

Welcome (Back)!

t has been two and one-half years since we last met face to face at a SWOG group meeting!

I'm thrilled to again have a chance to sit across the table from you rather than across the country, doing so in a way to minimize our risk from COVID-19.

This is SWOG's first truly "hybrid" group meeting. This simply means all sessions will also have a virtual component. All will be streamed live, and in many sessions, virtual participants will be able to submit questions or comments via a chat function.

I want to extend a particular thanks to those who have probably physically traveled farthest to be here – our colleagues from Central and South America. A face-to-face SWOG Latin America Initiative Symposium will be a high point of our meeting.



Other special events include a symposium on how oncology advanced practice providers can (and do!) contribute to SWOG research, and a special session on diversity, equity, and inclusion in genitourinary oncology (which has registered more than 100 attendees).

And then there are our plenary sessions. Our translational medicine plenary (Plenary I) will feature a progress report on some TM work supported by Hope Foundation grants and updates on TM in GU oncology and on working with CIMACs (Cancer Immune Monitoring and Analysis Centers). In Plenary II, after my updates on the state of SWOG, we'll hear progress reports on our truly important myeloma, GU, and NCORP research.

I'm really looking forward to seeing all of you in person once again. Welcome to Seattle!

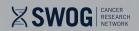
Charles D. Blanke, MD

SWOG Chair

Chalo Ble My

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Just What Is a "Hybrid" Meeting?

SWOG's first 85 or so group meetings were face-to-face affairs. With the arrival of COVID-19, we conducted our last four group meetings entirely virtually.

This time around, we're taking a middle route — the hybrid meeting.



This means all meeting sessions will be held in person in Seattle but will also be accessible everywhere via Zoom.



Zoom links to all open meetings are posted on the virtual meeting page on the SWOG website. Zoom links to closed, invitation-only meetings will be 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.



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 sessions will be recorded, and recordings will be available to attendees.

Meeting Plenary Sessions

Plenary I

Thursday, April 7, 3:00 - 4:30 pm PT
This spring's translational medicine plenary will feature the following speakers and topics:



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



Hope Award
Progress Update

Priyanka Sharma, MD

Univ of Kansas Cancer Center



Translational Medicine in GU Cancers

David J. McConkey, PhD

Johns Hopkins University



CIMAC Update Ignacio I. Wistuba, MD MD Anderson Cancer Center

Plenary II

Year of Progress: Myeloma, GU, and NCORP Friday, April 8, 12:00 – 2:00 pm PT

Three SWOG leaders will report on their committees' most significant results and undertakings over the last year, perhaps with glimpses of the year to come. Presentations will be followed by brief Q&A sessions.



Chair's Welcome and Update Charles D. Blanke, MD, FASCO, FAWM

SWOG Group Chair OHSU Knight Cancer Institute



Myeloma Research Updates

Robert Z. Orlowski, MD, PhD SWOG Myeloma Committee Chair MD Anderson Cancer Center



Genitourinary Research Updates

lan M. Thompson, Jr., MD SWOG Genitourinary Committee Chair Children's Hospital of San Antonio



NCORP Research Updates

Dawn L. Hershman, MD, MS SWOG Vice Chair for NCORP Research Columbia University

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.



Friday, April 8 | 9 – 11 am PT

Symposium: Radiation Oncology:

Targeting Oligometastatic Disease in GU Cancers

The symposium will cover the use of radiosurgery for metastatic genitourinary cancers. Presentation topics will include



defining oligometastatic disease



considerations when integrating systemic therapy and radiation for metastatic cancer



radiomics of oligometastatic disease treatment



practical considerations



radiation plan quality assurance considerations

and much more.

PRESENTERS INCLUDE



James Yu, MDDavid McConkey, PhD





Phuoc Tran, MD, PhDSanjay Aneja, MD





Abhishek Solanki, MDTJ Fitzgerald, MD





Chad Tang, MDBridget Koontz, MD





• Austin Kirschner, MD, PhD





THIS WILL BE AN INFORMATIVE SYMPOSIUM YOU WON'T WANT TO MISS!



Thanks To Our **CME Supporters!** We Value Their Partnership Lilly AbbVie AstraZeneca **Exact Sciences** Novocure



Wednesday, April 6 | 3 – 5pm PT

TAKE ACTION Symposium:

American Indians, Ensuring Equity in Clinical Research

Presented by SWOG Recruitment & Retention Committee



Ronny A. Bell, PhD, MS

Dr. Bell is a member of the Lumbee tribe and is a professor of social sciences and health policy, associate director of community outreach and engagement, and director of the Office of Cancer Health Equity at Wake Forest.



Linda Burhansstipanov, MSPH, DrPH

Dr. Burhansstipanov is a member of the Cherokee Nation.

She founded the Native American Cancer Research
Corporation (NACR) and Native American Cancer
Initiatives (NACI).



Daniel G. Petereit, MD, FABS, FASTRO

Dr. Petereit is a radiation oncologist and a PI of the Walking Forward Cancer Disparity Program. He has published on the establishment of trust within tribal communities.

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

OBJECTIVES:

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

Address cultural values of the specific population that support building trust

Review the current environment of the American Indian population that impacts trial participation

TAKE ACTION

Recruitment & Retention

Diversity, EQUITY, & Inclusion

Disparities Research Trust







Saturday, April 9 | 12 – 2 pm PT

Symposium: Diversity, Equity, and Inclusion in GU Oncology in SWOG

The SWOG GU committee will host an interactive symposium to develop goals and task forces to enhance diversity, equity, and inclusion (DEI) within the committee.

All are welcome to attend this symposium, GU committee members or not!

Panelists will share perspectives and experiences, but much of the time will be devoted to Q&A so members can share concerns and all can learn from each other's experiences.



Symposium moderators
Tanya Dorff, MD, City
of Hope Comprehensive
Cancer Center, and Ulka
Vaishampayan, MD,
University of Michigan



Rogel Cancer Center, will open the session with a brief overview of the characteristics of the GU committee membership and leadership.

PANELISTS

- Chunkit Fung, MD
 University of Rochester &
 ASCO Sexual Minority Task Force
- Joël Pointon
 SWOG patient advocate
- Chanita Hughes Halbert, PhD
 Director, Transdisciplinary
 Collaborative Center in Precision
 Medicine and Minority Men's Health,
 University of Southern California
- Hayley Thompson, PhD Wayne State University
- Desiree Walker
 SWOG patient advocate

Organizers would love for members of other committees to join the symposium!





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; and Bone Marrow & Stem Cell Transplantation Committee

Continuing Medical Education Credit

The Hope Foundation is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. 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 28.25 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



Complete the evaluation questions



Enter the credits being claimed



Press "submit"

Your certificate will automatically be emailed to you. Problems or questions?

Contact Courtney Wille in the SWOG operations office at cwille@swog.org. To keep track of your credits during the meeting, use the form on the next page.



Track Your CME Credits

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. Return to cwille@swog.org. Your certificate will be emailed to you.

		Credi	ts
Day/Time	Session Title	Available	Actual
WEDNESDAY, APRIL 6	, 2022		
12:30 pm - 2:30 pm	Digital Engagement Committee	2.0	
4:30 pm - 6:30 pm	Immunotherapeutics Committee	2.0	
THURSDAY, APRIL 7, 2	2022		
8:00 am – 10:00 am	Cancer Survivorship Committee	2.0	
10:00 am – 12:00 pm	Bone Marrow & Stem Cell Transplantation Committee	2.0	
10:00 am - 12:15 pm	Early Therapeutics and Rare Cancers Committee	2.25	5
10:15 am – 12:15 pm	Cancer Care Delivery Committee	2.0	
5:00 pm - 7:00 pm	Palliative and End of Life Care Committee	2.0	
FRIDAY, APRIL 8, 2022	2		
7:00 am - 9:00 am	Barlogie-Salmon Myeloma Committee	2.0	
7:30 am - 9:30 am	Symptom Control and Quality of Life Committee	2.0	
9:00 am – 11:00 am	Radiation Oncology: Targeting Oligometastatic		
	Disease in GU Cancers	2.0	
9:00 am – 12:00 pm	Lymphoma Committee	3.0	
9:45 am – 11:45 am	Prevention and Epidemiology Committee	2.0	
12:00 pm - 2:00 pm	Plenary II (General)	2.0	
2:15 pm - 4:15 pm	Adolescent and Young Adult (AYA) Committee	2.0	
2:15 pm - 4:15 pm	Surgery Committee	2.0	
2:30 pm - 4:30 pm	Melanoma Committee	2.0	
3:00 pm - 5:00 pm	GI Committee	2.0	
3:15 pm - 6:15 pm	GU Committee Part I: Renal, Trans Med, Cancer Control	3.0	
3:30 pm - 6:30 pm	Breast Committee	3.0	
SATURDAY, APRIL 9, 2	022		
8:15 am – 10:15 am	Leukemia Committee	2.0	
8:30 am – 11:30 am	Lung Committee	3.0	
8:30 am – 11:30 am	GU Committee Part II: Bladder, Prostate	3.0	
12:00 pm - 2:00 pm	Diversity, Equity, and Inclusion in GU Oncology in SWOG	2.0	
12:00 pm - 2:00 pm	Radiation Oncology Committee	2.0	
Total Possible Credits	3	28.25	

SWOG Spring 2022 Hybrid Group Meeting:

Health & Safety

In deciding to attend this meeting, you assume all responsibility for your own health and safety. Please wear a mask in indoor public spaces unless eating, drinking, or presenting. Extra masks are available at the registration desk.

Full Vaccination and Booster Shot Required

Many SWOG members work with immunocompromised patients every day. The last thing they want is to bring a dangerous virus back with them after a trip to a meeting.

With this in mind, and given data showing reduced risk among those who have received a booster shot, SWOG requires that to attend the spring 2022 group meeting in person, you must be fully vaccinated (received all required doses of an FDA- or WHO-authorized two-dose or one-dose vaccine), and you must have received a vaccine booster shot prior to March 31.

The following are approved forms of vaccine verification. You must show one of these at the SWOG registration table when you pick up your name badge:



- A CDC vaccine card or photo of vaccine card
- Documented proof of vaccination from medical record or vaccine provider
- Proof of vaccination from your state or county
- Printed certificate or digital record from MyIRMobile.com (available in several states) or other apps
- QR code or digital copy of your COVID-19 vaccination record from a system such as Washington state's WA Verify

If you cannot or choose not to comply with the mandate, or if you are unable to travel to the meeting, please join us online for live-streamed sessions.



Free Rapid COVID-19 Tests



To help minimize the risk of spreading COVID-19 within SWOG group meeting venues, we are providing a rapid test kit to all attending members.

When you pick up your name badge, you will get a self-test kit (with 2 tests).

If you test positive for COVID-19 during the meeting, please consult the CDC website at https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html for guidance on how to reduce your chances of infecting others.

If you test positive and need additional rapid tests, have questions about hotel policy, or need help with changing your travel plans, please reach out to us at healthandsafety@swog.org.





Our Top Accruers

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

These members topped the charts for SWOG-credited registrations to SWOG managed trials in 2021.

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

NCORP

Southeast Clinical Oncology Research Consortium NCORP

Kaiser Permanente NCORP

Heartland Cancer Research NCORP

Cancer Research Consortium of West Michigan NCORP

Gulf South Minority
Underserved NCORP

Main Member / LAPS

USC Norris Comprehensive Cancer Center

University of Texas MD Anderson
Cancer Center

City of Hope Comprehensive Cancer Center

University of Utah Huntsman
Cancer Institute

University of Rochester







Support SWOG Today

Hope Funds Research, Education, and Group Meetings!

Whether through a cash donation made now, or a planned gift for the future, you can make a direct impact for our network and patients. Thank you for your support of our shared mission to improve and lengthen lives.

thehopefoundation.org/donate



Support SWOG through planned giving

Your legacy gift will be an important part of imagining our shared future advancing clinical trials for patients everywhere.

Prefer the option of a stock gift?

Donating assets has never been easier using our online tool.

Learn more at thehopefoundation.org/donate

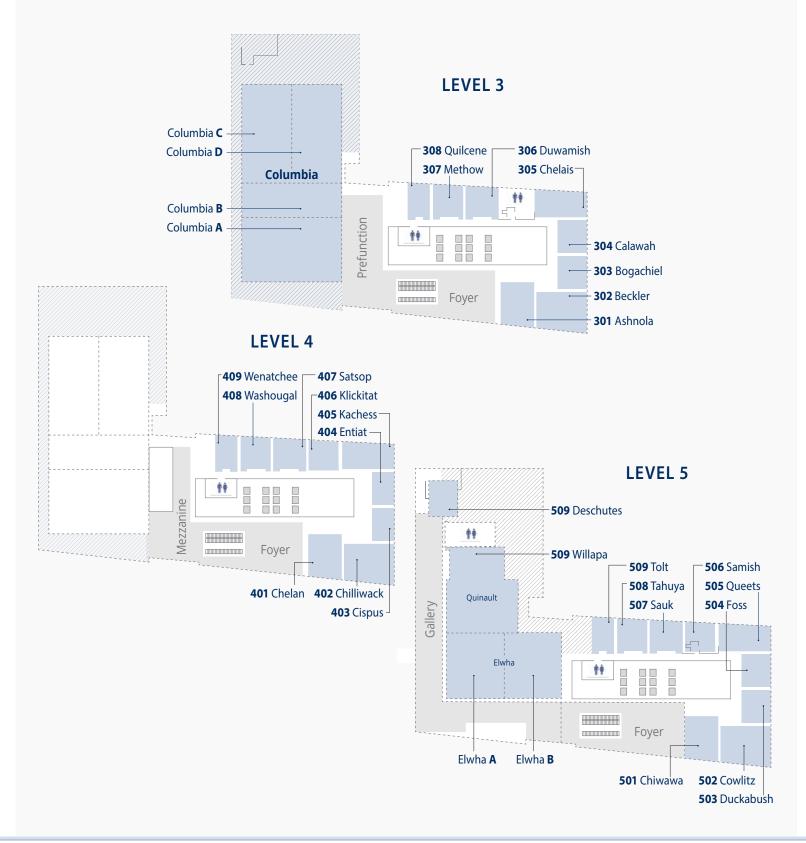
Or contact us about adding Hope to your estate plan

THE HOPE
FOUNDATION
FOR CANCER RESEARCH



Hyatt Regency Seattle Floor Levels

808 Howell Street | Seattle, WA 98101 | hyattregencyseattle.com | Phone: 206-973-1234



Seattle Travel & Hotel Information

808 Howell Street | Seattle, WA 98101 | hyattregencyseattle.com | Phone: 206-973-1234

Arrival/Departure:

Check-in time is **4:00 p.m.** Check-out time is **11:00 a.m.** Room amenities include a full bath, hair dryer, ironing board and iron, coffeemaker, refrigerator and in-room safe. The concierge staff serves as a liaison between guests and the hotel and outside services.

Hotel Safety Deposit Boxes:

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

Recreational Facilities:

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

Hotel Restaurants and Lounges:

 Andare Kitchen & Bar: Combines Italian flavors with fresh Seattle ingredients. Enjoy wood-fired pizzas, homemade pasta or salads

- and signature desserts. Restaurant is located on the Lobby Level and is open Sunday Thursday from 11:00 a.m. 9:30 p.m. and Friday-Saturday from 11:00 a.m. 11:00 p.m.
- Daniel's Broiler Lounge: The Rickhouse Whiskey Bar, located within
 Daniel's Broiler, features a wide selection of whiskey and other fine
 spirits from around the globe and TV's for viewing sports, all within a
 speak easy like setting. Lounge is located on the second floor and is
 open Tuesday Saturday from 4:00 p.m. to close.
- Market: The Market has a selection of personalized espresso beverages, pastries, freshly prepared sandwiches and salads, hot entrees and more. Market is located on the second floor and is open daily from 6:30 a.m. 11:00 a.m.

Business Center:

The Business Center is located on the second level. The Business Center offers fax machines, computer services, color copies, Internet access and photocopying.

THE ROBERT B. LIVINGSTON LECTURE

Collaborations with Bob Livingston: A Lasting Legacy

Presented with the breast committee session

Friday, April 8 | 3:30 pm PT
Featuring Daniel F. Hayes, MD | University of Michigan Rogel Cancer Center



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.



LUNG-MAP UPDATE MEETING | FRIDAY, APRIL 6, 2:30 – 4 PM PT

A Master Protocol to Evaluate Biomarker-Driven and Immune Therapies in Previously Treated Non-Small Cell Lung Cancer

CURRENT LUNG-MAP SUB-STUDIES:

- S1800D: N-803 + pembrolizumab vs standard of care in patients with Stage IV or recurrent NSCLC previously treated with anti-PD-1/PD-L1 therapy
- S1900E: Sotorasib (AMG 510) in patients with previously treated Stage IV or recurrent KRAS G12Cmutated NSCLC

Come learn more about where the NCI's first precision medicine master protocol is and where it is going.



All welcome! Can't attend in person? Attend virtually at bit.ly/3Mh6zut

Learn more about upcoming trials and partnership opportunities at the

SWOG CTP Update Forum

Wednesday, April 6, 11:30 am - 12:30 pm PT

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

CANCER CLINICAL TRIALS

swogctp.org

SWOG CLINICAL
TRIALS PARTNERSHIPS

AN LLC OF THE HOPE FOUNDATION FOR CANCER RESEARCH





Friday, April 8 | 10 am - 12 pm PT

Special Symposium:

Oncology Advanced Practice Providers Can Enhance Clinical Research

Hosted by the nursing research subcommittee and the palliative and end of life care committee

Find out how to leverage the power of APPs in your setting to expand access to clinical trials for patients.

Presentations and a panel of experts from the NCI and research bases will include examples of best practices in both academic and community sites. This symposium is the first component of an initiative to increase APP involvement and will be followed by an APP-specific workshop at the fall meeting.

We hope you can join us!



WEDNESDAY, APRIL 6, 2022

Group Meeting Registration & Information Desk

6:30 am - 5:00 pm - Level 4 Foyer

7:00 AM - 7:20 AM

Columbia A Foyer, Level 3 CRA Clinical Trials Training Course

Check-In

7:20 AM - 12:10 PM

CRA Clinical Trials Training Course

9:00 AM - 12:00 PM

Willapa, Level 5 Advocates Committee

(Invitation Only)

10:00 AM - 12:00 PM

306, Level 3 ORP Education Subcommittee

(Invitation Only)

11:30 AM - 12:30 PM

402, Level 4 Clinical Trials Partnerships Update Forum

12:30 PM - 2:00 PM

307, Level 3 Core Office Staff Networking Session

(Invitation Only)

12:00 PM - 1:45 PM

401, Level 4 Nursing Research Subcommittee

(Invitation Only)

12:30 PM - 2:30 PM

405, Level 4 Digital Engagement Committee

1:45 PM - 4:00 PM

Columbia A, Level 3 CRA Clinical Trials Training Course

Practicum

2:00 PM - 4:00 PM

403, Level 4 SWOG Tissue Banking Meeting

(Invitation Only)

3:00 PM - 5:00 PM

402, Level 4 Take Action Symposium: American

Indians, Ensuring Equity in Clinical
Research — presented by the SWOG

Recruitment and Retention Committee

3:30 PM - 5:00 PM

307, Level 3 Hope Foundation Board Meeting

(Invitation Only)

4:30 PM - 5:30 PM

401, Level 4 ORP Liaison Subcommittee

4:30 PM - 6:30 PM

Quinalt, Level 5 Immunotherapeutics Committee

5:30 PM - 7:30 PM

Columbia A, Level 3 Site Operations

5:30 PM - 8:00 PM

Willapa, Level 5 NCORP Research Base Executive

Committee Meeting (Invitation Only)



THURSDAY, APRIL 7, 2022

Group Meeting Registration & Information Desk

6:30 am - 5:00 pm - Level 4 Foyer

Hope Foundation Information Desk

8:00 am - 5:00 pm - Level 4 Foyer

Exhibits & Complimentary Coffee Service

8:00 am - 5:00 pm - Level 4 Foyer

7:00 AM - 8:00 AM

302, Level 3 NCORP/MU-NCORP Site PI Meeting

7:30 AM - 8:00 AM

Columbia B, Level 3 Jeri & Noboru Oishi Symposium Check-In

8:00 AM - 10:00 AM

307, Level 3 Quality Initiative Meeting

(Invitation Only)

8:00 AM - 11:30 AM

Columbia C, Level 3 Jeri & Noboru Oishi Symposium

8:00 AM - 10:00 AM

Quinalt, Level 5 Cancer Survivorship Committee

10:00 AM - 12:00 PM

Elwha B, Level 5 Bone Marrow & Stem Cell Transplantation

Committee

10:00 AM - 12:15 PM

Columbia D, Level 3 Early Therapeutics and Rare Cancers

Committee

10:00 AM - 12:15 PM

302, Level 3 SWOG Latin America Initiative

Symposium

10:15 AM - 12:15 PM

Quinalt, Level 5 Cancer Care Delivery Committee

12:00 PM - 1:00 PM

504, Level 5 Clinical Trials Partnerships Scientific

Advisory Board (Invitation Only)

12:00 PM - 2:00 PM

301, Level 3 Lung-MAP Site Coordinators Committee

(Invitation Only)

12:30 PM - 2:00 PM

Columbia C, Level 3 ORP Open Forum

1:00 PM - 2:00 PM

402. Level 4 S1912CD Breakout Session

1:00 PM - 2:30 PM

307, Level 3 ETxRC Committee Sarcoma Working

Group (Invitation Only)

1:00 PM - 3:00 PM

Elwha B, Level 5 Breast Working Group (Invitation Only)

1:00 PM - 3:00 PM

401, Level 4 Patient Advocacy Focus Group for

PREPARE For Your Care Activation Study

Concept (Invitation Only)

2:00 PM - 3:00 PM

302, Level 3 S2108CD Breakout Session

2:00 PM - 3:00 PM

Columbia Foyer, Level 3 Plenary Reception

3:00 PM - 4:30 PM

Columbia AB, Level 3 Plenary I (Translational Medicine)

4:30 PM - 6:30 PM

301, Level 3 Lung-MAP Administrative Meeting

(Invitation Only)

4:30 PM - 7:30 PM

Willapa, Level 5 Myeloma Working Group

(Invitation Only)

4:45 PM - 6:45 PM

302, Level 3 GI Translational Medicine Working Group

(Invitation Only)

5:00 PM - 7:00 PM

402, Level 4 Lymphoma Working Group

(Invitation Only)

5:00 PM - 7:00 PM

504, Level 5 Conflict Management Committee

(Invitation Only)

5:00 PM - 7:00 PM

Quinalt, Level 5 Palliative and End of Life Care Committee

5:00 PM - 7:00 PM

401, Level 4 Early Therapeutics Working Group

(Invitation Only)



FRIDAY	', APRIL 8	3 <i>, 2022</i>
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Group Meeting Registration & Information Desk 6:30 am - 5:00 pm - Level 4 Foyer

Hope Foundation Information Desk 8:00 am - 5:00 pm - Level 4 Foyer

Exhibits & Complimentary Coffee Service 8:00 am - 5:00 pm - Level 4 Foyer

7:00 AM - 9:00 AM

Columbia C, Level 3 Barlogie-Salmon Myeloma Committee

7:30 AM - 8:30 AM

303, Level 3 Lung Surgical Subcommittee (Invitation

Only)

7:30 AM - 9:30 AM

Columbia A, Level 3 Symptom Control and

Quality of Life Committee

7:30 AM - 9:30 AM

301, Level 3 Imaging Committee (Invitation Only)

7:30 AM - 9:30 AM

307, Level 3 SWOG Data and Safety Monitoring

Committee (Invitation Only)

7:30 AM - 9:30 AM

302, Level 3 Melanoma Working Group

(Invitation Only)

8:00 AM - 9:30 AM

408, Level 4 Professional Review Committee

(Invitation Only)

8:00 AM - 10:00 AM

401, Level 4 Breast Translational Medicine Working

Group (Invitation Only)

8:00 AM - 10:00 AM

305, Level 3 Pharmaceutical Sciences Committee and

Drug Information Subcommittee

8:00 AM - 12:00 PM

402, Level 4 GI Working Group (Invitation Only)

8:30 AM - 9:30 AM

303, Level 3 Lung Radiation Subcommittee (Invitation

Only)

8:30 AM - 9:30 AM

407, Level 4 Lung Translational Medicine

Subcommittee (Invitation Only)

