



It is impossible to understate the impact of immunotherapy on our patients, and on the cancer research community. Immunotherapy is dominating everything - research articles and conferences, grant review processes, and clinical trials. And it's keeping the U.S. Food and Drug Administration busy. There are now over 30 FDA-approved immunotherapies available to treat more than 20 different cancers,

including melanoma, lymphoma, leukemia, and lung, prostate, bladder, and kidney neoplasms.

At SWOG, we're in the process of creating a new research support committee dedicated to studying immunotherapy, one that will help our investigators and other members keep current with immunotherapy translational science, identify resources, and build partnerships. Here in San Francisco, you'll be hearing a lot on this topic.

At Plenary I, Ignacio Wistuba, MD, from MD Anderson Cancer Center, will explain how we can leverage the National Cancer Institute's Cancer Immune Monitoring and Analysis Centers (CIMACs) and the Cancer Immunologic Data Commons, (CIDC) which provide cutting-edge technology and expertise in genomic, proteomic, and functional molecular analysis, to enhance our



clinical trials. Also at that plenary, Peter O'Dwyer, MD, co-chair of ECOG-ACRIN and co-PI for the NCI-MATCH trial, will discuss the evolution of MATCH and give us some updates on the upcoming IMMUNO-MATCH.

Thanks to SWOG member Virginia Sun, RN, PhD, all SWOG members are welcome to attend a special symposium on immune-

related adverse events (IRAEs). The event aims to improve our understanding of the mechanisms, management, cardiovascular toxicities, and research gaps in IRAEs. This symposium is being offered thanks to a grant from The Hope Foundation for Cancer Research.

Our spring meeting also features the return of our fun run and walk along the Embarcadero, as well as a celebration of the 10th anniversary of the SWOG Latin America Initiative. Please enjoy this time with friends and colleagues, and take in the magical light and rhythms of San Francisco.

Thank you for joining us,

Charles D. Blanke, MD

Chalo Ble My

SWOG Chair



Group Meeting Index

Plenary Sessions	4, 19 & 21
Special Sessions	5-7
Jeri & Noboru Oishi Symposium	9 & 18
CME Credit Information	12 - 13
Hyatt Regency Travel and Hotel Information and Hotel Ma	ps 15 - 17
Clinical Trials Training Course	18
Schedule of Events	18 - 22
Future Meeting Dates	22
SWOG Administrative and Research Support Committees	23
Committee information:	
Adolescent and Young Adult (AYA) Committee	19
Barlogie-Salmon Myeloma Committee	19, 20 & 26 - 27
Breast Committee	19, 21 & 28 - 32
Board of Governors	22
Bone Marrow & Stem Cell Transplantation Committee	21
Cancer Care Delivery Committee	19 & 35 - 36
Cancer Survivorship Committee	20 & 37
Committee Chairs	22
Conflict Management Committee	19
Data and Safety Monitoring Committee	20
Digital Engagement Committee	18
Early Therapeutics & Rare Cancers Committee	19, 20 & 44 - 45
Gastrointestinal Committee	20, 21 & 46 - 49
Genitourinary Committee	21, 22 & 50 - 53
Imaging Committee	20
Leukemia Committee	21, 22 & 54 - 56
Lung Committee	21, 22 & 57 - 61
Lymphoma Committee	19, 21 & 62 - 63
Melanoma Committee	20 & 64 - 67
Palliative & End of Life Care Committee	19 & 38
Patient Advocate Committee	18 & 33
Pharmaceutical Science Committee	20
Prevention & Epidemiology Committee	20 & 39 - 40
Professional Review Committee	20
Quality Assurance Committee	21
Radiation Oncology Committee	22
Recruitment & Retention Committee	21
Surgery Committee	10 & 21
Symptom Control & Quality of Life Committee	18 & 41 - 43
SWOG Publications	68 - 78





Meeting Plenary

Grand Ballroom (Street Level)

Plenary Part I

This spring's translational medicine plenary will take place Thursday, April 25, 3:30-5:00 p.m. in the Grand Ballroom. Speakers and topics include the following:

Plenary Part II

This spring's general plenary will take place Friday, April 26, 12:00-2:00 p.m. in the Grand Ballroom. Speakers and topics include the following:

Welcome and Introduction Lee M. Ellis, MD, FASCO

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



Chair's Welcome and Update Charles D. Blanke, MD, FASCO Group Chair SWOG Cancer Research Network

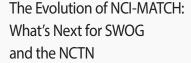


Ignacio I. Wistuba, MD Chair, Department of Translational Molecular Pathology University of Texas MD Anderson Cancer Center



Memorial Tribute to Charles A. Coltman, Jr., MD John Crowley, PhD Chief of Strategic Alliances Cancer Research And Biostatistics Former Group Statistician

SWOG Cancer Research Network



Peter J. O'Dwyer, MD

Director, Developmental Therapeutics Program University of Pennsylvania Abramson Cancer Center Study Co-Chair, NCI-MATCH ECOG-ACRIN Cancer Research Group



Celebrating the Achievements of Anne F. Schott, MD James M. Rae, PhD

SWOG Executive Officer for Translational Medicine The University of Michigan

Synthetic Lethal Approaches to Targeting DNA Repair **Deficiencies in Cancer**

Alan Ashworth, PhD, FRS

President, Helen Diller Family Comprehensive Cancer Center University of California San Francisco





Precisionalized" Cancer Therapies: The Next Frontier

Razelle Kurzrock, MD

Senior Deputy Director for Clinical Science Director, Center for Personalized Cancer Therapy & Clinical Trials Office University of California San Diego **Moores Cancer Center**



Special Sessions All Members Welcome!

Immune-Related Adverse Events Symposium

Friday, April 26 | 10 a.m. – 12:00 p.m. | Seacliff A-C (Bay Level)

The use of immunotherapies is exploding - and immune-related adverse events (IRAEs) are also on the rise.

Hear from a panel of experts about the mechanisms, management, and research gaps in IRAEs.

All members are welcome to attend this interdisciplinary and collaborative session.

This symposium is co-sponsored by SWOG's Immunotherapy Committee in Development,

Symptom Control and Quality of Life Committee,

and Nursing Research Subcommittee.

Topics and speakers include:

Overview of Immune-Related Adverse Events Margaret Gatti-Mays, MD, MPH National Cancer Institute Cardiotoxicities Associated with Immune Checkpoint Inhibitors: Emerging Evidence Javid J. Moslehi, MD

Vanderbilt University Medical Center

Patient-Centered Management of Immune-Related Adverse Events Marianne J. Davies, DNP, MSN, RN, APRN, CNS-BC, ACNP-BC, AOCNP Yale University

Pre-registration is required

PRESENTED WITH THE HOPE
SUPPORT FROM FOR CANCER RESEARCH



S1826 Kick-Off Meeting

Friday, April 26, 2019 | 9:30 – 10:30 a.m. | Pacific DE (Pacific Concourse Level)

Open To All SWOG Members; Suggested for Site Staff Interested in Opening the Trial

A Phase III, Randomized Trial of Nivolumab (Opdivo) or Brentuximab Vedotin (Adcetris) Plus AVD in Patients (Age ≥ 12 Years) With Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma

This session provides an overview of an upcoming lymphoma trial that will examine progression-free survival in adult and adolescent and young adult patients with previously untreated Stage III or Stage IV classical Hodgkin lymphoma.

\$1826 is scheduled to activate in June 2019. It is the largest National Clinical Trials Network trial ever undertaken for Hodgkin lymphoma.

S1826 Study Chair Dr. Alex Herrera, MD, of City of Hope, will discuss the trial goals, design, patient eligibility, and planned correlatives.

Over four years, Dr. Herrera and his team plan to enroll up to 987 patients ages 12 years and older in the U.S. and Canada. S1826 has support from four other National Clinical Trials Network groups – Alliance for Clinical Trials in Oncology, Children's Oncology Group, Canadian Cancer Trials Group, and ECOG-ACRIN Cancer Research Group.

\$1826 will randomize patients into two groups — those who receive six cycles of AVD chemotherapy plus either nivolumab (Opdivo) or brentuximab vedotin (Adcetris). The main goal is to compare progression-free survival between these groups.

Secondary objectives will include comparing response rates, event-free survival, and overall survival. The trial also has important correlative endpoints, and will measure quality of life through patientreported fatigue, neuropathy, health-related quality of life, and patient-reported symptoms over time. With patient's consent, \$1826 will also collect and bank PET-CT images and bio-specimens for future planned imaging and translational medicine objectives.

ROBERT B. LIVINGSTON

Translational Breast and Lung Cancer Lectureship

Saturday, April 27 | Lung Committee Meeting | Bayview Room (on the Bay Level) 2019 Speaker: David R. Gandara, MD

"Evolution of Immunophenotyping for Therapeutic Decision-Making in Advanced NSCLC"

CREDIT: OBR ONCOLOG



David R. Gandara, MD

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.



Are Patients Taking Their Medication?

Are The Drugs Effective?

A "Digital Pill"
Can Provide Answers



Thursday, April 25 | 12:30 – 1:30 p.m. | Seacliff D (Bay Level)

All SWOG Members Are Welcome To Attend; No Registration Necessary

S1916 is an innovative pilot study on a timely topic.

It will use digital medicine — consisting of an ingestible sensor, a wearable sensor patch, a mobile app, and a physician web portal — to track adherence to opioids prescribed to reduce pain from cancer treatment, as well as give physicians access to objective data that will help them alter drug dose or frequency. Data generated by the sensor, ingested along with the opioids, can also measure treatment effectiveness. Opioids are often a necessary part of a pain relief plan for cancer patients, but due to concerns about addiction, oncologists are seeking information on the safest, most effective ways to use these important drugs.

The pilot study is led by the SWOG Cancer Care Delivery Committee, and is scheduled to start enrolling this summer. Larger studies are being planned using this technology.

This SWOG trial is the first to test this system in a cancer clinical trial.

At this session, representatives from Proteus Digital Health will explain how the technologies work, and how they can be used to measure, manage, and improve the health of patients. Proteus Health technology is currently in use in sensor-enhanced chemotherapy treatments for people with colorectal cancer. The technology is also being marketed to help medication adherence in patients

with chronic conditions such as diabetes and hypertension.

Federal Site Payment Transition - Office Hours

Thursday, April 25th | 5:00pm - 6:00pm | Pacific A (Pacific Concourse Level)

Due to changes mandated by the National Cancer Institute, SWOG Cancer Research Network is changing the way it sends federal funds in 2019 to its member sites, moving from purchase service agreements (PSA's) to a fixed-price sub-award system.

What will this mean for you? Site staff are encouraged to drop by and talk with the SWOG grants team,

Pat Mize and Kyle Theige, to learn more about the new process.

No registration necessary. Just stop in!



INTERNATIONAL INITIATIVE CELEBRATES

A Decade of Service

The SWOG Latin America Initiative

was founded in 2009 by former group chair Larry Baker, DO, and former group statistician John Crowley, PhD. The first SWOG executive officer to oversee SLAI was Manuel Valdivieso, MD, and the position is now held by Alejandro Mohar, MD.

Since its founding, the cancer

institutes of Mexico, Colombia, and Peru have signed on as members — and more than 500 researchers in those countries have taken part in biostatistics and clinical trials training courses managed by SWOG staff. SLAI has sponsored two scientific research conferences.

has sponsored two scientific research conferences, one in Mexico and one in Colombia, with plans for a third in Chile later this year.

The goal of SLAI is simple: Train researchers in Latin America to run their own trials, and learn from these researchers to improve SWOG trials for Latinos.

The Hope Foundation for Cancer Research supports this initiative.

LA INICIATIVA INTERNACIONAL CELEBRA

Una Década de Servicio

La Iniciativa de SWOG para América Latina fue

fundada en 2009 por nuestro anterior presidente del grupo, el Dr. Larry Baker, el entonces estadístico del grupo SWOG,

el Dr. John Crowley, quien aún se encuentra activo en el liderazgo de la iniciativa y el entonces director ejecutivo de asuntos internacionales, el Dr. Manuel Valdivieso. El Dr. Alejandro Mohar, es el

nuevo oficial ejecutivo que supervisa esta iniciativa.

Desde su fundación, los institutos de cancerología de México, Colombia, y Perú se han inscrito como miembros y más de 500 investigadores de esos países han participado en cursos de capacitación en bioestadística y ensayos clínicos administrados por el personal de SWOG. SLAI ha patrocinado dos conferencias de investigación científica, una en México y otra en Colombia, con planes para una tercera en Chile a finales de este año.

El objetivo de SLAI es simple: respaldar los ensayos clínicos en esta región. El cáncer no tiene límites, como tampoco los ensayos clínicos en cáncer.

2009

Dr. Baker, Dr. Crowley and Dr. Valdivieso launch SLAI

Dr. Valdivieso becomes SWOG executive officer for international affairs

1st SWOG study activation in Chile, Colombia, Costa Rica, Honduras, Mexico and Nicaragua

SLAI Members from Guatemala attend YITC in Seattle

2010

INCan Mexico joins SWOG

2012

Dr. Baker, Dr. Crowley, and Dr. Valdivieso make a preliminary visit to Peru, Colombia, and Brazil for membership collaboration

Dr. Blanke becomes chair - elect and continues efforts

2013

INC- ESE Colombia joins SWOG

INEN - Peru joins SWOG

2015

SLAI members from Mexico and Colombia attend YITC in Seattle

2016

First biostatistical and clinical trials training program in Mexico

Second biostatistical and clinical trials training program in Peru

Peru establishes national cancer plan — Plan Esperanza (Hope Plan)

Third biostatistical and clinical trials training program in Colombia

2017

First Annual SLAI Scientific Research Conference in Mexico

Preliminary visit to Chile and Uruguay for membership collaboration

2018

Dr. Alejandro Mohar is appointed SWOG executive officer for international affairs

SLAI members from Mexico, Peru and Colombia attend YITC in Seattle

Second Annual SLAI Scientific Research Conference in Colombia

2019

Chile and Uruguay submit SWOG membership applications for approval

Third Annual SLAI Scientific Research Conference in Chile (Nov 2019)



Jeri and Noboru Oishi Symposium

A special session organized by the Oncology Research Professionals Committee

April 25 | 8:00 – 11:30 a.m. | Grand BC (Street Level)

Open to All Members

7:30 - 8:00	Registration	10:15 - 10:30	Break
<u>8:00 - 8:10</u>	Welcome and Introductions Keisha Humphries RN, BSN, MHCL, OCN Chair, Oncology Research Professionals Committee	10:30 - 11:00	Data Query Processing and CIRB for Protocol Integration <i>Martha Hering, RN, CCRP</i> Cancer Trials Support Unit, National Cancer Institute
8:10 - 9:00	Drug-Drug Interaction Database	11:00 - 11:30	Panel Discussion: Common Mistakes in
	Dan Hertz, PharmD, PhD Assistant Professor		Clinical Trials – Real Life Stories
	University of Michigan College of Pharmacy Yarden Ginsburg, MS		Amanda Dinsdale, MS, CCRP Montana NCORP
	Clinical Research Coordinator University of Michigan		Keisha Humphries, RN, BSN, MHCL, OCN Wichita NCORP
9:00 - 10:15	SWOG – Data Operations & Statistical Center (SDMC)		Connie Szczepanek, RN, BSN Cancer Research Consortium of West Michigan NCORP
	 Center update Reports for sites: DQP vs. Expectation reports Specimen tracking: Addressing quality errors Removal from protocol treatment vs. consent 		Joyce Tull, MSN, RN, CCRP University of Southern California Norris Comprehensive Cancer Center



When: 6 a.m. on Thursday, April 25.

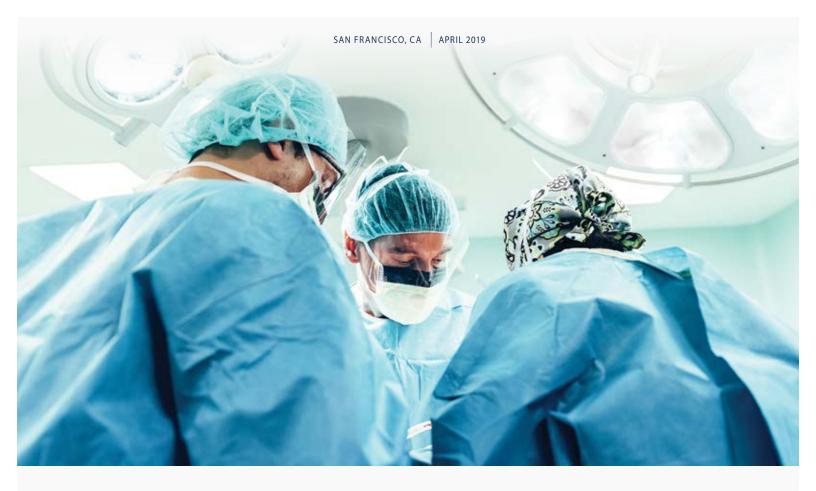
Where: Meet up in the Grand Ballroom Foyer of the hotel to sign in. At 6:15 a.m., we will walk to the race start.

What: The course will follow the Embarcadero, with views of San Francisco Bay and Alcatraz Island, with people watching along the piers.

The company SF Runs will divide participants into starting groups based on run and walk times.

Sign up at the registration desk and join us for some fresh air.





SWOG surgical trials & collaboration

Educational Session: Surgery Committee

Friday, April 26, 2019 | 2:00 p.m. – 4:00 p.m. | Waterfront CD (Atrium Lobby Level)

American Hepato-Pancreato-Biliary Association (AHBPA)-SWOG: Potential Future Areas of Collaboration

Adam Yopp, MD
Assistant Professor of Surgery
UT Southwestern

ECOG Update: Concepts in Esophageal, Rectal Cancer and Gastric HIPEC

Charles Staley, MDProfessor Surgery, Department of Surgery
Emory University

Is There a Role for Adjuvant Treatment in Pancreatic Neuroendocrine Tumors (NETs)?

Heloisa Soares, MD, PhD
GI Clinical Working Group Leader
University of New Mexico Comprehensive Cancer Center

Neoadjuvant Therapy for Cholangiocarcinoma

Flavio Rocha, MD

Clinical Associate Professor of Surgery University of Washington Virginia Mason Medical Center

Second Look Laparoscopy in Patients with High Risk Colon Cancer

Colette R. Pameijer, MDAssociate Professor of Surgery
Penn State College of Medicine

Phase I Palliative Laproscopic HIPEC trial

Jeremiah L. Deneve, DO, FACSAssociate Professor of Surgery
University of Tennessee Health Science Center



What We Do

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

What We Believe

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

Michael LeBlanc, PhD
Group Statistician
Fred Hutchinson Cancer
Research Center



Procedures for CME Credit

Group Meeting Target Audience and Educational Objectives

SWOG meets semi-annually to keep its members abreast of group science. The target audience for these meetings are physicians, nurse oncologists and clinical research associates.

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

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

Continuing Medical Education Credit

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

The Hope Foundation designates this live activity for a maximum of **24.0 AMA PRA Category 1 Credits.™** Physicians should only claim credit commensurate with the extent of their participation in the activity.



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

- Visit: http://swog.org/Members/CMECertification.asp
- Complete the evaluation questions
- Enter the credits being claimed
- Press "submit"

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



Track Your CME Credits

Time	Session Title		edits Actual
Time	THURSDAY, APRIL 25, 2019	Tranable	/ tetaai
	1110N3DA1, AFRIL 23, 2019		
8:00 am – 10:00 am	Symptom Control and Quality of Life Committee	2.0	
10:00 am – 12:15 pm	Early Therapeutics and Rare Cancers Committee	2.25	
10:15 am – 12:15 pm	Palliative and End of Life Care Committee	2.0	
3:30 pm - 5:00 pm	Plenary I (Translational Medicine)	1.0	
5:00 pm - 7:00 pm	Cancer Care Delivery Committee	2.0	
	FRIDAY, APRIL 26, 2019		
7:30 am – 9:30 am	Cancer Survivorship Committee	2.0	
7:30 am – 9:30 am	Barlogie-Salmon Myeloma Committee	2.0	
9:30 am – 11:30 am	Melanoma Committee	2.0	
9:45 am – 11:45 am	Prevention and Epidemiology Committee	2.0	
12:00 pm - 2:00 pm	Plenary II (General)	2.0	
2:00 pm - 4:00 pm	Surgery Committee	2.0	
2:15 pm - 5:15 pm	Breast Committee	3.0	
3:30 pm - 7:15 pm	GU Committee Part I	3.75	
4:00 pm - 6:00 pm	GI Committee	2.0	
4:00 pm - 7:00 pm	Lymphoma Committee	2.5	
	SATURDAY, APRIL 27, 2019		
9:30 am - 11:30 am	Radiation Oncology Committee	2.0	
9:30 am – 11:30 am	Leukemia Committee	2.0	
9:30 am - 12:00 pm	GU Committee Part II	2.5	
9:30 am - 12:30 pm	Lung Committee	3.0	
	Total Possible Credits		24.0





Thanks To

Our Top Accruers

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

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

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

SWOG NCORP Sites

1

Michigan CRC NCORP

2

Heartland NCORP Illinois

3

New Mexico MU-NCORP

4

Wisconsin NCORP

5

Kaiser Permanente NCORP California



A program of the National Cancer Institute of the National Institutes of Health SWOG Lead Academic Partner and Member Sites



MD Anderson Cancer Center



University of Kansas Cancer Center



Huntsman Cancer Institute at University of Utah



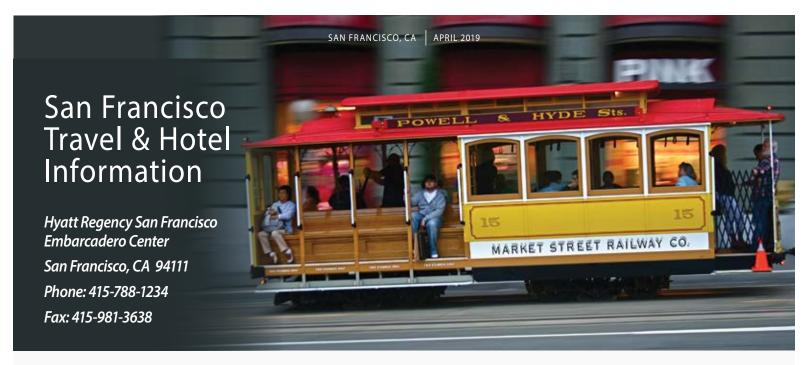
Yale Cancer Center



University of Michigan Rogel Cancer Center







Arrival/Departure:

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

Hotel Safety Deposit Boxes:

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

Recreational Facilities:

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

Hotel Restaurants and Lounges:

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

Business Center:

The Business Center is located on the Atrium Lobby level of the hotel. It is open 24 hours a day, 7 days a week. The Business Center offers fax machines, computer services, color copies, mail drop, Internet access and photo- copying.

