

Virtual Meeting

APRIL 19-23, 2021



A Welcome Spring

Even though it was a pretty mellow winter in Portland, where I and the group chair's office reside, I'm grateful for this season and its longer, warmer days. I am hoping better times are about to arrive.

More than 30 million Americans are fully vaccinated against COVID-19, including many of our members. Our trials are accruing, new study concepts are coming in, and we're hard at work building data dashboards for our members, creating plain language summaries of our trials for the public, and thinking of new and better ways to manage our staff time.

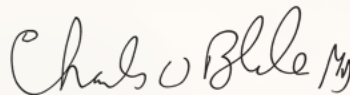
There is a spirit of renewal here at SWOG Cancer Research Network, and it's refreshing. We're focused on the future, making sure it's a bright one.

One particularly sunny spot for 2021 is our work to forge a more diverse and equitable future for the organization. I've asked Allison Caban-Holt, PhD, and Rick Bangs, MBA, the chairs of our recruitment and retention and patient advocacy committees, respectively, to speak at the general plenary and update you on a series of initiatives rolling out this year to increase diversity in our leadership, membership, and the patients who enter our clinical trials.

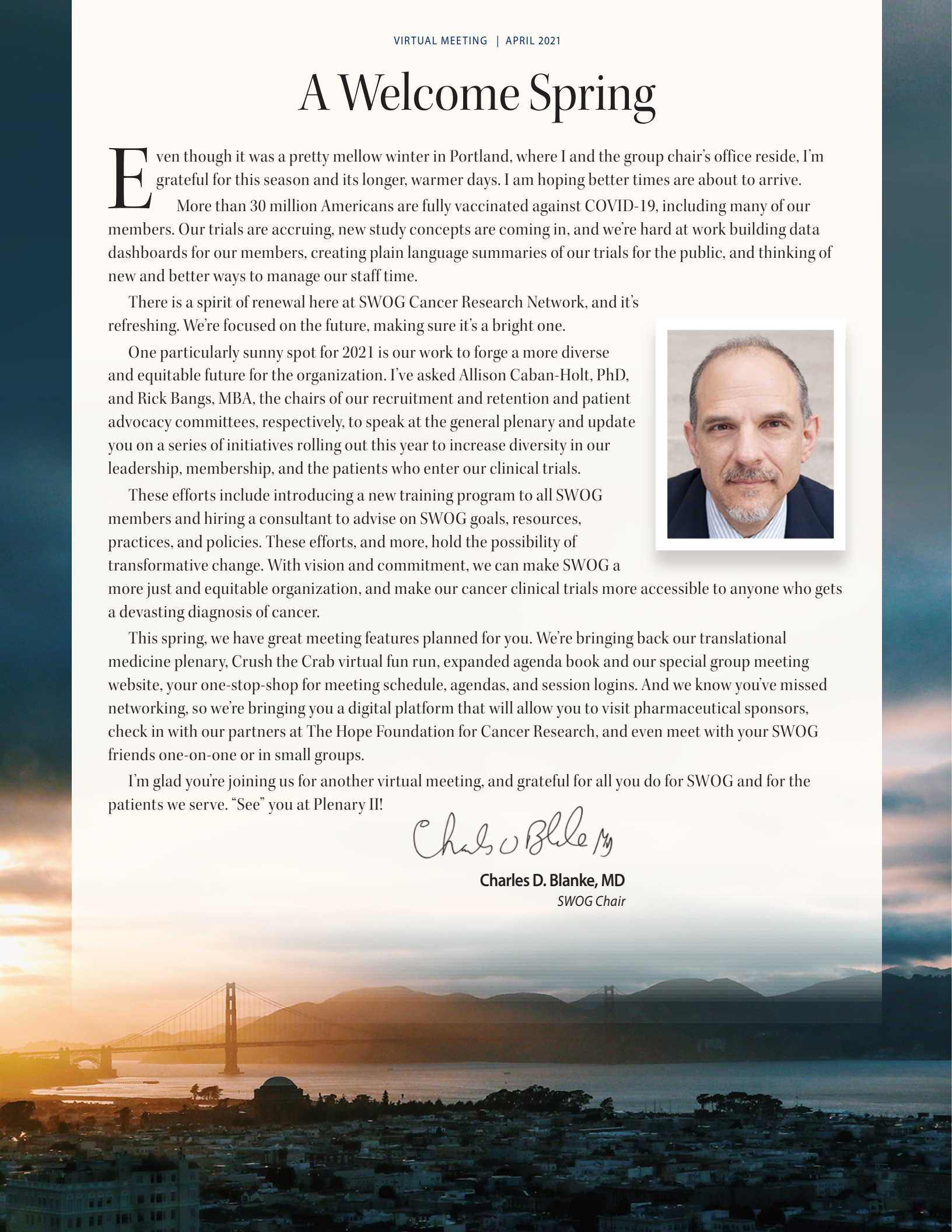
These efforts include introducing a new training program to all SWOG members and hiring a consultant to advise on SWOG goals, resources, practices, and policies. These efforts, and more, hold the possibility of transformative change. With vision and commitment, we can make SWOG a more just and equitable organization, and make our cancer clinical trials more accessible to anyone who gets a devastating diagnosis of cancer.

This spring, we have great meeting features planned for you. We're bringing back our translational medicine plenary, Crush the Crab virtual fun run, expanded agenda book and our special group meeting website, your one-stop-shop for meeting schedule, agendas, and session logins. And we know you've missed networking, so we're bringing you a digital platform that will allow you to visit pharmaceutical sponsors, check in with our partners at The Hope Foundation for Cancer Research, and even meet with your SWOG friends one-on-one or in small groups.

I'm glad you're joining us for another virtual meeting, and grateful for all you do for SWOG and for the patients we serve. "See" you at Plenary II!



Charles D. Blanke, MD
SWOG Chair



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This spring, both SWOG plenary sessions are back. *Everyone Will Be There*

Plenary I | Wednesday, April 21 | 10 a.m. to 11 a.m.



Welcome and Introductions

Lee M. Ellis, MD, FASCO

*MD Anderson Cancer Center, Professor of Surgery and
Molecular and Cellular Oncology*

*SWOG Cancer Research Network, Vice Chair for
Translational Medicine*



"Pancreatic Cancer Organoids as a Predictive
Model for Chemotherapy: Co-Clinical Trial"

David Tuveson, MD, PhD

*Cold Spring Harbor Laboratory, Cancer Center Director and
Roy J. Zuckerberg Professor of Cancer Research*

Lustgarten Foundation, Chief Scientist

American Association of Cancer Research, President-Elect



"Genomic Heterogeneity — Deciphering
Genomic Configuration for Enhanced Platinum
Sensitivity in TNBC and Ovarian Cancers"

Edison T. Liu, MD

*The Jackson Laboratory, President and
Chief Executive Officer*

Director, JAX Cancer Center

Plenary II | Friday, April 23 | 10 a.m. to 11 a.m.



Welcome and News

Charles D. Blanke, MD, FASCO

*Oregon Health & Science University, Professor
SWOG Cancer Research Network, Group Chair*



Tribute to
Julie Gralow, MD
delivered by
**Daniel Hayes,
MD**



"Diversity, Equity, and
Inclusion Update: Current
Efforts and Future Directions"

Allison Caban-Holt, PhD

*SWOG Cancer Research Network,
Recruitment and Retention
Committee Chair*



"Diversity, Equity, and
Inclusion Update: Current
Efforts and Future Directions"

Rick Bangs, MBA

*SWOG Cancer Research Network,
Patient Advocate Committee Chair*

Save the date
for the Fall 2021 meeting
October 13-16

What's New For Our Meeting

5 THINGS TO KNOW:

1 We've got a whole week together. To decrease scheduling conflicts, and increase your chances of joining all the SWOG meetings you want to, we're holding the spring meeting for a full week, Monday through Friday, from April 19-23.

2 We're bringing back the special website and extended agenda book. From the website, you can log into all open sessions, see agendas, get meeting highlights, and more. The agenda book includes updates from committee chairs on new projects and people.

3 We're also bringing back Plenary I. If you've missed the translational medicine talks, we've got you covered. A one-hour Plenary I will feature Edison Liu, MD, of The Jackson Laboratory and David Tuveson, MD, PhD, from Cold Spring Harbor Laboratory.



We're Making Meet Ups Possible!

At the spring meeting, visit the new Networking Lounge.

Grab a table and video chat with SWOG colleagues.

Connect with our pharmaceutical company sponsors to talk project possibilities.

Drop by the virtual Hope Foundation booth and get the latest on grants.

More details on Page 7.

4 We're holding meetings in Central Time. Session times on the meeting website and in this agenda book are Central Time. Mark your calendars accordingly!

5 We want you to run... or walk! We can't be racing together on the Embarcadero, but you can still lace up your sneakers to support The Hope Foundation for Cancer Research by joining the "Crush the Crab" fun run and walk.

Welcome to the Networking Lounge



We know you've missed the mingle! That's why for spring 2021, we're bringing you a virtual gathering space where you can connect with fellow attendees in real time over video.

IN THE LOUNGE, YOU CAN:



Hold impromptu video chats with colleagues at open tables



Meet with industry exhibitors at their designated spaces



Ask questions about funding or programs at the Hope desk

TO JOIN:



Click the main "Networking Lounge" link on the meeting site



Create your personal login



Find an open table to host a meet-up, or join one already underway



Reserved tables will be marked with labels

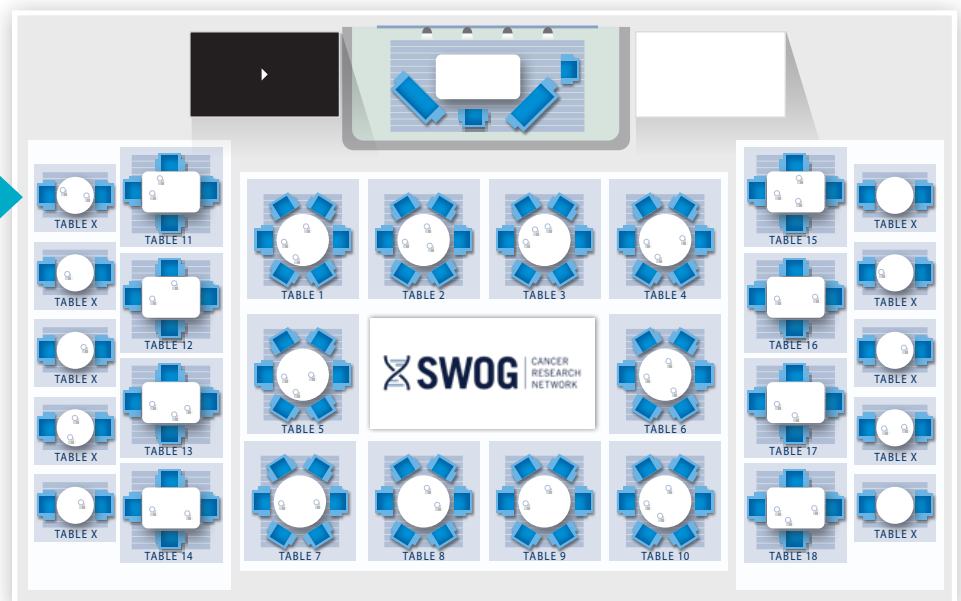
Look for labeled tables

to drop in when staff or exhibitors are present

The **Networking Lounge** will be open **Monday through Friday, 7am - 5pm CT.**

Check the meeting site

for details and specific table office hours.



Come Hear About An Innovative, New SWOG Study

KICK-OFF MEETING FOR S1912CD
ALSO KNOWN AS THE CREDIT STUDY

Thursday, April 22 | 1:00-2:00 p.m. CT

All NCORP principal investigators and site staff encouraged to attend

The study, which activates this month, is designed to help cancer patients and their spouses understand and navigate the costs of cancer care. The study will determine whether providing financial education and counseling to cancer patients and their spouse caregivers will help lessen the financial burden of treatment.

In this trial, participants will be asked to:

Watch up to 10 short (2-8 minute) online videos

Complete questionnaires about finances, insurance, and quality of life at the beginning of the study and at months 3, 6, and 12

Provide their Social Security number so that trial leaders can obtain their credit report

Attend free monthly counseling sessions for six months with two different organizations if they are randomly assigned to the intervention group

Come hear how this trial could be a good fit for your patients!

S1912CD is a follow-up to Dr. Shankaran's ground-breaking SWOG financial toxicity trial, S1417CD.

Dr. Veena Shankaran



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

Roy Decker, MD, PhD

Recruitment and Retention

Allison Caban-Holt, PhD

Surgery

Syed A. Ahmad, MD

Future Meeting Dates

2021

Fall

October 13-16
Chicago, IL

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



New Planned Giving Options

We know you believe deeply in
SWOG's mission and purpose,

and we'd like to help you plan for a lasting legacy with the group.
By partnering with **FreeWill**, The Hope Foundation can now provide
you with resources to complete your will, or update an existing one,
while also giving you the option to plan for a charitable bequest.

A legacy gift costs you nothing today but **will be an important
part of imagining our shared future advancing clinical trials
for patients everywhere.**

Prefer the option of a stock gift?

Donating assets has never been easier using our online tool.



Learn more at thehopefoundation.org/donate
Or contact us about adding Hope to your estate plan

THE HOPE
FOUNDATION
FOR CANCER RESEARCH

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, Cancer Survivorship Committee; Genitourinary Committee; Early Therapeutics & Rare Cancers Committee; Myeloma Committee; Melanoma Committee; Surgery Committee; Radiation Oncology Committee; Plenary Session; 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

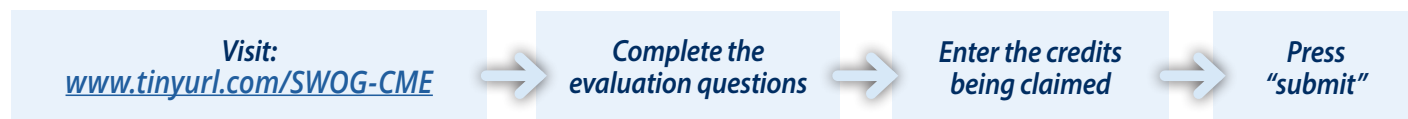
The Hope Foundation for Cancer Research is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Hope Foundation designates this live activity for a maximum of 24.5 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.

