperative Adjuvant Capecitabine and Temozolomide versus Observation in High-Risk Pancreatic Neuroendocrine Tumors." Dr. Soares.

### Active Studies

EA2142, "Randomized Phase II Study of Platinum and Etoposide Versus Temozolomide and Capecitabine in Patients with Advanced G3 Non-Small Cell Gastroenteropancreatic Neuroendocrine Carcinomas". Activated: 11/6/15.

### Closed Studies

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. 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.

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" Dr. Overman. Activated: 11/7/17.

### Closed Studies

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

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. Closed: 4/15/20.

## Rectal

### Active Studies

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



# Gastrointestinal Committee

Activated: 10/12/16.

## 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

## Proposed Studies

EA2176, "Immune checkpoint inhibition with chemotherapy in treatment-naïve metastatic anal cancer patients."

## Active Studies

EA2165, "A Randomized Phase II Study of Nivolumab After Combined Modality Therapy (CMT) in High Risk Anal Cancer." NCTN Activated: 4/13/18.

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

## 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.

## Other

## Active Studies

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

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.

S1316, "Prospective Comparative Effectiveness Trial For Malignant Bowel Obstruction." Dr. Krouse. Activated: 3/9/15; Closed: 6/6/19.



Save the date for the  
Spring 2021 meeting  
April 21-24

# Genitourinary Committee

## Committee Leadership

Chair: ..... Ian M. Thompson, Jr, MD  
Vice-Chair: ..... Nicholas J. Vogelzang, MD  
Executive Officer: ..... Christopher W. Ryan, MD  
Statisticians: ..... Cathy M. Tangen, DrPH  
..... Melissa Plets, MS  
..... Eddie Mayerson, MS

## Scientific Leadership

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

## Designates

Cancer Control: ..... Peter J. Van Veldhuizen, Jr, MD  
Digital Engagement: ..... Neema Navai, MD  
Data Coordinators: ..... Sean O'Bryan  
..... Joseph Sanchez  
..... Tonya Johnson  
Oncology Research Professionals:  
CRAs: ..... Abigail L. Cornette, MS  
..... Cheryl Farlow, RN, OCN  
Nurses: ..... Deborah A. Shaw, RN  
..... Cheryl Kefauver, RN  
Patient Advocates: ..... Rick Bangs, MBA (Bladder)  
..... Tony Crispino (Prostate)  
..... Margaret "Peggy" Zuckerman, MEd (Renal)  
Pharmaceutical Science: ..... Joyce Lee, PharmD  
..... Jason M. Reed, PharmD, RPh  
Protocol Coordinator: ..... Veronica Garcia, MS  
Clinical Trials Project Manager: ..... Sandi Hita, JD

## Agenda

Friday, September 25, 2020  
12:30 pm- 4:30 pm

- 12:30 – 12:35 pm:** Welcome (Dr. Thompson)  
**12:35 – 1:35 pm:** Bladder Organ Site (Dr. Lerner and Dr. Petrylak)  
**1:35 – 2:35 pm:** Renal Organ Site (Dr. Vaishampayan and Dr. Shuch)  
**2:35 – 3:35 pm:** Prostate Organ Site (Lin and Quinn)  
**3:35 – 4:35 pm:** Translational Medicine (McConkey et al)

Introductions and Announcements - Dr. Ian M. Thompson, Jr

## 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: 4/19/19

## Planned Activation

**S1937**, "A Phase III Randomized Trial of Eribulin (NSC #707389) With or Without Gemcitabine Versus Standard of Care (Physician's Choice) For Treatment of Metastatic Urothelial Carcinoma Refractory To, Or Ineligible For, Anti PD1/PDL1 Therapy. Planned Activation: October 2020.

## Active Studies

**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: 2/7/17.

**CTS/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." Drs. A. Gupta and Dr. S. Gupta. Activated: 8/1/18.

**CTS/A031803**, "Phase II Trial of Intravesical Gemcitabine and MK-3475

# Genitourinary Committee

(Pembrolizumab) in the Treatment of Patients with BCG-Unresponsive Non-Muscle Invasive Bladder Cancer." Dr. Woods. Activated: 1/6/20.

## 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: 8/1/11. Closed: 4/15/17.

S1314, "A Randomized Phase II Study of CO-eXpression Extrapolation (COXEN) Directed Neoadjuvant Chemotherapy for Localized, Muscle-Invasive Bladder Cancer." Dr. Flaig, Dr. Alva, Dr. Daneshmand, et al. Activated: 7/9/14. Closed 12/1/17.

S1605, "Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer." Dr. Black and Dr. Singh. Activated: 2/7/17. Closed: 7/5/19.

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. Godoy and Dr. Alva. Activated 4/10/15. Closed 1/5/18.

## Renal

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

## Planned Activation

S1931, "Phase III Trial of Immunotherapy-Based Drug Combinations With OR Without Cytoreductive Nephrectomy for Metastatic Renal Cell Carcinoma (Probe Trial)." Study Chairs: Drs. H. L. Kim, U.N. Vaishampayan. Planned Activation: October 2020.

## Active Studies

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 (trRCC) Across All Age Groups." Dr. Parikh. Activated: 10/9/18

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: 9/21/17.

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: 2/2/17.

CTSU/A031704, "PD-Inhibitor (Nivolumab) and Ipilimumab Followed by Nivolumab Vs. VEGF TKI Cabozantinib with Nivolumab: A Phase III Trial in Metastatic Untreated Renal Cell Cancer [PDIGREE]." Dr. Zhang. Activated: 5/9/19.

CTSU/A031801, "A Phase II Randomized Trial of Radium-223 Dichloride and Cabozantinib in Patients with Advanced Renal Cell Carcinoma with Bone Metastasis (RadiCal)." Dr. McKay. Activated: 12/13/20.

## Closed 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: 4/5/16. Closed: 12/15/19.

S0931, "EVEREST: Everolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study." Dr. Ryan, Dr. Heath, Dr. Lara, et al. Activated: 4/1/11. Closed: 9/15/16.

CTSU/E2810, "Randomized, Double-Blind Phase III Study of Pazopanib vs. Placebo in Patients with Metastatic Renal Cell Carcinoma Who Have No Evidence of Disease Following Metastatectomy." Dr. Pal. Activated 8/8/12. Closed 7/25/17.

## 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: 9/17/18

## 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

# Genitourinary Committee

Followed by High-Dose Carboplatin and Etoposide (TI-CE) as First Salvage Treatment in Re-lapsed or Refractory Germ Cell Tumors." Dr. Quinn. Activated: 7/1/15.

CTSU/EA8153, "Cabazitaxel with Abiraterone Versus Abiraterone Alone Randomized Trial for Extensive Disease Following Docetaxel: The CHARTED2 Trial." Dr. Corn. Activated: 2/8/18.

CTSU/EA8171, "Multiparametric MRI (mpMRI) for Preoperative Staging and Treatment Planning for New-ly-Diagnosed Prostate Cancer." Dr. Liss. Activated: 7/9/18.

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.

CTSU/NRG-GU007, "Randomized Phase II Trial of Niraparib with Standard Combination Radiotherapy and Androgen Deprivation Therapy (ADT) in High Risk Prostate Cancer (with Initial Phase I)." Dr. Michaelson. Activated: 6/3/19.

CTSU/NRG -GU008, "Randomized Phase III Trial Incorporating Abiraterone Acetate with Prednisone and Apalutamide and Advanced Imaging Into Salvage Treatment for Patients with Node-Positive Prostate Cancer After Radical Prostatectomy." Dr. Chen. Activated: 3/5/20.

## Closed Studies

S1216, "A Phase III Randomized Trial Comparing Androgen Deprivation Therapy + TAK-700 with Andro-gen Deprivation Therapy + Bicalutamide in Patients with Newly Diagnosed Metastatic Hormone Sensitive Prostate Cancer." Dr. Agarwal, Dr. Goldkorn, Dr. Gupta, et al. Activated: 3/1/13. Closed: 7/15/17.

CTSU/NRG-GU006, "A Phase II, Double-Blinded, Placebo-Controlled Randomized Trial of Salvage Radio-therapy with or Without Enhanced Anti-Androgen Therapy with Apalutamide in Recurrent Prostate Cancer." Dr. Zeng. Activated: 4/27/18. Closed: 5/19/20.

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: 7/7/11. Closed: 6/24/19.

## 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

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: 2/21/19.

## 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: 1/13/17.

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

## Closed Studies

S1316, "Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction." Dr. Krouse, Dr. Denevee, and Dr. Sun. Activated: 3/9/15. Closed: 5/15/20.

# Genitourinary Committee

## Cumulative Accrual by Institution and Study

Includes accrual through 7/10/2020. Includes studies that are currently open or that closed since 1/1/19.

	S1500	S1602	S1605	S1802	S1806	A031102	A031501	A031701	A031702	A031704	A031803	EA8134	EA8143	EA8153	EA8171	NRGGU002	NRGGU005	NRGGU006	R0924
Arizona CC, Univ of	-	-	-	3	-	-	-	-	-	-	-	-	6	-	-	-	-	-	-
Arkansas, U of	1	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Baylor College	-	20	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Beaumont NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2
CORA NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1
CRC West MI NCORP	1	-	-	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Cedars-Sinai Med Ctr	1	5	-	-	1	-	-	-	-	-	-	-	7	-	-	-	-	-	-
Cincinnati MC, U of	-	-	-	2	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
City of Hope Med Ctr	21	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Cleveland Clinic OH	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-	4
Colorado, U of	-	19	5	2	2	-	10	-	-	1	-	-	1	-	-	1	1	-	-
Columbia MU-NCORP	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Columbus NCORP	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Cotton O'Neil CC	1	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	6
Davis, U of CA	3	-	1	4	4	-	2	3	-	-	-	-	1	-	-	-	-	-	-
Dayton NCORP	-	1	1	2	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Desert Hospital	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	8
Essentia Hlth NCORP	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson CRC	-	15	-	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Greenville NCORP	1	1	1	5	-	-	-	-	-	1	-	-	1	-	-	-	-	-	-
Gulf South MU-NCORP	1	82	3	37	24	-	1	-	-	-	2	-	6	-	5	-	-	-	-
H Lee Moffitt CC	-	19	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Hawaii MU-NCORP	-	6	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Heartland NCORP	4	4	6	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	3	-	4	-	-	1	-	1	2	-	-	1	-	-	-	-	-	-
Houston Methodist	-	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Irvine, U of CA	-	11	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Kaiser Perm NCORP	-	12	-	1	-	-	12	-	-	12	-	-	24	6	-	-	-	-	-
Kansas MU-NCORP	-	15	8	7	2	-	4	-	1	2	-	-	2	-	-	-	-	-	-
Kentucky, U of	-	-	3	-	-	-	-	-	-	-	-	-	12	-	-	-	-	-	-
Lahey Hosp & Med Ctr	-	-	-	-	-	-	3	-	3	-	-	-	2	-	-	-	-	-	-
Los Angeles, U of CA	-	-	-	-	-	-	-	-	-	-	-	-	4	-	-	-	-	-	-
Loyola University	1	11	2	-	-	-	-	-	1	1	-	-	2	-	-	-	-	-	-

## Genitourinary Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/10/2020. Includes studies that are currently open or that closed since 1/1/19.

	S1500	S1602	S1605	S1802	S1806	A031102	A031501	A031701	A031702	A031704	A031803	EA8134	EA8143	EA8153	EA8171	NRGGU002	NRGGU005	NRGGU006	R0924
MD Anderson CC	-	31	-	35	-	-	-	-	-	-	-	-	-	6	-	-	-	-	-
MUSC MU-NCORP	1	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2
Michigan CRC NCORP	1	2	-	1	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Michigan, U of	5	29	-	2	-	-	13	-	-	-	-	-	-	-	-	-	-	-	-
Mississippi, Univ of	1	-	-	1	-	-	-	-	1	-	-	-	3	2	-	1	-	-	-
Montana NCORP	1	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Nevada CRF NCORP	4	2	1	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-
New Mexico MU-NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Northwestern Univ	-	31	1	-	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Ohio State Univ	-	2	-	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Oklahoma, Univ of	2	43	5	17	9	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Oregon Hlth Sci Univ	3	7	3	-	-	-	-	-	1	-	-	-	6	-	-	-	-	-	-
Ozarks NCORP	2	4	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
PCRC NCORP	2	18	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Rochester, Univ of	-	12	1	5	-	-	-	-	2	-	-	-	-	-	-	-	-	-	26
San Antonio, U of TX	-	48	5	-	-	-	-	-	-	-	1	-	9	-	18	-	-	3	-
San Diego, U of CA	-	-	5	-	-	-	-	-	-	-	-	-	2	-	-	-	-	-	-
So Calif, U of	3	32	-	1	-	6	10	-	-	-	-	6	-	-	-	-	-	-	-
Southeast COR NCORP	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Sutter Cancer RC	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2
Tulane University	-	-	-	-	-	-	-	-	-	-	-	-	4	-	-	-	-	-	-
Upstate NCORP	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Utah, U of	3	45	9	6	-	-	3	-	-	-	-	-	2	8	-	-	-	-	-
VAMC Kansas City	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	42
Virginia Mason MC	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Wayne State Univ	5	-	-	1	-	-	-	-	-	-	-	-	2	-	-	1	-	-	-
Wichita NCORP	1	-	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Wisconsin NCORP	1	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Yale University	-	3	3	-	-	-	5	-	-	-	-	-	1	2	-	-	-	-	-
Alliance	27	83	41	35	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CCTG	25	-	9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	18	75	27	10	10	-	-	-	-	-	-	-	-	-	-	-	-	-	-
NRG	11	65	20	21	10	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total</b>	<b>152</b>	<b>761</b>	<b>172</b>	<b>215</b>	<b>75</b>	<b>6</b>	<b>67</b>	<b>5</b>	<b>10</b>	<b>20</b>	<b>3</b>	<b>6</b>	<b>102</b>	<b>24</b>	<b>23</b>	<b>3</b>	<b>2</b>	<b>4</b>	<b>93</b>

# Leukemia Committee

## Committee Leadership

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

## Scientific Leadership

Translational Medicine: ..... Jerald P. Radich, MD  
Pathology: ..... David R. Head, MD  
Cytogenetics Liaison: ..... Min Fang, MD, PhD

## Designates

Cancer Control: ..... Stephanie B. Tsai, MD  
Data Coordinators: ..... Louise Highleyman  
..... Tracy Maher, CCRP  
..... Laura Kingsbury  
Oncology Research Professionals:  
CRA: ..... TBD  
Nurse: ..... TBD  
Patient Advocate: ..... Gail Sperling, MPH  
Pharmaceutical Science: ..... Holly O. Chan, PharmD  
..... Ila M. Saunders, PharmD  
Protocol Coordinator: ..... TBD  
Clinical Trials Project Manager: ..... Sandi Hita, JD

## Agenda

Friday, September 25, 2020  
12:30 pm- 2:30 pm

## AML/MDS Studies

## Active Studies

CTSU/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. Activated: 1/16/19.

## Closed 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, et al. Activated: 12/22/17; Temporary closed: 10/22/18; Permanently Closed: 9/1/20.

## ALL Studies

## Active Studies

S1905, "A Phase I/II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL) / T-Cell Lymphoblastic Lymphoma (T-LBL)." Drs. Advani, Papadantonakis, and Yeung. Activated: 8/17/20.

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. Activated: 1/12/15; Permanent closure of Cohort 1: 9/15/17.

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. Activated: 6/1/17.

# 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. Activated: 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. Activated: 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 / Small Lymphocytic Lymphoma (CLL): EVOLVE CLL Study." Dr. Stephens, Hill, Pagel, Danilov, Shadman, and Fisch.

## 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. Activated: 7/20/18.

Welcome to Chile and Uruguay, our latest international members.

We now have official member sites in the U.S., Canada and seven other countries.





## Leukemia Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/10/2020. Includes studies that are currently open or that closed since 1/1/19.

