

San Francisco



A Spring Meeting to Remember

R eturning to San Francisco for our spring group meeting, I'm reminded of our gathering in this same venue 11 years ago, the last time our board of governors met to elect new group leadership.

But this time, the process will be very, very different.

The board of governors' recent historic vote to amend our constitution allowing co-chairs to lead the group means that we're on track for yet another first when they meet this week. Our two candidates, Drs. Dawn Hershman and Primo Lara, will present at the board session Friday evening, and the governors will then decide whether to make them SWOG's first-ever co-chairs-elect.

If the board takes that step, the two will serve with the "-elect" qualifier until spring 2025, when my current term ends, and will spend much of that time developing our grant applications for the next cycle.

But the group chair election is by no means the only exciting item on our agenda this week. We have a genomic platform theater planned for you, a Take Action Symposium

that will review some of our most innovative initiatives for ensuring equity in our

trials, a membership profiles project that seeks your feedback (look for the posters), our first symposium dedicated to the microbiome, and a transatlantic general plenary on global oncology research. We also will take the first steps in celebrating the 30th birthday of The Hope Foundation for Cancer Research.

It is wonderful to be meeting in San Francisco once again, and I hope you take some time to enjoy what this glorious city has to offer!

Charles D. Blanke, MD SWOG Chair



Group Meeting Index

Chair's Welcome Message Top Accruers	
•	
Plenary Sessions	6-
Hotel Maps and Information	1
SWOG Clinical Trials Partnerships (CTP) Special Sessions	12-15, 2
CMF Credit Information	16-1
The Hybrid Meeting	10-1
Health & Safety	1
The Hope Foundation, 30 Years	2
Schedule of Events	22-2
Upcoming Funding Opportunities	22 2
SWOG Administrative and Research Support Committees	2
Future Meeting Dates	2
Committee Agendas and Accrual Reports	
Barlogie-Salmon Myeloma Committee	28-3
Breast Committee	31-3
Cancer Control & Prevention Committee Leadership	36-3
Cancer Care Delivery Committee	38-4
Cancer Survivorship Committee	42-4
Early Therapeutics & Rare Cancer Committee	52-5
Gastrointestinal Committee	56-6
Genitourinary Committee	62-6
Immunotherapeutics Committee	7
Leukemia Committee	71-7
Lung Committee	74-8
Lymphoma Committee	82-8
Melanoma Committee	85-8
Palliative & End of Life Care Committee	4
Prevention & Epidemiology Committee	45-4
Symptom Control & Quality of Life Committee	48-5
SWOG Publications	89-9





Our Top Accruers

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

SWOG-Credited Registrations to SWOG Managed Trials January 2022 – December 2022. We appreciate their hard work and their confidence in our research.



- University of Texas MD Anderson Cancer Center LAPS
- City of Hope Comprehensive Cancer
 - UC Davis Comprehensive Cancer Center LAPS
 - University of Texas Health Science Center at San Antonio

THREE-WAY TIE FOR FIFTH PLACE

- University of Rochester LAPS
 - Moffitt Cancer Center
- Oregon Health and Science University



- Heartland Cancer Research NCORP
- Kaiser Permanente NCI Community Oncology Research Program
- Southeast Clinical Oncology Research Consortium NCORP
- Gulf South Minority Underserved NCORP
 - University of Kansas Cancer Center MCA Rural MU NCORP







Plenary I

Thursday, May 11, 3:30 - 5:00 pm PT

This spring's translational medicine plenary will feature the following speakers and topics:

Plenary II Global Oncology Research: Transcending Borders Friday, May 12, 12:00 - 2:00 pm PT

This spring's general plenary will feature the following speakers and topics. Presentations will be followed by a Q&A session.



Welcome and Introduction Lee M. Ellis, MD, FASCO SWOG Vice-Chair for Translational Medicine MD Anderson Cancer Center



Chair's Welcome and Update Charles D. Blanke, MD, FASCO, FAWM **SWOG Group Chair OHSU Knight Cancer Institute**



The Hope Foundation Coltman Fellowship: Building a Career in Personalized Cancer Care through SWOG

Meghna S. Trivedi, MD, MS Herbert Irving CCC, Columbia University



SWOG Latin America Initiative (SLAI): **Progress and Directions**

Mariana Chavez MacGregor, MD, MSc SWOG Executive Officer for International Affairs MD Anderson Cancer Center



A Brief History of Time and Effort Jerald Radich, MD Fred Hutchinson Cancer Center



Partnership and Education as Components of Global Oncology Research

Julie R. Gralow, MD Executive Vice President and Chief Medical Officer, American Society of Clinical Oncology (ASCO)



Come Together: Collaborating with Statisticians for Productive Translational Medicine Research in SWOG

Megan Othus, PhD SWOG Statistics and Data Management Center Fred Hutchinson Cancer Center



Translating Global Health Lessons Learned in Africa to Latin America

Ophira Ginsburg, MSc, MD Senior Advisor for Clinical Research, Center for Global Health, National Cancer Institute



Enhancing Diversity through International Research

Angelica Nogueira-Rodrigues, MD, PhD Professor, Universidade Federal de Minas Gerais, Brazil

Both Plenary I and Plenary II will also be live-streamed via Zoom, and questions for speakers will be fielded both in person and via Zoom's text chat feature.



San Francisco Travel & Hotel Information

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

Arrival/Departure:



Check-in time is 4:00 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.

Recreational Facilities:



The fitness center offers a variety of exercise equipment, free weights, treadmills, and

more, exclusively for hotel quests. 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.
- The Market offers fresh, healthconscious food and beverage items for travelers on the go.
- In-room dining is available from 6:00 a.m. - 12:00 a.m. daily.



For other local dining considerations, see the next page. The hotel concierge can assist with reservations and suggestions.

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

\$45.00 - \$50.00 one-way.

- Hotel guests overnight parking: \$80/night
- Public parking: First hour: \$18; Each additional 20 minutes: \$6

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

We've Supported SWOG for a Generation. Let's Make a Plan for the Next.

You can plan a legacy of purpose for future generations of cancer researchers when you leave a gift in your will for The Hope Foundation. Your generosity will help fund the next trial that changes care and improves lives.

Including a gift in your will or estate plans is easy. Simply scan the QR code below or talk with your financial planner to get started.







Restaurants

near Hyatt Regency SF

Eclipse Kitchen & Bar

Hyatt Regency SF \$\$

Indulge in classic San Francisco cuisine or celebrate day's end with one of our signature cocktails at Eclipse Kitchen & Bar.

Sens

*CLOSED SUNDAY

4 Embarcadero Center \$\$\$

Bistro offering Mediterranean dining with views of Ferry Building and bay

Tadich Grill

*CLOSED SUNDAY

240 California Street \$\$

Oldest, continuously run restaurant in California. Fresh fish and Classic Cocktails

One Market

*CLOSED SUNDAY

1 Market Street \$\$\$

Upscale American eatery with extensive wine list, banquette seating and Embarcadero views

Slanted Door

Ferry Building \$\$\$

Eatery serving modern Vietnamese fare with bay views

Waterbar

399 Embarcadero \$\$\$

Stylish seafood spot with up close views of Bay Bridge

Epic

369 Embarcadero \$\$\$\$

Steak House with extensive wine list and views of Bay

Boulevard Café

*CLOSED SUNDAY & MONDAY

1 Mission Street \$\$\$\$

American Gastropub boasting bay views

Ozumo

161 Steuart Street \$\$\$

Japanese restaurant that has creative sushi, extensive sake list and Ferry Building views

Kokkari

200 Jackson Street \$\$\$\$ Greek inspired cuisine

Wayfare

*CLOSED SATURDAY & SUNDAY 558 Sacramento Street \$\$\$ American fare in a British pub style setting

Angler

132 Embarcadero \$\$\$

Sea-life focused restaurant with views of the San Francisco Bay

Perry's

155 Steuart Street \$\$\$

American fare with outdoor space for bay views

Schroeder's

*CLOSED SATURDAY & SUNDAY 240 Front Street \$\$

240 Front Street \$\$

Historic Beer Hall with German inspired menu

Other dining considerations

- 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
- Tadich Grill Steak and Seafood
- The Waterfront Seafood

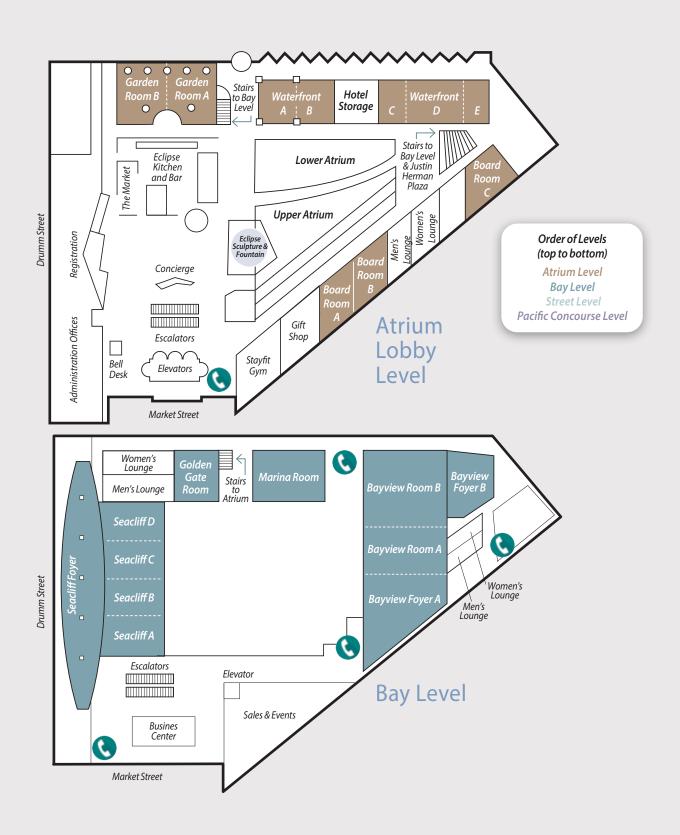
(The hotel concierge can assist with reservations and suggestions)





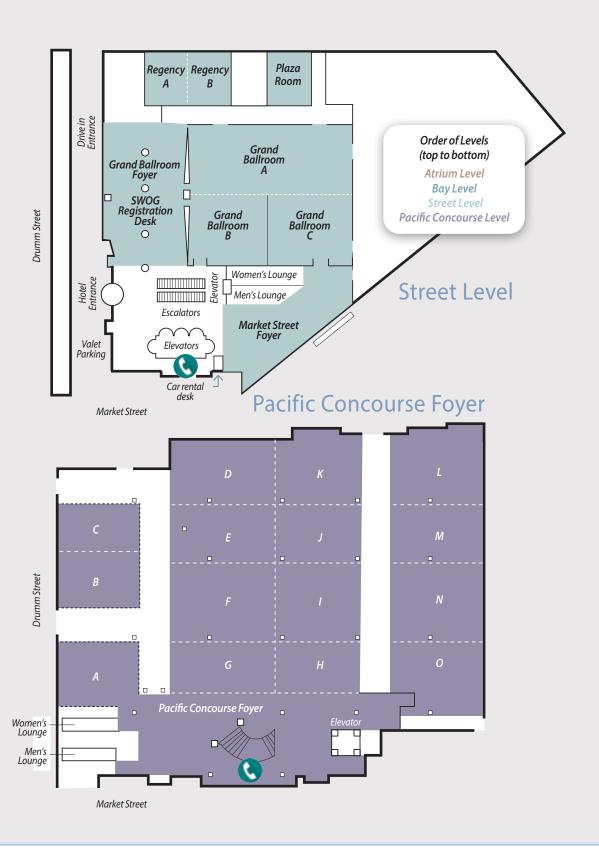
Hyatt Regency San Francisco Floor Levels

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



SWOG Clinical Trials Partnerships (CTP)

IS HOW SWOG CANCER RESEARCH NETWORK PARTNERS WITH INDUSTRY TO CONDUCT CANCER CLINICAL TRIALS.

SWOG CTP collaborates with research partners to develop rigorous, scientifically relevant trials that are jointly designed and conducted, use dedicated CTP infrastructure, and are fully industry funded.

Four projects have now been approved by the CTP Executive Review Committee peer review process and are nearing final contracting and protocol development. The first is expected to activate in late 2023 or early 2024.

- 21CTP.GU01: Phase II study in first-line muscle-invasive bladder cancer with multiple arms of neoadjuvant therapy defined by molecular subtype. SWOG GU Committee. Seth Lerner, MD; Joshua Meeks, MD, PhD; Thomas Flaig, MD; and Cathy M. Tangen, DrPh.
- 21CTP.LUNG01: Phase II study in metastatic NSCLC for patients with typical EGFR mutations with detectable ctDNA after start of first-line treatment. SWOG Lung Committee. |hanelle E. Gray, MD; Angel Qin, MD; Phillip C. Mack, PhD; and Mary Redman, PhD.
- 21CTP.HN01: Phase II study in recurrent metastatic head and neck cancer with cohorts defined by type of and/or response to prior systemic therapies. Head and Neck Working Group, SWOG Early Therapeutics and Rare Cancers Committee.

and Megan Othus, PhD.

Razelle Kurzrock, MD; Paul L. Swiecicki, MD; and Megan Othus, PhD. • 21CTP.LEUK01: Phase II trial for patients with newly diagnosed Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia. SWOG Leukemia Committee. Harry P. Erba, MD, PhD; Anjali Advani, MD; Michaela Liedtke, MD;

As these studies approach activation, SWOG member sites will be emailed details. All sites will be invited to participate in the feasibility assessments for these trials. The CTP team remains hard at work behind the scenes with additional trials in earlier stages of development and with budgeting and contracting.

To learn more, and to review the CTP update forum from fall 2022, visit swogctp.org or scan the QR code at right. We look forward to sharing more news at the next SWOG CTP Update Forum, scheduled for the fall group meeting!

The invitation-only SWOG CTP Scientific Advisory Board session will take place at the spring group meeting, Thursday, May 11, 12 - 1 pm PT.



SWOG CLINICAL TRIALS PARTNERSHIPS CONDUCTS

Industry-funded (100%) CTP trials

Preferred Partnership Program trials

- Built on pipeline access or multi-arm
 - Jointly developed and governed
- Use dedicated CTP infrastructure

SWOG committee-initiated trials

Can evolve into broader partnerships



Did you know? In 2022, the TROPION-Breast03 registration trial launched and enrolled its first patients. SWOG CTP provides scientific leadership and is the lead academic group for this AstraZeneca-sponsored trial.



We Value Our Meeting Partners – Thank You! Continuing Medical Education Supporters

Lilly | Novartis AbbVie | Exact Sciences Novocure | Takeda



THE ROBERT B. LIVINGSTON LECTURE

The Global Landscape of Lung Cancer

Presented with the lung committee session

Friday, May 12 | 4:30 pm PT

Speaker: Karen Kelly, MD | CEO, International Association for the Study of Lung Cancer (IASLC)
Professor Emeritus, University of California – Davis



Dr. Robert Boyd Livingston was a superb clinician and clinical trialist who greatly impacted the field of cancer research through a sweeping career at multiple institutions. Nationally, many of his discoveries in oncology were made through collaborative, multi-institutional efforts within SWOG Cancer Research Network, where he served as chair of the lung cancer committee (1974-1997) and the breast cancer committee (2000-2008).

In his honor and with the support of his wife Shirley, SWOG established the Dr. Robert B. Livingston Translational Breast and Lung Cancer Lectureship. The Hope Foundation for Cancer Research raises funds to support this lectureship in perpetuity and brings a special guest speaker to SWOG group meetings, alternating between a focus on lung and breast cancer advances in translational medicine.

Support Your Group With a Gift Today

Your Generosity Funds Vital Research and Educational Opportunities

The Hope Foundation directs .90 cents of every dollar to fund SWOG research. Hope has received the GuideStar Platinum Seal of Transparency and been in the top 3% of public charities for more than a decade.

thehopefoundation.org/donate





Thank you for a generation of support for our shared mission to improve and lengthen lives.





Microbiome as a New Frontier in SWOG Clinical Trials

Nicholas J. Vogelzang, MD, GU Symposium

Friday, May 12 | 8:30 – 11:30 am PT



Chair,
Michael A. Liss, MD, PhD,
UT Health San Antonio

Sumanta K. Pal, MD, City of Hope



KEYNOTE SPEAKER



Bertrand Routy, MD,
 Director of Immunology &
 Oncomicrobiome,
 University of Montreal



SPEAKERS

– **Laura Bukavina, MD,** Fox Chase Cancer Center

Nadim Ajami, PhD, MD Anderson Cancer Center





Nazli Dizman, MD, Yale University

Mike Wu, PhD, – Fred Hutchinson Cancer Center





This will be an informative symposium you won't want to miss! All disciplines invited!

The Nicholas J. Vogelzang, MD, GU Symposium honors the many valuable contributions Dr. Vogelzang made in support of his colleagues and patients throughout his career within SWOG's research network.

Vogelzang Symposia are held at SWOG group meetings to provide members with the latest and best resources for extending and improving the lives of those impacted by genitourinary cancers.



Wednesday, May 10, 2023 | 3 – 5:00 pm PT

TAKE ACTION Symposium: Reducing Structural Barriers, Ensuring Equity in Clinical Research

Presented by SWOG Recruitment & Retention Committee



Karen L. Reckamp, MD

Dr. Karen Reckamp is a Professor in Medicine, Director of the Division of Medical Oncology at Cedars-Sinai Medical Center and Associate Director of Clinical Research for the Samuel Oschin Comprehensive Cancer Institute (SOCCI).

She is an active member of SWOG Lung Cancer Committee and the study chair for S2302 Pragmatica-Lung Trial.



Rick Bangs, MBA, PMP

Rick Bangs, MBA/PMP is a bladder and prostate cancer survivor and serves as Chair of the SWOG Patient Advocate Committee, the SWOG Bladder Cancer Patient Advocate, the Bladder and Penile Cancer Patient Advocate for the National

Comprehensive Cancer Network (NCCN), and as one of three NCI Cancer Care Delivery Research (CCDR) Scientific Steering Committee Patient Advocates.



Saurabh Chhabra, MBBS, MD, MS

Dr. Saurabh Chhabra has been practicing as a Hematologist/Oncologist and Stem Cell Transplant physician since 2012. He is the chair/principal investigator of several important clinical trials for myeloma, transplant, and cellular

therapy, a member of study sections of American Society of Hematology, and American Society of Clinical Oncology, and has presented at several national/international hematology and transplant meetings. He is a study co-chair for S1803 (DRAMMATIC) clinical trial.

Target Audience: Investigators, research professionals, and patient advocates, NCORP and LAPS

OBJECTIVES:

Identify evidence-based practical strategies sites can use to ensure access and equity in SWOG clinical trials

- Address structural barriers to increase representativeness in clinical trials
- Review current environment impacting participation of diverse populations
 - Strategies for reducing barriers

TAKE ACTION

Recruitment & Retention

Diversity, EQUITY, & Inclusion

Disparities Research Trust







Saturday, May 13, 8 – 9 am PT

Join Us: Saturday Morning Update on Three Key Genitourinary Trials

This session will highlight three important studies now enrolling in genitourinary cancers.



Metastatic renal cell carcinoma:

What's the role for surgery with immunotherapy-based treatment?

S1931, the PROBE Trial, compares overall survival in patients newly diagnosed with metastatic renal cell carcinoma randomized to immunotherapy-based combination therapy either with or without surgery (cytoreductive nephrectomy).

Study chairs: Hyung L. Kim, MD, and Ulka N. Vaishampayan, MD



Metastatic urothelial carcinoma:

Eribulin, with or without gemcitabine, to treat the second most deadly GU cancer

\$1937 compares overall survival in patients with metastatic urothelial carcinoma refractory to or ineligible for anti-PD1/PD-L1 therapy, who are randomized to one of three arms: eribulin alone, eribulin with gemcitabine, or standard treatment.

Study chairs: Sarmad Sadeghi, MD, PhD, and Primo Lara, MD



Muscle-invasive urothelial carcinoma:

Neoadjuvant therapy with chemotherapy plus a PD-L1 inhibitor

S2011, the SWOG GAP Trial, compares pathologic complete response in patients with cisplatinineligible muscle-invasive urothelial carcinoma who are randomized to a combination of gemcitabine, carboplatin, and avelumab followed by surgery or to surgery alone (radical cystectomy, nephroureterectomy, or ureterectomy).

Study chairs: Guru P. Sonpavde, MD; Michael A. Liss, MD; Seth P. Lerner, MD; and Daniel P. Petrylak, MD

Three crucial questions in GU oncology.

Come learn more about how to take part in these trials. And about why it's important that you do



Procedures for CME Credit

Group Meeting Target Audience and Educational Objectives

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

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

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

Lymphoma Committee; Immunotherapeutics Committee; Digital Engagement Committee; Bone Marrow & Stem Cell Transplantation Committee; Recruitment and Retention Committee; and Advanced Practice Providers

Continuing Medical Education Credit

The Hope Foundation is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. In addition, nurses, CRAs, and other researchers may be able to claim credits through their respective credentialing bodies.

The Hope Foundation designates this live activity for a maximum of 30.5 AMA PRA Category 1 CreditsTM. Learners should only claim credit commensurate with the extent of their participation in the activity.

Speaker and Planner CME Disclosure Information

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

We've gone paperless! SWOG no longer requires members to submit paper forms to obtain CME credits.

Getting your credits online is easy:

Visit: www.tinyurl.com/SWOG-CME







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

Instructions:

- **1.** In the column labeled actual credit, please write in the amount of credit you are claiming for each meeting.
- 2. Then total the amount of credit you are claiming in the actual credit column. Visit www.tinyurl.com/SWOG-CME to complete the evaluation and submit your credits. Your certificate will automatically be emailed to you. Problems or questions? Contact Courtney Wille (cwille@swog.org).

Day/Time	S	-	edits able Actual
WEDNESDAY,			
12:30 pm - 2	2:30 pm	Digital Engagement Committee	2.0
3:00 pm - 5		Take Action Symposium: Reducing Structural Barriers,	
		Ensuring Equity in Clinical Research presented by the	
		SWOG Recruitment and Retention Committee	2.0
4:30 pm - 6	5:30 pm	Adolescent and Young Adult (AYA) Committee	2.0
THURSDAY, N	ЛАҮ 11, 20)23	
7:00 am - 9):00 am	Cancer Care Delivery Committee	2.0
9:15 am – 11	:15 am	Prevention and Epidemiology Committee	2.0
9:30 am – 12	2:00 pm	Early Therapeutics and Rare Cancers Committee	2.5
11:30 am - 1	:30 pm	Cancer Survivorship Committee	2.0
1:00 pm - 3	3:00 pm	Immunotherapeutics Committee	2.0
3:30 pm - 5	5:00 pm	Plenary I (Translational Medicine)	1.5
5:15 pm - 7	7:15 pm	Palliative and End of Life Care Committee	2.0
FRIDAY, MAY	12, 2023		
7:30 am - 9):30 am	Symptom Control and Quality of Life Committee	2.0
7:30 am - 9):30 am	Barlogie-Salmon Myeloma Committee	2.0
8:30 am - 11	:30 am	Nicholas Vogelzang GU Microbiome Symposium	3.0
9:00 am – 12	2:00 pm	Breast Committee	3.0
10:00 am – 12	2:00 pm	Leukemia Committee	2.0
12:00 pm - 2	2:00 pm	Plenary II (General)	2.0
2:15 pm - 4	l:15 pm	Surgery Committee	2.0
2:15 pm - 4	l:15 pm	Melanoma Committee	2.0
2:30 pm - 4	1:00 pm	Bone Marrow & Stem Cell Transplantation Committee	1.5
3:00 pm - 6	5:00 pm	Lung Committee	3.0
3:30 pm - 6	5:30 pm	GU Committee Part I: Prostate, TM, Cancer Control	3.0
4:30 pm - 6	5:30 pm	GI Committee	2.0
SATURDAY, M	1AY 13, 20	23	
9:00 am – 12	2:00 pm	GU Committee Part II: Bladder, Renal	3.0
9:30 am – 11	:30 am	Lymphoma Committee	2.0
10:00 am – 12	2:00 pm	Radiation Oncology Committee	2.0
Total Possible	e Credits		30.5



The Hybrid Meeting, Spring 2023

Welcome to SWOG's Spring 2023 Hybrid Group Meeting!













Most open meeting sessions held in person in San Francisco will also be accessible everywhere via Zoom.

Zoom links to open meetings are posted on the virtual meeting page on the SWOG website. Zoom links to closed, invitation-only meetings are emailed directly to those invited.

Each room will have a presentation laptop with a projector and screen. Virtual presentations by remote presenters will be visible on the projector screen to those in the room. All presenters will have their slides displayed in the Zoom meeting interface. Virtual attendees will view them via Zoom, while in-person attendees will view them on the projector screen.

Audio will be two way as needed. For virtual presenters, the Zoom audio will be amplified for the room. For in-room speakers, audio from microphones will be fed into Zoom.

Web cams will be used to give virtual attendees a live view into meeting rooms.

For many sessions, virtual attendees can post questions for the presenters using the Zoom chat feature. In these sessions, a moderator will monitor the chat.



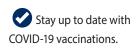
All hybrid sessions will be recorded, and recordings from open sessions will be available to attendees after the meeting.

Health & Safety

In deciding to attend this meeting in person, you assume all responsibility for your own health and safety.

Extra masks are available at the registration desk.

SWOG strongly recommends all in-person meeting attendees follow these precautions:





Do not attend sessions if you have symptoms consistent with COVID-19, and leave the meeting if you develop such symptoms.

Wear a medical mask in crowded indoor settings, in consideration of those around you and our patients back home. Extra masks are available at the registration desk.

Review current CDC and applicable local guidance for protecting yourself from COVID-19 at http://bit. ly/3KmqxFk or via the QR code at left.

If you find you need to take a COVID-19 test while onsite, a small number of tests will be available at the SWOG registration desk. Please reach out to us at meetings@swog.org.

Please remember that many SWOG members work with immunocompromised patients every day.





SWOG membership profiles will help us answer this question.

As we strive for diversity, equity, and inclusion (DEI) at SWOG, we need to be able to look at ourselves in our multiple dimensions. Membership profiles that include both self-reported information and data captured by our membership department will give us a clearer picture of who we are.

This summer, SWOG will roll out the first phase of our membership profile project, and we want your input.

Mock-ups of the screens we're proposing to use for creating our profiles are displayed on posters in public areas at the spring group meeting. They are also online.

We encourage you to visit swog.org/who-are-we – or scan the QR code below – to provide your feedback on what we have done and what we plan to do.

We aim to integrate principles of DEI into our membership, our work, and our trials, so that SWOG is known as an organization where everyone is seen and heard.

Scan to learn more, offer feedback, or volunteer.



We need your help.

swog.org/who-are-we





Friday, May 12, 9:30 – 10:30 am PT

Learn More About the First NCTN Trial Involving CAR T-cell Therapy: S2114

Diffuse large B-cell lymphoma – (DLBCL) is the most common lymphoid malignancy, with about 27,000 new diagnoses in the U.S. each year.

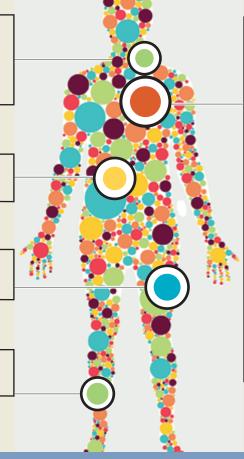
About two-thirds of these patients can be cured with first-line therapy.

Many of the remaining third—can now be treated with CD19 CAR T-cell therapy (CD19 CTCT)...

But 60-65% of DLBCL patients—who receive CD19 CTCT relapse and have a very poor prognosis.

DLBCL patients with stable disease or partial remission at one-month PET-CT after CD19 CTCT are a patient population at "high risk" for relapse.

- Can we identify a safe and effective consolidation strategy for these "high risk" patients after CD19 CAR T-cell therapy, one that will prevent relapse?
- Can we use biomarker studies in S2114 to refine our understanding of who is at "high risk" for relapse after CD19 CTCT for future
 studies?



These are the questions S2114 asks for patients with relapsed or refractory DLBCL or grade 3B follicular lymphoma.

ATTEND THE S2114 KICKOFF SESSION TO LEARN MORE AND GET YOUR QUESTIONS ANSWERED BY THE STUDY TEAM.

STUDY CHAIR



Brian T. Hess, MD



Nasheed Hossain, MD



Patrick Stiff,

STUDY CO-CHAIRS



Volkan Beylergil, MD





Founded in 1993, Hope today is one of the most direct and effective options for giving to cancer research.



Who We Are

The Hope Foundation supports the most promising studies and initiatives within SWOG, and has contributed more than \$40 million to advance research and those who lead the way.

Hope at 30

When physician-researchers generate good ideas, The Hope Foundation invests in them.

- Hope grantees go on to win nearly 3X additional funding from other organizations.
- Through training, we've helped early stage investigators launch their first group-wide cancer studies more than 50 times and counting.
- Through meeting and travel funds, we've supported thousands of SWOG members with training and career development opportunities.
- Through fellowships and career awards, dozens of investigators have launched trials, published in scientific journals, presented at scientific conferences, and changed the standards of care.

A Generation of Impact

Since 1993, donors like you have helped us advance SWOG's mission through critical professional development and training, research grants, travel funds, and infrastructure support nationwide and beyond.

Our Goal

We're raising \$300,000 to support the next generation of cancer researchers, and we need your help.

How You Can Help

- Make a Donation Today
 Gifts of every amount directly impact cancer research and treatment.
- Share Our Story

 Do you have family and friends who are passionate about the future of cancer care? Tell them about Hope in person, or via email and social media.
- Ask 3 to give \$30

 Ask your network to join you in supporting our mission with a gift honoring 30 years of impact.

THEHOPEFOUNDATION.ORG/DONATE30



Scan the QR Code to View Our Messaging Toolkit



WEDNESDAY, MAY 10, 2023

Group Meeting Registration & Information Desk 7:00 am - 5:00 pm - Grand Ballroom Foyer, Street Level

7:00 AM - 7:20 AM

Grand Foyer, Street Level CRA Clinical Trials Training Course

Check-In

7:20 AM - 12:00 PM

Grand Ballroom A, Street Level CRA Clinical Trials Training Course

1:45 PM - 5:00 PM

Grand Ballroom BC, Street Level CRA Clinical Trials Training Course

Practicum

8:30 AM - 11:30 AM

Pacific IJK, Concourse Level Advocates Committee (Cmte

Members Only)

9:30 AM - 11:00 AM

Plaza Room, Street Level Quality Initiative Meeting (Cmte

Members Only)

10:00 AM - 11:45 AM

Pacific F, Concourse Level Nursing Research Subcmte (Cmte

Members Only)

12:00 PM - 2:00 PM

Plaza Room, Street Level ORP Oishi/Open Forum Working

Meeting (Invitation Only)

12:30 PM - 2:00 PM

Pacific IJK, Concourse Level Core Office Staff Meeting

(Invitation Only)

12:30 PM - 2:30 PM

Bayview A, Bay Level Digital Engagement

Committee

1:00 PM - 3:00 PM

Pacific F, Concourse Level APP Task Force (Invitation

Only)

2:00 PM - 3:30 PM

Pacific G, Concourse Level SWOG Tissue Banking Meeting

(Invitation Only)

3:00 PM - 4:00 PM

Plaza Room, Street Level VA Program Development

Strategic Team Meeting (Invitation

Only)

3:00 PM - 5:00 PM

Grand Ballroom A, Street Level Take Action Symposium: Reducing

Structural Barriers, Ensuring Equity in Clinical Research presented by the SWOG Recruitment and

Retention Committee

3:30 PM - 5:00 PM

Pacific F, Concourse Level Hope Foundation Board Meeting

(Board Members Only)

4:30 PM - 6:30 PM

Bayview A, Bay Level Adolescent and Young Adult (AYA)

Committee

<u>5:30 PM - 7:30 PM</u>

Bayview B, Bay Level Site Operations

5:30 PM - 8:00 PM

Pacific IJK, Concourse Level NCORP Research Base Executive

Committee (Cmte Members Only)



THURSDAY, MAY 11, 2023

Group Meeting Registration & Information Desk

7:00 am - 5:00 pm - Grand Ballroom Foyer, Street Level

Hope Foundation Information Desk

8:00 am - 5:00 pm - Grand Ballroom Foyer, Street Level

Exhibits & Complimentary Coffee Service

8:00 am - 5:00 pm - Grand Ballroom Foyer, Street Level

7:30 AM - 8:00 AM

Bayview A Foyer, Bay Level Jeri & Noboru Oishi Symposium

Check-In

8:00 AM - 11:00 AM

Bayview Room, Bay Level Jeri & Noboru Oishi

Symposium

7:00 AM - 9:00 AM

Garden Room, Atrium Level Cancer Care Delivery

Committee

8:00 AM - 10:00 AM

Grand Ballroom A, Street Level Genomic Platform Theater:

Choosing an OMICs Platform for Your Clinical Trial; Learning from

Our Commercial Colleagues

8:00 AM - 10:00 AM

Lung-MAP Administrative Meeting Seacliff A, Bay Level

(Invitation Only)

9:15 AM - 11:15 AM

11:00 AM - 1:00 PM

Garden Room, Atrium Level Prevention and Epidemiology

Committee

9:30 AM - 12:00 PM

Seacliff B-D, Bay Level Early Therapeutics and Rare Cancers Committee

10:15 AM - 12:45 PM Pacific HI, Concourse Level **Breast TM Working Group**

(Working Group Members

Only)

SWOG Latin America Initiative Pacific JK, Concourse Level

Symposium

11:30 AM - 1:30 PM

Garden Room, Atrium Level Cancer Survivorship

Committee

12:00 PM - 1:00 PM

Plaza Room, Street Level

Clinical Trials Partnerships Scientific Advisory Board

(Invitation Only)

12:00 PM - 2:00 PM

Seacliff A, Bay Level

Lung-MAP Site Coordinators Committee (Cmte Members

Only)

12:00 PM - 3:00 PM

Pacific G, Concourse Level Myeloma Working Group (Working

Group Members Only)

12:30 PM - 2:30 PM

Pacific F, Concourse Level Sarcoma Working Group of the

ETxRC Committee

1:00 PM - 2:30 PM

Pacific L-O, Concourse Level ORP Open Forum

1:00 PM - 3:00 PM

Pacific HI, Concourse Level Breast Working Group (Working

Group Members Only)

1:00 PM - 3:00 PM

Seacliff B-D, Bay Level *Immunotherapeutics*

Committee

1:30 PM - 3:30 PM

Boardroom B, Atrium Level **DEI Monitoring Committee**

(Invitation Only)

2:30 PM - 3:30 PM

Lung Community Engagement Plaza Room, Street Level

Subcmte (Cmte Members

Only)

2:30 PM - 3:30 PM

Grand Foyer, Street Level Plenary Reception (Light Hors

D'oeuvres)

3:30 PM - 4:30 PM

Pacific F, Concourse Level DEI Leadership Council (Invitation

Only)



3:30 PM - 5:00 PM

Grand Ballroom, Street Level Plenary I (Translational

Medicine)

5:15 PM - 7:15 PM

Garden Room, Atrium Level Palliative and End of Life

Care Committee

<u>5:15 PM - 7:15 PM</u>

Seacliff A, Bay Level Leukemia Working Group

(Working Group Members

Only)

5:15 PM - 7:15 PM

Pacific JK, Concourse Level Lung Working Group (Working

Group Members Only)

5:15 PM - 7:45 PM

Pacific HI, Concourse Level CNS Working Group

FRIDAY, MAY 12, 2023

Group Meeting Registration & Information Desk

7:00 am - 5:00 pm - Grand Ballroom Foyer, Street Level

Hope Foundation Information Desk

8:00 am - 5:00 pm - Grand Ballroom Foyer, Street Level

Exhibits & Complimentary Coffee Service

8:00 am - 5:00 pm - Grand Ballroom Foyer, Street Level

7:00 AM - 9:00 AM

Plaza Room, Street Level Imaging Committee (Cmte

Members Only)

7:30 AM - 9:00 AM

Seacliff A, Bay Level Professional Review Committee

(Cmte Members Only)

7:30 AM - 9:30 AM

Pacific F, Concourse Level SWOG Data and Safety Monitoring

Committee (Cmte Members

Only)

7:30 AM - 9:30 AM

Garden Room, Atrium Level Symptom Control and Quality of

Life Committee

7:30 AM - 9:30 AM

Pacific JK, Concourse Level Barlogie-Salmon Myeloma

Committee

8:00 AM - 10:00 AM

Golden Gate, Bay Level Lung Radiation/Surgery Subcmte

(Cmte Members Only)

8:00 AM - 12:00 PM

Pacific HI, Concourse LevelGI Working Group (Working Group

Members Only)

8:30 AM - 11:30 AM

Seacliff B-D, Bay Level Nicholas Vogelzang Symposium:

"Microbiome as a New Frontier in SWOG Clinical Trials" hosted by the

GU Committee

9:00 AM - 12:00 PM

Bayview Room, Bay Level Breast Committee



9:30 AM - 10:30 AM

ORP Workgroup Pacific O, Concourse Level

(Invitation Only)

Pacific HI, Concourse Level

Seacliff B-D, Bay Level

Bone Marrow & Stem Cell Transplantation Committee

9:30 AM - 10:30 AM

Marina Room, Bay Level S2114 Kick Off Meeting 3:00 PM - 6:00 PM

2:30 PM - 4:00 PM

Lung Committee

9:30 AM - 11:30 AM

Pacific M, Concourse Level Melanoma Working Group (Working Group Members

Only)

3:30 PM - 6:30 PM

Bayview Room, Bay Level GU Committee Part I: Prostate; TM;

Cancer Control

10:00 AM - 12:00 PM

Garden Room, Atrium Level Leukemia Committee 4:00 PM - 5:00 PM

ORP Education Committee Plaza Room, Street Level

(Invitation Only)

10:00 AM - 12:00 PM

Pacific JK, Concourse Level **Pharmaceutical Sciences**

Committee and Drug Information

Subcommittee

4:30 PM - 6:30 PM

Grand Ballroom A, Street Level

GI Committee

10:30 AM - 12:00 PM

Plaza Room, Street Level **Quality Assurance Committee**

(Cmte Members Only)

4:30 PM - 6:30 PM

Seacliff A, Bay Level Lymphoma Working Group

(Working Group Members

Only)

11:00 AM - 12:00 PM

Grand Foyer, Street Level Plenary Reception

(Light Hors D'oeuvres)

Executive Reception (Invitation

Only)

11:30 AM - 12:00 PM

Publications Committee Pacific F, Concourse Level

(Cmte Members Only)

6:45 PM - 8:15 PM

5:30 PM - 6:30 PM

Grand Ballroom B, Street Level

Board of Governors (Board Members Only)

12:00 PM - 2:00 PM

Grand Ballroom, Street Level Plenary II (General) 6:45 PM - 8:30 PM

Atrium, Atrium Level

Group Reception

2:00 PM - 3:30 PM

GU Prostate Subcmte Seacliff A, Bay Level

(Invitation Only)

2:15 PM - 3:15 PM

Pacific JK, Concourse Level NCORP/MU-NCORP Site PI

Meeting

2:15 PM - 4:15 PM

Marina Room, Bay Level Surgery Committee

2:15 PM - 4:15 PM

Melanoma Committee Garden Room, Atrium Level



Tweeting the Meeting

Twitter remains a great place to share what you learn at the group meeting.