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
MONDAY, APRIL 19, 2021			
12:30 pm - 2:30 pm	Immunotherapeutics Committee	2.0	_____
3:00 pm - 4:30 pm	Digital Engagement Committee	1.5	_____
TUESDAY, APRIL 20, 2021			
10:00 am - 12:00 pm	Surgery Committee	2.0	_____
1:00 pm - 2:00 pm	Adolescent and Young Adult (AYA) Committee	1.0	_____
2:00 pm - 4:00 pm	Radiation Oncology Committee	2.0	_____
WEDNESDAY, APRIL 21, 2021			
10:00 am - 11:00 am	Plenary I (Translational Medicine)	1.0	_____
11:15 am - 12:45 pm	Symptom Control & Quality of Life Committee	1.5	_____
11:30 am - 1:00 pm	Bone Marrow & Stem Cell Transplantation Committee	1.5	_____
2:00 pm - 4:00 pm	Cancer Survivorship Committee	2.0	_____
2:00 pm - 4:00 pm	Lung Committee	2.0	_____
THURSDAY, APRIL 22, 2021			
10:00 am - 11:00 am	Cancer Care Delivery Committee	1.0	_____
10:00 am - 12:00 pm	GI Committee	2.0	_____
11:00 am - 1:00 pm	Leukemia Committee	2.0	_____
11:30 am - 1:30 pm	Breast Committee	2.0	_____
2:00 pm - 4:00 pm	Early Therapeutics & Rare Cancers Committee	2.0	_____
2:30 pm - 4:30 pm	GU Committee Part I	2.0	_____
2:45 pm - 4:45 pm	Palliative & End of Life Care Committee	2.0	_____
FRIDAY, APRIL 23, 2021			
10:00 am - 11:00 am	Plenary II (General)	1.0	_____
12:30 pm - 2:30 pm	Prevention & Epidemiology Committee	2.0	_____
1:00 pm - 3:00 pm	Melanoma Committee	2.0	_____
1:00 pm - 3:00 pm	Barlogie-Salmon Myeloma Committee	2.0	_____
2:30 pm - 4:30 pm	GU Committee Part II	2.0	_____
2:30 pm - 4:30 pm	Lymphoma Committee	2.0	_____
Total Possible Credits		24.5	_____

Schedule of Events

MONDAY, APRIL 19, 2021

10:00 AM – 11:00 AM	Nursing Research Subcommittee (Invitation Only)
10:00 AM – 12:00 PM	Patient Advocates Committee (Invitation Only)
11:00 AM – 1:00 PM	Clinical Trials Training Course (CTTC): Session #1
12:00 PM – 12:30 PM	Publications Committee (Invitation Only)
12:15 PM – 2:15 PM	Recruitment and Retention Committee
12:15 PM – 2:15 PM	Breast Working Group (Invitation Only)
12:30 PM – 2:30 PM	Immunotherapeutics Committee
2:00 PM – 4:00 PM	Clinical Trials Training Course (CTTC): Session #2
2:00 PM – 4:00 PM	Pharmaceutical Sciences & Drug Information Subcommittee
2:30 PM – 4:00 PM	Professional Review Committee (Invitation Only)
3:00 PM – 4:00 PM	Clinical Trials Partnerships Update Forum
3:00 PM – 4:30 PM	Digital Engagement Committee
4:30 PM – 5:30 PM	SWOG Staff Mingle (Invitation Only)

TUESDAY, APRIL 20, 2021

10:00 AM – 11:30 AM	Lung-MAP Administrative Meeting (Invitation Only)
10:00 AM – 12:00 PM	Surgery Committee
12:00 PM – 2:00 PM	Lung Working Group (Invitation Only)
12:30 PM – 2:30 PM	Melanoma Working Group (Invitation Only)
1:00 PM – 2:00 PM	Adolescent and Young Adult (AYA) Committee
2:00 PM – 4:00 PM	Radiation Oncology Committee
2:00 PM – 4:00 PM	Myeloma Working Group (Invitation Only)
2:30 PM – 4:30 PM	Hope Foundation Board Meeting (Invitation Only)
3:30 PM – 5:00 PM	Site Operations

WEDNESDAY, APRIL 21, 2021

10:00 AM – 11:00 AM	Plenary I (Translational Medicine)
11:15 AM – 12:45 PM	Symptom Control & Quality of Life Committee
11:30 AM – 1:00 PM	Bone Marrow & Stem Cell Transplantation Cmte
11:30 AM – 1:00 PM	Lung-MAP Update Meeting
11:30 AM – 2:30 PM	GI Working Group (Invitation Only)
1:00 PM – 2:00 PM	Jeri & Noboru Oishi Symposium
1:00 PM – 2:00 PM	SWOG Tissue Banking Meeting (Invitation Only)
2:00 PM – 4:00 PM	Cancer Survivorship Committee
2:00 PM – 4:00 PM	Lung Committee
2:15 PM – 3:15 PM	ORP Open Forum
4:00 PM – 5:00 PM	NCORP/MU-NCORP Site PI Meeting
4:30 PM – 5:30 PM	CTP Scientific Advisory Board Option 1 (Invitation Only)

THURSDAY, APRIL 22, 2021

10:00 AM – 11:00 AM	Cancer Care Delivery Committee
10:00 AM – 12:00 PM	GI Committee
10:00 AM – 12:00 PM	Conflict Management Committee (Invitation Only)
11:00 AM – 1:00 PM	Leukemia Committee
11:30 AM – 1:30 PM	Breast Committee
1:00 PM – 2:00 PM	S1912CD Kick-Off Meeting
2:00 PM – 4:00 PM	Early Therapeutics & Rare Cancers Committee
2:00 PM – 4:00 PM	Lymphoma Working Group (Invitation Only)
2:30 PM – 4:30 PM	GU Committee Part I: Prostate, Cancer Control & Prevention, Renal
2:45 PM – 4:45 PM	Palliative & End of Life Care Committee
4:30 PM – 6:00 PM	GU Executive Meeting (Invitation Only)
5:00 PM – 6:00 PM	SWOG Latin America Initiative Symposium

Schedule of Events

FRIDAY, APRIL 23, 2021

<u>9:00 AM – 11:00 AM</u>	<i>SWOG Data Safety Monitoring Committee (Invitation Only)</i>
<u>10:00 AM – 11:00 AM</u>	<i>Plenary II (General)</i>
<u>11:00 AM – 1:00 PM</u>	<i>CNS Working Group</i>
<u>11:15 AM – 12:15 PM</u>	<i>Board of Governors (Invitation Only)</i>
<u>12:30 PM – 1:30 PM</u>	<i>CTP Scientific Advisory Board Option 2 (Invitation Only)</i>
<u>12:30 PM – 2:30 PM</u>	<i>Imaging Committee (Invitation Only)</i>

<u>12:30 PM – 2:30 PM</u>	<i>Prevention & Epidemiology Committee</i>
<u>12:30 PM – 2:30 PM</u>	<i>VA Working Group</i>
<u>1:00 PM – 3:00 PM</u>	<i>Melanoma Committee</i>
<u>1:00 PM – 3:00 PM</u>	<i>Barlogie-Salmon Myeloma Committee</i>
<u>1:00 PM – 3:00 PM</u>	<i>Quality Initiative Meeting (Invitation Only)</i>
<u>2:30 PM – 4:30 PM</u>	<i>GU Committee Part II: Bladder, Translational Medicine</i>
<u>2:30 PM – 4:30 PM</u>	<i>Lymphoma Committee</i>



Crush the Crab!

Join our virtual 5K run/walk to support the SWOG Cancer Research Network community!

Sign up here: <https://tinyurl.com/CrushtheCrab>

The Hope Foundation for Cancer Research has organized a virtual Crush the Crab event. This takes the place of our regular spring fun run, and registration is free. (Donations are welcome and directly support SWOG's work.)

Complete your 5K between March 28 through April 11 – a great warm up for the group meeting! And take part in our video Tribute, a fun and easy way to come together. See meeting site for details.

**THE HOPE
FOUNDATION**
FOR CANCER RESEARCH

Thanks To

Our Top Accruers

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

In 2020, 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

University of Rochester
Wilmot Cancer Institute

City of Hope

USC Norris
Comprehensive Cancer Center

University of Utah
Huntsman Cancer Institute

NCORP

Southeast Clinical Oncology
Research Consortium NCORP

Gulf South Minority
Underserved NCORP

Cancer Research Consortium
of West Michigan NCORP

Upstate Carolina Consortium NCORP

Catholic Health Initiatives 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
..... Adam Rosenthal, 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
Data Coordinators: Sean O'Bryan
Oncology Research Professionals:
CRA: Erik Bailey, BA
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: Melissa Biddle
Clinical Trials Project Manager: Sandi Hita, JD

Agenda

Friday, April 23, 2021
1:00 pm - 3:00 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. Krishnan and Hari. Activated: 6/27/19.

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. Usmani, Ailawadhi, and 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. Parker and Sanchawala. Activated: 3/08/18; Closed: 9/30/19.

Proposed Studies

S2005, "A Phase II Randomized Study of Ibrutinib and Rituximab with or Without Venetoclax in Previously Untreated Waldenström's Macroglobulinemia (WM)." Drs. Ailawadhi and Bhutani.

S2105, "A Phase III Randomized Trial for Newly Diagnosed Multiple Myeloma (NDMM) Patients Considered Frail or Ineligible for Stem Cell Transplant Comparing Upfront Bortezomib-Lenalidomide-Dexamethasone-Lite (VRd-Lite) with Daratumumab-Lenalidomide-Dexamethasone (DRd)." Drs. Ailawadhi, Ye, and Gowin.

S2112, "A Randomized Phase III Study of Busulfan, Melphalan, and Bortezomib (BuMelVel) Versus Melphalan (Mel200) High Dose Therapy followed by Uniform Isatuximab Maintenance for Salvage Transplant in Multiple Myeloma (MM)." Dr. Hagen

Barlogie-Salmon Myeloma Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	S1702	S1803	A061202	EAA173
Arizona CC, Univ of	-	2	-	-
Boston Medical Ctr	6	4	-	-
CORA NCORP	2	1	-	-
CROWN NCORP	-	1	-	-
Cedars-Sinai Med Ctr	-	1	-	-
City of Hope Med Ctr	-	31	-	-
Cleveland Clinic OH	-	3	-	1
Columbia MU-NCORP	2	-	-	-
Columbus NCORP	-	5	-	-
Davis, U of CA	1	7	-	-
Dayton NCORP	-	1	-	-
Duke Univ Med Ctr	-	1	-	-
Fred Hutchinson CRC	-	-	-	3
Georgia NCORP	-	4	-	-
H Lee Moffitt CC	-	10	-	-
Heartland NCORP	1	7	-	-
Henry Ford Hospital	-	-	1	-
Irvine, U of CA	1	-	-	-
Kaiser Perm NCORP	-	8	-	-
Kansas MU-NCORP	-	9	-	-
Lahey Hosp & Med Ctr	-	3	-	-
Loyola University	3	6	-	2
MD Anderson CC	-	6	-	-
MUSC MU-NCORP	1	1	-	1
Michigan, U of	-	2	-	-
Montana NCORP	-	2	-	-
New Mexico MU-NCORP	-	4	-	-
Ohio State Univ	-	4	-	-
Oregon Hlth Sci Univ	2	5	-	2
PCRC NCORP	-	1	-	-
Providence Hosp	-	-	1	-
Rochester, Univ of	-	8	-	-
San Antonio, U of TX	-	9	-	-
Upstate NCORP	-	3	-	-
Utah, U of	-	5	-	1
Wayne State Univ	1	4	-	-
Wisconsin NCORP	-	8	-	-
Yale University	4	-	-	2
Alliance	3	51	-	-
ECOG-ACRIN	14	36	-	-
NRG	2	22	-	-
Total	43	275	2	12

Breast Committee

Committee Leadership

Chair: Lajos Pusztai, MD, PhD
Vice-Chair: Priyanka Sharma, MD
Executive Officer: TBD
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: George Somlo, MD

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
..... Jacqueline Scurlock
..... 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: Cara Laubach, MIIM
Clinical Trials Project Manager: Gretchen Goetz, MBA

Agenda

Thursday, April 22, 2021
11:30 am - 1:30 pm CT

11:30 am – 11:35 am Welcome and Introductions – Lajos Pusztai, MD, DPhil and Priyanka Sharma, MD

Breast Committee Mini-Symposium : Impact of COVID-19 pandemic on breast cancer management (11:35 am - 12:25 pm)

11:35 am – 11:50am Neoadjuvant Endocrine Therapy Use in Early Stage Breast Cancer During COVID-19 Pandemic: Ko Un “Clara” Park MD, Assistant Professor, Department of Surgery, Ohio State University, James Comprehensive Cancer Center

11:50 am – 12:05 pm COVID infection, COVID vaccines and cancer patients; Balazs Halmos, MD, MS, Professor, Director of the Multidisciplinary Thoracic Oncology Program and Section of Thoracic Medical Oncology, Director of Clinical Cancer Genetics and for Montefiore Medical Center, Albert Einstein College of Medicine.

12:05 pm – 12:15 pm Impact of COVID-19 Pandemic on NCTN trials specimen banking requirements; Nilsa Ramirez, MD, FCAP, Medical Director, Biopathology Center, The Abigail Wexner Research Institute at Nationwide Children’s Hospital, Professor of Clinical Pathology, The Ohio State University College of Medicine

12:15 pm – 12:25 pm Panel discussion, Q/A

12:25 pm – 12:35 pm Publications update – William Barlow, PhD

12:35 pm – 12:45 pm Patient Advocate update – Ginny Mason and Elda Railey

12:45 pm – 1:05 pm Review of open CTSU trials

1:10 pm – 1:25 pm Developing Concepts

- Neoadjuvant IO therapy for ER+ disease (Pusztai)
- DETECT (Kalinsky and Bardia)
- CDK 4/6i with Radiation (Cobain, Spears)

1:25 pm – 1:30 pm Translational Medicine Sub-Committee update – Alastair Thompson, MD and Andrew K. Godwin, PhD

1:30 pm Closing Comments and Adjourn

Breast Committee

Active Breast Cancer Committee Studies

S12007, "A Phase II Trial of Sacituzumab Govitecan for Patients with HER2-Negative Breast Cancer and Brain Metastases." Dr. Brenner. Activated: 12/15/20.

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 and Mammen. Activated: 11/15/16.

S1706, "A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy Alone for Inflammatory Breast Cancer." Dr. Jagsi. Activated: 9/12/18.

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: 2/7/14. Temporarily closed to Registration Step 2: 9/1/20.

CTSU/A011801, "The COMPASSHER2 Trials (COMprehensive Use of Pathologic Response ASSEssment to Optimize Therapy in HER2-Positive Breast Cancer): COMPASSHER2 Residual Disease (RD), A Double-Blinded, Phase III Randomized Trial of T-DM1 Compared with T-DM1 and Tucatinib." Dr. O'Sullivan. SWOG Champion: Dr. Murthy. Activated: 1/6/21.

CTSU/CCTG MA.39, "Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer." Dr. Whelan. SWOG Champion: Dr. Jagsi. Activated: 5/30/18.

CTSU/EA1131, "A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy vs. Capecitabine in Patients with Residual Triple-Negative Basal-Like Breast Cancer following Neoadjuvant Chemotherapy." Dr. Mayer. SWOG Champion: Dr. Rodler. Activated: 4/29/15.

CTSU EA1181, "(CompassHER2-pCR): Preoperative THP and Postoperative HP in Patients Who Achieve a Pathologic Complete Response Part 1 Component of: The CompassHER2 Trials (COMprehensive Use of Pathologic Response ASSEssment to Optimize Therapy in HER2-Positive Breast Cancer)" Dr. Tung. SWOG Champions: Breast Committee: Dr. Tang, Imaging Committee: Dr. Lu Activated: 2/11/20.

CTSU/EA1183, "FDG PET to Assess Therapeutic Response in Patients with Bone-dominant Metastatic Breast Cancer, FEATURE." Dr. Specht. SWOG Champion: Dr. Linden. Activated: 4/2/20.

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 to Accrual: 9/13/19.

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: 6/26/15.

CTSU/NRG- BR004, "A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer." Dr. Geyer. SWOG Champion: Dr. Cobain. Activated: 3/12/19.

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: 4/13/17. Temporarily closed to accrual: 7/2/19.

Active Cancer Survivorship Study

S1501, "Prospective Evaluation of Carvedilol vs No Treatment in Prevention of Cardiac Dysfunction in Women with Metastatic HER2+ Breast Cancer." Drs. Floyd and Leja. Activated: 9/15/17.