9:00 AM - 11:00 AM

405, Level 4 CNS Working Group

9:00 AM - 11:00 AM

Columbia D, Level 3 Radiation Oncology: Targeting

Oligometastatic Disease in GU Cancers

9:00 AM - 12:00 PM

Quinalt, Level 5 Lymphoma Committee

9:45 AM - 11:45 AM

302, Level 3 Lung Working Group (Invitation Only)

9:45 AM - 11:45 AM

Elwha B, Level 5 Prevention and Epidemiology Committee

10:00 AM - 11:30 AM

304, Level 3 Quality Assurance Committee Meeting

(Invitation Only)

10:00 AM - 12:00 PM

Elwha A, Level 5 Special Symposium: Oncology Advanced

Practice Providers Can Enhance Clinical

Research

11:00 AM - 12:00 PM

Columbia Foyer, Level 3 Plenary Reception (Light Hors D'oeuvres)

11:30 AM - 12:00 PM

307, Level 3 Publications Committee (Invitation Only)

12:00 PM - 2:00 PM

Columbia AB, Level 3 Plenary II (General)

2:15 PM - 4:15 PM

302, Level 3 Adolescent and Young Adult (AYA)

Committee

2:15 PM - 4:15 PM

402, Level 4 Surgery Committee



FRIDAY, APRIL 8, 2022

Group Meeting Registration & Information Desk 6:30 am - 5:00 pm - Level 4 Foyer

Hope Foundation Information Desk 8:00 am - 5:00 pm - Level 4 Foyer

Exhibits & Complimentary Coffee Service 8:00 am - 5:00 pm - Level 4 Foyer

2:30 PM - 4:00 PM

Elwha A, Level 5 Lung-MAP Update Meeting

2:30 PM - 4:30 PM

VIRTUAL ONLY Leukemia Working Group (Invitation

Only)

2:30 PM - 4:30 PM

Quinalt, Level 5 Melanoma Committee

2:45 PM - 4:45 PM

405, Level 4 VA Committee

3:00 PM - 5:00 PM

301, Level 3 ORP Executive Committee

(Invitation Only)

3:00 PM - 5:00 PM

Elwha B, Level 5 GI Committee

3:15 PM - 6:15 PM

Columbia CD, Level 3 GU Committee Part I: Renal Cancer

Organ Site; TM Organ Site;

Cancer Control

3:30 PM - 6:30 PM

Columbia A, Level 3 Breast Committee

6:00 PM - 7:00 PM

Executive Reception (Invitation Only)

6:45 PM - 8:30 PM

Level 3 Foyer Group Reception

SATURDAY, APRIL 9, 2022

Group Meeting Registration & Information Desk 6:30 am - 12:00 pm - Level 4 Foyer

Hope Foundation Information Desk 8:00 am - 12:00 pm - Level 4 Foyer

7:00 AM - 7:45 AM

Elwha B, Level 5 Board of Governors (Invitation Only)

8:15 AM - 10:15 AM

VIRTUAL ONLY Leukemia Committee

8:30 AM - 11:30 AM

Columbia A, Level 3 Lung Committee

8:30 AM - 11:30 AM

Columbia CD, Level 3 GU Committee Part II: Bladder Cancer

Organ Site; Prostate Cancer Organ Site

12:00 PM - 5:30 PM

402, Level 4 NCORP Strategic Retreat (Invitation Only)

12:00 PM - 2:00 PM

Elwha B, Level 5 Diversity, Equity, and Inclusion in GU

Oncology in SWOG

12:00 PM - 2:00 PM

301, Level 3 Radiation Oncology Committee



Upcoming Funding Opportunities

Virtual Grant Writing Workshop: May 1

NCORP Pilot Grants: June 1

SEED Fund Program: July 1

• Impact Award Program: July 1

VA Integration Support Program: August 1

See all Hope Foundation programs at

THEHOPEFOUNDATION.ORG/FUNDING-OPPORTUNITIES

THE HOPE
FOUNDATION
FOR CANCER RESEARCH

Committees

Administrative Committees

Board of Governors Charles D. Blanke, MD

Conflict ManagementPaul Okunieff, MD

PublicationsHagen F. Kennecke, MD

Professional ReviewPaul Hesketh, MD

Research Support Committees

Adolescent and Young Adult

Rebecca Johnson, MD

Bone Marrow and Stem Cell Transplantation

Patrick J. Stiff, MD

Digital Engagement

Don S. Dizon, MD

Imaging

Lawrence H. Schwartz, MD

Immunotherapeutics

Siwen Hu-Lieskovan, MD, PhD

Katerina Politi, PhD

Oncology Research Professionals

Connie Szczepanek, RN, BSN, CCRP Patient Advocates

Rick Bangs, MBA

Pharmaceutical Sciences

Siu-Fun Wong, PharmD

Radiation Oncology

Interim Chair Iames Yu. MD

Recruitment and

Retention

Allison Caban-Holt, PhD

Surgery

Syed A. Ahmad, MD

Veterans Affairs

Stephen D. Bartlett, RPh

Future Meeting Dates

2022

Fall

October 19-22 Chicago, IL

2023

Spring Fall
April 26-29 October 11-14
San Francisco, CA Chicago, IL

2024

Spring Fall
April 3-6 October 16-19
Seattle, WA Chicago, IL



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

Scientific Leadership

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

Digital Engagement:...... Saad Z. Usmani, MD, MBA

NCORP Representative:	Charles S. Kuzma, MD
Veterans Affairs:	Thomas R. Chauncey, MD, PhD
Data Coordinators:	Sean O'Bryan
	Hannah Hale
Oncology Research Professionals:	
CRA:	TBD
Nurses:	Deborah A. Shaw, RN

...... Teresa Witcher, BSN, RN Patient Advocate:.....Jack Aiello, MS Pharmaceutical Science: Craig Elg, PharmDlla M. Saunders, PharmD Protocol Project Manager: Sharon Palmer Clinical Trials Program Manager: TBD

Time/Location

Friday, April 8, 2022 7:00 - 9:00 am Room: Columbia C, Level 3

Agenda

Active Studies

\$1803, "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) Us-ing Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC Study)." Drs. A. Krishnan and P. Hari. Activated: 6/27/19.

- **S2005**, "A Phase II Randomized Study of Ibrutinib and Rituximab with or Without Venetoclax in Previous-ly Untreated Waldenström's Macroglobulinemia (WM)." Drs. S. Ailawadhi and D. Bhutani. Activated: 6/24/21. Temporarily Closed: 7/16/21. Re-opened to accrual: 10/15/21.
- **EAA171**, "Optimizing Prolonged Treatment in Myeloma Using MRD Assessment (OPTIMUM)." Dr. S. 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

- **S1211**, "A Randomized Phase I/II Study of Optimal Induction Therapy of Bortezomib, Dexamethasone and Lenalidomide with or Without Elotuzumab (NSC-764479) for Newly Diagnosed High Risk Multiple Myeloma (HRMM)." Drs. S. Usmani, S. Ailawadhi, and B. Lipe. Activated: 11/9/12. Closed: 6/2/16.
- **S1702**, "A Phase II Study of Isatuximab (SAR650984) (NSC-795145) for Patients with Previously Treated AL Amyloidosis." Drs. T. Parker and V. Sanchorawala. Activated: 3/08/18; 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. S. Ailawadhi, Activated: 10/18/13, Closed: 11/6/15,
- **S0777**, "Frontline Phase III Rev/Dex +/- Vel, no upfront transplant." Dr. B. Durie. Activated: 4/1/18. Closed: 2/2/12.
- **S0120**, "A prospective Observational Biologic Study of Asymptomatic Patients with Monoclonal Gammo-pathy and Plasmaproliferative Disorders." Dr. M. Dhodapkar. Activated: 6/1/02. Closed: 4/1/11.
- CTN 0702, "Single Autologous Transplant with or without RVD Consolidation versus Tandem Trans-plant and Maintenance Therapy." Dr. G. 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. A. Kuman Mahindra. Activated: 12/23/15. Closed: 8/15/19.



Tweeting the Meeting

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Barlogie-Salmon Myeloma Committee

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

E3A06 (was S0909), "High-risk AMM – Revlimid." Dr. M. 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. A. 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 Le-nalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDUR-ANCE)." Drs. S. Kumar, A. Cohen and J. Zonder, Activated: 11/22/13, Closed: 1/29/19.

Proposed Studies

52209, "A Phase III Randomized Trial for Newly Diagnosed Multiple Myeloma (NDMM) Patients Consid-ered Frail or Ineligible for Stem Cell Transplant Comparing Upfront Bortezomib-Lenalidomide-Dexamethasone-Lite (VRd-Lite) with Daratumumab-Lenalidomide-Dexamethasone (DRd)." Drs. S. Ai-lawadhi, C. Ye, and A. Gowin.

<u>\$2213</u>, "Daratumumab, Cyclophosphamide, Bortezomib, and Dexamethasone (D-VCD) Induction Fol-lowed by Autologous Stem Cell Transplant or D-VCD Consolidation and Daratumumab Maintenance in Patients with Newly Diagnosed AL Amyloidosis." Dr. P. Hagen

S1911, "Phase III Study of Optimal Induction Therapy for Newly Diagnosed High-Risk Multiple Myeloma (HRMM) RVd Dara +/- xx." Dr. B. Lipe.



Barlogie-Salmon Myeloma Committee

Accrual from trial opening through 12/31/2021 by Institution and Study

	51803	4061505	EAA173	EAA181
			<u>.</u>	
Ascension Providence Hospitals - Southfield	1	1	-	-
Banner University Medical Center - Tucson	6	-	-	-
Boston Medical Center	5	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	10	-	2	-
Cancer Research of Wisconsin and Northern Michigan Consortium	3	-	-	-
Cedars-Sinai Medical Center	5	-	-	-
City of Hope Comprehensive Cancer Center	66	-	-	-
Columbus NCI Community Oncology Research Program	7	-	-	-
CommonSpirit Health Research Institute	3	-	-	-
Dayton NCI Community Oncology Research Program	4	-	-	-
Duke University - Duke Cancer Institute LAPS	1	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	4	-
Georgia NCI Community Oncology Research Program	10	-	-	-
Gulf South Minority Underserved NCORP	2	-	-	-
Heartland Cancer Research NCORP	13	-	-	-
Henry Ford Hospital	-	1	-	-
Kaiser Permanente NCI Community Oncology Research Program	31	-	-	-
Lahey Hospital and Medical Center	3	-	-	-
Loyola University Medical Center	16	-	2	-
Medical University of South Carolina Minority Underserved NCORP	18	-	1	-
Moffitt Cancer Center	30	-	-	-
Montana Cancer Consortium NCORP	3	-	-	-
levada Cancer Research Foundation NCORP	-	-	1	-
New Mexico Minority Underserved NCORP	6	-	-	-
Ohio State University Comprehensive Cancer Center LAPS	4	-	-	-
Oregon Health and Science University	11	-	2	2
Pacific Cancer Research Consortium NCORP	5	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	3	-	-	-
UC Davis Comprehensive Cancer Center LAPS	15	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	2	-	-	-
University of Arkansas for Medical Sciences	-	-	-	1
University of Kansas Cancer Center - MCA Rural MU NCORP	18	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	7	-	-	-
University of Oklahoma Health Sciences Center LAPS	1	-	-	-
University of Rochester LAPS	11	-	-	-
University of Texas Health Science Center at San Antonio	11	-	-	-
University of Texas MD Anderson Cancer Center LAPS	17	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	10	-	2	-
Upstate Carolina Consortium Community Oncology Research Program	3	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	9	-	_	_
Wayne State Oniversity - Karmanos Cancer Institute LAFS Wisconsin NCI Community Oncology Research Program	13	-	_	
Yale University - Yale Cancer Center LAPS	-	_	2	
ALLIANCE	113		_	
ECOG-ACRIN	92 56		-	
NRG	56 644	2		



Leadership
Chair: Lajos Pusztai, MD, PhD
Vice-Chair:Priyanka Sharma, MD
Executive Officer: Anne Chiang, MD, PhD
Statisticians:William E. Barlow, PhD
Danika Lew, MA
Jieling Miao, MS
Scientific Leadership
Translational Medicine: Alastair M. Thompson, MD
Andrew K. Godwin, PhD
Radiation Oncology: Reshma Jagsi, MD
Surgery: Joshua M.V. Mammen, MD, PhD
Imaging:Joanne E. Mortimer, MD
Wei Tse Yang, MBBS
Pathology:
Early Therapeutics:TBD
Designates
Cancer Control Liaisons: Melinda L. Irwin, PhD, MPH (Survivorship)
Dawn L. Hershman, MD (Cancer Care Delivery)
Banu Arun, MD (Prevention)
Helen K. Chew, MD (Symptom Control & QOL)
Digital Engagement:Sarah S. Mougalian, MD
NCORP Representative:
Data Coordinators:
Larry Kaye
Ojasvi Mittal
Gabi Herbert
Oncology Research Professionals:
CRAs: Karyn N. Hart, CCRP
Avidanka Baftirovska, BS, CCRP
Nurse: TBD
Patient Advocates:
Roberta Albany
Pharmaceutical Science: Jorge G. Avila, PharmD
Dawud Nael Dawud Ellayan, PharmD
Protocol Project Manager: Alicia Aranda
Clinical Trials Program Manager: Michelle Maxim
Time/Location
Friday, April 8, 2022 3:30 - 6:30 pm
Room: Columbia A, Level 3

Leadershin

Agenda

3:30 – 3:35 pm Welcome and Introductions - Lajos Pusztai, M.D., D.Phil. (Chair) and Priyanka Sharma, M.D. (Vice-chair), and Alicia Aranda (SWOG Protocol Project Manager)

3:35 – 4:20 pm Robert Livingston lecture - "Collaborations with Bob Livingston: A Lasting Legacy" by Dr. Daniel F Hayes MD, FASCO, FACP

<u>4:20 – 4:30 pm</u> Publication update – William Barlow, Ph.D.

<u>4:30 – 4:40 pm</u> Patient Advocate update – Ginny Mason and Roberta

Albany

4:40 – 5:00 pm Translational Medicine Sub-Committee update -

Alastair Thompson, M.D. and Andrew K. Godwin, Ph.D.

5:00 – 5:40 pm Review of open CTSU trials

5:40 – 6:15 pm Recently approved and developing Concepts

<u>6:15 - 6:25 pm</u> Reports from Committee Liaisons

Radiotherapy - Reshma Jagsi, M.D.

Surgery – Joshua Mammen, M.D.

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

Cancer Care Delivery - Dawn Hershman, M.D.

Prevention – Banu Arun, M.D.

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

NCORP (NCI Community Oncology Research Program) – Philip Lammers, M.D.

DEI - Gayathri Nagaraj, M.D.

6:30 pm Closing Comments and Adjourn

Proposed Breast Cancer Committee Studies

S2202, "Phase II Clinical Trial for Patients with Minimal Residual Disease Despite Therapy for Triple Negative Breast Cancer with Trop-2 Antibody Drug Conjugate, Sacituzumab Govitecan (DETECT-01)." Drs. Bardia, Kalinsky, Bhave.

S2206, "Randomized Trial of Neoadjuvant Durvalumab 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.

S2212, "TIL Adapted Neo adjuvant Chemotherapy Optimization in Triple negative breast cancer (TACT-II)." Dr. Sharma



Active Breast Cancer Committee Studies

- **S2007**, "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.
- **S1706**, "A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy Alone for Inflammatory Breast Cancer." Drs. Jagsi, Chalasani, Moran, Speers. Activated: 09/12/18.
- <u>\$1007</u>, "A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and Her2-Negative Breast Cancer with Recurrence Score (Rs) of 25 or Less. Rxponder: A Clinical Trial Rx Fnr Positive Node, Endocrine Responsive Breast Cancer." Drs. Kalinsky, Meric-Bernstam. Step 3 open to accrual 07/22/2021.
- 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: 02/07/14.
- 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: 01/06/21.
- 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: 05/30/18.
- 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: 02/11/20.
- 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: 04/02/20.
- CTSU/NRG-BR002, "A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer." Drs. Chmura and White. SWOG

Champion: Dr. Jagsi. Activated: 12/24/14. Temporarily closed: 09/13/19.

- CTSU/NRG-BR003, "A Randomized Phase III Trial of Adjuvant Therapy
 Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly
 Paclitaxel with or without Carboplatin for Node-Positive or High-Risk
 Node-Negative Triple-Negative Invasive Breast Cancer." Dr. Valero. SWOG
 Champion: Dr. Makhoul. Activated: 06/26/15.
- 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: 03/12/19.
- CTSU/NRG-BR005, "A Phase II Trial Assessing the Accuracy of Tumor Bed Biopsies in Predicting Pathologic Response in Patients with Clinical/Radiologic Complete Response after Neoadjuvant Chemotherapy in Order to Explore the Feasibility of Breast Conserving Treatment without Surgery." Dr. Basik. SWOG Champion: Dr. Thompson. Activated: 04/13/17. Temporarily closed: 07/02/19.
- 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: 06/07/21.

Closed Breast Cancer Committee Studies

- 51418, "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, Mammen, Henry, Jagsi. Activated: 11/15/16. Permanently closed: 06/30/21.
- S1416, "Phase II Randomized Placebo-Controlled Trial of Cisplatin with or Without ABT-888 (Veliparib) in Metastatic Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer, with or Without Brain Metastases." Drs. Rodler, Sharma, Hicks, and Gralow. Activated 07/07/2016. Closed: 6/16/2019.
- **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: 09/04/13. Permanently closed: 05/01/19.
- **S1222**, "Fulvestrant Alone Versus Fulvestrant and Everolimus Versus Fulvestrant, Everolimus and Anastrozole: A Phase III Randomized



Accrual from trial opening through 12/31/2021 by Institution and Study

	51418	51706	52007	A011202	A017407	A011502	A011801	B51	EA1131	EA1181	EA1183	MA39	NRGBR003	NRGBRO
Ascension Prov Hospitals - Southfield	6	2	-	4	10	8	-	8	1	1	-	1	3	1
Ascension Via Christi Hospitals Wichita	9	-	-	-	-	-	-	-	-	-	-	-	-	-
Banner MD Anderson CC	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Banner U Med Ctr - Tucson	4	1	-	1	6	-	-	-	-	2	-	-	-	-
Baptist Mem HC/Mid South MU NCORP	9	3	-	1	4	-	-	-	-	-	-	-	-	1
Bay Area Tumor Inst NCORP	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Baylor U Med Ctr	-	-	-	1	-	-	-	2	-	-	-	-	-	-
Boston Med Ctr	-	-	-	-	3	-	-	-	-	2	-	-	-	-
CWRU Case CCC LAPS	12	-	-	-	2	-	-	5	-	-	-	1	9	1
Ca Res Consortium West Mich NCORP	24	-	-	-	1	-	-	-	-	-	-	-	-	-
Ca Res for the Ozarks NCORP	9	1	-	-	1	-	1	-	-	-	-	-	3	-
Ca Res of Wisconsin & N Mich Consort	7	-	-	-	-	-	-	-	-	-	-	-	-	-
Carle CC NCORP	3	-	1	-	-	-	-	-	-	-	-	-	-	-
City of Hope CCC	9	-	-	-	-	-	-	-	-	-	-	-	-	-
Columbia U MU NCORP	8	1	-	-	-	-	-	-	-	1	-	-	-	-
Columbus NCORP	13	-	-	-	-	-	-	-	-	-	-	-	-	-
CommonSpirit Health Research Inst	19	1	-	-	2	-	-	2	-	-	-	-	-	-
Cotton O'Neil CC / Stormont Vail HIth	-	-	-	1	1	-	-	-	-	-	-	-	1	-
Dayton NCORP	3	-	-	-	1	-	-	-	1	2	-	-	-	-
Desert Regional Med Ctr	1	-	-	7	4	-	-	4	-	-	-	-	-	-
Essentia Health NCORP	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	10	2	-	-	12	9	-	-	-	-	-	-	-	-
Georgia NCORP	23	2	-	-	2	1	-	-	4	-	-	-	1	-
Gulf South MU NCORP	5	1	-	-	-	-	-	-	-	2	-	-	4	-
Hawaii MU NCORP	5	-	-	-	-	-	-	-	-	-	-	-	-	-
Heartland Ca Res NCORP	19	3	-	-	-	1	-	-	-	-	-	-	-	-
Henry Ford Hospital	1	-	-	-	-	-	-	-	1	-	-	-	-	-
Houston Methodist Hospital	-	-	-	-	-	-	1	1	-	-	-	-	-	-
Kaiser Permanente NCORP	51	-	-	1	55	25	-	-	-	-	-	-	25	1
Lahey Hospital & Med Ctr	3	-	-	-	9	5	-	-	1	4	-	-	-	1
Loma Linda U Med Ctr	1	-	-	3	-	-	-	3	-	-	-	-	-	-
Loyola U Med Ctr	3	-	-	-	6	7	-	1	2	1	-	-	-	-
Massachusetts Veterans ERIC	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Medical U South Carolina MU NCORP	11	-	-	-	-	-	-	-	-	-	3	-	-	-
Meharry Medical College	-	-	-	-	3	-	-	-	-	-	-	-	1	-
Michigan Ca Res Consortium NCORP	21	1	-	-	-	-	-	-	-	-	-	-	-	-
Moffitt CC	-	-	-	1	3	2	-	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	2	3	-	-	-	-	-	-	-	-	-	-	-	-
Mount Sinai Hospital	3	-	-	-	-	-	-	-	-	-	-	-	-	-
NCORP Carolinas (Prisma HIth NCORP)	4	-	-	-	-	-	-	-	-	-	-	-	-	-
Nevada Ca Res Foundation NCORP	11	-	-	-	-	-	-	-	-	-	-	-	-	-
New Mexico MU NCORP	19	4	_	-	_	-	_	_	_	-		_	_	-



Accrual from trial opening through 12/31/2021 by Institution and Study

	51418	51706	52007	A011202	A017401	A011502	A011801	B51	EA1131	EA1181	EM183	MA39	NRGBR003	NRGBR
Northwell Health NCORP	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Northwestern U LAPS	2	1	-	-	-	-	-	-	-	2	1	-	1	-
Ohio State U CCC LAPS	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Oregon Health & Science U	19	-	-	-	-	-	-	1	-	-	3	-	3	-
Orlando Health Ca Inst	1	-	-	-	1	-	-	-	-	-	-	-	-	-
Pacific Ca Res Consortium NCORP	19	-	-	-	3	1	-	-	-	-	-	-	1	-
SCL Health Saint Joseph Hospital	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Salem Hospital	-	-	-	4	-	-	-	-	-	-	-	-	-	-
Scott & White Mem Hospital	-	-	-	-	4	-	-	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	46	-	-	-	-	6	-	-	-	-	-	-	-	-
Sutter Ca Res Consortium	3	-	-	-	8	2	2	2	1	3	-	-	4	2
Don & Sybil Harrington CC	7	3	-	11	8	-	1	1	-	-	-	-	-	-
James Graham Brown CC at U Louisville	-	-	-	2	-	-	-	-	-	-	-	-	-	-
West Clinic - Wolf River	-	-	-	9	-	-	-	4	-	-	-	-	-	-
UC Davis CCC LAPS	8	4	-	2	4	17	-	-	-	-	-	-	-	-
UC Irvine Health/Chao Family CCC	6	-	-	3	2	2	-	1	-	-	-	-	1	-
UC San Diego Moores CC	-	-	-	-	2	3	-	-	-	-	-	-	1	-
USC Norris CCC LAPS	3	-	-	4	-	6	-	-	-	-	-	2	-	-
U Arkansas for Medical Sciences	17	2	-	-	3	22	-	-	-	-	-	-	-	-
U Cincinnati CC-UC Med Ctr	-	-	-	-	-	-	-	1	-	-	-	-	-	-
U Colorado CC LAPS	11	1	-	42	27	7	1	3	-	10	-	-	-	-
U Kansas CC - MCA Rural MU NCORP	22	2	-	4	23	9	-	-	-	-	-	-	-	-
U Kentucky/Markey CC	-	-	-	-	-	3	-	1	-	-	-	-	-	-
U Michigan CCC LAPS	13	2	-	-	14	11	-	-	-	1	-	4	3	-
U Mississippi Med Ctr	-	-	-	-	-	-	-	-	-	1	-	-	-	-
U Oklahoma Health Sciences Ctr LAPS	2	-	-	-	-	-	-	-	-	-	-	-	-	-
U Rochester LAPS	2	1	-	-	-	15	-	-	7	1	-	-	9	-
U Texas HSC at San Antonio	5	-	1	6	2	1	-	5	-	-	-	-	4	-
U Texas MD Anderson CC LAPS	21	1	-	-	-	-	-	-	-	-	-	-	-	-
U Utah - Huntsman Ca Inst LAPS	6	2	-	-	7	-	1	-	-	2	-	-	-	-
Upstate Carolina Consortium NCORP	8	-	-	-	1	-	-	-	-	-	-	-	-	-
Virginia Mason Med Ctr	1	-	-	-	-	-	-	1	-	-	-	-	-	-
Wayne State U - Karmanos Ca Inst LAPS	3	-	-	11	12	9	-	-	6	9	2	-	6	-
Western States Ca Res NCORP	4	-	-	-	-	-	-	-	-	-	-	-	-	-
William Beaumont Hosp-Royal Oak	1	-	-	6	5	2	-	1	-	-	-	-	-	-
Wisconsin NCORP	2	1	-	-	-	-	-	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	8	-	-	5	81	31	-	-	6	1	-	-	9	-
ALLIANCE	144	10	-	-	-	-	-	-	-	-	-	-	-	-
CCTG	39	3	-	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	129	5	1	-	-	-	-	-	-	-	-	-	-	-
NRG	307	33	-	-	-	-	-	-	-	-	-	-	-	-
Total	1,195	97	4	129	333	206	7	47	30	45	9	8	89	7



Placebo-Controlled Trial in Postmenopausal Patients with Hormone-Receptor-Positive Stage IV Breast Cancer." Drs. Moore, Somlo, Hayes, Kuhn, and Hicks. Activated 05/09/2014. Permanently Closed 10/15/2015.

