



 **SWOG** | CANCER
RESEARCH
NETWORK

Chicago Virtual Fall Group Meeting

OCTOBER 12-16, 2021

Welcome



A Most Welcome Event!

Welcome to the SWOG fall 2021 group meeting. We had hoped to be basking in each other's company face to face in Chicago this week, feeling the brisk October winds blowing off of Lake Michigan. We'll have to bask remotely, but being once again virtual does not diminish the outstanding quality of offerings we have on our agenda this fall.

This will be our most ambitious virtual meeting yet, with more than 60 sessions offered. A couple I want to call to your attention are Hope Foundation office hours for discussing applications for the NCORP Pilot Grants or other funding opportunities (these are just before Plenary II on Thursday – come and get help with your grant applications!) and a joint kickoff/reactivation session Wednesday for the S2013 I-CHECKIT study of immune-related adverse events, and the recently reopened S1614, on the prophylactic use of antivirals in patients with hepatitis B.

There's also our NCORP Research Base Clinical Trials Workshop, an educational opportunity for oncology research professionals and investigators from both NCORP and NCTN institutions. And our Jeri and Noboru Oishi Symposium this fall will be combined with the Oncology Research Professionals Open Forum for an extended session on Wednesday.

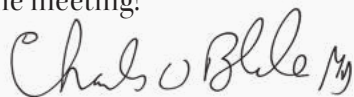
Our Plenary I session will highlight SWOG's translational research in gastrointestinal cancers and will feature an update on our Immunotherapeutics Committee's work on incorporating biomarkers in our immunotherapy trials.

Plenary II – Integrity and Ethical Behavior in Cancer Research – will be a super-sized version of the Crucial Conversations panel on sexual harassment and gender equity we pledged to hold. After the presentations, you'll be able to post your questions for the panel in real time. I recommend not missing either of our plenaries!

As in our last three SWOG group meetings, all sessions will be streamed live (most through Zoom). In many sessions you will be able to submit questions or comments via a chat function.

I want to close with a message of hope. The pandemic has tested us to our limits, but we've adapted and are again meeting virtually to move forward on vital work for our patients. Accrual to our trials has proven to be resilient – it rebounded early, thanks in part to new flexibility in trial processes, and remains strong. I'm grateful for your commitment and eager to carry on our important work.

Welcome to the meeting!



Charles D. Blanke, MD
SWOG Chair



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Plenary I

Wednesday, October 13, 2:30-4:00 p.m.

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

Welcome and Introduction

Lee M. Ellis, MD, FASCO

SWOG Vice-Chair for Translational Medicine

University of Texas MD Anderson Cancer Center



Hope Impact Award Progress Update

George Thomas, MD

Professor of Pathology and Laboratory Medicine

OHSU Knight Cancer Institute



Translational Medicine in GI Cancers: We have the guts!

Heinz-Josef Lenz, MD

Professor of Medicine and Preventive Medicine

J. Terrence Lanni Chair in Cancer Research

Associate Director, Clinical Sciences

Co-Director, Center for Cancer Drug Development

USC Norris Comprehensive Cancer Center



Christopher Lieu, MD

Associate Professor

Associate Director for Clinical Research

Co-Director, GI Medical Oncology

University of Colorado Cancer Center



Incorporating Biomarkers in SWOG IO Trials: Perspectives from the SWOG Immunotherapeutics Committee

Katerina Politi, PhD

Associate Professor of Pathology and Medicine

(Medical Oncology)

Co-leader, Cancer Signaling Networks Research Program

Scientific Director, Center for Thoracic Cancers

Yale Cancer Center and Yale School of Medicine



The presentations will be followed by a live Q&A session at which viewers can post questions via Zoom's text chat feature.

Plenary II

Integrity and Ethical Behavior in Cancer Research

Thursday, October 14, 1:00-2:30 p.m.

Chair's Welcome and Update

Charles D. Blanke, MD, FASCO, FAWM

SWOG Group Chair

OHSU Knight Cancer Institute



An Evidence-Based Approach to Fulfilling Our Duty to Promote Gender Equity in Oncology

Reshma Jagsi, MD, DPhil

Deputy Chair, Radiation Oncology

Newman Family Professor of Radiation Oncology

Residency Program Director

*Director, Center for Bioethics and Social Sciences
in Medicine*

University of Michigan



Characterizing Oncologists' Experiences with Sexual Harassment

Ishwaria M. Subbiah, MD, MS

*Department of Palliative, Rehabilitation,
and Integrative Medicine,*

Division of Cancer Medicine

University of Texas MD Anderson Cancer Center



Ensuring Integrity, Accountability, and Ethical Behavior in SWOG's Research Activities

Paul Hesketh, MD

Director, Lahey Health Cancer Institute

Director, Sophia Gordon Cancer Center

Director, Thoracic Oncology

Lahey Hospital & Medical Center

Professor of Medicine

Tufts University School of Medicine



Presentations are followed by a panel discussion with the presenters and

Lisa Kachnic, MD

Chu H. Chang Professor and Chair,

Department of Radiation Oncology

Columbia University Irving Medical Center

Herbert Irving Comprehensive Cancer Center



Viewers can post questions to the panel via Zoom's text chat feature.



Throughout sixty-five years of extraordinary collaboration,

SWOG members have produced many remarkable improvements in cancer care. Our teams have helped patients live longer, better lives. You have secured a better future for others through your exceptional dedication to research.

Now, you can help us continue our
support of SWOG by creating
your lasting legacy.

Planned gifts cost nothing today but can directly advance clinical trials for tomorrow's improved treatments.

thehopefoundation.org/donate

THE HOPE
FOUNDATION
FOR CANCER RESEARCH

TAKE ACTION Series II:

Ensuring health equity in SWOG clinical trials among Asian Americans

October 13, 2021 | 12:30-2:30 pm CT



Join SWOG's Recruitment & Retention Committee, a panel of experts, and featured speaker Richard J. Lee, MD, PhD, of Harvard Medical School and

Massachusetts General Hospital Cancer Center.

Dr. Lee is lead author of "Disparities in Cancer Care and the Asian American Population,"

The Oncologist, June 2021.

TAKE ACTION Series Target Audience:

Investigators, research professionals, and patient advocates from both NCORP and LAPS sites

TAKE ACTION Series Target Objectives:

- 1 Identify evidenced-based practical strategies sites can use to ensure access and equity in SWOG clinical trials
- 2 Address cultural values of specific populations that support building trust
- 3 Reflect the current environment a specific population is being challenged with that impacts trial participation
- 4 Recommend a metric for tracking success

The first event in the TAKE ACTION series was held in April, 2021 – TAKE ACTION Series I: Ensuring health equity in SWOG clinical trials among African Americans.



Administrative Committees

Board of Governors

Charles D. Blanke, MD

Conflict Management

Paul Okunieff, MD

Publications

Hagen F. Kennecke, MD

Professional Review

Paul Hesketh, MD

Research Support Committees

Adolescent and Young Adult

Rebecca Johnson, MD

Bone Marrow and Stem Cell Transplantation

Patrick J. Stiff, MD

Digital Engagement

Don S. Dizon, MD

Imaging

Lawrence H. Schwartz, MD

Immunotherapeutics

Siwen Hu-Lieskovan, MD, PhD

Katerina Politi, PhD

Oncology Research Professionals

Connie Szczepanek,

RN, BSN, CCRP

Patient Advocates

Rick Bangs, MBA

Pharmaceutical Sciences

Siu-Fun Wong, PharmD

Radiation Oncology

Interim Chair

James B. Yu, MD, MHS

Recruitment and Retention

Allison Caban-Holt, PhD

Surgery

Syed A. Ahmad, MD

Veterans Affairs

Stephen D. Bartlett, RPh

Future Meeting Dates

2022

SPRING | April 6-9 | Seattle, WA

FALL | October 19-22 | Chicago, IL

2023

SPRING | April 26-29 | San Francisco, CA

FALL | October 11-14 | Chicago, IL

SWOG NCORP Research Base Clinical Trials Workshop

An informative session on clinical trials focused on the research areas of cancer care delivery, cancer survivorship, prevention and epidemiology, palliative and end of life care, and symptom control and quality of life.

These SWOG trials are open to accrual to all sites (with the exception of Cancer Care Delivery trials, which are limited to NCORP sites).

Join us for presentations on topics related to clinical trial data, trial recruitment, cancer disparities, and patient-reported outcomes research.

Tuesday, October 12 | 12:00 – 2:00 pm CST

*All SWOG members welcome and encouraged to attend
Receive up to two hours of Society of Clinical Research Associates (SoCRA) credits*

Procedures for CME Credit

Group Meeting Target Audience and Educational Objectives

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

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

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

Continuing Medical Education Credit

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

The Hope Foundation designates this live activity for a maximum of 24.75 AMA PRA Category 1 Credits.™ Physicians should only claim credit commensurate with the extent of their participation in the activity.

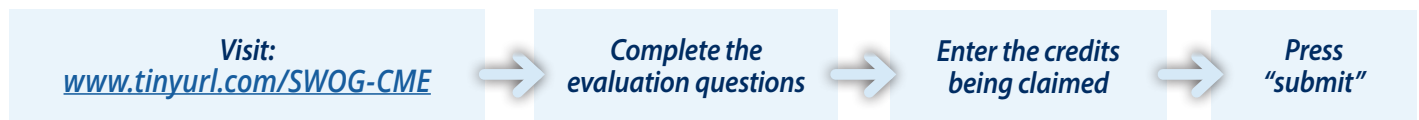
Speaker and Planner CME Disclosure Information

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.

**SWOG
gratefully
acknowledges
our CME
commercial
supporter**



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



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

Track Your CME Credits

Instructions:

1. In the column labeled actual credit, please write in the amount of credit you are claiming for each meeting.
2. Then total the amount of credit you are claiming in the actual credit column. Return to cwille@swog.org. Your certificate will be emailed to you.

Day/Time	Session Title	Credits	
		Available	Actual
TUESDAY, OCTOBER 12, 2021			
12:00 pm – 2:00 pm	Bone Marrow & Stem Cell Transplantation Committee	2.0	_____
12:30 pm – 2:30 pm	Digital Engagement Committee	2.0	_____
2:30 pm – 4:30 pm	Radiation Oncology Committee	2.0	_____
3:00 pm – 5:00 pm	Adolescent and Young Adult (AYA) Committee	2.0	_____
WEDNESDAY, OCTOBER 13, 2021			
10:00 am – 12:00 pm	Palliative and End of Life Care Committee	2.0	_____
10:00 am – 12:00 pm	Early Therapeutics and Rare Cancers Committee	2.0	_____
12:15 pm – 2:15 pm	Cancer Care Delivery Committee	2.0	_____
2:30 pm – 4:00 pm	Plenary I (Translational Medicine)	1.5	_____
THURSDAY, OCTOBER 14, 2021			
10:00 am – 12:00 pm	Barlogie-Salmon Myeloma Committee	2.0	_____
10:30 am – 12:30 pm	Symptom Control and Quality of Life Committee	2.0	_____
1:00 pm – 2:30 pm	Plenary II (General)	1.5	_____
2:45 pm – 5:45 pm	Lymphoma Committee	3.0	_____
3:00 pm – 5:00 pm	Surgery Committee	2.0	_____
3:00 pm – 5:00 pm	GU Committee Part I	2.0	_____
3:00 pm – 6:00 pm	Breast Committee	3.0	_____
3:30 pm – 5:30 pm	Melanoma Committee	2.0	_____
FRIDAY, OCTOBER 15, 2021			
9:30 am – 11:30 am	Cancer Survivorship Committee	2.0	_____
10:00 am – 12:00 pm	Immunotherapeutics Committee	2.0	_____
11:30 am – 1:30 pm	Prevention and Epidemiology Committee	2.0	_____
12:15 pm – 3:15 pm	Lung Committee	3.0	_____
12:30 pm – 2:30 pm	Leukemia Committee	2.0	_____
1:30 pm – 3:30 pm	GU Committee Part II	2.0	_____
2:00 pm – 4:00 pm	GI Committee	2.0	_____
Total Possible Credits		24.75	_____

Schedule of Events

TUESDAY, OCTOBER 12, 2021

9:00 A.M. – 12:00 P.M.	<i>Advocates Committee Meeting (Invitation Only)</i>
11:00 A.M. – 12:30 P.M.	<i>Hope Foundation Board Meeting (Invitation Only)</i>
11:00 A.M. – 1:00 P.M.	<i>Drug Information Subcommittee and Pharmaceutical Sciences Committee</i>
12:00 P.M. – 2:00 P.M.	<i>Bone Marrow & Stem Cell Transplantation Committee</i>
11:30 AM – 12:30 PM	<i>Clinical Trials Partnerships Update Forum (Open to all)</i>
12:00 P.M. - 2:00 P.M.	<i>SWOG NCORP Research Base Clinical Trials Workshop</i>
12:30 P.M. – 2:30 P.M.	<i>Digital Engagement Committee</i>
2:00 P.M. – 4:00 P.M.	<i>SWOG Tissue Banking Meeting (Invitation Only)</i>
2:15 P.M. – 3:15 P.M.	<i>NCORP/MU-NCORP Site PI Meeting</i>
2:30 P.M. – 4:30 P.M.	<i>Myeloma Working Group (Invitation Only)</i>
2:30 P.M. – 4:30 P.M.	<i>Radiation Oncology Committee</i>
3:00 P.M. – 5:00 P.M.	<i>Adolescent and Young Adult (AYA) Committee</i>
3:30 P.M. – 5:00 P.M.	<i>Site Operations</i>
4:15 P.M. – 6:15 P.M.	<i>NCORP Research Base Executive Committee Meeting (Invitation Only)</i>

WEDNESDAY, OCTOBER 13, 2021

10:00 A.M. – 12:00 P.M.	<i>Palliative and End of Life Care Committee</i>
10:00 A.M. – 12:00 P.M.	<i>Lung Working Group (Invitation Only)</i>
10:00 A.M. – 12:00 P.M.	<i>Early Therapeutics and Rare Cancers Committee</i>
10:00 A.M. – 1:00 P.M.	<i>Jeri & Noboru Oishi Symposium/Open Forum</i>
10:30 A.M. – 11:30 A.M.	<i>GI Translational Medicine Working Group (Invitation Only)</i>
10:30 A.M. – 12:30 P.M.	<i>Lymphoma Working Group (Invitation Only)</i>
11:00 A.M. – 12:15 P.M.	<i>S2013 Kick-Off / S1614 Reactivation Meeting</i>
11:00 A.M. – 1:00 P.M.	<i>Imaging Committee (Invitation Only)</i>

12:00 P.M. – 1:45 P.M.	<i>Nursing Research Subcommittee (Invitation Only)</i>
12:00 P.M. – 2:00 P.M.	<i>Melanoma Working Group (Invitation Only)</i>
12:15 P.M. – 2:15 P.M.	<i>Cancer Care Delivery Committee</i>
12:30 P.M. – 2:30 P.M.	<i>Recruitment and Retention Committee</i>
1:00 PM – 2:00 PM	<i>Clinical Trials Partnerships Scientific Advisory Board (Invitation Only)</i>
2:30 P.M. – 4:00 P.M.	<i>Plenary I (Translational Medicine)</i>
4:00 P.M. – 6:00 P.M.	<i>Breast Working Group (Invitation Only)</i>
4:00 P.M. – 6:00 P.M.	<i>Conflict Management Committee (Invitation Only)</i>
4:30 P.M. – 6:30 P.M.	<i>Coltman Fellowship Committee (Invitation Only)</i>

THURSDAY, OCTOBER 14, 2021

10:00 A.M. – 12:00 P.M.	<i>Barlogie-Salmon Myeloma Committee</i>
10:30 A.M. – 12:30 P.M.	<i>Breast Translational Medicine Working Group (Invitation Only)</i>
10:30 A.M. – 12:30 P.M.	<i>Symptom Control and Quality of Life Committee</i>
10:30 A.M. – 12:30 P.M.	<i>Lung-MAP Update Meeting</i>
11:00 A.M. - 12:30 P.M.	<i>Professional Review Committee (Invitation Only)</i>
11:30 A.M. – 1:00 P.M.	<i>Quality Assurance Committee (Invitation Only)</i>
12:00 P.M. – 1:00 P.M.	<i>Hope Foundation Office Hours</i>
1:00 P.M. – 2:30 P.M.	<i>Plenary II (General)</i>
2:30 P.M. – 3:00 P.M.	<i>Publications Committee (Invitation Only)</i>
2:30 P.M. – 5:00 P.M.	<i>Lung-MAP Executive Retreat (Invitation Only)</i>
2:45 P.M. – 5:45 P.M.	<i>Lymphoma Committee</i>
3:00 P.M. – 5:00 P.M.	<i>Surgery Committee</i>
3:00 P.M. – 5:00 P.M.	<i>GU Committee Part I (Renal, TM, Cancer Control)</i>
3:00 P.M. – 6:00 P.M.	<i>Breast Committee</i>
3:30 P.M. – 5:30 P.M.	<i>Melanoma Committee</i>

Schedule of Events

FRIDAY, OCTOBER 15, 2021

<u>9:30 A.M. – 11:30 A.M.</u>	Cancer Survivorship Committee
<u>9:30 A.M. – 11:30 A.M.</u>	SWOG Data and Safety Monitoring Committee (Invitation Only)
<u>10:00 A.M. – 12:00 P.M.</u>	CNS Working Group
<u>10:00 A.M. – 12:00 P.M.</u>	Immunotherapeutics Committee
<u>10:00 A.M. – 1:00 P.M.</u>	GI Working Group (Invitation Only)
<u>11:30 A.M. – 1:30 P.M.</u>	Prevention and Epidemiology Committee
<u>12:15 P.M. – 2:15 P.M.</u>	VA Committee

<u>12:15 P.M. – 3:15 P.M.</u>	Lung Committee
<u>12:30 P.M. – 2:30 P.M.</u>	Leukemia Committee
<u>1:30 P.M. – 3:30 P.M.</u>	GU Committee Part II (Bladder, Prostate)
<u>2:00 P.M. – 4:00 P.M.</u>	GI Committee
<u>3:15 P.M. – 4:45 P.M.</u>	SWOG Latin America Initiative Symposium

SATURDAY, OCTOBER 16, 2021

<u>10:00 A.M. – 10:45 A.M.</u>	Board of Governors (Invitation Only)
<u>11:00 A.M. – 12:00 P.M.</u>	Committee Chairs (Invitation Only)

Looking to take the SOCRA CCRP certification exam?

You can now do so online, from the comfort of your own home.

Because this option is now available, SWOG's ORP Committee will not offer a CCRP exam sitting at the fall group meeting.

Home Proctoring is SOCRA's remote exam proctoring service. It offers a secure and easy way to complete your CCRP certification exam from anywhere.

Visit the At Home CCRP Testing page on the SOCRA website at tinyurl.com/CCRP-exam to learn more and to apply to take the exam.





Thanks To

Our Top Accruers

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

Over the past year, from July 1, 2020, to June 30, 2021, these members topped the charts for SWOG-credited registrations to SWOG managed trials.

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

Main Member / LAPS

University of Texas MD Anderson
Cancer Center

USC Norris Comprehensive
Cancer Center

University of Rochester

Instituto Nacional de Cancerología
de Mexico (INCan)

University of Utah Huntsman
Cancer Institute

NCORP

Southeast Clinical Oncology
Research Consortium NCORP

Kaiser Permanente NCORP

Heartland Cancer Research NCORP

Cancer Research Consortium
of West Michigan NCORP

Gulf South Minority
Underserved NCORP



A program of the National Cancer Institute
of the National Institutes of Health



a National Cancer Institute program

Barlogie-Salmon Myeloma Committee

Committee Leadership

Chair: Robert Z. Orlowski, MD, PhD
Vice-Chair: Brian G.M. Durie, MD
Vice-Chair: Saad Z. Usmani, MD, MBA
Executive Officer: Susan M. O'Brien, MD
Statisticians: Antje Hoering, PhD
..... Rachael Sexton, MS

Scientific Leadership

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

Designates

Digital Engagement: Saad Z. Usmani, MD, MBA
NCORP Representative: Charles S. Kuzma, MD
Veterans Affairs: Thomas R. Chauncey, MD, PhD
Data Coordinators: Sean O'Bryan
..... Hannah Hale
Oncology Research Professionals:
CRA: TBD
Nurses: Deborah A. Shaw, RN
..... Teresa Witcher, BSN, RN
Patient Advocate: Jack Aiello, MS
Pharmaceutical Science: Craig Elg, PharmD
..... Ila M. Saunders, PharmD
Protocol Coordinator: TBD
Clinical Trials Project Manager: TBD

Macroglobulinemia (WM)." Drs. S. Ailawadhi and D. Bhutani. Activated: 6/24/21. Temporarily Closed: 7/16/21.

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: 10/12/12. Closed: 5/15/18.

S1702, "A Phase II Study of Isatuximab (SAR650984) (NSC-795145) for Patients with Previously Treated AL Amyloidosis." Drs. T. Parker and V. Sanchorawala. Activated: 3/08/18; Closed: 9/30/19.

Proposed Studies

"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, C. Ye, and A. Gowin.

"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." Dr. P. Hagen

"Phase II/III Study of Optimal Induction Maintenance Therapy for Newly Diagnosed High-Risk Multiple Myeloma (HRMM)." Dr. B. Lipe.

Agenda

Thursday, October 14, 2021
10:00 am - 12:00 pm CT

Active Studies

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

S2005, "A Phase II Randomized Study of Ibrutinib and Rituximab with or Without Venetoclax in Previously Untreated Waldenström's

Barlogie-Salmon Myeloma Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1803	A061202	EAA173	EAA181
Arizona CC, Univ of	4	-	-	-
Boston Medical Ctr	4	-	-	-
CORA NCORP	2	-	-	-
CROWN NCORP	2	-	-	-
Cedars-Sinai Med Ctr	4	-	-	-
City of Hope CCC	49	-	-	-
Cleveland Clinic OH	6	-	1	-
Columbus NCORP	7	-	-	-
Davis, U of CA	12	-	-	-
Dayton NCORP	2	-	-	-
Duke Univ Med Ctr	1	-	-	-
Fred Hutchinson CRC	-	-	3	-
Georgia NCORP	8	-	-	-
H Lee Moffitt CC	20	-	-	-
Heartland NCORP	10	-	-	-
Henry Ford Hospital	-	1	-	-
Irvine, U of CA	1	-	-	-
Kaiser Perm NCORP	24	-	-	-
Kansas MU-NCORP	12	-	-	-
Lahey Hosp & Med Ctr	3	-	-	-
Loyola University	8	-	2	-
MD Anderson CC	12	-	-	-
MUSC MU-NCORP	5	-	1	-
Michigan, U of	4	-	-	-
Montana NCORP	3	-	-	-
New Mexico MU-NCORP	6	-	-	-
Ohio State Univ	4	-	-	-
Oklahoma, Univ of	1	-	-	-
Oregon Hlth Sci Univ	6	-	2	1
PCRC NCORP	3	-	-	-
Providence Hosp	-	1	-	-
Rochester, Univ of	10	-	-	-
San Antonio, U of TX	9	-	-	-
Southeast COR NCORP	1	-	-	-
Upstate NCORP	3	-	-	-
Utah, U of	9	-	2	-
Wayne State Univ	8	-	-	-
Wisconsin NCORP	10	-	-	-
Yale University	-	-	2	-
ALLIANCE	89	-	-	-
ECOG-ACRIN	62	-	-	-
NRG	42	-	-	-
Total	466	2	13	1

Breast Committee

Committee Leadership

Chair: Lajos Pusztai, MD, DPhil
Vice-Chair:Priyanka Sharma, MD
Executive Officer:Anne Chiang, MD
Statisticians:William E. Barlow, PhD
..... Danika Lew, MA
..... Jieling Miao, MS

Scientific Leadership

Translational Medicine: Alastair M. Thompson, MD
..... Andrew K. Godwin, PhD
Radiation Oncology: Reshma Jagsi, MD
Surgery: Anees B. Chagpar, MD
Imaging: Joanne E. Mortimer, MD
..... Wei Tse Yang, MBBS
Pathology: David L. Rimm, MD, PhD
Early Therapeutics: TBD

Designates

Cancer Control Liaisons: Melinda L. Irwin, PhD, MPH (Survivorship)
..... Dawn L. Hershman, MD (Cancer Care Delivery)
..... Banu Arun, MD (Prevention)
..... Helen K. Chew, MD (Symptom Control & QOL)
Digital Engagement: Sarah S. Mougalian, MD
NCORP Representative: Philip E. Lammers, MD
Data Coordinators: Iris Syquia
..... Larry Kaye
..... Ojasvi Mittal
..... Gabi Herbert
Oncology Research Professionals:
CRAs: Karyn N. Hart, CCRP
..... Avidanka Baftirovska, BS, CCRP
Nurse: TBD
Patient Advocates: Ginny Mason, RN, BSN
..... Elda Railey
Pharmaceutical Science: Jorge G. Avila, PharmD
Protocol Coordinator: Alicia Aranda
Clinical Trials Project Manager: Gretchen Goetz, MBA

Agenda

Thursday, October 14, 2021
3:00 pm - 6:00 pm CT

3:00 – 3:05 pm Welcome and Introductions - Lajos Pusztai, M.D., D.Phil. and Priyanka Sharma, M.D.

Breast Committee Mini-Symposium - Current status and future directions for Immunotherapy in breast cancer (3:05 - 4:15 pm)

3:05 – 3:25 pm Current state of art for Immunotherapy in breast cancer- Elizabeth Mittendorf MD PhD, Professor of Surgery, Harvard Medical School, Rob and Karen Hale Distinguished Chair in Surgical Oncology, Brigham and Women’s Hospital.

3:25 – 3:45 pm PD1 testing, TILs and Immunotherapy - David Rimm MD, PhD Professor of Pathology and Medicine, Director of Pathology Tissue Services, Yale School of Medicine

3:45 – 4:00 pm New era of immunotherapy trials: NCTN Initiatives - Priyanka Sharma MD, Professor of Medicine, University of Kansas Medical Center

4:00 – 4:15 pm Panel discussion, Q/A

4:15 – 4:25 pm Publication update – William Barlow, Ph.D.

4:25 – 4:35 pm Patient Advocate update – Ginny Mason and Elda Railey

4:35 – 4:40 pm Translational Medicine Sub-Committee update – Alastair Thompson, M.D. and Andrew K. Godwin, Ph.D.

4:40 – 5:20 pm Review of open CTSU trials

5:20 – 5:30 pm Reports from Committee Liaisons

Radiotherapy - Reshma Jagsi, M.D.

Surgery - Anees B. Chagpar, M.D.

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

Cancer Care Delivery - Dawn Hershman, M.D.

Prevention – Banu Arun, M.D.

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

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

5:30 – 5:55 pm Developing Concepts

5:55 pm Closing Comments and Adjourn

Breast Committee

Proposed Studies

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

S2206, "Randomized Trial of Neoadjuvant Durvalumab plus Chemotherapy versus Chemotherapy alone for MammaPrint Ultrahigh (MP2) Hormone Receptor (HR) Positive/Human Epidermal Growth Factor Receptor (HER2) Negative Stage II-III Breast Cancer." Drs. Cobain, Puztai, Ellis.