	S1312	S1318	S1712	A041501	A041701	A041702	E1910	E2906	EA9161	EA9171
Arizona CC, Univ of	-	-	-	-	-	1	4	7	3	-
Arkansas, U of	-	1	-	-	3	-	3	-	-	-
Baylor College	7	-	-	-	-	-	-	-	-	-
Birmingham, U of AL	-	1	-	-	-	-	10	-	5	-
CRC West MI NCORP	-	-	-	-	-	-	-	4	-	-
Cincinnati MC, U of	-	-	-	-	-	-	-	3	-	-
City of Hope Med Ctr	18	4	-	-	-	-	-	-	-	-
Cleveland Clinic OH	11	6	-	3	-	2	11	-	-	-
Columbia MU-NCORP	-	-	-	-	-	-	-	3	-	-
Dayton NCORP	-	-	-	-	-	1	1	5	1	-
Duke Univ Med Ctr	-	-	2	-	-	-	-	-	8	-
Fred Hutchinson CRC	-	-	-	-	-	-	-	-	5	-
Greenville NCORP	-	1	1	-	-	-	1	-	1	-
H Lee Moffitt CC	-	-	7	-	-	-	-	-	-	-
Hawaii MU-NCORP	-	-	1	-	-	-	-	-	-	-
Heartland NCORP	-	1	4	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	-	2	1	4	-	-	-
Irvine, U of CA	-	3	-	1	-	-	10	-	-	-
Kaiser Perm NCORP	-	-	-	-	-	3	-	-	23	-
Kansas City NCORP	-	-	-	-	-	-	1	-	-	-
Kansas MU-NCORP	-	-	-	-	-	2	10	-	3	-
Kentucky, U of	-	-	-	-	-	-	-	7	-	-
Loma Linda Univ	-	1	-	-	-	-	-	-	-	-
Loyola University	-	-	1	-	-	1	2	9	1	-
Michigan, U of	-	2	-	-	-	-	-	-	-	-
Mississippi, Univ of	-	-	-	-	-	-	-	1	-	-
Montana NCORP	-	-	1	-	-	-	-	-	-	-
Nevada CRF NCORP	-	-	-	-	-	-	-	-	2	-
New Mexico MU-NCORP	-	1	2	-	-	-	-	1	-	-
Northwestern Univ	-	-	-	-	-	-	1	-	-	-
Oregon Hlth Sci Univ	-	-	1	3	-	3	-	-	6	-
Ozarks NCORP	-	-	1	-	-	-	-	-	-	-
Rochester, Univ of	12	3	2	3	8	1	10	27	1	-
Salem Hospital	-	-	-	-	-	-	-	-	4	-
San Diego, U of CA	-	1	-	-	-	-	3	-	-	-
So Calif, U of	-	3	-	-	-	-	-	-	-	-
Southeast COR NCORP	-	-	-	-	-	-	-	-	2	-
Stanford University	2	-	-	1	-	7	12	-	18	-
Upstate NCORP	-	-	-	-	-	-	-	3	-	-
Utah, U of	-	-	1	-	-	1	-	-	14	-
Virginia Mason MC	-	-	-	-	-	1	-	-	1	-
Wayne State Univ	-	-	-	-	-	-	6	-	1	-
Western States NCORP	-	-	-	1	-	1	10	-	-	-
Wichita NCORP	-	1	-	-	-	-	-	-	-	-
Yale University	-	1	-	1	-	1	20	5	7	1
Alliance	-	17	3	-	-	-	-	-	-	-
ECOG-ACRIN	-	6	1	-	-	-	-	-	-	-
NRG	-	2	2	-	-	-	-	-	-	-
<b>Total</b>	<b>50</b>	<b>55</b>	<b>30</b>	<b>13</b>	<b>13</b>	<b>26</b>	<b>119</b>	<b>75</b>	<b>106</b>	<b>1</b>

# Lung Committee

## Committee Leadership

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

## Scientific Leadership

Translational Medicine:  
Biology/Pathology ..... Philip C. Mack, PhD  
..... Fred R. Hirsch, MD, PhD  
..... Ignacio I. Wistuba MD  
Imaging: ..... Chadwick L. Wright MD, PhD  
..... Myrna C. Godoy, MD, PhD  
Radiation Oncology: ..... Roy H. Decker, MD, PhD  
Surgery: ..... Wayne L. Hofstetter, MD  
Subcommittee Chairs:  
Early Stage Disease: ..... Wayne L. Hofstetter, MD  
..... Raymond Osarogiagbon, MD  
Locally Advanced Disease: ..... Roy H. Decker, MD, PhD  
..... Shirish Gadgeel, MD (Early Therapeutics)  
Metastatic Disease: ..... Ross Camidge, MD  
..... Karen Reckamp, MD  
Community Engagement: ..... Paul J. Hesketh, MD  
..... Suzanne Cole, MD  
..... Alex R. Menter, MD

## Designates

Cancer Control Liaison: ..... Gary E. Goodman, MD  
Data Coordinators: ..... Leah Everhart  
..... Joni Harris  
..... Louise Highleyman  
..... Larry Kaye  
Clinical Research Project Manager: ..... Arthur Lee, MS  
Oncology Research Professionals:  
CRAs: ..... Courtney L. Williamson  
..... Ginny M. Keeling, MS  
Nurses: ..... Kimberly M. Belzer, MS, PAC  
..... Rosalie Zablocki, RN  
Patient Advocate: ..... Judy Johnson, MBA

Pharmaceutical Science: ..... Joyce Lee, PharmD  
..... Kimberly McConnell, PharmD  
Protocol Coordinators: ..... Gretchen Goetz, MBA  
..... Mariah Norman, MS (Lung-MAP)  
..... Laura Gildner, MS (Lung-MAP)  
..... Catrina De Los Santos-Mireles (Lung-MAP)  
Clinical Trials Project Manager: ..... Crystal Miwa

## Agenda

Friday, September 25, 2020  
10:00 am- 2:00 pm

**10:00-10:10 a.m.** General Update

**10:10-10:30 a.m.** Scientific Presentation: "Tackling Lung Cancer and COVID-19: Thoughts from the chair of the COVID-Lung Cancer Coalition" – Fred R. Hirsch, MD, PhD, Professor of Medicine, Icahn School of Medicine

**10:30-10:45 a.m.** Community Engagement Core: Paul J. Hesketh, MD

**10:45-11:00 a.m.** Thoracic Surgery Session: Wayne Hofstetter, MD

**11:00-11:30 a.m.** Thoracic Radiation Session: Roy H. Decker, MD, PhD

**11:30-11:45 a.m.** Translational Medicine Session: Phil Mack, PhD

**11:45-12:00 p.m.** Break

**12:00-12:15 p.m.** "A Lung Cancer Patient's Manifesto for Modernizing Clinical Trials" – Janet Freeman-Daily, Patient Research Advocate and Co-founder of the ROS1ders

**12:15-2:00 p.m.** Thoracic Medical Oncology Session: Karen Kelly, MD

**12:45-1:05 p.m.** Scientific Presentation: "Emerging Concepts for the Management of KRAS mutated NSCLC" – Shirish M. Gadgeel, MD, Chief, Division of Hematology and Oncology, Department of Internal Medicine, Henry Ford Cancer Institute/Henry Ford Hospital

## 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. Herbst, Gandara, et al. Activated: 1/28/19.

## Lung Committee

**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. Activated: 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. Activated: 1/28/19. Temporary Closure: Cohort 1 on 7/16/20; Cohort 2 on 4/6/20.

**S1900B**, "A Phase II Study of Selpercatinib (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. Activated: 2/10/20.

**S1900C**, "A Phase II Study of Talazoparib Plus Avelumab in Patients with Stage IV or Recurrent Non-Squamous Non-Small Cell Lung Cancer Bearing Pathogenic STK11 Genomic Alterations (Lung-MAP Sub-Study)." Drs. Skoulidis and Suga. Activated: 1/16/20.

**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. Activated: 8/9/18.

**S1827**, "MRI Brain Surveillance Alone Versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer (MAVERICK)." Drs. Rusthoven, Brown, Wefel, et al. Activated: 1/10/20.

**S1914**, "A Randomized Phase III trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT versus SBRT Alone in High Risk, Early Stage NSCLC." Drs. Daly, Simone, Kelly, et al. Activated: 3/25/20.

**S1929**, "Phase II Randomized 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, Reckamp, Byers, et al. Activated: 6/15/20.

**S1933**, "A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status." Drs. Aljumaily, Mitin, Wozniak, et al. Activated: 6/15/20.

**CTSU/EA5163/S1709**, "INSIGNA: A Randomized, Phase III Study of Firstline Immunotherapy alone or in Combination with Chemotherapy in Induction/Maintenance or Post-progression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature-driven Analysis." Dr. Chiang. Activated: 2/28/19.

**CTSU/A081105**, "Randomized Study of Erlotinib Vs Observation in Patients With Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC)." Dr. Kelly. Activated: 8/18/14; Temporary closure: 6/15/20; Reactivation: 7/15/20.

**CTSU/A081801**, "Integration of Immunotherapy into Adjuvant Therapy for Resected NSCLC: ALCHEMIST Chemo-IO." Dr. Gray. Activated: 6/3/20.

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

## Get the Scoop!

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# Lung Committee

**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. Activated: 8/18/14.

**CTSU/EA5181**, "Randomized Phase III Trial of MEDI4736 (Durvalumab) as Concurrent and Consolidative Therapy or Consolidative Therapy Alone for Unresectable Stage 3 NSCLC." Dr. Harkenrider. Activated: 4/9/20.

**CTSU/NRG-CC003**, "Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer." Dr. Gaspar. Activated: 12/7/15; Temporary closure: 5/28/20; Reactivation: 7/27/20.

**CTSU/NRG-LU002**, "Maintenance Systemic Therapy versus Consolidative Stereotactic Body Radiation Therapy (SBRT) Plus Maintenance Systemic Therapy for Limited Metastatic Non-Small Cell Lung Cancer (NSCLC): A Randomized Phase II/III Trial." Dr. Gomez. Activated: 4/7/17.

**CTSU/NRG-LU003**, "A Biomarker-Driven Protocol for Previously Treated ALK-Positive Non-Squamous NSCLC Patients: The NCI-NRG ALK Protocol." Dr. Doebele. Activated: 4/1/19.

**CTSU/NRG-LU005**, "Limited Stage Small Cell Lung Cancer (LS-SCLC): A Phase II/III Randomized Study of Chemoradiation Versus Chemoradiation Plus Atezolizumab." Dr. Hsu. Activated: 5/28/19.

## Closed Studies

**S1400F**, "A Phase II Study of MEDI4736 plus Tremelimumab as Therapy for Patients with Previously Treated Anti-PD-1/PD-L1 Resistant Stage IV Squamous Patients (Lung-MAP Sub-Study)." Drs. Leighl and Rizvi. Activated: 10/2/17; Cohort 1 Closure: 11/6/19; Cohort 2 Closure: 3/24/20.

**S1619**, "A Feasibility Trial of Neoadjuvant Cisplatin-Pemetrexed with Atezolizumab in Combination and in Maintenance for Resectable Malignant Pleural Mesothelioma." Drs. Tsao, Sepesi, Gomez, et al. Activated: 11/3/17; Closure: 5/1/20.

## NCI-Approved Concepts

**S1900D**, "A Randomized Phase II Study of TAK228 (MLN0128; Sapanisertib) 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.

**S1900E**, "A Phase II Study of AMG 510 in Participants with Previously Treated Stage IV or Recurrent KRAS G12C Mutated Non-Squamous Non-Small Cell Lung Cancer (ECOG-ACRIN Lung-MAP Sub-Study)." Drs. Padda and Gerber.

## Concepts in Development

**S1800D**, "IL-15 N-803 (Lung-MAP Non-Match Sub-Study)." Drs. Wrangle and Husain.

**S1900F**, "Osimertinib + Necitumumab in EGFR MT C797"X" After Progression on Osimertinib (Lung-MAP Sub-Study)." Dr. Riess.

**S1934**, "NASSIST (Neoadjuvant Chemoradiation +/- Immunotherapy before Surgery for Superior Sulcus Tumors): A Randomized Phase II Trial of Trimodality +/- Atezolizumab in Resectable Superior Sulcus Non-Small Cell Lung Cancer." Dr. Osarogiagbon.

**S2102**, "A Phase II Study to Evaluate Pembrolizumab with Single-Agent Chemotherapy or Platinum-Based Combination Chemotherapy in PS2 Patients with Stage IV or Recurrent NSCLC with Tumor PDL1 < 50%." Dr. Gadgeel.

## Lung Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/10/2020. Includes studies that are currently open or that closed since 1/1/19.

	LUNGMAP	S1400	S1400F	S1619	S1701	S1800A	S1827	S1900A	S1900B	S1900C	A061105	A151216	C30610	E4512	EA5142	EA5163	NRGCC003	NRGLU002	NRGLU005
Arizona CC, Univ of	-	1	-	-	-	-	-	-	-	-	-	5	-	2	-	-	-	-	-
Arkansas, U of	6	5	-	-	-	2	-	-	-	-	-	2	2	-	1	-	-	-	-
Baptist MU-NCORP	24	16	-	-	-	-	-	3	-	-	-	19	3	-	-	-	-	-	-
Baylor College	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Beaumont NCORP	-	2	-	-	-	-	-	-	-	-	-	2	-	-	1	-	-	-	-
Boston Medical Ctr	-	5	-	-	-	-	-	-	-	-	-	3	-	-	-	-	-	-	-
Brooke Army Med Ctr	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CORA NCORP	33	15	-	-	-	3	-	1	-	-	-	2	-	-	-	-	-	-	-
CRC West MI NCORP	3	11	-	-	-	1	-	1	-	-	-	1	-	-	-	-	-	-	-
CROWN NCORP	5	-	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-	-
Carle CC NCORP	2	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Cincinnati MC, U of	-	6	-	-	-	-	-	-	-	-	1	22	3	1	3	-	-	-	-
City of Hope Med Ctr	3	16	-	2	1	-	-	-	-	-	1	4	-	-	2	-	-	-	-
Cleveland Clinic OH	2	10	-	-	-	-	-	-	-	1	5	42	-	-	11	3	-	-	-
Colorado, U of	10	3	1	-	-	1	-	-	-	-	9	49	-	2	4	-	-	-	-
Columbia MU-NCORP	3	2	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Columbus NCORP	19	15	-	-	-	-	-	4	-	-	-	-	1	-	-	-	-	-	-
Cotton O'Neil CC	-	1	-	-	-	1	-	-	-	-	-	3	1	-	2	-	-	-	-
Davis, U of CA	15	21	-	-	3	1	-	3	-	-	4	40	13	1	3	3	-	-	-
Dayton NCORP	3	6	-	-	-	-	-	-	-	-	-	7	-	-	2	-	-	-	-
Essentia Hlth NCORP	11	9	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Fred Hutchinson CRC	4	20	-	2	-	-	-	-	-	-	1	15	-	-	1	-	-	-	-
Georgia NCORP	34	33	6	-	-	3	-	2	-	-	-	1	1	-	-	-	-	-	-
Greenville NCORP	5	16	-	-	-	1	-	-	-	-	-	1	-	-	-	-	-	-	-
Gulf South MU-NCORP	6	6	-	-	-	-	-	-	-	-	-	-	-	-	-	3	-	-	-
H Lee Moffitt CC	3	10	-	-	-	-	-	-	-	-	3	83	-	1	12	-	-	-	-
Harrington CC	4	9	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hawaii MU-NCORP	11	7	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Heartland NCORP	74	61	6	-	-	8	-	6	-	-	-	-	7	-	-	-	-	-	-
Henry Ford Hospital	7	9	-	-	-	-	-	2	-	-	2	25	-	-	4	-	-	-	-
Houston Methodist	-	5	-	-	-	-	-	-	-	-	2	6	-	-	1	-	-	-	-
Irvine, U of CA	11	9	2	-	-	-	-	-	-	-	2	10	-	-	3	-	-	-	-
Kaiser Perm NCORP	25	53	-	-	-	2	-	-	-	1	18	178	3	3	21	-	-	-	-
Kansas City NCORP	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Kansas MU-NCORP	39	43	-	-	-	4	-	4	-	1	1	24	-	-	6	1	-	-	-
Kentucky, U of	23	8	2	-	-	2	1	-	-	2	1	5	-	-	1	-	-	-	-
Lahey Hosp & Med Ctr	13	13	-	-	-	3	-	-	-	-	-	27	-	-	4	1	-	-	-
Loma Linda Univ	2	7	-	-	-	-	-	-	-	-	2	7	-	-	1	-	-	-	-
Loyola University	7	12	-	-	-	-	-	-	-	-	-	18	-	-	5	-	-	-	-

## Lung Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/10/2020. Includes studies that are currently open or that closed since 1/1/19.