Tag @SWOG so we can share your meeting content with our more than 13K followers!

Follow SWOG at twitter.com/SWOG

When you tweet from the group meeting ...

don't forget to use the hashtag #SWOGonc



Schedule of Events

SATURDAY, MAY 13, 2023

Group Meeting Registration & Information Desk 7:30 am - 11:00 am - Grand Ballroom Foyer, Street Level

Hope Foundation Information Desk 8:00 am - 11:00 am - Grand Ballroom Foyer, Street Level

8:00 AM - 9:00 AM

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

8:00 AM - 9:00 AM

Grand Ballroom A, Street Level GU Trials Update Meeting

9:00 AM - 12:00 PM

Grand Ballroom A, Street Level GU Committee Part II: Bladder;

Rena

9:30 AM - 11:30 AM

Seacliff C, Bay Level VA Committee

9:30 AM - 11:30 AM

Grand Ballroom B, Street Level Lymphoma Committee

10:00 AM - 12:00 PM

Marina Room, Bay Level Radiation Oncology

Committee



Committees

Administrative Committees

Board of Governors Charles D. Blanke, MD

Conflict Management Paul Okunieff, MD

Publications Hagen F. Kennecke, MD

Professional Review Paul Hesketh, MD

Future Meeting Dates

Fall 2023 October 11-14, 2023 Chicago, IL

Spring 2024 April 3-6, 2024 Seattle, WA

Fall 2024 Spring 2025 October 16-19, April 30-May 3, 2024 2025 Chicago, IL San Francisco,

CA

Research Support Committees

Adolescent and Young Adult

Rebecca Johnson, MD

Bone Marrow and Stem Cell Transplantation

Patrick J. Stiff, MD

Digital Engagement

Mark Lewis, MD

Imaging

Lawrence H. Schwartz, MD

Oncology Research Professionals Connie Szczepanek,

RN, BSN, CCRP

Patient Advocates Rick Bangs, MBA

Pharmaceutical Sciences

Siu-Fun Wong, PharmD

Radiation Oncology

Interim Chair, James Yu, MD

Recruitment and

Retention

Allison Caban-Holt, PhD

Surgery

Syed A. Ahmad, MD

Veterans Affairs Stephen D. Bartlett, RPh



Future Funding Opportunities

- NCORP Pilot Grant Program: June 1
 - SEED Fund Program: July 1
 - Impact Award Program: July 1
- Dr. Charles A. Coltman, Jr. Fellowship: September 1
 - Career Engagement Award: September 1



See all Hope Foundation programs at

THEHOPEFOUNDATION.ORG/FUNDING-OPPORTUNITIES



Barlogie-Salmon Myeloma Committee

Leadership

Chair:	Robert Z. Orlowski, MD, PhD
Vice-Chair:	Sikander Ailawadhi, MD
Vice-Chair:	Jing Christine Ye, MD, MSc
Executive Officer	Susan M. O'Brien, MD
Statisticians:	Antje Hoering, PhD
	Rachael Sexton, MS
	Adam Rosenthal

Scientific Leadership

Translational Medicine:	Brian A. Walker, BSc, PhD
Radiation:	Chelsea Camille Pinnix, MD, PhD
Surgery:	TBD
Imaging:	Eric M. Rohren, MD, PhD
Pathology:	Pei Lin, MD
Early Therapeutics:	Frits van Rhee, MD, PhD
Designates	

Designates	
DEI Champion:	Manuel Espinoza-Gutarra, MD
Digital Engagement:	TBD
NCORP Representative:	Charles S. Kuzma, MD
Veterans Affairs:	Thomas R. Chauncey, MD, PhD
Data Coordinators:	Daria Chugina
	Hannah Hale
Oncology Research Professionals:	
CDA	Duran dan Di dan add Labardia CCDD

Oncology Research Professionals:	
CRA:	Brandon Richard Labadie, CCRP
Nurses:	Teresa Witcher, BSN, RN
Patient Advocate:	Jack Aiello, MS
Pharmaceutical Science:	Craig Elg, PharmD
	Ila M. Saunders, PharmD
Protocol Project Manager:	Sharon Palmer

Clinical Trials Program Manager: Mariah Norman, MS

Time/Location

Friday, May 12, 2023 7:30 am - 9:30 am Room: Pacific JK (Pacific Concourse Level)

Agenda

Active Studies

- S1803, "Phase III Study of Daratumumab/rHuPH20 (NSC-810307) + Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) Using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC Study)." Drs. Krishnan and Hari. Activated: 6/27/19.
- <u>\$2005</u>, "A Phase II Randomized Study of Ibrutinib and Rituximab with or Without Venetoclax in Previously Untreated Waldenström's

- Macroglobulinemia (WM)." Drs. Ailawadhi and Bhutani. Activated: 6/24/21. Temporarily Closed: 7/16/21. Re-opened to accrual: 10/15/21. Temporary Closed: 4/8/22.
- EAA171, "Optimizing Prolonged Treatment in Myeloma Using MRD Assessment (OPTIMUM)." Dr. Kumar. Activated: 6/1/21.
- EAA173, "Lenalidomide, and Dexamethasone With or Without Daratumumab in Treating Patients With High-Risk Smoldering Myeloma." Activated: 4/30/19.
- **EAA181**, "Testing the Use of Combination Therapy in Adult Patients With Newly Diagnosed Multiple Myeloma, the EQUATE Trial." Activated: 10/27/20.

Closed Studies

- <u>\$1211</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: 11/9/12. Closed: 6/2/16.
- <u>\$1702</u>, "A Phase II Study of Isatuximab (\$AR650984) (NSC-795145) for Patients with Previously Treated AL Amyloidosis." Drs. Parker and Sanchorawala. Activated: 3/8/18; Closed: 9/30/19.
- <u>\$1304</u>, "A Phase II Randomized Study Comparing Two Doses of Carfilzomib with Dexamethasone for Relapse/Refractory Multiple Myeloma." Dr. Ailawadhi. Activated: 10/18/13. Closed: 11/6/15.
- <u>S0777</u>, "Frontline Phase III Rev/Dex +/- Vel, no upfront transplant." Dr. Durie. Activated: 4/1/18. Closed: 2/2/12.
- S0120, "A prospective Observational Biologic Study of Asymptomatic Patients with Monoclonal Gammopathy and Plasmaproliferative Disorders." Dr. Dhodapkar. Activated: 6/1/02. Closed: 4/1/11.
- CTN 0702, "Single Autologous Transplant with or without RVD Consolidation versus Tandem Transplant and Maintenance Therapy." Dr. Somlo. Activated: 2/15/11. Closed: 11/15/13.
- A061402, "Ixazomib Citrate, Lenalidomide, Dexamethasone, and Zoledronic Acid or Zoledronic Acid Alone after Radiation Therapy in Treating Patients with Solitary Plasmacytoma of Bone." Dr. Kuman Mahindra. Activated: 12/23/15. Closed: 8/15/19.
- E1A11, "Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite DURation



Barlogie-Salmon Myeloma Committee

Lenalidomide MaintenANCE in Patients with Newly Diagnosed
Symptomatic Multiple Myeloma (ENDURANCE)." Drs. Kumar, Cohen, and
Zonder. Activated: 11/22/13. Closed: 1/29/19.

E3A06 (was S0909), "High-risk AMM – Revlimid." Dr. Dhodopkar. Activated: 1/17/11. Closed: 7/14/17.

A061402, "Ixazomib Citrate, Lenalidomide, Dexamethasone, and Zoledronic Acid or Zoledronic Acid Alone after Radiation Therapy in Treating Patients with Solitary Plasmacytoma of Bone." Dr. Kumar Mahindra. Activated: 12/23/15. Closed: 8/15/19.

E1A11, "Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite DURation Lenalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE)." Drs. Kumar, Cohen and Zonder. Activated: 11/22/13. Closed: 1/29/19.

Developing Studies

<u>\$2209</u>, "A Phase III Randomized Trial for Newly Diagnosed Multiple Myeloma (NDMM) Patients Considered Frail or Ineligible for Stem Cell Transplant Comparing Upfront Bortezomib-Lenalidomide-Dexamethasone-Lite (VRd-Lite) with Daratumumab-Lenalidomide-Dexamethasone (DRd)." Drs. Ailawadhi, Ye, Lipe, Chauncey, and Gowin.

<u>S2213</u>, "Daratumumab, Cyclophosphamide, Bortezomib, and Dexamethasone (D-VCD) Induction Followed by Autologous Stem Cell Transplant or D-VCD Consolidation and Daratumumab Maintenance in Patients with Newly Diagnosed AL Amyloidosis." Drs. Hagen, Parker, and Sidana.

Proposed Studies

Sxxx, "Phase III Study of Optimal Induction Therapy for Newly Diagnosed High-Risk Multiple Myeloma (HRMM) RVd Dara +/- xx." Dr. Lipe.

Proposed Studies-Pre-Triage/On Hold

- Bhutani: Randomized Phase II of CAEL-101 vs Placebo in Renal AL Amyloidosis. Amyloid two-arm study.
- Gowin: PCL Phase II study of VTD-PACE like regimen/Belanatumab Mafodotin/Autologous menStem Cell Transplant (ASCT).
- 3. Atrash: PVd +/- Sel in RRMM with del(17p) and prior therapy.
- 4. Former S1710 (Now VTE substudy proposal for S2209): Randomized Phase II Trial of Apixaban (or Riveroxiban) for Prevention of Thromboembolism in High Risk Patients being Treated with IMiDs for Multiple Myeloma (MM)- David Calverly
- 5. Chakraborty: An Open-Label Randomized Phase 2 Trial to Incorporate Venetoclax in Early Relapsed t(11;14) Multiple Myeloma



Barlogie-Salmon Myeloma Committee

Accrual from trial opening through 12/31/2022 by Institution and Study

	51803	52005	EAA173	EAA181
Ascension Providence Hospitals - Southfield	1	-	1	-
Banner University Medical Center - Tucson	7	-	-	1
Boston Medical Center	5	-	-	_
CWRU Case Comprehensive Cancer Center LAPS	16	-	3	-
Cancer Research for the Ozarks NCORP	1	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	4	-	-	-
Cedars-Sinai Medical Center	6	-	-	-
City of Hope Comprehensive Cancer Center	93	-	-	-
Columbus NCI Community Oncology Research Program	8	-	-	-
CommonSpirit Health Research Institute	3	-	-	-
Dayton NCI Community Oncology Research Program	5	-	-	-
Duke University - Duke Cancer Institute LAPS	3	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	5	-
Froedtert and the Medical College of Wisconsin LAPS	2	-	_	-
Georgia NCI Community Oncology Research Program	13	-	-	-
Gulf South Minority Underserved NCORP	4	-	-	-
Heartland Cancer Research NCORP	14	-	-	_
Kaiser Permanente NCI Community Oncology Research Program	37	-	-	-
Lahey Hospital and Medical Center	3	-	-	-
Loyola University Medical Center	19	-	3	-
Medical University of South Carolina Minority Underserved NCORP	35	-	1	_
Michigan Cancer Research Consortium NCORP	2	-	-	-
Moffitt Cancer Center	39	_	-	-
Montana Cancer Consortium NCORP	4	-	-	-
Nevada Cancer Research Foundation NCORP		-	1	-
New Mexico Minority Underserved NCORP	10	-	-	-
Ohio State University Comprehensive Cancer Center LAPS	4	-	-	-
Oregon Health and Science University	22	-	2	7
Pacific Cancer Research Consortium NCORP	13	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	3	-	-	-
UC Davis Comprehensive Cancer Center LAPS	18	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	10	-	-	-
University of Arkansas for Medical Sciences	-	_	-	2
University of Cincinnati Cancer Center-UC Medical Center	-	-	-	1
University of Kansas Cancer Center - MCA Rural MU NCORP	27	_	-	_
University of Michigan Comprehensive Cancer Center LAPS	10	-	-	-
University of Oklahoma Health Sciences Center LAPS	2	-	-	-
University of Rochester LAPS	14	-	-	-
University of Texas Health Science Center at San Antonio	12	-	-	-
University of Texas MD Anderson Cancer Center LAPS	23	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	14	-	3	1
Upstate Carolina Consortium Community Oncology Research Program	4	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	12	-	-	-
Wisconsin NCI Community Oncology Research Program	18	-	-	-
Yale University - Yale Cancer Center LAPS	-	_	2	1
ALLIANCE	162	-	-	-
CCTG	1	_	-	-
ECOG-ACRIN	141	1	-	-
NRG	81	-	-	_
Total		1	21	13
Total	925	1	21	15



Leadership	Agenda
Chair: Lajos Pusztai, MD, PhD	9:00 - 9:05 am Welcome and Introductions
Vice-Chair:Priyanka Sharma, MD	Lajos Pusztai, MD, DPhil (Chair) and Priyanka Sharma, MD (Vice-chair),
Executive Officer: Anne Chiang, MD, PhD	Lajos rusztai, MD, Driii (Chaii) and riiyanka Shaima, MD (Mce-chaii),
Statisticians:William E. Barlow, PhD	Mini symposium: Locoregional therapy; What is next on horizon?
	9:05 - 9:20 am Surgical therapy: One shoe does not fit all.
Scientific Leadership	Joshua Mammen Professor MD, PhD; Chief, Division of Surgical Oncology,
Translational Medicine: Alastair M. Thompson, MD	Department of Surgery, University of Nebraska Medical Center
Andrew K. Godwin, PhD	9:20 – 9:35 am Optimization of Radiotherapy
Radiation Oncology: Reshma Jagsi, MD	Meena S. Moran, MD; Professor, Therapeutic Radiology Chief, Breast
Surgery: Joshua M.V. Mammen, MD, PhD	Radiation Oncology, Yale School of Medicine
Imaging:Joanne E. Mortimer, MD	
	9:35 – 9:50 am Using biomarkers to personalize local therapy
Pathology:	Shane Stecklein MD, PhD Assistant Professor, Department of Radiation
Early Therapeutics:Stephanie L. Graff, MD	Oncology , University of Kansas Medical Center
Designates	9:50 – 10:05 am Q&A and Panel Discussion
Cancer Control Liaisons: Melinda L. Irwin, PhD, MPH (Survivorship)	ACCE ACCE DISTRICT TO A SHIPLE DISTRICT
Dawn L. Hershman, MD (Cancer Care Delivery)	10:05 - 10:15 am Publication update – William Barlow, PhD
Banu Arun, MD (Prevention)	10:15 - 10:25 am Patient Advocate update – Ginny Mason and Roberta
Helen K. Chew, MD (Symptom Control & QOL)	Albany
DEI Champion:Gayathri Nagaraj, MD	
Digital Engagement: Sarah S. Mougalian, MD	10:25 - 10:35 am Translational Medicine Sub-Committee update
NCORP Representative:	Alastair Thompson, MD and Andrew K. Godwin, PhD
Data Coordinators:	10:35 - 11:15 am Review of open CTSU trials
Larry Kaye	4445 4425
Ojasvi Mittal	11:15 - 11:35 am Recently approved and developing Concepts
Gabi Herbert	11:35 - 11:55 am Reports from Committee Liaisons
Oncology Research Professionals:	Radiotherapy: Reshma Jagsi, MD
CRAs: Karyn N. Hart, CCRP	Surgery: Joshua Mammen, MD
Avidanka Baftirovska, BS, CCRP	Survivorship: Melinda L. Irwin, PhD, MPH
Nurse:	Cancer Care Delivery: Dawn Hershman, MD
Patient Advocates:	Prevention: Banu Arun, MD
Ginny Mason, RN, BSN	Symptom Control & QOL: Helen K. Chew, MD
Pharmaceutical Science: Jorge G. Avila, PharmD	NCORP: Philip Lammers, MD
Dawud Nael Dawud Ellayan, Pharm D	DEI: Gayathri Nagaraj, MD
Protocol Project Manager:	12:00 pm Closing Comments and Adjourn
Cirincal mais i rogram Manager	Developing Studies

Time/Location

Friday, May 12, 2023 9:00 am - 12:00 pm

Room: Bayview Room (Bay Level)

Developing Studies

<u>\$2212</u>, "Shorter Anthracycline-Free Chemo Immunotherapy Adapted to Pathological Response in Early Triple Negative Breast Cancer (SCARLET), a Randomized Phase III Study." Drs. Sharma and Mitri.



<u>\$2206</u>, "Phase III Trial of Neoadjuvant Durvalumab (NSC 778709) plus Chemotherapy versus Chemotherapy Alone for MammaPrint Ultrahigh (MP2) Hormone Receptor (HR) Positive / Human Epidermal Growth Factor Receptor (HER2) Negative Stage II-III Breast Cancer." Drs. Cobain and Pusztai.

Active Studies

- **52007**, "A Phase II Trial of Sacituzumab Govitecan (IMMU-132) (NSC #820016) for Patients with HER2-Negative Breast Cancer and Brain Metastases." Drs. Brenner and Kaklamani. Activated: 12/15/20.
- <u>S1706</u>, "A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy Alone for Inflammatory Breast Cancer." Drs. Jagsi and Chalasani. Activated: 9/12/18.
- CTSU/A011801, "The COMPASSHER2 Trials (COMprehensive Use of Pathologic Response ASSessment to Optimize Therapy in HER2-Positive Breast Cancer): COMPASSHER2 Residual Disease (RD), A Double-Blinded, Phase III Randomized Trial of T-DM1 and Placebo Compared with T-DM1 and Tucatinib." Dr. O'Sullivan. SWOG Champion: Dr. Murthy. Activated: 1/6/21.
- CTSU/CCTG MA.39, "Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive and T3N0 Breast Cancer." Dr. Whelan. SWOG Champion: Dr. Jagsi. Activated: 5/30/18.
- CTSU/EA1181, "(CompassHER2-pCR): Preoperative THP and Postoperative HP in Patients Who Achieve a Pathologic Complete Response Part 1 Component of: The CompassHER2 Trials (COMprehensive Use of Pathologic Response ASSessment to Optimize Therapy in HER2-Positive Breast Cancer)" Dr. Tung. SWOG Champions: Breast Committee: Dr. Tang, Imaging Committee: Dr. Lu. Activated: 2/11/20.
- CTSU/EA1183, "FDG PET to Assess Therapeutic Response in Patients with Bone-Dominant Metastatic Breast Cancer, FEATURE." Dr. Specht. SWOG Champions: Breast Committee: Dr. Linden, Imaging Committee: Dr. Wright. Activated: 4/2/20.
- CTSU/NRG-BR007, "A Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER2-Negative, Oncotype Recurrence Score Less Than or Equal to 18 Breast Cancer (DEBRA)." Dr. White. SWOG Champion: Dr. Shumway. Activated: 6/7/21.

Closed Studies

- §1418, "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 (ypN1mi, ypN1-3) after Neoadjuvant Chemotherapy." Drs. Pusztai and Mammen. Activated: 11/15/16. Permanently closed: 6/30/21.
- **S1207**, "Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer. e^3 Breast Cancer Study-Evaluating Everolimus with Endocrine Therapy." Drs. Chavez-MacGregor and Pusztai. Activated: 9/4/13. Permanently closed: 5/1/19.
- 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. Permanently closed: 7/1/22.
- 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. Permanently closed: 5/27/22.
- 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. Permanently closed: 4/22/22.
- CTSU/NRG-BR004, "A Randomized, Double-Blind, Phase III Trial of Taxane/ Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer." Dr. Geyer. SWOG Champion: Dr. Cobain. Activated: 3/12/19. Permanently closed: 71/22.
- 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. Permanently closed: 12/2/22.

Active Cancer Survivorship Study

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



Closed Symptom Control and Quality of Life Studies

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 and Lok. Activated: 2/21/19. Permanently closed: 11/15/22.

S1714, "A Prospective Observational Cohort Study to Develop a Predictive Model of Taxane-Induced Peripheral Neuropathy in Cancer Patients." Drs. Trivedi and Hershman. Activated 3/1/19. Permanently closed: 11/15/21.

Active Cancer Care Delivery Studies

<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 HER-2 Negative Breast Cancer." Drs. According and Hershman. Activated: 7/16/18. CTSU/EA1151, "Tomosynthesis Mammographic Imaging Screening Trial (TMIST)." Dr. Pisano. SWOG Champion: Dr. Arun. Activated: 7/6/17.

Active Cancer Prevention Study

<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 – Making Informed Choices on Incorporating Chemoprevention into Care (MiCHOICE)." Drs. Crew, and Kukafka. Activated: 9/1/20.

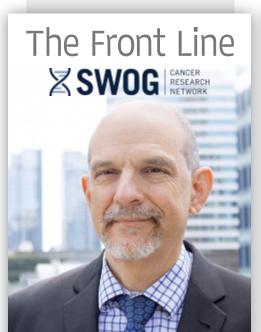
Closed Early Therapeutics and Rare Cancers Studies

S1609, "DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors." Drs. Patel and Chae. Activated 1/13/17. Permanently closed: 3/15/23.

CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)". Dr. Flaherty. Activated 8/12/15. Permanently closed: 12/30/22.

Get the Scoop!

Want the Front Line blog every Friday?



Or the Translational Medicine Link of the Week?



How about the Hope Foundation Monthly E-Newsletter?



Email communications@swog.org to get on a list – one or all three



Accrual from trial opening through 12/31/2022 by Institution and Study

	51418	51706	52007	A011202	A011801	EA1181	EA1183	MA39	NRGBR003	NRGBR004	NRGBR007
Ascension Prov Hosp - Southfield	6	2	_	4	1	3	_	1	3	1	-
Ascension Via Christi Hosp Wichita	9	-	_	-	-	-	_	-	-	-	_
Banner MD Anderson CC	3	_	_	-	-	_	_	_	-	-	_
Banner U Med Ctr - Tucson	4	1	_	1	-	7	_	-	-	-	_
Baptist Mem HC/Mid South MU NCORP	9	3	_	1	-	1	_	_	-	1	-
Bay Area Tumor Inst NCORP	3		-	-	-	_	_	-	-	-	-
Baylor U Med Ctr	_	-	_	1	-	-	_	_	-	-	_
Boston Med Ctr	-	-	_	-	4	12	_	-	-	-	_
CWRU Case CCC LAPS	12	-	1	-	-	1	-	1	9	1	-
Ca Res Consort of West Mich NCORP	24	-	_	-	-	-	_	-	-	-	-
Ca Res for the Ozarks NCORP	9	1	_	-	1	-	-	-	3	-	-
Ca Res of Wisconsin and N Mich Consort	7	-	-	-	-	-	-	-	-	-	-
Carle CC NCORP	3	-	2	-	-	-	-	-	-	-	-
City of Hope CCC	9	-	_	-	-	-	_	-	-	-	-
Columbia U MU NCORP	8	3	-	-	-	3	-	-	-	-	-
Columbus NCORP	13	-	-	-	-	-	-	-	-	-	-
CommonSpirit HIth Res Inst	19	1	-	-	-	-	-	-	-	-	-
Cotton O'Neil CC / Stormont Vail HIth	_	-	-	1	-	-	-	-	1	-	-
Dayton NCORP	3	-	1	-	-	7	2	-	-	-	-
Desert Regional Med Ctr	1	-	-	7	-	2	-	1	-	-	-
Essentia HIth NCORP	3	-	-	-	1	-	-	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	10	4	-	-	-	-	-	-	-	-	-
Georgia NCORP	23	2	-	-	-	-	-	-	1	-	-
Gulf South MU NCORP	5	1	-	-	-	2	-	-	4	-	-
Hawaii MU NCORP	5	-	-	-	-	-	-	-	-	-	-
Heartland Ca Res NCORP	19	3	-	-	1	-	-	-	-	-	-
Henry Ford Hospital	1	-	-	-	-	-	-	-	-	-	-
Houston Methodist Hospital	_	-	-	-	1	-	-	-	-	-	-
Kaiser Permanente NCORP	51	-	-	1	-	-	-	-	25	1	-
Lahey Hospital and Med Ctr	3	-	-	-	-	5	-	-	-	1	-
Loma Linda U Med Ctr	1	-	-	3	-	-	-	-	-	-	-
Loyola U Med Ctr	3	-	-	-	-	1	_	-	-	-	-
Medical U South Carolina MU NCORP	11	1	-	-	-	-	3	-	-	-	-
Meharry Medical College	-	-	-	-	-	-	_	-	1	-	-
Michigan Ca Res Consort NCORP	21	1	-	-	-	-	-	-	-	-	-
Moffitt CC	-	_	-	1	-	-	-	-	-	-	-
Montana Ca Consort NCORP	2	3	-	-	-	-	-	-	-	-	-
Mount Sinai Hospital	3	-	-	-	-	1	_	-	-	-	-
NCORP of the Carolinas (Prisma HIth NCORP)	4	-	_	-	-	-	_	-	-	-	-
Nevada Ca Res Foundation NCORP	11	-	_	-	-	_		_	-		_



Accrual from trial opening through 12/31/2022 by Institution and Study

	51418	51706	52007	A011202	A011801	EA1181	EA1183	MA39	NRGBR003	NRGBR004	NRGBR007
New Mexico MU NCORP	19	4	1		-	-	-	_	-	-	-
Northwell HIth NCORP	_	-	1	-	-	-	-	-	_	-	1
Northwestern U LAPS	2	1	-	-	-	4	1	-	1	-	-
Ohio State U CCC LAPS	-	1	-	-	-	-	-	-	_	-	-
Oregon HIth and Science U	19	-	-	-	-	-	3	-	3	-	-
Orlando Hlth Ca Inst	1	-	-	-	-	-	-	-	-	-	-
Pacific Ca Res Consort NCORP	19	-	-	-	-	-	-	-	3	-	-
Salem Hospital	-	-	-	4	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	46	-	-	-	-	-	-	-	-	-	-
Sutter Ca Res Consort	3	-	-	-	2	5	-	-	4	2	-
The Don and Sybil Harrington CC	7	3	-	11	2	-	-	-	-	-	-
James Graham Brown CC at U Louisville	-	-	-	2	-	-	-	-	-	-	-
The West Clinic - Wolf River	-	-	-	9	-	-	-	-	-	-	-
UC Davis CCC LAPS	8	6	-	2	-	4	-	-	-	1	1
UC Irvine Hlth/Chao Family CCC	6	-	1	3	-	-	-	-	1	-	-
UC San Diego Moores CC	-	-	-	-	-	-	-	-	1	-	-
USC Norris CCC LAPS	3	-	-	4	-	-	-	2	-	-	-
U Alabama Birm / Deep South Res Consort LAPS	-	-	1	-	-	-	-	-	-	-	-
U Arkansas for Medical Sciences	17	2	-	-	-	-	-	-	-	-	-
U Colorado CC LAPS	11	1	-	42	1	11	-	1	-	-	-
U Kansas CC - MCA Rural MU NCORP	22	2	-	4	-	-	-	1	-	-	-
U Michigan CCC LAPS	13	2	-	-	1	1	-	5	3	-	-
U Mississippi Med Ctr	-	-	-	-	-	1	-	-	-	-	-
U Oklahoma Hlth Sciences Ctr LAPS	2	-	-	-	-	-	-	-	-	-	-
U Rochester LAPS	2	1	-	-	-	1	-	-	9	-	-
U Texas HSC at San Antonio	5	-	1	6	-	-	-	-	4	-	-
U Texas MD Anderson CC LAPS	21	1	1	-	-	-	-	-	-	-	-
U Utah - Huntsman Ca Inst LAPS	6	4	-	-	1	5	-	-	-	-	-
Upstate Carolina Consort NCORP	8	-	-	-	-	-	-	-	-	-	-
Virginia Mason Med Ctr	1	-	-	-	-	-	-	-	_	-	-
Wayne State U - Karmanos Ca Inst LAPS	3	-	-	11	-	13	4	-	6	-	-
Western States Ca Res NCORP	3	-	-	-	-	-	-	-	-	-	-
William Beaumont Hosp-Royal Oak	1	-	-	6	-	-	-	-	-	-	-
Wisconsin NCORP	2	1	-	-	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	8	-	-	5	2	9	-	-	8	1	-
ALLIANCE	144	14	6	-	-	-	-	-	-	-	-
CCTG	39	6	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	129	6	1	-	-	-	-	-	-	-	-
NRG	307	39	-	-	-	-	-	-	-	-	-
Total	1,195	120	17	129	18	99	13	12	90	9	2



Cancer Control & Prevention Committee

Leadership
Vice-Chair NCORP: Dawn L. Hershman, MD, MS
Cancer Care Delivery Co-Chairs: Dawn L. Hershman, MD, MS
Scott D. Ramsey, MD, PhD
Cancer Survivorship Co-Chairs: Halle C.F. Moore, MD
Melinda L. Irwin, PhD, MPH
Palliative & End of Life Co-Chairs:Robert S. Krouse, MD, FACS
Marie Bakitas, DNSc, CRNP
Prevention & Epidemiology Co-Chairs:Banu Arun, MD
Symptom Control & QOL Co-Chairs: Michael J. Fisch, MD, MPH
Norah Lynn Henry, MD, PhD
Executive Officers: Katherine D. Crew, MD (CCD, Prevention, Symptom
Virginia Sun, PhD, MSN, RN (Palliative, Survivorship)
Senior Advisor: Frank L. Meyskens, Jr., MD
Statisticians:
William E. Barlow, PhD
Cathy Tangen, DrPH
Joseph M. Unger, PhD
Riha Vaidya, PhD
Kathryn B. Arnold, MS
Amy K. Darke, MS
Phyllis J. Goodman, MS
Danika Lew, MA
Hongli Li, MS
Anna Moseley, MS
Eddie Mayerson, MS
Administrative Lead
Statistics & Data Management Center (SDMC): Monica Yee, CCRP
Scientific Leadership
NCORP Representative: Mark A. O'Rourke, MD
Radiation Oncology Committee:Eileen P. Connolly, MD, PhD (CCD,
Prevention)
Kiri A. Cook, MD (Survivorship, Symptom Control & QOL)
Surgery Committee:
Translational Medicine: James (Jimmy) Rae, PhD

Leadership

Liaisons:
Barlogie-Salmon Myeloma:
Breast: Melinda L. Irwin, PhD, MPH (Survivorship)
Dawn Hershman, MD, MS (CCD)
Banu Arun, MD (Prevention)
Philip Lammers, MD
Early Therapeutics & Rare Cancers:Lara E. Davis, MD (Survivorship)
Jason M. Prosek, MD
Gastrointestinal:
Genitourinary: Peter J. Van Veldhuizen, Jr., MD
International Liaison:
Leukemia:
Lung:
Lymphoma:
Melanoma: Sancy Leachman, MD, PhD
Recruitment and Retention:
Digital Engagement:Jennifer R. Klemp, PhD (Survivorship)
Veterans Affairs: Yeun-Hee Anna Park, MD
Designates
Oncology Research Professionals
Clinical Research Associates:
Samantha Wright, MS, CCRP
Nurses: Connie Szczepanek, RN, BSN
Melyssa W. Foust, MSN, RN
Pharmaceutical Sciences Committee: Kimberly McConnell, PharmD
Siu-Fun Wong, PharmD
Sun "Coco" Yang, PharmD, PhD
SDMC Data Coordinators and Staff:Kimberly Carvalho



Cancer Control & Prevention Committee

	Mat Eng
F	
	Monica Yee, CCRP
Recruitment and Retention Specialist:	TBD
Patient Advocates:Barbara Segarra	a-Vazquez, DHSc (CCD)
Amy Geschwender, PhD (Syr	mptom Control & QOL)
Hartley "Lee" M. Jon	es, MBA (Survivorship)
Cheryl L. Jernigan, CPA (Preve	ntion & Epidemiology)
Valerie Fraser (Pallia	tive & End of Life Care)
Protocol Project Manager (Cancer Care Delivery;	
Prevention and Epidemiology):	Patricia O'Kane
Protocol Project Manager (Survivorship):	Megan Keim
Protocol Project Manager (Symptom Control and	
Quality of Life):	TBD
Protocol Project Manager (Palliative Care):	Christy Klepetko
Clinical Trials Program Manager (Palliative Care;	
Symptom Control):	Laura Gildner, MS
Clinical Trials Program Manager (CCD; Prevention;	
Survivorship):	Mariah Norman, MS



Leadership

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

Time/Location

Thursday, May 11, 2023 7:00 am - 9:00 am Room: Garden Room (Atrium Lobby Level)

Agenda

Presentations

Achieving Whole-Person Care via Patient Navigation in Cancer: The Thyme Care Experience, Samyukta Mullangi, MD MBA, Incoming Medical Director, Thyme Care

The Penn Telehealth Research Center of Excellence, Justin Bekelman, MD, University of Pennsylvania

Active Studies

S1912CD, "A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)." Veena Shankaran, MD, University of Washington. Activated 7/26/21.