Active Symptom Control and Quality of Life Studies

S1614, "Randomized Trial of Prophylactic Antiviral Therapy in Patients with Current or Past Hepatitis B Virus (HBV) Infection Receiving Cytotoxic Therapy for Solid Tumors." Dr. Hwang. Activated: 2/21/19. Temporarily Closed to Accrual: 5/20/20.

S1714, "A Prospective Observational Cohort Study to Develop a Predictive Model of Taxane-Induced Peripheral Neuropathy in Cancer Patients." Dr. Trivedi. Activated: 3/1/19.

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 Breast Cancer." Dr. Accordini. Activated: 7/16/18.

Breast Committee

CTSU/A011401, "Randomized Phase III Trial Evaluating the Role of Weight Loss In Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer." Drs. Ligibel and Hershman. Activated: 8/29/16.

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

Active Cancer Care 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)." Dr. Crew. Activated: 9/1/20.

Active Early Therapeutics and Rare Cancers Studies

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

CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)". Dr. Villalobos. Activated: 7/15/15.

Closed Breast Cancer Committee Studies

S1007, "A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone-Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less. RxPONDER: A Clinical Trial Rx for Positive Node, Endocrine Responsive Breast Cancer." Drs. Kalinsky, Gralow, Meric-Bernstam, Hortobagyi, Albain and Barlow. Activated: 1/15/11. Closed: 10/1/15.

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." Drs. Chavez-MacGregor, Rastogi, Puztai. Activated: 9/3/13. Closed: 4/15/19.

S1416, "Phase II Randomized Placebo-Controlled Trial of Cisplatin with or without ABT-888 (Veliparib) in Metastatic Triple Negative Breast Cancer (TNBC) and BRCA Mutation-Associated Breast Cancer." Drs. Rodler and Sharma. Activated: 7/7/16. Closed: 6/15/19.

CTSU/NSABP-51, "A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chest wall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy." Drs. Mamounas and White. SWOG champion: Dr Jagsi. Activated: 8/22/13. Closed: 12/28/20.

Closed Cancer Care Delivery Study

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. Ramsey, Hershman, Lyman and Sullivan. Activated: 10/7/16. Closed: 4/15/20.

Closed Cancer Care Prevention Study

CTSU/A011502, "A Randomized Phase III Double Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for Node Positive HER2 Negative Breast Cancer: The ABC Trial." Dr. Chen. SWOG Champion: Dr. Symington. Activated: 12/8/16. Closed: 12/4/20.

Breast Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	S1418	S1706	A011106	A011202	A011401	A011502	B51	EA1131	EA1181	MA39	NRGBR002	NRGBR003	NRGBR004	NRGBR005
Arizona CC, Univ of	4	-	33	1	8	-	-	-	-	-	-	-	-	-
Arkansas, U of	16	1	2	-	3	22	-	-	-	-	-	-	-	-
Banner MD Anderson	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Baptist MU-NCORP	6	2	12	1	7	-	-	-	-	-	-	1	-	-
Bay Area NCORP	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Boston Medical Ctr	-	-	-	-	3	-	-	-	-	-	-	-	-	-
CORA NCORP	15	1	1	-	-	-	2	-	-	-	-	-	-	-
CRC West MI NCORP	22	-	-	-	1	-	-	-	-	-	-	-	-	-
CROWN NCORP	4	-	-	-	-	-	-	-	-	-	-	-	-	-
Carle CC NCORP	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Cincinnati MC, U of	-	-	-	-	-	-	1	-	-	-	-	-	-	-
City of Hope Med Ctr	9	-	-	-	-	-	-	-	-	-	-	-	-	-
Cleveland Clinic OH	8	-	-	-	1	-	5	-	-	1	-	9	-	-
Colorado, U of	11	1	16	34	26	7	3	-	-	-	-	-	-	2
Columbia MU-NCORP	6	-	-	-	-	-	-	-	-	-	-	-	-	-
Columbus NCORP	10	-	-	-	-	-	-	-	-	-	-	-	-	-
Cotton O'Neil CC	-	-	-	1	1	-	-	-	-	-	-	1	-	-
Davis, U of CA	7	2	-	2	4	17	-	-	-	-	-	-	-	-
Dayton NCORP	1	-	3	-	1	-	-	1	1	-	-	-	-	-
Desert Hospital	1	-	-	5	4	-	4	-	-	-	-	-	-	-
Essentia Hlth NCORP	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson CRC	9	-	-	-	12	9	-	-	-	-	-	-	-	-
Georgia NCORP	21	2	-	-	2	1	-	4	-	-	-	1	-	-
Greenville NCORP	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Gulf South MU-NCORP	4	1	-	-	-	-	-	-	-	-	-	3	-	-
H Lee Moffitt CC	-	-	-	1	3	2	-	-	-	-	-	-	-	-
Harrington CC	6	3	-	10	8	-	1	-	-	-	-	-	-	-
Hawaii MU-NCORP	5	-	-	-	-	-	-	-	-	-	-	-	-	-
Heartland NCORP	17	1	-	-	-	1	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Houston Methodist	-	-	-	-	-	-	1	-	-	-	-	-	-	1
Irvine, U of CA	6	-	3	3	2	2	1	-	-	-	-	1	-	-
Kaiser Perm NCORP	44	-	-	1	54	25	-	-	-	-	-	24	1	-
Kansas City NCORP	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Kansas MU-NCORP	18	2	-	4	23	9	-	-	-	-	-	-	-	1
Kentucky, U of	-	-	-	-	-	3	1	-	-	-	-	-	-	-
Lahey Hosp & Med Ctr	3	-	-	-	9	5	-	1	1	-	-	-	1	-
Loma Linda Univ	1	-	1	2	-	-	3	-	-	-	-	-	-	-
Loyola University	3	-	-	-	5	7	1	2	-	-	-	-	-	-
MAVERIC	-	-	-	-	-	1	-	-	-	-	-	-	-	-
MD Anderson CC	15	1	-	-	-	-	-	-	-	-	-	-	-	3

Breast Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	S1418	S1706	A011106	A011202	A011401	A011502	B51	EA1131	EA1181	MA39	NRGBR002	NRGBR003	NRGBR004	NRGBR005
MUSC MU-NCORP	9	-	1	-	-	-	-	-	-	-	-	-	-	-
Michigan CRC NCORP	16	-	-	-	-	-	-	-	-	-	-	-	-	-
Michigan, U of	12	2	-	-	13	11	-	-	-	1	-	3	-	-
Montana NCORP	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Mount Sinai Hospital	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Nevada CRF NCORP	9	-	-	-	-	-	-	-	-	-	-	-	-	-
New Mexico MU-NCORP	18	3	2	-	-	-	-	-	-	-	-	-	-	-
Northwest NCORP	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Northwestern Univ	2	-	-	-	-	-	-	-	-	-	-	1	-	-
Ohio State Univ	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Oregon Hlth Sci Univ	15	-	-	-	-	-	1	-	-	-	-	3	-	-
Ozarks NCORP	6	1	-	-	-	-	-	-	-	-	-	3	-	-
PCRC NCORP	14	-	-	-	3	1	-	-	-	-	-	1	-	-
Providence Hosp	3	2	1	4	9	8	8	1	1	-	-	3	1	-
Rochester, Univ of	2	1	1	-	-	15	-	7	1	-	-	9	-	-
Salem Hospital	-	-	-	4	-	-	-	-	-	-	-	-	-	-
San Antonio, U of TX	5	-	1	4	2	1	5	-	-	-	-	4	-	-
San Diego, U of CA	-	-	-	-	2	3	-	-	-	-	-	1	-	-
Scott & White Mem	-	-	-	1	4	-	2	-	-	-	-	-	-	-
So Calif, U of	3	-	-	3	-	6	-	-	-	-	-	-	-	-
Southeast COR NCORP	44	-	-	-	1	6	-	-	-	-	-	-	-	-
St Louis University	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Sutter Cancer RC	-	-	4	-	8	2	2	1	-	-	-	3	-	-
Tennessee, U of	-	-	-	6	-	-	4	-	-	-	-	-	-	-
UF Cancer Center	1	-	-	-	1	-	-	-	-	-	-	-	-	-
Univ of Louisville	-	-	-	2	-	-	-	-	-	-	-	-	-	-
Upstate NCORP	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Utah, U of	3	2	-	-	5	-	-	-	-	-	-	-	-	-
Virginia Mason MC	-	-	-	-	-	-	1	-	-	-	-	-	-	-
Wayne State Univ	2	-	-	11	12	9	-	5	1	-	-	6	-	-
West Clinic	-	-	-	3	-	-	-	-	-	-	-	-	-	-
Western States NCORP	3	-	-	-	1	-	-	-	-	-	-	-	-	-
Wichita NCORP	11	-	-	-	-	-	-	-	-	-	-	-	-	-
William Beaumont	1	-	-	6	5	2	1	-	-	-	1	-	-	-
Yale University	8	-	12	-	78	31	-	6	-	-	-	9	-	-
Alliance	116	9	-	-	-	-	-	-	-	-	-	-	-	-
CCTG	17	1	-	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	113	4	-	-	-	-	-	-	-	-	-	-	-	-
NRG	263	23	-	-	-	-	-	-	-	-	-	-	-	-
Total	987	67	94	109	321	206	47	29	5	2	1	86	3	7

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
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
..... Mai Doung, 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" Constone, 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)
Recruitment and Retention Committee: Allison M. Caban-Holt, PhD
Digital Engagement: Jennifer R. Klemp, PhD (Survivorship)
..... Krishna Soujanya Gunturu, MD (Survivorship)
..... Mina S. Sedrak, MD (CCD)
..... Katherine D. Crew, MD (Prevention)
..... Michael J. Fisch, MD (Symptom Control & QOL)

Designates

Oncology Research Professionals:

Clinical Research Associates: Amanda R. Dinsdale, MHA, CCRC
Nurses: Connie Szczepanek, RN, BSN
..... Joyce N. Tull, RN, MSN
..... 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, DHSc (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)
Protocol Coordinator (Cancer Care Delivery;
Prevention and Epidemiology): Patricia O'Kane
Protocol Coordinator (Cancer Survivorship): TBD
Protocol Coordinator (Symptom Control & Quality of Life): Sonali Tinsley
Protocol Coordinator (Palliative Care): Christy Klepetko
Clinical Trials Project Manager (Palliative Care): Gretchen Goetz, MBA
Clinical Trials Project Manager (Cancer Care Delivery; Prevention and
Epidemiology; Survivorship): Sandi Hita, JD
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

Thursday, April 22, 2021
10:00 am - 11:00 am CT

Presentations

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

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

Preference-Weighted Quality of Life: Findings from the Selenium and
Vitamin E Cancer Prevention Trial (SELECT) – Matthew Rock, BA,
University of Pennsylvania

Screening for Social Determinants of Health in Oncology Practices: Potential
Benefits and Feasibility – Scott Ramsey, MD, PhD, HICOR

Up-and-Coming Studies

S1912CD, “A Randomized Trial Addressing Cancer-Related Financial
Hardship Through Delivery of a Proactive Financial Navigation
Intervention (CREDIT).” Dr. Shankaran, University of Washington

Developing Studies

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, MD, Columbia
University

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

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

Active 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 Breast Cancer,” Dr. M. Accordini.
Activated: 7/16/18.

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)

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

Published

Persistent Disparity: Socioeconomic Deprivation and Cancer Outcomes in
Patients Treated in Clinical Trials. Unger, Moseley, Cheung, Osarogiagbon,
Symington, Ramsey, Hershman. In press, JCO.

Representativeness of Black Patients in Cancer Clinical Trials Sponsored by the National Cancer Institute Compared with Pharmaceutical Companies. Unger, Hershman, Raghav. JNCI Cancer Spectrum, 2020.

Healthcare Utilization and Cost of Care in Elderly Breast Cancer Patients Enrolled in SWOG Clinical Trials. Dawn Hershman, M.D.

Association of the Coronavirus Disease 2019 (COVID-19) Outbreak with Enrollment in Cancer Clinical Trials. Unger, Blanke, Hershman. JAMA Network Open, 2020.

Association of Patient Demographic Characteristics and Insurance Status with Survival in Cancer Randomized Clinical Trials With Positive Findings. Unger, Hershman. JAMA Network Open, 2020.

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.

It's Spring. Time to Tweet!

Socialize your SWOG meeting.

Tweet your sessions with the hashtag #SWOGonc and tag your @SWOG friends.

We're now 10,000 followers strong.

Thanks for building the flock!

#StayConnected



Cancer Care Delivery (CCD) Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	S1415CD	S1703	S1916	A011104	A191402C	A231601C	A231602C	ACCL16W1	EA1151	EAQ162CD	EAQ171CD	NHLBIMDS	NRGCC007
Arizona CC, Univ of	-	-	-	-	-	-	-	-	47	-	-	-	-
Arkansas, U of	-	3	-	-	-	-	-	-	233	-	-	-	-
Baptist MU-NCORP	149	-	-	1	-	-	-	-	-	-	-	-	-
Bay Area NCORP	36	-	-	-	-	-	-	-	-	-	-	-	-
Brooke Army Med Ctr	-	-	-	2	-	-	-	-	-	-	-	-	-
CORA NCORP	60	5	-	-	-	-	-	-	-	-	-	-	-
CRC West MI NCORP	60	-	-	-	-	-	-	3	-	-	-	-	-
CROWN NCORP	-	1	-	-	-	-	-	-	-	-	-	-	-
Carle CC NCORP	60	5	1	-	-	-	-	-	-	-	-	-	-
Cleveland Clinic OH	-	5	-	-	-	-	-	-	-	-	-	5	-
Colorado, U of	-	-	-	-	-	-	-	-	2	-	-	3	-
Columbia MU-NCORP	118	8	-	-	1	-	-	-	-	-	-	4	-
Columbus NCORP	26	2	-	-	-	-	-	-	-	-	-	-	-
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	-	-	-	-	-	-	17	-	-	-	-	-
Greenville NCORP	61	5	-	-	-	-	-	-	150	-	-	2	-
Gulf South MU-NCORP	102	3	-	-	-	1	-	-	-	4	-	-	-
H Lee Moffitt CC	-	-	-	-	-	-	-	-	-	-	-	8	-
Hawaii MU-NCORP	73	3	-	-	-	-	-	-	-	10	-	5	-
Heartland NCORP	328	6	1	-	-	-	-	-	-	-	-	-	1
Henry Ford Hospital	-	-	-	-	-	-	-	-	129	-	-	-	-
Irvine, U of CA	-	-	-	-	-	-	-	-	-	-	-	5	-
Kaiser Perm NCORP	-	1	-	-	13	-	-	34	-	11	-	5	-
Kansas City NCORP	6	-	-	-	-	-	-	-	-	-	-	2	-
Kansas MU-NCORP	-	2	-	-	-	-	4	-	-	-	-	-	4

Cancer Care Delivery (CCD) Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	S1415CD	S1703	S1916	A011104	A191A02C	A231601C	A231602C	ACCL16W1	EA1151	EAQ162CD	EAQ171CD	NHLBIMDS	NRGCC007
Lahey Hosp & Med Ctr	-	4	-	-	-	-	-	-	-	-	-	-	-
Loyola University	-	1	-	-	-	-	-	-	-	-	-	-	-
MAVERIC	-	-	-	-	-	-	-	-	-	-	-	16	-
MUSC MU-NCORP	-	-	-	-	-	-	-	-	-	-	-	1	-
Memorial Hermann	-	-	-	-	-	-	-	-	8	-	-	-	-
Michigan CRC NCORP	276	2	-	-	-	-	-	-	-	-	-	-	-
Montana NCORP	126	6	-	-	-	-	-	-	-	-	-	-	-
Nevada CRF NCORP	-	-	-	-	-	-	-	-	-	1	-	-	-
New Mexico MU-NCORP	250	3	-	-	-	-	-	-	-	-	-	-	-
Northwest NCORP	104	-	-	-	-	-	-	-	-	-	-	-	-
Oregon Hlth Sci Univ	-	-	-	-	-	-	-	-	-	-	-	3	-
Ozarks NCORP	114	-	-	-	-	-	-	-	-	-	-	-	-
PCRC NCORP	186	6	-	-	-	-	-	-	-	4	-	-	-
Providence Hosp	-	-	-	13	-	-	-	-	-	-	-	1	-
Rochester, Univ of	-	4	-	-	-	-	-	-	203	-	-	-	-
San Diego, U of CA	-	-	-	-	-	-	-	-	-	-	-	13	-
Southeast COR NCORP	120	1	-	2	-	-	-	-	389	11	-	-	-
Upstate NCORP	-	-	-	-	-	-	-	-	230	1	-	-	-
VAMC Kansas City	-	-	-	-	-	-	-	-	-	-	-	4	-
Wayne State Univ	-	-	-	1	-	-	-	-	-	-	-	-	-
Western States NCORP	-	-	-	-	-	-	-	-	41	-	1	-	-
Wichita NCORP	60	-	-	-	-	-	-	-	-	-	-	-	-
William Beaumont	7	-	-	-	5	-	-	-	-	-	-	2	-
Wisconsin NCORP	163	1	-	-	-	-	-	-	-	-	-	-	-
Yale University	-	12	-	4	-	-	-	-	-	-	-	7	-
Alliance	360	3	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	394	12	-	-	-	-	-	-	-	-	-	-	-
NRG	178	9	-	-	-	-	-	-	-	-	-	-	-
Total	3,665	117	2	23	19	1	4	54	1,434	44	1	99	5

Cancer Survivorship Committee

Committee Leadership

Co-Chairs: Halle C.F. Moore, M.D.
..... Melinda Irwin, Ph.D., M.P.H.