	LUNGMAP	S1400	S1400F	S1619	S1701	S1800A	S1827	S1900A	S1900B	S1900C	A081105	A151216	C30610	E4512	E45142	E45163	NRGCC003	NRGLU002	NRGLU005
MAVERIC	16	19	2	-	-	2	-	1	-	-	1	12	-	-	3	1	-	-	-
MD Anderson CC	3	24	1	15	2	-	-	-	-	-	-	2	-	1	-	-	-	-	-
MUSC MU-NCORP	-	1	-	5	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Michigan CRC NCORP	49	38	1	-	-	7	-	3	-	2	-	-	-	-	-	-	-	-	-
Michigan, U of	-	13	1	-	-	-	-	-	-	-	1	61	1	-	1	-	-	-	-
Mississippi, Univ of	1	6	-	-	-	1	-	-	-	-	2	26	1	-	4	-	-	-	-
Montana NCORP	22	15	-	-	-	5	-	2	-	-	-	-	-	-	-	-	-	-	-
Mt Sinai Med Ctr	-	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Nevada CRF NCORP	6	5	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
New Mexico MU-NCORP	32	14	3	-	-	-	-	2	-	-	-	-	-	-	-	-	-	-	-
Northwest NCORP	-	6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Northwestern Univ	18	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Oklahoma, Univ of	23	10	1	-	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-
Oregon Hlth Sci Univ	-	9	1	-	-	-	-	-	-	-	1	8	-	-	1	-	-	-	-
Ozarks NCORP	20	16	-	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-
PCRC NCORP	10	18	-	-	-	-	-	-	-	-	-	4	-	-	-	-	-	-	-
Providence Hosp	10	15	1	-	-	-	-	-	-	-	-	13	2	1	3	-	-	-	-
Rochester, Univ of	28	22	1	-	-	2	-	3	-	-	-	-	-	-	-	1	4	-	1
Salem Hospital	3	6	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
San Antonio, U of TX	-	18	-	-	-	-	-	-	-	-	-	8	3	-	-	1	-	-	-
San Diego, U of CA	7	16	1	-	-	-	-	-	-	-	1	5	-	-	-	-	-	-	-
So Calif, U of	-	-	-	-	-	-	-	-	-	-	1	11	-	-	-	-	-	-	-
Southeast COR NCORP	38	75	6	-	-	9	1	2	-	-	-	-	-	-	-	-	-	-	-
Sutter Cancer RC	9	4	-	-	-	2	-	-	-	-	1	7	-	-	4	-	-	-	-
Tulane Univ MBCCOP	-	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Univ of Louisville	-	-	-	-	-	-	-	-	-	-	-	5	-	-	-	-	-	-	-
Upstate NCORP	14	2	-	-	-	3	-	-	-	1	-	-	-	-	-	-	-	-	-
Utah, U of	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
VAMC Kansas City	-	9	1	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Wayne State Univ	1	15	1	-	-	-	-	-	-	-	-	1	1	-	-	-	-	1	-
Western States NCORP	1	-	-	-	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-
Wichita NCORP	1	24	1	-	-	-	-	-	-	-	-	-	13	-	-	-	-	-	-
Wisconsin NCORP	24	9	-	-	-	1	-	2	-	-	-	-	-	-	-	-	-	-	-
Yale University	7	27	1	-	-	2	-	1	-	2	3	46	-	3	17	5	-	-	-
Alliance	311	399	12	1	1	23	3	9	-	3	-	-	-	-	-	-	-	-	-
CCTG	-	18	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	163	326	6	3	-	12	-	5	-	1	-	-	-	-	-	-	-	-	-
NRG	145	203	8	1	-	12	-	5	2	1	-	-	-	-	-	-	-	-	-
<b>Total</b>	<b>1,369</b>	<b>1,864</b>	<b>67</b>	<b>29</b>	<b>7</b>	<b>117</b>	<b>5</b>	<b>64</b>	<b>2</b>	<b>17</b>	<b>64</b>	<b>813</b>	<b>57</b>	<b>15</b>	<b>121</b>	<b>19</b>	<b>4</b>	<b>1</b>	<b>1</b>

# Lymphoma Committee

## Committee Leadership

Chair: .....Jonathan W. Friedberg, MD  
Vice-Chair: .....Sonali M. Smith, MD  
Executive Officer: .....Susan M. O'Brien, MD  
Statisticians: .....Michael LeBlanc, PhD  
..... Hongli Li, MS

## Scientific Leadership

Translational Medicine: ..... Alexey Danilov, MD, PhD  
Radiation Oncology: .....Louis S. Constine, MD  
Imaging: .....Lawrence H. Schwartz, MD  
Pathology: .....Joo Y. Song, MD  
Early Therapeutics: ..... Daruka Mahadevan, MD, PhD

## Designates

Cancer Control: .....Hayder Saeed, MD  
Digital Engagement: .....Mazyar Shadman, MD  
Data Coordinators: ..... Iris Syquia  
..... Gabi Herbert  
Oncology Research Professionals:  
CRA: ..... Erin M. Cebula, MPH  
Nurse: ..... Molly Beth Adamek, BSN, RN  
Patient Advocate: .....Hildy Dillon, MPH  
Pharmaceutical Science: ..... Holly O. Chan, PharmD  
.....Ali McBride, PharmD  
Protocol Coordinator: ..... Cara Laubach, MIIM  
Clinical Trials Project Manager: .....Vanessa Benavidez, BS, CCRC

## Agenda

Thursday, September 24, 2020

1:15 pm- 3:45 pm

**1:15 pm** Welcome: Drs. Jonathan Friedberg and Sonali Smith

**1:20-2:40 pm** Mini-Symposium: "Older patients with DLBCL"

Elizabeth Brém, MD, HS Assistant Clinical Professor, UC Irvine Health:  
"Landscape of Geriatric Lymphoma."

Leandro Cerchietti, MD, Associate Professor, Weill Cornell  
Medicine: "Epigenetic landscape of elderly DLBCL."

Melissa Loh, MBBCh, James P. Wilmot Cancer Institute: "Geriatric  
assessment in heme malignancies: focus on lymphoma and the FIL."

Questions and Discussion

Elizabeth Brém, MD, HS Assistant Clinical Professor, UC Irvine Health:  
"S1918: The first randomized trial in elderly lymphoma patients through  
the US Intergroup."

**2:40-3:15 pm** Recent and Upcoming Activations

S1925 (CLL): Dr. Stephens

S1905 (T-ALL): Dr. Advani; Presented by: Dr. Stephens

EA4181: Dr. Spurgeon

**3:15 - 3:40 pm** Ongoing Studies

S1826: Dr. Herrera

S1608: Dr. Barr

A051301: Dr. Stiff

EA4151: Dr. Till

E4412: Dr. Amengual

A051701: Dr. Vallurupalli

A041702: Dr. Hill

EA9161: Dr. Shadman

**3:40 pm** Other Business

**3:45 pm** Adjourn

## Open Studies

**S1826**, "Nivolumab (Opdivo) or Brentuximab Vedotin (Adcetris) Plus AVD  
in Patients with Newly Diagnosed Advanced Stage Classical Hodgkin  
Lymphoma." Drs. Herrera and Friedberg. Activated: 7/19/19.

**S1608**, "Randomized Phase II Trial in High-Risk Relapsed Refractory  
Follicular Lymphoma." Dr. Barr. Activated: 8/10/17.

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

**CTSU/A051701**, "Randomized Phase II/III Study of Venetoclax (ABT199)  
Plus Chemoimmunotherapy for MYC/BCL2 Double-Hit and Double  
Expressing Lymphomas." Dr. Abramson. Activated: 8/7/19. SWOG  
Champion: Dr. Smith. Temporarily Closed to Accrual: 8/13/19.

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

# Lymphoma Committee

**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 <= 70 years Old with Untreated Mantle Cell Lymphoma. Dr. Spurgeon.

**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.

## 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.

## Open Leukemia Studies

**S1905**, "A Phase I/II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL)/T-Cell Lymphoblastic Lymphoma (T-LBL)." Activated 08/17/20. Dr. Advani.

**A041702**, "A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib Plus Venetoclax and Obinutuzumab in Untreated Older Patients (>= 70 Years of Age) with Chronic Lymphocytic Leukemia (CLL)." Dr. Woyach. Activated: 01/04/2019. SWOG Champion: Dr. Hill.

**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.

## 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 7/10/2020.  
Includes studies that are currently open or that closed since 1/1/19.

	S1608	S1826	A051301	A051701	E4412	EA4151	EA4181
Arizona CC, Univ of	1	-	-	-	-	-	-
Baylor College	-	-	1	-	-	-	-
Birmingham, U of AL	-	-	-	2	4	-	-
CORA NCORP	-	1	-	-	-	-	-
CRC West MI NCORP	3	1	-	-	-	-	-
Carle CC NCORP	1	-	-	-	-	-	-
Cincinnati MC, U of	-	1	-	-	-	1	-
City of Hope Med Ctr	4	4	1	-	-	9	-
Cleveland Clinic OH	-	-	-	3	-	3	2
Colorado, U of	-	-	1	-	-	-	-
Columbus NCORP	1	-	-	-	-	-	-
Davis, U of CA	-	1	-	1	-	-	-
Fred Hutchinson CRC	-	-	-	-	-	8	-
Greenville NCORP	-	4	-	-	-	1	-
Heartland NCORP	1	5	-	-	-	-	-
Henry Ford Hospital	-	1	-	2	-	-	-
Irvine, U of CA	-	1	-	-	-	-	-
Kaiser Perm NCORP	-	4	-	-	3	-	1
King Faisal Spec Hos	-	-	1	-	-	-	-
Loyola University	-	1	-	-	-	2	-
MUSC MU-NCORP	2	4	-	3	-	1	-
Michigan CRC NCORP	1	-	-	-	-	-	-
Michigan, U of	-	-	-	-	-	1	-
Montana NCORP	-	5	-	-	-	-	-
Nevada CRF NCORP	-	1	-	-	1	-	-
Northwestern Univ	1	-	-	-	-	-	-
Oregon Hlth Sci Univ	-	-	-	2	-	1	-
Ozarks NCORP	1	1	-	-	-	-	-
Rochester, Univ of	11	10	3	6	-	1	4
San Antonio, U of TX	-	3	-	-	-	6	-
San Diego, U of CA	-	3	-	-	-	1	-
Upstate NCORP	-	3	-	-	-	-	-
Utah, U of	1	5	-	-	-	7	1
Wayne State Univ	-	-	1	-	-	-	-
Alliance	8	13	-	-	-	-	-
COG	-	54	-	-	-	-	-
ECOG-ACRIN	4	14	-	-	-	-	-
NRG	8	9	-	-	-	-	-
<b>Total</b>	<b>48</b>	<b>149</b>	<b>8</b>	<b>19</b>	<b>8</b>	<b>42</b>	<b>8</b>



# Melanoma Committee

## Committee Leadership

Chair: ..... Kenneth F. Grossmann, MD, PhD  
Vice-Chair: ..... Hussein A. Tawbi, MD, PhD  
Executive Officer: ..... Christopher W. Ryan, MD  
Statisticians: ..... Michael Wu, PhD  
..... Megan Othus, PhD  
..... James Moon, MS  
..... Hongli Li, MS

## Scientific Leadership

Translational Medicine: ..... William E. Carson, III, MD  
Radiation Oncology: ..... Evan J. Wuthrick, MD  
Surgery: ..... John Robert Hyingstrom, MD  
Dermatology: ..... Clara Curiel-Lewandrowski, MD  
Imaging: ..... Ari M. VanderWalde, MD  
Medical Oncology: ..... Sapna Pradyuman Patel, MD  
Pathology: ..... Michael T. Tetzlaff, MD, PhD  
Non-Melanoma Skin Cancer: ..... Nikhil I. Khushalani, MD  
Early Therapeutics: ..... Jeffrey A. Sosman, MD  
SWOG's ECOG Liaisons: ..... Sapna Pradyuman Patel, MD  
..... Kevin B. Kim, MD  
ECOG's SWOG Liaisons: ..... David H. Lawson, MD  
..... Andrew Poklepovic, MD  
Digital Engagement: ..... Zeynep Eroglu, MD

## Designates

Cancer Control Liaison: ..... Sancy Leachman, MD, PhD  
..... Thach-Giao Truong, MD (Survivorship)  
Data Coordinator: ..... Joseph Sanchez  
..... Tonya Johnson  
..... Laura Kingsbury, MRT  
..... Leah Everhart  
..... Hannah Hale  
Oncology Research Professionals:  
CRA: ..... Kacie L. Simpson, BS, CCRP  
Nurse: ..... Lisa S. Morgan, RN, OCN  
Patient Advocate: ..... Samantha Guild, JD  
Pharmaceutical Science: ..... Sun "Coco" Yang, PharmD, PhD  
Protocol Coordinator: ..... Danae Campos, MBA  
Clinical Trials Project Manager: ..... Vanessa Benavidez, BS, CCRC

## Agenda

Friday, September 25, 2020  
10:00 am- 12:00 pm

**10:00 am- 12:00 pm:** Presentation of ongoing SWOG melanoma committee clinical trials

**10:00-10:05 am:** Welcome: Kenneth Grossmann, MD, PhD (5 min)

**10:05-10:35 am:** Targeted therapy in melanoma – rational new combinations, Martin McMahon, PhD (30 min)

## Upcoming Studies / Studies in development (30 minutes, 10:35-11:05)

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

**S21\*\*** "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.

**SWOG 2015**, "Melanoma Margins Trial (MelMarT): A Phase III, multi-centre, multi-national randomised control trial investigating 1 cm v 2 cm wide excision margins for primary cutaneous melanoma." Dr. J. Mammen.

## Active Studies (25 minutes, 11:05-11:30)

**S1512**, "A Phase II Study of PD-1 Blockade with Pembrolizumab in Patients with Local-ly Advanced and Metastatic Desmoplastic Melanoma (DM)." Drs. Kendra and Hu-Lieskovan. Activated: 10/20/16.

**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." Drs. Hu-Lieskovan and Ribas. Activated: 10/2/17.

**S1801**, "A Phase II Randomized Study of Adjuvant Versus Neo-Adjuvant MK-3475 for Clinically Detect-able Stage III-IV High Risk Melanoma." Drs. Patel and Grossmann. Activated: 12/6/18.

## Follow Up on Recently Closed Studies (15 minutes, 11:30-11:45)

**S1221**, "Phase I/II Study of the Safety and Efficacy of the AKT Inhibitor GSK2141795 in Combination with the BRAF Inhibitor Dabrafenib and Trametinib in Patients with BRAF Mutant Cancer." Drs. Algazi (UCSF) and Ribas (UCLA). Activated: 7/1/13.

# Melanoma Committee

**S1404**, "A Phase III Randomized Trial Comparing Physician/Patient Choice of either High-Dose Interferon or Ipilimumab to MK-3475 (Pembrolizumab) in Patients with High-Risk Resected Melanoma." Drs. Grossmann and Patel. Activated: 10/15/15. Closed: 8/15/17.

**S1320**, "A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763760) and Trametinib (NSC-763093) in BRAFV600E/K Mutant Melanoma." Dr. Algazi. Activated: 7/22/14. Closed: 7/15/19.

**S1616**, "A Phase II Randomized Study of Nivolumab (NSC-748726) with Ipilimumab (NSC-732442) OR Ipilimumab Alone in Advanced Melanoma Patients Refractory to an Anti-PD-1 or Anti-PD-IL1 Agent." Drs. VanderWalde and Ribas. Activated: 7/17/17.

**ECOG/SWOG liaisons report (10 minutes, 11:45-11:55):** David Lawson/ Andrew Poklepovich

**Closing remarks:** Ken Grossmann and Sam Guild (5 minutes, 11:55-12:00)

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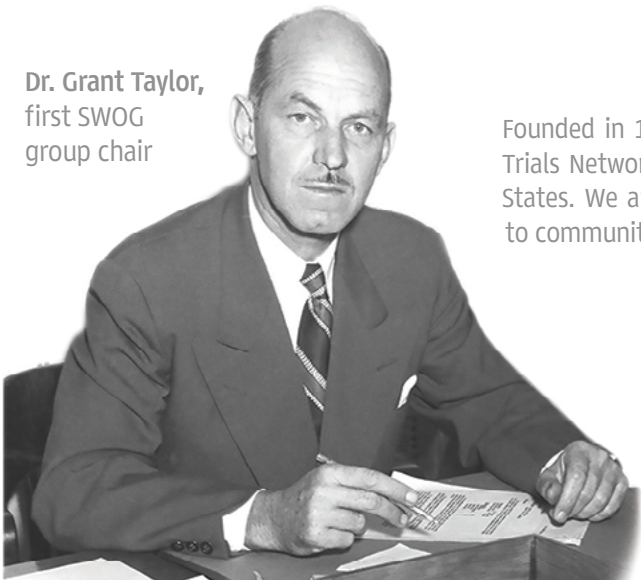
## Melanoma Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/10/2020. Includes studies that are currently open or that closed since 1/1/19.

	S1320	S1512	S1607	S1616	S1801	EA6134	EA6141	EA6174
Arizona CC, Univ of	2	-	-	-	5	-	-	1
Arkansas, U of	7	-	-	-	-	1	-	-
Bay Area NCORP	1	-	-	-	-	-	-	-
Boston Medical Ctr	1	-	-	-	1	-	-	-
CORA NCORP	1	-	-	-	-	-	-	-
CRC West MI NCORP	2	-	-	4	8	-	-	-
CROWN NCORP	-	-	-	1	-	-	-	-
Cincinnati MC, U of	-	-	-	-	-	-	-	2
City of Hope Med Ctr	-	-	-	4	4	2	3	-
Cleveland Clinic OH	-	-	-	-	-	6	-	3
Colorado, U of	2	-	-	-	-	1	-	-
Columbus NCORP	3	-	-	-	-	-	-	-
Dayton NCORP	1	-	-	1	-	-	-	-
Georgia NCORP	-	1	-	-	-	-	-	-
Greenville NCORP	-	-	-	-	-	1	-	-
H Lee Moffitt CC	-	14	-	7	-	-	-	-
Harrington CC	-	-	-	-	1	-	-	-
Hawaii MU-NCORP	1	-	-	-	-	1	-	-
Heartland NCORP	6	-	-	-	4	-	-	-
Henry Ford Hospital	-	-	4	-	-	-	-	-
Irvine, U of CA	-	-	-	-	-	-	-	2
Kaiser Perm NCORP	33	-	-	5	7	19	20	-
Kansas City NCORP	-	-	-	-	-	-	1	-
Kansas MU-NCORP	17	2	1	2	5	2	-	-
Lahey Hosp & Med Ctr	1	-	-	-	-	-	-	-
Los Angeles, U of CA	4	4	8	6	-	7	-	-
Loyola University	8	-	-	-	-	-	-	-
MAVERIC	-	-	-	-	2	-	-	-
MD Anderson CC	-	-	-	-	2	-	-	-

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.

