





Welcome to Chicago!

Last was able to welcome you to Chicago, but I'm thrilled to be able to revive that long-standing tradition.

This SWOG group meeting will be another "hybrid" event, with virtual versions of all sessions accessible online, but for many of us it will be an old-fashioned chance to meet face to face, and to learn, teach, and be incredibly energized by the work and the people around us. We have one new feature,

based on your survey responses after our spring meeting: each room will now include a webcam so virtual attendees can view the physical meeting space.

COVID remains as a serious threat to public health. Given the immune-compromised among our members and our patients, I strongly encourage you to mask up in all indoor public venues.



On a more positive note, we always have dynamic plenaries, but I think the ones you will attend at this meeting are particularly exciting.

Our translational medicine plenary (Plenary I) on Thursday will feature the work of a recent Coltman Fellow, an update on lung committee TM, and a presentation on using artificial intelligence to facilitate cancer trial enrollment (AI-aided accrual!).

Friday's general plenary (Plenary II) is all about MATCH making. MyeloMATCH, ComboMATCH, and ImmunoMATCH will soon launch, so come get educated! The program will start with an update on the Lung-MAP master protocol, which of course has led the way in NCI precision medicine trials.

Finally, our traditional Friday evening reception will feature a diversity, equity, and inclusion (DEI) meet-and-greet – a chance to meet, mingle, and learn more about DEI at SWOG.

Enjoy the meeting and Chicago, and please accept my gratitude for everything you contribute to SWOG! Chabo Ble M

Charles D. Blanke, MD

SWOG Chair

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WE VALUE OUR MEETING PARTNERS

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Hyatt Regency Chicago Floor Levels



WELCOME TO HYATT REGENCY CHICAGO.

Meeting rooms, ballrooms, restaurants and guest amenities are listed in alphabetical order and color coded by floor. For help, dial Guest Services at Extension **4460**.

ESCALATORS, ELEVATORS AND RESTROOMS are

indicated on each floor.
Elevators are conveniently
located throughout the hotel
for guests with disabilities or
where no escalator is present.

CROSSING BETWEEN

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

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- ACAPULCO (International and City Suites)
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- ADDAMS (Founders Suites)
 West Tower, Third Floor
- AMERICAN CRAFT KITCHEN & BAR East Tower, Lobby Level
- ATLANTA (International and City Suites)
 West Tower, Ballroom Level
- BELL DESK East Tower, Skyway Level
- BIG BAR
 East Tower, Skyway Level
- BURNHAM (Founders Suites)
 West Tower, Third Floor
- BUSINESS CENTER, PACKAGE ROOM
 East Tower, Exhibit Level
- COLUMBIAN (Landmark Suites)
 West Tower, Concourse Level
- COLUMBUS HALL (ROOMS A-L) East Tower, Ballroom Level
- COMISKEY (Landmark Suites)
 West Tower, Concourse Level
- CONCIERGE East Tower, Lobby Level
- CRYSTAL BALLROOM West Tower, Lobby Level
- DUSABLE (Founders Suites)
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- EAST TOWER VALET East Tower, Ballroom Level
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- FITNESS CENTER
 West Tower, Skyway Level
- FRONT DESK East Tower, Skyway Level
- THE GALLERY COLLECTION West Tower, Skyway Level
- GIFT SHOP East Tower, Concourse Level
- GOLD COAST (Landmark Suites)
 West Tower, Concourse Level
- GRAND BALLROOM East Tower, Ballroom Level
- GRAND SUITES
 East Tower, Ballroom Level
- HAYMARKET (Landmark Suites) West Tower, Concourse Level
- HERTZ
 East Tower, Lobby Level

- HONG KONG (International and City Suites)
 West Tower, Ballroom Level
- HORNER (Founders Suites)
 West Tower. Third Floor
- THE LIVING ROOM
 West Tower, Skyway Level
- MARKET CHICAGO
 East Tower, Lobby Level

 McCORMICK (Founders Suites)
- West Tower, Third Floor

 MICHIGAN (Lakeshore Meeting Rooms)
 East Tower, Concourse Level
- MONROE (Lakeshore Meeting Rooms)
- NEW ORLEANS (International and City Suites)
 West Tower, Ballroom Level
- OGDEN (Founders Suites)
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East Tower, Concourse Level

- PICASSO (Landmark Suites)
 West Tower, Concourse Level
- PLAZA BALLROOM East Tower, Lobby Level
- RANDOLPH (Lakeshore Meeting Rooms)

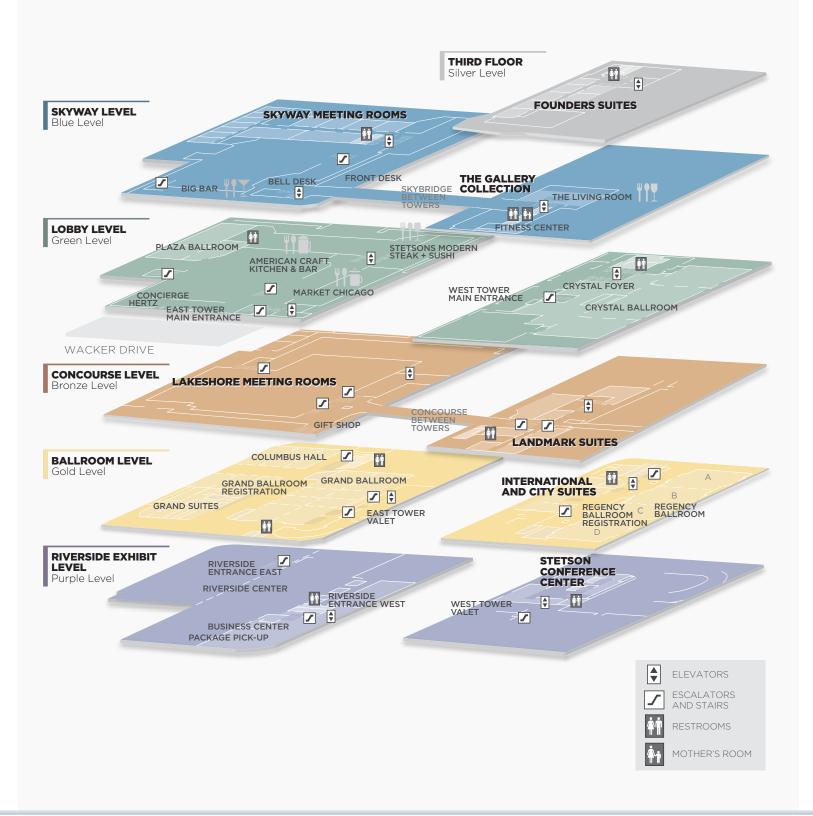
 East Tower, Concourse Level
- REGENCY BALLROOM West Tower, Ballroom Level
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 East Tower, Concourse Level
- SAN FRANCISCO (International and City Suites)
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- SANDBURG (Founders Suites)
 West Tower, Third Floor
- SKYWAY MEETING ROOMS

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- SOLDIER FIELD (Landmark Suites)
 West Tower, Concourse Level
- STETSON CONFERENCE CENTER
 West Tower, Exhibit Level
- STETSONS MODERN STEAK + SUSHI Fast Tower, Lobby Level
- TORONTO (International and City Suites)
 West Tower, Ballroom Level
- WATER TOWER (Landmark Suites)
 West Tower, Concourse Level
- WEST TOWER VALET West Tower, Exhibit Level
- WRIGHT (Founders Suites)
 West Tower, Third Floor
- WRIGLEY (Landmark Suites)
 West Tower. Concourse Level



Chicago Travel & Hotel Information

151 East Wacker Drive | Chicago, Illinois 60601, USA hyattregencychicago.com | Phone: 312 565 1234 | Fax: 312 239 4541



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Arrival/Departure:

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

Hotel Safety Deposit Boxes:

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

Recreational Facilities:

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

Hotel Restaurants and Lounges:

Stetsons Modern Steak & Sushi: Non-traditional steakhouse experience in a comfortable urban setting, specializing in steaks and seafood. *Restaurant is open daily at 5:00 p.m.*

American Craft Kitchen & Bar: Regionally inspired by all corners of the country, they offer an approachable dining experience with handcrafted food and drink. This atrium restaurant is the perfect stop for a casual meal. *Open daily from 6:30 a.m. – 11:00 p.m.*

Market Chicago: Offers breakfast, lunch or dinner for a quick meal or coffee to go. Open daily from 6:30 a.m. – 11:30 p.m.

The BIG Bar features the longest free-standing bar in North America and specializes in a wide variety of cocktails, wines, champagnes and cognacs and snacks. *Open daily at 4:00 p.m.*

In-room dining is available from 6:00 a.m. - 12:00 a.m. daily.



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Business Center:

The Business Center is located on the Exhibit level in the East Tower of the hotel. It is open 24 hours a day, 7 days a week. The Business Center offers fax machines, computer services, color copies, mail drop, Internet access and photocopying.

Ground Transportation:

- A taxi ride from O'Hare airport to the hotel is approximately \$52.00 one-way.
- A taxi ride from Midway airport to the hotel is approximately \$35.00 one-way.
- Valet parking at the hotel is \$79.00 per day for hotel guests.

Temperature:

The average high for October is 64 degrees and the average low is 46 degrees.

Area Attractions:

- Adler Planetarium and Astronomy Museum
- Architectural Boat Tours
- Art Institute of Chicago
- Brookfield Zoo
- Buckingham Fountain
- Chicago Architecture Foundation
- Chicago Botanic Garden
- Field Museum of National History
- John G. Shedd Aquarium
- John Hancock Center Observatory
- Lincoln Park Zoo and Conservatory
- Maggie Daley Park
- Millennium Park and Cloud Gate ("The Bean")
- Museum of Contemporary Art
- Museum of Science and Industry
- Navy Pier
- Rockefeller Memorial Chapel
- Willis Tower Skydeck





Hyatt Regency Chicago Restaurant Guide

DINING ON-SITE

BIG BAR

East Tower, Skyway Level

AMERICAN CRAFT KITCHEN & BAR

East Tower, Lobby Level

MARKET CHICAGO

East Tower, Lobby Level

LOCAL FAVORITES

BILLY GOAT TAVERN

American, \$ 430 N. Michigan Ave. • 312.222.1525 .1 miles from hotel

GARRETT POPCORN SHOPS

Gourmet Popcorn, \$
4 E. Madison St. • 888.476.7267
.7 miles from hotel

GIORDANO'S

Pizza, \$\$ 130 E. Randolph St. • 312.616.1200 .2 miles from hotel

LOU MALNATI'S

Pizza, \$\$ 439 N. Wells St. • 312.828.9800 .9 miles from hotel

PORTILLO'S HOT DOGS

Quick Service, \$
100 W. Ontario St. • 312.587.8910
.9 miles from hotel

STAN'S DONUTS & COFFEE

Gourmet Donuts, \$
181 Michigan Ave. • 312.729.5480
.3 miles from hotel

NEARBY DINING

BEATRIX

American, \$\$
519 N. Clark St. • 312.284.1377
1 mile from hotel

BROKEN ENGLISH TACO PUB

Mexican, \$\$
75 E. Lake St. • 312.929.3601
.4 miles from hotel

THE DEARBORN

American, \$\$ 145 N. Dearborn • 312.384.1242 .7 miles from hotel

GIBSONS BAR & STEAKHOUSE

Steakhouse, \$\$\$ 1028 N. Rush St. • 312.266.8999 1.2 miles from hotel

ITALIAN VILLAGE

Italian \$\$ 71 W. Monroe St. • 312.332.7005 1 mile from hotel

JOE'S SEAFOOD

Seafood, Steakhouse, \$\$\$
60 E. Grand Ave. • 312.379.5637
.7 miles from hotel

MAGNOLIA BAKERY

Coffee, Dessert, \$\$
108 N. State Street. • 312.346.7777 .7
miles from hotel

NANDO'S PERI-PERI

Portuguese, Quick Service, \$\$ 117 E. Lake St. • 312.729.5340 .2 miles from hotel

NUTELLA CAFE

Cafe, Coffee Bar, \$\$ 189 N. Michigan Ave. • 800.861.4888 .2 miles from hotel

POTBELLY SANDWICH SHOP

Sandwiches, Quick Service, \$
111 E. Wacker Dr. • 312.861.0013
.1 miles from hotel

PURPLE PIG

Mediterranean, \$\$ 500 N. MI Ave • 312.464.1744 .9 miles from hotel

QUARTINO RISTORANTE

Italian, \$\$
626 N. State St. • 312337.9400
.8 miles from hotel

RAMEN-SAN

Japanese, Sushi, \$\$
59 W. Hubbard St. #2 • 312.377.9950
.9 miles from hotel

ROT

Mediterranean, Quick Service, \$ 80 E. Lake St. • 312.858.8190 .3 miles from hotel

RPM ITALIAN

Italian, \$\$\$
52 W. Illinois St. • 312.222.1888
.7 miles from hotel

SHAKE SHACK

American, Quick Service, \$\$ 12 S. Michigan Ave. • 312.646.6005 .5 miles from hotel

SWEETWATER TAVERN & GRILLE

American, Pub, \$\$
225 N. Michigan Ave. • 312.698.7111
.3 miles from hotel

WILDBERRY PANCAKES & CAFE

Breakfast & Lunch, \$\$ 130 E. Randolph St. • 312.938.9777 .2 miles from hotel

YOLK

Brunch, Cafe, \$\$ 355 E. Ohio St. • 312.822.9655 .6 miles from hotel





Our Top Accruers

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

SWOG-Credited Registrations to SWOG Managed Trials

July 1, 2021 – June 30, 2022

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

NCORP

Kaiser Permanente NCI Community
Oncology Research Program

Heartland Cancer Research NCORP

Southeast Clinical Oncology Research Consortium NCORP

Gulf South Minority Underserved
NCORP

Cancer Research of Wisconsin and Northern Michigan Consortium

Main Member / LAPS

University of Texas MD Anderson Cancer Center LAPS

City of Hope Comprehensive Cancer Center

USC Norris Comprehensive Cancer Center LAPS

University of Rochester LAPS

Moffitt Cancer Center







Just What Is a "Hybrid" Meeting?

Welcome to SWOG's Fall 2022 Hybrid Group Meeting!

We've long since mastered the face-to-face meeting, have become adept at the fully virtual event, and are now learning to rock the hybrid version as well, with this as our second (but probably not last) hybrid group meeting.



"Hybrid" means all fall meeting sessions will be held in person in Chicago 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.



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



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



All sessions will be recorded, and recordings from open sessions will be available to attendees.

Support SWOG with a Gift Today

Hope Funds Research, Education, and Group Meetings!

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

thehopefoundation.org/donate



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





The Nicholas J. Vogelzang, MD, GU Symposium honors the many valuable contributions Dr. Vogelzang has made in

honors the many valuable contributions Dr. Vogelzang has made in support of his colleagues and patients throughout his career with the SWOG Cancer Research Network.

FRIDAY, OCTOBER 21 | 9:30 - 11:30 AM CT

FALL 2022 SYMPOSIUM

Organ Preservation in Bladder Cancer

- Introduction Daniel Petrylak, MD; Ian M. Thompson, Jr.,
 MD; & Seth Lerner, MD
- Patient advocate experience with bladder preservation
- Success and pitfalls of design in contemporary trials of bladder preservation **Parminder Singh, MD**
- Urologist Perspective Optimizing clinical staging and enrollment for bladder preservation trials – Scott Delacroix, MD
- Radiation Oncology Variables for stratification Daniel
 Allan Hamstra, MD
- Novel biomarker for new bladder preservation trials and optimizing biospecimen storage and processing for Aldriven biomarker discovery – David J. McConkey, PhD
- Panel Discussion of New Trial Ideas If S1806 is positive or negative
- Conclusion and next steps Seth Lerner, MD

The Nicholas J. Vogelzang, MD, Scholarship

Supporting a young investigator with mentorship and travel funding to attend SWOG group meetings

&

The Nicholas J. Vogelzang, MD, GU Symposium

A special group meeting session dedicated to a range of topics in GU research

Give Today

thehopefoundation.org/donate







Plenary I

Thursday, October 20, 3:30 - 5:00 pm CT - Regency B-D, Ballroom Level

This fall'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

Coltman Fellow Update – Image Analysis-Based TILs Measurement Predicts Breast Cancer pCR in SWOG S0800 Neoadjuvant Chemotherapy Trial Kim Blenman, PhD, MS

Yale Cancer Center





Updates from the Lung Cancer Translational Medicine Committee Phillip Mack, PhD UC Davis

Artificial Intelligence to Facilitate Cancer Clinical Trial Enrollment Aaron Cohen, MD, MSCE Flatiron Health





Plenary II

MATCH Making: NCI's New Precision Medicine Initiative Master Protocols

Friday, October 21, 12:00 - 2:00 pm CT - Regency B-D, Ballroom Level

This fall's general plenary will feature updates by leaders of the new NCI precision medicine trials, all of which are expected to have component activations this year: MyeloMATCH, ComboMATCH, and ImmunoMATCH. These will be preceded by an update on the ongoing Lung-MAP trial, the NCI's first precision medicine master protocol. Presentations will be followed by a Q&A session.

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

Lung-MAP Update
Roy S. Herbst, MD, PhD
Lung-MAP Study Chair
Yale Cancer Center

The MyeloMATCH Trial
Harry P. Erba, MD, PhD
SWOG Leukemia Committee Chair and
MyeloMATCH Senior Science Council Co-Chair
Duke University







The ComboMATCH Trial

James M. Ford, MD

ComboMATCH Study Chair

Stanford University

The ImmunoMATCH Trial

Siwen Hu-Lieskovan, MD, PhD

SWOG Immunotherapeutics Committee Co-Chair and ImmunoMATCH SWOG PI

Huntsman Cancer Institute





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.



October 19, 2022 | 4:30-6:30 PM CT

TAKE ACTION Symposium:

Hispanic/Latinx Populations: Ensuring Equity in Clinical Research

Presented by SWOG Recruitment & Retention Committee

SPEAKERS

Yonaira M. Rivera, PhD, MPH



Yonaira Rivera's scholarship focuses on reducing health inequities and improving the well-being of Latinx and underserved communities through health communication initiatives.

Her work uses qualitatively driven, mixed methods and community-based participatory research to study social media health misinformation, cancer control and prevention, and disaster relief. She conducts research in English and Spanish.

Barbara Segarra-Vázquez, DHSc

Barbara Segarra-Vázquez has been a faculty member at the University of Puerto Rico for more than 30 years, was the dean of the School of Health Professions for seven years, and is the

principal investigator of an R25 training program for young investigators. She is a two-time breast cancer survivor and is very active as a research advocate.



Gary W. Unzeitig, MD, FACS

Gary Unzeitig is the only breast surgeon serving more than 300,000 people in Laredo, nestled on the United States-Mexico border in southern Texas. Unzeitig has enrolled more than

1,200 patients on clinical trials over the past 20 years, and currently, he has more than 130 patients with breast cancer on clinical trials through the National Cancer Institute-funded National Clinical Trials Network.

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

LEARNING OBJECTIVES:

- **1. Identify** evidence-based practical strategies for sites to ensure access & equity in SWOG clinical trials
- 2. Address cultural values that support trust-building
- **3. Understand** current environment of the Hispanic/Latinx populations that impacts trial participation
- **4. Learn** strategies for enrolling Hispanic/Latinx populations in clinical trials

TAKE ACTION

Recruitment & Retention

Diversity, EQUITY, & Inclusion

Disparities Research Trust







Procedures for CME Credit

Group Meeting Target Audience and Educational Objectives

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

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

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

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

Continuing Medical Education Credit

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

The Hope Foundation designates this live activity for a maximum of 33.50 AMA PRA Category 1 Credits^{IM}. 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.

| | | Credits |
|---------------------|---|-----------------|
| Day/Time | | vailable Actual |
| WEDNESDAY, OCTOB | BER 19, 2022 | |
| 9:00 am – 12:00 pm | Advanced Practice Provider Clinical Research Worksh | nop 3.0 |
| 12:30 pm - 2:30 pm | Digital Engagement Committee | 2.0 |
| 2:30 pm - 4:30 pm | Adolescent and Young Adult (AYA) Committee | 2.0 |
| 4:30 pm - 6:30 pm | Take Action Symposium: Hispanic/Latinx Populations Ensuring Equity in Clinical Research presented by the SWOG Recruitment and Retention Committee | |
| 4:30 pm - 6:30 pm | Immunotherapeutics Committee | 2.0 |
| THURSDAY, OCTOBE | R 20, 2022 | |
| 9:00 am – 11:00 am | Cancer Care Delivery Committee | 2.0 |
| 10:00 am – 12:15 pm | Early Therapeutics and Rare Cancers Committee | 2.25 |
| 11:15 am - 1:15 pm | Prevention and Epidemiology Committee | 2.0 |
| 1:30 pm - 3:30 pm | Symptom Control and Quality of Life Committee | 2.0 |
| 3:30 pm - 5:00 pm | Plenary I (Translational Medicine) | 1.25 |
| 5:15 pm - 7:15 pm | Cancer Survivorship Committee | 2.0 |
| FRIDAY, OCTOBER 21 | , 2022 | |
| 7:30 am - 9:30 am | Palliative and End of Life Care Committee | 2.0 |
| 9:00 am – 11:00 am | Lymphoma Committee | 2.0 |
| 9:30 am – 11:30 am | Organ Preservation in Bladder Cancer Symposium | 2.0 |
| 10:30 am – 12:00 pm | Bone Marrow & Stem Cell Transplantation Committee | e 1.5 |
| 12:00 pm - 2:00 pm | Plenary II (General) | 2.0 |
| 2:00 pm - 4:00 pm | Radiation Oncology Committee | 2.0 |
| 2:30 pm - 4:30 pm | Melanoma Committee | 2.0 |
| 2:30 pm - 4:30 pm | Barlogie-Salmon Myeloma Committee | 2.0 |
| 2:30 pm - 6:15 pm | GU Committee Part I: Prostate, TM, Cancer Control | 3.75 |
| 4:00 pm - 6:00 pm | GI Committee | 2.0 |
| 4:15 pm - 7:15 pm | Lung Committee | 3.0 |
| SATURDAY, OCTOBE | R 22, 2022 | |
| 9:15 am – 11:15 am | Surgery Committee | 2.0 |
| 9:15 am – 12:15 pm | Breast Committee | 3.0 |
| 9:15 am – 12:15 pm | GU Committee Part II: Bladder, Renal | 3.0 |
| 9:30 am – 12:30 pm | Leukemia Committee | 3.0 |
| Total Possible Cred | its | 33.5 |

SWOG Fall 2022 Hybrid Group Meeting: Health & Safety

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

We strongly encourage you to wear a medical mask at all times while indoors.

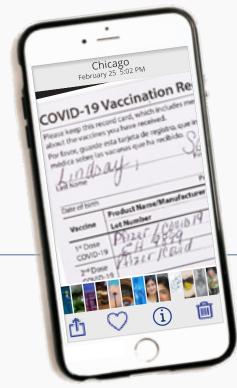
Extra masks are available at the registration desk.

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 fall 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 at least one vaccine booster shot prior to October 13.

We strongly encourage you to get the newly updated COVID-19 booster, which better protects against the most recently circulating variant.



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 MylRMobile.com (available in several states) or other apps
- QR code or digital copy of your COVID-19 vaccination record from a state-sponsored system

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.

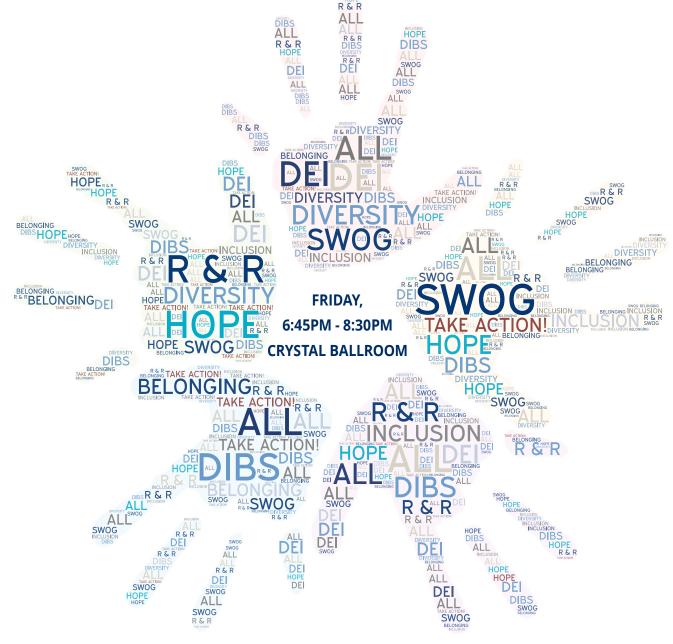
If you find you need to take a COVID-19 test while onsite, tests will be available at the SWOG registration desk.

Please reach out to us at <u>healthandsafety@swoq.orq</u>.



Diversity, Equity, and Inclusion Meet-and-Greet

Hosted by the Recruitment and Retention Committee



Look for our tables and balloons at the Friday evening reception to meet, mingle, and learn more about DEI at SWOG





Advanced Practice Provider Clinical Research Workshop

A special session of the SWOG Cancer Research Network fall group meeting











Sponsored by the SWOG nursing research subcommittee and the palliative and end of life care committee; funded by The Hope Foundation for Cancer Research

This hybrid event will focus on the essentials for advanced practice providers to provide safe care to patients on clinical trials and enhance their involvement with NCI-based research.

3 hours of CME devoted to the nuts and bolts of participating in NCI-sponsored trials at your practice site and beyond!



THE HOPE
FOUNDATION
FOR CANCER RESEARCH



ADVANCED
PRACTICE
PROVIDER
CLINICAL
RESEARCH
WORKSHOP
AGENDA

- Overview of NCI sponsored research and NCTN and NCORP Networks
- Becoming an NPIVR
- Different types of protocols
 - Treatment/Intervention
 - Cancer control
 - Symptom management
 - Survivorship
 - Palliative and EOL
 - Prevention
 - QOL
- CCDR

- Facilitators of/Barriers to APP participation in NCI-sponsored research
- Panel: Opportunities for increased involvement in research bases
- Protocol review
 - Eligibility/Consenting
 - CTCAE grading
 - Dose modifications
 - RECIST criteria

WORKSHOP FACULTY

SWOG

Christa Braun-Inglis,
DNP, APRN, FNP-BC, AOCNP (Member
Nursing Research Sub-Committee)
Nurse Practitioner/Assistant Researcher
University of Hawaii Cancer Center/Hawaii
M/U NCORP

Jamie S Myers PhD, RN, AOCNS, FAAN

(Chair of Nursing Research Sub-Committee) Research Associate Professor University of Kansas

Joyce Lee, PharmD, BCOP, BCPS

Senior Clinical Pharmacist, Investigational Drug Services and Oncology UC Davis Comprehensive Cancer Center

Joyce Tull, MSN

Executive Director, Office of Clinical Research

UC Davis Comprehensive Cancer Center

Nichole Mahaffey, PhD, CCRP

Data Coordinator Supervisor
UC Davis Comprehensive Cancer Center

ECOG

Bridget O'Brien, DNP, APRN, FNP-BC, AOCNP

(Chair Nursing Committee)
Director of the Family Nurse Practitioner
Program/Assistant Professor/ Family
Nurse Practitioner
Rush University

NRG

Melyssa Foust, MSN, RN, OCN

Cancer Control/CCDR Manager UC NCORP CCDR Coordinator Gibbs Cancer Center and Research Institute

COG

Maureen Haugen, MS, APRN, CPRP, CPON

APP Manager/Pediatric Nurse Practitioner Ann & Robert H. Lurie Children's Hospital of Chicago

URCC

Marie Flannery, PhD, RN, AOCN

Associate Professor, University of Rochester, School of Nursing

WAKE FOREST

Alisha T. DeTroye, PA-C, DFAAPA

Director of Advanced Practice Atrium Health Wake Forest Baptist

NCI

Kate Castro, RN, MS, AOCN

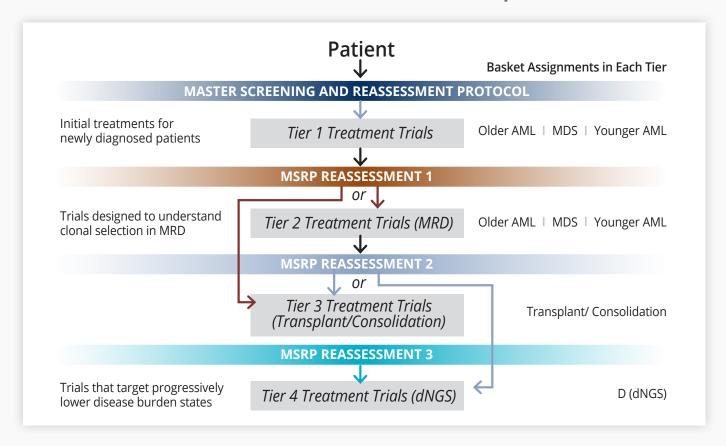
Nurse Consultant/Program Director Healthcare Delivery Research Program Office of the Associate Director, Division of Cancer Control and Population Science (DCCPS)



Saturday, Oct 22 | 9:50 am − 12:00 pm CT

Come Learn More About MyeloMATCH

at the SWOG Leukemia Committee Open Session



MyeloMATCH is the NCI's initiative to accelerate precision medicine and develop new therapies in myeloid malignancies.

Patients will be enrolled at diagnosis of acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS) and assigned to a trial in the MyeloMATCH portfolio based on clinical, cytogenetic, and molecular features.

Attend the Leukemia Committee Open Session to learn more about

| the nuts and bolts of the MyeloMATCH screening protocol how sites open MyeloMATCH studies | NCORP participation in MyeloMATCH | MyeloMATCH BEACON builds | the science underlying MyeloMATCH | MyeloMATCH cytogenetics and more! |
|--|---|-----------------------------|---|---|
|--|---|-----------------------------|---|---|

The MyeloMATCH Master Screening & Reassessment Protocol and the first wave of MyeloMATCH clinical trials are on track to open soon!