Ground Transportation:

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

Temperature:

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

Area Attractions:

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

Local Restaurants:

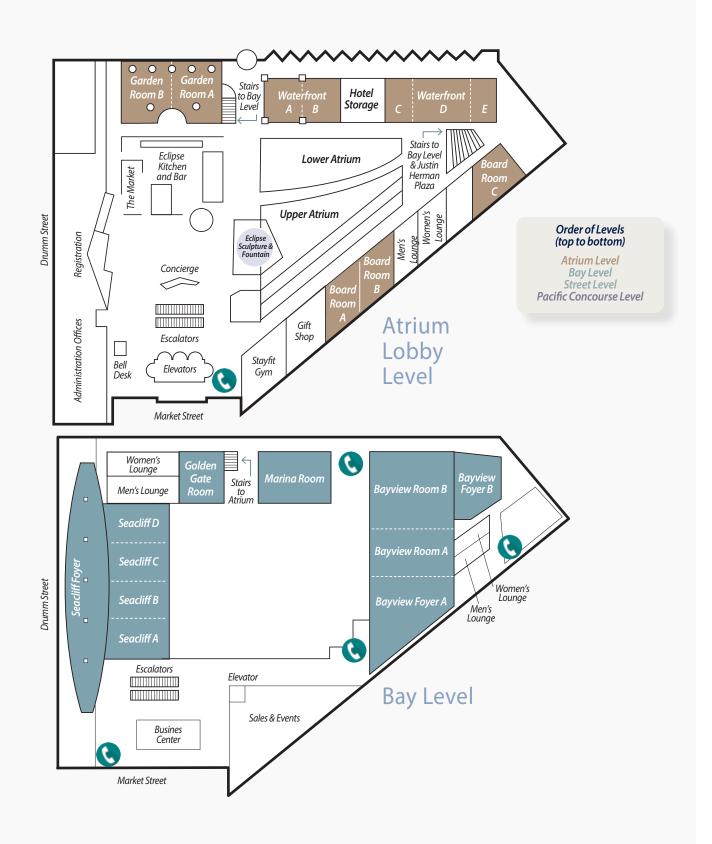
(The hotel concierge can assist with reservations and suggestions)

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



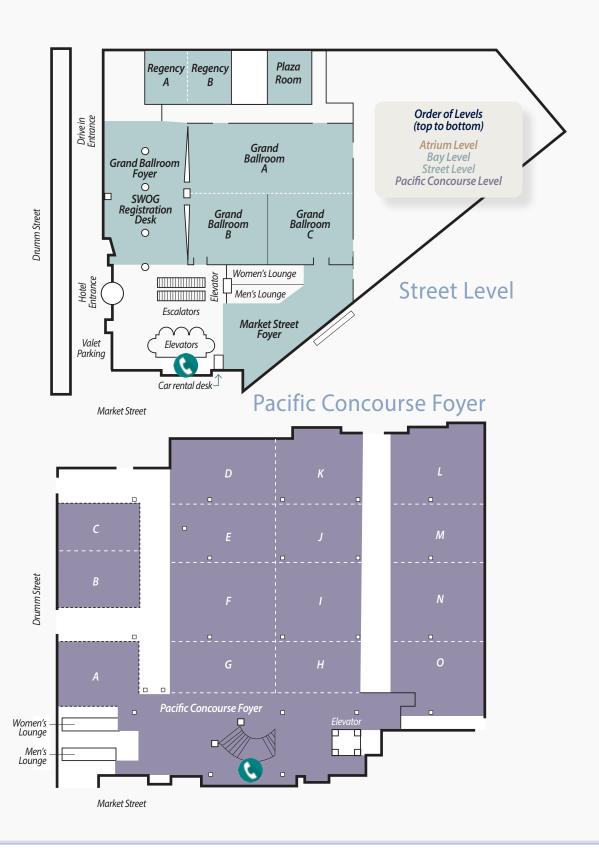
Hyatt Regency San Francisco Floor Levels

Embarcadero Center | San Francisco, CA 94111 | Phone: 415-788-1234 | Fax: 415-981-3638



Hyatt Regency San Francisco Meeting Rooms

Embarcadero Center | San Francisco, CA 94111 | Phone: 415-788-1234 | Fax: 415-981-3638





WEDNESDAY, APRIL 24, 2019

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

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

Plaza Room, Street Level

ITSC Steering Committee (Cmte Members Only)

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

Grand B Foyer, Street Level CRA Clinical Trials Training Course

Check-In

7:30 A.M. – 12:00 P.M.

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

Grand A, Street Level CRA Clinical Trials Training Course

Seacliff D, Bay Level SoCRA Certification Examination

12:00 P.M. – 2:00 P.M.

Waterfront AB, Atrium Level Core Office Staff Meeting

(Invitation Only)

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

Plaza Room, Street Level Nursing Research Subcommittee

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

Grand BC, Street Level CRA Clinical Trials Training Course

Practicum

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

Boardroom B, Atrium Level ORP Liaison Subcommittee

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

Garden A, Atrium Level SWOG Tissue Banking Meeting

(Invitation Only)

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

Garden B, Atrium Level ORP Executive Committee

(Cmte Members Only)

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

Regency B, Street Level Hope Foundation Board Meeting

(Board Members Only)

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

Seacliff A-C, Bay Level Site Operations (Open Session)

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

Waterfront CDE, Atrium Level NCORP Research Base Executive

Committee Meeting (Cmte

Members Only)

THURSDAY, APRIL 25, 2019

Group Meeting Registration & Information Desk

7:00 a.m.- 5:00 p.m.— Grand Foyer, Street Level

Hope Foundation Information Desk

8:00 a.m.- 5:00 p.m.— Grand Foyer, Street Level

Exhibits & Complimentary Coffee Service

7:00 a.m.- 4:00 p.m.— Grand Foyer, Street Level

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

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

Walk

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

Seacliff D, Bay Level Advocates Committee Meeting

(Cmte Members Only)

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

Grand B Foyer, Street Level Jeri & Noboru Oishi Symposium

Check-In

8:00 A.M. - 11:30 A.M.

Grand BC, Street Level Jeri & Noboru Oishi Symposium

8:00 A.M. – 10:00 A.M.

Seacliff A-C, Bay Level SYMPTOM CONTROL AND

QUALITY OF LIFE COMMITTEE

8:30 A.M. – 10:00 A.M.

Waterfront AB, Atrium Level Survivorship Liaisons Meeting

(Invitation Only)

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

Pacific K, Pacific Concourse Level Digital Engagement Committee

(Cmte Members Only)

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

Plaza Room, Street Level Qua

Quality Initiative Meeting (Cmte Members Only)



10:00 A.M. – 12:15 P.M.

Bayview B, Bay Level EARLY THERAPEUTICS AND RARE

CANCERS COMMITTEE

1:30 P.M. – 3:30 P.M.

Waterfront DE, Atrium Level Breast Working Group (Working

Group Members Only)

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

Seacliff A-C, Bay Level PALLIATIVE AND END OF LIFE CARE

COMMITTEE

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

Pacific G, Pacific Concourse Level Lung Community Engagement

Subcommittee (Working Group

Members only)

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

Pacific J, Pacific Concourse Level RUSTIC Protocol Planning Meeting

(Invitation Only)

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

Golden Gate, Bay Level ORP Education Subcommittee

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

Pacific BC, Pacific Concourse Level S1714 Protocol Training

2:30 P.M. – 3:30 P.M.

Grand Foyer, Street Level Plenary Reception

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

Pacific I, Pacific Concourse Level Lung-MAP Site Coordinators

Committee (Cmte Members Only)

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

Grand Ballroom, Street Level PLENARY I (TRANSLATIONAL

MEDICINE)

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

Garden Room, Atrium Level Leadership Academy (Invitation

Only)

5:00 P.M. - 6:00 P.M.

Pacific F, Pacific Concourse Level Lung Executive Subcommittee

(Cmte Members Only)

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

Seacliff D, Bay Level S1916 Digital Medicine Program

Demonstration

5:00 P.M. – 6:00 P.M.

Pacific A, Pacific Concourse Level Federal Site Payment Transition

Office Hours (Open for Drop-Ins)

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

Pacific M, Pacific Concourse Level ORP Open Forum

5:00 P.M. – 7:00 P.M.

Plaza Room, Street Level Conflict Management Committee

(Cmte Members Only)

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

Pacific L, Pacific Concourse Level Adolescent and Young Adult (AYA)

Committee

5:00 P.M. – 7:00 P.M.

Seacliff D, Bay Level Lymphoma Working Group

(Working Group Members Only)

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

Waterfront AB, Atrium Level Myeloma Working Group (Working

Group Members Only)

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

Seacliff A-C, Bay Level CANCER CARE DELIVERY

COMMITTEE

1:00 P.M. - 2:00 P.M.

Marina, Bay Level S1316 and S1820 Protocol Updates

Meeting

6:00 P.M. – 8:00 P.M.

Garden Room, Atrium Level TM Chair Roundtable Discussion &

Strategic Planning (Invitation Only)

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

Pacific D, Pacific Concourse Level Immunotherapeutics Committee

(Cmte Members Only)

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

Pacific H, Pacific Concourse Level S1415CD Protocol Update Meeting



6:00 P.M. - 9:00 P.M.

Waterfront AB, Atrium Level Latin America Symposium

(Invitation Only)

7:30 P.M. – 9:30 P.M.

Plaza Room, Street Level Coltman Fellowship Committee

(Cmte Members Only)

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

Pacific D, Pacific Concourse Level Early Therapeutics Working Group

(Invitation Only)

FRIDAY, APRIL 26, 2019

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

Hope Foundation Information Desk

8:00 a.m.- 5:00 p.m.— Grand Foyer, Street Level

Exhibits & Complimentary Coffee Service

Exhibits & Complimentary Coffee Service 7:00 a.m.- 4:00 p.m.— Grand Foyer, Street Level

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

Pacific I, Pacific Concourse Level Drug Information Subcommittee

and Pharmacy Working Group (Working Group Members Only)

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

Garden Room, Atrium Level CANCER SURVIVORSHIP

COMMITTEE

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

Seacliff A-C, Bay Level BARLOGIE-SALMON MYELOMA

COMMITTEE

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

Pacific BC, Pacific Concourse Level Melanoma Working Group

(Working Group Members Only)

7:30 A.M. – 9:30 A.M.

Golden Gate, Bay Level Imaging Committee (Cmte

Members Only)

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

Marina, Bay Level Lung-MAP Administrative Meeting

(Invitation Only)

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

Plaza Room, Street Level SWOG Data and Safety Monitoring

Committee (Cmte Members Only)

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

Bayview A, Bay Level S1806 Update Meeting

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

Boardroom B, Atrium Level Professional Review Committee

(Cmte Members Only)

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

Seacliff D, Bay Level Lung Surgery Subcommittee

(Working Group Members Only)

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

Pacific I, Pacific Concourse Level Pharmaceutical Sciences

Committee

9:00 A.M. - 12:00 P.M.

Pacific LM, Pacific Concourse Level Breast Translational Medicine

Working Group (Working Group

Members Only)

9:00 A.M. - 12:00 P.M.

Waterfront AB, Atrium Level New GU Investigator Workshop

(Invitation Only)

9:00 A.M. - 12:00 P.M.

Waterfront CDE, Atrium Level Gl Working Group (Working Group

Members Only)

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

Pacific DE, Pacific Concourse Level \$1826 Kick-Off Meeting

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

Bayview B, Bay Level MELANOMA COMMITTEE

9:45 A.M. – 11:45 A.M.

Garden Room, Atrium Level PREVENTION AND EPIDEMIOLOGY

COMMITTEE

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

Seacliff D, Bay Level Lung Radiation Subcommittee

(Working Group Members Only)



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

Pacific O, Pacific Concourse Level Quality Assurance Committee

(Cmte Members Only)

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

Seacliff A-C, Bay Level Immune-Related Adverse Events

Symposium: Interdisciplinary

Management and Research

10:30 A.M. – 12:00 P.M.

Bone Marrow & Stem Cell

Transplantation Committee

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

Plaza Room, Street Level Publications Committee

(Cmte Members Only)

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

Pacific N, Pacific Concourse Level Lung Translational Medicine

Subcommittee (Working Group

Members Only)

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

Grand Foyer, Street Level Plenary Reception (Light Hors

D'oeuvres)

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

Grand Ballroom, Street Level PLENARY II (GENERAL)

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

Pacific G, Pacific Concourse Level Cardiotoxicity Panel

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

Pacific K. Pacific Concourse Level Gl Translational

Medicine Working Group (Working Group

Members Only)

2:00 P.M. – 4:00 P.M.

Waterfront CD, Atrium Level SURGERY COMMITTEE

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

Garden Room, Atrium Level NCORP/MU-NCORP Site PI Meeting

2:15 P.M. - 5:15 P.M.

BREAST COMMITTEE

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

Seacliff Room, Bay Level Lung-MAP Update Meeting

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

Pacific N, Pacific Concourse Level VA Working Group (Invitation

Only)

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

Pacific I, Pacific Concourse Level ORP Planning Meeting (Cmte

Members Only)

3:30 P.M. - 7:15 P.M.

Grand A, Street Level GU COMMITTEE PART I: Renal

Cancer Organ Site (3:30-5:15); TM Organ Site (5:15-6:30); Cancer

Control (6:30-7:15)

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

Grand B, Street Level GI COMMITTEE

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

Waterfront AB, Atrium Level Leukemia Working Group

(Working Group Members Only)

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

Pacific O, Pacific Concourse Level Recruitment and Retention

Committee Meeting

4:00 P.M. - 7:00 P.M.

Grand C, Street Level LYMPHOMA COMMITTEE

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

Pacific LM, Pacific Concourse Level Lung Working Group (Working

Group Members Only)

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

Executive Reception (Invitation

Only)

6:45 P.M. – 8:00 P.M.

Atrium, Atrium Level Reception



Future Meeting Dates

2019 2020 October 2-5 April 22-25 Chicago, IL San Francisco, CA September 23-26 Chicago, IL 2021 2022 April 21-24 April 6-9 Seattle, WA San Francisco, CA October 13-16 October 19-22 Chicago, IL Chicago, IL 2023 2024 April 26-29 April 3-6 San Francisco, CA Seattle, WA October 11-14 October 16-19 Chicago, IL Chicago, IL



Schedule of Events

SATURDAY, APRIL 27, 2019

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

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

7:15 A.M. – 8:00 A.M.

Grand B, Street Level Board of Governors (Board Members Only)

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

Grand B, Street Level Committee Chairs (Cmte Chairs Only)

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

Waterfront AB, Atrium Level RADIATION ONCOLOGY

COMMITTEE

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

Seacliff Room, Bay Level LEUKEMIA COMMITTEE

9:30 A.M. - 12:00 P.M.

Grand A, Street Level GU COMMITTEE PART II: Bladder

Cancer Organ Site (9:30-11:00); Prostate Cancer Organ Site (11:00-

12:00

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

Bayview Room, Bay Level LUNG COMMITTEE

12:00 P.M. - 4:00 P.M.

Grand B, Street Level) Myeloid Neoplasms Precision

Medicine Initiative (Invitation

Only)





SWOG Administrative Committees

Administrative Committees

Board of Governors

Charles D. Blanke, MD

Conflict Management

Paul Okunieff, MD

Publications

Hagen F. Kennecke, MD

Professional ReviewPaul Hesketh, MD

Research Support Committees

Adolescent and Young Adult

Mark A. Lewis, MD Becky Johnson, MD

Bone Marrow and Stem Cell Transplantation Patrick J. Stiff, MD

Digital EngagementDon S. Dizon, MD

ImagingLawrence H. Schwartz, MD

Oncology Research Professionals

Keisha Humphries, RN, BSN

Patient AdvocatesRick Bangs, MBA

Pharmaceutical SciencesSiu-Fun Wong, PharmD

Radiation Oncology

Paul Okunieff, MD

Recruitment and Retention

Elise D. Cook, MD

Surgery

Syed A. Ahmed, MD



guidebook

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SAN FRANCISCO, CA APRIL 2019

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Barlogie-Salmon Myeloma Committee

Leadership

	· · ·
Vice-Chair:	Brian G.M. Durie, M.D.
Executive Officer	Susan M. O'Brien, M.D.
Statisticians:	
	Rachael Sexton, M.S.
	Kari Chansky, M.S.
Scientific Leadership	,
Translational Medicine:	Brian A. Walker, B.Sc., Ph.D.
Radiation:	
Surgery:	
Imaging:	
99	
Pathology:	, ,
Early Therapeutics:	
Designates	
Digital Engagement:	Saad 7 Usmani, M.D.
NCORP Representative:	
Data Coordinators:	
Oncology Research Professionals:	
CRA:	TRD
Nurses:	
TRUIDCS.	
Patient Advocate:	
Pharmaceutical Science:	
rnamaceutical science	
	5 5
Protocol Coordinator:	•
Clinical Trials Project Manager:	Crystal Milwa

Time/Location

Friday, April 26, 2019 7:30 a.m.- 9:30 a.m.

Room: Seacliff A-C (Bay Level)

Active Studies

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

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

CTSU/A061402, "Solitary Plasmacytoma of Bone: Randomized Phase III Trial to Evaluate Treatment with Adjuvant Systemic Treatment and Zoledronic Acid Versus Zoledronic Acid After Definite Radiation Therapy." Dr. Manasanch. Activated: 12/23/15.

Closed Studies

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

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

<u>S1304</u>, "A Phase II Randomized Study Comparing Two Doses of Carfilzomib (NSC-756640) with Dexamethasone for Multiple Myeloma Patients with Relapsed or Refractory Disease." Drs. Ailawadhi, Abidi, S. Lentzsch, et al. Activated: 10/18/13; Closed: 5/15/16.

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



Barlogie-Salmon Myeloma Committee

Cumulative Accrual by Institution and Study

Includes accrual through 2/18/2019. Includes studies that are currently open, or that closed since 7/1/2017.

	51211	51702	EIAII	E3A06
Arkansas, U of	_	_	3	_
Baylor College	_	_	9	_
Beaumont NCORP	_	_	6	_
Boston Medical Ctr	_	3	_	_
CORA NCORP	_	1	1	_
CRC West MI NCORP	1	_	_	_
City of Hope Med Ctr	7	_	_	_
Cleveland Clinic OH	10	_	_	_
Columbia MU-NCORP	_	1	_	_
Columbus NCORP	4	_	_	_
Davis, U of CA	_	_	26	_
Dayton NCORP	1	_	2	_
Essentia Hlth NCORP	1	_	_	_
Greenville NCORP	_	_	_	6
Hawaii MU-NCORP	_	_	1	_
Heartland NCORP	3	1	_	_
Henry Ford Hospital	_	_	15	1
Irvine, U of CA	_	_	6	1
Kaiser Perm NCORP	_	_	40	_
Kansas City NCORP	1	_	2	_
Kansas, U of	13	_	3	15
Loyola University	3	1	13	_
MD Anderson CC	10	_	_	_
Michigan CRC NCORP	5	_	_	_

	51211	51702	EIAII	E3A06
Michigan, U of	_	_	10	_
Montana NCORP	_	_	3	2
Nevada CRF NCORP	_	_	1	_
Oklahoma, Univ of	1	_	_	_
Oregon Hlth Sci Univ	_	2	4	_
Ozarks NCORP	2	_	6	1
PCRC NCORP	_	_	_	1
Providence Hosp	4	_	11	2
Rochester, Univ of	7	_	_	_
San Antonio, U of TX	15	_	9	_
San Diego, U of CA	_	_	1	_
So Calif, U of	2	_	_	_
Southeast COR NCORP	4	_	10	_
Sutter Cancer RC		_	6	_
Tennessee, U of	_	_	_	1
Tulane University	1	_	_	2
VAMC Kansas City	_	_	6	_
Wayne State Univ	3	1	13	_
Yale University	_	2	52	3
Alliance	10	1	_	_
ECOG-ACRIN	31	5	_	_
NRG	3	2	_	_
Total	142	20	259	35

Proposed Studies

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

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

<u>S1911</u>, "Randomized Phase III Study of Optimal Therapy for Newly Diagnosed High Risk Multiple Myeloma." Drs. Lipe and Usmani.

<u>S1927 (formally S1825)</u>, "Randomized Phase II Trial of Weekly Carfilzomib \pm Selinexor in Relapsed Multiple Myeloma (MM)." Dr. Zonder.

