

Wall-to-Wall Opportunities in Chicago

There's always a flurry of activity before our group meetings, and a packed schedule during, but it felt like there was even more activity than usual in the recent lead-up. So, I counted up the sessions on our schedule. Almost 90-a record, I think.

Most will have virtual attendance options. Please check our meeting app or meeting website for Zoom links.

We'll have several trial kickoffs, including one on Saturday for myeloMATCH and a Friday Lung-MAP Update Forum to launch the third generation of that landmark study: Lung-MAP 3.0, which allows a wide array of next-generation sequencing platforms. And while it's not an actual kick off, we'll also get an update on our ImmunoMATCH study at the translational medicine plenary (Plenary I) on Thursday.

Plenary II, our general plenary, will explore new routes to wrestling meaning out of data and will include presentations on artificial intelligence and on several important SWOG initiatives aimed at better tracking and imparting operational and scientific data. We'll also host a ctDNA symposium with presentations on half a dozen leading platforms, with opportunities for one-on-one discussions with platform experts.

As we go to press with this agenda book,we're eagerly awaiting the NCI's request-for-applications for its next round of NCTN core support grants. Release of that request is expected shortly, and we'll cap off our fall meeting with a grant planning mini-retreat that brings



together a small core team to review the RFA and plot out a work plan.

Finally, both at and between sessions in Chicago, you'll notice more than a few reminders to complete your SWOG member profile, including a prominent leaderboard that will track participation by committee. To boost the standing of your committee (or committees), go to swogdei.crab.org and submit your profile information. You can do it right now.

Hosting ninety sessions equates to lots to learn! I'm really looking forward to spending many of those together.

Charles D. Blanke, MD

SWOG Chair



Group Meeting Index

Chair's Welcome Message	2
Schedule of Events	4-6
Top Accruers & Top Performing Sites	7-8
Plenary Sessions	9
Meeting Sponsors	10
Take Action Symposium	11
myeloMATCH Kickoff	12
Lung-MAP 3.0 Update Forum	13
S2312 Kickoff	14
S2418 Pre-Launch	15
GU Symposium: Art of Patient Enrollment	16
NCORP Research Base Clinical Trials Workshop	17
Funding & Career Development Opportunities	18
Group Meeting App	20
SWOG Clinical Trials Partnerships (CTP) Update Forum	21
Community Matters & SWOG Member Profiles	22-23
CME Credit Information	24-25
SWOG Administrative and Research Support Committees	26
Future Meeting Dates	26
Adolescent and Young Adults Committee	27
Bone Marrow & Stem Cell Transplantation Committee	28
Digital Engagement Committee	29
Pharmaceutical Sciences and Drug Information Joint Meetir	ng 30
Surgery Committee	31
SWOG Latin America Initiative Symposium	32
VA Committee	33-34
Committee Agendas and Accrual Reports	
Barlogie-Salmon Myeloma Committee	35-38
Breast Committee	39-43
Cancer Control & Prevention Committee Leadership	44-45
Cancer Care Delivery Committee	46-48
Early Therapeutics & Rare Cancers Committee	60-64
Gastrointestinal Committee	65-74
Genitourinary Committee	75-82
Immunotherapeutics Committee	83-84
Leukemia Committee	85-87
	88-95
Lung Committee	
Lymphoma Committee	96-99
Melanoma Committee	100-102
Palliative Care Committee	49-50
Prevention, Screening, and Surveillance Committee	51-53
Radiation Oncology Committee	103
Symptom Management and Survivorship Committee	54-59
SWOG Publications	104-111

CHICAGO 2024

GROUP MEETING REGISTRATION & INFORMATION DESK

FALL PROGRAM-AT-A-GLANCE

REGENCY FOYER, BALLROOM LEVEL, WEST TOWER



WEDNESDAY-FRIDAY
7:00 AM - 5:00 PM
SATURDAY
7:00 AM - 11:00 AM
GO TO THE MEETING
APP ONLINE
SWOG.ORG/MEETINGAPPF24

THE HOPE FOUNDATION INFORMATION DESK:

THURSDAY - FRIDAY 8:00 AM - 5:00 PM
SATURDAY 8:00 AM - 11:00 AM

EXHIBITS & COFFEE SERVICE:
TORONTO, BALLROOM LEVEL, WEST TOWER
THURSDAY - FRIDAY 8:00 AM - 5:00 PM

WEDNESDAY, OCTOBER 16, 2024

		MEETING ROOM/LEVEL
8:30 AM-9:30 AM	ORP Liaison Subcommittee (Invitation Only)	SOLDIER FIELD
8:30 AM-11:30 AM	Advocates Committee (Invitation Only)	TORONTO
9:30 AM-10:30 AM	Quality Initiative Meeting (Invitation Only)	ACAPULCO =
10:00 AM-10:30 AM	NCORP Workshop Check-In	REGENCY D FOYER
10:30 AM-2:30 PM	SWOG NCORP Research Base Clinical Trials Workshop	REGENCY D
12:30 PM-2:00 PM	Core Office Staff Meeting (Invitation Only)	ACAPULCO
12:30 PM-2:15 PM	Nursing Research Subcommittee (Invitation Only)	GOLD COAST ■
12:30 PM-2:30 PM	Digital Engagement Committee	WATER TOWER

FALL 2024 PROGRAM-AT-A-GLANCE

2:00 PM-3:30 PM	SWOG Tissue Banking Meeting (Invitation Only)	SOLDIER FIELD
2:30 PM-4:30 PM	VA Committee Working Group (Invitation Only)	SAN FRANCISCO
2:30 PM-4:30 PM	Take Action Symposium	REGENCY A
3:00 PM-4:30 PM	CNS Working Group	COMISKEY
3:30 PM-4:30 PM	ORP Oishi/Open Forum Working Meeting (Invitation Only)	SOLDIER FIELD
3:30 PM-5:00 PM	Hope Foundation Board Meeting (Brd Mmbrs Only)	GOLD COAST
4:30 PM-5:30 PM	Clinical Trials Partnerships Update Forum	REGENCY D
5:30 PM-7:30 PM	Site Operations	REGENCY A
5:30 PM-8:00 PM	NCORP Research Base Executive Committee (Invitation Only)	ACAPULCO

THURSDAY, OCTOBER 17, 2024

7:30 AM-8:00 AM	Jeri & Noboru Oishi Symposium Check-In	REGENCY B FOYER
7:30 AM-8:30 AM	Clinical Trials Partnerships Scientific Advisory Board (Invitation Only)	SOLDIER FIELD
7:30 AM-9:30 AM	Lung-MAP Administrative Meeting (Invitation Only)	ACAPULCO =
7:30 AM-9:30 AM	GU Symposium: The Art of Patient Enrollment	CRYSTAL A
8:00 AM-10:00 AM	Prevention, Screening, and Surveillance Committee	REGENCY A
8:00 AM-11:00 AM	Jeri & Noboru Oishi Symposium	REGENCY B
8:30 AM-10:00 AM	ctDNA Symposium	REGENCY C
10:00 AM-12:00 PM	Early Therapeutics and Rare Cancers Committee	CRYSTAL C
10:00 AM-3:30 PM	GU Working Group (Invitation Only)	REGENCY D
10:15 AM-12:15 PM	Lung-MAP Site Coordinators Committee (Invitation Only)	ACAPULCO =
10:15 AM-12:45 PM	Breast TM Working Group (Invitation Only)	COMISKEY



CHICAGO 2024

FALL 2024 PROGRAM-AT-A-GLANCE

10:30 AM-12:30 PM SWOG Latin America Initiative Symposium 10:30 AM-12:30 PM Cancer Care Delivery Committee 10:45 AM-12:45 PM Immunotherapeutics Committee 11:00 AM-12:00 PM SR2204: Perioperative Physical Activity Study Meeting 12:30 PM-2:00 PM ORP Open Forum CRYSTAL B 12:30 PM-2:30 PM Sarcoma Working Group of the ETxRC Committee 1:00 PM-3:00 PM Breast Working Group (Invitation Only) 1:15 PM-3:15 PM Myeloma Working Group (Invitation Only) 1:30 PM-3:30 PM S2418 Pre-Launch WATER TOWER 2:00 PM-3:00 PM Lung Community Engagement Subcmte (Invitation Only) 2:30 PM-3:00 PM Thoracic Neuroendocrine Subcommittee (Invitation Only) 2:30 PM-3:30 PM Plenary Reception (Light Hors D'oeuvres)
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Engagement Subcmte (Invitation Only) 2:30 PM-3:00 PM Thoracic Neuroendocrine Subcommittee (Invitation Only) 2:30 PM-3:30 PM Plenary Reception (Light REGENCY FOYER
Subcommittee (Invitation Only) 2:30 PM-3:30 PM Plenary Reception (Light REGENCY FOYER
3:30 PM−5:00 PM APP Task Force GOLD COAST ■ (Invitation Only)
3:30 PM−5:00 PM Plenary I: Translational REGENCY BC Medicine
3:45 PM−4:25 PM DEI Leadership Council SOLDIER FIELD (Invitation Only)
4:25 PM−4:45 PM DEI Leadership Council SOLDIER FIELD ■ Open Forum (all welcome)
5:15 PM-7:15 PM Palliative Care Committee REGENCY A
5:15 PM-7:15 PM Leukemia Working Group ACAPULCO (Invitation Only)
5:15 PM-7:15 PM Lung Working Group COMISKEY (Invitation Only)
7:00 PM-9:00 PM Breast Committee Social ROOSEVELT 3AB RAST TOWER

FRIDAY, OCTOBER 18, 2024

	RIDAI, OCTOBER 18, 2024	'
7:00 AM-9:00 AM	Imaging Committee (Invitation Only)	SOLDIER FIELD
7:30 AM-9:00 AM	Professional Review Committee (Invitation Only)	SAN FRANCISCO
7:30 AM-9:00 AM	Lung Radiation/Surgery Subcommittee (Invitation Only)	ACAPULCO 🚾
7:30 AM-9:30 AM	SWOG Data and Safety Monitoring Committee (Invitation Only)	GOLD COAST
7:30 AM-9:30 AM	Symptom Management and Survivorship Committee	CRYSTAL A
7:30 AM-9:30 AM	Barlogie-Salmon Myeloma Committee	WATER TOWER -
7:45 AM-8:45 AM	GI Translational Research Subcommittee (Invitation Only)	COMISKEY
8:00 AM-9:00 AM	S2312 Kick Off Meeting	CRYSTAL C
8:30 AM-11:30 AM	Breast Committee	REGENCY A
9:00 AM-12:00 PM	Gl Working Group (Invitation Only)	COMISKEY
9:30 AM-11:00 AM	Quality Assurance Committee (Invitation Only)	SAN FRANCISCO
9:30 AM-11:00 AM	Lung Metastatic Subcmte (Invitation Only)	SOLDIER FIELD
9:30 AM-12:00 PM	GU Committee	REGENCY D
9:45 AM-11:45 AM	Melanoma Working Group (Invitation Only)	PLAZA A E EAST TOWER
9:45 AM-11:45 AM	Leukemia Committee	CRYSTAL C
10:00 AM-12:00 PM	Pharmaceutical Sciences Committee and Drug Information Subcommittee	ACAPULCO
10:15 AM-11:45 AM	Lung-MAP Update Meeting	CRYSTAL A
11:00 AM-12:00 PM	Plenary Reception (Light Hors D'oeuvres)	REGENCY FOYER
11:30 AM-12:00 PM	Publications Committee (Invitation Only)	GOLD COAST
12:00 PM-2:00 PM	Plenary II: General	REGENCY BC
2:15 PM-3:15 PM	NCORP/MU-NCORP Site PI Meeting	CRYSTAL A



FRIDAY, OCTOBER 18, 2024

2:15 PM-4:15 PM	Radiation Oncology Committee	PLAZA A EAST TOWER
2:15 PM-4:15 PM	Melanoma Committee	CRYSTAL C
2:30 PM-4:15 PM	Bone Marrow & Stem Cell Transplantation Committee	COMISKEY
3:00 PM-6:00 PM	Lung Committee	REGENCY A
3:30 PM-4:30 PM	ORP Executive Committee (Invitation Only)	SAN FRANCISCO
4:00 PM-6:00 PM	Adolescent and Young Adult (AYA) Committee	WATER TOWER
4:30 PM-6:30 PM	GI Committee	REGENCY D
4:30 PM-6:30 PM	Lymphoma Working Group (Invitation Only)	ACAPULCO
6:00 PM-7:00 PM	Executive Reception (Invitation Only)	
6:45 PM-8:30 PM	Group Reception	CRYSTAL BALLROOM

We've Supported **SWOG** for a Generation.

Let's Make a Plan for the Next.

You can plant a seed for future generations of cancer researchers when you leave a gift in your will for The Hope Foundation.



SCAN THE QR CODE TO LEARN MORE

THE HOPE
FOUNDATION
FOR CANCER RESEARCH

SATURDAY, OCTOBER 19, 2024

7:00 AM-7:45 AM	Board of Governors (Board Members Only)	REGENCY A
8:00 AM-9:00 AM	Committee Chairs (Committee Chairs Only)	REGENCY A
9:00 AM – 10:00 AM	myeloMATCH – Investigators/ NCI Staff (Closed Session)	REGENCY D
9:15 AM-11:15 AM	Surgery Committee	COMISKEY
9:30 AM-11:30 AM	VA Committee	WATER TOWER
9:30 AM-11:30 AM	Lymphoma Committee	REGENCY A
9:30 AM-3:30 PM	Grant Retreat (Invitation Only)	SOLDIER FIELD
10:00 AM-12:00 PM	myeloMATCH Kick-Off Meeting (Open Session)	REGENCY D



Complete your SWOG member profile
Help your committee win a prize!



SWOGDEI. CRAB.ORG



Our Top Accruers

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

SWOG-Credited Registrations to SWOG Managed Trials January 1 through June 30, 2024. We appreciate their hard work and their confidence in our research.



- Moffitt Cancer Center
- University of Texas Health Science Center at San Antonio
- Instituto Nacional De Cancerologia de Mexico
 - Northwestern University LAPS
 - University of Arkansas for Medical Sciences



- Heartland Cancer Research NCORP
- Southeast Clinical Oncology Research Consortium NCORP
- Kaiser Permanente NCI Community
 Oncology Research Program
- Michigan Cancer Research Consortium NCORP
 - Cancer Research of Wisconsin and Northern Michigan Consortium
 - University of Kansas Cancer Center -MCA Rural MU NCORP









Our Top Performing Sites

To help our data management sites track their performance relative to that of others, we have developed a new metric based on the quality and timeliness of data and biospecimen submissions. Data management institutions with at least 10 SWOG accruals in the prior 13 months are scored on this scale.

The members below are SWOG's top-performing sites for the period of January 2024 – July 2024.



- Universidad de la Republica Facultad de Medicina
- University of Arkansas for Medical Sciences
- Sutter Cancer Research Consortium
- Lahey Hospital and Medical Center
- Ascension Providence Hospitals -Southfield
- Case Western Reserve University
- Rhode Island Hospital
- Baylor College of Medicine/Dan L
 Duncan Comprehensive Cancer Center
- The Don and Sybil Harrington Cancer Center
- STCC at DHR Health Institute for Research and Development



- Baptist Memorial Health Care/ Mid South Minority Underserved NCORP
- Carle Cancer Center NCI Community Oncology Research Program
- Columbus NCI Community Oncology Research Program
- Georgia Cares Minority Underserved NCORP
- University of Kansas Cancer Center -MCA Rural MU NCORP
- Michigan Cancer Research Consortium NCORP



Plenary I Translational Medicine Thursday, October 17 • 3:30 – 5 pm CT Regency BC (Ballroom Level)



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



SEED or Soil in Bladder Cancer: The Hope of Dissecting Mechanisms of Response to Immunotherapy Joshua J. Meeks, MD, PhD Feinberg School of Medicine

The SWOG Immunotherapy Committee and an Update on the iMatch Pilot Study



Katerina Politi, PhD
Yale Cancer Center
&
Siwen Hu-Lieskovan,
MD, PhD
Huntsman Cancer Institute



No More Dancing in the Dark: Risk Refining Clinical Trial Designs with ctDNA-Informed Approaches Van K. Morris, MD MD Anderson Cancer Center

Attendees can earn Continuing Medical Education (CME) credits

Plenary II

Transforming Information into Insight: Solutions and Opportunities in Clinical Oncology Research *Friday, October 18 • 12 – 2 pm CT*

Regency BC (Ballroom Level)



Chair's welcome and update
- Charles D. Blanke, MD
SWOG Group Chair
Professor, Knight Cancer Institute, Oregon Health &
Science University



Artificial intelligence: Landscape of opportunity in oncology research

- Arturo Loaiza-Bonilla, MD, MSEd

Co-Founder & Chief Medical Officer, Massive Bio
Chair of Research, Capital Health



Mapping our past to our future: SWOG's key performance data dashboards

Nathan Eriksen SWOG Chief of Administration



Advancing data collection and management: Streamlining initiatives, EHR to electronic data capture, and the promise of AI data assistance

Michael LeBlanc, PhD SWOG Group Statistician Director, SWOG Statistical and Data Management Center Professor, Fred Hutch Cancer Center



TEFCA network access across EHR systems: Opportunities for clinical oncology research

-Stephen J. Konya III
Senior Advisor to Deputy National Coordinator and
Innovation Portfolio Lead,
Office of National Coordinator for Health Information
Technology, HHS

Q & A with presenters



Thank You to our Meeting Sponsors!

We are grateful to these partners for contributing to the success of the 2024 SWOG group meetings

Continuing Medical Education Supporters

Lilly Novartis Pfizer Janssen

Fall 2024 Exhibitors

Agendia | Camp Mak-a-Dream Caris Life Sciences Foundation Medicine Guardant Health Haystack Oncology | IROC Natera | nCoup Syndax | Tempus

TAKE ACTION SYMPOSIUM:

Diversity Plan in Action: Ensuring Equity in Clinical Research

Presented by SWOG Recruitment & Retention Committee

WEDNESDAY, OCTOBER 16 • 2:30-4:30 PM CT • REGENCY A (BALLROOM LEVEL)

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

OBJECTIVES:

- **1.** Understanding FDA diversity plans to improve enrollment of participants from underrepresented racial and ethnic populations
 - 2. Pragmatic approaches for clinical trial design
 - 3. Intentionality in recruitment plans

MODERATOR AND SPEAKER/PANELIST OUTLINE

5 min RRC Update



Allison Caban-Holt, PhD

10 min Introduction: Take Action Series: Speakers & Panelist



Allison Caban-Holt, PhD



Jamie Sundstrom

20 min Elements of Diversity Draft Guidance



Jessica McDermott, MD

25 min

Unlocking Insight: Where Every Voice Shapes the Knowledge We Share!



Audience Participation

15 min
Trial Design:
Engagement
Matters!



David Gandara, MD

15 min
Trial Design:
Pragmatic
Approach



Paul Hesketh, MD

15 min Recruitment Plan: Take Action!



Lucy Gansauer, MSN, RN, OCN, CCRP

<u>10 min</u>

Q & A All Speakers & Panelists



<u>5 min</u>

Wrap-Up

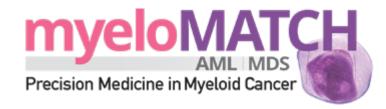


myeloMATCH Kickoff

NCI's precision medicine umbrella trial in myeloid malignancies

(The open kickoff session will be preceded by a closed session for myeloMATCH leadership from 9 – 10 am CT.)

SATURDAY, OCTOBER 19 • 10:00-12:00 PM CT • REGENCY D (BALLROOM LEVEL)



myeloMATCH has been activated – the MYELOMATCH screening protocol and a number of substudies are now open.

Attend the myeloMATCH Kickoff to learn more and have your questions answered!

SUBSTUDIES TO BE DISCUSSED:

MM1YA-S01 - open

MM10A-EA02 - open MM1YA-CTG01
- open

MM2YA-EA01
- imminent

MM1MDS-A01
- imminent

LEARN MORE ABOUT ACTIVATING AND CONDUCTING MYELOMATCH PROTOCOLS, WE'LL DISCUSS

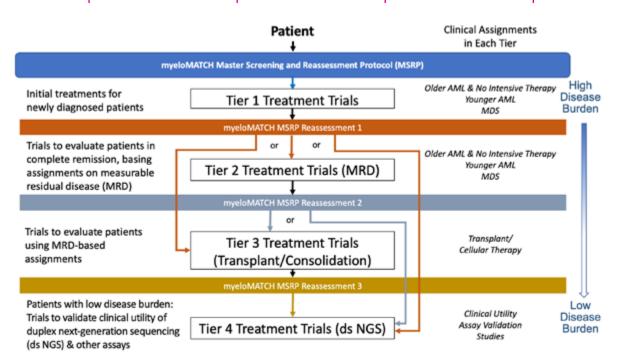
BEACON build templates

Funding

Verification team

Helpdesk support

Communication & recruitment resources



Generation 3 of the Lung Master Protocol, has arrived. Learn more at the

Lung-MAP 3.0 Update Forum

FRIDAY, OCTOBER 18 • 10:15-11:45 AM CT • CRYSTAL A (LOBBY LEVEL)



Lung-MAP 3.0 allows you to submit a patient's prior tissue test results from almost any CLIA-certified NGS platform that is sufficiently broad (likely any test greater than 150 markers) to have that patient assigned to a Lung-MAP sub-study at time of progression.

- A list of dozens of accepted commercial and academic tests is published with the protocol revision.
- This list covers the vast majority of all tests done in these patients currently.
- Additions will be made to the list regularly.
- If a test used with your patient is not on the list, you can submit it and the Lung-MAP team will certify, usually within one day, whether the test meets the requirements for Lung-MAP.

The session will include presentations on

- Lung-MAP 3.0: Expanded NGS testing options
- Lung-MAP accomplishments and publications
- Accrual and enrollment representativeness

Current sub-studies

- ° S1900E: Cohort 3 still enrolling
- ° S1900G: screening patients for MET amplification
- S1900K: NSCLC with METex14-skipping mutation
- S1900J: NSCLC with MET amplification

Committee progress

- Translational Medicine Committee
- Drug Selection Committee

The Lung-MAP leadership encourages all who work with lung cancer research to attend!



S2312 Kickoff

Phase 3 Trial in Metastatic Castrate-Resistant Prostate Cancer

Can testing for aggressive variant prostate cancer (AVPC-MS) help guide treatment of these patients?

FRIDAY, OCTOBER 18 • 8 – 9 AM CT • CRYSTAL A (LOBBY LEVEL)

Early evidence shows that adding carboplatin to cabazitaxel may improve radiographic progression free survival (rPFS) and overall survival (OS) in patients whose tumors have an aggressive variant prostate cancer molecular signature (AVPC-MS).

S2312 randomizes patients to cabazitaxel with or without carboplatin. All patients are screened centrally for the AVPC-MS, and patients are stratified according to their AVPC-MS status.

Hypothesis: adding carboplatin to cabazitaxel will significantly improve rPFS compared to cabazitaxel alone in men with AVPC-MS positive prostate tumors but not in those who are AVPC-MS negative.

This trial will fill important knowledge gaps regarding the development of biological, marker-driven treatment paradigms of prostate cancer and the value of platinum-based chemotherapy in lethal disease.

CHAIRS



Paul Corn, MD, PhD



Ana Aparicio,



David VanderWeele, MD, PhD



David J. McConkey, PhD



Amir Goldkorn, MD

PATIENT ADVOCATE



Lee Moultrie

BIOSTATISTICIANS



Cathy Tangen, DrPH



Sam Callis, MS

AGENDA

- Study background and rationale
- · Review of the AVPC-MS
- Review of protocol and study workflow
- Patient advocate perspective

S2312: A Phase III Study of Cabazitaxel with or Without Carboplatin in Patients with Metastatic Castrate-Resistant Prostate Cancer (mCRPC),
Stratified by Aggressive Variant Signature



Pre-Launch Town Hall Meeting

S2418: Distress Screening for Family Caregivers of Persons with Advanced Cancer: The FamilySTRONG Randomized Clinical Trial

THURSDAY, OCTOBER 17 • 1:30 - 3:30 PM CT • WATER TOWER (CONCOURSE LEVEL)

All NCORP-based members are invited!

We invite members from NCORP sites to help us learn how we can best run this caregiver-focused trial. We hope to better understand what is feasible at as many NCORP sites as possible.

S2418 will use a randomized trial design (intervention vs. usual care) to test the effect of a lay navigator-led family caregiver distress screening and support intervention (FamilyStrong) on caregiver and patient outcomes.

This trial-in-development is not yet funded (grant submitted).

AGENDA



PRO assessments



Background on cancer caregiving



Enrollment & activation



Trial objective, design, & eligibility



Selection of NCORP community chair



Overview of intervention



Discussion, closing remarks, & appreciation

THE FAMILYSTRONG RESEARCH TEAM

Study Chair



Nick Odom, PhD, RN



Frank Puga, PhD



Andres Azuero, PhD, MBA



Gabrielle Rocque, MD, MSPH



Marie Bakitas, DNSc, CRNP



Carole Seigel, MBA



Valerie Fraser



Virginia Sun, PhD, RN



Katherine Guthrie, PhD



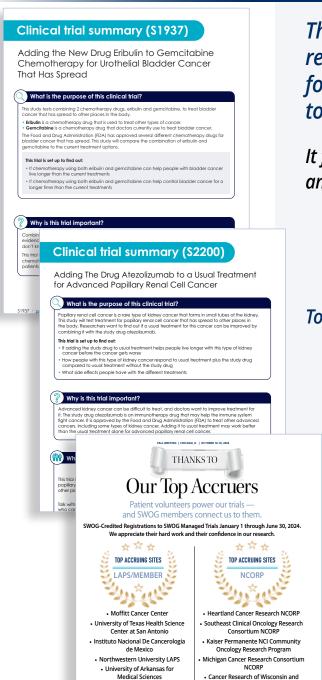
Richard Taylor, PhD, DNP, CRNP



SYMPOSIUM:

The Art of Patient Enrollment in **Genitourinary Oncology Clinical Trials**

THURSDAY, OCTOBER 17 • 7:30 – 930 AM CT • CRYSTAL A (LOBBY LEVEL)



This workshop on state-of-the-art accrual and retention strategies will explore best practices for robust trial accrual, with nuances specific to GU trials.

It features some of our top-accruing GU investigators and our patient advocates

- investigators from academic, NCORP, community, and VA sites
- specialists in biostatistics, radiation oncology, and medical oncology

Topics will include

- · Building a balanced portfolio of GU trials at your site
- Best practices
 - Introducing a trial to a patient
 - Informed consent
 - Investigator and patient perspectives
 - Roles of clinical research coordinators and nurses
- · Panel discussion on successful accrual to multidisciplinary and/or multimodal trials
- Exceeding expectations: setting the stage for robust, diverse accrual
 - Successful infrastructure models
 - Overcoming resource limitations
 - Improving enrollment diversity
 - Patient-centered, culturally sensitive recruitment

Early-career investigators are strongly encouraged to attend! But this session will have value for all SWOG members.

• Cancer Research of Wisconsin and Northern Michigan Consortium



NCORP Research Base Clinical Trials Workshop

WED, OCT 16 • 10:30 AM - 2:30 PM CT • REGENCY D (BALLROOM LEVEL)



(CHECK-IN BEGINS 10 AM)

SWOG members, oncology research professionals, and investigators at NCTN and NCORP institutions are encouraged to attend the informative presentations and breakout session discussions.

Presentation Session: in-person & virtual (hybrid)
Breakout Sessions: in-person only

The workshop provides information on conducting clinical trials in the following four SWOG committees:

- Cancer Care Delivery
- Palliative Care
- Prevention, Screening, and Surveillance
- Symptom Management and Survivorship

This is an opportunity for information sharing between attendees, SWOG NCORP research staff, study chairs, the NCI, and other subject matter experts.

Society of Clinical Research Associates (SOCRA) continuing education credit is available.







Upcoming Funding & Career Development Opportunities

- APP Mentorship Program:
 November 1
 - Meyskens Lectureship:

November 1

· SEED Fund:

December 1

Impact Award LOIs:

January 15

Vogelzang Scholars Program:

January 15

CRA/Nurse Travel Support:

January 15

Coltman Fellowship:

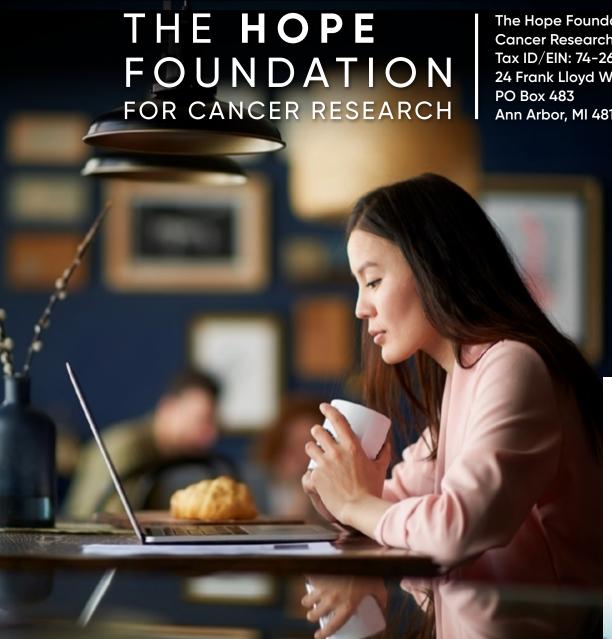
March 15

See all Hope Foundation programs at thehopefoundation.org/funding-opportunities

THE HOPE
FOUNDATION
FOR CANCER RESEARCH

DAF Highlight

Did you know you can give to Hope through your Donor-Advised Fund (DAF)?



The Hope Foundation for **Cancer Research** Tax ID/EIN: 74-2655302 24 Frank Lloyd Wright Drive Ann Arbor, MI 48106

A DAF is a charitable giving account that allows the account holder to make charitable contributions, receive an immediate tax deduction, and recommend grants from the fund over time.

Questions? Contact Mallory Glenn at mallory@thehopefoundation.org or stop by Hope's info table near SWOG meeting registration.



SWOG Group Meeting App

The SWOG group meeting mobile app is your pocket guide to the meeting.

With key features in an easily accessible format, the app not only replaces the agenda book as your on-site companion, it contains the agenda book – as a PDF you can flip through on your phone.

create your schedule, annotate sessions, and add them to your calendar

access a directory of presenters and session leaders, along with other attendees who have opted in

swog.org/ appleappf24



swog.org/ googleappf24 WITH THE APP, YOU CAN

The app also offers a single go-to source for speakers and presenters:

 find travel and lodging information and links

• submit conflict-of-interest disclosure forms

DON'T HAVE THE APP YET?

Download the app with the appropriate QR code or URL at left

DON'T WANT TO INSTALL
YET ANOTHER APP?

Access the web browser version with the QR code or URL at right.

Swipe up to open

claim continuing medical education (CME) credits for sessions you attend

access most of the key resources you've found in the agenda book

access the full agenda book itself as a PDF



swog.org/ meetingappf24



SWOG Clinical Trials Partnerships (CTP)

HOW SWOG PARTNERS WITH INDUSTRY TO CONDUCT CANCER CLINICAL TRIALS

WEDNESDAY, OCTOBER 16 • 4:30 PM - 5:30 PM CT • REGENCY D (BALLROOM LEVEL) AND VIA ZOOM

Update Forum How can you work with SWOG CTP?