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, Leja, Fabian, Godwin. Activated: 09/15/17.

Active 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, Lok, Gehring, Feld. Activated: 02/21/19.

S1714, "A Prospective Observational Cohort Study to Develop a Predictive Model of Taxane-Induced Peripheral Neuropathy in Cancer Patients." Drs. Trivedi, Hershman, Brannagan, Hertz. Activated 03/01/19.

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. Accordino, Hershman, Ramsey. Activated: 07/16/18.

Active Cancer Prevention Studies

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, Thomas, Caban-Holt. Activated: 09/01/20.

CTSU/EA1151, "Tomosynthesis Mammographic Imaging Screening Trial (TMIST)." Dr. Pisano. SWOG Champion: Dr. Arun. Activated: 07/06/17.

Active Early Therapeutics and Rare Cancers Studies

S1609, "DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors." Drs. Patel, Chae, Kurzrock. Activated 01/13/17.

CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)". Dr. Flaherty. Activated 08/12/15.



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
Mark A. O'Rourke, MD
Marie Bakitas, DNSc, CRNP
Prevention and Epidemiology Co-Chairs: Banu Arun, MD
Marian L. Neuhouser, PhD, RD
Symptom Control & QOL Co-Chairs: Michael J. Fisch, MD, MPH
Norah Lynn Henry, MD, PhD
Executive Officers:
Survivorship)
Gary H. Lyman, MD (CCD, Symptom Control & QOL)
Senior Advisor:Frank L. Meyskens, Jr., MD
Statisticians:
Cathy Tangen, DrPH
Joseph M. Unger, PhD
Riha Vaidya, PhD
Kathryn B. Arnold, MS
Phyllis J. Goodman, MS
Danika Lew, MA
Anna Moseley, MS
Eddie Mayerson, MS
Administrative Lead SDMC: Monica Yee, CCRP
Scientific Leadership
NCORP Representative: Mark A. O'Rourke, MD
Radiation Oncology Committee: Louis "Sandy" Constine, MD
Surgery Committee:
Translational Medicine:
Liaisons:
Barlogie-Salmon Myeloma Committee:
Breast Committee:
Dawn Hershman, MD, MS (CCD)
Philip Lammers, MD
Early Therapeutics & Rare Cancers: Lara E. Davis, MD (Survivorship)
Jason M. Prosek, MD

Gastrointestinal Committee:	Jason A. Zell, DO (Prevention)
	Afsaneh Barzi, MD (CCD)
Genitourinary Committee:	Peter J. Van Veldhuizen, Jr., MD
International Liaison:	Kathy S. Albain, MD
Leukemia Committee:	Stephanie B. Tsai, MD
Lung Committee:	Gary E. Goodman, MD
	Hayder Saeed, MD
	Sancy Leachman, MD, PhD
T	hach-Giao Truong, MD (Survivorship)
Recruitment and Retention Commit	tee: Allison M. Caban-Holt, PhD
Digital Engagement:	Jennifer R. Klemp, PhD (Survivorship)
Krishna	Soujanya Gunturu, MD (Survivorship)
	Mina S. Sedrak, MD (CCD)
	Katherine D. Crew, MD (Prevention)
Michael J	Fisch, MD (Symptom Control & QOL)
Veterans Affairs:	Yeun-Hee Anna Park, MD
Designates	
Clinical Research Associates:	Amanda R. Dinsdale, MHA, CCRC
	Samantha Wright, MS, CCRP
Nurses:	Connie Szczepanek, RN, BSN
	Melyssa W. Foust, MSN, RN
Pharmaceutical Sciences Committee	e: Kimberly McConnell, PharmD
	Siu-Fun Wong, PharmD
	Sun "Coco" Yang, PharmD, PhD
SDMC Data Coordinators and Staff: .	Kimberly Carvalho
	Sam Dzingle
	Diane Liggett, CCRP
	Roxanne Topacio, CCRP
	Monica Yee, CCRP
Recruitment and Retention Specialis	t: TBD
Patient Advocates:	Barbara Segarra-Vazquez, DHSc (CCD)
Amy Geschwe	ender, PhD (Symptom Control & QOL)
Hartle	ey "Lee" M. Jones, MBA (Survivorship)
Cheryl L. Jernig	an, CPA (Prevention & Epidemiology)
Valer	ie Fraser (Palliative & End of Life Care)
Desiree	Walker, BA (Recruitment & Retention)
Protocol Project Manager (CCD; Prev	rention): Patricia O'Kane
Protocol Project Manager (Survivors	hip):Taj Pereira
Protocol Project Manager (Symptom	n Control): Mariah Norman, MS
Protocol Project Manager (Palliative	Care):
Clinical Trials Program Manager (Pall	iative Care): Michelle Maxim
Clinical Trials Program Manager (CCI); Prevention; Survivorship): TBD
	otom Control): Crystal Miwa



Cancer Care Delivery (CCD) Committee

Leadership

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

Time/Location

Thursday, April 7, 2022 10:15 am - 12:15 pm

Room: Quinalt, Level 5

Agenda

Presentations

Using Implementation Science to Facilitate Deprescribing for Multimorbid Adults with Cancer, Cara McDermott, PharmD, PhD, Fred Hutchinson Cancer Research Institute

Recruiting Patient/Caregiver Dyads - Strategies and Challenges and Panel Discussion, Veena Shankaran, University of Washington; Christine Veenstra, M.D., University of Michigan; Daniela Wittman, University of Michigan; Lee Jones, SWOG Patient Advocate

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

Development of a Dyadic Module to Promote Guideline-Concordant Colorectal Cancer Surveillance – Christine Veenstra, M.D., University of Michigan

Approved Protocol

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, M.D., Maine Cancer Genomics Initiative; Meghna Trivedi, M.D., Columbia University

Active 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 Breast Cancer," Dr. M. Accordino. Activated 7/16/18.

Mednet Update - Elizabeth Henry, the Mednet

Developing Studies

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

Patient-centered Video Education Intervention to Improve Rural Cancer Care Delivery – Randall Holcombe, MD, MBA, 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. K. Crew. Activated 9/1/20. (Committee: Prevention/ Epidemiology)

S2010, Active Symptom Monitoring and Endocrine Therapy Persistence in Young Women with Breast Cancer – Lynn Henry, M.D., University of Michigan; Dawn Hershman, M.S. M.S., Columbia University

Closed Studies

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

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

Database/Grant Funded Projects

Ongoing

Trends in Obesity Among Patients Registered to SWOG Cancer Clinical Treatment Trials. Riha Vaidya, Ph.D.



Cancer Care Delivery (CCD) Committee

Published

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

Active and Completed CCDR Studies from Other Research Bases

- <u>A231601CD****</u> Use of a Pre-Surgical Toolkit in Improving Surgical Care and Outcomes in Older Participants With Cancer
- <u>A231701CD (closed to accrual)*</u> Increasing Patients' Engagement in Breast Cancer Surgery Decision-Making
- <u>A231901CD*</u> Improving Patient-Centered Communication in Breast Cancer Through Patient and Provider Interventions
- <u>A191402CD (completed)*</u> Decision Aids in Improving Knowledge in Patients With Newly Diagnosed Prostate Cancer
- <u>A231602CD** (completed)</u> Assessment of Financial Difficulty in Participants
 With Chronic Lymphocytic Leukemia and Multiple Myeloma
- COG-ACCL15N1CD (completed)***- Identifying, Understanding, and Overcoming Barriers to the Use of Clinical Practice Guidelines in Pediatric Oncology
- COG-ACCL16N1CD (closed to accrual)*** Cancer Care Delivery in Adolescent and Young Adult Patients With Acute Lymphoblastic Leukemia
- **EAQ171CD*** Implementing a Virtual Tobacco Treatment for Cancer Patients in Community Oncology Practices
- EAQ161CD (completed)*** Assessment of Current Biomarker Testing Practices for Common Solid Cancers in Precision Oncology in the Community Setting
- **EAQ162CD** (completed)*** Financial Burden Assessment in Patients With Stage I-III Colon or Rectal Cancer Undergoing Treatment
- NRG-CC007CD*** Increasing the Dose of Survivorship Care Planning in Improving Care and Outcomes in Prostate Cancer Survivors Receiving Androgen Deprivation Therapy
- <u>S1415CD</u> (completed)** A Pragmatic Trial To Evaluate a Guideline-Based Colony Stimulating Factor Standing Order Intervention and to Determine the Effectiveness of Colony Stimulating Factor Use as Prophylaxis for Patients Receiving Chemotherapy with Intermediate Risk for Febrile Neutropenia Trial Assessing CSF Prescribing, Effectiveness and Risk (TrACER)

- <u>S1417CD (completed)***</u> S1417CD Financial Impact Assessment Tool in Patients With Metastatic Colorectal Cancer
- <u>\$1912CD*</u> A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)
- <u>S2108CD****</u> Randomized Comparison of an Educationally Enhanced Genomic Tumor Board (eGTB) Intervention to Usual Practice of Incorporating Genomic Test Results into Clinical Care
- <u>WF-1803CD (completed)****</u> Supportive Care Service Availability for Cancer Caregivers in Community Oncology Practices
- <u>WF-30917CD (completed)*</u> Stepped-Care Telehealth for Distress in Cancer Survivors
- <u>WF-1804CD*</u> Assessing Effectiveness and Implementation of an EHR Tool to Assess Heart Health Among Survivors
- WF-1805CD** Implementation and Effectiveness Trial of HN-STAR
- <u>URCC-18110CD*</u> Learning Collaborative Vs Technical Assistance in Delivering a Palliative Care Program to Patients With Advanced Cancer and Their Caregivers
- <u>URCC-18004CD****</u> Understanding the Impact of Drug Shortages on Oncology Care Delivery
- * Studies funded by federal agencies and reviewed at CSR
- ** Studies funded by non-federal agencies and reviewed by Steering Committee
- ***Studies funded by NCORP and reviewed by Steering Committee



Cancer Care Delivery (CCD) Committee

Accrual from trial opening through 12/31/2021 by Institution and Study

	51703	519720	51916	A191901	A237607C	A237602C	A231701C	EAQ171CO	EA0202	NHLBIMDS	NRGCCOR
Ascension Prov Hospitals - Southfield	-	-	-	2	-	-	-	-	-	1	-
Banner U Med Ctr - Tucson	1	-	-	-	-	-	-	-	-	-	-
CWRU Case CCC LAPS	12	-	-	-	-	-	-	-	-	5	-
Ca Res for the Ozarks NCORP	-	1	-	-	-	-	-	-	-	-	-
Ca Res of Wisconsin & N Mich Consort	8	-	-	1	-	-	-	-	-	-	-
Carle CC NCORP	7	-	1	-	-	-	-	-	-	-	-
Columbia U MU NCORP	14	1	-	-	-	-	-	-	-	12	-
Columbus NCORP	3	-	-	-	-	-	-	-	-	-	-
CommonSpirit Health Research Inst	7	-	-	-	-	-	-	-	-	-	-
Cotton O'Neil CC / Stormont Vail HIth	1	-	-	-	-	-	-	-	-	-	-
Dayton NCORP	3	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	-	-	-	-	-	-	-	-	-	15	-
Georgia NCORP	1	-	-	-	-	-	-	-	-	-	-
Gulf South MU NCORP	6	-	-	-	1	-	-	-	-	-	-
Hawaii MU NCORP	4	-	-	-	-	-	-	-	-	5	-
Heartland Ca Res NCORP	10	2	1	-	-	-	-	-	-	-	1
Kaiser Permanente NCORP	4	-	-	-	-	-	-	-	-	5	-
Kansas City Veterans Affairs Med Ctr	-	-	-	-	-	-	-	-	-	4	-
Kansas Inst of Med Cancer & Blood Ctr	-	-	-	-	-	-	-	-	-	2	-
Lahey Hospital & Med Ctr	4	-	-	-	-	-	-	-	-	-	-
Loyola U Med Ctr	2	-	-	3	-	-	-	-	-	-	-
Massachusetts Veterans ERIC	-	-	-	-	-	-	-	-	-	26	-
Medical U South Carolina MU NCORP	-	-	-	-	-	-	1	-	-	2	-
Michigan Ca Res Consortium NCORP	7	-	-	-	-	-	-	-	-	-	-
Moffitt CC	-	-	-	-	-	-	-	-	-	8	-
Montana Cancer Consortium NCORP	7	-	-	-	-	-	-	-	-	-	-
MultiCare Tacoma General Hospital	-	-	-	13	-	-	-	1	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	6	-	-	-	-	-	-	-	6	2	-
Nevada Ca Res Foundation NCORP	1	-	-	-	-	-	-	-	-	-	-
New Mexico MU NCORP	9	-	-	-	-	-	-	-	-	-	-
Oregon Health & Science U	-	-	-	-	-	-	-	-	-	6	-
Pacific Ca Res Consortium NCORP	9	1	-	-	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	4	-	-	-	-	-	-	-	-	-	-
UC Irvine Health/Chao Family CCC	-	-	-	-	-	-	-	-	-	18	-
UC San Diego Moores CC	-	-	-	-	-	-	-	-	-	21	-
U Arkansas for Medical Sciences	3	-	-	-	-	-	-	-	-	-	-
U Colorado CC LAPS	-	-	-	-	-	-	-	-	-	6	-
U Kansas CC - MCA Rural MU NCORP	5	1	-	-	-	4	-	-	-	-	21
U Rochester LAPS	4	-	-	-	-	-	-	-	-	-	-
Western States Ca Res NCORP	-	-	-	1	-	-	-	-	-	-	-
William Beaumont Hosp-Royal Oak	-	-	-	-	-	-	-	-	-	2	-
Wisconsin NCORP	1	-	-	-	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	25	-	-	-	-	-	-	-	-	7	-
ALLIANCE	4	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	16	-	-	-	-	-	-	-	-	-	-
NRG	12	-	-	-	-	-	-	-	-	-	-
Total	200	6	2	20	1	4	1	1	6	147	22



Cancer Survivorship Committee

Leadership

Time/Location

Thursday, April 7, 2022 8:00 - 10:00 am Room: Quinalt, Level 5

Agenda

Welcome: Melinda Irwin and Halle Moore

Survivorship Presentation: NCI Cancer Survivorship Priorities - Emily Tonorezos, MD MPH Director, Office of Cancer Survivorship Division of Cancer Control and Population Sciences, National Cancer Institute.

Discussion

Patient Advocate Update: Lee Jones

New Ideas

Studies/Concepts:

S1501, "Prospective Evaluation of Carvedilol in Prevention of Cardiac Toxicity in Patients with Metastatic HER-2+ Breast Cancer." Justin Floyd, D.O. and Monika Leja, M.D.

S2204, "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.

S2013 I-CHECKIT: 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

Intervening with Cancer Caregivers to Improve Patient Health Outcomes and Optimize Health Care Utilization: Christine Duffy

Obesity, metabolomics, microbiome and cancer outcomes: Leah Ferrucci

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

Cardiac Advisory Panel Update

Other Business

Active Study

S1501, "Prospective Evaluation of Carvedilol in Prevention of Cardiac Toxicity in Patients with Metastatic HER-2+ Breast Cancer, Phase III." Drs. J. Floyd and M. Leja. Activated 9/15/2017.

Concepts in Development

S2204, "Randomized Phase III Trial of a Perioperative Physical Activity Intervention in Older Adults with Lung Cancer and their Family Caregivers." Drs. D. Raz and V. Sun.

Closed Study

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



Cancer Survivorship Committee

	51501	E1011	EA9131
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	43	-	-
Columbia University Minority Underserved NCORP	2	-	-
CommonSpirit Health Research Institute	1	-	-
Fred Hutchinson Cancer Research Center LAPS	3	-	-
Georgia Cares Minority Underserved NCORP	-	-	1
Georgia NCI Community Oncology Research Program	11	-	-
Gulf South Minority Underserved NCORP	4	-	-
Hawaii Minority Underserved NCORP	-	21	-
Heartland Cancer Research NCORP	18	-	-
Henry Ford Hospital	1	-	-
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	13	-	-
Montana Cancer Consortium NCORP	1	-	-
NCORP of the Carolinas (Prisma Health NCORP)	2	-	-
New Mexico Minority Underserved NCORP	5	1	-
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	6	-	-
University of Michigan Comprehensive Cancer Center LAPS	9	-	-
Upstate Carolina Consortium Community Oncology Research Program	-	1	-
Wayne State University - Karmanos Cancer Institute LAPS	6	-	-
ALLIANCE	19	-	-
ECOG-ACRIN	32	-	-
NRG	20	-	-
Total	260	23	62



Palliative and End of Life Care Committee

Leadership

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

Time/Location

Thursday, April 7, 2022 5:00 - 7:00 pm Room: Quinalt, Level 5

Agenda

	Ageilua
5 minutes	Welcome and Introductions – Co-Chairs
5 minutes	Committee Liaison Updates (Patient Advocates/ORP)
10 minutes	Committee Member Wellbeing Check-in / Marie A. Bakitas, DNSc, NP-C, FAAN
25 minutes	Plenary: "Redefining Professional Wellness for the Oncology Workforce" Ishwaria Subbiah, MD, MS
15 minutes	Developing Studies Updates
\$2016 , "Randon	nized Phase III Trial of a Primary Palliative Care

<u>\$2016</u>, "Randomized Phase III Trial of a Primary Palliative Care Intervention in Pancreatic Cancer." Drs. Chung and Sun.

S2106, "Depression Screening and Treatment in Patients Requesting Medical Aid in Dying (MAID)" Drs. Salman and Blanke.

10 minutes Active Study Updates

<u>\$1820</u>, "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.

Hope/CAPC Provider Communication Study: Subbiah/Agarwal

5 minutes Closed Study Update

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

35 minutes New Business

- Hope Intervention Workshop for Metastatic Breast Ca Proposal: Corn/Feldman
- PREPARE for Your Care: An outpatient advanced care planning intervention for older adults with advanced cancer (PCRC Submission) Myers/O'Rourke/Bakitas

Palliative and End of Life Care Committee

Accrual from trial opening through 12/31/2021 by Institution and Study

Banner University Medical Center - Tucson City of Hope Comprehensive Cancer Center	1 2 1
	1
	•
Columbus NCI Community Oncology Research Program	
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 Texas MD Anderson Cancer Center LAPS	7
Upstate Carolina Consortium Community Oncology	
Research Program	2
Virginia Mason Medical Center	5
ALLIANCE	4
ECOG-ACRIN	1
NRG	20
Total	<i>7</i> 9

- 3. READIBAND Activity Monitor Concept: Fowler/O'Rourke
- "Randomized multicenter placebo-controlled trial evaluating lanreotide for the reduction of postoperative pancreatic fistulae"-Jonathan G. Sham, MD submission for Charles A. Coltman, Jr. Fellowship Program
- 5. APP workshop f/u

5 Minutes Closing Comments and Adjourn: Co-Chairs



Palliative and End of Life Care Committee

Active Studies

51820, "A Randomized Phase II Trial of the Altering Intake, Managing Symptoms Intervention for Bowel Dysfunction in Rectal Cancer Survivors (AIMS-RC)." Dr. Sun. Activated: 12/9/19.

Proposed Studies

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

S2106, "Depression screening and treatment in patients requesting Medical Aid in Dying (MAID)." Drs. Salman and Blanke.

Closed Studies

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



Prevention & Epidemiology Committee

Leadership

Time/Location

Friday, April 8, 2022 9:45 - 11:45 am Room: Elwha B, Level 5

Agenda

Welcome and Opening Comments: Marian Neuhouser and Banu Arun

Cancer Prevention Presentation:

"Biomarker development for early phase clinical trials for melanoma prevention" Presented by Dr. Karen Taraszka Hastings, Associate Professor, University of AZ

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. J. Zell, P. Brown, M.P. Lance, et al. Activated: 3/1/13.
- **S1823**, "A Prospective Observational Cohort Study to Assess miRNA 371 for Outcome Prediction in Patients with Newly Diagnosed Germ Cell Tumors". Drs. C. Nichols and L. 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. K. Crew, R. Kukafka, et al. Activated 9/1/20.

- CTSU/NHLBI-MDS, "The National Myelodysplastic Syndromes Natural History Study." Drs. D. Hill and C. Arana Yi, Study Champions. SWOG Activated: 6/1/19.
- CTSU EA1151, "Tomosynthesis Mammographic Imaging Screening Trial (TMIST)." Dr. B. Arun, Study Champion. SWOG Activated: 7/24/19.
- CTSU A151804, "Establishment of a National Biorepository to Advance Studies of Immune-Related Adverse Events." Dr. G. Lyman. Activated: 6/15/20.
- CTSU A212102, "A Blinded Reference Set for Multicancer Early Detection Blood Tests." Dr. J. McGuinness. SWOG Activation: TBD.

Pending CTEP Approval

- Amendment to S1418, "Exploratory Study to Evaluate Mammographic Density Changes in Patients Receiving Pembrolizumab in S1418." Dr. B. Arun.
- Amendment to \$1007, "Effects of Chemoprevention and Adjuvant Endocrine Therapy on a Convolutional Neural Network-Based Breast Cancer Risk Model Using Mammographic Datasets from \$0812 and \$1007." Drs. K Crew, K. Kalinsky, R. Ha.

Concepts in Redesign

- "Phase II Study of Intraoperative Radiotherapy (IORT) for DCIS after Breast Conserving Surgery." Dr. E. Connolly.
- "Alternate Dosing of Exemestane Among Postmenopausal Women with Atypical Hyperplasia or Ductal Carcinoma In Situ", Dr. Julia McGuinness.