Active Studies

S2007, "A Phase II Trial of Sacituzumab Govitecan (IMMU-132) (NSC #820016) for Patients with HER2-Negative Breast Cancer and Brain Metastases." Drs. Brenner and Kaklamani. Activated: 12/15/20.

S1706, "A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy Alone for Inflammatory Breast Cancer." Drs. Jagsi, Chalasani, Moran, Speers. Activated: 09/12/18.

CTSU/A011202, "A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy." Dr. Boughey. SWOG Champion: Dr. Mammen. Activated: 02/07/14.

CTSU/A011801, "The COMPASSHER2 Trials (COMprehensive Use of Pathologic Response ASSESSment to Optimize Therapy in HER2-Positive Breast Cancer): COMPASSHER2 Residual Disease (RD), A Double-Blinded, Phase III Randomized Trial of T-DM1 and Placebo Compared with T-DM1 and Tucatinib." Dr. O'Sullivan. SWOG Champion: Dr. Murthy. Activated: 01/06/21.

CTSU/CCTG MA.39, "Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive and T3N0 Breast Cancer." Dr. Whelan. SWOG Champion: Dr. Jagsi. Activated: 05/30/18.

CTSU/EA1181, "(CompassHER2-pCR): Preoperative THP and Postoperative HP in Patients Who Achieve a Pathologic Complete Response Part 1 Component of: The CompassHER2 Trials (COMprehensive Use of Pathologic Response ASSESSment to Optimize Therapy in HER2-Positive Breast Cancer)" Dr. Tung. SWOG Champions: Breast Committee: Dr. Tang, Imaging Committee: Dr. Lu. Activated: 02/11/20.

CTSU/EA1183, "FDG PET to Assess Therapeutic Response in Patients with Bone-Dominant Metastatic Breast Cancer, FEATURE." Dr. Specht. SWOG Champions: Breast Committee: Dr. Linden, Imaging Committee: Dr.

Wright. Activated: 04/02/20.

CTSU/NRG-BR002, "A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer." Drs. Chmura and White. SWOG Champion: Dr. Jagsi. Activated: 12/24/14. Temporarily closed: 09/13/19.

CTSU/NRG-BR003, "A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer." Dr. Valero. SWOG Champion: Dr. Makhoul. Activated: 06/26/15.

CTSU/NRG-BR004, "A Randomized, Double-Blind, Phase III Trial of Taxane/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer." Dr. Geyer. SWOG Champion: Dr. Cobain. Activated: 03/12/19.

CTSU/NRG-BR005, "A Phase II Trial Assessing the Accuracy of Tumor Bed Biopsies in Predicting Pathologic Response in Patients with Clinical/Radiologic Complete Response after Neoadjuvant Chemotherapy in Order to Explore the Feasibility of Breast Conserving Treatment without Surgery." Dr. Basik. SWOG Champion: Dr. Thompson. Activated: 04/13/17. Temporarily closed: 07/02/19.

CTSU/NRG-BR007, "A Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER2-Negative, Oncotype Recurrence Score." Dr. White. SWOG Champion: Dr. Shumway. Activated: 06/07/21.

Closed Studies

S1418, "A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with ≥ 1 CM Residual Invasive Cancer or Positive Lymph Nodes (ypN1mi, ypN1-3) after Neoadjuvant Chemotherapy." Drs. Puztai, Mammen, Henry, Jagsi. Activated: 11/15/16. Permanently closed: 06/30/21.

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. e³ Breast Cancer Study-Evaluating Everolimus with Endocrine Therapy." Drs. Chavez-MacGregor and Puztai. Activated: 09/04/13. Permanently closed: 05/01/19.

Active Cancer Survivorship Study

S1501, "Prospective Evaluation of Carvedilol in Prevention of Cardiac Toxicity in Patients with Metastatic HER-2+ Breast Cancer, Phase III." Drs.

Breast Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1418	S1706	S2007	A011202	A011401	A011502	A011801	B51	EAT131	EAT181	EAT183	MA39	NRGBR003	NRGBR004
Arizona CC, Univ of	4	1	-	1	8	-	-	-	-	-	-	-	-	-
Arkansas, U of	17	1	-	-	3	22	-	-	-	-	-	-	-	-
Banner MD Anderson	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Baptist MU-NCORP	9	3	-	1	7	-	-	-	-	-	-	-	1	-
Bay Area NCORP	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Boston Medical Ctr	-	-	-	-	3	-	-	-	-	-	-	-	-	-
CORA NCORP	18	1	-	-	-	-	-	2	-	-	-	-	-	-
CRC West MI NCORP	24	-	-	-	1	-	-	-	-	-	-	-	-	-
CROWN NCORP	6	-	-	-	-	-	-	-	-	-	-	-	-	-
Carle CC NCORP	3	-	1	-	-	-	-	-	-	-	-	-	-	-
Cincinnati MC, U of	-	-	-	-	-	-	-	1	-	-	-	-	-	-
City of Hope CCC	9	-	-	-	-	-	-	-	-	-	-	-	-	-
Cleveland Clinic OH	12	-	-	-	2	-	-	5	-	-	-	1	9	1
Colorado, U of	11	1	-	38	27	7	-	3	-	3	-	-	-	-
Columbia MU-NCORP	8	-	-	-	-	-	-	-	-	-	-	-	-	-
Columbus NCORP	10	-	-	-	-	-	-	-	-	-	-	-	-	-
Cotton O'Neil CC	-	-	-	1	1	-	-	-	-	-	-	-	1	-
Davis, U of CA	7	4	-	2	4	17	-	-	-	-	-	-	-	-
Dayton NCORP	3	-	-	-	1	-	-	-	1	1	-	-	-	-
Desert Hospital	1	-	-	7	4	-	-	4	-	-	-	-	-	-
Essentia Hlth NCORP	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson CRC	10	2	-	-	12	9	-	-	-	-	-	-	-	-
Georgia NCORP	23	2	-	-	2	1	-	-	4	-	-	-	1	-
Greenville NCORP	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Gulf South MU-NCORP	4	1	-	-	-	-	-	-	-	2	-	-	3	-
H Lee Moffitt CC	-	-	-	1	3	2	-	-	-	-	-	-	-	-
Harrington CC	7	3	-	10	8	-	1	1	-	-	-	-	-	-
Hawaii MU-NCORP	5	-	-	-	-	-	-	-	-	-	-	-	-	-
Heartland NCORP	19	2	-	-	-	1	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	-	-	-	-	-	1	-	-	-	-	-
Houston Methodist	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Irvine, U of CA	6	-	-	3	2	2	-	1	-	-	-	-	1	-
Kaiser Perm NCORP	50	-	-	1	55	25	-	-	-	-	-	-	24	1
Kansas City NCORP	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Kansas MU-NCORP	19	2	-	4	24	9	-	-	-	-	-	-	-	-
Kentucky, U of	-	-	-	-	-	3	-	1	-	-	-	-	-	-
Lahey Hosp & Med Ctr	3	-	-	-	9	5	-	-	1	3	-	-	-	1
Loma Linda Univ	1	-	-	3	-	-	-	3	-	-	-	-	-	-
Loyola University	3	-	-	-	6	7	-	1	2	1	-	-	-	-
MAVERIC	-	-	-	-	-	1	-	-	-	-	-	-	-	-
MD Anderson CC	19	1	-	-	-	-	-	-	-	-	-	-	-	-
MUSC MU-NCORP	11	-	-	-	-	-	-	-	-	-	3	-	-	-

Breast Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1418	S1706	S2007	A011202	A011401	A011502	A011801	B51	EAT131	EAT181	EAT183	MA39	NRGBR003	NRGBR004
Michigan CRC NCORP	18	1	-	-	-	-	-	-	-	-	-	-	-	-
Michigan, U of	13	2	-	-	14	11	-	-	-	1	-	3	3	-
Mississippi, Univ of	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Montana NCORP	1	3	-	-	-	-	-	-	-	-	-	-	-	-
Mount Sinai Hospital	3	-	-	-	-	-	-	-	-	-	-	-	-	-
NYU Winthrop Hosp	3	-	-	-	2	3	-	-	-	-	-	-	1	-
Nevada CRF NCORP	11	-	-	-	-	-	-	-	-	-	-	-	-	-
New Mexico MU-NCORP	19	4	-	-	-	-	-	-	-	-	-	-	-	-
Northwest NCORP	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Northwestern Univ	2	1	-	-	-	-	-	-	-	-	-	-	1	-
Ohio State Univ	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Oklahoma, Univ of	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Oregon Hlth Sci Univ	19	-	-	-	-	-	-	1	-	-	2	-	3	-
Ozarks NCORP	8	1	-	-	-	-	1	-	-	-	-	-	3	-
PCRC NCORP	18	-	-	-	3	1	-	-	-	-	-	-	1	-
Providence Hosp	5	2	-	4	10	8	-	8	1	1	-	1	3	1
Rochester, Univ of	2	1	-	-	-	15	-	-	7	1	-	-	9	-
Salem Hospital	-	-	-	4	-	-	-	-	-	-	-	-	-	-
San Antonio, U of TX	5	-	-	4	2	1	-	5	-	-	-	-	4	-
Scott & White Mem	-	-	-	1	4	-	-	2	-	-	-	-	-	-
So Calif, U of	3	-	-	4	-	6	-	-	-	-	-	1	-	-
Southeast COR NCORP	49	-	-	-	1	6	-	-	-	-	-	-	-	-
Sutter Cancer RC	2	-	-	-	8	2	-	2	1	3	-	-	4	1
Tennessee, U of	-	-	-	6	-	-	-	4	-	-	-	-	-	-
UCSD Moores CC	-	-	-	-	2	3	-	-	-	-	-	-	1	-
UF Cancer Center	1	-	-	-	1	-	-	-	-	-	-	-	-	-
Univ of Louisville	-	-	-	2	-	-	-	-	-	-	-	-	-	-
Upstate NCORP	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Utah, U of	5	2	-	-	7	-	1	-	-	1	-	-	-	-
Virginia Mason MC	1	-	-	-	-	-	-	1	-	-	-	-	-	-
Wayne State Univ	2	-	-	11	12	9	-	-	6	4	2	-	6	-
West Clinic	-	-	-	3	-	-	-	-	-	-	-	-	-	-
Western States NCORP	3	-	-	-	1	-	-	-	-	-	-	-	-	-
Wichita NCORP	11	-	-	-	-	-	-	-	-	-	-	-	-	-
William Beaumont	1	-	-	6	5	2	-	1	-	-	-	-	-	-
Wisconsin NCORP	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Yale University	5	-	-	-	79	28	-	-	6	-	-	-	8	-
ALLIANCE	139	10	-	-	-	-	-	-	-	-	-	-	-	-
CCTG	35	2	-	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	126	5	-	-	-	-	-	-	-	-	-	-	-	-
NRG	301	24	-	-	-	-	-	-	-	-	-	-	-	-
Total	1,153	83	1	117	333	206	3	47	30	22	7	6	87	5

Tweeting the Meeting

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use the hashtag
#SWOGonc



Breast Committee

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

Active Symptom Control and Quality of Life Studies

S1614, "A Phase III Randomized Trial of Prophylactic Antiviral Therapy in Patients with Current or Past Hepatitis B Virus (HBV) Infection Receiving Anti-Cancer Therapy for Solid Tumors." Drs. Hwang, Lok, Gehring, Feld. Activated: 02/21/19.

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

Active Cancer Care Delivery Studies

S1703, "Randomized Non-Inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (STMDDM) versus Usual Care in Patients with Metastatic Hormone Receptor Positive HER-2 Negative Breast Cancer." Drs. Accordino, Hershman, Ramsey. Activated: 07/16/18.

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

Active Cancer Prevention Study

S1904, "Cluster Randomized Controlled Trial of Patient and Provider Decision Support to Increase Chemoprevention Informed Choice among Women with Atypical Hyperplasia or Lobular Carcinoma In Situ – Making Informed Choices on Incorporating Chemoprevention into Care (MiCHOICE)." Drs. Crew, Kukafka, Hershman, Thomas, Caban-Holt. Activated: 09/01/20.

Active Early Therapeutics and Rare Cancers Studies

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

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

Cancer Control & Prevention Committee

Committee Leadership

Vice-Chair NCORP: Dawn L. Hershman, MD, MS
 Cancer Care Delivery Cmte Co-Chairs: Dawn L. Hershman, MD, MS
 Scott D. Ramsey, MD, PhD
 Cancer Survivorship Cmte Co-Chairs: Halle C.F. Moore, MD
 Melinda L. Irwin, PhD, MPH
 Palliative & End of Life Cmte Co-Chairs: Robert S. Krouse, MD, FACS
 Mark A. O'Rourke, MD
 Marie Bakitas, DNSc, CRNP
 Prevention and Epidemiology Cmte Co-Chairs: Banu Arun, MD
 Marian L. Neuhouser, PhD, RD
 Recruitment and Retention Cmte: Allison M. Caban-Holt, PhD
 Symptom Control & QOL Cmte Co-Chairs: Michael J. Fisch, MD, MPH
 Norah Lynn Henry, MD, PhD
 Executive Officers: Katherine D. Crew, MD (Palliative, Prevention,
 Survivorship)
 Gary H. Lyman, MD (CCD, Symptom Control & QOL)
 Senior Advisor: Frank L. Meyskens, Jr., MD
 Statisticians: Garnet Anderson, PhD
 William E. Barlow, PhD
 Katherine Guthrie, PhD
 Cathy Tangen, DrPH
 Joseph M. Unger, PhD
 Riha Vaidya, PhD
 Kathryn B. Arnold, MS
 Amy K. Darke, MS
 Phyllis J. Goodman, MS
 Danika Lew, MA
 Hongli Li, MS
 Anna Moseley, MS
 Eddie Mayerson, MS

Administrative Lead

Statistics & Data Management Center (SDMC): Monica Yee, CCRP

Scientific Leadership

NCORP Representative: Mark A. O'Rourke, MD
 Radiation Oncology Committee: Louis "Sandy" Constine, MD
 Surgery Committee: Robert S. Krouse, MD, FACS
 Translational Medicine: James (Jimmy) Rae, PhD
 Liaisons:
 Barlogie-Salmon Myeloma Committee: Charles S. Kuzma, MD
 Breast Committee: Melinda L. Irwin, PhD, MPH (Survivorship)
 Helen K. Chew, MD (Symptom Control & QOL)
 Dawn Hershman, MD, MS (CCD)
 Banu Arun, MD (Prevention)
 Philip Lammers, MD

Early Therapeutics & Rare Cancers: Jason M. Prosek, MD
 Gastrointestinal Committee: Jason A. Zell, DO (Prevention)
 Afsaneh Barzi, MD (CCD)
 Genitourinary Committee: Peter J. Van Veldhuizen, Jr., MD
 International Liaison: Kathy S. Albain, MD
 Leukemia Committee: Stephanie B. Tsai, MD
 Lung Committee: Gary E. Goodman, MD
 Lymphoma Committee: Hayder Saeed, MD
 Melanoma Committee: Sancy Leachman, MD, PhD
 Thach-Giao Truong, MD (Survivorship)
 Digital Engagement: Jennifer R. Klemp, PhD (Survivorship)
 Krishna Soujanya Gunturu, MD (Survivorship)
 Mina S. Sedrak, MD (CCD)
 Katherine D. Crew, MD (Prevention)
 Michael J. Fisch, MD (Symptom Control & QOL)
 Veterans Affairs: Yeun-Hee Anna Park, MD

Designates

Oncology Research Professionals

Clinical Research Associates: Amanda R. Dinsdale, MHA, CCRC
 Samantha Wright, MS, CCRP
 Nurses: Connie Szczepanek, RN, BSN
 Melyssa W. Foust, MSN, RN
 Pharmaceutical Sciences Committee: Kimberly McConnell, PharmD
 Siu-Fun Wong, PharmD
 Sun "Coco" Yang, PharmD, PhD
 SDMC Data Coordinators and Staff: Kimberly Carvalho
 Sam Dzingle
 Diane Liggett, CCRP
 Roxanne Topacio, CCRP
 Monica Yee, CCRP
 Recruitment and Retention Specialist: Jennifer Maeser, MS
 Patient Advocates: Barbara Segarra-Vazquez, DHS (CCD)
 Amy Geschwender, PhD (Symptom Control & QOL)
 Hartley "Lee" M. Jones, MBA (Survivorship)
 Cheryl L. Jernigan, CPA (Prevention & Epidemiology)
 Valerie Fraser (Palliative & End of Life Care)
 Desiree Walker, BA (Recruitment & Retention)
 Protocol Coordinator (Cancer Care Delivery;
 Prevention and Epidemiology): Patricia O'Kane
 Protocol Coordinator (Cancer Survivorship): Taj Pereira
 Protocol Coordinator (Symptom Control and QOL): Mariah Norman
 Protocol Coordinator (Palliative Care): Christy Klepetko
 Clinical Trials Project Manager (Palliative Care): Gretchen Goetz, MBA
 Clinical Trials Project Manager (CCD; Prevention; Survivorship): TBD
 Clinical Trials Project Manager (Symptom Control): Crystal Miwa

Cancer Care Delivery (CCD) Committee

Committee Leadership

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

Agenda

Wednesday, October 13, 2021
12:15 pm - 2:15 pm CT

Presentations

Ruth Carlos - Addressing Social Determinants of Health to Improve Cancer Care Delivery and Outcomes Among Newly Diagnosed Cancer Patients in Community Settings: A Master Study Protocol

Alyce Sophia Adams - Advancing Equity in Cancer Treatment Outcomes: Policy & Health System Approaches

Dan Hertz - Drug-Drug Interaction (DDI) Screening for Oncology Clinical Trial Enrollment

Protocol in Development

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

Active Studies

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

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

Developing Studies

S2203CD, "Examining Clinical Work Intensity Among Medical Oncologists." Matt Hudson, PhD, MPH, Prisma Health

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

Patient-centered Video Education Intervention to Improve Rural Cancer Care Delivery – Randall Holcombe, MD, MBA, Izumi Okado, PhD, University of Hawaii

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

Dr. Grant Taylor,
first SWOG
group chair



Our History

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



Cancer Care Delivery Committee

Studies with CCD/CCP Components

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

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

Closed Studies

S1415CD, "A Pragmatic Trial To Evaluate a Guideline-Based Colony Stimulating Factor Standing Order Intervention and to Determine the Effectiveness of Colony Stimulating Factor Use as Prophylaxis for Patients Receiving Chemotherapy with Intermediate Risk for Febrile Neutropenia - Trial Assessing CSF Prescribing, Effectiveness and Risk (TrACER)." Drs. S. Ramsey, D. Hershman, G. Lyman, et al. Activated: 10/7/16. Closed: 4/15/20.

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

Substudies (Economic Analyses / Cost Effectiveness from NCTN trials)

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

Database/Grant Funded Projects

Ongoing

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

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

Association of BMI Categories and Healthcare Utilization and Costs Among Patients with the Four Most Common Cancers. Mariana Chavez-MacGregor, M.D.

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

Association of BMI Categories and Healthcare Utilization and Costs Among Patients with the Four Most Common Cancers. Mariana Chavez-MacGregor, M.D.



Where We Are

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

Cancer Care Delivery (CCD) Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1415CD	S1703	S1916	A191901	A231601C	A231602C	A231701C	ACC116N1	EA1151	EAQ162CD	EAQ171CD	NHLBIMDS	NRGCC007
Arizona CC, Univ of	-	1	-	-	-	-	-	-	52	-	-	-	-
Arkansas, U of	-	3	-	-	-	-	-	-	270	-	-	-	-
Baptist MU-NCORP	149	-	-	-	-	-	-	-	-	-	-	-	-
Bay Area NCORP	36	-	-	-	-	-	-	-	-	-	-	-	-
CORA NCORP	60	7	-	-	-	-	-	-	-	-	-	-	-
CRC West MI NCORP	60	-	-	-	-	-	-	3	-	-	-	-	-
CROWN NCORP	-	3	-	-	-	-	-	-	-	-	-	-	-
Carle CC NCORP	60	5	1	-	-	-	-	-	-	-	-	-	-
Cleveland Clinic OH	-	11	-	-	-	-	-	-	27	-	-	5	-
Colorado, U of	-	-	-	-	-	-	-	-	2	-	-	4	-
Columbia MU-NCORP	118	10	-	-	-	-	-	-	-	-	-	7	-
Columbus NCORP	26	3	-	-	-	-	-	-	-	-	-	-	-
Cotton O'Neil CC	-	1	-	-	-	-	-	-	-	-	-	-	-
Dayton NCORP	32	3	-	-	-	-	-	-	-	2	-	-	-
Essentia Hlth NCORP	96	-	-	-	-	-	-	-	2	-	-	-	-
Fred Hutchinson CRC	-	-	-	-	-	-	-	-	-	-	-	13	-
GACARES MU-NCORP	56	-	-	-	-	-	-	-	-	-	-	-	-
Georgia NCORP	64	1	-	-	-	-	-	17	-	-	-	-	-
Greenville NCORP	61	6	-	-	-	-	-	-	233	-	-	2	-
Gulf South MU-NCORP	102	5	-	-	1	-	-	-	-	4	-	-	-
H Lee Moffitt CC	-	-	-	-	-	-	-	-	-	-	-	8	-
Hawaii MU-NCORP	73	3	-	-	-	-	-	-	-	10	-	5	-
Heartland NCORP	328	7	1	-	-	-	-	-	-	-	-	-	1
Henry Ford Hospital	-	-	-	-	-	-	-	-	129	-	-	-	-
Irvine, U of CA	-	-	-	-	-	-	-	-	-	-	-	12	-
Kaiser Perm NCORP	-	2	-	-	-	-	-	34	-	11	-	5	-
Kansas City NCORP	6	-	-	-	-	-	-	-	-	-	-	2	-
Kansas MU-NCORP	-	3	-	-	-	4	-	-	-	-	-	-	14

SWOG CLINICAL TRIALS PARTNERSHIPS

Check out the new **SWOG CTP** website!

[swogctp.org](https://www.swogctp.org)

Learn more at the **SWOG CTP Update Forum**

Tuesday, October 12, 11:30 am - 12:30 pm CT

Cancer Care Delivery (CCD) Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1415CD	S1703	S1916	A191901	A231601C	A231602C	A231701C	ACC116N1	EAT151	EAQ162CD	EAQ171CD	NHLBMDS	NRGCC007
Kentucky, U of	-	-	-	-	-	-	-	-	3	-	-	-	-
Lahey Hosp & Med Ctr	-	4	-	-	-	-	-	-	-	-	-	-	-
Loyola University	-	2	-	2	-	-	-	-	-	-	-	-	-
MAVERIC	-	-	-	-	-	-	-	-	-	-	-	24	-
MUSC MU-NCORP	-	-	-	-	-	-	1	-	3	-	-	2	-
Memorial Hermann	-	-	-	-	-	-	-	-	8	-	-	-	-
Michigan CRC NCORP	276	5	-	-	-	-	-	-	-	-	-	-	-
Montana NCORP	126	7	-	-	-	-	-	-	-	-	-	-	-
Nevada CRF NCORP	-	1	-	-	-	-	-	-	-	1	-	-	-
New Mexico MU-NCORP	250	5	-	-	-	-	-	-	-	-	-	-	-
Northwest NCORP	104	-	-	-	-	-	-	-	-	-	-	-	-
Oregon Hlth Sci Univ	-	-	-	-	-	-	-	-	-	-	-	4	-
Ozarks NCORP	114	-	-	-	-	-	-	-	-	-	-	-	-
PCRC NCORP	186	7	-	-	-	-	-	-	-	4	-	-	-
Providence Hosp	-	-	-	-	-	-	-	-	-	-	-	1	-
Rochester, Univ of	-	4	-	-	-	-	-	-	208	-	-	-	-
Southeast COR NCORP	120	4	-	-	-	-	-	-	389	11	-	-	-
UCSD Moores CC	-	-	-	-	-	-	-	-	-	-	-	13	-
Upstate NCORP	-	-	-	-	-	-	-	-	230	1	-	-	-
VAMC Kansas City	-	-	-	-	-	-	-	-	-	-	-	4	-
Western States NCORP	-	-	-	-	-	-	-	-	49	-	1	-	-
Wichita NCORP	60	-	-	-	-	-	-	-	-	-	-	-	-
William Beaumont	7	-	-	-	-	-	-	-	-	-	-	2	-
Wisconsin NCORP	163	1	-	-	-	-	-	-	-	-	-	-	-
Yale University	-	20	-	-	-	-	-	-	-	-	-	7	-
ALLIANCE	360	4	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	394	15	-	-	-	-	-	-	-	-	-	-	-
NRG	178	10	-	-	-	-	-	-	-	-	-	-	-
Total	3,665	163	2	2	1	4	1	54	1,605	44	1	120	15

Cancer Survivorship Committee

Committee Leadership

Co-Chairs: Melinda Irwin, PhD, MPH
 Halle Moore, MD
 Statistician: Katherine Guthrie, PhD
 Executive Officer: Katherine Crew, MD, MS
 Patient Advocate: Lee Jones

Agenda

Friday, October 15, 2021
 9:30 am - 11:30 am CT

Welcome and Introduction: Melinda Irwin and Halle Moore

Survivorship Presentation: Changing the Standard of Care for

Insomnia in Cancer Survivors:

Eric Zhou, Ph.D. Assistant Professor of Pediatrics at Harvard Medical School, Attending Psychologist at Boston Children's Hospital and Dana-Farber Cancer Institute

Discussion of Survivorship concepts related to sleep

Patient Advocate Update: Lee Jones

Studies/Concepts:

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

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

S2013, "I-CHECKIT: Immune CHECKpoint Inhibitory Toxicity analysis." Krishna Gunturu

Concept approved (Also in QOL and Symptom Control Committee)

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

Obesity, metabolomics, microbiome and cancer outcomes: Leah Ferrucci: Coltman application to be resubmitted Sept 2021

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

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

Liaison Updates

Cardiac Advisory Panel Update

Request for Concepts:

Diversity, equity and inclusion (including how to improve minority accrual to clinical trials)

Sleep interventions and effect on other outcomes such as cognitive function or cardiovascular outcomes

Cancer Survivorship Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1501	E1Q11	EA9131
Baptist MU-NCORP	5	-	1
Bay Area NCORP	2	-	-
CORA NCORP	1	-	-
City of Hope CCC	41	-	-
Cleveland Clinic OH	14	-	-
Columbia MU-NCORP	2	-	-
Davis, U of CA	2	-	-
Fred Hutchinson CRC	3	-	-
GACARES MU-NCORP	-	-	1
Georgia NCORP	9	-	-
Greenville NCORP	2	-	-
Gulf South MU-NCORP	4	-	-
H Lee Moffitt CC	12	-	-
Hawaii MU-NCORP	-	21	-
Heartland NCORP	17	-	-
Henry Ford Hospital	1	-	-
Kaiser Perm NCORP	1	-	60
Kansas MU-NCORP	6	-	-
King Faisal - Riyadh	3	-	-
Lahey Hosp & Med Ctr	6	-	-
Loyola University	8	-	-
MUSC MU-NCORP	1	-	-
Michigan CRC NCORP	3	-	-
Michigan, U of	8	-	-
Montana NCORP	1	-	-
New Mexico MU-NCORP	3	1	-
Oregon Hlth Sci Univ	1	-	-
Ozarks NCORP	9	-	-
Providence Hosp	3	-	-
So Calif, U of	3	-	-
Southeast COR NCORP	-	1	-
Wayne State Univ	6	-	-
ALLIANCE	19	-	-
ECOG-ACRIN	32	-	-
NRG	20	-	-
Total	248	23	62

Palliative and End of Life Care Committee

Committee Leadership

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

Agenda

Wednesday, October 13, 2021
 10:00 am - 12:00 pm CT

- 5 min Welcome and Introductions:** Co-Chairs
- 5 min Committee Liaison Update (Patient Advocate / ORP)**
- 10 min Committee Member Wellbeing Check-in:** Marie A. Bakitas, DNSc, NP-C, FAAN
- 25 min Plenary: Caregiver Research:** J. Nicholas Dionne-Odom
- 15 min Developing Studies Updates**
 - S2016**, "Randomized Phase III Trial of a Primary Palliative Care Intervention in Pancreatic Cancer." Drs. Chung and Sun.
 - S2106**, "Depression screening and treatment in patients requesting Medical Aid in Dying (MAID)" Drs. Salman and Blanke.
 - Hope/CAPC Provider Communication Study: Ishwariah Subbiah
- 10 min Active Study Update**
 - S1820**, "A Randomized Trial of the Altering Intake, Managing Symptoms Intervention for Bowel Dysfunction in Rectal Cancer Survivors Compared to a Healthy Living Education Control: A Feasibility and Preliminary Efficacy Study (AIMS-RC)." Dr. Sun. Activated: 12/9/19.
- 5 min Closed Study Update**
 - S1316**, "Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction." Dr. Krouse. Activated: 3/9/15. Closed: 5/15/20.
- 35 min New Business**
 1. Hope Intervention Workshop: Corn/Feldman
 2. PREPARE-ACP Concept: Subbiah
 3. Empathy Concept: Agarwal/Deiningner
 4. READIBAND Activity Monitor Concept: Fowler/O'Rourke
 5. APP Proposal for Hope Funding
- 5 min Closing Comments and Adjourn: Co-Chairs**

Palliative and End of Life Care Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021
 by institution and study

	S1316	S1820
Arizona CC, Univ of	11	1
Arkansas, U of	6	-
Baylor College	1	-
City of Hope CCC	5	2
Columbia MU-NCORP	1	-
Columbus NCORP	-	1
Essentia Hlth NCORP	1	-
Fred Hutchinson CRC	-	6
Greenville NCORP	-	5
H Lee Moffitt CC	3	-
Hawaii MU-NCORP	-	2
Heartland NCORP	-	6
INC, Bogota	1	-
INCan	8	-
INEN	7	-
Irvine, U of CA	-	6
Kansas MU-NCORP	18	-
Loma Linda Univ	1	-
MD Anderson CC	2	3
MUSC MU-NCORP	5	-
Michigan CRC NCORP	-	2
Michigan, U of	8	-
New Mexico MU-NCORP	1	2
Northwestern Univ	-	1
Oklahoma, Univ of	2	-
San Antonio, U of TX	7	-
Tennessee, U of	42	-
Virginia Mason MC	-	5
ALLIANCE	27	3
ECOG-ACRIN	2	1
NRG	62	17
Total	221	63

Prevention & Epidemiology Committee

Committee Leadership

Co-Chairs: Banu Arun, MD
..... Marian L. Neuhouser, PhD, RD

Agenda

Friday, October 15, 2021
11:30 am - 1:30 pm CT

Introduction

Welcome and Opening Comments: Marian Neuhouser and Banu Arun

Cancer Prevention Presentation

“Harnessing the Power of Artificial Intelligence and Novel Technology to Assess Breast Cancer Risk.” Richard Ha, M.D., Herbert Irving Comprehensive Cancer Center, Columbia University

Active Studies

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

S1823, “A Prospective Observational Cohort Study to Assess miRNA 371 for Outcome Prediction in Patients with Newly Diagnosed Germ Cell Tumors”. Drs. C. Nichols and L. Nappi. Activated: 6/1/20.