Also: don't miss Harry Erba, MD, PhD, presenting on the MyeloMATCH trial at Plenary II, Friday, October 21, 12-2 pm CT.



Wednesday, Oct 19, 2022 | 4:30 – 5:10 pm CT in the Immunotherapeutics Committee Meeting

Come Learn About the Innovative ImmunoMATCH Study and Its Pilot Trial:

S2101 BiCaZO Kick-Off

ALL PRINCIPAL INVESTIGATORS AND SITE STAFF ARE ENCOURAGED TO ATTEND.

ImmunoMATCH is one of the next generation of NCI precision medicine master protocols (MATCH = Molecular Analysis for Therapy Choice).

S2101 BiCaZO is the iMATCH pilot: a phase II study combining cabozantinib and nivolumab in participants with advanced solid tumors (IO-refractory melanoma or head & neck squamous cell carcinoma) stratified by tumor biomarkers.

The kick-off features presentations and a Q&A with

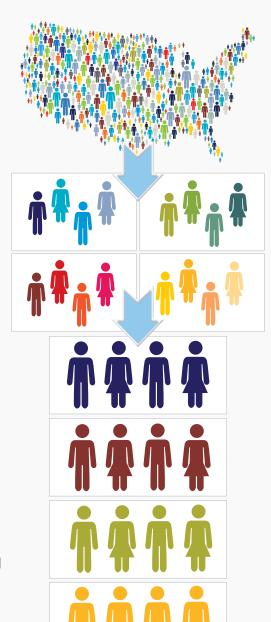
- Katerina Politi, PhD
- · Siwen Hu-Lieskovan, MD, PhD
- Paul Swiecicki, MD
- · Michael LeBlanc, PhD
- · Katherine Minichiello, MS
- Dana Sparks, MAT
- Chris Kippola,
- · James Moon, MS
- · Gary Lyman, MD
- and the rest of the SWOG iMATCH team

ImmunoMATCH uses whole exome sequencing to calculate tumor mutational burden and gene expression profiling to generate a tumor inflammation score.

The BiCaZO pilot will test the feasibility of using these two assays to stratify patients up front, so they can be used in future ImmunoMATCH subprotocols.

Come learn more about opening S2101 BiCaZO, the ImmunoMATCH pilot!

Also: don't miss Siwen Hu-Lieskovan, MD, PhD, presenting on the ImmunoMATCH trial at Plenary II, Friday, October 21, 12-2 pm CT.





SWOG has launched a new Learning Management System (LMS)!

THE EXPERTUSONE LMS WILL BE HOME TO ALL TRAINING THAT IS SPECIFIC TO SWOG MEMBERS.



Training certificates are viewable and printable for one year after completing a course.



Courses are available in brief 5- to 15-minute modules.



Content is regularly added and updated. See the "Announcements" window for new content.



In a user-friendly interface, you can view trainings, take surveys, and complete assessments all from one LMS content player – also available for mobile devices.



Allows us to host virtual classes integrated with WebEx or Zoom.

NCTN-wide training — such as for protocol-specific requirements and PRO training — will remain in the CTSU CLASS system. But SWOG internal training for members and staff will be in ExpertusOne.

Some of the training content now within ExpertusOne:

- Study Chair Workshop
- Young Investigator Workshop Online
- Investigational Agent Handling
- Clinical TrialsTraining Course
- Team Science

Access SWOG's new LMS at swog.exphosted.com, or link from the "Training for SWOG Members" item on the "Member Resources" menu. Use your CTEP IAM credentials to log in.

swog.exphosted.com



www.expertusone.com



Support SWOG Through Planned Giving

Your legacy gift can advance clinical trials for patients everywhere. By planning a gift for The Hope Foundation, you provide critical cancer prevention and treatment for future generations.

Including a charitable gift in your estate plans is easy. With the help of your tax advisor or estate planner, you can include language in your will or trust specifying a gift be made to The Hope Foundation as part of your estate plan. You can give a specific dollar amount or asset, a percentage of your estate, a gift from the balance or residue of your estate or make a beneficiary designation of certain assets.



Maximize your impact and tax savings through a stock gift

Have you considered supporting The Hope Foundation through a stock gift?

When you give appreciated shares over a year old to The Hope Foundation, you receive credit for the full market value and do not pay capital gains. If you itemize your tax deductions, your savings can be substantial.

Your gift of stock will directly impact the patients and researchers across SWOG's 1,300+ member sites – and beyond.

To learn about planning a gift or giving through stock, visit thehopefoundation.org/donate or contact funding@thehopefoundation.org or (734) 998-6887.





THE HOPE FOUNDATION FOR CANCER RESEARCH

Future Funding Opportunities

SEED Fund Program: December 1

•Impact Award Program: January 15 (LOI)

Coltman Fellowship Program: March 1

Career Development Award: March 1

See all Hope Foundation programs at

THEHOPEFOUNDATION.ORG/FUNDING-OPPORTUNITIES

SWOG CLINICAL TRIALS PARTNERSHIPS

AN LLC OF THE HOPE FOUNDATION FOR CANCER RESEARCH

Learn more about upcoming trials and partnership opportunities at the

SWOG CTP Update Forum

Wednesday, October 19, 11:30 am - 12:30 pm CT

Can't be there in person?

Attend virtually at bit.ly/3RD7GHb

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

swogctp.org





WEDNESDAY, OCTOBER 19, 2022

Group Meeting Registration & Information Desk 8:00 am - 5:00 pm - Regency Foyer, Ballroom Level, West Tower

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

8:30 AM - 11:30 AM

Acapulco, Ballroom Level Advocates Committee (Committee

Members Only)

9:00 AM - 12:00 PM

Regency B, Ballroom LevelAdvanced Practice Provider Clinical

Research Workshop

9:30 AM - 11:00 AM

Soldier Field, Concourse Level Quality Initiative Meeting

(Committee Members Only)

11:00 AM - 12:00 PM

Toronto, Ballroom Level ORP Executive and Education

Cmte Members Prep/Working Group (Cmte Members Only)

11:30 AM - 12:30 PM

Regency A, Ballroom Level Clinical Trials Partnerships Update

Forum

12:00 PM - 12:30 PM

Regency D Foyer, Ballroom Level SWOG NCORP Research Base

Clinical Trials Workshop Check-In

12:30 PM - 2:00 PM

Acapulco, Ballroom LevelCore Office Staff Networking

Session (Invitation Only)

12:30 PM - 2:30 PM

Regency C, Ballroom Level Digital Engagement Committee

12:30 PM - 4:00 PM

Regency D, Ballroom Level SWOG NCORP Research Base

Clinical Trials Workshop

1:00 PM - 2:45 PM

Soldier Field, Concourse Level Nursing Research Subcommittee

(Committee Members Only)

2:00 PM - 3:30 PM

Toronto, Ballroom Level SWOG Tissue Banking Meeting

(Invitation Only)

2:30 PM - 4:30 PM

Water Tower, Concourse Level Adolescent and Young Adult (AYA)

Committee

3:30 PM - 5:00 PM

Acapulco, Ballroom Level Hope Foundation Board Meeting

(Board Members Only)

4:30 PM - 6:30 PM

Regency C, Ballroom LevelTake Action Symposium: Hispanic/

Latinx Populations, Ensuring Equity in Clinical Research, presented by the SWOG Recruitment and Retention

Committee

4:30 PM - 6:30 PM

Regency B, Ballroom Level Immunotherapeutics Committee

5:30 PM - 7:30 PM

Regency A, Ballroom Level Site Operations

5:30 PM - 8:00 PM

Acapulco, Ballroom Level NCORP Research Base Executive

Committee Meeting (Committee

Members Only)

THURSDAY, OCTOBER 20, 2022

Group Meeting Registration & Information Desk 8:00 am - 5:00 pm - Regency Foyer, Ballroom Level, West Tower

Hope Foundation Information Desk 8:00 am - 5:00 pm - Regency Foyer, Ballroom Level, West Tower

Exhibits & Complimentary Coffee Service 8:00 am - 5:00 pm - Toronto, Ballroom Level, West Tower

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

8:30 AM - 9:00 AM

Regency B Foyer, Ballroom Level Jeri & Noboru Oishi Symposium

Check-In

9:00 AM - 12:00 PM

Regency B, Ballroom Level Jeri & Noboru Oishi Symposium

9:00 AM - 11:00 AM

Acapulco, Ballroom Level

Lung-MAP Administrative Meeting

(Invitation Only)

9:00 AM - 11:00 AM

Regency A, Ballroom LevelCancer Care Delivery Committee

10:00 AM - 12:15 PM

Regency C, Ballroom LevelEarly Therapeutics and Rare Cancers Committee

11:00 AM - 1:00 PM

Water Tower, Concourse Level SWOG Latin America Initiative

Symposium

11:15 AM - 1:15 PM

Regency A, Ballroom Level Prevention and Epidemiology

Committee

12:00 PM - 1:00 PM

New Orleans, Ballroom Level Clinical Trials Partnerships

Scientific Advisory Board

(Invitation Only)

12:00 PM - 2:00 PM

Acapulco, Ballroom Level Lung-I

Lung-MAP Site Coordinators Committee Meeting (Committee

Members Only)

12:30 PM - 1:10 PM

ORP Open Forum
Breakout Sessions 1-3
(choose 1 session below)

Comiskey, Concourse Level Columbian, Concourse Level Wrigley, Concourse Level Session 1: Regulatory 101

Session 2: Understanding the PMB

Session 3: Interactive Q&A

1:15 PM - 2:00 PM

ORP Open Forum Breakout Sessions 4-6 (choose 1 session

below

Comiskey, Concourse Level

Columbian, Concourse Level Session 5
Wrigley, Concourse Level Session 6

Session 4: SWOG Perspective &

Common Challenges
Session 5: Know Your IRBs
Session 6: Interactive O&A

12:30 PM - 2:15 PM

Picasso, Concourse Level

Sarcoma Working Group of the ETxRC Committee (Invitation Only)

12:30 PM - 3:15 PM

Gold Coast, Concourse Level

Myeloma Working Group (Working

Group Members Only)

1:30 PM - 2:30 PM

Soldier Field Concourse Level

Lung Community Engagement Subcommittee (Committee

Members Only)

1:30 PM - 3:30 PM

Regency A, Ballroom Level

Symptom Control and Quality of

Life Committee

2:30 PM - 3:30 PM

Wrigley, Concourse Level

S2108CD Update Meeting

2:30 PM - 3:30 PM

Picasso, Concourse Level

ORP Liaison Subcommittee (Committee Members Only)

2:30 PM - 3:30 PM

Regency Foyer, Ballroom Level

Plenary Reception (Light Hors D'oeuvres)



3:30 PM - 5:00 PM

Regency B-D, Ballroom Level Plenary I (Translational Medicine)

5:15 PM - 7:15 PM

Wrigley, Concourse Level CNS Working Group

5:15 PM - 7:15 PM

Regency A, Ballroom Level Cancer Survivorship Committee

5:15 PM - 7:15 PM

Acapulco, Ballroom Level Lymphoma Working Group (Working Group Members Only)

5:15 PM - 7:15 PM

Comiskey, Concourse Level Lung Working Group (Working Group Members Only)

5:15 PM - 7:15 PM

New Orleans, Ballroom LevelConflict Management Committee (Committee Members Only)

FRIDAY, OCTOBER 21, 2022

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

West Tower

Hope Foundation Information Desk

8:00 am - 5:00 pm - Regency Foyer, Ballroom Level,

West Tower

Exhibits & Complimentary Coffee Service

8:00 am - 5:00 pm - Toronto, Ballroom Level, West Tower

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

7:00 AM - 9:00 AM

New Orleans, Ballroom Level Imaging Committee (Committee

Members Only)

7:30 AM - 9:00 AM

Soldier Field, Concourse Level Professional Review Committee

(Committee Members Only)

7:30 AM - 9:30 AM

Picasso, Concourse Level SWOG Data and Safety Monitoring

Committee (Committee Members

Only)

7:30 AM - 9:30 AM

Regency A, Ballroom Level Palliative and End of Life Care

Committee

8:00 AM - 10:00 AM

Wrigley Concourse Level Lung Radiation/Surgery

Subcommittee

(Committee Members Only)

8:00 AM - 12:00 PM

Plaza B, Lobby Level (East Tower) Gl Working Group (Working Group

Members Only)

9:00 AM - 10:00 AM

Acapulco, Ballroom Level ORP Workgroup (Invitation Only)

9:00 AM - 11:00 AM

Crystal A, Lobby Level Lymphoma Committee

9:00 AM - 11:00 AM

Crystal C, Lobby Level Breast Working Group (Working

Group Members Only)



9:30 AM - 11:30 AM

Plaza A, Lobby Level (East Tower) Melanoma Working Group

(Working Group Members Only)

9:30 AM - 11:30 AM

Crystal B, Lobby Level Organ Preservation in Bladder

Cancer Symposium

10:00 AM - 11:30 AM

Picasso, Concourse Level Quality Assurance Committee

(Committee Members Only)

10:00 AM - 12:00 PM

Water Tower, Concourse Level Pharmaceutical Sciences

Committee and Drug Information

Subcommittee

10:30 AM - 12:00 PM

Comiskey, Concourse Level Bone Marrow & Stem Cell

Transplantation Committee

11:00 AM - 12:00 PM

Regency Foyer, Ballroom Level Plenary Reception (Light Hors

D'oeuvres)

11:30 AM - 12:00 PM

Acapulco, Ballroom Level Publications Committee

(Committee Members Only)

12:00 PM - 2:00 PM

Regency B-D, Ballroom Level Plenary II (General)

2:00 PM - 4:00 PM

Crystal A, Lobby Level Radiation Oncology Committee

2:15 PM - 3:15 PM

Water Tower, Concourse Level NCORP/MU-NCORP Site PI Meeting

2:15 PM - 3:45 PM

Crystal B, Lobby Level Lung-MAP Update Meeting

2:15 PM - 4:15 PM

Plaza A, Lobby Level (East Tower) Leukemia Working Group

(Working Group Members Only)

2:30 PM - 4:30 PM

Crystal C, Lobby Level Melanoma Committee

2:30 PM - 4:30 PM

Plaza B, Lobby Level (East Tower) Barlogie-Salmon Myeloma

Committee

2:30 PM - 6:15 PM

Regency A, Ballroom Level GU Committee Part I: Prostate; TM;

Cancer Control

3:00 PM - 6:00 PM

Comiskey, Concourse Level Breast Translational Medicine

Working Group (Working Group

Members Only)

4:00 PM - 5:00 PM

Acapulco, Ballroom Level ORP Executive Committee

(Committee Members Only)

4:00 PM - 6:00 PM

Regency B, Ballroom Level GI Committee

4:15 PM - 7:15 PM

Regency C, Ballroom Level Lung Committee

<u>6:00 PM - 7:00 PM</u> Executive Reception

(Invitation Only)

6:45 PM - 8:30 PM

Crystal Ballroom, Lobby Level Group Reception & Diversity,

Equity and Inclusion Meet

and Greet



Committees

SATURDAY, OCTOBER 22, 2022

Group Meeting Registration & Information Desk 7:00 am - 11:00 am - Regency Foyer, Ballroom Level, West Tower

Hope Foundation Information Desk 8:00 am - 11:00 am - Regency Foyer, Ballroom Level, West Tower

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

7:00 AM - 7:45 AM

Regency C, Ballroom Level Board of Governors (Board

Members Only)

8:00 AM - 9:00 AM

Regency C, Ballroom Level Committee Chairs (Committee

Chairs Only)

8:00 AM - 9:00 AM

Regency A, Ballroom Level GU Trials Kickoff Meeting (in

person only, no hybrid option)

9:15 AM - 11:15 AM

Water Tower, Concourse Level VA Committee

9:15 AM - 11:15 AM

Comiskey, Concourse Level Surgery Committee

9:15 AM - 12:15 PM

Regency B, Ballroom Level **Breast Committee**

9:15 AM - 12:15 PM

GU Committee Part II: Bladder; Regency A, Ballroom Level

Renal

9:30 AM - 12:30 PM

Regency C, Ballroom Level Leukemia Committee

Administrative Committees

Board of Governors

Charles D. Blanke, MD

Conflict Management Paul Okunieff, MD

Publications

Hagen F. Kennecke, MD

Professional Review

Paul Hesketh, MD

Research Support Committees

Adolescent and **Young Adult**

Rebecca Johnson, MD

Bone Marrow and Stem Cell Transplantation

Patrick J. Stiff, MD

Digital Engagement

Don S. Dizon, MD

Imaging

Lawrence H. Schwartz, MD

Oncology Research **Professionals**

Connie Szczepanek, RN, BSN, CCRP

Patient Advocates

Rick Bangs, MBA

Pharmaceutical Sciences

Siu-Fun Wong, PharmD

Radiation Oncology

Interim Chair James Yu, MD

Recruitment and

Retention

Allison Caban-Holt, PhD

Surgery

Syed A. Ahmad, MD

Veterans Affairs

Stephen D. Bartlett, RPh

Future Meeting Dates

| 2023 | | | 2024 | | | |
|------|-------------------|---------------|-------------|--|---------------|--|
| | Spring | Fall | Spring | | Fall | |
| | May 10-13 | October 11-14 | April 3-6 | | October 16-19 | |
| | San Francisco, CA | Chicago, IL | Seattle, WA | | Chicago, IL | |



| Leadership | |
|----------------------------------|---------------------------------|
| Chair: | Robert Z. Orlowski, MD, PhD |
| Vice-Chair: | Sikander Ailawadhi, MD |
| Vice-Chair: | Jing Christine Ye, MD, MSc |
| Executive Officer | Susan M. O'Brien, MD |
| Statisticians: | Antje Hoering, PhD |
| | Rachael Sexton, MS |
| | Adam Rosenthal |
| Scientific Leadership | |
| Translational Medicine: | • • |
| Radiation: | Chelsea Camille Pinnix, MD, PhD |
| Surgery: | |
| Imaging: | Eric M. Rohren, MD, PhD |
| Pathology: | |
| Early Therapeutics: | Frits van Rhee, MD, PhD |
| Designates | |
| DEI Champion: | • |
| Digital Engagement: | |
| NCORP Representative: | |
| Veterans Affairs: | |
| Data Coordinators: | • |
| | Hannah Hale |
| Oncology Research Professionals: | |
| CRA: | |
| Nurses: | • |
| | , , |
| Patient Advocate: | • |
| Pharmaceutical Science: | 5 5 |
| | , |
| Protocol Project Manager: | |
| Clinical Trials Program Manager: | TBD |

Time/Location

Friday, October 21, 2022 2:30 pm - 4:30 pm Room: Plaza B (Lobby Level, East Tower)

Active Studies

- S1803, "Phase III Study of Daratumumab/rHuPH20 (NSC-810307) +
 Lenalidomide or Lenalidomide as Post-Autologous Stem Cell Transplant
 Maintenance Therapy in Patients with Multiple Myeloma (MM) Using
 Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC
 Study)." Drs. A. Krishnan and P. Hari. Activated: 6/27/19.
- S2005, "A Phase II Randomized Study of Ibrutinib and Rituximab with or Without Venetoclax in Previ-ously Untreated Waldenström's Macroglobulinemia (WM)." Drs. S. Ailawadhi and D. Bhutani. Activat-ed: 6/24/21. Temporarily Closed: 7/16/21. Re-opened to accrual: 10/15/21. Temporary Closed: 4/08/22.
- 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.
- <u>\$1702</u>, "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>S1304</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.



- <u>S0777</u>, "Frontline Phase III Rev/Dex +/- Vel, no upfront transplant." Dr. B. Durie. Activated: 4/1/18. Closed: 2/2/12.
- <u>S0120</u>, "A prospective Observational Biologic Study of Asymptomatic Patients with Monoclonal Gam-mopathy 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 Transplant 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.
- E1A11, "Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite DURation Lenalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (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

- S2209, "A Phase III Randomized Trial for Newly Diagnosed Multiple Myeloma (NDMM) Patients Con-sidered 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>S2213</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
- <u>S1911</u>, "Phase III Study of Optimal Induction Therapy for Newly Diagnosed High-Risk Multiple Myelo-ma (HRMM) RVd Dara +/- xx." Dr. B. Lipe.

Proposed Studies-Pre-Triage/On Hold

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



Accrual from trial opening through 6/30/2022 by Institution and Study

| | 51803 | 52005 | EAA173 | EAA181 |
|---|------------|-------|--------|--------|
| Ascension Providence Hospitals - Southfield | 1 | - | - | - |
| Banner University Medical Center - Tucson | 6 | - | - | - |
| Boston Medical Center | 5 | - | - | - |
| CWRU Case Comprehensive Cancer Center LAPS | 15 | - | 3 | - |
| Cancer Research for the Ozarks NCORP | 1 | - | - | - |
| Cancer Research of Wisconsin and Northern Michigan Consortium | 3 | - | - | - |
| Cedars-Sinai Medical Center | 5 | - | - | - |
| City of Hope Comprehensive Cancer Center | <i>7</i> 8 | - | - | - |
| Columbus NCI Community Oncology Research Program | 7 | - | - | - |
| CommonSpirit Health Research Institute | 3 | - | - | - |
| Dayton NCI Community Oncology Research Program | 5 | - | - | - |
| Duke University - Duke Cancer Institute LAPS | 3 | - | - | - |
| Fred Hutchinson Cancer Research Center LAPS | - | - | 4 | - |
| Georgia NCI Community Oncology Research Program | 11 | - | - | - |
| Gulf South Minority Underserved NCORP | 4 | - | - | - |
| Heartland Cancer Research NCORP | 14 | - | - | - |
| Kaiser Permanente NCI Community Oncology Research Program | 37 | - | - | - |
| Lahey Hospital and Medical Center | 3 | - | - | - |
| Loyola University Medical Center | 19 | - | 3 | - |
| Medical University of South Carolina Minority Underserved NCORP | 29 | - | 1 | - |
| Moffitt Cancer Center | 36 | - | - | - |
| Montana Cancer Consortium NCORP | 4 | - | - | - |
| Nevada Cancer Research Foundation NCORP | - | - | 1 | - |



Accrual from trial opening through 6/30/2022 by Institution and Study

| | 51803 | 52005 | EAA173 | EAA181 |
|---|-------|-------|--------|--------|
| New Mexico Minority Underserved NCORP | 8 | - | - | - |
| Ohio State University Comprehensive Cancer Center LAPS | 4 | - | - | - |
| Oregon Health and Science University | 17 | - | 2 | 3 |
| Pacific Cancer Research Consortium NCORP | 10 | - | - | - |
| Southeast Clinical Oncology Research Consortium NCORP | 3 | - | - | - |
| UC Davis Comprehensive Cancer Center LAPS | 17 | - | - | - |
| UC Irvine Health/Chao Family Comprehensive Cancer Center | 7 | - | - | - |
| University of Arkansas for Medical Sciences | - | - | - | 1 |
| University of Cincinnati Cancer Center-UC Medical Center | - | - | - | 1 |
| University of Kansas Cancer Center - MCA Rural MU NCORP | 23 | - | - | - |
| University of Michigan Comprehensive Cancer Center LAPS | 9 | - | - | - |
| University of Oklahoma Health Sciences Center LAPS | 2 | - | - | - |
| University of Rochester LAPS | 12 | - | - | - |
| University of Texas Health Science Center at San Antonio | 12 | - | - | - |
| University of Texas MD Anderson Cancer Center LAPS | 19 | - | - | - |
| University of Utah - Huntsman Cancer Institute LAPS | 12 | - | 3 | 1 |
| Upstate Carolina Consortium Community Oncology Research Program | 3 | - | - | - |
| Wayne State University - Karmanos Cancer Institute LAPS | 10 | - | - | - |
| Wisconsin NCI Community Oncology Research Program | 16 | - | - | - |
| Yale University - Yale Cancer Center LAPS | - | - | 2 | 1 |
| ALLIANCE | 139 | - | - | - |
| ECOG-ACRIN | 117 | 1 | - | - |
| NRG | 72 | - | - | - |
| Total | 801 | 1 | 19 | 7 |



Breast Committee

| 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: |
| Surgery: Joshua M.V. Mammen, MD, PhD |
| Imaging:Joanne E. Mortimer, MD |
| |
| Pathology: |
| Early Therapeutics:Stephanie L. Graff, MD |
| Designates |
| Cancer Control Liaisons: Melinda L. Irwin, PhD, MPH (Survivorship) |
| Dawn L. Hershman, MD (Cancer Care Delivery) |
| |
| Helen K. Chew, MD (Symptom Control & QOL) |
| DEI Champion:Gayathri Nagaraj, MD |
| 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: |
| Patient Advocates: Roberta A. Albany |
| Ginny Mason, RN, BSN |
| Pharmaceutical Science: Jorge G. Avila, PharmD |
| Dawud Nael Dawud Ellayan, Pharm D |
| Protocol Project Manager: |
| Clinical Trials Program Manager: |
| j j |

Time/Location

Laadayabiy

Saturday, October 22, 2022 9:15 am - 12:15 pm Room: Regency B (Ballroom Level, West Tower)

Agenda

- **9:30 9:35 am Welcome and Introductions** Lajos Pusztai, M.D., D.Phil. (Chair) and Priyanka Sharma, M.D. (Vice-chair)
- 9:35 10:35 am Mini symposium "Improving Diversity in Clinical Trials Bridging Gaps and Creating Opportunities"
- Facilitator Andrew K. Godwin, PhD: Professor and Division Director,
 Genomic Diagnostics; Deputy Director, University of Kansas
 Comprehensive Cancer Center, & Founding Director, Kansas Institute for
 Precision Medicine, University of Kansas Medical Center).
- 9:35 9:50 am "Improving Diversity in Clinical Trials: Why, What and How?" Gayathri Nagaraj, MD Associate Professor of Medicine and Breast Medical Oncologist at Loma Linda University Cancer Center.
- <u>9:50 10:00 am</u> Interactive questions "Diversity, Equity, and Inclusion in Clinical Trials: What are You Doing at Your Institute?"
- <u>10:00 10:15 am</u> "Engaging Communities and Providers to Enhance Clinical Trials Access" - Hope Krebill, MSW, BSN, RN: Executive Director, Masonic Cancer Alliance, the University of Kansas Cancer Center) & Ronald Chen, MD, MPH, FASCO, FASTRO: Professor and Chair, Radiation Oncology, the University of Kansas Medical Center.
- 10:15 10:30 am "Building Trust and Relationships: A Patient Prospective" Roberta Albany: Patient Advocate SWOG Breast Committee
- 10:30 10:35 am "Plan of Action" Gayathri Nagaraj, MD
- 10:35 10:45 am Publication update William Barlow, Ph.D.
- 10:45 10:55 am Advocate update Ginny Mason & Roberta Albany
- **10:55 11:05 am Translational Medicine Sub-Committee update** Alastair Thompson, M.D. & Andrew K. Godwin, Ph.D.
- 11:05 11:45 am Review of open CTSU trials
- 11:45 12:05 pm Recently approved and developing Concepts
- 12:05 12:25 pm 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 – Philip Lammers, M.D.

DEI - Gayathri Nagaraj, M.D.

12:25 - 12:30 pm Closing Comments and Adjourn



Breast Committee

Proposed Studies

- <u>S2212</u>, "Shorter Anthracycline-Free Chemo Immunotherapy Adapted to Pathological Response in Early Triple Negative Breast Cancer (SCARLET), a Randomized Phase III Study." Drs. Sharma and Mitri.
- <u>S2206</u>, "Phase III Trial of Neoadjuvant Durvalumab (NSC 778709) plus Chemotherapy versus Chemotherapy Alone for MammaPrint Ultrahigh (MP2) Hormone Receptor (HR) Positive / Human Epidermal Growth Factor Receptor (HER2) Negative Stage II-III Breast Cancer." Drs. Cobain and Pusztai.

Active Studies

- <u>S2007</u>, "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 and Chalasani. Activated: 09/12/18.
- CTSU/A011202, "A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy." Dr. Boughey. SWOG Champion: Dr. Mammen. Activated: 02/07/14. Temporarily closed: 01/14/2022.
- 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 Studies

- S1418, "A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with ≥1 CM Residual Invasive Cancer or Positive Lymph Nodes (ypN1mi, ypN1-3) after Neoadjuvant Chemotherapy." Drs. Pusztai and Mammen. Activated: 11/15/16. Permanently closed: 06/30/21.
- <u>S1207</u>, "Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer. e^3 Breast Cancer Study-Evaluating Everolimus with Endocrine Therapy." Drs. Chavez-MacGregor and Pusztai. Activated: 09/04/13. Permanently closed: 05/01/19.



Tweeting the Meeting

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@SWOG has more than 12K followers and can amplify your message!

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With your group meeting tweets ...

tag your @SWOG friends

use the hashtag #SWOGonc



Breast Committee

Active Cancer Survivorship Study

<u>\$1501</u>, "Prospective Evaluation of Carvedilol in Prevention of Cardiac Toxicity in Patients with Metastatic HER-2+ Breast Cancer, Phase III." Drs. Floyd and Leja. Activated: 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 and Lok. 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 and Hershman. 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. According and Hershman. Activated: 07/16/18.

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

Active Cancer Prevention Study

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, and Kukafka. Activated: 09/01/20.

Active Early Therapeutics and Rare Cancers Studies

<u>\$1609</u>, "DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors." Drs. Patel and Chae. Activated 01/13/17.