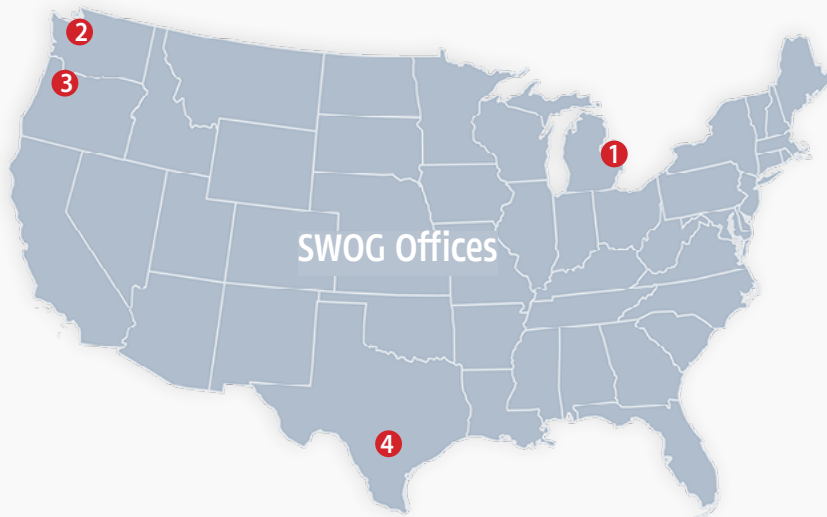


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Michigan CRC NCORP	-	-	-	-	3	-	-	-
Michigan, U of	7	-	-	-	5	-	-	-
Montana NCORP	-	-	-	1	1	-	-	-
Nevada CRF NCORP	4	-	-	-	-	-	-	1
New Mexico MU-NCORP	-	-	-	2	1	-	-	-
Northwestern Univ	-	1	-	6	6	-	-	-
Ohio State Univ	17	5	4	8	4	3	-	-
Ozarks NCORP	2	-	-	-	-	-	-	-
PCRC NCORP	2	-	-	-	2	-	-	-
Rochester, Univ of	4	-	-	5	-	2	-	-
San Antonio, U of TX	-	-	-	-	-	-	1	-
San Diego, U of CA	-	-	-	2	-	-	-	-
San Francisco, U-CA	8	-	-	-	-	-	-	-
So Calif, U of	-	4	5	-	4	-	-	1
Southeast COR NCORP	8	1	-	-	-	-	-	-
Sutter Cancer RC	-	-	-	-	-	2	5	-
Tennessee, U of	-	-	-	7	-	-	-	-
Utah, U of	12	3	10	1	10	-	-	1
Vanderbilt Univ	-	-	1	1	-	-	-	-
Wayne State Univ	-	-	-	-	-	2	-	-
Western States NCORP	-	1	-	-	-	-	-	-
Wichita NCORP	8	-	-	-	-	-	-	-
Wisconsin NCORP	1	-	-	1	5	-	-	-
Yale University	-	-	-	-	-	-	6	-
Alliance	15	-	-	9	13	-	-	-
ECOG-ACRIN	49	-	8	7	17	-	-	-
NRG	22	3	2	13	17	-	-	-
<b>Total</b>	<b>249</b>	<b>39</b>	<b>43</b>	<b>93</b>	<b>127</b>	<b>49</b>	<b>36</b>	<b>11</b>



## Where We Are

- 1 The Hope Foundation for Cancer Research, Ann Arbor, MI
- 2 Fred Hutch Cancer Research Center and Cancer Research And Biostatistics, Seattle, WA
- 3 SWOG Group Chair's Office, Knight Cancer Institute, Oregon Health & Science University, Portland, OR
- 4 SWOG Operations, San Antonio, TX

# News from Our Committees

It's been a year since we've met in person. When you can't drop into a conference room, it's hard to get the latest news on trial activations, concepts-in-progress, and new committee members.

That's why we asked our chairs — from every SWOG disease and research support committee — to give you the fast scoop from their teams. If you don't see a committee listed, the chair didn't provide an update.

We hope this SWOG check-in is helpful. Enjoy the fall meeting!

## DISEASE COMMITTEES

### Breast



PUSZTAI

**Chair:** Lajos Pusztai, MD

**A concept we're working on that we're excited about:**

S2103, "Neoadjuvant trial of Tumor Immune Lymphocyte Adapted Chemotherapy optimization in Triple Negative Breast Cancer (NeoTACT)."

This will be the first clinical trial to define an immune-rich subset of early stage triple negative breast cancer that has excellent prognosis and therefore could be treated with less toxicity and shorter chemotherapy.

#### **New publications or presentations:**

We are excited about the 2020 ASCO oral presentation by Dr. Priyanka Sharma: "Results of a phase II randomized trial of cisplatin+/-veliparib in metastatic triple-negative breast cancer (TNBC) and/or germline BRCA-associated breast cancer (SWOG S1416)." S1416 is the first randomized trial that shows benefit from a PARP inhibitor in germline BRCA normal but BRCA-like TNBC and at the same time demonstrated no benefit in the non-BRCA-like TNBC subset. This trial adds to earlier trial results that have already demonstrated benefit from PARP inhibitors in germline BRCA mutant TNBC.

### Cancer Care Delivery



HERSHMAN



RAMSEY

**Co-Chairs:** Dawn Hershman, MD and Scott Ramsey, MD, PhD

**A recently activated trial we're excited about:**

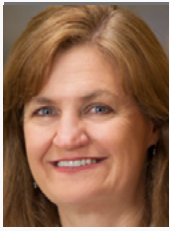
S1912CD, "Addressing Cancer-Related Financial Hardship

through Delivery of Proactive Financial Navigation Intervention (CREDIT)" seeks to determine the impact of a proactive financial navigation program on development of material household financial hardship. Contact PI Dr. Veena Shankaran at [vshank@uw.edu](mailto:vshank@uw.edu) if you want your site to participate.

**A concept we're working on that we're excited about:**

S2100CD, "Randomized comparison of an educationally enhanced genomic tumor board (eGTB) intervention to usual practice of incorporating genomic test results into clinical care." The study's primary objective is to determine whether an eGTB intervention compared to usual practice improves physician genomic confidence. Contact PIs Dr. Jens Rueter at [Jens.Rueter@jax.org](mailto:Jens.Rueter@jax.org) and Dr. Meghna S. Trivedi at [mst2134@cumc.columbia.edu](mailto:mst2134@cumc.columbia.edu) if you want your site to participate.

## Cancer Survivorship



MOORE



IRWIN

**Co-Chairs:** Halle Moore, MD and Melinda Irwin, MD

### A recently activated trial we're excited about:

The committee remains enthusiastic about enrolling patients on S1501, a study

evaluating an intervention to reduce cardiac toxicity in participants receiving trastuzumab based therapy for advanced breast cancer.

### A concept we're working on that we're excited about:

The committee is leveraging data available from ongoing or completed therapeutic studies to better understand survivorship concerns. Concepts in development are those investigating immunotherapy toxicities, including the effect of immunotherapy on fertility measures, as well as concepts evaluating sarcopenia using CT scans completed for disease related assessments.

### New publications or presentations:

- The Evolving Design of NIH-Funded Cardio-Oncology Studies to Address Cancer Treatment- Related Cardiovascular Toxicity. Minasian L et al. JACC: Cardiooncology 2019.
- Vitamin supplement use during chemotherapy and survival outcomes of breast patients enrolled in a cooperative group clinical trial (SWOG S0221). Ambrosone C et al. J Clinical Oncol 2020.
- Physical activity before, during and after chemotherapy for high-risk breast cancer (S0221). Cannioto RA et al. JNCI 2020.

### New committee leaders and members:

Dr. Leah Ferrucci, of Yale School of Public Health, was awarded a spot in the SWOG Young Investigator Training Course to develop her research focused on nutrition, obesity and cancer outcomes.

Dr. Brett Bade, of Yale School of Medicine, focuses on lung cancer survivorship research.

Dr. Rajshekhar Chakraborty, of Columbia University, focuses on thrombosis risk in myeloma patients.

## Early Therapeutics and Rare Cancers



KURZROCK

**Chair:** Razelle Kurzrock, MD

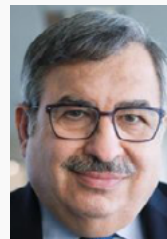
### A recently activated trial we're excited about:

1609 DART, "Nivolumab and Ipilimumab in Treating Patients with Rare Tumors." With DART Cohort 51, we added an angiosarcoma cohort, the first sarcoma cohort in this trial with 53 cohorts. Dr. Michael Wagner is leading this cohort. With DART Cohort 50, we have a cohort that is genomically-focused - PD-L1 amplified tumors (by next generation sequencing) regardless of histology. This is the only cohort in DART that is not tissue based.

### New publications or presentations:

Patel SP, et al. "A Phase II Basket Trial of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART SWOG 1609) in Patients with Nonpancreatic Neuroendocrine Tumors." Clinical Cancer Research: CCR-19-3356 Published May 2020. In this phase II study, patients with high-grade neuroendocrine carcinoma had an objective response rate of 44%.

## Gastrointestinal



PHILIP

**Chair:** Philip Philip, MD

### A recently activated trial we're excited about:

S1922 led by Dr. Michael Overman is a unique study of systemic therapy in patients with small bowel cancer that is an orphan disease with little knowledge on how best to treat. This a randomized phase II study of ramucirumab plus paclitaxel versus FOLFIRI in patients who failed frontline therapy. The importance of this study is that it is asking a question on how to manage patients in a situation that lacks standard of care and national guidelines. The goal is to accrue 94 patients.

### A concept we're working on that we're excited about:

S2001, led by Dr. Vincent Chung, builds on a recent phase III trial of PARP inhibition in patients with metastatic pancreatic cancer (mPC) and also pre-clinical work indicating synergy between PARP inhibition and immune checkpoint treatment. The randomized phase II study tests the combination of olaparib and pembrolizumab versus olapirib control arm in patients with mPC who have BRCA mutations and who favorably responded to platinum-based therapy.

## New publications or presentations:

SWOG S1505: Results of Perioperative Chemotherapy with mFOL-FIRINOX vs Gemcitabine/nab-Paclitaxel for Resectable Pancreatic Ductal Adenocarcinoma. Sohal D, et al, ASCO 2020 Randomized Phase II Study of PARP Inhibitor ABT-888 (Veliparib) with Modified FOLFIRI versus FOLFIRI as Second Line Treatment of Metastatic Pancreatic Cancer: SWOG S1513. Chiorean EG, et al, ASCO 2019

## New committee leaders and members:

- Dr. Zev Wainberg, co-chair of the gastroesophageal subcommittee
- Dr. Mary Kay Washington, pathology lead in the GI working group
- Dr. Rachna Shroff, co-chair of the hepatobiliary subcommittee
- Dr. Daniel Catenacci, member of translational medicine subcommittee
- Dr. Gary L. Buchsacher, community liaison for medical oncology
- Dr. Mohamed E. Salem, community liaison for medical oncology
- Dr. Jeremiah Lee Deneve, community liaison for surgery
- Dr. Flavio Rocha, community liaison for surgery

## Genitourinary



THOMPSON

**Chair:** Ian Thompson, MD

### A recently activated trial we're excited about:

Almost 20 years ago, the SWOG GU committee first proved that nephrectomy improved survival of patients with metastatic kidney cancer (NEJM 2001;345:1655). For decades, similar dogma

suggested that 'treatment of the primary' didn't matter in prostate cancer. With growing evidence that disease control in the prostate DOES make a difference, S1802 is testing whether surgery or radiation improves prostate cancer outcomes in the setting of metastatic disease, establishing a new standard of care.

### A concept we're working on that we're excited about:

On August 3, the committee received the formal approval to proceed with S2011. The study's origins date back to S8710 which found improved survival with MVAC neoadjuvant chemotherapy for bladder cancer. Unfortunately, >40% of these patients are ineligible for cisplatin. S2011 takes neoadjuvant (prior to radical cystectomy) to the next level combining gemcitabine and carboplatin with avelumab for this large group of patients for

whom optimal therapy is not known at this time.

## New publications or presentations:

The committee has a large number of phase III trials that are completing follow-up and will report out shortly, likely changing standard of care. The committee accrued 154/788 patients to the Alliance 90203 trial. This study was the first to test chemotherapy (docetaxel which, in M1 disease, significantly improves survival) as an adjuvant to radical prostatectomy. The study found that such therapy does not reduce disease progression, illustrating the need for new approaches to this disease.

## New committee leaders and members:

- Dr. Evan Hall, assistant professor, Division of Oncology, University of Washington
- Dr. Andrea Harzstark, leader of the Urologic Medical Oncology Subspecialty Team, Kaiser Permanente, Oakland and a member of the NCI GU Steering Committee as the NCORP representative
- Dr. Helen Moon, principal investigator for Kaiser Permanente Southern California Cancer Clinical Trials Access Program

## Lung



KELLY

**Chair:** Karen Kelly, MD

### A recently activated trial we're excited about:

The committee activated six trials in 2020, so it's hard to pick just one! Two trials evaluate radiation and immunotherapy in unique patient populations i.e. early stage medically inoperable

non-small cell lung cancer (NSCLC) (S1914) and poor performance status Stage III patients (S1933). In small cell lung cancer (SCLC), we are conducting the first biomarker driven trial in the NCTN (S1929) and evaluating PCI in all stages of SCLC (S1827). LUNG-MAP continues to evaluate novel agents in the second line and beyond setting (S1800C and S1800D).

### A concept we're working that we're excited about:

Approximately 30% of patients with advanced stage NSCLC are PS 2 at presentation. Trials evaluating immunotherapy plus chemotherapy excluded PS 2 patients. S2102 will evaluate immunotherapy with single agent chemotherapy and with doublet chemotherapy in patients with PD-L1 tumor expression <50% using a selection design approach. The primary endpoint is six-month PFS. One arm will be selected as the experimental arm for a subsequent randomized phase III trial compared to doublet chemotherapy.

## New publications or presentations:

Lead author Mary Redman, PhD, Lung-MAP (SWOG S1400): Design, implementation, and lessons learned from a biomarker-driven master protocol for previously-treated squamous lung cancer

Accepted to Lancet Oncology August 5, 2020

## Lymphoma



FRIEDBERG

**Chair:** Jonathan Friedberg, MD

### A recently activated trial we're excited about:

S1918 is a randomized phase II/III study of R-miniCHOP with or without oral azacitidine (CC-486) in patients age 75 and older with newly diagnosed DLBCL. This will be the first randomized trial ever focused on this under-studied population in the United States. The primary endpoint is improvement in two-year PFS. In addition, S1918 incorporates geriatric assessments aimed at better understanding how frailty impacts outcomes and how treatment affects patients' functioning over time.

### A concept we're working on that we're excited about:

We are designing a trial for patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) who are not transplant-eligible. This is a major unmet need in lymphoma right now. We are very excited to use new knowledge about molecular features of different subtypes of DLBCL to guide treatment in these patients. We are hoping to use novel therapies that are targeted or use the immune system to fight the lymphoma, as opposed to chemotherapy agents. They would also be easier to tolerate.

## New publications or presentations:

Persky et al, JCO online 2020: We have recently published results of NTCN study S1001 in limited stage diffuse large B-cell lymphoma (DLBCL), where the SWOG lymphoma committee has been a thought leader for many years. The study, shows that absolute majority of patients with limited stage DLBCL would do well with just four cycles of standard R-CHOP therapy, without requiring radiation. This reduces duration of treatment and decreases toxicity, while maintaining excellent outcomes.

## New committee leaders and members:

Dr. Alexey Danilov, translational medicine chair, City of Hope

Molly Adamek, BSN, RN, OCN, nurse liaison, University of Hawaii Cancer Center

## Melanoma



GROSSMANN

**Chair:** Ken Grossmann, MD

### A recently activated trial we're excited about:

S2000 is our most recently activated study investigating triplet therapy in b-raf mutated patients with brain metastasis. It is led by Dr. Zeynep Eroglu who is also a recent recipient of a Hope Foundation Coltman fellowship based on this work. We are hopeful that this study can redefine standard of care for melanoma patients with brain metastasis.

### Projects we're excited about:

We are currently proposing a study for the adjuvant treatment of the highest risk melanoma patients with dabrafenib/trametinib and spartalizumab in comparison to a PD-1 inhibitor alone (nivolumab or pembrolizumab). This study is being led by Dr. Hussein Tawbi and Dr. Thach-Giao Truong. We anticipate this study to be another opportunity to collaborate with ECOG in an intergroup effort, and are excited to be working with Dr. Allison Betof Warner on the study team as well.

## New publications or presentations:

The recent publication of S1320 in *Nature Medicine* is a huge accomplishment for our group. The study, led by Dr. Alain Algazi, is the focus of featured presentations at both AACR and ASCO in this past year, and defined continuous dosing of dabrafenib and trametinib as the optimal approach for using these drugs in the standard of care setting. The intermittent dosing schedule does leave open possibilities for future combinations as the feasibility of the approach was also shown by the study.

## New committee leaders and members:

We are excited to welcome Sam Guild, JD, as our patient advocate. This transition occurred sadly with the passing of Sam's mother, Val Guild, MBA, who was our steadfast patient advocate in the committee for many years. Sam brings extensive experience in melanoma advocacy through work with the AIM at Melanoma Foundation and she is a proven policy advocate, having successfully lobbied for tanning bed regulations in multiple states.