Agenda

Wednesday, April 21, 2021 | 2:00 pm- 4:00 pm CT

Welcome and Introduction: Melinda Irwin and Halle Moore

Presentation: Building a Learning Healthcare System for Oncology to Improve Personalized Care Delivery, Value, and Research

Catherine M. Alfano, PhD

Vice President, Cancer Care Management and Research

Northwell, Health Cancer Institute

Professor, Department of Medicine

Donald and Barbara Zucker School of Medicine at Hofstra/Northwell & Center for Personalized Health

Discussion

Patient Advocate Update: Lee Jones

Active Study

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

Concepts in Development:

Leah Ferrucci: Obesity, Metabolomics, Microbiome and Cancer Outcomes

Christine Duffy: Caregiver Care Plan

Dan Raz: Perioperative Physical Activity for Older Adults Scheduled for Lung Cancer Surgery and Their Caregivers.

William Evans: Changes in Muscle Mass in Patients with Lung Cancer.

Grant Williams: Sarcopenia, Dosing Strategies and Cancer Survival

Vickie Baracos: Loss of Muscle and Fat Mass Induced by Inflammation, Disease Progression and Treatment Toxicity in S0816

Halle Moore: COG/Intergroup Study "GnRH Agonists for Ovarian Function Protection During Chemotherapy Treatment of Non-Breast AYA Malignancies."

Other ideas

Liaison Updates

Cardiac Advisory Panel Update

Cancer Survivorship Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	S1501	A221405	EA9131
Baptist MU-NCORP	5	-	-
Bay Area NCORP	2	-	-
CORA NCORP	1	-	-
City of Hope Med Ctr	39	-	-
Cleveland Clinic OH	12	-	-
Colorado, U of	-	12	-
Columbia MU-NCORP	2	-	-
Davis, U of CA	2	-	-
Fred Hutchinson CRC	3	2	-
GACARES MU-NCORP	-	-	1
Georgia NCORP	8	-	-
Greenville NCORP	2	-	-
Gulf South MU-NCORP	3	-	-
H Lee Moffitt CC	9	-	-
Heartland NCORP	15	-	-
Henry Ford Hospital	1	-	-
Kaiser Perm NCORP	-	-	51
Kansas MU-NCORP	6	-	-
King Faisal Spec Hos	3	-	-
Lahey Hosp & Med Ctr	6	-	-
Loyola University	8	-	-
MUSC MU-NCORP	1	-	-
Michigan CRC NCORP	3	-	-
Michigan, U of	7	-	-
Montana NCORP	1	-	-
Northwestern Univ	-	1	-
Oregon Hlth Sci Univ	1	-	-
Ozarks NCORP	9	-	-
Providence Hosp	2	-	-
So Calif, U of	2	-	-
Wayne State Univ	6	-	-
Yale University	-	5	-
Alliance	17	-	-
ECOG-ACRIN	30	-	-
NRG	16	-	-
Total	222	20	52

Palliative & End of Life Care Committee

Committee Leadership

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

Agenda

Thursday, April 22, 2021

2:45 pm - 4:45 pm CT

5 minutes Welcome and Introductions – Co-Chairs

5 minutes Committee Liaison Updates (Patient Advocates/
Nursing)

10 minutes Committee Member Wellbeing Check-in / Marie A.
Bakitas, DNSc, NP-C, FAAN

25 minutes (each)

Plenary 1 - S1316 "Prospective Comparative
Effectiveness Trial for Malignant Bowel Obstruction." Dr.
R. Krouse.

Plenary 2 – Hope Drs. D. Feldman & B. Corn

30 minutes Developing Concepts Discussion

10 minutes Active Study Updates

10 minutes New Business

Closing Comments and Adjourn

Active Studies

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.

Developing Studies

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

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

Secondary Analysis

"Fatigue secondary analyses." Dr. Mo

Palliative & End of Life Care Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	S1316	S1820
Arizona CC, Univ of	11	1
Arkansas, U of	6	-
Baylor College	1	-
City of Hope Med Ctr	5	2
Columbia MU-NCORP	1	-
Columbus NCORP	-	1
Essentia Hlth NCORP	1	-
Fred Hutchinson CRC	-	2
Greenville NCORP	-	5
H Lee Moffitt CC	3	-
INC, Bogota	1	-
INCan	8	-
INEN	7	-
Irvine, U of CA	-	5
Kansas MU-NCORP	18	-
Loma Linda Univ	1	-
MD Anderson CC	2	-
MUSC MU-NCORP	5	-
Michigan CRC NCORP	-	2
Michigan, U of	8	-
New Mexico MU-NCORP	1	-
Northwestern Univ	-	1
Oklahoma, Univ of	2	-
San Antonio, U of TX	7	-
Tennessee, U of	42	-
Alliance	27	3
ECOG-ACRIN	2	1
NRG	62	10
Total	221	33

"Quality of Life and Survival/Toxicity in Cancer Treatment Trials." Dr. Hui

Closed Studies

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

SWOG Provider Hope and Burnout Survey with manuscript in preparation

Prevention & Epidemiology Committee

Committee Leadership

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

Agenda

Friday, April 23, 2021
12:30 pm - 2:30 pm CT

Introduction

Welcome and Opening Comments Dr. Marian Neuhouser and Dr. Banu Arun

Cancer Prevention Presentation:

"Precancer genome-immune interactions and malignant transformation"
Scott M. Lippman, MD, UC San Diego Moores Cancer Center

Active Studies

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

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

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

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

New Concepts Melanoma Update

Melanoma Chemoprevention. Sancy Leachman, MD

Pending CTEP Approval

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

Concept Reviewed by Cancer Prevention Steering Committee:

S2003, "Phase II Study of Intraoperative Radiotherapy (IORT) for DCIS after Breast Conserving Surgery." Dr. E. Connolly.

Next steps and updates

Concept pending R21 funding

"Effects of Chemoprevention and Adjuvant Endocrine Therapy on a Convolutional Neural Network (CNN)-Based Breast Cancer Risk Model Using Breast Imaging Datasets." Drs. K. Crew, K. Kalinsky, R. Ha.

New Business/Open Discussion

Prevention & Epidemiology Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	S0820	S1823	A211102	A211401	A211601
Arizona CC, Univ of	-	1	-	-	-
Banner MD Anderson	10	-	-	-	-
Baptist MU-NCORP	5	-	-	-	-
Bay Area NCORP	1	1	-	-	-
Brooke Army Med Ctr	1	-	-	-	-
CORA NCORP	4	-	-	-	-
CRC West MI NCORP	1	-	-	-	-
Carle CC NCORP	-	1	-	-	-
City of Hope Med Ctr	1	-	2	-	-
Colorado, U of	5	-	-	-	-
Columbia MU-NCORP	1	-	1	-	-
Columbus NCORP	5	-	-	-	-
Dayton NCORP	1	-	-	-	-
Essentia Hlth NCORP	4	-	-	-	-
GACARES MU-NCORP	2	-	-	-	-
Georgia NCORP	2	-	-	-	-
Greenville NCORP	-	4	-	-	-
Gulf South MU-NCORP	-	1	-	-	-
Hawaii MU-NCORP	10	-	-	-	-
Heartland NCORP	2	1	-	-	-
Irvine, U of CA	27	-	-	-	-
Kaiser Perm NCORP	37	6	-	-	-
Kansas MU-NCORP	3	-	-	-	-
Loma Linda Univ	2	-	-	-	-
Loyola University	2	-	-	-	-
MAVERIC	3	-	-	2	-
MD Anderson CC	4	-	-	-	-

	S0820	S1823	A211102	A211401	A211601
Michigan CRC NCORP	9	-	-	-	-
Mississippi, Univ of	1	-	-	4	-
Nevada CRF NCORP	1	-	-	-	-
New Mexico MU-NCORP	1	-	-	-	-
Northwell NCORP	-	1	-	-	-
Northwest NCORP	10	-	-	-	-
Oklahoma, Univ of	1	-	-	-	-
Ozarks NCORP	-	1	-	-	-
PCRC NCORP	2	-	-	-	-
Providence Hosp	1	-	-	-	2
Rochester, Univ of	-	2	-	2	-
San Antonio, U of TX	8	-	-	-	-
Scott & White Mem	-	-	-	2	-
So Calif, U of	5	9	-	-	-
Southeast COR NCORP	2	1	-	-	-
Vanderbilt Univ	-	2	-	-	-
Virginia Mason MC	2	2	-	-	-
Wayne State Univ	2	-	-	-	-
Wichita NCORP	13	-	-	-	-
Wisconsin NCORP	2	-	-	-	-
Yale University	22	-	-	-	-
Alliance	32	6	-	-	-
CCTG	-	1	-	-	-
ECOG-ACRIN	22	3	-	-	-
NRG	34	-	-	-	-
Total	303	43	3	10	2

Symptom Control & Quality of Life Committee

Committee Leadership

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

Agenda

Wednesday, April 21, 2021
11:15 am - 12:45 pm CT

Special Symposium: Wearables in Symptom Research for Cancer Patients

Plenary speaker: "Digital biomarkers, sensors, PROs and functional assessments: meeting patients where they are to improve person-centered oncology care." Dr. Wood

Plenary speaker: "Patient-centered digital outcome measures in chronic illness obtained using mobile health technologies" Dr. Bonato

Panel discussion about use of wearables

Active Studies

S1600, "A Randomized Phase III Double-Blind Clinical Trial Evaluating The Effect Of Immune-Enhancing Nutrition On Radical Cystectomy Outcomes." Dr. Hamilton-Reeves. Activated: 2/21/19.

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.

Temporarily Closed

S1614, "A Phase III Randomized Trial Of Prophylactic Antiviral Therapy In Patients With Current Or Past Hepatitis B Virus (HBV) Infection Receiving Anti-Cancer Therapy For Solid Tumors." Drs. Hwang, Lok, and Ghering, et al. Temporarily Closed to Accrual

Other Concepts in Development

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

S2010, Improving Endocrine Therapy-Emergent Symptoms in Young Women with Breast Cancer using Active Symptom Monitoring." Dr. Henry

S2013, "Immune Checkpoint Inhibitor Toxicity (I-Checkit): A Prospective Observational Study" – Drs. Gunturu, Hershman, and Kuderer.

Committee Business

What is happening with our open studies?

What other studies are we planning?

What has SCQOL contributed to the literature recently?

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." Dr. Van Poznak and Dr. Gralow M.D. Activated: 12/15/08. Closed to Accrual: 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-EGFR 18(FACT-EGFR 18) Questionnaire for EGFR-Induced Skin Toxicities." Dr. Wong, Pharm.D. and Dr. Wade M.D. Activated: 11/15/11. 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 and Crew. Activated: 3/27/12. 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 and Schott. Activated: 5/15/13. Closed to accrual 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. 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. Puztai Mammen, Henry, et al. Activated: 11/15/16.

Symptom Control & Quality of Life Committee

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

S1807, "A Phase II Randomized Double-Blinded, Controlled Study of Tucatinib (ONT-380) Following Stereotactic Radiosurgery (SRS) HER2-Positive Breast Cancer Brain Metastases." Dr. Tsien.

GU

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

S-N1806, "Phase III Randomized Trial of Concurrent Chemoradiotherapy with or Without Atezolizumab in Localized Muscle Invasive Bladder Cancer." Dr. Singh. Activated: 4/19/18.

Leukemia

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 (LEAP: Intergroup Less Intense AML Platform Trial)." Drs. Michaelis, Walter, Assouline, et al. Activated: 12/22/17. Permanently Closed to Accrual: 9/1/20

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

Lung

S1400I, "A Phase III Randomized Study of Nivolumab plus Ipilimumab Versus Nivolumab for Previously Treated Patients with Stage IV Squamous Cell Lung Cancer and No Matching Biomarker (LUNG-MAP Sub-Study)." Drs. Gettinger and Bazhenova. Activated: 12/18/15. Closed: 4/23/18.

S1400GEN, "Ancillary Study to Evaluate Patient and Physician Knowledge, Attitudes, and Preferences Related to Return of Genomic Results in S1400." Drs. Ramsey and Hershman. Activated: 2/5/18. Closed: 6/30/19.

S1827, "PCI vs Active MRI Surveillance in Small-Cell Lung Cancer." Dr. Rusthoven. Activated: 1/10/20 PRO is in progress, will be added to Revision #2.

Lymphoma

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." Dr. Herrera M.D. and Dr. Friedberg M.D. Activated: 7/19/19

Melanoma

S1404, "A Phase III Randomized Trial Comparing Physician/Patient Choice of Either High Dose Interferon or Ipilimumab to MK-3475 (Pembrolizumab) in Patients with High Risk Resected Melanoma." Drs. Grossmann, Patel, Knopp, et al. Activated: 10/15/15. Closed: 11/2/17.

Myeloma

S1803, "Phase III Study of Daratumumab (NSC-791647) + Lenalidomide (LD) or Lenalidomide (L) as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) Using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC Study)." Drs. Krishnan, Hari, Wallace, et al. Activated: 6/27/19. PRO is in progress will be added to Revision #5.