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



Breast Committee

| | 51418 | 51706 | 52007 | A011202 | A011401 | A011801 | EA1131 | EA1181 | EA1183 | MA39 | NRGBR003 | NRGBR004 | NRGBRO |
|---------------------------------------|-------|-------|-------|---------|---------|---------|--------|--------|--------|------|----------|----------|--------|
| Ascension Prov Hosp - Southfield | 6 | 2 | - | 4 | 10 | - | 1 | 2 | - | 1 | 3 | 1 | - |
| Ascension Via Christi Hosp Wichita | 9 | - | - | - | - | - | - | - | - | - | - | - | - |
| Banner MD Anderson CC | 3 | - | - | - | - | - | - | - | - | - | - | - | - |
| Banner U Med Ctr - Tucson | 4 | 1 | - | 1 | 6 | - | - | 6 | - | - | - | - | - |
| Baptist Mem HC/Mid South MU NCORP | 9 | 3 | - | 1 | 4 | - | - | 1 | - | - | - | 1 | - |
| Bay Area Tumor Inst NCORP | 3 | - | - | - | - | - | - | - | - | - | - | - | - |
| Baylor U Med Ctr | - | - | - | 1 | - | - | - | - | - | - | - | - | - |
| Boston Med Ctr | - | - | - | - | 3 | - | - | 10 | - | - | - | - | - |
| CWRU Case CCC LAPS | 12 | - | 1 | - | 2 | - | - | - | - | 1 | 9 | 1 | - |
| Ca Res Consortium of 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 | 2 | - | - | - | - | - | 3 | - | - | - | - | - |
| Columbus NCORP | 13 | - | - | - | - | - | - | - | - | - | - | - | - |
| CommonSpirit HIth Res Inst | 19 | 1 | - | - | 2 | - | - | - | - | - | - | - | - |
| Cotton O'Neil CC / Stormont Vail HIth | - | - | - | 1 | 1 | - | - | - | - | - | 1 | - | - |
| Dayton NCORP | 3 | - | - | - | 1 | - | 1 | 7 | - | - | - | - | - |
| Desert Regional Med Ctr | 1 | - | - | 7 | 4 | - | - | - | - | - | - | - | - |
| Essentia Health NCORP | 3 | - | - | - | - | - | - | - | - | - | - | - | - |
| Fred Hutchinson Ca Res Ctr LAPS | 10 | 3 | - | - | 12 | - | - | - | - | - | - | - | - |
| Georgia NCORP | 23 | 2 | - | - | 2 | - | 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 | - | - | - | - | - | - | - |
| Kaiser Permanente NCORP | 51 | - | - | 1 | 55 | - | - | - | - | - | 25 | 1 | - |
| Lahey Hospital & Med Ctr | 3 | - | - | - | 9 | - | 1 | 4 | - | - | - | 1 | - |
| Loma Linda U Med Ctr | 1 | - | - | 3 | - | - | - | - | - | - | - | - | - |
| Loyola U Med Ctr | 3 | - | - | - | 6 | - | 2 | 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 | - | - | - | - | - | - | - | - |
| Montana Cancer Consortium NCORP | 2 | 3 | - | - | - | - | - | - | - | - | - | - | - |
| Mount Sinai Hospital | 3 | - | - | - | - | - | - | 1 | - | - | - | - | - |
| NCORP Carolinas (Prisma HIth NCORP) | 4 | - | - | - | - | - | - | - | - | - | - | - | - |
| Nevada Ca Res Foundation NCORP | 11 | - | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ |



Breast Committee

| | 51418 | 51706 | 52007 | A011202 | A011401 | A011801 | EA1131 | EA1181 | EA1183 | MA39 | NRGBR003 | NRGBROO | 4 NRGBRO |
|--|-------|-------|-------|---------|---------|---------|--------|--------|--------|------|----------|---------|-------------|
| New Mexico MU NCORP | 19 | 4 | 1 | - | - | - | - | - | - | - | - | - | - |
| Northwell Health NCORP | - | - | 1 | - | - | - | - | - | - | - | - | - | 1 |
| Northwestern U LAPS | 2 | 1 | - | - | - | - | - | 2 | 1 | - | 1 | - | - |
| Ohio State U CCC LAPS | - | 1 | - | - | - | - | - | - | - | - | - | - | - |
| Oregon Health & Science U | 19 | - | - | - | - | - | - | - | 3 | - | 3 | - | - |
| Orlando Health Ca Inst | 1 | - | - | - | 1 | - | - | - | - | - | - | - | - |
| Pacific Ca Res Consortium NCORP | 19 | - | - | - | 3 | - | - | - | - | - | 1 | - | - |
| SCL Health Saint Joseph Hospital | - | - | - | - | 1 | - | - | - | - | - | - | - | - |
| Salem Hospital | - | - | - | 4 | - | - | - | - | - | - | - | - | - |
| Scott & White Mem Hospital | - | - | - | - | 4 | - | - | - | - | - | - | - | - |
| Southeast Clin Onc Res Consort NCORP | 46 | - | - | - | - | - | - | - | - | - | - | - | - |
| Sutter Ca Res Consortium | 3 | - | - | - | 8 | 2 | 1 | 3 | - | - | 4 | 2 | - |
| The Don and Sybil Harrington CC | 7 | 3 | - | 11 | 8 | 2 | - | - | - | - | - | - | - |
| James Graham Brown CC, U of Louisville | - | - | - | 2 | - | - | - | - | - | - | - | - | - |
| The West Clinic - Wolf River | - | - | - | 9 | - | - | - | - | - | - | - | - | - |
| UC Davis CCC LAPS | 8 | 5 | - | 2 | 4 | - | - | 4 | - | - | - | 1 | - |
| UC Irvine Hlth/Chao Family CCC | 6 | - | 1 | 3 | 2 | - | - | - | - | - | 1 | - | - |
| UC San Diego Moores CC | - | - | - | - | 2 | - | - | - | - | - | 1 | - | - |
| USC Norris CCC LAPS | 3 | - | - | 4 | - | - | - | - | - | 2 | | - | - |
| U Arkansas for Medical Sciences | 17 | 2 | - | - | 3 | - | - | - | - | - | - | - | - |
| U Colorado CC LAPS | 11 | 1 | - | 42 | 27 | 1 | - | 11 | - | 1 | | - | - |
| U Kansas CC - MCA Rural MU NCORP | 22 | 2 | - | 4 | 23 | - | _ | - | - | 1 | - | - | _ |
| U Michigan CCC LAPS | 13 | 2 | | - | 14 | - | - | 1 | - | 4 | 3 | - | - |
| U Mississippi Med Ctr | - | - | - | - | - | - | - | 1 | - | - | - | - | _ |
| U Oklahoma HSC LAPS | 2 | - | - | - | - | - | - | _ | - | - | - | - | _ |
| U Rochester LAPS | 2 | 1 | - | - | - | - | 7 | 1 | - | - | 9 | - | _ |
| U Texas HSC at San Antonio | 5 | - | 1 | 6 | 2 | - | - | - | - | - | 4 | - | - |
| U Texas MD Anderson CC LAPS | 21 | 1 | - | _ | - | - | _ | - | - | - | | - | - |
| U Utah - Huntsman Ca Inst LAPS | 6 | 2 | - | - | 7 | 1 | - | 3 | - | _ | - | - | _ |
| Upstate Carolina Consortium NCORP | 8 | - | - | - | 1 | - | _ | - | - | - | | - | _ |
| Virginia Mason Med Ctr | 1 | - | - | - | - | - | - | _ | - | - | - | - | _ |
| Wayne State U - Karmanos Ca Inst LAPS | 3 | - | - | 11 | 12 | - | 6 | 12 | 3 | - | 6 | - | _ |
| Western States Ca Res NCORP | 3 | - | - | - | - | - | - | - | - | - | | - | - |
| William Beaumont Hosp-Royal Oak | 1 | - | - | 6 | 5 | - | - | - | - | - | - | - | _ |
| Wisconsin NCORP | 2 | 1 | - | - | - | - | - | - | - | - | - | - | - |
| Yale U - Yale CC LAPS | 8 | - | - | 5 | 81 | 1 | 6 | 7 | - | - | 9 | 1 | - |
| ALLIANCE | 144 | 10 | 4 | - | _ | - | - | _ | - | _ | - | _ | _ |
| CCTG | 39 | 6 | _ | - | _ | - | _ | - | - | - | - | _ | _ |
| ECOG-ACRIN | 129 | 5 | 1 | _ | _ | - | - | - | - | - | - | - | - |
| NRG | 307 | 34 | _ | _ | - | _ | _ | _ | - | _ | _ | _ | _ |
| Total | 1,195 | 104 | 11 | 129 | 333 | 10 | 30 | 82 | 10 | 10 | 89 | 9 | 1 |



Cancer Control & Prevention Committee

| Leadership | Dawn Hershman, MD, MS (CCD) |
|---|---|
| Vice-Chair NCORP: Dawn L. Hershman, MD, MS | Banu Arun, MD (Prevention) |
| Cancer Care Delivery Cmte Co-Chairs: Dawn L. Hershman, MD, MS | Philip Lammers, MD |
| Scott D. Ramsey, MD, PhD | Early Therapeutics & Rare Cancers:Lara E. Davis, MD (Survivorship) |
| Cancer Survivorship Cmte Co-Chairs: | Jason M. Prosek, MD |
| Melinda L. Irwin, PhD, MPH | Gastrointestinal Committee: Jason A. Zell, DO (Prevention) |
| Palliative & End of Life Cmte Co-Chairs: Robert S. Krouse, MD, FACS | Afsaneh Barzi, MD (CCD) |
| Mark A. O'Rourke, MD | Genitourinary Committee: Peter J. Van Veldhuizen, Jr., MD |
| Marie Bakitas, DNSc, CRNP | International Liaison: |
| Prevention and Epidemiology Cmte Co-Chairs: Banu Arun, MD | Leukemia Committee: Stephanie B. Tsai, MD |
| | Lung Committee: Gary E. Goodman, MD |
| Symptom Control & QOL Cmte Co-Chairs: Michael J. Fisch, MD, MPH | Lymphoma Committee: |
| | Melanoma Committee: Sancy Leachman, MD, PhD |
| Executive Officers: Katherine D. Crew, MD (Palliative, Prevention, | Thach-Giao Truong, MD (Survivorship) |
| Survivorship) | Recruitment and Retention Committee: Allison M. Caban-Holt, PhD |
| | Digital Engagement:Jennifer R. Klemp, PhD (Survivorship) |
| Senior Advisor:Frank L. Meyskens, Jr., MD | Krishna Soujanya Gunturu, MD (Survivorship) |
| Statisticians: | Mina S. Sedrak, MD (CCD) |
| William E. Barlow, PhD | |
| | Michael J. Fisch, MD (Symptom Control & QOL) |
| | Veterans Affairs:Yeun-Hee Anna Park, MD |
| Joseph M. Unger, PhD | |
| Riha Vaidya, PhD | Designates Oncology Research Professionals |
| Kathryn B. Arnold, MS | Uncology research Projessionals |
| Radin yir b. 7 irrora, wis | |
| | CRAs: Amanda R. Dinsdale, MHA, CCRC |
| · | CRAs: |
| Amy K. Darke, MS | CRAs: Amanda R. Dinsdale, MHA, CCRC |
| | CRAs: Amanda R. Dinsdale, MHA, CCRC |
| | CRAs: Amanda R. Dinsdale, MHA, CCRC |
| | CRAs: Amanda R. Dinsdale, MHA, CCRC |
| Amy K. Darke, MS Phyllis J. Goodman, MS Danika Lew, MA Hongli Li, MS Anna Moseley, MS | CRAs: Amanda R. Dinsdale, MHA, CCRC |
| | CRAs: Amanda R. Dinsdale, MHA, CCRC Amy Jo Koffarnus, BS, CCRP Samantha Wright, MS, CCRP Shirley S. Sui, BS Nurses: Connie Szczepanek, RN, BSN Melyssa W. Foust, MSN, RN Pharmaceutical Sciences Committee: Kimberly McConnell, PharmD Siu-Fun Wong, PharmD |
| | CRAs: Amanda R. Dinsdale, MHA, CCRC |
| | CRAs: Amanda R. Dinsdale, MHA, CCRC Amy Jo Koffarnus, BS, CCRP Samantha Wright, MS, CCRP Shirley S. Sui, BS Nurses: Connie Szczepanek, RN, BSN Melyssa W. Foust, MSN, RN Pharmaceutical Sciences Committee: Kimberly McConnell, PharmD Siu-Fun Wong, PharmD Sun "Coco" Yang, PharmD, PhD SDMC Data Coordinators and Staff: Kimberly Carvalho |
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| | CRAs: Amanda R. Dinsdale, MHA, CCRC |



Cancer Control & Prevention Committee

| Amy Geschwender, PhD (Symptom Control & QOL) |
|---|
| Hartley "Lee" M. Jones, MBA (Survivorship) |
| Cheryl L. Jernigan, CPA (Prevention & Epidemiology) |
| Valerie Fraser (Palliative & End of Life Care) |
| Protocol Project Manager (Cancer Care Delivery; |
| Prevention and Epidemiology): Patricia O'Kane |
| Protocol Project Manager (Survivorship): |

| Protocol Project Manager (Symptom Control and | |
|---|---------------------|
| Quality of Life): | . Mariah Norman, MS |
| Protocol Project Manager (Palliative Care): | Christy Klepetko |
| Clinical Trials Program Manager (Palliative Care): | TBD |
| Clinical Trials Program Manager (CCD; Prevention; | |
| Survivorship): | TBD |
| Clinical Trials Project Manager (Symptom Control):. | Crystal Miwa |

LUNG-MAP UPDATE MEETING │ FRIDAY, OCTOBER 21 │ 2:15 – 3:45 PM CT

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
- S1900F: Carboplatin + pemetrexed with or without selpercatinib in patients with RET fusion-positive stage IV NSCLC that progressed on prior RET-directed therapy

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

And don't miss the Lung-MAP presentation at **Plenary II, Friday, 12:00 – 2:00 pm CT!**



All welcome! Can't attend in person? Attend virtually at https://bit.ly/3eX4Fmq



Leadership

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

Time/Location

Thursday, October 20, 2022 9:00 am - 11:00 am Room: Regency A (Ballroom Level, West Tower)

Agenda

Presentations

Development and Testing of a Culturally Responsive Decision Aid Intervention to Promote Diversity in Clinical Trial Participation, Vida Henderson, Ph.D., Pharm.D, Fred Hutchinson Cancer Center

Results from 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)," Dr. Scott Ramsey, M.D., Ph.D., Fred Hutchinson Cancer Center

Pragmatic Trials and Cluster Randomization Considerations, William Barlow, Ph.D., Fred Hutchinson Cancer Center

Active Studies

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

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

<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. Melissa Accordino, M.D., Activated 7/16/18.

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

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

Patient-centered Video Education Intervention to Improve Rural Cancer Care Delivery – Randall Holcombe, M.D., MBA, Izumi Okado, Ph.D., 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.

<u>S1417CD</u>, "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

S1204, A Sero-Epidemiologic Survey and Cost-effectiveness Study of Screening for Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer Patients, Dr. R. Vaidya

Database/Grant Funded Projects

Published

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

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

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

Virtual Symposium Will Feature Community Sites

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

Register for Symposium

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

Designed as a multi-phase, multi-year initiative, the <u>project kicks off on May 21 with a two-hou</u> <u>virtual symposium</u> highlighting the work of staff at community sites across the country who currently treat diverse and traditionally underserved patients with cancer.

Staff from eight community-based sites, part of the National Cancer Institute's Community Oncology Research Program (NCORP), will present short talks on trial accrual strategies, sharing deas about what does and does not work – and whv.



The NCORP community and Minority Underserved sites have been differesting and refining strategies to recruit patients to clinical trials or decades," says Dr. Dawn Hershman, SWOG Vice Chair of the CORP's research portfolio. "We want to harness all they have arned and work across the National Clinical Trials Network (NCTN) learn from each other and develop beet practices for strategies to the control of the process of the National Clinical Trials Network (NCTN)

Symposium talks will also showcase examples of real-time changes dinicians and researchers can make to boost poorly performing clinical trials when enrollment is lagging despite the potential value of the novel cancer treatments they offer. Discussion segments will be moderated by two panels, made up of select site leaders from within the NCORP and patient advocates.

Increasing accessibility of cancer clinical trials, and engaging inderserved communities effectively, is a core focus for Hope and MOG " says Hope President and CFO. To Hope." It requires a deep.



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



| | 51703 | S1912CD | A191901 | A231601C | A231602C | A231701C | A231901C | EAQ171CD | NHLBIMDS | NRGCCOC |
|--|-------|---------|---------|----------|----------|----------|----------|----------|----------|---------|
| Ascension Prov Hospitals - Southfield | - | - | 4 | - | - | - | - | - | 1 | - |
| Banner U Med Ctr - Tucson | 1 | - | - | - | - | - | - | - | - | - |
| Baptist Mem Hlth Care/Mid South MU NCORP | - | - | - | - | - | - | 1 | 2 | 1 | - |
| CWRU Case CCC LAPS | 17 | - | - | - | - | - | - | - | 5 | - |
| Ca Res Consortium of West Michigan NCORP | - | 3 | - | - | - | - | - | - | - | - |
| Ca Res for the Ozarks NCORP | - | 1 | - | - | - | - | - | - | - | - |
| Ca Res of Wisconsin & N Mich Consort | 10 | 1 | 1 | - | - | - | - | - | - | - |
| Carle CC NCORP | 8 | 1 | - | - | - | - | - | - | - | - |
| Columbia U MU NCORP | 16 | 3 | - | - | - | - | - | - | 13 | - |
| Columbus NCORP | 4 | - | - | - | - | - | - | - | - | - |
| CommonSpirit Health Research Inst | 8 | - | - | - | - | - | - | - | - | - |
| Cotton O'Neil CC / Stormont Vail Hlth | 1 | - | - | - | - | - | - | - | - | - |
| Dayton NCORP | 3 | 1 | - | - | - | - | - | - | - | - |
| Fred Hutchinson Ca Res Ctr LAPS | - | - | - | - | - | - | - | - | 16 | - |
| Georgia NCORP | 2 | - | - | - | - | - | - | - | - | - |
| Gulf South MU NCORP | 6 | - | - | 1 | - | - | - | - | - | - |
| Hawaii MU NCORP | 6 | - | - | - | - | - | - | - | 5 | - |
| Heartland Ca Res NCORP | 13 | 4 | - | - | - | - | - | - | - | 1 |
| Kaiser Permanente NCORP | 4 | 2 | - | - | - | - | - | - | 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 | - | 4 | - | - | - | - | - | - | - |
| Massachusetts Veterans ERIC | - | - | - | - | - | - | - | - | 28 | - |
| Medical U of South Carolina MU NCORP | - | - | - | - | - | 1 | - | - | 3 | - |
| Michigan Ca Res Consortium NCORP | 9 | 1 | _ | _ | _ | _ | _ | _ | _ | - |



| | 51703 | S1912CD | A191901 | A231601C | A231602C | A231701C | A231901C | EAQ171CD | NHLBIMDS | NRGCC00 |
|---|-------|---------|---------|----------|----------|----------|----------|----------|----------|---------|
| Moffitt CC | _ | - | - | - | - | - | - | - | 8 | - |
| Montana Cancer Consortium NCORP | 7 | - | - | - | - | - | - | - | - | - |
| MultiCare Tacoma General Hospital | - | - | 21 | - | - | - | - | 1 | - | - |
| NCORP Carolinas (Prisma HIth NCORP) | 6 | - | - | - | - | - | - | - | 2 | - |
| Nevada Ca Res Foundation NCORP | 1 | - | - | - | - | - | - | - | - | - |
| New Mexico MU NCORP | 12 | - | - | - | - | - | - | - | - | - |
| Northwell Health NCORP | - | - | - | - | - | - | - | - | 1 | - |
| Oregon Health & Science U | - | - | - | - | - | - | - | - | 9 | - |
| Pacific Ca Res Consortium NCORP | 10 | 2 | - | - | - | - | - | - | - | - |
| Southeast Clin Onc Res Consort NCORP | 4 | 1 | - | - | - | - | - | - | - | - |
| UC Davis CCC LAPS | - | - | 3 | - | - | - | - | - | - | - |
| UC Irvine Health/Chao Family CCC | - | - | - | - | - | - | - | - | 20 | - |
| UC San Diego Moores CC | - | - | - | - | - | - | - | - | 25 | - |
| U Arkansas for Medical Sciences | 3 | - | - | - | - | - | - | - | - | - |
| U Colorado CC LAPS | - | - | - | - | - | - | - | - | 8 | - |
| U Kansas CC - MCA Rural MU NCORP | 5 | 1 | - | - | 4 | - | - | - | - | 22 |
| U Rochester LAPS | 4 | - | - | - | - | - | - | - | - | - |
| U Utah - Huntsman Cancer Inst LAPS | - | - | 2 | - | - | - | - | - | - | - |
| Upstate Carol Consort Comm Onc Res Prog | - | 2 | - | - | - | - | - | - | - | - |
| Western States Ca Res NCORP | - | 1 | 1 | - | - | - | - | - | - | - |
| William Beaumont Hosp-Royal Oak | - | - | - | - | - | - | - | - | 2 | - |
| Wisconsin NCORP | 1 | 1 | - | - | - | - | - | - | _ | - |
| Yale U - Yale CC LAPS | 27 | - | - | - | - | - | - | - | 7 | - |
| ALLIANCE | 4 | 4 | - | - | - | - | - | - | - | - |
| ECOG-ACRIN | 16 | 1 | - | - | - | - | - | - | - | - |
| NRG | 14 | - | - | - | _ | - | - | - | - | - |
| Total | 228 | 30 | 36 | 1 | 4 | 1 | 1 | 3 | 165 | 23 |



Cancer Survivorship Committee

Leadership

Co-Chairs: Melinda Irwin, PhD, MPH Halle Moore, MD

Time/Location

Thursday, October 20, 2022 5:15 pm - 7:15 pm Room: Regency A (Ballroom Level, West Tower)

Agenda

Welcome: Melinda Irwin and Halle Moore

Survivorship Presentation: "Health Equity in Cancer"

Melissa A Simon MD MPH

Vice Chair of Research, Department of Obstetrics and Gynecology George H. Gardner Professor of Clinical Gynecology Professor of Obstetrics and Gynecology, Preventive Medicine and Medical Social Sciences

Founder/Director, Center for Health Equity Transformation Founder/Director, Chicago Cancer Health Equity Collaborative Northwestern University, Feinberg School of Medicine and Robert H. Lurie Comprehensive Cancer Center

Discussion

Patient Advocate Update: Lee Jones

New Ideas

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

<u>52204</u>, "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.

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

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

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

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

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

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

Liaison Updates

Cardiac Advisory Panel Update

Other Business

Closed Study

<u>S1316</u>, "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 | 4 | - | - |
| Georgia Cares Minority Underserved NCORP | - | - | 1 |
| Georgia NCI Community Oncology Research Program | 12 | - | |
| 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 | 17 | - | - |
| Montana Cancer Consortium NCORP | 1 | - | - |
| NCORP of the Carolinas (Prisma Health NCORP) | 2 | - | - |
| National Cancer Center-Korea | 1 | - | - |
| New Mexico Minority Underserved NCORP | 6 | 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 | 7 | - | - |
| University of Michigan Comprehensive Cancer Center LAPS | 10 | - | - |
| Upstate Carolina Consortium Community Oncology Research Program | - | 1 | - |
| Wayne State University - Karmanos Cancer Institute LAPS | 6 | - | - |
| ALLIANCE | 20 | - | - |
| ECOG-ACRIN | 34 | - | - |
| NRG | 20 | - | - |
| Total | 273 | 23 | 62 |



Palliative & End of Life Care Committee

Leadership

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

Time/Location

Friday, October 21, 2022 7:30 am- 9:30 am Room: Regency A (Ballroom Level, West Tower)

Agenda

7:30 - 7:35 am Welcome and Introductions – Co-Chairs

7:35 - 7:40 am Committee Liaison Updates - Patient Advocates/ORP

7:40 - 8:10 am Plenary: "Palliative Care Patient-Reported Experience Measures: Heard & Understood" - Katherine Ast, MSW, LCSW, PhD student, Director, Quality and Research, American Academy of Hospice and Palliative Medicine (AAHPM)

8:10 - 8:40 am Developing Studies Updates

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

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

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

8:40 - 8:45 am Active Study Update

<u>S1820</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. Permanently Closed to Accrual for Step 1: 4/12/22

8:45 - 8:50 am Pre-SWOG Active Study Updates

Hope/CAPC Provider Communication Study, Drs. Ishwaria M. Subbiah and Rajiv Agarwal

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

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

8:50 - 8:55 am Closed Study Update

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

8:55 - 9:10 am New Concepts

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

"Feasibility Study of a Hope Workshop Intervention Designed to Improve Cancer Survivor Hopefulness and Endocrine Therapy Adherence," David Feldman, PhD and Ben Corn, MD

Feasibility and Acceptability of an Online Intervention to Enhance
Hopefulness Among Oncology Professionals David Feldman, PhD and
Ben Corn, MD

9:10 - 9:25 am Open Discussion and Q&A

9:25 - 9:30 am Closing Comments and Adjourn: Co-Chairs



Palliative and End of Life Care Committee

| Accrual from trial opening through 6/30/2022 by Institution and Study | 51820 |
|---|-------|
| Banner University Medical Center - Tucson | 1 |
| City of Hope Comprehensive Cancer Center | 3 |
| Columbus NCI Community Oncology Research Program | 1 |
| Fred Hutchinson Cancer Research Center LAPS | 6 |
| Hawaii Minority Underserved NCORP | 2 |
| Heartland Cancer Research NCORP | 7 |
| Michigan Cancer Research Consortium NCORP | 2 |
| NCORP of the Carolinas (Prisma Health NCORP) | 5 |
| New Mexico Minority Underserved NCORP | 2 |
| Northwestern University LAPS | 2 |
| UC Irvine Health/Chao Family Comprehensive Cancer Center | 10 |
| University of Cincinnati Cancer Center-UC Medical Center | 1 |
| University of Texas MD Anderson Cancer Center LAPS | 11 |
| Upstate Carolina Consortium Community Oncology Research Program | 3 |
| Virginia Mason Medical Center | 5 |
| ALLIANCE | 4 |
| ECOG-ACRIN | 1 |
| NRG | 29 |
| Total | 95 |



Prevention & Epidemiology Committee

Leadership

| Co-Chairs: | Banu Arun, MD |
|------------|----------------------------|
| Mai | rian L. Neuhouser, PhD, RD |

Time/Location

Thursday, October 20, 2022 11:15 am - 1:15 pm Room: Regency A (Ballroom Level, West Tower)

Agenda

Introduction

Welcome & Opening Comments Marian Neuhouser & Banu Arun

Cancer Prevention Presentation: "The Promise of Multicancer Early Detection" Eric A. Klein, MD, Professor and Chair Emeritus, Glickman Urological and Kidney Institute, Cleveland Clinic Lerner College of Medicine

Patient Advocate update

Cheryl Jernigan

Active Studies

- Solve 20, "A Double-Blind Placebo-Controlled Trial of Effornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon or Rectal Cancer, Phase III Preventing Adenomas of the Colon with Effornithine and Sulindac (PACES)." Drs. J. Zell, P. Brown, M.P. Lance, et al. Activated: 3/1/13.
- <u>S1823</u>, "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.

Other Group Studies with SWOG Study Champions

- CTSU A151804, "Establishment of a National Biorepository to Advance Studies of Immune-Related Adverse Events." Dr. G. Lyman. Activated: 1/31/20.
- CTSU A212102, "A Blinded Reference Set for Multicancer Early Detection Blood Tests." Dr. J. McGuinness. Activated: 8/1/22.
- CTSU EA1151, "Tomosynthesis Mammographic Imaging Screening Trial (TMIST)." Dr. B. Arun. SWOG Activated: 7/6/17.
- <u>CTSU/NHLBI-MDS</u>, "The National Myelodysplastic Syndromes Natural History Study." Drs. D. Hill and C. Arana Yi. Activated: 4/5/16.

Studies approved by triage and pending DCP approval

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

Substudies - Pending CTEP Approval

- Amendment to S1418, "Exploratory Study to Evaluate Mammographic Density Changes in Patients Receiving Pembrolizumab in S1418." Dr. B. Arun.
- Amendment to S1007, "Effects of Chemoprevention and Adjuvant Endocrine Therapy on a Convolutional Neural Network-Based Breast Cancer Risk Model Using Mammographic Datasets from S0812 and S1007." Drs. K Crew, K. Kalinsky, R. Ha.