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

Open Forum Discussion

MRD testing & new response criteria in SWOG

Working Groups

Amyloidosis Working Group update

Waldenström's Working Group update

Myeloma Translational Medicine Subcommittee update



Leadership		
Chair: Lajos Pusztai, M.D., Ph.D.	Agenda	
Vice-Chair:	2:15 – 2:20 p.m.	Welcome and Introductions – Lajos Pusztai, M.D. D.Phil
Executive Officer:	•	·
Statisticians:William E. Barlow, Ph.D.	and Priyanka Sl	narma, IVI.D.
Mai Duong, M.S.		
Danika Lew, M.A.	Breast Comm	ittee Mini-Symposium Treatment de-escalation in
Jieling Miao, M.S.	Dieast Collins	breast cancer: New horizons
Scientific Leadership		breast cancer. New Horizons
Translational Medicine: Alastair M. Thompson, M.D.	2:20 – 2:35 p.m.	Optimal de-escalation clinical trial approaches: NCI
Andrew K. Godwin, Ph.D.		perspective – Larissa Korde, M.D.
Radiation Oncology:	2:35 – 2:50 p.m.	Role of PRO and toxicity assessment in de-escalation
Surgery:	2.33 2.30 p.iii.	strategies – Lynn Henry, M.D.
Imaging:Joanne E. Mortimer, M.D.		
	<u>2:50 – 3:05 p.m.</u>	Patient perspective – Ginny Mason, Patient Advocate
Pathology:	3:20 – 3:30 p.m.	Publications update – Bill Barlow, Ph.D.
Early Therapeutics:George Somlo, M.D.		•
Designates	3:30 – 4:20 p.m.	Update of open SWOG and SWOG-Championed CTSU
Cancer Control Liaisons: Melinda L. Irwin, Ph.D., M.P.H. (Survivorship)	trials – All	
Dawn L. Hershman, M.D. (Cancer Care Delivery)	4:30 – 4:50 p.m.	Studies in Development – All
Banu Arun, M.D. (Prevention)	4.50 5.05	Decreta from Committee Linians
	4:50 – 5:05 p.m.	Reports from Committee Liaisons
Digital Engagement: Sarah S. Mougalian, M.D.		Patient Advocate – Ginny Mason and Elda Railey
NCORP Representative:		Padiathorany Poshma lagsi M.D.
Data Coordinators:		Radiotherapy - Reshma Jagsi, M.D.
Larry KayeJacqueline Scurlock		Surgery - Christine Lee, M.D.
Oncology Research Professionals:		Cancer Survivorship -Melinda L. Irwin, Ph.D., M.P.H.
CRA: Karyn N. Hart, C.C.R.P.		•
Nurse:		Cancer Care Delivery - Dawn Hershman, M.D.
Patient Advocate: Ginny Mason, R.N., B.S.N.		Prevention – Banu Arun, M.D.
Elda Railey		Symptom Control & QOL- Helen K. Chew, M.D.
Pharmaceutical Science: Jessie Modlin, Pharm.D.		
Protocol Coordinator:		NCORP (NCI Community Oncology Research Program) –
Clinical Trials Project Manager:Vanessa Benavidez, B.S., C.C.R.C.		Philip Lammers, M.D.
Time/Location	<u>5:05 – 5:10 p.m.</u>	Translational Medicine Sub-Committee Update –
Friday, April 26, 2019 2:15 p.m 5:15 p.m.		Alastair Thompson, M.D. and Andrew K. Godwin, Ph.D
Room: Bayview Room (Bay Level)		•
	<u>5:10 – 5:15 p.m.</u>	New Business – All
	<u>5:15 p.m.</u>	Closing Comments and Adjourn



Active Studies

- 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.
- <u>S1418</u>, "A Randomized Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with ≥1 cm Residual Invasive Cancer or Positive Lymph Nodes (ypN+) After Neoadjuvant Chemotherapy." Drs. Pusztai and Mammen. Activated: 11/15/16.
- <u>S1706</u>, "A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy Alone for Inflammatory Breast Cancer." Dr. Jagsi. Activated: 9/12/18.
- 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 are Permanently Closed to Accrual, Effective 11/30/18.
- CTSU/A011202, "A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy." Dr. Boughey. SWOG Champion: Dr. Mammen. Activated: 2/7/14.
- CTSU/A011502, "A Randomized Phase III Double Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for Node Positive HER2 Negative Breast Cancer: The ABC Trial." Dr. Chen. SWOG Champion: Dr. Symington. Activated: 12/8/16.
- CTSU/A221405, "A Study Evaluating the Pregnancy Outcomes and Safety of Interrupting Endocrine Therapy for Young Women with Endocrine Responsive Breast Cancer who Desire Pregnancy." Dr. Pagani, SWOG champion Dr. Halle Moore. Activated: 10/15/15.
- CTSU/EA1131, "A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy vs. Capecitabine in Patients with Residual Triple-Negative Basal-Like Breast Cancer following Neoadjuvant Chemotherapy." Dr. Mayer. SWOG Champion: Dr. Rodler. Activated: 4/29/15.

- CTSU EA1151, "Tomosynthesis Mammographic Imaging Screening Trial (TMIST)." Dr. Pisano. SWOG Champion: Dr. Arun. Activated: 7/6/17.
- CTSU/NRG-BR002, "A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer." Drs. Chmura and White. SWOG Champion: Dr. Jagsi. Activated: 12/24/14.
- CTSU/NRG-BR003, "A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer." Dr. Valero. SWOG Champion: Dr. Makhoul. Activated: 6/26/15.
- CTSU/NRG- BR004, "A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer." Dr. Geyer. SWOG Champion: Dr. Cobain. Activated: 3/12/19.
- CTSU/NRG-BR005, "A Phase II Trial Assessing the Accuracy of Tumor Bed Biopsies in Predicting Pathologic Response in Patients with Clinical/Radiologic Complete Response after Neoadjuvant Chemotherapy in Order to Explore the Feasibility of Breast Conserving Treatment without Surgery." Dr. Basik. SWOG Champion: Dr. Thompson. Activated: 4/13/17.
- CTSU/NSABP-51, "A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chest wall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy." Drs. Mamounas and White. SWOG champion Dr Jagsi. Activated: 08/22/13.
- CTSU/NSABP-55, "Randomized, Double-Blind, Parallel Group, Placebo-Controlled Multi-Centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy." Drs. Geyer and Garber. SWOG Champion: Dr. Sharma. Activated: 7/3/14.



Cumulative Accrual by Institution and Study

Includes accrual through 2/18/2019. Includes studies that are currently open, or that closed since 7/1/2017.

	51007	51207	51416	51418	51706	A017106	A011202	A017407	A011502	A227405	B51	855	EIZII	E2112	EA1131	EA1151	NRGBROO2	NRGBR003	NRGBR005
Arizona MC, U of	_	14	_	_	_	31	1	1			_	_	_	_	_	_	MHO.	Mko.	Muo.
Arkansas, U of	22	16	_	7	_	2	_	2	_	_	_	_	_	_	_	_	_	_	_
Atlanta Reg CCOP	11	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Baptist MU-NCORP	1	5	1	1	_	12	1	7	_	_	_	_	1	1	_	_	_	1	_
Bay Area NCORP	3	1	_	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Baylor Univ Med Ctr	_	2	_	_	_	_	1	_	_	_	2	_	_	_	_	_	_	_	_
Beaumont NCORP	30	8	2	_	_	_	6	5	2	_	1	_	3	_	_	_	1	_	_
Boston Medical Ctr	_	2	_	_	_	_	_	1	_	_	_	_	_	_	_	_	_	_	_
Brooke Army Med Ctr	2	_	_	2	_	_	_	_	1	_	_	1	_	_	3	_	_	1	_
CORA NCORP	16	21	1	6	_	1	_	_	_	_	2	_	1	3	_	_	_	_	_
CRC West MI NCORP	7	10	3	13	_	_	_	1	_	_	_	_	2	_	_	_	_	_	_
Carle CC NCORP	_	12	2	2	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Cedars-Sinai Med Ctr	8	9	_	_	_	_	_	_	_	_	_	6	_	_	_	_	_	_	_
Cincinnati MC, U of	3	10	_	_	_	_	_	_	_	_	1	_	4	_	_	_	_	_	_
City of Hope Med Ctr	45	21	_	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Cleveland Clinic OH	27	12	8	2	_	_	_	_	_	_	1	2	_	18	_	_	_	7	_
Colorado, U of	29	16	4	8	_	15	32	16	4	9	3	2	2	_	_	_	_	_	2
Columbia MU-NCORP	16	6	_	3	_	_	_	_	_	_	_	_	17	2	_	_	_	_	_
Columbia University	2	_	_	_	_	_	_	_	_	_	_	_		_	_	_	_	_	_
Columbus NCORP	18	17	12	5	_	_	_	_	_	_	_	_	2	_	_	_	_	_	_
Davis, U of CA	8	7	11	4	_	_	2	_	12	_	_	_	1	_	_	_	_	_	_
Dayton NCORP	6	7	4	1	_	2	_	1	_	_	_	_	2	_	_	_	_	_	_
Desert Hospital	2	1	_	1	_	_	4	1	_	_	4	_		_	_	_	_	_	_
Essentia HIth NCORP	_	3	_	1	_	_		<u> </u>	_	_	_	_	_	_	_	_	_	_	_
Fred Hutchinson CRC	6	22	9	4	_	_	_	4	2	2	_	3	_	4	_	_	_	_	_
Georgia NCORP	_	2	_	7	_	_	_	2	_	_	_	_	8	_	_	_	_	_	_
Greenville NCORP	4	_	2	1	_	_	_	_	_	_	_	_	12	_	_	_	_	_	_
Gulf Coast MBCCOP	2	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Gulf South MU-NCORP	6	23	_	3	_	_	_	_	_	_	_	_	5	_	_	_	_	3	_
H Lee Moffitt CC	2	5	_	_	_	_	1	3	2	_	_	_	_	_	_	_	_	_	_
Harrington CC	2	3	_	2	_	_	9	4	_	_	_	_	_	_	_	_	_	_	_
Harrison Medical Ctr	9	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Hawaii MU-NCORP	12	13	_	_	_	_	_	_	_	_	_	_	23	_	_	_	_	_	_
Heartland NCORP	12	27	4	8	_	_	_	_	1	_	_	_	_	_	_	_	_	_	_
Henry Ford Hospital	11	6	_	_	_	_	_	_	_	_	_	_	_	1	1	_	_	_	_
INC, Bogota	11	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
INCan	96	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Intermountain MC	5	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Irvine, U of CA	21	11	_	1	_	3	3	2	_	_	_	_	_	_	_	_	_	_	_
Kaiser Perm NCORP	89	46	10	20	_	_	1	31	5	_	_	6	34	_	_	_	_	19	_
Kansas City NCORP	11	8	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Kansas, U of	33	51	_	10	_	_	5	15	_	_	_	2	_	9	_	_	_	1	1
Kentucky, U of	21	_	_	_	_	_	_	_	1	_	_	_	_	_	_	_	_	_	_
King Faisal Spec Hos	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Lahey Hosp & Med Ctr	19	4	_	1	_	_	_	4	2	_	_	_	_	_	_	_	_	_	_
Loma Linda Univ	5	10	_	_	_	1	2		_	_	3	_	_	_	_	_	_	_	_
Loyola University	30	15	2	3	_	_	_	4	_	_	1	_	_	_	1	_	_	_	_
Loyola Olliveisity			_								•								



Breast Committee, cont.

Cumulative Accrual by Institution and Study

Includes accrual through 2/18/2019. Includes studies that are currently open, or that closed since 7/1/2017.

	51007	51207	51416	51418	51706	A011706	4011202	A01740	4011502	A227405	B51	855	E1211	E2112	EA1131	EA1757	NRGBRO	NRGBRO	NRGBROOS
MAVERIC	٠,٠		۵,	۵,	5"	<i>VO.</i> .	Va.	VO.	1	ALL					Eu.	Eu.	NKOn.	NKGp.,	NKan.
MD Anderson CC	147	85		5			_												3
	21	14	8	8	_	1		_					5					_	3
MUSC MU-NCORP		- 14 	0	<u> </u>	_	'	_						,				_	_	
Madigan Army Med Ctr	3		_		_		_												_
Memorial Hermann	_	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Methodist Hospital	7	_		_	_	_	_	_		_	_	_	_	_	_	_		_	_
Michigan CRC NCORP	44	24	15	9	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Michigan, U of	29	21	8	5	_	_	_	8	5	_	_	1	11	_	_	_	_	3	_
Mississippi, Univ of	4	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Montana NCORP	9	11	2	_	_	_	_	_	_	_	_	_	4	_	_	_	_	_	_
National Cancer Ctr	143	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Nevada CRF NCORP	1	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
New Mexico MU-NCORP	27	29	14	5	_	1	_	_	—	_	_	_	—	_	_	_	_	_	_
Northwest NCORP	28	9	_	1	_	_	_	_	_	_	_	1	_	_	_	_	_	_	_
Northwestern Univ	3	19	_	1	_	_	_	_	_	1	_	_	_	2	_	_	_	1	_
Oklahoma, Univ of	8	9	_	_	_	_	_	_	_	_	_	_	—	_	_	_	_	_	_
Orange Reg Med Ctr	_	_	_	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Oregon Hlth Sci Univ	4	28	3	4	_	_	4	_	_	_	1	_	_	1	_	_	_	1	_
Ozarks NCORP	9	15	7	1	_	_	_	_	_	_	_	_	9	_	_	_	_	3	_
PCRC NCORP	31	21	4	4	_	_	_	2	_	_	_	_	6	_	_	_	_	1	_
Providence Hosp	8	10	2	2	_	1	4	6	3	_	6	1	2	_	_	_	_	3	_
Rochester, Univ of	7	9	_	_	_	1	_	_	_	_	_	1	_	5	2	122	_	5	_
San Antonio, U of TX	25	23	_	4	_	1	_	1	_	_	3	1	_	4	_	_	_	4	_
San Diego, U of CA	9	_	_	_	_	_	_	2	1	_	_	_	_	_	_	_	_	1	_
Scott & White Mem	_	_	_	_	_	_	_	3	_	_	_	_	_	_	_	_	_	_	_
So Calif, U of	15	18	_	1	_	_	3	_	_	_	_	2	_	_	_	_	_	_	_
Southeast COR NCORP	38	37	4	17	_	_	_	1	6	_	_	_	_	_	_	195	_	_	_
St Louis CCOP	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
St Louis University	1	1	_	_	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_
Sutter Cancer RC	_	10	1	_	_	4	_	5	1	_	1	_	_	_	_	_	_	2	_
Tennessee, U of	5	8	_	_	_	_	6	_	_	_	4	_	_	_	_	_	_	_	_
Tulane Univ MBCCOP	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Tulane University	6	2	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Univ of Louisville	8		_	_	_	_	2	_	_	_	_	_	_	_	_	_	_	_	_
Upstate Carolina	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Utah, U of	18	_	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Wayne State Univ	23	17	_	_	_	_	10	9	6	_	_	3	_	3	3	_	_	6	
Wichita NCORP	57	30	3	8			10	_	_			_		_	_			_	
	3/	2	4	0			_												
Wisconsin NCORP	24	50	_	4		8		70	23	1		1	2	7	4			7	
Yale University										-					4				_
Alliance	526	267	55	40	_	_		_	_		_		_	_	_	_	_	_	
CCTG	328			— 42	_	_			_				_	_		_	_	_	_
ECOG-ACRIN	713	239	33	42	1	_	_	_	_		_	_	_	_	_	_	_	_	
GEICAM	792		_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
NRG	265	392	59	87	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_
UNICANCER	1,022		_		_		_	-		- 42	_	_	-	_		-	_	_	_
Total	5,083	1,852	300	374	2	85	97	211	<i>7</i> 8	13	33	33	156	60	14	317	1	69	6



Active and Developing Cancer Control Studies

- S1415CD, "A Pragmatic Trial to Evaluate a Guideline Based Colony
 Stimulating Factor Standing Order Intervention and to Determine the
 Effectiveness of Colony Stimulating Factor Use as Prophylaxis for Patients
 Receiving Chemotherapy with Intermediate Risk for Febrile Neutropenia
 Trial Assessing CSF Prescribing Effectiveness and Risk (TRACER)." Drs.
 Ramsey, Hershman, Lyman and Sullivan. Activated: 10/7/16.
- <u>S1501</u>, "Prospective Evaluation of Carvedilol vs No Treatment in Prevention of Cardiac Dysfunction in Women with Metastatic HER2+ Breast Cancer." Drs. Floyd and Leja. Activated: 9/15/17.
- <u>S1614</u>, "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.
- <u>S1703</u>, "Randomized Non-Inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (STMDDM) Versus Usual Care in Patients with Metastatic Hormone Receptor Positive Breast Cancer." Dr. Accordino. Activated: 7/16/18.
- <u>S1714</u>, "A Prospective Observational Cohort Study to Develop a Predictive Model of Taxane-Induced Peripheral Neuropathy in Cancer Patients." Dr. Trivedi. Activated 3/1/19.
- CTSU/A011401, "Randomized Phase III Trial Evaluating the Role of Weight Loss In Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer." Drs. Ligibel and Hershman. Activated: 8/29/16.

Rare Cancers Active Studies

- <u>S1609</u>, "DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors." Drs. Patel and Chae. Activated 1/13/17.
- CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)". Dr. Villalobos. Activated 07/15/15.

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, Gralow, Meric-Bernstam, Hortobagyi, Albain and Barlow. Activated: 1/15/11; Closed: 10/1/15.

- <u>S1204</u>, "A Sero-Epidemiologic Survey and Cost-effectiveness Study of Screening for Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer Patients." Dr. Ramsey. Activated: 8/29/13; Closed: 2/15/17.
- <u>S1207</u>, "Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer." Drs. Chavez-MacGregor, Rastogi, Pusztai. Activated: 9/3/13; Closed: 4/15/19.
- CTSU/E2112, "A Randomized Phase III Trial of Endocrine Therapy plus Entinostat/Placebo in Patients with Hormone Receptor-Positive Advanced Breast Cancer." Dr. Connolly. SWOG Champion: Dr. Royce. Activated: 3/29/14; Closed: 10/17/18.

Closed Cancer Control Studies

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

- <u>S1919</u>, "Phase II, Multi-arm, Randomized Umbrella Study to Evaluate the Therapeutic Efficacy and Safety of Immune-Oncology Drug Combinations in Metastatic Breast Cancer (RUSTIC)." Drs. Pusztai and Sharma.
- <u>S1930</u>, "Phase II Randomized Trial to Evaluate the Safety and Efficacy of Pertuzumab and Trastuzumab plus Abemaciclib and Anti-estrogen therapy as treatment for HER2-positive and HR-positive Metastatic Breast Cancer (PETRA)." Dr. Giordano.
- "Continuation of checkpoint inhibitors with chemotherapy after progression of checkpoint inhibitor and chemotherapy received as first line therapy for metastatic triple negative breast cancer (TNBC)." Dr. Litton.
- "De-escalation of chemotherapy in patients with Triple Negative Breast Cancer (TNBC) who achieve pathologic Complete Response (pCR)." Drs. Kang, Moulder, Sharma, and Garcia.





Jack Aiello, MS, EE *Myeloma*



Rick Bangs, MBA, PMP Genitourinary



Tony Crispino Genitourinary



Hildy Dillon, MPH *Lymphoma*



Amy Geschwender, PhD

Symptom Control + Quality of Life



Valerie Guild, MBA, CPA *Melanoma*



Sandra Hamilton, RN, BSN, MEd Recruitment + Retention



Marcia K. Horn, JD

Early Therapeutics and Rare Cancers



Our Advocates

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



Cheryl Jernigan, CPA, FACHE Prevention and Epidemiology



Judy Johnson, MBA *Lung*



Lee Jones, MBA

Survivorship



Florence Kurttila, MS

Gastrointestinal



Ginny Mason, RN

Breast



Elda Railey Breast



Barbara Segarra-Vazquez, DHSc Cancer Care Delivery



Carole Seigel, MBA

Gastrointestinal



Gail Sperling, MPH *Leukemia*



Peggy Zuckerman, M.Ed. *Genitourinary*

Cancer Control & Prevention Committee

Leadership
Vice-Chair NCORP: Dawn L. Hershman, M.D., M.S
Cancer Care Delivery Cmte Co-Chairs: Dawn L. Hershman, M.D., M.S
Scott D. Ramsey, M.D., Ph.D
Cancer Survivorship Cmte Co-Chairs: Halle C.F. Moore, M.D.
Melinda L. Irwin, Ph.D., M.P.H
Palliative & End of Life Cmte Co-Chairs:Robert S. Krouse, M.D., F.A.C.S
Prevention & Epidemiology Cmte Co-Chairs:Banu Arun, M.D.
Marian Neuhouser, Ph.D., R.D.
Symptom Control & QOL Cmte Co-Chairs: Michael Fisch, M.D., M.P.H
Norah Lynn Henry, M.D., Ph.D
Executive Officers: Katherine D. Crew, M.D. (Palliative, Prevention
Survivorship
Gary Lyman, M.D. (CCD, Symptom Control & QOL
Senior Advisor: Frank L. Meyskens, Jr., M.D.
Statisticians:
William E. Barlow, Ph.D
Joseph M. Unger, Ph.D
Riha Vaidya, Ph.D
Phyllis J. Goodman, M.S
Danika Lew, M.A
Anna Moseley, M.S Eddie Mayerson, M.S
Administrative Lead
Statistics & Data Management Center (SDMC): Monica Yee, C.C.R.F.
Scientific Leadership
NCORP Representative: Mark A. O'Rourke, M.D.
Radiation Oncology Committee: Louis "Sandy" Constine, M.D.
Surgery Committee:
Translational Medicine:James (Jimmy) Rae, Ph.D.
Liaisons
Breast Committee:
Dawn Hershman, M.D, M.S. (CCD
Banu Arun, M.D. (Prevention
CCDR Committee: Afsaneh Barzi, M.D. (G
Early Therapeutics & Rare Cancers:Jason M. Prosek, M.D.
Gastrointestinal Committee Colon:Jason, Zell, D.O. (Prevention
Genitourinary Committee:Peter J. Van Veldhuizen, Jr., M.D.

International Liaison:
Designates
Oncology Research Professionals
$Pharmaceutical \ Sciences \ Committee: \dots \ Kimberly \ McConnell, Pharm.D.$
Siu-Fun Wong, Pharm.D.
Sun "Coco" Yang, Pharm.D., Ph.D.
SDMC Data Coordinators and Staff:
Diane Liggett
Roxanne Topacio
Monica Yee
Recruitment and Retention Specialist: Jennifer Maeser, M.S.
Patient Advocates: Barbara Segarra-Vazquez, D.H.Sc. (CCD)
Hartley "Lee" M. Jones, M.B.A. (Survivorship)
Sandra Jean Hamilton, R.N., M.E.D. (Recruitment &
Cheryl Jernigan, CPA (Prevention & Epidemiology)
Valerie Fraser (Palliative & End of Life Care) Protocol Coordinator (Cancer Care Delivery;
Prevention and Epidemiology Committees): Patricia O'Kane Protocol Coordinator (Cancer Survivorship
Committee):
Protocol Coordinator (Symptom Control and
Quality of Life Committee):
Clinical Trials Project Manager (Palliative Care): Vanessa Benavidez, B.S.,
CILL LT. LD. C. LAA. (CCD. D. C.)
Clinical Trials Project Manager (CCD; Prevention;
Survivorship):Sandi Hita, J.D.



Cancer Care Delivery (CCD) Committee

Leadership

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

Time/Location

Thursday, April 25, 2019 5:00 p.m.- 7:00 p.m.