- Industry and Investigators: How SWOG CTP works and ways we can collaborate
- Types of trials
 Scientific areas of interest
 Joint study development process
 Novel collaboration ideas
 - Sites: How sites can get involved in CTP trials
 - Feasibility survey outreach and site selection
 Site funding and contracts

SWOG CTP TRIALS IN DEVELOPMENT:

21CTP.LEUK01

Phase II trial for patients with newly diagnosed Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (activation expected Q4 2024)

21CTP.HN01

Phase II study in recurrent metastatic head and neck cancer with cohorts defined by type of and/or response to prior systemic therapies

21CTP.BREAST01

Phase II platform trial using circulating tumor DNA to monitor treatment response in HR+, HER2- metastatic breast cancer

- CTP scientific leadership in registration trials TROPION Breast 03
 - Other projects underway

Learn more: <u>swogctp.org</u> Email us: <u>CTP@swog.org</u>

All are invited!

SWOG CLINICAL TRIALS PARTNERSHIPS

AN LLC OF THE HOPE FOUNDATION FOR CANCER RESEARCH

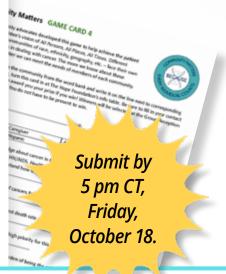


Play 'Community Matters'

by SWOG's Community Advocates with the Patient Advocate Committee









You'll find game cards in many places.



Submit completed cards in the ballot box at The Hope Foundation's table, near registration.



There are four different game cards. You may submit one of each.



Be sure to fill in your contact information!

We'll announce winners at the Friday evening reception.

No need to be present to win.

Want to increase your chances of winning?

Talk to your Community Advocates!



Complete Your SWOG Member Profile

Help your committee, win a prize! Visit <u>swogdei.crab.org</u>

Log in using your CTEP-linked ID.me account.



Which committees will have the highest profile completion rate?

They will earn bragging rights and a hospitality spread at the committee's session in spring 2025.

Check the leaderboard (near SWOG registration) to see how your committee compares!

Engage in a bit of friendly competition to help us paint a richer picture of our membership.



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 sessions: Adolescent and Young Adult Committee; Cancer Control and Prevention, including Cancer Care Delivery Committee, Symptom Management & Survivorship Committee, and Palliative Care Committee; Genitourinary Committee; Early Therapeutics & Rare Cancers Committee; Melanoma Committee; Surgery Committee; Radiation Oncology Committee; Translational Medicine Plenary Session; Leukemia Committee; Breast Committee; Gastrointestinal Committee; Lung Committee; Lymphoma Committee; Immunotherapeutics Committee; Bone Marrow & Stem Cell Transplantation Committee.

Continuing Medical Education Credit

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

The Hope Foundation designates this live activity for a maximum of 17.25 AMA PRA Category 1 Credits^T. 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.



Claim your CME credits using our Confex meeting app

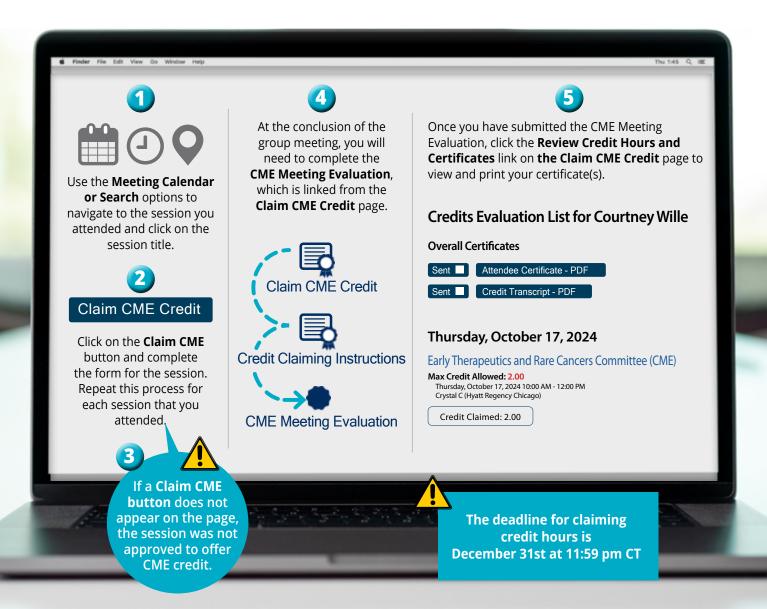
(this is the 3rd meeting with CME in Confex)

To claim credit, you must either create a **Confex user account** or use the one you created previously. You may use the account to navigate the meeting through the mobile app — or alternatively, via the browser-based version online.

To navigate the meeting and claim CME credit online, go here: swog.org/meetingappf24
To download the meeting app, find it in the Apple Store or via Google Play:







Committees

Administrative Committees

Board of Governors Charles D. Blanke, MD

Conflict ManagementPaul Okunieff, MD

Publications

Hagen F. Kennecke, MD

Professional ReviewPaul Hesketh, MD

Research Support Committees

Adolescent and Young Adult

Rebecca Johnson, MD

Bone Marrow and Stem Cell Transplantation

Patrick J. Stiff, MD

Digital Engagement

Mark Lewis, MD

Imaging

Lawrence H. Schwartz, MD

Oncology Research Professionals

Connie Szczepanek, RN, BSN, CCRP **Patient Advocates**

Anne Marie Mercurio

Barbara Segarra-Vazquez, DHS

Pharmaceutical Sciences

Siu-Fun Wong, PharmD Joyce Lee, PharmD

Radiation Oncology

Chul Ha, MD

Recruitment and

Retention

Allison Caban-Holt, PhD

Surgery

Syed A. Ahmad, MD

Veterans Affairs

Stephen D. Bartlett, RPh

Future Meeting Dates

2025

SPRING

April 30-May 3 San Francisco, CA

FALL

September 17-20 Chicago, IL

2026

April 29-May 2 San Francisco, CA

SPRING

FALL

October 7-10 Chicago, IL

2027

SPRING

April 14-17 San Francisco, CA

FALL

October 13-16 Chicago, IL



Adolescent and Young Adult Committee

Friday, October 18, 2024 • 4:00 PM – 6:00 PM CT Water Tower (Concourse Level)

Agenda

- A. Welcome Becky Johnson, MD
- B. Early Onset Colorectal Cancer Cathy Eng, MD
- C. Guest Speaker: Updates from COG Michael Roth, MD
- D. Trial Updates:
 - AYA Sexual Health Survey Adam Duvall, MD (virtual)
 - MAGESTIC MiRNA in Detecting Active Germ Cell Tumors in Early Suspected and MetastaTIC Disease Trial Siamak Daneshmand, MD (virtual)
 - ALTE2131 Gonadotropin-Releasing Hormone Analogs (GnRHa) and Protection of Ovarian Reserve in Adolescents and Young Adults with Cancer Halle Moore, MD
 - NCTN Sarcoma Trials Lara Davis, MD
 - NCORP Pilot Grant "TALK TO ME: Tailored AYA Trial Messaging" Allison Rosen, MS
- E. Q&A and discussion Becky Johnson, MD



Bone Marrow & Stem Cell Transplantation Committee

Friday, October 18, 2024 • 2:30 pm – 4:15 pm CT Comiskey (Concourse Level)

Welcome & Introductions Patrick Stiff, MD

SWOG Myeloma Maintenance and

New Initiatives of the NCTN/BMT-CTN Amrita Krishnan, MD

SWOG Amyloidosis Patrick Hagen, MD

ECOG Mantle Cell NHL Brian Till, MD

ECOG Autotransplant for T-NHL Marc Hoffmann, MD

ECOG Hodgkin's Autotransplant Sairah Ahmed, MD

SWOG CAR-T Consolidation Brian Hess, MD

MyeloMATCH (Alliance) Allograft Trial Stephanie Tsai, MD, MS

Potential New Trial to Treat Relapse and MRD in Allograft Setting for High-Risk

Heme Malignancies from Seattle Marie Bleakley, MD



Digital Engagement Committee

Wednesday, October 16, 2024 • 12:30 pm - 2:30 pm CT Water Tower (Concourse Level)

Welcome, review agenda,

introductions Mark Lewis, MD

Talk to Me: Leveraging Social Media to Educate AYAs about

Clinical Trials

Grace Hillyer, EdD, MPH [remote] Melissa Beauchemin, PhD [remote] Allison Rosen, MS, Patient Advocate Desiree Walker, Patient Advocate

Al & SWOG research

COSMO update

Breast cancer survey on

ovarian suppression

NeuroDetect:

An app to detect chemo-induced neuropathy - Integrating into

clinical trials or a stand-alone trial Dan Hertz, PharmD, PhD [remote]

Chul Soon Ha, MD [remote]

Don Dizon, MD, et al.

N. Lynn Henry, MD, PhD



Pharmaceutical Sciences Committee and Drug Information Subcommittee Joint Meeting

Friday October 18, 2024 • 10:00 am -12:00 pm CT Acapulco (Ballroom Level)

Agenda

Committee Reports:

- 1. Committee Administrative reports Joyce Lee/Siu Fun Wong
 - Introduction of new members
 - Review of PSC Member Roster
 - Summary report of committee activities
 - NCI CTEP Policy Advanced Practice Providers (APP) Task Force
 - Pharmaceutical-related events and inquiries

2. Drug Information Sub-Committee Report – Vy Bui

- Updates from the Chair Vy Bui
 - Workload Summary of drug section requests and acknowledgment of writers and reviewers
 - Introduction of resident and fellow writers for 2024-2025 academic year
 - Updates on Section 3 development process and participants
- Protocol Review activities Holly Chan/Jorge Avila
- Aurora roll-out updates Matt Boron

3. APP Initial Order Build Focus Group - Siu Fun Wong/Joyce Lee

Members: Holly Chan, Safae Chouraichi, Dawud Ellayan, Joyce Lee, Jane Rogers, Christa Braun-Inglis, Maggie Ryan, Dana Reeves

- Program development updates
- Pilot project
- Roles of Pharmacist Liaisons

4. Pharmacist Liaison Reports – All

- Review of Pharmacist Liaison Assignment List
- Disease Committee Liaison Pharmacist Reports Open

5. Open agenda - All



Surgery Committee

Saturday, October 19, 2024 • 9:15 – 11:15 AM CT Comiskey (Concourse Level)

Summary of Pancreas Cancer Retreat (GI Committee)

Davendra Sohal, MD

University of Cincinnati Cancer Center, Cincinnati OH

Trials and Projects in Development and Ongoing Trials

A Randomized Neoadjuvant Study of Nivo/ipi Versus Surgery Alone in High-Risk Resectable HCC

Ahmed Kaseb, MD

MD Anderson Cancer Center, Houston TX

Multicenter Selective Lymphadenectomy Trial – 3: Evaluating deescalation of nodal surgery in neoadjuvantly treated melanoma

Mark Faries, MD

Cedars Sinai Medical Center, Los Angeles CA

Total neoadjuvant therapy with modified FLOT vs modified FOLFOX6 in elderly, frail patients with locally advanced esophageal/gastric adenocarcinoma

Iván Lyra González, MD / David Zhen, MD (University of Washington) Hospital de Clínicas - Universidad de la República Montevideo, Uruguay

Total Neoadjuvant Therapy (TNT) for Operable Esophageal & GEJ Adenocarcinoma

Emerson Y Chen, MD, MCR

Knight Cancer Institute, OHSU, Portland OR



SWOG Latin America Initiative Symposium

Thursday, October 17, 2024 • 10:30 AM – 12:30 PM CT Crystal A (Lobby Level)

Agenda

Introductory Remarks, Dr. Mariana Chávez MacGregor

Part 1: Lymphoma Research and International Collaborations

Lymphomas in Latin America, Dr. Malpica
Real World Data in Lymphomas in Mexico, Dr. Rubalcava
Lymphomas: Epidemiology and Outcomes, Dr. Herrera
SWOG Lymphoma Committee: Opportunities for Collaboration, Dr. Smith

Part 2: Site Focus: SLAI Activities and Lymphoma Patient Overview by Country

Focus on Chile, Dr. Javier Retamales

SLAI activities and lymphoma patient overview by country, all SLAI sites

Part 3: Round Table of Lymphoma Research Proposals with Relevance in Latin American Setting

Closing Remarks, Dr. Mariana Chávez MacGregor



VA Committee

Saturday, October 19, 2024 • 9:30 AM – 11:30 AM CT Water Tower (Concourse Level)

A. Introductions and Opening Comments

Stephen Bartlett, RPh, MSPH

B. "Site – focus/Study – focus" — Operational perspectives for opening & conducting studies at VAs

Clinical Awareness and Recruitment Efforts - VAMC Long Beach

Neha Shah, PhD, CCRP

Program Manager, Cancer Clinical Trials Program

Lessons Learned and Future Directions of Implementing SWOG Trials Within VA

Stephanie Ferguson

National Program Manager, NAVIGATE

C. VA Disease Committee Liaison Updates

1. Semi-annual VA Liaison Meeting

Jessica D. McDermott, MD; Stephen Bartlett, RPh, MSPH

Rocky Mountain Regional VA Med Ctr

2. Open Committee Roles:

Cancer Care Delivery

Immunotherapeutics

Lung

Melanoma

Palliative Care

Prevention, Screening & Surveillance

How to Apply - vamember@swog.org



VA Committee

D. VA Committee Working Group Updates

- Storefront Award application
- SWOG-led and VA-led goals and strategies larger focus on pursuit of standardization and consistency in Privacy Office regulations.

E. Current VA Stats

Accrual/sites - SWOG Report

F. Other

AVAHO September 2024 - summary/feedback

G. Future Meetings

1st Quarter 2025 Virtual VA Committee Meeting - Date TBD



Barlogie-Salmon Myeloma Committee

Lea	ıae	ers	nı	ľ

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	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, MS
Scientific Leadership	
Translational Medicine:	Brian A. Walker, BSc, PhD
Radiation:	Chelsea Camille Pinnix, MD, PhD
Surgery:	TBD
Imaging:	Eric M. Rohren, MD, PhD
Pathology:	Pei Lin, MD
	Frits van Rhee, MD, PhD
Designates	
DEI Champion:	. Manuel Ricardo Espinoza-Gutarra, MD
Digital Engagement:	TBD
	Charles S. Kuzma, MD
•	Thomas R. Chauncey, MD, PhD
	Aubrey Gilmore, BA
	Daria Chugina, MD, CCRPS
	Pasarlai Ahmadzai, MD, MPH
Oncology Research Professionals:	, ,
3,	Brandon Richard Labadie, CCRP
	Teresa Witcher, BSN, RN
	Paul Gater, MPhil

Time/Location

Friday, October 18, 2024 7:30 a.m. - 9:30 a.m. Room: Water Tower (Concourse Level, West Tower)

Active Studies

<u>\$1803</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. A. Krishnan and S. Chhabra. Activated: 6/27/19.

......lla M. Saunders, PharmD

- S2005, "A Phase II Randomized Study Comparing Ibrutinib and Rituximab vs.Venetoclax and Rituximab in Previously Untreated Waldenström's Macroglobulinemia (WM) /Lymphoplasmacytic Lymphoma (LPL)" Drs. S. Ailawadhi and D. Bhutani. Activated: 6/24/21; Closed: 4/8/22; Reactivated: 2/15/24.
- **S2209**, "A Phase III Randomized Trial for Newly Diagnosed Multiple Myeloma (NDMM) Patients Considered Frail or Ineligible for Stem Cell Transplant Comparing Upfront Bortezomib-Lenalidomide-Dexamethasone-Lite (VRd-Lite) with Daratumumab-Lenalidomide-Dexamethasone (DRd)." Drs. S. Ailawadhi, J.C. Ye, B. Lipe, T. Chauncey, and K. Gowin. Activated 5/30/23.
- **S2213**, "Daratumumab, Cyclophosphamide, Bortezomib, and Dexamethasone (D-VCD) Induction Followed by Autologous Stem Cell Transplant or D-VCD Consolidation and Daratumumab Maintenance in Patients with Newly Diagnosed AL Amyloidosis." Drs. P. Hagen, T. Parker, and S. Sidana. Activated 12/1/23
- **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: 3/8/18; Closed: 9/30/19.
- **<u>\$1304</u>**, "A Phase II Randomized Study Comparing Two Doses of Carfilzomib with Dexamethasone for Relapse/Refractory Multiple Myeloma." Dr. S. Ailawadhi. Activated: 10/18/13. Closed: 11/6/15.
- **S0777**, "Frontline Phase III Rev/Dex +/- Vel, no upfront transplant." Dr. B. Durie. Activated: 4/1/18. Closed: 2/2/12.
- **S0120**, "A prospective Observational Biologic Study of Asymptomatic Patients with Monoclonal Gammopathy and Plasmaproliferative Disorders." Dr. M. Dhodapkar. Activated: 6/1/02. Closed: 4/1/11.



Barlogie-Salmon Myeloma Committee

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 (ENDURANCE)." 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.

EAA171, "Optimizing Prolonged Treatment in Myeloma Using MRD Assessment (OPTIMUM)." Dr. S. Kumar. Activated: 6/1/21. Closed 3/3/23.

Proposed Studies-Pre-Triage/On Hold

SXXXX, "A Phase II Study of Optimal Induction and MRD Driven Maintenance Therapy for Newly Diagnosed High Risk Multiple Myeloma." Drs. B. Lipe, J.C. Ye, and K. Gowin.

SXXXX, "Phase III Study Evaluating Freedom From Long-term Maintenance for Standard Risk Myeloma Patients Achieving Measurable Residual Disease Negativity." Dr. M. Mohyuddin.

SXXXX, "A Phase II Trial of BCMA Bi-Specific T-Cell Engager (BiTE)
Teclistamab in Patients with Systemic Light Chain (AL) Amyloidosis." Drs.
D. Bhutani and K. Dorritie.

SXXXX, "An Open-Label Randomized Phase 2 Trial to Incorporate Venetoclax in Early Relapsed t(11;14) Multiple Myeloma." Dr. R. Chakraborty.

SXXXX, "Developing Smoldering Multiple Myeloma Concept." Drs. P. Hagen and A. Cowan.



Barlogie-Salmon Myeloma Committee

	51803	52209	EAA173	EAA181
Ascension Providence Hospitals - Southfield	2	-	1	-
Banner University Medical Center - Tucson	8	-	-	5
Boston Medical Center	5	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	25	-	5	-
Cancer Research for the Ozarks NCORP	2	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	4	-	-	-
Cedars-Sinai Medical Center	6	-	-	-
City of Hope Comprehensive Cancer Center	110	-	-	-
Columbia University Minority Underserved NCORP	-	1	-	-
Columbus NCI Community Oncology Research Program	5	-	-	-
CommonSpirit Health Research Institute	1	3	-	-
Dayton NCI Community Oncology Research Program	5	-	-	-
Duke University - Duke Cancer Institute LAPS	3	-	-	-
Fred Hutchinson Cancer Research Center LAPS	3	-	8	-
Froedtert and the Medical College of Wisconsin LAPS	11	-	-	-
Georgia NCI Community Oncology Research Program	14	-	-	-
Gulf South Minority Underserved NCORP	4	-	-	-
Heartland Cancer Research NCORP	11	3	-	-
Henry Ford Hospital	-	-	1	-
Houston Methodist Hospital	8	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	47	1	-	-
Lahey Hospital and Medical Center	3	-	-	-
Loyola University Medical Center	24	-	3	1
MU Health Care Goldschmidt Cancer Center	3	-	-	-
Massachusetts Veterans Epidemiology Research and Information Center	-	-	-	2
Medical University of South Carolina Minority Underserved NCORP	46	-	1	1
Mercy Medical Center - Des Moines	1	-	-	-
Michigan Cancer Research Consortium NCORP	9	-	-	-
Moffitt Cancer Center	42	-	-	-
Montana Cancer Consortium NCORP	4	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	-	1	-	-



Barlogie-Salmon Myeloma Committee

Nevada Cancer Research Foundation NCORP New Mexico Minority Underserved NCORP	- 14 5	- 2	1	-
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Ohio State University Comprehensive Cancer Center LAPS	,	-	-	-
Oregon Health and Science University	30	-	3	9
Pacific Cancer Research Consortium NCORP	16	3	-	-
Parker Adventist Hospital	2	-	-	-
Riverside Methodist Hospital	3	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	3	-	-	-
Tulane University School of Medicine	-	-	1	-
UC Davis Comprehensive Cancer Center LAPS	23	4	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	12	-	-	-
University of Arkansas for Medical Sciences	-	2	-	2
University of Cincinnati Cancer Center-UC Medical Center	-	-	-	2
University of Kansas Cancer Center - MCA Rural MU NCORP	33	-	-	-
University of Kentucky/Markey Cancer Center	3	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	15	-	-	-
University of Oklahoma Health Sciences Center LAPS	2	-	-	-
University of Rochester LAPS	15	2	-	3
University of Texas Health Science Center at San Antonio	18	-	-	-
University of Texas MD Anderson Cancer Center LAPS	26	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	16	-	4	2
Upstate Carolina Consortium Community Oncology Research Program	4	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	16	-	-	-
Wisconsin NCI Community Oncology Research Program	20	-	-	-
Yale University - Yale Cancer Center LAPS	-	2	4	8
ALLIANCE	200	2	-	-
CCTG	11	-	-	-
ECOG-ACRIN	171	1	-	-
NRG	102	-	-	-
Total	1,166	27	32	35



Leadership		
Chair: Lajos Pusztai, MD, PhD		Agenda
Vice-Chair:Priyanka Sharma, MD	8:30 - 8:35 am	Welcome and Introductions - Lajos Pusztai, MD, DPhil
Executive Officer: Anne Chiang, MD, PhD		(Chair) and Priyanka Sharma, MD (Vice-chair)
Statisticians:Allison Meisner, PhD		CME Session
Danika Lew, MA		CIVIL SC331011
Jieling Miao, MS	"Optimiza	ation of endocrine therapy for advanced hormone
		positive breast cancer"
Scientific Leadership	8:35 - 8:50 am	Current treatment landscape of second line endocrine
Translational Medicine:		therapy - Christos Vaklavas, MD
Andrew K. Godwin, PhD		•
Radiation Oncology:	8:50 - 9:05 am	Emerging role of molecular response/ctDNA dynamics
Surgery: Joshua M.V. Mammen, MD, PhD		in treatment sequencing - Kevin Kalinsky MD
Imaging:	9:05 - 9:20 am	Androgen Receptors in Luminal Breast Cancer: Effects
Pathology:		on Response to Endocrine Therapy and an Immune-
Early Therapeutics:Stephanie L. Graff, MD		Suppressive Tumor Immune Microenvironment -
Designates Cancer Control Liaisons: Mariya Rozenblit, MD (Survivorship)		Anthony Elias MD
Dawn L. Hershman, MD (Cancer Care Delivery)	9:20 - 9:50 am	004
Banu Arun, MD (Prevention)	9:20 - 9:50 am	Q&A
		Committee Business and Updates
DEI Champion:	9:50 - 10:00 am	Publication update – Allison Meisner, PhD
Digital Engagement:TBD		·
NCORP Representative:	10:00 - 10:10 am	Patient Advocate update –
Veterans Affairs:Sarah V. Colonna, MD		Ginny Mason and Roberta Albany
Data Coordinators:Aubrey Gilmore, BA	10:10 - 10:20 am	Translational Medicine Sub-Committee update -
Gabi Herbert, MS, BS		Alastair Thompson, MD and Andrew K. Godwin, PhD
Kevin Moralda, BS	10.20 11.00	Daview of ener CTSI trials
Larry G. Kaye	10:20 - 11:00 am	Review of open CTSU trials
Oncology Research Professionals:	11:00 - 11:10 am	Recently approved concepts
CRAs: Karyn N. Hart, CCRP	11:10 - 11:25 am	Reports from Committee Liaisons
Nurse:	11.10 11.25 dill	reports from committee Liaisons
Patient Advocates: Roberta A. Albany		Radiotherapy: Reshma Jagsi, MD
Ginny Mason, RN, BSN		Surgery: Joshua Mammen, MD
Pharmaceutical Science: Jorge G. Avila, PharmD		Survivorship: Mariya Rozenblit, MD
Dawud Nael Dawud Ellayan, Pharm D		Cancer Care Delivery: Dawn Hershman, MD
Protocol Project Manager:		Prevention: Banu Arun, MD
Clinical Trials Program Manager:		Symptom Management: Helen K. Chew, MD
		NCORP: Philip Lammers, MD
Time/Location	11:25 am	Closing Comments and Adjourn
Friday, October 18, 2024 8:30 a.m 11:30 a.m.		·



Room: Regency A (Ballroom Level, West Tower)

Developing Studies

- **52428**, "Randomized Phase III trials of multimodality therapy versus palliative therapy in triple negative (TNBC) and HER2 positive (HER2+) de novo (AJCC stage IV) oligometastatic breast cancer." Drs. Rozenblit, Stecklein, and Lin.
- S2501, "ARIA: A Randomized Phase III Trial of Abemaciclib Versus Ribociclib In the Adjuvant Treatment of High-Risk, Hormone-Receptor Positive Early-Stage Breast Cancer." Drs. McGuinness, Sharma, Cobain, and Rozenblit.

Active Studies

- <u>\$2206</u>, "Phase III Trial of Neoadjuvant Durvalumab (NSC 778709) plus Chemotherapy versus Chemotherapy Alone for MammaPrint Ultrahigh (MP2) Hormone Receptor (HR) Positive / Human Epidermal Growth Factor Receptor (HER2) Negative Stage II-III Breast Cancer." Drs. Cobain and Pusztai. Activated: 10/30/23.
- **S2212**, "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. Activated: 7/21/23.
- **S2007**, "A Phase II Trial of Sacituzumab Govitecan (IMMU-132) (NSC #820016) for Patients with HER2-Negative Breast Cancer and Brain Metastases." Drs. Brenner and Kaklamani. Activated: 12/15/20.
- CTSU/A011801, "The COMPASSHER2 Trials (COMprehensive Use of Pathologic Response ASSessment to Optimize Therapy in HER2-Positive Breast Cancer): COMPASSHER2 Residual Disease (RD), A Double-Blinded, Phase III Randomized Trial of T-DM1 and Placebo Compared with T-DM1 and Tucatinib." Dr. O'Sullivan. SWOG Champion: Dr. Murthy. Activated: 1/6/21.
- CTSU/CCTG MA.39, "Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive and T3N0 Breast Cancer." Dr. Whelan. SWOG Champion: Dr. Jagsi. Activated: 5/30/18.
- CTSU/NRG-BR007, "A Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER2-Negative, Oncotype Recurrence Score Less Than or Equal to 18 Breast Cancer (DEBRA)." Dr. White. SWOG Champion: Dr. Shumway. Activated: 6/7/21.

Closed Studies

<u>S1418</u>, "A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with ≥1 CM Residual Invasive Cancer or Positive

- Lymph Nodes (ypN1mi, ypN1-3) after Neoadjuvant Chemotherapy." Drs. Pusztai and Mammen. Activated: 11/15/16; Permanently closed: 6/30/21.
- **S1207**, "Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer. e^3 Breast Cancer Study-Evaluating Everolimus with Endocrine Therapy." Drs. Chavez-MacGregor and Pusztai. Activated: 9/4/13; Permanently closed: 5/1/19.
- 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: 9/12/18. Permanently closed: 7/1/24.
- CTSU/A011202, "A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy." Dr. Boughey. SWOG Champion: Dr. Mammen. Activated: 2/7/14; Permanently closed: 7/1/22.
- CTSU/EA1181, "(CompassHER2-pCR): Preoperative THP and Postoperative HP in Patients Who Achieve a Pathologic Complete Response Part 1 Component of: The CompassHER2 Trials (COMprehensive Use of Pathologic Response ASSessment to Optimize Therapy in HER2-Positive Breast Cancer)" Dr. Tung. SWOG Champions: Breast Committee: Dr. Tang, Imaging Committee: Dr. Lu. Activated: 2/11/20; Permanently closed: 10/19/23.
- CTSU/EA1183, "FDG PET to Assess Therapeutic Response in Patients with Bone-Dominant Metastatic Breast Cancer, FEATURE." Dr. Specht. SWOG Champions: Breast Committee: Dr. Linden, Imaging Committee: Dr. Wright. Activated: 4/2/20; Permanently closed: 12/22/23.
- CTSU/NRG-BR002, "A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer." Drs. Chmura and White. SWOG Champion: Dr. Jagsi. Activated: 12/24/14; Permanently closed: 5/27/22.
- CTSU/NRG-BR003, "A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer." Dr. Valero. SWOG Champion: Dr. Makhoul. Activated: 6/26/15; Permanently closed: 4/22/22.
- CTSU/NRG-BR004, "A Randomized, Double-Blind, Phase III Trial of Taxane/ Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line



HER2-Positive Metastatic Breast Cancer." Dr. Geyer. SWOG Champion: Dr. Cobain. Activated: 3/12/19; Permanently closed: 7/1/22.

CTSU/NRG-BR005, "A Phase II Trial Assessing the Accuracy of Tumor Bed Biopsies in Predicting Pathologic Response in Patients with Clinical/Radiologic Complete Response after Neoadjuvant Chemotherapy in Order to Explore the Feasibility of Breast Conserving Treatment without Surgery." Dr. Basik. SWOG Champion: Dr. Thompson. Activated: 4/13/17; Permanently closed: 12/2/22.

Active Palliative Care Study

S1501, "Prospective Evaluation of Carvedilol in Prevention of Cardiac Toxicity in Patients with Metastatic HER-2+ Breast Cancer, Phase III." Drs. Floyd and Leja. Activated: 9/15/17; Temporary closure: 2/1/24.

Closed Symptom Management & Survivorship Studies

S1614, "A Phase III Randomized Trial of Prophylactic Antiviral Therapy in Patients with Current or Past Hepatitis B Virus (HBV) Infection Receiving Anti-Cancer Therapy for Solid Tumors." Drs. Hwang and Lok. Activated: 2/21/19; Permanently closed: 11/15/22.

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

Active Cancer Care Delivery Studies

<u>S1703</u>, "Randomized Non-Inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (STMDDM) versus Usual Care in Patients with Metastatic Hormone Receptor Positive HER-2 Negative Breast Cancer." Drs. Accordino and Hershman. Activated: 7/16/18.

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

Closed Prevention, Screening & Surveillance Study

<u>S1904</u>, "Cluster Randomized Controlled Trial of Patient and Provider Decision Support to Increase Chemoprevention Informed Choice among Women with Atypical Hyperplasia or Lobular Carcinoma In Situ – Making Informed Choices on Incorporating Chemoprevention into Care (MiCHOICE)." Drs. Crew, and Kukafka. Activated: 9/1/20. Permanently closed: 6/14/24.