S2108CD, "Randomized Comparison of an Educationally Enhanced Genomic Tumor Board (eGTB) Intervention to Usual Practice of Incorporating Genomic Test Results into Clinical Care." Jens Rueter, MD, Maine Cancer Genomics Initiative; Meghna Trivedi, MD, Columbia University. Activated: 8/22/22.

<u>\$1703</u>, "Randomized Non-inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (STMDDM) versus Usual Care in Patients with Metastatic Hormone Receptor Positive HER-2 Breast Cancer," Melissa Accordino, MD, Activated: 7/16/18.

Developing Studies

S2201CD, "Managing Oral Anti-Cancer Agents in Community Oncology Practices: Implementation and Impact." Karen B. Farris, PhD, Emily Mackler, PharmD, University of Michigan

Development of a Multilevel Intervention to Promote Guideline-Concordant Colorectal Cancer Surveillance. Christine Veenstra, MD, University of Michigan Patient-centered Video Education Intervention to Improve Rural Cancer Care Delivery. Randall Holcombe, MD, MBA and Izumi Okado, PhD, University of Hawaii

Studies with CCD/CCP Components

S1904, "Cluster Randomized Controlled Trial of Patient and Provider Decision Support to Increase Chemoprevention Informed Choice Among Women with Atypical Hyperplasia or Lobular Carcinoma In Situ – Making Informed Choices on Incorporating Chemoprevention into Care (MiCHOICE)," Dr. Crew. Activated: 9/1/20. (Committee: Prevention/ Epidemiology)

<u>\$2010</u>, "Active Symptom Monitoring and Endocrine Therapy Persistence in Young Women with Breast Cancer." Lynn Henry, MD, University of Michigan; Dawn Hershman, MS, MS, Columbia University

Closed Studies

Stimulating Factor Standing Order Intervention and to Determine the Effectiveness of Colony Stimulating Factor Use as Prophylaxis for Patients Receiving Chemotherapy with Intermediate Risk for Febrile Neutropenia - Trial Assessing CSF Prescribing, Effectiveness and Risk (TrACER)." Drs. S. Ramsey, D. Hershman, G. Lyman, et al. Activated: 10/7/16. Closed: 4/15/20.

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

Substudies (Economic Analyses / Cost Effectiveness from NCTN trials)

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

<u>\$1204</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. R. Vaidya



Published Studies

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

Trends in Obesity Among Patients Registered to SWOG Cancer Clinical Treatment Trials. Dr. R. Vaidya

Other Group Studies with SWOG Study Champions – Recently Closed

CTSU NRG-CC007CD, "Increasing the Dose of Survivorship Care Planning in Prostate Cancer Survivors Who Receive Androgen Deprivation Therapy." Dr. Van Veldhuizen. Activated: 3/27/19. Closed: 7/28/22.

CTSU ACCL16N1CD, "Documentation and Delivery of Guideline-Consistent Treatment in Adolescent and Young Adult (AYA) Acute Lymphoblastic Leukemia (ALL)." Drs. Advani, O'Dwyer and Hershman. Activated: 12/18/17. Closed: 8/19/22.

Triage Approved

S2309CD, "Preventing Financial Adversity Among Early-Stage Cancer Patients Through Unrestricted Cash (PAYMENT)." Dr. Shankaran.



	51703	S1912CD	52108CD	A191901	A231601C	A2317010	A231901C	AQ171CD	NHLBIMDS	NRGCC007
Ascension Prov Hosp - Southfield	-	-	-	4	-	-	-	-	1	-
Banner University Med Ctr - Tucson	1	-	-	-	-	-	-	-	-	-
Baptist Mem Hlth Care/Mid South MU NCORP	-	-	-	-	-	-	1	5	3	-
CWRU Case CCC LAPS	19	-	-	-	-	-	-	-	5	-
Ca Res Consort of West Michigan NCORP	-	3	-	-	-	-	-	-	-	-
Ca Res for the Ozarks NCORP	-	3	-	-	-	-	-	-	-	-
Ca Res of Wisconsin and N Mich Consort	10	3	-	1	-	-	-	-	-	-
Carle CC NCORP	8	1	12	-	-	-	-	-	-	-
Columbia University MU NCORP	17	4	-	-	-	-	-	-	15	-
Columbus NCORP	5	-	-	-	-	-	-	-	-	-
CommonSpirit HIth Research Inst	9	-	1	-	-	-	-	-	-	-
Cotton O'Neil CC / Stormont Vail Hlth	1	-	-	-	-	-	-	-	-	-
Dayton NCORP	3	1	-	-	-	-	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	-	-	-	-	-	-	-	-	17	-
Georgia NCORP	2	-	-	-	-	-	-	-	-	-
Gulf South MU NCORP	6	-	-	-	2	-	-	-	-	-
Hawaii MU NCORP	6	-	-	-	-	-	-	-	5	-
Heartland Ca Res NCORP	16	4	4	-	-	-	-	-	-	1
Kaiser Permanente NCORP	4	4	-	-	-	-	-	-	5	-
Kansas City Veterans Affairs Med Ctr	-	-	-	-	-	-	-	-	4	-
Kansas Inst of Med Ca and Blood Ctr	-	-	-	-	-	-	-	-	2	-
Lahey Hosp and Med Ctr	4	-	-	-	-	-	-	-	-	-
Loyola University Med Ctr	2	-	-	5	-	-	-	-	-	-
Massachusetts Veterans ERIC	-	-	-	-	-	-	-	-	30	-
Med U South Carolina MU NCORP	-	-	-	-	-	1	-	-	4	-
Michigan Ca Res Consort NCORP	10	3	-	-	-	-	-	-	-	-
Moffitt CC	-	-	-	-	-	-	-	-	8	-



	51703	51912CD	52108CD	A191901	A231601C	A2317010	A231901C	EAQ171CD	NHLBIMDS	NRGCC007
Montana Ca Consort NCORP	9	-	12	-	-	-	-	-	-	-
MultiCare Tacoma General Hosp	-	-	-	22	-	-	-	1	-	-
NCORP Carolinas (Prisma HIth NCORP)	6	-	-	-	-	-	-	-	2	-
Nevada Ca Res Foundation NCORP	2	-	-	1	-	-	-	-	-	-
New Mexico MU NCORP	12	1	-	-	-	-	-	-	-	-
Northwell HIth NCORP	-	1	-	-	-	-	-	-	10	-
Oregon HIth and Science U	-	-	-	-	-	-	-	-	10	-
Pacific Ca Res Consort NCORP	10	4	-	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	4	1	-	-	-	-	-	-	-	-
UC Davis CCC LAPS	-	-	-	3	-	-	-	-	-	-
UC Irvine Hlth/Chao Family CCC	-	-	-	-	-	-	-	-	22	-
UC San Diego Moores CC	-	-	-	-	-	-	-	-	28	-
U Arkansas for Med Sciences	4	-	-	-	-	-	-	-	-	-
U Colorado CC LAPS	-	-	-	-	-	-	-	-	9	-
U Kansas CC - MCA Rural MU NCORP	5	1	5	-	-	-	-	-	-	22
U Rochester LAPS	4	-	-	-	-	-	-	-	-	-
U Utah - Huntsman Ca Inst LAPS	-	-	-	2	-	-	-	-	-	-
Upstate Carol Consort Comm Onc Res Prog	-	2	-	-	-	-	-	-	-	-
Western States Ca Res NCORP	-	1	-	1	-	-	-	-	-	-
William Beaumont Hosp-Royal Oak	-	-	-	-	-	-	-	-	2	-
Wisconsin NCORP	2	4	-	-	-	-	-	-	-	-
Yale University - Yale CC LAPS	28	-	-	-	-	-	-	-	7	-
ALLIANCE	9	5	1	-	-	-	-	-	-	-
ECOG-ACRIN	20	4	-	-	-	-	-	-	-	-
NRG	16	2	-	-	-	-	-	-	-	-
Total	254	52	35	39	2	1	1	6	189	23



Cancer Survivorship Committee

Leadership

Co-Chairs: Melinda Irwin, PhD, MPH Halle Moore, MD
Statistician: Katherine Guthrie, Ph.D
Executive Officer: Virginia Sun Ph.D, RN
Patient Advocate: Lee Jones

Time/Location

Thursday, May 11, 2023 11:30 am - 1:30 pm Room: Garden Room (Atrium Lobby Level)

Agenda

Welcome & Introductions: Melinda Irwin and Halle Moore

Survivorship Presentation: Shelley Fuld Nasso, CEO National

Coalition for Cancer Survivorship

Discussion

Patient Advocate Update: Lee Jones

New Ideas

Studies/Concepts

<u>S150</u>1, "Prospective Evaluation of Carvedilol in Prevention of Cardiac Toxicity in Patients with Metastatic HER-2+ Breast Cancer." Justin Floyd, D.O. and Monika Leja, M.D.

<u>\$2204</u>, "Randomized Phase III Trial of a Perioperative Physical Activity Intervention in Older Adults with Lung Cancer and their Family Caregivers." Dan Raz and Virginia Sun.

<u>S2013 I-CHECKIT</u>, "Immune CHECKpoint Inhibitory Toxicity analysis."
Krishna Gunturu. Concept approved (Also in QOL and Symptom Control Committee)

Impact of immune checkpoint inhibitors on gonadal reserve: a longitudinal analysis of biospecimens from S1404: Katy Tsai

SWOG 0816 a secondary analysis of predictors of muscle wasting, Vickie Baracos

Randomized, phase II trial of vortioxetine for the reduction of ADT-induced cognitive impairment. Chethan Ramamurthy, MD and Ian M. Thompson II, MD

ALTE2131, "Gonadotropin-Releasing Hormone Analogs (GnRHa) and Protection of Ovarian Reserve in Adolescents and Young Adults with Cancer." COG led, SWOG champion is Halle Moore

Use of Continuous Glucose Monitoring to Improve Glycemic Safety and Reduce Infectious Complications in AYA ALL patients: GOG led (Allison Grimes), SWOG champion is Stephanie Tsai

Liaison Updates/Other Business

Active Study

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

Closed Study

<u>S1316</u>, "Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction." Drs. Krouse, Denevee, and Sun. Activated: 3/9/15; Permanently Closed: 5/15/20.



Cancer Survivorship Committee

	51501	EYOJ2.
Ascension Providence Hospitals - Southfield	4	-
Baptist Memorial Health Care/Mid South Minority Underserved NCORP	6	1
Bay Area Tumor Institute NCORP	2	-
CWRU Case Comprehensive Cancer Center LAPS	14	-
Cancer Research for the Ozarks NCORP	9	-
City of Hope Comprehensive Cancer Center	44	-
Columbia University Minority Underserved NCORP	2	-
CommonSpirit Health Research Institute	1	-
Fred Hutchinson Cancer Research Center LAPS	4	-
Georgia Cares Minority Underserved NCORP	-	1
Georgia NCI Community Oncology Research Program	12	-
Gulf South Minority Underserved NCORP	4	-
Heartland Cancer Research NCORP	19	-
Henry Ford Hospital	2	-
Kaiser Permanente NCI Community Oncology Research Program	1	60
King Faisal Specialist Hospital and Research Centre	3	-
Lahey Hospital and Medical Center	6	-
Loyola University Medical Center	8	-
Medical University of South Carolina Minority Underserved NCORP	1	-
Michigan Cancer Research Consortium NCORP	3	-
Moffitt Cancer Center	18	-
Montana Cancer Consortium NCORP	1	-
NCORP of the Carolinas (Prisma Health NCORP)	2	-
National Cancer Center-Korea	1	-
New Mexico Minority Underserved NCORP	6	-
Oregon Health and Science University	1	-
UC Davis Comprehensive Cancer Center LAPS	2	-
USC Norris Comprehensive Cancer Center LAPS	4	-
University of Kansas Cancer Center - MCA Rural MU NCORP	7	-
University of Michigan Comprehensive Cancer Center LAPS	10	-
Wayne State University - Karmanos Cancer Institute LAPS	6	-
ALLIANCE	22	-
ECOG-ACRIN	39	-
NRG	22	-
Total	286	62



Palliative & End of Life Care Committee

Leauership	
Co-Chairs:	Robert S. Krouse, MI
	Mark A. O'Rourke, MI
	Marie Bakitas DNSc CRN

Time/Location

Laadayabiy

Thursday, May 11, 2023 5:15 pm - 7:15 pm Room: Garden Room (Atrium Lobby Level)

Agenda

Welcome and Introductions – Co-Chairs

5 mins. Committee Liaison Updates

(Patient Advocates/ORP)

30 mins. Plenary: Results of Completed Pilot Study: Provider Communication Education: Dr. Ishwaria M. Subbiah

30 mins. Developing Studies Updates (NCORP exec approved)
Depression Screening and Treatment in Patients Requesting
Medical Aid in Dying (MAID)" (U34-June submission) Drs.
Salman and Blanke

Randomized multicenter placebo-controlled trial evaluating lanreotide for the reduction of postoperative pancreatic fistulae. Jonathan G. Sham, MD, Charles A. Coltman, Jr. Fellow

Optimizing Distress Screening and Support of Family Caregivers of Persons with Advanced Cancer (FamilyStrong) using a SMART Design Pl: J. Nicholas Dionne-Odom, PhD, RN

Phase III Trial of Telehealth Intervention for Self-Management of Eating after Gastroesophageal Cancer Surgery – Jae Kim, MD and Virginia Sun, PhD, RN

15 mins. Pre-SWOG Pilot Study Updates

"Study of Breast Cancer Survivor Symptoms Correlation with Fatigue Measured by Prolonged Wrist Actigraphy," Lauren A. Fowler PhD and Jamie S. Myers PhD, RN

Sleep Hygiene Education, ReadiWatchTM actigraphy, and telehealth cognitive behavioral training for insomnia Effect, on Symptom Relief for Men with Prostate Cancer Receiving Androgen Deprivation Therapy (ADT) (SHERE-Relief 2), funded by the Oncology Nursing Foundation as an RE03 two-year grant. Jamie S. Myers, PhD, RN and Lauren A. Fowler, PhD

Feasibility Study of a Hope Workshop Intervention Designed to Improve Cancer Survivor Hopefulness and Endocrine Therapy Adherence," David Feldman, PhD and Ben Corn, MD Feasibility and Acceptability of an Online Intervention to Enhance Hopefulness Among Oncology Professionals David Feldman, PhD and Ben Corn, MD

5 mins. Closed Study Update

<u>\$1316</u>, "Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction." Dr. Krouse. Activated: 3/9/15; Closed: 5/15/20.

S1820, "A Randomized Trial of the Altering Intake, Managing Symptoms Intervention for Bowel Dysfunction in Rectal Cancer Survivors Compared to a Healthy Living Education Control: A Feasibility and Preliminary Efficacy Study (AIMS-RC)." Dr. Sun. Activated: 12/9/19. Permanently Closed to Accrual for Step 1: 4/12/22

10 mins. New Concepts

Algorithm-enabled Patients Activated in Cancer care through Teams (A-PACT) to improve care for people with advanced stages of cancer Manali I. Patel MD MPH MS, Assistant Professor, Division of Oncology, Stanford University School of Medicine, Ravi B. Parikh, MD, MPP, FACP Assistant Professor of Medicine and Health Policy Perelman School of Medicine, University of Pennsylvania

5 mins. Closing Comments and Adjourn: Co-Chairs

Palliative and End of Life Care Committee

Accrual from trial opening through 12/31/2022 by Institution and Study

C1850

Banner University Medical Center - Tucson	1
City of Hope Comprehensive Cancer Center	3
Columbus NCI Community Oncology Research Program	1
Fred Hutchinson Cancer Research Center LAPS	6
Hawaii Minority Underserved NCORP	2
Heartland Cancer Research NCORP	7
Michigan Cancer Research Consortium NCORP	2
NCORP of the Carolinas (Prisma Health NCORP)	5
New Mexico Minority Underserved NCORP	2
Northwestern University LAPS	2
UC Irvine Health/Chao Family Comprehensive Cancer Center	10
University of Cincinnati Cancer Center-UC Medical Center	1
University of Texas MD Anderson Cancer Center LAPS	11
Upstate Carolina Consortium Community Oncology Research Prgm.	3
Virginia Mason Medical Center	5
ALLIANCE	4
ECOG-ACRIN	1
NRG	29
Total	95
	-



Prevention & Epidemiology Committee

Leadership

Time/Location

Thursday, May 11, 2023 9:15 am - 11:15 am Room: Garden Room (Atrium Lobby Level)

Agenda

Welcome and Opening Comments

Dr. Marian Neuhouser Dr. Banu Arun

Cancer Prevention Keynote Presentation

Cancer incidence in the Diabetes Prevention Program Outcomes Study and the Look AHEAD (Action for Health in Diabetes) Trial - Effects of metformin and intensive lifestyle intervention

Dr. Brandy Heckman-Stoddard, Chief, Breast and Gynecologic Cancer Division of Cancer Prevention, National Cancer Institute

Patient Advocate update

Cheryl Jernigan

Active Studies

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

<u>\$1823</u>, "A Prospective Observational Cohort Study to Assess miRNA 371 for Outcome Prediction in Patients with Newly Diagnosed Germ Cell Tumors". Drs. Nichols and Nappi. Activated: 6/1/20.

S1904, "Cluster Randomized Controlled Trial of Patient and Provider Decision Support to Increase Chemoprevention Informed Choice Among Women with Atypical Hyperplasia or Lobular Carcinoma In Situ – Making Informed Choices on Incorporating Chemoprevention into Care (MiCHOICE)." Drs. Crew, Kukafka, et al. Activated 9/1/20.

Other Group Studies with SWOG Study Champions

CTSU A151804, "Establishment of a National Biorepository to Advance Studies of Immune-Related Adverse Events." Dr. Lyman. Activated: 1/31/20.

CTSU A212102, "A Blinded Reference Set for Multicancer Early Detection Blood Tests." Dr. McGuinness. Activated: 8/1/22.

CTSU EA1151, "Tomosynthesis Mammographic Imaging Screening Trial (TMIST)." Dr. Arun. SWOG Activated: 7/6/17.

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

Studies approved by triage and pending DCP approval

S2304, Phase II Randomized Trial of Intraoperative Radiotherapy (IORT) versus NO IORT for Postmenopausal Women with Low-Risk Ductal Carcinoma In Situ (DCIS) after Breast Conserving Surgery." Dr. Connolly.

Substudies - Pending CTEP Approval

Amendment to S1007, "Effects of Chemoprevention and Adjuvant Endocrine Therapy on a Convolutional Neural Network-Based Breast Cancer Risk Model Using Mammographic Datasets from S0812 and S1007." Drs. Crew, Kalinsky, Ha.

Concepts in Development

"Treatment Tolerability with an Alternate Dose of Exemestane or Lowdose Tamoxifen Compared to Standard Dose Exemestane Among Postmenopausal Women with Atypical Hyperplasia, Lobular Carcinoma in situ and Hormone Receptor-Positive Ducal Carcinoma in situ", Dr. J. McGuinness.

New Business/Open Discussion for new ideas Other Group Studies in Prevention Committee

CTSU EA2185, Comparing the Clinical Impact of Pancreatic Cyst Surveillance Programs. Activated: 1/16/20.



Prevention & Epidemiology Committee

	50820	51823	51904	A211102	A211601	EA1151	EA2185	NRGCC008
Ascension Providence Hosp - Southfield	1	_	-	-	2	-	-	-
Ascension Via Christi Hosp Wichita	12	-	-	-	-	-	-	-
Banner MD Anderson CC	10	2	-	-	-	1	-	-
Banner U Med Ctr - Tucson	-	8	-	-	-	56	-	-
Baptist Mem Hlth Care/Mid South MU NCORP	4	-	2	-	-	2	-	-
Bay Area Tumor Inst NCORP	1	5	-	-	-	-	-	-
Baylor College of Med/Dan L Duncan CCC	-	-	-	-	-	-	2	4
Brooke Army Med Ctr	1	-	-	-	-	-	-	-
CWRU Case CCC LAPS	-	-	-	-	-	167	-	-
Ca Res Consort of W Mich NCORP	2	1	-	-	-	-	-	-
Ca Res for the Ozarks NCORP	1	5	-	-	-	-	-	-
Ca Res of Wisconsin and N Mich Consort	1	2	-	-	-	-	-	-
Carle CC NCORP	-	4	14	-	-	2	-	-
City of Hope CCC	1	-	9	2	-	-	-	-
Columbia U MU NCORP	1	-	23	1	-	-	-	-
Columbus NCORP	6	8	-	-	-	-	-	-
CommonSpirit HIth Res Inst	4	-	-	-	-	-	-	-
Dayton NCORP	1	-	-	-	-	-	-	-
Essentia HIth NCORP	5	3	-	-	-	100	-	-
Georgia Cares MU NCORP	2	-	-	-	-	-	-	-
Georgia NCORP	2	-	-	-	-	-	-	-
Gulf South MU NCORP	-	9	-	-	-	-	-	-
Hawaii MU NCORP	10	2	13	-	-	5	-	-
Heartland Ca Res NCORP	2	14	7	-	-	-	-	-
Henry Ford Hosp	-	-	-	-	-	133	-	-
Kaiser Permanente NCORP	40	112	8	-	-	-	-	-
Lahey Hosp and Med Ctr	-	-	3	-	-	-	-	-
Loma Linda U Med Ctr	2	6	-	-	-	-	-	-
Loyola U Med Ctr	2	-	3	-	-	-	-	-
Massachusetts Veterans ERIC	3	-	-	-	-	-	6	-
Med U South Carolina MU NCORP	-	-	-	-	-	4	-	-
Meharry Med College	1	-	-	-	-	-	-	-
Mem Hermann Texas Med Ctr	-	-	-	-	-	8	-	-
Michigan Ca Res Consort NCORP	12	-	-	-	-	-	-	-
MultiCare Tacoma General Hosp	2	-	-	-	-	-	-	-



Prevention & Epidemiology Committee

	50820	51823	51904	A211102	A211601	EA1151	EA2185	NRGCC008
NCORP Carolinas (Prisma Hlth NCORP)	-	11	-	-	-	459	-	-
Nevada Ca Res Foundation NCORP	1	1	-	-	-	-	-	-
New Mexico MU NCORP	2	5	-	-	-	-	-	-
Northwell HIth NCORP	1	8	-	-	-	-	-	1
Ohio State U CCC LAPS	-	2	-	-	-	-	-	-
Oregon HIth and Science U	-	14	-	-	-	-	1	-
Pacific Ca Res Consort NCORP	2	-	-	-	-	-	-	-
Salem Hosp	-	3	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	3	2	-	-	-	-	-	-
UC Irvine Hlth/Chao Family CCC	32	3	-	-	-	-	-	-
UC San Diego Moores CC	-	19	-	-	-	-	-	-
UCLA / Jonsson CCC	-	30	-	-	-	-	-	-
USC Norris CCC LAPS	5	30	-	-	-	-	-	-
U Arkansas for Med Sciences	-	-	-	-	-	361	2	-
U Cincinnati CC-UC Med Ctr	-	4	-	-	-	-	-	-
U Colorado CC LAPS	8	15	-	-	-	2	-	-
U Kansas CC - MCA Rural MU NCORP	4	-	-	-	-	-	-	-
U Kentucky/Markey CC	-	-	-	-	-	9	-	-
U Mississippi Med Ctr	1	5	-	-	-	-	-	-
U Oklahoma Hlth Sciences Ctr LAPS	-	4	-	-	-	-	-	-
U Rochester LAPS	-	13	-	-	-	251	-	-
U Texas HSC at San Antonio	9	-	-	-	-	-	-	-
U Texas MD Anderson CC LAPS	5	-	-	-	-	-	-	-
U Utah - Huntsman Ca Inst LAPS	-	-	19	-	-	-	-	-
Upstate Carolina NCORP	-	-	-	-	-	619	-	-
Vanderbilt U - Ingram CC LAPS	-	6	-	-	-	-	-	-
Virginia Mason Med Ctr	10	13	-	-	-	-	-	-
Wayne State U - Karmanos Ca Inst LAPS	2	-	-	-	-	2	-	-
Western States Ca Res NCORP	1	-	-	-	-	69	-	-
Wisconsin NCORP	1	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	25	-	-	-	-	-	-	-
ALLIANCE	<i>37</i>	67	60	-	-	-	-	-
CCTG	-	115	-	-	-	-	-	-
ECOG-ACRIN	30	54	24	-	-	-	-	-
NRG	38	36	52	-	-	-	-	-
Total	346	641	237	3	2	2,250	11	5



Leadership

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

Time/Location

Friday, May 12, 2023 7:30 am - 9:30 am Room: Garden Room (Atrium Lobby Level)

Agenda

Plenary Presentation:

Complex Care Issues for Individuals Living with Advanced and Metastatic Cancers, Michelle A. Mollica PhD, MPH, RN, OCN

Active Trials

- S1600, "A Randomized Phase III Double-Blind Clinical Trial Evaluating the Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes (SIMmune)." Drs. Hamilton-Reeves, Holzbeierlein, Kukreja, et al. Activated: 2/21/19; Temporarily closed: 8/9/22.
- <u>\$2013</u>, "Immune Checkpoint Inhibitor Toxicity (I-CHECKIT): A Prospective Observational Study." Drs. Gunturu, Hershman, Kuderer, et al. Activated: 8/16/21.
- <u>S2205</u>, "ICE COMPRESS: Randomized Trial of Limb Cryocompression Versus Continuous Compression Versus Low Cyclic Compression for the Prevention of Taxane-Induced Peripheral Neuropathy." Drs. Accordino, Pennington, Hershman, et al.
- S2010, "A Randomized Phase III Trial Comparing Active Symptom Monitoring Plus Patient Education Versus Patient Education Alone to Improve Persistence with Endocrine Therapy in Young Women with Stage I-III Breast Cancer (ASPEN)." Drs. Henry, Hershman, and Skaar.

Other Concepts in Development

- Acupuncture to decrease symptom burden in patients with metastatic breast cancer. Dr. Greenlee
- Emerging from the Haze™ (Haze)- A multi-dimensional, psychoeducational, cognitive rehabilitation program to improve perceived cognitive function for cancer survivors. Dr. Myers

Closed Trials

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, Gehring, et al. Permanently closed 11/15/22.

- S1714, "A Prospective Observational Cohort Study to Develop a Predictive Model of Taxane-Induced Peripheral Neuropathy in Cancer Patients." Drs. Trivedi, Hershman, Brannagan, et al. Activated: 3/1/19; Permanently closed 11/15/21.
- <u>S0702</u>, "A Prospective Observational Multicenter Cohort Study to Assess the Incidence of Osteonecrosis of the Jaw (ONJ) in Cancer Patients with Bone Metastases Starting Zoledronic Acid Treatment." Dr. Van Poznak, Activated: 12/15/08. Closed: 12/13/13.
- <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." Dr. Hershman. Activated: 3/27/12. Closed: 2/15/17.

Committee Business

- 1. What is happening with our open studies?
- 2. What other studies are we planning?
- 3. What other updates should we know about
 - Patient Advocate update
 - Statistical Center update

Other SWOG Studies with Symptom Control and QOL Component

Breast

<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.

Cancer Care Delivery

- S1703, "Randomized Non-Inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (Stmddm) Versus Usual Care in Patients with Metastatic Hormone Receptor Positive Her-2 Negative Breast Cancer." Drs. Accordino, Hershman, and Ramsey. Activated: 7/16/18.
- S1912CD, "A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)." Drs. Shankaran, Carlos, Hershman, et al. Activated: 7/26/21.



<u>S2108CD</u>, "A Cluster Randomized Trial Comparing an Educationally Enhanced Genomic Tumor Board (EGTB) Intervention to Usual Practice to Increase Evidence-Based Genome-Informed Therapy." Drs. Reuter, Trivedi, Symington, et al. Activated: 8/22/22.

GU

- S1802, "Phase III Randomized Trial of Standard Systemic Therapy (SST)
 Versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer." Dr. Chapin. Activated: 9/17/18.
- <u>S1806</u>, "Phase III Randomized Trial of Concurrent Chemoradiotherapy with or Without Atezolizumab in Localized Muscle Invasive Bladder Cancer." Dr. Singh. Activated: 4/19/18.

Leukemia

<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/Small Lymphocytic Lymphoma (CLL/SLL): EVOLVE CLL/SLL Study." Drs. Stephens, Hill, Pagel, et. al. Activated: 12/14/20.

Lung

- <u>\$1914</u>, "A Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC#783608) + SBRT Versus SBRT Alone in High Risk, Early Stage NSCLC." Drs. Daly, Simone, Kelly, et al. Activated: 3/25/20.
- S1827, "MRI Brain Surveillance Alone Versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer (MAVERICK)." Drs. Rusthoven, Brown, Wefel, et al. Activated: 1/10/20.

Lymphoma

- S1826, "A Phase III, Randomized Study of Nivolumab (Opdivo) Plus AVD or Brentuximab Vedotin (Adcetris) Plus AVD in Patients (Age >/= 12 Years) with Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma." Drs. Herrera, Friedberg. Activated: 7/19/19.
- S1918, "A Phase II/III Randomized Study of R-miniCHOP with or without Oral Azacitidine (CC-486) in Participants Age 75 Years or Older with Newly Diagnosed Diffuse Large B Cell Lymphoma, Grade IIIb Follicular Lymphoma, Transformed Lymphoma, and High-Grade B-cell Lymphomas with MYC and BCL2 and/or BCL6 Rearrangements." Drs. Brem, Smith, Henry, et al. Activated: 3/19/21.

Myeloma

<u>S1803</u>, "Phase III Study of Daratumumab/rHuPH20 (NSC- 810307) + Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) Using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC Study)." Drs. Krishnan, Chhabra, and Callander. Activated: 6/27/19.

Prevention and Epidemiology

- Solventral of Effornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon or Rectal Cancer, Phase III Preventing Adenomas of the Colon with Effornithine and Sulindac (PACES)." Drs. Zell, Brown, Lance, et al. Activated: 3/1/13.
- S1904, "Cluster Randomized Controlled Trial of Patient and Provider
 Decision Support To Increase Chemoprevention Informed Choice
 Among Women with Atypical Hyperplasia or Lobular Carcinoma in Situ-Making Informed Choices on Incorporating Chemoprevention into Care (MiCHOICE)." Drs. Crew, Kukafka, Hershman, et al. Activated: 9/1/20.

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; Temporarily closed: 6/4/20; Reactivated: 1/29/21.