Room: Seacliff A-C (Bay Level)

Presentations/Concepts:

Genetic Risk Evaluation in Patients and Families After Diagnosis of Cancer, Steven Katz, MD, MPH, University of Michigan

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

Improving the Delivery of Team-based Breast Cancer Survivorship Care, Lauren Wallner, PhD, MPH, University of Michigan

Use New Technology to Improve Patient Engagement and Outcomes, Deborah Keller, MD, Columbia University Irving Medical Center

Active Studies

- <u>S1400 (Genomics</u>), "Ancillary Study to Evaluate Patient & Physician Knowledge, Attitudes, and Preferences Related to Return of Genomic Results in SWOG 1400 (Lung-MAP)." Dr. Roth. Activated: 2/5/18.
- 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.
- <u>S1703</u>, "Randomized Non-inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (STMDDM) versus Usual Care in Patients with Metastatic Hormone Receptor Positive Breast Cancer." Dr. Accordino. Activated: 7/16/18.

Closed Studies

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

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

Concepts Disapproved by DCP

<u>\$1908</u>, "A Prospective, Patient-Level Survey Evaluating Health Insurance Coverage as a Barrier to Enrollment in Adult Cancer Treatment Clinical Trials." Dr. Roth.

Concepts in Development

- <u>S1903</u>, "Randomized Trial of a Medication Adherence Application to Improve Medication Adherence in Breast Cancer Survivors." Drs. Hershman and Mougalian.
- **S1912**, "Randomized Trial of a Proactive Financial Navigation Intervention for Cancer Patients and Caregivers." Dr. Shankaran
- <u>S1916</u>, "Feasibility of a Digital Health Offering in Optimizing Opioid Pain Control in Cancer Patients." Drs. Hershman and Shen. (Pilot study sponsored by Proteus).
- "A Pilot Project to Identify Techniques to Raise Awareness about SWOG Clinical Trials on an Online Oncologist Q&A Network." Dr. Housri (SEED Funded Pilot Trial).

Substudies (Economic Analyses / Cost Effectiveness from NCTN trials)

- **S1007**, "Update on Quality of Life and Economic Analysis Sub-study of Breast protocol S1007." Bill Barlow, Ph.D.
- <u>S1207</u>, "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. R. 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

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



Cancer Care Delivery (CCD) Committee

Database Studies

Association between Body Mass Index and Response to Duloxetine for Aromatase Inhibitor-Associated Musculoskeletal Symptoms in SWOG S1202. Dr. Henry.

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

Database Pilot Studies

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

Osteoporosis in Patients with Colorectal Cancer Enrolled on SWOG Trials.

Dr. Barzi (Manuscript submitted)

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

Cancer Care Delivery Committee

Cumulative Accrual by Institution and Study

Includes accrual through 2/18/2019. Includes studies that are currently open,

or that closed since 7/1/2017.

	51415CD	5147700	51703	A011704	A197402C	ACCL 16N1	ENO162CD
Baptist MU-NCORP	99	_	_	1	_	_	_
Bay Area NCORP	21	2	_	_	_	_	_
Beaumont NCORP	5	_	_	_	5	_	_
Brooke Army Med Ctr	_	_	_	2	_	_	_
CORA NCORP	56	18	_	_	_	_	_
CRC West MI NCORP	44	20	_	_	_	_	_
Carle CC NCORP	60	1	_	_	_	_	_
Columbia MU-NCORP	88	11	1	_	_	_	_
Columbus NCORP	20	26	_	_	_	_	_
Dayton NCORP	28	4	_	_	_	_	_
Essentia HIth NCORP	79	_	_	_	_	_	_
GRU MU-NCORP	36	_	_	_	_	_	_
Georgia NCORP	50	9	_	_	_	_	_
Greenville NCORP	61	20	_	_	_	_	_
Gulf South MU-NCORP	71	12	_	_	_	_	_
Hawaii MU-NCORP	54	9	_	_	_	_	5
Heartland NCORP	225	<i>37</i>	1	_	_	_	_
Kaiser Perm NCORP	_	41	_	_	12	34	1
Kansas City NCORP	5	1	_	_	_	_	_
Michigan CRC NCORP	193	13	_	_	_	_	_
Montana NCORP	80	1	_	_	_	_	_
Nevada CRF NCORP	_	1	_	_	_	_	_
New Mexico MU-NCORP	167	6	_	_	_	_	_
Northwest NCORP	84	3	_	_	_	_	_
Ozarks NCORP	107	3	_	_	_	_	_
PCRC NCORP	158	8	_	_	_	_	4
Providence Hosp	_	_	_	10	_	_	_
Southeast COR NCORP	120	16	_	2	_	_	8
Wayne State Univ	_	_	_	1	_	_	_
Wichita NCORP	60	8	_	_	_	_	_
Wisconsin NCORP	116	2	_	_	_	_	_
Yale University	_	_	_	3	_	_	_
Alliance	226	23	_	_	_	_	_
ECOG-ACRIN	259	65	_	_	_	_	_
NRG	95	20	_	_	_	_	_
Total	2,667	380	2	19	17	34	18



Cancer Survivorship Committee

Leadership

Time/Location

Friday, April 26, 2019 7:30 a.m.- 9:30 a.m. Room: Garden Room (Atrium Lobby Level)

Welcome and Introduction: Melinda Irwin and Halle Moore

Update from committee liaison mini-retreat

Survivorship Presentation: Cardio-Oncology:

Monika Leja, MD

Ana Barac, MD

Patrick Collier, MD

Salim Hayek, MD

Sarju Ganatra, MD

Cardio-Oncology Discussion: Group

Patient Advocate Update: Lee Jones

New Ideas

"Active Living after Cancer in Mexico, Impact of increasing physical activity on physical functioning and quality of life among cancer patients and survivors." Irene Tami-Maury DMD, MSc, DrPH and Karen Basen-Engquist PhD, MPH.

"Risk factors for cardiac toxicity in patients with early stage breast cancer." Kerryn Reding, PhD.

"Early assessment of chemotherapy toxicity" Paul Okunieff, MD

Active Study

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

Triage Approved Studies

<u>S1913</u>, "A Phase II Trial of Flibanserin to Improve Desire in Women with Cancer." Dr. Dizon.

<u>S1926</u>, "Tele-psychiatry for Women with Breast Cancer and Major Depression." Drs. Markowitz, Hellerstein, and Levenson.

Other Updates and Additional Business: Group

Cancer Survivorship Committee

Cumulative Accrual by Institution and Study

	51316	51501	E1011	EA9131
Arizona MC, U of	10	_	_	_
Arkansas, U of	6	_	_	_
Bay Area NCORP	_	2	_	_
Baylor College	1	_	_	_
CORA NCORP	_	1	_	_
City of Hope Med Ctr	4	9	_	_
Columbia MU-NCORP	1	2	_	_
Essentia HIth NCORP	1	_	_	_
Georgia NCORP	_	3	_	_
Greenville NCORP	_	1	_	_
H Lee Moffitt CC	2	_	_	_
Hawaii MU-NCORP	_	_	19	_
Heartland NCORP	_	8	_	_
INCan	2	_	_	_
INEN	1	_	_	_
Kaiser Perm NCORP	_	_	_	22
Kansas, U of	16	3	_	_
Lahey Hosp & Med Ctr	_	5	_	_
Loyola University	_	7	_	_
MD Anderson CC	1	_	_	_
MUSC MU-NCORP	5	1	_	_
Michigan, U of	7	1	_	_
New Mexico MU-NCORP	1	_	_	_
Oklahoma, Univ of	2	_	_	_
Ozarks NCORP	_	2	_	_
Providence Hosp	_	1	_	_
San Antonio, U of TX	5	_	_	_
Tennessee, U of	32	_	_	_
Wayne State Univ	_	1	_	_
Alliance	22	7	_	_
ECOG-ACRIN	1	12	_	_
NRG	54	8	_	_
Total	174	74	19	22



Palliative and End of Life Care Committee

Leadership

Co-Chairs: Robert S. Krouse, M.D.

Mark A. O'Rourke, M.D.

Marie Bakitas, D.N.Sc, C.R.N.P.

Time/Location

Thursday, April 25, 2019 10:15 a.m.- 12:15 p.m.

Room: Seacliff A-C (Bay Level)

Introduction and welcome of Dr. Sun

Dr. Krouse and Dr. Bakitas

Advocate Update

Introduction of Valerie Fraser: Dr. Krouse

Plenary

Palliative Care Research in GI Cancer: Collaboration, Progress, and Future Directions. Virginia Sun, PhD, RN, Associate Professor, Division of Nursing Research and Education, Department of Population Sciences, Cancer Control and Population Sciences Program, City of Hope, Duarte, CA

Active Studies

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

Approved Studies

<u>S1820</u>, "A Randomized Phase II Trial of the Altering Intake, Managing Symptoms Intervention for Bowel Dysfunction in Rectal Cancer Survivors (AIMS-RC)." Dr. Sun. Activation: anticipated summer 2019.

Proposed Concepts (5-minute overview and 10-minute discussion each)

"Randomized Phase III Trial of a Primary Palliative Care Intervention in Pancreatic Cancer." Dr. Chung.

"Intimacy in Palliative Care." Drs. Yung and Dizon.

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

"Hopefulness for Providers and Patients, Status of Survey." Drs. Corn and Feldman.

Aspirational Goals: Dr. O'Rourke

- 1. Intervention in Communication in End-of-Life Care
- 2. Intervention in Advance Care Planning
- 3. Secondary analysis of existing trial data

Other Business: Dr. O'Rourke

Membership list



SWOG Grant Writing Workshop

Apply by:

May 1, 2019

tinyurl.com/SWOG-Grants

Katherine Crew, MD, MS, SWOG Executive Officer and workshop lead



Prevention & Epidemiology Committee

Leadership

Time/Location

Friday, April 26, 2019 9:45 a.m.- 11:45 a.m. Room: Garden Room (Atrium Lobby Level)

Introduction

Welcome and Opening Comments: Marian Neuhouser and Banu Arun

Presentation

Cervical Cancer Prevention in Columbia. Dr Esperanza Pena and Dr. Carolina Wiesner, National Cancer Institute of Colombia, Bogota, Colombia

Active Studies

Solve 1982, "A Double-Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients With Stage 0-III Colon or Rectal Cancer, Phase III." Drs. Zell, Brown, Lance, et al. Activated: 3/1/13.

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

Protocol submitted to DCP

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

Concept Approved by DCP

<u>\$1823</u>, "miR-371-3a-p (miRNA371) for Biomarker-Based Care in Testicular Cancer." Drs. Nappi and Nichols.

Concept Submitted to CTEP

<u>Amendment to S1418</u>, "Exploratory Study to Evaluate Mammographic Density Changes in Patients Receiving Pembrolizumab in S1418." Dr. Arun.

Concept pending R01 funding

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

Concepts Approved By NCORP Executive Committee

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

Other Proposals in Development

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

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

Melanoma Chemoprevention. Dr. S. Leachman.

New Business



SWOG Young Investigator Training Course

Apply by:

June 21, 2019

tinyurl.com/SWOG-YITC

Elizabeth Brem, MD, 2018 Young Investigator



Prevention & Epidemiology Committee

Cumulative Accrual by Institution and Study

	50850	W511105	A217201	EA7747
Baptist MU-NCORP	3	_	_	_
Bay Area NCORP	1	_	_	_
Brooke Army Med Ctr	2	_	_	_
CORA NCORP	3	_	_	_
CRC West MI NCORP	1	_	_	_
City of Hope Med Ctr	1	2	_	_
Colorado, U of	4	_	_	_
Columbia MU-NCORP	1	1	2	_
Columbus NCORP	5	_	_	_
Dayton NCORP	1	_	_	_
Essentia HIth NCORP	4	_	_	_
Georgia NCORP	2	_	_	_
Hawaii MU-NCORP	9	_	_	_
Heartland NCORP	2	_	_	_
Irvine, U of CA	20	_	_	_
Kaiser Perm NCORP	28	_	9	_
Kansas, U of	3	_	_	_
Lahey Hosp & Med Ctr	_	_	1	44
Loma Linda Univ	2	_	_	_
Loyola University	2	_	_	_
MAVERIC	3	_	_	_
MD Anderson CC	9	_	_	_
Michigan CRC NCORP	4	_	_	_
Michigan, U of	_	_	2	_
Mississippi, Univ of	1	_	_	_
Nevada CRF NCORP	1	_	_	_
New Mexico MU-NCORP	1	_	_	_
Northwest NCORP	8	_	_	_
Oklahoma, Univ of	1	_	_	_
PCRC NCORP	1	_	_	_
Providence Hosp	1	_	_	_
San Antonio, U of TX	8	_	_	_
So Calif, U of	5	_	_	_
Southeast COR NCORP	2	_	_	_
Wayne State Univ	2	_	_	_
Wichita NCORP	13	_	_	_
Yale University	13	_	_	_
Alliance	23	_	_	_
ECOG-ACRIN	16	_	_	_
NRG	24	_	_	_
Total	230	3	14	44



Symptom Control & Quality of Life Committee

Leadership

Time/Location

Thursday, April 25, 2019 8:00 a.m.- 10:00 a.m.

Room: Seacliff A-C (Bay Level)

Feature Presentation (50 minutes)

"Interventional symptom research at the interface of palliative care and oncology" David Hui MD, MSc, Associate Professor, Departments of Palliative Care and Rehabilitation and General Oncology, University of Texas MD Anderson Cancer Center

Newly Activated Trials (15 min)

- <u>\$1600</u>, "Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes." Drs. Hamilton-Reeves and Holzbeierlein. Activated: 2/21/19.
- S1614, "A Phase III Randomized Trial of Prophylactic Antiviral Therapy in Patients with Current or Past Hepatitis B Virus (HBV) Infection Receiving Anti-Cancer Therapy for Solid Tumors." Drs. Hwang, Lok, Ghering, et al. Activated: 2/21/19.
- <u>S1714</u>, "A Prospective Observational Cohort Study to Develop a Predictive Model of Taxane-Induced Peripheral Neuropathy in Cancer Patients." Drs. Trivedi, Hershman, Brannagan, et al. Activated: 3/1/19.

Other Concepts in Development (30 min)

- "mHealth Mindfulness to Improve Quality of Life in Castration-Resistant Metastatic Prostate Cancer Patients and their Partners." Drs. Kubo and Greyz.
- "Integrative Mindfulness treatment for post-operative breast pain."

 Dr. Fukui.
- "Emerging from the Haze™ (Haze) A randomized, wait-list controlled trial to measure the impact of a multi-dimensional psycho-educational program on perceived cognitive function after breast cancer treatment." Drs. Asher and Myers.
- "A Phase II Randomized Placebo-Controlled Study to Evaluate the Use of Vitamin K1 Topical Cream in Patients with Cutaneous Toxicity Caused by Epidermal Growth Factor Receptor (HER1/EGFR) Inhibitors." Drs. Wong, Ryan, Moinpour, et al.

Other Discussion Topics (20 minutes)

Advocates update - Dr. Amy Geschwender

Stats update - Dr. Joe Unger

Closed Studies

- <u>S1200</u>, "Randomized Blinded Sham- and Waitlist-Controlled Trial of Acupuncture for Joint Symptoms Related to Aromatase Inhibitors in Women with Early Stage Breast Cancer." Drs. Hershman and Crew. Activated: 3/27/12; Closed: 2/15/17.
- <u>S1202</u>, "A Randomized Placebo-Controlled Phase III Study of Duloxetine for Treatment of Aromatase Inhibitor(AI)-Associated Musculoskeletal Symptoms in Women with Early Stage Breast Cancer." Drs. Henry and Schott. Activated: 5/15/13; Closed: 10/1/15.

Other SWOG Studies with Symptom Control and QOL Component

Breast

- <u>S1207</u>, "Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer. E^3 Breast Cancer Study Evaluating Everolimus with Endocrine Therapy." Dr. Chavez-MacGregor. Activated: 9/3/13.
- <u>S1418</u>, "A Randomized Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with ≥ 1 cm Residual Invasive Cancer or Positive Lymph Nodes (ypN+) After Neoadjuvant Chemotherapy." Drs. Pusztai Mammen, Henry, et al. Activated: 11/15/16.
- <u>S1706</u>, "A Phase II Randomized, Double-Blinded, Placebo-Controlled Trial of Olaparib Administered Concurrently with Radiotherapy for Inflammatory Breast Cancer." Dr. Jagsi. Activated: 9/12/18.
- <u>S1807</u>, "A Phase II Randomized Double-Blinded, Controlled Study of Tucatinib (ONT-380) Following Stereotactic Radiosurgery (SRS) HER2-Positive Breast Cancer Brain Metastases." Dr. Tsien.

GU

- <u>\$1802</u>, "Phase III Randomized Trial of Standard Systemic Therapy (SST) Versus Standard Systemic Therapy plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer." Dr. Chapin. Activated: 9/17/18.
- <u>S-N1806</u>, "Phase III Randomized Trial of Concurrent Chemoradiotherapy with or Without Atezolizumab in Localized Muscle Invasive Bladder Cancer." Dr. Singh.



Symptom Control & Quality of Life Committee

Leukemia

S1612, "A Randomized Phase II/III Trial of Novel Therapeutics Versus
Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia
(AML) or High-Risk Myelodysplastic Syndrome (MDS), Age 60 or Older
(LEAP: Intergroup Less Intense AML Platform Trial)." Drs. Michaelis,
Walter, Assouline, et al. Activated: 12/22/17; Temporarily Closed to
Accural: 10/2/18.

Lung

- <u>S14001</u>, "A Phase III Randomized Study of Nivolumab plus Ipilimumab Versus Nivolumab for Previously Treated Patients with Stage IV Squamous Cell Lung Cancer and No Matching Biomarker (LUNG-MAP Sub-Study)." Drs. Gettinger and Bazhenova. Activated: 12/18/15.
- <u>S1400GEN</u>, "Ancillary Study to Evaluate Patient and Physician Knowledge, Attitudes, and Preferences Related to Return of Genomic Results in S1400." Drs. Ramsey and Hershman. Activated: 2/5/18.
- <u>S1827</u>, "PCI vs Active MRI Surveillance in Small-Cell Lung Cancer." Dr. Rusthoven.
- "A Randomized Phase II Study of Irinotecan Alone Versus Combined Irinotecan with Atezolizumab in Patients with Relapsed or Refractory UGTA1*1 or UGTA1*28 Small Cell Lung Cancer (SCLC)." Dr. Karim.

Lymphoma

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

Melanoma

<u>S1404</u>, "A Phase III Randomized Trial Comparing Physician/Patient Choice of Either High Dose Interferon or Ipilimumab to MK-3475 (Pembrolizumab) in Patients with High Risk Resected Melanoma." Drs. Grossmann, Patel, Knopp, et al. Activated: 10/15/15; Closed: 11/2/17.

Myeloma

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

Survivorship

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

NCTN Studies

- CTSU/NRG-GI004, "Colorectal Cancer Metastatic dMMR Immunotherapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/
 Bevacizumab Combination Chemotherapy with or Without
 Atezolizumab or Atezolizumab Monotherapy in the First Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR) Metastatic Colorectal Cancer." Dr. Overman. Activated: 11/7/17.
- CTSU/A021202, "Prospective Randomized Phase II Trial of Pazopanib (NSC #737754, IND 75648) Versus Placebo in Patients with Progressive Carcinoid Tumors." Dr. Phan. Activated: 6/21/13; Closed: 10/7/16.
- CTSU/A041202, "A Randomized Phase III Study of Bendamustine plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (≥ 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL)". Dr. Coutre. Activated: 12/9/13; Closed: 5/16/16.
- CTSU/C30610, "Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer also Receiving Cisplatin or Carboplatin and Etoposide." Drs. Gadgeel and Gaspar. Activated: 3/15/2008; Closed: 8/30/17.
- CTSU/C51101, "A Randomized Phase II Trial of Myeloablative Versus Non-Myeloablative Consolidation Chemotherapy for Newly Diagnosed Primary CNS B-Cell Lymphoma." Dr. Mohile. Activated: 6/15/12; Closed 5/2/17.
- CTSU/C90203, "A Randomized Phase III Study of Neo-Adjuvant Docetaxel and Androgen Deprivation Prior to Radical Prostatectomy Versus Immediate Radical Prostatectomy in Patients with High-Risk, Clinically Localized Prostate Cancer." Dr. Kim. Activated: 12/15/06; Closed: 10/2/15.
- CTSU/E1411, "Intergroup Randomized Phase II Four Arm Study in Patients with Previously Untreated Mantle Cell Lymphoma of Therapy with: Arm A = Rituximab + Bendamustine Followed by Rituximab Consolidation (RB -->R); Arm B = Rituximab + Bendamustine + Bortezomib Followed by Rituximab Consolidation (RBV--> R), Arm C = Rituximab+Bendamustine Followed by Lenalidomide + Rituximab Consolidation (RB --> LR) or Arm D = Rituximab + Bendamustine + Bortezomib Followed by Lenalidomide + Rituximab Consolidation (RBV --> LR)." Dr. Till. Activated: 5/22/12; Closed: 9/9/16.



Symptom Control & Quality of Life Committee

CTSU/E1609, "A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy Versus High-Dose Interferon a-2b for Resected High-Risk Melanoma." Dr. Flaherty. Activated: 5/25/11; Closed: 7/26/16.

CTSU/E1912, "A Randomized Phase III Study of Ibrutinib (PCI-32765)-Based Therapy vs Standard Fludarabine, Cyclophosphamide, and Rituximab (FCR) Chemoimmunotherapy in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL)." Dr. O'Brien. Activated: 2/20/14; Closed: 6/9/16.

CTSU/E1A11, "Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide, Dexamethasone (CRd) Followed by Limited or Indefinite DURation Lenalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE)." Dr. Zonder. Activated: 12/2/13.

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

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

CTSU/E3A06, "Randomized Phase III Trial of Lenalidomide Versus
Observation Alone in Patients with Asymptomatic High-Risk Smoldering
Multiple Myeloma." Drs. Dhodapkar and Epstein. Activated: 10/5/10;
Closed: 7/14/17.

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

CTSU/N1048, "A Phase II/III Trial of Neoadjuvant FOLFOX, with Selective Use of Combined Modality Chemoradiation Versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision." Dr. Eng. Activated: 1/13/12.

Symptom Control & Quality of Life Committee

Cumulative Accrual by Institution and Study

Includes accrual through 2/18/2019. Includes studies that are currently open, or that closed since 7/1/2017.