Closed Early Therapeutics and Rare Cancers Studies

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

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



	51706	52007	52206	52212	A011801	A012103	EA1181	EA1183	EA1211	MA39	NRGBR007	NRGBR009
Ascension Providence Hospitals - Southfield	2	-	-	-	2	2	5	-	-	1	-	1
Banner MD Anderson Cancer Center	-	-	-	-	9	-	-	-	-	-	-	-
Banner University Medical Center - Tucson	1	-	-	-	-	-	10	-	-	-	-	-
Baptist Mem Health Care/Mid South MU-NCORP	3	-	1	2	-	-	1	-	-	-	-	-
Boston Medical Center	-	-	-	-	5	-	15	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	1	-	-	-	-	4	-	-	1	-	-
Cancer Research Consortium of West Michigan NCORP	1	-	-	2	-	-	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	3	-	-	1	1	-	-	-	-	-	-	-
Ca Research of Wisconsin and N Michigan Consort	-	-	-	2	-	-	-	-	-	-	-	-
Carle Cancer Center NCI Comm Oncology Research Prgrm	-	2	-	8	-	-	-	-	-	-	-	-
Cedars-Sinai Medical Center	-	-	1	-	1	1	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	-	-	-	1	-	-	-	-	-	-	-	-
Columbia University Minority Underserved NCORP	4	-	-	-	-	-	3	-	-	-	-	-
CommonSpirit Health Research Institute	2	-	-	6	-	-	-	-	-	2	-	-
Dayton NCI Community Oncology Research Program	-	1	-	-	-	-	6	2	-	-	-	-
Desert Regional Medical Center	1	-	-	-	-	-	2	-	-	1	-	-
Essentia Health NCI Comm Oncology Research Program	-	-	-	-	1	-	-	-	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	5	-	-	-	-	-	-	-	-	-	-	-
Georgia NCI Community Oncology Research Program	2	-	-	-	-	-	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	1	-	2	2	-	-	2	-	-	-	-	-
Heartland Cancer Research NCORP	4	-	2	9	1	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	-	-	1	-	-	-	-	-	-
Houston Methodist Hospital	-	-	-	-	1	-	-	-	-	3	-	-
Lahey Hospital and Medical Center	-	-	-	1	-	-	6	-	-	-	-	-
Loma Linda University Medical Center	-	-	-	3	-	-	-	-	-	-	-	-
Loyola University Medical Center	-	-	-	-	-	-	1	-	-	-	-	-
Med U of South Carolina Minority Underserved NCORP	1	-	-	-	-	-	-	3	-	-	-	-
Michigan Cancer Research Consortium NCORP	2	-	2	4	-	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	3	-	-	1	-	-	-	-	-	-	-	-
Mount Sinai Hospital	-	-	-	-	-	-	1	-	-	-	-	-
MultiCare Tacoma General Hospital	-	-	3	-	-	-	-	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	-	-	-	2	-	-	-	-	-	-	-	-
New Mexico Minority Underserved NCORP	6	1	-	-	-	-	-	-	-	-	-	-
Northwell Health NCORP	-	1	-	-	-	-	-	-	-	-	2	-
Northwestern University LAPS	1	2	-	11	1	-	4	1	-	-	-	-



	51706	52007	52206	52212	A011801	A012103	EA1181	EA1183	EA1211	MA39	NRGBR007	NRGBR009
Ohio State U Comprehensive Cancer Center LAPS	3	-	-	-	-	-	1	-	-	-	-	-
Oregon Health and Science University	-	-	1	-	-	-	-	3	-	-	1	-
Pacific Cancer Research Consortium NCORP	2	-	-	7	-	-	-	-	-	2	-	-
Rhode Island Hospital	-	-	-	1	-	-	-	-	-	-	-	-
SCL Health Saint Joseph Hospital	-	-	-	5	-	-	-	-	-	-	-	-
Southeast Clinical Oncology Research Consort NCORP	-	1	-	11	1	-	-	-	-	-	-	-
Sutter Cancer Research Consortium	-	-	-	1	2	-	5	-	-	-	-	1
The Don and Sybil Harrington Cancer Center	3	-	-	-	3	-	-	-	-	-	-	-
The West Clinic - Wolf River	-	-	-	6	-	-	-	-	-	-	-	1
UC Davis Comprehensive Cancer Center LAPS	7	-	-	-	-	1	4	-	-	-	1	-
UC Irvine Health/Chao Comprehensive Cancer Center	-	1	-	-	2	-	-	-	-	-	-	-
UPMC Hillman Cancer Center LAPS	1	-	-	-	-	-	-	-	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS	-	-	-	-	1	-	-	-	-	2	-	-
U of Alabama at Birm/Deep South Res Cnsrt LAPS	-	2	-	-	-	-	-	-	-	-	-	-
University of Arkansas for Medical Sciences	2	-	-	1	2	3	-	-	-	-	-	-
University of Colorado Cancer Center LAPS	1	-	1	-	1	-	11	-	-	1	1	-
U of Kansas Cancer Center - MCA Rural MU NCORP	4	-	-	5	1	-	-	-	-	1	-	-
U of Michigan Comprehensive Cancer Center LAPS	3	-	1	-	2	-	1	-	-	14	-	-
University of Mississippi Medical Center	-	-	-	-	-	-	1	-	-	-	-	-
University of Oklahoma Health Sciences Center LAPS	1	-	1	1	-	-	-	-	1	-	-	-
University of Rochester LAPS	1	-	-	-	-	-	1	-	-	-	1	-
University of Texas Health Science Center at San Antonio	-	1	1	-	-	-	-	-	-	-	3	-
University of Texas MD Anderson Cancer Center LAPS	1	1	-	-	-	-	-	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	5	-	-	-	1	-	7	-	-	-	-	-
Vanderbilt University - Ingram Cancer Center LAPS	-	-	-	-	1	-	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	-	-	2	-	14	4	-	1	-	-
Western States Cancer Research NCORP	-	-	-	-	-	-	2	-	-	-	-	-
Wisconsin NCI Community Oncology Research Program	1	-	-	-	-	-	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	-	1	6	3	-	13	-	-	-	-	-
ALLIANCE	18	7	4	38	-	-	-	-	-	-	-	-
CCTG	6	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	11	3	4	30	-	-	-	-	-	-	-	-
NRG	48	-	3	25	-	-	-	-	-	-	-	-
Total	160	24	28	192	44	8	120	13	1	29	9	3



Cancer Control & Prevention Committees

Leadership
Vice-Chair NCORP: Dawn L. Hershman, MD, MS
Cancer Care Delivery Committee Co-Chairs: Veena Shankaran, MD
Scott D. Ramsey, MD, PhD
Palliative Care Committee Co-Chairs: Robert S. Krouse, MD, FACS
Marie Bakitas, DNSc, CRNP
Prevention, Screening & Surveillance
Committee Co-Chairs:
Symptom Management & Survivorship
Committee Co-Chairs: Michael J. Fisch, MD, MPH
Norah Lynn Henry, MD, PhD
Executive Officers: Katherine D. Crew, MD (CCD, Prevention,
Symptom Management)
Virginia Sun, PhD, MSN, RN (Palliative)
Senior Advisor: Frank L. Meyskens, Jr., MD
Statisticians:Michael LeBlanc, PhD
Joseph M. Unger, PhD
Phyllis Goodman, MS
Kathryn B. Arnold, MS
Amy K. Darke, MS
Danika Lew, MA
Sarah Colby, MS
Anna Moseley, MS
Administrative Lead
Statistics & Data Management Center (SDMC): Monica Yee, CCRP
Scientific Leadership
NCORP Representative: Scott Edward Delacroix, Jr. MD
Helen Heng-Shan Moon, MD
Radiation Oncology Committee: Eileen P. Connolly, MD, PhD (CCD,
Kiri A. Cook, MD (Symptom Mgmt) Erin F. Gillespie, MD (Symptom Management)
Surgery Committee:
Translational Medicine: James (Jimmy) Rae, PhD
Liaisons:
Barlogie-Salmon Myeloma Committee:
Breast Committee: Mariya Rozenblit, MD (Survivorship)

David Hamburg MD MC (CCD)
Dawn Hershman, MD, MS (CCD)
Banu Arun, MD (Prevention)
Philip Lammers, MD
Early Therapeutics & Rare Cancers:Lara E. Davis, MD (Survivorship)
Jason M. Prosek, MD
Gastrointestinal Committee:
Afsaneh Barzi, MD (CCD)
Genitourinary Committee:
Sarah P. Psutka, MD
International Liaison:Kathy S. Albain, MD
Leukemia Committee: Stephanie B. Tsai, MD
Lung Committee:
Lymphoma Committee:Hayder Saeed, MD
Melanoma Committee: Sancy Leachman, MD, PhD
Thach-Giao Truong, MD (Survivorship)
Recruitment and Retention Committee: Allison M. Caban-Holt, PhD
Digital Engagement:Jennifer R. Klemp, PhD (Survivorship)
Krishna Soujanya Gunturu, MD (Survivorship)
Mina S. Sedrak, MD (CCD)
Michael J. Fisch, MD (Symptom Management)
Veterans Affairs: Yeun-Hee Anna Park, MD (Symptom Management)
Neha Patel, MD (Survivorship)
Jacqueline Ann Gesek, BSN, RN (Nursing)
Designates
Oncology Research Professionals
CRAs: Amanda R. Dinsdale, MHA, CCRC
Amy Jo Koffarnus, BS, CCRP
Samantha Wright, MS, CCRP
Shirley S. Sui, BS
Nurses:
Melyssa W. Foust, MSN, RN
Pharmaceutical Sciences Committee: Kimberly McConnell, PharmD
Siu-Fun Wong, PharmD
Sun "Coco" Yang, PharmD, PhD
Data Coordinators:
Sam Dzingle, BA
Manny Kharbanda
D. the second of

Recruitment and Retention Specialist: Jamie Sundstrom, BS



Cancer Control & Prevention Committees

Patient Advocates:Barbara Segarra-Vazquez, DHSc (CCD)
Amy Geschwender, PhD (Symptom Management)
Hartley "Lee" M. Jones, MBA (Survivorship)
Valerie Fraser (Palliative)
Sr. Protocol Project Manager (Cancer Care Delivery;
Prevention):Patricia O'Kane
Protocol Project Manager (Symptom Management):Megan Keim
Protocol Project Manager (Symptom Management): Justine Trevino
Protocol Project Manager (Palliative Care): Andrea Garcia
Protocol Project Manager (Palliative Care): Justine Trevino
Clinical Trials Program Manager (Palliative Care): Laura Gildner, MS
Clinical Trials Program Manager (CCD; Prevention;
Symptom Control):



Cancer Care Delivery (CCD) Committee

Leadership

Co-Chairs:	Scott D. Ramsey, MD, PhD
	Veena Shankaran, MD, MS

Time/Location

Thursday, October 17, 2024 10:30 a.m. - 12:30 p.m. Room: Regency A (Ballroom Level, West Tower)

Agenda

Presentations:

Updates on NCORP Grant Renewal and Committee Structure – Dawn Hershman, MD, MS, Columbia University Irving Medical Center

Integrative Medicine for Patient-reported Outcomes, Values, and Experience: Results of the IMPROVE trial - Robert Daly, MD, MBA, Memorial Sloan Kettering Cancer Center

Active Studies

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

S2108CD, "A Cluster Randomized Trial Comparing an Educationally Enhanced Genomic Tumor Board (EGTB) Intervention to Usual Practice to Increase Evidence-Based Genome-Informed Therapy." Drs. J. Rueter, M. Trivedi, B. Symington, P. Tseng, D. Hershman, S. Ramsey. Activated: 8/22/22.

<u>S1703</u>, "Randomized Non-inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (STMDDM) versus Usual Care in Patients with Metastatic Hormone Receptor Positive HER-2 Breast Cancer." Dr. M. Accordino. Activated: 7/16/18.

Developing Studies

S2417CD, "A Pragmatic Randomized Controlled Trial to Evaluate the Effectiveness of an Intervention to Promote Guideline-Concordant Colorectal Cancer Surveillance". Drs. C. Veenstra and S. Hawley.

R01 was funded. Grant start date is 8/1/24.

S2424CD, "Randomized Controlled Trial Lay Health Worker-led Intervention to Promote Goals of Care Communication". Drs. R. Parikh, C. Manz, and M. Patel.

 Received a fundable score at the 4th percentile. Awaiting the final funding decision and NOA. Employment and Related Outcomes in Newly Diagnosed Patients with Metastatic Breast Cancer. Dr. C. Sathe

Patient-centered Video Education Intervention to Improve Rural Cancer Care Delivery. Drs. R. Holcombe and I. Okado.

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.

<u>S1904</u>, "Cluster Randomized Controlled Trial of Patient and Provider Decision Support to Increase Chemoprevention Informed Choice Among Women with Atypical Hyperplasia or Lobular Carcinoma In Situ – Making Informed Choices on Incorporating Chemoprevention into Care (MiCHOICE)." Dr. K. Crew. Activated: 9/1/20. (Committee: Prevention/Epidemiology). Closed: 6/14/24.

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

Published Studies

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

Trends in Obesity Prevalence Among Patients Enrolled in Clinical Trials for Obesity-related Cancers, 1986 to 2016. Dr. R. Vaidya

Universal Viral Screening of Newly Diagnosed Cancer Patients in the United States: A Cost Efficiency Evaluation, Dr. R. Vaidya



Cancer Care Delivery (CCD) Committee

	51703	51912CD	52108CD	A191901	A231901CD	NHLBIMDS
Ascension Providence Hospitals - Southfield	-	-	-	4	-	1
Banner University Medical Center - Tucson	1	-	-	-	-	-
Baptist Memorial Health Care/Mid South Minority Underserved NCORP	-	-	-	-	1	3
Bay Area Tumor Institute NCORP	-	1	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	25	-	-	-	-	5
Cancer Research Consortium of West Michigan NCORP	-	7	-	-	1	-
Cancer Research for the Ozarks NCORP	-	10	33	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	14	10	45	1	-	-
Carle Cancer Center NCI Community Oncology Research Program	8	1	126	-	-	1
Columbia University Minority Underserved NCORP	26	10	-	-	-	24
Columbus NCI Community Oncology Research Program	3	-	-	-	-	-
CommonSpirit Health Research Institute	12	-	49	-	-	-
Corewell Health William Beaumont University Hospital	-	-	-	-	-	2
Cotton O'Neil Cancer Center / Stormont Vail Health	1	-	-	-	-	-
Dayton NCI Community Oncology Research Program	3	1	-	-	-	-
Essentia Health NCI Community Oncology Research Program	-	-	132	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	-	-	-	23
Georgia Cares Minority Underserved NCORP	-	6	-	-	-	-
Georgia NCI Community Oncology Research Program	3	-	30	-	-	-
Gulf South Minority Underserved NCORP	6	2	-	-	-	-
Hawaii Minority Underserved NCORP	11	8	85	-	-	5
Heartland Cancer Research NCORP	20	7	176	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	5	12	-	-	-	9
Kansas City Veterans Affairs Medical Center	-	-	-	-	-	4
Kansas Institute of Medicine Cancer and Blood Center	-	-	-	-	-	2
Lahey Hospital and Medical Center	4	-	-	-	-	-
Loyola University Medical Center	2	-	-	5	-	-
Massachusetts Veterans Epidemiology Research and Information Center	-	-	-	-	-	41
Medical University of South Carolina Minority Underserved NCORP	-	-	-	-	-	5



Cancer Care Delivery (CCD) Committee

	51703	S1912CD	52108CD	A191901	A231901CD	NHLBIMDS
Michigan Cancer Research Consortium NCORP	15	18	73	-	-	-
Moffitt Cancer Center	-	-	-	-	-	8
Montana Cancer Consortium NCORP	10	2	65	-	-	-
Mount Sinai Hospital	5	-	-	-	-	-
MultiCare Tacoma General Hospital	-	-	-	22	-	-
NCORP of the Carolinas (Prisma Health NCORP)	6	2	-	-	-	2
Nevada Cancer Research Foundation NCORP	2	2	-	1	-	-
New Mexico Minority Underserved NCORP	16	20	-	-	-	-
Northwell Health NCORP	-	3	-	-	-	18
Oregon Health and Science University	-	-	-	-	-	12
Pacific Cancer Research Consortium NCORP	10	22	-	-	-	-
Riverside Methodist Hospital	2	-	-	-	-	-
Salem Hospital	1	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	5	33	13	-	-	-
UC Davis Comprehensive Cancer Center LAPS	2	-	-	3	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	-	-	-	27
UC San Diego Moores Cancer Center	-	-	-	-	-	34
University of Arkansas for Medical Sciences	4	-	-	-	-	-
University of Colorado Cancer Center LAPS	-	-	-	-	-	16
University of Kansas Cancer Center - MCA Rural MU NCORP	8	10	<i>75</i>	-	-	-
University of Rochester LAPS	4	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	-	-	-	2	-	-
Upstate Carolina Consortium Community Oncology Research Program	-	8	64	-	-	-
Western States Cancer Research NCORP	-	2	-	1	-	-
Wisconsin NCI Community Oncology Research Program	5	4	-	-	-	-
Yale University - Yale Cancer Center LAPS	43	-	-	-	-	7
ALLIANCE	15	13	53	-	-	-
ECOG-ACRIN	26	27	44	-	-	-
NRG	19	14	-	-	-	-
Total	342	255	1,063	39	2	249



Palliative Care Committee

Leadership

Time/Location

Thursday, October 17, 2024 5:15 p.m. - 7:15 p.m. Room: Regency A (Ballroom Level, West Tower)

Agenda

Welcome and Opening Remarks: Drs. Krouse and Bakitas

Committee Name and Structure Update: Dr. Sun

Patient Advocate and ORP Updates: Valerie Fraser

Shriley Sui

SWOG Membership Profile Overview: Dr. Tami-Maury

Active Studies Update

<u>S1501</u>, "Prospective Evaluation of Carvedilol in Prevention of Cardiac Toxicity in Patients with Metastatic Her-2+ Breast Cancer, Ph III." Drs. Justin Floyd, Monika Jacqueline Leja, Carol Fabian

Developing Studies Update

- 52408, "A Randomized Phase III Multicenter Trial of Lanreotide for the Prevention of Postoperative Pancreatic Fistula" Drs. Sham and Pillarisetty, Concept Approved by DCP 01/23/24. Activating November 2024
- <u>\$2418</u>, "Distress Screening for Family Caregivers of Persons with Advanced Cancer: The FamilySTRONG Randomized Clinical Trial", Dr. Odom, R01 Re-submitted in July 2024
- <u>\$2422</u>, "Telehealth Intervention for Personalized Self-Management (TIPS) for Eating after Gastroesophageal Cancer Surgery", Dr. Kim, R01 Submitted in February 2024
- **S2415**, "Acupuncture to Decrease Symptom Burden in Patients with Metastatic Breast Cancer" Dr. Greenlee. R01 Re-submitted in July 2024

Mustafa Raoof Study Proposal Updates

Closed Studies Update

- <u>\$1316</u>, "Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction." Dr. Krouse. Activated: 3/9/15. Permanently Closed: 5/15/20
- S1820, "A Randomized Phase II Trial of the Altering Intake, Managing Symptoms Intervention for Bowel Dysfunction in Rectal Cancer Survivors (AIMS-RC)." Dr. Sun. Activated: 12/9/19. Closed to Accrual as of 4/12/22. Permanently Closed: 4/12/22

Dr. Jyotsana Parajuli Grant Awards

- National Institutes of Aging (NIA) R15 grant titled 'Development and Initial Validation of a Palliative Care Readiness Tool for Older Adults with Cancer' \$475,748
- Sigma/HPNF grant titled 'Development and Content Validation of a Palliative Care Readiness Tool for Family Caregivers of Older Adults with Cancer' \$10,000

Closing Remarks: Drs. Krouse and Bakitas



Palliative Care Committee

	51501
Ascension Providence Hospitals - Southfield	4
Baptist Memorial Health Care/Mid South Minority Underserved NCORP	7
CWRU Case Comprehensive Cancer Center LAPS	14
Cancer Research for the Ozarks NCORP	11
City of Hope Comprehensive Cancer Center	49
Columbia University Minority Underserved NCORP	2
CommonSpirit Health Research Institute	1
Fred Hutchinson Cancer Research Center LAPS	4
Georgia NCI Community Oncology Research Program	13
Gulf South Minority Underserved NCORP	4
Heartland Cancer Research NCORP	15
Henry Ford Hospital	2
Kaiser Permanente NCI Community Oncology Research Program	1
King Faisal Specialist Hospital and Research Centre	3
Lahey Hospital and Medical Center	6
Loyola University Medical Center	8
MU Health Care Goldschmidt Cancer Center	5
Medical University of South Carolina Minority Underserved NCORP	1
Michigan Cancer Research Consortium NCORP	3
Moffitt Cancer Center	24
Montana Cancer Consortium NCORP	1
NCORP of the Carolinas (Prisma Health NCORP)	2
National Cancer Center-Korea	1
New Mexico Minority Underserved NCORP	7
Oregon Health and Science University	1
UC Davis Comprehensive Cancer Center LAPS	2
USC Norris Comprehensive Cancer Center LAPS	4
University of Kansas Cancer Center - MCA Rural MU NCORP	7
University of Michigan Comprehensive Cancer Center LAPS	10
Wayne State University - Karmanos Cancer Institute LAPS	6
Western States Cancer Research NCORP	2
ALLIANCE	23
ECOG-ACRIN	43
NRG	24
Total	310



Prevention, Screening, & Surveillance Committee

Leadership

Time/Location

Thursday, October 17, 2024 8:00 a.m. - 10:00 a.m. Room: Regency A (Ballroom Level, West Tower)

Agenda

Welcome and Opening Comments: Dr. Marian Neuhouser &

Dr. Banu Arun

Patient Advocate Update: Cheryl Jernigan

Study Updates

Committee Retreat: Envisioning the Future of Cancer Prevention, Screening, and Surveillance

Closed Studies

- So820, "A Double-Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon or Rectal Cancer, Phase III – Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES)." Drs. J. Zell, P. Brown, M.P. Lance, et al. Activated: 3/1/13. Closed: 6/30/23.
- S1823, "A Prospective Observational Cohort Study to Assess miRNA 371 for Outcome Prediction in Patients with Newly Diagnosed Germ Cell Tumors". Drs. C. Nichols and L. Nappi. Activated: 6/1/20. Closed: 5/20/24.
- <u>S1904</u>, "Cluster Randomized Controlled Trial of Patient and Provider Decision Support to Increase Chemoprevention Informed Choice Among Women with Atypical Hyperplasia or Lobular Carcinoma In Situ – Making Informed Choices on Incorporating Chemoprevention into Care (MiCHOICE)." Drs. K. Crew, R. Kukafka, et al. Activated 9/1/20. Closed 6/14/24.

Concepts in Development (not yet approved by Triage)

SWOG/Alliance Tamoxifen/Exemestane Concept, Dr. J. McGuinness.

DCISionRT Biomarker for DCIS Concept, Dr. E. Connolly.

Substudies in Development

Imaging substudy associated with S1007, "Evaluation of a Convolutional Neural Network (CNN)-Based Breast Cancer Risk as a Potential Prognostic Biomarker in Early-Stage Breast Cancer using Imaging Datasets from S1007." Drs. J. McGuinness, K. Crew, K. Kalinsky, D. Kontos.

Imaging substudy associated with S1207, "Effects of Adjuvant Endocrine Therapy on a Convolutional Neural Network (CNN)-Based Breast Cancer Risk Model Using Breast Imaging Datasets from S1207." Drs. J. McGuinness, K. Crew, and R. Ha.

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, "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. Activated: 7/6/17.
- CTSU/NHLBI-MDS, "The National Myelodysplastic Syndromes (MDS) Study." Drs. D. Hill and C. Arana Yi. Activated: 4/5/16. Closed: 6/24/24.
- 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-CC005, "FORTE (Five or Ten Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps)". Dr. L. Kachnic. Activated: 10/6/21.



Prevention, Screening, and Surveillance Committee

	50820	51823	51904	A212102	EA1151	EA2185	EA8184	NRGCC005	NRGCC008
Ascension Providence Hospitals - Southfield	1	-	-	-	-	-	-	-	-
Ascension Via Christi Hospitals Wichita	12	-	-	-	-	-	-	-	-
Audie L Murphy VA Hospital	-	-	-	18	-	-	4	-	-
Banner MD Anderson Cancer Center	10	5	-	-	1	-	-	-	-
Banner University Medical Center - Tucson	-	14	-	-	56	-	-	-	-
Baptist Memorial Health Care/Mid South Minority Underserved NCORP	4	-	12	-	8	-	-	-	-
Bay Area Tumor Institute NCORP	-	1	-	-	-	-	-	-	-
Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center	-	-	-	-	-	3	-	-	4
Brooke Army Medical Center	1	-	-	-	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	1	284	-	-	-	-
Cancer Research Consortium of West Michigan NCORP	2	2	-	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	1	5	-	-	-	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	1	6	-	-	-	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	-	5	26	-	2	-	-	-	-
City of Hope Comprehensive Cancer Center	1	-	20	-	-	-	-	-	-
Columbia University Minority Underserved NCORP	1	-	42	-	-	-	-	-	-
Columbus NCI Community Oncology Research Program	-	7	-	-	-	-	-	-	-
CommonSpirit Health Research Institute	4	-	-	-	-	-	-	-	-
Dayton NCI Community Oncology Research Program	1	-	-	-	-	-	-	-	-
Essentia Health NCI Community Oncology Research Program	5	5	-	-	100	-	-	-	-
Georgia Cares Minority Underserved NCORP	2	-	-	-	-	-	-	-	-
Georgia NCI Community Oncology Research Program	2	-	-	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	-	13	-	-	-	-	-	-	1
Hawaii Minority Underserved NCORP	10	3	21	-	68	-	-	-	-
Heartland Cancer Research NCORP	2	15	11	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	4	133	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	40	178	15	-	-	-	-	-	-
Lahey Hospital and Medical Center	-	-	3	-	-	-	-	-	-
Loma Linda University Medical Center	2	8	-	-	-	-	-	-	-
Loyola University Medical Center	2	-	4	-	-	-	-	-	-
Massachusetts Veterans Epidemiology Research and Information Center	3	-	-	23	-	8	-	4	-
Medical University of South Carolina Minority Underserved NCORP	-	-	-	-	4	-	-	-	-
Meharry Medical College	1	-	-	-	-	-	-	-	-
Memorial Hermann Texas Medical Center	-	-	-	-	8	-	-	-	-
Mercy Medical Center - Des Moines	1	-	-	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	12	-	-	-	-	-	-	-	-
MultiCare Tacoma General Hospital	2	-	-	-	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	-	11	-	-	463	-	-	-	-



Prevention, Screening, and Surveillance Committee

	50820	51823	5190 ⁴	A212102	EA1151	EA2185	EA8184	NRGCC005	NRGCC008
Nevada Cancer Research Foundation NCORP	1	1	-	-	-	-	-	-	-
New Mexico Minority Underserved NCORP	2	12	-	-	-	-	-	-	-
Northwell Health NCORP	2	11	-	-	-	-	-	-	1
Ohio State University Comprehensive Cancer Center LAPS	-	8	2	-	-	-	-	-	-
Oregon Health and Science University	-	17	-	-	-	3	1	4	2
Pacific Cancer Research Consortium NCORP	2	-	1	-	-	-	-	-	-
Riverside Methodist Hospital	6	3	-	-	-	-	-	-	-
Salem Hospital	-	3	-	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	3	2	-	-	-	-	-	-	-
The Don and Sybil Harrington Cancer Center	-	-	-	2	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	-	-	-	-	-	1	1	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	33	4	-	42	-	-	-	-	-
UC San Diego Moores Cancer Center	-	24	-	-	-	1	-	-	-
UCLA / Jonsson Comprehensive Cancer Center	-	30	-	-	-	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS	5	33	-	-	-	-	-	-	-
University of Arkansas for Medical Sciences	-	-	-	-	386	3	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	6	-	-	-	-	-	-	-
University of Colorado Cancer Center LAPS	8	26	-	5	2	-	-	1	-
University of Kansas Cancer Center - MCA Rural MU NCORP	4	-	-	-	-	-	-	-	-
University of Kentucky/Markey Cancer Center	-	-	-	-	9	-	-	-	-
University of Mississippi Medical Center	1	6	-	-	-	-	-	-	-
University of Oklahoma Health Sciences Center LAPS	-	8	-	-	-	-	-	-	-
University of Rochester LAPS	-	20	-	-	263	-	-	-	-
University of Texas Health Science Center at San Antonio	9	-	-	17	-	-	-	-	1
University of Texas MD Anderson Cancer Center LAPS	5	-	-	-	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	-	-	21	-	-	-	-	-	-
Upstate Carolina Consortium Community Oncology Research Program	-	-	-	-	619	-	-	-	-
Vanderbilt University - Ingram Cancer Center LAPS	-	7	-	-	-	-	-	-	-
Virginia Mason Medical Center	11	16	-	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	2	-	-	-	8	-	-	-	-
Western States Cancer Research NCORP	2	5	-	-	69	-	-	-	-
Wisconsin NCI Community Oncology Research Program	1	-	-	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	25	-	-	-	-	-	-	-	-
ALLIANCE	<i>37</i>	96	106	-	-	-	-	-	-
CCTG	-	217	-	-	-	-	-	-	-
ECOG-ACRIN	34	76	43	-	-	-	-	-	-
NRG	38	55	85	-	-	-	-	-	-
Total	354	964	412	112	2,483	19	6	9	9



Leadership

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

Time/Location

Friday, October 18, 2024 7:30 a.m. - 9:30 a.m. Room: Crystal A (Lobby Level, West Tower)

Agenda

Presentations

Acupuncture for symptom management - Richard Harris, PhD

Concepts in Development

- **52423**, "Testing the Fatigue Diet in People with Early-Stage Breast Cancer: The GUIDE Study". Drs. S. Zick and H. Greenlee. Triage informally reviewed on 1/22/24. R01 application submitted February 8th. Scored a 38 in the 36th percentile, plan to resubmit R01 in November 2024.
- S2435, "Phase III Trial of an App-Supported Sleep Coaching Intervention in Post-Treatment Survivors of Diverse Cancers and their Bedroom Partners". Drs. Rina Fox and Terry Badger. R01 submitted June 5th. Review response expected Q4 2024.
- Weight management prior to radical prostatectomy to improve quality of life and obesity-driven prostate cancer biomarkers (WARRIOR). Dr. Hamilton-Reeves
- Fezolinetant for hot flashes in patients with breast cancer. Dr. Lo
- Acupuncture for symptom management in patients with non-muscle invasive bladder cancer. Dr. Psutka
- A phase III study evaluating a mindfulness tool to ameliorate treatmentrelated fatigue in patients with advanced renal cell carcinoma. Drs. Bergerot and Pal
- Emerging from the Haze™ (Haze)- A multi-dimensional, psychoeducational, cognitive rehabilitation program to improve perceived cognitive function for cancer survivors. S2406. Drs. Myers and Arash
- Acupuncture to decrease symptom burden in patients with metastatic breast cancer. Dr. Greenlee

Active Studies

S2013, "Immune Checkpoint Inhibitor Toxicity (I-CHECKIT): A Prospective Observational Study." Drs. Gunturu, Hershman, Kuderer, et al. Activated: 8/16/21; Temporarily closed to accrual: 5/6/24.

- **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. Activated: 3/16/23.
- **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. Activated: 1/17/23.

Closed Studies

- **S1600**, "A Randomized Phase III Double-Blind Clinical Trial Evaluating the Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes (SIMmune)." Drs. Hamilton-Reeves, Holzbeierlein, Kukreja, et al. Permanently closed 10/20/23.
- S1614, "A Phase III Randomized Trial of Prophylactic Antiviral Therapy in Patients with Current or Past Hepatitis B Virus (HBV) Infection Receiving Anti-Cancer Therapy for Solid Tumors." Drs. Hwang, Lok, Gehring, et al. Permanently closed 11/15/22.
- S1714, "A Prospective Observational Cohort Study to Develop a Predictive Model of Taxane-Induced Peripheral Neuropathy in Cancer Patients." Drs. Trivedi, Hershman, Brannagan, et al. Activated: 3/1/19; Permanently closed 11/15/21.
- **50702**, "A Prospective Observational Multicenter Cohort Study to Assess the Incidence of Osteonecrosis of the Jaw (ONJ) in Cancer Patients with Bone Metastases Starting Zoledronic Acid Treatment." Dr. Van Poznak, Activated 12/15/08. Closed 12/13/13.
- **S1200**, "Randomized Blinded Sham- and Waitlist-Controlled Trial of Acupuncture for Joint Symptoms Related to Aromatase Inhibitors in Women with Early Stage Breast Cancer." Dr. Hershman. Activated: 3/27/12. Closed: 2/15/17
- <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; Closed to accrual: 7/1/24.
- <u>\$1806</u>, "Phase III Randomized Trial of Concurrent Chemoradiotherapy with or Without Atezolizumab in Localized Muscle Invasive Bladder Cancer." Dr. Singh. Activated: 4/19/18; Closed to accrual: 4/1/24.
- <u>\$1826</u>, "A Phase III, Randomized Study of Nivolumab (Opdivo) Plus AVD or Brentuximab Vedotin (Adcetris) Plus AVD in Patients (Age >/= 12 Years) with Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma."