	51600	51674	51714	52013	A221505	A221602	A221702	A221805	A222004	EAQ202	EAZ171	NRGCC010
Ascension Providence Hosp - Southfield	-	-	-	15	-	-	-	-	-	-	-	-
Ascension Via Christi Hosp Wichita	-	-	1	-	-	-	-	-	-	-	-	-
Audie L Murphy VA Hosp	-	-	-	1	-	-	-	-	-	-	-	-
CWRU Case CCC LAPS	-	-	-	-	3	-	1	2	-	-	-	-
Ca Res Consort of W Mich NCORP	-	-	146	-	-	-	-	-	-	-	-	-
Ca Res for the Ozarks NCORP	-	-	10	1	-	-	-	-	-	-	-	-
Ca Res of Wisconsin and N Mich Consort	-	-	-	38	-	-	-	-	-	-	-	-
Carle CC NCORP	-	-	6	3	-	-	-	-	-	-	-	-
City of Hope CCC	6	-	-	-	-	-	-	-	-	-	-	-
Columbia U MU NCORP	-	-	27	14	-	3	-	-	-	-	-	-
Columbus NCORP	-	-	-	17	-	-	-	-	-	-	-	-
CommonSpirit HIth Res Inst	-	-	71	9	-	-	-	-	-	-	-	-
Dayton NCORP	-	-	-	-	-	1	-	1	-	-	-	-
Desert Regional Med Ctr	-	-	3	-	-	3	-	-	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	10	-	-	-	-	-	-	-	-	-	-	-
Georgia NCORP	-	-	18	35	-	-	-	-	-	-	-	-
Grupo Oncologico Cooperativo de Investigacion	-	-	10	-	-	-	-	-	-	-	-	-
Gulf South MU NCORP	1	-	26	12	1	-	-	-	-	-	1	2
Hawaii MU NCORP	-	-	70	-	-	-	-	-	-	-	-	-
Heartland Ca Res NCORP	-	-	38	99	-	-	-	-	-	-	-	-
Henry Ford Hosp	8	-	-	-	-	-	-	-	-	-	-	-
Instituto Nacional De Caologia	-	-	10	-	-	-	-	-	-	-	-	-
Instituto Nacional De Caologia de Mexico	-	-	60	-	-	-	-	-	-	-	-	-
Kaiser Permanente NCORP	-	2	65	15	-	-	-	-	-	-	-	-
Lahey Hosp and Med Ctr	-	-	22	29	-	-	-	-	-	-	-	-
Loyola U Med Ctr	-	-	2	-	-	-	-	-	-	-	-	-
Massachusetts Veterans ERIC	-	-	-	15	-	-	-	-	-	-	-	-



	51600	51674	51714	52013	A221505	A221602	A221702	A221805	A222004	EAQ202	EAZ171	NRGCC010
Med U South Carolina MU NCORP	-	-	-	-	-	-	-	-	-	-	2	-
Montana Ca Consort NCORP	-	-	-	2	-	-	-	-	-	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	-	-	30	-	-	-	-	-	-	39	-	-
Nevada Ca Res Foundation NCORP	-	-	-	-	-	-	-	-	-	4	-	-
Northwell Hith NCORP	-	-	-	-	2	3	-	-	-	-	-	-
Oregon Hlth and Science U	-	-	-	12	-	-	-	-	-	-	-	-
Pacific Ca Res Consort NCORP	-	-	2	1	-	-	-	-	-	-	-	-
STCC at DHR HIth Inst for Res and Dev	-	-	-	3	-	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	-	-	278	60	-	-	-	-	-	-	-	-
The West Clinic - Wolf River	-	-	-	-	6	-	-	-	-	-	-	-
Tulane U Hlth Sciences Ctr	-	-	1	-	-	-	-	-	-	-	-	-
UC Irvine Hlth/Chao Family CCC	-	-	-	4	1	4	-	-	-	-	-	-
USC Norris CCC LAPS	63	-	-	1	-	-	-	-	-	-	-	-
U Arkansas for Med Sciences	-	-	68	10	-	-	-	-	-	-	-	-
U Colorado CC LAPS	8	-	2	-	16	-	1	2	-	-	-	-
U Kansas CC - MCA Rural MU NCORP	45	-	24	14	-	-	-	2	-	-	-	-
U Kentucky/Markey CC	-	-	-	-	-	10	-	-	-	-	-	-
U Rochester LAPS	11	-	-	-	-	-	14	-	-	-	-	-
U Texas HSC at San Antonio	-	-	14	18	-	-	-	-	-	-	-	-
U Texas MD Anderson CC LAPS	-	1	-	-	-	-	-	-	-	-	-	-
U Utah - Huntsman Ca Inst LAPS	-	-	-	-	-	8	-	-	2	-	-	-
Upstate Carolina NCORP	-	-	118	-	1	-	-	-	-	-	-	-
Wayne State U - Karmanos Ca Inst LAPS	-	-	-	-	-	-	1	-	-	-	-	-
Wisconsin NCORP	-	-	-	9	-	-	-	-	-	-	-	-
ALLIANCE	5	-	44	77	-	-	-	-	-	-	-	-
ECOG-ACRIN	1	-	80	42	-	-	-	-	-	-	-	-
NRG	2	1	90	62	-	-	-	-	-	-	-	-
Total	160	4	1,336	618	30	32	17	7	2	43	3	2



Leadership	
Chair:	Razelle Kurzrock, MD
Vice-Chair:	Young Kwang Chae, MD, MPH
Executive Officer:	Christopher W. Ryan, MD
Statisticians:	Megan Othus, PhD
	Melissa Plets, MS
	Edward Mayerson, MS
Designates	
Data Coordinators:	Christine Magner
Digital Engagement:	Kanwal Raghav, MD, MBBS
Oncology Research Professionals:	
CRAs:	TBD
Nurse:	TBD
Pharmaceutical Science:	Craig Elg, PharmD
	Sun "Coco" Yang, PharmD, PhD
Patient Advocate:	Marcia K. Horn, JD
Protocol Project Manager:	Catrina De Los Santos-Mireles
Clinical Trials Program Manager:	Laura Gildner, MS
Early Therapeutics Liaisons	
Breast Committee Liaison:	Stephanie L. Graff, MD
Cancer Control Liaison:	Jason M. Prosek, MD
	Lara E. Davis, MD
Genitourinary Committee Liaison:	Neeraj Agarwal, MD
Imaging:	TBD
Lung Committee Liaison:	Shirish M. Gadgeel, MD
Lymphoma Committee Liaison:Na	asheed Mohammad Hossain, MD
Melanoma Committee Liaison:	Jeffrey A. Sosman, MD
Myeloma Committee Liaison:	Frits van Rhee, MD, PhD

Time/Location

9:30 - 9:35 am

Thursday, May 11, 2023 9:30 am - 12:00 pm

Room: Seacliff B-D (Bay Level)

Agenda

Welcome and Introduction - Razelle Kurzrock, MD

7.00 7.00	The control and the control of the c
9:35 - 10:00 am	Updates from Sarcoma Working Group - Lara Davis, MD
10:00 - 10:15 am	S2012, "Randomized Phase II/III Trial of First Line Platinum/Etoposide with or without Atezolizumab (NSC#783608) in Patients with Poorly Differentiated Extrapulmonary Neuroendocrine Carcinomas" - David Zhen, MD
10:15 - 10:35 am	CIMAC and Translational Immunology in DART - Young Chae, MD

	Neuroendocrine DART Cohorts from CIMAC - Cara Haymaker, PhD
10:55 - 11:15 am	DART: Clinical Trial Update - Sandip Patel, MD
11:15 - 11:30 am	Update from CNS Working Group - Manmeet Ahluwalia, MD
11:30 - 11:55 am	ComboMATCH - Reva Basho, MD
11:55 - 12:00 pm	Wrap Up - Razelle Kurzrock, MD

10:35 - 10:55 am Translational Findings from Non-Pancreatic

Active Studies

S2012, "Randomized Phase II/III Trial of First Line Platinum/Etoposide with or without Atezolizumab (NSC#783608) in Patients with Poorly Differentiated Extrapulmonary Small Cell Neuroendocrine Carcinomas (NEC)." Drs. Zhen, Chiorean, Burgess, Swisher. Activated: 12/2/21.

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

CTSU/NRG-BN007, "A Randomized Phase II/III Open-Label Study of Ipilimumab and Nivolumab versus Temozolomide in Patients with Newly Diagnosed MGMT (Tumor O-6-Methylguanine DNA Methyltransferase) Unmethylated Glioblastoma." Dr. Lassman. SWOG Champion: Dr. Ahluwalia. Activated: 8/6/20. Temporarily closed: 4/27/22.

CTSU/EA2183, "A Phase III Study of Consolidative Radiotherapy in Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma." Dr. Uboho. SWOG Champion: Dr. Saeed. Activated: 2/6/20.

CTSU/EA3163, "Phase II Randomized Trial of Neoadjuvant Chemotherapy Followed by Surgery and Post-Operative Radiation versus Surgery and Post-Operative Radiation for Organ Preservation of T3 and T4a (and Selected T4b) Nasal and Paranasal Sinus Squamous Cell Carcinoma (NPNSCC)." Dr. Saba. SWOG Champion: Dr. Swiecicki. Activated: 3/28/18.

CTSU/A071601, "Phase II Trial of BRAF/MEK Inhibitors in Papillary
Craniopharyngiomas." Dr. Brastianos. SWOG Champion: Dr. Ahluwalia.
Activated: 8/4/17. Temporarily Closed (Cohort A): 9/8/20.

CTSU/A071401, "Phase II Trial of SMO/AKT/NF2/CDK Inhibitors in Progressive Meningiomas with SMO/AKT/NF2/CDK Pathway Mutations." Dr. Brastianos. SWOG Champion: Dr. Piccioni. Activated: 8/28/15. New patient registration (Step 1) to the NF2, CDKN2A, CDK4, CDK6, CCND1, CCND2, CCND3, and CCNE1 Cohort (Abemaciclib Cohort) is closed to accrual as of 10/3/22.



- CTSU/A092001, "Phase 2 Randomized Trial of Neoadjuvant or Palliative Chemotherapy with or Without Immunotherapy for Peritoneal Mesothelioma". SWOG Champion: Dr. P.S.K. Raghav. Activated: 10/15/21.
- CTSU/AGCT1531, "A Phase III Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors" SWOG Champion: Dr. D'Souza Activated: 5/8/17.
- CTSU/AOST2031, "A Phase 3 Randomized Controlled Trial Comparing Open vs Thoracoscopic Management of Pulmonary Metastases in Patients with Osteosarcoma" SWOG Champion: Dr. Hofstetter. Activated: 2/15/22
- CTSU/AOST2032. "A Feasibility and Randomized Phase 2/3 Study of the VEFGR2/MET Inhibitor Cabozantinib in Combination with Cytotoxic Chemotherapy for Newly Diagnosed Osteosarcoma" SWOG Champion: Dr. J. A. Livingston. Activated: 2/17/23
- CTSU/A071702, "A Phase II Study of Checkpoint Blockade Immunotherapy in Patients with Somatically Hyper-mutated Recurrent Glioblastoma." SWOG Champion: Dr. M. Ahluwalia. Activated: 10/30/20

Proposed Studies

- NRG-BN1803, "NRG-COG Phase II Trial of Radiation Plus Concurrent and Adjuvant ONC201 for Newly Diagnosed, H3 K27M-Mutant Gliomas." SWOG Champion: Dr. Ahluwalia.
- NRG-OV1821, "A Randomized Phase II Trial of Olaparib Versus Olaparib + Tremelimumab in Platinum-Sensitive Recurrent Ovarian Cancer." Dr. Robinson.
- NRG-BN1855, "A Randomized Phase II/III Open Label Study of Ipilimumab and Nivolumab Vs Te-mozolomide in Patients with Newly Unmethylated MGMT (Tumor O-6-Methylguanine DNA Methyltransfer-ase)
 Glioblastoma." Dr. Ahluwalia.
- NRG-HN1854, "An Open-label, Phase III Study of Platinum-Gemcitabine with or Without Nivolumab in the First-line Treatment of Recurrent or Metastatic Nasopharyngeal Carcinoma." Dr. Swiecicki.
- NRG-UC1805, "Randomized Phase III Trial of Radiation +/- Pembrolizumab for High Intermediate Risk Mismatch Repair Deficient (dMMR)

 Endometrioid Endometrial Cancer." Dr. Robinson.

Closed Studies

- **S1609**, "DART: Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors." Drs. Patel, Chae, and Kurzrock. Activated: 1/13/17. Closed: 3/15/23.
- CTSU/NRG-GY006, "A Randomized Phase III Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIIB, or IVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer." Dr. Leath. SWOG Champion: Dr. Robinson. Activated: 1/15/16. Closed: 9/22/22
- CTSU/NRG-GY020, "A Phase III Randomized Trial of Radiation +/Pembrolizumab (MK-3475) for Newly Diagnosed Early Stage High
 Intermediate Risk Mismatch Repair Deficient (dMMR) Endometrioid
 Endometrial Cancer." Dr. Backes. SWOG Champion: Dr. Robinson.
 Activated: 2/7/20. Closed: 8/29/22.
- NCICOVID, "NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study." Dr. Karim. Activated: 5/21/20. Closed: 2/1/22.
- CTSU/NRG-GY009, "A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin, CTEP-Supplied Bevacizumab and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin and CTEP-Supplied Bevacizumab in Platinum Resistant Ovarian Cancer." Dr. O'Cearbhaill. SWOG Champion: Dr. Robinson. Activated: 5/12/17. Closed 10/14/21
- CTSU/NRG-HN007, "An Open-Label, Phase III Study of Platinum-Gemcitabine with or without Nivolumab in the First-Line Treatment of Recurrent or Metastatic Nasopharyngeal Carcinoma." Dr. Brigette B. Y. Activated: 9/8/20; Closed: 10/28/21

ComboMatch

Active Studies

EAY191-S3, "Phase 2 Study of Paclitaxel + Ipatasertib in Taxane-Refractory Participants with AKT-Altered Advanced Non-Breast Solid Tumors.". Study Chairs: Reva Basho, MD, Haider Mahdi, MD



	51609	52012	A077407	AGCT1531	EAY131
Ascension Providence Hospitals - Southfield	1	-	_	-	3
Baptist Memorial Health Care/Mid South Minority Underserved NCORP	2	-	-	-	-
Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center	-	-	-	-	3
CWRU Case Comprehensive Cancer Center LAPS	7	-	-	-	10
Cancer Research for the Ozarks NCORP	1	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	3	-		-	_
Carle Cancer Center NCI Community Oncology Research Program	3	-	-	-	_
Cedars-Sinai Medical Center	8	-	_	-	6
City of Hope Comprehensive Cancer Center	2	-	-	-	6
Columbus NCI Community Oncology Research Program	3	-	_	-	-
CommonSpirit Health Research Institute	17	-	1	-	9
Dayton NCI Community Oncology Research Program	2	-	-	-	1
Essentia Health NCI Community Oncology Research Program	4	-	-	-	_
Fred Hutchinson Cancer Research Center LAPS	10	-	_	-	2
Georgia NCI Community Oncology Research Program	6	_	_	-	_
Gulf South Minority Underserved NCORP	2	_	-	-	_
Hawaii Minority Underserved NCORP	4	-	-	-	1
Heartland Cancer Research NCORP	15	_	-	-	1
Henry Ford Hospital	17	_	-	-	11
•	17	_	-	-	1
Houston Methodist Hospital	1	_	-		,
Intermountain Medical Center	1	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	27	-	-	-	6
Loma Linda University Medical Center	6	-	-	-	1
Loyola University Medical Center	4	-	-	-	-
Massachusetts Veterans Epidemiology Research and Information Center	5	-	-	-	-
Medical University of South Carolina Minority Underserved NCORP	4	-	-	-	2
Michigan Cancer Research Consortium NCORP	12	2	-	-	-
Moffitt Cancer Center	22	-	-	-	-
Montana Cancer Consortium NCORP	16	-	-	-	-
MultiCare Tacoma General Hospital	2	-	-	-	-
Nevada Cancer Research Foundation NCORP	18	-	-	-	-
New Mexico Minority Underserved NCORP	18	-	-	-	-
Northwestern University LAPS	16	-	1	-	-
Oregon Health and Science University	12	-	-	-	-
Pacific Cancer Research Consortium NCORP	12	-	-	-	-
Saint Luke's Hospital of Kansas City	-	-	-	-	1
Southeast Clinical Oncology Research Consortium NCORP	-	1	-	-	8
Sutter Cancer Research Consortium	2	-	-	-	4
The Don and Sybil Harrington Cancer Center	-	-	-	1	-
Tulane University Health Sciences Center	-	-	-	-	1
UC Davis Comprehensive Cancer Center LAPS	11	-	-	-	9
UC Irvine Health/Chao Family Comprehensive Cancer Center	8	-	1	-	19
UC San Diego Moores Cancer Center	27	-	2	-	-
USC Norris Comprehensive Cancer Center LAPS	4	-	-	-	-
University of Arkansas for Medical Sciences	5	-	-	-	3
University of Colorado Cancer Center LAPS	6	-	1	-	9
University of Kansas Cancer Center - MCA Rural MU NCORP	35	-	-	-	6
University of Kentucky/Markey Cancer Center	-	-	-	-	13
University of Michigan Comprehensive Cancer Center LAPS	32	-	-	-	24
University of Mississippi Medical Center	5	-	-	-	-



	51609	52012	A077407	AGCT1531	ENY131
University of Oklahoma Health Sciences Center LAPS	3	-	-	-	-
University of Rochester LAPS	5	-	-	-	-
University of Texas Health Science Center at San Antonio	5	-	-	-	7
University of Texas MD Anderson Cancer Center LAPS	19	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	3	-	-	-	-
Upstate Carolina Consortium Community Oncology Research Program	4	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	-	-	3
Wisconsin NCI Community Oncology Research Program	12	-	-	-	-
Yale University - Yale Cancer Center LAPS	7	-	2	-	13
ALLIANCE	106	2	-	-	-
ECOG-ACRIN	<i>7</i> 8	-	-	-	-
NRG	137	1	-	-	-
Total	796	6	8	1	183



Leadership	
Chair:	Philip A. Philip, MD, PhD, FRCP
Vice-Chair:	E. Gabriela Chiorean, MD, FASCO
Executive Officer:	Christopher W. Ryan, MD
Statisticians:	Katherine A. Guthrie, PhD
	Sarah Colby, MS
Scientific Leadership	
Gastroesophageal:	Syma Iqbal, MD
	Zev A. Wainberg, MD
Pancreatic:	Davendra P.S. Sohal, MD
	. Andrew M. Lowy, MD (Surgical representative)
Hepatobiliary:	Anthony B. El-Khoueiry, MD
	Rachna T. Shroff, MD
	Syed A. Ahmad, MD (Surgical representative)
Colon:	Marwan G. Fakih, MD
	Philip J. Gold, MD
	.Sepideh Gholami, MD (Surgical representative)
Neuroendocrine Tumors:	Nageshwara Arvind Dasari, MD
	Jonathan R. Strosberg, MD
Ano-Rectal:	Lisa A. Kachnic, MD
	Hagen F. Kennecke, MD
lmaging:	Anthony F. Shields, MD, PhD
Pathology:	Mary Kay Washington, MD, PhD
Radiation Oncology:	Lisa A. Kachnic, MD
Surgery:	Stephen W. Behrman, MD
	Syed A. Ahmad, MD
	Flavio Rocha, MD
	Christopher lieu, MD (interim)
Designates	
Cancer Control Liaisons: .	Jason A. Zell, DO (Prevention)
	Afsaneh Barzi, MD (CCD)
Community Liaisons: G	ary Buchschacher, MD, PhD (Medical Oncology)
	Mohamed E. Salem, MD (Medical Oncology)
	Flavio Rocha, MD (Surgical)
	David Horowitz, MD (Radiation Oncology)
	Mark A. O'Rourke, MD (Palliative Care)
DEI Champion:	Colmar Figueroa-Moseley, PhD, MPH
·	Rachael Ann Safyan, MD
	Heloisa Soares, MD, PhD
	Christine Magner
	Brian Zeller
	Ojasvi Mittal
Oncology Research Profe	
~ .	Michelle A. Springer, BA

Patient Advocate (Pancreatic):	Carole Seigel, MBA
Patient Advocate (Colon):	Florence Kurttila, MS
Pharmaceutical Science:	Jane E. Rogers, PharmD
Protocol Project Manager:	Christy Klepetko
Clinical Trials Program Manager:	Laura Gildner, MS
T ' // /	

Time/Location

Friday, May 12, 2023 4:30 pm - 6:30 pm Room: Grand Ballroom A (Street Level)

Agenda

1. Welcome

2. Announcements & Introductions Philip Philip E. Gabriella Chiorean

3. GI Committee DEI initiatives Rachel Safyan

Colmar Figueroa-Moseley

4. SWOG GI Committee Led trials

Michael Overman a. S1922 S2001 Vincent Chung S2104 Heloisa Soares/Syed Ahmad c. d. S2107 Van Morris Jason Zell S0802 f. S2012 David Zhen E. Gabriella Chiorean

S2303 Anwaar Saeed/Paul Oberstein

5. SWOG GI Committee Co-Led Trials

Arvind Dasari A022104 b. A022001 Heloisa Soares EA2192 Anup Kasi NRG-GI004 Michael Overman NRG-GI008 e. Christopher Lieu

6. NCI/CTEP ctDNA working group update Philip Philip

7. Highlighted NCTN Trials

Steven Behrman A021806 Van Morris EA2176 b. NRG-GI005 Aaron Scott

8. Anal and Rectal Hagen Kennecke, Lisa Kachnic

Highlights of recent clinical trials

Future plans



9. Colon Marwan Fakih, Philip Gold, Sepideh Gholami

- Highlights of recent clinical trials
- Future plans
- 10. Gastroesophageal Cancers
 - a. Highlights of recent clinical trials
 - b. Future plans
- 11. Hepatobiliary

Anthony El-Khoueiry Rachna Shroff

Syma Igbal, Zev Wainberg

- Highlights of recent clinical trials
- b. Future plans
- 12. Neuroendocrine

Jon Strosberg, Arvind Dasari

- Highlights of recent clinical trials
- b. Future plans
- 13. Pancreatic

- Davendra Sohal, Andrew Lowy
- Highlights of recent clinical trials
- Future plans
- 14. Adjourn

Gastroesophageal

Proposed Studies

S2303, "Phase II/III Trial of Nivolumab + Cabozantinib or Nivolumab + Paclitaxel + Ramucirumab versus Paclitaxel + Ramucirumab in Patients with PD-L1 CPS ≥ 5 Advanced Gastric and Esophageal Adenocarcinoma." Dr. Saeed.

Active Studies

- CTSU/A022102, "Randomized Phase III Trial of mFOLFIRINOX +/- Nivolumab vs. FOLFOX +/- Nivolumab for First-Line Treatment of Metastatic HER2-Negative Gastroesophageal Adenocarcinoma." Dr. Oberstein. Activated: 1/17/19.
- CTSU/EA2174, "A Phase II/III Study of Peri-Operative Nivolumab and Ipilimumab in Patients with Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma." Dr. Kelly. Activated: 1/17/19.
- CTSU/EA2183, "A Phase III Study of Consolidative Radiotherapy in Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA)." Dr. Horowitz. Activated: 2/6/20. Temporarily closed: 6/15/21.

Pancreatic

Active Studies

- **\$2001**, "Randomized Phase II Clinical Trial of Olaparib + Pembrolizumab Alone as Maintenance Therapy in Metastatic Pancreatic Cancer Patients with Germline BRCA1 or BRCA2 Mutations." Dr. Chung. Activated: 12/4/20.
- CTSU/A021804, "A Prospective, Multi-Institutional Phase II Trial Evaluating Temozolomide vs. Temozolomide and Olaparib for Advanced Pheochromocytoma and Paraganglioma." Dr. C. Lopez. Activated: 11/2/20.
- CTSU/A021806, "A Phase III Trial of Perioperative Versus Adjuvant Chemotherapy for Resectable Pancreatic Cancer." Dr. Noel. Activated:
- CTSU/EA2186, "A Randomized Phase II Study of Gemcitabine and Nab-Paclitaxel Compared with 5-Fluorouracil, Leucovorin, and Liposomal Irinotecan in Older Patients with Treatment Naïve Metastatic Pancreatic Cancer (GIANT)." Dr. Zhen. Activated: 6/18/20.
- CTSU/EA2192, "APOLLO: A Randomized Phase II Double-Blind Study of Olaparib Versus Placebo Following Adjuvant Chemotherapy in Patients with Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation." Drs. Chiorean and Philip. Activated: 4/29/21.
- CTSU/EA2192, "APOLLO: A Randomized Phase II Double-Blind Study of Olaparib Versus Placebo Following Adjuvant Chemotherapy in Patients with Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation." Drs. Chiorean and Philip. Activated: 4/29/21.

Neuroendocrine

Active Studies

- <u>\$2104</u>, "Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolimide versus Observation in High-Risk Pancreatic Neuroendocrine Tumors." Dr. Soares. Activated: 10/14/21.
- CTSU/A021602, "Randomized Double-Blinded Phase III Study of CABozantinib versus Placebo IN Advanced NEuroendocrine Tumors after Progression on Prior Therapy (CABINET)." Dr. Strosberg. Activated: 7/18/18.



Hepatobiliary

Active Studies

CTSU/NRG-GI003, "A Phase III Randomized Trial of Protons Versus Photons for Hepatocellular Carcinoma." Dr. El-Khoueiry. Activated: 6/21/17.

CTSU/EA2197, "Optimal Perioperative Therapy for Incidental Gallbladder Cancer (OPT-IN): A Randomized Phase II/III Trial." Dr. Rocha. Activated: 12/22/20.

CTSU/EA2187, "A Phase 2 Study of Pevonedistat in Combination with Carboplatin and Paclitaxel in Advanced Intrahepatic Cholangiocarcinoma." Dr. Stein. Activated: 1/31/20. Temporarily closed: 3/31/21.

Closed Studies

<u>S1815</u>, "A Phase III Randomized Trial of Gemcitabine, Cisplatin, and Nab-Paclitaxel Versus Gemcitabine and Cisplatin in Newly Diagnosed, Advanced Biliary Tract Cancers." Dr. Shroff. Activated: 12/3/18. Permanently Closed: 2/15/21.

Colorectal

Active Studies

<u>S2107</u>, "Randomized Phase II Trial of Encorafenib and Cetuximab with or without Nivolumab for Patients with Microsatellite Stable, BRAFV600E Metastatic Colorectal Cancer." Dr. Morris. Activated: 6/6/22.

Gastrointestinal Committee

	51613	51922	52001	52104	52107	A021502	A021602	A021703	A021806
Ascension Providence Hospitals - Southfield	-	-	1	-	-	3	-	-	-
Banner University Medical Center - Tucson	-	-	-	3	-	2	2	-	1
Baptist Memorial Health Care/Mid South Minority Underserved NCORP	-	-	2	-	-	-	-	-	-
Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center	-	-	-	-	-	-	-	1	-
Boston Medical Center	-	-	-	-	-	1	3	-	1
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-	-	6	-	-	2
City of Hope Comprehensive Cancer Center	-	-	2	-	-	-	1	-	-
Columbia University Minority Underserved NCORP	-	-	1	-	-	-	-	-	-
CommonSpirit Health Research Institute	3	-	-	-	-	-	-	-	-
Dayton NCI Community Oncology Research Program	-	-	-	-	-	3	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	-	-	-	4	-	-	-
Gulf South Minority Underserved NCORP	-	-	-	-	-	-	-	-	-
Hawaii Minority Underserved NCORP	1	-	-	-	-	-	-	-	-
Heartland Cancer Research NCORP	3	-	-	-	2	-	-	-	-
Henry Ford Hospital	-	-	1	-	-	-	-	-	-
Houston Methodist Hospital	-	-	-	-	-	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	2	-	-	-	1	16	-	-	-
Lahey Hospital and Medical Center	1	-	-	-	-	-	-	-	-
Loyola University Medical Center	1	-	-	-	-	-	-	-	-
Medical University of South Carolina Minority Underserved NCORP	-	-	-	1	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	1	1	-	-	-	-	-	-	-
Moffitt Cancer Center	-	-	-	-	-	-	4	-	-
NCORP of the Carolinas (Prisma Health NCORP)	-	-	-	-	-	-	-	-	-
Northwell Health NCORP	-	-	-	-	-	-	-	9	1
Northwestern University LAPS	1	1	-	-	-	1	-	8	-
Oregon Health and Science University	-	-	-	-	-	-	-	-	-
Pacific Cancer Research Consortium NCORP	3	-	-	-	-	-	-	-	-
SCL Health Saint Joseph Hospital	-	-	-	-	-	-	-	-	-



Solventrolled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon or Rectal Cancer, Phase III – Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES)." Dr. Zell. Activated: 3/1/13.

CTSU/NRG-GI005, "Phase II/III Study of Circulating Tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Patients with Stage IIA Colon Cancer (COBRA)." Dr. Scott. Activated: 12/16/19.

CTSU/A021703, "Randomized Double-Blind Phase III Trial of Vitamin D3 Supplementation in Patients with Previously Untreated Metastatic Colorectal Cancer (SOLARIS)." Dr. Cohen. Activated: 9/30/19.

CTSU/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." Dr. Lieu. Activated: 9/12/17.

CTSU/NRG-GI004, "Colorectal Cancer Metastatic dMMR/MSI-H Immuno-Therapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/ Bevacizumab/Atezolizumab Combination versus Single Agent Atezolizumab in the First-Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR)/Microsatellite Instability-High (MSI-H) Metastatic Colorectal Cancer." Dr. Overman. Activated: 11/7/17.

Gastrointestinal Committee

	51613	51922	52001	52104	52107	A021502	A021602	A021703	A021806
Southeast Clinical Oncology Research Consortium NCORP	1	-	2	1	1	-	-	-	-
Sutter Cancer Research Consortium	-	-	-	-	-	3	-	-	-
The Don and Sybil Harrington Cancer Center	-	-	-	-	-	-	-	-	2
UC Davis Comprehensive Cancer Center LAPS	2	-	-	-	-	4	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	1	-	-	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS	1	-	-	-	-	2	-	1	-
University of Alabama at Birmingham/Deep South Research Consortium LAPS	-	-	-	-	-	-	-	-	-
University of Arkansas for Medical Sciences	-	-	-	-	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	-	-	-	-	-	-	3	-
University of Colorado Cancer Center LAPS	1	-	1	-	-	6	-	1	-
University of Kansas Cancer Center - MCA Rural MU NCORP	4	-	-	-	-	3	-	1	-
University of Kentucky/Markey Cancer Center	-	-	-	2	-	-	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	1	3	-	-	-	-	2	-	4
University of Rochester LAPS	-	1	-	-	-	2	6	-	4
University of Texas Health Science Center at San Antonio	-	-	-	-	-	-	-	-	3
University of Texas MD Anderson Cancer Center LAPS	13	9	-	-	1	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	-	-	1	1	-	-	-	-	-
University of Wisconsin Carbone Cancer Center	-	-	-	-	-	-	-	-	-
Vanderbilt University - Ingram Cancer Center LAPS	-	-	1	-	-	-	-	-	-
Virginia Mason Medical Center	-	-	-	-	-	4	2	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	1	-	-	2	-	-	-
William Beaumont Hospital-Royal Oak	-	-	-	-	-	1	-	-	-
Wisconsin NCI Community Oncology Research Program	-	-	-	-	1	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	-	-	-	-	3	-	8	-
ALLIANCE	6	8	4	-	2	-	-	-	-
ECOG-ACRIN	4	1	4	-	-	-	-	-	-
NRG	5	2	1	2	-	-	-	-	-
Total	54	26	23	10	8	66	20	32	18



Closed Studies Anal

S1613, "A Randomized Phase II Study of Trastuzumab and Pertuzumab (TP)
Compared to Cetuximab and Irinotecan (CETIRI) in Advanced/Metastatic
Colorectal Cancer (MCRC) with HER-2 Amplification." Dr. Raghav.
Activated: 10/19/17. Step 1 closed to accrual: 1/1/22.

Active Studies

CTSU/EA2176, "Randomized Phase III Study of Immune Checkpoint Inhibition with Chemotherapy in Treatment-Naïve Metastatic Anal Cancer Patients." Dr. Morris. Activated: 10/15/20.

CTSU/EA2182, "A Randomized Phase II Study of De-Intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE)." Dr. Murphy. Activated: 11/12/19.

CTSU/EA2201, "A Phase II Study of Neoadjuvant Nivolumab Plus Ipilimumab and Short-Course Radiation in MSI-H/dMMR Locally

Gastrointestinal Committee

	EA2165	EA2174	EA2176	EA2182	EA2186	EA2187	EA2197	NRGG100A	NRGGI005
Ascension Providence Hosp - Southfield	1	-	1	1	2	-	-	-	3
Banner U Med Ctr - Tucson	-	-	-	-	-	-	-	-	-
Baptist Mem Hlth Care/Mid South MU NCORP	-	-	-	-	-	-	-	-	3
Baylor College of Med/Dan L Duncan CCC	-	-	-	-	-	-	-	-	-
Boston Med Ctr	1	2	-	1	-	-	-	-	-
CWRU Case CCC LAPS	-	2	-	1	-	3	-	-	-
City of Hope CCC	-	-	-	-	1	-	-	-	-
Columbia U MU NCORP	-	-	-	-	-	-	-	-	-
CommonSpirit HIth Res Inst	-	-	-	-	-	-	-	-	-
Dayton NCORP	-	-	-	-	1	-	-	-	1
Fred Hutchinson Cancer Res Ctr LAPS	3	-	-	-	-	-	-	-	-
Gulf South MU NCORP	1	-	-	-	-	-	-	-	-
Hawaii MU NCORP	-	-	-	-	2	-	-	-	-
Heartland Cancer Res NCORP	-	-	-	-	-	-	-	-	-
Henry Ford Hosp	-	-	-	-	-	-	-	-	1
Houston Methodist Hosp	-	-	-	-	-	-	-	1	-
Kaiser Permanente NCORP	6	-	3	-	-	-	-	-	8
Lahey Hosp and Med Ctr	-	-	-	-	-	-	-	-	-
Loyola U Med Ctr	-	-	-	-	-	-	-	-	-
Med U South Carolina MU NCORP	-	-	-	-	-	-	-	-	-
Michigan Cancer Res Consort NCORP	-	-	-	-	-	-	-	-	1
Moffitt CC	-	-	-	-	-	-	-	-	-
NCORP of the Carolinas (Prisma HIth NCORP)	1	-	-	-	-	-	-	-	-
Northwell HIth NCORP	-	1	-	-	2	-	-	-	1
Northwestern U LAPS	-	-	1	-	1	-	-	-	-
Oregon HIth and Science U	4	-	1	1	-	-	1	-	1
Pacific Cancer Res Consort NCORP	-	-	-	-	-	-	-	-	-
SCL HIth Saint Joseph Hosp	1	-	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	-	-	-	-	-	-	-	-	-



Advanced Rectal Adenocarcinoma." Dr. Cho. Activated: 5/13/21.

Other

Active Studies

<u>\$2012</u>, "Randomized Phase II/III Trial of First Line Platinum/Etoposide with or without Atezolizumab in Patients with Poorly Differentiated Extrapulmonary Small Cell Neuroendocrine Carcinomas." Dr. Zhen. Activated: 12/2/21

<u>\$1922</u>, "Randomized Phase II Selection Study of Ramucirumab and Paclitaxel Versus FOLFIRI in Refractory Small Bowel Adenocarcinoma." Dr.

Overman, Activated: 12/16/19.