	A221701	A221102	A221504	A227505	NRGGU003
Arkansas, U of	1	_	_	_	_
CORA NCORP	_	7	_	_	_
Cleveland Clinic OH	_	_	_	_	3
Colorado, U of	_	_	_	6	_
Irvine, U of CA	8	_	_	1	_
Kansas, U of	2	_	_	_	_
Kentucky, U of	1	_	_	_	_
Loma Linda Univ	2	_	_	_	_
Northwest NCORP	1	_	_	_	_
PCRC NCORP	_	1	_	_	_
Providence Hosp	3	_	_	_	_
San Antonio, U of TX	1	_	_	_	_
So Calif, U of	_	_	1	_	_
Sutter Cancer RC	1	2	_	_	_
Upstate Carolina	1	_	_	_	_
VAMC Kansas City	_	_	1	_	3
Total	21	10	2	7	6

CTSU/N107C, "A Phase III Trial of Post-Surgical Stereotactic Radiosurgery (SRS) Compared with Whole Brain Radiotherapy (WBRT) for Resected Metastatic Brain Disease." Dr. Gaspar. Activated: 7/8/11; Closed: 12/18/15.

CTSU/R0848, "A Phase II-R and a Phase III Trial Evaluating Both Erlotinib (Ph II-R) and Chemoradiation (Ph III) as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma." Dr. Philip. Activated: 11/17/09.

CTSU/R1010, "A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2-Overexpressing Esophageal Adenocarcinoma." Dr. Leichman. Activated: 12/30/10; Closed: 11/10/15.

Committee Process

Sign and/or correct the meeting attendance/contact list



Early Therapeutics & Rare Cancers Committee

Leadership

Chair:	Razelle Kurzrock, M.D.
Vice-Chair:	. Young Kwang Chae, M.D., M.P.H.
Executive Officer:	Christopher W. Ryan, M.D.
Statisticians:	Megan Othus, Ph.D.
	Melissa Plets, M.S.
	Edward Mayerson, M.S.
Designates	
Data Coordinators:	Christine McLeod
	Sewan Gurung
Cancer Control Liaison:	Jason M. Prosek, M.D.
Digital Engagement:	Kanwal Raghav, M.D., M.B.B.S.
Oncology Research Professionals:	3
CRA:	Corrine Turrell, C.C.R.P.
Nurse:	TBD
Pharmaceutical Science:	
	Sun "Coco" Yang, PharmD
Patient Advocate:	•
Protocol Coordinator:	TBD
Clinical Trials Project Manager:	Vanessa Benavidez, B.S., C.C.R.C.
Early Therapeutics Liaisons	
Breast Committee Liaison:	George Somlo, M.D.
Genitourinary Committee Liaison:	
lmaging:	
Lung Committee Liaison:	
Lymphoma Committee Liaison:	
Melanoma Committee Liaison:	
Myeloma Committee Liaison:	Frits van Rhee, M.D., Ph.D.

Time/Location

Thursday, April 25, 2019 10:00 a.m.- 12:15 p.m.

Room: Bayview B (Bay Level)

Introduction

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

Presentations

<u>10:05 a.m. – 10:35 a.m.:</u> "Early Therapeutic Overview: The Cutting Edge?" Monica Mita, M.D., Associate Professor, Department of Medicine; Co-Director, Experimental Therapeutics Program, Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center.

- 10:35 a.m. 11:00 a.m.: "Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors (DART)." Sandip Patel M.D., Assistant Professor, UC San Diego Moores Comprehensive Cancer Center, San Diego, CA.
- 11:00am 11:20 a.m.: "Translational Medicine Initiatives in the DART trial." Young Kwang Chae, M.D., Assistant Professor Co-Director, Early Therapeutics, Northwestern University, Robert H. Lurie Comprehensive Cancer Center.
- 11:20 a.m. 11:40 a.m.: "A parallel phase II trial evaluating the efficacy of carboplatin + ATR inhibition with M-6620 and of carboplatin + ATR inhibition with M-6620+pembrolizumab in unresectable recurrent or metastatic head and neck squamous cell carcinoma." Paul Swiecicki, M.D., Assistant Professor, Divison of Hematology/Oncology Head and Neck Program, University of Michigan.
- 11:40 a.m. 12:00 p.m.: "Immune Checkpoint Inhibitors in Hypermutated Gliomas." Manmeet Ahluwalia, M.D., F.A.C.P., Professor of Medicine, Miller Family Endowed Chair in Neuro-Oncology, Head of Operations, Burkhardt Brain Tumor Center, Cleveland Clinic.
- 12:00 p.m. 12:15 p.m.: Wrap Up and Open Discussion. Razelle Kurzrock, M.D., Chief, Division of Hematology and Oncology, UCSD School of Medicine, Senior Deputy Center Director, Director, Center for Personalized Cancer Therapy, Director Clinical Trials Office, Chair, Early Therapeutics and Rare Cancer Committee (SWOG), UCSD Moores Comprehensive Cancer Center, San Diego, CA.

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.
- 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: 2/15/18.
- CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)." Dr. Villalobos. Activated: 8/12/15.
- 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.



Early Therapeutics & Rare Cancers Committee

Cumulative Accrual by Institution and Study

Includes accrual through 2/18/2019. Includes studies that are currently open, or that closed since 7/1/2017.

	5160 ⁹	4071702	A077407	ARST1321	EAV131
Arizona MC, U of	3	_	_	_	6
Arkansas, U of	3	_	_	_	3
Baptist MU-NCORP	2	_	_	_	_
Baylor College	_	2	_	_	2
Brooke Army Med Ctr	_	2	_	_	_
CORA NCORP	5	1	1	_	1
Carle CC NCORP	2	_	_	_	_
Cedars-Sinai Med Ctr	5	_	_	_	6
City of Hope Med Ctr	_	_	_	_	5
Cleveland Clinic OH	_	_	_	_	6
Colorado, U of	6	3	1	_	9
Columbus NCORP	3	_	_	_	_
Davis, U of CA	8	_	_	_	7
Dayton NCORP	1	_	_	_	1
Essentia HIth NCORP	3	_	_	_	_
Fred Hutchinson CRC	6	_	_	_	2
Georgia NCORP	3	_	_	_	_
Gulf South MU-NCORP	2	_	_	_	_
H Lee Moffitt CC	16	_	_	_	_
Hawaii MU-NCORP	3	_	_	_	1
Heartland NCORP	14	_	_	_	1
Henry Ford Hospital	12	_	_	_	11
Irvine, U of CA	7	2	1	_	8
Kaiser Perm NCORP	24	5	_	_	5
Kansas City NCORP	_	_	_	_	1
Kansas, U of	27	_	_	1	5
Kentucky, U of	_	_	_	_	9
Lahey Hosp & Med Ctr	_	3	_	_	_
Loma Linda Univ	2	_	_	_	1
Loyola University	1	_	_	_	_
MAVERIC	3	_	_	_	_

	51609	MO17102	AO77AO7	ARST1321	EN131
MD Anderson CC	17	_	_	_	_
MUSC MU-NCORP	4	_	_	_	_
Methodist Hospital	_	_	_	_	1
Michigan CRC NCORP	14	_	_	_	_
Michigan, U of	25	_	_	_	18
Mississippi, Univ of	3	1	_	_	_
Montana NCORP	10	_	_	_	_
Nevada CRF NCORP	15	_	_	_	_
New Mexico MU-NCORP	14	_	_	_	_
Northwest NCORP	2	_	_	_	_
Northwestern Univ	9	1	_	1	_
Oklahoma, Univ of	1	_	_	_	_
Oregon Hlth Sci Univ	2	_	_	4	_
Ozarks NCORP	1	2	_	_	_
PCRC NCORP	9	3	_	_	_
Providence Hosp	1	1	_	_	2
Rochester, Univ of	1	13	_	_	_
San Antonio, U of TX	5	_	_	3	5
San Diego, U of CA	16	7	2	_	_
Southeast COR NCORP	4	_	_	_	7
Sutter Cancer RC	2	_	_	_	4
Tulane University	_	_	_	_	1
Utah, U of	3	_	_	_	_
Wayne State Univ	_	_	_	_	3
Wisconsin NCORP	8	_	_	_	_
Yale University	5	3	_	_	9
Alliance	69	_	_	_	_
ECOG-ACRIN	66	_	_	_	_
NRG	90	_	_	_	_
Total	<i>557</i>	49	5	9	140

Recently Closed Studies

CTSU/ARST1321, "Pazopanib Neoadjuvant Trial in Non-

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

<u>CTSU/A071102</u>, "A Phase II/III Randomized Trial of Veliparib or Placebo in Combination with Adjuvant Temozolomide in Newly Diagnosed

Glioblastoma with MGMT Promoter Hypermethylation." Dr. Piccioni. Activated by Alliance: 12/15/14; Activated by SWOG: 4/1/15; Permanently closed to accrual (Step 1): 10/15/18.

Proposed Study

<u>S1921</u>, "A parallel phase II trial evaluating the efficacy of carboplatin + ATR inhibition with M-6620 and of carboplatin + ATR inhibition with M-6620 + pembrolizumab in unresectable recurrent or metastatic head and neck squamous cell carcinoma." Dr. Swiecicki.



Gastrointestinal Committee

Leadership

Leadership	
Interim Chair:	Andrew M. Lowy, M.D.
Vice-Chair:	Heinz-Josef Lenz, M.D.
	Christopher W. Ryan, M.D.
	Katherine A. Guthrie, Ph.D.
	Danika Lew, M.A.
	Mai Duong, M.S.
Scientific Leadership	
	Syma Iqbal, M.D.
	Lawrence P. Leichman, M.D.
Kaitl	yn J. Kelly, M.D. (Surgical representative)
Elena Gabriela	Chiorean, M.D. (Surgical representative)
Pancreatic:	Philip A. Philip, M.D., Ph.D.
Andrew	M. Lowy, M.D. (Surgical representative)
	Anthony B. El-Khoueiry, M.D.
	Milind Javle, M.D.
	d Ahmad, M.D. (Surgical representative)
	Philip J. Gold, M.D.
	Billingsley, M.D. (Surgical representative)
	Lisa A. Kachnic, M.D.
	Cathy Eng, M.D.
Translational Medicine:	Heinz-Josef Lenz, M.D.
	Christopher H. Lieu, M.D.
Drug Development:	Sunil Sharma, M.D.
Imaging:	Anthony F. Shields, M.D., Ph.D.
	David Shin-Kuo Lu, M.D.
	Hiram Shaish, M.D.
	Lisa A. Kachnic, M.D.
Designates	
•	Jason A. Zell, D.O.
	Heloisa Soares, M.D., Ph.D.
	Christine Magner
	Jacqueline Scurlock
	Brian Zeller
	Sewan Gurung
Oncology Research Professionals:	
CRA:	Sandy Annis, C.C.R.P.
Nurses:	Rita Kaul, R.N., B.S.N.
	Valerie A. Parks, R.N.
	Carole Seigel, M.B.A.
	Florence Kurttila, M.S.
	Jason M. Reed, Pharm.D., R.Ph.
	Danae Campos, M.B.A.
	Vanessa Benavidez, B.S., C.C.R.C.
Cirrical Iriais Froject Mariager	variessa beriaviuez, b.s., C.C.K.C.

Time/Location

Friday, April 26, 2019 4:00 p.m.- 6:00 p.m. Room: Grand B (Street Level)

Introduction: Andrew M. Lowy, M.D., UC San Diego Moores Cancer Center

Featured Trials:

COMMIT and ATOMIC: Michael Overman

S1613: Kanwal Raghav

Gastroesophageal

Active Studies

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

Pancreatic

Active Studies

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

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

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

Closed Studies

<u>\$1313</u>, "A Phase IB/II Randomized Study of Modified FOLFIRINOX + Pegylated Recombinant Human Hyaluronidase (PEGPH20) versus Modified FOLFIRINOX Alone in Patients with Good Performance Status Metastatic Pancreatic Adenocarcinoma." Dr. Ramanathan. Activated: 1/15/14; Closed: 7/1/17.

<u>S1513</u>, "Randomized Phase II Study of 2nd Line FOLFIRI versus Modified FOLFIRI with PARP Inhibitor ABT-888 (Veliparib) (NSC-737664) in Metastatic Pancreatic Cancer." Dr. Chiorean. Activated: 9/1/16; Closed: 12/13/17.



Gastrointestinal Committee

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

Hepatobiliary

Active Studies

<u>\$1815</u>, "Gemcitabine, cisplatin, and nab-paclitaxel versus gemcitabine and cisplatin in advanced biliary cancers: a randomized Phase II/III study." Dr. Rachna Shroff. Activated: 12/3/18.

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

Colon

Active Studies

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

S0820, "A Double Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon or Rectal Cancer, Phase III." Dr. Zell. Activated: 3/1/13.

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

S1415CD, "A Pragmatic Trial to Evaluate a Guideline-Based Colony
Stimulating Factor Standing Order Intervention and to Determine
the Effectiveness of Colony Stimulating Factor Use as Prophylaxis for
Patients Receiving Chemotherapy with Intermediate Risk for Febrile
Neutropenia – Trial Assessing CSF Prescribing Effectiveness and Risk
(TrACER)." Drs. Ramsey and Hershman. Activated: 10/7/16.

<u>S1613</u>, "A Randomized Phase II study of Trastuzumab and Pertuzumab (TP) compared to Cetuximab and Irinotecan (CETIRI) in HER2 Amplified Irinotecan-refractory Metastatic Colorectal Cancer (mCRC)." Dr. Raghav. Activated: 10/9/17. 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.

Rectal

Active Studies

CTSU/NRG-GI002, "A Phase II Clinical Trial Platform of Sensitization
Utilizing Total Neoadjuvant Therapy (TNT) in Rectal Cancer." Dr. Kachnic.
Activated: 10/12/16.

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

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.

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

<u>\$1316</u>, "Prospective Comparative Effectiveness Trial For Malignant Bowel Obstruction." Dr. Krouse, Activated: 3/9/15.

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

EAY131, "NCI-MATCH: Molecular Analysis for Therapy Choice." Dr. Villalobos. Activated: 8/12/15.



Gastrointestinal Committee

Cumulative Accrual by Institution and Study

Includes accrual through 2/18/2019. Includes studies that are currently open, or that closed since 7/1/2017.

	51313	51505	51513	51613	51815	A021501	A021502	E1508	EA2133	EA2742	EA2161	EA2765	N1048	ARGG1002	NRGGI004	R084
Arizona MC, U of	4	1	_	_	_	_	_	_	_	_	_	_	4	_	_	_
Arkansas, U of	_	_	_	_	_	_	_	_	_	_	_	1	_	_	_	_
Baptist MU-NCORP	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Baylor College	_	_	_	_	_	_	_	_	_	_	_	_	25	1	_	_
Beaumont NCORP	_	_	2	_	_	_	1	_	_	_	_	_	_	_	_	_
Boston Medical Ctr	_	_	_	_	_	_	1	_	_	_	_	_	4	_	_	-
CORA NCORP	_	_	2	_	_	_	_	1	_	_	_	_	2	_	_	_
CRC West MI NCORP	_	_	1	_	_	_	_	_	_	_	_	_	_	_	_	l –
Carle CC NCORP	_	2	1	_	_	_	_	_	_	_	_	_	_	_	_	_
Cincinnati MC, U of	_	2	_	_	_	2	_	_	_	_	_	_	_	_	_	_
City of Hope Med Ctr	3	_	2	_	_	_	_	_	_	_	_	_	_	_	_	_
Cleveland Clinic OH	_	6	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Colorado, U of	_	_	2	_	_	_	_	_	_	_	_	_	1	_	_	_
Columbia MU-NCORP	_	_	2	_	_	_	_	_	_	_	_	_	_	_	_	2
Columbia University	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	1
Columbus NCORP	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Davis, U of CA	1	_	_	_	_	_	3	_	_	_	_	1	2	_	_	_
Dayton NCORP	_	3	2	_	_	_	_	_	_	_	_	_	2	2	_	_
Fred Hutchinson CRC	14	_	2	_	_	_	_	_	_	_	_	_	17	3	_	_
Greenville NCORP	_	4	_	_	_	_	_	_	_	_	_	_	_	_	_	1
Gulf South MU-NCORP	_	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_
Hawaii MU-NCORP	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	1
Heartland NCORP	8	7	5	_	_	_	_	_	_	_	_	_	_	_	_	_
Irvine, U of CA	7	_	_	_	_	3	_	_	_	_	_	_	19	1	_	6
Kaiser Perm NCORP	_	5	8	_	_	1	3	_	_	1	_	_	22	_	_	-
Kansas City NCORP	7	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Kansas, U of	_	3	2	1	_	_	_	_	1	_	_	_	1	_	_	1
Kentucky, U of	_	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Lahey Hosp & Med Ctr	_	_	_	_	_	_	_	_	_	_	_	_	12	_	_	-
Loyola University	_	_	_	1	_	_	_	_	_	_	_	_	_	_	_	4

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.

Proposed Studies

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

Correlative Studies

S9008A, "Trial of Adjuvant Chemoradiation after Gastric Resection Adenocarcinoma, Phase III." Dr. Shridhar.

<u>S-C80405-A</u>, "Analysis of EGFR and ERCC1 Markers and Progression-Free Survival in Patients with Advanced Colorectal Cancer Enrolled on C80405." Drs. Shields and Lenz.



Gastrointestinal Committee, cont.

Cumulative Accrual by Institution and Study

Includes accrual through 2/18/2019. Includes studies that are currently open, or that closed since 7/1/2017.

	51313	51505	51513	51613	51815	A021501	A021502	E7208	EA2133	EA2742	EA2161	EA2765	N1048	NRGG1002	NRGGI004	R0848
MD Anderson CC	_	_	_	9	_	_	_	_	_	_	_	_	_	_	4	_
MUSC MU-NCORP	5	3	1	_	_	_	_	_	_	_	_	_	_	_	_	_
Methodist Hospital	_	_	_	_	_	_	_	_	_	_	_	_	12	_	_	_
Michigan CRC NCORP	_	2	2	_	_	_	_	_	_	_	_	_	_	_	_	_
Michigan, U of	_	6	2	1	_	6	_	1	_	3	1	_	5	_	_	_
Montana NCORP	_	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_
New Mexico MU-NCORP	_	1	5	_	_	_	_	_	_	_	_	_	2	_	_	_
Northwest NCORP	_	_	_	_	_	_	_	_	_	_	_	_	1	1	_	3
Northwestern Univ	_	_	_	_	_	_	_	1	_	_	_	_	1	_	_	_
Oklahoma, Univ of	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Orange Reg Med Ctr	_	_	_	_	_	_	_	_	_	_	_	_	_	1	_	_
Oregon Hlth Sci Univ	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Ozarks NCORP	_	2	_	_	_	_	_	_	_	_	_	_	1	_	_	_
PCRC NCORP	6	5	_	1	_	_	_	_	_	_	_	_	1	_	_	_
Providence Hosp	_	_	_	_	_	_	_	1	_	_	_	_	_	_	_	_
Rochester, Univ of	_	4	11	_	_	1	1	_	_	_	_	_	22	_	1	_
San Antonio, U of TX	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_
San Diego, U of CA	_	6	_	_	_	_	_	_	_	_	_	_	4	_	_	_
Scott & White Mem	_	_	_	_	_	_	_	1	_	_	_	_	1	_	_	_
So Calif, U of	6	_	_	1	_	_	_	6	_	_	_	_	4	2	_	_
Southeast COR NCORP	5	3	4	_	_	_	_	_	_	_	_	_	_	_	_	_
Sutter Cancer RC	9	_	_	_	_	1	1	_	_	_	_	_	_	_		_
Utah, U of	_	_	7	_	_	_	_	_	_	_	_	_	4	_	_	_
Wayne State Univ	11	_	2	_	_	1	_	1	_	_	_	_	_	2	_	_
Wichita NCORP	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	1
Wisconsin NCORP	_	3	1	_	_	_	_	_	_	_	_	_	_	_	_	_
Yale University	40	_	3	_	_	_	_	11	_	_	_	_	1	3	_	_
Alliance	_	18	17	2	_	_	_	_	_	_	_	_	_	_	_	_
ECOG-ACRIN	_	32	18	2	_	_	_	_	_	_	_	_	_	_	_	_
NRG	_	21	17	_	2	_	_	_	_	_	_	_	_	_	_	_
Total	126	147	123	18	2	15	10	23	1	4	1	2	170	16	5	20



Save the date for the Fall 2019 meeting

OCTOBER 2-5
CHICAGO, IL
FUTURE DATES ON SWOG.ORG
AND ON PAGE 22 OF THIS BOOKLET





Genitourinary Committee

Leadership

Leadership
Chair:lan M. Thompson, Jr., M.D.
Vice-Chair:Nicholas J. Vogelzang, M.D.
Executive Officer:
Statisticians:
Melissa Plets, M.S.
Scientific Leadership
Translational Medicine: David J. McConkey, Ph.D. (GU Chair)
Joshua J. Meeks, M.D., Ph.D. (Bladder)
Amir Goldkorn, M.D. (Prostate)
Brian Shuch, M.D. (Renal)
Radiation Oncology:
Imaging:
John D. Hazle, Ph.D.
Pathology:
Liaison to the SPORES:
Early Therapeutics:
Bladder Organ Site Chairs: Seth P. Lerner, M.D. (Localized)
Daniel P. Petrylak, M.D. (Advanced)
Prostate Organ Site Chairs: Daniel W. Lin, M.D. (Localized)
David I. Quinn, M.D., Ph.D. (Advanced)
Renal Organ Site Chairs: Brian Shuch, M.D. (Localized)
Ulka N. Vaishampayan, M.D. (Advanced)
Designates
Cancer Control: Peter J. Van Veldhuizen, Jr., M.D.
Digital Engagement:
Data Coordinators: Sean O'Bryan
Vicky Kim
Oncology Research Professionals:
CRA: TBD
Nurses:
Cheryl Kefauver, R.N.
Patient Advocates:
Margaret "Peggy" Zuckerman, M.Ed. (Renal)
Pharmaceutical Science: Joyce Lee, Pharm.D.
Jason M. Reed, Pharm.D., R.Ph.
Protocol Coordinator:
Clinical Trials Project Manager:Sandi Hita, J.D.
, , , , , , , , , , , , , , , , , , , ,

Time/Location

GU Committee Part I: Friday, April 26, 2019 3:30 p.m. - 7:15 p.m.