Concepts in Development

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

New Business/Open Discussion for new ideas



Prevention & Epidemiology Committee

| | 50820 | 51823 | 51904 | A271702 | A271601 | EA1151 | EA2185 | NRGCC008 |
|---|-------|-------|-------|---------|---------|--------|--------|----------|
| Ascension Providence Hospitals - Southfield | 1 | - | - | - | 2 | - | - | - |
| Ascension Via Christi Hospitals Wichita | 12 | - | - | - | - | - | - | - |
| Banner MD Anderson Cancer Center | 10 | - | - | - | - | 1 | - | - |
| Banner University Medical Center - Tucson | - | 4 | - | - | - | 56 | - | - |
| Baptist Memorial Health Care/Mid South Minority Underserved NCORP | 4 | - | 2 | - | - | 2 | - | - |
| Bay Area Tumor Institute NCORP | 1 | 4 | - | - | - | - | - | - |
| Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center | - | - | - | - | - | - | - | 2 |
| Brooke Army Medical Center | 1 | - | - | - | - | - | - | - |
| CWRU Case Comprehensive Cancer Center LAPS | - | - | - | - | - | 135 | - | - |
| Cancer Research Consortium of West Michigan NCORP | 2 | - | - | - | - | - | - | - |
| Cancer Research for the Ozarks NCORP | 1 | 5 | - | - | - | - | - | - |
| Cancer Research of Wisconsin and Northern Michigan Consortium | 1 | 1 | - | - | - | - | - | - |
| Carle Cancer Center NCI Community Oncology Research Program | - | 4 | 12 | - | - | 2 | - | - |
| City of Hope Comprehensive Cancer Center | 1 | - | 7 | 2 | - | - | - | - |
| Columbia University Minority Underserved NCORP | 1 | - | 18 | 1 | - | - | - | - |
| Columbus NCI Community Oncology Research Program | 6 | 8 | - | - | - | - | - | - |
| CommonSpirit Health Research Institute | 4 | - | - | - | - | - | - | - |
| Dayton NCI Community Oncology Research Program | 1 | - | - | - | - | - | - | - |
| Essentia Health NCI Community Oncology Research Program | 4 | 1 | - | - | - | 97 | - | - |
| Georgia Cares Minority Underserved NCORP | 2 | - | - | - | - | - | - | - |
| Georgia NCI Community Oncology Research Program | 2 | - | - | - | - | - | - | - |
| Gulf South Minority Underserved NCORP | - | 7 | - | - | - | - | - | - |
| Hawaii Minority Underserved NCORP | 10 | 2 | 10 | - | - | - | - | - |
| Heartland Cancer Research NCORP | 2 | 13 | 4 | - | - | - | - | - |
| Henry Ford Hospital | - | - | - | - | - | 133 | - | - |
| Kaiser Permanente NCI Community Oncology Research Program | 40 | 91 | 6 | - | - | - | - | - |
| Lahey Hospital and Medical Center | - | - | 3 | - | - | - | - | - |
| Loma Linda University Medical Center | 2 | 5 | - | - | - | - | - | - |
| Loyola University Medical Center | 2 | - | 1 | - | - | - | - | - |
| 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 | A271702 | A217607 | EA1151 | EA2185 | NRGCC008 |
|---|-------|-------|-------|---------|---------|--------|--------|----------|
| NCORP of the Carolinas (Prisma Health NCORP) | - | 10 | - | - | - | 416 | - | - |
| Nevada Cancer Research Foundation NCORP | 1 | 1 | - | - | - | - | - | - |
| New Mexico Minority Underserved NCORP | 2 | 4 | - | - | - | - | - | - |
| Northwell Health NCORP | - | 7 | - | - | - | - | - | - |
| Ohio State University Comprehensive Cancer Center LAPS | - | 2 | - | - | - | - | - | - |
| Oregon Health and Science University | - | 13 | - | - | - | - | 1 | - |
| Pacific Cancer Research Consortium NCORP | 2 | - | - | - | - | - | - | - |
| Salem Hospital | - | 3 | - | - | - | - | - | - |
| Southeast Clinical Oncology Research Consortium NCORP | 3 | 2 | - | - | - | - | - | - |
| UC Irvine Health/Chao Family Comprehensive Cancer Center | 30 | 3 | - | - | - | - | - | - |
| UC San Diego Moores Cancer Center | - | 18 | - | - | - | - | - | - |
| UCLA / Jonsson Comprehensive Cancer Center | - | 30 | - | - | - | - | - | - |
| USC Norris Comprehensive Cancer Center LAPS | 5 | 29 | - | - | - | - | - | - |
| University of Arkansas for Medical Sciences | - | - | - | - | - | 350 | 2 | - |
| University of Cincinnati Cancer Center-UC Medical Center | - | 3 | - | - | - | - | - | - |
| University of Colorado Cancer Center LAPS | 8 | 11 | - | - | - | 2 | - | - |
| University of Kansas Cancer Center - MCA Rural MU NCORP | 4 | - | - | - | - | - | - | - |
| University of Kentucky/Markey Cancer Center | - | - | - | - | - | 9 | - | - |
| University of Mississippi Medical Center | 1 | 3 | - | - | - | - | - | - |
| University of Oklahoma Health Sciences Center LAPS | - | 2 | - | - | - | - | - | - |
| University of Rochester LAPS | - | 11 | - | - | - | 231 | - | - |
| University of Texas Health Science Center at San Antonio | 9 | - | - | - | - | - | - | - |
| University of Texas MD Anderson Cancer Center LAPS | 5 | - | - | - | - | - | - | - |
| University of Utah - Huntsman Cancer Institute LAPS | - | - | 18 | - | - | - | - | - |
| Upstate Carolina Consortium Community Oncology Research Program | - | - | - | - | - | 619 | - | - |
| Vanderbilt University - Ingram Cancer Center LAPS | - | 6 | - | - | - | - | - | - |
| Virginia Mason Medical Center | 9 | 10 | - | - | - | - | - | - |
| Wayne State University - Karmanos Cancer Institute LAPS | 2 | - | - | - | - | - | - | - |
| Western States Cancer Research NCORP | 1 | - | - | - | - | 67 | - | - |
| Wisconsin NCI Community Oncology Research Program | 1 | - | - | - | - | - | - | - |
| Yale University - Yale Cancer Center LAPS | 25 | - | - | - | - | - | - | - |
| ALLIANCE | 36 | 61 | 44 | - | - | - | - | - |
| CCTG | - | 90 | - | - | - | - | - | - |
| ECOG-ACRIN | 30 | 39 | 21 | - | - | - | - | - |
| NRG | 38 | 25 | 37 | - | - | - | - | - |
| Total | 339 | 528 | 183 | 3 | 2 | 2,132 | 8 | 2 |



Leadership

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

Time/Location

Thursday, October 20, 2022 1:30 pm - 3:30 pm Room: Regency A (Ballroom Level, West Tower)

Agenda

The Translational Spectrum in Symptom Control: From Measurement Science to Biological Correlates

Patient-Reported Outcomes – What is a Meaningful Change?

Plenary speaker: Salene Jones, PhD

Opportunities and Challenges as a Translational Symptom Scientist at SWOG

Plenary speaker: Daniel Hertz, PhD

Active Studies

- <u>S1600</u>, "A Randomized Phase III Double-Blind Clinical Trial Evaluating the Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes (SIMmune)." Drs. Hamilton-Reeves, Holzbeierlein, Kukreja, et al. Activated: 2/21/19; Temporarily closed: 8/9/22.
- S1614, "A Phase III Randomized Trial of Prophylactic Antiviral Therapy in Patients with Current or Past Hepatitis B Virus (HBV) Infection Receiving Anti-Cancer Therapy for Solid Tumors." Drs. Hwang, Lok, Gehring, et al. Activated: 2/21/19.
- <u>S2013</u>, "Immune Checkpoint Inhibitor Toxicity (I-CHECKIT): A Prospective Observational Study." Drs. Gunturu, Hershman, Kuderer, et al. Activated: 8/16/21.

Other Concepts in Development (Soon to activate)

- S2010, "A Randomized Phase III Trial Comparing Active Symptom Monitoring Plus Patient Education Versus Patient Education Alone to Improve Persistence with Endocrine Therapy in Young Women with Stage I-III Breast Cancer (ASPEN)." Drs. Henry, Hershman, and Skaar.
- S2205, "ICE COMPRESS: Randomized Trial of Limb Cryocompression Versus Continuous Compression Versus Low Cyclic Compression for the Prevention of Taxane-Induced Peripheral Neuropathy." Drs. Accordino, Pennington, Hershman, et al.

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

Committee Business

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

Patient Advocate update

Statistical Center update

Other SWOG Studies with Symptom Control and QOL Component

Breast

<u>S1706</u>, "A Phase II Randomized, Double-Blinded, Placebo-Controlled Trial of Olaparib Administered Concurrently with Radiotherapy for Inflammatory Breast Cancer." Dr. Jagsi. Activated: 9/12/18.

Cancer Care Delivery

- <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, and Ramsey. Activated: 7/16/18.
- S1912CD, "A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)." Drs. Shankaran, Carlos, Hershman, et al. Activated: 7/26/21.



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

GU

- <u>S1802</u>, "Phase III Randomized Trial of Standard Systemic Therapy (SST) Versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer." 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

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

Lung

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

Lymphoma

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

Myeloma

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

Prevention and Epidemiology

- <u>S0820</u>, "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 | 51614 | 51714 | 52013 | A221505 | A221602 | A221702 | A221805 | A222004 | EAQ202 | EAZ171 |
|--|-------|-------|-------|-------|---------|---------|---------|---------|---------|--------|--------|
| Ascension Prov Hospitals - Southfield | - | - | - | 7 | - | - | - | - | - | - | - |
| Ascension Via Christi Hospitals Wichita | - | - | 1 | - | - | - | - | - | - | - | - |
| CWRU Case CCC LAPS | - | - | - | - | 3 | - | 1 | - | - | - | - |
| Ca Res Consortium of West Mich NCORP | - | - | 146 | - | - | - | - | - | - | - | - |
| Ca Res for the Ozarks NCORP | - | - | 10 | 1 | - | - | - | - | - | - | - |
| Ca Res of Wisconsin and N Mich Consort | - | - | - | 26 | - | - | - | - | - | - | - |
| Carle CC NCORP | - | - | 6 | 3 | - | - | - | - | - | - | - |
| City of Hope CCC | 4 | - | - | - | - | - | - | - | - | - | - |
| Columbia University MU NCORP | - | - | 27 | 8 | - | 3 | - | - | - | - | - |
| Columbus NCORP | - | - | - | 7 | - | - | - | - | - | - | - |
| CommonSpirit HIth Res Inst | - | - | 71 | 6 | - | - | - | - | - | - | - |
| Dayton NCORP | - | - | - | - | - | 1 | - | 1 | - | - | - |
| Desert Regional Med Ctr | - | - | 3 | - | - | 3 | - | - | - | - | - |
| Fred Hutchinson Ca Res Ctr LAPS | 10 | - | - | - | - | - | - | - | - | - | - |
| Georgia NCORP | - | - | 18 | 12 | - | - | - | - | - | - | - |
| Grupo Onc Cooperativo de Invest | - | - | 10 | - | - | - | - | - | - | - | - |
| Gulf South MU NCORP | 1 | - | 26 | 7 | 1 | - | - | - | - | - | 1 |
| Hawaii MU NCORP | - | - | 70 | - | - | - | - | - | - | - | - |
| Heartland Ca Res NCORP | - | - | 38 | 54 | - | - | - | - | - | - | - |
| Henry Ford Hospital | 7 | - | - | - | - | - | - | - | - | - | - |
| Instituto Nacional De Cancerologia | - | - | 10 | - | - | - | - | - | - | - | - |
| Instituto Nacional De Cancerologia de Mexico | - | - | 60 | - | - | - | - | - | - | - | - |
| Kaiser Permanente NCORP | - | 2 | 65 | 1 | - | - | - | - | - | - | - |
| Lahey Hospital and Med Ctr | - | - | 22 | 19 | - | - | - | - | - | - | - |
| Loyola University Med Ctr | - | - | 2 | - | - | - | - | - | - | - | - |
| Massachusetts Vet Epi Res & Info Ctr | - | - | - | 4 | - | - | - | - | - | - | - |



| | 51600 | 51614 | s171 ⁴ | 52013 | A221505 | A221602 | A221702 | A221805 | A222004 | EAQ202 | EAZ171 |
|---------------------------------------|-------|-------|-------------------|-------|---------|---------|---------|---------|---------|--------|--------|
| Medical U South Carolina MU NCORP | 2100- | - | | 52013 | AZZ | AZZIO | AZZV | AZZIO | ALLEG | EAUZ | 2 |
| Montana Cancer Consortium NCORP | - | _ | - | 2 | - | _ | - | - | - | - | 2 |
| NCORP Carolinas (Prisma HIth NCORP) | - | - | 30 | - | - | _ | - | - | - | 29 | - |
| Nevada Ca Res Foundation NCORP | - | | - | _ | _ | _ | - | - | - | 3 | - |
| Northwell Health NCORP | - | - | - | - | 2 | 3 | - | - | - | - | - |
| Oregon Health & Science U | - | _ | _ | 10 | _ | _ | | _ | _ | - | - |
| Pacific Ca Res Consortium NCORP | | _ | 2 | - | - | _ | - | - | - | _ | - |
| Southeast Clin Onc Res Consort NCORP | - | _ | 278 | 36 | _ | _ | - | _ | - | - | - |
| The West Clinic - Wolf River | | - | - | - | 6 | - | | - | - | - | |
| Tulane U HIth Sciences Ctr | - | _ | 1 | _ | - | _ | - | _ | _ | | |
| UC Irvine HIth/Chao Family CCC | | _ | - | _ | 1 | 4 | - | _ | - | | - |
| USC Norris CCC LAPS | 59 | _ | _ | _ | - | - | _ | _ | _ | _ | _ |
| U Arkansas for Medical Sciences | - | _ | 68 | 5 | - | - | - | _ | - | _ | |
| U Colorado CC LAPS | 6 | _ | 2 | - | 16 | _ | 1 | 2 | _ | _ | |
| U Kansas CC - MCA Rural MU NCORP | 37 | _ | 24 | _ | - | _ | - | 2 | _ | _ | |
| U Kentucky/Markey CC | - | _ | - | _ | _ | 10 | _ | _ | _ | _ | |
| U Rochester LAPS | 10 | _ | _ | _ | _ | - | 14 | _ | _ | _ | |
| U Texas HIth Science Ctr San Antonio | - | | 14 | 5 | _ | _ | - | _ | _ | _ | |
| U Texas MD Anderson CC LAPS | - | 1 | - | - | | _ | _ | _ | _ | _ | |
| U Utah - Huntsman Ca Inst LAPS | - | | _ | _ | _ | 8 | _ | _ | 2 | _ | _ |
| Upstate Carolina Consortium NCORP | _ | _ | 118 | _ | 1 | - | - | _ | - | _ | _ |
| Wayne State U - Karmanos Ca Inst LAPS | - | - | - | _ | - | _ | 1 | _ | _ | - | _ |
| Wisconsin NCORP | - | - | _ | 5 | _ | - | - | _ | _ | - | _ |
| ALLIANCE | 5 | - | 44 | 39 | | _ | _ | _ | _ | - | _ |
| ECOG-ACRIN | - | - | 80 | 23 | - | _ | - | _ | - | - | _ |
| NRG | 1 | 1 | 90 | 28 | _ | - | _ | _ | _ | - | _ |
| Total | 140 | 4 | 1,336 | 308 | 30 | 32 | 17 | 5 | 2 | 32 | 3 |



| Leadership |
|--|
| Chair: |
| Vice-Chair:Young Kwang Chae, MD, MPH |
| Executive Officer: |
| Statisticians: Megan Othus, PhD |
| Melissa Plets, MS |
| Edward Mayerson, MS |
| Designates |
| Data Coordinators: |
| Digital Engagement: Kanwal Raghav, MD, MBBS |
| Oncology Research Professionals: |
| CRAs: |
| Nurse: |
| Pharmaceutical Science: |
| Sun "Coco" Yang, PharmD, PhD |
| Patient Advocate: |
| Protocol Project Manager: Catrina Mireles |
| Clinical Trials Program Manager: |
| Early Therapeutics Liaisons |
| Breast Committee Liaison: Stephanie L. Graff, MD |
| Cancer Control Liaison:Jason M. Prosek, MD |
| Lara E. Davis, MD |
| Genitourinary Committee Liaison: Neeraj Agarwal, MD |
| Imaging: TBD |
| Lung Committee Liaison: |
| $Lymphoma\ Committee\ Liaison: \dots Na sheed\ Mohammad\ Hossain,\ MD$ |
| Melanoma Committee Liaison:Jeffrey A. Sosman, MD |

Time/Location

Thursday, October 20, 2022 10:00 am - 12:15 pm Room: Regency C (Ballroom Level, West Tower)

Agenda

10:00 - 10:05 am Welcome and Introduction - Razelle Kurzrock MD

Myeloma Committee Liaison: Frits van Rhee, MD, PhD

| 10.00 10.03 4111 | Welcome and introduction. Nazelie Narzhoek, Wib |
|--|--|
| <u>10:05 - 10:30 am</u> | Updates from Sarcoma Working Group - Lara Davis, MD |
| <u>10:30 - 10:45 am</u> Trial of First Line | New Approved Study: S2012, "Randomized Phase II/III Platinum/Etoposide with or without Atezolizumab (NSC |
| | ents with Poorly Differentiated Extrapulmonary Small |
| Cell Neuroendoo | crine Carcinomas (NEC)" - David Zhen, MD |

<u>10:45 - 11:10 am</u> CIMAC and Translational Immunology in DART - Young Chae, MD

| <u>11:10 - 11:30 am</u> | Translational findings from non-pancreatic |
|-------------------------|--|
| neuroendocrine | e DART cohorts from CIMAC - Cara Haymaker, PhD |

11:30 - 11:50 am DART: Clinical Trial Update - Sandip Patel, MD

11:50 - 12:10 pm Update from CNS Working Group - Manmeet

Ahluwalia, MD

12:10 - 12:15 pm Wrap-Up - Razelle Kurzrock, MD

Active Studies

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

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 Carci-nomas (NEC)." Drs. Zhen, Chiorean, Burgess, Swisher. Activated: 12/2/21.

CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)." Activated: 8/12/2015.

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

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

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

CTSU/A071601, "Phase II Trial of BRAF/MEK Inhibitors in Papillary Craniopharyngiomas." Dr. Brasti-anos. 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.
- AGCT1531, "A Phase III Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors" SWOG Champion: Dr. D'Souza Activated: 5/8/17.
- AOST2031, "A Phase 3 Randomized Controlled Trial Comparing Open vs Thoracoscopic Management of Pulmonary Metastases in Patients with Osteosarcoma" SWOG Champion: Dr. Hofstetter. Activated: 2/15/22
- A071702, "A Phase II Study of Checkpoint Blockade Immunotherapy in Patients with Somatically Hy-per-mutated Recurrent Glioblastoma." SWOG Champion: Dr. M. Ahluwalia. Activated: 10/30/20

Proposed Studies

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

Closed Studies

- 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) Endometri-oid
 Endometrial Cancer." Dr. Backes. SWOG Champion: Dr. Robinson.
 Activated: 2/7/20. Closed: 8/29/22.
- NCICOVID, "NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study." Dr. Karim. Activated: 5/21/20. Closed: 2/1/2022.
- 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. Robin-son. Activated: 5/12/17. Closed 10/14/2021
- CTSU/NRG-HN007, "An Open-Label, Phase III Study of Platinum-Gemcitabine with or without Nivolumab in the First-Line Treatment of Recurrent or Metastatic Nasopharyngeal Carcinoma." Dr. Brigette B. Y. Activated: 9/8/20; Closed: 10/28/21



| | 516 ⁰⁹ | 52012 | A071401 | AGCT1531 | EAY131 |
|---|-------------------|-------|---------|----------|--------|
| Ascension Providence Hospitals - Southfield | 1 | - | - | - | 3 |
| Baptist Memorial Health Care/Mid South Minority Underserved NCORP | 2 | - | - | - | - |
| Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center | - | - | - | - | 3 |
| CWRU Case Comprehensive Cancer Center LAPS | 7 | - | - | - | 10 |
| Cancer Research for the Ozarks NCORP | 1 | - | - | - | - |
| Cancer Research of Wisconsin and Northern Michigan Consortium | 3 | - | - | - | - |
| Carle Cancer Center NCI Community Oncology Research Program | 3 | - | - | - | - |
| Cedars-Sinai Medical Center | 8 | - | - | - | 6 |
| City of Hope Comprehensive Cancer Center | 2 | - | - | - | 6 |
| Columbus NCI Community Oncology Research Program | 3 | - | - | - | - |
| CommonSpirit Health Research Institute | 17 | - | 1 | - | 9 |
| Dayton NCI Community Oncology Research Program | 2 | - | - | - | 1 |
| Essentia Health NCI Community Oncology Research Program | 4 | - | - | - | - |
| Fred Hutchinson Cancer Research Center LAPS | 10 | - | - | - | 2 |
| Georgia NCI Community Oncology Research Program | 6 | - | - | - | - |
| Gulf South Minority Underserved NCORP | 2 | - | - | - | - |
| Hawaii Minority Underserved NCORP | 4 | - | - | - | 1 |
| Heartland Cancer Research NCORP | 15 | - | - | - | 1 |
| Henry Ford Hospital | 17 | - | - | - | 11 |
| 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 | - | - | - | - |



| | 5160 ⁹ | 52012 | A071401 | AGCT1531 | EAY131 |
|---|-------------------|-------|---------|----------|--------|
| New Mexico Minority Underserved NCORP | 18 | - | - | - | - |
| 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 | - | 1 | - | 19 |
| UC San Diego Moores Cancer Center | 27 | - | 2 | - | - |
| USC Norris Comprehensive Cancer Center LAPS | 4 | - | - | - | - |
| University of Arkansas for Medical Sciences | 5 | - | - | - | 3 |
| University of Colorado Cancer Center LAPS | 6 | - | 1 | - | 9 |
| University of Kansas Cancer Center - MCA Rural MU NCORP | 35 | - | - | - | 6 |
| University of Kentucky/Markey Cancer Center | - | - | - | - | 13 |
| University of Michigan Comprehensive Cancer Center LAPS | 32 | - | - | - | 24 |
| University of Mississippi Medical Center | 5 | - | - | - | - |
| 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 | - | 2 | - | 13 |
| ALLIANCE | 105 | 1 | - | - | - |
| ECOG-ACRIN | 78 | - | - | - | - |
| NRG | 137 | - | - | - | - |
| Total | 793 | 1 | 7 | 1 | 183 |



| Leadership | Oncology Research Professionals: |
|--|---|
| Chair:Philip A. Philip, MD, PhD, FRCP | CRA: Michelle A. Springer, BA |
| 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 |
| Sarah Colby, MS | Pharmaceutical Science: Jane E. Rogers, PharmD |
| Scientific Leadership | Protocol Project Manager: |
| Phase I Studies: | Clinical Trials Program Manager: |
| Gastroesophageal:Syma Iqbal, MD | |
| Zev A. Wainberg, MD | Time/Location |
| Pancreatic: Elena Gabriela Chiorean, MD | Friday, October 21, 2022 4:00 pm - 6:00 pm |
| Andrew M. Lowy, MD (Surgical representative) | Room: Regency B (Ballroom Level, West Tower) |
| Hepatobiliary: Anthony B. El-Khoueiry, MD | noons regeries b (builtoon Level, west rower) |
| Rachna T. Shroff, MD | |
| Syed Ahmad, MD (Surgical representative) | Agenda |
| Colon:Philip J. Gold, MD | 1. Welcome |
| | |
| Neuroendocrine Tumors:Nageshwara Arvind Dasari, MD | 2. Announcements & Introductions Philip Philip / Gabriella Chiorean |
| Jonathan R. Strosberg, MD | 3. GI Committee DEI initiatives Rachel Safyan |
| Ano-Rectal:Lisa A. Kachnic, MD | Colmar Figueroa- Moseley |
| Hagen F. Kennecke, MD | |
| Translational Medicine: Heinz-Josef Lenz, MD | 4. SWOG led trials (15 min) |
| Christopher H. Lieu, MD | a. S2104 Heloisa Soares/Syed Ahmed |
| Daniel Catenacci, MD | b. S2107 Van Morris/ Steve Kopetz |
| Imaging: | c. S2001 Vincent Chung |
| Pathology: Mary Kay Washington, MD, PhD | d. S1992 Michael Overman |
| Radiation Oncology: Lisa A. Kachnic, MD | e. S0802 Jason Zell |
| Surgery: Stephen W. Behrman, MD | 5. CTEP ctDNA working group update Philip Philip |
| Designates | 6. Select NCTN Studies and new approvals |
| Cancer Control Liaisons: Jason A. Zell, DO (Prevention) | a. EA2183 mGE cancers oligomet Paul Oberstein |
| | b. EA2186 GIANT pancreatic David Zhen |
| Community Liaisons:Gary L. Buchschacher, MD, PhD (Med Oncology) | c. A021602 NET cabo vs placebo Arvind Dasari |
| | d. NRG GI-004 MSI-High 1L mCRC Michael Overman |
| | e. EA2201 MSI-High rectal May Cho |
| Flavio Rocha, MD (Surgical)David Horowitz, MD (Radiation Oncology) | c. LAZZOT MOLTINGITICECTIC May cho |
| | 7. Gastroesophageal Cancers (12 min) Syma Iqbal, Zev Wainberg |
| | a. Highlights of major recent clinical trials |
| DEI Champion: | b. Ongoing NCTN studies |
| Digital Engagement: | c. Future plans |
| Data Coordinators: | 8. Hepatobiliary (12 min) Anthony El-Khoueiry |
| Brian Zeller | Rachna Shroff |
| Ojasvi Mittal | a. Highlights of major recent clinical trials |
| Ojasvi iviittai | agringing of major recent emilian than |



- b. Ongoing NCTN studies
- c. Future plans
- 9. Pancreatic (12 min) Andrew Lowy, Davendra Sohal
 - a. Highlights of major recent clinical trials
 - b. Ongoing NCTN studies
 - c. Future plans
- 10. Colon (12 min) Marwan Fakih, Philip Gold, Sepideh Gholami
 - a. Highlights of major recent clinical trials
 - b. Ongoing NCTN studies
 - c. Future plans
- 11. Anal and Rectal (12 min Lisa Kachnic, Hagen Kennecke
 - a. Highlights of major recent clinical trials
 - b. Ongoing NCTN studies
 - c. Future plans
- 12. Neuroendocrine (12 min) Jon Strosberg, Arvind Dasari
 - a. Highlights of major recent clinical trials
 - b. Ongoing NCTN studies
 - c. Future plans
- 13. Adjourn

Gastroesophageal

Proposed Studies

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

Active Studies

- CTSU/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 closed: 06/15/21.

Pancreatic

Active Studies

<u>\$2001</u>, "Randomized Phase II Clinical Trial of Olaparib + Pembrolizumab

Alone as Maintenance Therapy in Metastatic Pancreatic Cancer Patients with Germline BRCA1 or BRCA2 Mutations." Dr. Chung. Activated: 12/4/20.

- CTSU/A021804, "A Prospective, Multi-Institutional Phase II Trial Evaluating Temozolomide vs. Temozolomide and Olaparib for Advanced Pheochromocytoma and Paraganglioma." Dr. C. Lopez. Activated: 11/2/20.
- CTSU/A021806, "A Phase III Trial of Perioperative Versus Adjuvant Chemotherapy for Resectable Pancreatic Cancer." Dr. Noel. Activated: 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

<u>S2211</u>, "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

- <u>S2104</u>, "Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolimide versus Observation in High-Risk Pancreatic Neuroendocrine Tumors." Dr. Soares. Activated: 10/14/21.
- CTSU/A021602, "Randomized Double-Blinded Phase III Study of CABozantinib versus Placebo IN Advanced NEuroendocrine Tumors after Progression on Prior Therapy (CABINET)." Dr. Strosberg. Activated: 7/18/18.

Hepatobiliary

Proposed Studies

<u>S2301</u>,"Phase II Single Arm Study of Tremelimumab and Durvalumab (T300+D) in Advanced Hepatocellular Carcinomas with Child-Pugh-B Cirrhosis (STRIDE in CP-B)." Dr. Arora.



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

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

Colorectal

Active Studies

<u>S2107</u>, "Randomized Phase II Trial of Encorafenib and Cetuximab with or without Nivolumab for Patients with Microsatellite Stable, BRAFV600E Metastatic Colorectal Cancer." Dr. Morris. Activated: 6/06/22.