Survivorship

"A Randomized study of Usual Care with or without Fracture Prevention Education and Postural and Spine Strengthening Exercise to improve quality of life and kyphosis angle in Cancer Patients." Dr. Hayostek

NCTN Studies

CTSUNRG-GI004, "Colorectal Cancer Metastatic dMMR Immunotherapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/Bevacizumab Combination Chemotherapy with or Without Atezolizumab or Atezolizumab Monotherapy in the First Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR) Metastatic Colorectal Cancer." Dr. Overman. Activated: 11/7/17.

Symptom Control & Quality of Life Committee

[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. 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. 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. 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. 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. 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 \rightarrow R); Arm B = Rituximab + Bendamustine + Bortezomib Followed by Rituximab Consolidation (RBV \rightarrow R), Arm C = Rituximab + Bendamustine Followed by Lenalidomide + Rituximab Consolidation (RB \rightarrow LR) or Arm D = Rituximab + Bendamustine + Bortezomib Followed by Lenalidomide + Rituximab Consolidation (RBV \rightarrow LR)." Dr. Till. Activated: 5/22/12. 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. 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. 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.

[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. 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. Temporarily closed: 2/23/15.

[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. 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.

[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. 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. Closed: 11/10/15.

Symptom Control & Quality of Life Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	S1600	S1614	S1714	A171601	A221504	A221505	A221602	A221702	A221805	EA2171
Arkansas, U of	-	-	41	-	-	-	-	-	-	-
CORA NCORP	-	-	49	-	-	-	-	-	-	-
CRC West MI NCORP	-	-	99	-	-	-	-	-	-	-
Carle CC NCORP	-	-	3	-	-	-	-	-	-	-
Cleveland Clinic OH	-	-	-	-	-	3	-	-	-	-
Colorado, U of	2	-	-	-	-	14	-	-	-	-
Columbia MU-NCORP	-	-	18	-	-	-	1	-	-	-
Davis, U of CA	-	-	-	1	-	-	-	-	-	-
Dayton NCORP	-	-	-	-	1	-	1	-	1	-
Desert Hospital	-	-	-	-	-	-	2	-	-	-
Georgia NCORP	-	-	11	-	-	-	-	-	-	-
Greenville NCORP	-	-	6	-	-	-	-	-	-	-
Gulf South MU-NCORP	-	-	10	-	-	1	-	-	-	1
Hawaii MU-NCORP	-	-	47	-	-	-	-	-	-	-
Heartland NCORP	-	-	15	-	-	-	-	-	-	-
Henry Ford Hospital	2	-	-	-	-	-	-	-	-	-
INC, Bogota	-	-	7	-	-	-	-	-	-	-
INCan	-	-	13	-	-	-	-	-	-	-
Irvine, U of CA	-	-	-	-	-	1	3	-	-	-
Kaiser Perm NCORP	-	1	10	-	-	-	-	-	-	-
Kansas MU-NCORP	13	-	9	-	-	-	-	-	-	-
Kentucky, U of	-	-	-	-	-	-	5	-	-	-
Lahey Hosp & Med Ctr	-	-	13	-	-	-	-	-	-	-
Loyola University	-	-	2	-	1	-	-	-	-	-
Northwell NCORP	-	-	-	-	-	-	1	-	-	-
Ozarks NCORP	-	-	6	-	-	-	-	-	-	-
PCRC NCORP	-	-	2	-	-	-	-	-	-	-
Rochester, Univ of	-	-	-	-	1	-	-	14	-	-
San Antonio, U of TX	-	-	8	-	-	-	-	-	-	-
So Calif, U of	6	-	-	-	1	-	-	-	-	-
Southeast COR NCORP	-	-	123	-	-	-	-	-	-	-
Upstate NCORP	-	-	70	-	-	1	-	-	-	-
Utah, U of	-	-	-	-	-	-	8	-	-	-
VAMC Kansas City	-	-	-	-	2	-	-	-	-	-
Wayne State Univ	-	-	-	1	-	-	-	1	-	-
West Clinic	-	-	-	-	-	1	-	-	-	-
Wichita NCORP	-	-	1	-	-	-	-	-	-	-
Alliance	1	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	21	-	-	-	-	-	-	-
NRG	1	1	38	-	-	-	-	-	-	-
Total	25	2	622	2	6	21	21	15	1	1

Early Therapeutics & Rare Cancers Committee

Committee Leadership

Chair: Razelle Kurzrock, MD
Vice-Chair: Young Kwang Chae, MD, MPH
Executive Officer: Christopher W. Ryan, MD
Statisticians: Megan Othus, PhD
..... Melissa Plets, MS
..... Edward Mayerson, MS

Designates

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

Early Therapeutics Liaisons

Breast Committee Liaison: George Somlo, MD
Cancer Control Liaison: Jason M. Prosek, MD
Genitourinary Committee Liaison: Neeraj Agarwal, MD
Imaging: TBD
Lung Committee Liaison: Shirish M. Gadgil, MD
Lymphoma Committee Liaison: Daruka Mahadevan, MD, PhD
Melanoma Committee Liaison: Jeffrey A. Sosman, MD
Myeloma Committee Liaison: Frits van Rhee, MD, PhD

Agenda

Thursday, April 22, 2021
2:00 pm - 4:00 pm CT

Introduction

12:00 - 12:05 pm Pacific: Razelle Kurzrock, MD, Director, Center for Personalized Cancer Therapy and Rare Tumor Clinic, UCSD Moores Comprehensive Cancer Center, San Diego, CA; Chair, Early Therapeutics and Rare Cancer Committee (SWOG).

Presentations

2:05 - 2:25 pm "Updates from Sarcoma Working Group." Lara Davis, MD, Associate Professor Knight Cancer Institute, Co-Leader, Translational Oncology Research Program, Sarcoma Disease Site Leader, Knight Cancer Institute, Oregon Health & Science University.

2:25 - 2:45 pm "Updates from CNS Working Group." Manmeet Ahluwalia, MD, Chief of Medical Oncology, Deputy Director, Chief

Scientific Officer, Miami Cancer Institute.

2:45 - 3:10 pm "CIMAC and Translational Immunology in DART." Young Chae, MD, Associate Professor, Co-Director, Early Therapeutics, Vice Chair, Early Therapeutics and Rare Cancers (SWOG), North-western University, Robert H. Lurie Comprehensive Cancer Center.

3:10 - 3:35 pm "DART: Clinical Trial Updates." Sandip Patel, MD, Associate Professor, Deputy Director, San Diego Center for Precision Immunotherapy, UC San Diego Moores Comprehensive Cancer Center, San Diego, CA.

3:35 - 3:55 pm "New Drugs in Oncology." Monica Mita, MD, Professor of Medicine, Co-Director, Experimental Therapeutics Program, Samuel Oschin Comprehensive Cancer Institute Cedars-Sinai Medical Center.

3:55 - 4:00 pm Wrap Up and Open Discussion. Razelle Kurzrock, MD, Director, Center for Personalized Cancer Therapy, UCSD Moores Comprehensive Cancer Center, San Diego, CA; 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, Giles, and Kurzrock. Activated: 1/13/17.

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

NCI COVID Study, "NCI COVID-19 in Cancer Patients Study (N-CCaPS): A Longitudinal Natural History Study." Dr. Karim.

CTSU/A071702, "A Phase II Study of Checkpoint Blockade Immunotherapy in Patients with Somatic 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. Swiechicki. Activated: 9/8/20.

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

Early Therapeutics & Rare Cancers Committee

Patients with Oligometastatic HER2 Negative Esophageal and Gastric Adenocarcinoma." Dr. Saeed. Activated: 2/6/20.

CTSU/EA3163, "Phase II Randomized Trial of Neo-Adjuvant 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 to Accrual to 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. Temporarily Closed to Accrual: 2/9/21.

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.

CTSU/A071401, "Phase II Trial of SMO/AKT/NF2/CDK Inhibitors in Progressive Meningiomas with SMO/AKT/NF2/CDK Pathway Mutations." Dr. Piccioni. Activated: 8/28/15. Temporarily Closed to Accrual: 2/15/18.

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.

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.



Early Therapeutics & Rare Cancers Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	S1609	EAY131		S1609	EAY131
Arizona CC, Univ of	7	8	MUSC MU-NCORP	4	1
Arkansas, U of	4	3	Michigan CRC NCORP	16	-
Baptist MU-NCORP	2	-	Michigan, U of	32	23
Baylor College	-	3	Mississippi, Univ of	5	-
CORA NCORP	8	1	Montana NCORP	12	-
CROWN NCORP	1	-	Nevada CRF NCORP	18	-
Carle CC NCORP	3	-	New Mexico MU-NCORP	17	-
Cedars-Sinai Med Ctr	7	6	Northwest NCORP	2	-
City of Hope Med Ctr	2	6	Northwestern Univ	16	-
Cleveland Clinic OH	4	9	Oklahoma, Univ of	1	-
Colorado, U of	6	9	Oregon Hlth Sci Univ	10	-
Columbus NCORP	3	-	Ozarks NCORP	1	-
Davis, U of CA	11	8	PCRC NCORP	11	-
Dayton NCORP	2	1	Providence Hosp	1	3
Essentia Hlth NCORP	4	-	Rochester, Univ of	5	-
Fred Hutchinson CRC	9	2	San Antonio, U of TX	5	7
Georgia NCORP	5	-	San Diego, U of CA	26	-
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	Utah, U of	3	-
Houston Methodist	-	1	Wayne State Univ	-	3
Irvine, U of CA	8	18	Western States NCORP	1	-
Kaiser Perm NCORP	26	6	Wisconsin NCORP	13	-
Kansas City NCORP	-	1	Yale University	7	13
Kansas MU-NCORP	35	5	Alliance	99	-
Kentucky, U of	-	13	ECOG-ACRIN	76	-
Loma Linda Univ	6	1	NRG	127	-
Loyola University	4	-	Total	758	177
MAVERIC	5	-			
MD Anderson CC	19	-			

Gastrointestinal Committee

Committee Leadership

Chair: Philip A. Philip, MD, PhD, FRCP
Vice-Chair: Cathy Eng, MD
Executive Officer: Christopher W. Ryan, MD
Statisticians: Katherine A. Guthrie, PhD
..... Mai Duong, MS

Scientific Leadership

Phase I Studies: Sandip P. Patel, MD
Gastroesophageal: Syma Iqbal, MD
..... Zev A. Wainberg, MD
..... Daneil Catenacci, MD, PhD (Translational Medicine)
Pancreatic: Elena Gabriela Chiorean, MD
..... Andrew M. Lowy, MD (Surgical representative)
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)
..... Mark A. O'Rourke, MD (Palliative Care)
Digital Engagement: Heloisa Soares, MD, PhD
Data Coordinators: Christine Magner
..... Jacqueline Scurlock
..... Brian Zeller
..... Sewan Gurung

Oncology Research Professionals:

CRA: Sandy Annis, 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

Thursday, April 22, 2021
10:00 am - 12:00 pm CT

5 minutes	Welcome and Introductions – Drs. Philip and Eng
10 minutes	Committee Liaison Updates (Patient Advocates/ Nursing)
30 minutes	Featured Trials

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 S2104, Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolomide Versus Observation in High-Risk Pancreatic Neuroendocrine Tumors. Drs. Soares and Ahmed.

70 minutes Active Study Updates and Developing Concepts

5 minutes New Business

Closing Comments and Adjourn

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.

CTS/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.

Gastrointestinal Committee

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.

Neuroendocrine

Proposed Studies

S2104, "Randomized Phase II Trial of Postoperative Adjuvant Capecitabine and Temozolimide 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.

CTSU/EA2142, "Randomized Phase II Study of Platinum and Etoposide versus Temozolomide and Capecitabine in Patients with Advanced G3 Non-Small Cell Gastroenteropancreatic Neuroendocrine Tumors Including Poorly Differentiated Neuroendocrine Carcinomas and Well-Differentiated Neuroendocrine Neoplasms." Dr. Soares. Activated: 11/6/15.

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.

RTOG-1112, "Randomized Phase III Study of Sorafenib Versus Stereotactic Body Radiation Therapy Followed by Sorafenib in Hepatocellular Carcinoma." Dr. Mitin. Activated: 4/24/13.

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. 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. Temporarily closed to accrual for U.S. sites: 12/28/20.

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

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

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

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

Gastrointestinal Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	S1613	S1815	S1922	A021502	A021602	A021703	A021806	EA2142	EA2161	EA2165	EA2186	EA2187	NRGG1004	NRGG1005
Arizona CC, Univ of	-	12	-	2	-	-	-	-	-	-	-	-	-	-
Arkansas, U of	-	1	-	-	-	-	-	-	-	6	-	-	-	-
Baylor College	-	5	-	-	-	-	-	-	-	-	-	-	-	-
Boston Medical Ctr	-	-	-	1	1	-	-	-	-	1	-	-	-	-
CORA NCORP	1	3	-	-	-	-	-	-	-	-	-	-	-	-
CRC West MI NCORP	-	2	-	-	-	-	-	-	-	-	-	-	-	-
CROWN NCORP	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Cincinnati MC, U of	-	2	-	-	-	3	-	-	-	2	-	-	-	-
City of Hope Med Ctr	-	4	-	-	1	-	-	-	-	-	1	-	-	-
Cleveland Clinic OH	-	-	-	3	-	-	-	-	-	-	-	-	-	-
Colorado, U of	1	-	-	4	-	-	-	-	-	-	-	-	-	-
Columbus NCORP	-	3	-	-	-	-	-	-	-	-	-	-	-	-
Davis, U of CA	2	4	-	4	-	-	-	-	-	5	-	-	-	1
Dayton NCORP	-	2	-	3	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson CRC	-	-	-	2	-	-	-	-	-	3	-	-	-	-
Greenville NCORP	-	11	-	-	-	-	-	-	-	-	-	-	-	-
Gulf South MU-NCORP	-	3	-	-	-	-	-	-	-	-	-	-	-	-
H Lee Moffitt CC	-	-	-	-	4	-	-	-	-	-	-	-	-	-
Hawaii MU-NCORP	-	10	-	-	-	-	-	-	-	-	1	-	-	-
Heartland NCORP	2	7	-	-	-	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	2	-	-	-	-	-	1	-	-	-	-	-	1
Houston Methodist	-	-	-	-	-	-	-	-	-	-	-	-	1	-
Kaiser Perm NCORP	-	-	-	11	-	-	-	2	-	5	-	-	-	1
Kansas MU-NCORP	3	-	-	2	-	1	-	-	-	-	-	-	-	-
Lahey Hosp & Med Ctr	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Lee Memorial Health	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Loyola University	1	-	-	-	-	-	-	-	-	-	-	-	-	-
MD Anderson CC	11	21	4	-	-	-	-	-	-	-	-	-	12	-

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/EA2165, "A Randomized Phase III Study of Nivolumab After Combined Modality Therapy (CMT) in High Risk Anal Cancer." Dr. Morris. Activated: 4/13/18.