## Palliative and End of Life Care

**Co-Chairs:** Marie Bakitas, DNSc; Mark O'Rourke, MD; and Robert Krouse, MD

### A concept we're working on that we're excited about:

Reducing oncology provider burnout may improve delivery of palliative and EOL care. SWOG members were randomly selected for an online survey with 226 of the 1000 invitees



BAKITAS O'ROURKE KROUSE

responding. Hopefulness was associated negatively with burnout and positively with life satisfaction. The abstract is

submitted to ASCO Quality and the manuscript preparation is nearly complete. Single-session hope-enhancement interventions have been shown to increase hope and psychological well-being in non-healthcare professionals. Drs. David Feldman and Ben Corn are in the process of converting their in-person hope workshop to an online webinar for healthcare professionals with plans for pilot testing later in 2020. Another project we're working on is Improving oncology provider communication to improve delivery of palliative and EOL care. Dr. Ishwaria Subbiah submitted a multisite feasibility pilot study to the Hope Foundation on July 1, to evaluate the feasibility of implementing a communication curriculum for oncology providers in practice. Participants will complete the Delivering Serious News on-line course developed by VITALtalk. A phase 3 randomized communication intervention trial in SWOG is planned.

### New publications or presentations:

- The Association of Patient Fatigue and Outcomes in Advanced Cancer: An Analysis of Four SWOG Treatment Trials, submitted to Journal of Clinical Oncology, first author Julia Mo
- Hope, Burnout, and Life Satisfaction: An Intriguing Trinity Among Investigators of the SWOG Cancer Research Network, abstract submitted to ASCO Quality Symposium and manuscript preparation nearly complete, first author David B. Feldman, PhD., Santa Clara University

## Prevention and Epidemiology



ARUN NEUHOUSER

**Co-Chairs:** Banu Arun, MD and Marian Neuhouser, PhD, RD

### A recently activated trial we're excited about:

We are excited about S1823, "A Prospective Observational Cohort Study to Assess miRNA 371 for Outcome Prediction in Patients with Newly Diagnosed Germ Cell Tumors." Study chairs: Dr. Lucia Nappi and Dr. Craig Nichols. Activated on 6/1/20. We are excited about it because the study has shared leadership between a young investigator (Dr. Nappi) and senior investigator (Dr. Nichols), and the study is expected to have high impact for biomarker-driven clinical decisions for patient care.

### Projects we're excited about:

S2003, Phase II Study of Intraoperative Radiotherapy (IORT) for DCIS after Breast Conserving Surgery. Study chair: Dr. Eileen Connolly (Young investigator.) Study may have clinical relevance for whether IORT is a good alternative to whole breast irradiation for DCIS. Includes novel cosmesis endpoints.

S1418-Amendment, Exploratory Study to Evaluate Mammographic Density Changes in Patients Receiving Pembrolizumab. Study Chair: Dr. Banu Arun. Examines MD changes with pembro use.

### New publications or presentations:

Presentation: "Are Biomarkers Going to Change the Future of Testicular Cancer?" ASCO 2020 Genitourinary Cancers Symposium – San Francisco – Feb 14, 2020; Educational Section - Current Developments in Rare Urologic Malignancies; Presenter: Dr. Lucia Nappi. Design of S1823 was presented with a focus on the potential impact of miR371 in the management of germ cell tumor patients.

## Symptom Control and Quality of Life



FISCH HENRY

**Co-Chairs:** Michael Fisch, MD and Lynn Henry, MD

### A recently activated trial we're excited about:

The committee does not have a recently activated trial, but we are eagerly awaiting the replenishment of the supply of nutritional intervention and

subsequent reactivation of our immune-nutrition trial led by Dr. Jill Hamilton-Reeves: S1600, "A Randomized Phase III Double-Blind Clinical Trial Evaluating the Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes." In addition, our trial led by Dr. Krishna Gunturu, S2013, "Immune Checkpoint Inhibitor Toxicity (I-CHECKIT): A Prospective Observational Study" has been concept approved by the NCI and is in protocol development—stay tuned!

### Projects we're excited about:

A multidisciplinary concept led by our NCORP colleagues at Kaiser Permanente, Dr. Ai Kubo and Dr. Natalya Greyz with collaboration from the GU committee is S2014, "Health Mindfulness to Improve Quality of Life in Metastatic Prostate Cancer Patients and their Romantic Partners." Traditional mind-body intervention programs are too demanding for most prostate cancer patients, and thus this study is focused on investigating the efficacy of a six-week mobile-delivered mindfulness intervention for improving quality of life compared to active control at six and at 12 weeks.

### New publications or presentations:

We submitted a manuscript for our S0702 study led by Drs. Cathy Van Poznak and Joe Unger and previously presented as an oral paper at ASCO 2019. In this prospective observational study of nearly 3,500 patients, we are able to define the cumulative incidence of osteonecrosis of the jaw at three years in patients with metastatic bone disease from any malignancy receiving zoledronic acid.

### New committee leaders and members:

- Dr. Evan Hall, University of Washington
- Dr. Javier Retamales, Chilean Cooperative Group for Oncologic Research
- Stephanie Smith, MSN, RN, OCN, St. Joseph's/Candler Health System
- Dr. Michelle Loch, Louisiana State University Health Sciences Center

## RESEARCH SUPPORT COMMITTEES

### Adolescent & Young Adult



LEWIS

**Co-Chairs:** Mark Lewis, MD

#### A recently activated trial we're excited about:

Plasma miR371 and other biomarkers are easy to obtain, inexpensive to analyze, and are highly associated with active seminomatous and non-seminomatous germ cell malignancy with positive predictive value and specificity exceeding 95%. S1823 is a prospective observational cohort study to assess miRNA371 for outcome prediction in patients with early-stage germ cell tumors. If validated, it holds the promise to eliminate/reduce CT scans in the longitudinal follow-up of such GCT patients.

#### Projects we're excited about:

Patients enrolled on S1823 who are undergoing evaluation of suspected relapse can roll over to S200X. Using miRNA371 expression analysis for guidance and an expert surgical network, we aim to estimate the 2-year overall disease free-survival and 2-year abdominal regional control in seminoma and non-seminoma managed with primary surgical management for suspected, classic marker (AFP, bHCG, LDH) non-definitive, recurrence of < 3 cm stage II disease without adjuvant chemotherapy or radiation.

### New publications or presentations:

- Kaddas HK, et al. Age-Related Differences in Financial Toxicity and Unmet Resource Needs Among Adolescent and Young Adult Cancer Patients. *J Adolesc Young Adult Oncol.* 2020;9(1):105-110.
- Holowatyj AN, Wet al. Early-Onset Appendiceal Cancer Survival by Race or Ethnicity in the United States [published online ahead of print, 2020 Jun 12]. *Gastroenterology.* 2020.
- Lewis MA. Between Scylla and Charybdis - Oncologic Decision Making in the Time of Covid-19. *N Engl J Med.* 2020;382(24):2285-2287.

### New committee leaders and members:

- Dr. Monique Hartley-Brown
- Dr. Elizabeth Ann Bowhay-Carnes

## Bone Marrow & Stem Cell Transplantation



STIFF

**Chair:** Patrick J. Stiff, MD

### A recently activated trial we're excited about:

With the myeloma committee and the BMT-CTN, we recently opened S1803, "Lenalidomide +/- Daratumumab as Post-ASCT Maintenance for MM w/MRD to Direct Therapy Duration (DRAMMATIC)." Patients are randomized between lenalidomide for 2 years and lenalidomide + daratumumab. After two years of maintenance, MRD is assessed to guide further therapy. MRD-positive patients will continue with the assigned treatment. MRD-negative patients will be further randomized to continue vs stopping.

### Projects we're excited about:

With the lymphoma committee, a post CAR-T consolidation proposal for those in SD/PR, and with the leukemia committee, a post allograft maintenance study for Ph+ ALL in 2nd/3rd remission with novel therapy

## Digital Engagement



DIZON

**Chair:** Don Dizon, MD

### Projects we're excited about:

We're working to make some critical introductions between new technology industries and start-ups to SWOG, with backing from The Hope Foundation. At our last virtual group meeting, we got to meet leadership from Doximity and Oura. It's an extension of our role in SWOG, hoping to bring in an "out of the box" approach to clinical research, and forge relationships that can ultimately help our patients. We continue to develop three short videos, called Cancer Briefs, with advocate Jonathan Sommers and SWOG friend and TV producer, Erik Stone. With the pandemic, we are looking for the right window to help launch them. We are also excited about the efforts lead by the SWOG communications manager to develop a social media toolkit for projects that are launching. It's our hope that having these available will be an additional asset to PI's as they seek to accrue to their trials.

## New publications or presentations:

- Gunturu KS, Dizon DS, Johnson J, et al. Clinical Trials in the Era of Digital Engagement: A SWOG Call to Action. JCO Clin Cancer Inform. 2020; 4:254-258. doi:10.1200/CCI.19.00128
- Inan, O.T., Tenaerts, P., Prindiville, S.A. et al. Digitizing clinical trials. npj Digit. Med. 3, 101 (2020). <https://doi.org/10.1038/s41746-020-0302-y>

## New committee leaders and members:

Dr. Sanjay Aneja, Yale School of Medicine

## Immunotherapeutics



POLITI



HU-LIESKOVAN

**Co-Chairs:** Katerina Politi, PhD and Siwen Hu-Lieskovan, MD, PhD

### Projects we're excited about:

The committee is leading the design and development of the NCI's immunoMatch (iMatch) trial. Most recently, we have been working on the concept for an iMatch pilot study to explore the feasibility of prospective biomarker stratification in preparation for iMatch. This pilot is a phase II study of combining cabozantinib and nivolumab in patients with advanced solid tumors stratified by tumor biomarkers (Biomarker Stratified CaboZantinib and NivOlumab, BiCaZO).

## New committee leaders and members:

- Dr. Erin Cobain, University of Michigan
- Dr. Shou-Ching Tang, University of Mississippi
- Dr. Cecilia Yeung, Fred Hutchinson Cancer Research Center
- Dr. Thomas Marron, Mt. Sinai School of Medicine
- Dr. Robert Orlowski, MD Anderson Cancer Center
- Dr. Saad Usmani, Levine Cancer Institute
- Dr. Sepideh Gholami, UC Davis
- Dr. Zahi Mitri, Oregon Health & Science University

## Oncology Research Professionals



SZCZEPANKEK

**Chair:** Connie Szczepanek, RN, BSN, CCRP

### A recently activated trial we're excited about:

We're excited about S1820, "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)." This study aims to test the preliminary impact of the AIMS-RC intervention relative to an attention control group. The purpose of the study is to assess whether coaching rectal cancer survivors to appropriately modify their diet can improve bowel symptoms after treatment completion. The trial is led by nursing research committee member Virginia Sun, PhD, RN, with member Christa Braun-Inglis, MS, APRN, FNP-BC, AOCNP, as protocol nurse coordinator. The nursing research committee is a sub-committee of the SWOG ORP Committee.

### Projects we're excited about:

We're excited about rebuilding our executive committee and structure; streamlining our membership process; exploring ways to further support training and education as well as sharing updates and information; and piloting use of additional virtual meeting tools as part of this SWOG fall group meeting

### New committee leaders and members:

Anthony Hicks, BS, CCRP: Executive Committee Member; Co-Chair, Membership Sub-Committee

Lisa Stoppenhagen, BS, CCRP, RHIT: Executive Committee Member; Co-Chair, Membership Sub-Committee

Kristine Abueg, RN, MSN, OCN, CBCN: Education Sub-Committee Chair; Lead for Oishi Symposium Planning

Education subcommittee members Debra Bergevin, BS; Jessica Hynes, BS; and Tosia Courtney, RN, BSN, CCRP

Disease committee liaisons Melyssa Foust, MSN, RN; Erik Bailey, CCRP; and Molly Adamek, RN, BSN, OCN

## Patient Advocates



BANGS

**Chair:** Rick Bangs, MBA

### A recently activated trial we're excited about:

This is like asking a parent to choose their favorite child. We are excited about all of the recently activated trials.

### Projects we're excited about:

We are thrilled to announce TeamScience Module 6, "Improving Diversity and Representativeness in SWOG Clinical Trial Participants," will be completed by year end and will launch in 2021. Module 6 is targeted to SWOG study chairs, patient advocates, and biostatisticians. We will encourage SWOG leadership and other members of the SWOG team to take the course as well.

### New publications or presentations:

Again, this is like asking a parent to choose their favorite child. We are excited about all of the recent publications and presentations.

### New committee leaders and members:

This summer, we onboarded five new community advocates, for a total of seven out of the 10 we will ultimately have:

Allison Rosen - Adolescent and young adult

Howard Krongard - Older adult/senior

Bruce Wright - Military veterans

Robert Taylor - African American

Janice Choe - Asian-Pacific Islander

We also this year welcome two new research advocates:

Samantha Guild, melanoma committee

Desiree A. H. Walker, recruitment and retention committee

## Pharmaceutical Sciences:



WONG

**Chair:** Siu-Fun Wong, PharmD

### Projects we're excited about:

We're excited about three projects - Dr. Dan Hertz' multi-institution SWOG study "Evaluation of Drug Interaction Screening Tool Against Standard of Care;" a collaborative initiative

to mentor junior practitioners in SWOG drug information with the research pharmacy residency programs at the University of Michigan and The Johns Hopkins Hospital; and a project by Dr. Jane Rogers, who is working with Dr. Cathy Eng on the COVID-19 working group to create an electronic medical records order set for BEACON. Additional committee members will work on this project as it progresses.

### New publications or presentations:

- Improvement initiative to develop and implement a tool for detecting drug-drug interactions during oncology clinical trial enrollment eligibility screening. Marcath LA. (In press 2020) Journal of Patient Safety.
- Drug-drug interactions in patients enrolled in SWOG trials of oral chemotherapy. Marcath LA. (Under review 2020). BMC Cancer

A Prospective Study to Validate the Functional Assessment of Cancer Therapy (FACT) for Epidermal Growth Factor Receptor Inhibitor (EGFRI)-Induced Dermatologic

### New committee leaders and members:

Alex Chan, PharmD, UC Irvine School of Pharmacy  
Jane Rogers, PharmD, MD Anderson Cancer Center  
Kim Redic, PharmD; Jola Mehmett, PharmD; and Andrew Smith, PharmD, from University of Michigan  
Janet Mighty, PharmD, MBA; Jacqueline Saunders, PharmD; and Michelle Yu, PharmD from The Johns Hopkins Hospital

## Recruitment and Retention



CABAN-HOLT

**Chair:** Allison Caban-Holt, PhD

### Projects we're excited about:

We're implementing O365/Planner as a tool to share, edit, and archive committee documents, assign tasks, and communicate with members. In August, we submitted to The Hope Foundation for Cancer Research a proposal called "Realizing Diversity, Equity, and Inclusion (DEI) at SWOG," in collaboration with the patient advocate committee. The proposal aims to move SWOG forward with the mission to become a national and international leader in practice-changing clinical research through diversity and inclusion in leadership.

### New publications or presentations:

- A committee-related paper by Dr. Elise Cook and Lynne Nguyen published in the health equity research focused *Advances in Cancer Research*: "A primer for cancer research programs on defining and evaluating the catchment area and evaluating minority clinical trials recruitment."
- "Setting Benchmarks for Disparities Integration," October 2019 SWOG Group Meeting, Lucy Gansauer
- "Minority Recruitment to NCORP Studies," October 2020 SWOG Group Meeting, Colmar Figueroa-Moseley, PhD
- "Integrating Care Delivery Research Into Practice – Implementation Science," April 2020 SWOG Group Meeting, Kate Castro, RN, MS, AOCN

### New committee leaders and members:

Desiree Walker, patient advocate  
Jeffrey Berenberg, MD, MACP  
Kate Castro, RN, MS, AOCN  
Melyssa Foust, MSN, RN  
Vanessa Benavides, clinical trials project manager  
Mercedes Lopez, MA, SWOG Latin America specialist

## Surgery



AHMAD

**Chair:** Syed A. Ahmad, MD

### Projects we're excited about:

We are working on three concepts, 1. A platform study for management of colorectal liver metastases, stratifying treatment based on mutational analysis 2. Role of HIPEC for high grade appendix cancer, 3. Adjuvant therapy for high risk pancreas neuroendocrine tumor.

### New publications or presentations:

SWOG 1505 Surgical Results- Lead author- S. Ahmad, MD  
SWOG 1505 Results- Lead author- D. Sohal, MD

### New committee leaders and members:

Dr. Syed A. Ahmad, chair of surgery committee  
Dr. Flavio Rocha, vice chair of surgery committee

# Publication List by Committee

The publications listed below were received by the Group Chair's Office as published, accepted, and submitted or reflect change in status since the Spring 2020 SWOG Virtual Group Meeting. Conference abstracts are not included.