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

CTS/NHLBI-MDS, “The National Myelodysplastic Syndromes Natural History Study.” Drs. D. Hill and C. Arana Yi, Study Champions. SWOG Activated: 6/1/19.

CTSU EA1151, “Tomosynthesis Mammographic Imaging Screening Trial (TMIST).” Dr. B. Arun, Study Champion. SWOG Activated: 7/24/19.

Pending CTEP Approval

Amendment to S1418, “Exploratory Study to Evaluate Mammographic Density Changes in Patients Receiving Pembrolizumab in S1418.” Dr. B. Arun.

Amendment to S1007, “Effects of Chemoprevention and Adjuvant

Endocrine Therapy on a Convolutional Neural Network-Based Breast Cancer Risk Model Using Mammographic Datasets from S0812 and S1007.” Drs. K Crew, K. Kalinsky, R. Ha.

Concepts in Redesign

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

“Alternate Dosing of Exemestane Among Postmenopausal Women with Atypical Hyperplasia or Ductal Carcinoma In Situ”, Dr. Julia McGuinness.

Concept pending R01 funding

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

New Business/Open Discussion for new ideas



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THE HOPE
FOUNDATION
FOR CANCER RESEARCH

Upcoming Funding Opportunities

SEED Fund Grants
NCORP Pilot Grants
APPLY BY DECEMBER 1

EARLY 2022
Charles A. Coltman Jr. Fellowship
SWOG/Hope Impact Award Program
Career Engagement Award Program
LETTERS OF INTENT DUE JANUARY 15

THEHOPEFOUNDATION.ORG/FUNDING-OPPORTUNITIES

THE HOPE
FOUNDATION
FOR CANCER RESEARCH

Office Hours Event

Come Ask About NCORP Pilot Grants
Or Other Hope Funding
Opportunities!

HOPE FOUNDATION OFFICE HOURS
THURSDAY, 10/14, 12-1PM CT

This session is provided as a means to talk with Hope Foundation and SWOG representatives – as well as other interested NCTN/NCORP members – to discuss project feasibility, ask questions about budgeting or team planning, or to explore DEI actions as they relate to SWOG and/or the NCTN/NCORP more broadly.



Prevention & Epidemiology Committee

Prevention & Epidemiology Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S0820	S1823	S1904	A211102	A211601	EA2185	NRGCC008
Arizona CC, Univ of	-	2	-	-	-	-	-
Banner MD Anderson	10	-	-	-	-	-	-
Baptist MU-NCORP	5	-	-	-	-	-	-
Bay Area NCORP	1	2	-	-	-	-	-
Baylor College	-	-	-	-	-	-	1
Brooke Army Med Ctr	1	-	-	-	-	-	-
CORA NCORP	4	-	-	-	-	-	-
CRC West MI NCORP	2	-	-	-	-	-	-
Carle CC NCORP	-	3	8	-	-	-	-
City of Hope CCC	1	-	5	2	-	-	-
Colorado, U of	6	-	-	-	-	-	-
Columbia MU-NCORP	1	-	8	1	-	-	-
Columbus NCORP	5	6	-	-	-	-	-
Dayton NCORP	1	-	-	-	-	-	-
Essentia Hlth NCORP	4	-	-	-	-	-	-
GACARES MU-NCORP	2	-	-	-	-	-	-
Georgia NCORP	2	-	-	-	-	-	-
Greenville NCORP	-	4	-	-	-	-	-
Gulf South MU-NCORP	-	3	-	-	-	-	-
Hawaii MU-NCORP	10	1	-	-	-	-	-
Heartland NCORP	2	8	-	-	-	-	-
Irvine, U of CA	28	-	-	-	-	-	-
Kaiser Perm NCORP	38	36	-	-	-	-	-
Kansas MU-NCORP	3	-	-	-	-	-	-
Lahey Hosp & Med Ctr	-	-	2	-	-	-	-
Loma Linda Univ	2	1	-	-	-	-	-
Los Angeles, U of CA	-	8	-	-	-	-	-
Loyola University	2	-	-	-	-	-	-
MAVERIC	3	-	-	-	-	3	-
MD Anderson CC	4	-	-	-	-	-	-

Prevention & Epidemiology Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S0820	S1823	S1904	A21102	A211601	EA2185	NRGCC008
Michigan CRC NCORP	10	-	-	-	-	-	-
Mississippi, Univ of	1	-	-	-	-	-	-
Nevada CRF NCORP	1	1	-	-	-	-	-
New Mexico MU-NCORP	2	-	-	-	-	-	-
Northwell NCORP	-	2	-	-	-	-	-
Northwest NCORP	10	-	-	-	-	-	-
Ohio State Univ	-	1	-	-	-	-	-
Oklahoma, Univ of	1	1	-	-	-	-	-
Oregon Hlth Sci Univ	-	8	-	-	-	-	-
Ozarks NCORP	-	5	-	-	-	-	-
PCRC NCORP	2	-	-	-	-	-	-
Providence Hosp	1	-	-	-	2	-	-
Rochester, Univ of	-	6	-	-	-	-	-
Salem Hospital	-	1	-	-	-	-	-
San Antonio, U of TX	8	-	-	-	-	-	-
So Calif, U of	5	16	-	-	-	-	-
Southeast COR NCORP	3	2	-	-	-	-	-
UCSD Moores CC	-	9	-	-	-	-	-
Utah, U of	-	-	9	-	-	-	-
Vanderbilt Univ	-	6	-	-	-	-	-
Virginia Mason MC	2	6	-	-	-	-	-
Wayne State Univ	2	-	-	-	-	-	-
Wichita NCORP	13	-	-	-	-	-	-
Wisconsin NCORP	2	-	-	-	-	-	-
Yale University	22	-	-	-	-	-	-
ALLIANCE	33	21	3	-	-	-	-
CCTG	-	29	-	-	-	-	-
ECOG-ACRIN	26	15	-	-	-	-	-
NRG	35	5	6	-	-	-	-
Total	316	208	41	3	2	3	1

Symptom Control & Quality of Life Committee

Committee Leadership

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

Agenda

Thursday, October 14, 2021
10:30 am - 12:30 pm CT

Symposium: Aromatase Inhibitor Therapy Toxicity

Plenary speaker: "Highlights from the E1Z11 clinical trial – genetic predictors of aromatase inhibitor-associated musculoskeletal symptoms." Lynne Wagner, PhD

Committee speaker: "Increasing endocrine therapy persistence by focusing on symptoms", Norah Lynn Henry, MD, PhD

Panel discussion

Active Trials

S1600, "A Randomized Phase III Double-Blind Clinical Trial Evaluating the Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes (SIMmune)." Drs. Hamilton-Reeves, Holzbeierlein, Kukreja, et al. Activated: 2/21/19; Temporarily closed: 4/15/21; Reactivated: 5/12/21.

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.

S1614, "A Phase III Randomized Trial of Prophylactic Antiviral Therapy in Patients with Current or Past Hepatitis B Virus (HBV) Infection Receiving Anti-Cancer Therapy for Solid Tumors." Drs. Hwang, Lok, Ghering, et al. Activated: 2/21/19; Temporarily closed: 5/20/20; Reactivated: 7/1/21.

S2013, "Immune Checkpoint Inhibitor Toxicity (I-CHECKIT): A Prospective Observational Study." Drs. Gunturu, Hershman, Kuderer, et al. Activated: 8/16/21.

Other Concepts in Development

S2014, "mHealth Mindfulness versus Wait-List Control to Improve Quality of Life in Castration-Resistant Metastatic Prostate Cancer Patients and their Romantic Partners." Drs. Kubo and Greyz.

S2010, "Active Symptom Monitoring and Endocrine Therapy Persistence in Young Women with Breast Cancer." Drs. Henry, Desta, Hershman, et al.

S2205, "STOP CIPN: Randomized trial of Limb Cryocompression versus Continuous Compression versus Low Cyclic Compression for the Prevention of Taxane-Induced Peripheral Neuropathy." Dr. Accordini

Committee Business

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

Closed Studies

S0702, "A Prospective Observational Multicenter Cohort Study to Assess the Incidence of Osteonecrosis of the Jaw (ONJ) in Cancer Patients with Bone Metastases Starting Zoledronic Acid Treatment." Drs. Van Poznak, Gralow. Activated: 12/15/08; Permanently closed: 6/1/19.

S1013, "A Prospective Study of Epidermal Growth Factor Receptor (HER-1/EGFR) Inhibitor-Induced Dermatologic Toxicity: Validation of the Functional Assessment of Cancer Therapy-EGFRI 18(FACT-EGFRI 18) Questionnaire for EGFRI-Induced Skin Toxicities." Drs. Wong, Wade. Activated: 11/15/11; Permanently closed: 1/31/17.

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

S1202, "A Randomized Placebo-Controlled Phase III Study of Duloxetine for Treatment of Aromatase Inhibitor(AI)-Associated Musculoskeletal Symptoms in Women with Early Stage Breast Cancer." Drs. Henry, Schott. Activated: 5/15/13; Permanently closed: 10/1/15.

Other SWOG Studies with Symptom Control and QOL Component

Breast

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. E³ Breast Cancer Study Evaluating Everolimus with Endocrine Therapy" Dr. Chavez-MacGregor. Activated: 9/3/13; Permanently closed: 2/1/19.

S1418, "A Randomized Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with ≥ 1 cm Residual Invasive Cancer or Positive Lymph Nodes (ypN+) After Neoadjuvant Chemotherapy." Drs. Pusztai Mammen, Henry, et al. Activated: 11/15/16.

Symptom Control & Quality of Life Committee

Colorectal Cancer." Dr. Overman. Activated: 11/7/17.

[CTSU/A021202](#), "Prospective Randomized Phase II Trial of Pazopanib (NSC #737754, IND 75648) Versus Placebo in Patients with Progressive Carcinoid Tumors." Dr. Phan. Activated: 6/21/13; Permanently closed: 10/7/16.

[CTSU/A041202](#), "A Randomized Phase III Study of Bendamustine plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (≥ 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL)." Dr. Coutre. Activated: 12/9/13; Permanently closed: 5/16/16.

[CTSU/C30610](#), "Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer also Receiving Cisplatin or Carboplatin and Etoposide." Drs. Gadgeel and Gaspar. Activated: 3/15/08; Permanently closed: 8/30/17.

[CTSU/C51101](#), "A Randomized Phase II Trial of Myeloablative Versus Non-Myeloablative Consolidation Chemotherapy for Newly Diagnosed Primary CNS B-Cell Lymphoma." Dr. Mohile. Activated: 6/15/12; Permanently closed: 5/2/17.

[CTSU/C90203](#), "A Randomized Phase III Study of Neo-Adjuvant Docetaxel and Androgen Deprivation Prior to Radical Prostatectomy Versus Immediate Radical Prostatectomy in Patients with High-Risk, Clinically Localized Prostate Cancer." Dr. Kim. Activated: 12/15/06; Permanently closed: 10/2/15.

[CTSU/E1411](#), "Intergroup Randomized Phase II Four Arm Study in Patients with Previously Untreated Mantle Cell Lymphoma of Therapy with: Arm A = Rituximab + Bendamustine Followed by Rituximab Consolidation (RB -->R); Arm B = Rituximab + Bendamustine + Bortezomib Followed by Rituximab Consolidation (RBV--> R), Arm C = Rituximab+Bendamustine Followed by Lenalidomide + Rituximab Consolidation (RB --> LR) or Arm D = Rituximab + Bendamustine + Bortezomib Followed by Lenalidomide + Rituximab Consolidation (RBV --> LR)." Dr. Till. Activated: 5/22/12; Permanently closed: 9/9/16.

[CTSU/E1609](#), "A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy Versus High-Dose Interferon α -2b for Resected High-Risk Melanoma." Dr. Flaherty. Activated: 5/25/11; Permanently closed: 7/26/16.

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

[CTSU/E1A11](#), "Randomized Phase III Trial of Bortezomib, LENalidomide

and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide, Dexamethasone (CRd) Followed by Limited or Indefinite DURation Lenalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE)." Dr. Zonder. Activated: 12/2/13; Permanently closed: 1/29/19.

[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 Metastectomy." Dr. Pal. Activated: 8/8/12; Permanently closed: 7/25/17.

[CTSU/E2906](#), "Phase III Randomized Trial of Clofarabine as Induction and Post-Remission Therapy vs. Standard Daunorubicin & Cytarabine Induction and Intermediate Dose Cytarabine Post-Remission Therapy, Followed by Decitabine Maintenance vs. Observation in Newly-Diagnosed Acute Myeloid Leukemia in Older Adults (Age ≥ 60 Years)." Dr. Godwin. Activated: 12/28/10; Permanently closed: 1/24/2019.

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

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

[CTSU/N1048](#), "A Phase II/III Trial of Neoadjuvant FOLFOX, with Selective Use of Combined Modality Chemoradiation Versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision." Dr. Eng. Activated: 1/13/12; Permanently closed: 12/28/18.

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

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

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

Symptom Control & Quality of Life Committee

Symptom Control & Quality of Life Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1600	S1614	S1714	A171601	A221504	A221505	A221602	A221702	A221805	EA1711
Arkansas, U of	-	-	55	-	-	-	-	-	-	-
CORA NCORP	-	-	63	-	-	-	-	-	-	-
CRC West MI NCORP	-	-	127	-	-	-	-	-	-	-
Carle CC NCORP	-	-	3	-	-	-	-	-	-	-
Cleveland Clinic OH	-	-	-	-	-	3	-	-	-	-
Colorado, U of	2	-	1	-	-	15	-	-	1	-
Columbia MU-NCORP	-	-	21	-	-	-	2	-	-	-
Davis, U of CA	-	-	-	1	-	-	-	-	-	-
Dayton NCORP	-	-	-	-	1	-	1	-	1	-
Desert Hospital	-	-	-	-	-	-	3	-	-	-
Fred Hutchinson CRC	2	-	-	-	-	-	-	-	-	-
GOCCHI	-	-	1	-	-	-	-	-	-	-
Georgia NCORP	-	-	16	-	-	-	-	-	-	-
Greenville NCORP	-	-	14	-	-	-	-	-	-	-
Gulf South MU-NCORP	1	-	21	-	-	1	-	-	-	1
Hawaii MU-NCORP	-	-	63	-	-	-	-	-	-	-
Heartland NCORP	-	-	29	-	-	-	-	-	-	-
Henry Ford Hospital	6	-	-	-	-	-	-	-	-	-
INC, Bogota	-	-	8	-	-	-	-	-	-	-
INCan	-	-	60	-	-	-	-	-	-	-
Irvine, U of CA	-	-	-	-	-	1	4	-	-	-
Kaiser Perm NCORP	-	1	33	-	-	-	-	-	-	-
Kansas MU-NCORP	24	-	20	-	-	-	-	-	1	-
Kentucky, U of	-	-	-	-	-	-	10	-	-	-
Lahey Hosp & Med Ctr	-	-	19	-	-	-	-	-	-	-
Loyola University	-	-	2	-	1	-	-	-	-	-
MUSC MU-NCORP	-	-	-	-	-	-	-	-	-	2
Northwell NCORP	-	-	-	-	-	1	2	-	-	-
Ozarks NCORP	-	-	8	-	-	-	-	-	-	-
PCRC NCORP	-	-	2	-	-	-	-	-	-	-
Rochester, Univ of	2	-	-	-	1	-	-	14	-	-
San Antonio, U of TX	-	-	12	-	-	-	-	-	-	-
So Calif, U of	39	-	-	-	1	-	-	-	-	-
Southeast COR NCORP	-	-	216	-	-	-	-	-	-	-
Tulane University	-	-	1	-	-	-	-	-	-	-
Upstate NCORP	-	-	96	-	-	1	-	-	-	-
Utah, U of	-	-	-	-	-	-	8	-	-	-
VAMC Kansas City	-	-	-	-	2	-	-	-	-	-
Wayne State Univ	-	-	-	1	-	-	-	1	-	-
West Clinic	-	-	-	-	-	3	-	-	-	-
Wichita NCORP	-	-	1	-	-	-	-	-	-	-
ALLIANCE	4	-	19	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	62	-	-	-	-	-	-	-
NRG	1	1	71	-	-	-	-	-	-	-
Total	81	2	1,044	2	6	25	30	15	3	3

Early Therapeutics & Rare Cancers Committee

Committee Leadership

Chair: Razelle Kurzrock, MD
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..... Melissa Plets, MS
..... Edward Mayerson, MS

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Digital Engagement: Kanwal Raghav, MD, MBBS
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CRAs: TBD
Nurse: TBD
Pharmaceutical Science: Craig Elg, PharmD
..... Sun "Coco" Yang, PharmD, PhD
Patient Advocate: Marcia K. Horn, JD
Protocol Coordinator: Catrina Mireles
Clinical Trials Project Manager: Gretchen Goetz, MBA

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Genitourinary Committee Liaison: Neeraj Agarwal, MD
Imaging: TBD
Lung Committee Liaison: Shirish M. Gadgeel, MD
Lymphoma Committee Liaison: Daruka Mahadevan, MD, PhD
Melanoma Committee Liaison: Jeffrey A. Sosman, MD
Myeloma Committee Liaison: Frits van Rhee, MD, PhD

Agenda

Wednesday, October 13, 2021
10:00 am - 12:00 pm CT

Introduction

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

Presentations

10:05 - 10:30 am "New Drugs in Oncology." Monica Mita, M.D., Professor of Medicine, Co-Director, Experimental Therapeutics Program, Samuel Oschin Comprehensive Cancer Institute Cedars-Sinai Medical Center.

10:30 - 10:55 am "DART: Clinical Trial Updates." Sandip Patel, M.D., PI, DART Trial, UC San Diego Moores Comprehensive Cancer Center, San Diego, CA

10:55 - 11:15 am "CIMAC and Translational Immunology in DART." Young Chae, M.D., Vice Chair, Early Therapeutics and Rare Cancers (SWOG), Northwestern University, Robert H. Lurie Comprehensive Cancer Center.

11:15 - 11:35 am "Updates from Sarcoma Working Group." Lara Davis, M.D., Associate Professor Knight Cancer Institute, Co-Leader, Translational Oncology Research Program, Sarcoma Disease Site Leader, Knight Cancer Institute, Oregon Health & Science University.

11:35 - 11:55 am "Updates from CNS Working Group." Manmeet Ahluwalia, M.D., Chief of Medical Oncology, Deputy Director, Chief Scientific Officer, Miami Cancer Institute.

11:55 - 12:00 pm Wrap Up. Razelle Kurzrock, M.D., Chair, Early Therapeutics and Rare Cancer Committee (SWOG)

Active Studies

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

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

NCIC019, "NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study." Dr. Karim. Activated: 5/21/20.

CTSU/A071702, "A Phase II Study of Checkpoint Blockade Immunotherapy in Patients with Somatically Hypermutated Recurrent Glioblastoma." Dr. Ahluwalia. Activated: 10/30/20.

CTSU/NRG-HN007, "An Open-Label, Phase III Study of Platinum-Gemcitabine with or without Nivolumab in the First-Line Treatment of Recurrent or Metastatic Nasopharyngeal Carcinoma." Dr. Swiecicki. Activated: 9/8/20; Temporarily Closed: 6/14/21

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

CTSU/NRG-GY020, "A Phase III Randomized Trial of Radiation +/- Pembrolizumab (MK-3475) for Newly Diagnosed Early Stage High Intermediate Risk Mismatch Repair Deficient (dMMR) Endometrioid Endometrial Cancer." Dr. Robinson. Activated: 2/7/20.

CTSU/EA2183, "A Phase III Study of Consolidative Radiotherapy in Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma." Dr. Saeed. Activated: 2/6/20. Temporarily Closed: 6/15/21.

Early Therapeutics & Rare Cancers Committee

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. Swiecicki. Activated: 3/28/18.

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

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. Robinson. Activated: 5/12/17.

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. Robinson. Activated: 1/15/16; Temporarily Closed: 5/28/21.

CTSU/A071401, "Phase II Trial of SMO/AKT/NF2/CDK Inhibitors in Progressive Meningiomas with SMO/AKT/NF2/CDK Pathway Mutations." Dr. Piccioni. Activated: 8/28/2015.

Proposed 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)." Dr. Zhen.

NRG-BN1803, "NRG-COG Phase II Trial of Radiation Plus Concurrent and Adjuvant ONC201 for Newly Diagnosed, H3 K27M-Mutant Gliomas." Dr. Ahluwalia.

NRG-OV1821, "A Randomized Phase II Trial of Olaparib Versus Olaparib + Tremelimumab in Platinum-Sensitive Recurrent Ovarian Cancer." Dr. Robinson.

NRG, SWOG study in HPV-associated malignancies by the use of AZD2811, an Aurora B kinase inhibitor, and MEDI4736, anti-PD-L1. Dr. Fu.