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

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

Gastrointestinal Committee

	EA2165	EA2174	EA2176	EA2182	EA2186	EA2187	EA2197	NRGGI004	NRGGI005
Sutter Cancer Res Consort	2	-	-	-	-	1	-	-	-
Don and Sybil Harrington CC	-	-	-	-	-	-	-	-	-
UC Davis CCC LAPS	5	-	-	-	-	-	1	-	1
UC Irvine Hlth/Chao Family CCC	-	-	1	-	2	-	-	-	1
USC Norris CCC LAPS	-	1	-	-	-	-	-	-	-
U Alabama at Birm / Deep South Res Consort LAPS	1	-	-	-	-	-	-	-	-
U Arkansas for Med Sciences	7	-	1	-	-	-	-	-	-
U Cincinnati CC-UC Med Ctr	1	-	1	-	-	-	-	-	-
U Colorado CC LAPS	-	-	-	-	1	-	-	-	-
U Kansas CC - MCA Rural MU NCORP	-	-	-	-	-	1	-	-	2
U Kentucky/Markey CC	-	-	-	-	-	-	-	-	-
U Michigan CCC LAPS	-	-	-	-	-	-	-	-	-
U Rochester LAPS	-	-	-	-	4	2	-	1	-
U Texas HIth Science Ctr at San Antonio	-	-	-	-	3	-	-	-	-
U Texas MD Anderson CC LAPS	-	-	7	-	-	-	-	12	1
U Utah - Huntsman Cancer Inst LAPS	-	-	-	-	-	-	-	-	-
U Wisconsin Carbone CC	-	-	-	-	-	-	-	1	-
Vanderbilt U - Ingram CC LAPS	-	-	-	-	-	-	-	-	1
Virginia Mason Med Ctr	-	-	-	-	-	-	-	-	-
Wayne State U - Karmanos Cancer Inst LAPS	3	-	-	1	-	-	-	-	-
William Beaumont Hosp-Royal Oak	-	-	-	-	-	-	-	-	-
Wisconsin NCORP	-	-	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	-	-	-	-	-	-	-	-	4
ALLIANCE	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-	-	-	-
NRG	-	-	-	-	-	-	-	-	-
Total	37	6	16	5	19	7	2	15	29



Chair:	Leadership
Vice-Chair: Daniel P. Petrylak, MD Executive Officer: Christopher W. Ryan, MD Statisticians: Cathy M. Tangen, DrPH	•
Executive Officer: Christopher W. Ryan, MD Statisticians: Cathy M. Tangen, DrPH	•
Statisticians: Cathy M. Tangen, DrPH	
Melissa Plets, MS Sam Callis, MS Gabby Lopez, BS Scientific Leadership Translational Medicine: David J. McConkey, PhD (GU Chair) Joshua J. Meeks, MD, PhD (Bladder) Amir Goldkorn, MD (Prostate) Sumanta "Monty" K. Pal, MD (Renal) Radiation Oncology: James B. Yu, MD Daniel A. Hamstra, MD Imaging: Evan Y. Yu, MD Hiram Shaish, MD John D. Hazle, PhD Pathology: M. Scott Lucia, MD Surgery: Kelly L. Stratton, MD Early Therapeutics: Neeraj Agarwal, MD Bladder Organ Site Chairs: Seth P. Lerner, MD (Localized) Thomas W. Flaig, MD (Localized) Daniel P. Petrylak, MD (Advanced) Prostate Organ Site Chairs: Daniel W. Lin, MD (Localized) Tanya Dorff, MD, PhD (Advanced) Renal Organ Site Chairs: Brian Shuch, MD (Localized) Ulka N. Vaishampayan, MD (Advanced) Designates Cancer Control: Peter J. Van Veldhuizen, Jr., MD Del Champion: Jessica D. McDermott, MD Digital Engagement: Neema Navai, MD Veterans Affairs Michael M. Goodman, MD Data Coordinators: Jeri Jardine Tonya Johnson Michele Counts Laura Wells Oncology Research Professionals:	
Sam Callis, MS Gabby Lopez, BS Scientific Leadership Translational Medicine: David J. McConkey, PhD (GU Chair)	
Scientific Leadership Translational Medicine: David J. McConkey, PhD (GU Chair)	
Scientific Leadership Translational Medicine: David J. McConkey, PhD (GU Chair)	
Amir Goldkorn, MD (Prostate)	Translational Medicine: David J. McConkey, PhD (GU Chair
	Joshua J. Meeks, MD, PhD (Bladder)
Radiation Oncology: James B. Yu, MD Daniel A. Hamstra, MD Imaging: Evan Y. Yu, MD Hiram Shaish, MD John D. Hazle, PhD Pathology: M. Scott Lucia, MD Surgery: Kelly L. Stratton, MD Early Therapeutics: Neeraj Agarwal, MD Bladder Organ Site Chairs: Seth P. Lerner, MD (Localized) Thomas W. Flaig, MD (Localized) Daniel P. Petrylak, MD (Advanced) Prostate Organ Site Chairs: Daniel W. Lin, MD (Localized) Tanya Dorff, MD, PhD (Advanced) Renal Organ Site Chairs: Brian Shuch, MD (Localized) Ulka N. Vaishampayan, MD (Advanced) Designates Cancer Control: Peter J. Van Veldhuizen, Jr., MD DEI Champion: Jessica D. McDermott, MD Digital Engagement: Neema Navai, MD Veterans Affairs Michael M. Goodman, MD Data Coordinators: Jeri Jardine Tonya Johnson Michele Counts Laura Wells Oncology Research Professionals:	
Daniel A. Hamstra, MD Imaging:	Sumanta "Monty" K. Pal, MD (Renal)
Imaging:	Radiation Oncology: James B. Yu, MD
Hiram Shaish, MD John D. Hazle, PhD Pathology: M. Scott Lucia, MD Surgery: Kelly L. Stratton, MD Early Therapeutics: Neeraj Agarwal, MD Bladder Organ Site Chairs: Seth P. Lerner, MD (Localized) Thomas W. Flaig, MD (Localized) Daniel P. Petrylak, MD (Advanced) Prostate Organ Site Chairs: Daniel W. Lin, MD (Localized) Tanya Dorff, MD, PhD (Advanced) Renal Organ Site Chairs: Brian Shuch, MD (Localized) Ulka N. Vaishampayan, MD (Advanced) Designates Cancer Control: Peter J. Van Veldhuizen, Jr., MD DEI Champion: Jessica D. McDermott, MD Digital Engagement: Neema Navai, MD Veterans Affairs Michael M. Goodman, MD Data Coordinators: Jeri Jardine Tonya Johnson Michele Counts Laura Wells Oncology Research Professionals:	Daniel A. Hamstra, MD
Hiram Shaish, MD John D. Hazle, PhD Pathology: M. Scott Lucia, MD Surgery: Kelly L. Stratton, MD Early Therapeutics: Neeraj Agarwal, MD Bladder Organ Site Chairs: Seth P. Lerner, MD (Localized) Thomas W. Flaig, MD (Localized) Daniel P. Petrylak, MD (Advanced) Prostate Organ Site Chairs: Daniel W. Lin, MD (Localized) Tanya Dorff, MD, PhD (Advanced) Renal Organ Site Chairs: Brian Shuch, MD (Localized) Ulka N. Vaishampayan, MD (Advanced) Designates Cancer Control: Peter J. Van Veldhuizen, Jr., MD DEI Champion: Jessica D. McDermott, MD Digital Engagement: Neema Navai, MD Veterans Affairs Michael M. Goodman, MD Data Coordinators: Jeri Jardine Tonya Johnson Michele Counts Laura Wells Oncology Research Professionals:	Imaging:Evan Y. Yu, MD
Pathology:	
Surgery: Kelly L. Stratton, MD Early Therapeutics: Neeraj Agarwal, MD Bladder Organ Site Chairs: Seth P. Lerner, MD (Localized) Thomas W. Flaig, MD (Localized) Daniel P. Petrylak, MD (Advanced) Prostate Organ Site Chairs: Daniel W. Lin, MD (Localized) Tanya Dorff, MD, PhD (Advanced) Renal Organ Site Chairs: Brian Shuch, MD (Localized) Ulka N. Vaishampayan, MD (Advanced) Designates Cancer Control: Peter J. Van Veldhuizen, Jr., MD DEI Champion: Jessica D. McDermott, MD Digital Engagement: Neema Navai, MD Veterans Affairs Michael M. Goodman, MD Data Coordinators: Jeri Jardine Tonya Johnson Michael Counts Laura Wells Oncology Research Professionals:	
Surgery: Kelly L. Stratton, MD Early Therapeutics: Neeraj Agarwal, MD Bladder Organ Site Chairs: Seth P. Lerner, MD (Localized) Thomas W. Flaig, MD (Localized) Daniel P. Petrylak, MD (Advanced) Prostate Organ Site Chairs: Daniel W. Lin, MD (Localized) Tanya Dorff, MD, PhD (Advanced) Renal Organ Site Chairs: Brian Shuch, MD (Localized) Ulka N. Vaishampayan, MD (Advanced) Designates Cancer Control: Peter J. Van Veldhuizen, Jr., MD DEI Champion: Jessica D. McDermott, MD Digital Engagement: Neema Navai, MD Veterans Affairs Michael M. Goodman, MD Data Coordinators: Jeri Jardine Tonya Johnson Michael Counts Laura Wells Oncology Research Professionals:	Pathology:
Early Therapeutics:	
	- ·
Daniel P. Petrylak, MD (Advanced) Prostate Organ Site Chairs: Daniel W. Lin, MD (Localized) Tanya Dorff, MD, PhD (Advanced) Renal Organ Site Chairs: Brian Shuch, MD (Localized) Ulka N. Vaishampayan, MD (Advanced) Designates Cancer Control: Peter J. Van Veldhuizen, Jr., MD DEI Champion: Jessica D. McDermott, MD Digital Engagement: Neema Navai, MD Veterans Affairs Michael M. Goodman, MD Data Coordinators: Jeri Jardine Tonya Johnson Michele Counts Laura Wells Oncology Research Professionals:	
Prostate Organ Site Chairs:	
Tanya Dorff, MD, PhD (Advanced) Renal Organ Site Chairs: Brian Shuch, MD (Localized) Ulka N. Vaishampayan, MD (Advanced) Designates Cancer Control: Peter J. Van Veldhuizen, Jr., MD DEI Champion: Jessica D. McDermott, MD Digital Engagement: Neema Navai, MD Veterans Affairs Michael M. Goodman, MD Data Coordinators: Jeri Jardine Tonya Johnson Michele Counts Laura Wells Oncology Research Professionals:	
Renal Organ Site Chairs:	
Designates Cancer Control: Peter J. Van Veldhuizen, Jr., MD DEI Champion: Jessica D. McDermott, MD Digital Engagement: Neema Navai, MD Veterans Affairs Michael M. Goodman, MD Data Coordinators: Jeri Jardine Tonya Johnson Michele Counts Laura Wells Oncology Research Professionals:	
DEI Champion: Jessica D. McDermott, MD Digital Engagement: Neema Navai, MD Veterans Affairs Michael M. Goodman, MD Data Coordinators: Jeri Jardine Tonya Johnson Michele Counts Laura Wells Oncology Research Professionals:	
DEI Champion: Jessica D. McDermott, MD Digital Engagement: Neema Navai, MD Veterans Affairs Michael M. Goodman, MD Data Coordinators: Jeri Jardine Tonya Johnson Michele Counts Laura Wells Oncology Research Professionals:	Cancer Control: Peter J. Van Veldhuizen, Jr., MD
Digital Engagement: Neema Navai, MD Veterans Affairs Michael M. Goodman, MD Data Coordinators: Jeri Jardine Tonya Johnson Michele Counts Laura Wells Oncology Research Professionals:	
Veterans Affairs	•
Data Coordinators: Jeri Jardine Tonya Johnson Michele Counts Laura Wells Oncology Research Professionals:	
Oncology Research Professionals:	
	Oncology Research Professionals:
Nurse: Cheryl Kefauver, RN	
Patient Advocates: Rick Bangs, MBA (Bladder)	
	•
Laura B. Esfeller, MA (Renal)	· · · · · · · · · · · · · · · · · · ·

Pharmaceutical Science:	Joyce Lee, PharmD
	Allison Schepers, PharmD
Protocol Project Manager:	Megan Keim
Clinical Trials Program Manager:	Mariah Norman, MS

Time/Location

GU Committee Part I: Prostate, TM, Cancer Control Friday, May 12, 2023 3:30 pm - 6:30 pm Room: Bayview Room (Bay Level)

GU Committee Part II: Bladder, Renal Saturday, May 13, 2023 9:00 am - 12:00 pm Room: Grand Ballroom A (Street Level)

Agenda

GU Committee Part I: Prostate, TM, Cancer Control

3:30 – 3:40 pm:	Chair's Welcome and Opening Remarks. Ian Thompson
3:40 – 4:40 pm:	Prostate Organ Site (Dr. Tanya Dorff and Dr. Daniel Lin)
4:40 – 5:40pm:	Translational Medicine (Dr. David McConkey)
5:40 – 6:30 pm:	Cancer Control (Dr. Peter Van Veldhuizen)

Prostate

Organ Site Chairs: Dr. Tonya Dorff (Advanced) and Dr. Daniel W. Lin (Local)

Priority Study

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

Concepts in Development

XXXX, "A Phase III Study of Cabazitaxel with or without Carboplatin in Patients with metastatic castrate-resistant prostate cancer (mCRPC), Stratified by Aggressive Variant Signature." Dr. Corn.

<u>\$2210</u>, "Targeted neoadjuvant treatment for patients with localized prostate cancer and germline DNA repair deficiency." Dr. Cheng. 2nd resubmission to CTEP on 2/15/23.

Active Studies

CTSU/A031102, "A Randomized Phase III Trial Comparing Conventional-Dose Chemotherapy Using Paclitaxel, Ifosfamide, and Cisplatin (TIP) with High-Dose Chemotherapy Using Mobilizing Paclitaxel Plus Ifosfamide



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

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

CTSU/EA8184, "A Phase II Randomized Double Blinded Study of Green Tea Catechins (GTC) vs. Placebo in Men on Active Surveillance for Prostate Cancer: Modulation of Biological and Clinical Intermediate Biomarkers." Dr. Kopp. Activated: 5/10/21.

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

CTSU/NRG-GU008, "Randomized Phase III Trial Incorporating Abiraterone Acetate with Prednisone and Apalutamide and Advanced Imaging into Salvage Treatment for Patients with Node-Positive Prostate Cancer After Radical Prostatectomy (INNOVATE*) *Intensifying Treatment for Node Positive Prostate Cancer by Varying the Hormonal Therapy." Dr. Lin. Activated: 3/5/20; Temporarily Closed: 6/24/21; Re-activated: 12/1/21.

CTSU/NRG-GU009, "Parallel Phase III Randomized Trials for High Risk Prostate Cancer Evaluating De-Intensification for Lower Genomic Risk and Intensification of Concurrent Therapy for Higher Genomic Risk with Radiation (PREDICT-RT*)." Dr. Zhang. Activated: 10/15/20; Temporarily Closed: 6/24/21; Re-activated: 12/15/21.

Closed Studies

<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: 3/6/13; Permanently Closed: 7/15/17.

CTSU/NRG-GU005, "Phase III IGRT and SBRT Vs IGRT and Hypofractionated IMRT for Localized Intermediate Risk Prostate Cancer." Dr. Solanki. Activated: 11/16/17; Closed to accrual: 6/8/22.

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; Permanently Closed: 5/19/20. CTSU/RTOG-0924, "Androgen Deprivation Therapy and High Dose Radiotherapy with or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial. Dr. Marshall. Activated: 7/7/11; Permanently Closed: 6/24/19.

CTSU/NRG-GU007, "Randomized Phase II Trial of Niraparib with Standard Combination Radiotherapy and Androgen Deprivation Therapy (ADT) in High Risk Prostate Cancer (with Initial Phase I) (NADIR*) *Randomized Phase II Trial of Niraparib With Standard Combination Androgen Deprivation Therapy (ADT) and Radiotherapy In High Risk Prostate Cancer (With Initial Phase I)." Dr. VanderWeele. Activated: 6/3/19; Temporarily Closed: 5/5/21; Reactivated of dose level 2 (phase I) for 1 additional patient: 9/14/21; Temporarily closed to accrual for phase I dose level 2: 11/4/21; Re-activated to accrual for phase I/dose level 3: 12/6/21; Temporarily Closed: 7/11/22.

CTSU/EA8153, "Cabazitaxel with Abiraterone Versus Abiraterone Alone Randomized Trial for Extensive Disease Following Docetaxel: The CHAARTED2 Trial." Dr. Corn. Activated: 2/8/18; Permanently Closed: 4/2/21; Tobacco use assessment sub-study permanently closed: 10/8/21.

CTSU/AGCT1531, "A Phase 3 Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors." Dr. D'Souza. Activated: 5/8/17; PRO study Temporarily Closed: 2/12/21.

Translational Medicine

Chair: Dr. David McConkey

Bladder Chair: Dr. Joshua Meeks

Prostate Chair: Dr. Amir Goldkorn

Renal Chair: Dr. Sumanta "Monty" Pal

Cancer Control

Liaison: Dr. Peter J. Van Veldhuizen

Active Studies

<u>\$1600</u>, "A Randomized Phase III Double-Blind Clinical Trial Evaluating the Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes." Drs. Hamilton-Reeves and Holzbeierlein. Activated: 2/21/19.

51823, "A Prospective Observational Cohort Study to Assess miRNA 371 for Outcome Prediction in Patients with Early Stage Germ Cell Tumors", Pl: Craig Nichols– Activated 6/1/20 GU Champions: Drs. Frye and D'Souza.



- **<u>S1931 (Companion Study),</u>** "Examining Psychosocial and Emotional Issues for Metastatic Kidney Cancer." Pl: Cristiane Bergerot.
- S1937 (Companion Study), "Assessment of Quality of Life for S1937: A Phase III Randomized Trial of Eribulin with or without Gemcitabine Versus Standard of Care (Physician's Choice) for Treatment of Metastatic Urothelial Carcinoma Refractory to, or Ineligible for, Anti PD1/PDL1 Therapy." QoL Study Chair: Dr. Barzi. On hold until accrual picks up on S1937.

Diverse Studies of Interest

- **S1609**, "DART: Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors." Drs. Patel, Chae, Kurzrock, et al. Activated: 1/13/17; Permanently Closed: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 13, 14, 15, 16, 17, 18, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 39, 41, 42, 43, 44, 45, 48, 51, 52, and 53; Temporarily Closed: 38, 40, 46, and 51.
- CTSU/A031702, "A Phase II Study of Ipilimumab, Cabozantinib, and Nivolumab in Rare Genitourinary Cancers (ICONIC)" Dr. Liu. Activated: 4/12/19; Temporarily Closed: Cohort A, B, C, E, F, G, I.
- CTSU/EAY 131, "Molecular Analysis for Therapy Choice (MATCH)." Dr. Villalobos. Activated: 8/12/15; EAY131 (MATCH) Subprotocol Z1C, EAY131-Z1C, is permanently Closed to Accrual: 5/25/21; EAY131 (MATCH) Subprotocol M, or EAY131-M, is suspended, effective immediately: 8/3/21; AY131 Subprotocols A, C1, C2, E, L, V, Z1E, and Z1G are closed to accrual: 1/31/22; Subprotocol ZIG reactivated: 2/23/22
- CTSU/EA8134, "InPACT- International Penile Advanced Cancer Trial (International Rare Cancers Initiative Study)." Dr. Pettaway. Activated: 9/8/17.

GU Committee Part II: Bladder, Renal

2:30 – 2:45 pm: Chair's Welcome and Opening Remarks. Ian Thompson

9:00 – 10:15 am: Bladder Organ Site (Dr. Seth Lerner and Dr. Thomas

Flaig)

10:15 – 12:00 pm: Renal Organ Site (Dr. Ulka Vaishampayan and Dr. Brian

Shuch)

Bladder

Organ Site Chairs: Dr. Thomas Flaig (Advanced) and Dr. Seth Lerner (Local)

Priority Study

S2011, "Randomized Phase II Trial of Gemcitabine, Avelumab, and Carboplatin vs. No Neoadjuvant Therapy Preceding Surgery for Cisplatin Ineligible Muscle-Invasive Urothelial Carcinoma." Drs. Sonpavde, Liss, and Lerner, et al. Activated: 10/6/21.

Concepts in Development

XXXX, "Bladder preservation with chemoradiotherapy or immunoradiotherapy after a good response to neoadjuvant chemotherapy in patients with muscle invasive bladder cancer (PRESERVE)." Dr. Ballas. Submitted to GU Bladder Task Force 2/21/23.

Active Studies

- **S1937**, "A Phase III Trial of Eribulin (NSC #707389) with or Without Gemcitabine Versus Standard of Care (Physician's Choice) for Treatment of Metastatic Urothelial Carcinoma Refractory to, or Ineligible for, Anti PD1/PDL1 Therapy." Drs. Sadeghi and Lara. Activated: 2/16/21.
- **S1806**, "Phase III Randomized Trial of Concurrent Chemoradiotherapy with or Without Atezolizumab in Localized Muscle Invasive Bladder Cancer." Drs. Singh, Lerner, Efstathiou, et al. Activated: 4/19/19.
- CTSU/A031701, "A Phase II Study of Dose-Dense Gemcitabine Plus Cisplatin (ddGC) in Patients with Muscle-Invasive Bladder Cancer with Bladder Preservation for Those Patients Whose Tumors Harbor Deleterious DNA Damage Response (DDR) Gene Alterations." Drs. A. Gupta and S. Gupta. Activated: 8/1/18.
- CTSU/A031803, "Phase II Trial of Intravesical Gemcitabine and MK-3475 (Pembrolizumab) in the Treatment of Patients with BCG-Unresponsive Non-Muscle Invasive Bladder Cancer." Drs. Tyson and Ramamurthy. Activated: 1/6/20.
- CTSU/EA8185, "Phase II Study of Bladder-Sparing Chemoradiation with MEDI4736 (Durvalumab) in Clinical Stage III, Node Positive Bladder Cancer (INSPIRE)." Drs. Mitin and Meeks. Activated: 8/25/20.
- CTSU/EA8192, "A Phase II/III Trial of MED14736 (Durvalumab) and Chemotherapy for Patients with High Grade Upper Tract Urothelial Cancer Prior to Nephroureterectomy" Drs. Psutka and Tripathi. Activated: 5/6/21.



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, and Koppie, et al. Activated: 8/1/11; Permanently Closed: 4/15/17.
- **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." Drs. Svatek, Alva, and Lerner. Activated: 2/7/17; Permanently Closed: 12/15/20.
- <u>S1605</u>, "Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer." Drs. Black, Singh, and Lerner. Activated: 2/7/17; Permanently Closed: 7/5/19.

Renal

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

Priority Study

S1931, "Phase III Trial of Immunotherapy-Based Combination Therapy with or Without Cytoreductive Nephrectomy for Metastatic Renal Cell Carcinoma (PROBE Trial)." Drs. Kim and Vaishampayan. Activated: 11/16/20.

Active Studies

- **S2200**, "A Phase II Randomized Trial of Cabozantinib (NSC #761968) with or without Atezolizumab (NSC #783608) in Patients with Advanced Papillary Renal Cell Carcinoma (PAPMET2)" Drs. Maughan and Pal. Activated 9/19/22.
- CTSU/AREN1721, "A Randomized Phase 2 Trial of Axitinib/Nivolumab Combination Therapy vs. Single Agent Nivolumab for the Treatment of TFE/Translocation Renal Cell Carcinoma (tRCC) Across All Age Groups." Dr. Parikh. Activated: 10/9/18; Temporarily Closed: 3/24/21; Re-activated: 2/7/22.
- CTSU/A031704, "PD-Inhibitor (Nivolumab) and Ipilimumab Followed by Nivolumab vs. VEGF TKI Cabozantinib with Nivolumab: A Phase III Trial in Metastatic Untreated Renal Cell Cancer [PDIGREE]." Dr. Zhang. Activated: 5/9/19; Step 1 temporarily closed: 3/8/21; Step 1 re-activated: 3/26/21.

- CTSU/A031801, "A Phase II Randomized Trial of Radium-223 Dichloride and Cabozantinib in Patients with Advanced Renal Cell Carcinoma with Bone Metastasis (Radical)." Dr. Parikh, Activated: 12/13/19.
- CTSU/A031901, "Duration of Immune Checkpoint Therapy in Locally Advanced or Metastatic Urothelial Carcinoma: A randomized Phase 3 non-Inferiority Trial." Dr. Vaena. Activated: 12/10/20.

Closed Studies

- **S1500**, "A Randomized, Phase II Efficacy Assessment of Multiple MET Kinase Inhibitors (Cabozantinib [NSC #761968], Crizotinib [NSC #749005], Savolitinib [NSC #785348], and Sunitinib [NSC #736511]) in Metastatic Papillary Renal Carcinoma (PAPMET)." Drs. Pal and Lara. Activated 4/5/16; Permanently closed: 12/15/19.
- **S0931**, "EVEREST: Everolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study." Drs. Ryan, Heath, Lara, et al. Activated: 4/1/11; Permanently 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; Permanently closed: 7/25/17.
- CTSU/A031501, "Phase III Randomized Adjuvant study of Pembrolizumab in Muscle Invasive and Locally Advanced Urothelial Carcinoma (AMBASSADOR) Versus Observation." Dr. Sonpavde. Activated: 9/21/17; Permanently Closed: 8/24/21.
- CTSU/EA8143, "A Phase 3 Randomized Study Comparing Perioperative Nivolumab vs. Observation in Patients with Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC)." Drs. Lara and Shuch. Activated: 2/2/17; Permanently Closed: 6/9/21.



	51802	51806	51931	51937	52011	A031102	A031501	A031701	A031702	A031704	A031801	A031803	A031901
Ascension Providence Hosp - Southfield	-	-	-	-	-	-	-	-	-	1	-	-	-
Audie L Murphy VA Hosp	-	-	-	-	-	-	-	-	-	-	-	1	-
Banner MD Anderson CC	4	-	-	-	-	-	-	-	-	-	-	-	-
Banner U Medical Ctr - Tucson	7	-	1	-	-	-	-	-	-	-	-	-	-
Baylor College of Med/Dan L Duncan CCC	2	3	-	-	-	-	1	-	-	-	-	-	-
CWRU Case CCC LAPS	-	-	-	-	-	-	-	5	-	-	-	-	-
Ca Res Consort of W Mich NCORP	2	4	-	-	-	-	-	-	-	-	-	-	-
Ca Res for the Ozarks NCORP	1	3	-	-	-	-	-	-	-	-	-	-	-
Ca Res of Wisconsin and N Mich Consort	1	5	-	-	-	-	-	-	-	-	-	-	-
Cedars-Sinai Medical Ctr	-	7	1	-	-	-	-	-	-	-	-	-	-
City of Hope CCC	1	-	-	-	-	-	-	-	-	-	-	-	-
Columbia U MU NCORP	2	3	-	-	-	-	3	-	-	-	-	-	-
CommonSpirit HIth Res Institute	3	4	-	2	-	-	-	-	-	-	-	-	-
Cotton O'Neil CC / Stormont Vail Hlth	-	-	-	-	-	-	1	-	-	-	-	-	-
Dayton NCORP	4	1	-	-	-	-	-	-	-	1	-	-	-
Desert Regional Medical Ctr	1	-	-	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	13	-	-	-	-	-	-	-	-	-	-	-	-
Georgia Cares MU NCORP	1	-	-	-	-	-	-	-	-	-	-	-	-
Gulf South MU NCORP	72	58	1	-	-	-	2	-	-	-	1	13	-
Hawaii MU NCORP	-	3	-	-	-	-	-	-	-	-	-	-	-
Heartland Ca Res NCORP	8	6	-	-	2	-	-	-	-	-	-	-	-
Henry Ford Hosp	22	4	-	1	-	-	1	-	2	6	-	-	2
Instituto Nacional De Caologia de Mexico	1	-	-	-	-	-	-	-	-	-	-	-	-
Kaiser Permanente NCORP	15	-	-	-	-	-	14	-	-	52	-	-	-
Lahey Hosp and Medical Ctr	-	-	-	-	-	-	4	-	6	-	-	-	-
Loma Linda U Medical Ctr	-	-	-	-	-	-	2	-	-	-	-	-	-
Loyola U Medical Ctr	9	5	1	2	-	-	-	-	1	1	-	-	-
Massachusetts Veterans ERIC	-	-	-	-	-	-	-	-	-	-	-	-	-
Medical U South Carolina MU NCORP	5	-	-	1	-	-	-	-	-	-	-	-	-
Michigan Ca Res Consort NCORP	7	16	-	1	-	-	-	-	-	-	-	-	-
Montana Ca Consort NCORP	3	-	-	-	-	-	-	-	-	-	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	10	-	-	-	-	-	-	-	-	1	-	-	-
Nevada Ca Res Foundation NCORP	1	-	-	-	-	-	-	-	1	-	-	-	-
New Mexico MU NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-
Northwell HIth NCORP	_	2	-	-	-	-	-	-	-	1	-	-	-



	51802	51806	51931	51937	52011	A031102	A031501	A031701	A031702	A031704	A031801	A031803	A031901
Northwestern U LAPS	_	6	_	-	_	_	_	_	_	2	-	-	-
Ohio State U CCC LAPS	2	1	-	-	-	-	-	-	_	-	_	-	-
Oregon HIth and Science U	-	1	_	-	_	-	_	_	3	3	_	_	-
SCL HIth Saint Joseph Hosp	2	_	-	-	-	-	-	-	-	-	_	-	-
Southeast Clin Onc Res Consort NCORP	4	1	-	-	-	-	-	-	_	-	-	-	-
Sutter Ca Res Consort	_	2	-	-	-	-	-	-	_	-	_	-	-
Tulane U Hlth Sciences Ctr	_	-	9	-	-	-	-	-	_	1	-	-	-
UC Davis CCC LAPS	12	9	_	3	-	-	4	9	_	3	4	5	-
UC Irvine Hlth/Chao Family CCC	4	6	-	-	-	-	_	-	_	-	-	-	-
UC San Diego Moores CC	2	3	-	-	-	-	-	-	_	-	_	-	-
UPMC Hillman CC LAPS	-	2	-	-	-	-	-	-	_	-	-	-	-
USC Norris CCC LAPS	5	-	-	3	-	12	13	-	4	-	-	-	-
U Alabama at Birm / Deep South RC LAPS	-	-	1	-	-	-	-	-	1	-	1	6	-
U Arkansas for Medical Sciences	2	-	_	-	-	-	-	-	_	-	_	-	-
U Cincinnati CC-UC Medical Ctr	5	5	3	-	-	-	-	-	_	6	-	-	-
U Colorado CC LAPS	4	5	_	-	-	-	13	-	_	11	_	-	-
U Kansas CC - MCA Rural MU NCORP	7	7	-	-	-	-	5	-	1	6	-	-	-
U Kentucky/Markey CC	_	3	-	-	-	-	-	-	_	-	_	-	-
U Michigan CCC LAPS	2	-	11	-	-	-	18	-	_	-	-	-	-
U Mississippi Medical Ctr	1	-	-	1	-	-	_	-	1	-	-	-	-
U Oklahoma Hlth Sciences Ctr LAPS	26	15	4	-	-	-	-	-	-	-	-	-	-
U Rochester LAPS	21	-	1	-	-	-	-	-	3	5	-	-	-
U Texas HSC San Antonio	5	-	2	-	-	_	-	-	_	-	-	6	-
U Texas MD Anderson CC LAPS	73	-	-	-	-	-	-	-	_	-	-	-	-
U Utah - Huntsman Ca Institute LAPS	18	-	1	-	-	_	3	-	_	-	-	-	-
Upstate Carolina NCORP	2	2	-	-	-	-	_	-	_	-	-	-	-
Vanderbilt U - Ingram CC LAPS	3	2	-	-	-	_	-	-	_	-	-	-	-
Virginia Mason Medical Ctr	-	-	-	-	-	-	1	-	_	-	-	-	-
Wayne State U - Karmanos Ca Inst LAPS	1	-	-	-	-	_	-	-	_	-	-	-	-
Western States Ca Res NCORP	_	1	-	-	-	-	-	-	_	-	_	-	-
Wisconsin NCORP	8	5	_	-	_	-	_	-	_	-	-	-	-
Yale U - Yale CC LAPS	1	2	-	-	-	-	8	-	_	-	_	-	-
ALLIANCE	87	24	3	1	-	_	-	-	_	_	-	-	-
ECOG-ACRIN	68	31	3	1	1	-	-	-	-	-	_	-	_
NRG	76	101	4	1	-	-	_	_	_	_	-	-	-
Total	636	358	46	17	3	12	93	14	23	100	6	31	2



	A031902	A032001	EA8134	EA8171	EA8183	EA8185	EA8191	EA8192	NRGGU002	NRGGU005	NRGGU008	NRGGU009	NRGGU010
Ascension Providence Hosp - Southfield	-	-	-	-	-	-	-	-	-	-	-	-	-
Audie L Murphy VA Hosp	-	-	-	45	-	-	-	-	-	-	-	-	-
Banner MD Anderson CC	-	-	-	-	-	-	-	-	-	-	-	-	-
Banner U Medical Ctr - Tucson	-	-	-	-	-	-	-	-	-	-	-	-	-
Baylor College of Med/Dan L Duncan CCC	-	-	-	-	-	-	-	-	-	-	-	-	-
CWRU Case CCC LAPS	3	1	-	-	-	-	-	-	-	-	-	-	-
Ca Res Consort of W Mich NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-
Ca Res for the Ozarks NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-
Ca Res of Wisconsin and N Mich Consort	-	-	-	-	-	-	-	-	-	-	-	-	-
Cedars-Sinai Medical Ctr	-	-	-	-	-	-	-	-	-	-	-	-	-
City of Hope CCC	-	-	-	-	-	-	-	-	-	-	-	-	-
Columbia U MU NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-
CommonSpirit HIth Res Institute	-	-	-	-	-	-	-	-	-	-	-	-	-
Cotton O'Neil CC / Stormont Vail Hlth	-	-	-	-	-	-	-	-	-	-	-	-	-
Dayton NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-
Desert Regional Medical Ctr	-	-	-	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	-	-	-	-	-	-	5	-	-	-	-	-	-
Georgia Cares MU NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-
Gulf South MU NCORP	-	-	-	11	-	1	-	-	1	1	3	6	-
Hawaii MU NCORP	-	-	-	2	-	-	-	-	-	-	-	-	-
Heartland Ca Res NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-
Henry Ford Hosp	-	-	-	1	-	-	-	-	-	-	-	-	-
Instituto Nacional De Caologia de Mexico	-	-	-	-	-	-	-	-	-	-	-	-	-
Kaiser Permanente NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-
Lahey Hosp and Medical Ctr	-	-	-	-	4	-	-	-	-	-	-	-	-
Loma Linda U Medical Ctr	-	-	-	-	-	-	-	-	-	-	-	-	-
Loyola U Medical Ctr	-	-	-	-	-	-	-	-	-	-	-	-	-
Massachusetts Veterans ERIC	1	-	-	-	-	-	-	-	-	-	-	-	-
Medical U South Carolina MU NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-
Michigan Ca Res Consort NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-
Montana Ca Consort NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	-	-	-	-	-	-	-	-	-	-	-	-	-
Nevada Ca Res Foundation NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-
New Mexico MU NCORP	-	-	-	-	-	-	-	-	-	1	-	-	-
Northwell HIth NCORP	-	-	-	-	-	-	-	-	-	-	-	2	-



	A031902	A032001	EA8134	EA8171	EA8183	EA8185	EA8191	EA8192	NRGGU002	NRGGU005	NRGGU008	NRGGU009	NRGGU010
Northwestern U LAPS	-	-	-	-	-	-	-	-	-	-	-	-	4
Ohio State U CCC LAPS	-	-	-	-	-	-	-	-	-	-	-	-	-
Oregon HIth and Science U	-	-	-	9	-	-	2	-	-	-	-	-	-
SCL HIth Saint Joseph Hosp	-	-	-	-	-	-	-	-	-	-	-	-	3
Southeast Clin Onc Res Consort NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-
Sutter Ca Res Consort	-	-	-	-	-	-	-	-	-	2	-	-	-
Tulane U Hlth Sciences Ctr	-	-	-	-	-	-	-	-	-	1	-	-	-
UC Davis CCC LAPS	-	-	-	-	-	-	-	-	-	-	-	1	-
UC Irvine Hlth/Chao Family CCC	-	-	-	-	-	-	-	-	-	-	1	-	-
UC San Diego Moores CC	-	-	-	-	-	-	-	-	-	-	-	-	-
UPMC Hillman CC LAPS	-	-	-	-	-	-	-	-	-	-	-	-	-
USC Norris CCC LAPS	-	-	8	-	-	-	-	-	-	-	-	-	-
U Alabama at Birm / Deep South RC LAPS	-	-	-	-	-	-	-	-	-	-	-	-	-
U Arkansas for Medical Sciences	-	-	-	-	-	-	-	-	-	-	-	-	-
U Cincinnati CC-UC Medical Ctr	-	-	-	-	-	-	-	-	-	-	-	-	-
U Colorado CC LAPS	-	-	1	-	-	-	-	1	1	1	-	-	-
U Kansas CC - MCA Rural MU NCORP	-	-	-	-	-	-	-	-	-	-	1	-	-
U Kentucky/Markey CC	-	-	-	-	-	-	-	-	-	-	-	-	-
U Michigan CCC LAPS	-	-	-	-	-	-	-	-	-	-	-	-	-
U Mississippi Medical Ctr	-	-	-	-	-	-	-	-	1	-	-	-	-
U Oklahoma Hlth Sciences Ctr LAPS	-	-	-	-	-	-	1	-	-	-	-	-	-
U Rochester LAPS	-	-	-	-	-	-	-	-	-	-	-	-	1
U Texas HSC San Antonio	-	-	-	13	-	-	2	-	-	-	-	-	-
U Texas MD Anderson CC LAPS	-	-	-	-	-	-	-	-	-	-	-	-	-
U Utah - Huntsman Ca Institute LAPS	-	-	-	-	-	-	-	-	-	-	-	-	-
Upstate Carolina NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-
Vanderbilt U - Ingram CC LAPS	-	-	-	-	-	-	-	-	-	-	-	-	-
Virginia Mason Medical Ctr	-	-	-	-	-	-	-	-	-	3	-	1	1
Wayne State U - Karmanos Ca Inst LAPS	-	-	-	-	-	-	-	-	1	-	-	-	-
Western States Ca Res NCORP	-	-	-	-	-	-	-	-	-	-	-	1	-
Wisconsin NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	-	-	-	-	-	-	-	-	-	-	-	-	-
ALLIANCE	-	-	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-	-	-	-	-	-	-	-
NRG	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	4	1	9	81	4	1	10	1	4	9	5	11	9
	,			3,	,		. 0		,				



Immunotherapeutics Committee

Leadership

Time/Location

Thursday, May 11, 2023 1:00 pm - 3:00 pm

Room: Seacliff B-D (Bay Level)

Agenda

1:00 – 1:20 PM Autoantibodies and Response to Therapy

Aaron Ring, MD, PhD

Associate Professor of Immunobiology at Yale School of

Medicine

1:20 – 2:00 PM IO Efforts in the NCTN Network: Current Status and

Future Directions

Current IO Efforts in Each Cooperative Group:

SWOG: Katie Politi, Siwen Hu-Lieskovan

ECOG/ACIRN: Ignacio Wistuba Alliance: Mark Klein, David Kozono

NRG: Susanna Ulahannan

Panel Discussion: Future Directions and Collaborations:

SWOG: Katie Politi, Siwen Hu-Lieskovan

ECOG/ACIRN: Ignacio Wistuba Alliance: Mark Klein, David Kozono

NRG: Susanna Ulahannan

2:00 – 2:15 PM How to Utilize SWOG Data for Immunotherapeutic

Studies

Michael LeBlanc, PhD

Group Statistician and Director of Statistical Center

2:15 - 2:20 PM Q & A

2:20 – 3:00 PM S2101 iMATCH Pilot – Trial Updates, Site Coordinators

Experience and Protocol 101

Katerina Politi, Siwen Hu-Lieskovan, Paul Swiecicki and

iMATCH site coordinators

Active Studies

S2101, "Biomarker Stratified CaboZantinib (NSC#761968) and NivOlumab (NSC#748726) (BiCaZO) - A Phase II Study of Combining Cabozantinib and Nivolumab in Participants with Advanced Solid Tumors (IO Refractory Melanoma or HNSCC) Stratified by Tumor Biomarkers - an immunoMATCH Pilot Study." Drs. Hu-Lieskovan, Swiecicki and Politi. Activated: 10/14/22.