## ADOLESCENT AND YOUNG ADULT (AYA) COMMITTEE

### Published/Accepted Manuscripts

(none this cycle)

### Submitted Manuscripts

**C10403** Comparison of toxicities when adult and pediatric hematologists/ oncologists treat acute lymphoblastic leukemia in adolescents and young adults with the same regimen (CALGB 10403 and COG AALL0232). Advani A, Larsen E, Laumann K, Luger S, Liedtke M, Devidas M, Chen Z, Chen Z, Yen J, Foster M, Claxton D, Coffan K, Tallman M, Appelbaum F, Erba H, Erba H, Stone R, Hunger S, McNeer J, Loh M, Raetz E, Winick N, Carroll W, Larson R, Stock W. *Blood Advances*, submitted 2020. [see also Leukemia Committee]

## BARLOGIE-SALMON MYELOMA COMMITTEE

### Published/Accepted Manuscripts

**S0120** Race-dependent differences in risk, genomics and Epstein-Barr virus exposure in monoclonal gammopathies (SWOG S0120). Dhodapkar M, Sexton R, Hoering A, van Rhee F, Barlogie B, Orlowski RZ. *Clinical Cancer Research*, Aug 18;clincanres.2119.2020. doi: 10.1158/1078-0432.CCR-20-2119. Online ahead of print. 2020. <https://pubmed.ncbi.nlm.nih.gov/32816893/>

**S0777** Longer Term Follow-up of the Randomized Phase III Trial SWOG S0777: Bortezomib, Lenalidomide and Dexamethasone Vs. Lenalidomide and Dexamethasone in Patients (Pts) with Previously Untreated Multiple Myeloma without an Intent for Immediate Autologous Stem Cell Transplant (ASCT). Durie BGM, Hoering A, Sexton R, Abidi M, Epstein J, Rajkumar V, Dispenzieri A, Thakuri M, Reu F, Reynolds CM, Orlowski RZ, Barlogie B. *Blood Cancer Journal*, May 11;10(5):53, 2020. <https://pubmed.ncbi.nlm.nih.gov/32393732/>

**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 R. *Clinical Cancer Research* Aug 1;26(15):3969-3978, 2020. <https://pubmed.ncbi.nlm.nih.gov/32299820/>

### Submitted Manuscripts

**S1211** Bortezomib, Lenalidomide, Dexamethasone with or without Elotuzumab for Untreated, High-Risk Myeloma: Primary Analysis of the

SWOG-1211 Randomized Phase II Trial. Usmani S, Hoering A, Ailawadhi S, Sexton R, Lipe B, Hita S, Valent J, Rosenzweig M, Zonder J, Dhodapkar M, Callander N, Zimmerman T, Voorhees P, Durie B, Rajkumar V, Richardson P, Orlowski R. *Lancet Haematology*, submitted 2020.

## BREAST COMMITTEE

### Published/Accepted Manuscripts

**S0221** Physical activity before, during and after chemotherapy for high-risk breast cancer: relationships with survival. 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. *JNCI* Apr 2:djaa046. doi: 10.1093/jnci/djaa046, 2020. <https://pubmed.ncbi.nlm.nih.gov/32239145/>

**S0221** Dietary 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* Mar 10;38(8):804-814, 2020. <https://www.ncbi.nlm.nih.gov/pubmed/31855498> [see also Cancer Survivorship Committee]

**S0307** Phase III Randomized Trial of Bisphosphonates as Adjuvant Therapy in Breast Cancer: 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* Jul 1;112(7):698-707, 2020. <https://pubmed.ncbi.nlm.nih.gov/31693129/>

**C40503** Clinical significance of circulating tumor cells in hormone receptor-positive metastatic breast cancer patients who received letrozole with or without bevacizumab. Magbanua M, Savenkov O, Asmus E, Ballman K, Scott J, Park J, Dickler M, Partridge A, Carey L, Winer E, Rugo H [note: D. Tripathy recognized in acknowledgements as SWOG study champion]. *Clinical Cancer Research* Jun 25; online ahead of print:clincanres.1329.2020. doi: 10.1158/1078-0432, 2020. <https://pubmed.ncbi.nlm.nih.gov/32586939/>

**MA.32 (CCTG)** The effect of metformin vs placebo on sex hormones in CCTG MA.32. Pimentel I, Chen B, Lohman A, Ennis M, Ligibel J, Shepherd L, Hershman D, Whelan T, Stambolic V, Mayer I, Hobday T, Lemieux J,

# Publication List by Committee

Thompson A, Rastogi P, Gelmon K, Rea D, Rabaglio M, Ellard S, Mates M, Bedard P, Petre L, Vandenberg T, Dowling R, Parulekar W, Goodwin P. *Journal of the National Cancer Institute* Jun 4;djaa082.:doi: 10.1093/jnci/djaa082. Online ahead of print, 2020. <https://pubmed.ncbi.nlm.nih.gov/32497219/>

**PACCT-1 (E-A)** Patient-Reported Cognitive Impairment Among Women With Early Breast Cancer Randomly Assigned to Endocrine Therapy Alone Versus Chemoendocrine Therapy: Results From TAILORx. Wagner L, Gray R, Sparano J, Whelan T, Garcia S, Yanez B, Tevaarwerk A, Carlos R, Albain K, Olson J, Goetz M, Pritchard K, Hayes D, Geyer C, Dees E, McCaskill-Stevens W, Minasian L, Sledge G, Cella D. *Journal of Clinical Oncology* Jun 10;38(17):1875-1886, 2020. <https://pubmed.ncbi.nlm.nih.gov/32271671/>  
[see also SXQOL Cmte]

## Submitted Manuscripts

**S0307** Risk factors for bisphosphonate-associated osteonecrosis of the jaw in the prospective randomized trial of adjuvant bisphosphonates for early-stage breast cancer (SWOG 0307). Kizub D, Miao J, Schubert M, Paterson A, Clemons M, Dees E, Ingle J, Falkson C, Barlow W, Hortobagyi G, Gralow J. *Supportive Care in Cancer*, under revision/resubmission 2020.

## CANCER CONTROL AND PREVENTION COMMITTEES

### CANCER CARE DELIVERY COMMITTEE

## Published/Accepted 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. *Journal of Clinical Oncology*, Jul 1;38(19):2122-2129. <https://pubmed.ncbi.nlm.nih.gov/32369401/>

**S1417CD** Design, Data Linkage, and Implementation Considerations in the First Cooperative Group Led Study Assessing Financial Outcomes in Cancer Patients and their Informal Caregivers. Shankaran V, Unger J, Darke A, Hershman DL, Ramsey SD. *Contemporary Clinical Trials* May 30;95:106037, 2020. <https://pubmed.ncbi.nlm.nih.gov/32485324/>

**Multiple Studies** Association of the Coronavirus Disease 2019 (COVID-19) Outbreak With Enrollment in Cancer Clinical Trials [Research Letter]. Unger J, Blanke CD, Leblanc M, Hershman D. *JAMA Network Open* Jun 1;3(6):e2010651, 2020. <https://pubmed.ncbi.nlm.nih.gov/32478845/>

**Multiple Studies\*** Association of Patient Demographic Characteristics and Insurance Status with Survival in Cancer Randomized Clinical Trials with Positive Findings. Unger JM, Blanke CD, Leblanc M, Barlow W, Vaidya R, Fleury M, Ramsey SD, Hershman DL. *JAMA Network Open* Apr 1;3(4):e203842, 2020. [\*S0200, S0777, S8494, S8501, S8591, S8624, S8710, S8736, S8797, S8814, S8892, S8897, S8949, S9008, S9126, S9210, S9226, S9308, S9916, MULTIPLE] <https://pubmed.ncbi.nlm.nih.gov/32352530/>

**Multiple Studies\*** Healthcare utilization and cost of care in elderly breast cancer patients enrolled in SWOG clinical trials. Hershman D, Till C, Wright J, Accordini M, Vaidya R, Barlow W, Ramsey S, Unger J. *Breast Cancer Research and Treatment* Jun;181(2):455-463, 2020. [\*S0012, S0221, S0226, S0307, S0500]. <https://www.ncbi.nlm.nih.gov/pubmed/32306168>

**Multiple Studies** Representativeness of Black Patients in Cancer Clinical Trials Sponsored by the National Cancer Institute Compared with Pharmaceutical Companies. Unger J, Hershman D, Osarogiagbon R, Gothwal A, Anand S, Dasari NA, Overman M, Loree J, Raghav K. *JNCI Cancer Spectrum* Apr 24;4(4):pkaa034. doi: 10.1093/jncics/pkaa034. eCollection 2020 Aug. <https://pubmed.ncbi.nlm.nih.gov/32704619/>

**Multiple Studies\*** Economic evaluations in NCI-sponsored network cancer clinical trials. Nghiem VT, Vaidya R, Lyman GH, Hershman DL, Ramsey SD, Unger JM. *Value in Health*, accepted 2020. [\*E2100, E4494, IBCSG25, JMA17, N9741, N9831, S8494, S8710, S8794, S8797, S9031, S9412, S9509]

N/A A primer for cancer research programs on defining and evaluating the catchment area and evaluating minority clinical trials recruitment [book chapter]. Nguyen L, Cook E. *Advances in Cancer Research* Volume 146, Chapter 10:219-226, 2020. <https://authors.elsevier.com/b/1apn4,1Ux2JizL>

## Submitted Manuscripts

**S0000/S9217** Long-term Complications of Prostate Cancer Treatment. Unger J, Till C, Tangen C, Goodman P, Leblanc M, Barlow W, Vaidya R, Minasian L, Parnes H, Thompson IM. *JAMA*, submitted 2020. [see also Prevention & Epidemiology Committee]

**S1105** Patient Reported Outcomes Predict Non-Adherence to Aromatase Inhibitors Among Women Enrolled in a Randomized Trial of Text-Messaging. Hershman D, Neugut A, Moseley A, Arnold K, Gralow J, Henry NL, Clarke Hillyer G, Ramsey S, Unger J. *Journal of Clinical Oncology*, submitted 2020.

**S1400GEN** Patient Knowledge and Expectations About Return of Genomic Results in a Biomarker-Driven Master Protocol Trial (LungMAP

# Publication List by Committee

SWOG S1400GEN). Roth J, Trivedi M, Gray S, Patrick D, Delaney D, Watabayashi K, Litwin P, Shah P, Crew K, Yee M, Redman M, Unger J, Papadimitrakopoulou V, Johnson J, Kelly K, Gandara D, Herbst RS, Hershman D, Ramsey S. *Journal of Oncology Practice*, submitted 2020. [see also Lung Committee]

**Multiple Studies** Persistent disparity: Socioeconomic deprivation and cancer outcomes in patients treated in SWOG NCTN clinical trials. Unger J, Moseley A, Cheung C, Osarogiagbon R, Symington B, Ramsey S, Hershman D. *Journal of Clinical Oncology*, submitted 2020.

**Multiple Studies** "When offered to participate:" A systematic review and meta-analysis of patient agreement to participate in cancer clinical trials. Unger J, Hershman D, Till C, Minasian L, Osarogiagbon R, Fleury M, Vaidya R. *JAMA Oncology*, under revision/resubmission 2020.

## CANCER SURVIVORSHIP COMMITTEE

### Published/Accepted Manuscripts

**S0221** Dietary 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* Mar 10;38(8):804-814, 2020. <https://www.ncbi.nlm.nih.gov/pubmed/31855498> [see also Breast Cmte]

**S0221** Physical activity before, during and after chemotherapy for high-risk breast cancer: relationships with survival. 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. *JNCI* Apr 2:djaa046. doi: 10.1093/jnci/djaa046, 2020. <https://pubmed.ncbi.nlm.nih.gov/32239145/> [see also Breast Cmte]

**C80405** Coffee Intake and Survival in Patients with Advanced or Metastatic Colorectal Cancer: Results from Cancer and Leukemia Group B/SWOG 80405 (Alliance). Mackintosh C, Yuan C, Ou F-S, Zhang S, Niedzwiecki D, Chang I-W, O'Neil B, Mullen B, Lenz H-J, Blanke CD, Venook A, Mayer R, Fuchs C, Innoxwri F, Nixon A, Goldberg R, O'Reilly E, Meyerhardt J, Ng K. *JAMA Oncology*, accepted 2020. [see also GI Committee]

**C89803** The Diet of Higher Insulinemic Potential Is Not Associated with Worse Survival in Patients with Stage III Colon Cancer. Cheng

E, Zhang S, Ou F-S, Mullen B, Ng K, Saltz L, Niedzwiecki D, Mayer R, Mowat R, Whittom R, Hantel A, Benson AB, Atienza D, Messino M, Kindler H, Giovannucci E, Van Blarigan E, Meyerhardt E, Fuchs C. *Cancer Epidemiology, Biomarkers & Prevention* Aug;29(8):1692-1695, 2020. [see also GI Committee] <https://pubmed.ncbi.nlm.nih.gov/32499312/>

### Submitted Manuscripts

**C80405** Association of diet quality with survival among people with metastatic colorectal cancer: data from CALGB/SWOG 80405 (Alliance). Van Blarigan E, Zhang S, Ou F-S, Venook A, Ng K, Atreya C, Van Loon K, Niedzwiecki D, Giovannucci E, Wolfe E, Lenz H-J, Innocenti F, O'Neil B, Shaw J, Polite B, Hochster H, Atkins J, Goldberg R, Mayer R, Blanke CD, O'Reilly E, Fuchs C, Meyerhardt J. *JAMA Network Open*, submitted 2020. [see also GI Committee]

## PALLIATIVE AND END OF LIFE CARE COMMITTEE

### Published/Accepted Manuscripts

(none this cycle)

### Submitted Manuscripts

**S1820 (Pilot)** 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, Fakhri M, Krouse R, Thomson CA. *Supportive Care in Cancer*, under review 2020.

**Multiple Studies\*** Outcomes in Advanced Cancer: An Analysis of Four SWOG Treatment Trials. Mo J, Darke A, Guthrie K, Sloan J, Unger J, Hershman D, O'Rourke M, Bakitas M, Krouse R. *The Association of Patient Fatigue and Journal of Clinical Oncology*, submitted 2020. [\*S0027,S0421,S9509,S9916]

## PREVENTION AND EPIDEMIOLOGY COMMITTEE

### Published/Accepted Manuscripts

**S9217** Vitamin D Pathway and Other Related Polymorphisms and Risk of Prostate Cancer: Results from the Prostate Cancer Prevention Trial. Torkko KC, Till C, Tangen CM, Goodman P, Schenk-Kisser JM, Song X, Lucia MS, van Bokhoven A, Peters U, Thompson IM, Neuhauser ML. *Cancer Prevention Research*, Jun;13(6):521-530, 2020. <https://pubmed.ncbi.nlm.nih.gov/32102946/>

**S9217** The association between serum sex steroid hormone concentrations and intraprostatic inflammation in men without prostate cancer and irrespective of clinical indication for biopsy in the



# Publication List by Committee

placebo arm of the Prostate Cancer Prevention Trial. Chadid S, Song X, Schenk J, Gurel B, Lucia MS, Thompson IM, Neuhouser M, Goodman P, Tangen C, Parnes H, Lippman S, Nelson W, De Marzo A, Platz E. Prostate Aug;80(11):895-905, 2020.

<https://pubmed.ncbi.nlm.nih.gov/32506665/>

**S9217** Use of Aspirin and Statins in Relation to Inflammation in

Benign Prostate Tissue in the Placebo Arm of the Prostate Cancer Prevention Trial. Hurwitz L, Kulac I, Gumuskaya B, Baena-Del Valle J, Benedetti I, Pan F, Liu JO, Marrone M, Arnold K, Goodman P, Tangen C, Lucia MS, Thompson IM, Drake CG, Isaacs W, Nelson W, De Marzo A, Platz EA. Cancer Epidemiology, Biomarkers & Prevention Jun 24;canprevres.0450.2019.:doi: 10.1158/1940-6207.CAPR-19-0450; online, 2020. <https://pubmed.ncbi.nlm.nih.gov/32581009/>

**S9217** 5a-Reductase Inhibitor Use in Patients With Prostate Cancer [Letter to the Editor/Comment & Response re: Sarkar RR, Parsons JK, Bryant AK, et al.]. Thompson IM, Tangen CM, Kramer B. JAMA Internal Medicine Oct 1;179(10):1440, 2019. \_

<https://www.ncbi.nlm.nih.gov/pubmed/31589258>

**S0000A** Mental Component score (MCS) from Health-related Quality of Life Predicts Incidence of Dementia in U.S. Males. Ding X, Abner E, Schmitt F, Crowley J, Goodman P, Kryscio R. Journal of Prevention of Alzheimer's Disease, accepted 2020.