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 Effornithine and Sulindac

to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon or Rectal Cancer, Phase III – Preventing Adenomas of the Colon with Effornithine and Sulindac (PACES)." 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

<u>S1922</u>, "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.



| | | | | _ | | | | | |
|--|--------|--------|--------|--------|--------|--------|--------|----------|----------|
| | EA2765 | EA2174 | EA2176 | EA2182 | EA2186 | EA2187 | EA2197 | NRGG1004 | NRGGI005 |
| Ascension Prov Hospitals - Southfield | 1 | - | - | - | 2 | - | - | - | 1 |
| Ascension Via Christi Hospitals Wichita | - | - | - | - | - | - | - | - | - |
| Banner U Med Ctr - Tucson | - | - | - | - | - | - | - | - | - |
| Baptist Mem HIth Care/Mid South MU NCORP | - | - | - | - | - | - | - | - | 2 |
| Baylor Coll Med/Dan L Duncan CCC | - | - | - | - | - | - | - | - | - |
| Boston Med Ctr | 1 | - | - | - | - | - | - | - | - |
| CWRU Case CCC LAPS | - | 1 | - | 1 | - | 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 | - | - | - | - | 1 | - | - | - | - |
| Fred Hutchinson Ca Res Ctr LAPS | 3 | - | - | - | - | - | - | - | - |
| Gulf South MU NCORP | 1 | - | - | - | - | - | - | - | - |
| Hawaii MU NCORP | - | - | - | - | 2 | - | - | - | - |
| Heartland Ca Res NCORP | - | - | - | - | - | - | - | - | - |
| Henry Ford Hospital | - | - | - | - | - | - | - | - | 1 |
| Houston Methodist Hospital | - | - | - | - | - | - | - | 1 | - |
| Kaiser Permanente NCORP | 6 | - | 3 | - | - | - | - | - | 6 |
| Lahey Hospital & Med Ctr | - | - | - | - | - | - | - | - | - |
| Loyola U Med Ctr | - | - | - | - | - | - | - | - | - |
| Michigan Ca Res Consortium NCORP | - | - | - | - | - | - | - | - | - |
| Moffitt CC | - | - | - | - | - | - | - | - | - |
| Montana Cancer Consortium NCORP | - | - | - | - | - | - | - | - | - |
| NCORP Carolinas (Prisma Hlth NCORP) | 1 | - | - | - | - | - | - | - | - |
| New Mexico MU NCORP | - | - | - | - | - | - | - | - | - |
| Northwell Health NCORP | - | - | - | - | 1 | - | - | - | - |
| Northwestern U LAPS | - | - | - | - | 1 | - | - | - | - |



| | EA2765 | EA2174 | EA2176 | EA2182 | EA2186 | EA2187 | EA2197 | NRGG1004 | NRGGIOOS |
|---------------------------------------|--------|--------|--------|--------|--------|--------|--------|----------|----------|
| Oregon Health & Science U | 4 | - | 1 | 1 | - | - | 1 | - | 1 |
| Pacific Ca Res Consortium NCORP | - | - | - | - | - | - | - | - | - |
| SCL Health Saint Joseph Hospital | 1 | - | - | - | - | - | - | - | - |
| Southeast Clin Onc Res Consort NCORP | - | - | - | - | - | - | - | - | - |
| Sutter Ca Res Consortium | 2 | - | - | - | - | 1 | - | - | - |
| The Don and Sybil Harrington CC | - | - | - | - | - | - | - | - | - |
| The West Clinic - Wolf River | - | - | - | - | - | - | - | - | - |
| UC Davis CCC LAPS | 5 | - | - | - | - | - | 1 | - | 1 |
| UC Irvine Health/Chao Family CCC | - | - | 1 | - | 1 | - | - | - | 1 |
| USC Norris CCC LAPS | - | 1 | - | - | - | - | - | - | - |
| U Alabama Birm/Deep South RC LAPS | 1 | - | - | - | - | - | - | - | - |
| U Arkansas for Medical Sciences | 7 | - | - | - | - | - | - | - | - |
| U Cincinnati CC-UC Med Ctr | 1 | - | 1 | - | - | - | - | - | - |
| U Colorado CC LAPS | - | - | - | - | 1 | - | - | - | - |
| U Kansas CC - MCA Rural MU NCORP | - | - | - | - | - | 1 | - | - | 2 |
| U Michigan CCC LAPS | - | - | - | - | - | - | - | - | - |
| U Rochester LAPS | - | - | - | - | 4 | 2 | - | 1 | - |
| U Texas HSC at San Antonio | - | - | - | - | 2 | - | - | - | - |
| U Texas MD Anderson CC LAPS | - | - | 6 | - | - | - | - | 13 | 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 | 3 | - | - | - | - | - | - | - | - |
| William Beaumont Hosp-Royal Oak | - | - | - | - | - | - | - | - | - |
| Wisconsin NCORP | - | - | - | - | - | - | - | - | - |
| Yale U - Yale CC LAPS | - | - | - | - | - | - | - | - | 4 |
| ALLIANCE | - | - | _ | - | - | - | - | - | _ |
| ECOG-ACRIN | - | - | - | - | - | - | - | - | - |
| NRG | - | - | _ | - | - | - | - | - | - |
| Total | 37 | 2 | 12 | 2 | 16 | 7 | 2 | 15 | 20 |



| Leadership | |
|----------------------------------|--------------------------------------|
| • | lan M. Thompson, Jr., MD |
| | Daniel P. Petrylak, MD |
| | |
| | Christopher W. Ryan, MD |
| | Cathy M. Tangen, DrPH |
| | Melissa Plets, MS |
| | Eddie Mayerson, MS |
| Scientific Leadership | |
| Translational Medicine: | David J. McConkey, PhD (GU Chair) |
| | Joshua J. Meeks, MD, PhD (Bladder) |
| | Amir Goldkorn, MD (Prostate) |
| | Sumanta "Monty" K. Pal, MD (Renal) |
| | James B. Yu, MD |
| | Daniel A. Hamstra, MD |
| | Evan Y. Yu, MD |
| | |
| | Hiram Shaish, MD |
| | John D. Hazle, PhD |
| | M. Scott Lucia, MD |
| | Kelly L. Stratton, MD |
| Liaison to the SPORES: | Colin P.N. Dinney, MD |
| Early Therapeutics: | Neeraj Agarwal, MD |
| Bladder Organ Site Chairs: | Seth P. Lerner, MD (Localized) |
| | Thomas W. Flaig, MD (Localized) |
| | Daniel P. Petrylak, MD (Advanced) |
| | Daniel W. Lin, MD (Localized) |
| | David I. Quinn, MD, PhD (Advanced) |
| | Brian Shuch, MD (Localized) |
| • | |
| | Jlka N. Vaishampayan, MD (Advanced) |
| Designates | D : 17 7/18 : 1 MD |
| | Peter J. Van Veldhuizen, Jr., MD |
| | Jessica McDermott, MD |
| Digital Engagement: | Neema Navai, MD |
| Veterans Affairs | Michael M. Goodman, MD |
| Data Coordinators: | Jeri Jardine |
| | Tonya Johnson |
| | Michele Counts |
| | Laura Wells |
| Oncology Research Professionals: | |
| | Abagail L. Cornette, MS |
| | Cheryl Farlow, RN, OCN |
| | |
| | Deborah A. Shaw, RN |
| | Cheryl Kefauver, RN |
| | Rick Bangs, MBA (Bladder) |
| | Tony Crispino (Prostate) |
| Marg | paret "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, October 21, 2022 2:30 pm - 6:15 pm Room: Regency A (Ballroom Level, West Tower)

Time/Location

GU Committee Part II: Saturday, October 22, 2022 9:15 am - 12:15 pm Room: Regency A (Ballroom Level, West Tower)

Agenda

GU Committee Part I

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

2:45 – 4:00 pm: Prostate Organ Site (Dr. Tanya Dorff and Dr. Daniel Lin)

4:00 – 5:15 pm: Translational Medicine (Dr. David McConkey)

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

Prostate

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

Priority Study

S1802, "Phase III Randomized Trial of Standard Systemic Therapy (SST)
Versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer." Drs. 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. CTEP Concept approval: 8/2/22.

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 Relapsed or Refractory Germ Cell Tumors." Dr. D. Quinn. Activated: 7/1/15.



- CTSU/EA8171, "Multiparametric MRI (mpMRI) for Preoperative Staging and Treatment Planning for Newly-Diagnosed Prostate Cancer." Dr. M. Liss. Activated: 7/9/18.
- CTSU/EA8184, "A Phase II Randomized Double Blinded Study of Green Tea Catechins (GTC) vs. Placebo in Men on Active Surveillance for Prostate Cancer: Modulation of Biological and Clinical Intermediate Biomarkers." Dr. R. Kopp. Activated: 5/10/21.
- CTSU/NRG-GU002, "Phase II-III Trial of Adjuvant Radiotherapy and Androgen Deprivation Following Radical Prostatectomy with or Without Adjuvant Docetaxel." Dr. D. Raben. Activated: 12/30/16.
- CTSU/NRG-GU008, "Randomized Phase III Trial Incorporating Abiraterone Acetate with Prednisone and Apalutamide and Advanced Imaging into Salvage Treatment for Patients with Node-Positive Prostate Cancer After Radical Prostatectomy (INNOVATE*) *Intensifying Treatment for Node Positive Prostate Cancer by Varying the Hormonal Therapy." Dr. D. Lin. Activated: 3/5/20; Temporarily Closed: 6/24/21; Re-activated: 12/1/21.
- CTSU/NRG-GU009, "Parallel Phase III Randomized Trials for High Risk Prostate Cancer Evaluating De-Intensification for Lower Genomic Risk and Intensification of Concurrent Therapy for Higher Genomic Risk with Radiation (PREDICT-RT*)." Dr. S. Zhang. Activated: 10/15/20; Temporarily Closed: 6/24/21; Re-activated: 12/15/21.

Closed Studies

- <u>S1216</u>, "A Phase III Randomized Trial Comparing Androgen Deprivation Therapy + TAK-700 with Androgen Deprivation Therapy + Bicalutamide in Patients with Newly Diagnosed Metastatic Hormone Sensitive Prostate Cancer." Drs. N. Agarwal, A. Goldkorn, S. Gupta, et al. Activated: 3/6/13; Permanently Closed: 7/15/17.
- CTSU/NRG-GU005, "Phase III IGRT and SBRT Vs IGRT and Hypofractionated IMRT for Localized Intermediate Risk Prostate Cancer." Dr. A. Solanki. Activated: 11/16/17: Closed to accrual: 6/8/22.
- CTSU/NRG-GU006, "A Phase II, Double-Blinded, Placebo-Controlled Randomized Trial of Salvage Radiotherapy with or Without Enhanced Anti-Androgen Therapy with Apalutamide in Recurrent Prostate Cancer." Dr. J. Zeng. Activated: 4/27/18; Permanently Closed: 5/19/20.
- CTSU/RTOG-0924, "Androgen Deprivation Therapy and High Dose Radiotherapy with or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial. Dr. 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. Ac-tivated: 6/3/19; Temporarily Closed: 5/5/21; Reactivated of dose level 2 (phase I) for 1 additional pa-tient: 9/14/21; Temporarily closed to accrual for phase I dose level 2: 11/4/21; Re-activated to accrual for phase I/dose level 3: 12/6/21; Temporarily Closed: 7/11//2022.
- CTSU/EA8153, "Cabazitaxel with Abiraterone Versus Abiraterone Alone Randomized Trial for Exten-sive 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.
- CTSU/AGCT1531, "A Phase 3 Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors." Dr. A. D'Souza. Activated: 5/8/17; PRO study Temporarily Closed: 2/12/21.

Translational Medicine

Chair: Dr. David McConkey

Bladder Chair: Dr. Joshua Meeks

Prostate Chair: Dr. Amir Goldkorn

Renal Chair: Dr. Sumanta "Monty" Pal

Cancer Control

Liaison: Dr. Peter J. Van Veldhuizen

Closed Studies

<u>S1600</u>, "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. Temporarily Closed to Accrual: 8/9/2022.



Agenda

GU Committee Part II

9:15 – 10:30 am: Bladder Organ Site (Dr. Seth Lerner and Dr. Thomas Flaig)

10:30 – 12:15 pm: Renal Organ Site (Dr. Ulka Vaishampayan and Dr. Brian Shuch)

Bladder

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

Priority Study

<u>S2011</u>, "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>S1806</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 Treatment 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 Clinical Stage III, Node Positive Bladder Cancer (INSPIRE)." Drs. T. Mitin and J. Meeks. Activated: 8/25/20.
- CTSU/EA8192, "A Phase II/III Trial of MED14736 (Durvalumab) and Chemotherapy for Patients with High Grade Upper Tract Urothelial Cancer Prior to Nephroureterectomy" Drs. S. Psutka and A. Tripathi. Activated: 5/6/21.

Closed Studies

- S1011, "A Phase III Surgical Trial to Evaluate the Benefit of a Standard Versus an Extended Pelvic Lymphadenectomy Performed at Time of Radical Cystectomy for Muscle Invasive Urothelial Cancer." Drs. 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 Invasive Bladder Cancer." Drs. R. Svatek, A. Alva, and S. Lerner. Activated: 2/7/17; Permanently Closed: 12/15/2020.
- <u>S1605</u>, "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.

Renal

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

Priority Study

S1931, "Phase III Trial of Immunotherapy-Based Combination Therapy with or Without Cytoreductive Nephrectomy for Metastatic Renal Cell Carcinoma (PROBE Trial)." Drs. H. Kim and U. Vaishampayan. Activated: 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. CTEP Approval on hold: 8/15/22.

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 [PDI-GREE]." 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.
- <u>S0931</u>, "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.

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, C, 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 Subprotocols A, C1, C2, E, L, V, Z1E, and Z1G are closed to accrual: 1/31/22; Subprotocol ZIG reactivated: 2/23/22
- CTSU/EA8134, "InPACT- International Penile Advanced Cancer Trial (International Rare Cancers Initi-ative Study)." Dr. C. Pettaway. Activated: 9/8/17.



| | 51802 | 51806 | 51931 | 51937 | A037702 | A031501 | A031701 | A031702 | A031704 | A031801 | A031803 | A03790 |
|--|-------|-------|-------|-------|---------|---------|---------|---------|---------|---------|---------|--------|
| Ascension Prov Hosp - Southfield | - | - | - | - | - | - | - | - | 1 | - | - | - |
| Banner MD Anderson CC | 2 | - | - | - | - | - | - | - | - | - | - | - |
| Banner U Med Ctr - Tucson | 6 | - | 1 | - | - | - | - | - | - | - | - | - |
| Baylor College of Med/Dan L Duncan CCC | 2 | 3 | - | - | - | 1 | - | - | - | - | - | - |
| CWRU Case CCC LAPS | - | - | - | - | - | - | 5 | - | - | - | - | 3 |
| Ca Res Consort of West Mich NCORP | 2 | 3 | - | - | - | - | - | - | - | - | - | - |
| Ca Res for the Ozarks NCORP | 1 | 1 | - | - | - | - | - | - | - | - | - | - |
| Ca Res of Wisconsin & N Mich Consort | 1 | 4 | - | - | - | - | - | - | - | - | - | - |
| Cedars-Sinai Med Ctr | - | 5 | 1 | - | - | - | - | - | - | - | - | - |
| City of Hope CCC | 1 | - | - | - | - | - | - | - | - | - | - | - |
| Columbia U MU NCORP | 1 | 1 | - | - | - | 3 | - | - | - | - | - | - |
| CommonSpirit HIth Res Inst | 1 | 4 | - | 2 | - | - | - | - | - | - | - | - |
| Cotton O'Neil CC / Stormont Vail HIth | - | - | - | - | - | 1 | - | - | - | - | - | - |
| Dayton NCORP | 4 | 1 | - | - | - | - | - | - | 1 | - | - | - |
| Fred Hutchinson Ca Res Ctr LAPS | 11 | - | - | - | - | - | - | - | - | - | - | - |
| Georgia Cares MU NCORP | 1 | - | - | - | - | - | - | - | - | - | - | - |
| Gulf South MU NCORP | 66 | 45 | 1 | - | - | 2 | - | - | - | 1 | 12 | - |
| Hawaii MU NCORP | - | 2 | - | - | - | - | - | - | - | - | - | - |
| Heartland Ca Res NCORP | 8 | 6 | - | - | - | - | - | - | - | - | - | - |
| Henry Ford Hosp | 19 | 4 | - | - | - | 1 | - | 2 | 5 | - | - | - |
| Kaiser Permanente NCORP | 15 | - | - | - | - | 14 | - | - | 45 | - | - | - |
| Lahey Hosp and Med Ctr | - | - | - | - | - | 4 | - | 6 | - | - | - | - |
| Loma Linda U Med Ctr | - | - | - | - | - | 2 | - | - | - | - | - | - |
| Loyola U Med Ctr | 9 | 5 | 1 | 2 | - | - | - | 1 | 1 | - | - | - |
| Massachusetts Vet Epi Res & Info Ctr | - | - | - | - | - | - | - | - | - | - | - | 1 |
| Medical U South Carolina MU NCORP | 5 | - | - | 1 | - | - | - | - | - | - | - | - |
| Michigan Ca Res Consort NCORP | 7 | 13 | - | 1 | - | - | - | - | - | - | - | - |
| Moffitt CC | - | - | - | - | - | - | - | - | - | - | - | - |
| Montana Cancer Consort NCORP | 3 | - | - | - | - | - | - | - | - | - | - | - |
| NCORP Carolinas (Prisma Hlth NCORP) | 9 | - | - | - | - | - | - | - | 1 | - | - | - |
| Nevada Ca Res Foundation NCORP | 1 | - | - | - | - | - | - | 1 | - | - | - | - |
| New Mexico MU NCORP | - | - | - | - | - | - | - | - | - | - | - | - |
| Northwell Hith NCORP | - | 1 | - | - | - | - | - | - | 1 | - | - | - |
| Northwestern U LAPS | _ | 6 | _ | _ | _ | _ | _ | _ | 1 | _ | _ | _ |



| | 51802 | 51806 | 51931 | 51937 | A031702 | A037507 | A031701 | A031702 | A031704 | A031801 | A031803 | A03790 |
|---|-------|-------|-------|-------|---------|---------|---------|---------|---------|---------|---------|--------|
| Ohio State U CCC LAPS | 2 | 1 | - | - | - | - | - | - | - | - | - | - |
| Oregon Hlth and Science U | - | 1 | - | - | - | - | - | 3 | 3 | - | - | - |
| SCL HIth Saint Joseph Hosp | 2 | - | - | - | - | - | - | - | - | - | - | - |
| Southeast Clin Onc Res Consort NCORP | 3 | - | - | - | - | - | - | _ | - | - | - | _ |
| Sutter Ca Res Consort | - | 2 | - | - | - | - | - | - | - | - | - | - |
| Tulane U Hlth Sciences Ctr | - | - | 7 | - | - | - | - | _ | 1 | _ | _ | _ |
| UC Davis CCC LAPS | 11 | 8 | - | - | - | 4 | 5 | - | 2 | 4 | 4 | - |
| UC Irvine Hlth/Chao Family CCC | 2 | 4 | - | - | - | - | - | _ | _ | - | _ | _ |
| UC San Diego Moores CC | 1 | 1 | - | - | - | - | - | _ | - | _ | - | - |
| UCLA / Jonsson CCC | - | - | - | - | - | - | - | _ | _ | - | _ | _ |
| USC Norris CCC LAPS | 5 | - | - | 3 | 12 | 13 | - | 4 | - | - | - | - |
| U Alabama Birm/Deep South RC LAPS | - | - | - | - | - | - | - | 1 | _ | 1 | 4 | _ |
| U Arkansas for Medical Sciences | 1 | - | - | - | - | - | - | - | - | - | - | - |
| U Cincinnati CC-UC Med Ctr | 5 | 4 | 1 | - | - | - | - | _ | 6 | - | - | _ |
| U Colorado CC LAPS | 4 | 5 | - | - | - | 13 | - | _ | 10 | _ | - | - |
| U Kansas CC - MCA Rural MU NCORP | 7 | 4 | - | - | - | 5 | - | 1 | 6 | - | _ | - |
| U Kentucky/Markey CC | - | 3 | - | - | - | - | - | - | - | - | - | - |
| U Michigan CCC LAPS | 2 | - | 9 | - | - | 18 | - | _ | _ | _ | _ | - |
| U Mississippi Med Ctr | 1 | - | - | - | - | - | - | 1 | - | - | - | - |
| U Oklahoma Hlth Sciences Ctr LAPS | 26 | 14 | 4 | - | - | _ | - | _ | _ | - | _ | - |
| U Rochester LAPS | 17 | - | 1 | - | - | - | - | 3 | 5 | - | - | - |
| U Texas HIth Science Ctr at San Antonio | 2 | - | 2 | - | - | - | - | _ | _ | - | 4 | - |
| U Texas MD Anderson CC LAPS | 69 | - | - | - | - | - | - | - | - | - | - | - |
| U Utah - Huntsman Ca Inst LAPS | 15 | - | 1 | - | - | 3 | - | _ | _ | _ | _ | - |
| Upstate Carolina Consort NCORP | 1 | 1 | - | - | - | - | - | _ | - | _ | - | - |
| Vanderbilt U - Ingram CC LAPS | 1 | 2 | - | - | - | - | - | _ | - | - | _ | - |
| Virginia Mason Med Ctr | - | - | - | - | - | 1 | - | - | - | - | - | - |
| Wayne State U - Karmanos Ca Inst LAPS | 1 | - | - | - | - | - | _ | _ | _ | - | _ | - |
| Western States Ca Res NCORP | - | 1 | - | - | - | - | - | - | - | _ | - | - |
| Wisconsin NCORP | 8 | 5 | - | - | - | - | - | _ | _ | _ | _ | - |
| Yale U - Yale CC LAPS | 1 | 2 | - | - | - | 8 | - | - | - | - | - | - |
| ALLIANCE | 81 | 18 | 2 | - | - | - | - | - | - | - | - | - |
| ECOG-ACRIN | 56 | 27 | 1 | - | - | - | - | - | - | - | - | - |
| NRG | 66 | 86 | 1 | 1 | - | - | - | - | - | - | - | - |
| Total | 565 | 293 | 33 | 10 | 12 | 93 | 10 | 23 | 89 | 6 | 24 | 4 |



Genitourinary Committee

| | EA8134 | EA8743 | EA8153 | EA8171 | EA8183 | EA8797 | EA8192 | NRGGU002 | NRGGU005 | NRGGU008 | NRGGU009 | NRGGU010 |
|--|--------|--------|--------|--------|--------|--------|--------|----------|----------|----------|----------|----------|
| Ascension Prov Hosp - Southfield | - | - | - | - | - | - | - | - | - | - | - | - |
| Banner MD Anderson CC | - | - | - | - | - | - | - | - | - | - | - | - |
| Banner U Med Ctr - Tucson | - | 7 | - | - | - | - | - | - | - | - | - | - |
| Baylor College of Med/Dan L Duncan CCC | - | 1 | - | - | - | - | - | - | - | - | - | - |
| CWRU Case CCC LAPS | - | - | - | - | - | - | - | - | - | - | - | - |
| Ca Res Consort of West Mich NCORP | - | - | - | - | - | - | - | - | - | - | - | - |
| Ca Res for the Ozarks NCORP | - | - | - | - | - | - | - | - | - | - | - | - |
| Ca Res of Wisconsin & N Mich Consort | - | - | - | - | - | - | - | - | - | - | - | - |
| Cedars-Sinai Med Ctr | - | 8 | - | - | - | - | - | - | - | - | - | - |
| City of Hope CCC | - | - | - | - | - | - | - | - | - | - | - | - |
| Columbia U MU NCORP | - | 1 | - | - | - | - | - | - | - | - | - | - |
| CommonSpirit HIth Res Inst | - | 4 | - | - | - | - | - | - | - | - | - | - |
| Cotton O'Neil CC / Stormont Vail HIth | - | - | - | - | - | - | - | - | - | - | - | - |
| Dayton NCORP | - | 1 | - | - | - | - | - | - | - | - | - | - |
| Fred Hutchinson Ca Res Ctr LAPS | - | 4 | - | - | - | - | - | - | - | - | - | - |
| Georgia Cares MU NCORP | - | - | - | - | - | - | - | - | - | - | - | - |
| Gulf South MU NCORP | - | 10 | - | 11 | - | - | - | 1 | 1 | 3 | 2 | - |
| Hawaii MU NCORP | - | 2 | - | 2 | - | - | - | - | - | - | - | - |
| Heartland Ca Res NCORP | - | - | - | - | - | - | - | - | - | - | - | - |
| Henry Ford Hosp | - | 3 | - | - | - | - | - | - | - | - | - | - |
| Kaiser Permanente NCORP | - | 41 | 10 | - | - | - | - | - | - | - | - | - |
| Lahey Hosp and Med Ctr | - | 4 | - | - | 3 | - | - | - | - | - | - | - |
| Loma Linda U Med Ctr | - | - | - | - | - | - | - | - | - | - | - | - |
| Loyola U Med Ctr | - | 4 | - | - | - | - | - | - | - | - | - | - |
| Massachusetts Vet Epi Res & Info Ctr | - | - | - | - | - | - | - | - | - | - | - | - |
| Medical U South Carolina MU NCORP | - | - | - | - | - | - | - | - | - | - | - | - |
| Michigan Ca Res Consort NCORP | - | - | - | - | - | - | - | - | - | - | - | - |
| Moffitt CC | - | 1 | - | - | - | - | - | - | - | - | - | - |
| Montana Cancer Consort NCORP | - | - | - | - | - | - | - | - | - | - | - | - |
| NCORP Carolinas (Prisma Hlth NCORP) | - | 1 | - | - | - | - | - | - | - | - | - | - |
| Nevada Ca Res Foundation NCORP | - | 2 | - | - | - | - | - | - | - | - | - | - |
| New Mexico MU NCORP | - | - | - | - | - | - | - | - | 1 | - | - | - |
| Northwell Hith NCORP | - | - | - | - | - | - | - | - | - | - | - | - |
| Northwestern U LAPS | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ |



Genitourinary Committee

| | EA8134 | EA8143 | EA8153 | EA8171 | EA8183 | EA8797 | EA8192 | NRGGU002 | NRGGU005 | NRGGU008 | NRGGU009 | NRGGU019 |
|---|--------|--------|--------|--------|--------|--------|--------|----------|----------|----------|----------|----------|
| Ohio State U CCC LAPS | - | - | - | - | - | - | - | - | - | - | - | - |
| Oregon Hlth and Science U | - | 14 | - | 7 | - | - | - | - | - | - | - | - |
| SCL HIth Saint Joseph Hosp | - | - | - | - | - | - | - | - | - | - | - | 3 |
| Southeast Clin Onc Res Consort NCORP | - | - | - | - | - | - | - | - | - | - | - | - |
| Sutter Ca Res Consort | - | - | - | - | - | - | - | - | 2 | - | - | - |
| Tulane U HIth Sciences Ctr | - | 10 | - | - | - | - | - | - | 1 | - | - | - |
| UC Davis CCC LAPS | - | 1 | - | - | - | - | - | - | - | - | - | - |
| UC Irvine Hlth/Chao Family CCC | - | 1 | - | - | - | - | - | - | - | 1 | - | - |
| UC San Diego Moores CC | - | 2 | - | - | - | - | - | - | - | - | - | - |
| UCLA / Jonsson CCC | - | 8 | - | - | - | - | - | - | - | - | - | - |
| USC Norris CCC LAPS | 8 | - | - | - | - | - | - | - | - | - | - | - |
| U Alabama Birm/Deep South RC LAPS | - | 6 | - | - | - | - | - | - | - | - | - | - |
| U Arkansas for Medical Sciences | - | - | - | - | - | - | - | - | - | - | - | - |
| U Cincinnati CC-UC Med Ctr | - | - | - | - | - | - | - | - | - | - | - | - |
| U Colorado CC LAPS | - | 1 | - | - | - | - | 1 | 1 | 1 | - | - | - |
| U Kansas CC - MCA Rural MU NCORP | - | 2 | 1 | - | - | - | - | - | - | 1 | - | - |
| U Kentucky/Markey CC | - | 12 | - | - | - | - | - | - | - | - | - | - |
| U Michigan CCC LAPS | - | - | - | - | - | - | - | - | - | - | - | - |
| U Mississippi Med Ctr | - | 3 | 2 | - | - | - | - | 1 | - | - | - | - |
| U Oklahoma Hlth Sciences Ctr LAPS | - | - | - | - | - | 1 | - | - | - | - | - | - |
| U Rochester LAPS | - | 1 | - | - | - | - | - | - | - | - | - | - |
| U Texas HIth Science Ctr at San Antonio | - | 14 | - | 50 | - | - | - | - | - | - | - | - |
| U Texas MD Anderson CC LAPS | - | - | 8 | - | - | - | - | - | - | - | - | - |
| U Utah - Huntsman Ca Inst LAPS | - | 2 | 8 | - | - | - | - | - | - | - | - | - |
| Upstate Carolina Consort NCORP | - | - | - | - | - | - | - | - | - | - | - | - |
| Vanderbilt U - Ingram CC LAPS | - | - | - | - | - | - | - | - | - | - | - | - |
| Virginia Mason Med Ctr | - | - | - | - | - | - | - | - | 3 | - | - | - |
| Wayne State U - Karmanos Ca Inst LAPS | - | 2 | - | - | - | - | - | 1 | - | - | - | - |
| Western States Ca Res NCORP | - | - | - | - | - | - | - | - | - | - | 1 | - |
| Wisconsin NCORP | - | - | - | - | - | - | - | - | - | - | - | - |
| Yale U - Yale CC LAPS | - | 1 | 2 | - | - | - | - | - | - | - | - | - |
| ALLIANCE | - | - | - | - | - | - | - | - | - | - | - | - |
| ECOG-ACRIN | - | - | - | - | - | - | - | - | - | - | - | - |
| NRG | - | - | - | - | - | - | - | - | - | - | - | - |
| Total | 8 | 174 | 31 | 70 | 3 | 1 | 1 | 4 | 9 | 5 | 3 | 3 |



Immunotherapeutics Committee

Leadership

| Co-Chairs: | Siwen Hu-Lieskovan, MD, PhD |
|---------------------------------|-----------------------------|
| | Katerina Politi, PhD |
| Executive Officer: | Gary H. Lyman, MD |
| Protocol Project Manager: | Christopher Kippola |
| Clinical Trial Program Manager: | TBD |

Time/Location

Wednesday, October 19, 2022 4:30 pm - 6:30 pm Room: Regency B (Ballroom Level, West Tower)

Agenda

4:30 - 5:00 pm S2101 - iMATCH Pilot (BICAZO) kick-off

Katerina Politi, Siwen Hu-Lieskovan, Paul Swiecicki, Michael LeBlanc, Katherine Minichiello, Dana Sparks, Chris Kippola, James Moon, Gary Lyman, and the SWOG

iMATCH team

5:00-5:10 pm Q & A

5:10-5:40 pm Computational modeling of response to immune

Checkpoint inhibitors

Shirley Liu, PhD

Founder and CEO, GV20 Therapeutics

Previously Professor of Biostatistics and Computational Biology at Dana-Farber Cancer Institute, Harvard T.H.

Chan School of Public Health

5:40-5:50 pm Q & A

5:50-6:20 pm Single-cell based immune-monitoring for IO clinical

trials

Sean Bendall, PhD

Associate Professor of Pathology at Stanford University

6:20-6:30 pm Q & A

Developing Studies

S2101, Biomarker Stratified CaboZantinib (NSC#761968) and NivOlumab (NSC#748726) (BiCaZO) - A Phase II Study of Combining Cabozantinib and Nivolumab in Participants with Advanced Solid Tumors (IO Refractory Melanoma or HNSCC) Stratified by Tumor Biomarkers - an immunoMATCH Pilot Study. Dr. Hu-Lieskovan.