Patient Advocate update: Cheryl Jernigan

New Business/Open Discussion for new ideas



Prevention & Epidemiology Committee

	50820	51823	519 ⁰⁴	A217102	A271601	EA7151	EA2185	NRGCC005
Ascension Providence Hospitals - Southfield	1	-	-	-	2	-	-	-
Ascension Via Christi Hospitals Wichita	12	-	-	-	-	-	-	-
Banner MD Anderson Cancer Center	10	-	-	-	-	1	-	-
Banner University Medical Center - Tucson	-	3	-	-	-	56	-	-
Baptist Memorial Health Care/Mid South Minority Underserved NCORP	4	-	2	-	-	-	-	-
Bay Area Tumor Institute NCORP	1	4	-	-	-	-	-	-
Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center	-	-	-	-	-	-	-	1
Brooke Army Medical Center	1	-	-	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-	-	83	-	-
Cancer Research Consortium of West Michigan NCORP	2	-	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	-	5	-	-	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	1	-	-	-	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	-	4	10	-	-	-	-	-
City of Hope Comprehensive Cancer Center	1	-	7	2	-	-	-	-
Columbia University Minority Underserved NCORP	1	-	17	1	-	-	-	-
Columbus NCI Community Oncology Research Program	6	7	-	-	-	-	-	-
CommonSpirit Health Research Institute	4	-	-	-	-	-	-	-
Dayton NCI Community Oncology Research Program	1	-	-	-	-	-	-	-
Essentia Health NCI Community Oncology Research Program	4	1	-	-	-	77	-	-
Georgia Cares Minority Underserved NCORP	2	-	-	-	-	-	-	-
Georgia NCI Community Oncology Research Program	2	-	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	-	6	-	-	-	-	-	-
Hawaii Minority Underserved NCORP	10	2	2	-	-	-	-	-
Heartland Cancer Research NCORP	2	12	2	-	-	-	-	-
Henry Ford Hospital	-	-	-	-	-	129	-	-
Kaiser Permanente NCI Community Oncology Research Program	40	68	-	-	-	-	-	-
Lahey Hospital and Medical Center	-	-	3	-	-	-	-	-
Loma Linda University Medical Center	2	2	-	-	-	-	-	-
Loyola University Medical Center	2	-	-	-	-	-	-	-
Massachusetts Veterans Epidemiology Research and Information Center	3	-	-	-	-	-	5	-
Medical University of South Carolina Minority Underserved NCORP	-	-	-	-	-	4	-	-
Meharry Medical College	1	-	-	-	-	-	-	-
Memorial Hermann Texas Medical Center	-	-	-	-	-	8	-	-
Michigan Cancer Research Consortium NCORP	11	-	-	-	-	-	-	-
MultiCare Tacoma General Hospital	2	-	-	-	-	-	-	-



Prevention & Epidemiology Committee

	50820	51823	51904	A277702	A271601	EA1151	EA2185	NRGCO
NCORP of the Carolinas (Prisma Health NCORP)	-	7	-	-	-	313	-	-
Nevada Cancer Research Foundation NCORP	1	1	-	-	-	-	-	-
New Mexico Minority Underserved NCORP	2	3	-	-	-	-	-	-
Northwell Health NCORP	-	6	-	-	-	-	-	-
Ohio State University Comprehensive Cancer Center LAPS	-	1	-	-	-	-	-	-
Oregon Health and Science University	-	9	-	-	-	-	-	-
Pacific Cancer Research Consortium NCORP	2	-	-	-	-	-	-	-
Salem Hospital	-	2	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	3	2	-	-	-	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	29	2	-	-	-	-	-	-
UC San Diego Moores Cancer Center	-	16	-	-	-	-	-	-
UCLA / Jonsson Comprehensive Cancer Center	-	24	-	-	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS	5	24	-	-	-	-	-	-
University of Arkansas for Medical Sciences	-	-	-	-	-	314	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	2	-	-	-	-	-	-
University of Colorado Cancer Center LAPS	7	6	-	-	-	2	-	-
University of Kansas Cancer Center - MCA Rural MU NCORP	4	-	-	-	-	-	-	-
University of Kentucky/Markey Cancer Center	-	-	-	-	-	8	-	-
University of Mississippi Medical Center	1	3	-	-	-	-	-	-
University of Oklahoma Health Sciences Center LAPS	-	1	-	-	-	-	-	-
University of Rochester LAPS	-	9	-	-	-	223	-	-
University of Texas Health Science Center at San Antonio	9	-	-	-	-	-	-	-
University of Texas MD Anderson Cancer Center LAPS	4	-	-	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	-	-	15	-	-	-	-	-
Upstate Carolina Consortium Community Oncology Research Program	-	-	-	-	-	619	-	-
Vanderbilt University - Ingram Cancer Center LAPS	-	6	-	-	-	-	-	-
Virginia Mason Medical Center	9	8	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	2	-	-	-	-	-	-	-
Western States Cancer Research NCORP	1	-	-	-	-	57	-	-
Wisconsin NCI Community Oncology Research Program	1	-	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	23	-	-	-	-	-	-	-
ALLIANCE	34	47	20	-	-	-	-	-
CCTG	-	57	-	-	-	-	-	-
ECOG-ACRIN	26	26	6	-	-	-	-	-
NRG	<i>37</i>	13	23	-	-	-	-	-
Total	326	389	107	3	2	1.894	5	1



Leadership

Time/Location

Friday, April 8, 2022 7:30 - 9:30 am Room: Columbia A, Level 3

Agenda

Symposium: Patient-Reported Outcomes and Toxicity Evaluation

Plenary speaker: Gita Thanarajasingam, MD

Panel discussion

Active Studies

- <u>\$1600</u>, "A Randomized Phase III Double-Blind Clinical Trial Evaluating The Effect Of Immune-Enhancing Nutrition On Radical Cystectomy Outcomes" - Dr.Hamilton-Reeves. Activated 2/21/19.
- S1614, "A Phase III Randomized Trial Of Prophylactic Antiviral Therapy In Patients With Current Or Past Hepatitis B Virus (HBV) Infection Receiving Anti-Cancer Therapy For Solid Tumors." Drs. Hwang, Lok, and Ghering, et al. Activated 2/21/19, re-activated 7/1/21.
- <u>\$2013</u>, "Immune Checkpoint Inhibitor Toxicity (I-Checkit): A Prospective Observational Study" – Drs. Gunturu, Hershman, and Kuderer. Activated 8/16/21

Other Concepts in Development

- **S2205**, "STOP CIPN: Randomized trial of Limb CryocompreSsion versus ConTinuous cOmPression versus Low Cyclic Compression for the Prevention of Taxane-InduCed perIPheral Neuropathy." Dr. Accordino
- **S2010**, "Improving Endocrine Therapy Persistence in Young Women with Breast Cancer using Active Symptom Monitoring." Dr. Henry

Closed Studies

- **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.
- **S0702**, "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 and Dr. Gralow M.D. Activated 12/15/2008. Closed to Accrual 06/01/19.

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

Committee Business

- 1. What is happening with our open studies?
- 2. What other studies are we planning?
- 3. What has SCQOL contributed to the literature recently?
- 4. What other updates should we know about

Other SWOG Studies with Symptom Control and QOL Component

Breast

<u>\$1706</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.

GU

- <u>\$1802</u>, "Phase III Randomized Trial of Standard Systemic Therapy (SST)
 Versus Standard Systemic Therapy plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer." Dr. Chapin. Activated: 9/17/18.
- <u>**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

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

Lymphoma

- **51826**, "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.

Palliative Care and End of Life

51820, "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)." Drs. Sun, Thomson, Crane, et al. Activated: 12/9/20.

Prevention and Epidemiology

- 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.
- 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	516 ¹⁴	51714	52013	A22150
Ascension Providence Hospitals - Southfield	-	-	-	1	-
Ascension Via Christi Hospitals Wichita	-	-	1	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-	3
Cancer Research Consortium of West Michigan NCORP	-	-	146	-	-
Cancer Research for the Ozarks NCORP	-	-	10	1	-
Cancer Research of Wisconsin and Northern Michigan Consortium	-	-	-	9	-
Carle Cancer Center NCI Community Oncology Research Program	-	-	6	-	-
City of Hope Comprehensive Cancer Center	2	-	-	-	-
Columbia University Minority Underserved NCORP	-	-	27	-	-
Columbus NCI Community Oncology Research Program	-	-	-	1	-
CommonSpirit Health Research Institute	-	-	71	1	-
Dayton NCI Community Oncology Research Program	-	-	-	-	-
Desert Regional Medical Center	-	-	3	-	-
Fred Hutchinson Cancer Research Center LAPS	7	-	-	-	-
Georgia NCI Community Oncology Research Program	-	-	18	-	-
Grupo Oncologico Cooperativo de Investigacion	-	-	10	-	-
Gulf South Minority Underserved NCORP	1	-	26	-	1
Hawaii Minority Underserved NCORP	-	-	70	-	-
Heartland Cancer Research NCORP	-	-	38	10	-
Henry Ford Hospital	7	-	-	-	-
Instituto Nacional De Cancerologia	-	-	10	-	-
Instituto Nacional De Cancerologia de Mexico	-	-	60	-	-
Kaiser Permanente NCI Community Oncology Research Program	-	2	65	-	-
Lahey Hospital and Medical Center	-	-	22	6	-
Loyola University Medical Center	-	-	2	-	-
Medical University of South Carolina Minority Underserved NCORP	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	-	-	30	-	-
Northwell Health NCORP	-	-	-	-	2
Pacific Cancer Research Consortium NCORP	-	-	2	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	-	278	3	-
The West Clinic - Wolf River	-	-	-	-	6
Tulane University Health Sciences Center	-	-	1	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	-	-	1
USC Norris Comprehensive Cancer Center LAPS	58	-	-	-	-
University of Arkansas for Medical Sciences	-	-	68	-	-
University of Colorado Cancer Center LAPS	2	-	2	-	16
University of Kansas Cancer Center - MCA Rural MU NCORP	32	-	24	-	-
University of Kentucky/Markey Cancer Center	-	-	-	-	-
University of Rochester LAPS	6	-	-	-	-
University of Texas Health Science Center at San Antonio	-	-	14	-	-
University of Utah - Huntsman Cancer Institute LAPS	-	-	-	-	-
Upstate Carolina Consortium Community Oncology Research Program	-	-	118	-	1
Wayne State University - Karmanos Cancer Institute LAPS	-	-	-	-	-
ALLIANCE	5	-	44	9	-
ECOG-ACRIN	-	-	80	7	-
NRG	1	1	90	9	-
Total	121	3	1,336	<i>57</i>	30



	A227602	A221702	A221805	EAZ171
Ascension Providence Hospitals - Southfield	-	-	-	-
Ascension Via Christi Hospitals Wichita	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-
Cancer Research Consortium of West Michigan NCORP	-	-	-	-
Cancer Research for the Ozarks NCORP	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	-	-	-	-
City of Hope Comprehensive Cancer Center	-	-	-	-
Columbia University Minority Underserved NCORP	3	-	-	-
Columbus NCI Community Oncology Research Program	-	-	-	-
CommonSpirit Health Research Institute	-	-	-	-
Dayton NCI Community Oncology Research Program	1	-	1	-
Desert Regional Medical Center	3	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	-	-
Georgia NCI Community Oncology Research Program	-	-	-	-
Grupo Oncologico Cooperativo de Investigacion	-	-	-	-
Gulf South Minority Underserved NCORP	-	-	-	1
Hawaii Minority Underserved NCORP	-	-	-	-
Heartland Cancer Research NCORP	-	-	-	-
Henry Ford Hospital	-	-	-	-
Instituto Nacional De Cancerologia	-	-	-	-
Instituto Nacional De Cancerologia de Mexico	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	-	-	-	-
Lahey Hospital and Medical Center	-	-	-	-
Loyola University Medical Center	-	-	-	-
Medical University of South Carolina Minority Underserved NCORP	-	-	-	2
NCORP of the Carolinas (Prisma Health NCORP)	-	-	_	_
Northwell Health NCORP	3	-	-	-
Pacific Cancer Research Consortium NCORP	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	-	-	-
The West Clinic - Wolf River	-	-	-	-
Tulane University Health Sciences Center	-	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	4	-	-	-
USC Norris Comprehensive Cancer Center LAPS	-	-	-	-
University of Arkansas for Medical Sciences	-	-	-	-
University of Colorado Cancer Center LAPS	-	-	2	-
University of Kansas Cancer Center - MCA Rural MU NCORP	-	-	1	-
University of Kentucky/Markey Cancer Center	10	-	_	-
University of Rochester LAPS	-	14	-	-
University of Texas Health Science Center at San Antonio	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	8	-	-	-
Upstate Carolina Consortium Community Oncology Research Program	-	-	_	-
Wayne State University - Karmanos Cancer Institute LAPS	-	1	-	_
ALLIANCE	-	-	-	-
ECOG-ACRIN	-	_	-	_
NRG	-	-	-	-
mo				



Early Therapeutics & Rare Cancers Committee

Leadership

Chair:	Razelle Kurzrock, MD
Vice-Chair:	Young Kwang Chae, MD, MPH
Executive Officer:	Christopher W. Ryan, MD
Statisticians:	Megan Othus, PhD
	Melissa Plets, MS
	Edward Mayerson, MS
Designates	
•	Christin a Magnay
Data Coordinators:	•
Digital Engagement:	Kanwal Raghav, MD, MBBS
Oncology Research Professionals:	
CRAs:	
Nurse:	TBD
Pharmaceutical Science:	Craig Elg, PharmD
	Sun "Coco" Yang, PharmD, PhD
Patient Advocate:	Marcia K. Horn, JD
Protocol Project Manager:	Catrina Mireles
Clinical Trials Program Manager:	Michelle Maxim
Early Therapeutics Liaisons	
Breast Committee Liaison:	TBD
Cancer Control Liaison:	Jason M. Prosek, MD
Genitourinary Committee Liaison:	Neeraj Agarwal, MD
Imaging:	TBD
Lung Committee Liaison:	Shirish M. Gadgeel, MD
Lymphoma Committee Liaison:N	
Melanoma Committee Liaison:	Jeffrey A. Sosman, MD
Myeloma Committee Liaison:	•
•	. ,

Time/Location

Thursday, April 7, 2022 10:00 am - 12:15 pm

Room: Columbia D, Level 3

Agenda

Introduction

<u>10:00 - 10:05 am</u>: Razelle Kurzrock, M.D., Chair, Early Therapeutics and Rare Cancer Committee (SWOG).

Presentations

10:05 - 10:20 am: "Updates from Sarcoma Working Group" - Lara Davis, M.D., Associate Professor Knight Cancer Institute, Co-Leader, Translational Oncology Research Program, Sarcoma Disease Site Leader, Knight Cancer Institute, Oregon Health & Science University.

- 10:20 10:35 am: "Update on Sarcoma Concept" Michael Wagner, M.D., Assistant Professor, Division of Medical Oncology, University of Washington, Fred Hutchinson Cancer Research Center.
- <u>10:35 10:55 am</u>: "Updates from CNS Working Group." Manmeet Ahluwalia, M.D., Chief of Medical Oncology, Deputy Director, Chief Scientific Officer, Miami Cancer Institute.
- 10:55 11:15 am: "CIMAC and Translational Immunology in DART." Young Chae, M.D., Vice Chair, Early Therapeutics and Rare Cancers (SWOG), Northwestern University, Robert H. Lurie Comprehensive Cancer Center.
- 11:15 11:35 am: "DART: Clinical Trial Updates." Sandip Patel, M.D., Associate Professor Deputy Director, San Diego Center for Precision Immunotherapy, UC San Diego Moores Comprehensive Cancer Center, San Diego, CA
- <u>11:35 11:55 am</u>: "New Drugs in Oncology." Monica Mita, M.D., Professor of Medicine, Co-Director, Experimental Therapeutics Program, Samuel Oschin Comprehensive Cancer Institute Cedars-Sinai Medical Center.
- 11:55 am 12:10 pm: "New Approved Study: 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)" David Zhen, M.D.,
 Assistant Professor of Medicine, University of Washington, Fred
 Hutchinson Cancer Research Center.
- <u>12:10 12:15 pm</u>: Wrap Up. Razelle Kurzrock, M.D., Chair, Early Therapeutics and Rare Cancer Committee (SWOG).

Active Studies

- **S1609**, "DART: Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors." Drs. Patel, Chae, and Kurzrock. Activated: 1/13/17.
- CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)." Activated: 8/12/2015.
- CTSU/A071702, "A Phase II Study of Checkpoint Blockade Immunotherapy in Patients with Somatically Hypermutated Recurrent Glioblastoma." Dr. Dunn. Activated: 10/30/20.
- 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; Temporarily Closed: 10/28/21



Early Therapeutics & Rare Cancers Committee

- 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.
- 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.
- 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. Temporarily Closed: 6/15/21.
- 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/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.
- 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: 8/28/2015.
- **52012**, "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.

Proposed Studies

<u>\$2208</u>, "Neoadjuvant Nivolumab and Paclitaxel Followed by Definitive Local Control for Patients with Locoregional Angiosarcoma." Dr. Wagner.

- NRG-BN1803, "NRG-COG Phase II Trial of Radiation Plus Concurrent and Adjuvant ONC201 for Newly Diagnosed, H3 K27M-Mutant Gliomas." Dr. Ahluwalia.
- NRG-OV1821, "A Randomized Phase II Trial of Olaparib Versus Olaparib + Tremelimumab in Platinum-Sensitive Recurrent Ovarian Cancer." Dr. Robinson.
- NRG, SWOG study in HPV-associated malignancies by the use of AZD2811, an Aurora B kinase inhibitor, and MEDI4736, anti-PD-L1. Dr. Fu.

Closed Studies

- NCICOVID, "NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study." Dr. Karim. Activated: 5/21/20. Closed: 2/1/2022.
- 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 10/14/2021
- 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.
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- **<u>\$2012</u>**, "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.
- NRG-OV1821, "A Randomized Phase II Trial of Olaparib Versus Olaparib + Tremelimumab in Platinum-Sensitive Recurrent Ovarian Cancer." Dr. Robinson.
- NRG, SWOG study in HPV-associated malignancies by the use of AZD2811, an Aurora B kinase inhibitor, and MEDI4736, anti-PD-L1. Dr. Fu.



We have welcomed a number of new patient advocates since our last in-person meeting!

Roberta Albany, research advocate, breast cancer | Janice Choe, community advocate, Asian/ Pacific Islander community | **Valerie Fraser**, research advocate, palliative and end-of-life care **Eileen Z. Fuentes, MA,** community advocate, Latinx community | **Samantha Guild, JD,** research advocate, melanoma | **Howard Krongard**, **JD**, community advocate, older adult cancer community Joël Pointon, MSPH, community advocate, LGBTQ community | Allison Rosen, research advocate, adolescent & young adult cancer | Lauren Wagner, community advocate, adolescent & young adult community | **Desirée A.H. Walker**, research advocate, recruitment & retention |

Bruce A. Wright, community advocate, military veterans community



Introduce yourself to your SWOG patient advocates today!

Early Therapeutics & Rare Cancers Committee

	51609	AGCT1531	EN131
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	6	-	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	-	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	3	-	1
Heartland Cancer Research NCORP	15	-	1
Henry Ford Hospital	17	-	11
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	-	-
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	17	-	-



Early Therapeutics & Rare Cancers Committee

	51609	AGCT1531	EN131
Northwestern University LAPS	16	-	-
Oregon Health and Science University	11	-	-
Pacific Cancer Research Consortium NCORP	12	-	-
Saint Luke's Hospital of Kansas City	-	-	1
Southeast Clinical Oncology Research Consortium NCORP	-	-	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	-	19
UC San Diego Moores Cancer Center	27	-	-
USC Norris Comprehensive Cancer Center LAPS	4	-	-
University of Arkansas for Medical Sciences	5	-	3
University of Colorado Cancer Center LAPS	6	-	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	-	-
University of Oklahoma Health Sciences Center LAPS	2	-	-
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	-	13
ALLIANCE	105	-	-
ECOG-ACRIN	78	-	-
NRG	136	-	-
Total	789	1	183



Leadership	Oncology Research Professionals:	
Chair:Philip A. Philip, MD, PhD, FRCP	CRA:	Sandy Annis, CCRP
Vice-Chair:Elena G. Chiorean, MD	Nurse:	TBD
Executive Officer:	Patient Advocate (Pancreatic):	Carole Seigel, MBA
Statisticians: Katherine A. Guthrie, PhD	Patient Advocate (Colon):	Florence Kurttila, MS
Shay Bellasea, MS	Pharmaceutical Science:	Jane E. Rogers, PharmD
Scientific Leadership	Protocol Project Manager:	• •
Phase I Studies:	Clinical Trials Program Manager:	Michelle Maxim
Gastroesophageal:Syma Iqbal, MD	Time/Location	
Zev A. Wainberg, MD	Friday, April 8, 2022 3:00 - 5:00 pm	
Pancreatic: Elena Gabriela Chiorean, MD	Room: Elwha B, Level 5	
Andrew M. Lowy, MD (Surgical representative)	Agondo	
Hepatobiliary: Anthony B. El-Khoueiry, MD	Agenda	
Rachna T. Shroff, MD	1. Welcome	
Syed Ahmad, MD (Surgical representative)	2. Announcements& Introductions	
Colon:Philip J. Gold, MD		
	3. SWOG led trials (15 minutes)	
Neuroendocrine Tumors:Nageshwara Arvind Dasari, MD	a. S2104	Soares, Ahmed
Jonathan R. Strosberg, MD	h 62107	Marria Kanata
Ano-Rectal:Lisa A. Kachnic, MD	b. <u>S2107</u>	Morris, Kopetz
Hagen F. Kennecke, MD	c. <u>\$2001</u>	Chung
Translational Medicine:	4. Select NCTN Studies championed by S	SWOG (25 minutes)
	beleet ite itt bedales endinploned by s	71700 (25 milliaces)
	a. EA2174 perioperative eso/GEJ	Kelly
Imaging:	b. A021806 perioperative PDA	Behrman
Pathology:	·	
Radiation Oncology:	c. <u>EA2192</u> adjuvant PDA	Kasi
Surgerystephen w. beniman, MD	d. EA2176 1st line met anal	Morris
Designates	a EA3107 paviaparativa gallbladdar	Docho
Cancer Control Liaisons: Jason A. Zell, DO (Prevention)	e. EA2197 perioperative gallbladder	Rocha
Afsaneh Barzi, MD (CCD)	Gastroesophageal Cancers (12 minutes)	Iqbal, Wainberg
Community Liaisons: Gary L. Buchschacher, MD, PhD (Medical Oncology)	a. Recent highlights	
	b. Ongoing NCTN studies	
Flavio Rocha, MD (Surgical)David Horowitz, MD (Radiation Oncology)	c. Future plans	
		EL 141
	Hepatobiliary (12 minutes)	El-Khoueiry, Shroff
Digital Engagement:	a. Recent highlights	
Data Coordinators:	h Ongoing NCTN studies	
Brian Zeller	b. Ongoing NCTN studies	
Ojasvi Mittal	c. Future plans	
-,		



Pancreatic (12 minutes

Lowy, Sohal

closed: 06/15/21.

a. Recent highlights

3 3

b. Ongoing NCTN studies

c. Future plans

Colon (12 minutes)

Fakih, Gold, Gholami

a. Recent highlights

b. Ongoing NCTN studies

c. Future plans

Anal and Rectal (12 minutes)

Kachnic, Kennecke

a. Recent highlights

b. Ongoing NCTN studies

c. Future plans

Neuroendocrine (12 minutes)

Strosberg, Dasari

a. Recent highlights

b. Ongoing NCTN studies

c. Future plans

5. Patient advocates (5 minutes)

6. Other business

7. Adjourn

Gastroesophageal

Proposed Studies

52214, "A Randomized Phase II Trial of Perioperative Trastuzumab and Atezolizumab given with FLOT or FOLFOX vs. FLOT or FOLFOX alone in Resectable HER2-Overexpressing Gastric/GEJ Adenocarcinoma." Dr. Chao.

Active Studies

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: 2/6/2020. Temporarily

Active Studies

S2001, "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.

Pancreatic

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: 7/1/20.

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.

Proposed Studies

S2211, "Randomized Phase II/III Study of Gemcitabine and nab-paclitaxel with and without CEND-1 for 1st Line Treatment of Metastatic Pancreatic Cancer." Dr. Botta.

Neuroendocrine

Active Studies

S2104, "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

Proposed Studies



<u>52109</u>, "A Phase II Study of Neoadjuvant Nivolumab plus Ipilimumab for Patients with Resectable Hepatocellular Carcinoma." Dr. Kaseb.

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: 03/31/21.

Closed Studies

S1815, "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

Proposed Studies

<u>\$2107</u>, "Randomized Phase II Trial of Encorafenib and Cetuximab with or without Nivolumab for Patients with Microsatellite Stable, BRAFV600E Metastatic Colorectal Cancer." Dr. Morris.

Active Studies

- 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.

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

Closed Studies

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: 1/1/2022.

Anal

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

Other

Active Studies

- **S1922**, "Randomized Phase II Selection Study of Ramucirumab and Paclitaxel Versus FOLFIRI in Refractory Small Bowel Adenocarcinoma." Dr. Overman. Activated: 12/16/19.
- **S1609**, "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.