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Early Therapeutics & Rare Cancers Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1609	EAY131		S1609	EAY131
Arizona CC, Univ of	7	8	MD Anderson CC	19	-
Arkansas, U of	4	3	MUSC MU-NCORP	4	1
Baptist MU-NCORP	2	-	Michigan CRC NCORP	16	-
Baylor College	-	3	Michigan, U of	32	23
CORA NCORP	10	1	Mississippi, Univ of	5	-
CROWN NCORP	1	-	Montana NCORP	12	-
Carle CC NCORP	3	-	Nevada CRF NCORP	18	-
Cedars-Sinai Med Ctr	7	6	New Mexico MU-NCORP	17	-
City of Hope CCC	2	6	Northwest NCORP	2	-
Cleveland Clinic OH	5	9	Northwestern Univ	16	-
Colorado, U of	6	9	Oklahoma, Univ of	1	-
Columbus NCORP	3	-	Oregon Hlth Sci Univ	10	-
Davis, U of CA	11	8	Ozarks NCORP	1	-
Dayton NCORP	2	1	PCRC NCORP	12	-
Essentia Hlth NCORP	4	-	Providence Hosp	1	3
Fred Hutchinson CRC	9	2	Rochester, Univ of	5	-
Georgia NCORP	5	-	San Antonio, U of TX	5	7
Gulf South MU-NCORP	2	-	So Calif, U of	4	-
H Lee Moffitt CC	22	-	Southeast COR NCORP	4	8
Hawaii MU-NCORP	3	1	Sutter Cancer RC	2	4
Heartland NCORP	15	1	Tulane University	-	1
Henry Ford Hospital	17	11	UCSD Moores CC	26	-
Houston Methodist	-	1	Utah, U of	3	-
Irvine, U of CA	8	19	Wayne State Univ	-	3
Kaiser Perm NCORP	26	6	Western States NCORP	1	-
Kansas City NCORP	-	1	Wisconsin NCORP	13	-
Kansas MU-NCORP	35	5	Yale University	7	13
Kentucky, U of	-	13	ALLIANCE	103	-
Loma Linda Univ	6	1	ECOG-ACRIN	77	-
Loyola University	4	-	NRG	131	-
MAVERIC	5	-	Total	771	178

Gastrointestinal Committee

Committee Leadership

Chair: Philip A. Philip, MD, PhD, FRCP
Vice-Chair: Elena Gabriela Chiorean, MD
Executive Officer: Christopher W. Ryan, MD
Statisticians: Katherine A. Guthrie, PhD
..... Shay Bellasea, MS

Scientific Leadership

Phase I Studies: Sandip P. Patel, MD
Gastroesophageal: Syma Iqbal, MD
..... Zev A. Wainberg, MD
..... Daniel Catenacci, MD, PhD (Translational Medicine)
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..... Andrew M. Lowy, MD
Hepatobiliary: Anthony B. El-Khoueiry, MD
..... Rachna T. Shroff, MD
..... Syed Ahmad, MD (Surgical representative)
Colon: Philip J. Gold, MD
..... Wells A. Messersmith, MD
Neuroendocrine Tumors: Nageshwara Arvind Dasari, MD
..... Jonathan R. Strosberg, MD
Ano-Rectal: Lisa A. Kachnic, MD
..... Hagen F. Kennecke, MD
Translational Medicine: Heinz-Josef Lenz, MD
..... Christopher H. Lieu, MD
..... Daniel Catenacci, MD
Imaging: Anthony F. Shields, MD, PhD
Pathology: Mary Kay Washington, MD, PhD
Radiation Oncology: Lisa A. Kachnic, MD
Surgery: Stephen W. Behrman, MD

Designates

Cancer Control Liaisons: Jason A. Zell, DO (Prevention)
..... Afsaneh Barzi, MD (CCD)
Community Liaisons: Gary L. Buchsacher, MD, PhD (Medical Oncology)
..... Mohamed E. Salem, MD (Medical Oncology)
..... Jeremiah Lee Deneve, DO (Surgical)
..... Flavio Rocha, MD (Surgical)
..... David Horowitz, MD (Radiation Oncology)
..... Chan Shen, PhD, MS (Health Outcomes)
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Digital Engagement: Heloisa Soares, MD, PhD
Data Coordinators: Christine Magner
..... Brian Zeller
..... Ojasvi Mittal
Oncology Research Professionals:
CRA: Sandy Annis, BA, CCRP

Nurse: TBD
Patient Advocate (Pancreatic): Carole Seigel, MBA
Patient Advocate (Colon): Florence Kurttila, MS
Pharmaceutical Science: Jane E. Rogers, PharmD
..... Jason M. Reed, PharmD
Protocol Coordinator: Christy Klepetko
Clinical Trials Project Manager: Gretchen Goetz, MBA

Agenda

Friday, October 15, 2021
2:00 pm - 4:00 pm CT

5 minutes Welcome and Introductions – Drs Philip and Chiorean
5 minutes Committee Liaison Updates (Patient Advocates/Nursing)
15 minutes Featured Trials

SWOG S2107, “Randomized Phase II Trial of Encorafenib and Cetuximab With or Without Nivolumab (NSC #748726) for Patients with Microsatellite Stable, BRAFV600E Metastatic Colorectal Cancer” (Dr Van Morris)

SWOG S2001, “Randomized Phase II Clinical Trial of Olaparib + Pembrolizumab Vs. Olaparib Alone as Maintenance Therapy in Metastatic Pancreatic Cancer Patients with Germline BRCA1 or BRCA2 Mutations” (Dr Vincent Chung)

SWOG 2104, “Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide Versus Observation in High-Risk Pancreatic Neuroendocrine Tumors” (Drs Soares and Ahmed)

SWOG 1610/GI004 (COMMIT): Colorectal Cancer Metastatic dMMR. A randomized phase III study of mFOLFOX6/bevacizumab combination chemotherapy with or without atezolizumab or atezolizumab monotherapy in the first-line treatment of patients (pts) with deficient DNA mismatch repair (dMMR) metastatic colorectal cancer (mCRC).

90 minutes Active Study Updates and Developing Concepts
5 minutes New Business

Closing Comments and Adjourn

Gastroesophageal

Active Studies

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

Gastrointestinal Committee

CTSU/EA2183, "A Phase III Study of Consolidative Radiotherapy in Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma (EGA)." Dr. Horowitz. Activated: 2/6/2020. Temporarily closed: 06/15/21.

Pancreatic

Active Studies

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/EA2186, "A Randomized Phase II Study of Gemcitabine and Nab-Paclitaxel Compared with 5-Fluorouracil, Leucovorin, and Liposomal Irinotecan in Older Patients with Treatment Naïve Metastatic Pancreatic Cancer (GIANT)." Dr. Zhen. Activated: 6/18/20.

CTSU/EA2192, "APOLLO: A Randomized Phase II Double-Blind Study of Olaparib Versus Placebo Following Adjuvant Chemotherapy in Patients with Resected Pancreatic Cancer and a Pathogenic BRCA1, BRCA2 or PALB2 Mutation." Drs. Chiorean and Philip. Activated: 4/29/21.

Neuroendocrine

Proposed Studies

S2104, "Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide versus Observation in High-Risk Pancreatic Neuroendocrine Tumors." Dr. Soares.

Active 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.

Hepatobiliary

Proposed Studies

S2109, "A Phase II Study of Neoadjuvant Nivolumab plus Ipilimumab for Patients with Resectable Hepatocellular Carcinoma." Dr. Kaseb.

Active Studies

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

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

CTSU/EA2187, "A Phase 2 Study of Pevonedistat in Combination with Carboplatin and Paclitaxel in Advanced Intrahepatic Cholangiocarcinoma." Dr. Stein. Activated: 1/31/20. Temporarily closed: 03/31/21.

Closed Studies

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

Colorectal

Proposed Studies

S2107, "Randomized Phase II Trial of Encorafenib and Cetuximab with or without Nivolumab for Patients with Microsatellite Stable, BRAFV600E Metastatic Colorectal Cancer." Dr. Morris.

Active Studies

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.

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

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

Gastrointestinal Committee

CTSU/A021502, "Randomized Trial of Standard Chemotherapy Alone or Combined with Atezolizumab as Adjuvant Therapy for Patients with Stage III Colon Cancer and Deficient DNA Mismatch Repair." Dr. Lieu. Activated: 9/12/17.

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

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

Anal

Active Studies

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

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

CTSU/EA2201, "A Phase II Study of Neoadjuvant Nivolumab Plus Ipilimumab and Short-Course Radiation in MSI-H/dMMR Locally Advanced Rectal Adenocarcinoma." Dr. Cho. Activated 5/13/21.

Other

Active Studies

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

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

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

Celebrating the

50 NATIONAL
CANCER
ACT 1971-2021

The **National Cancer Act of 1971**

gave our country a holistic approach to addressing cancer and its many challenges. This broad legislation gave new authority to the **National Cancer Institute** and established some of the programs that form the backbone of today's cancer research enterprise.



Gastrointestinal Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1613	S1815	S1922	S2001	A021502	A021602	A021703	A021806
Arizona CC, Univ of	-	13	-	-	2	-	-	-
Arkansas, U of	-	2	-	-	-	-	-	-
Baylor College	-	6	-	-	-	-	-	-
Boston Medical Ctr	-	-	-	-	1	1	-	-
CORA NCORP	2	4	-	-	-	-	-	-
CRC West MI NCORP	-	2	-	-	-	-	-	-
CROWN NCORP	-	2	-	-	-	-	-	-
Cincinnati MC, U of	-	2	-	-	-	-	3	-
City of Hope CCC	-	4	-	-	-	1	-	-
Cleveland Clinic OH	-	-	-	-	3	-	-	-
Colorado, U of	1	-	-	-	4	-	1	-
Columbus NCORP	-	3	-	-	-	-	-	-
Davis, U of CA	2	4	-	-	4	-	-	-
Dayton NCORP	-	2	-	-	3	-	-	-
Fred Hutchinson CRC	-	-	-	-	2	-	-	-
Greenville NCORP	-	11	-	-	-	-	-	-
Gulf South MU-NCORP	-	4	-	-	-	-	-	-
H Lee Moffitt CC	-	-	-	-	-	4	-	-
Hawaii MU-NCORP	-	11	-	-	-	-	-	-
Heartland NCORP	3	7	-	-	-	-	-	-
Henry Ford Hospital	-	2	-	-	-	-	-	-
Houston Methodist	-	-	-	-	-	-	-	-
Irvine, U of CA	-	3	-	-	-	-	-	-
Kaiser Perm NCORP	1	-	-	-	13	-	-	-
Kansas MU-NCORP	4	-	-	-	2	-	1	-
Lahey Hosp & Med Ctr	1	-	-	-	-	-	-	-
Lee Memorial Health	-	1	-	-	-	-	-	-
Loyola University	1	-	-	-	-	-	-	-
MD Anderson CC	12	22	5	-	-	-	-	-
Michigan CRC NCORP	-	-	1	-	-	-	-	-

Gastrointestinal Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1613	S1815	S1922	S2001	A021502	A021602	A021703	A021806
Michigan, U of	1	3	-	-	-	1	-	2
Montana NCORP	-	4	-	-	-	-	-	-
New Mexico MU-NCORP	-	9	-	-	-	-	-	-
Northwell NCORP	-	-	-	-	-	-	5	-
Northwestern Univ	1	17	-	-	-	-	1	-
Oregon Hlth Sci Univ	-	3	-	-	-	-	-	-
Ozarks NCORP	-	3	-	-	-	-	-	-
PCRC NCORP	3	9	-	-	-	-	-	-
Providence Hosp	-	-	-	1	1	-	-	-
Rochester, Univ of	-	9	1	-	2	3	-	1
SCL Hlth St Joseph	-	-	-	-	-	-	-	-
San Antonio, U of TX	-	1	-	-	-	-	-	2
So Calif, U of	1	9	-	-	1	-	-	-
Southeast COR NCORP	1	-	-	1	-	-	-	-
Sutter Cancer RC	-	-	-	-	3	-	-	-
Upstate NCORP	-	1	-	-	-	-	-	-
Utah, U of	-	5	-	-	-	-	-	-
Vanderbilt Univ	-	4	-	-	-	-	-	-
Virginia Mason MC	-	-	-	-	4	2	-	-
Wayne State Univ	-	2	-	-	1	-	-	-
West Clinic	-	1	-	-	-	-	-	-
Wichita NCORP	-	1	-	-	-	-	-	-
William Beaumont	-	-	-	-	1	-	-	-
Wisconsin NCORP	-	1	-	-	-	-	-	-
Yale University	-	10	-	-	1	-	1	-
ALLIANCE	6	122	5	-	-	-	-	-
ECOG-ACRIN	4	92	1	-	-	-	-	-
NRG	5	41	1	-	-	-	-	-
Total	49	452	14	2	48	12	12	5

Gastrointestinal Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	EA2142	EA2165	EA2174	EA2186	EA2187	NRGG1004	NRGG1005
Arizona CC, Univ of	-	-	-	-	-	-	-
Arkansas, U of	-	7	-	-	-	-	-
Baylor College	-	-	-	-	-	-	-
Boston Medical Ctr	-	1	-	-	-	-	-
CORA NCORP	-	-	-	-	-	-	-
CRC West MI NCORP	-	-	-	-	-	-	-
CROWN NCORP	-	-	-	-	-	-	-
Cincinnati MC, U of	-	2	-	-	-	-	-
City of Hope CCC	-	-	-	1	-	-	-
Cleveland Clinic OH	-	-	-	-	3	-	-
Colorado, U of	-	-	-	1	-	-	-
Columbus NCORP	-	-	-	-	-	-	-
Davis, U of CA	-	5	-	-	-	-	1
Dayton NCORP	-	-	-	-	-	-	-
Fred Hutchinson CRC	-	3	-	-	-	-	-
Greenville NCORP	-	-	-	-	-	-	-
Gulf South MU-NCORP	-	1	-	-	-	-	-
H Lee Moffitt CC	-	-	-	-	-	-	-
Hawaii MU-NCORP	-	-	-	2	-	-	-
Heartland NCORP	-	-	-	-	-	-	-
Henry Ford Hospital	1	-	-	-	-	-	1
Houston Methodist	-	-	-	-	-	1	-
Irvine, U of CA	-	-	-	-	-	-	-
Kaiser Perm NCORP	2	5	-	-	-	-	1
Kansas MU-NCORP	-	-	-	-	1	-	-
Lahey Hosp & Med Ctr	-	-	-	-	-	-	-
Lee Memorial Health	-	-	-	-	-	-	-
Loyola University	-	-	-	-	-	-	-
MD Anderson CC	-	-	-	-	-	12	1
Michigan CRC NCORP	-	-	-	-	-	-	-

Gastrointestinal Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	EA2142	EA2165	EA2174	EA2186	EA2187	NRGG1004	NRGG1005
Michigan, U of	3	-	-	-	-	-	-
Montana NCORP	-	-	-	-	-	-	-
New Mexico MU-NCORP	-	-	-	-	-	-	-
Northwell NCORP	-	-	-	-	-	-	-
Northwestern Univ	-	-	-	-	-	-	-
Oregon Hlth Sci Univ	-	3	-	-	-	-	-
Ozarks NCORP	-	-	-	-	-	-	-
PCRC NCORP	-	-	-	-	-	-	-
Providence Hosp	-	-	-	1	-	-	-
Rochester, Univ of	-	-	-	2	2	1	-
SCL Hlth St Joseph	-	1	-	-	-	-	-
San Antonio, U of TX	-	-	-	-	-	-	-
So Calif, U of	-	-	1	-	-	-	-
Southeast COR NCORP	-	-	-	-	-	-	-
Sutter Cancer RC	-	2	-	-	1	-	-
Upstate NCORP	-	-	-	-	-	-	-
Utah, U of	-	-	-	-	-	-	-
Vanderbilt Univ	-	-	-	-	-	-	-
Virginia Mason MC	-	-	-	-	-	-	-
Wayne State Univ	-	3	-	-	-	-	-
West Clinic	-	-	-	-	-	-	-
Wichita NCORP	-	-	-	-	-	-	-
William Beaumont	-	-	-	-	-	-	-
Wisconsin NCORP	-	-	-	-	-	-	-
Yale University	-	-	-	-	-	-	-
ALLIANCE	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-	-
NRG	-	-	-	-	-	-	-
Total	6	33	1	7	7	14	4

Genitourinary Committee

Committee Leadership

Chair: Ian M. Thompson, Jr., MD
 Vice-Chair: Daniel P. Petrylak, MD
 Executive Officer: Christopher W. Ryan, MD
 Statisticians: Cathy M. Tangen, DrPH
 Melissa Plets, MS
 Eddie Mayerson, MS

Scientific Leadership

Translational Medicine: David J. McConkey, PhD (GU Chair)
 Joshua J. Meeks, MD, PhD (Bladder)
 Amir Goldkorn, MD (Prostate)
 Sumanta "Monty" K. Pal, MD (Renal)
 Radiation Oncology: James B. Yu, MD
 Jing Zeng, MD
 Imaging: Evan Y. Yu, MD
 Hiram Shaish, MD
 John D. Hazle, PhD
 Pathology: M. Scott Lucia, MD
 Surgery: Kelly L. Stratton, MD
 Liaison to the SPORES: Colin P.N. Dinney, MD
 Early Therapeutics: Neeraj Agarwal, MD
 Bladder Organ Site Chairs: Seth P. Lerner, MD (Localized)
 Daniel P. Petrylak, MD (Advanced)
 Prostate Organ Site Chairs: Daniel W. Lin, MD (Localized)
 David I. Quinn, MD, PhD (Advanced)
 Renal Organ Site Chairs: Brian Shuch, MD (Localized)
 Ulka N. Vaishampayan, MD (Advanced)

Designates

Cancer Control: Peter J. Van Veldhuizen, Jr., MD
 Digital Engagement: Neema Navai, MD
 Veterans Affairs Michael M. Goodman, MD
 Data Coordinators: Sean O'Bryan
 Tonya Johnson
 Kelly Kasa
 Oncology Research Professionals:
 CRAs: Abigail L. Cornette, MS
 Cheryl Farlow, RN, OCN
 Nurses: Deborah A. Shaw, RN
 Cheryl Kefauver, RN
 Patient Advocates: Rick Bangs, MBA (Bladder)
 Tony Crispino (Prostate)
 Margaret "Peggy" Zuckerman, MEd (Renal)
 Pharmaceutical Science: Joyce Lee, PharmD
 Jason M. Reed, PharmD, RPH
 Protocol Coordinator: Taj Pereira

Clinical Trials Project Manager: TBD

GU Committee Part I: Renal, Translational Medicine, Cancer Control

Thursday, October 14, 2021
 3:00 pm - 5:00 pm CT

3:00 - 3:10 pm Welcome and Opening Remarks (Ian Thompson Jr MD)
 3:10 - 4:00 pm Renal Organ site (Dr Ulka Vaishampayan and Dr. Brian Shuch)
 4:00 - 4:40 pm Translational Medicine (Dr. David McConkey)
 4:40 - 5:00 pm Cancer Control (Dr Peter Van Veldhuizen)
 5:00 - 6:15 pm *GU Executive Committee (Closed Session – EC members only) Dr. Thompson*

GU Committee Part II: Bladder, Prostate

Friday, October 15, 2021
 1:30 pm - 3:30 pm CT

1:30 - 2:30 pm Bladder Organ Site (Drs Seth Lerner and Daniel Petrylak)
 2:30 - 3:30 pm Prostate Organ Site (Drs. David Quinn and Daniel Lin)

Bladder

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.

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.

CTS/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." Dr. A. Gupta and Dr. S. Gupta. Activated: 8/1/18.

Genitourinary Committee

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.

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, T. Koppie, et al. Activated: 8/1/11; Permanently Closed: 4/15/17.

S1602, "A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG Before Intravesical Therapy for BCG Naïve High-Grade Non-Muscle Invasive Bladder Cancer." Dr. R. Svatek. Activated: 2/7/17; Permanently Closed: 12/15/2020.

S1605, "Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer." Drs. P. Black and P. Singh. Activated: 2/7/17; Permanently Closed: 7/5/19.

Renal

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.

Active Studies

CTSU/AREN1721, "A Randomized Phase 2 Trial of Axitinib/Nivolumab Combination Therapy vs. Single Agent Nivolumab for the Treatment of TFE/Translocation Renal Cell Carcinoma (trCC) Across All Age Groups." Dr. M. Parikh. Activated: 10/9/18; Temporarily Closed: 3/24/21.

CTSU/A031704, "PD-Inhibitor (Nivolumab) and Ipilimumab Followed by Nivolumab vs. VEGF TKI Cabozantinib with Nivolumab: A Phase III Trial in Metastatic Untreated Renal Cell Cancer [PDIGREE]." Dr. T. Zhang. Activated: 5/9/19.

CTSU/A031801, "A Phase II Randomized Trial of Radium-223 Dichloride and Cabozantinib in Patients with Advanced Renal Cell Carcinoma with Bone Metastasis (Radical)." Dr. M. Parikh. Activated: 12/13/19.

CTSU/A031901, "Duration of Immune Checkpoint Therapy in Locally Advanced or Metastatic Urothelial Carcinoma: A randomized Phase 3 non-Inferiority Trial." Dr. A. Vaena. Activated: 12/10/20.

Closed Studies

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. Pal. Activated 8/8/12; Permanently closed 7/25/17.

CTSU/A031501, "Phase III Randomized Adjuvant study of Pembrolizumab in Muscle Invasive and Locally Advanced Urothelial Carcinoma (AMBASSADOR) Versus Observation." Dr. Sonpavde. Activated: 9/21/17; Permanently Closed 8/24/21.

CTSU/EA8143, "A Phase 3 Randomized Study Comparing Perioperative Nivolumab vs. Observation in Patients with Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC)." Drs. P. Lara and B. Shuch. Activated: 2/2/17; Permanently Closed: 6/9/21.

Prostate

Priority Study

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

Active Studies

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

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

CTSU/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.

Genitourinary Committee

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.

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; Temporarily Closed: 2/12/21.

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: 3/1/13; Permanently Closed: 7/15/17.

CTSU/NRG-GU006, "A Phase II, Double-Blinded, Placebo-Controlled Randomized Trial of Salvage Radiotherapy with or Without Enhanced Anti-Androgen Therapy with Apalutamide in Recurrent Prostate Cancer." Dr. J. Zeng. Activated: 4/27/18; Permanently Closed: 5/19/20.

CTSU/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

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. Activated: 6/3/19; Temporarily Closed: 5/5/21.

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

CTSU/EA8153, "Cabazitaxel with Abiraterone Versus Abiraterone Alone Randomized Trial for Extensive Disease Following Docetaxel: The CHARTED2 Trial." Dr. P. Corn. Activated: 2/8/18; Permanently Closed 4/2/21.

Translational Medicine

Chair: Dr. David McConkey

Bladder Chair: Dr. Joshua Meeks

Prostate Chair: Dr. Amir Goldkorn

Renal Chair: Dr. Sumanta "Monty" Pal

Cancer Control

Active Studies

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

Diverse Studies of Interest

S1609, "DART: Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors." Drs. S. Patel, Y. Chae, R. Kurzrock, et al. Activated: 1/13/17; Permanently Closed: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 13, 14, 15, 16, 17, 20, 21, 22, 23, 24, 25, 26, 27, 28, 30, 31, 32, 33, 34, 35, 36, 37, 39, 41, 42, 43, 44, 45, 48, 51, and 52; Temporarily Closed: 18, 29, 46, and 53.

CTSU/A031702, "A Phase II Study of Ipilimumab, Cabozantinib, and Nivolumab in Rare Genitourinary Cancers (ICONIC)" Dr. S. Liu. Activated: 4/12/19.

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

CTSU/EA8134, "Inpact- International Penile Advanced Cancer Trial (International Rare Cancers Initiative Study)." Dr. C. Pettaway. Activated 9/8/17.

Closed Studies

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

Genitourinary Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1602	S1802	S1806	S1931	S1937	A031102	A031501	A031701	A031702	A031704
Arizona CC, Univ of	-	5	-	-	-	-	-	-	-	-
Arkansas, U of	-	1	-	-	-	-	-	-	-	-
Banner MD Anderson	7	1	-	-	-	-	-	-	-	-
Baylor College	21	-	-	-	-	-	-	-	-	-
Birmingham, U of AL	-	-	-	-	-	-	-	-	1	-
CORA NCORP	-	-	1	-	-	-	-	-	-	-
CRC West MI NCORP	-	2	2	-	-	-	-	-	-	-
CROWN NCORP	-	-	1	-	-	-	-	-	-	-
Cedars-Sinai Med Ctr	12	-	4	-	-	-	-	-	-	-
Cincinnati MC, U of	-	3	2	-	-	-	-	-	-	5
City of Hope CCC	1	1	-	-	-	-	-	-	-	-
Cleveland Clinic OH	-	-	-	-	-	-	-	4	-	-
Colorado, U of	23	3	2	-	-	-	12	-	-	7
Columbia MU-NCORP	-	-	-	-	-	-	3	-	-	-
Cotton O'Neil CC	-	-	-	-	-	-	1	-	-	-
Davis, U of CA	-	8	4	-	-	-	4	4	-	1
Dayton NCORP	1	2	-	-	-	-	-	-	-	-
Fred Hutchinson CRC	26	6	-	-	-	-	-	-	-	-
Greenville NCORP	1	6	-	-	-	-	-	-	-	1
Gulf South MU-NCORP	95	53	37	-	-	-	2	-	-	-
H Lee Moffitt CC	26	-	-	-	-	-	-	-	-	-
Harrison Medical Ctr	-	-	1	-	-	-	-	-	-	-
Hawaii MU-NCORP	9	-	1	-	-	-	-	-	-	-
Heartland NCORP	4	7	1	-	-	-	-	-	-	-
Henry Ford Hospital	13	9	3	-	-	-	1	-	1	5
Houston Methodist	3	-	-	-	-	-	-	-	-	-
Irvine, U of CA	16	-	3	-	-	-	-	-	-	-
Kaiser Perm NCORP	12	7	-	-	-	-	14	-	-	33
Kansas MU-NCORP	20	7	3	-	-	-	4	-	1	2
Kentucky, U of	-	-	1	-	-	-	-	-	-	-
Lahey Hosp & Med Ctr	-	-	-	-	-	-	4	-	4	-
Loma Linda Univ	-	-	-	-	-	-	2	-	-	-
Los Angeles, U of CA	-	-	-	-	-	-	-	-	-	-
Loyola University	12	4	3	-	-	-	-	-	1	1
MD Anderson CC	38	50	-	-	-	-	-	-	-	-

Genitourinary Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1602	S1802	S1806	S1951	S1957	A031102	A031501	A031701	A031702	A031704
MUSC MU-NCORP	2	1	-	-	-	-	-	-	-	-
Michigan CRC NCORP	6	4	6	-	1	-	-	-	-	-
Michigan, U of	30	2	-	3	-	-	18	-	-	-
Mississippi, Univ of	-	1	-	-	-	-	-	-	1	-
Montana NCORP	1	3	-	-	-	-	-	-	-	-
Nevada CRF NCORP	2	1	-	-	-	-	-	-	-	-
New Mexico MU-NCORP	-	-	-	-	-	-	-	-	-	-
Northwell NCORP	-	-	1	-	-	-	-	-	-	1
Northwestern Univ	35	-	6	-	-	-	-	-	-	-
Ohio State Univ	4	1	1	-	-	-	-	-	-	-
Oklahoma, Univ of	51	24	11	-	-	-	-	-	-	-
Oregon Hlth Sci Univ	14	-	-	-	-	-	-	-	3	3
Ozarks NCORP	10	1	-	-	-	-	-	-	-	-
PCRC NCORP	24	-	-	-	-	-	-	-	-	-
Providence Hosp	-	-	-	-	-	-	-	-	-	1
Rochester, Univ of	20	12	-	-	-	-	-	-	3	3
SCL Hlth St Joseph	-	1	-	-	-	-	-	-	-	-
San Antonio, U of TX	58	1	-	-	-	-	-	-	-	-
So Calif, U of	44	3	-	-	-	8	13	-	3	-
Southeast COR NCORP	-	1	-	-	-	-	-	-	-	-
Sutter Cancer RC	-	-	2	-	-	-	-	-	-	-
Tulane University	-	-	-	1	-	-	-	-	-	-
UCSD Moores CC	-	1	1	-	-	-	-	-	-	-
Upstate NCORP	-	-	1	-	-	-	-	-	-	-
Utah, U of	47	14	-	-	-	-	3	-	-	-
VAMC Kansas City	-	-	-	-	-	-	-	-	-	-
Vanderbilt Univ	-	1	2	-	-	-	-	-	-	-
Virginia Mason MC	-	-	-	-	-	-	1	-	-	-
Wayne State Univ	-	1	-	-	-	-	-	-	-	-
Western States NCORP	-	-	1	-	-	-	-	-	-	-
Wisconsin NCORP	-	4	1	-	-	-	-	-	-	-
Yale University	3	-	1	-	-	-	8	-	-	-
ALLIANCE	110	61	9	-	-	-	-	-	-	-
ECOG-ACRIN	111	37	15	-	-	-	-	-	-	-
NRG	88	37	45	-	-	-	-	-	-	-
Total	1,000	387	172	4	1	8	90	8	18	63