Leadership

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

Time/Location

Saturday, October 22, 2022 9:30 am - 12:30 pm Room: Regency C (Ballroom Level, West Tower)

Agenda

Protocol Project Manager - MyeloMATCH: Sarah Cantu

| 9:30 - 9:50 am | Update in CLL clinical trials - Mazyar Shadman |
|-------------------------------------|---|
| <u>9:50 - 10:20 am</u> Radich | Screening Trial for Myelomatch: Nuts and Bolts - Jerry |
| <u>10:20 - 10:50 am</u> | Myelomatch: Science - Cecilia Yeung |
| <u>10:50 - 11:10 am</u> | Cytogenetics and Myelomatch - Min Fang |
| <u>11:10 - 11:40 am</u> | Myelomatch: Clinical Trials - Laura Michaelis |
| 11:40 - 12:00 pm Builds, NCORP S | How do sites open studies in Myelomatch, Beacon ites - Harry Erba and group |
| <u>12:00 - 12:20 pm</u> | CML - Current and Upcoming Trials - Jerry Radich |

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.
- <u>S0919</u>, "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.
- 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

<u>S2113</u>, "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

- <u>S0333</u>, "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

<u>S1925</u>, "Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab Versus Delayed Therapy with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia / Small Lymphocytic Lymphoma (CLL): EVOLVE CLL/SLL Study." Drs. 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

<u>S1712</u>, "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." Drs. P. Shami and T. Lin.
- MM1OA-S02, "A Phase 2 Study of Targeted Agents with the Oral DNMT1 Inhibitor C-DEC (ASTX727) for the Treatment of TP53-Mutated Acute Myeloid Leukemia: A myeloMATCH treatment trial." Drs. R. Shallis, D. Sallman, and A. Zeidan.

Proposed Studies (Pre-Triage)

MM1XX-S##, "A Randomized Phase 2 trial of C-DEC, venetoclax, and enasidenib compared with azacitidine and venetoclax for newly diagnosed older adults with IDH2 mutant AML: A myeloMATCH treatment trial." Drs. U. Borate and E. Huselton.



| | 51318 | 51712 | 519 ⁰⁵ | 51925 | A047507 | A041701 | A041702 | A047703 | EA9767 | EA9777 | EA9181 |
|---|-------|-------|-------------------|-------|---------|---------|---------|---------|--------|--------|--------|
| Ascension Via Christi Hospitals Wichita | 1 | - | - | - | - | - | - | - | - | - | - |
| Banner U Med Ctr - Tucson | - | - | - | - | - | - | 5 | - | 4 | - | - |
| Baptist Mem HC/Mid South MU NCORP | - | 1 | - | - | - | - | - | - | - | - | - |
| CWRU Case CCC LAPS | 6 | - | 1 | 2 | 4 | - | 5 | - | - | - | - |
| Ca Res for the Ozarks NCORP | - | 1 | - | - | - | - | - | - | - | - | - |
| City of Hope CCC | 4 | - | 2 | 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 | 2 | - | - | - | - | - | 9 | - | _ |
| Hawaii MU NCORP | - | 6 | - | - | - | - | - | - | - | - | 1 |
| Heartland Ca Res NCORP | 1 | 4 | - | - | - | - | - | - | - | - | - |
| Henry Ford Hospital | - | - | - | 2 | - | 4 | 3 | - | 1 | - | - |
| Intermountain Med Ctr | - | - | - | - | 2 | - | - | - | - | - | _ |
| Kaiser Permanente NCORP | - | - | - | - | - | - | 7 | - | 32 | - | - |
| Lahey Hospital & Med Ctr | - | - | - | - | - | - | 1 | - | - | - | _ |
| Loma Linda U Med Ctr | 1 | - | - | - | - | - | - | - | - | - | - |
| Loyola U Med Ctr | - | 1 | - | - | - | _ | 1 | - | 2 | - | 1 |
| Medical U of South Carolina MU NCORP | - | - | - | 1 | - | _ | 1 | - | 7 | - | - |
| Michigan Ca Res Consortium NCORP | - | 1 | - | 4 | - | - | 1 | - | - | - | _ |
| Moffitt CC | - | 16 | - | - | - | _ | - | - | - | - | - |
| Montana Cancer Consortium NCORP | - | 1 | - | - | - | - | - | - | - | - | _ |
| NCORP Carolinas (Prisma Hth NCORP) | 1 | 1 | - | - | - | - | - | - | 1 | - | _ |
| Nevada Ca Res Foundation NCORP | - | 2 | - | - | - | _ | 3 | _ | 5 | _ | _ |
| New Mexico MU NCORP | 1 | 3 | - | - | _ | _ | - | _ | 1 | _ | _ |



| | 51318 | 51712 | 51905 | 51925 | A041501 | A047707 | A041702 | A041703 | EA9767 | EA9171 | EA9181 |
|---------------------------------------|-----------|-------|-------|-------|---------|---------|---------|---------|--------|--------|--------|
| Northwell Health NCORP | - | - | - | - | · - | 2 | - | - | - | - | - |
| Northwestern U LAPS | - | - | - | - | 3 | 1 | 2 | - | - | - | 3 |
| Oregon Health & Science U | - | 3 | 1 | - | 8 | - | 5 | - | 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 | - | - | - | 1 | 2 | - | - | - | - | - | - |
| UC Irvine Health/Chao Family CCC | 4 | - | - | - | 3 | - | - | - | - | - | 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 | 6 | 1 | 3 | 7 | 27 | 1 | 3 | 1 | - | 5 |
| U Utah - Huntsman Ca Inst LAPS | - | 7 | - | 5 | 1 | - | 5 | - | 22 | - | - |
| Wayne State U - Karmanos Ca Inst LAPS | - | - | - | - | - | - | - | - | 4 | - | 2 |
| Western States Ca Res NCORP | - | - | - | - | - | - | 2 | - | 1 | - | - |
| Yale U - Yale CC LAPS | 1 | - | - | - | 5 | - | 3 | - | 10 | 2 | - |
| ALLIANCE | 17 | 11 | 2 | 4 | - | - | - | - | - | - | - |
| ECOG-ACRIN | 6 | 6 | - | 4 | - | - | - | - | - | - | - |
| NRG | 2 | 2 | - | - | - | - | - | - | - | - | - |
| Total | <i>57</i> | 76 | 10 | 27 | 44 | 38 | 64 | 4 | 172 | 2 | 16 |



| Leadership |
|---|
| Chair: Jhanelle E. Gray, MD |
| Vice-Chair: |
| Executive Officer: Anne Chiang, MD, PhD |
| Statisticians:Mary Redman, PhD |
| Yingqi Zhao, PhD |
| |
| |
| |
| Lu Qian, MS Scientific Leadership |
| Translational Medicine: |
| Biology/PathologyPhilip C. Mack, PhD |
| Fred R. Hirsch, MD, PhD |
| Ignacio I. Wistuba MD |
| Imaging:Chadwick L. Wright MD, PhD |
| Myrna C. Godoy, MD, PhD |
| Radiation Oncology:Roy H. Decker, MD, PhD |
| Surgery:Wayne L. Hofstetter, MD |
| Subcommittee Chairs: |
| Early Stage Disease:Wayne L. Hofstetter, MD |
| Raymond Osarogiagbon, MD |
| Locally Advanced Disease: |
| Shirish Gadgeel, MD (Early Therapeutics) |
| Metastatic Disease: |
| |
| Community Engagement: |
| Suzanne Cole, MD Designates |
| Cancer Control Liaison: |
| DEI Champion: Lucy Gansauer, MSN, RN, OCN, CCRP |
| Veterans Affairs: |
| |
| Data Coordinators:Leah Everhart |
| Louise Highleyman |
| Larry Kaye |
| Amy Johnson |
| Clinical Research Project Manager:TBD |
| Oncology Research Professionals: |
| CRAs:Courtney L. Williamson |
| Ginny M. Keeling, MS |
| Nurses: Kimberly M. Belzer, MS, PAC |
| Rosalie Zablocki, RN |
| Patient Advocate:Judy Johnson, MBA |
| |

| Joyce Lee, PharmD | Pharmaceutical Science: |
|------------------------------|-------------------------------|
| Kimberly McConnell, PharmD | |
| Mariah Norman | Protocol Project Managers: |
| Laura Gildner, MS (Lung-MAP) | |
| Jennifer Beeler (Lung-MAP) | |
| r: Crystal Miwa | Clinical Trials Program Manag |

Time/Location

Friday, October 21, 2022 4:15 pm - 7:15 pm Room: Regency C (Ballroom Level, West Tower)

Agenda

| <u>4:15 - 4:25 pm</u> | General Update: Jhanelle E. Gray, MD |
|-----------------------|--|
| <u>4:25 - 4:35 pm</u> | Patient Advocate Update: Judy Johnson, MBA |
| <u>4:35 - 4:45 pm</u> | Thoracic Surgery Session: Wayne Hofstetter, MD |
| <u>4:45 - 4:55 pm</u> | Thoracic Radiation Session: Megan Daly, MD |
| <u>4:55 - 5:05 pm</u> | Translational Medicine Session: Phillip C. Mack, PhD |
| <u>5:05 - 5:15 pm</u> | Community Engagement Core: Paul J. Hesketh, MD |
| <u>5:15 - 5:25 pm</u> | DEI Session: Lucy Gansauer, MSN, RN |
| <u>5:25 - 5:45 pm</u> | Scientific Presentation #1 |

Patricia A. Robinson, MD

Assistant Dean - Diversity, Equity and Inclusion, SSOM, Associate Professor of Medicine, Hematology Oncology, Loyola Medicine

5:45 - 6:45 pm Thoracic Medical Oncology Session: Jhanelle Gray, MD

<u>6:45 - 7:15 pm</u> Scientific Presentation #2

A Randomized Study of Pembrolizumab plus Ramucirumab Versus Standard of Care for Patients Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer

Karen L. Reckamp, MD

Directory of the Division of Medical Oncology, Medical Director of the Women's Guild Lung Institute, Associate Director for Clinical Research, Department of Medicine, Cedars-Sinai Center

Active Studies

<u>LUNGMAP</u>, "A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung



- Cancer (Lung-MAP Screening Study)." Drs. 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.
- <u>S1900F</u>, "A Randomized Phase II Study of Carboplatin and Pemetrexed with or Without Selpercatinib (LY3527723) in Participants with Non-Squamous RET Fusion-Positive Stage IV Non-Small Cell Lung Cancer and Progression of Disease on Prior RET Directed Therapy (Lung-MAP Sub-Study)." Drs. Gray and Elamin. Activation: 7/25/22.
- <u>S1701</u>, "A Randomized Phase II Trial of Carboplatin-Paclitaxel with or without Ramucirumab in Patients with Unresectable Locally Advanced, Recurrent, or Metastatic Thymic Carcinoma." Drs. Tsao and Koczywas. 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>S1914</u>, "A Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT versus SBRT Alone in High Risk, Early Stage NSCLC." Drs. Daly, Simone, Kelly, et al. Activation: 3/25/20.
- <u>S1929</u>, "Phase II Randomized Study of Maintenance Atezolizumab Versus Atezolizumab in Combination with Talazoparib in Patients with SLFN11 Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC)." Drs. Karim, Reckamp, Gay, et al. Activation: 6/15/20; Step 1 Registration Permanently Closed 8/15/22.
- S1933, "A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status." Drs. Aljumaily, Mitin, and Wozniak. Activation: 6/15/20.
- <u>S1934</u>, "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 Firstline Immunotherapy Alone or in Combination with Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature-driven Analysis." Dr. Chiang. Activation: 2/28/19.
- CTSU/A081801, "Integration of Immunotherapy into Adjuvant Therapy for Resected NSCLC: ALCHEMIST Chemo-IO (ACCIO)." Dr. Gray. Activation: 6/3/20.
- 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/EA5182, "Randomized Phase III Study of Combination AZD9291 (Osimertinib) and Bevacizumab Versus AZD9291 (Osimertinib) Alone as First-Line Treatment for Patients with Metastatic EGFR-Mutant Non-Small Cell Lung Cancer (NSCLC)." Dr. Goldberg. Activated:10/22/20.
- CTSU/EA5191, "A Randomized Phase II Trial of Cabozantinib and Cabozantinib Plus Nivolumab Versus Standard Chemotherapy in Patients with Previously Treated Non-Squamous NSCLC." Dr. Massarelli. Activated: 5/22/20.
- CTSU/NRG-LU002, "Maintenance Systemic Therapy versus Local Consolidative Therapy (LCT) Plus Maintenance Systemic Therapy for Limited Metastatic Non-Small Cell Lung Cancer (NSCLC): A Randomized Phase II/III Trial." Dr. Gomez. 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 to US and Canadian sites 6/23/22.
- <u>CTSU/NRG-LU007</u>, "Randomized Phase II/III Trial of Consolidation Radiation + Immunotherapy for ES-SCLC: RAPTOR Trial." Dr. Park. Activated: 8/17/20.



Closed Studies

- CTSU/NRG-CC003, "Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer." Dr. Gaspar. Activation: 12/7/15; Temporary closure: 5/28/20; Reactivation: 7/27/20; Permanent closure: 6/21/22.
- S1900A, "A Pase II Study of Rucaparib in Patients with Genomic LOH High and/or Deleterious BRCA1/2 Mutation Stage IV or Recurrent Non-Small Cell Lung Cancer (LUNG-MAP Sub-Study)." Drs. Riess and Wheatley-Price. Activation: 1/28/19. Permanently closed: 2/2/21.
- <u>\$1900B</u>, "A Phase II Study of Selpercatinib (LOXO-292) in Patients with RET Fusion-Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (LUNG-MAP Sub-Study)." Drs. Elamin and Gray. Activation: 2/10/20. Permanently closed: 5/1/21.
- S1900C, "A Phase II Study of Talazoparib Plus Avelumab in Patients with Stage IV or Recurrent Non-Squamous Non-Small Cell Lung Cancer Bearing Pathogenic STK11 Genomic Alterations (LUNG-MAP Sub-Study)." Drs. Skoulidis and Suga. Activation: 1/16/20. Permanently closed: 12/18/20.
- S1800A," A Phase II Randomized Study of Ramucirumab Plus
 Pembrolizumab (MK-3475) Versus Standard of Care for Patients Previously
 Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell
 Lung Cancer (Lung-MAP Non-Matched Sub-Study)." Drs. Reckamp and
 Dragnev. Activation: 5/17/19. Permanently closed: 10/20/20.

NCI-Approved Concepts

- 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.
- <u>S2302</u>, "PROJECT PRAGMATICA: A Prospective Randomized Study of Ramucirumab (NSC 749128) Plus Pembrolizumab (MK-3475; NSC 776864) Versus Standard of Care for Participants Previously Treated With Immunotherapy for Stage IV or Recurrent Non-small Cell Lung Cancer in Standard Practice." Drs. Reckamp and Dragnev.

Concepts in Development

- <u>S1900I</u>, "A Randomized Phase II study of Mobocertinib (TAK-788) with or without Ramucirumab in Participants with Previously Treated EGFR Exon 20 Insertion Non-Small-Cell Lung Cancer (Lung-MAP Sub-Study)." Drs. Doroshow and Patel.
- <u>S1800E</u>, "A Randomized Phase II/III Study of Docetaxel and Ramucirumab with or without Cemiplimab for Participants Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Non-Matched Sub-Study)." Drs. Reckamp, Dragnev, and Wagar.
- S1800F, "A Phase II Study Of MK7684A (coformulation of Vibostolimab plus Pembrolizumab) in combination with Lenvatinib versus Standard of Care in Patients with Anti-PD-1 or Anti-PD-L1 Relapsed and Refractory Stage IV Non-Small Cell Lung Cancer (Lung-MAP Non-Match Sub-Study)." Drs. Massarelli and Li.



| | LUNGMAP | 51701 | 51800D | 51827 | 51900B | 51900E | 51914 | 51929 | 51933 | A081105 | A0818 |
|--|---------|-------|--------|-------|--------|--------|-------|-------|-------|---------|-------|
| Ascension Prov Hosp - Southfield | 13 | - | - | - | - | - | - | 1 | - | - | - |
| Ascension Via Christi Hosp Wichita | 1 | - | - | - | - | - | - | - | - | - | - |
| Banner MD Anderson CC | - | - | - | 1 | - | - | - | - | - | - | 1 |
| Banner U Med Ctr - Tucson | - | - | - | - | - | _ | - | - | - | - | - |
| Baptist Mem HC/Mid South MU NCORP | 34 | - | - | - | - | 1 | 4 | 2 | - | - | 1 |
| Baylor College of Med/Dan L Duncan CCC | - | - | - | 1 | - | - | - | - | - | - | - |
| Boston Med Ctr | - | - | - | 4 | - | - | - | - | - | - | - |
| CWRU Case CCC LAPS | 10 | - | - | - | - | 2 | - | - | - | 6 | 4 |
| Ca Res Consort of W Mich NCORP | 3 | - | - | - | - | - | 2 | - | - | - | - |
| Ca Res for the Ozarks NCORP | 29 | - | 1 | - | - | - | - | 2 | 3 | 1 | |
| Ca Res of Wisconsin & N Mich Consort | 23 | - | 1 | - | - | 3 | - | - | - | - | - |
| Carle CC NCORP | 2 | - | - | - | - | _ | 2 | - | - | - | |
| Cedars-Sinai Med Ctr | 7 | - | - | - | - | 1 | - | - | - | - | |
| City of Hope CCC | 5 | 1 | - | 1 | - | - | - | - | - | 1 | |
| Columbia U MU NCORP | 8 | - | - | - | - | - | - | - | - | - | |
| Columbus NCORP | 26 | - | - | 3 | - | - | - | - | - | - | |
| CommonSpirit HIth Res Inst | 43 | - | - | - | - | - | 1 | 2 | - | - | |
| Cotton O'Neil CC / Stormont Vail Hlth | _ | _ | - | - | - | - | - | - | - | - | |
| Dayton NCORP | 2 | - | - | - | - | - | - | 1 | - | - | 1 |
| Essentia HIth NCORP | 15 | - | 2 | - | - | - | 1 | - | - | - | |
| Fred Hutchinson Ca Res Ctr LAPS | 4 | - | - | - | - | - | - | - | - | 1 | |
| Georgia Cares MU NCORP | 6 | - | - | 1 | - | - | 2 | 3 | 1 | - | |
| Georgia NCORP | 50 | - | - | 2 | - | 1 | 2 | - | - | - | - |
| Gulf South MU NCORP | 8 | - | - | 1 | - | - | 1 | 1 | - | - | |
| Hawaii MU NCORP | 21 | - | - | - | - | _ | - | - | - | - | |
| Heartland Ca Res NCORP | 108 | _ | - | 2 | 1 | 4 | 18 | 16 | 2 | - | |
| Henry Ford Hospital | 7 | - | - | - | - | - | - | 1 | - | 2 | 2 |
| Houston Methodist Hosp | _ | - | - | - | - | - | - | - | - | 2 | |
| Kaiser Permanente NCORP | 60 | - | 1 | - | - | 6 | 1 | - | - | 19 | 2 |
| Lahey Hospital & Med Ctr | 29 | _ | - | - | - | _ | 1 | 1 | 2 | - | |
| Loma Linda U Med Ctr | 5 | _ | - | - | - | - | - | - | - | 3 | |
| Loyola U Med Ctr | 22 | - | - | - | - | - | - | 1 | - | - | |
| Massachusetts Vet Epi Res & Info Ctr | 39 | - | 1 | 1 | - | _ | - | - | - | 1 | 6 |
| Medical U South Carolina MU NCORP | 10 | - | - | - | - | 1 | - | - | - | - | |
| Michigan Ca Res Consort NCORP | 99 | - | 4 | - | - | 4 | 1 | 1 | - | - | |
| Moffitt CC | 9 | 2 | - | 1 | - | 1 | - | - | - | 3 | é |
| Montana Cancer Consort NCORP | 24 | - | - | - | - | _ | - | 3 | 1 | - | |
| Mount Sinai Hospital | - | - | - | - | - | _ | 7 | - | - | - | |
| NCORP Carolinas (Prisma Hlth NCORP) | 15 | | | _ | _ | 1 | _ | _ | _ | - | |



| | LUNGMAP | 51701 | 51800D | 51827 | 51900B | 51900E | 51914 | 51929 | 51933 | A081105 | A08180A |
|---|---------|-------|--------|-------|--------|--------|-------|-------|-------|---------|---------|
| Nevada Ca Res Foundation NCORP | 12 | - | - | - | - | - | - | 1 | - | - | - |
| New Mexico MU NCORP | 66 | - | - | 1 | - | - | 5 | 5 | 1 | - | _ |
| Northwell Hith NCORP | - | - | - | - | - | - | - | - | - | - | 1 |
| Northwestern U LAPS | 23 | 1 | - | 1 | - | - | - | 3 | - | - | - |
| Oregon HIth & Science U | 1 | - | - | - | - | - | 1 | - | - | 1 | 5 |
| Pacific Ca Res Consort NCORP | 14 | - | - | - | - | - | - | 3 | - | - | - |
| SCL HIth Saint Joseph Hospital | 1 | - | - | - | - | - | 1 | - | - | - | 1 |
| Salem Hospital | 3 | - | - | - | - | - | - | - | - | - | _ |
| Southeast Clin Onc Res Consort NCORP | 45 | - | - | 4 | - | - | 3 | 5 | - | - | - |
| Sutter Ca Res Consort | 22 | - | - | - | - | 1 | - | - | - | 1 | _ |
| The Don and Sybil Harrington CC | 7 | - | 1 | - | - | - | - | - | - | - | - |
| The James Graham Brown CC at U Louisville | - | - | - | - | - | - | - | - | - | - | - |
| UC Davis CCC LAPS | 26 | 3 | 5 | 1 | - | - | 6 | 2 | - | 4 | - |
| UC Irvine Hlth/Chao Family CCC | 18 | - | - | 1 | - | - | 1 | - | - | 2 | - |
| UC San Diego Moores CC | 11 | - | - | - | - | 1 | - | - | - | 1 | - |
| UPMC Hillman CC LAPS | 27 | - | - | 2 | - | 5 | - | 1 | 2 | - | - |
| USC Norris CCC LAPS | - | - | - | 1 | - | - | 3 | - | - | 1 | - |
| U Arkansas for Medical Sciences | 11 | - | - | - | - | - | 5 | - | - | - | - |
| U Cincinnati CC-UC Med Ctr | - | - | - | - | - | - | - | - | - | 1 | - |
| U Colorado CC LAPS | 10 | - | - | 1 | - | - | 3 | 2 | - | 9 | 3 |
| U Kansas CC - MCA Rural MU NCORP | 79 | - | 1 | - | - | 1 | - | - | - | 1 | - |
| U Kentucky/Markey CC | 42 | - | - | 1 | - | - | - | - | - | 1 | - |
| U Michigan CCC LAPS | 1 | - | - | - | - | - | - | - | - | 1 | - |
| U Mississippi Med Ctr | 1 | - | - | - | - | - | - | - | - | 2 | - |
| U Oklahoma Hlth Sciences Ctr LAPS | 28 | - | - | 1 | - | - | - | 1 | 8 | - | - |
| U Rochester LAPS | 53 | - | 1 | - | - | 5 | 2 | - | - | - | - |
| U Texas HIth Science Ctr at San Antonio | - | - | - | - | - | - | - | 1 | - | - | - |
| U Texas MD Anderson CC LAPS | 3 | 6 | - | - | - | - | - | 4 | - | - | - |
| U Utah - Huntsman Ca Inst LAPS | - | - | - | 1 | - | - | 2 | 1 | - | - | - |
| Upstate Carolina Consort NCORP | 32 | - | - | - | - | - | 1 | - | - | - | - |
| Wayne State U - Karmanos Ca Inst LAPS | 1 | - | - | - | - | - | - | - | - | - | - |
| Western States Ca Res NCORP | 2 | - | - | - | - | - | - | - | - | - | - |
| William Beaumont Hosp-Royal Oak | - | - | - | - | - | - | - | - | - | - | - |
| Wisconsin NCORP | 37 | - | - | 1 | - | - | 5 | - | - | - | - |
| Yale U - Yale CC LAPS | 17 | - | - | 2 | - | - | - | - | - | 3 | 3 |
| ALLIANCE | 620 | 3 | 3 | 11 | 1 | 13 | 5 | 7 | 2 | - | - |
| CCTG | - | - | - | 11 | - | - | - | - | - | - | - |
| ECOG-ACRIN | 298 | 2 | 3 | 2 | 2 | 11 | 9 | 7 | - | - | - |
| NRG | 316 | - | 1 | 42 | 2 | 4 | 13 | 5 | 1 | - | - |
| Total | 2,564 | 18 | 25 | 102 | 6 | 66 | 108 | 83 | 23 | 67 | 36 |



| | A151216 | E4512 | EA5163 | EA5181 | EA5182 | EA5191 | NRGCC003 | NRGLU002 | NRGQU005 | R1308 |
|--|---------|-------|--------|--------|--------|--------|----------|----------|----------|-------|
| Ascension Prov Hosp - Southfield | 14 | 1 | 2 | 3 | - | 1 | - | - | - | - |
| Ascension Via Christi Hosp Wichita | - | - | - | - | - | - | - | - | - | - |
| Banner MD Anderson CC | 1 | - | - | - | - | - | - | - | 2 | - |
| Banner U Med Ctr - Tucson | 7 | 2 | - | 4 | - | - | - | - | 1 | - |
| Baptist Mem HC/Mid South MU NCORP | 21 | - | 1 | - | - | - | - | 1 | 4 | - |
| Baylor College of Med/Dan L Duncan CCC | - | - | - | - | - | - | - | - | - | - |
| Boston Med Ctr | 3 | - | - | 1 | - | - | - | - | - | - |
| CWRU Case CCC LAPS | 48 | - | 8 | 14 | - | - | - | - | - | - |
| Ca Res Consort of W 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 HIth Res Inst | 2 | - | - | - | - | - | - | - | - | - |
| Cotton O'Neil CC / Stormont Vail Hlth | 3 | - | - | - | - | - | - | - | - | - |
| Dayton NCORP | 8 | - | - | - | - | - | - | - | - | - |
| Essentia HIth 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 | 29 | - | - | - | - | - | - | - | - | - |
| Houston Methodist Hosp | 8 | - | - | - | - | - | - | - | - | - |
| Kaiser Permanente NCORP | 199 | 4 | 5 | - | 1 | - | - | - | - | - |
| Lahey Hospital & Med Ctr | 30 | - | 2 | - | - | - | - | - | - | - |
| Loma Linda U Med Ctr | 9 | - | - | - | - | - | - | - | - | 1 |
| Loyola U Med Ctr | 21 | - | - | 2 | - | - | - | - | - | - |
| Massachusetts Vet Epi Res & Info Ctr | 25 | - | 3 | - | - | 2 | - | - | - | - |
| Medical U South Carolina MU NCORP | - | - | - | - | - | - | - | - | - | - |
| Michigan Ca Res Consort NCORP | - | - | - | - | - | - | - | - | - | - |
| Moffitt CC | 83 | 1 | - | - | - | - | - | - | - | - |
| Montana Cancer Consort NCORP | - | - | - | - | - | - | - | - | - | - |
| Mount Sinai Hospital | _ | - | - | 1 | - | - | - | - | 1 | - |
| NCORP Carolinas (Prisma Hlth NCORP) | 1 | _ | | _ | | | | _ | | _ |



| | A151216 | E4512 | EA5163 | EA5181 | EA5182 | EA5191 | NRGCC003 | NRGLU007 | NRGLU005 | R1308 |
|---|---------|-------|--------|--------|--------|--------|----------|----------|----------|-------|
| Nevada Ca Res Foundation NCORP | - | - | - | - | - | - | - | - | - | - |
| New Mexico MU NCORP | - | - | - | - | - | - | - | - | - | - |
| Northwell Hith NCORP | 1 | - | - | - | - | - | - | - | - | - |
| Northwestern U LAPS | - | - | - | - | - | - | - | - | - | - |
| Oregon HIth & Science U | 20 | - | - | - | - | - | - | - | - | - |
| Pacific Ca Res Consort NCORP | 4 | - | - | - | - | - | - | - | - | - |
| SCL HIth Saint Joseph Hospital | 2 | - | - | - | - | - | - | - | - | - |
| Salem Hospital | - | - | - | - | - | - | - | - | - | - |
| Southeast Clin Onc Res Consort NCORP | - | - | - | - | - | - | - | - | - | - |
| Sutter Ca Res Consort | 10 | - | - | 2 | - | - | - | - | - | - |
| The Don and Sybil Harrington CC | - | - | - | - | - | - | - | - | - | - |
| The James Graham Brown CC at U Louisville | 5 | - | - | - | - | - | - | - | - | - |
| UC Davis CCC LAPS | 41 | 1 | 6 | - | 1 | - | - | - | - | - |
| UC Irvine Hlth/Chao Family CCC | 13 | - | - | - | - | - | - | - | - | - |
| UC San Diego Moores CC | 5 | - | - | - | - | - | - | - | - | - |
| UPMC Hillman CC LAPS | - | - | - | - | - | - | - | - | 1 | - |
| USC Norris CCC LAPS | 12 | - | - | - | - | - | - | - | - | - |
| U Arkansas for Medical Sciences | 2 | - | 1 | - | - | - | - | - | 1 | - |
| U Cincinnati CC-UC Med Ctr | 22 | 1 | - | - | 1 | - | - | - | - | - |
| U Colorado CC LAPS | 58 | 2 | - | - | - | 1 | - | - | 1 | - |
| U Kansas CC - MCA Rural MU NCORP | 28 | - | 5 | - | - | 1 | - | - | 2 | - |
| U Kentucky/Markey CC | 5 | - | - | - | - | - | - | - | - | - |
| U Michigan CCC LAPS | 62 | - | - | - | - | - | - | - | - | - |
| U Mississippi Med Ctr | 26 | - | - | - | - | - | - | - | - | - |
| U Oklahoma HIth Sciences Ctr LAPS | - | - | - | - | - | - | - | - | - | - |
| U Rochester LAPS | - | - | 2 | 13 | - | - | 4 | - | 1 | - |
| U Texas HIth Science Ctr at San Antonio | - | - | 2 | - | - | - | - | - | - | - |
| U Texas MD Anderson CC LAPS | 2 | 1 | - | - | - | - | - | - | - | - |
| U Utah - Huntsman Ca Inst LAPS | - | - | 1 | - | - | - | - | - | - | - |
| Upstate Carolina Consort 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 | 52 | 4 | 10 | - | - | - | - | - | - | - |
| ALLIANCE | - | - | - | - | - | - | - | - | _ | - |
| ССТБ | - | - | - | - | - | - | - | - | - | - |
| ECOG-ACRIN | - | - | - | - | - | - | - | - | _ | - |
| NRG | - | - | - | - | - | - | - | - | - | - |
| Total | 916 | 17 | 52 | 40 | 3 | 5 | 5 | 2 | 14 | 1 |



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|---------------------------|---------------------------|
| 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 Leadershi | p |
| Translational Medicine: . | Alexey Danilov, MD, PhD |

Designates

CRA: Erin M. Cebula, MPH
Nurse: Molly Beth Adamek, BSN, RN

Time/Location

Friday, October 21, 2022 9:00 am - 11:00 am Room: Crystal A (Lobby Level, West Tower)

Agenda

9:00 - 9:05 am Welcome - Jonathan Friedberg and Sonali Smith

9:05 - 9:45 am Mini-symposium: The pursuit of equity and inclusion in lymphoma careers - Sonali Smith, Elwood V. Jensen Professor, Chief, Hematology/Oncology Section, University of Chicago

9:45 - 10:45 am Spotlight on studies pending activationS2114 DLBCL post CAR-T cell therapy Dr. Hess
COG Early stage Hodgkin lymphoma Dr. Hu

10:50 - 11:55 am Ongoing Studies S1826: Dr. Herrera

S1918: Dr. Brem

S1608: Dr. Barr

A051902: Dr. Amengual

ANHL1931: Dr. Kamdar

EA4151: Dr. Till

EA4181: Dr. Spurgeon S1925 (CLL): Dr. Stephens

A051301: Dr. Stiff

11:55 - 12:00 pm Other Business/Concluding Remarks

Proposed Studies

<u>S2114</u>, "A Randomized Phase II Trial of Consolidation Therapy Following CD19 CAR T-Cell Treatment for Relapsed/Refractory Diffuse Large B-cell Lymphoma or Grade IIIB Follicular Lymphoma." Drs. Hess and Hossain.