Drs. Herrera, Friedberg. Activated: 7/19/19; Closed to accrual: 12/1/22.

S0820, "A Double-Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon or Rectal Cancer, Phase III – Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES)." Drs. Zell, Brown, Lance, et al. Activated: 3/1/13; Closed to accrual: 6/30/23.

<u>\$1904</u>, "Cluster Randomized Controlled Trial of Patient and Provider Decision Support To Increase Chemoprevention Informed Choice Among Women with Atypical Hyperplasia or Lobular Carcinoma in Situ - Making Informed Choices on Incorporating Chemoprevention into Care (MiCHOICE)." Drs. Crew, Kukafka, Hershman, et al. Activated: 9/1/20; Closed to accrual: 6/14/24.

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

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.
- **S2108CD**, "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

\$1802, "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.

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

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

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

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	52010	52013	52205	A171901	A211901	A221805	A222001	A222004
Ascension Providence Hospitals - Southfield	-	-	29	-	-	-	-	-	-
Audie L Murphy VA Hospital	-	-	26	-	-	-	-	-	-
Banner MD Anderson Cancer Center	-	-	-	-	-	-	1	-	-
Banner University Medical Center - Tucson	-	-	5	-	-	-	-	1	-
Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center	5	-	-	-	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-	-	-	4	-	-
Cancer Research for the Ozarks NCORP	-	-	1	-	-	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	-	2	125	-	-	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	-	1	16	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	6	-	-	-	-	-	-	-	-
Columbia University Minority Underserved NCORP	-	13	27	19	-	-	-	-	1
Columbus NCI Community Oncology Research Program	-	-	35	-	-	-	-	-	-
CommonSpirit Health Research Institute	-	11	-	-	-	-	-	-	-
Dayton NCI Community Oncology Research Program	-	-	-	-	-	-	1	-	-
Fred Hutchinson Cancer Research Center LAPS	13	-	-	-	-	-	-	-	-
Georgia Cares Minority Underserved NCORP	-	-	22	-	-	-	-	-	-
Georgia NCI Community Oncology Research Program	-	13	67	-	-	-	-	-	-
Grupo Oncologico Cooperativo de Investigacion	-	-	9	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	1	2	25	-	-	-	-	-	-
Hawaii Minority Underserved NCORP	-	3	4	3	-	-	-	-	-
Heartland Cancer Research NCORP	-	20	243	-	-	-	-	-	-
Henry Ford Hospital	8	-	-	2	-	-	-	-	-
Instituto Nacional De Cancerologia de Mexico	-	5	13	-	-	-	-	-	-
Instituto Nacional de Enfermedades Neoplasicas	-	19	-	-	-	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	-	16	74	-	-	-	-	-	-
Lahey Hospital and Medical Center	-	5	63	-	-	-	-	-	-
Massachusetts Veterans Epidemiology Research and Information Center	-	-	63	-	-	-	-	-	-
Mercy Medical Center - Des Moines	-	-	9	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	-	13	1	-	-	-	-	-	-
Moffitt Cancer Center	-	7	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	-	-	7	-	-	-	-	-	-
Mount Sinai Hospital	-	-	-	-	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	-	-	-	-	-	-	-	-	-



	51600	52010	52013	52205	A171901	A211901	A221805	A222001	A222004
Nevada Cancer Research Foundation NCORP	-	-	-	-	1	-	-	-	-
New Mexico Minority Underserved NCORP	-	13	-	8	-	-	-	-	-
Northwestern University LAPS	-	7	-	-	-	-	-	-	-
Oregon Health and Science University	-	-	12	-	-	-	-	-	-
Pacific Cancer Research Consortium NCORP	-	5	2	-	-	-	-	-	-
Rhode Island Hospital	-	-	-	5	-	-	-	-	-
SCL Health Saint Joseph Hospital	-	-	3	-	-	-	-	-	-
STCC at DHR Health Institute for Research and Development	-	13	55	-	-	4	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	2	146	32	-	-	-	-	-
Stanford Cancer Institute Palo Alto	-	-	-	-	-	-	-	-	-
The Don and Sybil Harrington Cancer Center	-	6	4	-	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	-	6	13	-	-	-	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	6	-	-	-	-	-	-
UC San Diego Moores Cancer Center	-	1	2	-	-	-	-	-	-
UPMC Hillman Cancer Center LAPS	-	2	-	-	-	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS	<i>7</i> 8	-	12	-	-	-	-	-	-
Universidad de la Republica - Facultad de Medicina	-	3	22	-	-	-	-	-	-
U of Alabama at Birmingham / Deep South Research Consortium LAPS	-	-	-	2	-	-	-	-	-
University of Arkansas for Medical Sciences	-	5	25	-	-	-	-	-	-
University of Colorado Cancer Center LAPS	14	1	38	-	-	-	2	-	-
University of Kansas Cancer Center - MCA Rural MU NCORP	51	13	82	11	-	1	2	-	-
University of Michigan Comprehensive Cancer Center LAPS	-	23	-	-	-	-	-	-	-
University of Mississippi Medical Center	-	1	-	-	-	-	-	-	-
University of Oklahoma Health Sciences Center LAPS	-	1	-	-	-	-	-	-	-
University of Rochester LAPS	16	-	-	-	-	-	-	-	-
University of Texas Health Science Center at San Antonio	-	10	53	-	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	-	1	3	-	-	4	-	1	2
Upstate Carolina Consortium Community Oncology Research Program	-	-	-	2	-	-	-	-	-
Western States Cancer Research NCORP	-	-	-	4	-	-	-	-	-
Wisconsin NCI Community Oncology Research Program	-	6	27	-	-	-	-	-	-
ALLIANCE	5	26	351	33	-	-	-	-	-
ECOG-ACRIN	4	21	109	4	-	-	-	-	-
NRG	2	47	255	41	-	-	-	-	-
Total	203	343	2,084	166	1	9	10	2	3



	ACCL1931	EAQ202	NRGCC010	NRGCC011
Ascension Providence Hospitals - Southfield	-	-	-	-
Audie L Murphy VA Hospital	-	-	-	-
Banner MD Anderson Cancer Center	-	-	-	-
Banner University Medical Center - Tucson	-	-	-	-
Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-
Cancer Research for the Ozarks NCORP	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	-	-	-	-
City of Hope Comprehensive Cancer Center	-	-	-	-
Columbia University Minority Underserved NCORP	-	-	-	-
Columbus NCI Community Oncology Research Program	-	-	-	-
CommonSpirit Health Research Institute	-	-	-	-
Dayton NCI Community Oncology Research Program	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	-	-
Georgia Cares Minority Underserved NCORP	-	-	-	-
Georgia NCI Community Oncology Research Program	-	-	-	-
Grupo Oncologico Cooperativo de Investigacion	-	-	-	-
Gulf South Minority Underserved NCORP	-	-	8	-
Hawaii Minority Underserved NCORP	-	-	-	-
Heartland Cancer Research NCORP	-	-	-	-
Henry Ford Hospital	-	-	-	-
Instituto Nacional De Cancerologia de Mexico	-	-	-	-
Instituto Nacional de Enfermedades Neoplasicas	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	-	-	-	-
Lahey Hospital and Medical Center	-	-	-	-
Massachusetts Veterans Epidemiology Research and Information Center	-	-	-	-
Mercy Medical Center - Des Moines	-	-	-	-
Michigan Cancer Research Consortium NCORP	-	-	-	-
Moffitt Cancer Center	-	-	-	-
Montana Cancer Consortium NCORP	-	-	-	-
Mount Sinai Hospital	-	-	-	1
NCORP of the Carolinas (Prisma Health NCORP)	-	39	-	-



 $Accrual from \ trials \ that \ are \ open \ as \ of \ 6/30/2024 \ or \ have \ closed \ in \ the \ prior \ 18 \ Months \ by \ Institution \ and \ Study$

	ACCL1931	EAQ202	NRGCC010	NRGCC011
Nevada Cancer Research Foundation NCORP	-	4	-	-
New Mexico Minority Underserved NCORP	-	-	-	-
Northwestern University LAPS	-	-	-	-
Oregon Health and Science University	-	-	-	-
Pacific Cancer Research Consortium NCORP	-	-	-	-
Rhode Island Hospital	-	-	-	-
SCL Health Saint Joseph Hospital	-	-	-	-
STCC at DHR Health Institute for Research and Development	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	-	-	-
Stanford Cancer Institute Palo Alto	2	-	-	-
The Don and Sybil Harrington Cancer Center	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	-	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	-	-
UC San Diego Moores Cancer Center	-	-	-	-
UPMC Hillman Cancer Center LAPS	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS	-	-	-	-
Universidad de la Republica - Facultad de Medicina	-	-	-	-
U Alabama at Birmingham / Deep South Research Consortium LAPS	-	-	-	-
University of Arkansas for Medical Sciences	-	-	-	-
University of Colorado Cancer Center LAPS	-	-	-	-
University of Kansas Cancer Center - MCA Rural MU NCORP	-	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	-	-	-	-
University of Mississippi Medical Center	-	-	-	-
University of Oklahoma Health Sciences Center LAPS	-	-	2	-
University of Rochester LAPS	-	-	-	-
University of Texas Health Science Center at San Antonio	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	-	-	-	-
Upstate Carolina Consortium Community Oncology Research Program	-	-	-	-
Western States Cancer Research NCORP	-	-	-	-
Wisconsin NCI Community Oncology Research Program	-	-	-	-
ALLIANCE	-	-	-	-
ECOG-ACRIN	-	-	-	-
NRG	-	-	-	-
Total	2	43	10	1



Leadership
Chair:
Vice-Chair:Young Kwang Chae, MD, MPH
Executive Officer:
Statisticians: Megan Othus, PhD
Anna B. Moseley, MS
Sara Threlkel, BS
Designates
Data Coordinator:
Digital Engagement: Kanwal Raghav, MD, MBBS
Veterans Affairs:Jimmy Ruiz, MD
Oncology Research Professionals:
CRAs:
Nurse:TBD
Pharmaceutical Science:
Sun "Coco" Yang, PharmD, PhD
Patient Advocate: Marcia K. Horn, JD
Protocol Project Manager: Catrina De Los Santos-Mireles
Clinical Trials Program Manager: Laura Gildner, MS
Early Therapeutics Liaisons
Breast Committee Liaison: Stephanie L. Graff, MD
Cancer Control Liaison:
Lara E. Davis, MD (Survivorship)
$\label{thm:committee} \textit{Genitourinary Committee Liaison:} \dots \\ \textit{Parminder Singh, MD}$
Imaging: TBD
Lung Committee Liaison: Shirish M. Gadgeel, MD
$Lymphoma\ Committee\ Liaison:Na sheed\ Mohammad\ Hossain, MD$
Melanoma Committee Liaison:Jeffrey A. Sosman, MD
Myeloma Committee Liaison: Frits van Rhee, MD, PhD

Time/Location

Laadarchin

Thursday, October 17, 2024 10:00 a.m. - 12:00 p.m. Room: Crystal C (Lobby Level, West Tower)

Agenda

Walcome and Introduction Dazella Kurzrack MD

10:00 - 10:05 am	welcome and introduction - Razelle Kurzrock, MD
10:05 - 10:30 am	DART II - Young Chae, MD
10:30 - 10:50 am	Sarcoma Working Group Updates - Lara Davis, MD
10:50 - 11:10 am	S2012, "Randomized Phase II/III Trial of First Line Platinum/Etoposide with or without Atezolizumab (NSC#783608) in Patients with Poorly Differentiated Extrapulmonary Neuroendocrine Carcinomas" - David Zhen, MD

11:10 - 11:30 am	Clinical Update: DART Results - Sandip Patel, MD
11:30 - 11:55 am	ComboMATCH - Funda Meric-Bernstam, MD
11·55 - 12·00 pm	Wran Un - Razelle Kurzrock, MD

Active Studies

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

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

CTSU/A071401, "Phase II Trial of SMO/AKT/NF2/CDK Inhibitors in Progressive Meningiomas with SMO/AKT/NF2/CDK Pathway Mutations." Dr. Brastianos. SWOG Champion: Dr. Piccioni. Activated: 8/28/15. New patient registration (Step 1) to the NF2, CDKN2A, CDK4, CDK6, CCND1, CCND2, CCND3, and CCNE1 Cohort (Abemaciclib Cohort) is closed to accrual as of 10/03/22.

CTSU/A092001, "Phase 2 Randomized Trial of Neoadjuvant or Palliative Chemotherapy with or Without Immunotherapy for Peritoneal Mesothelioma". SWOG Champion: Dr. P.S.K. Raghav. Activated: 10/15/21.

CTSU/AGCT1531, "A Phase III Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors" SWOG Champion: Dr. D'Souza Activated: 5/8/17. Stratum 2 is temporarily closed to accrual 10/19/23

CTSU/AOST2031, "A Phase 3 Randomized Controlled Trial Comparing Open vs Thoracoscopic Management of Pulmonary Metastases in Patients with Osteosarcoma" SWOG Champion: Dr. Hofstetter. Activated: 2/15/22

CTSU/AOST2032. "A Feasibility and Randomized Phase 2/3 Study of the VEFGR2/MET Inhibitor Cabozantinib in Combination with Cytotoxic Chemotherapy for Newly Diagnosed Osteosarcoma" SWOG Champion: Dr. J. A. Livingston. Activated: 2/17/23



CTSU/A071702, "A Phase II Study of Checkpoint Blockade Immunotherapy in Patients with Somatically Hyper-mutated Recurrent Glioblastoma." SWOG Champion: Dr. M. Ahluwalia. Activated: 10/30/20. Pre-Registration is temporarily Closed to accrual 12/12/23

CTSU/ HN.11 (CCTG-HN11), "SPECT-CT Guided Elective Contralateral Neck Treatment (SELECT) for Patients with Lateralized Oropharyngeal Cancer: A Phase III Randomized Controlled Trial SWOG" Champion: Dr. Paul Swiecicki. Activated: 9/29/22

Studies in Debvelopment

- **S2425**, "A Randomized Phase II Study of Temozolomide in Combination with Atezolizumab (Tem-Atezo) versus Temozolomide Alone in Adults with Advanced Bronchopulmonary Neuroendocrine Tumors.". Dr. Sukrithan
- <u>52426</u>, "A Randomized Phase II Study of Amivantamab versus Cetuximab in Immunocompromised Patients with Recurrent Inoperable or Metastatic Cutaneous Squamous Cell Carcinoma". Dr. Swiecicki.
- **52429**, "A phase lb/II study of encorafenib, binimetinib and regorafenib in advanced or metastatic BRAF V600E mutated solid tumors that have progressed on prior RAF +/- MEK inhibition". Dr.Ang
- **S2432**, "D ART-II: Dual Anti-LAG-3 and Anti-PD-1 Blockade in Rare Tumors". Dr. Chae, Dr. Kurzrock, Dr. Patel

Closed Studies

- **S1609**, "DART: Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors." Drs. Patel, Chae, and Kurzrock. Activated: 1/13/17. Closed: 3/15/23.
- CTSU/NRG-GY006, "A Randomized Phase III Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIIB, or IVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer." Dr. Leath. SWOG Champion: Dr. Robinson. Activated: 1/15/16. Closed: 9/22/22
- CTSU/NRG-GY020, "A Phase III Randomized Trial of Radiation +/Pembrolizumab (MK-3475) for Newly Diagnosed Early Stage High
 Intermediate Risk Mismatch Repair Deficient (dMMR) Endometrioid
 Endometrial Cancer." Dr. Backes. SWOG Champion: Dr. Robinson.
 Activated: 2/7/20. Closed: 8/29/22.
- NCICOVID, "NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study." Dr. Karim. Activated: 5/21/20. Closed: 2/1/22.

- CTSU/NRG-GY009, "A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin, CTEP-Supplied Bevacizumab and CTEP-Supplied Atezolizumab versus Pegylated Liposomal Doxorubicin and CTEP-Supplied Bevacizumab in Platinum Resistant Ovarian Cancer." Dr. O'Cearbhaill. SWOG Champion: Dr. Robinson. Activated: 5/12/17. Closed 10/14/21
- CTSU/NRG-HN007, "An Open-Label, Phase III Study of Platinum-Gemcitabine with or without Nivolumab in the First-Line Treatment of Recurrent or Metastatic Nasopharyngeal Carcinoma." Dr. Brigette B. Y. Activated: 9/8/20; Closed: 10/28/21
- CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)." Activated: 8/12/15. Closed: 12/23/22
- ctsu/nrg-bnoot, "A Randomized Phase II/III Open-Label Study of Ipilimumab and Nivolumab versus Temozolomide in Patients with Newly Diagnosed MGMT (Tumor O-6-Methylguanine DNA Methyltransferase) Unmethylated Glioblastoma." Dr. Lassman. SWOG Champion: Dr. Ahluwalia. Activated: 8/6/20. Closed: 3/29/23.
- 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. Closed: 11/7/23

Proposed Studies

- NRG-BN1803, "NRG-COG Phase II Trial of Radiation Plus Concurrent and Adjuvant ONC201 for Newly Diagnosed, H3 K27M-Mutant Gliomas." SWOG Champion: Dr. Ahluwalia.
- NRG-OV1821, "A Randomized Phase II Trial of Olaparib Versus Olaparib + Tremelimumab in Platinum-Sensitive Recurrent Ovarian Cancer." Dr. Robinson.
- NRG-BN1855, "A Randomized Phase II/III Open Label Study of Ipilimumab and Nivolumab Vs Te-mozolomide in Patients with Newly Unmethylated MGMT (Tumor O-6-Methylguanine DNA Methyltransferase) 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.

ComboMatch Proposed Studies

EAY191-S6, "CAMELOT Phase II Basket Trial: ATR inhibitor Camonsertib and PKMYT1 Inhibitor Lunresertib Combination in Advanced Solid Tumors with CCNE1 Amplification or Deleterious Alterations in FBXW7 or PPP2R1A" Dr. T. Yap.

ComboMATCH Active Studies

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



	EAY197-53	51609	52012	A077407	AGCT1531	EAY 191	EAY191A3	EAY191EA
Ascension Providence Hospitals - Southfield	-	1	-	-	-	-	-	-
Baptist Memorial Health Care/Mid South Minority Underserved NCORP	-	2	-	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	7	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	-	1	1	-	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	-	3	-	-	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	-	3	-	-	-	-	-	-
Cedars-Sinai Medical Center	-	8	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	-	2	-	-	-	-	-	-
Columbus NCI Community Oncology Research Program	-	2	-	-	-	-	-	-
CommonSpirit Health Research Institute	-	15	1	1	-	-	-	-
Dayton NCI Community Oncology Research Program	-	2	-	-	-	-	-	-
Essentia Health NCI Community Oncology Research Program	-	4	-	-	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	10	7	-	-	-	-	-
Georgia NCI Community Oncology Research Program	-	6	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	-	2	1	-	-	-	-	-
Hawaii Minority Underserved NCORP	-	4	-	-	-	-	-	-
Heartland Cancer Research NCORP	-	14	-	-	-	-	-	-
Henry Ford Hospital	-	17	2	-	-	-	-	-
Intermountain Medical Center	-	1	-	-	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	-	27	1	-	-	-	-	-
Loma Linda University Medical Center	-	6	-	-	-	-	-	-
Loyola University Medical Center	-	4	-	-	-	-	-	-
MU Health Care Goldschmidt Cancer Center	-	1	-	-	-	-	-	-
Massachusetts Veterans Epidemiology Research and Information Center	-	6	-	-	-	-	-	-
Medical University of South Carolina Minority Underserved NCORP	-	4	-	-	-	-	-	-
Mercy Medical Center - Des Moines	-	2	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	-	12	2	-	-	-	-	-
Moffitt Cancer Center	-	22	3	-	-	-	-	-
Montana Cancer Consortium NCORP	-	16	-	-	-	-	-	-
Mount Sinai Hospital	-	-	-	-	1	-	-	-
MultiCare Tacoma General Hospital	-	2	-	-	-	-	-	-
Nevada Cancer Research Foundation NCORP	-	18	-	-	-	-	_	_



$Accrual from \ trials \ that \ are \ open \ as \ of \ 6/30/2024 \ or \ have \ closed \ in \ the \ prior \ 18 \ Months \ by \ Institution \ and \ Study$

	EAY191-53	51609	52012	A077407	AGCT1531	EAY191	EN191A3	EAY197EA
New Mexico Minority Underserved NCORP	-	18	-	-	-	-	-	-
Northwestern University LAPS	-	16	3	1	-	-	-	-
Ohio State University Comprehensive Cancer Center LAPS	-	-	4	-	-	-	-	-
Oregon Health and Science University	-	12	-	-	-	-	-	-
Pacific Cancer Research Consortium NCORP	-	12	-	-	-	-	-	-
Riverside Methodist Hospital	-	1	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	-	1	-	-	-	-	-
Sutter Cancer Research Consortium	-	2	-	-	-	-	-	-
The Don and Sybil Harrington Cancer Center	-	-	-	-	1	-	-	-
UC Davis Comprehensive Cancer Center LAPS	-	11	-	-	-	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	8	-	1	-	4	-	3
UC San Diego Moores Cancer Center	-	27	-	2	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS	-	4	-	-	-	-	-	-
University of Arkansas for Medical Sciences	-	5	-	-	-	-	-	-
University of Colorado Cancer Center LAPS	-	6	-	1	-	-	-	-
University of Kansas Cancer Center - MCA Rural MU NCORP	-	35	-	-	-	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	-	32	1	-	-	-	-	-
University of Mississippi Medical Center	-	5	-	-	-	-	-	-
University of Oklahoma Health Sciences Center LAPS	-	3	-	-	-	-	-	-
University of Rochester LAPS	-	5	-	-	-	-	-	-
University of Texas Health Science Center at San Antonio	-	5	1	-	-	-	-	-
University of Texas MD Anderson Cancer Center LAPS	1	19	-	-	-	6	2	-
University of Utah - Huntsman Cancer Institute LAPS	-	3	1	-	-	-	-	-
Upstate Carolina Consortium Community Oncology Research Program	-	4	-	-	-	-	-	-
Vanderbilt University - Ingram Cancer Center LAPS	-	-	1	-	-	-	-	-
Wisconsin NCI Community Oncology Research Program	-	12	1	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	7	1	2	-	-	-	-
ALLIANCE	-	106	9	-	-	-	-	-
ECOG-ACRIN	1	<i>7</i> 8	2	-	-	-	-	-
NRG	-	138	6	-	-	-	-	-
Total	2	<i>7</i> 98	49	8	2	10	2	3



Leadership	Oncology Research Professionals:	
Chair:Philip A. Philip, MD, PhD, FRCP	CRA:	TBD
Vice-Chair:Elena G. Chiorean, MD	Nurse:	TBD
Executive Officer: Christopher W. Ryan, MD	Patient Advocate (Pancreatic):	Carole Seigel, MBA
Statisticians: Katherine A. Guthrie, PhD	Patient Advocate (Colon):	Marielle McLeod, MHA, CPN
Sarah Colby, MS	Pharmaceutical Science:	Jane E. Rogers, PharmD
		Safae Chouraichi, PharmD
Scientific Leadership	Protocol Project Manager:	Andrea Garcia
Gastroesophageal:Syma Iqbal, MD	Clinical Trials Program Manager:	Laura Gildner, MS
Zev A. Wainberg, MD	Time/Location	
Pancreatic: Davendra P.S. Sohal, MD	Friday, October 18, 2024 4:30 p.m 6:	30 p.m.
Andrew M. Lowy, MD (Surgical representative)	Room: Regency D (Ballroom Level, W	
Hepatobiliary: Anthony B. El-Khoueiry, MD		
	Age	enda
Syed A. Ahmad, MD (Surgical representative)	1. Welcome	
Colon:Marwan G. Fakih, MD		-1 · 1 · -1 · 1 ·
Philip J. Gold, MD	2. Announcements & Introductions	Philip Philip
Sepideh Gholami, MD (Surgical representative)		E. Gabriela Chiorean
Neuroendocrine Tumors:Nageshwara Arvind Dasari, MD	3. HEARD Subcommittee Initiatives	Rachel Safyan, Colmar Figueroa-
Jonathan R. Strosberg, MD	Moseley, Carole Seigel, Marielle Mo	•
Ano-Rectal:Lisa A. Kachnic, MD	•	
Hagen F. Kennecke, MD	4. SWOG Led Trials Updates	
Imaging: Anthony F. Shields, MD, PhD	a. \$1922	Michael Overman
Pathology:	b. S2001	Vincent Chung
Radiation Oncology:Lisa A. Kachnic, MD	c. S2104	Heloisa Soares/S. Ahmad
Surgery: Stephen W. Behrman, MD	d. S2107	Van Morris
Syed A. Ahmad, MD	e. S2012	David Zhen/E. Gabriela Chiorean
Flavio Rocha, MD	f. S2303	Anwaar Saeed/Paul Oberstein
Translational Medicine:	5. SWOG Co-Led Trials Updates	
	a. A022102	Paul Oberstein
Designates	b. A022104	Arvind Dasari
Cancer Control Liaisons:Jason A. Zell, DO (Prevention)	c. A022001	Heloisa Soares
Afsaneh Barzi, MD (CCD)	d. A022101	Sepideh Gholami
Community Liaisons: Gary L. Buchschacher, MD, PhD (Medical Oncology)	e. A021804	Charles Lopez
Mohamed E. Salem, MD (Medical Oncology)	f. A021806	Steve Behrman
Flavio Rocha, MD (Surgical)	g. EA2192	Philip Philip/E. Gabriela Chiorean
David Horowitz, MD (Radiation Oncology)	h. EA2183	David Horowitz
DEI Champion:	i. EA2197	Flavio Rocha
	j. EA2176	Van Morris
Digital Engagement:	k. EA2182	J. Murphy
Veterans Affairs:	I. NRG-GI003	A. El-Khoueiry
Data Coordinators:	m. NRG-Gl004	Michael Overman
Brian Zeller	n. CCTG NE1	Aman Chauhan
Christine Magner		



Davendra Sohal, Andrew Lowy

Hagen Kennecke, Lisa Kachnic

Marwan Fakih, Philip Gold,

Syma Iqbal, Zev Wainberg

Anthony El-Khoueiry

Arvind Dasari, Aman Chauhan

Rachna Shroff

Sepideh Gholami

- 6. Pancreatic
 - a. Major recent clinical results
 - b. NCTN trials update
 - c. Future SWOG plans
- 7. Anal and Rectal
 - a. Major recent clinical results
 - b. NCTN trials update
 - c. Future SWOG plans
- 8. Colon
 - a. Major recent clinical results
 - b. NCTN trials update
 - c. Future SWOG plans
- 9. Gastroesophageal
 - a. Major recent clinical results
 - b. NCTN trials update
 - c. Future SWOG plans
- 10. Hepatobiliary
 - a. Major recent clinical results
 - b. NCTN trials update
 - c. Future SWOG plans
- 11. Neuroendocrine
 - a. Major recent clinical results
 - b. NCTN trials update
 - c. Future SWOG plans
- 12. Discussion/Other business
- 13. Adjourn

Gastroesophageal

Active Studies

- **S2303**, "Randomized Phase II/III Trial of 2nd Line Nivolumab + Paclitaxel + Ramucirumab versus Paclitaxel + Ramucirumab in Patients with PD-L1 CPS ≥ 1 Advanced Gastric and Esophageal Adenocarcinoma (PARAMUNE)", Dr. Saeed. Activated: 5/6/24
- CTSU/A022102, "Randomized Phase III Trial of mFOLFIRINOX +/-Nivolumab vs. FOLFOX +/- Nivolumab for First-Line Treatment of Metastatic HER2-Negative Gastroesophageal Adenocarcinoma." Dr. Oberstein. Activated: 1/17/19.

CTSU/EA2174, "A Phase II/III Study of Peri-Operative Nivolumab and Ipilimumab in Patients with Locoregional Esophageal and Gastroesophageal Junction Adenocarcinoma." Dr. Kelly. Activated: 1/17/19. Temporarily Closed to Accrual as of 12/29/22.

CTSU/EA2183, "A Phase III Study of Consolidative Radiotherapy in Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA)." Dr. Horowitz. Activated: 2/6/20.

Pancreatic

Developing Studies

<u>\$2433</u>, "Randomized Phase II Study of Second-Line Chemotherapy with or without Panitumumab for Locally Advanced or Metastatic KRAS/BRAF V600E Wild Type Pancreatic Adenocarcinoma." Dr. Safyan.

Active Studies

- **S2001**, "Randomized Phase II Clinical Trial of Olaparib + Pembrolizumab Alone as Maintenance Therapy in Metastatic Pancreatic Cancer Patients with Germline BRCA1 or BRCA2 Mutations." Dr. Chung. Activated: 12/4/20.
- 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/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.

Closed Studies

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)." Activated: 6/18/20. Dr. Zhen. Closed to Accrual as of 10/17/23

Neuroendocrine

Active Studies

S2104, "Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolimide versus Observation in High-Risk Pancreatic



Neuroendocrine Tumors." Dr. Soares. Activated: 10/14/21

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

Closed Studies

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. Closed to Accrual as of 9/8/23

Hepatobiliary

Active Studies

- CTSU/NRG-GI003, "A Phase III Randomized Trial of Protons Versus Photons for Hepatocellular Carcinoma." Dr. El-Khoueiry. Activated: 6/21/17.
- CTSU/EA2197, "Optimal Perioperative Therapy for Incidental Gallbladder Cancer (OPT-IN): A Randomized Phase II/III Trial." Dr. Rocha. Activated: 12/22/20.

Closed Studies

- S1815, "A Phase III Randomized Trial of Gemcitabine, Cisplatin, and Nab-Paclitaxel Versus Gemcitabine and Cisplatin in Newly Diagnosed, Advanced Biliary Tract Cancers." Dr. Shroff. Activated: 12/3/18. Permanently Closed: 2/15/21.
- CTSU/EA2187, "A Phase 2 Study of Pevonedistat in Combination with Carboplatin and Paclitaxel in Advanced Intrahepatic Cholangiocarcinoma." Dr. Stein. Activated: 1/31/20. Permanently Closed: 3/22/23.

Colorectal

Active Studies

- **S2107**, "Randomized Phase II Trial of Encorafenib and Cetuximab with or without Nivolumab for Patients with Microsatellite Stable, BRAFV600E Metastatic Colorectal Cancer." Dr. Morris. Activated: 6/6/22.
- A022101, "A Pragmatic Randomized Phase III Trial Evaluating Total Ablative Therapy for Patients with Limited Metastatic Colorectal Cancer: Evaluating Radiation, Ablation, and Surgery (ERASur)" SWOG Champion: S. Gholami Activated: 1/10/23.
- CTSU/NRG-GI008, Colon Adjuvant Chemotherapy Based on Evaluation

- of Residual Disease (CIRCULATE-US) SWOG GI Committee Co-Chairs: P. Philip & C. Eng Activated: 3/10/22
- 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/NRG-GI004/ S1610, "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.