Leukemia Committee

Leadership

Chair:	Harry P. Erba, MD, PhD
Vice-Chair:	Anjali S. Advani, MD
Executive Officer:	Susan M. O'Brien, MD
Statisticians:	Megan Othus, PhD
	Anna Moseley, MS
Scientific Leadership	
Translational Medicine:	Jerald P. Radich, MD
Pathology:	David R. Head, MD
Cytogenetics Liaison:	Min Fang, MD, PhD
Designates	
Cancer Control:	Stephanie B. Tsai, MD
Data Coordinators:	Louise Highleyman
	Laura Kingsbury
	Matt Gospe
Oncology Research Professionals:	
CRA:	TBD
Nurse:	TBD
Patient Advocate:	Gail Sperling, MPH
Pharmaceutical Science:	Holly O. Chan, PharmD
	Ila M. Saunders, PharmD
Protocol Project Manager:	Sharon Palmer
Protocol Project Manager - MyeloMATCH:	Sarah Cantu
Clinical Trials Program Manager:	Mariah Norman, MS

Time/Location

Friday, May 12, 2023 10:00 am - 12:00 pm Room: Garden Room (Atrium Lobby Level)

Agenda

AML/MDS Studies

Active Studies

CTSU/A041701, "A Randomized Phase II/III Study of Conventional Chemotherapy +/- Uproleselan (GMI-1271) in Older Adults with Acute Myeloid Leukemia Receiving Intensive Induction Chemotherapy." Dr. Liesveld. Activated: 1/16/19. Temporarily closed to accrual 11/19/21

Closed Studies

S1612, "A Randomized Phase II/III Trial of "Novel Therapeutics" Versus Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia (AML) or High-Risk Myelodysplastic Syndrome (MDS), Age 60 or Older." Drs. Michaelis, Walter, Assouline, et al. Activated: 12/22/17; Closed: 9/3/20.

- S0919, "A Phase II Study of Idarubicin and Ara-C in Combination with Pravastatin for Poor-Risk Acute Myelogenous Leukemia (AML)." Dr. Advani. Re-Activated: 4/1/13; Closed: 9/15/17; Complete: 10/21/21.
- 51203, "A Randomized Phase III Study of Standard Cytarabine Plus Daunorubicin (7+3) Therapy or Idarubicin with High Dose Cytarabine (IA) versus IA with Vorinostat (NSC-701852) (IA+V) in Younger Patients with Previously Untreated Acute Myeloid Leukemia (AML)." Drs. Garcia-Manero and Pagel. Activated: 12/15/12; Closed: 11/4/15; Complete: 3/29/22.

ALL Studies

Active Studies

- **S1905**, "A Phase I/II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL) / T-Cell Lymphoblastic Lymphoma (T-LBL)." Drs. Advani, Papadantonakis, and Yeung. Activated: 8/17/20.
- CTSU/A041501, "A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin (a Conjugated Anti-CD22 Monoclonal Antibody) to Frontline Therapy in Young Adults (Ages 18-39 Years) with Newly Diagnosed Precursor B-Cell ALL." Dr. Advani. Activated: 6/1/17. Temporarily closed to accrual: 5/24/22.

Developing Studies

- **52306**, "A Randomized Phase 2 Trial to Evaluate the Efficacy of Bcl-2 Inhibitor Therapy with Chemotherapy Compared to Chemotherapy Alone in Adult Patients with Newly Diagnosed T-Cell ALL and T-Cell Lymphoblastic Lymphoma." Drs. O'Dwyer, Aldoss, Advani, and Stock.
- **<u>\$2307</u>**, "A Phase 1B Study Assessing the Safety and Activity of SNDX-5613 (revumenib) in Combination with Age-Modified Chemotherapy in Newly Diagnosed patients with KMT2Ar acute lymphoblastic leukemia (ALL) or acute leukemia with ambiguous lineage (ALAL)." Drs. Aldoss, Advani, and Stock.

Closed Studies

- So333, "A Phase II Study of Double Induction Chemotherapy for Newly Diagnosed Non-L3 Adult Acute Lymphoblastic Leukemia with Investigation of Minimal Residual Disease and Risk of Relapse Following Maintenance Chemotherapy." Drs. Forman and O'Donnell. Activated: 4/15/05; Closed: 11/1/09.
- **S1312**, "A Phase I Study of Inotuzumab Ozogamicin in Combination with CVP (Cyclophosphamide, Vincristine, Prednisone) for Patients with



Leukemia Committee

Relapsed/Refractory CD22-Positive Acute Leukemia (Including B-ALL, Mixed Phenotypic Leukemia, and Burkitt's Leukemia)." Drs. Advani and Liedtke. Activated: 4/1/14; Closed: 8/2/19.

S1318, "A Phase II Study of Blinatumomab and POMP (Prednisone, Vincristine, Methotrexate, 6-Mercaptopurine) for Patients ≥ 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Negative (Ph-) Acute Lymphocytic Leukemia (ALL) and of Dasatinib, Prednisone and Blinatumomab for Patients ≥ 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Positive (Ph+) ALL and Philadelphia-Chromosome-Like Signature (Ph-like) ALL (Newly Diagnosed or Relapsed/Refractory) with Known or Presumed Activating Dasatinib-Sensitive Mutations or Kinase Fusions (DSMKF)." Drs. Advani and O'Dwyer. Activated: 1/12/15; Closed: 4/15/21.

CLL Studies

Active Studies

<u>S1925</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 / Small Lymphocytic Lymphoma (CLL): EVOLVE CLL/SLL Study." Drs. Stephens, Hill, Pagel, et al. Activated: 12/14/20.

Closed Studies

CTSU/EA9161, "A Randomized Phase III Study of the Addition of Venetoclax to Ibrutinib and Obinutuzumab Versus Ibrutinib and Obinutuzumab in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL)." Dr. Shadman. Activated: 1/3/19. Closed: 4/30/21.

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. Activated: 1/4/19. Closed: 1/4/19.

CML Studies

Closed 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. Closed: 10/20/22.

MyeloMATCH

Proposed Studies

MYELOMATCH, "Master Screening and Reassessment Protocol (MSRP) for the NCI MyeloMATCH Trials." Dr. Radich.

MM1YA-S01, "A Randomized Phase II Study of Novel Therapeutics in Younger Patients with High-Risk Acute Myeloid Leukemia." Drs. Shami and Lin.

MM1OA-S02, "A Phase 2 Study of Targeted Agents with the Oral DNMT1 Inhibitor C-DEC (ASTX727) for the Treatment of TP53-Mutated Acute Myeloid Leukemia: A myeloMATCH treatment trial." Drs. Shallis, Sallman, and Zeidan.

MM1OA-S03, "A Randomized Phase 2 trial of C-DEC, Venetoclax, and Enasidenib Compared with Azacitidine and Venetoclax for Newly Diagnosed Older Adults with IDH2 mutant AML: A myeloMATCH Treatment Trial." Drs. Borate and Huselton.



Leukemia Committee

	51712	51905	51925	A041501	A041701	A041702	A041703	EA9161	EA9171	EA9181
Banner U Med Ctr - Tucson	_	_	_	_	_	5	_	4	_	
Baptist Mem Hlth Care/Mid South MU NCORP	1	-	_	_	_	-	_	-	_	_
CWRU Case CCC LAPS	-	1	3	4	_	5	_	_	_	-
Ca Res for the Ozarks NCORP	1	-	-		_	-	_	-	-	-
City of Hope CCC	-	3	1	_	_	_	_	_	_	-
CommonSpirit HIth Res Inst	_	_	<u>.</u>	-	_	-	_	1	-	-
Dayton NCORP	_	_	_	_	_	1	_	2	-	-
Duke U - Duke Ca Inst LAPS	3	-	_	-	_	-	_	9	-	1
Fred Hutchinson Ca Res Ctr LAPS	1	3	_	_	_	_	_	9	-	-
Hawaii MU NCORP	6	_	_	-	_	-	_	_	-	3
Heartland Ca Res NCORP	5	_	_	_	_	_	_	_	-	-
Henry Ford Hospital	-	-	2	-	4	3	_	1	_	-
Intermountain Med Ctr	_	_	-	2		-	_	-	-	-
Kaiser Permanente NCORP	-	-	_	-	_	8	_	32	_	-
Lahey Hospital and Med Ctr	-	_	_	_	_	1	_	-	-	-
Loyola U Med Ctr	1	_	1	-	_	1	-	2	-	1
Med U South Carolina MU NCORP	-	_	1	_	_	1	_	7	-	-
Michigan Ca Res Consort NCORP	1	-	4	-	_	1	_	_	-	-
Moffitt CC	16	_	_	_	_	-	_	_	-	-
Montana Ca Consort NCORP	1	-	_	-	_	-	_	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	1	_	_	_	_	_	_	1	_	-
Nevada Ca Res Foundation NCORP	2	-	_	-	_	3	_	5	-	-
New Mexico MU NCORP	3	_	_	_	_	-	_	1	-	-
Northwell HIth NCORP	-	-	_	-	2	-	_	-	-	-
Northwestern U LAPS	-	_	_	3	1	2	_	_	-	4
Oregon HIth and Science U	3	1	_	8	_	5	_	9	_	-
STCC at DHR HIth Inst for Res and Dev	-	_	1	-	_	-	-	-	-	-
Salem Hospital	-	-	-	-	_	-	_	4	_	-
Southeast Clin Onc Res Consort NCORP	_	-	-	-	_	-	-	2	-	-
Stanford Ca Inst Palo Alto	-	-	-	8	_	11	-	29	-	-
UC Davis CCC LAPS	_	-	2	2	_	-	-	-	-	-
UC Irvine Hlth/Chao Family CCC	-	-	-	3	_	-	-	-	-	5
UC San Diego Moores CC	-	-	-	-	_	-	-	-	-	1
U Alabama Birm / Deep South RC LAPS	-	-	-	1	_	-	-	7	-	-
U Arkansas for Med Sciences	-	-	-	-	4	-	-	-	-	-
U Cincinnati CC-UC Med Ctr	-	2	-	-	_	-	1	-	-	1
U Colorado CC LAPS	-	-	-	-	_	1	-	1	-	-
U Kansas CC - MCA Rural MU NCORP	-	-	-	-	_	6	-	8	-	-
U Rochester LAPS	7	1	6	7	27	1	3	1	-	5
U Utah - Huntsman Ca Inst LAPS	7	-	9	1	-	5	-	22	-	-
Wayne State U - Karmanos Ca Inst LAPS	-	-	-	-	-	-	-	4	-	3
Western States Ca Res NCORP	_	-	-	-	-	2	-	1	-	-
Yale U - Yale CC LAPS	-	-	-	5	-	3	-	10	2	-
ALLIANCE	13	2	7	-	-	-	-	-	-	-
ECOG-ACRIN	7	-	7	-	-	-	-	-	-	-
NRG	2	-	1	-	-	-	-	-	-	-
Total	81	13	45	44	38	65	4	172	2	24



Leadership		Melissa Bidd
Chair:		Jennifer Beeld
Vice-Chair:		ogram Manager: Lau
Executive Officer: Anne Chiang, MD	i ime/Locatio	on
Statisticians:Mary Redman	Friday, Iviay 12, 2	2023 3:00 pm - 6:00 pm
Yingqi Zhac	KOOM: Seaciiii i	B-D (Bay Level)
		Agenda
		Agenda
	3.00 - 3.10 pili	General Update: Jhanelle E. Gray, MD
Lu Qia	•	Dationt Advocate Undate, Judy Johnson
cientific Leadership	3:10 - 3:20 pm	Patient Advocate Update: Judy Johnso
ranslational Medicine:	3:20 - 3:30 pm	Thoracic Surgery Session: Eric Toloza, N
Biology/PathologyPhilip C. Mack		
Fred R. Hirsch, MD		Thoracic Radiation Session: Megan Dal
lgnacio I. Wistub	J.TU J.JU DIII	Translational Medicine Session: Philip C
maging:Chadwick L. Wright MD	, PhD	·
Myrna C. Godoy, MD		Statistical Group: Mary Redman, PhD
Radiation Oncology:	. TBD 4:00 - 4:10 pm	Community Engagement Core: Paul J. I
urgery:Wayne L. Hofstette	r, MD	, 55
Subcommittee Chairs:	4:10 - 4:20 pm	DEI Session: Lucy Gansauer, MSN, RN
arly Stage Disease:Wayne L. Hofstette	r, MD 4:20 - 4:30 pm	Accrual Enhancement Discussion
Raymond Osarogiagboi	n, MD	
ocally Advanced Disease: Shirish Gadgeel, MD (Early Therape		Livingston Lecture Keynote Speaker: Ka
letastatic Disease: Ross Camidgo	e, MD CEO-Internat	tional Association for the Study of Lung Cand
Karen Reckam _l	o, MD Professor Em	eritus, University of California, Davis
Ommunity Engagement:	n, MD 4:50 - 4:55 pm	S2302, "Project Pragmatica-Lung Trial":
Suzanne Col	· MD	d: 3/6/23; Accrual: 4
Designates Designates	MD, Activate	a. 5/0/25, Accidal. 4
ancer Control Liaison:	n, MD 4:55 - 5:25 pm	Discussion Panel: S2302 Pragmatica-Lu
El Champion: Lucy Gansauer, MSN, RN, OCN,	CCRP Karen I Recl	kamp, MD, Co-Director of the Lung Cancer a
eterans Affairs:	, MD	ogram at City of Hope
Cheryl M. Czerlani	- OHCOIOUV FI	одгантат стту от поре
Data Coordinators:Louise Highle	14 D I	n, PhD, Lead Statistician, Lung Cancer Comn
Larry	Varia	ah MD Divertor of the Division of Openlary
Pasarlai Ahm	' Harpreet Sill	gh, MD, Director of the Division of Oncology
Amy Joh	61 1 44 10	ς, MD, Head of Thoracic Cancer Therapeutics
linical Research Project Manager:	TDD	DID Chianna de la Final de
Oncology Research Professionals:	Ellen v. Sigai,	PhD, Chairperson and Founder, Friends of C
TRA:	TRD Dan Carrizos	a, MD, Lung Community Engagement Comr
Nurses:	L: DNI	, , ,
Patient Advocate: Judy Johnson,	3.23 - 0.00 pm	Thoracic Medical Oncology Session: Jha
Pharmaceutical Science: Joyce Lee, Ph.		A Master Protocol to Evaluate Biomarker-Driv
		otherapies in Previously-Treated Non-Small C
Protocol Project Managers:		,,

	Molissa Riddlo (Lupa MAP)
	Jennifer Beeler (Lung-MAP)
Clinical Trials Program Manager:	Laura Gildner, MS

nda

3:10 - 3:20 pm	Patient Advocate Update: Judy Johnson, MBA						
3:20 - 3:30 pm	Thoracic Surgery Session: Eric Toloza, MD, PhD						
3:30 - 3:40 pm	Thoracic Radiation Session: Megan Daly, MD						
3:40 - 3:50 pm	Translational Medicine Session: Philip C. Mack, PhD						
3:50 - 4:00 pm	Statistical Group: Mary Redman, PhD						
4:00 - 4:10 pm	Community Engagement Core: Paul J. Hesketh, MD						
4:10 - 4:20 pm	DEI Session: Lucy Gansauer, MSN, RN						
4:20 - 4:30 pm	Accrual Enhancement Discussion						
	Livingston Lecture Keynote Speaker: Karen Kelly, MD nal Association for the Study of Lung Cancer (IASLC) tus, University of California, Davis						
4:50 - 4:55 pm MD; Activated: 3	S2302, "Project Pragmatica-Lung Trial": Karen Reckamp, 3/6/23; Accrual: 4						
4:55 - 5:25 pm	Discussion Panel: S2302 Pragmatica-Lung Trial						
	np, MD, Co-Director of the Lung Cancer and Thoracic ram at City of Hope						
Mary Redman, F	PhD, Lead Statistician, Lung Cancer Committee, SWOG						
Harpreet Singh,	MD, Director of the Division of Oncology, FDA						
Shakun Malik, M	ND, Head of Thoracic Cancer Therapeutics, NCI CTEP						
Ellen V. Sigal, Ph	D, Chairperson and Founder, Friends of Cancer Research						
Dan Carrizosa, N	MD, Lung Community Engagement Committee, SWOG						
5:25 - 6:00 pm	Thoracic Medical Oncology Session: Jhanelle Gray, MD						
<u>Lung-MAP</u> , "A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer							



(Lung-MAP Screening Study)." Drs. Karen Reckamp and David Gandara (SWOG). Activated: 1/28/19; Accrual: 2992

<u>S1900E</u>, "A Phase II Study of Sotorasib (AMG 510) in Participants with Previously Treated Stage IV or Recurrent KRAS G12C Mutated Non-Squamous Non-Small Cell Lung Cancer (ECOG-ACRIN Lung-MAP Sub-Study)." Drs. Sukhmani Padda (SWOG) and David Gerber (ECOG). Activated: 4/2/21; Accrual: 87

S1900F, "A Phase II Study of Selpercatinib, Carboplatin And Pemetrexed In Patients With RET Fusion-Positive Stage IV Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)." Dr. Yasir Elamin (SWOG) and Dr. Jhanelle Gray (SWOG). Accrual Goal: 74

<u>S1827</u>, "MRI Brain Surveillance Alone Versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer (MAVERICK)." Dr. Chad Rusthoven. Activated: 1/10/20; Accrual:139

<u>S1933</u>, "A Pilot Trial of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status." Dr. Raid Aljumaily. Activated: 6/15/20; Accrual: 28

<u>S1914</u>, "A Randomized Phase III trial of Induction/Consolidation Atezolizumab +SBRT versus SBRT Alone in High risk, Early Stage NSCLC." Dr. Megan Daly. Activated: 3/25/20; Accrual: 186

EA5163/S1709, "INSIGNA: A Randomized, Phase III Study of Firstline Immunotherapy alone or in Combination with Chemotherapy in Induction/Maintenance or Post-progression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature-driven Analysis." Dr. Anne Chiang. Activated: 2/28/19. Accrual: 488 total; 64 SWOG.

6:00 pm Closing Remarks and Adjourn

Active Studies

- **LUNGMAP**, "A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study)." Drs. Borghaei, Reckamp, Gandara, et al. Activated: 1/28/19.
- **S1800D**, "A Phase II/III Study of N-803 (ALT-803) plus Pembrolizumab versus Standard of Care in Participants with Stage IV or Recurrent Non-Small Cell Lung Cancer Previously Treated with Anti-PD-1 or Anti-PD-L1 Therapy (Lung-MAP Non-Match Sub-Study)." Drs. Wrangle and Husain. Activated: 2/15/22.

- **S1900E**, "A Phase II Study of Sotorasib (AMG 510) in Participants with Previously Treated Stage IV or Recurrent KRAS G12C Mutated Non-Squamous Non-Small Cell Lung Cancer (ECOG-ACRIN Lung-MAP Sub-Study)." Drs. Padda and Gerber. Activated: 4/2/21.
- **S1900F**, "A Randomized Phase II Study of Carboplatin and Pemetrexed with or Without Selpercatinib (LY3527723) in Participants with Non-Squamous RET Fusion-Positive Stage IV Non-Small Cell Lung Cancer and Progression of Disease on Prior RET Directed Therapy (Lung-MAP Sub-Study)." Drs. Gray and Elamin. Activated: 7/25/22.
- S1701, "A Randomized Phase II Trial of Carboplatin-Paclitaxel with or without Ramucirumab in Patients with Unresectable Locally Advanced, Recurrent, or Metastatic Thymic Carcinoma." Drs. Tsao and Koczywas. Activated: 8/9/18.
- S1827, "MRI Brain Surveillance Alone Versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer (MAVERICK)." Drs. Rusthoven, Brown, Wefel, et al. Activated: 1/10/20.
- <u>S1914</u>, "A Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT versus SBRT Alone in High Risk, Early Stage NSCLC." Drs. Daly, Simone, Kelly, et al. Activated: 3/25/20.
- S1933, "A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status." Drs. Aljumaily, Mitin, and Wozniak. Activated: 6/15/20.
- CTSU/EA5163/S1709, "INSIGNA: A Randomized, Phase III Study of Firstline Immunotherapy Alone or in Combination with Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature-driven Analysis." Dr. Chiang. Activated: 2/28/19.
- CTSU/A081801, "Integration of Immunotherapy into Adjuvant Therapy for Resected NSCLC: ALCHEMIST Chemo-IO (ACCIO)." Dr. Gray. Activated: 6/3/20.
- CTSU/A151216, "Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)." Dr. Gandara. 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/EA5181, "Randomized Phase III Trial of MEDI4736 (Durvalumab) as Concurrent and Consolidative Therapy or Consolidative Therapy Alone for Unresectable Stage 3 NSCLC." Dr. Harkenrider. Activated: 4/9/20.
- CTSU/EA5182, "Randomized Phase III Study of Combination AZD9291 (Osimertinib) and Bevacizumab Versus AZD9291 (Osimertinib) Alone as First-Line Treatment for Patients with Metastatic EGFR-Mutant Non-Small Cell Lung Cancer (NSCLC)." Dr. Goldberg. Activated:10/22/20.
- CTSU/EA5191, "A Randomized Phase II Trial of Cabozantinib and Cabozantinib Plus Nivolumab Versus Standard Chemotherapy in Patients with Previously Treated Non-Squamous NSCLC." Dr. Massarelli. Activated: 5/22/20.
- CTSU/NRG-LU002, "Maintenance Systemic Therapy versus Local Consolidative Therapy (LCT) Plus Maintenance Systemic Therapy for Limited Metastatic Non-Small Cell Lung Cancer (NSCLC): A Randomized Phase II/III Trial." Dr. Gomez. Activated: 4/7/17; Temporary closure: 11/12/21.
- CTSU/NRG-LU005, "Limited Stage Small Cell Lung Cancer (LS-SCLC): A
 Phase III Randomized Study of Chemoradiation Versus Chemoradiation
 Plus Atezolizumab." Dr. Hsu. Activated: 5/28/19; Closed to US and
 Canadian sites 6/23/22.
- <u>CTSU/NRG-LU007</u>, "Randomized Phase II/III Trial of Consolidation Radiation + Immunotherapy for ES-SCLC: RAPTOR Trial." Dr. Park. Activated: 8/17/20.

Closed Studies

- CTSU/NRG-CC003, "Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer." Dr. Gaspar. Activated: 12/7/15; Temporary closure: 5/28/20; Reactivated: 7/27/20; Permanent closure: 6/21/22.
- **S1800A**," A Phase II Randomized Study of Ramucirumab Plus Pembrolizumab (MK-3475) 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. Activated: 5/17/19. Permanently closed: 10/20/20.
- **S1900A**, "A Pase 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. Permanently closed: 2/2/21.
- **S1900B**, "A Phase II Study of Selpercatinib (LOXO-292) in Patients with RET Fusion-Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (LUNG-MAP Sub-Study)." Drs. Elamin and Gray. Activated: 2/10/20. Permanently closed: 5/1/21.

- S1900C, "A Phase II Study of Talazoparib Plus Avelumab in Patients with Stage IV or Recurrent Non-Squamous Non-Small Cell Lung Cancer Bearing Pathogenic STK11 Genomic Alterations (LUNG-MAP Sub-Study)." Drs. Skoulidis and Suga. Activated: 1/16/20. Permanently closed: 12/18/20.
- **<u>\$1929</u>**, "Phase II Randomized Study of Maintenance Atezolizumab Versus Atezolizumab in Combination with Talazoparib in Patients with SLFN11 Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC)." Drs. Karim, Reckamp, Gay, et al. Activated: 6/15/20; Step 1 Registration Permanently Closed 8/15/22; Step 2 Permanently Closed 10/15/22.
- S1934, "NASSIST (Neoadjuvant Chemoradiation +/- Immunotherapy Before Surgery for Superior Sulcus Tumors): A Randomized Phase II Trial of Trimodality +/- Atezolizumab in Resectable Superior Sulcus Non-Small Cell Lung Cancer." Drs. Osarogiagbon, Huang, Decker, et al. Activated: 9/9/21; Temporary closure: 11/5/21; Re-activated: 2/15/22; Permanently closed 3/1/23.

NCI-Approved Concepts

- S1900G, "A Randomized Phase II Study of INC280 (capmatinib) plus Osimertinib with or without Ramucirumab in Participants with EGFR-Mutant, MET-Amplified Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)." Drs. Goldberg and Camidge.
- **S1900I**, "A Randomized Phase II study of Mobocertinib (TAK-788) with or without Ramucirumab in Participants with Previously Treated EGFR Exon 20 Insertion Non-Small-Cell Lung Cancer (Lung-MAP Sub-Study)." Drs. Doroshow and Patel.
- **S1900J**, "A Phase II Study of Amivantamab in Participants with MET Amplification-Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)." Drs. Rolfo and Gadgeel.
- **S1900K**, "A Randomized Phase II Study of Tepotinib with or without Ramucirumab in Participants with MET Exon 14 Skipping Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)." Drs. Paik and Le.
- **S2302**, "PROJECT PRAGMATICA: A Prospective Randomized Study of Ramucirumab (NSC 749128) Plus Pembrolizumab (MK-3475; NSC 776864) Versus Standard of Care for Participants Previously Treated With Immunotherapy for Stage IV or Recurrent Non-small Cell Lung Cancer in Standard Practice." Drs. Reckamp and Dragnev.



$Accrual from \ trial \ opening \ through \ 12/31/2022 \ by \ Institution \ and \ Study$

	LUNGMAP	51701	51800D	51827	51900E	51914	51929	51933	A081801	A082002	A151216
Ascension Providence Hosp - Southfield	13	-	-	-	-	-	3	-	-	-	14
Ascension Via Christi Hosp Wichita	1	-	-	-	-	-	-	-	-	-	-
Banner MD Anderson CC	-	-	-	1	-	-	-	-	1	-	1
Banner U Med Ctr - Tucson	-	-	-	-	-	-	-	-	-	-	7
Baptist Mem Hlth Care/Mid South MU NCORP	34	-	-	-	1	5	2	-	3	-	24
Baylor College of Medicine/Dan L Duncan CCC	-	-	-	1	-	-	-	-	-	-	-
Boston Med Ctr	-	-	-	4	-	-	-	-	-	-	3
CWRU Case CCC LAPS	11	-	-	-	2	-	-	-	6	-	50
Ca Res Consort of W Mich NCORP	3	-	-	-	-	2	-	-	-	-	1
Ca Res for the Ozarks NCORP	32	-	3	-	-	-	2	3	-	-	3
Ca Res of Wisconsin and N Mich Consort	25	-	2	-	3	-	-	-	-	-	-
Carle CC NCORP	2	1	-	-	-	5	-	-	-	-	-
Cedars-Sinai Med Ctr	13	-	-	-	1	-	-	-	-	-	-
City of Hope CCC	5	1	-	1	-	-	-	-	-	-	5
Columbia U MU NCORP	8	-	-	-	-	-	-	-	-	-	-
Columbus NCORP	26	-	-	3	-	-	-	-	-	-	-
CommonSpirit HIth Res Inst	44	-	-	-	-	1	2	-	-	-	2
Cotton O'Neil CC / Stormont Vail HIth	-	-	-	-	-	-	-	-	-	-	3
Dayton NCORP	2	-	-	-	-	-	2	-	1	-	8
Essentia HIth NCORP	16	-	2	-	-	2	-	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	4	-	-	-	-	-	-	-	-	-	15
Georgia Cares MU NCORP	6	-	-	1	-	2	3	1	-	-	-
Georgia NCORP	58	-	3	2	1	3	-	-	-	-	9
Gulf South MU NCORP	16	-	1	1	-	1	1	-	1	-	1
Hawaii MU NCORP	22	-	-	1	-	-	-	-	-	-	-
Heartland Ca Res NCORP	121	-	6	2	4	21	19	2	-	-	-
Henry Ford Hosp	7	-	-	-	-	-	1	-	2	-	29
Houston Methodist Hosp	-	-	-	-	-	-	-	-	-	-	8
Kaiser Permanente NCORP	67	-	3	-	7	2	-	-	2	-	200
Lahey Hosp and Med Ctr	30	-	-	-	-	2	1	2	-	-	30
Loma Linda U Med Ctr	6	-	-	-	-	-	-	-	-	-	9
Loyola U Med Ctr	22	-	1	-	-	-	2	-	-	-	21
Massachusetts Veterans ERIC	48	-	1	2	1	-	-	-	7	-	26
Med U South Carolina MU NCORP	14	-	1	-	1	-	-	-	-	-	-
Michigan Ca Res Consort NCORP	105	-	4	-	6	2	3	-	-	-	-
Moffitt CC	12	2	1	1	1	-	-	-	11	-	83
Montana Ca Consort NCORP	25	-	-	-	1	-	3	1	-	-	-
Mount Sinai Hosp	-	-	-	-	-	8	1	-	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	15	-	-	-	1	-	-	-	-	-	1
Nevada Ca Res Foundation NCORP	14	-	-	-	-	-	1	-	-	-	-



	LUNGMAP	51701	51800D	51827	51900E	51914	51929	51933	A081801	A082002	A151216
New Mexico MU NCORP	69	-	-	1	-	6	5	1	-	-	-
Northwell Hith NCORP	-	-	-	-	-	-	-	-	1	-	3
Northwestern U LAPS	26	1	1	1	-	-	4	-	-	-	-
Oregon Hlth and Science U	7	-	1	-	-	1	-	-	5	-	21
Pacific Ca Res Consort NCORP	15	-	-	-	-	-	3	-	-	-	4
SCL HIth Saint Joseph Hosp	1	-	-	-	-	1	-	-	1	-	3
Salem Hosp	3	-	-	-	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	49	-	1	7	-	5	8	-	-	-	-
Sutter Ca Res Consort	24	-	-	-	1	-	-	-	-	-	11
The Don and Sybil Harrington CC	8	-	1	-	-	-	-	-	-	-	-
James Graham Brown CC at U Louisville	-	-	-	-	-	-	-	-	-	-	5
UC Davis CCC LAPS	31	3	6	1	-	9	2	-	-	2	41
UC Irvine Hlth/Chao Family CCC	22	-	-	1	-	1	-	-	-	-	14
UC San Diego Moores CC	11	-	-	-	1	-	-	-	-	-	5
UPMC Hillman CC LAPS	46	-	2	2	5	-	3	2	-	-	-
USC Norris CCC LAPS	-	-	-	2	-	3	-	-	-	-	12
U Arkansas for Med Sciences	11	-	-	-	-	6	-	-	-	-	2
U Cincinnati CC-UC Med Ctr	-	-	-	-	-	-	-	-	-	-	22
U Colorado CC LAPS	10	-	-	1	-	3	2	-	3	-	58
U Kansas CC - MCA Rural MU NCORP	85	-	1	1	1	-	-	-	1	-	28
U Kentucky/Markey CC	47	-	-	1	-	-	-	-	-	-	5
U Michigan CCC LAPS	1	-	-	-	-	-	-	-	-	-	62
U Mississippi Med Ctr	1	-	-	-	-	-	-	-	-	-	26
U Oklahoma Hlth Sciences Ctr LAPS	31	-	-	1	-	1	2	10	-	-	-
U Rochester LAPS	59	-	1	-	6	2	-	-	-	-	-
U Texas HSC at San Antonio	-	-	-	-	-	-	1	-	-	-	-
U Texas MD Anderson CC LAPS	3	6	-	-	-	-	4	-	-	-	2
U Utah - Huntsman Ca Inst LAPS	-	-	-	3	-	2	1	-	-	-	-
Upstate Carolina NCORP	35	-	-	-	-	1	-	-	-	-	-
Wayne State U - Karmanos Ca Inst LAPS	1	-	-	-	-	-	-	-	-	-	1
Western States Ca Res NCORP	2	-	-	-	-	-	-	-	-	-	1
William Beaumont Hosp-Royal Oak	-	-	-	-	-	-	-	-	-	-	2
Wisconsin NCORP	39	-	-	1	-	6	-	-	-	-	-
Yale U - Yale CC LAPS	17	-	-	3	-	1	-	-	4	-	52
ALLIANCE	699	3	12	13	16	20	9	3	-	-	-
сст д	-	-	-	14	-	-	-	-	-	-	-
ECOG-ACRIN	323	3	4	4	13	13	10	-	-	-	-
NRG	356	1	4	46	6	25	6	1	-	-	-
Total	2,859	21	62	123	79	162	106	26	49	2	933



$Accrual from \ trial \ opening \ through \ 12/31/2022 \ by \ Institution \ and \ Study$