Genitourinary Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	A031801	A031803	EA8134	EA8143	EA8153	EA8171	NRGGU002	NRGGU005	NRGGU006	NRGGU008
Arizona CC, Univ of	-	-	-	11	-	-	-	-	-	-
Arkansas, U of	-	-	-	-	-	-	-	-	-	-
Banner MD Anderson	-	-	-	-	-	-	-	-	-	-
Baylor College	-	-	-	1	-	-	-	-	-	-
Birmingham, U of AL	-	-	-	6	-	-	-	-	-	-
CORA NCORP	-	-	-	-	-	-	-	-	-	-
CRC West MI NCORP	-	-	-	-	-	-	-	-	-	-
CROWN NCORP	-	-	-	-	-	-	-	-	-	-
Cedars-Sinai Med Ctr	-	-	-	8	-	-	-	-	-	-
Cincinnati MC, U of	-	-	-	-	-	-	-	-	-	-
City of Hope CCC	-	-	-	-	-	-	-	-	-	-
Cleveland Clinic OH	-	-	-	-	-	-	-	-	-	-
Colorado, U of	-	-	-	1	-	-	1	1	-	-
Columbia MU-NCORP	-	-	-	1	-	-	-	-	-	-
Cotton O'Neil CC	-	-	-	-	-	-	-	-	-	-
Davis, U of CA	1	2	-	1	-	-	-	-	-	-
Dayton NCORP	-	-	-	1	-	-	-	-	-	-
Fred Hutchinson CRC	-	-	-	4	-	-	-	-	-	-
Greenville NCORP	-	-	-	1	-	-	-	-	-	-
Gulf South MU-NCORP	1	8	-	10	-	11	1	1	-	3
H Lee Moffitt CC	-	-	-	1	-	-	-	-	-	-
Harrison Medical Ctr	-	-	-	-	-	-	-	-	-	-
Hawaii MU-NCORP	-	-	-	2	-	-	-	-	-	-
Heartland NCORP	-	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	3	-	-	-	-	-	-
Houston Methodist	-	-	-	-	-	-	-	-	-	-
Irvine, U of CA	-	-	-	1	-	-	-	-	-	-
Kaiser Perm NCORP	-	-	-	41	10	-	-	-	-	-
Kansas MU-NCORP	-	-	-	2	1	-	-	-	-	-
Kentucky, U of	-	-	-	12	-	-	-	-	-	-
Lahey Hosp & Med Ctr	-	-	-	4	-	-	-	-	-	-
Loma Linda Univ	-	-	-	-	-	-	-	-	-	-
Los Angeles, U of CA	-	-	-	8	-	-	-	-	-	-
Loyola University	-	-	-	4	-	-	-	-	-	-
MD Anderson CC	-	-	-	-	8	-	-	-	-	-

Genitourinary Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	A031801	A031803	EA8134	EA8143	EA8153	EA8171	NRGGU002	NRGGU005	NRGGU006	NRGGU008
MUSC MU-NCORP	-	-	-	-	-	-	-	-	-	-
Michigan CRC NCORP	-	-	-	-	-	-	-	-	-	-
Michigan, U of	-	-	-	-	-	-	-	-	-	-
Mississippi, Univ of	-	-	-	3	2	-	1	-	-	-
Montana NCORP	-	-	-	-	-	-	-	-	-	-
Nevada CRF NCORP	-	-	-	2	-	-	-	-	-	-
New Mexico MU-NCORP	-	-	-	-	-	-	-	1	-	-
Northwell NCORP	-	-	-	-	-	-	-	-	-	-
Northwestern Univ	-	-	-	-	-	-	-	-	-	-
Ohio State Univ	-	-	-	-	-	-	-	-	-	-
Oklahoma, Univ of	-	-	-	-	-	-	-	-	-	-
Oregon Hlth Sci Univ	-	-	-	14	-	-	-	-	-	-
Ozarks NCORP	-	-	-	-	-	-	-	-	-	-
PCRC NCORP	-	-	-	-	-	-	-	-	-	-
Providence Hosp	-	-	-	-	-	-	-	-	-	-
Rochester, Univ of	-	-	-	1	-	-	-	-	-	-
SCL Hlth St Joseph	-	-	-	-	-	-	-	-	-	-
San Antonio, U of TX	-	3	-	14	-	35	-	-	3	-
So Calif, U of	-	-	7	-	-	-	-	-	-	-
Southeast COR NCORP	-	-	-	-	-	-	-	-	-	-
Sutter Cancer RC	-	-	-	-	-	-	-	1	-	-
Tulane University	-	-	-	10	-	-	-	-	-	-
UCSD Moores CC	-	-	-	2	-	-	-	-	-	-
Upstate NCORP	-	-	-	-	-	-	-	-	-	-
Utah, U of	-	-	-	2	8	-	-	-	-	-
VAMC Kansas City	-	-	-	-	-	-	-	-	1	-
Vanderbilt Univ	-	-	-	-	-	-	-	-	-	-
Virginia Mason MC	-	-	-	-	-	-	-	2	-	-
Wayne State Univ	-	-	-	2	-	-	1	-	-	-
Western States NCORP	-	-	-	-	-	-	-	-	-	-
Wisconsin NCORP	-	-	-	-	-	-	-	-	-	-
Yale University	-	-	-	1	2	-	-	-	-	-
ALLIANCE	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-	-	-	-	-
NRG	-	-	-	-	-	-	-	-	-	-
Total	2	13	7	174	31	46	4	6	4	3

Leukemia Committee

Committee Leadership

Chair: Harry P. Erba, MD, PhD
Vice-Chair: Steven E. Coutre, MD
Executive Officer: Susan M. O'Brien, MD
Statisticians: Megan Othus, PhD
..... Anna Moseley, MS

Scientific Leadership

Translational Medicine: Jerald P. Radich, MD
Pathology: David R. Head, MD
Cytogenetics Liaison: Min Fang, MD, PhD

Designates

Cancer Control: Stephanie B. Tsai, MD
Data Coordinators: Louise Highleyman
..... Tracy Maher, CCRP
..... Laura Kingsbury
Oncology Research Professionals:
CRA: Kristien B. Lewis, BS, CCRP
Nurse: Kristine D. Abueg, RN, MSN
Patient Advocate: Gail Sperling, MPH
Pharmaceutical Science: Holly O. Chan, PharmD
..... Ila M. Saunders, PharmD
Protocol Coordinator: TBD
Protocol Coordinator - MyeloMATCH: Sarah Cantu
Clinical Trials Project Manager: TBD

Agenda

Friday, October 15, 2021
12:30 pm - 2:30 pm CT

AML/MDS Studies

Active Studies

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

Closed Studies

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

ALL Studies

Active Studies

S1905, "A Phase I/II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL) / T-Cell Lymphoblastic Lymphoma (T-LBL)." Drs. A. Advani, N. Papadantonakis, and C. Yeung. Activated: 8/17/20.

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

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

Proposed Studies

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

CLL Studies

Active Studies

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

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

Leukemia Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1318	S1712	S1905	S1925	A041501	A041701	A041702	A041703	EA9161	EA9171	EA9181
Arizona CC, Univ of	-	-	-	-	-	-	3	-	4	-	-
Arkansas, U of	-	-	-	-	-	4	-	-	-	-	-
Birmingham, U of AL	1	-	-	-	1	-	-	-	7	-	-
CORA NCORP	-	-	-	-	-	-	-	-	1	-	-
Cincinnati MC, U of	-	-	1	-	-	-	-	1	-	-	-
City of Hope CCC	4	-	-	-	-	-	-	-	-	-	-
Cleveland Clinic OH	6	-	1	1	4	-	2	-	-	-	-
Colorado, U of	-	-	-	-	-	-	-	-	1	-	-
Dayton NCORP	-	-	-	-	-	-	1	-	2	-	-
Duke Univ Med Ctr	-	3	-	-	-	-	-	-	9	-	-
Fred Hutchinson CRC	-	-	1	-	-	-	-	-	9	-	-
Greenville NCORP	1	1	-	-	-	-	-	-	1	-	-
H Lee Moffitt CC	-	10	-	-	-	-	-	-	-	-	-
Hawaii MU-NCORP	-	5	-	-	-	-	-	-	-	-	-
Heartland NCORP	1	4	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	-	-	3	2	-	1	-	-
Irvine, U of CA	4	-	-	-	3	-	-	-	-	-	-
Kaiser Perm NCORP	-	-	-	-	-	-	5	-	32	-	-
Kansas MU-NCORP	-	-	-	-	-	-	4	-	8	-	-
Lahey Hosp & Med Ctr	-	-	-	-	-	-	1	-	-	-	-
Loma Linda Univ	1	-	-	-	-	-	-	-	-	-	-
Loyola University	-	1	-	-	-	-	1	-	2	-	-
MUSC MU-NCORP	-	-	-	-	-	-	1	-	7	-	-
Michigan CRC NCORP	-	1	-	-	-	-	-	-	-	-	-
Michigan, U of	2	-	-	-	-	-	-	-	-	-	-
Montana NCORP	-	1	-	-	-	-	-	-	-	-	-
Nevada CRF NCORP	-	1	-	-	-	-	-	-	2	-	-
New Mexico MU-NCORP	1	3	-	-	-	-	-	-	1	-	-
Oregon Hlth Sci Univ	-	1	1	-	5	-	4	-	9	-	-
Ozarks NCORP	-	1	-	-	-	-	-	-	-	-	-
Rochester, Univ of	4	4	-	-	5	22	1	3	1	-	1
Salem Hospital	-	-	-	-	-	-	-	-	4	-	-
So Calif, U of	3	-	-	-	-	-	-	-	-	-	-
Southeast COR NCORP	-	-	-	-	-	-	-	-	2	-	-
Stanford University	-	-	-	-	5	-	10	-	29	-	-
UCSD Moores CC	1	-	-	-	-	-	-	-	-	-	-
UF Cancer Center	1	-	-	-	-	-	-	-	-	-	-
Utah, U of	-	5	-	3	1	-	2	-	22	-	-
Virginia Mason MC	-	-	-	-	-	-	2	-	3	-	-
Wayne State Univ	-	-	-	-	-	-	-	-	4	-	-
Western States NCORP	-	-	-	-	2	-	2	-	1	-	-
Wichita NCORP	1	-	-	-	-	-	-	-	-	-	-
Yale University	1	-	-	-	4	-	1	-	10	1	-
ALLIANCE	17	7	1	-	-	-	-	-	-	-	-
ECOG-ACRIN	6	5	-	-	-	-	-	-	-	-	-
NRG	2	2	-	-	-	-	-	-	-	-	-
Total	57	55	5	4	30	29	42	4	172	1	1

Leukemia Committee

Closed Studies

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

CML Studies

Active Studies

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

MyeloMATCH

Proposed Studies

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

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

"Phase III Study of Azacitidine + Magrolimab Versus Azacitidine + Venetoclax in TP53 Mutant Acute Myeloid Leukemia." Dr. D. Sallman.

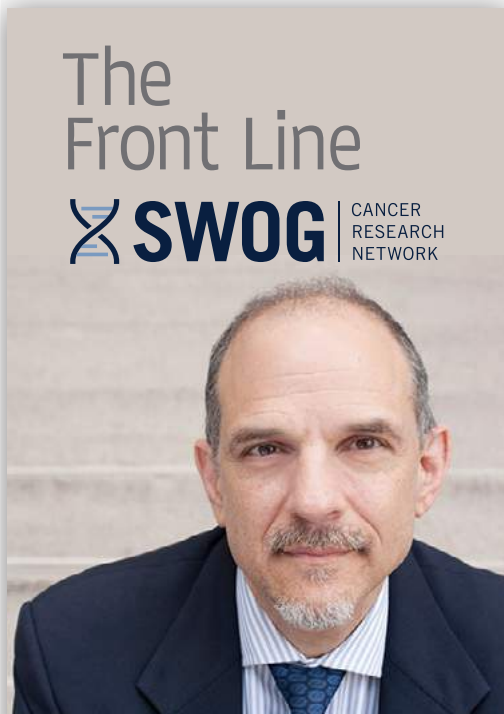
"A Phase II Study of Targeted Agents with the Oral DNMT1 Inhibitor C-DEC (ASTX727) for the Treatment of TP53 Mutated Acute Myeloid Leukemia: A myeloMATCH Treatment Trial." Dr. R. Shallis.

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Lung Committee

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Statisticians: Mary Redman, PhD
..... Yingqi Zhao, PhD
..... Katherine Minichiello, MS
..... Jieling Miao, MS
..... James Moon, MS
..... Lu Qian, MS

Scientific Leadership

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Biology/Pathology: Philip C. Mack, PhD
..... Fred R. Hirsch, MD, PhD
..... Ignacio I. Wistuba MD
Imaging: Chadwick L. Wright MD, PhD
..... Myrna C. Godoy, MD, PhD
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Surgery: Wayne L. Hofstetter, MD
Subcommittee Chairs:
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..... Raymond Osarogiagbon, MD
Locally Advanced Disease: Roy H. Decker, MD, PhD
..... Shirish Gadgeel, MD (Early Therapeutics)
Metastatic Disease: Ross Camidge, MD
..... Karen Reckamp, MD
Community Engagement: Paul J. Hesketh, MD
..... Suzanne Cole, MD

Designates

Cancer Control Liaison: Gary E. Goodman, MD
Veterans Affairs: Chao H. Huang, MD
..... Cheryl M. Czerlanis, MD
Data Coordinators: Leah Everhart
..... Louise Highleyman
..... Larry Kaye
Clinical Research Project Manager: Arthur Lee, MS
Oncology Research Professionals:
CRAs: Courtney L. Williamson
..... Ginny M. Keeling, MS
Nurses: Kimberly M. Belzer, MS, PAC
..... Rosalie Zablocki, RN
Patient Advocate: Judy Johnson, MBA
Pharmaceutical Science: Joyce Lee, PharmD
..... Kimberly McConnell, PharmD

Protocol Coordinators: Mariah Norman
..... Jennifer Beeler (Lung-MAP)
..... Laura Gildner, MS (Lung-MAP)
Clinical Trials Project Manager: Crystal Miwa

Agenda

Friday, October 15, 2021
12:15 pm - 3:15 pm CT

12:15 - 12:30 pm General Update

12:30 - 1:00 pm Dr. Robert B. Livingston Lectureship - Advances in lung cancer care: perspectives from a surgeon
Valerie W. Rusch, MD, FACS, FRCSI (Hon)
Attending Thoracic Surgeon and Member
Miner Family Chair in Intrathoracic Cancers
Vice Chair for Clinical Research
Department of Surgery
Memorial Sloan Kettering Cancer Center
Immediate Past President, American College of Surgeons

1:00 - 1:15 pm Thoracic Surgery Session: Wayne Hofstetter, MD

1:15 - 1:45 pm Thoracic Radiation Session: Megan Daly, MD

1:45 - 2:00 pm Translational Medicine Session: Phil Mack, PhD

2:00 - 2:10 pm Community Engagement Core: Paul J. Hesketh, MD

2:10 - 3:15 pm Thoracic Medical Oncology Session: Karen Kelly, MD

2:10 - 2:30 pm Scientific presentation: Overcoming disparities across the spectrum of thoracic oncology
Raymond Osarogiagbon, MD
Chief Scientist, Baptist Memorial Healthcare Corporation
Director, Multidisciplinary Thoracic Oncology Program
Baptist Cancer Center, Memphis, TN

Active Studies

LUNGMAP, "A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previously-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study)." Drs. Herbst, Patel, Gandara, et al. Activation: 1/28/19.

Lung Committee

S1900E, "A Phase II Study of Sotorasib (AMG 510) in Participants with Previously Treated Stage IV or Recurrent KRAS G12C Mutated Non-Squamous Non-Small Cell Lung Cancer (ECOG-ACRIN LUNG-MAP SUB-STUDY)." Drs. Padda and Gerber. Activation: 4/2/21.

S1701, "A Randomized Phase II Trial of Carboplatin-Paclitaxel with or without Ramucirumab in Patients with Unresectable Locally Advanced, Recurrent, or Metastatic Thymic Carcinoma." Drs. Tsao and Koczywas. Activation: 8/9/18.

S1827, "MRI Brain Surveillance Alone Versus MRI Surveillance and Prophylactic Cranial Irradiation (PCI): A Randomized Phase III Trial in Small-Cell Lung Cancer (MAVERICK)." Drs. Rusthoven, Brown, Wefel, et al. Activation: 1/10/20.

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

S1929, "Phase II Randomized Study of Maintenance Atezolizumab Versus Atezolizumab in Combination with Talazoparib in Patients with SLFN11-Positive Extensive Stage Small Cell Lung Cancer (ES-SCLC)." Drs. Karim, Reckamp, Byers, et al. Activation: 6/15/20.

S1933, "A Pilot Study of Hypofractionated Radiotherapy Followed by Atezolizumab Consolidation in Stage II or III NSCLC Patients with Borderline Performance Status." Drs. Aljumaily, Mitin, and Wozniak. Activation: 6/15/20.

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

CTSU/A081105, "Randomized Study of Erlotinib Vs Observation in Patients With Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC)." Dr. Kelly. Activation: 8/18/14; Temporary closure: 6/15/20; Reactivation: 7/15/20. Closed to Accrual: 1/20/21

CTSU/A081801, "Integration of Immunotherapy into Adjuvant Therapy for Resected NSCLC: ALCHEMIST Chemo-IO." Dr. Gray. Activation: 6/3/20.

CTSU/A151216, "Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)." Dr. Gandara. Activation: 8/18/14.

CTSU/E4512, "A Randomized Phase III Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib Versus Observation for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein." Dr. Li. Activation: 8/18/14.

CTSU/EA5181, "Randomized Phase III Trial of MEDI4736 (Durvalumab) as Concurrent and Consolidative Therapy or Consolidative Therapy Alone for Unresectable Stage 3 NSCLC." Dr. Harkenrider. Activation: 4/9/20.

CTSU/NRG-CC003, "Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer." Dr. Gaspar. Activation: 12/7/15; Temporary closure: 5/28/20; Reactivation: 7/27/20.

CTSU/NRG-LU002, "Maintenance Systemic Therapy versus Consolidative Stereotactic Body Radiation Therapy (SBRT) 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.

CTSU/NRG-LU003, "A Biomarker-Driven Protocol for Previously Treated ALK-Positive Non-Squamous NSCLC Patients: The NCI-NRG ALK Protocol." Dr. Doebele. Activation: 4/1/19. Permanently closed: 5/03/21

CTSU/NRG-LU005, "Limited Stage Small Cell Lung Cancer (LS-SCLC): A Phase II/III Randomized Study of Chemoradiation Versus Chemoradiation Plus Atezolizumab." Dr. Hsu. Activation: 5/28/19.

Closed Studies

S1619, "A Feasibility Trial of Neoadjuvant Cisplatin-Pemetrexed with Atezolizumab in Combination and in Maintenance for Resectable Malignant Pleural Mesothelioma." Drs. Tsao, Sepesi, Gomez, et al. Activation: 11/3/17; Permanently closed: 5/1/20.

S1800A, "A Phase II Randomized Study of Ramucirumab plus MK3475 (Pembrolizumab) versus Standard of Care for Patients Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Non-Match Sub-Study)." Drs. Reckamp and Dragnev. Activation: 5/17/19; Permanently closed: 11/16/20.

S1900A, "A Phase II Study of Rucaparib in Patients with Genomic LOH high and/or Deleterious BRCA 1/2 Mutation Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-Map Sub-Study)." Drs. Riess and Wheatley-Price. Activation: 1/28/19; Cohort 1 Closure: 11/16/20; Cohort 2 Closure/ Permanently closed: 2/1/21.

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-

Lung Committee

Map Sub-Study)." Drs. Elamin and Gray. Activation: 2/10/20; Permanently closed: 4/30/21.

S1900C, "A Phase II Study of Talazoparib plus Avelumab in Patients with STK11-Mutant Stage IV Non-Squamous Cell Lung Cancer (Lung-MAP Sub-study)." Drs. Skoulidis and Suga. Activation: 1/16/20; Permanently closed: 12/18/20.

NCI-Approved Concepts

S1934, "NASSIST (Neoadjuvant Chemoradiation +/- Immunotherapy before Surgery for Superior Sulcus Tumors): A Randomized Phase II Trial of Trimodality +/- Atezolizumab in Resectable Superior Sulcus Non-Small

Cell Lung Cancer." Dr. Osarogiagbon.

S1800D, "A Phase II/III Study Of N-803 plus Pembrolizumab versus Stand of Care in Patients with Anti-PD-1 or Anti-PD-L1 Relapsed and Refractory Stage IV Non-Small Cell Lung Cancer (Lung-MAP Non-Match Sub-Study)." Drs. Wrangle and Husain.

Concepts in Development

S1900F, "A Phase II Study of Selpercatinib, Carboplatin and Pemetrexed In Patients With RET Fusion-Positive Stage IV Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)," Drs. Elamin and Gray.

Find Clinical Research Resources on the SWOG Website

SWOG is about to launch a clinical research clearinghouse that features a wide range of curated resources that are relevant to conducting clinical trials (from idea inception, to design, logistics, funding, data analysis, and publication), as well as specific information related to conducting research within the cooperative group network.

The goal is simple: provide a one-stop shop for educational and professional development resources for our members and staff!

The link to this clearinghouse will go live Wednesday, October 6 – just before the fall group meeting.

Check it out at [swog.org/clinical-research-resources](https://www.swog.org/clinical-research-resources)



Lung Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	LUNGMAP	S1400F	S1619	S1701	S1800A	S1827	S1900A	S1900B	S1900C	S1900E	S1914	S1929
Arizona CC, Univ of	-	-	-	-	-	-	-	-	-	-	-	-
Arkansas, U of	7	-	-	-	3	-	-	-	-	-	3	-
Baptist MU-NCORP	33	-	-	-	-	-	3	-	1	-	1	1
Boston Medical Ctr	-	-	-	-	-	1	-	-	-	-	-	-
CORA NCORP	42	-	-	-	6	-	1	-	1	-	1	-
CRC West MI NCORP	3	-	-	-	1	-	1	-	1	-	1	-
CROWN NCORP	14	-	-	-	-	-	1	-	2	3	-	-
Carle CC NCORP	2	-	-	-	-	-	-	-	-	-	-	-
Cedars-Sinai Med Ctr	2	-	-	-	-	-	-	-	-	-	-	-
Cincinnati MC, U of	-	-	-	-	-	-	-	-	-	-	-	-
City of Hope CCC	5	-	2	1	-	1	-	-	-	-	-	-
Cleveland Clinic OH	4	-	-	-	-	-	-	-	1	-	-	-
Colorado, U of	10	1	-	-	1	1	-	-	-	-	1	-
Columbia MU-NCORP	5	-	-	-	-	-	1	-	1	-	-	-
Columbus NCORP	21	-	-	-	-	2	4	-	-	-	-	-
Cotton O'Neil CC	-	-	-	-	1	-	-	-	-	-	-	-
Davis, U of CA	20	-	-	3	3	1	3	-	-	-	3	1
Dayton NCORP	5	-	-	-	-	-	-	-	-	-	-	-
Essentia Hlth NCORP	15	-	-	-	-	-	-	-	1	-	-	-
Fred Hutchinson CRC	4	-	2	-	-	-	-	-	-	-	-	-
GACARES MU-NCORP	6	-	-	-	1	1	-	-	-	-	1	3
Georgia NCORP	41	6	-	-	3	2	2	-	-	-	1	-
Greenville NCORP	12	-	-	-	1	-	-	-	-	-	-	-
Gulf South MU-NCORP	7	-	-	-	-	1	-	-	-	-	1	-
H Lee Moffitt CC	5	-	-	1	-	1	-	-	-	-	-	-
Harrington CC	6	1	-	-	-	-	-	-	-	-	-	-
Hawaii MU-NCORP	20	-	-	-	1	-	-	-	-	-	-	-
Heartland NCORP	98	6	-	-	11	-	6	1	1	1	9	5
Henry Ford Hospital	7	-	-	-	-	-	2	-	-	-	-	-
Houston Methodist	-	-	-	-	-	-	-	-	-	-	-	-
Irvine, U of CA	17	2	-	-	1	1	-	-	-	-	1	-
Kaiser Perm NCORP	39	-	-	-	2	-	-	-	1	-	-	-
Kansas MU-NCORP	66	-	-	-	4	-	4	-	2	-	-	-
Kentucky, U of	39	2	-	-	2	1	-	-	3	-	-	-
Lahey Hosp & Med Ctr	23	-	-	-	4	-	-	-	-	-	-	1
Loma Linda Univ	5	-	-	-	-	-	-	-	1	-	-	-
Loyola University	17	-	-	-	1	-	-	-	-	-	-	-
MAVERIC	24	2	-	-	4	-	1	-	-	-	-	-
MD Anderson CC	3	1	15	4	-	-	-	-	-	-	-	-

Lung Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	LUNGMAP	S1400F	S1619	S1701	S1800A	S1827	S1900A	S1900B	S1900C	S1900E	S1914	S1929
MUSC MU-NCORP	4	-	5	-	-	-	-	-	-	-	-	-
Michigan CRC NCORP	78	1	-	-	10	-	3	-	5	2	-	-
Michigan, U of	1	1	-	-	-	-	-	-	-	-	-	-
Mississippi, Univ of	1	-	-	-	1	-	-	-	-	-	-	-
Montana NCORP	24	-	-	-	5	-	2	-	1	-	-	2
Mount Sinai Hospital	-	-	-	-	-	-	-	-	-	-	2	-
Nevada CRF NCORP	9	-	-	-	1	-	-	-	-	-	-	-
New Mexico MU-NCORP	57	3	-	-	3	1	2	-	-	-	2	2
Northwell NCORP	-	-	-	-	-	-	-	-	-	-	-	-
Northwestern Univ	19	-	-	1	-	-	-	-	-	-	-	-
Oklahoma, Univ of	24	1	-	-	2	1	1	-	-	-	-	-
Oregon Hlth Sci Univ	1	1	-	-	-	-	-	-	-	-	1	-
Ozarks NCORP	25	-	-	-	-	-	-	-	2	-	-	1
PCRC NCORP	12	-	-	-	-	-	-	-	-	-	-	3
Providence Hosp	11	1	-	-	-	-	-	-	-	-	-	1
Rochester, Univ of	39	1	-	-	2	-	3	-	-	2	1	-
Salem Hospital	3	-	-	-	1	-	-	-	-	-	-	-
San Antonio, U of TX	-	-	-	-	-	-	-	-	-	-	-	-
So Calif, U of	-	-	-	-	-	-	-	-	-	-	-	-
Southeast COR NCORP	44	6	-	-	9	2	2	-	-	-	-	3
Sutter Cancer RC	19	-	-	-	2	-	-	-	-	1	-	-
UCSD Moores CC	8	1	-	-	-	-	-	-	-	1	-	-
UPMC Hillman CC	3	-	-	-	-	-	-	-	-	-	-	-
Univ of Louisville	-	-	-	-	-	-	-	-	-	-	-	-
Upstate NCORP	18	-	-	-	4	-	-	-	1	-	1	-
Utah, U of	-	-	-	-	-	-	-	-	-	-	2	-
VAMC Kansas City	-	1	-	-	-	-	-	-	-	-	-	-
Wayne State Univ	1	1	-	-	-	-	-	-	-	-	-	-
Western States NCORP	2	-	-	-	-	-	-	-	-	-	-	-
Wichita NCORP	1	1	-	-	-	-	-	-	-	-	-	-
William Beaumont	-	-	-	-	-	-	-	-	-	-	-	-
Wisconsin NCORP	33	-	-	-	1	-	2	-	1	-	1	-
Yale University	16	1	-	-	7	-	1	-	3	-	-	-
ALLIANCE	517	12	1	2	36	9	9	1	9	2	1	1
CCTG	-	-	-	-	-	1	-	-	-	-	-	-
ECOG-ACRIN	253	6	3	1	17	1	5	2	7	6	2	1
NRG	237	8	1	-	15	22	5	2	2	1	1	3
Total	2,087	67	29	13	166	50	64	6	47	19	37	28