Room: Grand A (Street Level)

Time/Location

GU Committee Part II: Saturday, April 27, 2019 9:30 a.m. - 12:00 p.m. Room: Grand A (Street Level)

Agenda

GU Committee, Part I: Friday April 26, 9, 3:30 p.m. - 7:15 p.m.

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

Renal

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

Active Studies

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

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

Closed Studies

<u>S0931</u>, "EVEREST: EVErolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study." Drs. Ryan, Heath, Lara, et al. Activated: 4/1/11; Closed: 9/15/16.

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

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



Genitourinary Committee

Active Study

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

<u>S1600</u>, "A Randomized Phase III Double-Blind Clinical Trial Evaluating the Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes." Drs. Hamilton-Reeves and Holzbeierlein. Activated: 2/21/19.

Diverse Studies of Interest

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

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

GU Committee, Part II: Saturday, April 27, 2019 9:30 a.m. - 12:00 p.m.

Prostate

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

Priority Study

<u>S1802</u>, "Phase III Randomized Trial of Standard Systemic Therapy (SST) versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer." Drs. Chapin and Aparicio. Activated: 9/17/18

Active Studies

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

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/EA8153, "Cabazitaxel with Abiraterone Versus Abiraterone Alone Randomized Trial for Extensive Disease Following Docetaxel: The CHAARTED2 Trial." Dr. Corn. Activated: 2/8/18.

CTSU/ A031102, "A Randomized Phase III Trial Comparing Conventional-Dose Chemotherapy Using Paclitaxel, Ifosfamide, and Cisplatin (TIP) with High-Dose Chemotherapy Using Mobilizing Paclitaxel Plus Ifosfamide Followed by High-Dose Carboplatin and Etoposide (TI-CE) as First Salvage Treatment in Relapsed or Refractory Germ Cell Tumors." Dr. Quinn. Activated: 7/1/15.

RTOG-0924, "Androgen Deprivation Therapy and High Dose Radiotherapy with or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial. Dr. Marshall. Activated: 7/7/11.

Closed Study

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

Bladder

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

Priority Studies

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

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.

<u>S1605</u>, "Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer." Drs. Black and Singh. Activated: 2/7/17.

Closed Studies

S1011, "A Phase III Surgical Trial to Evaluate the Benefit of a Standard Versus an Extended Pelvic Lymphadenectomy Performed at Time of Radical Cystectomy for Muscle Invasive Urothelial Cancer." Drs. Lerner, Alva, Koppie, et al. R. Bangs. Activated: 8/1/11; Closed: 2/15/17.

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

CTSU/EA8141, "A Prospective Phase II Trial of Neoadjuvant Systemic Chemotherapy Followed by Extirpative Surgery for Patients with High Grade Upper Tract Urothelial Carcinoma." Drs. Godoy and Alva. Activated 4/10/15; Closed: 1/5/18.



Genitourinary Committee

Cumulative Accrual by Institution and Study

	51216	51314	51500	51602	5160 ⁵	51802	A037702	A031501	A031701	E2810	EA8747	EA8143	EA8153	NRGGU002	R0924
Arizona MC, U of	10	3	_	_	_	_		- Ho.	- Ros	_	_	3	_		_
Arkansas, U of	6	_	1	_	_	_	_	_	_	_	_	_	_	_	_
Baptist MU-NCORP	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Baylor College	16	3	_	9	_	_	_	_	_	_	_	_	_	_	_
Beaumont NCORP	3	_	_	_	_	_	_	_	_	_	_	_	_	_	2
Birmingham, U of AL	_	1	_	_	_	_	_	_	_	_	1	_	_	_	_
Boston MC MBCCOP	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_
CORA NCORP	2	_	_	_	_	_	_	_	_	_	_	_	_	_	1
CRC West MI NCORP	4	_	1	_	_	_	_	_	_	_	_	_	_	_	_
Carle CC NCORP	2	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Cedars-Sinai Med Ctr	_	_	1	_	_	_	_	_	_	_	_	2	_	_	_
Cincinnati MC, U of	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_
City of Hope Med Ctr	49	8	20	1	_	_	_	_	_	16	_	_	_	_	_
Cleveland Clinic OH	_	12	_	_	_	_	_	_	_	_	_	_	_	_	4
Colorado, U of	4	11	_	3	3	_	_	4	_	_	5	1	_	1	_
Columbia MU-NCORP	2	_	_	_	_	_	_	_	_	1	_	_	_	_	_
Columbus NCORP	6	_	1	_	_	_	_	_	_	_	_	_	_	_	_
Davis, U of CA	37	4	2	_	1	_	_	_	1	_	_	1	_	_	_
Dayton NCORP	9	_	_	1	_	_	_	_	_	_	_	_	_	_	_
Desert Hospital	_	_	_	_	_	_	_	_	_	_	_	_	_	_	8
Essentia Hith NCORP	_	_	_	_	1	_	_	_	_	_	_	_	_	_	_
Fred Hutchinson CRC	28	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Georgia NCORP	2	_	_	_	_	_	_	_	_	1	_	_	_	_	_
Greenville NCORP	_	3	_	1	1	_	_	_	_	_	_	_	_	_	_
Gulf South MU-NCORP	2	3	1	33	3	15	_	_	_	_	_	_	_	_	_
H Lee Moffitt CC	32	_	_	_	_	_	_	_	_	_	_	1	_	_	_
Hawaii MU-NCORP	_	_	_	_	1	_	_	_	_	_	_	_	_	_	_
Heartland NCORP	38	18	4	3	4	_	_	_	_	_	_	_	_	_	_
Henry Ford Hospital	_	_	_	_	_	_	_	_	_	1	_	_	_	_	_
Irvine, U of CA	6	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Kaiser Perm NCORP	83	_	_	3	_	_	_	6	_	_	_	3	_	_	_
Kansas City NCORP	6	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Kansas, U of	29	10	_	6	2	_	_	1	_	6	1	1	_	_	6
Kentucky, U of	16	_	_	_	1	_	_	_	_	_	_	3	_	_	_
Lahey Hosp & Med Ctr	3	_	_	_	_	_	_	_	_	_	_	2	_	_	_
Loma Linda Univ	11	6	_	_	_	_	_	_	_	_	_	_	_	_	_



Genitourinary Committee, cont.

Cumulative Accrual by Institution and Study

	51216	51314	51500	51602	5160 ⁵	51802	A031702	A031501	4031701	E2810	EA8141	EA8143	EA8153	NRGGU002	R0924
Loyola University	6	2	_	3	2	_	· —	—		1	_	_	_	· –	_
MAVERIC	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_
MD Anderson CC	4	2	_	7	_	9	_	_	_	_	1	_	_	_	_
MUSC MU-NCORP	12	1	1	_	_	_	_	_	_	_	_	_	_	_	2
Madigan Army Med Ctr	2	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Michigan CRC NCORP	17	6	1	_	_	1	_	_	_	_	_	_	_	_	_
Michigan, U of	17	_	4	9	_	_	_	6	_	1	_	_	_	_	_
Mississippi, Univ of	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Montana NCORP	3	2	_	1	_	_	_	_	_	_	_	_	_	_	_
Nevada CRF NCORP	45	10	4	_	1	_	_	_	_	_	_	_	_	_	_
New Mexico MU-NCORP	26	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Northwest NCORP	4	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Northwestern Univ	3	_	_	12	_	_	_	_	_	_	_	_	_	_	_
Oklahoma, Univ of	16	5	2	10	4	6	_	_	_	_	_	_	_	_	_
Orange Reg Med Ctr	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Oregon HIth Sci Univ	21	4	3	2	3	_	_	_	_	6	_	_	_	_	_
Ozarks NCORP	5	3	2	_	_	_	_	_	_	_	_	_	_	_	_
PCRC NCORP	7	_	2	12	1	_	_	_	_	_	_	_	_	_	_
Rochester, Univ of	7	5	_	1	_	_	_	_	_	_	_	_	_	_	25
San Antonio, U of TX	3	8	_	19	3	_	_	_	_	_	_	3	_	_	_
San Diego, U of CA	6	1	_	_	5	_	_	_	_	_	_	2	_	_	_
So Calif, U of	34	11	1	4	_	_	4	1	_	1	_	_	_	_	_
Southeast COR NCORP	6	2	_	_	_	_	_	_	_	1	_	_	_	_	_
Sutter Cancer RC	5	_	_	_	_	_	_	_	_	_	_	_	_	_	2
Tennessee, U of	_	_	_	_	_	_	_	_	_	1	_	_	_	_	_
Upstate Carolina	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Utah, U of	106	5	2	25	7	_	_	2	_	12	_	1	4	_	_
VAMC Kansas City	2	_	_	_	_	_	_	_	_	_	_	_	_	_	41
Wayne State Univ	_	1	2	_	_	_	_	_	_	_	_	_	_	1	_
Wichita NCORP	12	1	1	_	2	_	_	_	_	_	_	_	_	_	_
Wisconsin NCORP	2	2	1	_	_	_	_	_	_	_	_	_	_	_	_
Yale University	7	1	_	_	2	_	_	4	_	_	_	1	_	_	_
Alliance	239	45	17	27	30	_	_	_	_	_	_	_	_	_	_
CCTG	_	_	18	_	3	_	_	_	_	_	_	_	_	_	_
ECOG-ACRIN	241	20	15	18	22	_	_	_	_	_	_	_	_	_	_
NRG	40	18	11	24	19	3	_	_	_	_	_	_	_	_	_
Total	1,313	237	118	234	121	34	4	24	1	48	8	24	4	2	91
Total	1,313	237	118	234	121	34	4	24	1	48	8	24	4	2	9



Leukemia Committee

Leadership

•	
Chair:	Harry P. Erba, M.D., Ph.D.
Vice-Chair:	Steven E. Coutre, M.D.
Executive Officer:	Susan M. O'Brien, M.D.
Statisticians:	Megan Othus, Ph.D.
	_
Scientific Leadership	· · · · · · · · · · · · · · · · · · ·
Translational Medicine:	Jerald P Radich, M D
Pathology:	
Cytogenetics Liaison:	
Designates	, i iii.i i aiig, ivi.b., i ii.b.
Designates	
Cancer Control:	Stephanie B. Tsai, M.D.
Data Coordinators:	Louise Highleyman
	Tracy Maher, C.C.R.P.
	Laura Kingsbury
Oncology Research Professionals:	,
CRA:	TBD
Nurse:	
Patient Advocate:	
	• •
Pharmaceutical Science:	Mai T. Nguyen, Pharm.D.
	Holly O. Chan, Pharm.D.
Protocol Coordinator:	Cynthia Smith, MBA
Clinical Trials Project Manager:	Sandi Hita, J.D.

Time/Location

Saturday, April 27, 2019 9:30 a.m.- 11:30 a.m.

Room: Seacliff Room (Bay Level)

Introduction

Leukemia Committee Updates – Dr. Harry Erba

AML/MDS Studies

Active Studies

S1612, "A Randomized Phase II/III Trial of "Novel Therapeutics" versus Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia (AML) or High-Risk Myelodysplastic Syndrome (MDS), Age 60 or Older." Drs. Michaelis and Walter. Activated: 12/22/17; Temporary closure: 10/22/18.

ALL Studies

Active Studies

S1318, "A Phase II Study of Blinatumomab (NSC-765986) and POMP (Prednisone, Vincristine, Methotrexate, 6-Mercaptopurine) for Patients ≥ 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Negative (Ph-) Acute Lymphoblastic Leukemia (ALL) and of Dasatinib (NSC-732517), Prednisone and Blinatumomab for Patients ≥ 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Positive (Ph+) ALL, Relapsed/Refractory Philadelphia-Chromosome Positive (Ph+) ALL, and Philadelphia-Chromosome-Like Signature (Ph-Like) ALL (Newly Diagnosed or Relaposed/Refractory) with Known or Presumed Activating Dasatinib-Sensitive Mutations or Kinase Fusions (DSMKF)." Drs. Advani and O'Dwyer. Activated: 1/12/15; Permanent closure of Cohort 1: 9/15/17; Temporary closure of Cohort 2: 4/15/17.



Since 1956,

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

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



Leukemia Committee

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

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

CTSU/A041501, "A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin (a Conjugated Anti-CD22 Monoclonal Antibody) to Frontline Therapy in Young Adults (Ages 18-39 years) with Newly Diagnosed Precursor B-Cell ALL." Dr. Advani. Alliance Activation: 6/1/17.

Proposed Studies

<u>S1902</u>, "Randomized Phase III Study Comparing a Combination of miniHCVD with and without Inotuzumab Ozogamicin (InO) in Patients ≥ 60 Years with Newly Diagnosed Philadelphia (Ph)-negative B-cell Acute Lymphoblastic Leukemia (ALL)." Dr. Jabbour.

S1905, "A Phase I/II Study of OBI-3424 in Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia." Dr. Advani.

CTSU/EA9181, "A Phase II Randomized Trial of Steroids + TKI Induction with Chemotherapy or Blinatumomab and Allo-HCT for Newly Diagnosed BCR-ABL-Positive ALL in Adults." Drs. Phelan, Ofran, and Jamieson.

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. ECOG-ACRIN Activation: 1/3/19.

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

Proposed Studies

<u>\$1925</u>, "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.

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.

Thanks, team!















Leukemia Committee

Cumulative Accrual by Institution and Study

	50919	51312	51318	51672	51712	A041501	E1910	E3906	NHLBIMDS
Arizona MC, U of	_	_	_	1	_	_	4	7	_
Arkansas, U of	_	_	1	_	_	_	3	_	_
Baylor College	5	7	_	_	_	_	_	_	_
Beaumont NCORP	_	_	_	_	_	_	_	_	2
Birmingham, U of AL	3	_	1	_	_	_	10	_	_
CRC West MI NCORP	_	_	_	_	_	_	_	4	_
Carle CC NCORP	_	_	_	1	_	_	_	_	_
Cincinnati MC, U of	_	_	_	_	_	_	_	3	_
City of Hope Med Ctr	_	17	4	_	_	_	_	_	_
Cleveland Clinic OH	23	11	4	_	_	_	8	_	3
Colorado, U of	6	_	_	_	_	_	_	_	_
Columbia MU-NCORP	_	_	_	_	_	_	_	3	_
Davis, U of CA	_	_	_	1	_	_	_	_	_
Dayton NCORP	_	_	_	_	_	_	1	5	_
Fred Hutchinson CRC	_	_	_	_	_	_	_	_	1
Georgia NCORP	_	_	_	1	_	_	_	_	_
Greenville NCORP	_	_	1	2	_	_	1	_	1
Gulf South MU-NCORP	1	_	_	_	_	_	<u>,</u>	_	<u>.</u>
H Lee Moffitt CC	11		_	3	1	_	_	_	5
Hawaii MU-NCORP			_	_			_	_	3
Heartland NCORP	_	_	1	6	2	_	_	_	_
	_		<u>'</u>	_	_	_	3	_	_
Henry Ford Hospital		_	3	_	_	_	9	_	_
Irvine, U of CA	_		_	9	_		_	_	3
Kaiser Perm NCORP	_	_		_		_	1	_	2
Kansas City NCORP	_		_		_		10	_	_
Kansas, U of	_	_	_	_	_	_	—	7	_
Kentucky, U of	_		1			_	_	_	
Loma Linda Univ	4	_	_	1		_	1	9	
Loyola University	_	_	_	2	_		_	_	_
Michigan CRC NCORP		_	2	_	_	_			_
Michigan, U of	1	_	_	_	_			1	
Mississippi, Univ of Montana NCORP	_	_	_	3	_	_	_		
	5	_	1	3	_		_	1	_
New Mexico MU-NCORP						_	8	_	
Northwest NCORP	_	_	_	_	_		1	_	_
Northwestern Univ	6	_	_	_	_	_	,		3
Oregon HIth Sci Univ	2	_	_	2		_	_		
PCRC NCORP	15	11	1	3	_	1	9	27	
Rochester, Univ of	15 —	——————————————————————————————————————	1	_		_	3		
San Diego, U of CA			3	_					
So Calif, U of	_	_	_	1	_	_	_	_	_
Southeast COR NCORP	<u> </u>	2	_	_	_	_	<u> </u>	_	
Stanford University	1	_	_	_	_	_			_
Tulane Univ MBCCOP	2			_	_	_	_	_	
Tulane University	_	_	_	_	_	_	_	3	_
Upstate Carolina		_	_	2	_	_	<u> </u>	_	_
Wayne State Univ	<u> </u>	_	1	_	_		_		_
Wichita NCORP	0		1				 18	5	1
Yale University	_	_			_	_		<u> </u>	1
Alliance	_	_	15 6	23 2	_	_	_		
ECOG-ACRIN	_	_			_		_	_	_
NRG	115	48	<u> </u>	12 78	_	1	— 106	— 75	24
Total	115	40	4/	/0	3	I	100	/3	24



Leadership		
Chair:	Protocol Co	ordinators:Gretchen Goetz, M.B.A.
Vice-Chair:Roy S. Herbst, M.D., Ph.D.		Mariah Norman, M.S. (Lung-MAP)
Executive Officer:		Sara Rice (Lung-MAP)
Statisticians: Mary Redman, Ph.D.	Clinical Tria	ls Project Manager: Crystal Miwa
Yingqi Zhao, Ph.D.	Time/Loca	tion
Katherine Minichiello, M.S.		pril 27, 2019 9:30 a.m 12:30 p.m.
		view Room (Bay Level)
James Moon, M.S.	Nooiii. Day	view Noom (bay Level)
Lu Qian, M.S.		
Scientific Leadership	Agenda	
Translational Medicine:	9:30 a.m.	Opening Remarks – Dr. Kelly
Biology/Pathology Philip C. Mack, Ph.D.		· · ·
Fred R. Hirsch, M.D., Ph.D.		General Update
lgnacio I. Wistuba M.D.		Patient Advocate Judy Johnson
Imaging: Chadwick L. Wright M.D., Ph.D.		·
Myrna C. Godoy, M.D., Ph.D.	9:45 a.m.	Translational Medicine Session – Imaging – Dr. Wright
Radiation Oncology: Roy H. Decker, M.D., Ph.D.		Scientific Presentation: "Integrating Quantitative Imaging
Surgery:Wayne L. Hofstetter, M.D.		Biomarkers - Radiomics and Al into Lung-MAP" - Lawrence
Subcommittee Chairs:		H. Schwartz, M.D., James Picker Professor and Chairman,
Early Stage Disease:Wayne L. Hofstetter, M.D.		Department of Radiology, Columbia University College of
Raymond Osarogiagbon, M.D.		Physicians and Surgeons Chair SWOG Radiology Committee
Locally Advanced Disease: Roy H. Decker, M.D., Ph.D.	10.00	
Shirish Gadgeel, M.D. (Early Therapeutics)	10:00 a.m.	2nd Annual Robert B. Livingston Translational Breast and
Metastatic Disease:		Lung Cancer Lecture: "Evolution of Immunophenotyping for
Karen Reckamp, M.D.		Therapeutic Decision-Making in Advanced NSCLC" - David
Community Engagement:		R. Gandara, M.D., Professor of Medicine Emeritus, Director - Thoracic Oncology, Senior Advisor to the Director, UC Davis
Suzanne Cole, M.D.		Comprehensive Cancer Center
		Comprehensive Cancer Center
Designates Cancer Control Liaison:	10:45 a.m.	Community Engagement Session – Dr. Hesketh
Data Coordinators:	11:00 a.m.	Thoracic Surgery Session – Dr. Hofstetter
Joni Harris	11:15 a.m.	Thoracic Radiation Session – Dr. Decker
Louise Highleyman	11:30 a.m.	Translational Medicine Session – Biology/Pathology –
Larry Kaye Clinical Research Project Manager:Sarah Basse	11.50 a.111.	Dr. Mack
Oncology Research Professionals:		
CRAs:		Scientific Presentation: "Leveraging Tumor Molecular
Ginny M. Keeling, M.S.		Profiling Data to Infer Patient Specific Therapies and
Nurses: Kimberly M. Belzer, M.S., P.A.C		Combination" Adam A. Margolin, Ph.D., Director, Icahn
Rosalie Zablocki, R.N.		Institute For Data Science And Genomic Technology, Senior
Patient Advocate: Judy Johnson, M.B.A.		Associate Dean For Precision Medicine, Mount Sinai Health
Pharmaceutical Science: Joyce Lee, Pharm.D.		System, New York, NY
	12:00 p.m.	Thoracic Medical Oncology Session – Dr. Kelly
	12:30 p.m.	Closing Remarks



Active Studies

- <u>LUNGMAP</u>, "A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study)." Drs. Papadimitrakopoulou, Herbst, Gandara, et al. Activated: 1/28/19.
- <u>S1400F</u>, "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.
- <u>S1400GEN</u>, "Ancillary Study to Evaluate Patient and Physician Knowledge, Attitudes, and Preferences Related to Return of Genomic Results in the Lung-MAP Screening Study." Drs. Ramsey and Roth. Activated: 2/5/18.
- 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.
- <u>S1619</u>, "A Feasibility Trial of Neoadjuvant Cisplatin-Pemetrexed with Atezolizumab in Combination and in Maintenance for Resectable Malignant Pleural Mesothelioma." Drs. Tsao, Cetnar, Sepesi, et al. Activated: 11/3/17.
- <u>S1701</u>, "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.
- CTSU/S1709/EA5163, "INSIGNA: A Randomized, Phase III Study of Firstline Immunotherapy Alone or in Combination with Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature-driven Analysis." Dr. Chiang. Activated: 2/28/19.

- <u>CTSU/A151216</u>, "Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)." Dr. Gandara. Activated: 8/18/14.
- CTSU/A081105, "Randomized Study of Erlotinib versus Observation in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC)." Dr. Kelly. Activated: 8/18/14.
- CTSU/E4512, "A Randomized Phase III Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib Versus Observation for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein." Dr. Li. Activated: 8/18/14.
- CTSU/EA5142, "Adjuvant Nivolumab in Resected Lung Cancers (ANVIL) A Randomized Phase III Study of Nivolumab after Surgical Resection and Adjuvant Chemotherapy in Non-Small Cell Lung Cancers." Activated: 5/6/16.
- CTSU/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.
- CTSU/CALGB 30610, "Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer Also Receiving Cisplatin or Carboplatin and Etoposide." Drs. Gadgeel and Gaspar. Activated: 3/15/08.
- CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)." Dr. Villalobos. Activated: 8/12/15.