Accrual from trial opening through 12/31/2021 by Institution and Study

	51613	51815	51922	52001	A021502	4051605	A021703	A021806	EA2142	EA2165
Ascension Prov Hospitals - Southfield	-	-	-	1	2	-	-	-	-	1
Ascension Via Christi Hospitals Wichita	-	1	-	-	-	-	-	-	-	-
Banner U Med Ctr - Tucson	-	13	-	-	2	-	-	1	-	-
Baylor Coll Med/Dan L Duncan CCC	-	6	-	-	-	-	-	-	-	-
Boston Med Ctr	-	-	-	-	1	3	-	1	-	1
CWRU Case CCC LAPS	-	-	-	-	3	-	-	1	-	-
Ca Res Consortium West Mich NCORP	-	2	-	-	-	-	-	-	-	-
Ca Res for the Ozarks NCORP	-	3	-	-	-	-	-	-	-	-
Ca Res of Wisconsin & N Mich Consort	-	2	-	-	-	-	-	-	-	-
City of Hope CCC	-	4	-	1	-	1	-	-	-	-
Columbus NCORP	-	3	-	-	-	-	-	-	-	-
CommonSpirit Health Research Inst	3	4	-	-	-	-	-	-	-	-
Dayton NCORP	-	2	-	-	3	-	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	-	-	-	-	3	-	-	-	-	3
Gulf South MU NCORP	-	4	-	-	-	-	-	-	-	1
Hawaii MU NCORP	-	11	-	-	-	-	-	-	-	-
Heartland Ca Res NCORP	3	7	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	2	-	-	-	-	-	-	1	-
Kaiser Permanente NCORP	2	-	-	-	14	-	-	-	2	6
Lahey Hospital & Med Ctr	1	-	-	-	-	-	-	-	-	-
Loyola U Med Ctr	1	-	-	-	-	-	-	-	-	-
Michigan Ca Res Consortium NCORP	1	-	1	-	-	-	-	-	-	-
Moffitt CC	-	-	-	-	-	4	-	-	-	-
Montana Cancer Consortium NCORP	-	4	-	-	-	-	-	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	-	11	-	-	-	-	-	-	-	1
New Mexico MU NCORP	-	9	-	-	-	-	-	-	-	-
Northwell Health NCORP	-	-	-	-	-	-	6	1	-	-
Northwestern U LAPS	1	17	1	-	-	-	4	-	-	-
Oregon Health & Science U	-	3	-	-	-	-	-	-	-	4



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







Dr. Grant Taylor, first SWOG

group chair

Accrual from trial opening through 12/31/2021 by Institution and Study

	51613	51815	51922	52001	A021502	A021602	A021703	A027806	EA2142	EA2165
Pacific Ca Res Consortium NCORP	3	9	-	-	-	-	-	-	-	-
SCL Health Saint Joseph Hospital	-	-	-	-	-	-	-	-	-	1
Southeast Clin Onc Res Consort NCORP	1	1	-	1	-	-	-	-	-	-
Sutter Ca Res Consortium	-	-	-	-	3	-	-	-	-	2
West Clinic - Wolf River	-	1	-	-	-	-	-	-	-	-
UC Davis CCC LAPS	2	4	-	-	4	-	-	-	-	5
UC Irvine Health/Chao Family CCC	-	3	-	-	-	-	-	-	-	-
USC Norris CCC LAPS	1	9	-	-	1	-	1	-	-	-
U Alabama Birm/Deep South RC LAPS	-	-	-	-	-	-	-	-	-	1
U Arkansas for Medical Sciences	-	2	-	-	-	-	-	-	-	7
U Cincinnati CC-UC Med Ctr	-	2	-	-	-	-	3	-	-	1
U Colorado CC LAPS	1	-	-	-	6	-	1	-	-	-
U Kansas CC - MCA Rural MU NCORP	4	-	-	-	3	-	1	-	-	-
U Michigan CCC LAPS	1	3	2	-	-	2	-	4	3	-
U Rochester LAPS	-	9	1	-	2	4	-	2	-	-
U Texas HSC at San Antonio	-	1	-	-	-	-	-	3	-	-
U Texas MD Anderson CC LAPS	13	22	5	-	-	-	-	-	-	-
U Utah - Huntsman Ca Inst LAPS	-	5	-	1	-	-	-	-	-	-
Upstate Carolina Consortium NCORP	-	1	-	-	-	-	-	-	-	-
Vanderbilt U - Ingram CC LAPS	-	4	-	-	-	-	-	-	-	-
Virginia Mason Med Ctr	-	-	-	-	4	2	-	-	-	-
Wayne State U - Karmanos Ca Inst LAPS	-	2	-	-	2	-	-	-	-	3
William Beaumont Hosp-Royal Oak	-	-	-	-	1	-	-	-	-	-
Wisconsin NCORP	-	1	-	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	-	10	-	-	2	-	3	-	-	-
ALLIANCE	6	122	6	1	-	-	-	-	-	-
ECOG-ACRIN	4	92	1	-	-	-	-	-	-	-
NRG	5	41	2	-	-	-	-	-	-	-
Total	53	452	19	5	56	16	19	13	6	37



Where We Are

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



	EA2174	EA2176	EA2186	EA2187	EA2797	NRGG1005
Ascension Prov Hospitals - Southfield	-	-	2	-	-	1
Ascension Via Christi Hospitals Wichita	-	-	-	-	-	-
Banner U Med Ctr - Tucson	-	-	-	-	-	-
Baylor Coll Med/Dan L Duncan CCC	-	-	-	-	-	-
Boston Med Ctr	-	-	-	-	-	-
CWRU Case CCC LAPS	-	-	-	3	-	-
Ca Res Consortium West Mich NCORP	-	-	-	-	-	-
Ca Res for the Ozarks NCORP	-	-	-	-	-	-
Ca Res of Wisconsin & N Mich Consort	-	-	-	-	-	-
City of Hope CCC	-	-	1	-	-	-
Columbus NCORP	-	-	-	-	-	-
CommonSpirit Health Research Inst	-	-	-	-	-	-
Dayton NCORP	-	-	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	-	-	-	-	-	-
Gulf South MU NCORP	-	-	-	-	-	-
Hawaii MU NCORP	-	-	2	-	-	-
Heartland Ca Res NCORP	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	-	-	1
Kaiser Permanente NCORP	-	2	-	-	-	4
Lahey Hospital & Med Ctr	-	-	-	-	-	-
Loyola U Med Ctr	-	-	-	-	-	-
Michigan Ca Res Consortium NCORP	-	-	-	-	-	-
Moffitt CC	-	-	-	-	-	-
Montana Cancer Consortium NCORP	-	-	-	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	-	-	-	-	-	-
New Mexico MU NCORP	-	-	-	-	-	-
Northwell Health NCORP	-	-	1	-	-	-
Northwestern U LAPS	-	-	1	-	-	-
Oregon Health & Science U	-	-	-	-	1	-



	EA2174	EA2176	EA2186	EA2187	EA2797	NRGG1005
Pacific Ca Res Consortium NCORP	-	-	-	-	-	-
SCL Health Saint Joseph Hospital	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	-	-	-	-	-	-
Sutter Ca Res Consortium	-	-	-	1	-	-
West Clinic - Wolf River	-	-	-	-	-	-
UC Davis CCC LAPS	-	-	-	-	-	1
UC Irvine Health/Chao Family CCC	-	-	-	-	-	-
USC Norris CCC LAPS	1	-	-	-	-	-
U Alabama Birm/Deep South RC LAPS	-	-	-	-	-	-
U Arkansas for Medical Sciences	-	-	-	-	-	-
U Cincinnati CC-UC Med Ctr	-	-	-	-	-	-
U Colorado CC LAPS	-	-	1	-	-	-
U Kansas CC - MCA Rural MU NCORP	-	-	-	1	-	1
U Michigan CCC LAPS	-	-	-	-	-	-
U Rochester LAPS	-	-	4	2	-	-
U Texas HSC at San Antonio	-	-	2	-	-	-
U Texas MD Anderson CC LAPS	-	3	-	-	-	1
U Utah - Huntsman Ca Inst LAPS	-	-	-	-	-	-
Upstate Carolina Consortium NCORP	-	-	-	-	-	-
Vanderbilt U - Ingram CC LAPS	-	-	-	-	-	-
Virginia Mason Med Ctr	-	-	-	-	-	-
Wayne State U - Karmanos Ca Inst LAPS	-	-	-	-	-	-
William Beaumont Hosp-Royal Oak	-	-	-	-	-	-
Wisconsin NCORP	-	-	-	-	-	-
Yale U - Yale CC LAPS	-	-	-	-	-	4
ALLIANCE	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-
NRG	-	-	-	-	-	-
Total	1	5	14	7	1	13



Leadership
Chair:lan M. Thompson, Jr., MD
Vice-Chair: Daniel P. Petrylak, MD
Executive Officer:
Statisticians:
Melissa Plets, MS
Eddie Mayerson, MS
Scientific Leadership
Translational Medicine: David J. McConkey, PhD (GU Chair)
Joshua J. Meeks, MD, PhD (Bladder)
Amir Goldkorn, MD (Prostate)
Sumanta "Monty" K. Pal, MD (Renal)
Radiation Oncology: James B. Yu, MD
Daniel A. Hamstra, MD
Imaging:Evan Y. Yu, MD
Hiram Shaish, MD
John D. Hazle, PhD
Pathology:
Surgery: Kelly L. Stratton, MD
Liaison to the SPORES:
Early Therapeutics:Neeraj Agarwal, MD
Bladder Organ Site Chairs:Seth P. Lerner, MD (Localized)
Thomas W. Flaig, MD (Localized)
Prostate Organ Site Chairs:Daniel W. Lin, MD (Localized)
David I. Quinn, MD, PhD (Advanced)
Renal Organ Site Chairs: Brian Shuch, MD (Localized)
Ulka N. Vaishampayan, MD (Advanced)
Designates
Cancer Control: Peter J. Van Veldhuizen, Jr., MD
Digital Engagement:
Veterans AffairsMichael M. Goodman, MD
Data Coordinators:Jeri Jardine
Tonya Johnson
Michele Counts
Laura Wells
Oncology Research Professionals:
CRAs:Abagail L. Cornette, MS
Cheryl Farlow, RN, OCN
Nurses: Deborah A. Shaw, RN
Patient Advocates:

Margaret "	Peggy" Zuckerman, MEd (Renal)
Pharmaceutical Science:	Joyce Lee, PharmD
	Allison Schepers, PharmD
Protocol Project Manager:	Taj Pereira
Clinical Trials Program Manager:	TBD

Time/Location

GU Committee Part I: Friday, April 8, 2022 3:15 - 6:15 pm

Room: Colubmia CD, Level 3

Time/Location

GU Committee Part II: Saturday, April 9, 2022 8:30 - 11:30 am Room: Colubmia CD, Level 3

Agenda

GU Committee Part I

3:15 – 3:30 – Chair's Welcome and Opening Remarks. Ian Thompson

3:30 – 4:45 – Renal Organ site. (Dr Ulka Vaishampayan and Dr. Brian Shuch)

4:45 – 5:55 – Translational Medicine (Dr. David McConkey)

5:55 – 6:15 – Cancer Control (Dr Peter Van Veldhuizen)

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 Ne-phrectomy for Metastatic Renal Cell Carcinoma (PROBE Trial)." Drs. H. Kim and U. Vaishampayan. Acti-vated: 11/16/20.

Concepts in Development

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. B. Maughan and S. Pal. Initial protocol submission to CTEP: 1/21/22.

Active Studies

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. M. 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. T. 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. M. 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. D. 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. S. Pal and P. Lara. Activated 4/5/16; Permanently closed: 12/15/19.
- **S0931**, "EVEREST: Everolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study." Drs. C. Ryan, E. Heath, P. 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. S. 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. G. 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. P. Lara and B. Shuch. Activated: 2/2/17; Permanently Closed: 6/9/21.

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

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

Diverse Studies of Interest

- **S1609**, "DART: Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors." Drs. S. Patel, Y. Chae, R. 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. S. Liu. Activated: 4/12/19; Temporarily Closed: Cohort A, B, E, F, G, I.
- CTSU/EAY 131, "Molecular Analysis for Therapy Choice (MATCH)." Dr. V. 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 Subproto-cols A, C1, C2, E, L, V, Z1E, and Z1 are closed to accrual: 1/31/22.
- CTSU/EA8134, "InPACT- International Penile Advanced Cancer Trial (International Rare Cancers Initia-tive Study)." Dr. C. Pettaway. Activated: 9/8/17.

Agenda

GU Committee Part II

8:30-9:45 – Bladder Organ Site (Drs Seth Lerner and Thomas Flaig)

9:45-11:30 – Prostate Organ Site (Drs. Tanya Dorff and Daniel Lin)

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 M. Liss, and S. Lerner, et al. Activated: 10/6/21.



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. S. Sadeghi and P. Lara. Activated: 2/16/21.
- **<u>\$1806</u>**, "Phase III Randomized Trial of Concurrent Chemoradiotherapy with or Without Atezolizumab in Localized Muscle Invasive Bladder Cancer." Drs. P. Singh, S. Lerner, J. 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 Treat-ment of Patients with BCG-Unresponsive Non-Muscle Invasive Bladder Cancer." Drs. D. Tyson and C. Ramamurthy. Activated: 1/6/20.
- CTSU/EA8185, "Phase II Study of Bladder-Sparing Chemoradiation with MEDI4736 (Durvalumab) in Clin-ical Stage III, Node Positive Bladder Cancer (INSPIRE)." Drs. T. Mitin and J. Meeks. Activated: 8/25/20.

Closed Studies

- **S1011**, "A Phase III Surgical Trial to Evaluate the Benefit of a Standard Versus an Extended Pelvic Lym-phadenectomy Performed at Time of Radical Cystectomy for Muscle Invasive Urothelial Cancer." Drs. S. Lerner, A. Alva, and T. 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 Inva-sive Bladder Cancer." Drs. R. Svatek, A. Alva, and S. Lerner. Activated: 2/7/17; Permanently Closed: 12/15/2020.
- **S1605**, "Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer." Drs. P. Black, P. Singh, and S. Lerner. Activated: 2/7/17; Permanently Closed: 7/5/19.

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. B. Chapin, A. Aparicio, and R. Valicenti. Activated: 9/17/18.

Concepts in Development

<u>52210</u>, "Targeted neoadjuvant treatment for patients with localized prostate cancer and germline DNA repair deficiency." Dr. H. Cheng. Concept submission to CTEP: 2/8/22.

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 Re-lapsed or Refractory Germ Cell Tumors." Dr. D. Quinn. Activated: 7/1/15.
- CTSU/EA8171, "Multiparametric MRI (mpMRI) for Preoperative Staging and Treatment Planning for New-ly-Diagnosed Prostate Cancer." Dr. M. Liss. Activated: 7/9/18.
- CTSU/NRG-GU002, "Phase II-III Trial of Adjuvant Radiotherapy and Androgen Deprivation Following Radical Prostatectomy with or Without Adjuvant Docetaxel." Dr. D. Raben. Activated: 12/30/16.
- CTSU/NRG-GU005, "Phase III IGRT and SBRT Vs IGRT and Hypofractionated IMRT for Localized In-termediate Risk Prostate Cancer." Dr. A. Solanki. Activated: 11/16/17.
- CTSU/AGCT1531, "A Phase 3 Study of Active Surveillance for Low Risk and a Randomized Trial of Car-boplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors." Dr. A. D'Souza. Activated: 5/8/17; PRO study Temporarily Closed: 2/12/21.

Closed Studies

- S1216, "A Phase III Randomized Trial Comparing Androgen Deprivation Therapy + TAK-700 with Andro-gen Deprivation Therapy + Bicalutamide in Patients with Newly Diagnosed Metastatic Hormone Sensitive Prostate Cancer." Drs. N. Agarwal, A. Goldkorn, S. Gupta, et al. Activated: 3/6/13; Permanently Closed: 7/15/17.
- CTSU/NRG-GU006, "A Phase II, Double-Blinded, Placebo-Controlled Randomized Trial of Salvage Radi-otherapy with or Without Enhanced Anti-Androgen Therapy with Apalutamide in Recurrent Prostate Cancer." Dr. J. Zeng. Activated: 4/27/18; Permanently Closed: 5/19/20.
- <u>CTSU/NRG-GU009</u>, "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. S. Zhang. Activated: 10/15/20; Temporarily Closed: 6/24/21; Re-activated: 12/15/21.

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. T. 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. D. VanderWeele. Acti-vated: 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.

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

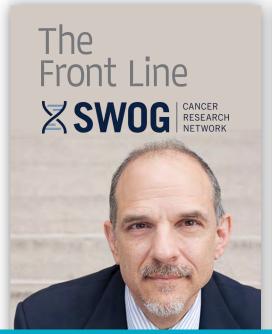
Cancer by Varying the Hormonal Therapy." Dr. D. Lin. Activated: 3/5/20; Temporarily Closed: 6/24/21; Re-activated: 12/1/21

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

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?





THE HOPE FOUNDATION FOR CANCER RESEARCH

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Virtual Symposium Will Feature Community Sites

Part of a New Initiative to Improve Representation in Cancer Clinical Trials

Davidson for Community

The Hope Foundation is helping SWOG launch an effort in collaboration with Genentech, a member of the Roche Group, and other future funders to improve representation of minority and launch amend consultations in source fairful brings.

Designed as a multi-phase, multi-year initiative, the project kicks off on May 21 with a two-hour virtual symposium highlighting the work of staff at community sites across the country who

aff from eight community-based sites, part of the National Cancer Institute's Community ncology Research Program (NCORP), will present short talks on trial accrual strategies, sharing eas about what does and these not work — and why.



he NCORP community and Minority Underserved sites have been dressing and refning strategies to recruit patients to clinical trisis of leaders, "says Dr. Dawn Hershman, SWOG Vice Chair of the 'ODRP's research portfolio." We want to harness all they have armed and work across the National Clinical Trials Network (NCTN) learn from each other and develop best practices for strategies to thance diverse acrowal to all of our trisis."

Symposium talks will also showcase examples of real-time change clinicians and researchers can make to boost poorly performing

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



	51602	51802	51806	51931	51937	A037702	A031501	A031701	A031702	A031704	A031801	A031803	A037902	EA8134	EA81
Ascension Prov Hospitals - Southfield	-	-	-	-	-	-	-	-	-	1	-	-	-	-	
Banner MD Anderson CC	7	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Banner U Med Ctr - Tucson	-	6	-	1	-	-	-	-	-	-	-	-	-	-	7
Baylor Coll Med/Dan L Duncan CCC	21	1	2	-	-	-	1	-	-	-	-	-	-	-	1
CWRU Case CCC LAPS	-	-	-	-	-	-	-	4	-	-	-	-	2	-	-
Ca Res Consortium West Mich NCORP	-	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Ca Res for the Ozarks NCORP	10	1	1	-	-	-	-	-	-	-	-	-	-	-	
Ca Res of Wisconsin & N Mich Consort	-	1	2	-	-	-	-	-	-	-	-	-	-	-	
Cedars-Sinai Med Ctr	12	-	5	1	-	-	-	-	-	-	-	-	-	-	8
City of Hope CCC	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Columbia U MU NCORP	-	-	1	-	-	-	3	-	-	-	-	-	-	-	1
CommonSpirit Health Research Inst	-	-	2	-	1	-	-	-	-	-	-	-	-	-	4
Cotton O'Neil CC / Stormont Vail Hlth	-	-	-	-	-	-	1	-	-	-	-	-	-	-	
Dayton NCORP	1	3	-	-	-	-	-	-	-	1	-	-	-	-	
Fred Hutchinson Ca Res Ctr LAPS	26	8	-	-	-	-	-	-	-	-	-	-	-	-	4
Georgia Cares MU NCORP	-	1	-	-	-	-	-	-	-	-	-	-	-	-	
Gulf South MU NCORP	95	60	40	-	-	-	2	-	-	-	1	9	-	-	1
Hawaii MU NCORP	9	-	2	-	-	-	-	-	-	-	-	-	-	-	2
Heartland Ca Res NCORP	4	8	3	-	-	-	-	-	-	-	-	-	-	-	
Henry Ford Hospital	13	16	3	-	-	-	1	-	1	5	-	-	-	-	3
Houston Methodist Hospital	3	-	-	-	-	-	-	-	-	-	-	-	-	-	
Kaiser Permanente NCORP	12	14	-	-	-	-	14	-	-	40	-	-	-	-	4
Lahey Hospital & Med Ctr	-	-	-	-	-	-	4	-	6	-	-	-	-	-	4
Loma Linda U Med Ctr	-	-	-	-	-	-	2	-	-	-	-	-	-	-	
Loyola U Med Ctr	12	9	4	-	-	-	-	-	1	1	-	-	-	-	4
Massachusetts Veterans ERIC	-	-	-	-	-	-	-	-	-	-	-	-	1	-	
Medical U South Carolina MU NCORP	2	2	-	-	-	-	-	-	-	-	-	-	-	-	
Michigan Ca Res Consortium NCORP	6	7	9	-	1	-	-	-	-	-	-	-	-	-	
Moffitt CC	26	-	-	-	-	-	-	-	-	-	-	-	-	-	
Montana Cancer Consortium NCORP	1	3	-	-	-	-	-	-	-	-	-	-	-	-	
NCORP Carolinas (Prisma Hlth NCORP)	1	6	-	-	-	-	-	-	-	1	-	-	-	-	:
Nevada Ca Res Foundation NCORP	2	1	-	-	-	-	-	-	-	-	-	-	-	-	2
New Mexico MU NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Northwell Health NCORP	-	-	1	-	-	-	-	-	-	1	-	-	-	-	
Northwestern U LAPS	35	-	6	-	-	-	-	-	-	1	-	-	-	-	
Ohio State U CCC LAPS	4	1	1	-	_	-	-	-	-	-	_	_	_	-	



	51602	51802	51806	51931	51937	A031702	A031501	A031701	A031702	A031704	A031801	A031803	A037902	EA8134	EA87A
Oregon Health & Science U	14	-	1	-	-	-	-	-	3	3	-	-	-	-	14
Pacific Ca Res Consortium NCORP	24	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SCL Health Saint Joseph Hospital	-	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	-	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Sutter Ca Res Consortium	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-
Tulane U Health Sciences Ctr	-	-	-	4	-	-	-	-	-	-	-	-	-	-	10
UC Davis CCC LAPS	-	9	7	-	-	-	4	4	-	2	2	3	-	-	1
UC Irvine Health/Chao Family CCC	16	2	3	-	-	-	-	-	-	-	-	-	-	-	1
UC San Diego Moores CC	-	1	1	-	-	-	-	-	-	-	-	-	-	-	2
UCLA / Jonsson CCC	-	-	-	-	-	-	-	-	-	-	-	-	-	-	8
USC Norris CCC LAPS	44	5	-	-	2	11	13	-	3	-	-	-	-	8	-
U Alabama Birm/Deep South RC LAPS	-	-	-	-	-	-	-	-	1	-	1	1	-	-	6
U Arkansas for Medical Sciences	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
U Cincinnati CC-UC Med Ctr	-	4	3	1	-	-	-	-	-	6	-	-	-	-	-
U Colorado CC LAPS	23	4	2	-	-	-	13	-	-	7	-	-	-	-	1
U Kansas CC - MCA Rural MU NCORP	20	7	4	-	-	-	5	-	1	4	-	-	-	-	2
U Kentucky/Markey CC	-	-	2	-	-	-	-	-	-	-	-	-	-	-	12
U Michigan CCC LAPS	30	2	-	5	-	-	18	-	-	-	-	-	-	-	-
U Mississippi Med Ctr	-	1	-	-	-	-	-	-	1	-	-	-	-	-	3
U Oklahoma Health Sciences Ctr LAPS	51	25	14	2	-	-	-	-	-	-	-	-	-	-	-
U Rochester LAPS	20	17	-	-	-	-	-	-	3	5	-	-	-	-	1
U Texas HSC at San Antonio	58	2	-	1	-	-	-	-	-	-	-	4	-	-	14
U Texas MD Anderson CC LAPS	38	61	-	-	-	-	-	-	-	-	-	-	-	-	-
U Utah - Huntsman Ca Inst LAPS	47	15	-	1	-	-	3	-	-	-	-	-	-	-	2
Upstate Carolina Consortium NCORP	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Vanderbilt U - Ingram CC LAPS	-	1	2	-	-	-	-	-	-	-	-	-	-	-	-
Virginia Mason Med Ctr	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Wayne State U - Karmanos Ca Inst LAPS	-	1	-	-	-	-	-	-	-	-	-	-	-	-	2
Western States Ca Res NCORP	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Wisconsin NCORP	-	4	3	-	-	-	-	-	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	3	1	1	-	-	-	8	-	-	-	-	-	-	-	1
ALLIANCE	110	72	12	-	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	111	51	22	-	-	-	-	-	-	-	-	-	-	-	-
NRG	88	54	68	-	-	-	-	-	-	-	-	-	-	-	-
Total	1,000	497	233	16	4	11	93	8	20	78	4	17	3	8	17