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 3 permanently closed: 11/30/23
- **SO820**, "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-Ill Colon or Rectal Cancer, Phase III Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES)." Dr. Zell. Activated: 3/1/13. Permanently Closed: 6/30/23
- 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. Permanently Closed: 1/17/23
- 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. Permanently
 Closed: 12/15/22

Anal

Active Studies

- A022104, "The Janus Rectal Cancer Trial: A Randomized Phase II Trial
 Testing the Efficacy of Triplet Versus Doublet Chemotherapy to Achieve
 Clinical Complete Response in Patients with Locally Advanced Rectal
 Cancer" Activated 11/9/22. SWOG Champion: A. Dasari
- 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

Developing Studies

52408, "A Randomized Phase III Blinded Trial of Lanreotide for the Prevention of Postoperative Pancreatic Fistula" Dr. Sham. Activating November 2024.



	51922	52001	52104	52107	52303	A021502	A021602	A021806	A022001	A022102
Ascension Providence Hospitals - Southfield	-	2	-	-	-	3	-	-	-	-
Banner University Medical Center - Tucson	-	-	6	-	-	2	3	1	-	-
Baptist Mem Health Care/Mid South Minority Underserved NCORP	-	2	-	-	-	-	-	-	-	-
Baylor College of Medicine/Duncan Comprehensive Cancer Center	-	-	-	-	-	-	-	-	-	-
Boston Medical Center	-	-	-	-	-	1	3	1	-	3
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-	-	6	-	2	-	-
Cancer Research Consortium of West Michigan NCORP	-	-	-	2	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	-	1	-	-	-	-	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	-	-	-	-	1	-	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	1	-	1	1	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	-	4	-	-	-	-	1	-	-	-
Columbia University Minority Underserved NCORP	-	1	-	-	-	-	-	-	-	-
CommonSpirit Health Research Institute	-	-	1	2	-	-	-	-	-	-
Corewell Health William Beaumont University Hospital	-	-	-	-	-	1	-	-	-	-
Dayton NCI Community Oncology Research Program	-	-	-	-	-	3	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	2	-	-	4	-	2	-	-
Gulf South Minority Underserved NCORP	-	-	-	3	-	-	-	-	-	-
Hawaii Minority Underserved NCORP	-	-	-	-	-	-	-	-	-	-
Heartland Cancer Research NCORP	1	1	-	3	-	-	-	-	-	-
Henry Ford Hospital	-	1	-	-	-	-	-	-	-	-
Houston Methodist Hospital	-	-	-	-	-	-	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	-	-	-	5	-	17	-	-	-	-
Loma Linda University Medical Center	-	-	-	-	-	-	-	-	-	-
Medical University of South Carolina Minority Underserved NCORP	-	-	1	-	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	1	2	-	3	-	-	-	-	-	-
Moffitt Cancer Center	-	-	2	-	-	-	4	-	-	-
Montana Cancer Consortium NCORP	-	-	-	1	-	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	-	-	1	-	-	-	-	-	-	-
Northwell Health NCORP	-	-	-	-	-	-	-	1	-	-
Northwestern University LAPS	1	-	-	-	-	1	-	1	-	-
Ohio State University Comprehensive Cancer Center LAPS	-	-	1	-	-	-	-	-	-	-



	51922	52001	52104	52107	52303	A021502	A021602	A021806	A022001	A022102
Oregon Health and Science University	-	-	1	-	-	-	-	-	-	-
Pacific Cancer Research Consortium NCORP	-	1	2	2	-	-	-	-	-	-
STCC at DHR Health Institute for Research and Development	-	-	-	-	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	2	4	4	-	-	-	-	-	-
Sutter Cancer Research Consortium	-	-	-	-	-	3	-	-	-	-
The Don and Sybil Harrington Cancer Center	-	-	-	-	-	-	-	2	-	-
The West Clinic - Wolf River	-	-	-	-	-	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	-	-	-	-	-	4	-	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	2	-	2	-	-	-	-	-	3
USC Norris Comprehensive Cancer Center LAPS	-	-	1	-	-	2	-	-	-	-
U of Alabama at Birmingham/Deep South Research Consortium LAPS	-	-	-	-	-	-	-	-	-	1
University of Arkansas for Medical Sciences	-	-	-	-	-	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	-	1	-	-	-	-	-	-	-
University of Colorado Cancer Center LAPS	-	2	-	6	-	6	-	-	-	-
University of Kansas Cancer Center - MCA Rural MU NCORP	-	-	-	-	-	3	-	-	-	5
University of Kentucky/Markey Cancer Center	-	-	3	-	-	-	-	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	3	3	1	-	-	-	4	4	-	-
University of Oklahoma Health Sciences Center LAPS	-	-	-	-	-	-	-	-	-	-
University of Rochester LAPS	1	-	-	-	-	2	8	11	-	1
University of Texas Health Science Center at San Antonio	-	-	-	-	-	-	-	3	-	-
University of Texas MD Anderson Cancer Center LAPS	11	-	-	8	-	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	-	1	3	-	-	-	-	-	1	-
Vanderbilt University - Ingram Cancer Center LAPS	-	4	-	1	-	-	-	-	-	-
Virginia Mason Medical Center	-	-	-	-	-	4	2	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	1	-	-	-	2	-	-	-	2
Wisconsin NCI Community Oncology Research Program	-	-	1	1	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	-	-	-	-	4	-	2	1	-
ALLIANCE	10	5	3	7	-	-	-	-	-	-
ECOG-ACRIN	2	11	5	11	-	-	-	-	-	-
NRG	3	5	7	7	-	-	-	-	-	-
Total	34	51	47	69	1	68	25	30	2	15



	A022104	CCTGCO32	CCTGNET	EA2174	EA2176	EA2182	EA2186	EA2187	EA2192
Ascension Providence Hospitals - Southfield	-	-	-	-	1	2	2	-	-
Banner University Medical Center - Tucson	-	-	-	-	-	-	-	-	-
Baptist Memorial Health Care/Mid South Minority Underserved NCORP	-	-	-	-	-	-	-	-	-
Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center	4	-	-	-	-	-	-	-	-
Boston Medical Center	5	-	-	2	-	2	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	2	-	4	1	3	-
Cancer Research Consortium of West Michigan NCORP	-	-	-	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	-	-	-	-	-	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	-	-	-	-	-	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	-	-	-	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	-	-	-	-	-	-	3	-	-
Columbia University Minority Underserved NCORP	-	-	-	-	-	-	-	-	-
CommonSpirit Health Research Institute	-	-	-	-	-	-	-	-	-
Corewell Health William Beaumont University Hospital	-	-	-	-	-	-	-	-	-
Dayton NCI Community Oncology Research Program	-	-	-	-	-	-	1	-	-
Fred Hutchinson Cancer Research Center LAPS	6	-	-	-	-	-	1	-	-
Gulf South Minority Underserved NCORP	-	-	-	-	-	-	-	-	-
Hawaii Minority Underserved NCORP	-	-	-	-	-	-	2	-	-
Heartland Cancer Research NCORP	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	-	-	-	-	-	-
Houston Methodist Hospital	-	-	-	-	-	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	-	-	-	-	6	-	-	-	-
Loma Linda University Medical Center	-	-	-	-	-	-	-	-	-
Medical University of South Carolina Minority Underserved NCORP	-	-	-	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	-	-	-	-	-	-	-	-	-
Moffitt Cancer Center	-	-	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	-	-	-	-	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	-	-	-	-	-	-	-	-	-
Northwell Health NCORP	-	-	-	1	-	-	2	-	-
Northwestern University LAPS	-	-	-	-	1	-	1	-	-
Ohio State University Comprehensive Cancer Center LAPS	-	-	-	-	-	-	-	-	-
Oregon Health and Science University	-	-	-	-	4	1	-	-	2



	A022104	ccTGCO32	CCTGNET	EA2174	EA2176	EA2182	EA2186	EA2187	EA2192
Pacific Cancer Research Consortium NCORP	-	-	-	-	-	-	-	-	-
STCC at DHR Health Institute for Research and Development	-	-	-	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	-	-	-	-	-	-	-	-
Sutter Cancer Research Consortium	-	-	-	-	-	-	-	1	-
The Don and Sybil Harrington Cancer Center	1	-	-	-	-	-	-	-	-
The West Clinic - Wolf River	11	-	-	-	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	1	-	-	-	-	-	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	4	1	-	-	4	1	2	-	-
USC Norris Comprehensive Cancer Center LAPS	-	-	-	1	2	-	-	-	-
University of Alabama at Birmingham/Deep South Research Consortium LAPS	-	-	-	-	-	-	-	-	-
University of Arkansas for Medical Sciences	-	-	-	-	2	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	-	-	-	1	1	-	-	-
University of Colorado Cancer Center LAPS	-	-	1	-	-	2	1	-	-
University of Kansas Cancer Center - MCA Rural MU NCORP	-	-	-	-	-	-	-	1	-
University of Kentucky/Markey Cancer Center	-	-	-	-	-	-	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	1	-	-	-	-	-	-	-	-
University of Oklahoma Health Sciences Center LAPS	-	-	-	-	-	-	-	-	-
University of Rochester LAPS	13	-	-	-	-	-	7	2	-
University of Texas Health Science Center at San Antonio	4	-	-	-	-	-	3	-	-
University of Texas MD Anderson Cancer Center LAPS	-	-	-	-	10	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	-	-	-	-	-	-	-	-	-
Vanderbilt University - Ingram Cancer Center LAPS	8	-	-	-	-	-	-	-	-
Virginia Mason Medical Center	3	-	-	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	-	-	-	1	-	-	-
Wisconsin NCI Community Oncology Research Program	-	-	-	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	-	-	-	-	-	-	-	-
ALLIANCE	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-	-	-	-
NRG	-	-	-	-	-	-	-	-	-
Total	61	1	1	6	31	14	26	7	2



Gastrointestinal Committee

	EA2197	EA2222	NRGGI004	NRGG1005	NRGG1006	NRGG1008
Ascension Providence Hospitals - Southfield	-	-	-	5	-	1
Banner University Medical Center - Tucson	-	-	-	-	-	-
Baptist Memorial Health Care/Mid South Minority Underserved NCORP	-	-	-	3	-	1
Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center	-	-	-	-	-	1
Boston Medical Center	-	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-	-	-
Cancer Research Consortium of West Michigan NCORP	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	-	-	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	-	-	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	-	-	-	-	-	-
Columbia University Minority Underserved NCORP	-	-	-	-	-	-
CommonSpirit Health Research Institute	-	-	-	-	-	-
Corewell Health William Beaumont University Hospital	-	-	-	-	-	-
Dayton NCI Community Oncology Research Program	-	-	-	1	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	-	-	-	-	-	-
Hawaii Minority Underserved NCORP	-	-	-	-	-	-
Heartland Cancer Research NCORP	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	1	-	-
Houston Methodist Hospital	-	-	1	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	-	-	-	11	-	-
Loma Linda University Medical Center	-	-	-	-	-	1
Medical University of South Carolina Minority Underserved NCORP	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	-	-	-	1	-	-
Moffitt Cancer Center	-	-	-	-	-	-
Montana Cancer Consortium NCORP	-	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	-	-	-	-	-	-
Northwell Health NCORP	-	-	-	1	-	1
Northwestern University LAPS	-	-	-	-	-	-
Ohio State University Comprehensive Cancer Center LAPS	-	-	-	-	-	-



Gastrointestinal Committee

	EA2197	EA2222	NRGGI004	NRGG1005	NRGG1006	NRGG1008
Oregon Health and Science University	4	-	-	1	-	-
Pacific Cancer Research Consortium NCORP	-	-	-	-	-	-
STCC at DHR Health Institute for Research and Development	-	-	-	1	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	-	-	-	-	-
Sutter Cancer Research Consortium	-	-	-	-	-	-
The Don and Sybil Harrington Cancer Center	-	-	-	-	-	-
The West Clinic - Wolf River	-	-	-	-	-	2
UC Davis Comprehensive Cancer Center LAPS	1	-	-	1	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	-	1	-	-
USC Norris Comprehensive Cancer Center LAPS	-	-	-	-	-	-
U of Alabama at Birmingham / Deep South Research Consortium LAPS	-	-	-	-	-	-
University of Arkansas for Medical Sciences	-	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	-	-	-	-	-
University of Colorado Cancer Center LAPS	-	-	-	-	-	5
University of Kansas Cancer Center - MCA Rural MU NCORP	-	-	-	2	-	-
University of Kentucky/Markey Cancer Center	-	-	-	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	-	1	-	-	-	-
University of Oklahoma Health Sciences Center LAPS	-	-	-	-	1	1
University of Rochester LAPS	-	-	1	-	-	5
University of Texas Health Science Center at San Antonio	-	-	-	-	-	-
University of Texas MD Anderson Cancer Center LAPS	-	-	13	1	-	-
University of Utah - Huntsman Cancer Institute LAPS	-	-	-	-	-	-
Vanderbilt University - Ingram Cancer Center LAPS	-	-	-	1	-	3
Virginia Mason Medical Center	1	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	-	-	-	-
Wisconsin NCI Community Oncology Research Program	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	-	-	4	-	-
ALLIANCE	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-
NRG	-	-	-	-	-	-
Total	6	1	15	35	1	21



Leadership	
Chair:	Seth P. Lerner, MD
Vice-Chair:	Daniel P. Petrylak, MD
Chair Emeritus:	lan M. Thompson, Jr., MD
Executive Officer:	Christopher W. Ryan, MD
Statisticians:	Cathy M. Tangen, DrPH
	Melissa Plets, MS
	Sam Callis, MS
	Sara Threlkel, BS
Scientific Leadership	
	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
•	Shuchi Gulati, MD (Medical Onc)
	Robert Svatek, MD (Urologic Onc)
•	M. Scott Lucia, MD
	Kelly L. Stratton, MD
	Parminder Singh, MD
	. Siamak Daneshmand, MD (Localized)
	Thomas W. Flaig, MD (Advanced)
_	Daniel W. Lin, MD (Localized)
	Tanya B. Dorff, MD (Advanced)
	Brian Shuch, MD (Localized)
Designates	Ulka N. Vaishampayan, MD (Advanced)
	Clara Hwang, MD
	Sarah P. Psutka, MD, MSC
	Jessica D. McDermott, MD
	Neema Navai, MD
	Scott Edward Delacroix, Jr., MD
	Michael M. Goodman, MD
Data Coordinators:	
	Laura Wells, BA
	Michele Counts, BS
	Tonya Johnson, BS
Oncology Research Professionals:	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
= :	Abagail L. Cornette, MS
	Gary Lee Duvall, RN
	•

Patient Advocates:	Rick Bangs, MBA (Emeritus, Bladder))
	Darrell Nakagawa (Bladder)
	Tony Crispino (Emeritus, Prostate)
	Lee Henry Moultrie (Prostate)
	Laura B. Esfeller, MA (Renal)
Pharmaceutical Science:	Joyce Lee, PharmD
	Allison Schepers, PharmD
Protocol Project Manager:	Megan Keim
Clinical Trials Program Manager:	Mariah Norman, MS

Time/Location

Friday, October 18, 2024 9:30 a.m. - 12:00 p.m. Room: Regency D (Ballroom Level, West Tower)

Agenda

9:30 - 9:45 am: Chair's Welcome and Opening Remarks - Seth Lerner

9:45 - 10:15 am: Cancer Control - Clara Hwang and Sarah Psutka

10:15 - 12:00 pm: Review of open approved trials - all organ site chairs

Bladder – Sia Daneshmand and Tom Flaig

Prostate – Dan Lin and Tanya Dorff

Renal – Brian Shuch and Ulka Vaishampayan

Cancer Control

Organ Site Chairs: Drs. Clara Hwang and Dr. Sarah Psutka

Active Studies

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

S1823, "A Prospective Observational Cohort Study to Assess miRNA 371 for Outcome Prediction in Patients with Early Stage Germ Cell Tumors", Pl: Craig Nichols – Activated 6/1/20 GU Champions: Thomas Frye & Anishka D'Souza

<u>\$1931</u> (Companion Study): Examining Psychosocial and Emotional Issues for Metastatic Kidney Cancer. Pl: Cristiane Bergerot.

<u>S1937</u> (Companion Study): Assessment of Quality of Life for S1937: A Phase III Randomized Trial of Eribulin with or without Gemcitabine Versus Standard of Care (Physician's Choice) for Treatment of Metastatic Urothelial Carcinoma Refractory to, or Ineligible for, Anti PD1/PDL1



Therapy. QoL Study Chair: Dr. Afsaneh Barzi. On hold until accrual picks up on S1937.

Bladder

Organ Site Chairs: Dr. Thomas Flaig (Advanced) and Dr. Siamak Daneshmand (Local).

Priority Study

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. Temporary Closure: 5/30/23. Re-opened Arms 1&3 to accrual and permanently closed Arm 2 on 2/15/24.

Concepts in Development

S2427, "Bladder preservation with chemoradiotherapy or immunoradiotherapy after a good response to neoadjuvant chemotherapy in patients with muscle invasive bladder cancer (BRIGHT)." Dr. L. Ballas. Submitted to GUSC on 5/28. Received pending response. Response to GUSC comments due 8/7 for 8/21 GUSC meeting.

Active Studies

- **S1806**, "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. Step 1 accrual closed 3/1/24.
- 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 In-vasive Bladder Cancer." Drs. R. Svatek, A. Alva, and S. Lerner. Activated: 2/7/17; Permanently Closed: 12/15/20.
- <u>\$1605</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.
- **S2011**, "Randomized Phase II Trial of Gemcitabine, Avelumab, and Carboplatin vs. No Neoadjuvant Therapy Preceding Surgery for Cisplatin Ineligible Muscle-Invasive Urothelial Carcinoma." Drs. Son-pavde, M. Liss, and S. Lerner, et al. Activated: 10/6/21. Closed to Accrual: 11/15/23.

Prostate

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

Priority Study

52210, "Targeted neoadjuvant treatment for patients with localized prostate cancer and germline DNA repair deficiency." Dr. H. Cheng. Activated 8/14.

Concepts in Development

S2312, "A Phase III Study of Cabazitaxel with or without Carboplatin in Patients with metastatic cas-trate-resistant prostate cancer (mCRPC), Stratified by Aggressive Variant Signature." Dr. Paul Corn. CIRB provided approval-on-hold 7/11. Awaiting CTEP full approval and completion of dry run. Target activation mid-September.

Active Studies

- S1802, "Phase III Randomized Trial of Standard Systemic Therapy (SST)
 Versus Standard Sys-temic 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. Revision #5 released 8/15.
- 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. Ouinn. 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 In-termediate 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

S1216, "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 Pros-tate 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: 7/11/22.

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; Permanent-ly 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.

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

S2419, "Phase III Double Blinded Trial of Immune-Based Therapy with a Live Biotherapeutic CBM588, or Placebo for Frontline Therapy of Advanced Clear Cell Renal Cell Carcinoma [BioFront Trial]". Drs. P. Barata and U. Vaishampayan. Concept submitted to GUSC for 9/18 review.

Active Studies

52200, "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. Activated 9/19/22.



- CTSU/AREN1721, "A Randomized Phase 2 Trial of Axitinib/Nivolumab Combination Therapy vs. Sin-gle 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; Reactivated: 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 Urotheli-al Carcinoma: A randomized Phase 3 non-Inferiority Trial." Dr. D. Vaena. Activated: 12/10/20.

Closed Studies

- S1500, "A Randomized, Phase II Efficacy Assessment of Multiple MET Kinase Inhibitors (Cabozantinib [NSC #761968], Crizotinib [NSC #749005], Savolitinib [NSC #785348], and Sunitinib [NSC #736511]) in Metastatic Papillary Renal Carcinoma (PAPMET)." Drs. S. Pal and P. Lara. Activated 4/5/16; Permanently closed: 12/15/19.
- **S0931**, "EVEREST: Everolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study." Drs. C. Ryan, E. Heath, P. Lara, et al. Activated: 4/1/11; Permanently Closed: 9/15/16.
- CTSU/E2810, "Randomized, Double-Blind Phase III Study of Pazopanib vs. Placebo in Patients with Metastatic Renal Cell Carcinoma Who Have No Evidence of Disease Following Metastatectomy." Dr. S. Pal. Activated: 8/8/12; Permanently closed: 7/25/17.
- CTSU/A031501, "Phase III Randomized Adjuvant study of Pembrolizumab in Muscle Invasive and Lo-cally Advanced Urothelial Carcinoma (AMBASSADOR) Versus Observation." Dr. G. Sonpavde. Activated: 9/21/17; Permanently Closed: 8/24/21.
- CTSU/EA8143, "A Phase 3 Randomized Study Comparing Perioperative Nivolumab vs. Observation in Patients with Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC)." Drs. P. Lara and B. Shuch. Activated: 2/2/17; Permanently Closed: 6/9/21.

Translational Medicine

Chair: Dr. David McConkey

Co-Chair: Dr. Joshua Meeks

Bladder Chair: Dr. Joshua Meeks

Prostate Chair: Dr. Amir Goldkorn

Renal Chair: Dr. Sumanta "Monty" Pal

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.



$Accrual from \ trials \ that \ are \ open \ as \ of \ 6/30/2024 \ or \ have \ closed \ in \ the \ prior \ 18 \ Months \ by \ Institution \ and \ Study$

	51802	51806	51931	51937	52011	52200	52210	A021804	A031701	A031702
Ascension Providence Hospitals - Southfield	-	-	-	-	-	-	-	-	-	-
Audie L Murphy VA Hospital	-	-	-	-	-	-	-	-	-	-
Banner MD Anderson Cancer Center	6	-	1	-	-	-	-	-	-	-
Banner University Medical Center - Tucson	7	-	1	-	-	-	-	-	-	-
Baylor College of Medicine/Duncan Comprehensive Cancer Center	2	8	-	-	-	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	-	-	-	-	-	9	-
Cancer Research Consortium of West Michigan NCORP	2	8	-	-	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	1	5	-	-	-	-	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	1	6	-	-	-	-	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	1	1	1	-	-	-	-	-	-	-
Cedars-Sinai Medical Center	-	11	4	-	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	4	-	2	-	-	5	-	-	-	-
Columbia University Minority Underserved NCORP	2	4	-	-	-	-	-	-	-	-
CommonSpirit Health Research Institute	3	4	-	3	-	-	-	-	-	-
Dayton NCI Community Oncology Research Program	5	2	-	-	-	-	-	-	-	-
Desert Regional Medical Center	1	-	-	-	-	-	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	21	-	-	-	-	-	1	-	-	-
Georgia Cares Minority Underserved NCORP	1	-	-	-	-	-	-	-	-	-
Grupo Oncologico Cooperativo de Investigacion	3	-	-	-	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	83	<i>7</i> 3	1	-	-	1	-	-	-	-
Hawaii Minority Underserved NCORP	-	4	-	-	-	-	-	-	-	-
Heartland Cancer Research NCORP	11	8	1	-	4	2	-	-	2	-
Henry Ford Hospital	25	4	-	1	-	-	-	-	-	2
Houston Methodist Hospital	-	-	-	-	-	-	-	-	-	-
Instituto Nacional De Cancerologia	3	-	-	-	-	-	-	-	-	-
Instituto Nacional De Cancerologia de Mexico	11	-	-	-	-	-	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	18	-	2	-	-	-	-	-	-	-
Lahey Hospital and Medical Center	-	-	-	-	-	-	-	-	-	6
Loyola University Medical Center	9	6	1	2	-	-	-	-	-	1
Mass Veterans Epidemiology Research and Information Cntr	-	-	-	-	-	-	-	-	-	-
Medical University of South Carolina Minority Underserved NCORP	7	-	-	1	-	-	-	-	-	-
Mercy Medical Center - Des Moines	-	1	-	-	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	9	20	-	2	-	1	-	-	1	-
Montana Cancer Consortium NCORP	3	-	-	-	-	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	11	-	-	-	-	-	-	-	-	-
Nevada Cancer Research Foundation NCORP	1	-	-	-	-	-	-	-	-	1
New Mexico Minority Underserved NCORP	-	-	1	-	-	-	-	-	-	-
Northwell Health NCORP	-	3	-	-	-	-	-	-	-	-
Northwestern University LAPS	-	8	1	1	-	1	-	-	-	-



	51802	51806	51931	51937	52011	52200	52210	A021804	A031701	A031702
Ohio State University Comprehensive Cancer Center LAPS	2	3	-	-	-	_	-	-	-	-
Oregon Health and Science University	-	1	1	-	-	1	-	1	-	5
SCL Health Saint Joseph Hospital	2	-	-	-	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	8	1	-	-	-	-	-	-	-	-
Sutter Cancer Research Consortium	-	3	-	-	-	-	-	-	-	-
The West Clinic - Wolf River	-	-	-	1	-	-	-	-	-	-
Tulane University School of Medicine	-	-	9	-	-	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	12	9	2	3	-	-	-	-	9	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	6	6	-	-	-	-	-	-	-	-
UC San Diego Moores Cancer Center	4	3	-	-	-	-	-	-	-	-
UCLA / Jonsson Comprehensive Cancer Center	-	-	3	-	-	-	-	-	-	-
UPMC Hillman Cancer Center LAPS	-	8	2	-	-	-	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS	5	-	-	8	-	-	-	-	-	5
U of Alabama at Birmingham/Deep South Research Consortium LAPS	-	-	3	-	-	-	-	-	-	1
University of Arkansas for Medical Sciences	6	-	-	-	-	1	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	7	6	3	-	-	-	-	-	-	-
University of Colorado Cancer Center LAPS	6	6	-	4	1	-	-	-	-	-
University of Kansas Cancer Center - MCA Rural MU NCORP	7	9	-	-	-	-	-	-	-	1
University of Kentucky/Markey Cancer Center	-	3	-	-	-	-	-	-	-	-
University of Michigan Comprehensive Cancer Center LAPS	2	-	20	-	-	-	-	-	-	-
University of Mississippi Medical Center	1	-	-	1	-	1	-	-	-	1
University of Oklahoma Health Sciences Center LAPS	34	15	4	-	-	2	-	-	-	-
University of Rochester LAPS	25	-	3	-	-	-	-	-	-	3
University of Texas Health Science Center at San Antonio	11	-	4	-	-	-	-	-	-	-
University of Texas MD Anderson Cancer Center LAPS	84	-	-	-	-	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	19	-	1	1	-	3	-	-	-	-
Upstate Carolina Consortium Comm Oncology Research Program	3	2	-	-	-	-	-	-	-	-
Vanderbilt University - Ingram Cancer Center LAPS	8	6	-	-	-	-	-	-	-	-
Virginia Mason Medical Center	-	-	-	-	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	1	-	-	-	-	-	-	-	-	-
Western States Cancer Research NCORP	-	2	-	-	-	-	-	-	-	-
Wisconsin NCI Community Oncology Research Program	11	6	-	-	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	1	6	-	-	-	-	-	-	-	-
ALLIANCE	106	34	4	3	-	1	-	-	-	-
ECOG-ACRIN	92	44	11	5	1	1	-	-	-	-
NRG	103	136	10	1	-	1	-	-	-	-
Total	817	485	96	37	6	21	1	1	21	26



	A031704	1081E0A	A031803	A031902	A032001	A032101	A032103	EA8134	EA8171	EA8183
Ascension Providence Hospitals - Southfield	3	-	-	-	-	-	-	-	-	-
Audie L Murphy VA Hospital	-	-	2	-	-	-	-	-	49	-
Banner MD Anderson Cancer Center	-	-	-	-	-	-	-	-	-	-
Banner University Medical Center - Tucson	-	-	-	-	-	-	-	-	-	-
Baylor College of Medicine/Duncan Comprehensive Cancer Center	-	-	4	-	-	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	4	12	-	-	-	-	-
Cancer Research Consortium of West Michigan NCORP	-	-	-	-	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	-	-	-	-	-	-	-	-	-	-
Cancer Research of Wisconsin and Northern Michigan Consortium	-	-	-	-	-	-	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	-	-	-	-	-	-	-	-	-	-
Cedars-Sinai Medical Center	-	-	-	-	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	-	-	-	-	-	-	-	-	-	-
Columbia University Minority Underserved NCORP	-	-	-	-	-	-	-	-	-	-
CommonSpirit Health Research Institute	-	-	-	-	-	-	-	-	-	-
Dayton NCI Community Oncology Research Program	1	-	-	-	-	-	-	-	-	-
Desert Regional Medical Center	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	-	-	-	-	-	-	-	-
Georgia Cares Minority Underserved NCORP	-	-	-	-	-	-	-	-	-	-
Grupo Oncologico Cooperativo de Investigacion	-	-	-	-	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	-	1	16	-	-	-	-	-	11	-
Hawaii Minority Underserved NCORP	-	-	-	-	-	-	-	-	2	-
Heartland Cancer Research NCORP	-	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	6	-	-	-	-	-	-	-	1	-
Houston Methodist Hospital	-	-	-	-	-	-	-	-	-	-
Instituto Nacional De Cancerologia	-	-	-	-	-	-	-	-	-	-
Instituto Nacional De Cancerologia de Mexico	-	-	-	-	-	-	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	66	-	-	-	-	-	-	-	-	-
Lahey Hospital and Medical Center	-	-	-	-	-	-	-	-	-	4
Loyola University Medical Center	2	-	-	-	-	-	-	-	-	-
Mass Veterans Epidemiology Research and Information Cntr	-	-	-	1	-	-	-	-	-	-
Medical University of South Carolina Minority Underserved NCORP	-	-	-	-	-	-	-	-	-	-
Mercy Medical Center - Des Moines	-	-	-	-	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	-	-	-	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	-	-	-	-	-	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	1	-	-	-	-	-	-	-	-	-
Nevada Cancer Research Foundation NCORP	-	-	-	-	-	-	-	-	-	-
New Mexico Minority Underserved NCORP	1	-	-	-	-	-	-	-	-	-
Northwell Health NCORP	1	-	-	-	-	-	-	-	-	-
Northwestern University LAPS	2	-	-	-	-	1	-	-	-	-