Closed Studies

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

S1400K, "A Phase II Study of ABBV-399 (Process II) in Patients with c-MET Positive Stage IV or Recurrent Squamous Cell Lung Cancer (Lung-MAP Sub-Study)." Drs. Waqar and Arnold. Activated: 2/5/18; Closed: 12/21/18.

NCI Approved Concepts

<u>S1800A</u>, "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-Matched Sub-Study)." Drs. Reckamp and Dragnev.

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

<u>S1827</u>, "A Randomized Phase III Trial of MRI Surveillance with or without Prophylactic Cranial Irradiation (PCI) in Small-Cell Lung Cancer." Dr. Rusthoven.

<u>\$1914,</u> "A Randomized Phase III Trial of Induction/Consolidation Atezolizumab + SBRT versus SBRT alone in High Risk, Early Stage NSCLC." Drs. Daly and Simone.

Concepts in Development

<u>S1900C</u>, "A Phase II Study of Talazoparib plus Avelumab in Patients with STK11/LKB1-Mutant Stage IV Non-Squamous Cell Lung Cancer (Lung-MAP Sub-Study)." Drs. Skoulidis and Suga.

<u>S1900D</u>, "A Phase II Study of TAK228 plus Paclitaxel in Patients with NFE2L2 and KEAP1-Mutant Stage IV Squamous Cell Lung Cancer (Lung-MAP Sub-Study)." Dr. Paik.

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

<u>S1929</u>, "Phase II Study of Maintenance Atezolizumab versus Atezolizumab in Combination with Talazoparib in Patients with SLFN11 Positive Extensive Stage Small Cell Lung Cancer (SCLC)." Dr. Karim.

Your SWOG Support Teams

SWOG investigators can tap several research support committees for advice and resources as they develop and launch their clinical trials. To find contact information for each committee, visit the "Member Resources" section of SWOG.org

Recruitment and Retention Committee

For help enrolling minority, underserved, or special population patients



Elise Cook, MD

Recruitment and Retention Chair

Digital Engagement Committee

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



Don Dizon, MDDigital Engagement Chair

Adolescent and Young Adult Committee

For help enrolling patients aged 15-39 onto trials



Mark Lewis, MD

AYA Chair

Pharmaceutical Sciences Committee

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



Siu-Fun Wong, PharmD *Pharmaceutical Sciences Chair*



Cumulative Accrual by Institution and Study

	LUNGMAP	51206	57400	51400F	57400G	574001	51400K	57403	51507	51679	A087705	A157216	C30670	E4572	EA5142	EA5161	NRGCC003	R1306
Arizona MC, U of	_	3	1	_	_	_	_	_	_	_	_	4	_	1	_	_	_	_
Arkansas, U of	_	_	5	_	_	_	_	_	_	_	_	1	2	_	_	3	_	_
Baptist MU-NCORP	_	_	16	_	_	5	1	2	1	_	_	18	2	_	_	_	_	_
Baylor College	_	_	1	_	_	1	_	_	_	_	_	_	_	_	_	_	_	_
Beaumont NCORP	_	_	2	_	_	_	_	_	_	_	_	2	_	_	1	_	_	_
Boston Medical Ctr	_	_	5	_	_	2	_	_	_	_	_	3	_	_	_	_	_	_
Brooke Army Med Ctr	_	_	6	_	_	2	_	_	_	_	_	8	_	_	_	_	_	_
CORA NCORP	_	_	15	_	1	3	_	_	_	_	_	2	_	_	_	_	_	_
CRC West MI NCORP	_	_	11	_	_	1	_	2	_	_	_	1	_	_	_	_	_	_
Carle CC NCORP	_	1	4	_	_	3	_	_	_	_	_	_	_	_	_	_	_	_
Cincinnati MC, U of	_	_	6	_	_	2	_	_	_	_	1	15	3	1	3	_	_	_
City of Hope Med Ctr	_	2	16	_	_	2	_	_	_	_	1	4	_	_	1	_	_	_
Cleveland Clinic OH	_	_	10	_	_	1	_	_	1	_	3	35	_	_	9	_	_	_
Colorado, U of	_	_	3	1	_	1	_	_	_	_	6	32	_	2	2	_	_	1
Columbia MU-NCORP	_	_	2	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Columbus NCORP	_	_	15	_	_	1	_	3	2	_	_	_	1	_	_	_	_	_
Davis, U of CA	_	10	21	_	3	3	_	4	2	_	2	34	13	1	2	_	_	_
Dayton NCORP	_	1	6	_	_	1	_	2	_	_	_	3	_	_	2	_	_	_
Essentia HIth NCORP	_	_	9	_	1	2	_	_	_	_	_	_	_	_	_	_	_	_
Fred Hutchinson CRC	_	_	20	_	1	4	1	_	_	1	1	15	_	_	1	_	_	_
Georgia NCORP	1	_	33	5	1	5	4	_	1	_	_	_	1	_	_	_	_	_
Greenville NCORP	_	_	16	_	1	6	_	2	_	_	_	1	_	_	_	_	_	_
Gulf South MU-NCORP	_	_	6	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_
H Lee Moffitt CC	_	_	10	_	_	1	_	_	_	_	3	83	_	1	10	1	_	_
Harrington CC	_	_	9	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Hawaii MU-NCORP	_	4	7	_	_	1	1	7	1	_	_	_	_	_	_	_	_	_
Heartland NCORP	6	7	61	5	_	8	1	2	7	_	_	_	7	_	_	_	_	_
Henry Ford Hospital	_	2	9	_	_	_	1	_	_	_	1	21	_	_	4	_	_	_
Irvine, U of CA	_	_	9	1	_	2	_	_	1	_	2	6	_	_	1	_	_	_
Kaiser Perm NCORP	_	_	53	_	1	6	_	28	_	_	16	150	3	2	13	1	_	_
Kansas City NCORP	_	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Kansas, U of	_	1	44	_	_	12	1	2	_	_	_	25	1	_	7	_	_	_
Kentucky, U of	_	_	8	1	_	4	_	_	_	_	_	1	_	_	1	_	_	_
Lahey Hosp & Med Ctr	_	1	13	_	1	1	_	3	1	_	_	22	_	_	4	1	_	2
Loma Linda Univ	_	_	7	_	1	1	_	_	1	_	1	2	_	_	1	_	_	_
Loyola University	_	4	12	_	_	4	_	_	_	_	_	13	_	_	3	1	_	_
MAVERIC	1	_	19	2	_	9	1	_	_	_	_	5	_	_	2	_	_	_



Cumulative Accrual by Institution and Study

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	LUNGMAP	51206	51400	57400F	574000	514001	51400K	51403	51507	51619	A081705	A151216	C30610	E4572	EA5742	EA5161	NRGCC003	R13
MD Anderson CC	_	3	24	1	_	1	_	_	_	6	_	2	_	_	_	_	_	5
MUSC MU-NCORP	_	_	1	_	_	_	_	_	2	3	_	_	1	_	_	_	_	_
Methodist Hospital	_	_	5	_	_	_	_	_	_	_	1	4	_	_	_	_	_	_
Michigan CRC NCORP	2	_	38	1	3	4	1	7	4	_	_	_	_	_	_	_	_	_
Michigan, U of	_	_	13	1	_	4	_	3	1	_	_	50	1	_	1	_	_	_
Mississippi, Univ of	_	_	6	_	_	3	_	_	_	_	2	17	1	_	4	_	_	_
Montana NCORP	1	_	15	_	_	2	_	2	1	_	_	_	_	_	_	_	_	_
Mt Sinai Med Ctr	_	_	4	_	_	_	1	_	_	_	_	_	_	_	_	_	_	_
Nevada CRF NCORP	_	_	5	_	_	3	_	_	_	_	_	_	_	_	_	_	_	_
New Mexico MU-NCORP	_	_	14	1	_	_	_	1	_	_	_	_	_	_	_	_	_	_
Northwest NCORP	_	_	6	_	_	_	1	_	_	_	_	_	_	_	_	_	_	_
Northwestern Univ	_	_	2	_	_	1	_	_	3	_	_	_	_	_	_	_	_	_
Oklahoma, Univ of	_	_	10	_	1	2	_	4	_	_	_	_	_	_	_	_	_	_
Oregon HIth Sci Univ	_	_	15	1	3	7	_	_	_	_	1	4	_	_	1	_	_	_
Ozarks NCORP	1	_	16	_	_	2	_	3	1	_	1	1	_	_	_	_	_	_
PCRC NCORP	_	_	18	_	_	_	_	_	_	_	_	4	_	_	_	_	_	_
Providence Hosp	_	_	15	1	_	_	_	_	_	_	_	12	2	1	2	2	_	_
Rochester, Univ of	_	_	22	1	1	1	_	2	1	_	_	_	_	_	_	4	4	_
San Antonio, U of TX	_	_	13	_	_	3	_	5	_	_	_	_	3	_	_	_	_	_
San Diego, U of CA	_	_	16	1	_	1	_	7	_	_	1	3	_	_	_	_	_	_
So Calif, U of	_	_	-	_	_	_	_	_	_	_	1	9	_	_	_	_	_	_
Southeast COR NCORP	_	1	75	4	3	14	2	2	_	_	_	_	_	_	_	4	_	_
Sutter Cancer RC	_	_	4	_	_	1	_	_	_	_	1	5	_	_	4	_	_	_
Tulane Univ MBCCOP	_	_	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Univ of Louisville	_	_	-	_	_	_	_	_	_	_	_	5	_	_	_	_	_	_
Upstate Carolina	_	_	2	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Utah, U of	_	_	1	_	_	_	_	_	4	_	_	_	_	_	_	_	_	_
VAMC Kansas City	_	_	9	1	_	1	_	_	_	_	_	_	1	_	_	_	_	
Wayne State Univ	_	_	15	1	2		_	2	1	_	_	1	1	_	_	2	_	_
Wichita NCORP	_	_	24	1	1	3	1	8	_	_	_	_	13	_	_	_	_	
Wisconsin NCORP	_	_	9		_	_	1	1	_	_	_		_	_	_		_	_
Yale University	_	12	27	1	1	4	_	24	_	_	3	39	_	3	14		_	
Alliance	_	_	399	10	12	39	5	24	9	_	_	_	_	_	_	_	_	_
CCTG			18	_	1	3	_	_	_		_		_	_			_	
ECOG-ACRIN	1		326	6	9	58	1	9	9	_	_		_	_		_		Ξ
NRG	_	1	203	7	2	24	4	13	6									
Total	13	53	1,864	55	51	275	28	174	60	10	48	662	56	12	93	19	4	8
างเลา	13	23	1,004	23	31	2/3	20	1/4	00	10	40	002	30	12	73	17	4	0



Lymphoma Committee

Leadership

Chair:	Jonathan W. Friedberg, M.D.
Vice-Chair:	Sonali M. Smith, M.D.
Executive Officer:	Susan M. O'Brien, M.D.
Statisticians:	Michael LeBlanc, Ph.D.
	Hongli Li, M.S.
	Michael Wu, Ph.D.
Scientific Leadership	
Translational Medicine:	Lisa M. Rimsza, M.D.
Radiation Oncology:	Louis S. Constine, M.D.
Imaging:	Lawrence H. Schwartz, M.D.
Pathology:	Lisa M. Rimsza, M.D.
Early Therapeutics:	Daruka Mahadevan, M.D., Ph.D.
Destance	
Designates	
Cancer Control:	TBD
•	
Cancer Control:	Mazyar Shadman, M.D.
Cancer Control:	Mazyar Shadman, M.D.
Cancer Control:	Mazyar Shadman, M.DIris Syquia
Cancer Control:	Mazyar Shadman, M.DIris SyquiaErin M. Cebula, M.P.H.
Cancer Control: Digital Engagement: Data Coordinators: Oncology Research Professionals: CRA:	Mazyar Shadman, M.DIris SyquiaErin M. Cebula, M.P.HTBD
Cancer Control: Digital Engagement: Data Coordinators: Oncology Research Professionals: CRA: Nurse:	Mazyar Shadman, M.DIris SyquiaErin M. Cebula, M.P.HTBDHildy Dillon, M.P.H.
Cancer Control: Digital Engagement: Data Coordinators: Oncology Research Professionals: CRA: Nurse: Patient Advocate:	
Cancer Control: Digital Engagement: Data Coordinators: Oncology Research Professionals: CRA: Nurse: Patient Advocate: Pharmaceutical Science:	Mazyar Shadman, M.Dlris SyquiaErin M. Cebula, M.P.HTBDHildy Dillon, M.P.HLara M. Au, Pharm.DHolly Chan, Pharm.D.
Cancer Control: Digital Engagement: Data Coordinators: Oncology Research Professionals: CRA: Nurse: Patient Advocate: Pharmaceutical Science:	

Time/Location

Friday, April 26, 2019 4:00 p.m.- 7:00 p.m.

Room: Grand C (Street Level)

Welcome: Drs. Jonathan Friedberg and Sonali Smith

S1826 (cHL): Dr. Herrera. (Note: S1826 Kickoff Meeting will be held: 4/26/19, 9:30 a.m. - 10:30 a.m.)

Presentation by Mark Chao, M.D.:

"Therapeutic targeting of CD47, a macrophage immune checkpoint, in non-Hodgkin's lymphoma"

Updates on Open Studies:

- a. S1608: Dr. P. Barr
- b. A051301: Dr. P. Stiff
- c. EA4151: Dr. B. Till
- d. E4412: Dr. Amengual

Studies in Development

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

Other Business

Adjourn

Active Studies

<u>\$1608</u>, "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; Temporarily closed to accrual: 8/24/18.

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.

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

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



Lymphoma Committee

Developing Studies

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

<u>S1918</u>, "A Phase II/III Randomized Study of R-miniCHOP With or Without Oral Azacytidine in Very Elderly Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma." Drs. Brem and Smith.

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

CTSU/ EA4181, "A Randomized 3-Arm Phase II Study Comparing 1.)

Bendamustine, Rituximab and High Dose Cytarabine (BRC) 2.)

Bendamustine, Rituximab, High Dose Cytarabine and Acalabrutinib (BRCA), and 3.) Bendamustine, Rituximab and Acalabrutinib (BRA) in Patients </= 70 years Old with Untreated Mantle Cell Lymphoma." Dr. Spurgeon.

"Randomized Phase II/III Study of Venetoclax (ABT199) Plus Chemoimmunotherapy for MYC/BCL2 Double-Hit and Double Expressing Lymphomas." Dr. Smith.

Developing Leukemia Study

<u>S1925</u>, "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.

Recently Closed Studies (Cancer Care Delivery)

S1204, "A Sero-Epidemiologic Survey and Cost-effectiveness Study of Screening for Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer Patients." Dr. Ramsey. Activated: 8/29/13; Closed: 2/16/17.

Lymphoma Committee

Cumulative Accrual by Institution and Study

	51608	A051301	EA4151
Baylor College	_	1	_
CRC West MI NCORP	1	_	_
City of Hope Med Ctr	1	1	7
Colorado, U of	_	1	_
Fred Hutchinson CRC	_	_	3
Greenville NCORP	_	_	1
Heartland NCORP	1	_	_
King Faisal Spec Hos	_	1	_
Oregon HIth Sci Univ	_	_	2
Rochester, Univ of	6	2	_
San Antonio, U of TX	_	_	4
San Diego, U of CA	_	_	1
Utah, U of	1	_	1
Alliance	1	_	_
ECOG-ACRIN	2	_	_
NRG	1	_	_
Total	14	6	19



Melanoma Committee

Leadership

Chair:	Antoni Ribas, M.D., Ph.D.
Vice-Chair:	Kenneth F. Grossmann, M.D., Ph.D.
Executive Officer:	Christopher W. Ryan, M.D.
Statisticians:	Michael Wu, Ph.D.
	Megan Othus, Ph.D.
	James Moon, M.S.
	Hongli Li, M.S.
Scientific Leadership	
Translational Medicine:	William E. Carson, III, M.D.
Radiation Oncology:	Evan J. Wuthrick, M.D.
Surgery:	John Hyngstrom, M.D.
	Kenneth F. Grossmann, M.D., Ph.D.
	Martin Allen-Auerbach, M.D.
Medical Oncology:	Lawrence E. Flaherty, M.D.
Pathology:	Michael T. Tetzlaff, M.D., Ph.D.
Non-Melanoma Skin Cancer:	Nikhil I. Khushalani, M.D.
Early Therapeutics:	Jeffrey A. Sosman, M.D.
SWOG's ECOG Liaisons:	Sapna Pradyuman Patel, M.D.
	Kevin B. Kim, M.D.
ECOG's SWOG Liaisons:	David H. Lawson, M.D.
	Andrew Poklepovic, M.D.
Digital Engagement:	Zeynep Eroglu, M.D.
Designates	
Cancer Control Liaison:	Sancy Leachman, M.D., Ph.D.
	Thach-Giao Truong, M.D. (Survivorship)
Data Coordinator:	Vicky Kim
	Jourdain Hayward
	Laura Kingsbury, M.R.T.
Oncology Research Professionals:	
CRA:	Kacie L. Simpson, B.S., C.C.R.P.
Nurse:	Lisa S. Morgan, R.N., O.C.N.
Patient Advocate:	Valerie Guild, M.B.A.
Pharmaceutical Science:	Sun "Coco" Yang, Pharm.D., Ph.D.
	Mai T. Nguyen, Pharm.D.
Protocol Coordinator:	Danae Campos, M.B.A.
Clinical Trials Project Manager:	Vanessa Benavidez, B.S., C.C.R.C.

Time/Location

Friday, April 26, 2019 9:30 a.m.- 11:30 a.m.

Room: Bayview B (Bay Level)

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

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

Biomarkers for immuno-oncology (20 min, 9:35-9:45): Kenneth Grossmann MD, PhD

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

- <u>S1320</u>, "A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763760) and Trametinib (NSC-763093) in BRAFV600E/K Mutant Melanoma." Dr. Algazi. Activated: 7/22/14.
- <u>\$1512</u>, "A Phase II Study of PD-1 Blockade with Pembrolizumab in Patients with Locally Advanced and Metastatic Desmoplastic Melanoma (DM)." Drs. Kendra and Hu-Lieskovan, Activated: 10/20/16.
- <u>S1616</u>, "A Phase II Randomized Study of Nivolumab (NSC-748726) with Ipilimumab (NSC-732442) OR Ipilimumab Alone in Advanced Melanoma Patients Refractory to an Anti-PD-1 or Anti-PD-IL1 Agent." Drs. VanderWalde and Ribas. Activated 7/17/17.
- <u>S1607</u>, "A Phase II Study of Combining T-VEC (NSC-785349) and Pembrolizumab (NSC-776864) in Patients with Advanced Melanoma who have Progressed on Anti-PD1/L1 Based Therapy." Dr. Hu-Lieskovan. Activated: 10/2/17.
- <u>S1801</u> "A Phase II Randomized Study of Adjuvant Versus Neo-Adjuvant MK-3475 for Clinically Detectable Stage III-IV High Risk Melanoma." Dr. Sapna Patel. Activated: 12/6/18.
- CTSU/EA6134, "A Randomized Phase III Trial of Dabrafenib + Trametinib Followed by Ipilimumab + Nivolumab at Progression vs. Ipilimumab + Nivolumab followed by Dabrafenib + Trametinib at Progression in Patients with Advanced BRAFV600 Mutant Melanoma". Dr. Chmielowski. Activated: 7/13/15.
- CTSU/EA6141, "Randomized Phase II/III Study of Nivolumab Plus Ipilimumab Plus Sargramostim versus Nivolumab Plus Ipilimumab in Patients with Unresectable Stage III or Stage IV Melanoma." Dr. Kim. Activated: 9/10/15; Temporarily closed: 6/23/17.

Upcoming Studies

<u>S1901</u>, "Randomized Phase 3 Study of Adjuvant Pembrolizumab in combination with Dabrafenib and Trametinib vs Dabrafenib and Trametinib vs Pembrolizumab Alone in Patients with High-Risk Resected Melanoma."



Melanoma Committee

<u>S1920</u>, "A randomized phase 2 trial of ipilimumab + nivolumab +/- binimetinib in BRAF-WT and encoraf-enib + binimetinib + pembrolizumab vs ipilimumab/nivolumab in BRAFV600-mutant melanoma brain metastases."

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

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

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



Melanoma Committee

Cumulative Accrual by Institution and Study

Includes accrual through 2/18/2019. Includes studies that are currently open, or that closed since 7/1/2017.

	51320	574 ⁰⁴	51512	51607	51616	51801	E3612	EN6134	EA6141
Arizona MC, U of	2	11	_	_	_	_	_	_	_
Arkansas, U of	7	12	_	_	_	_	_	1	_
Bay Area NCORP	1	_	_	_	_	_	_	_	_
Baylor Univ Med Ctr	_	12	_	_	_	_	_	_	_
Boston Medical Ctr	1	_	_	_	_	_	_	_	_
CORA NCORP	1	9	_	_	_	_	_	_	_
CRC West MI NCORP	2	13	_	_	2	_	_	_	_
Cedars-Sinai Med Ctr	_	8	_	_	_	_	_	_	_
Cincinnati MC, U of	_	3	_	_	_	_	_	_	_
City of Hope Med Ctr	_	8	_	_	_	_	_	2	3
Cleveland Clinic OH	_	25	_	_	_	_	_	2	_
Colorado, U of	2	29	_	_	_	_	_	1	_
Columbia MU-NCORP	_	3	_	_	_	_	_	_	_
Columbus NCORP	3	4	_	_	_	_	_	_	_
Davis, U of CA	_	3	_	_	_	_	_	_	_
Dayton NCORP	1	7	_	_	_	_	_	_	_
Essentia HIth NCORP	_	1	_	_	_	_	_	_	_
Georgia NCORP	_	20	1	_	_	_	_	_	_
Greenville NCORP	_	_	_	_	_	_	1	_	_
Gulf South MU-NCORP	_	4	_	_	_	_	_	_	_
H Lee Moffitt CC	_	52	6	_	_	_	_	_	_
Hawaii MU-NCORP	1	3	_	_	_	_	_	_	_
Heartland NCORP	6	27	_	_	_	1	_	_	_
Irvine, U of CA	_	1	_	_	_	_	_	_	_
Kaiser Perm NCORP	32	74	_	_	_	_	4	11	20
Kansas City NCORP	_	1	_	_	_	_	_	_	1
Kansas, U of	17	25	1	_	1	_	_	2	_
Lahey Hosp & Med Ctr	1	4	_	_	_	_	_	_	_
Los Angeles, U of CA	4	23	3	5	3	_	_	5	_
Loyola University	8	1	_	_	_	_	_	_	_
MD Anderson CC	_	43	_	_	_	_	_	_	_
Michigan CRC NCORP	_	8	_	_	_	_	_	_	_



Our History

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







Melanoma Committee, cont.