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: 8/12/1

Gastrointestinal Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	S1613	S1815	S1922	A021502	A021602	A021703	A021806	EA2142	EA2161	EA2165	EA2186	EA2187	NRGG1004	NRGG1005
Michigan, U of	1	3	-	-	-	-	1	3	1	-	-	-	-	-
Montana NCORP	-	4	-	-	-	-	-	-	-	-	-	-	-	-
New Mexico MU-NCORP	-	8	-	-	-	-	-	-	-	-	-	-	-	-
Northwell NCORP	-	-	-	-	-	2	-	-	-	-	-	-	-	-
Northwestern Univ	-	17	-	-	-	1	-	-	-	-	-	-	-	-
Oregon Hlth Sci Univ	-	3	-	-	-	-	-	-	-	2	-	-	-	-
Ozarks NCORP	-	3	-	-	-	-	-	-	-	-	-	-	-	-
PCRC NCORP	3	8	-	-	-	-	-	-	-	-	-	-	-	-
Providence Hosp	-	-	-	-	-	-	-	-	-	-	1	-	-	-
Rochester, Univ of	-	9	-	2	2	-	-	-	-	-	-	1	1	-
San Antonio, U of TX	-	1	-	-	-	-	1	-	-	-	-	-	-	-
So Calif, U of	1	8	-	-	-	-	-	-	-	-	-	-	-	-
Southeast COR NCORP	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Sutter Cancer RC	-	-	-	3	-	-	-	-	-	-	-	-	-	-
Utah, U of	-	5	-	-	-	-	-	-	-	-	-	-	-	-
Vanderbilt Univ	-	3	-	-	-	-	-	-	-	-	-	-	-	-
Virginia Mason MC	-	-	-	2	2	-	-	-	-	-	-	-	-	-
Wayne State Univ	-	2	-	1	-	-	-	-	-	3	-	-	-	-
West Clinic	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Western States NCORP	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Wichita NCORP	-	1	-	-	-	-	-	-	-	-	-	-	-	-
William Beaumont	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Wisconsin NCORP	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Yale University	-	9	-	-	-	-	-	-	-	-	-	-	-	-
Alliance	4	108	1	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	3	83	-	-	-	-	-	-	-	-	-	-	-	-
NRG	2	37	1	-	-	-	-	-	-	-	-	-	-	-
Total	37	408	6	41	10	7	2	6	1	28	3	1	14	3

Genitourinary Committee

Committee Leadership

Chair: Ian M. Thompson, Jr., MD
Vice-Chair: Nicholas J. Vogelzang, 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
Data Coordinators: Sean O'Bryan
..... Tonya Johnson
..... Kelly Kasa
..... Laura Kingsbury
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)
..... Hartley "Lee" M. Jones, M.B.A.
Pharmaceutical Science: Joyce Lee, PharmD
..... Jason M. Reed, PharmD, RPh

Protocol Coordinator: TBD
Clinical Trials Project Manager: Sandi Hita, JD

GU Committee Part I: Prostate, Cancer Control and Prevention, Renal

Thursday, April 22, 2021
2:30 pm - 4:30 pm CT

2:30 – 2:35 pm Welcome (Dr. Thompson)
2:35 – 3:25 pm Prostate (Drs. Quinn and Lin)
3:25 – 3:40 pm Cancer Control and Prevention
3:40 – 4:30 pm Renal (Drs. Vaishampayan and Shuch)

GU Committee Part II: Bladder, Translational Medicine

Friday, April 23, 2021
2:30 pm - 4:30 pm CT

2:30 – 3:30 pm Bladder Organ Site (Drs. Lerner and Petrylak)
3:30 – 4:25 pm Translational Medicine (Drs. McConkey et al)
4:25 – 4:30 pm Wrap-up and Announcements

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. Sadeghi and 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. Singh, Lerner, Efsthathiou, et al. Activated: 4/19/19

CTSU/A031701, "A Phase II Study of Dose-Dense Gemcitabine Plus Cisplatin (ddGC) in Patients with Muscle-Invasive Bladder Cancer with Bladder Preservation for Those Patients Whose Tumors Harbor Deleterious DNA Damage Response (DDR) Gene Alterations." Dr. A. Gupta and Dr. S. Gupta. Activated: 8/1/18.

CTSU/A031803, "Phase II Trial of Intravesical Gemcitabine and MK-3475 (Pembrolizumab) in the Treatment of Patients with BCG-Unresponsive Non-Muscle Invasive Bladder Cancer." Drs. Tyson and Ramamurthy. Activated: 1/6/20.

Genitourinary Committee

CTSU/NRG-GU005, "Phase III IGRT and SBRT Vs IGRT and Hypofractionated IMRT for Localized Intermediate Risk Prostate Cancer." Dr. Yu. Activated: 11/16/17.

CTSU/NRG-GU007, "Randomized Phase II Trial of Niraparib with Standard Combination Radiotherapy and Androgen Deprivation Therapy (ADT) in High Risk Prostate Cancer (with Initial Phase I) (NADIR*) *Randomized Phase II Trial of Niraparib With Standard Combination Androgen Deprivation Therapy (ADT) and Radiotherapy In High Risk Prostate Cancer (With Initial Phase I)." Dr. VanderWeele. Activated: 6/3/19.

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

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. Agarwal, Goldkorn, Gupta, et al. Activated: 3/1/13. 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. Zeng. Activated: 4/27/18. Closed: 5/19/20.

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

Translational Medicine

Chair: Dr. David McConkey

Bladder Chair: Dr. Joshua Meeks

Prostate Chair: Dr. Amir Goldkorn

Renal Chair: Dr. Sumanta "Monty" Pal

Cancer Control

Liaison: Dr. Peter J. Van Veldhuizen

Active Studies

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

Diverse Studies of Interest

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

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

Closed Studies

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



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Genitourinary Committee

Closed Studies

S1011, "A Phase III Surgical Trial to Evaluate the Benefit of a Standard Versus an Extended Pelvic Lymphadenectomy Performed at Time of Radical Cystectomy for Muscle Invasive Urothelial Cancer." Drs. Lerner, Alva, Koppie, et al. Activated: 8/1/11. 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. Svatek. Activated: 2/7/17. Closed: 12/15/20.

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

Renal

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

Priority Study

S1931, "Phase III Trial of Immunotherapy-Based Combination Therapy with or Without Cytoreductive Nephrectomy for Metastatic Renal Cell Carcinoma (PROBE Trial)." Drs. H. Kim, and 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. Parikh. Activated: 10/9/18.

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.

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

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

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. McKay. Activated: 12/13/19.

Closed Studies

S1500, "A Randomized, Phase II Efficacy Assessment of Multiple MET Kinase Inhibitors (Cabozantinib [NSC #761968], Crizotinib [NSC #749005], Savolitinib [NSC #785348], and Sunitinib [NSC #736511]) in Metastatic Papillary Renal Carcinoma (PAPMET)." Drs. Pal, Lara, and Shuch. Activated: 4/5/16. Closed: 12/15/19.

S0931, "EVEREST: Everolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study." Drs. Ryan, Heath, Lara, et al. Activated: 4/1/11. 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. Closed 7/25/17.

Prostate

Organ Site Chairs: Dr. David I. Quinn (Advanced) and Dr. Daniel W. Lin (Local)

Priority Study

S1802, "Phase III Randomized Trial of Standard Systemic Therapy (SST) Versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer." Drs. Chapin and 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 (TICE) as First Salvage Treatment in Relapsed or Refractory Germ Cell Tumors." Dr. Quinn. Activated: 7/1/15.

CTSU/EA8153, "Cabazitaxel with Abiraterone Versus Abiraterone Alone Randomized Trial for Extensive Disease Following Docetaxel: The CHAARTED2 Trial." Dr. Corn. Activated: 2/8/18.

CTSU/EA8171, "Multiparametric MRI (mpMRI) for Preoperative Staging and Treatment Planning for Newly-Diagnosed Prostate Cancer." Dr. 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. Raben. Activated: 12/30/16.

Genitourinary Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	S1500	S1602	S1605	S1802	S1806	A031102	A031501	A031701	A031702	A031704	A031801	A031803	EA8134	EA8143	EA8153	EA8171	NRGGU002	NRGGU005	NRGGU006	NRGGU008
Arizona CC, Univ of	-	-	-	4	-	-	-	-	-	-	-	-	-	7	-	-	-	-	-	-
Arkansas, U of	1	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Banner MD Anderson	-	7	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Baylor College	-	21	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Birmingham, U of AL	-	-	-	-	-	-	-	-	1	-	-	-	-	4	-	-	-	-	-	-
CRC West MI NCORP	1	-	-	2	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Cedars-Sinai Med Ctr	1	12	-	-	3	-	-	-	-	-	-	-	-	8	-	-	-	-	-	-
Cincinnati MC, U of	-	-	-	2	-	-	-	-	-	4	-	-	-	-	-	-	-	-	-	-
City of Hope Med Ctr	21	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Cleveland Clinic OH	-	-	-	-	-	-	-	4	-	-	-	-	-	-	-	-	-	-	-	-
Colorado, U of	-	23	5	3	2	-	12	-	-	5	-	-	-	1	-	-	1	1	-	-
Columbia MU-NCORP	-	-	-	-	-	-	2	-	-	-	-	-	-	1	-	-	-	-	-	-
Columbus NCORP	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Cotton O'Neil CC	1	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Davis, U of CA	3	-	1	6	4	-	3	3	-	-	1	1	-	1	-	-	-	-	-	-
Dayton NCORP	-	1	1	2	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Essentia Hlth NCORP	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson CRC	-	26	-	5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Greenville NCORP	1	1	1	5	-	-	-	-	-	1	-	-	-	1	-	-	-	-	-	-
Gulf South MU-NCORP	1	95	3	44	31	-	2	-	-	-	1	3	-	10	-	11	1	1	-	2
H Lee Moffitt CC	-	26	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Harrison Medical Ctr	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hawaii MU-NCORP	-	9	3	-	1	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Heartland NCORP	4	4	6	2	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	13	-	5	-	-	1	-	1	5	-	-	-	1	-	-	-	-	-	-
Houston Methodist	-	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Irvine, U of CA	-	16	-	-	2	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-
Kaiser Perm NCORP	-	12	-	4	-	-	13	-	-	24	-	-	-	32	8	-	-	-	-	-
Kansas MU-NCORP	-	20	8	7	2	-	4	-	1	2	-	-	-	2	1	-	-	-	-	-
Kentucky, U of	-	-	3	-	1	-	-	-	-	-	-	-	-	12	-	-	-	-	-	-
Lahey Hosp & Med Ctr	-	-	-	-	-	-	4	-	4	-	-	-	-	3	-	-	-	-	-	-
Loma Linda Univ	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Los Angeles, U of CA	-	-	-	-	-	-	-	-	-	-	-	-	-	5	-	-	-	-	-	-
Loyola University	1	12	2	1	2	-	-	-	1	1	-	-	-	3	-	-	-	-	-	-

Genitourinary Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	S1500	S1602	S1605	S1802	S1806	A031702	A031501	A031701	A031702	A031704	A031801	A031803	EA8134	EA8143	EA8153	EA8171	NRGGU002	NRGGU005	NRGGU006	NRGGU008
MD Anderson CC	-	38	-	42	-	-	-	-	-	-	-	-	-	-	8	-	-	-	-	-
MUSC MU-NCORP	1	2	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Michigan CRC NCORP	1	6	-	3	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Michigan, U of	5	30	-	2	-	-	15	-	-	-	-	-	-	-	-	-	-	-	-	-
Mississippi, Univ of	1	-	-	1	-	-	-	-	1	-	-	-	-	3	2	-	1	-	-	-
Montana NCORP	1	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Nevada CRF NCORP	4	2	1	1	-	-	-	-	-	-	-	-	-	2	-	-	-	-	-	-
New Mexico MU-NCORP	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-
Northwestern Univ	-	35	1	-	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Ohio State Univ	-	4	-	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Oklahoma, Univ of	2	51	5	18	10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Oregon Hlth Sci Univ	3	14	3	-	-	-	-	-	3	2	-	-	-	8	-	-	-	-	-	-
Ozarks NCORP	2	10	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
PCRC NCORP	2	24	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Rochester, Univ of	-	20	1	8	-	-	-	-	3	2	-	-	-	-	-	-	-	-	-	-
San Antonio, U of TX	-	58	5	-	-	-	-	-	-	-	-	1	-	11	-	28	-	-	3	-
San Diego, U of CA	-	-	5	1	1	-	-	-	-	-	-	-	-	2	-	-	-	-	-	-
So Calif, U of	3	44	-	1	-	7	12	-	1	-	-	-	6	-	-	-	-	-	-	-
Southeast COR NCORP	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tulane University	-	-	-	-	-	-	-	-	-	-	-	-	-	6	-	-	-	-	-	-
Upstate NCORP	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Utah, U of	3	47	9	11	-	-	3	-	-	-	-	-	-	2	8	-	-	-	-	-
VAMC Kansas City	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-
Vanderbilt Univ	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Virginia Mason MC	-	-	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	2	-	-
Wayne State Univ	5	-	-	1	-	-	-	-	-	-	-	-	-	2	-	-	1	-	-	-
Wichita NCORP	1	-	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Wisconsin NCORP	1	-	-	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Yale University	-	3	3	-	-	-	7	-	-	-	-	-	-	1	2	-	-	-	-	-
Alliance	27	110	41	47	5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CCTG	25	-	9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	18	111	27	19	13	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
NRG	11	88	20	30	23	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	152	1,000	172	287	113	7	81	7	16	46	2	5	6	132	29	39	4	5	4	2

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
..... Mai Duong, 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: TBD
Nurse: TBD
Patient Advocate: Gail Sperling, MPH
Pharmaceutical Science: Holly O. Chan, PharmD
..... Ila M. Saunders, PharmD
Protocol Coordinator: Melissa Biddle
Protocol Coordinator - MyeloMATCH: Danae Campos
Clinical Trials Project Manager: Sandi Hita, JD

Agenda

Thursday, April 22, 2021
11:00 am - 1:00 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. Liesveld. Activation: 01/16/19.

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. Michaelis, Walter, Assouline, et al. Activation: 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. Advani, Papadantonakis, and Yeung. Activation: 8/17/20.

S1318, "A Phase II Study of Blinatumomab (NSC-765986) and POMP (Prednisone, Vincristine, Methotrexate, 6-Mercaptopurine) for Patients ≥ 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Negative (Ph-) Acute Lymphoblastic Leukemia (ALL) and of Dasatinib (NSC-732517), Prednisone and Blinatumomab for Patients ≥ 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Positive (Ph+) ALL, Relapsed/Refractory Philadelphia-Chromosome Positive (Ph+) ALL, and Philadelphia-Chromosome-Like Signature (Ph-Like) ALL (Newly Diagnosed or Relapsed/Refractory) with Known or Presumed Activating Dasatinib-Sensitive Mutations or Kinase Fusions (DSMKF)." Drs. Advani, O'Dwyer, and Wood. Activation: 1/12/2015; Permanent closure of Cohort 1: 9/15/17.

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

Proposed Studies

SXXXX, "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. O'Dwyer

Leukemia Committee

CLL Studies

Active Studies

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

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

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. Stephens, Hill, Pagel, et al. Activated: 12/14/20.

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. Sweet and Radich. Activation: 7/20/18.

MyeloMATCH

Proposed Studies

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

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

Update on MDnet. Dr. Radich

Get the Scoop!