Ohio State University Comprehensive Cancer Center LAPS Oregon Health and Science University 5		A031704	A031801	A031803	A031902	A032001	A032101	A032103	EA8134	EA8171	EA8183
Oregon Health and Science University SCL Health Saint Joseph Hospital Southeast Clinical Oncology Research Consortium NCORP Sutter Cancer Research Consortium The West Clinic - Wolf River Tulane University School of Medicine UC Davis Comprehensive Cancer Center LAPS UC Invine Health/Chao Family Comprehensive Cancer Center UC San Diego Moores Cancer Center LAPS US An Diego Moores Cancer Center LAPS UNIVERSITY OF Albamas for Medical Sciences 2	Ohio State University Comprehensive Cancer Center LAPS	-	-	-	-	-	-	-	-	-	-
SCL Health Saint Joseph Hospital Southeast Clinical Oncology Research Consortium NCORP Sutter Cancer Research Consortium The West Clinic - Wolf River Tulane University School of Medicine 1		5	-	-	-	-	-	-	-	13	-
Southeast Clinical Oncology Research Consortium NCORP Sutter Cancer Research Consortium The West Clinic - Wolf River Tulane University School of Medicine 1	•	-	-	-	-	-	-	-	-	-	-
Tulane University School of Medicine 1	· ·	-	-	-	-	-	-	-	-	-	-
Tulane University School of Medicine 1	Sutter Cancer Research Consortium	-	-	-	-	-	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS UC Irvine Health/Chao Family Comprehensive Cancer Center UC San Diego Moores Cancer Center UC San Diego Moores Cancer Center UCLA / Jonsson Comprehensive Cancer Center UPMC Hillman Cancer Center LAPS USC Norris Comprehensive Cancer Center LAPS Us of Alabama at Birmingham/Deep South Research Consortium LAPS University of Arkansas for Medical Sciences University of Cincinnati Cancer Center-UC Medical Center University of Colorado Cancer Center LAPS University of Kansas Cancer Center LAPS University of Kansas Cancer Center MCA Rural MU NCORP University of Kentucky/Markey Cancer Center University of Michigan Comprehensive Cancer Center LAPS University of Mississippi Medical Center University of Mississippi Medical Center University of Mississippi Medical Center University of Rochester LAPS 9	The West Clinic - Wolf River	-	-	-	-	-	-	-	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center UC San Diego Moores Cancer Center UCLA / Jonsson Comprehensive Cancer Center UPMC Hillman Cancer Center LAPS USC Norris Comprehensive Cancer Center LAPS U of Alabama at Birmingham/Deep South Research Consortium LAPS University of Arkansas for Medical Sciences University of Cincinnati Cancer Center-UC Medical Center University of Colorado Cancer Center-LAPS University of Kansas Cancer Center-LAPS University of Kansas Cancer Center-LAPS University of Kentucky/Markey Cancer Center University of Michigan Comprehensive Cancer Center LAPS University of Michigan Comprehensive Cancer Center LAPS University of Michigan Comprehensive Cancer Center LAPS University of Rochester LAPS University of Rochester LAPS University of Texas Health Science Center at San Antonio University of Texas MD Anderson Cancer Center LAPS University of Texas MD Anderson Cancer Center LAPS University of Utah - Huntsman Cancer Institute LAPS University of Utah - Huntsman Cancer Institute LAPS	Tulane University School of Medicine	1	-	-	-	-	-	-	-	-	-
UC San Diego Moores Cancer Center UCLA / Jonsson Comprehensive Cancer Center UPMC Hillman Cancer Center LAPS USC Norris Comprehensive Cancer Center LAPS U of Alabama at Birmingham/Deep South Research Consortium LAPS University of Arkansas for Medical Sciences University of Cincinnati Cancer Center-UC Medical Center University of Colorado Cancer Center-UC Medical Center University of Colorado Cancer Center LAPS 11	UC Davis Comprehensive Cancer Center LAPS	3	7	5	-	2	-	-	-	-	-
UCLA / Jonsson Comprehensive Cancer Center UPMC Hillman Cancer Center LAPS	UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	-	-	-	-	-	-	-	-
UPMC Hillman Cancer Center LAPS USC Norris Comprehensive Cancer Center LAPS U of Alabama at Birmingham/Deep South Research Consortium LAPS University of Arkansas for Medical Sciences 2	UC San Diego Moores Cancer Center	-	-	-	-	-	1	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS U of Alabama at Birmingham/Deep South Research Consortium LAPS University of Arkansas for Medical Sciences University of Arkansas for Medical Sciences University of Cincinnati Cancer Center-UC Medical Center To comprehensive Concer Center LAPS Inviversity of Colorado Cancer Center LAPS Inviversity of Kansas Cancer Center - MCA Rural MU NCORP Winiversity of Kentucky/Markey Cancer Center University of Michigan Comprehensive Cancer Center LAPS University of Mississippi Medical Center University of Mississippi Medical Center University of Oklahoma Health Sciences Center LAPS University of Rochester LAPS University of Texas Health Science Center at San Antonio University of Texas MD Anderson Cancer Center LAPS University of Utah - Huntsman Cancer Institute LAPS On the Markey Cancer Center LAPS University of Utah - Huntsman Cancer Institute LAPS On the Markey Cancer Center LAPS On the Markey Cancer Center LAPS On the Markey Cancer Center Cancer Center Cancer Center Cancer Center Cancer Center Cancer Cancer Center Cancer Cancer Center Cancer	UCLA / Jonsson Comprehensive Cancer Center	-	-	-	-	-	-	-	-	-	-
U of Alabama at Birmingham/Deep South Research Consortium LAPS University of Arkansas for Medical Sciences 2	UPMC Hillman Cancer Center LAPS	-	-	-	-	-	-	-	-	-	-
University of Arkansas for Medical Sciences 2	USC Norris Comprehensive Cancer Center LAPS	-	-	-	-	-	-	-	12	-	-
University of Cincinnati Cancer Center-UC Medical Center 7	U of Alabama at Birmingham/Deep South Research Consortium LAPS	-	1	10	-	-	-	-	-	-	-
University of Colorado Cancer Center LAPS 11 2 - 1 - University of Kansas Cancer Center - MCA Rural MU NCORP 8	University of Arkansas for Medical Sciences	2	-	-	-	-	-	-	-	-	-
University of Kansas Cancer Center - MCA Rural MU NCORP University of Kentucky/Markey Cancer Center University of Michigan Comprehensive Cancer Center LAPS University of Mississippi Medical Center University of Oklahoma Health Sciences Center LAPS University of Rochester LAPS University of Texas Health Science Center at San Antonio University of Texas MD Anderson Cancer Center LAPS University of Utah - Huntsman Cancer Institute LAPS 6	University of Cincinnati Cancer Center-UC Medical Center	7	-	-	-	-	-	-	-	-	-
University of Kentucky/Markey Cancer Center University of Michigan Comprehensive Cancer Center LAPS University of Mississippi Medical Center University of Oklahoma Health Sciences Center LAPS University of Rochester LAPS University of Texas Health Science Center at San Antonio University of Texas MD Anderson Cancer Center LAPS University of Utah - Huntsman Cancer Institute LAPS University of Utah - Huntsman Cancer Institute LAPS University of Utah - Huntsman Cancer Institute LAPS	University of Colorado Cancer Center LAPS	11	-	-	-	-	2	-	1	-	-
University of Michigan Comprehensive Cancer Center LAPS 12	University of Kansas Cancer Center - MCA Rural MU NCORP	8	-	-	-	-	-	-	-	-	-
University of Mississippi Medical Center University of Oklahoma Health Sciences Center LAPS University of Rochester LAPS 9 1	University of Kentucky/Markey Cancer Center	-	-	-	-	-	-	-	-	-	-
University of Oklahoma Health Sciences Center LAPS University of Rochester LAPS 9	University of Michigan Comprehensive Cancer Center LAPS	-	-	-	-	-	12	-	-	-	-
University of Rochester LAPS 9 1	University of Mississippi Medical Center	-	-	-	-	-	-	1	-	-	-
University of Texas Health Science Center at San Antonio 6 13 University of Texas MD Anderson Cancer Center LAPS	University of Oklahoma Health Sciences Center LAPS	-	-	-	-	-	-	-	-	-	-
University of Texas MD Anderson Cancer Center LAPS	University of Rochester LAPS	9	-	-	-	1	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS - 6	University of Texas Health Science Center at San Antonio	-	-	6	-	-	-	-	-	13	-
	University of Texas MD Anderson Cancer Center LAPS	-	-	-	-	-	-	-	-	-	-
Upstate Carolina Consortium Comm Oncology Research Program	University of Utah - Huntsman Cancer Institute LAPS	-	6	-	-	-	-	-	-	-	-
. ,	Upstate Carolina Consortium Comm Oncology Research Program	-	-	-	-	-	-	-	-	-	-
Vanderbilt University - Ingram Cancer Center LAPS	Vanderbilt University - Ingram Cancer Center LAPS	-	-	-	-	-	-	-	-	-	-
Virginia Mason Medical Center	Virginia Mason Medical Center	-	-	-	-	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	Wayne State University - Karmanos Cancer Institute LAPS	-	-	-	-	-	-	-	-	-	-
Western States Cancer Research NCORP	Western States Cancer Research NCORP	-	-	-	-	-	-	-	-	-	-
Wisconsin NCI Community Oncology Research Program	Wisconsin NCI Community Oncology Research Program	-	-	-	-	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS 1	Yale University - Yale Cancer Center LAPS	1	-	-	-	-	-	-	-	-	-
ALLIANCE	ALLIANCE	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	ECOG-ACRIN	-	-	-	-	-	-	-	-	-	-
NRG	NRG	-	-	-	-	-	-	-	-	-	-
Total 130 15 43 5 15 16 1 13 89	Total	130	15	43	5	15	16	1	13	89	4



Immunotherapeutics Committee

Leadership		11:30 – 11:40 am	Q&A
Executive Officer:	Siwen Hu-Lieskovan, MD, PhD Katerina Politi, PhD Anne Chiang, MD, PhD Michael LeBlanc, PhD Katie Minichiello, MS James Moon, MS	11:40 – 11:50 am	S2013 I-CHECKIT Trial Update Krishna Soujanya Gunturu, MD Associate Chief, Clinical Trials and Correlative Science Research Hartford HealthCare Cancer Institute
	Allison Hayes, BS	11:50 – 11:55 am	Q&A
Pharmaceutical Sci Sr. Protocol Project	Ence: Taylor Vlaming Sence: Jordan P. McPherson, PharmD Kimberly McConnell, PharmD Manager: Chris Kippola, BS Manager: Laura Gildner, MS	11:55 – 12:05 pm	SITC's Resistance Data Collection Effort, led by SITC's Immunotherapy Resistance Committee Megan Othus, PhD Professor, Biostatistics and Biomathematics Public Health Sciences Division, Fred Hutch
	· · · 5 · · · · · · · · · · · · · · · · · · ·	12:05 – 12:10 pm	Q&A
•	17, 2024 10:45 a.m 12:45 p.m. er (Concourse Level, West Tower) Agenda	12:10 – 12:20 pm	S1609 DART Trial Update Young Kwang Chae, MD, MPH Associate Professor, Medicine Hematology Oncology Division Northwestern University
10:45 – 10:50 am	Welcome & Introductions Siwen Hu-Lieskovan & Katerina Politi	12:20 – 12:25 pm	Q&A
	SWOG Immunotherapeutics Committee Co-Chairs	12:25 – 12:35 pm	Alliance Update - IO Committee Efforts & Initiatives
10:50 - 11:05 am	RNA Lipid Particle Aggregates in Brain Tumors Elias Sayour, MD, PhD Associate Professor, Assistant Dean Stop Children's Cancer/Bonnie R. Freeman Professor for Pediatric Oncology Research	12:35 – 12:40 pm	David E. Kozono, MD, PhD Assistant Professor of Radiation Oncology Harvard Medical School Director, Thoracic Radiation Oncology Q&A
11:05 – 11:15 am	Q&A	12:40 – 12:45 pm	Final Comments & Closing Remarks
11:15 – 11:30 am	New IO Agents in the CTEP Portfolio		Siwen Hu-Lieskovan & Katerina Politi SWOG Immunotherapeutics Committee Co-Chairs
	Helen Chen, MD Associate Chief and Senior Investigator		•

Active Study

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



Cancer Therapy Evaluation Program

Cancer Therapy Evaluation Program

National Cancer Institute

Investigational Drug Branch,

Brian Ko, MD

Medical Officer

Immunotherpeutics Committee

	52701
Essentia Health NCI Community Oncology Research Program	1
Froedtert and the Medical College of Wisconsin LAPS	2
Heartland Cancer Research NCORP	1
New Mexico Minority Underserved NCORP	1
Northwestern University LAPS	1
Pacific Cancer Research Consortium NCORP	1
University of Arkansas for Medical Sciences	2
University of Michigan Comprehensive Cancer Center LAPS	12
University of Utah - Huntsman Cancer Institute LAPS	8
ALLIANCE	7
ECOG-ACRIN	6
NRG	5
Total	47



Leukemia Committee

Leadership Chair: Harry P. Erba, MD, PhD Vice-Chair: Anjali S. Advani, MD Statisticians: Megan Othus, PhDAnna Moseley, MS Scientific Leadership Translational Medicine: Jerald P. Radich, MD Cytogenetics Liaison: Min Fang, MD, PhD **Designates** Cancer Control: Stephanie B. Tsai, MD Data Coordinators:.....Louise Highleyman, BARoula BustamiTaylor Vlaming (MyeloMATCH) Oncology Research Professionals: CRA: Heather A. Thulean, BS Pharmaceutical Science: Holly O. Chan, PharmDlla M. Saunders, PharmD Protocol Project Manager: Amy Doyle Sr. Protocol Project Manager: Sarah Cantu (MyeloMATCH) Clinical Trials Program Manager:Sharon Palmer

Time/Location

Friday, October 18, 2024 9:45 a.m. - 11:45 a.m. Room: Crystal C (Lobby Level, West Tower)

Agenda

Clinical Trials Program Manager: Mariah Norman, MS (MyeloMATCH)

- Updates in Leukemia Translational Medicine Cecilia Yeung (20 minutes)
- 2. Updates in MyeloMATCH Tara Lin & Laura Michaelis (40 minutes)
- 3. Updates in Acute Lymphoblastic Leukemia Kristen O'Dwyer (20 minutes)
- 4. Updates in MPN Alex Coltoff (20 minutes)
- 5. Updates in CLL Deb Stephens & Mazyar Shadman (20 minutes)

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. Temporarily closed to accrual 11/19/21

Closed Studies

- **S1612**, "A Randomized Phase II/III Trial of "Novel Therapeutics" Versus Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia (AML) or High-Risk Myelodysplastic Syndrome (MDS), Age 60 or Older." Drs. L. Michaelis, R. Walter, S. Assouline, et al. Activated: 12/22/17; Closed: 9/3/20.
- **S0919**, "A Phase II Study of Idarubicin and Ara-C in Combination with Pravastatin for Poor-Risk Acute Myelogenous Leukemia (AML)." Dr. A. Advani. Re-Activated: 4/1/13; Closed: 9/15/17; Complete: 10/21/21.
- **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; Complete: 3/29/22.

ALL Studies

Active Studies

- **S1905**, "A Phase I/II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL) / T-Cell Lymphoblastic Lymphoma (T-LBL)." Drs. 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. Temporarily closed to accrual: 5/24/22.

Developing Studies

52434, "A Phase 1B Study of Revumenib (SNDX-5613) in Combination with Age-Guided Chemotherapy and Blinatumomab in Newly Diagnosed Patients with KMT2Ar ALL or ALAL." Drs. I. Aldoss, A. Advani, W. Stock, and C. Saygin.



Leukemia Committee

Closed Studies

S0333, "A Phase II Study of Double Induction Chemotherapy for Newly Diagnosed Non-L3 Adult Acute Lymphoblastic Leukemia with Investigation of Minimal Residual Disease and Risk of Relapse Following Maintenance Chemotherapy." Drs. Forman and O'Donnell. Activated: 4/15/05; Closed: 11/1/09.

S1312, "A Phase I Study of Inotuzumab Ozogamicin in Combination with CVP (Cyclophosphamide, Vincristine, Prednisone) for Patients with Relapsed/Refractory CD22-Positive Acute Leukemia (Including B-ALL, Mixed Phenotypic Leukemia, and Burkitt's Leukemia)." Drs. A. Advani and Liedtke. Activated: 4/1/14; Closed: 8/2/19.

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

CLL Studies

Active Studies

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

Developing Studies

S2421, "A Randomized Phase II Study of Pirtobrutinib Plus R-CHOP vs. R-CHOP for Patients with Previously Untreated Richter Transformation (RT)." Drs. M. Shadman, D. Stephens, and A. Danilov.

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.

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: 1/4/19.

CML Studies

Closed Studies

S1712, "A Randomized Phase II Study of Ruxolitinib (NSC-752295) in Combination with BCR-ABL Tyrosine Kinase Inhibitors in Chronic Myeloid Leukemia (CML) Patients with Molecular Evidence of Disease." Drs. K. Sweet and J. Radich. Activated: 7/20/18. Closed: 10/20/22.

MDS/MPN Studies

Developing Studies

52502, "A Phase I/II Study of TP-3654 in Combination with Decitabine for Myelodysplastic Syndrome/Myeloproliferative Neoplasm Overlap Syndromes (MDS/MPNs) and Accelerated- or Blast-Phase MPNs (MPN-AP/BP)." Drs. A. Coltoff, A. Gerds, and U. Borate.

MyeloMATCH

Active Studies

MYELOMATCH, "Master Screening and Reassessment Protocol (MSRP) for Tier Advancement in the NCI MyeloMATCH Clinical Trials." Drs. J. Radich and S. Jiwani. Activated: 5/16/24.

MM1YA-S01, "A Randomized Phase II Study Comparing Cytarabine + Daunorubicin (7+3) vs. (Daunorubicin and Cytarabine) Liposome, Cytarabine + Daunorubicin + Venetoclax, Azacitidine + Venetoclax, and (Daunorubicin and Cytarabine) Liposome + Venetoclax in Patients Aged 59 or Younger who are Considered High-Risk (Adverse) Acute Myeloid Leukemia as Determined by myeloMATCH; A myeloMATCH Clinical Trial." Drs. P. Shami and T. Lin. Activated: 5/16/24.

Developing Studies

MM1OA-S03, "A Randomized Phase II 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.



Leukemia Committee

	MYELOMATCH	s1905	51925	A041501	A041701	A041703	A042001	EA9152	EA9171	EA9181	EA9213
CWRU Case Comprehensive Cancer Center LAPS	-	1	7	4	-	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	-	-	1	-	-	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	-	3	1	-	-	-	-	-	-	-	-
Duke University - Duke Cancer Institute LAPS	-	-	1	-	-	-	-	-	-	2	-
Fred Hutchinson Cancer Research Center LAPS	-	4	2	-	-	-	-	-	-	-	3
Hawaii Minority Underserved NCORP	-	-	-	-	-	-	-	-	-	3	-
Henry Ford Hospital	-	-	2	-	4	-	-	-	-	-	-
Intermountain Medical Center	-	-	-	2	-	-	-	-	-	-	-
Loyola University Medical Center	-	-	1	-	-	-	-	-	-	1	-
Medical University of South Carolina Minority Underserved NCORP	-	-	3	-	-	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	-	-	7	-	-	-	-	-	-	-	-
Northwell Health NCORP	-	-	-	-	2	-	-	-	-	-	-
Northwestern University LAPS	-	-	-	3	1	-	1	-	-	4	-
Oregon Health and Science University	-	1	-	8	-	-	-	-	-	-	-
STCC at DHR Health Institute for Research and Development	-	-	1	-	-	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	-	1	-	-	-	-	-	-	-	-
Stanford Cancer Institute Palo Alto	-	-	-	8	-	-	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	-	-	4	2	-	-	-	-	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	1	3	-	1	-	-	-	10	-
UC San Diego Moores Cancer Center	-	-	-	-	-	-	-	-	-	1	-
U of Alabama at Birmingham/Deep South Research Consortium LAPS	-	-	-	1	-	-	1	-	-	-	-
University of Arkansas for Medical Sciences	-	-	-	-	4	-	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	2	-	-	-	1	-	-	-	3	-
University of Rochester LAPS	-	2	11	7	27	3	-	-	-	6	-
University of Utah - Huntsman Cancer Institute LAPS	-	-	16	1	-	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	-	-	-	-	-	-	-	3	-
Western States Cancer Research NCORP	-	-	-	-	-	-	-	-	2	-	-
Yale University - Yale Cancer Center LAPS	-	-	-	5	-	-	-	3	2	1	-
ALLIANCE	1	2	22	-	-	-	-	-	-	-	-
CCTG	-	-	10	-	-	-	-	-	-	-	-
ECOG-ACRIN	4	-	11	-	-	-	-	-	-	-	-
NRG	-	-	3	-	-	-	-	-	-	-	-
Total	5	15	105	44	38	5	2	3	4	34	3



Leadership
Chair: Jhanelle E. Gray, MD
Vice-Chair:Roy S. Herbst, MD, PhD
Executive Officer: Anne Chiang, MD, PhD
Statisticians:Mary Redman, PhD
Yingqi Zhao, PhD
Kari Chansky, MS
Mia Hsieh, MS
Katie Minichiello, MS
Jieling Miao, MS
James Moon, MS
Scientific Leadership
Translational Medicine:
Biology/PathologyPhilip C. Mack, PhD
Fred R. Hirsch, MD, PhD
Ignacio I. Wistuba MD
Imaging:
Myrna C. Godoy, MD, PhD
Radiation Oncology:
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: Ross Camidge, MD
Community Engagement:Paul J. Hesketh, MD
Suzanne Cole, MD
Designates
Cancer Control Liaison:
DEI Champion:Lucy Gansauer, MSN, RN, OCN, CCRP
Veterans Affairs: Chao H. Huang, MD
Data Coordinators:Amy Johnson, CCRP
Kevin Moralda, BS
Larry Kaye
Louise Highleyman, BA
Pasarlai Ahmadzai, MD, MPH
Clinical Research Project Manager:TBD
Oncology Research Professionals:
CRA:
Nurses:Rosalie Zablocki, RN
Lisa G. Davis, RN
Patient Advocate:Judy Johnson, MBA

F	harmaceutical Science:	Joyce Lee, PharmD
		Safae Ghouraichi, PharmD
F	Protocol Project Managers:	Justine Trevino
		Gabe Chadwell (Lung-MAP)
5	r. Protocol Project Manager:	Jennifer Beeler (Lung-MAP)
(Clinical Trials Program Manager:	Mariah Norman, MS
		Crystal Miwa (Lung-MAP)

Time/Location

Friday, October 18, 2024 3:00 p.m. - 6:00 p.m. Room: Regency A (Ballroom Level, West Tower)

Agenda

3:00 - 3:15 pm	General Update & Accruals: Jhanelle E. Gray, MD
3:15 - 3:20 pm	Patient Advocate Update: Judy Johnson, MBA
3:20 - 3:25 pm	Thoracic Surgery Session: Eric Toloza, MD, PhD
3:25 - 3:30 pm	Thoracic Radiation Session: Megan Daly, MD
3:30 - 3:35 pm	Translational Medicine Session: Philip C. Mack, PhD
3:35 - 3:40 pm	Community Engagement Core: Paul J. Hesketh, MD
3:40 - 3:45 pm	DEI Session: Lucy Gansauer, MSN, RN
Chair & Director	Role of Pathologic Response Assessment in CLC - Sanja Dacic, MD, PhD, Professor of Pathology, Vice of Anatomic Pathology, Pathology Medical Director, Laboratory, Yale School of Medicine

4:20 - 4:55 pm Thoracic Medical Oncology: Jhanelle Gray, MD

<u>S2302</u>, "Project Pragmatica-Lung Trial." Dr. Karen Reckamp. Activated: 3/6/23; Accrual Goal: 700; Accrual: 608

<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. Karen Reckamp and David Gandara (SWOG). Activated: 1/28/19; Accrual Goal: 6000; Accrual: 3467.

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)." Dr. Karen Reckamp (SWOG). Dr. Suki Padda and Dr. David Gerber (ECOG). Activated: 4/2/21; Accrual Goal: 116; Accrual: 241.



<u>S1900G</u>, "A Randomized Phase II Study of Capmatinib plus Osimertinib (Tagrisso) with or without Ramucirumab in Participants with EGFR-Mutant, MET-Amplified Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung- MAP Sub-Study)". Dr. Sarah Goldberg and Dr. Ross Camidge (SWOG). Activated: 4/3/23; Accrual Goal: 66 (60 eligible); Accrual: 21.

S1900K, "A Randomized Phase II Study of Tepotinib with or without Ramucirumab in Participants with MET Exon 14 Skipping Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)." Dr. Paul Paik and Dr. Xiuning Le. Activated: 12/18/23; Accrual Goal: 56; Accrual: 5.

<u>S1827</u>, "MRI Brain Surveillance Alone Versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small- Cell Lung Cancer (MAVERICK)." Dr. Chad Rusthoven (SWOG). Activated: 1/10/20; Accrual Goal: 668; Accrual: 233.

<u>S1933</u>, "A Pilot Trial of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status." Dr. Raid Aljumaily (SWOG). Activated: 6/15/20; Accrual Goal: 47; Accrual: 39.

<u>S1914</u>, "A Randomized Phase III trial of Induction/Consolidation Atezolizumab +SBRT versus SBRT Alone in High risk, Early Stage NSCLC." Dr. Megan Daly (SWOG). Activated: 3/25/20; Accrual Goal: 480; Accrual: 412.

4:55 - 6:00 pm Open Discussion

Active Studies

- **LUNGMAP**, "A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study)." Drs. Borghaei, Reckamp, Gandara, et al. Activation: 1/28/19.
- **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.
- **S1900G**, "A Randomized Phase II Study of INC280 (Capmatinib) plus Osimertinib with or without Ramucirumab in Participants with EGFR-Mutant, MET-Amplified Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)." Drs. Goldberg and Camidge. Activation: 4/3/23.

- **S1900K**, "A Randomized Phase II Study of Tepotinib with or without Ramucirumab in Participants with MET Exon 14 Skipping Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)." Drs. Paik and Le. Activation: 12/18/23.
- S1827, "MRI Brain Surveillance Alone Versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer (MAVERICK)." Drs. Rusthoven, Brown, Wefel, et al. Activation: 1/10/20.
- <u>\$1914</u>, "A Randomized Phase III Trial of Induction/Consolidation Atezolizumab (NSC #783608) + SBRT versus SBRT Alone in High Risk, Early Stage NSCLC." Drs. Daly, Simone, Kelly, et al. Activation: 3/25/20.
- <u>\$1933</u>, "A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status." Drs. Aljumaily, Mitin, and Wozniak. Activation: 6/15/20.
- **S2302**, "PRAGMATICA: A Prospective Randomized Study of Ramucirumab (LY3009806; 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" Drs. Reckamp and Dragnev. Activation: 3/6/23.
- 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/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/NRG-LU007, "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.



- 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.
- **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. Permanently closed: 3/10/23.
- 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.
- **S1900B**, "A Phase II Study of Selpercatinib (LOXO-292) in Patients with RET Fusion-Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (LUNG-MAP Sub-Study)." Drs. Elamin and Gray. 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.
- **S1900F**, "A Randomized Phase II Study of Carboplatin and Pemetrexed with or Without Selpercatinib (LY3527723) in Participants with Non-Squamous RET Fusion-Positive Stage IV Non-Small Cell Lung Cancer and Progression of Disease on Prior RET Directed Therapy (Lung-MAP Sub-Study)." Drs. Gray and Elamin. Activation: 7/25/22. Permanently closed: 6/27/23.
- **S1929**, "Phase II Randomized Study of Maintenance Atezolizumab Versus Atezolizumab in Combination with Talazoparib in Patients with SLFN11 Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC)." Drs. Karim, Reckamp, Gay, et al. Activation: 6/15/20; Step 1 Registration Permanently Closed 8/15/22; Step 2 Permanently Closed 10/15/22.
- **S1934**, "NASSIST (Neoadjuvant Chemoradiation +/- Immunotherapy Before Surgery for Superior Sul-cus 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; Permanently closed 3/1/23.

- 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.; Closed to accrual: 3/1/24.
- **S1701**, "A Randomized Phase II Trial of Carboplatin-Paclitaxel with or without Ramucirumab in Patients with Unresectable Locally Advanced, Recurrent, or Metastatic Thymic Carcinoma." Drs. Tsao and Koczywas. Activation: 8/9/18; Closed to accrual: 10/15/22.
- 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; Closed to accrual: 5/10/24.
- 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; Closed to accrual: 11/20/23.
- 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; Closed to accrual: 12/06/23.
- 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; Closed to accrual: 12/31/23.
- 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; Closed to accrual: 10/13/23.

NCI-Approved Concepts

- <u>S1900J</u>, "A Phase II Study of Amivantamab SC (subcutaneous) in Participants with MET Amplification-Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)." Drs. Rolfo and Gadgeel.
- **S1800E**, "A Randomized Phase II/III Study of Docetaxel and Ramucirumab with or without Cemiplimab for Participants Previously Treated with Platinum-based Chemotherapy and Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Non-Matched Sub-Study)." Drs. Waqar and Li.



52404, "Accelerating Drug Efficacy Evaluation thru Growth Rate and Overall Survival Correlations" Dr. Lawrence Schwartz and Dr. Karen Reckamp.

Concepts in Development

- S1900N, "A Phase II Study of Sacituzumab Govitecan and Ivonescimab in Participants with Relapsed/Refractory Advanced Non-Small-Cell Lung Cancer with Actionable Genomic Alteration (Lung-MAP Sub-Study)." Drs. Scott and Riess.
- **S2409**, "PRISM: PRecIsion in SCLC via a Multicohort Study: Randomized Phase II Studies Evaluating Maintenance Durvalumab with or without Biomarker-Directed Therapy for Extensive Stage Small Cell Lung Cancer (ES-SCLC)" Drs. Chiang, Chiappori, Kim, et al.
- <u>\$2414</u>, "Incorporating Pathologic Response in Patients with Early Stage Lung Cancer to Optimize Immunotherapy in the Adjuvant Setting (INSIGHT)." Drs. Cetnar and Osarogiagbon.