Cumulative Accrual by Institution and Study

	51320	57404	51512	51607	51676	51807	E3612	EN613A	EA6141
Michigan, U of	5	12	_	_	_	_	_	_	_
Mississippi, Univ of	_	1	_	_	_	_	_	_	_
Montana NCORP	_	4	_	_	_	_	_	_	_
Mt Sinai Med Ctr	_	10	_	_	_	_	_	_	_
Nevada CRF NCORP	4	_	_	_	_	_	_	_	_
New Mexico MU-NCORP	_	9	_	_	2	_	_	_	_
Northwest NCORP	_	11	_	_	_	_	_	_	_
Northwestern Univ	_	16	_	_	2	_	1	_	_
Ohio State Univ	17	33	4	1	3	_	_	2	_
Oregon Hlth Sci Univ	_	12	_	_	_	_	_	_	_
Ozarks NCORP	2	4	_	_	_	_	_	_	_
PCRC NCORP	2	17	_	_	_	_	_	_	_
Rochester, Univ of	4	6	_	_	1	_	_	2	_
San Antonio, U of TX	_	7	_	_	_	_	_	_	1
San Diego, U of CA	_	6	_	_	_	_	_	_	_
San Francisco, U-CA	8	_	_	_	_	_	_	_	_
So Calif, U of	_	_	2	1	_	_	_	_	_
Southeast COR NCORP	8	10	1	_	_	_	_	_	_
Sutter Cancer RC	_	5	_	_	_	_	_	2	5
Tennessee, U of	_	6	_	_	4	_	_	_	_
Utah, U of	12	31	_	1	_	_	_	_	_
VAMC Kansas City	_	1	_	_	_	_	_	_	_
Wayne State Univ	_	9	_	_	_	_	_	2	_
Wichita NCORP	7	13	_	_	_	_	_	_	_
Wisconsin NCORP	1	8	_	_	_	_	_	_	_
Yale University	_	6	_	_	_	_	_	_	6
Alliance	13	144	_	_	4	_	_	_	_
CCTG	_	122	_	_	_	_	_	_	_
ECOG-ACRIN	48	302	_	3	1	_	_	_	_
NRG	21	106	_	_	7	_	_	_	_
Total	241	1,345	18	11	30	1	6	32	36





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

ADOLESCENT AND YOUNG ADULT (AYA) COMMITTEE

Published/Accepted Manuscripts

- C10403 A pediatric regimen for older adolescents and young adults with acute lymphoblastic leukemia: results of CALGB 10403. Stock W, Luger S, Advani A, Yin J, Harvey R, Mullighan C, Willman C, Fulton N, Laumann K, Malnassy M, Paietta E, Parker E, Geyer S, Mrozek K, Bloomfield C, Sanford B, Marcucci G, Liedtke M, Claxton D, Foster M, Bogart J, Grecula J, Appelbaum F, Erba H, Litzow M, Tallman M, Stone R, Larson R. Blood Jan 18. pii: blood-2018-10-881961. doi: 10.1182/blood-2018-10-881961[Epub ahead of print], 2019. https://www.ncbi.nlm.nih.gov/pubmed/30658992 [see also Leuk Cmte]
- Multiple Studies* Treatment of young adults with Philadelphia-negative acute lymphoblastic leukemia and lymphoblastic lymphoma: Hyper-CVAD vs. pediatric-inspired regimens. [Review]. Siegel SE, Advani A, Seibel N, Muffly L, Stock W, Luger S, Shah B, DeAngelo D, Freyer DR, Douer D, Johnson RH, Hayes-Lattin B, Lewis M, Jaboin JJ, Coccia PF, Bleyer A. Am J Hematol Oct;93(10):1254-1266, 2018. [*SWOG/Other NCTN-led Group AYA, leukemia, lymphoma trials] https://www.ncbi.nlm.nih.gov/pubmed/30058716 [see also Leuk and Lymph Cmtes]
- Multiple Studies * Pediatric-Inspired Treatment Regimens for Adolescents and Young Adults With Philadelphia Chromosome-Negative Acute Lymphoblastic Leukemia: A Review. [Review]. Siegel SE, Stock W, Johnson RH, Advani A, Muffly L, Douer D, Reed D, Lewis M, Freyer DR, Shah B, Luger S, Hayes-Lattin B, Jaboin JJ, Coccia PF, DeAngelo DJ, Seibel N, Bleyer A. JAMA Oncol. May 1;4(5):725-734, 2018. [*Multiple group-led trials] https://www.ncbi.nlm.nih.gov/pubmed/29450465 [see also Leuk Cmte]

Submitted Manuscripts

(none this cycle)

BARLOGIE-SALMON MYELOMA COMMITTEE

Published/Accepted Manuscripts

<u>Multiple Studies</u>* Antigen-mediated regulation in monoclonal gammopathies and myeloma. Nair S, Sng J, Boddupalli CS, Seckinger A, Chesi M, Fulciniti M, Zhang L, Rauniyar N, Lopez M, Neparidze N, Parker T, Munshi NC, Sexton R, Barlogie B, Orlowski R, Bergsagel L, Hose D, Flavell RA, Mistry PK, Meffre E, Dhodapkar MV. <u>JCl Insight</u> Apr 19;3(8), 2018. [*S0120 and other]. https://www.ncbi.nlm.nih.gov/pubmed/29669929

- Multiple Studies * Clinical predictors of long-term survival in newly diagnosed transplant eligible multiple myeloma an IMWG Research Project. Usmani SZ, Hoering A, Cavo M, Miguel JS, Goldschimdt H, Hajek R, Turesson I, Lahuerta JJ, Attal M, Barlogie B, Lee JH, Kumar S, Lenhoff S, Morgan G, Rajkumar SV, Durie BGM, Moreau P. Blood Cancer J. Nov 23;8(12):123, 2018. [*S9321 and other]. https://www.ncbi.nlm.nih.gov/pubmed/30470751
- <u>Multiple Studies</u>* End points and statistical considerations in immunooncology trials: impact on multiple myeloma. Hoering A, Durie B, Wang H, Crowley J. <u>Future Oncol</u>. Jun;13(13):1181-1193, 2017. [*S0106, S9321 and other] https://www.ncbi.nlm.nih.gov/pubmed/28395525

Submitted Manuscripts

(none this cycle)

BREAST COMMITTEE

- So221 Associations between self-reported diet during treatment and chemotherapy-induced peripheral neuropathy in a cooperative group trial (S0221) Mongiovi J, Zirpoli G, Cannioto R, Sucheston-Campbell L, Hershman D, Unger JM, Moore HCF, Stewart JA, Isaacs C, Hobday TJ, Salim M, Hortobagyi G, Gralow JR, Budd GT, Albain KS, Ambrosone C, McCann SE. Breast Cancer Research 20:146, 2018. https://www.ncbi.nlm.nih.gov/pubmed/30486865 (see also SXCQOL Cmte)
- So226 A phase III randomized trial of anastrozole and fulvestrant versus anastrozole or sequential anastrozole and fulvestrant as first-line therapy for postmenopausal women with metastatic breast cancer: Final survival outcomes of SWOG S0226. Mehta R, Barlow W, Albain K, Vandenberg T, Dakhil S, Tirumali N, Lew DL, Hayes D, Gralow J, Linden H, Livingston R. New England Journal of Medicine, in press 2019.
- S0230 Final Analysis of the Prevention of Early Menopause Study (POEMS)/SWOG Intergroup S0230. Moore H, Unger J, Phillips K-A, Boyle F, Hitre E, Moseley A, Porter D, Francis P, Goldstein L, Gomez H, Vallejos C, Partridge A, Dakhil S, Garcia A, Gralow J, Lombard J, Forbes J, Martino S, Barlow W, Fabian C, Minasian L, Meyskens F, Gelber R, Hortobagyi G, Albain K. <u>Journal of the National Cancer Institute</u> Feb 1;111(2):210-213, 2019. https://www.ncbi.nlm.nih.gov/pubmed/30371800 (see also Ca Surv Cmte)



<u>S0800</u> Immune profiling of pre- and post-treatment breast cancer tissues from the SWOG S0800 neoadjuvant trial. Li X, Warren S, Pelekanou V, Wali V, Cesano A, Liu M, Danaher P, Elliott N, Nahleh Z, Hayes D, Hortobagyi G, Barlow W, Hatzis C, Pusztai L. <u>Journal for ImmunoTherapy of Cancer</u>, accepted 2019.

S8897 Germline Genetic Variants in GATA3 and Breast Cancer Treatment Outcomes in SWOG S8897 Trial and the Pathways Study. Larsen V, Barlow W, Yang JJ, Zhu Q, Liu S, Kwan M, Ergas I, Roh J, Hutchins L, Kadlubar S, Albain K, Rae J, Yeh I-T, Ravdin P, Martino S, Lyss A, Osborne CK, Hortobagyi G, Kushi L, Hayes D, Ambrosone C, Yao S. Clinical Breast Cancer, accepted, 2019.

C49907 Functional decline and resilience among older women receiving adjuvant chemotherapy for breast cancer: a secondary analysis of Cancer and Leukemia Group B (CALGB) 49907 (Alliance/CALGB 361007). Hurria A, Cohen HJ, Allred J, Soto-Perez-de-Celis E, Arsenyan A, Ballman K, Jatoi A, Gralow J, Filo J, Mandelblatt J, Lafky JM, Kimmick G, Klepin H, Freedman RA, Barginear M, Muss H. Journal of the American Geriatrics Society Aug 26.doi:10.1111/jgs.15493 [Epub ahead of print], 2018. https://www.ncbi.nlm.nih.gov/pubmed/30146695

CCTG MA.17R Quality of Life From Canadian Cancer Trials Group MA.17R:

A Randomized Trial of Extending Adjuvant Letrozole to 10 Years.

Lemieux J, Brundage MD, Parulekar WR, Goss PE, Ingle JN, Pritchard KI,
Celano P, Muss H, Gralow J, Strasser-Weippl K, Whelan K, Tu D, Whelan TJ.

Journal of Clinical Oncology Feb 20;36(6):563-571, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29328860 [see also SCQOL Cmte]

Submitted Manuscripts

S0500 Circulating Tumor Cell Clusters in Patients with Metastatic Breast Cancer Starting First Line Chemotherapy: A SWOG S0500 Translational Medicine Study. Paoletti C, Miao J, Dolce E, Darga E, Repollet M, Doyle G, Gralow J, Hortobagyi G, Smerage J, Barlow W, Hayes D. <u>Clinical Cancer</u> <u>Research</u>, submitted, 2019.

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

CANCER CONTROL AND PREVENTION COMMITTEES CANCER CARE DELIVERY COMMITTEE

Published/Accepted Manuscripts

<u>S1204</u> The prevalence of HIV, Hepatitis B, and Hepatitis C among newly diagnosed cancer patients treated in academic and community oncology practices: SWOG S1204. Ramsey S, Unger J, Baker L, Little R, Loomba R, Hwang J, Chugh R, Konerman M, Arnold K, Menter AR, Thomas E, Michels R, Walker Jorgensen C, Burton GV, Bhadkamkar N, Hershman D. <u>JAMA Oncology</u> Jan 17. doi: 10.1001/jamaoncol.2018.6437. [Epub ahead of print], 2019. https://www.ncbi.nlm.nih.gov/pubmed/30653226

Multiple Studies Association of Patient Comorbid Conditions with Cancer Clinical Trial Participation. Unger J, Hershman D, Fleury M, Vaidya R. JAMA Oncology Jan 10. doi: 10.1001/jamaoncol.2018.5953. [Epub ahead of print], 2019. https://www.ncbi.nlm.nih.gov/pubmed/30629092

Multiple Studies Acquisition of sexual orientation and gender identity data among NCI Community Oncology Research Program practice groups. Cathcart-Rake EJ, Zemla T, Jatoi I, Weaver KE, Neuman H, Kazak AE, Carlow R, Gansauer LJ, Unger J, Pajewski NM, Kamen C. <u>Cancer</u> Dec 18. doi: 10.1002/cncr.31925. [Epub ahead of print], 2018. https://www.ncbi.nlm.nih.gov/pubmed/30561776

Multiple Studies Systematic Review and Meta-Analysis of the Magnitude of Structural, Clinical, and Physician/Patient Barriers to Cancer Clinical Trial Participation [Brief Report]. Unger J, Vaidya R, Hershman DL, Minasian L, Fleury M. Journal of the National Cancer Institute Mar 1;111(3):245-255, 2019. https://www.ncbi.nlm.nih.gov/pubmed/30856272

<u>Multiple Studies</u> Geographic Distribution and Survival Outcomes for Rural Cancer Patients Treated in Clinical Trials. Unger J, Moseley A, Symington B, Chavez-MacGregor M, Ramsey S, Hershman D. <u>JAMA</u> <u>Network Open</u> Aug 3;1(4):e181235, 2018. https://www.ncbi.nlm.nih.gov/ pubmed/30646114

Lung Cancer Screening in the National Cancer Institute Community
Oncology Research Program: Availability and Service Organization.
Carlos RC, Sicks JD, Chiles C, Gansauer L, Kamen CS, Kazak AE, Neuman
HB, Unger JM, Weaver KE. J Am Coll Radiol. 2019 Feb 25. pii: S15461440(18)31581-3. doi: 10.1016/j.jacr.2018.12.016. [Epub ahead of print]
https://www.ncbi.nlm.nih.gov/pubmed/30819455

Submitted Manuscripts

C1415CD Effective Stakeholder Engagement: Design and Implementation of a Clinical Trial (SWOG S1415CD) to Improve Cancer Care. Barger S, Bell-Brown A, Bott B, Ciccarella AM, Golenski J, Gorman M, Johnson J, Kreizenbeck K, Kurttila F, Mason G, Myers J, Seigel C, Wade JL, III, Walia G, Watabayashi K, Lyman GH, Sullivan SD, Ramsey SD. BMC Medical Research Methodology, under review 2019.



<u>Multiple Studies</u>* The Impact of NCI-Sponsored Network Group Clinical Trials on Guideline Care and New Drug Indications. Unger JM, Nghiem VT, Hershman DL, Vaidya R, LeBlanc M, Blanke CD. [*multiple SWOG and other NCTN-led trials]. JAMA, submitted 2019.

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

Multiple Studies * Osteoporosis in Colorectal Cancer Survivors: Analysis of the Linkage between SWOG Trial Enrollees and Medicare Claims. Barzi A, Hershman D, Till C, Barlow W, Ramsey S, Lenz H-J, Hochster H, Unger J. [*S9304, S9415, S9420] Osteoporosis International, pending revision/resubmission, 2019. [see also GI Cmte]

CANCER SURVIVORSHIP COMMITTEE

Published/Accepted Manuscripts

S0230 Final Analysis of the Prevention of Early Menopause Study (POEMS)/SWOG Intergroup S0230. Moore H, Unger J, Phillips K-A, Boyle F, Hitre E, Moseley A, Porter D, Francis P, Goldstein L, Gomez H, Vallejos C, Partridge A, Dakhil S, Garcia A, Gralow J, Lombard J, Forbes J, Martino S, Barlow W, Fabian C, Minasian L, Meyskens F, Gelber R, Hortobagyi G, Albain K. <u>Journal of the National Cancer Institute</u> Feb 1;111(2):210-213, 2019. https://www.ncbi.nlm.nih.gov/pubmed/30371800 (see also Breast Cmte)

S1008 Phase II Feasibility Study of a Physical Activity and Dietary Change Weight Loss Intervention in Breast and Colorectal Cancer Survivors (SWOG S1008). Greenlee H, Lew D, Hershman DL, Newman V, Hansen L, Hartman S, Korner J, Shi Z, Sardo Molmenti C, Sayegh A, Fehrenbacher L, Lo S, Klemp J, Rinn K, Robertson JM, Unger JM, Gralow JR, Albain K, Krouse RS, Fabian C. Obesity Oct;26(10):1539-1549, 2018. https://www.ncbi.nlm.nih.gov/pubmed/30272836

C89803 Association of Survival With Adherence to the American Cancer Society Nutrition and Physical Activity Guidelines for Cancer Survivors After Colon Cancer Diagnosis: The CALGB 89803/Alliance Trial. Van Blarigan E, Fuchs C, Niedzwiecki D, Ye X, Zhang S, Saltz L, Mayer R, Mowat R, Whittom R, Hantel A, Benson A, Atienza D, Messino M, Kindler H, Venook A, Ogino S, Giovannucci E, Ng K, Meyerhardt J. JAMA Oncology Jun 1;4(6):783-790, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29710284 [see also GI Cmte]

C89803 The influence of dietary insulin load on cancer recurrence and survival in patients with stage III colon cancer: findings from CALGB 89803 (Alliance). Morales-Oyarvide V, Yuan C, Babic A, Zhang S, Niedzwiecki D, Brand-Miller JC, Sampson-Kent L, Ye X, Li Y, Saltz L, Mayer RJ, Mowat RB, Whittom R, Hantel A, Benson A, Atienza D, Messino M, Kindler H, Venook A, Ogino S, Wu K, Willet W, Giovannucci EL, Wolpin BM, Meyerhardt JA, Fuchs CS, Ng K. <u>Journal of the National Cancer Institute</u> Feb 1;111(2):170-179, 2019. https://www.ncbi.nlm.nih.gov/pubmed/30726946 [see also GI Cmte]

C89803 Associations of artificially sweetened beverage intake with disease recurrence and mortality in stage III colon cancer: Results from CALGB 89803 (Alliance). Guercio B, Zhang S, Niedzwiecki D, Yee Z, Li Y,Babic A, Morales-Oyarvide V, Saltz L, Mayer RJ, Mowat R, Whittom R, Hantel A, Benson A, Atienza DM, Messino M, Kindler H, Venook A, Ogino S, Zoltick E, Stempfer M, Ng K, Wu K, Willett W, Giovannucci E, Meyerhardt J, Fuchs C. PLOS ONE Jul 19;13(7):e0199244, 2018. https://www.ncbi.nlm.nih.gov/pubmed/30024889 [see also Gl Cmte]

N1047 Physical Activity and Outcomes in Patients with Stage III Colon Cancer: A Correlative Analysis of Phase III Trial NCCTG N0147 (Alliance). Phipps AI, Shi Q, Zemla TJ, Dotan E, Gill S, Goldberg RM, Hardikar S, Jahagirdar B, Limburg PJ, Newcomb PA, Shields A, Sinicrope FA, Sargent DJ, Alberts SR. Cancer Epidemiology, Biomarkers, Prevention Jun;27(6):696-703, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29563133 [see also GI Cmte]

Submitted Manuscripts

S1316 Intellectual Equipoise and Challenges: Accruing Patients with Advanced Cancer to a Trial Randomizing to Surgical or Non-Surgical Management (SWOG S1316). Deutsch G, Deneve J, Al-Kasspooles M, Nfonsam V, Gunderson C, Alvarez Secord A, Rodgers P, Hendren S, Silberfein E, Grant ML, Sloan J, Sun V, Arnold K, Anderson G, Krouse R. Palliative and Supportive Care, submitted 2019.

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, Fakih M, Krouse R, Thomson CA. Cancer Nursing, submitted 2019.

PREVENTION AND EPIDEMIOLOGY COMMITTEE

Published/Accepted Manuscripts

<u>S9217</u> Long-term effects of finasteride on prostate cancer mortality.
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GENITOURINARY COMMITTEE

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

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LUNG COMMITTEE

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LYMPHOMA COMMITTEE

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MELANOMA COMMITTEE

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PHARMACEUTICAL SCIENCES COMMITTEE

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RADIATION ONCOLOGY COMMITTEE

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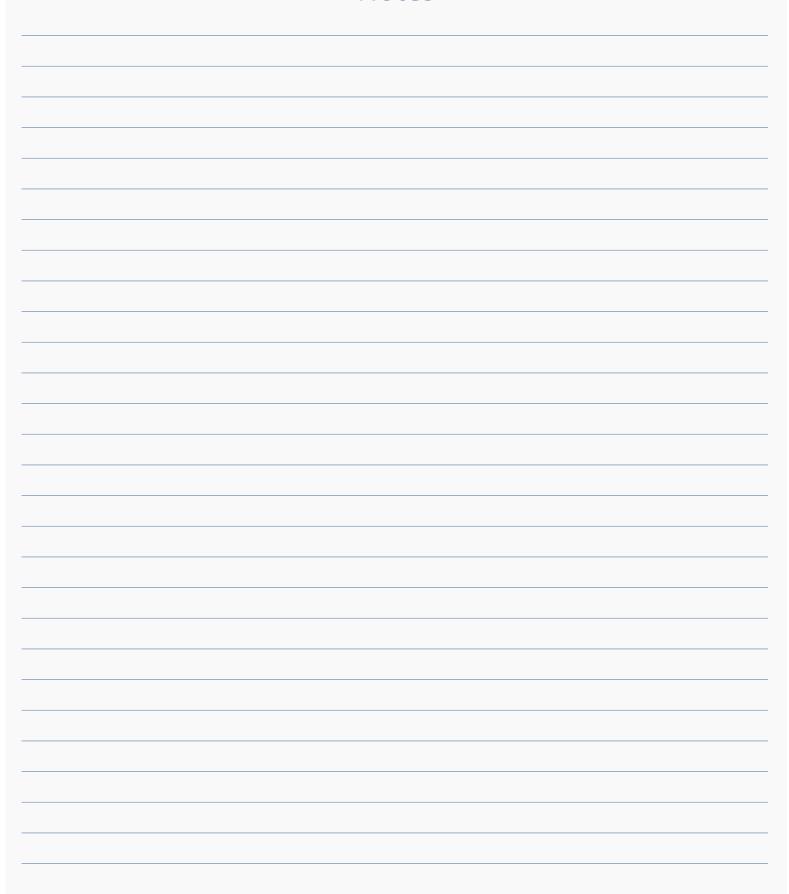
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