	A171901	E4512	EA5163	EA5181	EA5182	EA5191	NRGCC003	NRGLU002	NRGLU005	NRGLU006	R1308
Ascension Providence Hosp - Southfield	-	1	2	3	-	1	-	-			
Ascension Via Christi Hosp Wichita	-	-	-	-	-	-	-	-	-	-	-
Banner MD Anderson CC	-	-	-	-	-	-	-	-	-	-	-
Banner U Med Ctr - Tucson	-	2	-	7	-	-	-	-	2	-	-
Baptist Mem Hlth Care/Mid South MU NCORP	-	-	1	1	1	-	-	1	1	-	-
Baylor College of Medicine/Dan L Duncan CCC	-	-	-	-	-	-	-	-	4	-	-
Boston Med Ctr	-	-	-	1	-	-	-	-	-	2	-
CWRU Case CCC LAPS	-	-	9	14	1	1	-	-	-	-	-
Ca Res Consort of W Mich NCORP	-	-	-	-	-	-	-	-	-	-	-
Ca Res for the Ozarks NCORP	-	-	-	-	-	-	-	-	-	-	-
Ca Res of Wisconsin and N Mich Consort	-	-	-	-	-	-	-	-	-	-	-
Carle CC NCORP	-	-	-	-	-	-	-	-	-	-	-
Cedars-Sinai Med Ctr	-	-	-	-	-	-	-	-	-	-	-
City of Hope CCC	-	-	-	-	-	-	-	-	-	-	-
Columbia U MU NCORP	-	-	-	-	-	-	-	-	-	-	-
Columbus NCORP	-	-	-	-	-	-	-	-	-	-	-
CommonSpirit HIth Res Inst	-	-	-	-	-	-	-	-	-	-	-
Cotton O'Neil CC / Stormont Vail HIth	-	-	-	-	-	-	-	-	-	-	-
Dayton NCORP	-	-	-	-	-	-	-	-	-	-	-
Essentia HIth NCORP	-	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	-	-	-	3	-	-	-	-	-	-	-
Georgia Cares MU NCORP	-	-	-	-	-	-	-	-	-	-	-
Georgia NCORP	-	-	1	-	-	-	-	-	-	-	-
Gulf South MU NCORP	-	-	3	-	-	-	-	-	-	-	-
Hawaii MU NCORP	-	-	-	-	-	-	-	-	-	-	-
Heartland Ca Res NCORP	-	-	-	-	-	-	1	-	-	-	-
Henry Ford Hosp	-	-	-	-	-	-	-	-	-	-	-
Houston Methodist Hosp	-	-	-	-	-	-	-	-	-	-	-
Kaiser Permanente NCORP	-	4	6	-	2	-	-	-	-	-	-
Lahey Hosp and Med Ctr	-	-	2	-	-	-	-	-	-	-	-
Loma Linda U Med Ctr	-	-	-	-	-	-	-	-	-	-	-
Loyola U Med Ctr	-	-	1	2	-	-	-	-	-	-	1
Massachusetts Veterans ERIC	-	-	3	-	-	2	-	-	-	-	-
Med U South Carolina MU NCORP	-	-	-	-	-	-	-	-	-	-	-
Michigan Ca Res Consort NCORP	-	-	-	-	-	-	-	-	-	-	-
Moffitt CC	-	1	-	-	-	-	-	-	-	-	-
Montana Ca Consort NCORP	-	-	-	-	-	-	-	-	-	-	-
Mount Sinai Hosp	-	-	-	1	-	-	-	-	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	-	-	-	-	-	-	-	-	1	-	-
Nevada Ca Res Foundation NCORP	1	-	-	-	-	-	-	-	-	-	-



	A171901	E4512	EA5163	EA5181	EA5182	EA5191	NRGCC003	NRGLU002	NRGLU005	NRGLU006	R1308
New Mexico MU NCORP	-	-	-	-	-	-	-	-	-	-	-
Northwell Hith NCORP	-	-	-	-	-	-	-	-	-	-	-
Northwestern U LAPS	-	-	-	-	-	-	-	-	-	-	-
Oregon Hlth and Science U	-	-	-	-	-	-	-	-	-	-	-
Pacific Ca Res Consort NCORP	-	-	-	-	-	-	-	-	-	-	-
SCL HIth Saint Joseph Hosp	-	-	-	-	-	-	-	-	-	-	-
Salem Hosp	-	-	-	-	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	-	-	-	-	-	-	-	-	-	-	-
Sutter Ca Res Consort	-	-	-	2	-	-	-	-	-	-	-
The Don and Sybil Harrington CC	-	-	-	-	-	-	-	-	-	-	-
James Graham Brown CC at U Louisville	-	-	-	-	-	-	-	-	-	-	-
UC Davis CCC LAPS	-	1	6	-	1	-	-	-	-	-	-
UC Irvine Hlth/Chao Family CCC	-	-	-	-	-	-	-	-	-	-	-
UC San Diego Moores CC	-	-	-	-	-	-	-	-	-	-	-
UPMC Hillman CC LAPS	-	-	-	-	-	-	-	-	-	-	-
USC Norris CCC LAPS	-	-	-	-	-	-	-	-	-	-	-
U Arkansas for Med Sciences	-	-	1	2	-	-	-	-	1	-	-
U Cincinnati CC-UC Med Ctr	-	1	-	-	1	-	-	-	-	-	-
U Colorado CC LAPS	-	2	-	-	-	1	-	-	1	-	-
U Kansas CC - MCA Rural MU NCORP	-	-	5	-	-	2	-	-	2	-	-
U Kentucky/Markey CC	-	-	-	-	-	-	-	-	-	-	-
U Michigan CCC LAPS	-	-	-	-	-	-	-	-	-	-	-
U Mississippi Med Ctr	-	-	-	-	-	-	-	-	-	-	-
U Oklahoma Hlth Sciences Ctr LAPS	-	-	-	1	-	-	-	-	-	-	-
U Rochester LAPS	-	-	2	15	-	-	4	-	1	-	-
U Texas HSC at San Antonio	-	-	2	-	-	-	-	-	-	-	-
U Texas MD Anderson CC LAPS	-	1	-	-	-	-	-	-	-	-	-
U Utah - Huntsman Ca Inst LAPS	-	-	1	-	-	-	-	-	-	-	-
Upstate Carolina NCORP	-	-	-	-	-	-	-	-	-	-	-
Wayne State U - Karmanos Ca Inst LAPS	-	-	-	-	-	-	-	1	-	-	-
Western States Ca Res NCORP	-	-	-	-	-	-	-	-	-	-	-
William Beaumont Hosp-Royal Oak	-	-	-	-	-	-	-	-	-	-	-
Wisconsin NCORP	-	-	-	-	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	-	4	11	-	-	-	-	-	-	-	-
ALLIANCE	-	-	-	-	-	-	-	-	-	-	-
сст с	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-	-	-	-	-	-
NRG	-	-	-	-	-	-	-	-	-	-	-
Total	1	17	56	52	6	7	5	2	13	2	1



Concepts in Development

S1800E, "A Randomized Phase II Study of Docetaxel and Ramucirumab with or without Cemiplimab for Participants Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Non-Matched Sub-Study)." Drs. Waqar and Li.

S1800F, "A Phase II Study of MK7684A (coformulation of Vibostolimab plus Pembrolizumab) in combination with Lenvatinib versus Standard of Care in Patients with Anti-PD-1 or Anti-PD-L1 Relapsed and Refractory Stage IV Non-Small Cell Lung Cancer (Lung-MAP Non-Match Sub-Study)." Drs. Massarelli and Li.

S2302 Pragmatica-Lung Trial presentation and discussion panel

FRIDAY, MAY 12 | 4:50 – 5:25 PM PT (IN THE LUNG COMMITTEE SESSION, FOLLOWING THE LIVINGSTON LECTURE)

The S2302 Pragmatica-Lung Trial has generated wide interest as a phase III registration trial with a paradigm-changing, pragmatic design that significantly reduces enrollment barriers and data collection requirements. Attend this session to learn more about how the trial differs, its genesis, and what it means for the design and conduct of future NCTN trials.



S2302 PROJECT PRAGMATICA LUNG TRIAL A PRESENTATION BY STUDY CHAIR KAREN L. RECKAMP, MD

after immunotherapy

S2302 DISCUSSION PANEL WITH PANELISTS

Karen L. Reckamp, MD, associate director of Clinical Research and director of Medical Oncology in the Department of Medicine, Cedars-Sinai Cancer Mary Redman, PhD, lead statistician, SWOG Lung Cancer Committee Harpreet Singh, MD, director of the Division of Oncology 2, FDA **Shakun Malik, MD,** head of Thoracic Cancer Therapeutics, NCI CTEP **Ellen V. Sigal, PhD,** chairperson and founder, Friends of Cancer Research





Lymphoma Committee

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

Scientific Leadership

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

Designates	
Cancer Control:	Hayder Saeed, MD
Digital Engagement:	Mazyar Shadman, MD
Veterans Affairs:	Helen Ma, MD
Data Coordinators:	Gabi Herbert
Oncology Research Professionals:	
CRA:	Erin M. Cebula, MPH
Nurse:	TBD
Patient Advocate:	Hildy Dillon, MPH
Pharmaceutical Science:	Holly O. Chan, PharmD
	Martina Fraga, PharmD
Protocol Project Manager:	Katarina Gasic
Clinical Trials Program Manager:	Crystal Miwa

Time/Location

Saturday, May 13, 2023 9:30 am - 11:30 am Room: Grand Ballroom B (Street Level)

ANHL1931: Dr. Kamdar

Agenda

9:30 - 9:35 am	Welcome - Jonathan Friedberg, MD & Sonali Smith, MD
9:35 - 9:55 am	Impact of SWOG trials: Katherine Albert, PhD, Patient advocate
9:55 - 10:15 am	S2114 launch - Dr. Hess
10:15 - 10:35 am	S2207 launch - Drs. Amengual & Reagan
10:35 - 10:45 am	S0016 long-term follow-up update - Dr. Shadman
10:45 - 10:55 am	COG Hodgkin early stage launch - Dr. Hu
10:55 - 11:30 am	Ongoing study updates
a. S1918 Dr.	Brem
b. S1608 Dr.	. Barr

- d. EA4151: Dr. Till
- EA4181: Dr. Spurgeon e.
- f. A051701: pending speaker
- S1925 (CLL): Dr. Stephens

Proposed Studies

- **S2207**, "Randomized phase II study of the addition of Targeted therapeutic agents to tafasitamab-based therapy in non-transplant-eligible patients with Relapsed/refractory Large B-cell Lymphoma." Drs. Amengual and Reagan.
- **S2308**, "Randomized Phase III Study of Mosunetuzumab vs. Rituximab for Low Tumor Burden Follicular Lymphoma." Drs. Ghosh and Friedberg.

Active Studies

- \$1608, "Randomized Phase II Trial in Early Relapsing or Refractory Follicular Lymphoma." Drs. Barr and Burack. Activated: 8/10/17.
- **\$1918**, "A Phase II/III Randomized Study of R-miniCHOP With or Without CC-486 (Oral Azacytidine) in Participants Age 75 Years or Older with Newly Diagnosed Diffuse Large B Cell Lymphoma, Grade IIIB Follicular Lymphoma, Transformed Lymphoma, and High-Grade B-Cell Lymphomas with MYC and BCL2 and/or BCL6 Rearrangements." Drs. Brem and Smith. Activated: 3/19/21.
- **<u>\$2114</u>**, "A Randomized Phase II Trial of Consolidation Therapy Following CD19 CAR T-Cell Treatment for Relapsed/Refractory Diffuse Large B-cell Lymphoma or Grade IIIB Follicular Lymphoma." Drs. Hess and Hossain. Activated: 2/23/23.
- CTSU/A051701, "Randomized Phase II/III Study of Venetoclax (ABT199) Plus Chemoimmunotherapy for MYC/BCL2 Double-Hit and Double Expressing Lymphomas." Dr. Abramson. SWOG Champion: Dr. Vallurupalli. Activated: 8/7/19. Temporarily closed: 8/2/21.
- 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. Dr. Fenske. SWOG Champion: Dr. Till. Activated: 8/29/17.
- CTSU/EA4181, "A Randomized 3-Arm Phase II Study Comparing 1.) Bendamustine, Rituximab and High Dose Cytarabine (BR/CR) 2.) Bendamustine, Rituximab, High Dose Cytarabine and Acalabrutinib (BR/ CA-A), and 3.) Bendamustine, Rituximab and Acalabrutinib (BR-A)



c.

Lymphoma Committee

	51608	51826	51918	A051301	A051701	ANHL1931	E4412	EA4151	EA4181
Ascension Providence Hosp - Southfield	-	5	-	-	-	-	-	-	-
Banner U Med Ctr - Tucson	2	-	-	1	-	-	-	1	2
Baptist Mem HIth Care/Mid South MU NCORP	-	3	-	-	-	-	-	-	-
Baylor College of Med/Dan L Duncan CCC	-	-	-	1	-	-	-	-	-
Boston Med Ctr	-	3	-	-	-	-	-	-	-
CWRU Case CCC LAPS	-	-	-	-	8	-	-	12	12
Ca Res Consort of W Mich NCORP	3	13	-	-	-	-	-	-	-
Ca Res for the Ozarks NCORP	1	5	-	-	-	-	-	-	-
Ca Res of Wisconsin and N Mich Consort	-	2	-	-	-	-	-	-	-
Carle CC NCORP	1	3	-	-	-	-	-	-	-
City of Hope CCC	8	21	2	1	-	1	-	18	-
Columbia U MU NCORP	-	2	2	-	-	-	1	-	-
Columbus NCORP	1	2	-	-	-	-	-	-	-
CommonSpirit HIth Res Inst	-	4	-	-	-	-	-	-	-
Essentia HIth NCORP	-	3	-	-	-	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	-	-	-	-	-	-	-	13	-
Georgia Cares MU NCORP	-	6	1	-	-	-	-	-	-
Gulf South MU NCORP	-	-	2	-	-	-	-	-	-
Heartland Ca Res NCORP	1	20	-	-	-	-	-	-	-
Henry Ford Hosp	-	8	-	-	2	-	-	-	-
Kaiser Permanente NCORP	2	11	1	-	-	-	11	-	12
King Faisal Specialist Hosp and Res Centre	-	-	-	4	-	-	-	-	-
Loyola U Med Ctr	-	8	-	-	-	-	-	3	-
Med U South Carolina MU NCORP	2	19	3	-	3	-	-	2	-
Michigan Ca Res Consort NCORP	1	6	3	-	-	-	-	-	-
Moffitt CC	-	15	-	-	-	-	-	-	-
Montana Ca Consort NCORP	-	8	-	-	-	-	-	-	-
NCORP Carolinas (Prisma HIth NCORP)	-	11	-	-	-	-	-	2	-
Nevada Ca Res Foundation NCORP	-	2	-	-	-	-	1	-	-
Northwell Hith NCORP	-	-	-	-	1	-	-	-	-



Lymphoma Committee

	51608	51826	51918	A051301	A051701	ANHL1931	E4412	EA4151	EA4181
Northwestern U LAPS	1	-	-	-	_	1	-	-	-
Oregon HIth and Science U	-	4	-	-	2	-	-	5	5
Pacific Ca Res Consort NCORP	-	7	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	-	6	-	-	-	-	-	-	-
UC Davis CCC LAPS	-	18	-	-	4	-	-	-	-
UC Irvine Hlth/Chao Family CCC	-	4	1	-	-	1	-	-	-
UC San Diego Moores CC	-	8	-	-	-	-	-	1	-
U Alabama Birm / Deep South RC LAPS	-	12	-	-	3	-	7	5	-
U Arkansas for Med Sciences	-	1	-	-	-	-	-	-	-
U Cincinnati CC-UC Med Ctr	-	9	-	-	-	-	-	2	2
U Colorado CC LAPS	-	4	-	1	-	-	-	-	-
U Kansas CC - MCA Rural MU NCORP	-	-	-	-	-	-	-	-	1
U Kentucky/Markey CC	-	2	-	-	-	-	-	1	-
U Michigan CCC LAPS	-	-	-	-	-	-	-	1	-
U Mississippi Med Ctr	-	1	-	-	-	-	-	-	-
U Rochester LAPS	13	33	-	3	11	2	-	10	16
U Texas HSC at San Antonio	-	17	-	-	-	-	-	11	-
U Texas MD Anderson CC LAPS	3	34	-	-	-	-	-	-	-
U Utah - Huntsman Ca Inst LAPS	1	14	1	-	-	-	-	14	12
Upstate Carolina NCORP	1	7	-	-	-	-	-	-	-
Wayne State U - Karmanos Ca Inst LAPS	-	4	-	1	-	-	-	1	6
Wisconsin NCORP	-	11	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	-	7	-	-	-	-	-	4	-
ALLIANCE	15	134	21	-	-	-	-	-	-
CCTG	-	30	-	-	-	-	-	-	-
COG	-	313	-	-	-	-	-	-	-
ECOG-ACRIN	5	83	8	-	-	-	-	-	-
NRG	11	51	3	-	-	-	-	-	-
Total	72	994	48	12	34	5	20	106	68



Leadership	
Chair:	Sapna P. Patel, MD
Vice-Chair:	Roger S. Lo, MD, PhD
Executive Officer:	Christopher W. Ryan, MD
Statisticians:	Michael Wu, PhD
	Megan Othus, PhD
	James Moon, MS
	Hongli Li, MS
	Gabby Lopez
Scientific Leadership	
Translational Medicine:	William E. Carson, III, MD
Radiation Oncology:	Evan J. Wuthrick, MD
Surgery:	John Robert Hyngstrom, MD
Dermatology:	Clara Curiel-Lewandrowski, MD
Imaging:	Ari M. VanderWalde, MD
Medical Oncology:	Sapna Pradyuman Patel, MD
Pathology:	TBD
Non-Melanoma Skin Cancer:	Nikhil I. Khushalani, MD
Early Therapeutics:	Jeffrey A. Sosman, MD
SWOG's ECOG Liaisons:	Thach-Giao Truong, MD
ECOG's SWOG Liaisons:	David H. Lawson, MD
	Andrew Poklepovic, MD
Digital Engagement:	Zeynep Eroglu, MD
Designates	
Cancer Control Liaison:	Sancy Leachman, MD, PhD
Tha	ach-Giao Truong, MD (Survivorship)
Data Coordinator:	• •
	Leah Everhart
	Hannah Hale
Oncology Research Professionals:	
CRA:	· · · · · · · · · · · · · · · · · · ·
Nurse:	3 , ,
Patient Advocate:	
Pharmaceutical Science:	•
	•
Protocol Project Manager:	
Clinical Trials Program Manager:	Laura Gildner, MS

Time/Location

Friday, May 12, 2023 2:15 pm - 4:15 pm Room: Garden Room (Atrium Lobby Level)

Agenda

2:15 - 2:25 pm: Welcome and Introduction: Sapna Patel, MD
 2:25 - 3:05 pm: Keynote Speaker: The issue with the tissue – pathological review in neoadjuvant trials
 Victor G. Prieto, MD, PhD, MD Anderson Cancer Center

3:05 - 3:20 pm Active Studies Update

S2015, Melanoma Margins Trial (MelMarT-II): A Phase III, Multi-centre, Multi-National Randomised Controlled Trial Investigating 1cm vs. 2cm Wide Excision Margins for Primary Cutaneous Melanoma PI: Joshua Mammen, MD, PhD (University of Nebraska) Biostatisticians: Michael Wu, PhD & James Moon, MS

S2000, A Randomized Phase II Trial Of Encorafenib + Binimetinib + Nivolumab Vs Ipilimumab + Nivolumab In Braf-V600 Mutant Melanoma With (Symptomatic) Brain Metastases Pl: Zeynep Eroglu, MD (Moffit) Biostatisticians: Michael Wu, PhD & James Moon, MS

3:20 - 3:45 pm Closed to Patient Accrual, Manuscript & Translational Medicine Udpates

S1512, A Study of PD-1 Blockade with Pembrolizumab In Patients with Primary Desmoplastic Melanoma (DM), Locally Advanced, Locally Recurrent, or Metastatic Desmoplastic Melanoma (DM) Pl: Kari Kendra, MD (Ohio State) Biostatisticians: Michael Wu, PhD & James Moon, MS

S1607, A Phase II Study of Combining T-VEC and PD-1 Blockade With Pembrolizumab In Patients With Advanced Melanoma Who Have Progressed On Anti-PD1 Therapy.

Pl: Siwen Hu-Lieskovan, MD, PhD (Huntsman Cancer Institute) Biostatisticians: Michael Wu, PhD & James Moon, MS

S1616, A Phase II Study of Ipilimumab and Nivolumab in Advanced Melanoma Following Progression on a PD-1 Inhibitor Alone PI: Ari VanderWalde, MD, MPH (West Cancer Clinic, now with Caris Life Sciences)

Biostatisticians: Michael Wu, PhD & James Moon, MS

S1801, A Phase II Randomized Study of Adjuvant Versus Neo-Adjuvant Pembrolizumab (MK-3475) for Clinically Detectable Stage III-IV High-risk Melanoma. Activated PI: Sapna Patel, MD (MD Anderson)

Biostatisticians: Megan Othus, PhD & James Moon, MS



S1404, A Phase III Randomized Study of MK3475 versus High-Dose Interferon alfa-2b for Resected High-Risk Melanoma PI: Sapna Patel, MD (MD Anderson) Biostatisticians: Megan Othus, PhD, James Moon, MS, & Hongli Li, MS

3:45 - 3:55 pm ECOG-ACRIN Updates: David Lawson, MD

3:55 - 4:05 pm Advocacy Remarks: Samantha Guild, JD, AIM at

Melanoma

4:05 - 4:15 pm Wrap Up and Adjourn

Active Studies

- **S2015**, "Melanoma Margins Trial (MelMarT): A Phase III, Multi-Centre, Multi-National Randomised Control Trial Investigating 1cm v 2cm Wide Excision Margins for Primary Cutaneous Melanoma." Dr. Mammen. Activated: 4/8/22.
- **S2000**, "A Randomized Phase II Trial of Encorafenib + Binimetinib + Nivolumab vs Ipilimumab + Nivolumab in BRAF-V600 Mutant Melanoma with Brain Metastases." Dr. Eroglu. Activated: 9/23/20.
- CTSU/EA6174, "STAMP: Surgically Treated Adjuvant Merkel Cell Carcinoma with Pembrolizumab, a Phase III Trial." SWOG Champion: Dr. Hsu. Activated: 10/1/18.
- 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." SWOG Champion: Dr. K. Kim. Activated: 9/10/15.
- CTSU/EA6192, "The BAMM2 (BRAF, Autophagy, MEK Inhibition in Melanoma) Study: A Randomized Double Blind Phase II Study of Dabrafenib and Trametinib with or Without Hydroxychloroquine in Advanced BRAF V600E/K Melanoma with Elevated LDH". SWOG Champion: Dr. Truong. Activated:10/23/20.
- A091903, "A Randomized Phase II Trial of Adjuvant Nivolumab with or Without Cabozantinib in Patients with Resected Mucosal Melanoma." SWOG Champion: Dr. Tsai (SWOG) Activated 6/1/22.

Closed Studies

<u>\$1801</u>, "A Phase II Randomized Study of Adjuvant Versus Neoadjuvant Pembrolizumab (MK-3475) for Clinically Detectable Stage III-IV High Risk Melanoma." Dr. Patel. Activated: 12/6/18. Closed: 5/5/22.

- S1512, "A Phase II and Pilot Trial of PD-1 Blockade with MK-3475 (Pembrolizumab) in Patients with Resectable or Unresectable Desmoplastic Melanoma (DM)." Drs. Kendra and Hu-Lieskovan. Activated: 10/20/16. Closed: 6/4/21.
- S1607, "A Phase II Study of Combining Talimogene Laherparepvec (T-VEC) (NSC-785349) and MK-3475 (Pembrolizumab) in Patients with Advanced Melanoma who have Progressed on Anti-PD1/L1 Based Therapy." Dr. Hu-Lieskovan. Activated: 10/2/17. Closed: 11/1/20.
- S1616, "A Phase II Randomized Study of Nivolumab (NSC-748726) with Ipilimumab (NSC-732442) or Ipilimumab Alone in Advanced Melanoma Patients Refractory to an Anti-PD1 or Anti-PD-L1 Agent." Dr. VanderWalde. Activated: 7/17/17. Closed: 7/15/20.
- **S1404**, "A Phase III Randomized Study of MK3475 versus High-Dose Interferon a-2b for Resected High-Risk Melanoma." Dr. Patel. Activated: 10/15/15. Closed: 11/2/17.
- CTSU/EA6134, "DREAMseq (Doublet, Randomized Evaluation in Advanced Melanoma Sequencing) a Phase III Trial." SWOG Champion: Dr. Chmielowski. Activated: 7/13/15. Closed: 9/30/21.
- CTSU/EA6183, "A Phase II Neoadjuvant Study of Encorafenib with Binimetinib in Patients with Resectable Locoregional Metastases from Cutaneous or Unknown Primary Melanoma (Stages III N1B/C/D)." SWOG Champion: Dr. Lao. Activated: 2/18/20. Closed: 9/23/22.

Studies in Development

S2305, "Phase II Study of the Triplet Combination of Relatlimab, Nivolumab, and Ipilimumab for Melanoma with Prior Progression on Immune Checkpoint Inhibitor Therapy" Drs. Naing and Patel



	51801	52000	52015	A091903	EA6134	EA6747	EA6174	EA6192
Banner MD Anderson CC	3	_	-	_	_	_	-	_
Banner U Med Ctr - Tucson	7	_	_	_	_	_	3	-
Baptist Mem Hlth Care/Mid South MU NCORP	1	-	-	-	_	-	-	_
Boston Med Ctr	1	-	_	-	-	-	_	-
CWRU Case CCC LAPS	-	_	-	-	6	-	16	-
Ca Res Consort of W Mich NCORP	26	-	27	-	_	-	_	-
Ca Res for the Ozarks NCORP	-	1	-	-	1	1	-	-
Ca Res of Wisconsin and N Mich Consort	2	-	_	-	_	-	_	-
Carle CC NCORP	1	1	-	-	-	-	-	-
City of Hope CCC	6	-	-	-	1	3	-	-
Columbus NCORP	1	-	-	-	-	-	-	-
Dayton NCORP	-	1	-	-	-	2	-	-
Fred Hutchinson Ca Res Ctr LAPS	-	-	-	-	-	-	1	-
Gulf South MU NCORP	1	-	-	-	-	-	-	-
Hawaii MU NCORP	2	-	-	-	2	-	-	-
Heartland Ca Res NCORP	6	-	-	-	-	-	-	-
Kaiser Permanente NCORP	14	-	-	-	19	23	-	-
Loma Linda U Med Ctr	2	-	-	-	-	-	-	-
Massachusetts Veterans ERIC	5	-	-	-	-	-	-	-
Med U South Carolina MU NCORP	1	-	3	-	-	-	-	-
Michigan Ca Res Consort NCORP	5	-	-	-	-	-	-	-
Moffitt CC	-	12	6	-	-	-	-	-
Montana Ca Consort NCORP	4	-	-	-	-	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	-	-	-	-	2	-	-	-
Nevada Ca Res Foundation NCORP	-	-	-	-	1	-	1	-
New Mexico MU NCORP	1	-	-	-	-	-	-	-
Northwell HIth NCORP	7	-	-	-	-	-	-	-
Northwestern U LAPS	13	-	7	-	-	1	1	5
Ohio State U CCC LAPS	13	1	4	-	4	-	3	1



	51801	52000	52015	A091903	EA6134	EA6747	EA6174	EA6192
Pacific Ca Res Consort NCORP	3	-	-	-	-	-	-	-
SCL HIth Saint Joseph Hosp	-	-	-	-	-	-	1	-
Sutter Ca Res Consort	-	-	-	-	2	5	1	-
Don and Sybil Harrington CC	3	-	-	-	-	-	-	-
UC Irvine Hlth/Chao Family CCC	3	-	-	-	-	3	8	-
UCLA / Jonsson CCC	6	-	-	-	7	-	-	-
UPMC Hillman CC LAPS	-	1	-	-	-	-	-	-
USC Norris CCC LAPS	8	-	-	1	-	-	3	-
U Alabama Birm / Deep South RC LAPS	1	-	-	-	-	-	-	-
U Arkansas for Med Sciences	-	-	2	-	3	-	-	-
U Cincinnati CC-UC Med Ctr	-	-	-	-	-	2	3	-
U Colorado CC LAPS	-	-	-	-	1	-	-	-
U Kansas CC - MCA Rural MU NCORP	8	-	6	-	1	-	-	-
U Kentucky/Markey CC	4	-	-	-	-	-	-	-
U Michigan CCC LAPS	15	2	-	-	-	-	-	-
U Oklahoma Hlth Sciences Ctr LAPS	-	-	1	-	-	-	-	-
U Rochester LAPS	4	-	-	-	2	1	1	-
U Texas HSC at San Antonio	-	-	-	-	-	1	-	-
U Texas MD Anderson CC LAPS	10	-	-	-	-	-	-	-
U Utah - Huntsman Ca Inst LAPS	20	-	4	-	-	-	8	-
Wayne State U - Karmanos Ca Inst LAPS	-	-	-	-	2	-	-	-
Western States Ca Res NCORP	-	-	-	-	-	1	-	-
Wisconsin NCORP	9	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	-	-	1	-	-	6	1	-
ALLIANCE	32	1	4	-	-	-	-	-
ECOG-ACRIN	50	4	10	-	-	-	-	-
NRG	47	1	3	-	-	-	-	-
Total	345	25	<i>7</i> 8	1	54	49	51	6



The publications listed below were received by the Group Chair's Office as published (including online), accepted, or submitted since the SWOG Fall 2022 Group Meeting. Conference abstracts are not included.

ADOLESCENT AND YOUNG ADULT (AYA) COMMITTEE

Published/Accepted Manuscripts

N/A Inclusion of a core patient-reported outcomes battery in adolescent and young adult cancer clinical trials. Roth M, Parsons S, Ganz P, Wagner L, Hinds P, Alexander S, Bingen K, Bober S, Brackett J, Cella D, Henry NL, Indelicato D, Johnson RH, Miller T, Rosenberg S, Schmitz K, Thanarajasingam G, Reeve B, Salsman J. <u>Journal of the National Cancer Institute</u> Jan 10;115(1):21-28, 2023. [see also SXCQOL committee] https://pubmed.ncbi.nlm.nih.gov/36266760/

Submitted Manuscripts

(none this cycle)

BARLOGIE-SALMON MYELOMA COMMITTEE

Published/Accepted Manuscripts

(none this cycle)

Submitted Manuscripts

(none this cycle)

BREAST COMMITTEE

Published/Accepted Manuscripts

- S0226 Thymidine Kinase Activity Levels in Serum Can Identify HR+ Metastatic Breast Cancer Patients with a Low Risk of Early Progression (SWOG S0226). Bergqvist M, Nordmark A, Williams A, Paolett C, Barlow W, Cobain E, Mehta R, Gralow J, Hortobagyi G, Albain K, Pusztai L, Sharma P, Godwin A, Thompson A, Hayes D, Rae J. <u>Biomarkers</u> Jan 29:1-10, 2023. https://pubmed.ncbi.nlm.nih.gov/36647745/
- S0500 Tumor-derived Extracellular Vesicles as Complementary Prognostic Factors to Circulating Tumor Cells in Metastatic Breast Cancer. Nanou A, Miao J, Coumans F, Dolce E, Darga E, Barlow W, Smerage J, Hortobagyi G, Terstappen L, Hayes D. <u>JCO Precision Oncology</u>, Jan;7:e2200372, 2023. https://pubmed.ncbi.nlm.nih.gov/36634296/
- SO800 Image analysis-based tumor infiltrating lymphocyte measurement predicts pathologic complete response to neoadjuvant chemotherapy in breast cancer (SWOG S0800). Fanucci K, Blenman K, Bai Y, Pelekanou V, Nahleh Z, Shafi S, Burela S, Barlow W, Sharma P, Thompson A, Godwin A, Rimm D, Hortobagyi G, Pusztai L. npj Breast Cancer, accepted, 2023.

Results of a Phase II Randomized Trial of Cisplatin With ABT-888 (Veliparib) or Placebo in Metastatic Triple-Negative Breast Cancer and/or BRCA1/2 Mutation-Associated Breast Cancer (S1416). Rodler E, Sharma P, Barlow W, Gralow J, Puhalla S, Anders C, Goldstein L, Tripathy D, Brown-Glaberman U, Huynh T, Szyarto C, Godwin A, Pathak H, Swisher E, Radke M, Timms K, Lew D, Miao J, Pusztai L, Hayes D, Hortobagyi G. Lancet Oncology Feb;24(2):162-174, 2023.

https://pubmed.ncbi.nlm.nih.gov/36623515/

S8814 Evaluation of the predicted sensitivity to endocrine therapy (SET2,3 index) and the 21-gene Breast Recurrence Score assay in the SWOG S8814 trial. Speers C, Symmans WF, Barlow W, Trevarton A, The S, Du L, Rae J, Shak S, Baehner R, Sharma P, Pusztai L, Hortobagyi G, Hayes D, Albain K, Godwin A, Thompson A. <u>Journal of Clinical Oncology</u>, Jan 17;JCO2201499. doi: 10.1200/JCO.22.01499. Online ahead of print, 2023.. https://pubmed.ncbi.nlm.nih.gov/36649570/

Submitted Manuscripts

- S0221 Vitamin D insufficiency as a risk factor for paclitaxel-induced peripheral neuropathy in White and Black patients in SWOG S0221. Chen C, Zirpoli G, McCann S, Barlow W, Budd GT, Pusztai L, Henry NL, Godwin A, Thompson A, Ambrosone C, Stringer K, Hertz D. <u>Clinical Cancer Research</u>, submitted 2023. [see also SXCQOL Committee]
- S0221 Adherence to cancer prevention guidelines before, during, and after treatment for high-risk breast cancer in S0221: Associations withdisease recurrence and mortality. Cannioto R, Attwood K, Hutson A, Davis E, Zirpoli G, Barlow W, Hershman D, Unger J, Moore H, Stewart J, Isaacs C, Hobday T, Salim M, Hortobagyi G, Gralow J, Albain K, Budd GT, Tang L, Ambrosone C, McCann S. JAMA Network Open, under revision for resubmission 2023.
- S1007 Radiotherapy Use and Incidence of Locoregional Recurrence in Patients with Favorable-Risk Node-Positive Breast Cancer Enrolled in the SWOG S1007 Trial. Jagsi R, Barlow W, Woodward W, Connolly E, Mahtani R, Shumway D, Speers C, Stecklein S, Zeidan Y, Zhang H, Sharma P, Pusztai L, Hortobagyi G, Kalinsky K. JAMA Oncology, under review, 2023.
- Dual Prognostic Classification of Triple-Negative Breast Cancer by DNA Damage Immune Response and Homologous Recombination Deficiency. Stecklein S, Barlow W, Pusztai L, Timms K, Kennedy R, Logan G, Seitz R, Badve S, Gökmen-Polar Y, Porter P, Linden H, Tripathy D, Hortobagyi G, Godwin A, Thompson A, Hayes D, Sharma P. <u>Journal of</u> <u>Clinical Oncology</u>, submitted 2023.