Lung Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1933	A081105	A081801	A151216	E4512	E45163	E45181	E45182	E45191	NRGCC003	NRGLU002	NRGLU005
Arizona CC, Univ of	-	-	-	7	2	-	1	-	-	-	-	-
Arkansas, U of	-	-	-	2	-	1	-	-	-	-	-	-
Baptist MU-NCORP	-	-	-	19	-	-	-	-	-	-	1	1
Boston Medical Ctr	-	-	-	3	-	-	1	-	-	-	-	-
CORA NCORP	-	-	-	2	-	-	-	-	-	-	-	-
CRC West MI NCORP	-	-	-	1	-	-	-	-	-	-	-	-
CROWN NCORP	-	-	-	-	-	-	-	-	-	-	-	-
Carle CC NCORP	-	-	-	-	-	-	-	-	-	-	-	-
Cedars-Sinai Med Ctr	-	-	-	-	-	-	-	-	-	-	-	-
Cincinnati MC, U of	-	1	-	22	1	-	-	-	-	-	-	-
City of Hope CCC	-	1	-	4	-	-	-	-	-	-	-	-
Cleveland Clinic OH	-	6	3	47	-	7	7	-	-	-	-	-
Colorado, U of	-	9	-	53	2	-	-	-	1	-	-	1
Columbia MU-NCORP	-	-	-	-	-	-	-	-	-	-	-	-
Columbus NCORP	-	-	-	-	-	-	-	-	-	-	-	-
Cotton O'Neil CC	-	-	-	3	-	-	-	-	-	-	-	-
Davis, U of CA	-	4	-	40	1	6	-	1	-	-	-	-
Dayton NCORP	-	-	-	8	-	-	-	-	-	-	-	-
Essentia Hlth NCORP	-	-	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson CRC	-	1	-	15	-	-	-	-	-	-	-	-
GACARES MU-NCORP	-	-	-	-	-	-	-	-	-	-	-	-
Georgia NCORP	-	-	-	9	-	-	-	-	-	-	-	-
Greenville NCORP	-	-	-	1	-	-	-	-	-	-	-	-
Gulf South MU-NCORP	-	-	-	-	-	3	-	-	-	-	-	-
H Lee Moffitt CC	-	3	3	83	1	-	-	-	-	-	-	-
Harrington CC	-	-	-	-	-	-	-	-	-	-	-	-
Hawaii MU-NCORP	-	-	-	-	-	-	-	-	-	-	-	-
Heartland NCORP	-	-	-	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	2	1	28	-	-	-	-	-	-	-	-
Houston Methodist	-	2	-	6	-	-	-	-	-	-	-	-
Irvine, U of CA	-	2	-	12	-	-	-	-	-	-	-	-
Kaiser Perm NCORP	-	19	-	195	4	3	-	-	-	-	-	-
Kansas MU-NCORP	-	1	-	27	-	3	-	-	-	-	-	2
Kentucky, U of	-	1	-	5	-	-	-	-	-	-	-	-
Lahey Hosp & Med Ctr	-	-	-	30	-	1	-	-	-	-	-	-
Loma Linda Univ	-	3	-	7	-	-	-	-	-	-	-	-
Loyola University	-	-	-	19	-	-	2	-	-	-	-	-
MAVERIC	-	1	5	21	-	3	-	-	-	-	-	-
MD Anderson CC	-	-	-	2	1	-	-	-	-	-	-	-

Lung Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1933	A081105	A081801	A151216	E4512	E45163	E45181	E45182	E45191	NRGCC003	NRGLU002	NRGLU005
MUSC MU-NCORP	-	-	-	-	-	-	-	-	-	-	-	-
Michigan CRC NCORP	-	-	-	-	-	-	-	-	-	-	-	-
Michigan, U of	-	1	-	62	-	-	-	-	-	-	-	-
Mississippi, Univ of	-	2	-	26	-	-	-	-	-	-	-	-
Montana NCORP	-	-	-	-	-	-	-	-	-	-	-	-
Mount Sinai Hospital	-	-	-	-	-	-	-	-	-	-	-	1
Nevada CRF NCORP	-	-	-	-	-	-	-	-	-	-	-	-
New Mexico MU-NCORP	1	-	-	-	-	-	-	-	-	-	-	-
Northwell NCORP	-	-	1	-	-	-	-	-	-	-	-	-
Northwestern Univ	-	-	-	-	-	-	-	-	-	-	-	-
Oklahoma, Univ of	4	-	-	-	-	-	-	-	-	-	-	-
Oregon Hlth Sci Univ	-	1	3	18	-	-	-	-	-	-	-	-
Ozarks NCORP	-	1	-	1	-	-	-	-	-	-	-	-
PCRC NCORP	-	-	-	4	-	-	-	-	-	-	-	-
Providence Hosp	-	-	-	14	1	2	1	-	1	-	-	-
Rochester, Univ of	-	-	-	-	-	2	6	-	-	4	-	1
Salem Hospital	-	-	-	-	-	-	-	-	-	-	-	-
San Antonio, U of TX	-	-	-	-	-	1	-	-	-	-	-	-
So Calif, U of	-	1	-	12	-	-	-	-	-	-	-	-
Southeast COR NCORP	-	-	-	-	-	-	-	-	-	-	-	-
Sutter Cancer RC	-	1	-	10	-	-	2	-	-	-	-	-
UCSD Moores CC	-	1	-	5	-	-	-	-	-	-	-	-
UPMC Hillman CC	-	-	-	-	-	-	-	-	-	-	-	-
Univ of Louisville	-	-	-	5	-	-	-	-	-	-	-	-
Upstate NCORP	-	-	-	-	-	-	-	-	-	-	-	-
Utah, U of	-	-	-	-	-	1	-	-	-	-	-	-
VAMC Kansas City	-	-	-	-	-	-	-	-	-	-	-	-
Wayne State Univ	-	-	-	1	-	-	-	-	-	-	1	-
Western States NCORP	-	-	-	2	-	-	-	-	-	-	-	-
Wichita NCORP	-	-	-	-	-	-	-	-	-	-	-	-
William Beaumont	-	-	-	2	-	-	-	-	-	-	-	-
Wisconsin NCORP	-	-	-	-	-	-	-	-	-	-	-	-
Yale University	-	3	-	47	3	7	-	-	-	-	-	-
ALLIANCE	-	-	-	-	-	-	-	-	-	-	-	-
CCTG	-	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-	-	-	-	-	-	-
NRG	1	-	-	-	-	-	-	-	-	-	-	-
Total	6	67	16	880	16	40	20	1	2	4	2	6

Lymphoma Committee

Committee Leadership

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

Scientific Leadership

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

Designates

Cancer Control:Hayder Saeed, MD
Digital Engagement: Mazyar Shadman, MD
Veterans Affairs: Helen Ma, MD
Data Coordinators: Iris Syquia
..... Gabi Herbert
Oncology Research Professionals:
CRA: Erin M. Cebula, MPH
Nurse: Molly Beth Adamek, BSN, RN
Patient Advocate: Hildy Dillon, MPH
Pharmaceutical Science: Holly O. Chan, PharmD
Protocol Coordinator: Alicia Aranda
Clinical Trials Project Manager: Gretchen Goetz, MBA

Agenda

Thursday, October 14, 2021
2:45 pm - 5:45 pm CT

2:45 pm Welcome: Drs. Jonathan Friedberg and Sonali Smith

2:50 – 3:50 pm Presentation (mini-symposium): Integration of New Agents in Lymphoma

Integration of bispecifics with other agents/regimens
Dr. Nilanjan Ghosh

Integration of epigenetic modifiers in lymphoma treatment
Dr. Jennifer Amengual

Integration of ADCs into lymphoma regimens
Dr. Shadman Mazyar

3:55 – 4:25 pm Recent Activations

Alliance 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. Jennifer Amengual

ANHL1931, "Nivolumab in Combination With Chemo-Immunotherapy for the Treatment of Newly Diagnosed Primary Mediastinal B-Cell Lymphoma"
Dr. Manali Kamdar

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"
Dr. Elizabeth Brem

4:25 – 4:40 pm ASH Abstract

Extranodal presentation in limited stage DLBCL as a prognostic marker in three sequential SWOG trials S0014, S0313 and S1001 (NCT00005089, NCT00070018, NCT01359592)
Dr. Deborah Stephens

4:40 – 5:40 pm Ongoing Studies

S1826: Dr. Herrera
S1608: Dr. Barr
A051301: Dr. Stiff
EA4151: Dr. Till
E4412: Dr. Amengual
EA4181: Dr. Spurgeon
A051701: Dr. Vallurupalli
S1925: Dr. Stephens
S1905 (T-ALL): Dr. Advani; Presented by: Dr. Stephens

5:40 – 5:45 pm Other Business/Concluding Remarks

Proposed Studies

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." Dr. Hess

Lymphoma Committee

Active Studies

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

S1608, "Randomized Phase II Trial in Early Relapsing or Refractory Follicular Lymphoma." Drs. Barr and Burack. Activated: 8/10/17.

S1918, "A Phase II/III Randomized Study of R-miniCHOP With or Without CC-486 (Oral Azacytidine) in Participants Age 75 Years or Older with Newly Diagnosed Diffuse Large B Cell Lymphoma, Grade IIIB Follicular Lymphoma, Transformed Lymphoma, and High-Grade B-Cell Lymphomas with MYC and BCL2 and/or BCL6 Rearrangements." Drs. Brem and Smith. Activated: 3/19/21.

CTSU/A051301, "A Randomized Double-Blind Phase III Study of Ibrutinib During and Following Autologous Stem Cell Transplantation Versus Placebo in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma of the Activated B-Cell Subtype." Drs. Andreadis, Fenske, Leonard, Devine, Shea, Hsi, Kelley, and Richards. SWOG Champion: Dr. Stiff. Activated: 7/6/16.

CTSU/A051701, "Randomized Phase II/III Study of Venetoclax (ABT199) Plus Chemoimmunotherapy for MYC/BCL2 Double-Hit and Double Expressing Lymphomas." Dr. Abramson. SWOG Champion: Dr. Vallurupalli. Activated: 8/7/19. Temporarily closed: 8/2/21.

CTSU/EA4151, "A Randomized Phase III Trial of Consolidation with Autologous Hematopoietic Cell Transplantation Followed by Maintenance Rituximab vs. Maintenance Rituximab Alone for Patients with Mantle Cell Lymphoma in Minimal Residual Disease-Negative First Complete Remission. Drs. Fenske, Till, Blum, Lazarus, Scott, and Kostakoglu. SWOG Champion: Dr. Till. Activated: 8/29/17.

CTSU/EA4181, "A Randomized 3-Arm Phase II Study Comparing 1.) Bendamustine, Rituximab and High Dose Cytarabine (BR/CR) 2.) Bendamustine, Rituximab, High Dose Cytarabine and Acalabrutinib (BR/CA-A), and 3.) Bendamustine, Rituximab and Acalabrutinib (BR-A) in Patients \leq 70 years Old with Untreated Mantle Cell Lymphoma. Dr. Wagner-Johnson. SWOG Champion: Dr. Spurgeon. Activated: 10/3/19.

CTSU/ANHL1931, "A Randomized Phase 3 trial of Nivolumab (NSC# 748726 IND# 125462) in Combination with Chemo-immunotherapy for the Treatment of Newly Diagnosed Primary Mediastinal B-cell Lymphoma." SWOG Champion: Dr. Kamdar. SWOG Champion: Dr. Manali. Activated 6/7/2021.

CTSU/A051902, "A Randomized Phase II Study of CHO(E)P vs Oral Azacitidine-CHO(E)P vs Duvelisib-CHO(E)P in Previously Untreated CD30 Negative Peripheral T-cell Lymphomas." Dr. Neha Mehta-Shah. SWOG Champion: Dr. Amengual. Activated 7/30/2021.

Open Leukemia Studies

S1925, "A Randomized, Phase III Study of Early Intervention with Venetoclax and Obinutuzumab versus Delayed Therapy with Venetoclax and Obinutuzumab in Newly Diagnosed Asymptomatic High-Risk Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL): EVOLVE CLL/SLL Study. Dr. Stephens. Activated: 12/14/20.

S1905, "A Phase I/II Study of AKR1C3-Activated Prodrug OBI-3424 (OBI-3424) in Patients with Relapsed/Refractory T-Cell Acute Lymphoblastic Leukemia (T-ALL)/T-Cell Lymphoblastic Lymphoma (T-LBL)." Drs. Advani and Papadantonakis. Activated: 8/17/20.

A041702, "A Randomized Phase III Study of Ibrutinib Plus Obinutuzumab Versus Ibrutinib Plus Venetoclax and Obinutuzumab in Untreated Older Patients (\geq 70 Years of Age) with Chronic Lymphocytic Leukemia (CLL)." Dr. Woyach. SWOG Champion: Dr. Hill. Activated: 1/4/19.

Open Rare Cancers Study

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

Open Cancer Care Delivery Study

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

Lymphoma Committee

Lymphoma Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1608	S1826	S1918	A051301	A051701	EA412	EA4151	EA4181
Arizona CC, Univ of	2	-	-	1	-	-	1	1
Arkansas, U of	-	1	-	-	-	-	-	-
Baptist MU-NCORP	-	1	-	-	-	-	-	-
Baylor College	-	-	-	1	-	-	-	-
Birmingham, U of AL	-	11	-	-	3	7	3	-
Boston Medical Ctr	-	1	-	-	-	-	-	-
CORA NCORP	-	3	-	-	-	-	-	-
CRC West MI NCORP	3	6	-	-	-	-	-	-
CROWN NCORP	-	1	-	-	-	-	-	-
Carle CC NCORP	1	-	-	-	-	-	-	-
Cincinnati MC, U of	-	5	-	-	-	-	1	-
City of Hope CCC	5	10	-	1	-	-	13	-
Cleveland Clinic OH	-	-	-	-	8	-	5	6
Colorado, U of	-	2	-	1	-	-	-	-
Columbia MU-NCORP	-	-	-	-	-	1	-	-
Columbus NCORP	1	2	-	-	-	-	-	-
Davis, U of CA	-	5	-	-	4	-	-	-
Fred Hutchinson CRC	-	-	-	-	-	-	11	-
GACARES MU-NCORP	-	1	-	-	-	-	-	-
Greenville NCORP	-	7	-	-	-	-	2	-
H Lee Moffitt CC	-	7	-	-	-	-	-	-
Heartland NCORP	1	15	-	-	-	-	-	-
Henry Ford Hospital	-	4	-	-	2	-	-	-
Irvine, U of CA	-	3	-	-	-	-	-	-
Kaiser Perm NCORP	2	9	-	-	-	11	-	3
Kentucky, U of	-	2	-	-	-	-	-	-
King Faisal - Riyadh	-	-	-	4	-	-	-	-

Lymphoma Committee

Lymphoma Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1608	S1826	S1918	A051301	A051701	EA412	EA4151	EA4181
Loyola University	-	2	-	-	-	-	2	-
MD Anderson CC	2	12	-	-	-	-	-	-
MUSC MU-NCORP	2	9	-	-	3	-	2	-
Michigan CRC NCORP	1	-	-	-	-	-	-	-
Michigan, U of	-	-	-	-	-	-	1	-
Montana NCORP	-	8	-	-	-	-	-	-
Nevada CRF NCORP	-	1	-	-	-	1	-	-
Northwestern Univ	1	-	-	-	-	-	-	-
Oregon Hlth Sci Univ	-	-	-	-	2	-	1	5
Ozarks NCORP	1	3	-	-	-	-	-	-
PCRC NCORP	-	1	-	-	-	-	-	-
Providence Hosp	-	3	-	-	-	-	-	-
Rochester, Univ of	13	23	-	3	11	-	6	10
San Antonio, U of TX	-	3	-	-	-	-	8	-
Southeast COR NCORP	-	3	-	-	-	-	-	-
UCSD Moores CC	-	5	-	-	-	-	1	-
Upstate NCORP	1	5	-	-	-	-	-	-
Utah, U of	1	9	-	-	-	-	10	5
Wayne State Univ	-	1	-	1	-	-	-	3
Wisconsin NCORP	-	4	-	-	-	-	-	-
Yale University	-	2	-	-	-	-	1	-
ALLIANCE	10	63	-	-	-	-	-	-
COG	-	172	-	-	-	-	-	-
ECOG-ACRIN	4	41	2	-	-	-	-	-
NRG	11	28	-	-	-	-	-	-
Total	62	494	2	12	33	20	68	33

Melanoma Committee

Committee Leadership

Chair: Sapna P. Patel, MD
Vice-Chair: TBD
Executive Officer: Christopher W. Ryan, MD
Statisticians: Michael Wu, PhD
..... Megan Othus, PhD
..... James Moon, MS
..... Hongli Li, MS

Scientific Leadership

Translational Medicine: William E. Carson, III, MD
Radiation Oncology: Evan J. Wuthrick, MD
Surgery: John Robert Hyingstrom, MD
Dermatology: Clara Curiel-Lewandrowski, MD
Imaging: Ari M. VanderWalde, MD
Medical Oncology: TBD
Pathology: TBD
Non-Melanoma Skin Cancer: Nikhil I. Khushalani, MD
Early Therapeutics: Jeffrey A. Sosman, MD
SWOG's ECOG Liaisons: Thach-Giao Truong, MD
ECOG's SWOG Liaisons: David H. Lawson, MD
Digital Engagement: Zeynep Eroglu, MD

Designates

Cancer Control Liaison: Sancy Leachman, MD, PhD
..... Thach-Giao Truong, MD (Survivorship)
Data Coordinator: Tonya Johnson
..... Laura Kingsbury, MRT
..... Leah Everhart
..... Hannah Hale
Oncology Research Professionals:
CRA: TBD
Nurse: Lisa S. Morgan, RN, OCN
Patient Advocate: Samantha Guild, JD
Pharmaceutical Science: Sun "Coco" Yang, PharmD, PhD
..... Kimberly McConnell, PharmD
Protocol Coordinator: Catrina De Los Santos-Mireles
Clinical Trials Project Manager: Gretchen Goetz, MBA

Agenda

Thursday, October 14, 2021
3:30 pm - 5:30 pm CT

Welcome and passing the torch: Kenneth Grossmann (10 min)

Presentation: The Inside Scoop on Poop: The Intestinal Microbiome in Cancer Immunotherapy - Diwakar Davar, UPMC (30 min)

Studies in Development / Upcoming Studies (30 min)

SWOG Studies in Development: Thach-Giao Truong
ECOG / Alliance Studies in Development: David Lawson
Gaps in our portfolio – Open discussion

Active Studies Update (10 min)

S2000, "A Randomized Phase II Trial Of Encorafenib + Binimetinib + Nivolumab Vs Ipilimumab + Nivolumab In Braf-V600 Mutant Melanoma With Brain Metastases."
PI: Zeynep Eroglu (Moffitt)
Biostatisticians: M Wu, PhD & J Moon, MS

S1801, "A Phase II Randomized Study of Adjuvant Versus Neo-Adjuvant Pembrolizumab (MK-3475) for Clinically Detectable Stage III-IV High-risk Melanoma."
PI: Sapna Patel (MDACC)
Biostatisticians: M Othus, PhD & J Moon, MS

Closed to Patient Accrual, Translational Medicine Updates (30 min)

S1320, "A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib and Trametinib in BRAFV600E/K Mutant Melanoma."
PI: Alain Algazi (UCSF)
Biostatisticians: M Othus, PhD & J Moon, MS

S1512, "A Study of PD-1 Blockade with Pembrolizumab In Patients with Primary Desmoplastic Melanoma (DM), Locally Advanced, Locally Recurrent, or Metastatic Desmoplastic Melanoma (DM)."
PI: Kari Kendra (OSU) and Siwen Hu-Lieskovan (UCLA)
Biostatisticians: M Wu, PhD & J Moon, MS

S1607, A Phase II Study of Combining T-VEC and PD-1 Blockade With Pembrolizumab In Patients With Advanced Melanoma Who Have Progressed On Anti-PD1 Therapy."
PI: Siwen Hu-Lieskovan (Huntsman Cancer Institute)
Biostatisticians: M Wu, PhD & J Moon, MS

S1616, "A Phase II Study of Ipilimumab and Nivolumab in Advanced Melanoma Following Progression on a PD-1 Inhibitor Alone."
PI: Ari VanderWalde (WCC)
Biostatisticians: M Wu, PhD & J Moon, MS

Melanoma Committee

S1404, "A Phase III Randomized Study of MK3475 versus High-Dose Interferon alfa-2b for Resected High-Risk Melanoma."

PI: Sapna Patel (MDACC)

Biostatisticians: M Othus, PhD, J Moon, MS & H Li, MS

S1221, "Phase I/II Study of the Safety and Efficacy of the AKT Inhibitor GSK2141795 in Combination with the BRAF Inhibitor Dabrafenib and

Trametinib in Patients with BRAF Mutant Cancer."

PI: Alain Algazi (UCSF) and Antoni Ribas (UCLA)

Biostatisticians: M Othus, PhD & J Moon, MS

ADVOCACY: Remarks (Sam Guild, JD, AIM at Melanoma)

CLOSING: New Chair remarks

MISSION AND VALUES

What We Do

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

What We Believe

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



Dana B. Sparks, MAT
Director of Operations and Protocols
SWOG Operations Office
San Antonio, TX

Melanoma Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1512	S1607	S1616	S1801	S2000	EA6134	EA6141	EA6174
Arizona CC, Univ of	-	-	-	6	-	-	-	3
Arkansas, U of	-	-	-	-	-	3	-	-
Boston Medical Ctr	-	-	-	1	-	-	-	-
CRC West MI NCORP	-	-	4	18	-	-	-	-
CROWN NCORP	-	-	1	1	-	-	-	-
Carle CC NCORP	-	-	-	1	-	-	-	-
Cincinnati MC, U of	-	-	-	-	-	-	-	2
City of Hope CCC	-	-	4	6	-	2	3	-
Cleveland Clinic OH	-	-	-	-	-	6	-	8
Colorado, U of	-	-	-	-	-	1	-	-
Columbus NCORP	-	-	-	1	-	-	-	-
Dayton NCORP	-	-	1	-	-	-	2	-
Georgia NCORP	1	-	-	-	-	-	-	-
Greenville NCORP	-	-	-	-	-	2	-	-
H Lee Moffitt CC	19	-	8	-	2	-	-	-
Harrington CC	-	-	-	2	-	-	-	-
Hawaii MU-NCORP	-	-	-	2	-	2	-	-
Heartland NCORP	-	-	-	5	-	-	-	-
Henry Ford Hospital	-	4	-	-	-	-	-	-
Irvine, U of CA	-	-	-	2	-	-	-	5
Kaiser Perm NCORP	-	-	5	11	-	19	21	-
Kansas City NCORP	-	-	-	-	-	-	1	-
Kansas MU-NCORP	2	1	2	5	-	2	-	-
Kentucky, U of	-	-	-	2	-	-	-	-
Loma Linda Univ	-	-	-	2	-	-	-	-
Los Angeles, U of CA	4	8	6	2	-	7	-	-
MAVERIC	-	-	-	4	-	-	-	-
MD Anderson CC	-	-	-	5	-	-	-	-
MUSC MU-NCORP	-	-	-	1	-	-	-	-

Melanoma Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 6/30/2021 by institution and study

	S1512	S1607	S1616	S1801	S2000	EA6134	EA6141	EA6174
Michigan CRC NCORP	-	-	-	4	-	-	-	-
Michigan, U of	-	-	-	15	-	-	-	-
Montana NCORP	-	-	1	2	-	-	-	-
Nevada CRF NCORP	-	-	-	-	-	-	-	1
New Mexico MU-NCORP	-	-	2	1	-	-	-	-
Northwell NCORP	-	-	-	4	-	-	-	-
Northwestern Univ	1	-	6	12	-	-	-	-
Ohio State Univ	6	4	8	9	-	4	-	-
Ozarks NCORP	-	-	-	-	1	-	-	-
PCRC NCORP	-	-	-	2	-	-	-	-
Rochester, Univ of	-	-	5	3	-	2	-	1
SCL Hlth St Joseph	-	-	-	-	-	-	-	1
San Antonio, U of TX	-	-	-	-	-	-	1	-
So Calif, U of	5	5	-	5	-	-	-	1
Southeast COR NCORP	1	-	-	-	-	-	-	-
Sutter Cancer RC	-	-	-	-	-	2	5	1
Tennessee, U of	-	-	7	-	-	-	-	-
UCSD Moores CC	-	-	2	-	-	-	-	-
Utah, U of	10	10	1	16	-	-	-	3
Vanderbilt Univ	-	1	1	-	-	-	-	-
Wayne State Univ	-	-	-	-	-	2	-	-
Western States NCORP	1	-	-	-	-	-	-	-
Wisconsin NCORP	-	-	1	8	-	-	-	-
Yale University	-	-	-	-	-	-	6	-
ALLIANCE	1	-	9	21	-	-	-	-
ECOG-ACRIN	2	8	7	35	1	-	-	-
NRG	4	2	13	36	1	-	-	-
Total	57	43	94	250	5	54	39	26

News from Our Committees

It's been a long time since we've met in person.

When you can't drop into a conference room, it's hard to get the latest news on trial activations, concepts-in-progress, and new committee members.

That's why we asked our chairs — from every SWOG disease/research and research support committee — to give you the fast scoop from their teams.

If you don't see a committee listed, the chair didn't provide an update.

We hope this check-in is helpful. Enjoy the fall meeting!

DISEASE/RESEARCH COMMITTEES

Breast



PUSZTAI

Chair: Lajos Pusztai, MD, DPhil

A recently activated trial we're excited about:

A unique trial to address systemic therapy of brain metastases in HER2-negative breast cancer: S2007, "A Phase II Trial of Sacituzumab Govitecan for Patients with HER2-Negative

Breast Cancer and Brain Metastases." The PI is Andrew Brenner, MD, PhD.

A concept we're working on that we're excited about:

Later this year we hope to activate one of the first circulating tumor DNA (ctDNA) monitoring and early intervention trials for molecular relapse in high-risk triple-negative breast cancer: S2202/DETECT-01 "Single arm Phase II Clinical Trial for Patients with Minimal Residual Disease Despite Therapy for Triple Negative Breast Cancer with Trop-2 Antibody Drug Conjugate, Sacituzumab Govitecan." This single arm phase II trial will implement ctDNA monitoring of high-risk triple-negative breast cancer after completion of all adjuvant therapy and will

treat patients with positive ctDNA with sacituzumab govitecan to assess ctDNA clearance and estimate the rate of recurrence at two years. Results will be used to design a definitive phase III randomized trial – DETECT-02.

A project we're excited about:

Integrated translational medicine studies on the recently completed S1416 trial are assessing homologous recombination deficiency (HRD) using liquid biopsy samples (circulating tumor cells and circulating tumor DNA) and correlate liquid biopsy HRD as a marker of response to PARP inhibitor-based therapy in patients with metastatic triple-negative breast cancer.