	EA8153	EA8171	EA8183	EA8191	NRGGU002	NRGGU005	NRGGU008	NRGGY023
Ascension Prov Hospitals - Southfield	-	-	-	-	-	-	-	-
Banner MD Anderson CC	-	-	-	-	-	-	-	-
Banner U Med Ctr - Tucson	-	-	-	-	-	-	-	-
Baylor Coll Med/Dan L Duncan CCC	-	-	-	-	-	-	-	-
CWRU Case CCC LAPS	-	-	-	-	-	-	-	-
Ca Res Consortium West Mich NCORP	-	-	-	-	-	-	-	-
Ca Res for the Ozarks NCORP	-	-	-	-	-	-	-	-
Ca Res of Wisconsin & N Mich Consort	-	-	-	-	-	-	-	-
Cedars-Sinai Med Ctr	-	-	-	-	-	-	-	-
City of Hope CCC	-	-	-	-	-	-	-	-
Columbia U MU NCORP	-	-	-	-	-	-	-	-
CommonSpirit Health Research Inst	-	-	-	-	-	-	-	-
Cotton O'Neil CC / Stormont Vail HIth	-	-	-	-	-	-	-	-
Dayton NCORP	-	-	-	-	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	-	-	-	-	-	-	-	-
Georgia Cares MU NCORP	-	-	-	-	-	-	-	-
Gulf South MU NCORP	-	11	-	-	1	1	3	-
Hawaii MU NCORP	-	1	-	-	-	-	-	-
Heartland Ca Res NCORP	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	-	-	-	-	-
Houston Methodist Hospital	-	-	-	-	-	-	-	-
Kaiser Permanente NCORP	10	-	-	-	-	-	-	-
Lahey Hospital & Med Ctr	-	-	1	-	-	-	-	-
Loma Linda U Med Ctr	-	-	-	-	-	-	-	-
Loyola U Med Ctr	-	-	-	-	-	-	-	-
Massachusetts Veterans ERIC	-	-	-	-	-	-	-	-
Medical U South Carolina MU NCORP	-	-	-	-	-	-	-	-
Michigan Ca Res Consortium NCORP	-	-	-	-	-	-	-	-
Moffitt CC	-	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	-	-	-	-	-	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	-	-	-	-	-	-	-	-
Nevada Ca Res Foundation NCORP	-	-	-	-	-	-	-	-
New Mexico MU NCORP	-	-	-	-	-	1	-	-
Northwell Health NCORP	-	-	-	-	-	-	-	-
Northwestern U LAPS	-	-	-	-	-	-	-	-
Ohio State U CCC LAPS	_	_	_	-	_	-	_	-



	EA8153	EA8171	EA8183	EA8191	NRGGU002	NRGGU005	NRGGU008	NRGGYO
Oregon Health & Science U	-	2	-	-	-	-	-	-
Pacific Ca Res Consortium NCORP	-	-	-	-	-	-	-	-
SCL Health Saint Joseph Hospital	-	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	-	-	-	-	-	-	-	-
Sutter Ca Res Consortium	-	-	-	-	-	2	-	1
Tulane U Health Sciences Ctr	-	-	-	-	-	1	-	-
UC Davis CCC LAPS	-	-	-	-	-	-	-	-
UC Irvine Health/Chao Family CCC	-	-	-	-	-	-	-	-
UC San Diego Moores CC	-	-	-	-	-	-	-	-
UCLA / Jonsson CCC	-	-	-	-	-	-	-	-
USC Norris CCC LAPS	-	-	-	-	-	-	-	-
U Alabama Birm/Deep South RC LAPS	-	-	-	-	-	-	-	-
U Arkansas for Medical Sciences	-	-	-	-	-	-	-	-
U Cincinnati CC-UC Med Ctr	-	-	-	-	-	-	-	-
U Colorado CC LAPS	-	-	-	-	1	1	-	-
U Kansas CC - MCA Rural MU NCORP	1	-	-	-	-	-	-	-
U Kentucky/Markey CC	-	-	-	-	-	-	-	-
U Michigan CCC LAPS	-	-	-	-	-	-	-	-
U Mississippi Med Ctr	2	-	-	-	1	-	-	-
U Oklahoma Health Sciences Ctr LAPS	-	-	-	1	-	-	-	-
U Rochester LAPS	-	-	-	-	-	-	-	-
U Texas HSC at San Antonio	-	45	-	-	-	-	-	-
U Texas MD Anderson CC LAPS	8	-	-	-	-	-	-	-
U Utah - Huntsman Ca Inst LAPS	8	-	-	-	-	-	-	-
Upstate Carolina Consortium NCORP	-	-	-	-	-	-	-	-
Vanderbilt U - Ingram CC LAPS	-	-	-	-	-	-	-	-
Virginia Mason Med Ctr	-	-	-	-	-	3	-	-
Wayne State U - Karmanos Ca Inst LAPS	-	-	-	-	1	-	-	-
Western States Ca Res NCORP	-	-	-	-	-	-	-	-
Wisconsin NCORP	-	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	2	-	-	-	-	-	-	-
ALLIANCE	-	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-	-	-
NRG	-	-	-	-	-	-	-	-
Total	31	59	1	1	4	9	3	1



Leadership

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

Time/Location

Saturday, April 9, 2022 8:15 - 10:15 am VIRTUAL ONLY

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. L. Liesveld. Activated: 1/16/19.

Closed Studies

S1612, "A Randomized Phase II/III Trial of "Novel Therapeutics" Versus Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia (AML) or High-Risk Myelodysplastic Syndrome (MDS), Age 60 or Older." Drs. L. Michaelis, R. Walter, S. Assouline, et al. Activated: 12/22/17; Closed: 9/1/20.

- **S0919**, "A Phase II Study of Idarubicin and Ara-C in Combination with Pravastatin for Poor-Risk Acute Myelogenous Leukemia (AML)." Dr. A. Advani. Re-Activated: 4/1/13; Closed: 9/15/17.
- **S1203**, "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.
- **S1612**, "A Randomized Phase II/III Trial of "Novel Therapeutic(s)" versus Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia Age 60 or Older." Drs. Michaelis and Walter. Activated: 12/22/17; Closed: 10/22/18.

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. A. Advani, N. Papadantonakis, and C. Yeung. Activated: 8/17/20.
- S1318, "A Phase II Study of Blinatumomab (NSC-765986) and POMP (Prednisone, Vincristine, Methotrexate, 6-Mercaptopurine) for Patients ≥ 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Negative (Ph-) Acute Lymphoblastic Leukemia (ALL) and of Dasatinib (NSC-732517), Prednisone and Blinatumomab for Patients ≥ 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Positive (Ph+) ALL, Relapsed/Refractory Philadelphia-Chromosome Positive (Ph+) ALL, and Philadelphia-Chromosome-Like Signature (Ph-Like) ALL (Newly Diagnosed or Relapsed/Refractory) with Known or Presumed Activating Dasatinib-Sensitive Mutations or Kinase Fusions (DSMKF)." Drs. Advani, O'Dwyer, and Wood. Activated: 1/12/15; Permanent Closure of Cohort 1: 9/15/17; Permanent Closure of Steps 1 and 2: 4/15/21.
- 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. A. Advani. Activated: 6/1/17.

Proposed Studies

S2113, "A Randomized Phase II Trial to Evaluate the Efficacy of Combination Bcl-2 Inhibitor Therapy with Chemotherapy Compared to Chemotherapy Alone in Adult Patients with Newly Diagnosed T-Cell ALL and T-Cell Lymphoblastic Lymphoma." Dr. K. O'Dwyer.



Closed Studies

S0333, "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: 11/01/09.

S1312, "A Phase I Study of Inotuzumab Ozogamicin in Combination with CVP (Cyclophosphamide, Vincristine, Prednisone) for Patients with Relapsed/Refractory CD22-Positive Acute Leukemia (Including B-ALL, Mixed Phenotypic Leukemia, and Burkitt's Leukemia)." Drs. A. 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. A. Advani and K. O'Dwyer. Activated: 1/12/15; Closed: 4/15/21.

CLL Studies

Active Studies

S1925, "Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab Versus Delayed Therapy with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia / Small Lymphocytic Lymphoma (CLL): EVOLVE CLL/SLL Study." Drs. D. Stephens, B. Hill, J. Pagel, et al. Activated: 12/14/20.

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. B. Hill. Activation: 1/4/19.

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. M. Shadman. Activated: 1/3/19. Closed: 4/30/21.

CML Studies

Active Studies

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

MyeloMATCH

Proposed Studies

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

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

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." Dr. R. Shallis.



	51318	51712	51905	51925	A041501	A041701	A041702	A047703	EA9161	EA9171	EA9181
Ascension Via Christi Hospitals Wichita	1	-	-	-	-	-	-	-	-	-	-
Banner U Med Ctr - Tucson	-	-	-	-	-	-	4	-	4	-	-
Baptist Mem HC/Mid South MU NCORP	-	1	-	-	-	-	-	-	-	-	-
CWRU Case CCC LAPS	6	-	1	1	4	-	3	-	-	-	-
Ca Res for the Ozarks NCORP	-	1	-	-	-	-	-	-	-	-	-
City of Hope CCC	4	-	1	-	-	-	-	-	-	-	-
CommonSpirit Health Research Inst	-	-	-	-	-	-	-	-	1	-	-
Dayton NCORP	-	-	-	-	-	-	1	-	2	-	-
Duke U - Duke Ca Inst LAPS	-	3	-	-	-	-	-	-	9	-	-
Fred Hutchinson Ca Res Ctr LAPS	-	1	1	-	-	-	-	-	9	-	-
Hawaii MU NCORP	-	6	-	-	-	-	-	-	-	-	1
Heartland Ca Res NCORP	1	4	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	1	-	4	3	-	1	-	-
Intermountain Med Ctr	-	-	-	-	2	-	-	-	-	-	-
Kaiser Permanente NCORP	-	-	-	-	-	-	6	-	32	-	-
Lahey Hospital & Med Ctr	-	-	-	-	-	-	1	-	-	-	-
Loma Linda U Med Ctr	1	-	-	-	-	-	-	-	-	-	-
Loyola U Med Ctr	-	1	-	-	-	-	1	-	2	-	-
Medical U South Carolina MU NCORP	-	-	-	1	-	-	1	-	7	-	-
Michigan Ca Res Consortium NCORP	-	1	-	1	-	-	-	-	-	-	-
Moffitt CC	-	11	-	-	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	-	1	-	-	-	-	-	-	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	1	1	-	-	-	-	-	-	1	-	-
Nevada Ca Res Foundation NCORP	-	1	-	-	-	-	3	-	5	-	-
New Mexico MU NCORP	1	3	-	-	-	-	-	-	1	-	-
Northwell Health NCORP	-	-	-	-	-	2	-	-	_	-	-



	51318	51712	51905	51925	A047507	A041707	A041702	A041703	EA9161	EA9777	EA9181
Northwestern U LAPS	-	-	-	-	1	1	2	-	-	-	3
Oregon Health & Science U	-	3	1	-	7	-	4	-	9	-	-
Orlando Health Ca Inst	1	-	-	-	-	-	-	-	-	-	-
Salem Hospital	-	-	-	-	-	-	-	-	4	-	-
Southeast Clin Onc Res Consort NCORP	-	-	-	-	-	-	-	-	2	-	-
Stanford Ca Inst Palo Alto	-	-	-	-	8	-	11	-	29	-	-
UC Davis CCC LAPS	-	-	-	-	2	-	-	-	-	-	-
UC Irvine Health/Chao Family CCC	4	-	-	-	3	-	-	-	-	-	-
UC San Diego Moores CC	1	-	-	-	-	-	-	-	-	-	-
USC Norris CCC LAPS	3	-	-	-	-	-	-	-	-	-	-
U Alabama Birm/Deep South RC LAPS	1	-	-	-	1	-	-	-	7	-	-
U Arkansas for Medical Sciences	-	-	-	-	-	4	-	-	-	-	-
U Cincinnati CC-UC Med Ctr	-	-	1	-	-	-	-	1	-	-	1
U Colorado CC LAPS	-	-	-	-	-	-	1	-	1	-	-
U Kansas CC - MCA Rural MU NCORP	-	-	-	-	-	-	6	-	8	-	-
U Michigan CCC LAPS	2	-	-	-	-	-	-	-	-	-	-
U Rochester LAPS	4	5	1	2	5	27	1	3	1	-	5
U Utah - Huntsman Ca Inst LAPS	-	5	-	4	1	-	4	-	22	-	-
Wayne State U - Karmanos Ca Inst LAPS	-	-	-	-	-	-	-	-	4	-	2
Western States Ca Res NCORP	-	-	-	-	-	-	2	-	1	-	-
Yale U - Yale CC LAPS	1	-	-	-	4	-	2	-	10	2	-
ALLIANCE	1 <i>7</i>	9	2	1	-	-	-	-	-	-	-
ECOG-ACRIN	6	5	-	2	-	-	-	-	-	-	-
NRG	2	2	-	-	-	-	-	-	-	-	-
Total	<i>57</i>	64	8	13	38	38	56	4	172	2	12



Lung Committee

Leadership
Chair:
Vice-Chair: Roy S. Herbst, MD, PhD
•
Executive Officer:
Statisticians:
Yingqi Zhao, PhD
Katherine Minichiello, MS
Jieling Miao, MS
James Moon, MS
Lu Qian, MS
Scientific Leadership
Translational Medicine:
Biology/PathologyPhilip C. Mack, PhD
Fred R. Hirsch, MD, PhD
Ignacio I. Wistuba ME
Imaging:Chadwick L. Wright MD, PhD
Radiation Oncology:
Surgery:
Subcommittee Chairs:
Early Stage Disease:
Locally Advanced Disease:
Shirish Gadgeel, MD (Early Therapeutics
Metastatic Disease: Ross Camidge, MD
Karen Reckamp, MD
Community Engagement:
Suzanne Cole, MD
Designates
Cancer Control Liaison:
Veterans Affairs:
Cheryl M. Czerlanis, MD
Data Coordinators: Leah Everhar
Louise Highleymar
Larry Kaye
•
Clinical Research Project Manager: TBD
Oncology Research Professionals:
CRAs:
Nurses: Kimberly M. Belzer, MS, PAC
Rosalie Zablocki, RN
Patient Advocate:Judy Johnson, MBA
Pharmaceutical Science: Joyce Lee, PharmD
Kimberly McConnell, PharmE

Protocol Project Managers:	Mariah Norman
Laura Gi	Idner, MS (Lung-MAP)
Jenni	fer Beeler (Lung-MAP)
Clinical Trials Program Manager:	Crvstal Miwa

Time/Location

Saturday, April 9, 2022 8:30 - 11:30 am Room: Columbia A, Level 3

Agenda

	· ·
8:30 – 8:40 am	General Update
8:40 – 8:50 am	Patient Advocate Update: Judy Johnson, MBA
8:50 – 9:00 am	Thoracic Surgery Session: Wayne Hofstetter, MD
9:00 – 9:10 am	Thoracic Radiation Session: Megan Daly, MD
9:10 – 9:20 am	Translational Medicine Session: Phil C. Mack, PhD
9:20 – 9:30 am	Community Engagement Core: Paul J. Hesketh, MD
9:30 – 10:00 am	Scientific Presentation #1 Targeting myeloid lineage cells to improve ICB efficacy in NSCLC McGarry Houghton, MD Lung SPORE PI Professor, Clinical Research Division & Human Biology Division Fred Hutchinson Cancer Research Center
10:00 – 11:00 am	Thoracic Medical Oncology Session: Jhanelle Gray, MD
11:00 – 11:30 am	Scientific presentation #2 Immuno-oncology Biomarkers on Lung Cancer and the CIMAC-CIDC Network Ignacio I. Wistuba, MD Head ad <i>interim</i> , Division of Pathology and Laboratory Medicine Chair, Department of Translational Molecular Pathology The University of Texas MD Anderson Cancer Center
	Active Studies

Active Studies

LUNGMAP, "A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study)." Drs. Herbst, Patel, Gandara, et al. Activation: 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. Activation: 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. Activation: 4/2/21.
- **S1701**, "A Randomized Phase II Trial of Carboplatin-Paclitaxel with or without Ramucirumab in Patients with Unresectable Locally Advanced, Recurrent, or Metastatic Thymic Carcinoma." Drs. Tsao and Koczywas. Activation: 8/9/18.
- **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. Activation: 1/10/20.
- **<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. Activation: 3/25/20.
- **S1929**, "Phase II Randomized Study of Maintenance Atezolizumab Versus Atezolizumab in Combination with Talazoparib in Patients with SLFN11 Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC)." Drs. Karim, Reckamp, Gay, et al. Activation: 6/15/20.
- <u>S1933</u>, "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. Activation: 6/15/20.
- 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. Activation: 9/9/21; Temporary closure: 11/5/21; Reactivation: 2/15/22.
- CTSU/EA5163/S1709, "INSIGNA: A Randomized, Phase III Study of First-line Immunotherapy Alone or in Combination with Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature-driven Analysis." Dr. Chiang. Activation: 2/28/19.
- CTSU/A081105, "Randomized Study of Erlotinib Vs Observation in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC)." Dr. Kelly. Activation: 8/18/14; Temporary closure: 6/15/20; Reactivation: 7/15/20. Closed to Accrual: 1/20/21.
- CTSU/A081801, "Integration of Immunotherapy into Adjuvant Therapy for

- Resected NSCLC: ALCHEMIST Chemo-IO (ACCIO)." Dr. Gray. Activation: 6/3/20; Temporary closure: 10/22/21.
- CTSU/A082002, "A Randomized Phase II/III Trial of Modern Immunotherapy Based Systemic Therapy with or without SBRT for PD-L1-Negative, Advanced Non-small Cell Lung Cancer." Dr. Armini. Activation: 12/21/21.
- CTSU/A151216, "Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)." Dr. Gandara. Activation: 8/18/14.
- CTSU/E4512, "A Randomized Phase III Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib Versus Observation for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein." Dr. Li. Activation: 8/18/14.
- CTSU/EA5181, "Randomized Phase III Trial of MEDI4736 (Durvalumab) as Concurrent and Consolidative Therapy or Consolidative Therapy Alone for Unresectable Stage 3 NSCLC." Dr. Harkenrider. Activation: 4/9/20.
- CTSU/NRG-CC003, "Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer." Dr. Gaspar. Activation: 12/7/15; Temporary closure: 5/28/20; Reactivation: 7/27/20.
- 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. Activation: 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. Activation: 5/28/19.

Closed Studies

None since October 2021.

NCI-Approved Concepts

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)." Drs. Elamin and Gray.

Concepts in Development

- **S1900G**, "A Randomized Phase II Study of Capmatinib plus Osimertinib with or without Ramucirumab in Participants with EGFR-Mutant, MET-Amplified Stage IV Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)." Drs. Goldberg and Camidge.
- **S1900H**, "A Phase II Study of Tepotinib and Ramucirumab in Participants with Met Exon 14 Skipping and Advanced Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)." Drs. Paik and Le.



	LUNGMAP	51707	51800A	51827	51900A	51900B	51900C	51900E	51914	51929	51933	A08110
Ascension Prov Hospitals - Southfield	12	-	-	-	-	-	-	-	-	1	-	-
Ascension Via Christi Hospitals Wichita	1	-	-	-	-	-	-	-	-	-	-	-
Banner MD Anderson CC	-	-	-	-	-	-	-	-	-	-	-	-
Banner U Med Ctr - Tucson	-	-	-	-	-	-	-	-	-	-	-	-
Baptist Mem HC/Mid South MU NCORP	34	-	-	-	3	-	1	1	2	2	-	-
Boston Med Ctr	-	-	-	3	-	-	-	-	-	-	-	-
CWRU Case CCC LAPS	5	-	-	-	-	-	1	1	-	-	-	6
Ca Res Consortium West Mich NCORP	3	-	1	-	1	-	1	-	2	-	-	-
Ca Res for the Ozarks NCORP	27	-	-	-	-	-	2	-	-	2	3	1
Ca Res of Wisconsin & N Mich Consort	18	-	-	-	2	-	2	3	-	-	-	-
Carle CC NCORP	2	-	-	-	-	-	-	-	-	-	-	-
Cedars-Sinai Med Ctr	2	-	-	-	-	-	-	-	-	-	-	-
City of Hope CCC	5	1	-	1	-	-	-	-	-	-	-	1
Columbia U MU NCORP	6	-	-	-	1	-	1	-	-	-	-	-
Columbus NCORP	21	-	-	2	4	-	-	-	-	-	-	-
CommonSpirit Health Research Inst	43	-	6	-	1	-	1	-	1	2	-	-
Cotton O'Neil CC / Stormont Vail HIth	-	-	1	-	-	-	-	-	-	-	-	-
Dayton NCORP	6	-	-	-	-	-	-	-	-	1	-	-
Essentia Health NCORP	15	-	-	-	-	-	1	-	1	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	4	-	-	-	-	-	-	-	-	-	-	1
Georgia Cares MU NCORP	6	-	1	1	-	-	-	-	2	3	1	-
Georgia NCORP	45	-	3	2	2	-	-	-	1	-	-	-
Gulf South MU NCORP	7	-	-	1	-	-	-	-	1	-	-	-
Hawaii MU NCORP	21	-	1	-	-	-	-	-	-	-	-	-
Heartland Ca Res NCORP	102	-	11	-	6	1	1	4	13	10	1	-
Henry Ford Hospital	7	-	-	-	2	-	-	-	-	1	-	2
Houston Methodist Hospital	-	-	-	-	-	-	-	-	-	-	-	2
Kaiser Permanente NCORP	51	-	2	-	-	-	1	6	1	-	-	19
Lahey Hospital & Med Ctr	25	-	4	-	-	-	-	-	1	1	2	-
Loma Linda U Med Ctr	5	-	-	-	-	-	1	-	-	-	-	3
Loyola U Med Ctr	18	-	1	-	-	-	-	-	-	-	-	-
Massachusetts Veterans ERIC	28	-	4	-	1	-	-	-	-	-	-	1
Medical U South Carolina MU NCORP	7	-	-	-	-	-	-	1	-	-	-	-
Michigan Ca Res Consortium NCORP	84	-	10	-	3	-	5	4	1	1	-	-
Moffitt CC	5	2	-	1	-	-	-	-	-	-	-	3
Montana Cancer Consortium NCORP	24	-	5	-	2	-	1	-	-	3	1	-
Mount Sinai Hospital	-	-	-	-	-	-	-	-	6	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	15	-	1	-	-	-	-	1	-	-	-	-
Nevada Ca Res Foundation NCORP	11	-	1	-	-	-	-	-	-	-	-	-