CANCER CONTROL AND PREVENTION COMMITTEES CANCER CARE DELIVERY COMMITTEE

Published/Accepted Manuscripts

- S1204 Antiviral Therapy Use, Changes in Anticancer Treatment, and Adverse Viral Outcomes in Patients with Cancer and Viral Infections: Results from a Multicenter Observational Study (SWOG S1204). Hwang J, Arnold K, Unger J, Chugh R, Tincopa M, Loomba R, Hershman D, Ramsey S. Supportive Care in Cancer Dec 31;31(1):93, 2022. https://pubmed.ncbi.nlm.nih.gov/36585488/
- S1204 Risk Prediction of Hepatitis B or C or HIV Among Newly Diagnosed Cancer Patients. Unger JM, Till C, Hwang JP, Arnold KB, Hershman DL, Ramsey SD. <u>Journal of the National Cancer Institute</u>, accepted 2023.
- S1400I Novel Approaches for Dynamic Visualization of Adverse Event Data in Oncology Clinical Trials: A Case Study Using Immunotherapy Trial S1400-I (SWOG). Lee S, Fan W, Wang A, Vaidya R, Redman M, Gettinger S, Bazhenova L, Herbst R, Hershman D, Unger J., JCO Clinical Cancer Informatics, accepted 2023. [see also Lung Committee]
- S1404 Adjuvant pembrolizumab improves quality-of-life outcomes compared to high dose interferon or ipilimumab in patients with resected melanoma; SWOG S1404, A Randomized Clinical Trial. Unger J, Darke A, Othus M, Tarhini A, Kirkwood J, Sharon E, Sondak V, Guild S, Truong T, Eroglu Z, Kendra K, Lewis K, Faller B, Funchain P, Buchbinder E, Grossmann K, Ribas A, Patel S. <u>JAMA Oncology</u>, Feb 1;9(2):251-260, 2023. [see also Melanoma Committee] https://pubmed.ncbi.nlm.nih.gov/36416836/
- S1415CD An Evaluation of Stakeholder Engagement in Comparative Effectiveness Research: Lessons Learned from SWOG S1415CD. Bell-Brown A, Watabayashi K, Kreizenbeck K, Ramsey S, Bansal A, Barlow W, Lyman G, Hershman DL, Mercurio A, Segarra-Vazquez B, Kurttila F, Myers J, Golenski J, Johnson J, Erwin R, Sullivan S. <u>Journal of Comparative Effectiveness Research</u> Dec;11(18):1313-1321, 2022. https://pubmed.ncbi.nlm.nih.gov/36378570/
- S1415CD A Pragmatic Cluster-Randomized Trial of a Standing Order Entry Intervention for Colony Stimulating Factor Use Among Patients at Intermediate Risk for Febrile Neutropenia. Hershman DL, Bansal A, Sullivan S, Lyman G, Barlow W, Arnold K, Watabayashi K, Bell-Brown A, Le-Lindquister N, Dul C, Brown-Glaberman U, Behrens R, Vogel V, Alluri N, Ramsey S. <u>Journal of Clinical Oncology</u>, Jan 20;41(3):590-598, 2023. https://pubmed.ncbi.nlm.nih.gov/36228177/

- S1415CD Effects of a guideline-informed clinical decision support system intervention to improve colony stimulating factor prescribing: A Pragmatic Cluster-Randomized Trial. Ramsey S, Bansal S, Sullivan S, Lyman G, Barlow W, Arnold K, Watabayashi K, Bell-Brown A, Kreizenbeck K, Le-Lindqwister N, Dul C, Brown-Glaberman U, Behrens R, Vogel V, Alluri N, Hershman D. JAMA Network Open, Oct 3;5(10):e2238191, 2022. https://pubmed.ncbi.nlm.nih.gov/36279134/
- Multiple Studies Trends in Obesity Prevalence Among Patients
 Registered to Cancer Clinical Treatment Trials. Vaidya R, Till C, Greenlee
 H, Hershman D, Unger J. JAMA Open Network, Oct 3;5(10):e2234445,
 2022. https://pubmed.ncbi.nlm.nih.gov/36215073/
- Multiple Studies Population, Clinical, and Scientific Impact of National Cancer Institute's National Clinical Trials Network Treatment Studies. Unger J, LeBlanc M, Bertagnolli M, Wolmark N, Curran W, O'Dwyer P, Schnall M, Mannel R, Mandrekar S, Gray R, Zhao F, Bah M, Hong F, Vaidya R, Blanke C. <u>Journal of Clinical Oncology</u>, Dec 8:JCO2201826. doi: 10.1200/JCO.22.01826. Online ahead of print, 2022. https://pubmed.ncbi.nlm.nih.gov/36480773/

Submitted Manuscripts

- S1204 Prediction Model for Identifying Patients Enrolled in SWOG S1204 at Highest Risk of Hepatitis B Virus, Hepatitis C Virus, and HIV Infection Among Patients with Newly Diagnosed Cancer. Unger JM, Till C, Hwang JP, Arnold KB, Hershman DL, Ramsey SD. <u>Journal of the National Cancer</u> Institute, revisied/resubmitted 2023.
- S1204 Universal Viral Screening of Newly Diagnosed Cancer Patients in the United States: A Cost Efficiency Evaluation. Vaidya R, Unger J, Schwartz N, Loomba R, Hwang J, Chugh R, Tincopa M, Arnold K, Hershman D, Ramsey S. JCO Oncology Practice, submitted 2023.
- S1912CD A Randomized Trial Addressing Cancer-Related Financial Hardship through Delivery of a Proactive Financial Navigation Intervention (CREDIT) (SWOG S1912CD). Shankaran V, Unger J, Carlos R, Langer S, Darke A, Hershman D, Ramsey S. Trials, pending revision/resubmission, 2023.
- Multiple Studies The Medicaid Expansion of the Affordable Care Act and the Participation of Patients with Medicaid in Cancer Clinical Trials. Unger J, Xiao H, Vaidya R, LeBlanc M, Hershman DL. <u>Journal of Clinical Oncology</u>, under revision for resubmission, 2023.



CANCER SURVIVORSHIP COMMITTEE

Published/Accepted Manuscripts

N/A NCCN Guidelines Insights: Survivorship, Version 1.2022. Sanft T, Day A, Peterson L, Rodriguez MA, Ansbaugh S, Armenian S, Baker KS, Ballinger T, Broderick G, Demark-Wahnefried W, Dickinson K, Fairman NP, Friedman DL, Goldman M, Henry NL, Hill-Kayser C, Hudson M, Khakpour N, Koura D, McDonough AL, Melisko M, Mooney K, Moore HCF, Moryl N, Neuman H, O'Connor T, Overholser L, Paskett ED, Patel C, Pirl W, Porpiglia A, Ruddy KJ, Schapira L, Shockney L, Smith S, Syrjala KL, Tevaarwerk A, Yang EH, Zee P, McMillian NR, Freedman-Cass DA. Journal of the National Comprehensive Cancer Network. Oct;20(10):1080-1090, 2022. https://pubmed.ncbi.nlm.nih.gov/36240847/

Submitted Manuscripts

(none tlhis cycle)

PALLIATIVE AND END OF LIFE CARE COMMITTEE

Published/Accepted Manuscripts

Source Source Source Science States and Ethnic Disparity in Preference-Weighted Quality of Life: Findings from the Selenium and Vitamin E Cancer Prevention Trial (SELECT). Rock M, Vaidya R, Till C, Unger J, Hershman D, Ramsey S, Nehemiah A, Maeng D, Krouse R. Journal of the National Cancer Institute Jan 10. doi: 10.1089/pop.2022.0143. Online ahead of print., 2023. [see also PREV and SXQOL Committees]

https://pubmed.ncbi.nlm.nih.gov/36625863/

None Healthcare Professionals' Lay Definitions of Hope. Feldman D, Jazaieri H, O'Rourke MA; Bakitas MA, Krouse RS, Deininger HE, Hudson MF, Corn BW. Submitted to <u>Journal of Happiness Studies</u>, 24:231–247, 2023. https://doi.org/10.1007/s10902-022-00589-0

Submitted Manuscripts

None Feasibility and Acceptability of an Online Intervention to Enhance Hopefulness Among Oncology Professionals. David Feldman; Hooria Jazaieri; Mark A. O'Rourke; Marie A. Bakitas; Robert S. Krouse; Heidi E. Deininger; Matthew F. Hudson; Benjamin W. Corn. JNCI Cancer Spectrum revised/resubmitted 2023.

PREVENTION AND EPIDEMIOLOGY COMMITTEE

Published/Accepted Manuscripts

S0000 Racial and Ethnic Disparity in Preference-Weighted Quality of Life: Findings from the Selenium and Vitamin E Cancer Prevention Trial (SELECT). Rock M, Vaidya R, Till C, Unger J, Hershman D, Ramsey S, Nehemiah A, Maeng D, Krouse R. <u>Journal of the National Cancer Institute</u> Jan 10. doi: 10.1089/pop.2022.0143. Online ahead of print., 2023. [see also PALEOL and SXQOL Committees]

https://pubmed.ncbi.nlm.nih.gov/36625863/

S0000 Differential Biopsy Patterns Influence Associations Between Multivitamin Use and Prostate Cancer Risk in the Selenium and Vitamin E Cancer Prevention Trial. Schenk J, Till C, Neuhouser M, Goodman P, Lucia MS, Thompson IM, Tangen CM. <u>Cancer Epidemiology, Biomarkers & Prevention</u>, Nov 2;31(11):2063-2069, 2022.

https://pubmed.ncbi.nlm.nih.gov/36084322/

S0000/other Accommodating population differences when validating risk prediction models. Pfeiffer R, Chen Y, Gail M, Ankerst D. Statistics in Medicine Oct 30;41(24):4756-4780, 2022.

https://pubmed.ncbi.nlm.nih.gov/36224712/

S0000/S9217 Genetically Adjusted PSA Levels for Prostate Cancer Screening. Kachuri L, Hoffmann T, Jiang Y, Berndt S, Shelley J, Schaffer K, Machiela M, Freedman N, Huang W, Li S, Easterlin R, Goodman P, Till C, Thompson I, Lilja H, Van Den Eeden S, Chanock S, Haiman C, Conti D, Klein R, Mosley J, Graff R, Witte J. Nature Medicine, accepted, 2023.

S0000/S9217 Genetically proxied therapeutic inhibition of antihypertensive drug targets and risk of common cancers: A mendelian randomization analysis. Yarmolinsky J, Díez-Obrero V, Richardson TG, Pigeyre M, Sjaarda J, Paré G, Walker VM, Vincent EE, Tan VY, Obón-Santacana M, Albanes D, Hampe J, Gsur A, Hampel H, Pai RK, Jenkins M, Gallinger S, Casey G, Zheng W, Amos CI; International Lung Cancer Consortium; PRACTICAL consortium; MEGASTROKE consortium; Smith GD, Martin RM, Moreno V. <u>PLoS Medicine</u> Feb 3;19(2):e1003897, 2022. https://pubmed.ncbi.nlm.nih.gov/35113855/

Submitted Manuscripts

Soudo/Other Shedding light on the association between genetically-defined BMI and early-onset colorectal cancer in a pooled analysis [Brief Communication]. Archambault A, Gruber S, Le Marchand L, Hsu L, Peters U, Hayes R, on behalf of the Colorectal Transdisciplinary (CORECT) Study, the Colon Cancer Family Registry (CCFR), Genetics and Epidemiology of Colorectal Cancer Consortium (GECCO) [P Goodman, C Tangen, GECCO collaborators)]. Gastroenterology, under review, 2023

S0000/S9217/Other A prostate cancer susceptibility PSA variant that confers lower risk is also associated with more aggressive disease and poor survival. Srinivasan S, Kryza T, Bock N, Stephens C, Dong Y, Panchadsaram J, Moya L, Rohl J, Perry-Keene J, Buzacott K, Gago M, Schleutker J, Maier C, Muir K, Tangen C, Gronberg H, Pashayan N,



Albanes D, Wolk A, Eles R, Clements J, Batra J. <u>Cancer Discovery</u>, under review, 2023.

Symptom Control and Quality of Life Committee

Published/Accepted Manuscripts

N/A Inclusion of a core patient-reported outcomes battery in adolescent and young adult cancer clinical trials. Roth M, Parsons S, Ganz P, Wagner L, Hinds P, Alexander S, Bingen K, Bober S, Brackett J, Cella D, Henry NL, Indelicato D, Johnson RH, Miller T, Rosenberg S, Schmitz K, Thanarajasingam G, Reeve B, Salsman J. <u>Journal of the National Cancer Institute</u> Jan 10;115(1):21-28, 2023. [see also AYA Committee] https://pubmed.ncbi.nlm.nih.gov/36266760/

<u>S1200</u> Comparison of Acupuncture vs Sham Acupuncture or Waiting List Control in the Treatment of Aromatase Inhibitor-Related Joint Pain: A Randomized Clinical Trial. Hershman D, Unger J, Greenlee H, Capodice J, Lew D, Darke A, Minasian L, Fisch M, Henry NL, Crew K. <u>JAMA Open</u> <u>Network</u> Nov 1;5(11):e2241720, 2022.

https://pubmed.ncbi.nlm.nih.gov/36367721/

S14001 Quality-of-life outcomes and risk-prediction for advanced lung cancer treated with Nivolumab/Ipilimumab vs Nivolumab. Unger J, Qian L, Redman M, Tavernier S, Minasian L, Sigal E, Papadimitrakopoulou V, LeBlanc M, Cleeland C, Dzingle S, Summers T, Chao H, Madhusudhana S, Villaruz L, Crawford J, Gray JE, Kelly KL, Gandara DR, Bazhenova L, Herbst RS, Gettinger S, Moinpour C. Journal of the National Cancer Institute Jan 10;djad003. doi:10.1093/jnci/djad003. Online ahead of print, 2023. [see also Lung committee] https://pubmed.ncbi.nlm.nih.gov/36625510/

S0000 Racial and Ethnic Disparity in Preference-Weighted Quality of Life: Findings from the Selenium and Vitamin E Cancer Prevention Trial (SELECT). Rock M, Vaidya R, Till C, Unger J, Hershman D, Ramsey S, Nehemiah A, Maeng D, Krouse R. Journal of the National Cancer Institute Jan 10. doi: 10.1089/pop.2022.0143. Online ahead of print., 2023. [see also PALEOL and PREV and Committees] https://pubmed.ncbi.nlm.nih.gov/36625863/

Submitted Manuscripts

So221 Vitamin D insufficiency as a risk factor for paclitaxel-induced peripheral neuropathy in White and Black patients in SWOG S0221. Chen C, Zirpoli G, McCann S, Barlow W, Budd GT, Pusztai L, Henry NL, Godwin A, Thompson A, Ambrosone C, Stringer K, Hertz D. Clinical Cancer Research, submitted 2023. [see also Breast Committee]

DIGITAL ENGAGEMENT COMMITTEE

Published/Accepted Manuscripts

N/A Crisis of the clinical trials staff attrition following the COVID-19 pandemic. Sun G, Dizon D, Szczepanek C, Petrylak D, Sparks D, Tangen C, Lara P, Thompson I, Blanke CD. JCO Oncology Practice, accepted 2023.

Submitted Manuscripts

(none this cycle)

EARLY THERAPEUTICS AND RARE CANCERS COMMITTEE

Published/Accepted Manuscripts

(none this cycle)

Submitted Manuscripts

S1609 A Phase II Basket Trial of Dual Anti-CTLA-4 and Anti-PD-1
Blockade in Rare Tumors (DART) SWOG S1609: The Salivary Gland Tumor
Cohort. Chae Y, Sun R, Patel S, Giles F, Ohr J, Worden F, Suga J, Naing A,
Cohen E, Wallace J, Fenton S, Il-Young Chung L, Kang H, McLeod C, Chen
H, Sharon E, Streicher H, Ryan C, Othus M, Blanke CD, Kurzrock R. Clinical
Cancer Research, submitted 2023.

EXECUTIVE COMMITTEE

Published/Accepted Manuscripts

(none this cycle)

Submitted Manuscripts

(none this cycle)

GASTROINTESTINAL COMMITTEE

Published/Accepted Manuscripts

Solve Solve

Solvisual Abstract: Adjuvant Chemoradiation in Patients with Lymph Node-Positive Biliary Tract Cancers – Secondary Analysis of a Single-Arm Clinical Trial (SWOG 0809). Gholami S, Colby S, Horowitz DP, Guthrie KA, Ben-Josef E, El-Khoueiry AB, Blanke CD, Philip PA, Kachnic LA, Ahmad SA, Rocha FG. Annals of Surgical Oncolology Mar;30(3):1364-1365, 2023. https://pubmed.ncbi.nlm.nih.gov/36542251/



A021501 Efficacy of Preoperative mFOLFIRINOX vs mFOLFIRINOX Plus Hypofractionated Radiotherapy for Borderline Resectable Adenocarcinoma of the Pancreas: The A021501 Phase 2 Randomized Clinical Trial. Katz M, Shi Q, Meyers J, Herman J, Chuong M, Wolpin B, Ahmad S, Marsh R, Schwartz L, Behr S, Frankel W, Collisson E, Leenstra J, Williams T, Vaccaro G, Venook A, Meyerhardt J, O'Reilly E. JAMA Oncology Sep 1;8(9):1263-1270, 2022.

https://pubmed.ncbi.nlm.nih.gov/35834226/

C/S 80405 Acquired Genomic Alterations on First Line Chemotherapy with Cetuximab/Bevacizumab in Advanced Colorectal Cancer:
Circulating Tumor DNA Analysis of CALGB/SWOG-80405 Trial. Raghav K, Ou F-S, Venook A, Innocenti F, Sun R, Lenz H-J, Kopetz ES. <u>Journal of Clinical Oncology</u> Jan 20;41(3):472-478, 2023.
https://pubmed.ncbi.nlm.nih.gov/36067452/

C/S 80405 Johnson R, Qu X, Lin C-F, Huw L, Venkatanarayan A, Sokol E, Ou F-S, Ihuegbu N, Zill O, Kabbarah O, Wang L, Bolen C, Daemen A, Bourgon R, de Sousa e Melo F, Venook A, Innocenti F, Lenz H-J, Bais C. ARID1A mutations induce an EGFR-like signature and confer intrinsic and acquired resistance to cetuximab treatment in colon cancer. Nature Communications Sep 19;13(1):5478, 2022.

https://pubmed.ncbi.nlm.nih.gov/36117191/

- C/S 80702 Associations of Inflammatory Biomarkers with Survival Among Patients with Stage III Colon Cancer (CALGB/SWOG 80702 [Alliance]).

 Cheng E, Shi Q, Shields A, Nixon A, Nader R, Shergill A, Ma C, Guthrie K, Couture F, Kuebler P, Kumar P, Lewis D, Tan B, Krishnamurthi S, Ng K, O'Reilly E, Brown J, Philip P, Caan B, Feliciano E, Meyerhardt J. JAMA Oncology Jan 26. doi: 10.1001/jamaoncol.2022.6911. Online ahead of print, 2023. https://pubmed.ncbi.nlm.nih.gov/36701146/
- C/S 80702 Physical Activity in Stage III Colon Cancer: CALGB/SWOG 80702 (Alliance). Brown J, Ma C, Shi Q, Fuchs C, Meyer J, Niedzwiecki D, Zemla T, Couture F, Kuebler P, Kumar P, Lewis D, Tan B, O'Reilly E, Shields AF, Meyerhardt J. Journal of Clinical Oncology Jan 10;41(2):243-254, 2023. https://pubmed.ncbi.nlm.nih.gov/35944235/
- C/S80702 Potential Mediators of Oxaliplatin-Induced Peripheral Neuropathy from Adjuvant Therapy in Stage III Colon Cancer: Findings from CALGB/SWOG 80702 (Alliance). Lee S, Ma C, Shi Q, Kumar P, Coutoure F, Kuebler JP, Krishnamurthi S, Lewis D, Tan B, Goldberg R, Venook A, Blanke CD, O'Reilly E, Shields A, Meyerhardt J. <u>Journal of Clinical Oncology</u>, Feb 10;41(5):1079-1091, cheng2023. https://pubmed.ncbi.nlm.nih.gov/36367997/
- <u>E1292</u> Phase III Prospectively Randomized Trial of Perioperative 5-FU after Curative Resection, Followed by 5-FU/Leucovorin for Patients

with Colon Cancer-Intergroup: A trial of the ECOG-ACRIN Research Group (E1292). Kemeny MM, Zhao F, Forastiere A, Catalano P, Heimann D, Hamilton SR, Meidema B, Dawson N, Weiner LM, Smith B, Mason BA, Graziano S, Gilman PB, Venook A, Pinto H, Whitehead RP, O'Dwyer PJ, Benson AB. <u>Annals Surgical Oncology</u> Feb;30(2):1099-1109, 2023. https://pubmed.ncbi.nlm.nih.gov/36305992/

Submitted Manuscripts

Solve The Effect of Radiation Modality on Outcomes of Patients
Receiving Adjuvant Chemoradiotherapy for Extrahepatic
Cholangiocarcinoma and Gallbladder Carcinoma: A Secondary Analysis
of SWOG Solve Horowitz D, Colby S, Gholami S, Guthrie K, Ben-Josef E,
El-Khoueiry A, Blanke CD, Philip P, Chiorean E, Rocha F, Ahmad S, Ahmad
S, Kachnic L. International Journal of Radiation Oncology, Biology,
Physics, revised/resubmitted 2023.

GENITOURINARY COMMITTEE

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

Published/Accepted Manuscripts

- S0337 Paper Alert: Implementing a New Standard of Care [Commentary]. Messing E. <u>Bladder Cancer</u>, volume 8; issue 4, 2022. https://www.bladdercancerjournal.com/paper-alert
- S1216 Bone biomarkers and subsequent survival in men with hormone sensitive prostate cancer: results from the SWOG S1216 phase III trial of androgen deprivation therapy with or without orteronel. Lara P, Mayerson E, Gertz E, Tangen C, Goldkorn A, Van Loan M, Hussain M, Gupta S, Zhang J, Parikh M, Twardowski P, Quinn D, Vogelzang N, Thompson I, Agarwal N. European Urology, accepted, 2023.
- Cell-free DNA Methylation as a Predictive Biomarker of Response to Neoadjuvant Chemotherapy for Patients with Muscle-invasive Bladder Cancer in SWOG S1314. Lu Y-T, Plets M, Morrison G, Cunha A, Cen S, Rhie S, Siegmund K, Daneshmand S, Quinn D, Meeks J, Lerner S, Petrylak D, McConkey D, FlaigT, Thompson I, Goldkorn A. European Urology Oncology, accepted, 2023.
- N/A Checklist for Improving Patient Communication on Bladder
 Preservation Options: The Patient Advocate Perspective. Bangs R, Quale
 DZ, Reed T. <u>Clinical Oncology</u> Oct;34(10):625-629, 2022.
 https://pubmed.ncbi.nlm.nih.gov/36057507/

Submitted Manuscripts

<u>S1314</u> A randomized phase II study of co-expression extrapolation



(COXEN) with neoadjuvant chemotherapy for localized, muscle-invasive bladder cancer with overall survival follow up (SWOG S1314; NCT02177695). Flaig TW, Tangen CM, Daneshmand S, Alva AS, Lucia MS, McConkey, Theodorescu D, Goldkorn A, Milowsky M, Bangs R, MacVicar G, Bastos BR, Fowles JS, Gustafson DL, Plets M, Thompson IM, Jr, Lerner. SP. <u>European Urology</u>, submitted 2023.

S1314 Association of Molecular Subtypes with Pathologic Response, PFS and OS in a Phase II Study of Co-Expression Extrapolation (COXEN) with Neoadjuvant Chemotherapy (NAC) for Localized, Muscle-Invasive Bladder Cancer (SWOG S1314; NCT02177695). Lerner S, McConkey DJ, Tangen C, Meeks JJ, Flaig T, Hua X, Daneshmand S, Alva A, Lucia MS, Theodorescu D, Goldkorn A, Milowsky M, Choi W, Bangs R, Gustafson D, Plets M, Thompson IM. Clinical Cancer Research, submitted 2023.

S1605 Phase II Trial of Atezolizumab in BCG-Unresponsive High Risk Non-Muscle Invasive Bladder Cancer: SWOG S1605. Black P, Tangen C, Singh P, McConkey D, Lucia MS, Lowrance WT, Koshkin V, Stratton K, Bivalacqua T, Kassouf W, Porten S, Bangs R, Plets M, Thompson, IM, Lerner SP. <u>European Urology</u>, submitted 2023.

LEUKEMIA COMMITTEE

Published/Accepted Manuscripts

<u>S1318</u> Dasatinib and Blinatumomab for Ph+ or Ph-Like Acute Lymphoblastic Leukemia. Advani A, Moseley A, O'Dwyer K, Wood B, Park J, Wieduwilt M, Jeyakumar D, Yaghmour G, Attalah E, Gerds A, O'Brien S, Liesveld J, Othus M, Litzow M, Stone R, Sharon E, Erba H. <u>Blood Advances</u>, Nov 2;bloodadvances.2022008216. doi: 10.1182/bloodadvances.2022008216.
Online ahead of print, 2022.

https://pubmed.ncbi.nlm.nih.gov/36322825/

A Randomized Phase II/III Study Of Novel Therapeutics versus
Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia
(AML), High-Risk Myelodysplastic Syndrome (MDS) or Chronic
Myelomonocytic Leukemia (CMML), Age 60 or Older: A Report of the
Comparison of Azacitidine and Nivolumab to Azacitidine: SWOG S1612.
Assouline S, Michaelis L, Othus M, Hay A, Walter R, Jacoby M, Schroeder M,
Uy G, Law L, Cheema F, Sweet K, Asch A, Liu J, Moseley A, Maher T, Kingsbury
L, Fang M, Radich J, Little R, Erba H. Leukemia and Lymphoma, Feb;64(2):473-477, 2023 https://pubmed.ncbi.nlm.nih.gov/36517990/

C10403 The impact of early PEG-asparaginase discontinuation in young adults with ALL: A post hoc analysis of the C10403 study. Aldoss I, Yin J, Wall A, Mrozek K, Liedtke M, Claxton D, Foster M, Appelbaum F, Erba H, Litzow M, Tallman M, Stone R, Advani A, Stock W, Luger S. Blood Advances Jan 24;7(2):196-204, 2023.

https://pubmed.ncbi.nlm.nih.gov/36269846/

Multiple Studies* Identification and Validation of Novel Prognostic Transcript Biomarkers in CD34-Positive Blasts from Patients with AML: A SWOG Report. Pogosova-Agadjanyan E, Hua X, Othus M, Appelbaum F, Chauncey T, Erba H, Fitzgibbon M, Godwin J, Jenkins I, Fang M, Moseley A, Naru J, Radich J, Willborg B, Willman C, Wu F, Meshichi S, Stirewalt D. Biomarker Research, accepted 2023. [*S0106,S0112,S9031,S9333]

Multiple Studies* Long Non-coding RNA Expression Independently Predicts Outcome in Pediatric Acute Myeloid Leukemia. Ferrar J, Smith J, Othus M, Huang B, Wang Y, Ries R, Hylkema T, Pogosova-Agadjanyan E, Leonti A, Shaw T, Triche T, Gamis A, Aplenc R, Kolb E, Ma X, Stirewalt D, Alonzo T, Meshinchi S. Journal of Clinical Oncology, Feb 16; JCO2201114. doi: 10.1200/JCO.22.01114. Online ahead of print., 2023.. [*S0106,S0112,S9031,S9333,OTHER] https://pubmed.ncbi.nlm.nih.gov/36795987/

Multiple Studies* Early Mortality Risk with Non-Intensive Acute Myeloid Leukemia (AML) Therapies: Analysis of 1,336 Patients from MRC/NCRI and SWOG. Othus M, Thomas I, Wang X, Ariti C, Mehta P, Sydenham M, Hills R, Burnett A, Nand S, Assouline S, Michaelis L, Erba H, Russell N, Kerr K, Walter R, Dennis M. Leukemia and Lymphoma Jan;64(1):250-252. 2023. [*S0432,S0702,S1612,MULTIPLE]

https://pubmed.ncbi.nlm.nih.gov/36226777/

Submitted Manuscripts

Multiple Studies* Examining the impact of age on the prognostic value of ELN-2017 and ELN-2022 AML risk stratifications: A SWOG report. Termini C, Moseley A, Othus M, Appelbaum F, Chauncey T, Erba H, Fang M, Lee S, Naru J, Pogosova- Agadjanyan E, Radich J, Willman C, Wu F, Meshinchi S, Stirewalt D. Blood Advances, submitted 2023. [*S0106,S0112,S9031,S9333]

LUNG COMMITTEE

Published/Accepted Manuscripts

S1400I Novel Approaches for Dynamic Visualization of Adverse Event Data in Oncology Clinical Trials: A Case Study Using Immunotherapy Trial S1400-I (SWOG). Lee S, Fan W, Wang A, Vaidya R, Redman M, Gettinger S, Bazhenova L, Herbst R, Hershman D, Unger J. <u>JCO Clinical Cancer Informatics</u>, accepted 2023.[see also CCD Committee]

S1400! Quality-of-life outcomes and risk-prediction for advanced lung cancer treated with Nivolumab/Ipilimumab vs Nivolumab. Unger J, Qian L, Redman M, Tavernier S, Minasian L, Sigal E, Papadimitrakopoulou V, LeBlanc M, Cleeland C, Dzingle S, Summers T, Chao H, Madhusudhana S, Villaruz L, Crawford J, Gray JE, Kelly KL, Gandara DR, Bazhenova L, Herbst RS, Gettinger S, Moinpour C. Journal of the National Cancer Institute Jan 10;djad003.



doi:10.1093/jnci/djad003. Online ahead of print, 2023. [see also SXCQOL committee] https://pubmed.ncbi.nlm.nih.gov/36625510/

C140503 Lobar or Sublobar Resection for Peripheral Stage IA Non-Small-Cell Lung Cancer. Altorki N, Wang X, Kozono D, Watt C, Landreneau R, Wigle D, Port J, Jones D, Conti M, Ashrafi A, Lieberman M, Yasufuku K, Yang S, Mitchell J, Pass H, Keenan R, Bauer T, Miller D, Kohman L, Stinchcombe T, Vokes E.New England Journal of Medicine Feb 9;388(6):489-498, 2023. https://pubmed.ncbi.nlm.nih.gov/36780674/

Submitted Manuscripts

S1507 Phase II study of docetaxel and trametinib in patients with G12C and non-G12C KRAS mutation positive recurrent non-small cell lung cancer (NSCLC) (SWOG S1507, NCT). Gadgeel S, Miao J, Riess J, Mack P, Gerstner G, Burns T, Taj A, Akerley W, Dragnev K, Laudi N, Moon J, Gray JE, Gandara DR, Kelly KL. Clinical Cancer Research, under revision for resubmission, 2023.

LYMPHOMA COMMITTEE

Published/Accepted Manuscripts

C50303 Is local review of positron emission tomography scans sufficient in diffuse large B-cell lymphoma clinical trials? A CALGB 50303 analysis. Torka P, Pederson L, Knopp M, Poon D, Zhang J, Kahl B, Higley H, Kelloff G, Friedberg JW, Schwartz L, Wilson W, Leonard J, Bartlett N, Schoder H, Ruppert A.

Cancer Medicine Feb 17. doi:10.1002/cam4.5628. Online ahead of print, 2023. https://pubmed.ncbi.nlm.nih.gov/36799072/

Multiple Studies* The Advanced-Stage Hodgkin Lymphoma International Prognostic Index (A-HIPI): Development and Validation of a Clinical Prediction Model from the HoLISTICConsortium. Rodday A, Parsons S, Upshaw J, Friedberg JW, Gallamini A, Hawkes E, Hodgson D, Johnson P, Link B, Mou E, Savage K, Zinzani P, Maurer M, Evens A. Journal of Clinical Oncology 2022 Dec 10;JCO2202473. doi: 10.1200/JCO.22.02473. Online ahead of print, 2022. [*S0816,OTHER]

https://pubmed.ncbi.nlm.nih.gov/36495588/

Submitted Manuscripts

S0016 Impact of intra-clonal genetic heterogeneity on progression of follicular lymphomaRunning title: genetic heterogeneity in follicular lymphoma. Burack R, Li H, Adlowitz D, Spence J, Rimsza L, Shadman M, Spier C, Kaminski M, Leonard J, LeBlanc M, Smith S, Friedberg J. <u>Blood Advances</u>, submitted 2023.

CTSU 9177 Prognostic Factors for Adult Burkitt Lymphoma Patients Treated with Dose-Adjusted EPOCH-R. Lakhotia R, Kieron D, Abramson J, Brian K, Powell B, Melani C, Lucas N, Steinberg S, Friedberg JW, Kahl B, Little R,

Bartlett N, Noy A, Wilson W, Roschewski M. <u>Blood</u> [Brief Report], submitted. 2023.

MELANOMA COMMITTEE

Published/Accepted Manuscripts

S1404 Adjuvant pembrolizumab improves quality-of-life outcomes compared to high dose interferon or ipilimumab in patients with resected melanoma; SWOG S1404, A Randomized Clinical Tria.Unger J, Darke A, Othus M, Tarhini A, Kirkwood J, Sharon E, Sondak V, Guild S, Truong T, Eroglu Z, Kendra K, Lewis K, Faller B, Funchain P, Buchbinder E, Grossmann K, Ribas A, Patel S. JAMA Oncology Feb 1;9(2):251-260, 2023. [see also CCD Committee] https://pubmed.ncbi.nlm.nih.gov/36416836/

S1801 Neoadjuvant versus adjuvant pembrolizumab for resectable stage III-IV melanoma. Patel SP, Othus M, Chen Y, Wright GP, Yost K, Hyngstrom J, Hu-Lieskovan S, Lao C, Fecher L, Truong T-G, Eisenstein J, Chandra S, Sosman J, Kendra K, Wu R, Devoe C, Deutsch G, Hedge A, Khalil M, Reese A, Ross M, Poklepovic A, Phan G, Onitilo A, Gokalp Yasar D, Powers B, Doolittle G, In G, Kokot N, Gibney G, Atkins M, Shaheen M, Warneke J, Ikeguchi A, Eugenio Najero J, Chmielowski B, Crompton J, Floyd J, Hsueh E, Margolin K, Chow W, Grossmann K, Dietrich E, Prieto V, Lowe M, Buchbinder E, Kirkwood J, Korde L, Moon J, Sharon E, Sondak V, Ribas A. New England Journal of Medicine Mar 2;388(9):813-823, 2023. https://pubmed.ncbi.nlm.nih.gov/36856617/

EA6134 Combination Dabrafenib and Trametinib Versus Combination Nivolumab and Ipilimumab For Patients With Advanced BRAF-Mutant Melanoma: The DREAMseq Trial-ECOG-ACRIN EA6134. Atkins M, Lee S, Chmielowski B, Tarhini A, Truong Moon, Davar D, O'Rourke M, Curti B, Brell J, Kendra K, Ikeguchi A, Wolchok A, Ribas A, Kirkwood J. <u>Journal of Clinical Oncology</u> Jan 10;41(2):186-197, 2023.

https://pubmed.ncbi.nlm.nih.gov/36166727/

Submitted Manuscripts

(none this cycle)

PHARMACEUTICAL SCIENCES COMMITTEE

Published/Accepted Manuscripts

(none this cycle)

Submitted Manuscripts

(none this cycle)