	LUNGMAP	518000	51827	51900E	51900G	51914	51933	52302	108180A	A082002	A151216
Ascension Providence Hospitals - Southfield	13	_	_		_	_	_	_	_		15
Ascension Via Christi Hospitals Wichita	1	-	_	-	-	-	-	_	_	-	-
Banner MD Anderson Cancer Center	-	_	1	-	_	-	_	_	1	-	1
Banner University Medical Center - Tucson	-	-	-	-	-	-	-	2	_	-	7
Baptist Mem Health Care/Mid South MU-NCORP	36	-	2	2	-	8	1	10	4	-	26
Baylor College of Medicine/Duncan CCC	-	-	3	-	-	-	-	-	-	-	-
Boston Medical Center	-	-	5	-	-	-	-	2	-	-	3
CWRU Case Comprehensive CC LAPS	11	-	2	2	-	-	-	14	11	-	55
Ca Res Consort of W Mich NCORPP	3	-	-	-	-	5	-	1	-	-	1
Cancer Research for the Ozarks NCORP	39	3	-	-	-	7	4	4	-	-	1
Ca Res of Wisconsin and N Mich Consort	28	2	3	4	-	6	-	2	-	-	-
Carle Cancer Center NCORP	3	-	1	1	-	6	-	8	-	-	-
Cedars-Sinai Medical Center	21	-	-	1	1	4	-	8	-	-	-
City of Hope Comprehensive Cancer Center	5	-	1	-	-	-	-	2	-	-	5
Columbia U MU NCORP	13	-	-	-	-	-	1	5	-	-	-
Columbus NCORP	28	-	5	-	-	-	-	3	-	-	-
CommonSpirit Health Research Institute	39	-	1	-	-	1	-	1	-	-	2
Corewell Health William Beaumont U Hospital	-	-	-	-	-	-	-	-	-	-	2
Cotton O'Neil CC / Stormont Vail HIth	-	-	-	-	-	-	-	-	-	-	3
Dayton NCORP	2	-	-	-	-	-	-	-	1	-	8
Duke University - Duke Cancer Institute LAPS	-	-	-	-	-	-	-	1	-	-	-
Essentia HIth NCORP	16	2	-	-	-	3	-	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	4	-	-	-	-	-	-	3	-	-	15
Froedtert & the Med College of Wisconsin LAPSS	2	-	-	-	-	-	-	-	-	-	-
Georgia Cares Minority Underserved NCORP	6	-	1	-	-	2	1	-	-	-	-
Georgia NCORP	63	4	3	1	-	9	-	11	-	-	9
Gulf South Minority Underserved NCORP	24	1	1	-	-	3	-	5	1	-	1
Hawaii Minority Underserved NCORP	27	-	2	-	-	-	-	5	-	-	-
Heartland Cancer Research NCORP	149	9	9	5	-	36	4	41	-	-	-
Henry Ford Hospital	7	-	-	-	-	-	-	-	2	-	29
Houston Methodist Hospital	-	-	-	-	-	-	-	-	-	-	8
Instituto Nacional De Cancerologia de Mexico	-	-	5	-	-	-	-	-	-	-	-
Kaiser Permanente NCORP	88	6	-	8	-	3	-	19	5	-	206
Kansas City Veterans Affairs Medical Center	-	-	-	-	-	-	-	1	-	-	-
Lahey Hospital and Medical Center	32	-	-	-	-	4	2	10	-	-	30
Lona Linda University Medical Center	6	-	-	-	-	-	-	-	-	-	10
Loyola University Medical Center	25	1	-	-	-	1	-	4	-	-	25
MAVERIC	73	3	3	1	-	-	-	7	11	-	32
Med U South Carolina MU NCORP	19	1	-	2	1	-	-	10	-	-	-
Mercy Medical Center - Des Moines Michigan Cancer Research Consortium NCORP	8	-	-	- 7	-	- 11	-	- 11	-	-	-
Mission Hospital	108	4	2	7	1	11	-	11	-	-	-
Moffitt Cancer Center	1	- 1	-	- 1	-	-	-	-	-	-	- 02
Montana Cancer Consortium NCORP	17	1	1	1	1	1	- 1	32	20	-	83
Mount Sinai Hospital	25	-	-	1	-	1	1	1	-	-	-
точна этин погрнин	-	-	-	-	-	9	-	2	-	-	-



	LUNGMAP	518000	51827	51900E	51900G	51914	51933	52302	A081801	A082002	A151216
MultiCare Tacoma General Hospital	-	-	-	_	-	_	-	2	-	-	_
NCORP of the Carolinas (Prisma Health NCORP)	20	-	_	1	_	_	_	-	-	_	1
National Cancer Center-Korea	-	-	1	-	-	_	-	-	-	-	_
Nevada Cancer Research Foundation NCORP	14	-	_	-	_	_	_	-	-	_	_
New Mexico Minority Underserved NCORP	97	-	1	2	-	8	1	2	-	_	_
Northwell Health NCORP	-	-	_	-	-	1	_	-	1	-	3
Northwestern University LAPS	26	2	1	-	-	-	-	14	_	-	_
Oregon Health and Science University	10	1	-	-	-	1	-	-	8	-	24
Pacific Cancer Research Consortium NCORP	20	-	-	-	-	-	-	-	-	-	4
SCL Health Saint Joseph Hospital	1	-	-	-	-	1	-	-	1	-	3
Salem Hospital	7	-	-	2	-	-	-	-	_	-	-
Southeast Clin Onc Res Consort NCORP	51	1	7	1	-	13	_	6	-	-	_
Sutter Cancer Research Consortium	29	_	-	1	-	-	-	-	-	1	11
The Don and Sybil Harrington Cancer Center	13	2	_	_	-	-	_	-	-	-	-
James Graham Brown CC at U Louisville	-	-	-	-	-	_	_	-	-	_	5
UC Davis Comprehensive Cancer Center LAPS	40	6	1	1	1	11	_	11	-	2	46
UC Irvine Hlth/Chao Family CCCr	29	-	1	-	-	5	_	1	-	-	15
UC San Diego Moores Cancer Center	15	-	-	1	-	-	_	-	-	_	5
UPMC Hillman Cancer Center LAPS	74	5	9	7	-	2	4	10	-	_	-
USC Norris Comprehensive Cancer Center LAPS	-	-	5	-	-	6	-	3	-	_	12
U of Alabama at Birm/Deep South Res Cnsrt LAPS	-	_	-	_	_	-	_	11	-	_	-
University of Arkansas for Medical Sciences	11	1	_	-	_	16	_	8	-	_	3
U of Cincinnati Cancer Center-UC Medical Center	-	-	_	_	_	-	_	-	-	_	24
University of Colorado Cancer Center LAPS	14	-	4	-	1	5	_	3	2	_	58
U of Kansas C C - MCA Rural MU NCORP	96	1	1	1	-	-	_	3	1	_	31
University of Kentucky/Markey Cancer Center	51	-	1	-	_	_	_	7	-	1	5
U of Michigan Comprehensive C C LAPS	1	-	-	_	-	_	_	2	-	-	62
University of Mississippi Medical Center	1	_	_	_	_	_	_	-	_	_	26
U of Oklahoma Health Sciences Center LAPS	33	_	1	_	_	3	13	7	-	_	-
University of Rochester LAPS	67	2	-	6	_	3	-	10	-	_	_
U of Texas Health Science Center at San Antonio	-	-	_	-	_	-	_	16	-	_	_
U of Texas MD Anderson Cancer Center LAPS	3	-	5	-	_	5	_	-	-	_	2
U of Utah - Huntsman Cancer Institute LAPS	-	_	4	_	_	5	_	4	-	_	-
Upstate Carolina NCORP	39	-	3	-	_	2	_	-	-	_	_
Vanderbilt U - Ingram Cancer Center LAPS	-	_	-	_	-	-	_	3	-	_	_
Wayne State U - Karmanos Ca Inst LAPS	1	_	_	_	_	_	_	-	_	_	1
Western States Cancer Research NCORP	2	_	_	-	_	-	_	_	-	_	1
Wisconsin NCORP	40	_	1	1	_	13	_	3	_	_	-
Yale University - Yale Cancer Center LAPS	25	_	4	3	1	10	-	11	7	_	57
ALLIANCE	822	15	21	21	3	38	5	90	_	_	-
CCTG	-	-	31	-	-	-	-	-	_	_	-
ECOG-ACRIN	353	5	8	19	_	27	_	46		-	_
NRG	456	4	66	12	2	88	1	29	-	-	-
Total	3,403	82	227	115	12	382	38	527	76	4	976
Total	3,403	02	221	113	12	302	50	321	70	4	970



	E4512	EA5162	EA5163	EA5181	EA5182	EA5191	NRGLU002	NRGLU005	NRGLU006	NRGLU008	R1308
Ascension Providence Hospitals - Southfield	2	1	2	3	-	1	_	_	-	-	-
Ascension Via Christi Hospitals Wichita	-	-	-	-	-	-	_	-	-	-	-
Banner MD Anderson Cancer Center	-	-	-	-	-	-	-	2	-	-	-
Banner University Medical Center - Tucson	2	-	-	10	-	-	-	1	-	-	-
Baptist Mem Health Care/Mid South MU-NCORP	-	-	1	1	2	-	1	4	-	-	-
Baylor College of Medicine/Duncan CCC	-	-	-	-	-	-	-	-	3	-	-
Boston Medical Center	-	-	-	2	-	-	-	-	-	-	-
CWRU Case Comprehensive CC LAPS	-	-	17	21	1	4	-	-	-	-	-
Ca Res Consort of W Mich NCORPP	-	-	-	-	-	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	-	-	-	-	-	-	-	-	-	-	-
Ca Res of Wisconsin and N Mich Consort	-	-	-	-	-	-	-	-	-	-	-
Carle Cancer Center NCORP	-	-	-	-	-	-	-	-	-	-	-
Cedars-Sinai Medical Center	-	-	-	-	-	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	-	-	-	-	-	-	_	-	-	-	-
Columbia U MU NCORP	-	-	-	1	-	-	-	-	-	-	-
Columbus NCORP	-	-	-	-	-	-	_	-	-	-	-
CommonSpirit Health Research Institute	-	-	-	-	-	-	-	-	-	-	-
Corewell Health William Beaumont U Hospital	-	-	-	-	-	-	_	-	-	-	-
Cotton O'Neil CC / Stormont Vail HIth	-	-	-	-	-	-	-	-	-	-	-
Dayton NCORP	-	-	-	-	-	-	-	-	-	-	-
Duke University - Duke Cancer Institute LAPS	-	-	-	-	-	-	-	-	-	-	-
Essentia HIth NCORP	-	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	-	4	-	-	-	-	-	-	-
Froedtert & the Med College of Wisconsin LAPSS	-	-	-	-	-	-	-	-	-	-	-
Georgia Cares Minority Underserved NCORP	-	-	-	-	-	-	-	-	-	-	-
Georgia NCORP	-	-	1	-	-	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	-	-	3	-	-	-	-	-	-	-	-
Hawaii Minority Underserved NCORP	-	-	-	1	-	-	-	-	-	-	-
Heartland Cancer Research NCORP	-	-	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	-	-	-	-	-	-	-	-
Houston Methodist Hospital	-	-	1	-	-	-	-	-	-	-	-
Instituto Nacional De Cancerologia de Mexico	-	-	-	-	-	-	-	-	-	-	-
Kaiser Permanente NCORP	6	-	8	-	6	-	-	-	-	-	-
Kansas City Veterans Affairs Medical Center	-	-	-	-	-	-	-	-	-	-	-
Lahey Hospital and Medical Center	-	-	2	-	-	-	-	-	-	-	-
Loma Linda University Medical Center	-	-	-	-	-	-	-	-	-	-	1
Loyola University Medical Center	-	-	2	2	-	-	-	-	-	-	-
MAVERIC	-	-	3	-	-	2	-	-	-	-	-
Med U South Carolina MU NCORP	-	-	-	-	-	-	-	-	-	-	-
Mercy Medical Center - Des Moines	-	-	-	-	-	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	-	-	-	-	-	-	-	-	-	-	-
Mission Hospital	-	-	-	-	-	-	-	-	-	-	-
Moffitt Cancer Center	1	-	5	-	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	-	-	-	-	-	-	-	-	-	-	-
Mount Sinai Hospital	-	-	-	1	5	-	-	1	-	-	-



	E4512	EA5162	EA5163	EA5181	EA5182	EA5191	NRGLU002	NRGLU005	NRGLU006	NRGLU008	R1308
MultiCare Tacoma General Hospital	_	_	_	_	-	_	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	_	_	-	-	-	-	-	-	-	-	-
National Cancer Center-Korea	_	_	-	_	-	_	-	-	-	-	-
Nevada Cancer Research Foundation NCORP	_	-	_	-	_	-	-	-	-	-	-
New Mexico Minority Underserved NCORP	_	_	_	-		_	-	-	-	-	-
Northwell Health NCORP	_	-	_	-	_	-	-	-	-	-	-
Northwestern University LAPS	_	_	_	-		_	-	-	-	-	-
Oregon Health and Science University	_	-	_	-	_	-	-	-	-	-	-
Pacific Cancer Research Consortium NCORP	_	_	_	-		_	-	-	-	-	-
SCL Health Saint Joseph Hospital	_	-	-	-		_	-	-	-	-	-
Salem Hospital	_	_	-	-		_	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	_	_	_		_	_	-	-	-	-	-
Sutter Cancer Research Consortium		_	_	3		_	-	-	-	1	-
The Don and Sybil Harrington Cancer Center		_	_	-	_	_	-	-	-	-	-
James Graham Brown CC at U Louisville		-		-		-	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	1	-	6	-	1	_	-	-	-	-	-
UC Irvine HIth/Chao Family CCCr	1	-	-	-	-	-	-	-	-	-	-
UC San Diego Moores Cancer Center	,	_	-	-	_	_	-	-	-	-	-
UPMC Hillman Cancer Center LAPS		-	-	-		-	_	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS	-	-	-	-	-	_	-	-	-	-	_
U of Alabama at Birm/Deep South Res Cnsrt LAPS	-		-				-	-	-	-	-
·	1	-	-	-	-	-	_	1	-	-	-
University of Arkansas for Medical Sciences	1	-	1	3	-	-	_	-	-	-	-
U of Cincinnati Cancer Center-UC Medical Center	1	-	2	-	1	-	_	1	-	-	_
University of Colorado Cancer Center LAPS	2	-	-	-	-	1	_	2	-	-	_
U of Kansas C C - MCA Rural MU NCORP	-	-	7	-	-	3	_	_	-	-	_
University of Kentucky/Markey Cancer Center	-	-	-	-	-	-	-	_	_	-	
U of Michigan Comprehensive C C LAPS	-	-	-	-	-	-	-		-	_	
University of Mississippi Medical Center	-	-	-	-	-	-	-	-	-		-
U of Oklahoma Health Sciences Center LAPS	-	-	-	1	-	-	-	-	-	-	-
University of Rochester LAPS	-	-	6	19	-	-	-	1	-	-	-
U of Texas Health Science Center at San Antonio	-	-	2	-	-	-	-	-	-	-	-
U of Texas MD Anderson Cancer Center LAPS	1	-	-	-	-	-	-	-	-	-	-
U of Utah - Huntsman Cancer Institute LAPS	-	-	1	-	-	-	-	-	-	-	-
Upstate Carolina NCORP	-	-	-	-	-	-	-	-	-	-	-
Vanderbilt U - Ingram Cancer Center LAPS	-	-	-	-	-	-	-	-	-	-	-
Wayne State U - Karmanos Ca Inst LAPS	-	-	-	-	-	-	1	-	-	-	-
Western States Cancer Research NCORP	-	-	-	-	1	-	-	-	-	-	-
Wisconsin NCORP	-	-	-	-	-	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	4	-	14	-	-	-	-	-	-	-	-
ALLIANCE	-	-	-	-	-	-	-	-	-	-	-
CCTG	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-	-	-	-	-	-
NRG	-	-	-	-	-	-	-	-	-	-	-
Total	22	1	84	72	17	11	2	13	3	1	1



Leadership

Chair:	Jonathan W. Friedberg, MD
Vice-Chair:	Sonali M. Smith, MD
Executive Officer:	Susan M. O'Brien, MD
Statisticians:	Michael LeBlanc, PhD
	Hongli Li, MS
	Shay Bellasea, MS
	Matt Chansky, BS
Scientific Leadership	
Translational Medicine:	Alexey Danilov, MD, PhD

Radiation Oncology: Nicholas Burden Figura, MD

 Imaging:
 Lawrence H. Schwartz, MD

 Immunotherapeutics:
 Sweetha Kambhampati, MD

 Pathology:
 Joo Y. Song, MD

Early Therapeutics:.....Nasheed Mohammad Hossain, MD

Designates	
Cancer Control:	Hayder Saeed, MD
Digital Engagement:	Elizabeth A. G. Brem, MD
Veterans Affairs:	Helen Ma, MD
Data Coordinators:	Alex Rangel, BS
	Gabi Herbert, MS, BS
	Laura Wells, BA
	Daria Chugina, MD, CCRPS
Oncology Research Professionals:	

CRA: Erin M. Cebula, MPH

Nurse:	180
Patient Advocate:	Tricia Hernandez, MS
Pharmaceutical Science:	Holly O. Chan, PharmD
	Martina Fraga, PharmD
Protocol Project Manager:	Erin Rogers
Clinical Trials Program Manager:	Laura Gildner, MS

......Jacob Kedroske, BA

Time/Location

Saturday, October 19, 2024 9:30 a.m. - 11:30 a.m. Room: Regency A (Ballroom Level, West Tower)

Agenda

- 1. Welcome & Introductions Dr. Jonathan Friedberg & Dr. Sonali Smith
- 2. S2308 Launch Dr. Nilanjan Ghosh
- 3. Special Abstract Presentation: New Consensus Guidelines for Radiation Treatment Planning in Lymphoma/Heme Malignancies Dr. Nick Figura

- 4. Marginal Zone Lymphoma Mini-Symposium Dr. Smith
 - a. Pathology of MZL Dr. Joo Song
 - b. MZL Current Treatment Landscape Dr. Bei Hu
 - c. Challenges and Opportunities in Clinical Trial Design for MZL Dr. Boyu Hu
 - d. Discussion and Q&A Drs. Smith, Song, Hu, and Hu
- 5. S1826 Brief Update Dr. Herrera

6. Committee Reports

a.	Immunotherapeutics	Dr. Kambhampati
b.	Cancer Control	Dr. Saeed
c.	Digital Engagement	Dr. Brem
d.	Patient Advocacy	Ms. Hernandez

7. Ongoing Trials

S1918

b.	S1925	Dr. Stephens
c.	S2114	Dr. Hess
d.	S2207	Drs. Amengual and Reagan
e.	AHOD2131	Dr. Hu
f.	AO51902	Dr. Amengual
g.	AO52101	Dr. Phillips
h.	ANHL1931	Dr. Kamdar

Dr. Brem

Proposed Studies

MOZART MZL, "A Randomized 3-Arm Phase II Study Evaluating
Mosunetuzumab Alone and In Combination with Either Zanubrutinib
or Polatuzumab Vedotin for The Treatment of Patients with Relapsed/
Refractory Marginal Zone Lymphoma." Drs. Hu and Smith.

Active Studies

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.

S2114, "A Randomized Phase II Trial of Consolidation Therapy Following CD19 CAR T-Cell Treatment for Relapsed/Refractory Diffuse Large B-cell Lymphoma or Grade IIIB Follicular Lymphoma." Drs. Hess and Hossain. Activated: 2/23/23.



- **S2207**, "Randomized phase II study of the addition of Targeted therapeutic agents to tafasitamab-based therapy in non-transplant-eligible patients with Relapsed/refractory Large B-cell Lymphoma." Drs. Amengual, Reagan, and Smith. Activated: 6/30/23
- **S2308**, "Randomized Phase III Study of Mosunetuzumab vs. Rituximab for Low Tumor Burden Follicular Lymphoma." Drs. Ghosh and Friedberg. Activated: 8/1/24
- 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/ANHL1931, "A Randomized Phase 3 trial of Nivolumab in Combination with Chemo immunotherapy for the Treatment of Newly Diagnosed Primary Mediastinal B cell Lymphoma." Dr. Roth. SWOG Champion: Dr. Kamdar. Activated 6/7/21.
- 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. Mehta-Shah. SWOG Champion: Dr. Amengual. Activated 7/30/21.
- CTSU/A052101, "A Randomized Phase 3 Trial of Continuous vs. Intermittent Maintenance Therapy with Zanubrutinib as Upfront Treatment in Older Patients with Mantle Cell Lymphoma (INTERCON)." Dr. Beaven. SWOG Champion: Dr. Tycel. Activated 9/8/23.
- CTSU/AHOS2131, "A Randomized Phase 3 Interim Response Adapted Trial Comparing Standard Therapy with Immuno-oncology Therapy for Children and Adults with Newly Diagnosed Stage I and II Classic Hodgkin Lymphoma." Dr. Henderson. SWOG Champion: Dr. Hu. Activated 4/28/23.

Closed Lymphoma Studies

- <u>\$1608</u>, "Randomized Phase II Trial in Early Relapsing or Refractory Follicular Lymphoma." Drs. Barr and Burack. Activated: 8/10/17. Closed: 7/15/24
- 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. Closed: 12/14/23.

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

Bendamustine, Rituximab and High Dose Cytarabine (BR/CR) 2.)

Bendamustine, Rituximab, High Dose Cytarabine and Acalabrutinib (BR/CA-A), and 3.) Bendamustine, Rituximab and Acalabrutinib (BR-A) in Patients </= 70 years Old with Untreated Mantle Cell Lymphoma." Dr. Wagner-Johnson. SWOG Champion: Dr. Spurgeon. Activated: 10/3/19. Closed: 4/7/23

Open Leukemia Studies

- S1925, "A Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab versus Delayed Therapy with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL): EVOLVE CLL/SLL Study." Dr. Stephens. Activated: 12/14/20.
- S1905, "A Phase I/II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL)/T-Cell Lymphoblastic Lymphoma (T-LBL)." Drs. Advani and Papadantonakis. Activated: 8/17/20.

Open Cancer Care Delivery Study

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



	51608	51918	52114	52207	A051701	A051902	A052101	AHOD2131
Banner University Medical Center - Tucson	2	-	-	-	-	-	-	-
Baptist Memorial Health Care/Mid South Minority Underserved NCORP	-	1	1	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	3	-	-	8	-	-	-
Cancer Research Consortium of West Michigan NCORP	3	-	3	-	-	-	-	1
Cancer Research for the Ozarks NCORP	1	-	-	-	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	1	1	-	3	-	-	-	-
Cedars-Sinai Medical Center	-	1	-	1	-	-	-	-
City of Hope Comprehensive Cancer Center	8	10	-	-	-	-	-	8
Columbia University Minority Underserved NCORP	-	5	4	1	-	1	-	-
Columbus NCI Community Oncology Research Program	1	-	-	-	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	-	-	-	4	-	-
Froedtert and the Medical College of Wisconsin LAPS	-	-	1	-	-	-	-	-
Georgia Cares Minority Underserved NCORP	-	2	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	-	2	-	-	-	-	-	-
Hawaii Minority Underserved NCORP	-	1	-	-	-	-	-	-
Heartland Cancer Research NCORP	1	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	-	2	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	3	3	-	-	-	-	-	-
Loyola University Medical Center	-	-	2	-	-	-	-	-
Medical University of South Carolina Minority Underserved NCORP	2	3	12	-	3	-	-	-
Michigan Cancer Research Consortium NCORP	1	7	-	1	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	-	-	-	-	-	-	-	-
Nevada Cancer Research Foundation NCORP	-	-	-	-	-	-	-	-
Northwell Health NCORP	-	-	-	-	1	-	-	-
Northwestern University LAPS	1	-	-	-	-	-	-	-
Oregon Health and Science University	-	-	2	-	2	-	-	1
Pacific Cancer Research Consortium NCORP	-	-	6	1	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	-	-	-	-	4	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	4	-	-	-	-	-	-
UC San Diego Moores Cancer Center	-	-	-	-	-	-	-	-
U of Alabama at Birmingham / Deep South Research Consortium LAPS	-	-	-	-	3	-	-	-
University of Arkansas for Medical Sciences	-	-	1	-	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	-	-	-	-	-	-	-
University of Kansas Cancer Center - MCA Rural MU NCORP	-	-	-	-	-	-	-	-
University of Kentucky/Markey Cancer Center	-	-	-	-	-	-	-	-
University of Rochester LAPS	16	-	6	6	11	2	4	5
University of Texas Health Science Center at San Antonio	-	-	8	1	-	-	-	1
University of Texas MD Anderson Cancer Center LAPS	3	-	-	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	1	8	-	-	-	-	-	3
Upstate Carolina Consortium Community Oncology Research Program	1	-	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	1	-	-	-	-	-
Wisconsin NCI Community Oncology Research Program	-	1	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	-	-	-	-	-	1	-
ALLIANCE	16	32	8	2	-	-	-	-
ECOG-ACRIN	5	16	2	-	-	-	-	-
NRG	11	6	-	1	2.4	- 7	-	10
Total	77	106	57	17	34	7	5	19



	ANHL1931	E4412	EA4151	EA4181
Banner University Medical Center - Tucson	_	-	1	2
Baptist Memorial Health Care/Mid South Minority Underserved NCORP	_	-	-	-
CWRU Case Comprehensive Cancer Center LAPS		-	22	14
Cancer Research Consortium of West Michigan NCORP	_	-	-	-
Cancer Research for the Ozarks NCORP	_	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	_	-	-	-
Cedars-Sinai Medical Center	-	-	-	-
City of Hope Comprehensive Cancer Center	8	-	18	-
Columbia University Minority Underserved NCORP	2	1	-	-
Columbus NCI Community Oncology Research Program	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	15	-
Froedtert and the Medical College of Wisconsin LAPS	-	-	-	-
Georgia Cares Minority Underserved NCORP	-	-	-	-
Gulf South Minority Underserved NCORP	-	-	-	-
Hawaii Minority Underserved NCORP	-	-	-	-
Heartland Cancer Research NCORP	-	-	-	-
Henry Ford Hospital	-	-	-	-
Kaiser Permanente NCI Community Oncology Research Program	-	11	-	12
Loyola University Medical Center	-	-	3	-
Medical University of South Carolina Minority Underserved NCORP	-	-	2	-
Michigan Cancer Research Consortium NCORP	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	1	-	2	-
Nevada Cancer Research Foundation NCORP	-	1	-	-
Northwell Health NCORP	-	-	-	-
Northwestern University LAPS	1	-	-	-
Oregon Health and Science University	-	-	7	5
Pacific Cancer Research Consortium NCORP	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	-	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	2	-	-	-
UC San Diego Moores Cancer Center	-	-	1	-
U of Alabama at Birmingham / Deep South Research Consortium LAPS	-	7	5	-
University of Arkansas for Medical Sciences	-	-	-	-
University of Cincinnati Cancer Center-UC Medical Center	-	-	2	3
University of Kansas Cancer Center - MCA Rural MU NCORP	-	-	-	1
University of Kentucky/Markey Cancer Center	-	-	3	-
University of Rochester LAPS	8	-	11	18
University of Texas Health Science Center at San Antonio	-	-	13	-
University of Texas MD Anderson Cancer Center LAPS	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	-	-	20	12
Upstate Carolina Consortium Community Oncology Research Program	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	1	6
Wisconsin NCI Community Oncology Research Program	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	-	5	-
ALLIANCE	-	-	-	-
ECOG-ACRIN	-	-	-	-
NRG	-	-	-	-
Total	22	20	131	73



Melanoma Committee

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
	Allison Hayes, BS
Scientific Leadership	
	William E. Carson, III, MD
	Evan J. Wuthrick, MD
Surgery:	John Robert Hyngstrom, MD
	Clara Curiel-Lewandrowski, MD
Imaging:	Ari M. VanderWalde, MD
Medical Oncology:	Sapna Pradyuman Patel, MD
Pathology:	TBD
Non-Melanoma Skin Cancer:	Nikhil I. Khushalani, MD
Early Therapeutics:	Jeffrey A. Sosman, MD
	Thach-Giao Truong, MD
ECOG's SWOG Liaisons:	David H. Lawson, MD
	Andrew Poklepovic, MD
Digital Engagement:	Zeynep Eroglu, MD
Designates	
	Sancy Leachman, MD, PhD
	Thach-Giao Truong, MD (Survivorship)
	Cassie Villasin, BA
	Michele Counts, BS
	Tonya Johnson, BS
Oncology Research Professionals:	
	Kathryn Allen, BA, CCRP
	TBD
Patient Advocate:	Samantha Guild, J.D.
	Sun "Coco" Yang, PharmD, PhD
	Kimberly McConnell, PharmD
, ,	Catrina De Los Santos-Mireles
Clinical Trials Program Manager:	Laura Gildner, MS

Time/Location

Friday, October 18, 2024 2:15 p.m. - 4:15 p.m. Room: Crystal C (Lobby Level, West Tower)

Keynote Speaker

Translational approaches to melanoma: perspectives of a surgeon Genevieve Boland, MD, PhD, Vice Chair of Research, Harvard Medical School, Massachusetts General Hospital

Presentation

SWOG S1616: Translational insights stratifying primary resistance to Anti-PD-1in melanoma Katie Campbell, PhD

Active Studies

S2015, "Melanoma Margins Trial (MelMarT): A Phase III, Multi-Centre, Multi-National Randomised Control Trial Investigating 1cm v 2cm Wide Excision Margins for Primary Cutaneous Melanoma." Dr. Mammen. Activated: 4/8/22.

CTSU/EA6174, "STAMP: Surgically Treated Adjuvant Merkel Cell Carcinoma with Pembrolizumab, a Phase III Trial." SWOG Champion: Dr. Hsu. Activated: 10/1/18. Temporarily Closed to Accrual as of 4/7/23

CTSU/EA6141, "Randomized Phase II/III Study of Nivolumab plus Ipilimumab plus Sargramostim versus Nivolumab plus Ipilimumab in Patients with Unresectable Stage III or Stage IV Melanoma." SWOG Champion: Dr. K. Kim. Activated: 9/10/15.

CTSU/EA6192, "The BAMM2 (BRAF, Autophagy, MEK Inhibition in Melanoma) Study: A Randomized Double Blind Phase II Study of Dabrafenib and Trametinib with or Without Hydroxychloroquine in Advanced BRAF V600E/K Melanoma with Elevated LDH". SWOG Champion: Dr. Truong. Activated:10/23/20.

A091903, "A Randomized Phase II Trial of Adjuvant Nivolumab with or Without Cabozantinib in Patients with Resected Mucosal Melanoma." SWOG Champion: K. Tsai, MD (SWOG) Activated 06/01/2022. Temporarily Closed to Accrual as of 10/10/23

Studies in Development

52431, "Randomized, open-label, phase III study of anti-PD-1, anti-CTLA-4, and anti-LAG-3 antibodies in patients with previously untreated unresectable or metastatic melanoma". Dr.Chandra

Closed Studies

<u>\$2000</u>,"A Randomized Phase II Trial of Encorafenib + Binimetinib + Nivolumab vs Ipilimumab + Nivolumab in BRAF-V600 Mutant Melanoma with Brain Metastases." Dr. Eroglu. Activated: 9/23/20. Closed: 6/18/24



Melanoma Committee

- <u>S1801</u>, "A Phase II Randomized Study of Adjuvant Versus Neoadjuvant Pembrolizumab (MK-3475) for Clinically Detectable Stage III-IV High Risk Melanoma." Dr. Patel. Activated: 12/6/18. Closed: 5/5/22.
- S1512, "A Phase II and Pilot Trial of PD-1 Blockade with MK-3475 (Pembrolizumab) in Patients with Resectable or Unresectable Desmoplastic Melanoma (DM)." Drs. Kendra and Hu-Lieskovan. Activated: 10/20/16. Closed: 6/4/21.
- S1607, "A Phase II Study of Combining Talimogene Laherparepvec (T-VEC) (NSC-785349) and MK-3475 (Pembrolizumab) in Patients with Advanced Melanoma who have Progressed on Anti-PD1/L1 Based Therapy." Dr. Hu-Lieskovan, Activated: 10/2/17. Closed: 11/1/20.
- S1616, "A Phase II Randomized Study of Nivolumab (NSC-748726) with Ipilimumab (NSC-732442) or Ipilimumab Alone in Advanced Melanoma Patients Refractory to an Anti-PD1 or Anti-PD-L1 Agent." Dr. VanderWalde. Activated: 7/17/17. Closed: 7/15/20.
- **S1404**, "A Phase III Randomized Study of MK3475 versus High-Dose Interferon a-2b for Resected High-Risk Melanoma." Dr. Patel. Activated: 10/15/15. Closed: 11/2/17.
- CTSU/EA6134, "DREAMseq (Doublet, Randomized Evaluation in Advanced Melanoma Sequencing) a Phase III Trial." SWOG Champion: Dr. Chmielowski. Activated: 7/13/15. Closed: 9/30/21.
- CTSU/EA6183, "A Phase II Neoadjuvant Study of Encorafenib with Binimetinib in Patients with Resectable Locoregional Metastases from Cutaneous or Unknown Primary Melanoma (Stages III N1B/C/D)." SWOG Champion: C. D. Lao, MD, MPh Activated: 2/18/20. Closed: 9/23/22.