	LUNGMAP	51707	51800A	51827	51900A	51900B	51900C	51900E	51974	51929	51933	A0811
New Mexico MU NCORP	64	-	3	1	2	-	-	-	3	3	1	-
Northwell Health NCORP	-	-	-	-	-	-	-	-	-	-	-	-
Northwestern U LAPS	19	1	-	-	-	-	-	-	-	1	-	-
Oregon Health & Science U	1	-	-	-	-	-	-	-	1	-	-	1
Pacific Ca Res Consortium NCORP	12	-	-	-	-	-	-	-	-	3	-	-
SCL Health Saint Joseph Hospital	1	-	-	-	-	-	-	-	1	-	-	-
Salem Hospital	3	-	1	-	-	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	43	-	8	4	2	-	-	-	2	3	-	-
Sutter Ca Res Consortium	20	-	2	-	-	-	-	1	-	-	-	1
Don & Sybil Harrington CC	6	-	-	-	-	-	-	-	-	-	-	-
James Graham Brown CC at U Louisville	-	-	-	-	-	-	-	-	-	-	-	-
UC Davis CCC LAPS	20	3	3	1	3	-	-	-	4	1	-	4
UC Irvine Health/Chao Family CCC	17	-	1	1	-	-	-	-	1	-	-	2
UC San Diego Moores CC	9	-	-	-	-	-	-	1	-	-	-	1
UPMC Hillman CC LAPS	13	-	-	-	-	-	-	3	-	-	-	-
USC Norris CCC LAPS	-	-	-	-	-	-	-	-	1	-	-	1
U Arkansas for Medical Sciences	9	-	3	-	-	-	-	-	4	-	-	-
U Cincinnati CC-UC Med Ctr	-	-	-	-	-	-	-	-	-	-	-	1
U Colorado CC LAPS	10	-	1	1	-	-	-	-	2	1	-	9
U Kansas CC - MCA Rural MU NCORP	72	-	4	-	4	-	2	1	-	-	-	1
U Kentucky/Markey CC	40	-	2	1	-	-	3	-	-	-	-	1
U Michigan CCC LAPS	1	-	-	-	-	-	-	-	-	-	-	1
U Mississippi Med Ctr	1	-	1	-	-	-	-	-	-	-	-	2
U Oklahoma Health Sciences Ctr LAPS	24	-	2	1	1	-	-	-	-	-	7	-
U Rochester LAPS	49	-	2	-	3	-	-	5	1	-	-	-
U Texas HSC at San Antonio	-	-	-	-	-	-	-	-	-	-	-	-
U Texas MD Anderson CC LAPS	3	4	-	-	-	-	-	-	-	2	-	-
U Utah - Huntsman Ca Inst LAPS	-	-	-	1	-	-	-	-	2	-	-	-
Upstate Carolina Consortium NCORP	23	-	5	-	-	-	1	-	1	-	-	-
Wayne State U - Karmanos Ca Inst LAPS	1	-	-	-	-	-	-	-	-	-	-	-
Western States Ca Res NCORP	2	-	-	-	-	-	-	-	-	-	-	-
William Beaumont Hosp-Royal Oak	-	-	-	-	-	-	-	-	-	-	-	-
Wisconsin NCORP	34	-	1	-	1	-	1	-	2	-	-	-
Yale U - Yale CC LAPS	16	-	7	1	1	-	3	-	-	-	-	3
ALLIANCE	562	3	36	9	9	1	9	6	4	3	1	-
сст	-	-	-	2	-	-	-	-	-	-	-	-
ECOG-ACRIN	270	2	17	2	5	2	7	8	4	5	-	-
NRG	265	-	15	34	5	2	2	2	6	5	1	-
Total	2,275	16	166	70	64	6	47	48	71	54	18	67



	A081801	A151216	E4572	EA5163	EA5181	EA5182	EA5191	NRGCC003	NRGLU002	NRGLU005	R1308
Ascension Prov Hospitals - Southfield	-	14	1	2	1	-	1	-	-	-	-
Ascension Via Christi Hospitals Wichita	-	-	-	-	-	-	-	-	-	-	-
Banner MD Anderson CC	1	1	-	-	-	-	-	-	-	1	-
Banner U Med Ctr - Tucson	-	7	2	-	4	-	-	-	-	-	-
Baptist Mem HC/Mid South MU NCORP	-	19	-	-	-	-	-	-	1	3	-
Boston Med Ctr	-	3	-	-	1	-	-	-	-	-	-
CWRU Case CCC LAPS	4	48	-	7	10	-	-	-	-	-	-
Ca Res Consortium West Mich NCORP	-	1	-	-	-	-	-	-	-	-	-
Ca Res for the Ozarks NCORP	-	1	-	-	-	-	-	-	-	-	-
Ca Res of Wisconsin & N Mich Consort	-	-	-	-	-	-	-	-	-	-	-
Carle CC NCORP	-	-	-	-	-	-	-	-	-	-	-
Cedars-Sinai Med Ctr	-	-	-	-	-	-	-	-	-	-	-
City of Hope CCC	-	4	-	-	-	-	-	-	-	-	-
Columbia U MU NCORP	-	-	-	-	-	-	-	-	-	-	-
Columbus NCORP	-	-	-	-	-	-	-	-	-	-	-
CommonSpirit Health Research Inst	-	2	-	-	-	-	-	-	-	-	-
Cotton O'Neil CC / Stormont Vail HIth	-	3	-	-	-	-	-	-	-	-	-
Dayton NCORP	-	8	-	-	-	-	-	-	-	-	-
Essentia Health NCORP	-	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	-	15	-	-	-	-	-	-	-	-	-
Georgia Cares MU NCORP	-	-	-	-	-	-	-	-	-	-	-
Georgia NCORP	-	9	-	1	-	-	-	-	-	-	-
Gulf South MU NCORP	-	-	-	3	-	-	-	-	-	-	-
Hawaii MU NCORP	-	-	-	-	-	-	-	-	-	-	-
Heartland Ca Res NCORP	-	-	-	-	-	-	-	1	-	-	-
Henry Ford Hospital	2	29	-	-	-	-	-	-	-	-	-
Houston Methodist Hospital	-	8	-	-	-	-	-	-	-	-	-
Kaiser Permanente NCORP	1	197	4	3	-	1	-	-	-	-	-
Lahey Hospital & Med Ctr	-	30	-	1	-	-	-	-	-	-	-
Loma Linda U Med Ctr	-	9	-	-	-	-	-	-	-	-	1
Loyola U Med Ctr	-	21	-	-	2	-	-	-	-	-	-
Massachusetts Veterans ERIC	6	25	-	3	-	-	-	-	-	-	-
Medical U South Carolina MU NCORP	-	-	-	-	-	-	-	-	-	-	-
Michigan Ca Res Consortium NCORP	-	-	-	-	-	-	-	-	-	-	-
Moffitt CC	5	83	1	-	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	-	-	-	-	-	-	-	-	-	-	-
Mount Sinai Hospital	-	-	-	-	1	-	-	-	-	1	-
NCORP Carolinas (Prisma Hlth NCORP)	-	1	-	-	-	-	-	-	-	-	-
Nevada Ca Res Foundation NCORP	-	-	-	-	-	-	-	-	-	-	-



	A081801	A757276	E4512	EA5163	EA5181	EA5182	EA5191	NRGCC003	NRGLU002	NRGLU005	R130
New Mexico MU NCORP	-	-	-	-	-	-	-	-	-	-	-
Northwell Health NCORP	1	1	-	-	-	-	-	-	-	-	-
Northwestern U LAPS	-	-	-	-	-	-	-	-	-	-	-
Oregon Health & Science U	4	19	-	-	-	-	-	-	-	-	-
Pacific Ca Res Consortium NCORP	-	4	-	-	-	-	-	-	-	-	-
SCL Health Saint Joseph Hospital	1	2	-	-	-	-	-	-	-	-	-
Salem Hospital	-	-	-	-	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	-	-	-	-	-	-	-	-	-	-	-
Sutter Ca Res Consortium	-	10	-	-	2	-	-	-	-	-	-
Don & Sybil Harrington CC	-	-	-	-	-	-	-	-	-	-	-
James Graham Brown CC at U Louisville	-	5	-	-	-	-	-	-	-	-	-
UC Davis CCC LAPS	-	41	1	6	-	1	-	-	-	-	-
UC Irvine Health/Chao Family CCC	-	12	-	-	-	-	-	-	-	-	-
UC San Diego Moores CC	-	5	-	-	-	-	-	-	-	-	-
UPMC Hillman CC LAPS	-	-	-	-	-	-	-	-	-	-	-
USC Norris CCC LAPS	-	12	-	-	-	-	-	-	-	-	-
U Arkansas for Medical Sciences	-	2	-	1	-	-	-	-	-	-	-
U Cincinnati CC-UC Med Ctr	-	22	1	-	-	-	-	-	-	-	-
U Colorado CC LAPS	3	58	2	-	-	-	1	-	-	1	-
U Kansas CC - MCA Rural MU NCORP	-	28	-	3	-	-	-	-	-	2	-
U Kentucky/Markey CC	-	5	-	-	-	-	-	-	-	-	-
U Michigan CCC LAPS	-	62	-	-	-	-	-	-	-	-	-
U Mississippi Med Ctr	-	26	-	-	-	-	-	-	-	-	-
U Oklahoma Health Sciences Ctr LAPS	-	-	-	-	-	-	-	-	-	-	-
U Rochester LAPS	-	-	-	2	9	-	-	4	-	1	-
U Texas HSC at San Antonio	-	-	-	2	-	-	-	-	-	-	-
U Texas MD Anderson CC LAPS	-	2	1	-	-	-	-	-	-	-	-
U Utah - Huntsman Ca Inst LAPS	-	-	-	1	-	-	-	-	-	-	-
Upstate Carolina Consortium NCORP	-	-	-	-	-	-	-	-	-	-	-
Wayne State U - Karmanos Ca Inst LAPS	-	1	-	-	-	-	-	-	1	-	-
Western States Ca Res NCORP	-	1	-	-	-	-	-	-	-	-	-
William Beaumont Hosp-Royal Oak	-	2	-	-	-	-	-	-	-	-	-
Wisconsin NCORP	-	-	-	-	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	3	51	4	10	-	-	-	-	-	-	-
ALLIANCE	-	-	-	-	-	-	-	-	-	-	-
CCTG	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-	-	-	-	-	-
NRG	-	-	-	-	-	-	-	-	-	-	-
Total	31	909	17	45	30	2	2	5	2	9	1



Leadership

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

Scientific Leadership

Translational Medicine: Alexey V. 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

Oncology Research Professionals: CRA:

CRA: Erin M. Cebula, MPH

Nurse: Molly Beth Adamek, BSN, RN

Patient Advocate: Hildy Dillon, MPH

Pharmaceutical Science: Holly O. Chan, PharmD

Martina Fraga, PharmD

Protocol Project Manager: Alicia Aranda Clinical Trials Program Manager: Michelle Maxim

Time/Location

Friday, April 8, 2022 9:00 am - 12:00 pm

Room: Quinalt, Level 5

Agenda

9:00 am: Welcome - Drs. Jonathan Friedberg and Sonali Smith

9:05 - 9:50 am: Mini-symposium: Novel diagnostic and therapeutic

approaches to B-cell malignancies

Ultrasensitive Duplex Sequencing for Applications in

Hematologic Malignancies

Jesse Salk MD, PhD CEO, CSO, Founder

TwinStrand Biosciences Inc. Clinical Assistant Professor

University of Washington, Division of Medical Oncology

Targeting CD20 with novel CAR-T constructs

Brian Till, MD Associate Professor

University of Washington, Division of Medical Oncology

Fred Hutchinson Cancer Research Center

9:50 - 10:30 am: New Concepts

52114, "A Randomized Phase II Trial of Consolidation Therapy Following CD19 CAR T-cell Treatment for Re-lapsed/Refractory Diffuse Large B-cell Lymphoma or Grade IIIB Follicular Lymphoma." Dr. Hess.

S2207, "Randomized phase II study of the addition of COO (cell-of-origin)-directed therapeutic agents to ta-fasitamab-based therapy in non-transplant-eligible patients with relapsed/refractory diffuse large B-cell lymphoma." Drs. Persky, Amengual and Reagan

Alliance Mantle Cell lymphoma - Dr. Phillips

COG Early stage Hodgkin lymphoma - Dr. Hu

10:30 - 10:50 am: ASH Review - New treatment approaches to newly diagnosed and relapsed diffuse large B-cell lymphoma - Dr. Kamdar

10:50 - 11:50 am: Ongoing Studies

S1826: Dr. Herrera

S1918: Dr. Brem

S1608: Dr. Barr

A051301: Dr. Stiff

A051902: Dr. Amengual

ANHL1931: Dr. Kamdar

EA4151: Dr. Till

E4412: Dr. Amengual

EA4181: Dr. Spurgeon

A051701: Dr. Vallurupalli

S1925 (CLL): Dr. Stephens

11:50 am - 12:00 pm: Other Business/Concluding Remarks



Active Studies

- <u>S1826</u>, "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 and Friedberg, Activated: 7/19/19.
- **S1608**, "Randomized Phase II Trial in Early Relapsing or Refractory Follicular Lymphoma." Drs. Barr and Burack. Activated: 8/10/17. Temporarily Closed as of 02/09/22
- S1918, "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.
- CTSU/A051301, "A Randomized Double-Blind Phase III Study of Ibrutinib During and Following Autologous Stem Cell Transplantation Versus Placebo in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma of the Activated B-Cell Subtype." Drs. Andreadis, Fenske, Leonard, Devine, Shea, Hsi, Kelley, and Richards. SWOG Champion: Dr. Stiff. Activated: 7/6/16.
- 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. Drs. Fenske, Till, Blum, Lazarus, Scott, and Kostakoglu. 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) in Patients </= 70 years Old with Untreated Mantle Cell Lymphoma. Dr. Wagner-Johnson. SWOG Champion: Dr. Spurgeon. Activated: 10/3/19.

- CTSU/ANHL1931, "A Randomized Phase 3 trial of Nivolumab (NSC# 748726 IND# 125462) in Combination with Chemo-immunotherapy for the Treatment of Newly Diagnosed Primary Mediastinal B-cell Lymphoma." SWOG Champion: Dr. Kamdar. SWOG Champion: Dr. Manali. Activated 6/7/2021.
- CTSU/A051902, "A Randomized Phase II Study of CHO(E)P vs Oral Azacitidine-CHO(E)P vs Duvelisib-CHO(E)P in Previously Untreated CD30 Negative Peripheral T-cell Lymphomas." Dr. Neha Mehta-Shah. SWOG Champion: Dr. Amengual. Activated 7/30/2021.

Open Leukemia Studies

- S1925, A Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab versus Delayed Therapy with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL): EVOLVE CLL/SLL Study. Dr. Stephens. Activated: 12/14/20.
- S1905, "A Phase I/II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients with Re-lapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL)/T-Cell Lymphoblastic Lymphoma (T-LBL)." Drs. Advani and Papadantonakis. Activated: 8/17/20.
- A041702, "A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib Plus Veneto-clax and Obinutuzumab in Untreated Older Patients (>/= 70 Years of Age) with Chronic Lymphocytic Leukemia (CLL)." Dr. Woyach. SWOG Champion: Dr. Hill. Activated: 1/4/19.

Open Rare Cancers Study

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

Open Cancer Care Delivery Study

S1912CD, "A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)." Dr. Shankaran. Activated 7/27/2021.



	51608	51826	51918	A051301	A051701	EAA72	EA4757	EA4181
Ascension Providence Hospitals - Southfield	-	5	-	-	-	-	-	-
Banner University Medical Center - Tucson	2	-	-	1	-	-	1	2
Baptist Memorial Health Care/Mid South Minority Underserved NCORP	-	2	-	-	-	-	-	-
Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center	-	-	-	1	-	-	-	-
Boston Medical Center	-	2	-	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-	8	-	8	10
Cancer Research Consortium of West Michigan NCORP	3	8	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	1	4	-	-	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	-	1	-	-	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	1	-	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	8	15	-	1	-	-	15	-
Columbia University Minority Underserved NCORP	-	1	2	-	-	1	-	-
Columbus NCI Community Oncology Research Program	1	2	-	-	-	-	-	-
CommonSpirit Health Research Institute	-	3	-	-	-	-	-	-
Essentia Health NCI Community Oncology Research Program	-	1	-	-	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	-	-	-	-	11	-
Georgia Cares Minority Underserved NCORP	-	2	1	-	-	-	-	-
Gulf South Minority Underserved NCORP	-	-	1	-	-	-	-	-
Heartland Cancer Research NCORP	1	16	-	-	-	-	-	-
Henry Ford Hospital	-	6	-	-	2	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	2	10	-	-	-	11	-	5
King Faisal Specialist Hospital and Research Centre	-	-	-	4	-	-	-	-
Loyola University Medical Center	-	5	-	-	-	-	3	-
Medical University of South Carolina Minority Underserved NCORP	2	13	-	-	3	-	2	-
Michigan Cancer Research Consortium NCORP	1	2	-	-	-	-	-	-
Moffitt Cancer Center	-	13	-	-	-	-	-	-
Montana Cancer Consortium NCORP	-	8	-	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	-	10	-	-	-	-	2	-



	51608	51826	51918	A051301	A051701	E4472	EA4151	EA418
Nevada Cancer Research Foundation NCORP	-	1	-	-	-	1	-	-
Northwell Health NCORP	-	-	-	-	1	-	-	-
Northwestern University LAPS	1	-	-	-	-	-	-	-
Oregon Health and Science University	-	2	-	-	2	-	4	5
Pacific Cancer Research Consortium NCORP	-	3	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	4	-	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	-	8	-	-	4	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	4	-	-	-	-	-	-
UC San Diego Moores Cancer Center	-	7	-	-	-	-	1	-
University of Alabama at Birmingham / Deep South Research Consoritum LAPS	-	11	-	-	3	7	5	-
University of Arkansas for Medical Sciences	-	1	-	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	6	-	-	-	-	1	1
University of Colorado Cancer Center LAPS	-	2	-	1	-	-	-	-
University of Kentucky/Markey Cancer Center	-	2	-	-	-	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	-	-	-	-	-	-	1	-
University of Rochester LAPS	13	27	-	3	11	-	8	14
University of Texas Health Science Center at San Antonio	-	8	-	-	-	-	9	-
University of Texas MD Anderson Cancer Center LAPS	3	14	-	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	1	12	-	-	-	-	12	10
Upstate Carolina Consortium Community Oncology Research Program	1	6	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	3	-	1	-	-	1	4
Wisconsin NCI Community Oncology Research Program	-	6	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	4	-	-	-	-	2	-
ALLIANCE	15	85	9	-	-	-	-	-
ССТБ	-	2	-	-	-	-	-	-
COG	-	227	-	-	-	-	-	-
ECOG-ACRIN	5	57	4	-	-	-	-	-
NRG	11	38	2	-	-	-	-	-
Total	72	669	19	12	34	20	86	51



	51608	51826	51918	A051301	A051701	EAA72	EA4757	EA4181
Ascension Providence Hospitals - Southfield	-	5	-	-	-	-	-	-
Banner University Medical Center - Tucson	2	-	-	1	-	-	1	2
Baptist Memorial Health Care/Mid South Minority Underserved NCORP	-	2	-	-	-	-	-	-
Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center	-	-	-	1	-	-	-	-
Boston Medical Center	-	2	-	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-	8	-	8	10
Cancer Research Consortium of West Michigan NCORP	3	8	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	1	4	-	-	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	-	1	-	-	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	1	-	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	8	15	-	1	-	-	15	-
Columbia University Minority Underserved NCORP	-	1	2	-	-	1	-	-
Columbus NCI Community Oncology Research Program	1	2	-	-	-	-	-	-
CommonSpirit Health Research Institute	-	3	-	-	-	-	-	-
Essentia Health NCI Community Oncology Research Program	-	1	-	-	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	-	-	-	-	11	-
Georgia Cares Minority Underserved NCORP	-	2	1	-	-	-	-	-
Gulf South Minority Underserved NCORP	-	-	1	-	-	-	-	-
Heartland Cancer Research NCORP	1	16	-	-	-	-	-	-
Henry Ford Hospital	-	6	-	-	2	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	2	10	-	-	-	11	-	5
King Faisal Specialist Hospital and Research Centre	-	-	-	4	-	-	-	-
Loyola University Medical Center	-	5	-	-	-	-	3	-
Medical University of South Carolina Minority Underserved NCORP	2	13	-	-	3	-	2	-
Michigan Cancer Research Consortium NCORP	1	2	-	-	-	-	-	-
Moffitt Cancer Center	-	13	-	-	-	-	-	-
Montana Cancer Consortium NCORP	-	8	-	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	-	10	-	-	-	-	2	-



	51608	51826	51918	A051301	A051701	E4472	EA4151	EA418
Nevada Cancer Research Foundation NCORP	-	1	-	-	-	1	-	-
Northwell Health NCORP	-	-	-	-	1	-	-	-
Northwestern University LAPS	1	-	-	-	-	-	-	-
Oregon Health and Science University	-	2	-	-	2	-	4	5
Pacific Cancer Research Consortium NCORP	-	3	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	4	-	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	-	8	-	-	4	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	4	-	-	-	-	-	-
UC San Diego Moores Cancer Center	-	7	-	-	-	-	1	-
University of Alabama at Birmingham / Deep South Research Consoritum LAPS	-	11	-	-	3	7	5	-
University of Arkansas for Medical Sciences	-	1	-	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	6	-	-	-	-	1	1
University of Colorado Cancer Center LAPS	-	2	-	1	-	-	-	-
University of Kentucky/Markey Cancer Center	-	2	-	-	-	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	-	-	-	-	-	-	1	-
University of Rochester LAPS	13	27	-	3	11	-	8	14
University of Texas Health Science Center at San Antonio	-	8	-	-	-	-	9	-
University of Texas MD Anderson Cancer Center LAPS	3	14	-	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	1	12	-	-	-	-	12	10
Upstate Carolina Consortium Community Oncology Research Program	1	6	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	3	-	1	-	-	1	4
Wisconsin NCI Community Oncology Research Program	-	6	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	4	-	-	-	-	2	-
ALLIANCE	15	85	9	-	-	-	-	-
CCTG	-	2	-	-	-	-	-	-
COG	-	227	-	-	-	-	-	-
ECOG-ACRIN	5	57	4	-	-	-	-	-
NRG	11	38	2	-	-	-	-	-
Total	72	669	19	12	34	20	86	51



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
Scientific Leadership	
Translational Medicine:	William E. Carson, III, MD
	Evan J. Wuthrick, MD
Surgery:	John Robert Hyngstrom, MD
	Clara Curiel-Lewandrowski, MD
	Ari M. VanderWalde, MD
	Sapna Pradyuman Patel, MD
Pathology:	TBD
	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
	Thach-Giao Truong, MD (Survivorship)
Data Coordinator:	Tonya Johnson
	Laura Kingsbury, MRT
	Leah Everhart
	Hannah Hale
Oncology Research Professionals	S:
CRA:	Kathryn Allen, BA, CCRP
Nurse:	Lisa S. Morgan, RN, OCN
Patient Advocate:	Samantha Guild, JD
Pharmaceutical Science:	Sun "Coco" Yang, PharmD, PhD
	Kimberly McConnell, PharmD
Protocol Project Manager:	Catrina De Los Santos-Mireles
	Michelle Maxim
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Time/Location

Friday, April 8, 2022 2:30 - 4:30 pm

Room: Quinalt, Level 5

Agenda

Welcome and Introduction: Sapna Patel, M.D. (10 min)

Keynote Speaker: The Role of the Oncology Community in Addressing Financial Hardships from Cancer Care - Veena Shankaran, M.D., Fred Hutchinson Cancer Research Center, co-director Hutchinson Institute for Cancer Outcomes Research (HICOR) (40 min)

Active Studies Update (15 min, 5 min ea) – Study design, eligibility criteria, endpoints, accrual to date

S2015, A Phase III, Multi-centre Randomised Controlled Trial Investigating 1cm vs. 2cm Wide Excision Margins for Primary Cutaneous Melanoma, MASC. Pl: Joshua Mammen, M.D., Ph.D. (University of Nebraska)

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

S1801, A Phase II Randomized Study of Adjuvant Versus Neo-Adjuvant Pembrolizumab (MK-3475) for Clinically Detectable Stage III-IV High-risk Melanoma. Sapna Patel (MDACC). Activated PI: Sapna Patel, M.D. (MD Anderson) Biostatisticians: Megan Othus, Ph.D. & James Moon, M.S.

Closed to Patient Accrual (30 min), TM Updates

S1616, A Phase II Study of Ipilimumab and Nivolumab in Advanced Melanoma Following Progression on a PD-1 Inhibitor Alone. Pl: Ari VanderWalde, M.D., M.P.H. (West Cancer Clinic). Biostatisticians: Michael Wu, Ph.D. & James Moon, M.S.

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. PI: Siwen Hu-Lieskovan, M.D., Ph.D. (Huntsman Cancer Institute). Biostatisticians: Michael Wu, Ph.D. & James Moon, M.S.

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, M.D. (Ohio State) and Siwen Hu-Lieskovan, M.D., Ph.D. (Huntsman Cancer Institute). Biostatisticians: Michael Wu, Ph.D. & James Moon, M.S.