<u>S2207</u>, "Randomized phase II study of the addition of Targeted therapeutic agents to tafasitamab-based therapy in non-transplant-eligible patients with Relapsed/refractory Large B-cell Lymphoma." Drs. Amegual and Reagan.

Active Studies

S1826, "A Phase III, Randomized Study of Nivolumab (Opdivo) Plus AVD or Brentuximab Vedotin (Adcetris) Plus AVD in Patients (Age >/= 12 Years) with Newly Diagnosed Advanced Stage Classical Hodgkin Lymhoma." Drs. Herrera and Friedberg. Activated: 7/19/19.

<u>S1608</u>, "Randomized Phase II Trial in Early Relapsing or Refractory Follicular Lymphoma." Drs. Barr and Burack. Activated: 8/10/17. Temporarily closed: 02/09/2022.

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. 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. Dr. Fenske. SWOG Champion: Dr. Till. Activated: 8/29/17.
- CTSU/EA4181, "A Randomized 3-Arm Phase II Study Comparing 1.)
 Bendamustine, Rituximab and High Dose Cytarabine (BR/CR) 2.)
 Bendamustine, Rituximab, High Dose Cytarabine and Acalabrutinib (BR/CA-A), and 3.) Bendamustine, Rituximab and Acalabrutinib (BR-A) in Patients </= 70 years Old with Untreated Mantle Cell Lymphoma. Dr. Wagner-Johnson. SWOG Champion: Dr. Spurgeon. Acti-vated: 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

- <u>S1925</u>, A Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab ver-sus 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 Ve-netoclax and Obinutuzumab in Untreated Older Patients (>/= 65 Years of Age) with Chronic Lympho-cytic 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

<u>S1912CD</u>, "A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CREDIT)." Dr. Shankaran. Activated 7/26/2021.



| | 51608 | 51826 | 51918 | A051301 | ANHL1931 | E4412 | EA4151 | EA4181 |
|---|-------|-------|-------|---------|----------|-------|--------|--------|
| Ascension Providence Hospitals - Southfield | - | 5 | - | - | - | - | - | - |
| Banner University Medical Center - Tucson | 2 | - | - | 1 | - | - | 1 | 2 |
| Baptist Memorial Health Care/Mid South Minority Underserved NCORP | - | 3 | - | - | - | - | - | - |
| Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center | - | - | - | 1 | - | - | - | - |
| Boston Medical Center | - | 2 | - | - | - | - | - | - |
| CWRU Case Comprehensive Cancer Center LAPS | - | - | - | - | - | - | 11 | 11 |
| Cancer Research Consortium of West Michigan NCORP | 3 | 13 | - | - | - | - | - | - |
| Cancer Research for the Ozarks NCORP | 1 | 4 | - | - | - | - | - | - |
| Cancer Research of Wisconsin and Northern Michigan Consortium | - | 2 | - | - | - | - | - | - |
| Carle Cancer Center NCI Community Oncology Research Program | 1 | 3 | - | - | - | - | - | - |
| City of Hope Comprehensive Cancer Center | 8 | 20 | 2 | 1 | - | - | 17 | - |
| 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 | - | 3 | - | - | - | - | - | - |
| Fred Hutchinson Cancer Research Center LAPS | - | - | - | - | - | - | 13 | - |
| Georgia Cares Minority Underserved NCORP | - | 5 | 1 | - | - | - | - | - |
| Gulf South Minority Underserved NCORP | - | - | 1 | - | - | - | - | - |
| Heartland Cancer Research NCORP | 1 | 17 | - | - | - | - | - | - |
| Henry Ford Hospital | - | 7 | - | - | - | - | - | - |
| Kaiser Permanente NCI Community Oncology Research Program | 2 | 10 | - | - | - | 11 | - | 9 |
| King Faisal Specialist Hospital and Research Centre | - | - | - | 4 | - | - | - | - |
| Loyola University Medical Center | - | 8 | - | - | - | - | 3 | - |
| Medical University of South Carolina Minority Underserved NCORP | 2 | 17 | 1 | - | - | - | 2 | - |
| Michigan Cancer Research Consortium NCORP | 1 | 5 | 2 | - | - | - | - | - |
| Moffitt Cancer Center | - | 15 | - | - | - | - | - | - |
| Montana Cancer Consortium NCORP | - | 8 | - | - | - | - | - | - |
| NCORP of the Carolinas (Prisma Health NCORP) | - | 11 | - | - | - | _ | 2 | - |



| | 51608 | 51826 | 51918 | 4051301 | ANHL1931 | E4412 | EA4151 | EA418 |
|---|-------|-------|-------|---------|----------|-------|--------|-------|
| Nevada Cancer Research Foundation NCORP | - | 2 | - | - | - | 1 | - | - |
| Northwestern University LAPS | 1 | - | - | - | - | - | - | - |
| Oregon Health and Science University | - | 4 | - | - | - | - | 5 | 5 |
| Pacific Cancer Research Consortium NCORP | - | 5 | - | - | - | - | - | - |
| Southeast Clinical Oncology Research Consortium NCORP | - | 5 | - | - | - | - | - | - |
| UC Davis Comprehensive Cancer Center LAPS | - | 15 | - | - | - | - | - | - |
| UC Irvine Health/Chao Family Comprehensive Cancer Center | - | 4 | - | - | 1 | - | - | - |
| UC San Diego Moores Cancer Center | - | 8 | - | - | - | - | 1 | - |
| University of Alabama at Birmingham / Deep South Research Consortium LAPS | - | 11 | - | - | - | 7 | 5 | - |
| University of Arkansas for Medical Sciences | - | 1 | - | - | - | - | - | - |
| University of Cincinnati Cancer Center-UC Medical Center | - | 6 | - | - | - | - | 2 | 2 |
| University of Colorado Cancer Center LAPS | - | 3 | - | 1 | - | - | - | - |
| University of Kansas Cancer Center - MCA Rural MU NCORP | - | - | - | - | - | - | - | 1 |
| University of Kentucky/Markey Cancer Center | - | 2 | - | - | - | - | - | - |
| University of Michigan Comprehensive Cancer Center LAPS | - | - | - | - | - | - | 1 | - |
| University of Mississippi Medical Center | - | 1 | - | - | - | - | - | - |
| University of Rochester LAPS | 13 | 30 | - | 3 | - | - | 10 | 17 |
| University of Texas Health Science Center at San Antonio | - | 16 | - | - | - | - | 11 | - |
| University of Texas MD Anderson Cancer Center LAPS | 3 | 29 | - | - | - | - | - | - |
| University of Utah - Huntsman Cancer Institute LAPS | 1 | 14 | 1 | - | - | - | 14 | 11 |
| Upstate Carolina Consortium Community Oncology Research Program | 1 | 7 | - | - | - | - | - | - |
| Wayne State University - Karmanos Cancer Institute LAPS | - | 3 | - | 1 | - | - | 1 | 6 |
| Wisconsin NCI Community Oncology Research Program | - | 9 | - | - | - | - | - | - |
| Yale University - Yale Cancer Center LAPS | - | 6 | - | - | - | - | 4 | - |
| ALLIANCE | 15 | 119 | 18 | - | - | - | - | - |
| CCTG | - | 20 | - | - | - | - | - | - |
| cog | - | 288 | - | - | - | - | - | - |
| ECOG-ACRIN | 5 | 77 | 5 | - | - | - | - | - |
| NRG | 11 | 44 | 2 | - | - | - | - | - |
| Total | 72 | 893 | 35 | 12 | 1 | 20 | 103 | 64 |



| 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 | • |
| | William E. Carson, III, MD |
| Radiation Oncology: | Evan J. Wuthrick, MD |
| | John Robert Hyngstrom, MD |
| | Clara Curiel-Lewandrowski, MD |
| | Ari M. VanderWalde, MD |
| | Sapna Pradyuman Patel, MD |
| Pathology: | TBD |
| Non-Melanoma Skin Cancer: | Nikhil I. Khushalani, MD |
| Early Therapeutics: | Jeffrey A. Sosman, MD |
| SWOG's ECOG Liaisons: | Thach-Giao Truong, MD |
| ECOG's SWOG Liaisons: | David H. Lawson, MD |
| | Andrew Poklepovic, MD |
| Digital Engagement: | Zeynep Eroglu, MD |
| Designates | |
| Cancer Control Liaison: | Sancy Leachman, MD, PhD |
| T | hach-Giao Truong, MD (Survivorship) |
| Data Coordinator: | Tonya Johnson |
| | Laura Kingsbury, MRT |
| | Leah Everhart |
| | Hannah Hale |
| Oncology Research Professionals: | |
| CRA: | Kathryn Allen, BA, CCRP |
| Nurse: | Lisa S. Morgan, RN, OCN |
| Patient Advocate: | Samantha Guild, J.D. |
| | Sun "Coco" Yang, PharmD, PhD |
| | Kimberly McConnell, PharmD |
| Protocol Project Manager: | Catrina De Los Santos-Mireles |
| Clinical Trials Program Manager: | TBD |
| | |

Time/Location

Friday, October 21, 2022 2:30 pm - 4:30 pm Room: Crystal C (Lobby Level, West Tower)

Agenda

2:30 - 2:40 pm Welcome and Introduction: Sapna Patel, MD

2:40 - 3:20 pm Keynote Speaker: Treating Mucosal Melanoma:
Progress and Challenges in the PD-1 Era - Alexander Shoushtari, M.D.,
Memorial Sloan Ketterin Cancer Center

3:20 - 3:35 pm Active Studies update - 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)

<u>S2000</u>, 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.

biostatisticiaris. Micriael Wu, 1 11.0. & James Moon, M.S.

3:35 - 4:10 pm Closed to Patient Accrual, Manuscript & Translational Medicine Updates

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.

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.

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.

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

Pl: Siwen Hu-Lieskovan, 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.
- <u>S1320</u>, A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib and Trametinib in BRAFV600E/K Mutant Melanoma PI: 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 PI: Alain Algazi, M.D. (University of California San Francisco) and Antoni Ribas (UCLA)

Biostatisticians: Megan Othus, Ph.D. & James Moon, M.S.

Closing

4:25 - 4:30 pm

| 4:10 - 4:20 pm | ECOG / ALLIANCE Updates: David Lawson, MD |
|------------------------------------|--|
| 4:20 - 4:25 pm Melanoma) | Advocate Update: Remarks (Samantha Guild, JD, AIM at |

Other Active Studies

- CTSU/EA6174, "STAMP: Surgically Treated Adjuvant Merkel Cell Carcinoma with Pembrolizumab, a Phase III Trial." SWOG Champion: Dr. Hsu. Activated: 10/1/18.
- CTSU/EA6141, "Randomized Phase II/III Study of Nivolumab plus Ipilimumab plus Sargramostim versus Nivolumab plus Ipilimumab in Patients with Unresectable Stage III or Stage IV Melanoma." SWOG Champion: Dr. K. Kim. Activated: 9/10/15.
- CTSU/EA6192, "The BAMM2 (BRAF, Autophagy, MEK Inhibition in Melanoma) Study: A Randomized Double Blind Phase II Study of Dabrafenib and Trametinib with or Without Hydroxychloroquine in Advanced BRAF V600E/K Melanoma with Elevated LDH". SWOG Champion: Dr. Truong. Activated:10/23/20.

Other Closed Studies

CTSU/EA6134, "DREAMseq (Doublet, Randomized Evaluation in Advanced Melanoma Sequencing) a Phase III Trial." SWOG Champion: Dr. Chmielowski. Activated: 7/13/15. Closed: 9/30/2021.

Studies in Development

<u>S2300</u>, "A Phase 3 Randomized Trial of Complete Circumferential Peripheral and Deep Margin Assessment for Excision of Localized Cutaneous Melanoma: The CAEC ("Cake") Trial" Dr. Yu.



| | 51512 | 51801 | 52000 | 52015 | EA6134 | EA6747 | EA6174 | EA6192 |
|--|-------|-------|-------|-------|--------|--------|--------|--------|
| Banner MD Anderson CC | - | 3 | - | - | - | - | - | - |
| Banner U Med Ctr - Tucson | - | 7 | - | - | - | - | 3 | - |
| Baptist Mem Hlth Care/Mid South MU NCORP | - | 1 | - | - | - | - | - | - |
| Boston Med Ctr | - | 1 | - | - | - | - | - | - |
| CWRU Case CCC LAPS | - | - | - | - | 6 | - | 14 | - |
| Ca Res Consort of W Mich NCORP | - | 26 | - | 8 | - | - | - | - |
| Ca Res for the Ozarks NCORP | - | - | 1 | - | - | 1 | - | - |
| Ca Res of Wisconsin & N Mich Consort | - | 2 | - | - | - | - | - | - |
| Carle CC NCORP | - | 1 | 1 | - | - | - | - | - |
| City of Hope CCC | - | 6 | - | - | 2 | 3 | - | - |
| Columbus NCORP | - | 1 | - | - | - | - | - | - |
| Dayton NCORP | - | - | - | - | - | 2 | - | - |
| Georgia NCORP | 1 | - | - | - | - | - | - | - |
| Gulf South MU NCORP | - | 1 | - | - | - | - | - | - |
| Hawaii MU NCORP | - | 2 | - | - | 2 | - | - | - |
| Heartland Ca Res NCORP | - | 6 | - | - | - | - | - | - |
| Intermountain Med Ctr | 1 | - | - | - | - | - | - | - |
| Kaiser Permanente NCORP | - | 14 | - | - | 19 | 23 | - | - |
| Loma Linda U Med Ctr | - | 2 | - | - | - | - | - | - |
| Massachusetts Vet Epi Res & Info Ctr | - | 5 | - | - | - | - | - | - |
| Medical U South Carolina MU NCORP | - | 1 | - | - | - | - | - | - |
| Michigan Ca Res Consort NCORP | - | 5 | - | - | - | - | - | - |
| Moffitt CC | 19 | - | 4 | - | - | - | - | - |
| Montana Cancer Consort NCORP | - | 4 | - | - | - | - | - | - |
| NCORP Carolinas (Prisma Hlth NCORP) | - | - | - | - | 2 | - | - | - |
| Nevada Ca Res Foundation NCORP | - | - | - | - | - | - | 1 | - |
| New Mexico MU NCORP | - | 1 | - | - | - | - | - | - |
| Northwell Hith NCORP | - | 7 | - | - | _ | _ | _ | - |



| | 51512 | 51801 | 52000 | 52015 | EA6134 | EA6747 | EA6174 | EA6197 |
|---|-------|-------|-------|-------|--------|--------|--------|--------|
| Northwestern U LAPS | 1 | 13 | - | - | - | - | - | 2 |
| Ohio State U CCC LAPS | 6 | 13 | - | - | 4 | - | 3 | 1 |
| Pacific Ca Res Consort NCORP | - | 3 | - | - | - | - | - | - |
| SCL HIth Saint Joseph Hospital | - | - | - | - | - | - | 1 | - |
| Southeast Clin Onc Res Consort NCORP | 1 | - | - | - | - | - | - | - |
| Sutter Ca Res Consort | - | - | - | - | 2 | 5 | 1 | - |
| The Don and Sybil Harrington CC | - | 3 | - | - | - | - | - | - |
| UC Irvine Hlth/Chao Family CCC | - | 3 | - | - | - | 2 | 7 | - |
| UCLA / Jonsson CCC | 4 | 6 | - | - | 7 | - | - | - |
| USC Norris CCC LAPS | 5 | 8 | - | - | - | - | 2 | - |
| U Alabama Birm/Deep South RC LAPS | - | 1 | - | - | - | - | - | - |
| U Arkansas for Medical Sciences | - | - | - | - | 3 | - | - | - |
| U Cincinnati CC-UC Med Ctr | - | - | - | - | - | 2 | 3 | - |
| U Colorado CC LAPS | - | - | - | - | 1 | - | - | - |
| U Kansas CC - MCA Rural MU NCORP | 2 | 8 | - | - | 2 | - | - | - |
| U Kentucky/Markey CC | - | 4 | - | - | - | - | - | - |
| U Michigan CCC LAPS | - | 15 | 1 | - | - | - | - | - |
| U Rochester LAPS | - | 4 | - | - | 2 | - | 1 | - |
| U Texas Hlth Science Ctr at San Antonio | - | - | - | - | - | 1 | - | - |
| U Texas MD Anderson CC LAPS | - | 10 | - | - | - | - | - | - |
| U Utah - Huntsman Ca Inst LAPS | 10 | 20 | - | - | - | - | 6 | - |
| Wayne State U - Karmanos Ca Inst LAPS | - | - | - | - | 2 | - | - | - |
| Western States Ca Res NCORP | - | - | - | - | - | 1 | - | - |
| Wisconsin NCORP | - | 9 | - | - | - | - | - | - |
| Yale U - Yale CC LAPS | - | - | - | - | - | 6 | - | - |
| ALLIANCE | 1 | 32 | 1 | - | - | - | - | - |
| ECOG-ACRIN | 2 | 50 | 3 | - | - | - | - | - |
| NRG | 4 | 47 | 1 | - | - | - | - | - |
| Total | 57 | 345 | 12 | 8 | 54 | 46 | 42 | 3 |



The publications listed below were received by the Group Chair's Office as published (including online), accepted, or submitted since the SWOG Spring 2022 Hybrid 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

S0777 Restricted survival benefit with right-censored data. Zhang S, LeBlanc M, Zhao Y. <u>Biometrical Journal</u> Apr;64(4):696-713,2022. https://pubmed.ncbi.nlm.nih.gov/34970772/

S0777/S1211 Current approaches to management of newly diagnosed multiple myeloma [Review]. Goel U, Usmani S, Kumar S. American Journal of Hematology May;97 Suppl 1:S3-S25, 2022. https://pubmed.ncbi.nlm.nih.gov/35234302/

Submitted Manuscripts

(none this cycle)

BREAST COMMITTEE

Published/Accepted Manuscripts

MA.32 Effect of Metformin vs Placebo on Invasive Disease-Free Survival in Patients With Breast Cancer: The MA.32 Randomized Clinical Trial. Goodwin PJ, Chen BE, Gelmon KA, Whelan TJ, Ennis M, Lemieux J, Ligibel JA, Hershman DL, Mayer IA, Hobday TJ, Bliss JM, Rastogi P, Rabaglio-Poretti M, Mukherjee SD, Mackey JR, Abramson VG, Oja C, Wesolowski R, Thompson AM, Rea DW, Stos PM, Shepherd LE, Stambolic V, Parulekar WR. JAMA. May 24;327(20):1963-1973, 2022. https://pubmed.ncbi.nlm.nih.gov/35608580/

S1202/S1207 Recent Advances in Adjuvant Endocrine Therapy in Estrogen Receptor–Positive, Human Epidermal Growth Factor Receptor 2–Negative Breast Cancer [Editorial]. Cobain EF, Hayes DF. <u>Journal of Clinicl Oncology</u> Jun 29:JCO2200702. doi: 10.1200/JCO.22.00702. Online ahead of print, 2022. https://pubmed.ncbi.nlm.nih.gov/35767772/

<u>S1418/Other</u> Use of Immune Checkpoint Inhibitors in the Treatment of High-Risk, Early-Stage Triple-Negative Breast Cancer: ASCO Guideline

Rapid Recommendation Update Q and A. Vikas P, Korde LA, Somerfield MR, Hershman DL. <u>JCO Oncol Pract</u>. May 20;40(15):1696-1698, 2022. https://pubmed.ncbi.nlm.nih.gov/35417251/

Multiple Studies* Biomarkers for Adjuvant Endocrine and Chemotherapy in Early-Stage Breast Cancer: ASCO Guideline Update. Andre F, Ismaila N, Allison KH, Barlow WE, Collyar DE, Damodaran S, Henry NL, Jhaveri K, Kalinsky K, Kuderer NM, Litvak A, Mayer EL, Pusztai L, Raab R, Wolff AC, Stearns V. <u>Journal of Clinical Oncology</u> Jun 1;40(16):1816-1837, 2022. [*including S1007] https://pubmed.ncbi.nlm.nih.gov/35439025/

Submitted Manuscripts

S0500 Tumor-derived Extracellular Vesicles as Complementary Prognostic Factors to Circulating Tumor Cells in Metastatic Breast Cancer (SWOG S0500). Nanou A, Miao J, Coumans F, Dolce E, Darga E, Barlow W, Smerage J, Hortobagyi G, Terstappen L, Hayes D. <u>JCO Precision</u> <u>Oncology</u>, submitted 2022.

S0800 Image analysis-based tumor infiltrating lymphocyte measurement predicts pathologic complete response to neoadjuvant chemotherapy in breast cancer (SWOG S0800). Fanucci K, Blenman K, Bai Y, Pelekanou V, Nahleh Z, Shafi S, Burela S, Barlow W, Sharma P, Thompson A, Godwin A, Rimm D, Hortobagyi G, Pusztai L. npj <u>Breast Cancer</u>, submitted 2022.

S1416 Results of a Phase II Randomized Trial of Cisplatin With ABT-888 (Veliparib) or Placebo in Metastatic Triple-Negative Breast Cancer and/or BRCA1/2 Mutation-Associated Breast Cancer (S1416). Rodler E, Sharma P, Barlow W, Gralow J, Puhalla S, Anders C, Goldstein L, Tripathy D, Brown-Glaberman U, Huynh T, Szyarto C, Godwin A, Pathak H, Swisher E, Radke M, Timms K, Lew D, Miao J, Pusztai L, Hayes D, Hortobagyi G. Lancet Oncology, submitted 2022

<u>S8814</u> Evaluation of the predicted sensitivity to endocrine therapy (SET2,3 index) and the 21-gene Breast Recurrence Score assay in the SWOG S8814 trial. Speers C, Symmans WF, Barlow W, Trevarton A, The S, Du L, Rae J, Shak S, Baehner R, Sharma P, Pusztai L, Hortobagyi G, Hayes D, Albain K, Godwin A, Thompson A. <u>Journal of Clinical Oncology</u>, submitted 2022.



CANCER CONTROL AND PREVENTION COMMITTEES CANCER CARE DELIVERY COMMITTEE

Published/Accepted Manuscripts

- S1404 Adjuvant pembrolizumab improves quality-of-life outcomes compared to high dose interferon or ipilimumab in patients with resected melanoma; SWOG S1404, A Randomized Clinical Trial Unger J, Darke A, Othus M, Tarhini A, Kirkwood J, Sharon E, Sondak V, Guild S, Truong T, Eroglu Z, Kendra K, Lewis K, Faller B, Funchain P, Buchbinder E, Grossmann K, Ribas A, Patel S. <u>JAMA Oncology</u>, accepted 2022.[see also Melanoma Committee]
- 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. BMC Health Services Research Apr 1;22(1):432, 2022. https://pubmed.ncbi.nlm.nih.gov/35365139/
- S1415CD Effects of a guideline-informed clinical decision support system intervention to improve colony stimulating factor prescribing: A Pragmatic Cluster-Randomized Trial. Ramsey S, Bansal S, Sullivan S, Lyman G, Barlow W, Arnold K, Watabayashi K, Bell-Brown A, Kreizenbeck K, Le-Lindqwister N, Dul C, Brown-Glaberman U, Behrens R, Vogel V, Alluri N, Hershman D. JAMA Network Open, accepted 2022.
- S1415CD A Pragmatic Cluster-Randomized Trial of a Standing Order Entry Intervention for Colony Stimulating Factor Use Among Patients at Intermediate Risk for Febrile Neutropenia. Hershman DL, Bansal A, Sullivan S, Lyman G, Barlow W, Arnold K, Watabayashi K, Bell-Brown A, Le-Lindquister N, Dul C, Brown-Glaberman U, Behrens R, Vogel V, Alluri N, Ramsey S. <u>Journal of Clinical Oncology</u>, accepted 2022.
- Multiple Studies Patterns of Scientific and Clinical Impact in Cancer Randomized Clinical Trials. Nghiem VT, Vaidya R, Unger JM. <u>JAMA Network Open</u> Jun 1;5(6):e2219657, 2022. https://pubmed.ncbi.nlm.nih.gov/35771578/
- Multiple Studies Trends in Obesity Prevalence Among Patients
 Registered to Cancer Clinical Treatment Trials. Vaidya R, Till C, Greenlee
 H, Hershman D, Unger J. JAMA Open Network, accepted 2022.

Submitted Manuscripts

S1204 Antiviral Therapy Use and Related Outcomes in Patients with Cancer and Viral Infections: Results from SWOG S1204. Hwang J, Arnold K, Unger J, Chugh R, Tincopa M, Loomba R, Hershman D, Ramsey S. Supportive Care in Cancer, revised and resubmitted 2022.

- <u>S1204</u> Prediction Model for Identifying Patients at Highest Risk of Hepatitis B Virus, Hepatitis C Virus, and HIV Infection Among Patients with Newly Diagnosed Cancer Enrolled in SWOG S1204. Unger JM, Till C, Hwang JP, Arnold KB, Hershman DL, Ramsey SD. <u>Journal of the National</u> Cancer Institute, submitted 2022.
- S14001 Novel Approaches for Dynamic Visualization of Adverse Event Data in Oncology Clinical Trials: A Case Study Using Immunotherapy Trial S1400-I (SWOG). Lee S, Fan W, Wang A, Vaidya R, Redman M, Gettinger S, Bazhenova L, Herbst R, Hershman D, Unger J. Pending submission to alternative journal, 2022. [see also Lung Committee]
- S1415CD An Evaluation of Stakeholder Engagement in Comparative Effectiveness Researcch: Lessons Learned from SWOG S1415CD. Bell-Brown A, Watabayashi K, Kreizenbeck K, Ramsey S, Bansal A, Barlow W, Lyman G, Hershman D, Mercurio AM, Segarra-Vazquez B, Kurttila F, Myers J, Golenski J, Johnson J, Erwin R, Walia G, Crawford J, Sullivan S. Journal of Comparative Effectiveness Research, submitted 2022.
- S1912CD A Randomized Trial Addressing Cancer-Related Financial Hardship through Delivery of a Proactive Financial Navigation Intervention (CREDIT) (SWOG S1912CD). Shankaran V, Unger J, Carlos R, Langer S, Darke A, Hershman D, Ramsey S. Trials, submitted 2022.
- Multiple Studies Population, Clinical, and Scientific Impact of National Cancer Institute's National Clinical Trials Network Treatment Studies.

 Unger J, LeBlanc M, Bertagnolli M, Wolmark N, Curran W, O'Dwyer P,
 Schnall M, Mannel R, Mandrekar S, Gray R, Zhao F, Bah M, Hong F, Vaidya R, Blanke C. <u>Journal of Clinical Oncology</u>, under revision for resubmission 2022.
- Multiple Studies The Medicaid Expansion of the Affordable Care Act and the Participation of Patients with Medicaid in Cancer Clinical Trials.

 Unger J, Xiao H, Vaidya R, LeBlanc M, Hershman DL. <u>Journal of Clinical Oncology</u>, submitted 2022.