Melanoma Committee

	52000	A091903	EA6747	EA6174	EA6192	EA6194	52015
Banner MD Anderson Cancer Center	-	-	-	-	-	-	13
Banner University Medical Center - Tucson	-	-	-	3	-	1	-
CWRU Case Comprehensive Cancer Center LAPS	-	-	-	16	-	-	-
Cancer Research Consortium of West Michigan NCORP	-	-	-	-	-	-	74
Cancer Research for the Ozarks NCORP	1	-	1	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	1	-	-	-	-	-	-
Cedars-Sinai Medical Center	-	-	-	-	-	-	17
City of Hope Comprehensive Cancer Center	-	-	3	-	-	-	-
Columbia University Minority Underserved NCORP	-	-	-	-	-	-	1
Dayton NCI Community Oncology Research Program	1	-	2	-	-	-	-
Duke University - Duke Cancer Institute LAPS	-	-	-	-	-	-	10
Fred Hutchinson Cancer Research Center LAPS	-	-	-	1	-	-	-
Froedtert and the Medical College of Wisconsin LAPS	-	-	-	-	-	-	7
Georgia NCI Community Oncology Research Program	-	-	-	-	-	-	7
Intermountain Medical Center	-	-	-	-	-	-	19
Kaiser Permanente NCI Community Oncology Research Program	-	-	26	-	-	-	1
Medical University of South Carolina Minority Underserved NCORP	-	-	-	-	-	-	12
Moffitt Cancer Center	20	-	-	-	-	-	46
Nevada Cancer Research Foundation NCORP	-	-	-	1	-	-	-
New Mexico Minority Underserved NCORP	-	-	-	-	-	-	2
Northwell Health NCORP	-	-	-	-	-	-	6
Northwestern University LAPS	-	-	1	1	5	-	28
Ohio State University Comprehensive Cancer Center LAPS	3	-	-	3	3	-	24
SCL Health Saint Joseph Hospital	-	-	-	1	-	-	-
Sutter Cancer Research Consortium	-	-	7	1	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	-	4	8	-	3	8
UPMC Hillman Cancer Center LAPS	1	-	-	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS	-	1	-	3	-	-	-
University of Arkansas for Medical Sciences	-	-	-	-	1	-	5
University of Cincinnati Cancer Center-UC Medical Center University of Kansas Cancer Center - MCA Rural MU NCORP	-	-	2 1	4	-	-	41
University of Kentucky/Markey Cancer Center University of Kentucky/Markey Cancer Center	-	-	,	,	-	-	41
University of Michigan Comprehensive Cancer Center LAPS	2	_		-		-	12
University of Nebraska Medical Center University of Nebraska Medical Center	_	_	_	_		_	2
University of Oklahoma Health Sciences Center LAPS		_	_	_		-	1
University of Rochester LAPS	_	_	4	1		_	5
University of Texas Health Science Center at San Antonio		_	1	-	_	-	3
University of Texas MD Anderson Cancer Center LAPS	_	-	-	-	_	-	15
University of Utah - Huntsman Cancer Institute LAPS	_	-	_	8	-	-	25
Western States Cancer Research NCORP	_	-	1	-	_	-	-
Wisconsin NCI Community Oncology Research Program		-	_	-	-	-	10
Yale University - Yale Cancer Center LAPS	_	-	8	1	-	-	21
ALLIANCE	1	-	-	-	-	-	59
ECOG-ACRIN	6	-	-	-	-	-	146
NRG	1	-	-	-	-	-	66
Total	37	1	61	53	9	4	690



Radiation Oncology Committee

Leadership	3:27 - 3:39 pm	GU clinical trials landscape - James Yu, MD
Chair:	3:39 - 3:51 pm	Radiation as a part of CAR-T cell therapy - Nick Figura, MD
Statisticians:	3:51 - 4:03 pm	Next steps for testing hypofractionation with S2310 - Jeremy Harris, MD
Breast Committee Liaison:	4:03 - 4:15 pm	Phase I/II study of TRC 102 in patients with newly diagnosed MGMT promotor methylation GBM / Phase II study of Atezolizumab and Tocilizumab with radiotherapy in patients with newly diagnosed MGMT unmethylated GBM - Tony Wang, MD
Genitourinary Committee Liaison:	4:15 pm	Closing Remarks - Chul S. Ha, MD

Time/Location

Friday, October 18, 2024 2:15 p.m. - 4:15 p.m. Room: Plaza A (Lobby Level, East Tower)

Symptom Management & Survivorship

Agenda

Committee liaison: Erin Gillespie, MD, MPH
Data Coordinator: Larry Kaye

2:15 - 2:16 pm	Welcome - Chul S. Ha, MD
2:16 - 2:20 pm	Report from Executive Officer - Lisa Kachnic, MD
2:20 - 2:25 pm	Update from IROC - T.J. FitzGerald, MD
2:25 - 2:30 pm	Update from NCI - Jacek Capala, PhD, DSc
2:30 - 3:00 pm	Keynote Lecture: Update Prostate Cancer Theranostics 2024 - A. Oliver Sartor, MD
3:00 - 3:15 pm	Applying Al/Deep learning techniques to SWOG dataset - Yugyung Lee, PhD and John Park, MD
3:15 - 3:27 pm	New DCIS concept and Re-radiation therapy concept - Eileen Connolly, MD



The publications listed below were received by the Group Chair's Office as published (including online), accepted, or submitted since the SWOG Spring 2024 Group Meeting. Conference abstracts are not included.

Because of journal embargo policies, journal names are omitted for submitted or accepted manuscripts

ADOLESCENT AND YOUNG ADULT (AYA) COMMITTEE

Published/Accepted Manuscripts

N/A Characteristics of Health Care Settings Where Adolescents and Young Adults Receive Care for ALL. Wolfson J, Grimes A, Nuno M, Kerber C, Ramakrishnan S, Beauchemin M, Dickens D, Levine J, Roth M, Scialla M, Woods W, Vargas S, Boayue K, Chang G, Stock W, Hershman D, Curran E, Advani A, O'Dwyer K, Luger S, Liu J, Freyer D, Sung L, Parsons S. JCO Oncology Practice Apr;20(4):491-502, 2024. https://pubmed.ncbi.nlm.nih.gov/38252911/

Submitted Manuscripts

None this cycle

BARLOGIE-SALMON MYELOMA COMMITTEE

Published/Accepted Manuscripts

None this cycle

Submitted Manuscripts

<u>S0777/S1211</u> Dexamethasone dose intensity does not impact outcomes in newly diagnosed multiple myeloma: a secondary SWOG analysis.
Banerjee R, Sexton R, Cowan A, Rosenberg A, Ailawadhi S, Rajkumar V,
Kumar S, Lonial S, Durie B, Richardson P, Usmani S, Hoering A, Orlowski R.
Submitted, 2024.

BREAST COMMITTEE

Published/Accepted Manuscripts

CTP TROPION-Breast03 TROPION-Breast03: a randomized phase III global trial of datopotamab deruxtecan ± durvalumab in patients with triple-negative breast cancer and residual invasive disease at surgical resection after neoadjuvant therapy.Bardia A, Pusztai L, Albain K, Ciruelos EM, Im SA, Hershman D, Kalinsky K, Isaacs C, Loirat D, Testa L, Tokunaga E, Wu J, Dry H, Barlow W, Kozarski R, Maxwell M, Harbeck N, Sharma P. Ther Adv Med Oncol. Apr 29;16:17588359241248336, 2024. https://pubmed.ncbi.nlm.nih.gov/38686016/

Pre-treatment Amino Acids and Risk of Paclitaxel-induced
Peripheral Neuropathy in SWOG S0221. Chen C, Zirpoli G, Barlow W,
Budd GT, Pusztai L, Hortobagyi G, Albain K, Godwin A, Thompson A,
Henry NL, Ambrosone C, Stringer K, Hertz D. Cancer Chemotherapy and
Pharmacology May 30. doi: 10.1007/s00280-024-04680-6. Online ahead

of print, 2024. https://pubmed.ncbi.nlm.nih.gov/38814343/

Phase III Randomized, Placebo-Controlled Trial of Endocrine
Therapy ± 1 Year of Everolimus in Patients With High-Risk, Hormone
Receptor-Positive, Early-Stage Breast Cancer. Chavez MacGregor M, Miao
J, Pusztai L, Goetz M, Rastogi P, Ganz P, Mamounas E, Paik S, Bandox
H, Razaq W, O'Dea A, Kaklamani V, Silber A, Flaum L, Andreopoulou E,
Wendt A, Carney J, Sharma P, Gralow J, Lew D, Barlow W, Hortobagyi
G. Journal of Clinical Oncology Jun 4:JCO2302344. doi: 10.1200/
JCO.23.02344. Online ahead of print, 2024.
https://pubmed.ncbi.nlm.nih.gov/38833643/

E1105 A randomized phase III double-blind placebo-controlled trial of first line chemotherapy and trastuzumab with or without bevacizumab for patients with HER2/neu over-expressing metastatic breast cancer: a trial of the ECOG-ACRIN Cancer Research Group (E1105). Mezzanotte-Sharpe J, O'Neill A, Mayer I, Arteaga C, Yang X, Wagner L, Celia D, Meropol N, Alpaugh R, Saphner T, Swaney R, Hoelzer K, Gradishar W, Abramson V, Sundaram K, Jilani S, Perez E, Lin N, Jahanzeb M, Sledge G, Reid S. Breast Cancer Research and Treatment Sep;207(2):275-282, 2024. https://pubmed.ncbi.nlm.nih.gov/38967884/

Submitted Manuscripts

S1007 Race and Clinical Outcomes in Hormone Receptor-Positive, HER2-Negative, Node-Positive BCin the Phase III RxPONDER Trial (SWOG S1007). Abdou Y, Barlow W, Gralow J, Meric-Bernstam F, Albain K, Hayes D, Lin N, Perez E, Goldstein L, Chia S, Dhesy-Thind S, Rastogi P, Alba E, Delaloge S, Schott A, Shak S, Sharma P, Lew D, Miao J, Unger J, Tripathy D, Pusztai L, Hortobagyi G, Kalinsky K. Submitted, 2024.

S1007/S8814 Development and validation of the RSClinN+ tool that integrates the 21-gene recurrence score and clinical variables to predict prognosis and chemotherapy benefit for hormone receptor-positive (HR+), HER2-negative (HER2-), node-positive breast cancer. Pusztai L, Hoag J, Albain K, Barlow W, Stemmer S, Meisner A, Hortobagyi G, Shak S, Rae J, Baehner R, Sharma P, Kalinsky K. Submitted, 2024.

CANCER CONTROL AND PREVENTION CANCER CARE DELIVERY COMMITTEE

Published/Accepted Manuscripts

<u>Multiple Studies</u> Socioeconomic Deprivation and Healthcare Utilization in Patients Enrolled in SWOG Cancer Clinical Trials. Hershman D, Vaidya



R, Till C, Barlow W, LeBlanc M, Ramsey S, Unger J. <u>JAMA Network Open</u> Mar 4;7(3):e244008, 2024. <u>https://pubmed.ncbi.nlm.nih.gov/38546646/</u>

Multiple Studies Interventions addressing health-related social needs among patients with cancer. Graboyes EM, Lee SC, Lindau ST, Adams AS, Adjei BA, Brown M, Sadigh G, Incudine A, Carlos RC, Ramsey SD, Bangs R. J Natl Cancer Inst. 2024 Apr 5;116(4):497-505.

https://pubmed.ncbi.nlm.nih.gov/38175791/

EAQ162CD Patient-Reported Financial Burden of Treatment for Colon or Rectal Cancer. Kircher S, Duan F, An N, Gareen I, Sicks J, Sadigh G, Suga J, Kean H, Mehan P, Bajaj R, Acoba J, Hanson D, Dalia S, Gokalp Yasar D, Park E, Wagner L, Carlos R. JAMA Network Open Jan 2;7(1):e2350844, 2024. https://pubmed.ncbi.nlm.nih.gov/38194233/

Submitted Manuscripts

S1415CD/Other Intracluster Correlation Coefficients from Cluster Randomized Trials Conducted within the NCI Community Oncology Research Program (NCORP). Snavely A, Gunn H, Lee J-W,. Pugh S, Barlow W, Culakova E, Arnold K, Kittel C, Smith S, Hanlon B, Tan A, Dockter T, Zahrieh D, Dressler E. Submitted 2024.

Multiple Studies Prevalence of tobacco use and association with socio-demographic variables in patients enrolled on clinical trials: the SWOG Cancer Research Network experience. Presant C, Vaidya R, Till C, Ashing K, Warren G, Hershman D, Sun V, Salgia R, Massarelli E, Mortimer J, Idos G, Pal S, Dorff T, Amini A, Erhunmwunsee L, Phillips T, Johnson A, Adesunloye B, Bedell F, Tergas A, Amanam I, Rosen S, Unger J. Submitted 2024.

<u>Multiple Studies*</u> Neighborhood Socioeconomic Deprivation and Patient-Reported Outcomes in Symptom Management Trials for Breast Cancer Patients. Vaidya R, Till C, Henry NL, Fisch M, Hershman D, Unger J. Submitted 2024. [*S0927,S1200,S1202]

PALLIATIVE CARE COMMITTEE

Published/Accepted Manuscripts

S1820 Baseline Characteristics and Recruitment for SWOG S1820:
Altering Intake, Managing Bowel Symptoms in Survivors of Rectal
Cancer (AIMS-RC). Sun V, Thomson C, Crane T, Arnold K, Guthrie K,
Freylersythe S, Braun-Inglis C, Jones L, Carmichael J, Messick C, Flaherty
D, Ambrale S, Cohen S, Krouse R. Supportive Care in Cancer May
22;32(6):371, 2024. https://pubmed.ncbi.nlm.nih.gov/38775966/

Submitted Manuscripts

<u>S1316</u> Intake and Nutritional Adequacy in Cancer Patients Diagnosed with Malignant Bowel Obstruction: A secondary analysis of a

randomized trial. Thomson CA, Arnold KB, Anderson G, Sun V, Secord A, Yung A, Al-Kaspooles M, Nfonsam V, Grant M, Deutsch G, Deneve J, Krouse R. Submitted 2024.

PREVENTION, SCREENING, AND SURVEILLANCE COMMITTEE

Published/Accepted Manuscripts

<u>S0000</u> Letter: Survival After Selenium and Vitamin E Supplementation: Long-Term Followup of the Selenium and Vitamin E Cancer Prevention Trial. Till C, Goodman PJ, Tangen C, Lucia MS, Thompson IM Jr. <u>Journal of</u> Urology Jul;212(1):228-229, 2024.

https://pubmed.ncbi.nlm.nih.gov/38657020/

Sonoo/S9217/Other Genome-Wide Analysis to Assess if Heavy Alcohol Consumption Modifies the Association between SNPs and Pancreatic Cancer Risk. Ni Z, Kundu P, McKean DF, Wheeler W, Albanes D, Andreotti G, Antwi SO, Arslan AA, Bamlet WR, Beane Freeman LE, Berndt SI, Bracci PM, Brennan P, Buring JE, Chanock SJ, Gallinger S, Gaziano JM, Giles GG, Giovannucci EL, Goggins MG, Goodman PJ, Haiman CA, Hassan MM, Holly EA, Hung RJ, Katzke V, Kooperberg C, Kraft P, Le Marchand L, Li D, McCullough ML, Milne RL, Moore SC, Neale RE, Oberg AL, Patel AV, Peters U, Rabe KG, Risch HA, Shu XO, Smith Byrne K, Visvanathan K, Wactawski-Wende J, White E, Wolpin BM, Yu H, Zeleniuch-Jacquotte A, Zheng W, Zhong J, Amundadottir LT, Stolzenberg-Solomon RZ, Klein AP. Cancer Epidemiol Biomarkers Prev. Jun 13. doi: 10.1158/1055-9965. EPI-24-0096. Online ahead of print, 2024.

https://pubmed.ncbi.nlm.nih.gov/38869494/

Effects of vitamin D supplementation on a convolutional neural network-based mammographic evaluation among premenopausal women at high risk for breast cancer enrolled in SWOG S0812.

McGuiness J, Mutasa S, Anderson G, Hershman D, Terry M, Tehranifar P, Lew DL, Yee M, Kairouz S, Kuwajerwala N, Bevers T, Doster J, Zarwan C, Kruper L, Minasian L, Ford L, Arun B, Neuhouser M, Goodman G, Brown P, Ha R, Crew K. JNCI Cancer Spectrum Jul 1;8(4):pkae042, 2024.

https://pubmed.ncbi.nlm.nih.gov/38814817/

Making Informed Choices On Incorporating Chemoprevention into carE (MiCHOICE, SWOG 1904): Design and methods of a cluster randomized controlled trial. Crew KD, Anderson GL, Arnold KB, Stieb AP, Amenta JN, Collins N, Law CW, Pruthi S, Sandoval-Leon A, Bertoni D, Grosse Perdekamp MT, Colonna S, Krisher S, King T, Yee LD, Ballinger TJ, Braun-Inglis C, Mangino D, Wisinski KB, DeYoung CA, Ross M, Floyd J, Kaster A, Vander Walde L, Saphner T, Zarwan C, Lo S, Graham C, Conlin A, Yost K, Agnese D, Jernigan C, Hershman DL, Neuhouser ML, Arun B, Kukafka R. Contemporary Clinical Trials Jul:142:107564, 2024. https://pubmed.ncbi.nlm.nih.gov/38704119/



S9217/Other Genome-Wide Gene-Environment Interaction Analyses to Understand the Relationship between Red Meat and Processed Meat Intake and Colorectal Cancer Risk. Stern MC, Sanchez Mendez J, Kim AE, Obón-Santacana M, Moratalla-Navarro F, Martín V, Moreno V, Lin Y, Bien SA, Qu C, Su YR, White E, Harrison TA, Huyghe JR, Tangen CM, Newcomb PA, Phipps AI, Thomas CE, Kawaguchi ES, Lewinger JP, Morrison JL, Conti DV, Wang J, Thomas DC, Platz EA, Visvanathan K, Keku TO, Newton CC, Um CY, Kundaje A, Shcherbina A, Murphy N, Gunter MJ, Dimou N, Papadimitriou N, Bézieau S, van Duijnhoven FJB, Männistö S, Rennert G, Wolk A, Hoffmeister M, Brenner H, Chang-Claude J, Tian Y, Le Marchand L, Cotterchio M, Tsilidis KK, Bishop DT, Melaku YA, Lynch BM, Buchanan DD, Ulrich CM, Ose J, Peoples AR, Pellatt AJ, Li L, Devall MAM, Campbell PT, Albanes D, Weinstein SJ, Berndt SI, Gruber SB, Ruiz-Narvaez E, Song M, Joshi AD, Drew DA, Petrick JL, Chan AT, Giannakis M, Peters U, Hsu L, Gauderman WJ. Cancer Epidemiol Biomarkers Prev. Mar 1;33(3):400-410, 2024. https://pubmed.ncbi.nlm.nih.gov/38112776/

<u>S9217</u> Long-term side effects and complications after prostate cancer treatment.Unger J, Till C, Tangen C, Hershman D, Goodman P, Leblanc M, Barlow W, Vaidya R, Minasian L, Parnes H, Thompson IM. Accepted 2024.

Submitted Manuscripts

None this cycle

SYMPTOM MANAGEMENT AND SURVIVORSHIP COMMITTEE

Published/Accepted Manuscripts

ECOG E1Z11 A Cohort Study to Evaluate Genetic Predictors of Aromatase Inhibitor Musculoskeletal Symptoms: Results from ECOG-ACRIN E1Z11. Stearns V, Jegede OA, Chang VT, Skaar TC, Berenberg JL, Nand R, Shafqat A, Jacobs NL, Luginbuhl W, Gilman P, Benson AB 3rd, Goodman JR, Buchschacher GL Jr, Henry NL, Loprinzi CL, Flynn PJ, Mitchell EP, Fisch MJ, Sparano JA, Wagner LI. Clinical Cancer Research Jul 1;30(13):2709-2718. https://pubmed.ncbi.nlm.nih.gov/38640040/

IBCSG 48-14 Fertility preservation and assisted reproductive technologies in breast cancer patients interrupting adjuvant endocrine therapy to attempt pregnancy. Azim HA, Jr, Niman SM, Partridge AH, Demeestere I, Ruggeri M, Colleoni M, Saura C, Shimizu C, Satersdal AB, Kroep JR, Mailliez A, Warner E, Borges VF, Amant F, Gombos A, Kataoka A, Rousset Jablonski C, Borstnar S, Takei J, Eon Lee J, Walshe JM, Ruiz Borrego M, Moore HCF, Saunders C, Bjelic Radisic V, Susnjar S, Cardoso F, Klar NJ, Spanic T, Ruddy K, Piccart M, Korde LA, Goldhirsch A, Gelber RD, Pagani O, Peccatori FA. Journal of Clinical Oncology May 29:JCO2302292, 2024. https://pubmed.ncbi.nlm.nih.gov/38810178/

NSABP R04 Overall side effect assessment of oxaliplatin toxicity in rectal cancer patients in NRG oncology/NSABP R04. Peipert JD, Roydhouse J, Tighiouart M, Henry NL, Kim S, Hays RD, Rogatko A, Yothers G, Ganz PA. Quality of Life Research Jul 30. doi: 10.1007/s11136-024-03746-5. Online ahead of print.

https://pubmed.ncbi.nlm.nih.gov/39080091/

Submitted Manuscripts

S1714 A Prospective Observational Cohort Study to Develop a Predictive Model of Taxanelnduced Peripheral Neuropathy in Patients with Cancer: SWOG S1714. Trivedi M, Unger J, Darke A, Hertz D, Brannagan T, Smith S, Hershman D, Henry NL, Fisch M. Submitted 2024.

S2010 Active symptom monitoring for premenopausal women with breast cancer initiating adjuvant endocrine therapy: Protocol for the SWOG S2010 randomized controlled efficacy trial. Henry NL, Unger J, Darke A, Skaar T, Fisch M, Hershman D. Submitted 2024.

DIGITAL ENGAGEMENT COMMITTEE

Published/Accepted Manuscripts

None this cycle

Submitted Manuscripts

None this cycle

EARLY THERAPEUTICS AND RARE CANCERS COMMITTEE

Published/Accepted Manuscripts

S1609 A Phase II Basket Trial of Dual Anti-CTLA-4 and Anti-PD-1
Blockade in Rare Tumors (DART) SWOG S1609: Adrenocortical
Carcinoma Cohort. Patel S, Othus M, Chae Y, Huynh T, Tan B, Kuzel T,
Vogelzang N, McLeod C, Lopez G, Chen H, Sharon E, Streicher H, Ryan
C, Blanke C, Kurzrock R Journal for ImmunoTherapy of Cancer (JITC) Jul
27;12(7):e009074, 2024. https://pubmed.ncbi.nlm.nih.gov/39067873/

S1609 A Phase II Basket Trial of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART) SWOG S1609: The Desmoid Tumors. Chae Y, Othus M, Patel S, Powers B, Hsueh C, Govindarajan R, Bucur S, Kim H, Il-Young Chung L, McLeod C, Chen H, Sharon E, Streicher H, Ryan C, Blanke CD, Kurzrock R. Accepted 2024.

Submitted Manuscripts

S1609 Correlations Between First Cycle Toxicity and Overall Survival in Patients with Rare Cancers Treated with Immune Checkpoint Inhibitors (NCI/SWOG S1609).Othus M, Patel S, Chae YK, Deitrich E, Streicher H, Sharon E, Kurzrock R. Submitted, 2024.



- S1609 A Phase II Basket Trial of Dual Anti-CTLA-4 and Anti-PD-1
 Blockade in Rare Tumors (DART) SWOG S1609: The Salivary Gland Tumor
 Cohort. Chae Y, Sun R, Patel S, Giles F, Ohr J, Worden F, Suga J, Naing
 A, Cohen E, Wallace J, Fenton S, Il-Young Chung L, Kang H, McLeod C,
 Chen H, Sharon E, Streicher H, Ryan C, Othus M, Blanke CD, Kurzrock R.
 Submitted 2024.
- SWOG/NCI S1609 Phase II Basket Trial Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART): Non-Epithelial Ovarian Cancer. Chae Y, Othus M, Patel S, Wilkinson K, Whitman-Purves E, Lea J, Schallenkamp J, Adra N, Appleman L, Alden M, Thomes Pepin J, Ellerton J, Poklepovic A, Walter A, Rampurwala M, Robinson W, Il-Young Chung L, Kim H, McLeod C, Lopez G, Chen H, Sharon E, Streicher H, Ryan C, Blanke C, Kurzrock R. Submitted 2024.
- S1609 Phase II Trial of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART) SWOG/NCI Experience: Invasive Mucinous or Non-mucinous Lepidic Adenocarcinoma of the Lung (Formerly Bronchioloalveolar Carcinoma). Chae Y, Othus M, Patel S, Gerber D, Tanvetyanon T, Il-Young Chung L, Kim H, McLeod C, Lopez G, Chen H, Sharon E, Streicher H, Ryan C, Blanke C, Kurzrock R. Submitted 2024.
- S1609 DART/SWOG/NCI Phase II Anti-CTLA-4/PD-1 Trial: Clear Cell Carcinomas of Ovary, Endometrium, Cervix. Chae Y, Othus M, Patel S, Backes F, O'Malley D, Cristea M, Naing A, Kurnit K, Eskander R, Goodrich S, Robinson W, Kim H, II-Young Chung L, McLeod C, Chen H, Sharon E, Streicher H, Ryan C, Blanke CD, Kurzrock R. Submitted 2024.

GASTROINTESTINAL COMMITTEE

Published/Accepted Manuscripts

- S1505 Body Composition Measurements and Clinical Outcomes in Patients with Resectable Pancreatic Adenocarcinoma: Analysis from SWOG S1505 [Brief Report]. Sohal D, Boutin R, Lenchik L, Kim J, Beg S, Wang-Gillam A, Wade J, Guthrie KA, Chiorean E, Ahmad S, Lowy A, Philip P, Chang V. J Gastrointest Surg . Mar;28(3):232-235, 2024. https://pubmed.ncbi.nlm.nih.gov/38445914/
- <u>S1505</u> Failure to Undergo Resection Following Neoadjuvant Therapy for Resectable Pancreatic Cancer: A Secondary Analysis of SWOG S1505. Cloyd J, Colby S, Guthrie KA, Lowy A, Chiorean E, Philip P, Sohal D, Ahmad S. <u>J Natl Compr Canc Netw</u> Apr 29:1-6. 2024. https://pubmed.ncbi.nlm.nih.gov/38688309/
- A021501 Postoperative Adverse Events Following Neoadjuvant Therapy and Surgery in a Phase 2 Borderline Resectable Pancreatic Cancer Clinical Trial (Alliance A021501). Snyder R, Zemla T, Shi Q, Segovia D, Ahmad S, O'Reilly E, Herman J, Katz M. Annals of Surgical Oncology Jul

- 15. doi: 10.1245/s10434-024-15670-6. Online ahead of print, 2024. https://pubmed.ncbi.nlm.nih.gov/39008208/
- A022104 Alliance A022104/NRG-GI010: The Janus Rectal Cancer Trial: a randomized phase II/III trial testing the efficacy of triplet versus doublet chemotherapy regarding clinical complete response and disease-free survival in patients with locally advanced rectal cancer. Alvarez J, Shi Q, Dasari A, Garcia-Aguilar J, Sanoff H, George TJ, Hong TS, Yothers G, Philip PA, Nelson GD, Al Baghdadi T, Alese O, Zambare W, Omer DM, Verheij FS, Buckley J, Williams H, George M, Garcia R, O'Reilly EM, Meyerhardt JA, Shergill A, Horvat N, Romesser PB, Hall WA, Smith JJ. BMC Cancer Jul 26;24(1):901, 2024. https://pubmed.ncbi.nlm.nih.gov/39060961/
- C80405 HER2 gene expression levels are predictive and prognostic in patients with metastatic colorectal cancer enrolled in CALGB/SWOG 80405. Battaglin F, Ou F, Qu X, Bertagnolli M, Hochster H, Niedzwiecki D, Goldberg R, Mayer R, Ashouri K, Zemla T, Blanke CD, Venook A, Kabbarah O, Lenz H-J, Innocenti F. Journal of Clinical Oncology Jun 1;42(16):1890-1902, 2024. https://pubmed.ncbi.nlm.nih.gov/38457761/
- CR5 and CCL5 gene expression in colorectal cancer: comprehensive profiling and clinical value. Battaglin F, Baca Y, Millstein J, Xiu J, Arai Y, Wang J, Ou F, Innocenti F, Jayachandran P, Kawanishi N, Lenz A,Soni S, Algaze S, Zhang W, Yang Y, Seeber A, Abraham J, Lou E, Philip PA, Weinberg B, Shields AF, Goldberg R, Marshall J, Venook A, Korn W, Lenz H-J. Journal of Immunotherapy of Cancer Jan 11;12(1):e007939, 2024. https://pubmed.ncbi.nlm.nih.gov/38212126/
- C80405 DNA Mutational Profiling in Patients With Colorectal Cancer Treated With Standard of Care Reveals Differences in Outcome and Racial Distribution of Mutations. Innocenti F, Mu W, Qu X, Ou FS, Kabbarah O, Blanke CD, Venook AP, Lenz HJ, Rashid NU. <u>Journal of Clinical Oncology</u> Feb 1;42(4):399-409, 2024. https://pubmed.ncbi.nlm.nih.gov/37992266/
- C80405 q-Diffusion leverages the full dimensionality of gene coexpression in single-cell transcriptomics.Marmarelis M, Singh N, Littman R, Battaglin F, Ambite J, Galstyan A, Lenz H-J, Ver Steeg G. Communications Biology Apr 2;7(1):400, 2024. https://pubmed.ncbi.nlm.nih.gov/38565955/
- C80702 Improved survival with adjuvant COX-2 inhibition in PIK3CA-activated stage III colon cancer.Nowak J, Twombly T, Ma C, Shi Q, Haruki K, Fujiyoshi K, Vayrynen J, Zhao M, Knight J, Mane S, Kumar P, Couture F, Kuebler P, Krishnamurthi S, Tan B, Philip P, O'Reilly E, Shields A, Ogino S, Fuchs C, Meyerhardt J. <u>Journal of Clinical Oncology</u> Jun18:JCO2301680. doi: 10.1200/JCO.23.01680. Online ahead of print, 2024. https://pubmed.ncbi.nlm.nih.gov/38889377/



C80702/Other Oxaliplatin-Based Adjuvant Chemotherapy in Older Patients With Stage III Colon Cancer: An ACCENT/IDEA Pooled Analysis of 12 Trials. Gallois C, Shi Q, Pederson LD, André T, Iveson TJ, Sobrero AF, Alberts S, de Gramont A, Meyerhardt JA, George T, Schmoll HE, Souglakos I, Harkin A, Labianca R, Sinicrope FA, Oki E, Shields AF, Boukovinas I, Kerr R, Lonardi S, Yothers G, Yoshino T, Goldberg RM, Taieb J, Papamichael D. Journal of Clinical Oncology Jul 1;42(19):2295-2305, 2024. https://pubmed.ncbi.nlm.nih.gov/38547438/

Submitted Manuscripts

- S1505 Chemotherapy Dose Density is Prognostic for Overall Survival in Patients with Resectable Pancreas Cancer: A Landmark Analysis of SWOG 1505. Patel S, Colby S, Sohal D, Guthrie K, Kachnic L, Chiorean EG, Lowy A, Rocha F, Hochster H, Philip P, Ahmad S. Submitted 2024.
- S1613 Trastuzumab Plus Pertuzumab Versus Cetuximab Plus Irinotecan in Patient with RAS/BRAF wild-type, HER2-positive, Metastatic Colorectal Cancer(S1613): A Randomized Phase 2 Trial. Raghav K, Guthrie K, Tan B, Denlinger C, Fakih M, Overman M, Dasari NA, Corum L, Hicks L, Patel M, Esparaz B, Kazmi S, Alluri N, Colby S, Gholami S, Gold P, Chiorean EG, Kopetz ES, Hochster H, Philip PA. Submitted 2024.
- SWOG S1815: A Phase III Randomized Trial of Gemcitabine, Cisplatin, and Nab-Paclitaxel versus Gemcitabine and Cisplatin in Newly Diagnosed, Advanced Biliary Tract Cancers (SWOG S1815; NCT#03768414). Shroff R, King G, Colby S, Scott A, Borad M, Matin K, Mahipal A, Kalyan A, Javle M, El Dika I, Tan B, Cheema P, Patel A, Iyer R, Kelley R, Thumar J, El-Khoueiry A, Guthrie K, Chiorean EG, Hochster H, Philip P. Submitted 2024.
- Solve The Effect of Radiation Modality on Outcomes of Patients
 Receiving Adjuvant Chemoradiotherapy for Extrahepatic
 Cholangiocarcinoma and Gallbladder Carcinoma: A Secondary Analysis
 of SWOG Solve. Horowitz D, Colby S, Gholami S, Guthrie KA, Ben-Josef
 E, El-Khoueiry A, Blanke CD, Philip P, Chiorean E, Rocha F, Ahmad S,
 Kachnic L. Submitted/in revision 2024.
- 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. Submitted 2024.

GENITOURINARY COMMITTEE

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

Published/Accepted Manuscripts

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IMMUNOTHERAPEUTICS COMMITTEE

Published/Accepted Manuscripts

None this cycle

Submitted Manuscripts

None this cycle)

LEUKEMIA COMMITTEE

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LYMPHOMA COMMITTEE

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MELANOMA COMMITTEE

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