*Want the Front Line blog every Friday?
Or the Translational Medicine Link
of the Week?*

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Leukemia Committee

Cumulative Accrual by Institution and Study Accrual from trial opening through 12/31/2020 by Institution and Study

	S1312	S1318	S1712	A041501	A041701	A041702	A041703	E1910	EA9161	EA9171
Arizona CC, Univ of	-	-	-	-	-	1	-	4	4	-
Arkansas, U of	-	-	-	-	3	-	-	3	-	-
Baylor College	7	-	-	-	-	-	-	-	-	-
Birmingham, U of AL	-	1	-	1	-	-	-	10	7	-
CORA NCORP	-	-	-	-	-	-	-	-	1	-
Cincinnati MC, U of	-	-	-	-	-	-	1	-	-	-
City of Hope Med Ctr	18	4	-	-	-	-	-	-	-	-
Cleveland Clinic OH	11	6	-	3	-	2	-	11	-	-
Colorado, U of	-	-	-	-	-	-	-	-	1	-
Dayton NCORP	-	-	-	-	-	1	-	1	2	-
Duke Univ Med Ctr	-	-	3	-	-	-	-	-	8	-
Fred Hutchinson CRC	-	-	-	-	-	-	-	-	5	-
Greenville NCORP	-	1	1	-	-	-	-	1	1	-
H Lee Moffitt CC	-	-	9	-	-	-	-	-	-	-
Hawaii MU-NCORP	-	-	4	-	-	-	-	-	-	-
Heartland NCORP	-	1	4	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	-	3	2	-	4	-	-
Irvine, U of CA	-	4	-	2	-	-	-	10	-	-
Kaiser Perm NCORP	-	-	-	-	-	3	-	-	30	-
Kansas City NCORP	-	-	-	-	-	-	-	1	-	-
Kansas MU-NCORP	-	-	-	-	-	2	-	10	5	-
Loma Linda Univ	-	1	-	-	-	-	-	-	-	-
Loyola University	-	-	1	-	-	1	-	2	1	-
MUSC MU-NCORP	-	-	-	-	-	1	-	-	2	-
Michigan CRC NCORP	-	-	1	-	-	-	-	-	-	-
Michigan, U of	-	2	-	-	-	-	-	-	-	-
Montana NCORP	-	-	1	-	-	-	-	-	-	-
Nevada CRF NCORP	-	-	1	-	-	-	-	-	2	-
New Mexico MU-NCORP	-	1	2	-	-	-	-	-	1	-
Northwestern Univ	-	-	-	-	-	-	-	1	-	-
Oregon Hlth Sci Univ	-	-	1	4	-	4	-	-	7	-
Ozarks NCORP	-	-	1	-	-	-	-	-	-	-
Rochester, Univ of	12	4	4	5	13	1	2	10	1	-
Salem Hospital	-	-	-	-	-	-	-	-	4	-
San Diego, U of CA	-	1	-	-	-	-	-	3	-	-
So Calif, U of	-	3	-	-	-	-	-	-	-	-
Southeast COR NCORP	-	-	-	-	-	-	-	-	2	-
Stanford University	2	-	-	3	-	10	-	12	24	-
UF Cancer Center	-	1	-	-	-	-	-	-	-	-
Utah, U of	-	-	3	1	-	1	-	-	17	-
Virginia Mason MC	-	-	-	-	-	2	-	-	2	-
Wayne State Univ	-	-	-	-	-	-	-	6	2	-
Western States NCORP	-	-	-	2	-	2	-	10	1	-
Wichita NCORP	-	1	-	-	-	-	-	-	-	-
Yale University	-	1	-	2	-	1	-	20	8	1
Alliance	-	17	6	-	-	-	-	-	-	-
ECOG-ACRIN	-	6	2	-	-	-	-	-	-	-
NRG	-	2	2	-	-	-	-	-	-	-
Total	50	57	46	23	19	34	3	119	138	1

Lung Committee

Committee Leadership

Chair: Karen Kelly, MD
Vice-Chair: Roy S. Herbst, MD, PhD
Executive Officer: TBD
Statisticians: Mary Redman, PhD
..... Yingqi Zhao, PhD
..... Katherine Minichiello, MS
..... Jieling Miao, MS
..... James Moon, MS
..... Lu Qian, MS
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..... Fred R. Hirsch, MD, PhD
..... Ignacio I. Wistuba MD
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..... Myrna C. Godoy, MD, PhD
Radiation Oncology: Roy H. Decker, MD, PhD
Surgery: Wayne L. Hofstetter, MD
Subcommittee Chairs:
Early Stage Disease: Wayne L. Hofstetter, MD
..... Raymond Osarogiagbon, MD
Locally Advanced Disease: Roy H. Decker, MD, PhD
..... Shirish Gadgil, MD (Early Therapeutics)
Metastatic Disease: Ross Camidge, MD
..... Karen Reckamp, MD
Community Engagement: Paul J. Hesketh, MD
..... Suzanne Cole, MD
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Cancer Control Liaison: Gary E. Goodman, 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: Chrissy Laubach, MBA, MHA
..... Mariah Norman, MS (Lung-MAP)
..... Laura Gildner, MS (Lung-MAP)
Clinical Trials Project Manager: Crystal Miwa

Agenda

Wednesday, April 21, 2021
2:00 pm - 4:00 pm CT

2:00 – 2:15 pm General Update
2:15 – 2:30 pm Thoracic Surgery Session: Wayne Hofstetter, MD
2:30 – 2:45 pm Thoracic Radiation Session: Roy H. Decker, MD, PhD
2:45 – 3:00 pm Translational Medicine Session: Phil Mack, PhD
3:00 – 3:20 pm Scientific Presentation: “Transforming SCLC into a Molecularly Targeted Disease” – Lauren A. Byers, MD, Associate Professor, Thoracic/Head and Neck Medical Oncology, MD Anderson Cancer Center
3:20 – 3:30 pm Community Engagement Core: Paul J. Hesketh, MD
3:30 – 4:00 pm Thoracic Medical Oncology Session: Karen Kelly, MD

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.
S1900B, “A Phase II Study of Selpercatinib (LOXO-292) in Patients with RET Fusion-Positive Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study).” Drs. Elamin and Gray. Activation: 2/10/20.
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

Lung Committee

Borderline Performance Status." Drs. Aljumaily, Mitin, Wozniak, et al.
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 (ALCHE-MIST)." 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 Ki-nase (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 Hippo-campal 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.

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

S1400F, "A Phase II Study of MEDI4736 plus Tremelimumab as Therapy

for Patients with Previously Treated Anti-PD-1/PD-L1 Resistant Stage IV Squamous Patients (Lung-MAP Sub-Study)." Drs. Leighl and Rizvi.
Activation: 10/2/17; Cohort 1 Closure: 11/6/19; Cohort 2 Closure: 3/24/20.

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; Closure: 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.

S1900A, "A Phase II Study of Rucaparib in Patients with Genomic LOH High and/or Deleterious BRCA1/2 Mutation Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Sub-Study)." Drs. Riess and Wheatley-Price. Activation: 1/28/19. Temporary Closure: Cohort 1 on 7/16/20; Cohort 2 on 4/6/20.

S1900C, "A Phase II Study of Talazoparib Plus Avelumab in Patients with Stage IV or Recurrent Non-Squamous Non-Small Cell Lung Cancer Bearing Pathogenic STK11 Genomic Alterations (Lung-MAP Sub-Study)." Drs. Skoulidis and Suga. Activation: 1/16/20.

NCI-Approved Concepts

S1900E, "A Phase II Study of 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.

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.

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.

Concepts in Development

S2102, "A Phase II Study to Evaluate Pembrolizumab with Single-Agent Chemotherapy or Platinum-Based Combination Chemotherapy in PS2 Patients with Stage IV or Recurrent NSCLC with Tumor PDL1 < 50%." Dr. Gadgeel.

Lung Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	LUNGMAP	S1400F	S1619	S1701	S1800A	S1827	S1900A	S1900B	S1900C	S1914	S1929	A081105
Arizona CC, Univ of	-	-	-	-	-	-	-	-	-	-	-	-
Arkansas, U of	7	-	-	-	3	-	-	-	-	-	-	-
Baptist MU-NCORP	31	-	-	-	-	-	3	-	1	-	-	-
Boston Medical Ctr	-	-	-	-	-	-	-	-	-	-	-	-
CORA NCORP	42	-	-	-	6	-	1	-	1	-	-	-
CRC West MI NCORP	3	-	-	-	1	-	1	-	1	-	-	-
CROWN NCORP	10	-	-	-	-	-	1	-	2	-	-	-
Carle CC NCORP	2	-	-	-	-	-	-	-	-	-	-	-
Cincinnati MC, U of	-	-	-	-	-	-	-	-	-	-	-	1
City of Hope Med Ctr	3	-	2	1	-	1	-	-	-	-	-	1
Cleveland Clinic OH	3	-	-	-	-	-	-	-	1	-	-	6
Colorado, U of	10	1	-	-	1	-	-	-	-	-	-	9
Columbia MU-NCORP	5	-	-	-	-	-	1	-	1	-	-	-
Columbus NCORP	20	-	-	-	-	-	4	-	-	-	-	-
Cotton O'Neil CC	-	-	-	-	1	-	-	-	-	-	-	-
Davis, U of CA	18	-	-	3	3	-	3	-	-	2	-	4
Dayton NCORP	4	-	-	-	-	-	-	-	-	-	-	-
Essentia Hlth NCORP	15	-	-	-	-	-	-	-	1	-	-	-
Fred Hutchinson CRC	4	-	2	-	-	-	-	-	-	-	-	1
GACARES MU-NCORP	5	-	-	-	1	-	-	-	-	-	1	-
Georgia NCORP	39	6	-	-	3	-	2	-	-	1	-	-
Greenville NCORP	7	-	-	-	1	-	-	-	-	-	-	-
Gulf South MU-NCORP	7	-	-	-	-	1	-	-	-	-	-	-
H Lee Moffitt CC	4	-	-	-	-	-	-	-	-	-	-	3
Harrington CC	4	1	-	-	-	-	-	-	-	-	-	-
Hawaii MU-NCORP	18	-	-	-	1	-	-	-	-	-	-	-
Heartland NCORP	84	6	-	-	11	-	6	1	1	2	2	-
Henry Ford Hospital	7	-	-	-	-	-	2	-	-	-	-	2
Houston Methodist	-	-	-	-	-	-	-	-	-	-	-	2
Irvine, U of CA	16	2	-	-	1	-	-	-	-	-	-	2
Kaiser Perm NCORP	33	-	-	-	2	-	-	-	1	-	-	19
Kansas MU-NCORP	48	-	-	-	4	-	4	-	2	-	-	1
Kentucky, U of	30	2	-	-	2	1	-	-	3	-	-	1
Lahey Hosp & Med Ctr	20	-	-	-	4	-	-	-	-	-	-	-
Loma Linda Univ	5	-	-	-	-	-	-	-	1	-	-	3
Loyola University	12	-	-	-	1	-	-	-	-	-	-	-

Lung Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	A081801	A151216	C30610	E4512	E45142	E45163	E45181	E45191	NRGCC003	NRGLU002	NRGLU005
Arizona CC, Univ of	-	7	-	2	-	-	1	-	-	-	-
Arkansas, U of	-	2	2	-	1	-	-	-	-	-	-
Baptist MU-NCORP	-	19	3	-	-	-	-	-	-	-	-
Boston Medical Ctr	-	3	-	-	-	-	-	-	-	-	-
CORA NCORP	-	2	-	-	-	-	-	-	-	-	-
CRC West MI NCORP	-	1	-	-	-	-	-	-	-	-	-
CROWN NCORP	-	-	-	-	-	-	-	-	-	-	-
Carle CC NCORP	-	-	-	-	-	-	-	-	-	-	-
Cincinnati MC, U of	-	22	3	1	3	-	-	-	-	-	-
City of Hope Med Ctr	-	4	-	-	2	-	-	-	-	-	-
Cleveland Clinic OH	3	46	-	-	11	7	4	-	-	-	-
Colorado, U of	-	50	-	2	4	-	-	1	-	-	-
Columbia MU-NCORP	-	-	-	-	-	-	-	-	-	-	-
Columbus NCORP	-	-	1	-	-	-	-	-	-	-	-
Cotton O'Neil CC	-	3	1	-	2	-	-	-	-	-	-
Davis, U of CA	-	40	13	1	3	5	-	-	-	-	-
Dayton NCORP	-	8	-	-	2	-	-	-	-	-	-
Essentia Hlth NCORP	-	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson CRC	-	15	-	-	1	-	-	-	-	-	-
GACARES MU-NCORP	-	-	-	-	-	-	-	-	-	-	-
Georgia NCORP	-	9	1	-	-	-	-	-	-	-	-
Greenville NCORP	-	1	-	-	-	-	-	-	-	-	-
Gulf South MU-NCORP	-	-	-	-	-	3	-	-	-	-	-
H Lee Moffitt CC	-	83	-	1	12	-	-	-	-	-	-
Harrington CC	-	-	-	-	-	-	-	-	-	-	-
Hawaii MU-NCORP	-	-	-	-	-	-	-	-	-	-	-
Heartland NCORP	-	-	7	-	-	-	-	-	-	-	-
Henry Ford Hospital	-	26	-	-	4	-	-	-	-	-	-
Houston Methodist	-	6	-	-	1	-	-	-	-	-	-
Irvine, U of CA	-	11	-	-	3	-	-	-	-	-	-
Kaiser Perm NCORP	-	184	3	4	21	-	-	-	-	-	-
Kansas MU-NCORP	-	27	-	-	6	2	-	-	-	-	-
Kentucky, U of	-	5	-	-	1	-	-	-	-	-	-
Lahey Hosp & Med Ctr	-	28	-	-	4	1	-	-	-	-	-
Loma Linda Univ	-	7	-	-	1	-	-	-	-	-	-
Loyola University	-	18	-	-	5	-	-	-	-	-	-

Lung Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	LUNGMAP	S1400F	S1619	S1701	S1800A	S1827	S1900A	S1900B	S1900C	S1914	S1929	A081105
MAVERIC	22	2	-	-	4	-	1	-	-	-	-	1
MD Anderson CC	3	1	15	3	-	-	-	-	-	-	-	-
MUSC MU-NCORP	-	-	5	-	-	-	-	-	-	-	-	-
Michigan CRC NCORP	71	1	-	-	10	-	3	-	5	-	-	-
Michigan, U of	1	1	-	-	-	-	-	-	-	-	-	1
Mississippi, Univ of	1	-	-	-	1	-	-	-	-	-	-	2
Montana NCORP	24	-	-	-	5	-	2	-	1	-	2	-
Nevada CRF NCORP	7	-	-	-	1	-	-	-	-	-	-	-
New Mexico MU-NCORP	42	3	-	-	3	1	2	-	-	1	-	-
Northwestern Univ	19	-	-	1	-	-	-	-	-	-	-	-
Oklahoma, Univ of	24	1	-	-	2	1	1	-	-	-	-	-
Oregon Hlth Sci Univ	1	1	-	-	-	-	-	-	-	-	-	1
Ozarks NCORP	23	-	-	-	-	-	-	-	2	-	1	1
PCRC NCORP	12	-	-	-	-	-	-	-	-	-	1	-
Providence Hosp	10	1	-	-	-	-	-	-	-	-	1	-
Rochester, Univ of	36	1	-	-	2	-	3	-	-	-	-	-
Salem Hospital	3	-	-	-	1	-	-	-	-	-	-	-
San Antonio, U of TX	-	-	-	-	-	-	-	-	-	-	-	-
San Diego, U of CA	7	1	-	-	-	-	-	-	-	-	-	1
So Calif, U of	-	-	-	-	-	-	-	-	-	-	-	1
Southeast COR NCORP	41	6	-	-	9	2	2	-	-	-	-	-
Sutter Cancer RC	9	-	-	-	2	-	-	-	-	-	-	1
Univ of Louisville	-	-	-	-	-	-	-	-	-	-	-	-
Upstate NCORP	16	-	-	-	4	-	-	-	1	-	-	-
Utah, U of	-	-	-	-	-	-	-	-	-	-	-	-
VAMC Kansas City	-	1	-	-	-	-	-	-	-	-	-	-
Wayne State Univ	1	1	-	-	-	-	-	-	-	-	-	-
Western States NCORP	1	-	-	-	-	-	-	-	-	-	-	-
Wichita NCORP	1	1	-	-	-	-	-	-	-	-	-	-
William Beaumont	-	-	-	-	-	-	-	-	-	-	-	-
Wisconsin NCORP	32	-	-	-	1	-	2	-	1	-	-	-
Yale University	15	1	-	-	7	-	1	-	3	-	-	3
Alliance	432	12	1	2	36	7	9	1	9	-	-	-
ECOG-ACRIN	219	6	3	1	17	1	5	1	7	2	-	-
NRG	202	8	1	-	15	8	5	2	2	-	2	-
Total	1,791	67	29	11	166	23	64	5	47	8	10	67