**S0000B** Age-related Macular Degeneration in a Randomized Trial of Selenium and Vitamin E in Men: The SELECT Eye Endpoints (SEE) Study (SWOG S0000B) [Letter to the Editor]. Christen W, Darke A, Gaziano JM, Glynn RJ, Goodman P, Minasian LM, Thompson IM. Acta Ophthalmologica, Jul 23. doi: 10.1111/aos.14538. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/32701201/>

**Multiple Studies\*** Genome-wide association study data reveal genetic susceptibility to chronic inflammatory intestinal diseases and pancreatic ductal adenocarcinoma risk. Yuan F, Hung R, Walsh N, Zhang H, Platz E, Wheeler W, Goodman P, Albanes D, Fuchs C, Gaziano J, Thompson I, Petersen G, Wolpin B, Risch H, Yu K, Klein A. Cancer Research Jul 8;canres.0447.2020:doi:10.1158/0008-5472. Online ahead of print, 2020. [\*S0000, MULTIPLE] <https://pubmed.ncbi.nlm.nih.gov/32641412/>

**Multiple Studies\*** Meta-analysis of 16 studies of the association of alcohol with colorectal cancer. McNabb S, Harrison T, Albanes D, Berndt S, Brenner H, Caan B, Goodman P, Tangen C, Woods MO, Phipps AI, Peters U. International Journal of Cancer Feb;146(3):861-873, 2020. [\*S0000, MULTIPLE] <https://www.ncbi.nlm.nih.gov/pubmed/31037736>

**Multiple Studies\*** Assessment of Polygenic Architecture and Risk

Prediction based on Common Variants Across Fourteen Cancers. Zhang Y, Wilcox A, Easton D, Milne RL, Simard J, Eeles R, Haiman C, Kote-Jarai Z, Berchuck A, Pharoah P, Sellers T, O'Mara T, Spurdle A, Thompson DJ, Campbell PT, Hoffmeister M, Jenkins M, Peters U, Landi M, Law MH, Iles M, Bondy M, Houlston R, Wiencke J, Wrensch M, Purdue M, Scelo G, Wu X, Amundadottir L, Amos C, Brennan P, McKay JD, McGlynn K, Abnet C, Berndt S, Birmann B, Camp N, Cerhan J, Kane E, Kraft P, Rothman N, Slager S, BCAC, PRACTICAL, ILCCO/TRICL, OCAC, ECAC, GECCO/CORECT, GenoMEL, Cancer Consortium Renal. Nature Communications Jul 3;11(1):3353, 2020. [\*S0000, MULTIPLE]

<https://pubmed.ncbi.nlm.nih.gov/32620889/>

**Multiple Studies\*** Genome-wide Modeling of Polygenic Risk Score in Colorectal Cancer Risk. Thomas M, Sakoda L, Hoffmeister M, Rosenthal E, Lee J, van Duijnhoven F, Platz E, Tangen C, Albanes D, Corley D, Peters U, Hsu L. American Journal of Human Genetics Jul 29;S0002-9297(20)30236-6. Online ahead of print, 2020. [\*S0000, MULTIPLE] <https://pubmed.ncbi.nlm.nih.gov/32758450/>

**Multiple Studies\*** A Germline Variant at 8q24 Contributes to Familial Clustering of Prostate Cancer in Men of African Ancestry [Brief Correspondence]. Darst B, Wan P, Sheng X, Bensen J, Ingles S, Rybicki B, Nemesure B, John E, Fowke J, Stevens V, Berndt S, Huff C, Strom S, Park J, Zheng W, Ostrander E, Walsh P, Yeboah E, Tettey Y, Biritwum R, Adjei A, Tay E, Srivastava S, Carpten J, Truelove A, Niwa S, Sellers T, Yamoah K, Murphy A, Sanderson M, Crawford D, Gapstur S, Bush W, Aldrich M, Cussenot O, Petrovics G, Cullen J, Neslung-Dudas C, Kittles R, Xu J, Stern M, Jarai Z, Govindasami K, Chokkalingam A, Multigner L, Parent M, Menegaux F, Cancel-Tassin G, Kibbel A, Klein E. European Urology Sep;78(3):316-320, 2020. [\*S0000, S9217, other] <https://pubmed.ncbi.nlm.nih.gov/32409115/>

**Multiple Studies\*** Genome-wide Gene-Diabetes and Gene-Obesity Interaction Scan in 8,255 Cases and 11,900 Controls From the PanScan and PanC4 Consortia. Tang H, Jiang L, Stolzenberg-Solomon R, Arslan A, Beane Freeman L, Bracchi P, Goodman P, Albanes D, Fuchs C, Gaziano J, Thompson I, Risch H, Chatterjee N, Klein A, Li D, Kraft P, Wei P. Cancer Epidemiology, Biomarkers & Prevention Jun 16;cebp.0275.2020. doi: 10.1158/1055-9965.EPI-20-0275. Online ahead of print., 2020. [\*S0000, S9217, other] <https://pubmed.ncbi.nlm.nih.gov/32546605/>

**Multiple Studies\*** African-specific improvement of a polygenic hazard score for age at diagnosis of prostate cancer. Karunamuni R, Huynh-Le MP, Fan C, Thompson W, Eeles R, Kote-Jarai Z, Tangen C, Goodman P, Thompson IM Jr., Andreassen O, Dale A, Seibert T. International Journal of Cancer, accepted, 2020. [\*S0000, S9217, other]

# Publication List by Committee

**Multiple Studies\*** Physical activity and risks of breast and colorectal cancer: a Mendelian randomisation analysis. Papadimitriou N, Dimou N, Tsilidis K, Banbury B, Martin R, Lewis S, Albanes D, Platz E, Tangen C, Peters U, Gunter M, Murphy N. *Nature Communications* 11:597, 2020. [\*S0000, other] <https://pubmed.ncbi.nlm.nih.gov/32001714/>

**Multiple Studies\*** Associations between Genetically Predicted Blood Protein Biomarkers and Pancreatic Cancer Risk. Zhu J, Shu X, Guo X, Liu D, Bao J, Milne R, Goodman P, Shu X-O, Zheng W, Wu L. *Cancer Epidemiology, Biomarkers & Prevention* Jul;29(7):1501-1508, 2020. [\*S0000, MULTIPLE] <https://pubmed.ncbi.nlm.nih.gov/32439797/>

**Multiple Studies\*** Circulating Levels of Insulin-like Growth Factor 1 and Insulin-like Growth Factor Binding Protein 3 Associate With Risk of Colorectal Cancer Based on Serologic and Mendelian Randomization Analyses. Murphy N, Carreras-Torres R, Song M, Chan A, Martin R, Papadimitriou N, Albanes D, Platz E, Tangen C, Zheng W, Peters U, Gunter M. *Gastroenterology* Apr;158(5):1300-1312, 2020. [\*S0000, MULTIPLE] <https://pubmed.ncbi.nlm.nih.gov/31884074/>

## Submitted Manuscripts

**S0000/S9217** Long-term Complications of Prostate Cancer Treatment. Unger J, Till C, Tangen C, Goodman P, Leblanc M, Barlow W, Vaidya R, Minasian L, Parnes H, Thompson IM. *JAMA*, submitted 2020. [see also Cancer Care Delivery Committee]

**S0000/S9217** Prostate Cancer Prevention: A Perspective. Thompson IM, Tangen C. *Science*, under review, 2020.

**S0000/S9217** A Latent Disease Model to Reduce Detection Bias in Cancer Risk Prediction Studies. Aleshin-Guendel S, Lange J, Tangen C, Goodman P, Weiss N, Etzioni R. *Evaluation and the Health Professions*, submitted 2020.

**S9217** Obesity-related Biomarkers Mediating the Association Between Obesity and Prostate Cancer Risk: Results from the Prostate Cancer Prevention Trial. Chau C, Till C, Price D, Goodman P, Tangen C, Thompson I, Figg W. *British Journal of Cancer*, submitted 2020.

**Multiple Studies\*** Multiethnic GWAS meta-analysis identifies novel variants and informs genetic risk prediction for prostate cancer across populations. Conti D, Chemenyan L, Darst B, Saunders EJ, Sheng X, Schumacher F, Albanes D, Tangen C, Goodman P, Thompson IM, Klein EA, Hsing A, Kote-Jarai Z, Haiman C. *Nature Genetics*, submitted 2020. [S0000, S9217, 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*, 2020. [\*S0000, S9217, other]

**Multiple Studies\*** Mendelian randomization analysis of n-6 polyunsaturated fatty acid levels and pancreatic cancer risk. Ghoneim D, Zhu J, Zheng W, Long J, Murff H, Ye F, Goodman P, Albanes D, Fuchs C, Gaziano JM, Thompson I, Amundadottir L, Kraft P, Klein A, Stolzenberg-Solomon R, Shu X-O, Wu L. *Cancer Epidemiology, Biomarkers & Prevention*, submitted (provisionally accepted) 2020. [\*S0000, S9217, 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 revision for resubmission, 2020. [\*S0000, Other]

## SYMPTOM CONTROL AND QUALITY OF LIFE COMMITTEE

### Published/Accepted Manuscripts

**S1013** A Prospective Study to Validate the Functional Assessment of Cancer Therapy (FACT) for Epidermal Growth Factor Receptor Inhibitor(EGFRI)-Induced Dermatologic Toxicities FACT-EGFRI 18 questionnaire: SWOG S1013. Wong S-F, Unger JM, Wade JL 3rd, Wagner L, Lacouture M, Humphries K, Moseley A, Arnold K, Velasco M, Floyd J, Esparaz B, Barzi A, Lenz H-J, Koczywas M, Dakhil S, Burton GV, Fisch MJ, Henry NL, Hershman DL, Moynour CM. *Journal of Patient Reported Outcomes* Jul 8;4(1):54, 2020. <https://pubmed.ncbi.nlm.nih.gov/32642992/>

**PACCT-1 (E-A)** Patient-Reported Cognitive Impairment Among Women With Early Breast Cancer Randomly Assigned to Endocrine Therapy Alone Versus Chemoendocrine Therapy: Results From TAILORx. Wagner L, Gray R, Sparano J, Whelan T, Garcia S, Yanez B, Tevaarwerk A, Carlos R, Albain K, Olson J, Goetz M, Pritchard K, Hayes D, Geyer C, Dees E, McCaskill-Stevens W, Minasian L, Sledge G, Cella D. *Journal of Clinical Oncology* Jun 10;38(17):1875-1886, 2020. <https://pubmed.ncbi.nlm.nih.gov/32271671/> [see also Breast Cmte]

### Submitted Manuscripts

**S0702** Osteonecrosis of the jaw in patients with cancer receiving zoledronic acid for bone metastases: SWOG S0702, NCT00874211. Van Poznak C, Unger J, Darke A, Moynour C, Bagramian R, Schubert M,

# Publication List by Committee

Hansen L, Floyd J, Dakhil S, Lew D, Wade J, Fisch M, Henry NL, Hershman D, Gralow J. JAMA Oncology, revised/resubmitted 2020.

**S1202** Relationship of Adverse Events to Patient Perception of Benefit from Duloxetine for Treating Aromatase Inhibitor-Associated Arthralgias. Schnell P, Lustberg M, Henry NL. Journal of the National Cancer Institute, revised/resubmitted 2020.

**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, under review 2020. [see also GI Committee]

## DIGITAL ENGAGEMENT COMMITTEE

### Published/Accepted Manuscripts

**N/A** Clinical Trials in the Era of Digital Engagement: A SWOG Call to Action. Gunturu K, Dizon D, Johnson J, Mercurio AM, Mason G, Sparks D, Lawton W, Klemp J. JCO Clinical Cancer Informatics 4:254-258, 2020. <https://pubmed.ncbi.nlm.nih.gov/32191544/>

### Submitted Manuscripts

(none this cycle)

## EARLY THERAPEUTICS AND RARE CANCERS COMMITTEE

### Published/Accepted Manuscripts

**S1609** A Phase II Basket Trial of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART) SWOG S1609: The Neuroendocrine Cohort. Patel S, Othus 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. Clinical Cancer Research May 15;26(10):2290-2296, 2020. <https://www.ncbi.nlm.nih.gov/pubmed/31969335>

**S1609** Ipilimumab and Nivolumab in Rare Tumors S1609: Neuroendocrine-Response [Response to Letter to Editor]. Patel S, Othus M, Chae YK, Kurzrock R. Clinical Cancer Research May 15;26(10):2434, 2020. <https://pubmed.ncbi.nlm.nih.gov/32414761/>

**S1609** Dual Checkpoint Blockade in a Neuroendocrine Carcinoma with Dual PD-L1/PD-L2 Amplification and High Tumor Mutational Burden [case report]. Gong J, Adashek D, Frishberg D, Guan M, Placencio-Hickock V, Gangi A, Gresham G, Tuli R, Othus M, Chae YK, Kurzrock R, Hendifar A. JCO Precision Oncology, accepted 2020.

### Submitted Manuscripts

**S1609** A Phase II Basket Trial of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART) SWOG S1609: High-Grade Neuroendocrine Neoplasm Cohort. Patel SP, Othus M, Chae YK, J Strosberg J, Wang J, Konda B, Hayward J, McLeod C, Chen H, Sharon E, Mayerson E, Ryan C, Plets M, Blanke CD, Kurzrock R. JAMA Oncology, submitted 2020.

## GASTROINTESTINAL COMMITTEE

### Published/Accepted Manuscripts

**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, Mar 29;130:219-227, 2020. <https://pubmed.ncbi.nlm.nih.gov/32234665/>

**S1505** Surgical Outcome Results from SWOG S1505: A Randomized Clinical Trial of mFOLFIRINOX vs. Gemcitabine/nab-Paclitaxel for Perioperative Treatment of Resectable Pancreatic Ductal Adenocarcinoma (PDA). Ahmad S, Duong M, Sohal D, Gandhi N, Beg S, Wang-Gillam A, Wade JI 3rd, Chiorean E, Guthrie K, Lowy A, Philip P, Hochster H. Annals of Surgery Jul 24 Online ahead of print, 2020. <https://pubmed.ncbi.nlm.nih.gov/32740235/>

**C80405** Coffee Intake and Survival in Patients with Advanced or Metastatic Colorectal Cancer: Results from Cancer and Leukemia Group B/SWOG 80405 (Alliance). Mackintosh C, Yuan C, Ou F-S, Zhang S, Niedzwiecki D, Chang I-W, O'Neil B, Mullen B, Lenz H-J, Blanke CD, Venook A, Mayer R, Fuchs C, Innoxwnri F, Nixon A, Goldberg R, O'Reilly E, Meyerhardt J, Ng K. JAMA Oncology, accepted 2020. [see also Cancer Survivorship Committee]

**C89803** The Diet of Higher Insulinemic Potential Is Not Associated with Worse Survival in Patients with Stage III Colon Cancer. Cheng E, Zhang S, Ou F-S, Mullen B, Ng K, Saltz L, Niedzwiecki D, Mayer R, Mowat R, Whittom R, Hantel A, Benson AB, Atienza D, Messino M, Kindler H, Giovannucci E, Van Blarigan E, Meyerhardt E, Fuchs C. Cancer Epidemiology, Biomarkers & Prevention Aug;29(8):1692-1695, 2020. [see also Cancer Survivorship Committee] <https://pubmed.ncbi.nlm.nih.gov/32499312/>

**N0147** Contribution of Immunoscore and Molecular Features to Survival Prediction in Stage III Colon Cancer. Sinicrope F, Shi Q, Hermitte F, Zemla T, Mlecnik B, Benson A, Gill S, Goldberg RM, Kahlenberg M, Nair S, Shields AF, Smyrk T, Galon J, Alberts S. JNCI Cancer Spectrum Apr 5;4(3):pkaa023, 2020. <https://pubmed.ncbi.nlm.nih.gov/32455336/>

# Publication List by Committee

## Submitted Manuscripts

**S1406** Randomized trial of irinotecan and cetuximab with or without vemurafenib in BRAF-mutant metastatic colorectal cancer (SWOG S1406). Kopetz S, Guthrie K, Morris V, Lenz H-J, Magliocco A, Maru D, Airhart S, Yan Y, Lanman R, Manyam G, Hong D, Sorokin A, Atreya C, Allegra C, Raghav K, Wang S, Lieu C, McDonough S, Philip P, Hochster H. *Journal of Clinical Oncology*, under review 2020.

**S1505** SWOG S1505: Results of Perioperative Chemotherapy with mFOLFIRINOX vs Gemcitabine/nab-Paclitaxel for Resectable Pancreatic Ductal Adenocarcinoma. Sohal D, Duong M, Ahmad S, Gandhi N, Beg S, Wang-Gillam A, Wade JL, Chiorean EG, Guthrie K, Lowy A, Philip P, Hochster H. *Journal of the American Medical Association*, submitted 2020.

**S1513** Randomized Phase II Study of PARP Inhibitor ABT-888 (Veliparib) with Modified FOLFIRI versus FOLFIRI as Second Line Treatment of Metastatic Pancreatic Cancer: SWOG S1513. Chiorean EG, Guthrie K, Philip P, Swisher E, Jalikis F, Pishvaian M, Berlin J, Noel M, Suga J, Garrido-Laguna I, Cardin D, Radke M, Duong M, Lowy A, Hochster H. *JAMA Oncology*, under review 2020.