CANCER SURVIVORSHIP COMMITTEE

Published/Accepted Manuscripts

C70807 Diet and Health-related Quality of Life Among Men on Active Surveillance for Early-Stage Prostate Cancer: The Men's Eating and Living (MEAL) Study (CALGB 70807 [Alliance]). Parsons JK, Zahrieh D, Patel D, Mohler J, Chen R, Paskett E, Liu H, Peil E, Rock C, Hahn O, Taylor J, Van Veldhuizen P, Small E, Morris M, Naughton M, Pierce J, Marshall J. European Urology Focus Apr 30;:S2405-4569(22)00061-X, 2022. https://pubmed.ncbi.nlm.nih.gov/35504836/ [See also GU and Prevention & Epidemiology Committees]



C89803 Diet- and Lifestyle-Based Prediction Models to Estimate Cancer Recurrence and Death in Stage III Colon Cancer Patients (Alliance). Cheng E, Ma C, Spiegelman D, Zhou X, Ou F, Niedzwiecki D, Mayer R, Whittom R, Hantel A, Benson A, Atienza D, Messino M, Kindler H, Giovannucci E, Van Blarigan E, Ng K, Gross C, Meyerhardt J, Fuchs C. <u>Journal of Clinical Oncology</u> Mar 1;40(7):740-751, 2022.

https://pubmed.ncbi.nlm.nih.gov/34995084/ [see also GI Committee]

C89803 Associations Between Unprocessed Red Meat and Processed Meat With Risk of Recurrence and Mortality in Patients With Stage III Colon Cancer. Van Blarigan E, Ou F, Bainter T, Fuchs C, Niedzwiecki D, Zhang S, Saltz L, Mayer R, Hantel A, Benson A, Atienza D, Messino M, Kindler H, Venook A, Ogino S, Sanoff H, Giovannucci E, Ng K, Meyerhardt J. JAMA Network Open Feb 1;5(2):e220145, 2022. https://pubmed.ncbi.nlm.nih.gov/35191970/ [see also Gl Committee]

C89803 Marital Status, Living Arrangement, and Cancer Recurrence and Survival in Patients with Stage III Colon Cancer: Findings from CALGB 89803 (Alliance). Lee S, Ma C, Zhang S, Ou F-S, Bainter T, Niedzwiecki D, Saltz L, Mayer R, Whittom R, Hantel A, Benson AB, Atienza D, Kindler H, Gross C, Irwin M, Meyerhardt J, Fuchs C. Oncologist Jun 8;27(6):e494-e505, 2022. https://pubmed.ncbi.nlm.nih.gov/35641198/ [see also Gl Committee]

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 Jun 1;26(3):283-292, 2022. https://pubmed.ncbi.nlm.nih.gov/35604741/

None Development of a measure of clinicians' self-efficacy for medical communication (SEMC). Feldman DB, O'Rourke MA, Corn BW, Hudson MF, Patel N, Agarwal R, Fraser VL, Deininger H, Fowler LA, Bakitas MA, Krouse RA, Subbiah IM. Support Palliat Care. 2022 May 9;. doi: 10.1136/bmjspcare-2022-003593. [Epub ahead of print]. https://pubmed.ncbi.nlm.nih.gov/35534186/

Submitted Manuscripts

S1316 A Novel Trial for Patients with Advanced Cancer: S1316
Prospective Comparative Effectiveness Trial for Malignant Bowel
Obstruction (SWOG S1316). Krouse R, Anderson G, Arnold K, Thomson C,
Nfonsam V, Al-kasspooles M, Walker J Sun V, Alvarez Secord A, Han E,
Leon-Takahashi A, Isla-Ortiz D, Rodgers P, Hendren S, Sanchez Salcedo
M, Laryea J, Graybill W, Flaherty D, Mogal H, Miner T, Pimiento J, Kitano
M, Badgwell B, Whalen G, Lamont J, Guevara O, Senthil M, Dewdney S,
Silberfein E, Wright J, Friday B, Fahy B, Anantha S, O'Rourke M, Bakitas
M, Sloan J, Grant M., Deutsch G, Deneve J. Journal of Clinical Oncology,
submitted 2022.

None Healthcare Professionals' Lay Definitions of Hope. Feldman D, Jazaieri H, O'Rourke M, Bakitas M, Krouse R, Deininger H, Hudson M, Corn B. Submitted to <u>Journal of Happiness Studies</u>, submitted 2022.

None Feasibility and Acceptability of an Online Intervention to Enhance Hopefulness Among Oncology Professionals. Feldman D, Jazaieri H, O'Rourke M, Bakitas M, Krouse R, Deininger H, Hudson M, Corn B. Submitted to BMJ Supportive and Palliative Care, submitted 2022.

PREVENTION AND EPIDEMIOLOGY COMMITTEE

Published/Accepted Manuscripts

Source Differential Biopsy Patterns Influence Associations Between Multivitamin Use and Prostate Cancer Risk in the Selenium and Vitamin E Cancer Prevention Trial. Schenk J, Till C, Neuhouser M, Goodman P, Lucia MS, Thompson IM, Tangen CM. Cancer Epidemiology, Biomarkers & Prevention, accepted 2022.

S0000/S9217 Large-scale integrated analysis of genetics and metabolomic data reveals potential links between lipids and colorectal cancer risk. Shu X, Chen Z, Long J, Guo X, Yang Y, Qu C, Ahn Y, Tangen C, Wu A, Peters U, Zheng W. Cancer Epidemiology, Biomarkers & Prevention Jun 1;31(6):1216-1226. 2022. https://pubmed.ncbi.nlm.nih.gov/35266989/

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. BMC Urology Mar 26;22(1):45. doi: 10.1186/s12894-022-00986-w, 2022. https://pubmed.ncbi.nlm.nih.gov/35351104/

Sound GWAS of Colorectal Cancer: Evidence of Interaction with Alcohol Consumption and Putative Causal Variant for the 10q24.2 Region. Jordahl K, Shcherbina A, Kim A, Su Y, Lin Y, Wang J, Albanes D, Platz E, Tangen C, Hsu L, Kundaje A, Peters U. Cancer Epidemiology,



Biomarkers & Prevention May 4;31(5):1077-1089, 2022. https://pubmed.ncbi.nlm.nih.gov/35438744/

<u>S0000/Other</u> A causal inference approach to the external validation of risk prediction models. Chen Y, Pfeiffer R, Shepherd B, Ankerst D. <u>Biometrical Journal</u>, accepted 2021.

S9217 Association of Serum Carotenoids and Retinoids with Intraprostatic Inflammation in Men without Prostate Cancer or Clinical Indication for Biopsy in the Placebo Arm of the Prostate Cancer Prevention Trial. Chadid S, Song X, Schenk J, Gurel B, Lucia MS, Thompson I, Jr., Neuhouser M, Goodman P, Parnes H, Lippman S, Nelson W, DeMarzo A, Platz E. Nutrition and Cancer 74(1):141-148, 2022. https://pubmed.ncbi.nlm.nih.gov/33511883/

S9217/Other Circulating free testosterone and risk of aggressive prostate cancer: prospective and Mendelian randomisation analyses in international consortia. Watts E, Perez-Cornago A, Fensom G, Smith-Byrne K, Noor A, Andrews C, Gunter M, Holmes M, Martin R, Tsilidis K, Albanes D, Goodman G, Platz E, Schenk J, Consortium Practical, Allen N, Key T, Travis R.International Journal of Cancer, Oct 1;151(7):1033-1046, 2022. https://pubmed.ncbi.nlm.nih.gov/35579976/

aggressive and early-onset prostate cancer: a collaborative analysis of 20 prospective studies and Mendelian randomization analysis. Watts EL, Perez-Cornago A, Fensom GK, Smith-Byrne K, Noor U, Andrews CD, Gunter MJ, Holmes MV, Martin RM, Tsilidis KK, Albanes D, Barricarte A, Bueno-de-Mesquita HB, Cohn BA, Deschasaux-Tanguy M, Dimou NL, Ferrucci L, Flicker L, Freedman ND, Giles GG, Giovannucci EL, Haiman CA, Hankey GJ, Holly JMP, Huang J, Huang WY, Hurwitz LM, Kaaks R, Kubo T, Le Marchand L, MacInnis RJ, Männistö S, Metter EJ, Mikami K, Mucci LA, Olsen AW, Ozasa K, Palli D, Penney KL, Platz EA, Pollak MN, Roobol MJ, Schaefer CA, Schenk JM, Stattin P, Tamakoshi A, Thysell E, Tsai CJ, Touvier M, Van Den Eeden SK, Weiderpass E, Weinstein SJ, Wilkens LR, Yeap BB; PRACTICAL Consortium, CRUK, BPC3, CAPS, PEGASUS, Allen NE, Key TJ, Travis RC. International Journal of Epidemiology Jun 21;dyac124. doi: 10.1093/ije/dyac124. Online ahead of print.

https://pubmed.ncbi.nlm.nih.gov/35726641/

S9217/Other Assessing the causal role of epigenetic clocks in the development of multiple cancers: a Mendelian randomization study. Morales Berstein F, McCartney DL, Lu AT, Tsilidis KK, Bouras E, Haycock P, Burrows K, Phipps AI, Buchanan DD, Cheng I; PRACTICAL consortium, Martin RM, Davey Smith G, Relton CL, Horvath S, Marioni RE, Richardson TG, Richmond RC. eLife Mar 29;11:e75374.

https://pubmed.ncbi.nlm.nih.gov/35346416/

S9217/Other Intake Patterns of Specific Alcoholic Beverages by Prostate Cancer Status. Lin HY, Tseng TS, Wang X, Fang Z, Zea AH, Wang L, Pow-Sang J, Tangen CM, Goodman PJ, Wolk A, Håkansson N, Kogevinas M, Llorca J, Brenner H, Schöttker B, Castelao JE, Gago-Dominguez M, Gamulin M, Lessel D, Claessens F, Joniau S, The Practical Consortium, Park JY. Cancers (Basel). 2022 Apr 14;14(8):1981. doi: 10.3390/cancers14081981. https://pubmed.ncbi.nlm.nih.gov/35454886/

C70807 Diet and Health-related Quality of Life Among Men on Active Surveillance for Early-Stage Prostate Cancer: The Men's Eating and Living (MEAL) Study (CALGB 70807 [Alliance]). Parsons JK, Zahrieh D, Patel D, Mohler J, Chen R, Paskett E, Liu H, Peil E, Rock C, Hahn O, Taylor J, Van Veldhuizen P, Small E, Morris M, Naughton M, Pierce J, Marshall J. European Urology Focus Apr 30;:S2405-4569(22)00061-X, 2022. [See also GU and Cancer Surviorship Committees] https://pubmed.ncbi.nlm.nih.gov/35504836/

Submitted Manuscripts

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

Multiple Studies* A prostate cancer susceptibility PSA variant that confers lower risk is also associated with more aggressive disease and poor survival. Srinivasan S, Kryza T, Bock N, Stephens C, Dong Y, Panchadsaram J, Moya L, Rohl J, Perry-Keene J, Buzacott K, Gago M, Schleutker J, Maier C, Muir K, Tangen C, Gronberg H, Pashayan N, Albanes D, Wolk A, Eles R, Clements J, Batra J. Cancer Discovery, under review.[*S0000, S9217, OTHER]

Symptom Control and Quality of Life Committee

Published/Accepted Manuscripts

(none this cycle)

Submitted Manuscripts

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

(none this cycle)

Submitted Manuscripts

(none this cycle)

EXECUTIVE COMMITTEE

Published/Accepted Manuscripts

(none this cycle)

Submitted Manuscripts

(none this cycle)

GASTROINTESTINAL COMMITTEE

Published/Accepted Manuscripts

Solve Adjuvant Chemoradiation in Patients with Lymph Node Positive Biliary Tract Cancers: A Secondary Analysis of SWOG S0809. Gholami S, Colby S, Horowitz D, Guthrie K, Ben-Josef E, El-Khoueiry A, Blanke CD, Philip P, Kachnic L, Ahmad S, Rocha F. Trial. Annals of Surgical Oncology, accepted 2022.

C89803 Associations Between Unprocessed Red Meat and Processed Meat With Risk of Recurrence and Mortality in Patients With Stage III Colon Cancer. Van Blarigan E, Ou F, Bainter T, Fuchs C, Niedzwiecki D, Zhang S, Saltz L, Mayer R, Hantel A, Benson A, Atienza D, Messino M, Kindler H, Venook A, Ogino S, Sanoff H, Giovannucci E, Ng K, Meyerhardt J. JAMA Network Open Feb 1;5(2):e220145, 2022.

https://pubmed.ncbi.nlm.nih.gov/35191970/ [see also Cancer Survivorship Committee]

C89803 Marital Status, Living Arrangement, and Cancer Recurrence and Survival in Patients with Stage III Colon Cancer: Findings from CALGB 89803 (Alliance). Lee S, Ma C, Zhang S, Ou F-S, Bainter T, Niedzwiecki D, Saltz L, Mayer R, Whittom R, Hantel A, Benson AB, Atienza D, Kindler H, Gross C, Irwin M, Meyerhardt J, Fuchs C. Oncologist Jun 8;27(6):e494-e505, 2022.

https://pubmed.ncbi.nlm.nih.gov/35641198/ [see also Cancer Survivorship Committee]

C89803 Diet- and Lifestyle-Based Prediction Models to Estimate Cancer Recurrence and Death in Stage III Colon Cancer Patients (Alliance).

Cheng E, Ma C, Spiegelman D, Zhou X, Ou F, Niedzwiecki D, Mayer R, Whittom R, Hantel A, Benson A, Atienza D, Messino M, Kindler H, Giovannucci E, Van Blarigan E, Ng K, Gross C, Meyerhardt J, Fuchs C. Journal of Clinical Oncology Mar 1;40(7):740-751, 2022.

https://pubmed.ncbi.nlm.nih.gov/34995084/ [see also Cancer Survivorship Committee]

C80405 Dietary fat in relation to all-cause mortality and cancer progression and death among people with metastatic colorectal cancer: data from CALGB 80405 (Alliance)/SWOG 80405, Van Blarigan EL, Ma C, Ou FS, Bainter TM, Venook AP, Ng K, Niedzwiecki D, Giovannucci E, Lenz HJ, Polite BN, Hochster HS, Goldberg RM, Mayer RJ, Blanke CD, O'Reilly EM, Ciombor KK, Meyerhardt JA. International Journal of Cancer Jul 29. doi: 10.1002/ijc.34230. Online ahead of print, 2022. https://pubmed.ncbi.nlm.nih.gov/35904874/

C80405 Tumor immunogenomic features determine outcomes in patients with metastatic colorectal cancer of CALGB/SWOG 80405 (Alliance) treated with standard-of-care combinations of bevacizumab and cetuximab. Innocenti F, Yazdani A, Rashid N, Qu X, Ou F-S, Van Buren S, Bertagnolli M, Kabbarah O, Blanke C, Venook A, Lenz H-J, Vincent B. Clinical Cancer Research Apr 14;28(8):1690-1700, 2022. https://pubmed.ncbi.nlm.nih.gov/35176136/

C80701 Everolimus with or without bevacizumab in advanced pNET:

CALGB 80701 (Alliance). Kulke M, Ou F-S, Niedwiecki D, Heubner L,

Kunz P, Kennecke H, Wolin E, Chan J, O'Reilly E, Meyerhardt J, Venook A.

Endocrine Related Cancer May 9;29(6):335-344, 2022.

https://pubmed.ncbi.nlm.nih.gov/35324465/

Submitted Manuscripts

No.147 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 (No.147 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. <u>Journal of Patient Reported Outcomes</u>, under review. [see also SCQOL Cmte]

GENITOURINARY COMMITTEE

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

Published/Accepted Manuscripts

- S0337 Risk-Based Assessment Of the Impact Of Intravesical Therapy on Recurrence-Free Survival Rate Following Resection of Suspected Low-grade, Non-muscle-invasive Bladder Cancer (NMIBC): A Southwest Oncology Groups (SWOG) S0337 Posthoc Analysis. Corsi N, Messing E, Sood A, Keeley J, Bronchema C, Rakic N, Jamil M, Dalela D, Arora S, Piontkowski A, Majdalany S, Butaney M, Rakic I, Li P, Menon M, Rogers C, Abdollah F. Clinical Genitourinary Cancer Jun 25;:S1558-7673(22)00140-9, 2022. https://pubmed.ncbi.nlm.nih.gov/35871040/
- <u>S0337</u> Paper Alert: Implementing a New Standard of Care [Commentary]. Messing E. <u>Bladder Cancer</u>, accepted 2022.
- S1216 Orteronel for Metastatic Hormone-Sensitive Prostate Cancer: A Multicenter, Randomized, Open-Label Phase III Trial (SWOG-1216). 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 Dl. <u>Journal of Clinical Oncology</u> Apr 21;JCO2102517. doi: 10.1200/ JCO.21.02517. Online ahead of print, 2022. https://pubmed.ncbi.nlm.nih.gov/35446628/
- S1314 Using Cell Lines To Guide Neoadjuvant Therapy in Bladder Cancer COXEN and SWOG S1314. Dancik G, Theodorescu D. <u>European Urology Focus</u> Mar 23;S2405-4569(22)00067-0, 2022. https://pubmed.ncbi.nlm.nih.gov/35339415/
- <u>S1931</u> "PROBE"ing the Role of Cytoreductive Nephrectomy in Advanced Renal Cancer. Bell H, Cotta BH, Salami SS, Kim H, Vaishampayan U. <u>Kidney</u> <u>Cancer Journal</u> Mar 15;6(1):3-9. doi: 10.3233/kca-210010, 2022. https://pubmed.ncbi.nlm.nih.gov/35310961/
- C70807 Diet and Health-related Quality of Life Among Men on Active Surveillance for Early-Stage Prostate Cancer: The Men's Eating and Living (MEAL) Study (CALGB 70807 [Alliance]). Parsons JK, Zahrieh D, Patel D, Mohler J, Chen R, Paskett E, Liu H, Peil E, Rock C, Hahn O, Taylor J, Van Veldhuizen P, Small E, Morris M, Naughton M, Pierce J, Marshall J. European Urology Focus Apr 30;:S2405-4569(22)00061-X, 2022. [See also Cancer Surviorship and Prevention & Epidemiology Committees] https://pubmed.ncbi.nlm.nih.gov/35504836/

- Association between baseline body mass index and survival in men with metastatic hormone-sensitive prostate cancer: ECOG-ACRIN CHAARTED E3805. Morgans A, Chen Y, Jarrard D, Carducci M, Liu G, Eisenberger M, Plimack E, Bryce A, Garcia J, Dreicer R, Vogelzang N, Picus J, Shevin D, Hussain M, DiPaola R, Cella D, Sweeney C. Prostate Sep;82(12):1176-1185, 2022. https://pubmed.ncbi.nlm.nih.gov/35538398/
- None Bangs R, Lynn J, Obot E, Osborne S, Norris K. Improving Patient Advocacy in NCI Scientific Steering Committees and Task Forces. <u>Journal of the National Cancer Institute</u>, Aug 8;114(8):1059-1064.2022. https://pubmed.ncbi.nlm.nih.gov/35552713/
- None Checklist for Improving Patient Communication on Bladder Preservation Options: The Patient Advocate Perspective. Bangs R, Quale DZ, Reed T. <u>Clinical Oncology</u>. https://pubmed.ncbi.nlm.nih.gov/36057507/

Submitted Manuscripts

- Bone biomarkers and subsequent survival in men with hormone sensitive prostate cancer. Lara P, Mayerson E, Gertz E, Tangen C, Goldkorn A, Van Loan M, Hussain M, Gupta S, Zhang J, Parikh M, Twardowski P, Quinn D, Vogelzang N, Thompson I, Agarwal N. <u>Clinical Cancer Research</u>, revised/resubmitted, 2022.
- S1314 A randomized phase II study of co-expression extrapolation (COXEN) with neoadjuvant chemotherapy for localized, muscleinvasive bladder cancer with overall survival follow up (SWOG S1314; NCT02177695). Flaig TW, Tangen CM, Daneshmand S, Alva AS, Lucia MS, McConkey, Dan Theodorescu,6 Amir Goldkorn,7 Matthew I. Milowsky,8 Rick Bangs,9 Gary R. MacVicar,10 DJ, Bastos BR, Fowles JS, Gustafson DL, Plets M, Thompson IM, Jr, Lerner. SP <u>Journal of Clinical Oncology</u>, submitted 2022.
- 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

C10403 Disparities in trial enrollment and outcomes of Hispanic adolescent and young adult acute lymphoblastic leukemia. Muffly L, Yin J, Jacobson S, Wall A, Quiroz E, Advani A, Luger S, Tallman M, Litzow M, Foster M, Appelbaum F, Erba H, Larson R, Keegan T, Stock W. Blood



Advances Jul 26;6(14):4085-4092, 2022. https://pubmed.ncbi.nlm.nih.gov/35838753/

Long-term outcomes for ibrutinib-rituximab and chemoimmunotherapy in CLL: updated results of the E1912 trial. Shanafelt TD, Wang XV, Hanson CA, Paietta EM, O'Brien S, Barrientos J, Jelinek DF, Braggio E, Leis JF, Zhang CC, Coutre SE, Barr PM, Cashen AF, Mato AR, Singh AK, Mullane MP, Little RF, Erba H, Stone RM, Litzow M, Tallman M, Kay NE. Blood. 2022 Jul 14;140(2):112-120. https://pubmed.ncbi.nlm.nih.gov/35427411/

Multiple Studies* Improved outcomes with 7+3 induction chemotherapy for acute myeloid leukemia over the past four decades: Analysis of SWOG trial data. Othus M, Garcia-Manero G, Godwin J, Weick J, Appelbaum F, Erba H, Estey E. Haematologica Jun 14;14(12):2934, 2022. [*S0106,S1203,S8600,S9031] https://pubmed.ncbi.nlm.nih.gov/35833298/

Submitted Manuscripts

Dasatinib and Blinatumomab for Ph+ or Ph-Like Acute Lymphoblastic Leukemia [Letter]. Advani A, Moseley A, O'Dwyer K, Wood B, Park J, Wieduwilt M, Jeyakumar D, Yaghmour G, Attalah E, Gerds A, O'Brien S, Liesveld J, Othus M, Litzow M, Stone R, Sharon E, Erba H. Blood Advances, revised/resubmitted 2022.

A Randomized Phase II/III Study Of Novel Therapeutics versus Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia (AML), High-Risk Myelodysplastic Syndrome (MDS) or Chronic Myelomonocytic Leukemia (CMML), Age 60 or Older: A Report of the Comparison of Azacitidine and Nivolumab to Azacitidine: SWOG S1612. Assouline S, Michaelis L, Othus M, Hay A, Walter R, Jacoby M, Schroeder M, Uy G, Law L, Cheema F, Sweet K, Asch A, Liu J, Moseley A, Maher T, Kingsbury L, Fang M, Radich J, Little R, Erba H. Leukemia and Lymphoma, under revision for resubmission 2022.

Multiple Studies* Identification and Validation of Novel Prognostic Transcript Biomarkers in CD34-Positive Blasts from Patients with AML: A SWOG Report. Pogosova-Agadjanyan E, Hua X, Othus M, Appelbaum F, Chauncey T, Erba H, Fitzgibbon M, Godwin J, Jenkins I, Fang M, Moseley A, Naru J, Radich J, Willborg B, Willman C, Wu F, Meshichi S, Stirewalt D. Leukemia, submitted 2022. [*S0106,S0112,S9031,S9333]

Multiple Studies* Long Non-coding RNA Expression Independently Predicts Outcome in Pediatric AcuteMyeloid Leukemia. Ferrar J, Smith J, Othus M, Huang B, Wang Y, Ries R, Hylkema T, Pogosova-Agadjanyan E, Leonti A, Shaw T, Triche T, Gamis A, Aplenc R, Kolb E, Ma X, Stirewalt D, Alonzo T, Meshinchi S.Journal of Clinical Oncology, submitted 2022. [*S0106,S0112,S9031,S9333,OTHER]

LUNG COMMITTEE

Published/Accepted Manuscripts

<u>\$14001</u> Nivolumab Plus Ipilimumab for Previously Treated Stage IV Squamous Cell Lung Cancer-Reply. Gettinger S, Redman M, Herbst R. JAMA Oncology Apr 1;8(4):1, 2022.

https://pubmed.ncbi.nlm.nih.gov/35142793/

S1403 Circulating tumor DNA (ctDNA) kinetics predict progression-free and overall survival in EGFR TKI-treated patients with EGFR-mutant NSCLC (SWOG S1403). Mack P, Miao J, Redman M, Moon J, Goldberg S, Herbst R, Melnick M, Walther Z, Hirsch F, Politi K, Kelly K, Gandara D. Clinical Cancer Research Jun 17; clincanres. CCR-22-0741-A. 2022-3-8 14:09:41.447. doi:10.1158/1078-0432.CCR-22-0741. Online ahead of print., 2022. https://pubmed.ncbi.nlm.nih.gov/35713632/

S1800A Phase II Randomized Study of Ramucirumab and Pembrolizumab Versus Standard of Care in Advanced Non-Small Cell Lung Cancer Previously Treated with Immunotherapy: Lung-MAP S1800A. Rekcamp K, Redman M, Dragnev K, Villaruz L, Faller B, Al Baghdadi T, Hines S, Everhart L, Highleyman L, Minichiello K, Papadimitrakopoulou V, Neal J, Wagar S, Patel J, Gray J, Gandara D, Kelly K, Herbst R. Journal of Clinical Oncology Jul 20;40(21):2295-2306, 2022. https://pubmed.ncbi.nlm.nih.gov/35658002/

A082002 Alliance 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. Schild S, Wang X, Bestvina C, Williams T, Masters G, Singh A, Stinchcombe T, Salama J, Wolf S, Zemla T, Duma N, Chun S, Amini A, Kozono D, Watt C. Clinical Lung Cancer Apr 30;S1525-7304(22)00065-1. doi: 10.1016/j.cllc.2022.04.004. Online ahead of print., 2022.

https://pubmed.ncbi.nlm.nih.gov/35613998/

A151216 Rates of Guideline-Concordant Surgery and Adjuvant Chemotherapy Among Patients With Early-Stage Lung Cancer in the US ALCHEMIST Study (Alliance A151216). Kehl KL, Zahrieh D, Yang P, Hillman SL, Tan AD, Sands JM, Oxnard GR, Gillaspie EA, Wigle D, Malik S, Stinchcombe TE, Ramalingam SS, Kelly K, Govindan R, Mandrekar SJ, Osarogiagbon RU, Kozono D. JAMA Oncology May 1;8(5):717-728, 2022. https://pubmed.ncbi.nlm.nih.gov/35297944/

Multiple Studies* Lung-MAP: A Collaborative Roadmap to Improve Cancer Outcomes [Editorial]. Leal T, Dahlberg S, Ramalingam S. <u>Journal</u> of Clinical Oncology Jun 3;JCO2201035. doi: 10.1200/JCO.22.01035, 2022. [*S1400, S1800A] https://pubmed.ncbi.nlm.nih.gov/35658027/



Submitted Manuscripts

<u>S1400I</u> Lee S, Fan W, Wang A, Vaidya R, Redman M, Gettinger S, Bazhenova L, Herbst R, Hershman D, Unger J. Novel Approaches for Dynamic Visualization of Adverse Event Data in Oncology Clinical Trials: A Case Study Using Immunotherapy Trial S1400-I (SWOG). Pending submission to alternative journal, 2022. [see also CCD Committee]

LYMPHOMA COMMITTEE

Published/Accepted Manuscripts

Multiple Studeis* Relevance of bone marrow biopsies for response assessment in U.S. National Cancer Institute National Clinical Trials Network follicular lymphoma clinical trials. Rutherford S, Yin J, Pederson L, Perez Burbano G, LaPlant P, Shadman M, Li H, LeBlanc M, Kenkre V, Hong F, Blum K, Dockter T, Martin P, Jung S, Grant B, Rosenbaum C, Ujjani C, Barr P, Unger J, Cheson B, Bartlett N, Kahl B, Friedberg JW, Mandrekar S, Leonard J. Journal of Clinical Oncology, Jul 5:JCO2102301. doi: 10.1200/JCO.21.02301. Online ahead of print.2022. [*CALGB,S0016,S0801] https://pubmed.ncbi.nlm.nih.gov/35787017/

Multiple Studies* Extranodal presentation in limited stage DLBCL as a prognostic marker in three SWOG trials S0014, S0313 and S1001 [Letter to Editor]. Stephens D, Li H, Constine L, Fitzgerald T, Leonard J, Kahl B, LeBlanc M, Smith S, Friedberg JW, Persky D. Haematologica Jul 14. doi: 10.3324/haematol.2022.281004. Online ahead of print., 2022. [*S0014,S0313,S1001] https://pubmed.ncbi.nlm.nih.gov/35833300/

Submitted Manuscripts

(none this cycle)

MELANOMA COMMITTEE

Published/Accepted Manuscripts

<u>S1404</u> Adjuvant pembrolizumab improves quality-of-life outcomes compared to high dose interferon or ipilimumab in patients with resected melanoma; SWOG S1404, A Randomized Clinical Trial Unger J, Darke A, Othus M, Tarhini A, Kirkwood J, Sharon E, Sondak V, Guild S, Truong T, Eroglu Z, Kendra K, Lewis K, Faller B, Funchain P, Buchbinder E, Grossmann K, Ribas A, Patel S. <u>JAMA Oncology</u>, accepted 2022.[see also CCD Committee]

Submitted Manuscripts

S0826 SWOG S0826: A phase II trial of SCH 727965 (NSC727135, dinaciclib) in patients with stage IV melanoma. Lao CD, Moon J, Fruehauf JP, Flaherty LE, Bury MJ, Ribas A, Sondak V. <u>BMC Cancer</u>, pending resubmission, Melanoma management, 2022.

S1404 Adjuvant pembrolizumab improves quality-of-life outcomes compared to high dose interferon or ipilimumab in patients with resected melanoma; SWOG S1404, A Randomized Clinical Trial Unger J, Darke A, Othus M, Tarhini A, Kirkwood J, Sharon E, Sondak V, Guild S, Truong T, Eroglu Z, Kendra K, Lewis K, Faller B, Funchain P, Buchbinder E, Grossmann K, Ribas A, Patel S. JAMA Oncology, accepted 2022.[see also CCD Committee]

PHARMACEUTICAL SCIENCES COMMITTEE

Published/Accepted Manuscripts

None Survey of US Medical Oncologists: Practices and Beliefs regarding DPYD Testing Prior to Fluoropyrimidine Chemotherapy.

Koo K, Pasternak A, Henry NL, Sahai V, Hertz D. Journal of Oncology Practice Jun;18(6):e958-e965, 2022.

https://pubmed.ncbi.nlm.nih.gov/35239419/

Submitted Manuscripts

(none this cycle)