New publications or presentations:

We have changed practice. Results of the S1007/RxPONDER trial demonstrated that premenopausal women with one to three positive lymph nodes and a Recurrence Score <25 have improved disease free survival with adjuvant chemotherapy in addition to subsequent endocrine therapy compared to endocrine therapy alone, while postmenopausal women with similar characteristics can forego adjuvant chemotherapy. Results were presented at a 2020 San Antonio Breast Cancer Symposium oral session by Kevin Kalinsky, MD.

New committee leaders or members:

The breast committee has welcomed several new members in the past six months, including Anne Chiang, MD, PhD; Jade E.

Jones, MD; Kelsey E. Larson, MD; Sonya Reid, MD; Ruth Lauren Sacks, MD; Sagar Sardesai, MD; and Karla Sepulveda, MD.

Cancer Survivorship



MOORE



IRWIN

Co-Chairs: Halle Moore, MD and Melinda Irwin, MD

A recently activated trial we're excited about:

We are excited for Dan Raz, MD, MS, and Virginia Sun, PhD, MSN, RN's S2204

"Randomized Phase III Trial of a Perioperative Physical Activity Intervention in Older Adults with Lung Cancer and Their Family Caregivers."

A concept we're working on that we're excited about:

A concept we're working on that we're excited about is a focused "Cancer cachexia proposal: SWOG 0816 a secondary analysis of predictors of muscle wasting," led by Vickie Baracos, PhD.

New publications or presentations:

We will be having a presentation at our fall SWOG survivorship committee meeting on sleep and cancer outcomes given by Eric Zhou, PhD, from Dana-Farber Cancer Institute. His presentation is timely given a new Hope Foundation IMPACT award to Kerryn Reding, PhD, MPH, to address sleep disturbance in women with breast cancer.

Early Therapeutics and Rare Cancers



KURZROCK

Chair: Razelle Kurzrock, MD

Publications and presentations:

Michael Wagner, MD, showed that a subset of patients with the rare cancer angiosarcoma show remarkable responses to the combination of nivolumab and ipilimumab (DART trial). This work was recently published

in the *Journal for ImmunoTherapy of Cancer*.

Sylvia Adams, MD, showed that a subset of patients with

metaplastic breast cancer, a rare and aggressive type of breast cancer, show exceptional responses to the combination of nivolumab and ipilimumab (DART trial). An abstract was presented at ASCO and a paper has been submitted.

New leaders and members:

We have launched our Sarcoma Working Group under the leadership of Lara Davis, MD, and our CNS Working Group under the leadership of Manmeet Ahluwalia, MD, MBA.

Lung



KELLY

Chair: Karen Kelly, MD

A recently activated trial we're excited about:

We are very excited about the recent activation of LUNG MAP S1900E. This study is evaluating the recently approved KRAS G12C inhibitor sotorasib in distinct cohorts based on co-mutation status. Accrual has been brisk!

A concept we're working on that we're excited about:

Just in time for the fall meeting, S1934 "NASSIST: A randomized phase II trial of trimodality therapy +/- atezolizumab in resectable superior sulcus non-small cell lung cancer" will be activated. The current standard of care was established by a single-arm phase II trial led by SWOG, S9416 (INT 0160), over two decades ago. Given the overall survival benefit of durvalumab in stage III NSCLC, the addition of an immune checkpoint inhibitor warrants evaluation. Kudos to the multidisciplinary study team. Their dedication and hard work to bring you this trial has been exceptional. Please help us by accruing patients!

A project we're excited about:

We are currently designing the first-of-its-kind trial utilizing ctDNA for medical decision making. This SWOG CTP randomized trial will evaluate whether a combination regimen for patients with EGFR mutation positive tumors with persistent ctDNA at 3 weeks could be beneficial versus continuing osimertinib. The rationale for this study is based on data from FLAURA and S1403 demonstrating that patients who remain ctDNA positive after starting a TKI have poorer outcomes.

Lymphoma



FRIEDBERG

Chair: Jonathan Friedberg, MD

A recently activated trial we're excited about:

S1918, a randomized trial exploring the role of hypomethylating agents in older patients (age 75 years and above) with diffuse large B-cell lymphoma. This is one of the first NCTN trials

focused on this population of patients.

A concept we're working on that we're excited about:

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." This concept has been submitted to Lymphoma Steering Committee and will evaluate the role of three consolidation approaches for patients who achieve partial response or stable disease after CAR T-cell therapy for relapsed or refractory diffuse large B-cell lymphoma (DLBCL). This concept has also been reviewed and endorsed by the Bone Marrow Transplant Clinical Trials Network.

New publications or presentations:

ASH 2021 abstract submission: "Extranodal presentation in limited stage DLBCL as a prognostic marker in three sequential SWOG trials: S0014, S0313, and S1001 (NCT00005089, NCT00070018, NCT01359592)," Deborah M. Stephens, DO; Hongli Li, MS; Louis S. Constine, MD; Thomas J. Fitzgerald, MD; John P. Leonard, MD; Brad S. Kahl, MD; Joo Y. Song, MD; Michael L. LeBlanc, PhD; Sonali M. Smith, MD; Jonathan W. Friedberg, MD; and Daniel O. Persky, MD

Patients with limited stage DLBCL treated on three SWOG studies had excellent and prolonged progression-free survival and overall survival regardless of extranodal versus nodal presentation, or whether they had received consolidative radiation therapy. Our dataset does not support extranodal disease as an adverse prognostic factor for patients with limited stage DLBCL. As such, we do not recommend consolidation with radiotherapy in patients with non-bulky limited DLBCL presenting with extranodal disease.

Symptom Control and Quality of Life



FISCH



HENRY

Co-Chairs: Michael Fisch, MD, and Lynn Henry, MD

A recently activated trial we're excited about:

We have activated two trials focused on treatment toxicity. S2013, "Immune Checkpoint

Inhibitor Toxicity (I-CHECKIT): A Prospective Observational Study," is focused on patients receiving standard of care immunotherapy (without chemotherapy). It will inform us about immune-related adverse events that occur in these patients and who is at increased risk of developing them. We have also reactivated S1614, a study testing prophylactic antiviral therapy in patients with a solid tumor and current or past hepatitis B infection who are on anticancer therapy. This updated study now allows physician's choice of one of three commercial antiviral HBV agents that have high potency and low risk of drug resistance.

A concept we're working on that we're excited about:

We are developing a multidisciplinary concept involving a novel intervention for prevention of taxane-induced peripheral neuropathy. This initiative is being led by Melissa Accordini, MD, of Columbia University, and involves an intergroup collaboration with NRG and Alliance. This study is supported by pilot data and builds on our work in the ongoing S1714 trial led by Meghna Trivedi, MD: "A Prospective Observational Cohort Study to Assess the Incidence of Chemotherapy-Induced Peripheral Neuropathy (CIPN) in Cancer Patients."

New SWOG publications or presentations from our committee we're excited about:

SWOG colleagues from several different cancer control realms published a paper in the *ASCO Journal of Oncology Practice* about one of the most prevalent and troublesome symptoms – fatigue. Dr. Julia Mo and colleagues found that trial participants with clinically significant fatigue at baseline had worse survival and more adverse events than those without such fatigue. This indicates fatigue as an important baseline prognostic factor in oncology trials.

New committee members or leaders:

Yeun-Hee Park, MD, assistant professor, Columbia University and the James J. Peters Veterans Affairs Hospital in Bronx, NY.

RESEARCH SUPPORT COMMITTEES

Digital Engagement



DIZON

Chair: Don Dizon, MD

A project we're excited about:

The DEC has developed an industry outreach questionnaire to initially screen organizations interested in collaborating with SWOG or SWOG CTP on digital health initiatives.

The online form will make it easier for the committee to field inquiries about possible collaborative projects.

We are about to roll out our social media toolkits, which will accompany plain language summaries for each new SWOG trial. SWOG is also ready to post an opening for a plain language writer to draft the summaries and the accompanying social media toolkits for new trials as they approach launch.

Finally, the committee is also supporting the development of an online drug-drug interaction tool, a digital tool project led by DEC member Dan Hertz, PharmD, PhD. A phase I pilot completed in 2019 earned overwhelmingly positive feedback from end users and enabled sites to more quickly and easily screen patients on SWOG studies for possible drug-drug interactions. The project has funding from The Hope Foundation for a phase II quasi-experimental trial (comparing site screening data pre- vs. post-implementation) and is now recruiting oncology research professionals (ORPs) who screen patients for study eligibility, including drug-drug interactions. ORP staff receive financial compensation for their participation. Please contact Dr. Hertz if you are interested in participating: DLHertz@med.umich.edu.

Oncology Research Professionals



SZCZEPANEK

Chair: Connie Szczepanek, RN, BSN, CCRP

New publications and presentations:

Jamie Myers, PhD, RN, AOCNS, chair of the SWOG nursing research subcommittee and associate research professor for the University of Kansas School of Nursing has been selected to be a Fellow of the American Academy of Nursing. Induction into the Academy is a significant milestone in a nurse leader's career in which their accomplishments are honored by their colleagues within and outside the profession. Fellows are selected based on their contributions and impact to advance the public's health. As an inductee, Dr. Myers will be recognized for her significant contributions to health and health care at the Academy's annual Health Policy Conference, which takes place October 7-9, 2021.

Connie Szczepanek, RN, BSN, CCRP, SWOG ORP committee chair, was a presenter at the 2021 ASCO Annual Meeting. She shared "Changes in Clinical Trial Operations, Management, and Accessibility in a Post-COVID-19 World" as part of the "Transforming Clinical Trials to Improve Access and to Benefit All Patients with Cancer" education session.

Patient Advocates



BANGS

Chair: Rick Bangs, MBA

A recently activated trial we're excited about:

We look forward to seeing trials from SWOG research support committees, such as the digital engagement committee, that use tools like wearables to capture patient data.

We anticipate such tools will expand SWOG's reach into rural areas, though we recognize the challenges this may present for potential disparities.

A concept we're working on that we're excited about:

We are excited about the diversity, equity, and inclusion (DEI) work that SWOG is doing with Pope Consulting and will be looking for opportunities to contribute and to continue our partnership with the recruitment and retention committee.

A project we're excited about:

TeamScience Module 6, "Improving Diversity and Representativeness in SWOG Clinical Trial Participants," is rolling out across SWOG. Module 6 includes a brand-new methodology built from the ground up, an implementation guide, and 30-45 minutes of training and is targeted to leadership, SWOG study chairs, patient advocates, and SWOG biostatisticians (others can participate if they would like). The first wave of training started in August and includes the patient advocate and recruitment and retention committees. Leadership, study chairs, and biostatisticians follow. The implementation will be supported by our new DEI Fellow, Patricia Robinson, MD, funded with the generous support of The Hope Foundation.

New committee leaders or members:

We onboarded two new community advocates in the spring (La'Shae Wilson-Johnson/rural and Joël Pointon/LGBTQ) and opened up applications for three remaining community advocates in August: caregivers, advanced/metastatic, and adolescent and young adult (AYA). We hope to bring them onboard during the fall meeting.

Radiation Oncology



YU

Interim Chair: James B. Yu, MD, MHS

A recently activated trial we're excited about:

Two studies: One was actually activated two years ago: SWOG 1806, "Phase III Randomized Trial of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle Invasive Bladder Cancer." This study is poised to define the standard of care in trimodality therapy when it is completed.

Another study that SWOG is championing: NRG GU009 (PREDICT-RT). This study stratifies high-risk prostate cancer using the Decipher score and randomizes patients with high genomic risk cancers to radiation in combination with systemic therapy escalation (24 months androgen deprivation therapy [ADT] + apalutamide) or standard therapy (24 months ADT alone). For low genomic risk patients, patients are randomized to systemic therapy de-escalation (12 months ADT) vs. standard therapy (24 months ADT).

A concept we're working on that we're excited about:

Corey Speers, MD, PhD, and team at University of Michigan are working on a phase II study of a CDK 4/6 inhibitor administered concurrently with breast/chest wall and nodal radiation therapy in patients with locally advanced breast cancer. Patients with estrogen receptor-positive breast cancer may benefit from selective radiosensitization of breast cancer cells from CDK 4/6 inhibition.

New publications or presentations:

At ASCO 2021, a secondary analysis of S0809 presented by Sepideh Gholami, MD, indicated that patients with resected extrahepatic cholangiocarcinoma and gallbladder cancers who have lymph nodes involved by cancer have improved outcomes from chemoradiation (gemcitabine followed by combined capecitabine and radiotherapy) compared to historical data.

New committee leaders or members:

Last month we welcomed presentations by Josh Walker, MD, PhD, from Oregon Health & Science University and Michael Wagner, MD, from Fred Hutchinson Cancer Center. Dr. Walker presented a phase II study examining the addition of stereotactic ablative radiotherapy and losartan immunomodulation to standard of care treatment for metastatic nonsquamous non-small cell lung cancer. Dr. Wagner presented a neoadjuvant radiotherapy concept for angiosarcoma that he has been working on in the early therapeutics and rare cancers committee. As the radiation oncology committee is a research support committee, we welcome any and all investigators interested in radiotherapy and clinical trials.

Recruitment and Retention



CABAN-HOLT

Chair: Allison Caban-Holt, PhD

A recently activated trial we're excited about:

S1614 was recently re-activated. This trial was discussed at the SWOG group meeting recruitment and retention meeting in 2019. We're excited to see how the new protocol impacts accrual. Study chair Jessica Hwang, MD, MPH, will participate

in the fall 2021 group meeting (recruitment and retention meeting) as part of a panel for TAKE ACTION Series II – Ensuring Health Equity in SWOG Clinical Trials Among Asian Americans.

A project we're excited about:

Our committee and working group DIBS (Diversity, Inclusion, and Belonging), in collaboration with the patient advocate committee and with funding from The Hope Foundation, continues diversity, equity, and inclusion (DEI) planning for SWOG. The DIBS strategic plan and champion description have been finalized, a DEI consultant hired, and a DEI fellow named. We look forward to the next phase of implementation to promote DEI and provide guidance at all levels of SWOG membership and leadership.

New publications or presentations:

The TAKE ACTION series, developed by the education working group, kicked off in 2021. Series I – Ensuring Health Equity in SWOG Clinical Trials Among African Americans was held at the spring 2021 group meeting. Series II – Ensuring Health Equity in SWOG Clinical Trials Among Asian Americans will be held at the fall 2021 group meeting.

New committee leaders or members:

We greatly appreciate the leadership of the following RRC members:

Education working group and TAKE ACTION series: Kamara Mertz-Rivera, CCRC, and Lucy Gansauer, MSN, RN, OCN, CCRP

DIBS working group members: Marian Neuhouser, PhD, RD; Colmar Figueroa-Moseley, PhD, MPH; Electra Paskett, PhD; Melyssa Foust, MSN, RN; Desiree Walker, BA; Kamara Mertz-Rivera, CCRC; Lucy Gansauer, MSN, RN, OCN, CCRP; and Allison Caban-Holt, PhD

Veterans Affairs



BARTLETT

Chair: Stephen D. Bartlett, RPh, MSPH

A new committee we're excited about:

At the spring 2021 SWOG group meeting, the board of governors recognized the promotion of the VA working group to officially become the VA committee, a new member of the

SWOG research support committees. Our current roster of

approximately 80 members looks forward to continuing the effort of expanding the treatment horizons offered to veterans needing care.

During our first meeting as an official research support committee, tentative agenda topics include:

- VA Tandem Enrollment Advisory Group status/report
- S2105 presentation – Two Standards of Care in Frontline Myeloma Regimen

A project we're working on that we're excited about:

Following many months of planning, the SWOG VA program development team recently finalized the development of a new liaison position to work with SWOG's research committees. The VA liaisons will help provide a voice and perspective in protocol development and design regarding common VA population implementation issues. Our initial application search recently concluded with the VA representative selection subcommittee approving VA liaisons to five SWOG research committees. We look forward to adding additional liaisons in the future.

In addition, we and the NRG veterans workgroup have started conversations to coordinate our efforts to provide clinical research options for veterans.

New committee members or leaders:

VA program development team:

- Sara Schiller, MPH (MAVERIC); Connie Barnes (SWOG); Leslie Weissenstein (SWOG)

VA representative selection subcommittee:

- Stephen Bartlett, RPh, MSPH; Sara Schiller, MPH; Mary Brophy, MD, MPH (MAVERIC PI, VAMC Boston); Mark Garzotto, MD (OHSU); Suman Kambhampati, MD (VAMC Kansas City); Robert Krouse, MD (VAMC Philadelphia)

Our new VA research committee liaison members are:

- Genitourinary – Michael M. Goodman, MD
- Lung – Cheryl M. Czerlanis, MD; Chao Hui Huang, MD
- Lymphoma – Helen Ma, MD
- Myeloma – Thomas R. Chauncey, MD, PhD
- Symptom Control and Quality of Life – Yeun-Hee Anna Park, MD

Publication List by Committee

The publications listed below were received by the Group Chair's Office as published, accepted, submitted or reflect change in status since the SWOG Spring 2021 Group Meeting. Conference abstracts are not included.

ADOLESCENT AND YOUNG ADULT (AYA) COMMITTEE

Published/Accepted Manuscripts

Multiple Studies Adolescent and young adult enrollment to a National Cancer Institute-sponsored National Clinical Trials Network Research Group over 25 years. Unger J, Beauchemin M, Hershman DL. *Cancer*, Aug 5. doi: 10.1002/cncr.33855. Online ahead of print, 2021. [see also CCD Cmte] <https://pubmed.ncbi.nlm.nih.gov/34351619/>

N/A Breast Cancer in Adolescent and Young Adult Women Under the Age of 40 Years. Cathcart-Rake EJ, Ruddy KJ, Bleyer A, Johnson RH. *JCO Oncology Practice*, Jun 17(6): 305-313, 2021. <https://pubmed.ncbi.nlm.nih.gov/33449828/>

C10403 Superior survival with pediatric-style chemotherapy compared to myeloablative allogeneic hematopoietic cell transplantation in older adolescents and young adults with Ph-negative acute lymphoblastic leukemia in first complete remission: analysis from CALGB 10403 and the CIBMTR. Wieduwilt M, Stock W, Advani A, Luger S, Larson R, Tallman M, Appelbaum F, Zhang M-J, Bo-Subait K, Wang H-L, Bhatt V, Dholaria B, Eapen M, Hamadani M, Jamy O, Prestidge T, Pulsipher M, Ritchie D, Rizzieri D, Sharma A, Barba P, Sandmaier B, de Lima M, Kebriaei P, Litzow M, Saber W, Weisdorf D. *Leukemia*, Jul;35(7):2076-2085, 2021. [see also Leuk Cmte] <https://pubmed.ncbi.nlm.nih.gov/33785862/>

Submitted Manuscripts

(none this cycle)

BARLOGIE-SALMON MYELOMA COMMITTEE

Published/Accepted Manuscripts

(none this cycle)

Submitted Manuscripts

(none this cycle)

BREAST COMMITTEE

Published/Accepted Manuscripts

S0226 Evaluating Serum Thymidine Kinase 1 in Hormone Receptor Positive Metastatic Breast Cancer Patients Receiving First Line Endocrine Therapy in the SWOG S0226 Trial. Paoletti C, Barlow W, Cobain E, Bergqvist M, Mehta R, Gralow J, Hortobagyi G, Albain K, Pusztai L, Sharma P, Godwin A, Thompson A, Hayes D, Rae J. *Clinical Cancer Research*, Sep 14;clinres.1562.2021. doi: 10.1158/1078-0432.CCR-21-

1562. Online ahead of print, 2021.

<https://pubmed.ncbi.nlm.nih.gov/34521624/>

S1007/Other Gene expression signatures for tailoring adjuvant chemotherapy of luminal breast cancer: stronger evidence, greater trust [Editorial]. Piccart MJ, Kalinsky K, Gray R, Barlow WE, Poncet C, Cardoso F, Winer E, Sparano J. *Annals of Oncology*, Sep;32(9):1077-1082, 2021.

<https://pubmed.ncbi.nlm.nih.gov/34082017/>

E2112 E2112: Randomized phase III trial of endocrine therapy plus entinostat/placebo in hormone receptor-positive advanced breast cancer. A trial of the ECOG-ACRIN Cancer Research Group. Connolly RM, Zhao F, Miller K, Lee M, Piekarz R, Smith K, Brown-Glaberman U, Faller B, Onitilo AA, Burkard M, Budd GT, Levine E, Royce M, Kaufman P, Thomas A, Trepel J, Wolff A, Sparano J. *Journal of Clinical Oncology*, Aug 6;JCO2100944. doi: 10.1200/JCO.21.00944. Online ahead of print, 2021.

<https://pubmed.ncbi.nlm.nih.gov/34357781/>

EA1131 Randomized Phase III Postoperative Trial of Platinum-Based Chemotherapy Versus Capecitabine in Patients With Residual Triple-Negative Breast Cancer Following Neoadjuvant Chemotherapy: ECOG-ACRIN EA1131. Mayer I, Zhao F, Arteaga C, Symmans WF, Park B, Burnette B, Tevaarwerk A, Garcia S, Smith K, Makower D, Block M, Morley K, Jani C, Mescher C, Dewani S, Tawfik B, Flaum L, Mayer E, Sikov W, Rodler E, Wagner L, DeMichele A, Sparano J, Wolff A, Miller K. *Journal of Clinical Oncology*, Aug 10;39(23):2539-2551, 2021.

<https://pubmed.ncbi.nlm.nih.gov/34092112/>

MA.32 Effect of metformin versus placebo on metabolic factors in the MA.32 randomized breast cancer trial. Goodwin P, O'Dowling R, Ennis M, Chen B, Parulekar W, Shepherd L, Burnell M, Vander Meer R, Molckovsky A, Gurjal A, Gelmon K, Ligibel J, Hershman D, Mayer I, Whelan T, Hobday T, Rostogi P, Rabaglio-Poretti M, Lemieux J, Thompson A, Rea D, Stambolic V. *NPJ Breast Cancer* Jun 8;7(1):74, 2021.

<https://pubmed.ncbi.nlm.nih.gov/34103538/>

N0733 Randomized Phase II Trial of Capecitabine and Lapatinib with or without IMC-A12 (Cituxumumab) in Patients with HER2-Positive Advanced Breast Cancer Previously Treated with Trastuzumab and Chemotherapy: NCCTG N0733 (Alliance). Haddad T, He J, O'Sullivan C, Chen B, Northfelt D, Dueck A, Ballman K, Tenner K, De Silva C, Linden H, Perez E, Goetz M, Haluska P. *Breast Cancer Research and Treatment* Jul;188(2):477-487, 2021. <https://pubmed.ncbi.nlm.nih.gov/33852121/>

Publication List by Committee

Submitted Manuscripts

S1007 21-Gene Assay to Inform Chemotherapy Benefit in Node-Positive Breast Cancer. Kalinsky K, 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, Martin M, Kelly C, Ruiz-Borrego M, Gil-Gil M, Arce-Salinas C, Brain E, Lee E, Pierga J-Y, Bermejo B, Ramos-Vasquez M, Jung K, Ferrero J-M, Schott A, Shak S, Sharma P, Lew DL, Miao J, Tripathy D, Puzstai L, Hortobagyi G. *New England Journal of Medicine*, resubmitted/under review 2021.

S1222 A randomized trial of fulvestrant, everolimus and anastrozole in the front line treatment of advanced hormone receptor positive breast cancer, SWOG S1222. Moore HCF, Barlow W, Somlo G, Gralow J, Schott A, Hayes D, Kuhn P, Hicks J, Dy P, Yeon C, Conlin A, Balcueva E, Lew D, Tripathy D, Puzstai L, Hortobagyi G. *Clinical Cancer Research*, submitted 2021.

CANCER CONTROL AND PREVENTION

Cancer Care Delivery Committee

Published/Accepted Manuscripts

S1400GEN Patient Knowledge and Expectations About Return of Genomic Results in a Biomarker-Driven Master Protocol Trial (LungMAP SWOG S1400GEN). Roth J, Trivedi M, Gray S, Patrick D, Delaney D, Watabayashi K, Litwin P, Shah P, Crew K, Yee M, Redman M, Unger J, Papadimitrakopoulou V, Johnson J, Kelly K, Gandara D, Herbst RS, Hershman D, Ramsey S. *Journal of Oncology Practice* Apr 2;OP2000770. doi: 10.1200/OP.20.00770. Online ahead of print, 2021. [see also Lung Committee] <https://pubmed.ncbi.nlm.nih.gov/33797955/>

Multiple Studies Persistent disparity: Socioeconomic deprivation and cancer outcomes in patients treated in SWOG NCTN clinical trials. Unger J, Moseley A, Cheung C, Osarogiagbon R, Symington B, Ramsey S, Hershman D. *Journal of Clinical Oncology* Apr 20;39(12):1339-1348, 2021. <https://pubmed.ncbi.nlm.nih.gov/33729825/>

Multiple Studies Cancer Clinical Trial Participation at the 1-Year Anniversary of the Outbreak of the COVID-19 Pandemic. Unger J, Xiao H, Leblanc M, Hershman D, Blanke CD. *JAMA Network Open*, Jul 1;4(7):e2118433, 2021. <https://pubmed.ncbi.nlm.nih.gov/34323986/>

Multiple Studies Adolescent and young adult enrollment to a National Cancer Institute-sponsored National Clinical Trials Network Research Group over 25 years. Unger J, Beauchemin M, Hershman DL. *Cancer*, Aug 5. doi: 10.1002/cncr.33855. Online ahead of print, 2021. [see also AYA committee] <https://pubmed.ncbi.nlm.nih.gov/34351619/>

N/A* Current Practices for Screening and Addressing Financial Hardship within the NCI Community Oncology Research Program. McLouth LE, Nightingale CL, Dressler EV, Snavey AC, Hudson MF, Unger JM, Kazak AE, Lee SJC, Edward J, Carlos R, Kamen CS, Neuman HB, Weaver KE. *Cancer Epidemiology, Biomarkers & Prevention*. Apr;30(4):669-675, 2021. [*NCORP 2017 Landscape Survey] <https://pubmed.ncbi.nlm.nih.gov/33355237/>

N/A* Caregiver engagement practices in National Cancer Institute Clinical Oncology Research Program settings: Implications for research to advance the field. Nightingale CL, Sterba KR, McLouth LE, Kent EE, Dressler EV, Dest A, Snavey AC, Adonizio CS, Wojtowicz M, Neuman HB, Kazak AE, Carlos RC, Hudson MF, Unger JM, Kamen CS, Weaver KE. *Cancer*, Feb 15;127(4):639-647, 2021. [*NCORP 2017 Landscape Survey] <https://pubmed.ncbi.nlm.nih.gov/33136296/>

Submitted Manuscripts

S1204 Antiviral Therapy Use, Changes in Anticancer Treatment, and Adverse Viral Outcomes in Patients with Cancer and Viral Infections: Results from a Multicenter Observational Study (SWOG S1204). Hwang J, Arnold K, Unger J, Chugh R, Tincopa M, Loomba R, Hershman D, Ramsey S. *JCO Oncology Practice*, revised/resubmitted 2021.

S1204 Universal Viral Screening of Newly Diagnosed Cancer Patients in the United States: A Cost Efficiency Evaluation. Schwartz N, Unger J, Loomba R, Hwang J, Chugh R, Konerman M, Arnold K, Hershman D, Ramsey S. *American Journal of Preventive Medicine*, submitted 2021.