**C80405** Association of diet quality with survival among people with metastatic colorectal cancer: data from CALGB/SWOG 80405 (Alliance). Van Blarigan E, Zhang S, Ou F-S, Venook A, Ng K, Atreya C, Van Loon K, Niedzwiecki D, Giovannucci E, Wolfe E, Lenz H-J, Innocenti F, O'Neil B, Shaw J, Polite B, Hochster H, Atkins J, Goldberg R, Mayer R, Blanke CD, O'Reilly E, Fuchs C, Meyerhardt J. *JAMA Network Open*, submitted 2020. [see also Cancer Survivorship Committee]

**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*, under review 2020. [see also SCQOL Cmte]

## GENITOURINARY COMMITTEE

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

## Published/Accepted Manuscripts

**S0421** Designing precision medicine trials to yield a greater population impact. Zhao Y, Leblanc M. *Biometrics* Jun;76(2):643-653, 2020. <https://pubmed.ncbi.nlm.nih.gov/31598964/>

**S1314** Review of SWOG S1314: Lessons from a randomized phase II study of co-expression extrapolation (COXEN) with neoadjuvant chemotherapy for localized, muscle-invasive bladder cancer [Review]. Boxley P, Plets M, Flaig. *Bladder Cancer*, Jun 11;6(2):123-129, 2020. <https://pubmed.ncbi.nlm.nih.gov/32793789/>

**S1823 (Pilot)** Developing a Highly Specific Biomarker for Germ Cell Malignancies: Plasma miR371 Expression Across the Germ Cell Malignancy Spectrum. Nappi L, Thi M, Lum A, Huntsman D, Eigl B, Martin C, O'Neil B, Maughan B, Chi K, So A, Black P, Gleave M, Wyatt A, Lavoie J, Khalaf D, Bell R, Daneshmand S, Hamilton R, Leao R, Nichols C, Kollmannsberger C. *Journal of Clinical Oncology*, Nov 20;37 (33), 3090-3098, 2019. <https://pubmed.ncbi.nlm.nih.gov/31553692/>

**C90203** Cancer and Leukemia Group B 90203 (Alliance): Radical Prostatectomy With or Without Neoadjuvant Chemohormonal Therapy in Localized, High-Risk Prostate Cancer. Eastham J, Heller G, Halabi S, Monk JP, Beltran H, Gleave M, Evans CP, Clinton S, Szmulewitz R, Coleman J, Hillman D, Watt CR, Hahn O, Taplin ME, JK, Small E, Mohler J, Morris MJ. *Journal of Clinical Oncology* Jul 24;JCO2000315. doi: 10.1200/JCO.20.00315. Online ahead of print, 2020. <https://pubmed.ncbi.nlm.nih.gov/32706639/>

**E2805** Local Recurrence Following Resection of Intermediate-High Risk Nonmetastatic Renal Cell Carcinoma: An Anatomical Classification and Analysis of the ASSURE (ECOG-ACRIN E2805) Adjuvant Trial. Lee Z, Jegede O, Haas N, Pins M, Messing E, Manola J, Wood C, Kane C, Jewett M, Flaherty K, Dutcher J, DiPaola R, Uzzo R. *Journal of Urology* Apr;203(4):684-689, 2020. <https://pubmed.ncbi.nlm.nih.gov/31596672/>

**E3805** HSD3B1 Genotype and Clinical Outcomes in Metastatic Castration-Sensitive Prostate Cancer. Hearn J, Sweeney CJ, Almassi N, Reichard C, Reddy CA, Li H, Hobbs B, Jarrard D, Chen Y-H, Dreicer R, Garcia J, Carducci M, DiPaola R, Sharifi N. *JAMA Oncology* Feb 13;6(4):e196496, 2020. <https://pubmed.ncbi.nlm.nih.gov/32053149/>

**Multiple Studies\*** Comparative Survival of Asian and White Men with Metastatic Castration-Resistant Prostate Cancer Treated with Docetaxel. Halabi S, Dutta S, Tangen C, Rosenthal M, Petrylak D, Thompson I, Chi K, de Bono J, Araujo J, Logothetis C, Eisenberger M, Quinn D, Fizazi K, Morris M, Higano C, Tannock I, Small E, Kelly W. *JNCI Cancer Spectrum* Jan 29;4(2):pkaa003. doi: 10.1093/jncics/pkaa003, 2020. [\*S0421,S9916, OTHER] <https://pubmed.ncbi.nlm.nih.gov/32368717/>

**Multiple Studies\*** Clinical outcomes in men of diverse ethnic backgrounds with metastatic castration-resistant prostate cancer. Halabi S, Dutta S, Tangen C, Rosenthal M, Petrylak D, Thompson IM, Chi K, DeBono J, Araujo J, Logothetis C, Eisenberger M, Quinn D, Fizazi

# Publication List by Committee

K, Morris M, Higano C, Tannock I, Small E, Kelly W. Annals of Oncology Jul;31(7):930-941, 2020. [\*S0421,S9916, OTHER]  
<https://pubmed.ncbi.nlm.nih.gov/32289380/>

## Submitted Manuscripts

**S1216** Baseline circulating tumor cell count as a prognostic marker of PSA response and disease progression in metastatic castrate sensitive prostate cancer (SWOG S1216). Goldkorn A, Tangen C, Plets M, Morrison GJ, Cunha A, Xu T, Pinski JK, Ingles SA, Triche T, Harzstark AL, Kohli M, MacVicar GR, Vaena DA, Crispino AW, McConkey DJ, Lara PN Jr., Hussain MHA, Quinn DI, Vogelzang NJ, Thompson IM Jr., Agarwal N. Lancet Oncology, submitted 2020.

**S1314** A randomized phase II study of coexpression extrapolation (COXEN) with neoadjuvant chemotherapy for bladder cancer (SWOG S1314; NCT02177695). Flaig TW, Tangen CM, Daneshmand S, Alva AS, Lerner SP, Lucia MS, McConkey DJ, Theodorescu D, Goldkorn A, Milowsky MI, Bangs R, MacVicar GR, Bastos BR, Fowler J, Gustafson D, Plets M, Thompson IM. Clinical Cancer Research, submitted 2020.

**E3805** Effect of Metformin and Body Mass Index on Quality of Life and Survival in the E3805 CHAARTED Trial. Jerrard D, Chen Y, Morgans A, Carducci M, Liu G, Eisenberger M, Wong Y-N, Hahn N, Bryce A, Cooney M, Dreicer R, Vogelzang N, Picus J, Shevrin D, Hussain M, Garcia J, DiPaola R, Sweeney C. Prostate Cancer and Prostatic Diseases, submitted 2020.

## LEUKEMIA COMMITTEE

### Published/Accepted Manuscripts

**S0535** A Phase II Study of ATRA, Arsenic Trioxide and Gemtuzumab Ozogamicin in Patients with Previously Untreated High-Risk Acute Promyelocytic Leukemia (SWOG S0535). Lancet JE, Moseley AB, Komrokj RS, Coutre SE, DeAngelo DJ, Othus M, Tallman MS, Litzow MR, Erba HP, Appelbaum FR. Blood Advances, Apr 28;4(8):1683-1689, 2020.  
<https://pubmed.ncbi.nlm.nih.gov/32330241/>

**Multiple Studies\*** AML Risk Stratification Models Utilizing ELN-2017 Guidelines and Additional Prognostic Factors: A SWOG Report. 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, Pogossova GL, Radich JP, Stevens E, Willborg B, Willman CL, Wood BL, Zhang Q, Meshinchi S, Stirewalt DL. Biomarker Research, Aug 12;8:29, 2020. [\*S0106, S0112, S9031, S9333]  
<https://pubmed.ncbi.nlm.nih.gov/32817791/>

**Multiple Studies\*** Bias in mean survival from fitting cure models with limited follow-up. Othus M, Bansal A, Erba H, Ramsey S. Value in Health, accepted 2020. [\*S0106, S0325, S0703, S0805, S1117, S1203]

**Multiple Studies\*** Association of immunophenotype with expression of topoisomerase II  $\alpha$  and  $\beta$  in adult acute myeloid leukemia. Michelson A, McDonough S, Willman C, Koegle E, Godwin J, Petersdorf S, List A, Othus M, Appelbaum F, Radich J, Ganapathi R, Advani A, Ganapathi R. Scientific Reports Mar 26;10(1):5486, 2020. [\*S9031, S9126, S9333 and S9500].  
<https://pubmed.ncbi.nlm.nih.gov/32218491/>

## 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, Luger S, Mohan S, Moseley A, Appelbaum F, Erba HP. Leukemia, resubmitted/under review 2020.

**C10403** Comparison of toxicities when adult and pediatric hematologists/oncologists treat acute lymphoblastic leukemia in adolescents and young adults with the same regimen (CALGB 10403 and COG AALL0232). Advani A, Larsen E, Laumann K, Luger S, Liedtke M, Devidas M, Chen Z, Chen Z, Yen J, Foster M, Claxton D, Coffan K, Tallman M, Appelbaum F, Erba H, Stone R, Hunger S, McNeer J, Loh M, Raetz E, Winick N, Carroll W, Larson R, Stock W. Blood Advances, submitted 2020. [see also AYA Committee]

**C10603** Midostaurin reduces the cumulative incidence of relapse and is tolerable for maintenance in FLT3-mutant acute myeloid leukemia (CALGB 10603). Larson RA, Mandrekar S, Huebner L, Sanford B, Laumann C, Geyer S, Bloomfield C, Thiede C, Prior T, Dohner K, Marcucci G, Voso M, Klisovic R, Galinsky I, Wei A, Sierra J, Sanz M, Brandwein J, de Witte T, Niederwieser D, Appelbaum F, Medeiros B, Tallman M, Krauter J, Schlenk R, Ganser R, Serve H, Ehninger G, Amadori S, Gathmann I, Dohner H, Stone R. Blood, submitted 2020.

**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. Leukemia, under review 2020. [\*S0106, S1203, S8600, S9031, S9333]

## LUNG COMMITTEE

### Published/Accepted Manuscripts

**S1400** On the Design, Conduct, and Lessons Learned from Lung-MAP (SWOG S1400): A Biomarker-Driven Master Protocol to Evaluate Biomarker-Driven Therapies for Previously-Treated Squamous Lung Cancer. Redman M, Papadimitrakopoulou V, Minichiello K, Hirsch F, Mack

# Publication List by Committee

P, Schwartz L, Vokes E, Ramalingam S, Leighl N, Bradley J, Miao J, Moon J, Highleyman L, Miwa C, LeBlanc M, Malik S, Miller V, Sigal E, Adam S, Wholley D, Blanke CD, Kelly K, Gandara D, Herbst RS. Lancet Oncology, accepted 2020.

## Submitted Manuscripts

**S1206 (8811)** A dose-finding study followed by a phase II randomized, placebo-controlled trial of chemoradiotherapy with or without veliparib in stage III non-small cell lung cancer: SWOG S1206 (8811). Argiris A, Miao J, Cristea M, Chen AM, Sands J, Decker R, Gettinger S, Daly M, Faller B, Albain K, Yanagihara R, Garland L, Byers L, Wang D, Koczywas M, Redman M, Kelly K, Gandara D. International Journal of Radiation Oncology, Biology, Physics, under review 2020.

**S1400A** SWOG S1400A (NCT #02154490): A phase II study of Durvalumab for previously treated patients with stage IV squamous cell lung cancer (Lung-MAP sub-study). Borghaei H, Redman M, Kelly K, Waqar S, Robert F, Kiefer G, Stella P, Minichiello K, Gandara D, Herbst RS, Papadimitrakopoulou V. Clinical Lung Cancer, submitted 2020.

**S1400G** A Phase II Study of Talazoparib in Patients with Homologous Recombination Repair Deficiency (HRRD) Positive Stage IV Squamous Cell Lung Cancer (Lung-MAP Sub-Study S1400G). Owonikoko T, Redman M, Byers L, Hirsch F, Mack P, Schwartz L, Bradley J, Stinchcombe T, Lleighl N, Al Baghdadi T, Lara P, Miao J, Kelly K, Ramalingam S, Herbst RS, Papadimitrakopoulou V, Gandara D. Clinical Cancer Research, under review 2020.

**S1400K** A Phase II Study of Telisotuzumab Vedotin (Teliso-V, Abbv-399) in Patients with C-Met Positive Stage I or Recurrent Squamous Cell Lung Cancer (Lung-MAP Sub-Study SWOG S1400K, NCT03574753). Waqar S, Redman M, Arnold SM, Hirsch FR, Mack PC, Schwartz LH, Gandara D, Stinchcombe T, Ramalingam S, Tanna S, Raddin R, Minichiello K, Kelly K, Bradley JD, Herbst RS, Papadimitrakopoulou V. Clinical Cancer Research, under review 2020.

**S1400GEN** Patient Knowledge and Expectations About Return of Genomic Results in a Biomarker-Driven Master Protocol Trial (LungMAP SWOG S1400GEN). Roth J, Trivedi M, Gray S, Patrick D, Delaney D, Watabayashi K, Litwin P, Shah P, Crew K, Yee M, Redman M, Unger J, Papadimitrakopoulou V, Johnson J, Kelly K, Gandara D, Herbst RS, Hershman D, Ramsey S. Journal of Oncology Practice, submitted 2020. [see also CCD Committee]

**S1403** Afatinib plus cetuximab versus afatinib alone for first-line treatment of EGFR-mutant non-small cell lung cancer: final results from SWOG S1403. Goldberg S, Redman M, Lilenbaum R, Politi K,

Stinchcombe T, Horn L, Chen E, Mashru S, Gettinger S, Melnick M, Herbst R, Baumgart M, Miao J, Moon J, Kelly K, Gandara D. Journal of Clinical Oncology, under revision for re-submission 2020.

## LYMPHOMA COMMITTEE

### Published/Accepted Manuscripts

**S0816** Potential Impact of Consolidation Radiation Therapy for Advanced Hodgkin Lymphoma: a Secondary Analysis of SWOG S0816. Ha CS, Leblanc M, Schoder H, Pinnix C, Brem E, Bartlett N, Evens AM, Hsi ED, Rimsza L, Leonard JP, Kahl BS, Li H, Smith SM, Constine LS, Friedberg JW. Leukemia & Lymphoma May 26;1-6, 2020. <https://pubmed.ncbi.nlm.nih.gov/32452714/>

**S1001** Positron Emission Tomography-Directed Therapy for Patients With Limited-Stage Diffuse Large B-Cell Lymphoma: Results of Intergroup National Clinical Trials Network Study S1001. Persky D, Li H, Stephens D, Park S, Bartlett N, Swinnen L, Barr P, Winegarden J, Constine L, Fitzgerald T, Leonard J, Kahl B, LeBlanc M, Song J, Fisher R, Rimsza L, Smith S, Miller T, Friedberg JW. Journal of Clinical Oncology Jul 13;JCO2000999. doi: 10.1200/JCO.20.00999. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/32658627/>

**CTS09177** Multicenter Study of Risk-Adapted Therapy With Dose-Adjusted EPOCH-R in Adults With Untreated Burkitt Lymphoma. Roschewski M, Dunleavy K, Abramson JS, Powell BL, Link B, Patel P, Bierman PJ, Jagadeesh D, Parekh S, Nagpal S, O'Brien TE, Mitsuyasu R, Peace D, Watson PR, Battini R, Hanna W, Melani C, Lucas AN, Steinberg SM, Pittaluga S, Jaffe ES, Friedberg JW, Kahl BS, Little R, Bartlett NL, Finale M, Noy A, Wilson WH. Journal of Clinical Oncology, Aug 1;38(22):2519-2529, 2020. <https://pubmed.ncbi.nlm.nih.gov/32453640/>

**C50303** Prognostic Value of InterimFDG-PET in Diffuse Large Cell Lymphoma: Results From the CALGB 50303 Clinical Trial. Schoder H, Polley M, Knopp M, Hall N, Kostakoglu L, Zhang J, Higley H, Kelloff G, Liu H, Zelenetz A, Cheson B, Wagner-Johnston N, Kahl B, Friedberg J, Hsi E, Leonard JP, Schwartz LH, Wilson W, Bartlett N. Blood Jun 18;135(25):2224-2234, 2020. <https://pubmed.ncbi.nlm.nih.gov/32232481/>

### Submitted Manuscripts

**S1826** A Phase III, Randomized Study of Nivolumab (Opdivo) Plus AVD or Brentuximab Vedotin (Adcetris) Plus AVD in Patients (Age  $\geq$  12 years) with Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma (SWOG Intergroup S1826). Herrera A, Kahl B. Hematologist [Clinical Trials Corner], submitted 2020.

# Publication List by Committee

**Multiple Studies\*** Reply to LTE, Interim PET assessment of advanced Hodgkin Lymphoma: is it sufficient? [Letter to Editor]. Stephens D, Schoder H, Li H, Friedberg J. *Journal of Nuclear Medicine*, submitted 2020. [\*S0816, S1826]

**E1412** Addition of Lenalidomide to R-CHOP (R2CHOP) Improves Outcomes in Newly Diagnosed Diffuse Large B-cell Lymphoma: ECOG-ACRIN Study E1412 a Randomized Phase 2 US Intergroup Study of R2CHOP vs R-CHOP. Nowakowski G, Hong F, Scott D, Macon W, King R, Habermann T, Wagner-Johnston M, Casulo C, Wade JL, III, Nagargoje G, Reynolds C, Cohen J, Khan N, Amengual J, Richards K, Little R, Leonard J, Friedberg JW, Kostakoglu L, Kahl B, Witzig T. *Journal of Clinical Oncology*, submitted 2020.

## MELANOMA COMMITTEE

### Published/Accepted Manuscripts

**S1320** Continuous compared to intermittent therapy for BRAF mutated melanoma. Algazi A, Othus M, Othus M, Daud A, Lo R, Mehnert J, Truong T-G, Conry R, Kendra K, Doolittle G, Clark J, Messino M, Moore D, Lao C, Faller B, Govindarajan R, Harker-Murray A, Dreisbach L, Moon J, Grossmann K, Ribas A. *Nature Medicine*, accepted 2020.

### 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*, under review 2020.

## PHARMACEUTICAL SCIENCES COMMITTEE

### Published/Accepted Manuscripts

**Multiple Studies** Development of a tool for detecting drug-drug interactions during oncology clinical trial enrollment eligibility screening. Marcath LA, Coe T, Shakeel F, Reynolds E, Bayuk M, Haas S, Redman BG, Wong S-F, Hertz DL. *Journal of Patient Safety*, accepted 2020.

### Submitted Manuscripts

**Multiple Studies** Drug-drug interactions in subjects enrolled in SWOG trials of oral chemotherapy. Marcath LA, Finley C, Wong S-F, Hertz DL. *BMC Cancer*, under review 2020.

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