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



- **S1320**, A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib and Trametinib in BRAFV600E/K Mutant Melanoma. Pl: Alain Algazi, M.D. (University of California San Francisco). Biostatisticians: Megan Othus, Ph.D., James Moon, M.S.
- S1221, Phase I/II Study of the Safety and Efficacy of the AKT Inhibitor GSK2141795 in Combination with the BRAF Inhibitor Dabrafenib and Trametinib in Patients with BRAF Mutant Cancer. Pl: Alain Algazi, M.D. (University of California San Francisco) and Antoni Ribas (UCLA). Biostatisticians: Megan Othus, Ph.D. & James Moon, M.S.

ECOG / ALLIANCE Updates: David Lawson, M.D. (10 min)

Advocacy: Remarks (Samantha Guild, J.D., AIM at Melanoma)

Closing Remarks

Active Studies

- 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.
- <u>S1801</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.
- 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.

Closed Studies

- 51512, "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: 10/02/17. 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: 07/17/17. Closed: 7/15/20.
- CTSU/EA6134, "DREAMseq (Doublet, Randomized Evaluation in Advanced Melanoma Sequencing) a Phase III Trial." Dr. Chmielowski. Activated: 7/13/15. Closed: 9/30/2021.

Studies in Development

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.



	51572	51607	51616	51801	52000
Banner University Medical Center - Tucson	-	-	-	7	-
Boston Medical Center	-	-	-	1	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-	-
Cancer Research Consortium of West Michigan NCORP	-	-	4	20	-
Cancer Research for the Ozarks NCORP	-	-	-	-	1
Cancer Research of Wisconsin and Northern Michigan Consortium	-	-	1	2	-
Carle Cancer Center NCI Community Oncology Research Program	-	-	-	1	1
City of Hope Comprehensive Cancer Center	-	-	4	6	-
Columbus NCI Community Oncology Research Program	-	-	-	1	-
Dayton NCI Community Oncology Research Program	-	-	1	-	-
Georgia NCI Community Oncology Research Program	1	-	-	-	-
Hawaii Minority Underserved NCORP	-	-	-	2	-
Heartland Cancer Research NCORP	-	-	-	5	-
Henry Ford Hospital	-	4	-	-	-
Intermountain Medical Center	1	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	-	-	5	13	-
Loma Linda University Medical Center	-	-	-	2	-
Massachusetts Veterans Epidemiology Research and Information Center	-	-	-	5	-
Medical University of South Carolina Minority Underserved NCORP	-	-	-	1	-
Michigan Cancer Research Consortium NCORP	-	-	-	4	-
Moffitt Cancer Center	19	-	8	-	3
Montana Cancer Consortium NCORP	-	-	1	4	-
NCORP of the Carolinas (Prisma Health NCORP)	-	-	-	-	-
Nevada Cancer Research Foundation NCORP	-	-	-	-	-
New Mexico Minority Underserved NCORP	-	-	2	1	-
Northwell Health NCORP	-	-	-	6	-
Northwestern University LAPS	1	-	6	13	-
Ohio State University Comprehensive Cancer Center LAPS	6	4	8	12	-
Pacific Cancer Research Consortium NCORP	-	-	-	2	-



	51512	57607	51616	51801	52000
SCL Health Saint Joseph Hospital	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	1	-	-	-	-
Sutter Cancer Research Consortium	-	-	-	-	-
The Don and Sybil Harrington Cancer Center	-	-	-	2	-
The West Clinic - Wolf River	-	-	7	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	-	3	-
UC San Diego Moores Cancer Center	-	-	2	-	-
UCLA / Jonsson Comprehensive Cancer Center	4	8	6	5	-
USC Norris Comprehensive Cancer Center LAPS	5	5	-	8	-
University of Alabama at Birmingham / Deep South Research					
Consoritum LAPS	-	-	-	1	-
University of Arkansas for Medical Sciences	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	-	-	-	-
University of Colorado Cancer Center LAPS	-	-	-	-	-
University of Kansas Cancer Center - MCA Rural MU NCORP	2	1	2	6	-
University of Kentucky/Markey Cancer Center	-	-	-	2	-
University of Michigan Comprehensive Cancer Center LAPS	-	-	-	15	1
University of Rochester LAPS	-	-	5	4	-
University of Texas Health Science Center at San Antonio	-	-	-	-	-
University of Texas MD Anderson Cancer Center LAPS	-	-	-	10	-
University of Utah - Huntsman Cancer Institute LAPS	10	10	1	18	-
Vanderbilt University - Ingram Cancer Center LAPS	-	1	1	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	-	-	-
Wisconsin NCI Community Oncology Research Program	-	-	1	8	-
Yale University - Yale Cancer Center LAPS	-	-	-	-	-
ALLIANCE	1	-	9	27	1
ECOG-ACRIN	2	8	7	40	2
NRG	4	2	13	43	1
Total	57	43	94	300	10



The publications listed below were received by the Group Chair's Office as published (including online), accepted, or submitted since the SWOG Fall 2021 Virtual Group Meeting. Conference abstracts are not included.

ADOLESCENT AND YOUNG ADULT (AYA) COMMITTEE

Published/Accepted Manuscripts

(none this cycle)

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

S1007 21-Gene Assay to Inform Chemotherapy Benefit in Node-Positive Breast Cancer. Kalinsky K, Barlow WE, Gralow JR, Meric-Bernstam F, Albain KS, Hayes DF, Lin NU, Perez EA, Goldstein LJ, Chia SKL, Dhesy-Thind S, Rastogi P, Alba E, Delaloge S, Martin M, Kelly CM, Ruiz-Borrego M, Gil-Gil M, Arce-Salinas CH, Brain EGC, Lee ES, Pierga JY, Bermejo B, Ramos-Vasquez M, Jung KH, Ferrero JM, Schott AF, Shak S, Sharma P, Lew DL, Miao J, Tripathy D, Pusztai L, Hortobagyi GN. New England Journal of Medicine Dec 16;385(25):2336-2347:2336-2347, 2021. PMID34914339. https://pubmed.ncbi.nlm.nih.gov/34914339/

S1222 A randomized trial of fulvestrant, everolimus and anastrozole in the front line treatment of advanced hormone receptor positive breast cancer, SWOG S1222. Moore HCF, Barlow WE, Somlo G, Gralow JR, Schott AF, Hayes DF, Kuhn P, Hicks JB, Dy PA, Yeon CH, Conlin AK, Balcueva E, Lew DL, Tripathy D, Pusztai L, Hortobagyi GN. Clinical Cancer Research, Nov 29;clincanres. 3131.2021. doi: 10.1158/1078-0432.CCR-21-3131. Online ahead of print., 2021. PMID34844978.

https://pubmed.ncbi.nlm.nih.gov/34844978/

C40603 CALGB 40603 (Alliance): Long-Term Outcomes and Genomic Correlates of Response and Survival After Neoadjuvant Chemotherapy With or Without Carboplatin and Bevacizumab in Triple-Negative Breast Cancer. Shepherd JH, Ballman K, Polley MC, Campbell JD, Fan C, Selitsky S, Fernandez-Martinez A, Parker JS, Hoadley KA, Hu Z, Li Y, Soloway MG, Spears PA, Singh B, Tolaney SM, Somlo G, Port ER, Ma C, Kuzma C, Mamounas E, Golshan M, Bellon JR, Collyar D, Hahn OM, Hudis CA, Winer

EP, Partridge A, Hyslop T, Carey LA, Perou CM, Sikov WM. <u>Journal of Clinical Oncology</u>. Jan 19:JCO2101506. doi: 10.1200/JCO.21.01506. Online ahead of print, 2022. PMID35044810

https://pubmed.ncbi.nlm.nih.gov/35044810/

MA.32 Cancer Antigen 15-3/Mucin 1 Levels in CCTG MA.32: A Breast Cancer Randomized Trial of Metformin vs Placebo.Goodwin P, O'Dowling R, Ennis M, Chen B, Parulekar W, Shepherd L, Gelmon K, Whelan T, Ligibel J, Hershman D, Mayer I, Hobday T, Rastogi P, Rabaglio-Poretti M, Lemieux J, Thompson A, Rea D, Stambolic Vuk. JNCI Cancer Spectrum Jul 28;5(5):pkab066, 2021.PMID34485814; PMC8410139. https://pubmed.ncbi.nlm.nih.gov/34485814/

Randomized Phase III Trial Evaluating Radiation Following
Surgical Excision for Good-Risk Ductal Carcinoma In Situ: Long-Term
Report From NRG Oncology/RTOG 9804. McCormick B, Winter KA,
Woodward W, Kuerer HM, Sneige N, Rakovitch E, Smith BL, Germain I,
Hartford AC, O'Rourke MA, Walker EM, Strom EA, Hopkins JO, Pierce LJ,
Pu AT, Sumida KNM, Vesprini D, Moughan J, White JR. Journal of Clinical
Oncology, Nov 10;39(32):3574-3582, 2021. PMID34406870; PMC8577682
https://pubmed.ncbi.nlm.nih.gov/34406870/

Submitted Manuscripts

(none this cycle)

CANCER CONTROL AND PREVENTION COMMITTEES CANCER CARE DELIVERY COMMITTEE

Published/Accepted Manuscripts

S1417CD S1417CD: A Prospective Multicenter Cooperative Group-Led Study of Financial Hardship in Metastatic Colorectal Cancer Patients. Shankaran V, Unger J, Darke A, Suga J, Wade J, Kourlas P, Chandana S, O'Rourke M, Satti S, Liggett D, Hershman D, Ramsey S. <u>Journal of the National Cancer Institute</u> Jan 4;djab210. doi: 10.1093/jnci/djab210. Online ahead of print., 2022. PMID34981117.

https://pubmed.ncbi.nlm.nih.gov/34981117/

Multiple Studies Sex Differences in Risk of Severe Adverse Events in Patients Receiving Immunotherapy, Targeted Therapy, or Chemotherapy in Cancer Clinical Trials. Unger J, Vaidya R, Albain K, LeBlanc M, Minasian L, Gotay C, Henry NL, Fisch M, Lee S, Blanke CD, Hershman D. <u>Journal of Clinical Oncology</u> Feb 4;JCO2102377. doi: 10.1200/JCO.21.02377. Online ahead of print., 2022. PMID35119908.

https://pubmed.ncbi.nlm.nih.gov/35119908/



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S1415CD S1415CD: Successes and challenges of implementing a cancer care delivery intervention in community oncology practices: lessons learned from SWOG S1415CD. Watabayashi K, Bell-Brown A, Kreizenbeck K, Egan K, Lyman G, Hershman D, Arnold K, Bansal A, Barlow WE, Sullivan S, Ramsey S. <u>BMC Health Services Research</u>, submitted 2022.

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H, Hershman D, Unger J. <u>Cancer</u>, submitted 2022.

CANCER SURVIVORSHIP COMMITTEE

Published/Accepted Manuscripts

A011401 The Breast Cancer Weight Loss (BWEL) Trial (Alliance 011401):

A Description of the Lifestyle Intervention .Delahanty L, Wadden T,
Goodwin P, Alfano C, Thomson C, Irwin M, Neuhouser M, Crane T, Frank
E, Spears P, Gillis B, Hershman D, Paskett E, Salem W, Bernstein V, Stearns
V, White J, Hudis C, Winer E, Carey L, Partridge A, Ligibel J. Obesity
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Submitted Manuscripts

(none tlhis cycle)

PALLIATIVE AND END OF LIFE CARE COMMITTEE

Published/Accepted Manuscripts

S1820 Altering Intake and Managing Symptoms (AIMS): Feasibility of a Diet Modification Intervention for Post-Treatment Bowel Dysfunction in Rectal Cancer [S1820 Pilot]. .Sun V, Crane T, Freylersythe S, Slack S, Yung A, Krouse R, Thomson C Clinical Journal of Oncology Nursing, accepted 2022.

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PREVENTION AND EPIDEMIOLOGY COMMITTEE

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activity and secretion, and confers risk of pancreatic cancer. Jermusyk A, Zhong J, Connelly K, Gordon N, Perera S, Abdolalizadeh E, Zhang T, O'Brien A, Hoskins J, Collins I, Eiser D, Yuan C, PanScan Consortium [Goodman P, collaborator], PanC4 Consortium, Risch H, Jacobs E, Li D, Du M, Stolzenberg-Solomon R, Klein A, Smith J, Wolpin B, Chanock S, Shi J, Petersen G, Westlake C, Amundadottir L. American Journal of Human Genetics, Oct 7;108(10):1852-1865, 2021. PMID34559995; PMC8546220 https://pubmed.ncbi.nlm.nih.gov/34559995/

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and Prostate Cancer Risk: Results From the Prostate Cancer Prevention
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A011401 The Breast Cancer Weight Loss (BWEL) Trial (Alliance 011401):

A Description of the Lifestyle Intervention .Delahanty L, Wadden T,
Goodwin P, Alfano C, Thomson C, Irwin M, Neuhouser M, Crane T, Frank
E, Spears P, Gillis B, Hershman D, Paskett E, Salem W, Bernstein V, Stearns
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S0000/Other Prediction of future risk of any and higher-grade prostate cancer based on the PLCO and SELECT trials. Gelfond J, Hernandez B, Goros M, Ibrahim J, Chen M, Sun W, Liss M, Leach R, Thompson I, Ankerst D. World Journal of Urology, under review.

S0000/Other Accommodating population differences in model validation. Pfeiffer R, Chen Y, Gail M, Ankerst D. Statistics in Medicine, under review.

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SYMPTOM CONTROL AND QUALITY OF LIFE COMMITTEE

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Patient-Reported Outcomes, and Early Discontinuation of
 Endocrine Therapy for Breast Cancer Risk Reduction in NRG Oncology/
 NSABP B-35. Henry NL, Kim S, Hays R, Diniz M, Luu M, Cecchini R, Yothers
 G, Rogatko A, Ganz P. Toxicity Index, <u>Journal of Clinical Oncology</u>, Dec 1;39(34):3800-3812, 2021. PMID34554865.

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Multiple Studies Sex Differences in Risk of Severe Adverse Events in Patients Receiving Immunotherapy, Targeted Therapy, or Chemotherapy in Cancer Clinical Trials. Unger J, Vaidya R, Albain K, LeBlanc M, Minasian L, Gotay C, Henry NL, Fisch M, Lee S, Blanke CD, Hershman D. <u>Journal of Clinical Oncology</u> Feb 4;JCO2102377. doi: 10.1200/JCO.21.02377. Online ahead of print., 2022. PMID35119908.

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

NO147 Cetuximab reduces patient quality of life when administered with mFOLFOX6 as adjuvant treatment following complete resection of KRAS wild-type tumors for stage III colorectal cancer (N0147 Alliance). Mahoney MR, Sloan JA, Hubbard JM, Tan AD, Liu H, Goldberg RM, Nair SG, Shields AF, Gill S, Jahagirdar B, Benson A, Sargent DJ, Alberts SR. Journal of Patient Reported Outcomes, under review. [see also Gl Committee]

DIGITAL ENGAGEMENT COMMITTEE

Published/Accepted Manuscripts

(none this cycle)

Submitted Manuscripts

(none this cycle)

EARLY THERAPEUTICS AND RARE CANCERS COMMITTEE

Published/Accepted Manuscripts

S1609 A Multicenter Phase II Trial of Ipilimumab and Nivolumab in Unresectable or Metastatic Metaplastic Breast Cancer: Cohort 36 of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART, SWOG S1609). Adams S, Othus M, Patel S, Miller K, Chugh R, Schuetze S, Chamberlin M, Haley B, Storniolo A, Cawley K, Reddy M, Anderson S, Zimmerman C, O'Dea A, Mirshahidi M, Ahnert J, Brescia F, Hahn O, Raymond J, Biggs D, Thompson M, Connolly R, Sharon E, Korde L, Gray R, Mayerson E, Plets M, Blanke CD, Chae YK, Kurzrock R. Clinical Cancer Research Jan 15;28(2):271-278, 2022. PMID34716198;PMC8776596 https://pubmed.ncbi.nlm.nih.gov/34716198/

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GASTROINTESTINAL COMMITTEE

Published/Accepted Manuscripts

Randomized Phase II Study of PARP Inhibitor ABT-888 (Veliparib) **S1513** with Modified FOLFIRI versus FOLFIRI as Second Line Treatment of Metastatic Pancreatic Cancer: SWOG S1513. Chiorean EG, Guthrie K, Philip P, Swisher E, Jalikis F, Pishvaian M, Berlin J, Noel M, Suga J, Garrido-Laguna I, Cardin D, Radke M, Duong M, Lowy A, Hochster H. Clinical Cancer Research, Dec 1;27(23):6314-6322, 2021. PMID34580114; PMC8639715. https://pubmed.ncbi.nlm.nih.gov/34580114/

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C80405 Plasma protein biomarkers predictive of benefit from bevacizumab versus cetuximab in colorectal cancer: Results from CALGB 80405 (Alliance). Nixon A, Sibley A, Liu Y, Hatch A, Jiang C, Mulkey F, Starr M, Brady J, Niedzwiecki D, Venook A, Hochster H, Lenz H-J, O'Neil B, Meyerhardt J, O'Reilly E, Owzar K, Innocenti F, Hurwitz H. Clinical Cancer Research Dec 29.doi: 10.1158/1078-0432.CCR-21-2389. Online ahead of print, 2021. PMID34965954.

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R1010 Trastuzumab with trimodality treatment for oesophageal adenocarcinoma with HER2 overexpression (NRG Oncology/RTOG



1010): a multicentre, randomised, phase 3 trial. Safran HP, Winter K, Ilson DH, Wigle D, DiPetrillo T, Haddock MG, Hong TS, Leichman LP, Rajdev L, Resnick M, Kachnic LA, Seaward S, Mamon H, Diaz Pardo DA, Anderson CM, Shen X, Sharma AK, Katz AW, Salo J, Leonard KL, Moughan J, Crane CH. Lancet Oncology Feb;23(2):259-269, 2022. PMID35038433 https://pubmed.ncbi.nlm.nih.gov/35038433/

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NO147 Cetuximab reduces patient quality of life when administered with mFOLFOX6 as adjuvant treatment following complete resection of KRAS wild-type tumors for stage III colorectal cancer (N0147 Alliance). Mahoney MR, Sloan JA, Hubbard JM, Tan AD, Liu H, Goldberg RM, Nair SG, Shields AF, Gill S, Jahagirdar B, Benson A, Sargent DJ, Alberts SR. Journal of Patient Reported Outcomes, under review. [see also SCQOL Cmte]

GENITOURINARY COMMITTEE

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

Published/Accepted Manuscripts

<u>S1602/S8507</u> The Who, What, When, Where, and Why of Bacillus Calmette-Guérin-unresponsive Bladder Cancer [Editorial]. Li R, Lerner SP, Kamat AM. <u>European Urology</u> Apr;79(4):437-439, 2021. PMID33454163 https://pubmed.ncbi.nlm.nih.gov/33454163/

S1806/Other Targeting barriers to wider use of trimodality therapy in localized muscle invasive bladder cancer [Seminars Article; Review]. Ballas L, Singh P, Lerner SP. <u>Urologic Oncology</u> Nov 2;:S1078-1439(20)30478-6, 2020. PMID33153882. [NB: correction to previously reported citation]. https://pubmed.ncbi.nlm.nih.gov/33153882/

Sertion Neoadjuvant chemotherapy in bladder cancer: Clinical benefit observed in prospective trials computed with restricted mean survival times. McCaw ZR, Odisho AY, Chaparala H, Yin M, Cloyd J, Svatek RS, Carson WE, Lee CT, Sundi D. <u>Urologic Oncology</u> (Seminars and Original Investigations) Jul;39(7):435.e17-435.e22, 2021. PMID: 33436327 https://pubmed.ncbi.nlm.nih.gov/33436327/

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S1216 Orteronel for Metastatic Hormone Sensitive Prostate Cancer.
Agarwal N, Tangen C, Hussain M, Gupta S, Plets M, Lara P, Harzstark A,
Twardowski P, Paller C, Zylla D, Zibelman M, Levine E, Roth B, Goldkorn A, Vaena D, Kohli M, Crispino A, Vogelzang N, Thompson IM, Quinn DI.
Journal of Clinical Oncology, submitted.

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

LEUKEMIA COMMITTEE

Published/Accepted Manuscripts

SWOG 1318: A Phase 2 Trial of Blinatumomab Followed by POMP Maintenance in Older Patients with Newly Diagnosed Philadelphia Chromosome-Negative B-Cell Acute Lymphoblastic Leukemia. Advani A, Moseley A, O'Dwyer K, Wood B, Fang M, Wieduwilt M, Aldoss I, Park J, Klisovic R, Baer M, Stock W, Bhave R, Othus M, Harvey R, Willman C, Litzow M, Stone R, Sharon E, Erba H. Journal of Clinical Oncology, Feb 14;JCO2101766. doi: 10.1200/JCO.21.01766. Online ahead of print, 2022. PMID: 35157496 https://pubmed.ncbi.nlm.nih.gov/35157496/

C10701 Dasatinib and dexamethasone followed by hematopoietic cell transplantation for adults with Ph-positive ALL.Wieduwilt M, Yin J, Wetzler M, Uy G, Powell B, Kolitz J, Liedtke M, Stock W, Beumer J, Mattison R, Storrick E, Christner S, Lewis L, Devine S, Stone R, Larson R. Blood Advances, Nov 23;5(22):4691-4700, 2021. PMID34492682; PMC8759134. https://pubmed.ncbi.nlm.nih.gov/34492682/

E2902 Tipifarnib as maintenance therapy did not improve disease-free survival in patients with acute myelogenous leukemia at high risk of relapse: Results of the phase III randomized E2902 trial. Luger SM, Wang VX, Rowe JM, Litzow MR, Paietta E, Ketterling RP, Lazarus H, Rybka WB, Craig MD, Karp J, Cooper BW, Makary AZ, Kaminer LS, Appelbaum FR, Larson RA, Tallman MS. Leukemia Research Dec;111:106736, 2021. PMID34773794; PMC8643322.

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LUNG COMMITTEE

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LYMPHOMA COMMITTEE

Published/Accepted Manuscripts

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MELANOMA COMMITTEE

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PHARMACEUTICAL SCIENCES COMMITTEE

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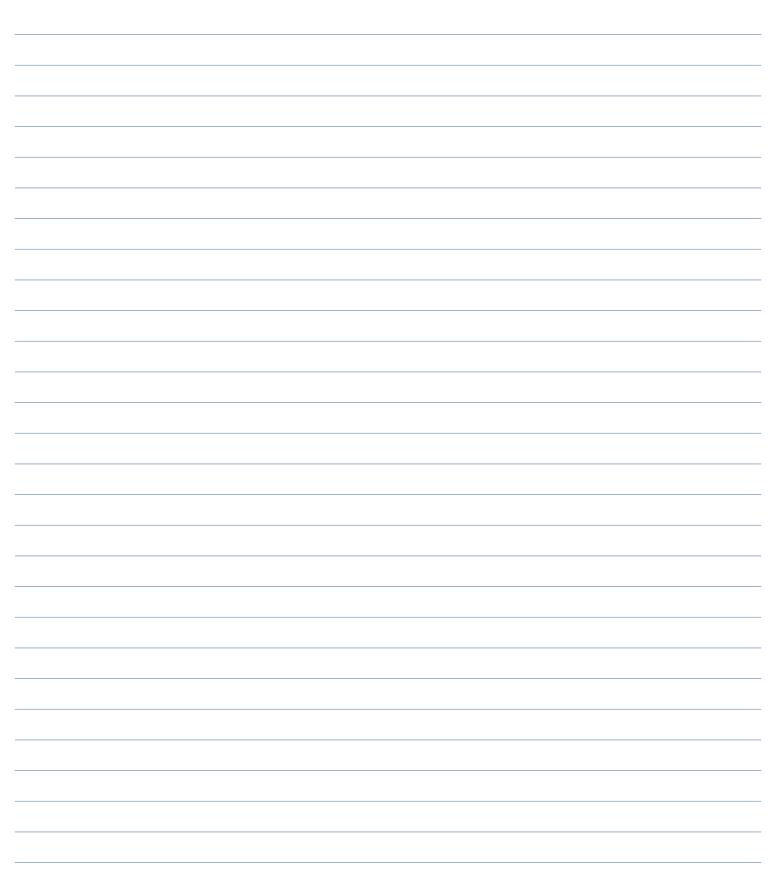
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Submitted Manuscripts

(none this cycle)



Notes





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