S1417CD S1417CD: A Prospective Multicenter Cooperative Group-Led Study of Financial Hardship in Metastatic Colorectal Cancer Patients. Shankaran V, Unger J, Darke A, Suga J, Wade J, Kourlas P, Chandana S, O'Rourke M, Satti S, Liggett D, Hershman D, Ramsey S. *Journal of the National Cancer Institute*, revised/resubmitted 2021.

Cancer Survivorship Committee

Published/Accepted Manuscripts

C89803 Race, Income, and Survival in Stage III Colon Cancer: CALGB 89803 (Alliance). Lee S, Zhang S, Ou F-S, Ogino S, Niedzwiecki D, Saltz L, Mayer R, Mowat R, Whittom R, Hantel A, Benson A, Atienza D, Messino M, Kindler H, Venook A, Gross C, Irwin M, Meyerhardt J, Fuchs C. *JNCI Cancer Spectrum* Apr 12;5(3):pkab034, 2021. [see also GI Cmte] <https://pubmed.ncbi.nlm.nih.gov/34104867/>

C/S80405 Racial Differences in Survival and Response to Therapy in Patients with Metastatic Colorectal Cancer: A Secondary Analysis of CALGB/SWOG 80405 (Alliance A151931). Snyder R, He J, Le-Rademacher J, Ou F-S, Dodge A, Zemla T, Paskett E, Chang G, Innocenti F, Blanke

Publication List by Committee

CD, Lenz H-J, Polite B, Venook A. *Journal of Clinical Oncology*, Aug 10. doi: 10.1002/cncr.33649. Online ahead of print, 2021. [see also GI Cmte] <https://pubmed.ncbi.nlm.nih.gov/34374082/>

E1505 Smoking Behavior in Patients With Early-Stage NSCLC: A Report From ECOG-ACRIN 1505 Trial. Steuer C, Jegede O, Dahlberg S, Wakelee H, Keller S, Tester W, Gandara D, Graziano S, Adjei A, Butts C, Ramalingam S, Schiller J. *Journal of Thoracic Oncology* Jun;16(6):960-967, 2021. [see also Lung Cmte] <https://pubmed.ncbi.nlm.nih.gov/33539971/>

N/A Who are the women who enrolled in the POSITIVE trial: A global study to support young hormone receptor positive breast cancer survivors desiring pregnancy. Partridge AH, Niman SM, Ruggeri M, Peccatori FA, Azim HA Jr, Colleoni M, Saura C, Shimizu C, Sætersdal AB, Kroep JR, Mailliez A, Warner E, Borges VF, Amant F, Gombos A, Kataoka A, Rousset-Jablonski C, Borstnar S, Takei J, Lee JE, Walshe JM, Borrego MR, Moore HC, Saunders C, Cardoso F, Susnjar S, Bjelic-Radisic V, Smith KL, Piccart M, Korde LA, Goldhirsch A, Gelber RD, Pagani O. *Breast*, Aug 3;59:327-338, 2021 <https://pubmed.ncbi.nlm.nih.gov/34390999/>

Submitted Manuscripts

(none this cycle)

Palliative and End of Life Care Committee

Published/Accepted Manuscripts

S1820 SWOG S1820: Altering Intake, Managing Symptoms for bowel dysfunction in survivors of Rectal Cancer (The AIMS-RC intervention trial). Sun V, Crane T, Arnold K, Guthrie K, Freylersthe S, Braun-Inglis C, Jones L, Cohen S, Al-Kasspooles M, Krouse R, Thomson CA. *Contemporary Clinical Trials* Apr 8;22:100768, 2021. <https://pubmed.ncbi.nlm.nih.gov/33997460/>

Multiple Studies* The Association of Patient Fatigue and Outcomes in Advanced Cancer: An Analysis of Four SWOG Treatment Trials. Mo J, Darke A, Guthrie K, Sloan J, Unger J, Hershman D, O'Rourke M, Bakitas M, Krouse R. *JCO Journal of Oncology Practice*, Aug;17(8):e1246-e1257, 2021. [*S0027,S0421,S9509,S9916] <https://pubmed.ncbi.nlm.nih.gov/34255538/>

Multiple Studies* Association between Health-Related Quality of Life and Progression Free Survival in Patients with Advanced Cancer: A Secondary Analysis of SWOG Clinical Trials. Hui D, Darke A, Guthrie K, Subbiah I, Unger J, Hershman D, Krouse R, Bakitas M, O'Rourke M. *JCO Oncology Practice*, accepted 2021. [*S0027,S0421,S9509]

N/A Hope, Burnout, and Life Satisfaction: An Intriguing Trinity Among Investigators of the SWOG Cancer Research Network. Feldman

D, O'Rourke M, Bakitis M, Krouse R, Deiniger H, Hudson M, Corn B. *JCO Oncology Practice* Jul;17(7):e908-e916, 2021. <https://pubmed.ncbi.nlm.nih.gov/33900801/>

Submitted Manuscripts

(none this cycle)

Prevention and Epidemiology Committee

Published/Accepted Manuscripts

S0000/Other Discovery and fine-mapping of height loci via high-density imputation of GWASs in individuals of African ancestry. Graff M, Justice A, Young K, Marouli E, Zhang X, Fine R, Goodman P, Hsing A, Klein E, Neuhauser M, Sucheston L, Loos R, Ng M, North K. *American Journal of Human Genetics* Apr 1;108(4):564-582, 2021. <https://pubmed.ncbi.nlm.nih.gov/33713608/>

S0000/Other Smoking modifies pancreatic cancer risk loci on 2q21.3. Mocci E, Kundu P, Wheeler W, Arslan A, Freeman L, Bracci P, Goodman P, Albanes D, Fuchs C, Gaziano JM, Thompson IM, Wolpin B, Risch H, Kraft P, Chatterjee N, Klein A, Stolzenberg-Solomon R. *Cancer Research*, Jun 1;81(11):3134-3143, 2021. <https://pubmed.ncbi.nlm.nih.gov/33574088/>

S0000/Other Large-scale cross-cancer fine-mapping of the 5p15.33 region reveals multiple independent signals. Chen H, Majumdar A, Wang L, Kar S, Brown K, Feng H, Pharoah P, Hung R, Amundadottir L, Kraft P, Pasanici B, Lindstrom S, GECCO Consortium [C Tangen]. *HGG Advances* Jul 8;2(3):100041, 2021. <https://pubmed.ncbi.nlm.nih.gov/34355204/>

S0000/Other A 584bp deletion in CTRB2 inhibits chymotrypsin B2 activity and secretion, and confers risk of pancreatic cancer. Jermusyk A, Zhong J, Connelly K, Gordon N, Perera S, Abdolizadeh E, Zhang T, O'Brien A, Hoskins J, Collins I, Eiser D, Yuan C, PanScan Consortium [Goodman P, collaborator], PanC4 Consortium, Risch H, Jacobs E, Li D, Du M, Stolzenberg-Solomon R, Klein A, Smith J, Wolpin B, Chanock S, Shi J, Petersen G, Westlake C, Amundadottir L. *American Journal of Human Genetics*, accepted 2021.

S0820/Other Using increased trust in medical researchers to increase minority recruitment: The RECRUIT cluster randomized clinical trial. Tilley B, Mainous A, Amorrortuac R, McKee M, Smith D, Li R, DeSantisa S, Vernon S, Koch G, Ford M, Diaz V, Alvidrez J, additional RECRUIT Trial Center and Parent Trials' investigators [includes PACES trial (S0820 – Jason Zell, PI)]. *Contemporary Clinical Trials*, Jul 30;109:106519, 2021. <https://pubmed.ncbi.nlm.nih.gov/34333138/>

S9217 Adherence with protocol medication use and mortality from

Publication List by Committee

unrelated causes in a prevention trial. Pinsky P, Goodman P, Parnes H, Ford L, Minasian L. *Preventive Medicine*, Aug 24;106778. doi: 10.1016/j.ypmed.2021.106778. Online ahead of print, 2021.

<https://pubmed.ncbi.nlm.nih.gov/34450188/>

Multiple Studies* Genetically predicted circulating concentrations of micronutrients and risk of colorectal cancer among individuals of European descent: a Mendelian randomization study. Tsilidis K, Papadimitriou N, Dimou N, Gill D, Lewis S, Martin R, Albanes D, Goodman P, Platz E, Schenk J, Gruber S, Peters U, Gunter M. *American Journal of Clinical Nutrition* Jun 1;113(6):1490-1502, 2021. [*S0000, S9217, Other] <https://pubmed.ncbi.nlm.nih.gov/33740060/>

Multiple Studies* Performance of African-ancestry-specific polygenic hazard score varies according to local ancestry in 8q24. Karunamuni RA, Huynh-Le M-P, Fan CC, Thompson W, Lui A, Martinez ME, Rose BS, Mahal B, Eeles RA, Kote-Jarai Z, Muir K, Lophatananon A, Tangen CM, Goodman PJ, Thompson IM, Andreassen O, Dale AM, Seibert TM. *Prostate Cancer and Prostatic Diseases*, Jun 14. doi: 10.1038/s41391-021-00403-7. Online ahead of print, 2021. [*S0000, S9217, Other] <https://pubmed.ncbi.nlm.nih.gov/34127801/>

Multiple Studies* Hepcidin-regulating iron-metabolism genes and pancreatic ductal adenocarcinoma: a pathway analysis of genome-wide association studies. Julian-Serrano S, Yuan F, Wheeler W, Benyamin B, Machiela M, Arslan A, Goodman P, Zheng W, Albanes D, Fuchs C, Thompson IM, Wolpin B, Risch H, Amundadottir L, Klein A, Yu K, Stolzenberg-Solomon R, PanCfour Consortia PanScan. *American Journal of Clinical Nutrition* Jul 13;nqab217. doi: 10.1093/ajcn/nqab217. Online ahead of print, 2021. [*S0000, S9217, Other] <https://pubmed.ncbi.nlm.nih.gov/34258619/>

Submitted Manuscripts

S0000/Other Prediction of future risk of any and higher-grade prostate cancer based on the PLCO and SELECT trials. Gelfond J, Hernandez B, Goros M, Ibrahim J, Chen M, Sun W, Liss M, Leach R, Thompson I, Ankerst D. *World Journal of Urology*, submitted 2021.

S0000/Other Accommodating population differences in model validation. Pfeiffer R, Chen Y, Gail M, Ankerst D. *Statistics in Medicine*, submitted 2021.

S0000/Other Dysregulated super-enhancers in colorectal cancer are beacons for discovering genetic risk loci. Bien S, Harrison T, Huyghe J, Lu Y, Wang H, Shcherbina A, Albanes D, Goodman P, Platz E, Tangen C, Le Marchand L, Zheng W, Gruber S, Hsu L, Schacheri P, Peters U. *Nature Communications*, submitted 2021.

S0000/Other Shedding light on the association between genetically-defined BMI and early-onset colorectal cancer in a pooled analysis [Brief Communication]. Archambault A, Gruber S, Le Marchand L, Hsu L, Peters U, Hayes R, on behalf of the Colorectal Transdisciplinary (CORECT) Study, the Colon Cancer Family Registry (CCFR), Genetics and Epidemiology of Colorectal Cancer Consortium (GECCO) [P Goodman, C Tangen, GECCO collaborators]. *Gastroenterology*, submitted 2021.

S0000/S9217 Long-term Complications of Prostate Cancer Treatment. Unger J, Till C, Tangen C, Goodman P, Leblanc M, Barlow W, Vaidya R, Minasian L, Parnes H, Thompson IM. *Journal of the National Cancer Institute*, submitted 2020.

S0000C Change in Plasma Alpha-Tocopherol Associations with Attenuated Pulmonary Function Decline and with CYP4F2 Missense Variation. Xu J, Guertin K, Gaddis N, Agler A, Parker R, Feldman J, Kristal A, Arnold K, Goodman P, Tangen C, Hancock D, Cassano P. *American Journal of Clinical Nutrition*, submitted 2021.

S9217 Serum Markers, Obesity and Prostate Cancer Risk: Results from the Prostate Cancer Prevention Trial. Chau C, Till C, Price D, Goodman P, Neuhaus M, Pollak M, Thompson I, Figg W. *Endocrine-Related Cancer*, under revision for re-submission 2021.

Multiple Studies* A prostate cancer susceptibility PSA variant that confers lower risk is also associated with more aggressive disease and poor survival. Srinivasan S, Kryza T, Bock N, Stephens C, Dong Y, Panchadsaram J, Moya L, Rohl J, Perry-Keene J, Buzacott K, Gago M, Schleutker J, Maier C, Muir K, Tangen C, Gronberg H, Pashayan N, Albanes D, Wolk A, Eles R, Clements J, Batra J. *Cancer Discovery*, submitted 2021. [*S0000, S9217, OTHER]

Symptom Control and Quality of Life Committee

Published/Accepted Manuscripts

S1202 Adverse Events and Perception of Benefit From Duloxetine for Treating Aromatase Inhibitor-Associated Arthralgias. Schnell P, Lustberg M, Henry NL. *JNCI Cancer Spectrum* Feb 8;5(2):pkab018, 2021. <https://pubmed.ncbi.nlm.nih.gov/33842832/>

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S1200 Long-term findings from a Randomized Trial Comparing Acupuncture vs Sham Acupuncture or Waitlist Control on Joint Pain Related to Aromatase Inhibitors Among Women with Early-Stage Breast Cancer: SWOG S1200 [Brief Report]. Hershman D, Unger J, Greenlee H, Capodice J, Lew D, Darke A, Minasian L, Fisch M, Henry NL, Crew K. *JAMA Oncology*, submitted 2021.

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

Multiple Studies* Predictors of pain reduction in trials of interventions for aromatase inhibitor-associated musculoskeletal symptoms. Henry NL, Unger JM, Till C, Crew KD, Fisch MJ, Hershman DL. JNCI Cancer Spectrum, under review. [*S0927, S1200, S1202]

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

DIGITAL ENGAGEMENT COMMITTEE

Published/Accepted Manuscripts

(none this cycle)

Submitted Manuscripts

(none this cycle)

EARLY THERAPEUTICS AND RARE CANCERS COMMITTEE

Published/Accepted Manuscripts

S1609 A Multicenter Phase II Trial (SWOG S1609, Cohort 5) of Ipilimumab and Nivolumab in Metastatic or Unresectable Angiosarcoma: a Sub-Study of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART). Wagner M, Othus M, Patel S, Ryan C, Sangal A, Powers B, Budd G, Victor A, Hsueh C-T, Chugh R, Nair S, Leu K, Agulnik M, Sharon E, Mayerson E, Plets M, Blanke C, Streicher H, Chae YK, Kurzrock R. Journal of Immunotherapy of Cancer, Aug;9(8):e002990. doi: 10.1136/jitc-2021-002990, 2021. <https://pubmed.ncbi.nlm.nih.gov/34380663/>

S1609 A Phase II Basket Trial of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART) SWOG S1609: High-Grade Neuroendocrine Neoplasm Cohort. Patel S, Othus M, Chae YK, Strosberg J, Wang J, Konda B, Hayward J, McLeod C, Chen H, Sharon E, Mayerson E, Ryan C, Plets M, Blanke CD, Kurzrock R. Cancer, Sep 1;127(17):3194-3201, 2021. <https://pubmed.ncbi.nlm.nih.gov/33882143/>

S1609 A Multicenter Phase II Trial of Ipilimumab and Nivolumab in Unresectable or Metastatic Metaplastic Breast Cancer: Cohort 36 of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART, SWOG S1609). Adams S, Othus M, Patel S, Miller K, Chugh R, Schuetz S, Chamberlin M, Haley B, Storniolo A, Cawley K, Reddy M, Anderson S, Zimmerman C, O'Dea A, Mirshahidi M, Ahnert J, Brescia F, Hahn O, Raymond J, Biggs D, Thompson M, Connolly R, Sharon E, Korde L, Gray R, Mayerson E, Plets M, Blanke CD, Chae YK, Kurzrock R. Clinical Cancer Research, accepted 2021.

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S8006/Others Chemotherapy and radiotherapy in locally advanced head and neck cancer: an individual patient data network meta-analysis. Petit C, Lacas B, Pignon JP, Le QT, Grégoire V, Grau C, Hackshaw A, Zackrisson B, Parmar MKB, Lee JW, Ghi MG, Sanguineti G, Temam S, Cheugoua-Zanetsie M, O'Sullivan B, Posner MR, Vokes EE, Cruz Hernandez JJ, Szutkowski Z, Lartigau E, Budach V, Suwiński R, Poulsen M, Kumar S, Ghosh Laskar S, Mazon JJ, Jeremic B, Simes J, Zhong LP, Overgaard J, Fortpied C, Torres-Saavedra P, Bourhis J, Aupérin A, Blanchard P; MACH-NC and MARCH Collaborative Groups [including SWOG collaborators, J Moon, G Wolf, J Adelstein, A Argiris]. Lancet Oncology May;22(5):727-736, 2021. <https://pubmed.ncbi.nlm.nih.gov/33862002/>

Submitted Manuscripts

(none this cycle)

EXECUTIVE COMMITTEE

Published/Accepted Manuscripts

(none this cycle)

GASTROINTESTINAL COMMITTEE

Published/Accepted Manuscripts

S1513 Randomized Phase II Study of PARP Inhibitor ABT-888 (Veliparib)

Publication List by Committee

with Modified FOLFIRI versus FOLFIRI as Second Line Treatment of Metastatic Pancreatic Cancer: SWOG S1513. Chiorean EG, Guthrie K, Philip P, Swisher E, Jalikis F, Pishvaian M, Berlin J, Noel M, Suga J, Garrido-Laguna I, Cardin D, Radke M, Duong M, Lowy A, Hochster H. Clinical Cancer Research, accepted 2021.

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C/S80405 Racial Differences in Survival and Response to Therapy in Patients with Metastatic Colorectal Cancer: A Secondary Analysis of CALGB/SWOG 80405 (Alliance A151931). Snyder R, He J, Le-Rademacher J, Ou F-S, Dodge A, Zemla T, Paskett E, Chang G, Innocenti F, Blanke CD, Lenz H-J, Polite B, Venook A. Journal of Clinical Oncology, Aug 10. doi: 10.1002/jco.33649. Online ahead of print, 2021. [see also Ca Surv Committee] <https://pubmed.ncbi.nlm.nih.gov/34374082/>

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C80702 Combining tumor deposits with the number of lymph node metastases to improve the prognostic accuracy in stage III colon cancer: a post hoc analysis of the CALGB/SWOG 80702 phase III study (Alliance). Cohen R, Shi Q, Meyers J, Jin Z, Svrcek M, Fuchs C, Couture F, Kuebler P, Bendell J, De Jesus-Acosta A, Kumar P, Lewis D, Tan B, Bertagnolli M, Philip PA, Blanke CD, O'Reilly E, Shields AF, Meyerhardt J. Annals of Oncology, Jul 19;S0923-7534(21)02187-6. doi: 10.1016/j.annonc.2021.07.009. Online ahead of print, 2021. <https://pubmed.ncbi.nlm.nih.gov/34293461/>

C80702 Effect of Celecoxib vs Placebo Added to Standard Adjuvant Therapy on Disease-Free Survival Among Patients With Stage III Colon Cancer: The CALGB/SWOG 80702 (Alliance) Randomized Clinical Trial. Meyerhardt J, Shi Q, Fuchs C, Meyer J, Niedzwiecki D, Zemla T, Kumthekar P, Guthrie K, Couture F, Kuebler JP, Bendell J, Kumar P, Lewis D, Tan B, Bertagnolli M, Grothey A, Hochster H, Goldberg R, Venook A, Blanke CD, O'Reilly E, Shields AF. Journal of the American Medical Association Apr 6;325(13):1277-1286, 2021. <https://pubmed.ncbi.nlm.nih.gov/33821899/>

C89803 Race, Income, and Survival in Stage III Colon Cancer: CALGB

89803 (Alliance). Lee S, Zhang S, Ou F-S, Ogino S, Niedzwiecki D, Saltz L, Mayer R, Mowat R, Whittom R, Hantel A, Benson A, Atienza D, Messino M, Kindler H, Venook A, Gross C, Irwin M, Meyerhardt J, Fuchs C. JNCI Cancer Spectrum Apr 12;5(3):pkab034, 2021. [see also Ca Surv Cmte] <https://pubmed.ncbi.nlm.nih.gov/34104867/>

Multiple Studies* Sex and Adverse Events of Adjuvant Chemotherapy in Colon Cancer: An Analysis of 34 640 Patients in the ACCENT Database. Wagner A, Grothey A, Andre T, Dixon J, Wolmark N, Haller D, Allegra C, de Gramont A, VanCutsem E, Alberts S, George T, O'Connell M, Twelves C, Taieb J, Saltz L, Blanke CD, Francini E, Kerr R, Yothers G, Seitz J, Marsoni S, Goldberg R, Shi Q. Journal of the National Cancer Institute, Apr 6;113(4):400-407, 2021. [*ACCENT (meta-analysis)]. <https://pubmed.ncbi.nlm.nih.gov/32835356/#affiliation-17>

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GENITOURINARY COMMITTEE

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

Published/Accepted Manuscripts

S1806/Other Advancing bladder preservation: Biomarkers, decision-making, and therapy [Review]. McConkey D, Best CJM, Gumminger JA, Olumi AF. Urologic Oncology, Apr;39(4):199-200, 2021. <https://pubmed.ncbi.nlm.nih.gov/33487562/>

S1806/Other Targeting barriers to wider use of trimodality therapy in localized muscle invasive bladder cancer [Seminars Article]. Ballas L, Singh P, Lerner SP. Urologic Oncology: Seminars and Original

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Investigations, in press 2021.

<https://doi.org/10.1016/j.urolonc.2020.10.005>

S1823 (pilot) Integrated Expression of Circulating miR375 and miR371 to Identify Teratoma and Active Germ Cell Malignancy Components in Malignant Germ Cell Tumors [Brief Correspondence]. Nappi L, Thi M, Adra N, Hamilton R, Lavoie J-M, Soleimani M, Eigl B, Chi K, Gleave M, So A, Black P, Bell R, Daneshmand S, Cary C, Masterson T, Einhorn L, Nichols C, Kollmannsberger C. *European Urology* Jan;79(1):16-19, 2021.

<https://pubmed.ncbi.nlm.nih.gov/33158661/>

S1823 (pilot) Reply to John T. Lafin, Aditya Bagrodia's Letter to the Editor re: Lucia Nappi, Marisa Thi, Nabil Adra, et al. Integrated Expression of Circulating miR375 and miR371 to Identify Teratoma and Active Germ Cell Malignancy Components in Malignant Germ Cell Tumors. *European Urology* 79:16-9, 2021 [Letter to the Editor]. Nappi L, Nichols C, Kollmannsberger C. *European Urology*, Mar;79(3):e85-e86, 2021.

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S8507/Other 100 years of Bacillus Calmette-Guérin immunotherapy: from cattle to COVID-19 [Review/Perspective]. Lobo N, Brooks NA, Zlotta AR, Cirillo JD, Boorjian S, Black PC, Meeks JJ, Bivalacqua TJ, Gontero P, Steinberg GD, McConkey D, Babjuk M, Alfred Witjes J, Kamat AM. *Nature Reviews Urology*, Jun 15;1-12, 2021.

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E2805 Predicting Disease Recurrence, Early Progression, and Overall Survival Following Surgical Resection for High-risk Localized and Locally Advanced Renal Cell Carcinoma. Correa A, Jegede O, Haas H, Flaherty K, Pins M, Andeniran A, Messing E, Manola J, Wood C, Kane C, Jewett M, Dutcher J, DiPaola R, Carducci M, Uzzo R. *European Urology* Jul;80(1):20-31, 2021. <https://pubmed.ncbi.nlm.nih.gov/33707112/>

JPR7 The Association Between Statin Use and Outcomes in Patients Initiating Androgen Deprivation Therapy. Hamilton RJ, Ding K, Crook JM, O'Callaghan CJ, Higano CS, Dearnaley DP, Horwitz EM, Goldenberg SL, Gospodarowicz MK, Klotz L. *European Urology*, Apr;79(4):446-452, 2021. <https://pubmed.ncbi.nlm.nih.gov/33390282/>

R0415 Tolerance doses for late adverse events after hypofractionated

radiotherapy for prostate cancer on trial NRG Oncology/RTOG 0415. Thor M, Deasy JO, Paulus R, Robert Lee W, Amin MB, Bruner DW, Low DA, Shah AB, Malone SC, Michalski JM, Dayes IS, Seaward SA, Gore EM, Albert M, Pisansky TM, Faria SL, Chen Y, Koontz BF, Swanson GP, Pugh SL, Sandler HM. *Radiother Oncol*. Jun;135:19-24, 2019 [note: not previously captured/reported] <https://pubmed.ncbi.nlm.nih.gov/31015166/>

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

LEUKEMIA COMMITTEE

Published/Accepted Manuscripts

S0106/S1203 Predicting Severe Toxicities with Intensive Induction Chemotherapy for Adult Acute Myeloid Leukemia: Analysis of SWOG Trials S0106 and S1203. Moseley A, Othus M, Garcia-Manero G, Appelbaum F, Erba H, Walter R. *Leukemia and Lymphoma* Jul;62(7):1774-1777, 2021. <https://pubmed.ncbi.nlm.nih.gov/33560164/>

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Publication List by Committee

Brown JR, Nattam S, Larson RA, Erba H, Litzow M, Owen C, Kuzma CS, Abramson JS, Little RF, Smith SE, Stone RM, Byrd JC, Mandrekar SJ, Woyach JA. *Leukemia*, Jul 17. doi: 10.1038/s41375-021-01342-x. Online ahead of print, 2021. <https://pubmed.ncbi.nlm.nih.gov/34274940/>

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LUNG COMMITTEE

Published/Accepted Manuscripts

S1206 A dose-finding study followed by a phase II randomized, placebo-controlled trial of chemoradiotherapy with or without veliparib in stage III non-small cell lung cancer: SWOG S1206 (8811). Argiris A, Miao J, Cristea M, Chen AM, Sands J, Decker R, Gettinger S, Daly M, Faller B, Albain K, Yanagihara R, Garland L, Byers L, Wang D, Koczywas M, Redman M, Kelly K, Gandara D. *Clinical Lung Cancer* Jul;22(4):313-323, 2021. <https://pubmed.ncbi.nlm.nih.gov/33745865/>

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Publication List by Committee

Multiple Studies* Novel Clinical Trial Designs in Pursuit of Precision Oncology: Lung-MAP As a Model [Editorial]. Riess J, Rolfo C, Gandara D. *Clin Lung Cancer* May;22(3):153-155, 2021. [*S1400, S1400A, S1400B, S1400C, S1400D, S1400E, S1400G, S1900A] <https://pubmed.ncbi.nlm.nih.gov/33879399/>

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S0819 EGFR High Copy Number Together with High EGFR Protein Expression Predicts Improved Outcome for Cetuximab-based Therapy in Squamous Cell Lung Cancer: Analysis from SWOG S0819, a phase III trial of chemotherapy with or without Cetuximab in advanced NSCLC. Hirsch FR, Redman MW, Moon J, Augustino F, Herbst RS, Semrad T, Varella Garcia M, Rivard C, Kelly K, Gandara DR, Mack PC. *Clinical Lung Cancer*, under revision for resubmission, 2021.

LYMPHOMA COMMITTEE

Published/Accepted Manuscripts

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