Lung Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	A081801	A151216	C30610	E4512	EA5142	EA5163	EA5181	EA5191	NRGCC003	NRGLU002	NRGLU005
MAVERIC	-	15	-	-	3	2	-	-	-	-	-
MD Anderson CC	-	2	-	1	-	-	-	-	-	-	-
MUSC MU-NCORP	-	-	1	-	-	-	-	-	-	-	-
Michigan CRC NCORP	-	-	-	-	-	-	-	-	-	-	-
Michigan, U of	-	61	1	-	1	-	-	-	-	-	-
Mississippi, Univ of	-	26	1	-	4	-	-	-	-	-	-
Montana NCORP	-	-	-	-	-	-	-	-	-	-	-
Nevada CRF NCORP	-	-	-	-	-	-	-	-	-	-	-
New Mexico MU-NCORP	-	-	-	-	-	-	-	-	-	-	-
Northwestern Univ	-	-	-	-	-	-	-	-	-	-	-
Oklahoma, Univ of	-	-	-	-	-	-	-	-	-	-	-
Oregon Hlth Sci Univ	1	11	-	-	1	-	-	-	-	-	-
Ozarks NCORP	-	1	-	-	-	-	-	-	-	-	-
PCRC NCORP	-	4	-	-	-	-	-	-	-	-	-
Providence Hosp	-	13	2	1	3	1	1	-	-	-	-
Rochester, Univ of	-	-	-	-	-	2	2	-	4	-	1
Salem Hospital	-	-	-	-	-	-	-	-	-	-	-
San Antonio, U of TX	-	-	3	-	-	1	-	-	-	-	-
San Diego, U of CA	-	5	-	-	-	-	-	-	-	-	-
So Calif, U of	-	12	-	-	-	-	-	-	-	-	-
Southeast COR NCORP	-	-	-	-	-	-	-	-	-	-	-
Sutter Cancer RC	-	7	-	-	4	-	-	-	-	-	-
Univ of Louisville	-	5	-	-	-	-	-	-	-	-	-
Upstate NCORP	-	-	-	-	-	-	-	-	-	-	-
Utah, U of	-	-	-	-	-	1	-	-	-	-	-
VAMC Kansas City	-	-	1	-	-	-	-	-	-	-	-
Wayne State Univ	-	1	1	-	-	-	-	-	-	1	-
Western States NCORP	-	2	-	-	-	-	-	-	-	-	-
Wichita NCORP	-	-	13	-	-	-	-	-	-	-	-
William Beaumont	-	2	-	-	1	-	-	-	-	-	-
Wisconsin NCORP	-	-	-	-	-	-	-	-	-	-	-
Yale University	-	46	-	3	17	5	-	-	-	-	-
Alliance	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	-	-	-	-	-	-	-	-	-	-	-
NRG	-	-	-	-	-	-	-	-	-	-	-
Total	4	840	57	16	121	30	8	1	4	1	1

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
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: Cara Laubach, MIlM
Clinical Trials Project Manager: Gretchen Goetz, MBA

Agenda

Friday, April 23, 2021

2:30 pm - 4:30 pm CT

2:30 pm

Welcome: Drs. Jonathan Friedberg and Sonali Smith

2:35 – 3:05 pm

Presentation: "Defining risk in CLL": Dr. Stephens

S1925 (CLL): Dr. Stephens

A041702: Dr. Hill

EA9161: Dr. Shadman

3:05 – 3:15 pm

Recent Activations

S1918: Dr. Brem

3:15 – 4:15 pm

Ongoing Studies

S1826: Dr. Herrera

S1608: Dr. Barr

S1905 (T-ALL): Dr. Adani; Presented by: Dr. Stephens

A051301: Dr. Stiff

EA4151: Dr. Till

E4412: Dr. Amengual

EA4181: Dr. Spurgeon

A051701: Dr. Vallurupalli

Other Business

Wrap Up and Adjourn

4:15 pm

4:25 pm

Active Studies

S1826, "Nivolumab (Opdivo) or Brentuximab Vedotin (Adcetris) Plus AVD in Patients with Newly Diag-nosed Advanced Stage Classical Hodgkin Lymphoma." Drs. Herrera and Friedberg. Activated: 7/19/19.

S1608, "Randomized Phase II Trial in High-Risk Relapsed Refractory Follicular Lymphoma." Dr. Barr. Ac-tivated: 8/10/17.

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, Shea, His, Kelley, and Richards. Activated: 7/6/16. SWOG Champion: Dr. Stiff.

CTSU/A051701, "Randomized Phase II/III Study of Venetoclax (ABT199) Plus Chemoimmunotherapy for MYC/BCL2 Double-Hit and Double Expressing Lymphomas." Dr. Abramson. Activated: 8/7/19. SWOG Champion: Dr. Smith. Temporarily Closed to Accrual: 8/13/19.

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, Crump, Scott, and Kostakoglu. Activated: 8/29/17. SWOG Champion: Dr. Till.

CTSU/EA4181, "A Randomized 3-Arm Phase II Study Comparing 1.) Bendamustine, Rituximab and High Dose Cytarabine (BRC) 2.) Bendamustine, Rituximab, High Dose Cytarabine and Acalabrutinib (BRCA), and 3.) Bendamustine, Rituximab and Acalabrutinib (BRA) in Patients <= 70 years Old with Untreated Mantle Cell Lymphoma. Activated: 10/3/19. Dr. Spurgeon.

CTSU/E4412, A Phase I Study with an Expansion Cohort/Randomized Phase II Study of the Combinations of Ipilimumab, Nivolumab and Brentuximab Vedotin in Patients with Relapsed/Refractory Hodgkin Lymphoma. Drs. Diefenbach, Ansell, and Kostakoglu. Activated 11/15/18. SWOG Champion: Dr. Amengual.

Lymphoma Committee

Developing Studies

S1918, "A Phase II/III Randomized Study of R-miniCHOP With or Without Oral Azacytidine in Very Elderly Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma." Drs. Brem and Smith.

CTSU/ANHL1931, "A Randomized Phase 3 trial of Pembrolizumab in Combination with Chemo-immunotherapy for the Treatment of Newly Diagnosed Primary Mediastinal B-cell Lymphoma." SWOG Champion: Dr. Kamdar.

CTSU/AHOD1931, "A Randomized Phase 3 Interim Response Adapted Trial Comparing Standard Therapy with Immuno-oncology Therapy for Children and Adults with Newly Diagnosed Stage I and II Classical Hodgkin Lymphoma." SWOG Champion: Dr. Hu.

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." SWOG Champion: Dr. Amengual.

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 (CLL): EVOLVE CLL Study. Activated: 1/4/20. Dr. Stephens.

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)." Activated: 8/17/20. Dr. Advani.

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

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)." Drs. Shanafelt and Kay. Activated: 1/3/19. SWOG Champion: Dr. Shadman.

Open Rare Cancers Study

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

Developing Cancer Care Delivery Study

S1912CD, "A Randomized Trial Addressing Cancer-Related Financial Hardship Through Delivery of a Proactive Financial Navigation Intervention (CRED-IT)." Dr. Shankaran.

Lymphoma Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	S1608	S1826	A051301	A051701	EA412	EA4151	EA4181
Arizona CC, Univ of	2	-	1	-	-	-	1
Baylor College	-	-	1	-	-	-	-
Birmingham, U of AL	-	8	-	3	5	1	-
Boston Medical Ctr	-	1	-	-	-	-	-
CORA NCORP	-	2	-	-	-	-	-
CRC West MI NCORP	3	4	-	-	-	-	-
Carle CC NCORP	1	-	-	-	-	-	-
Cincinnati MC, U of	-	1	-	-	-	1	-
City of Hope Med Ctr	4	5	1	-	-	9	-
Cleveland Clinic OH	-	-	-	8	-	3	2
Colorado, U of	-	-	1	-	-	-	-
Columbus NCORP	1	-	-	-	-	-	-
Davis, U of CA	-	2	-	4	-	-	-
Fred Hutchinson CRC	-	-	-	-	-	9	-
Greenville NCORP	-	5	-	-	-	1	-
H Lee Moffitt CC	-	2	-	-	-	-	-
Heartland NCORP	1	7	-	-	-	-	-
Henry Ford Hospital	-	3	-	2	-	-	-
Irvine, U of CA	-	1	-	-	-	-	-
Kaiser Perm NCORP	-	5	-	-	6	-	2
Kentucky, U of	-	1	-	-	-	-	-
King Faisal Spec Hos	-	-	3	-	-	-	-
Loyola University	-	1	-	-	-	2	-
MD Anderson CC	1	5	-	-	-	-	-
MUSC MU-NCORP	2	7	-	3	-	1	-
Michigan CRC NCORP	1	-	-	-	-	-	-
Michigan, U of	-	-	-	-	-	1	-
Montana NCORP	-	7	-	-	-	-	-
Nevada CRF NCORP	-	1	-	-	1	-	-
Northwestern Univ	1	-	-	-	-	-	-
Oregon Hlth Sci Univ	-	-	-	2	-	1	3
Ozarks NCORP	1	3	-	-	-	-	-
Providence Hosp	-	3	-	-	-	-	-
Rochester, Univ of	12	16	3	9	-	5	7
San Antonio, U of TX	-	3	-	-	-	6	-
San Diego, U of CA	-	5	-	-	-	1	-
Upstate NCORP	1	3	-	-	-	-	-
Utah, U of	1	7	-	-	-	8	3
Wayne State Univ	-	1	1	-	-	-	2
Wisconsin NCORP	-	3	-	-	-	-	-
Alliance	10	35	-	-	-	-	-
COG	-	101	-	-	-	-	-
ECOG-ACRIN	4	27	-	-	-	-	-
NRG	11	17	-	-	-	-	-
Total	57	292	11	31	12	49	20

Melanoma Committee

Committee Leadership

Chair: Kenneth F. Grossmann, MD, PhD
Vice-Chair: Hussein A. Tawbi, MD, PhD
Executive Officer: Christopher W. Ryan, MD
Statisticians: Michael Wu, PhD
..... Megan Othus, PhD
..... James Moon, MS
..... Hongli Li, MS
Scientific Leadership
Translational Medicine: William E. Carson, III, MD
Radiation Oncology: Evan J. Wuthrick, MD
Surgery: John Robert Hyngstrom, MD
Dermatology: Clara Curiel-Lewandrowski, MD
Imaging: Ari M. VanderWalde, MD
Medical Oncology: Sapna Pradyuman Patel, MD
Pathology: Michael T. Tetzlaff, MD, PhD
Non-Melanoma Skin Cancer: Nikhil I. Khushalani, MD
Early Therapeutics: Jeffrey A. Sosman, MD
SWOG's ECOG Liaisons: Sapna Pradyuman Patel, MD
..... Kevin B. Kim, MD
ECOG's SWOG Liaisons: David H. Lawson, MD
..... Andrew Poklepovic, MD
Digital Engagement: Zeynep Eroglu, MD
Designates
Cancer Control Liaison: Sancy Leachman, MD, PhD
..... Thach-Giao Truong, MD (Survivorship)
Data Coordinator: Tonya Johnson
..... Laura Kingsbury, MRT
..... Leah Everhart
..... Hannah Hale
Oncology Research Professionals:
CRA: Kacie L. Simpson, BS, CCRP
Nurse: Lisa S. Morgan, RN, OCN
Patient Advocate: Samantha Guild, JD
Pharmaceutical Science: Sun "Coco" Yang, PharmD, PhD
Protocol Coordinator: Danae Campos, MBA
Clinical Trials Project Manager: Gretchen Goetz, MBA

Agenda

Friday April 23, 2021
1:00 pm - 3:00 pm CT

Welcome: Kenneth Grossmann, MD, PhD (5 min)

Circulating tumor markers in melanoma - (30 min): David Polsky, MD, PhD, NYU Langone

Upcoming Studies / Studies in development (30 minutes, 10:35-11:05)

S**** – Adjuvant triple therapy in BRAF mutated stage III melanoma. Dr. H. Tawbi and Dr. T.G.Troung

S**** - MEK and autophagy inhibition in NRAS mutated melanoma (MAIN), Dr. T. Johannis (Wash U St. Louis), Mentorship, Dr. R. Amaravadi (ECOG/ Penn)

S2015, Melanoma Margins Trial (MelMarT). Dr. J. Mammen.

Active Studies

S2000, "A Randomized Phase II Trial Of Encorafenib + Binimetinib + Nivolumab vs Ipilimumab + Nivolumab in BRAF-V600 Mutant Melanoma with Brain Metastases." Dr. Eroglu. Activated: 9/23/20.

S1801, "A Phase II Randomized Study of Adjuvant Versus Neoadjuvant Pembrolizumab (MK-3475) for Clinically Detectable Stage III-IV High Risk Melanoma." Dr. Patel. Activated: 12/6/18.

S1512, "A Phase II and Pilot Trial of PD-1 Blockade with MK-3475 (Pembrolizumab) in Patients with Resectable or Unresectable Desmoplastic Melanoma (DM)." Drs. Kendra and Hu-Lieskovan. Activated: 10/20/16.

CTSU/EA6174, "STAMP: Surgically Treated Adjuvant Merkel Cell Carcinoma with Pembrolizumab, a Phase III Trial." Dr. Hsu. Activated: 10/1/18.

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

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

Closed Studies

S1607, "A Phase II Study of Combining Talimogene Laherparepvec (T-VEC) (NSC-785349) and MK-3475 (Pembrolizumab) in Patients with Advanced Melanoma who have Progressed on Anti-PD1/L1 Based Therapy." Dr. Hu-

Melanoma Committee

Lieskovan. Activated: 10/02/17. Closed: 11/1/20.

S1616, "A Phase II Randomized Study of Nivolumab (NSC-748726) with Ipilimumab (NSC-732442) or Ipilimumab Alone in Advanced Melanoma Patients Refractory to an Anti-PD1 or Anti-PD-L1 Agent." Dr. VanderWalde. Activated: 07/17/17. Closed: 7/15/20.

S1320, "A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763760) and Trametinib (NSC-763093) in BRAFV600E/K Mutant Melanoma." Drs. Algazi and Lo. Activated: 7/22/14. Closed: 4/19/19.

S1404, "A Phase III Randomized Trial Comparing Physician/Patient Choice of Either High Dose Interferon or Ipilimumab to MK-3475 (Pembrolizumab)

in Patients with High Risk Resected Melanoma." Drs. Grossmann and Patel. Activated: 10/15/15. Closed: 11/2/17.

S1221, "Phase I/II Study of the Safety and Efficacy of the AKT Inhibitor GSK2141795 in Combination with Dabrafenib and Trametinib in Patients with BRAF Mutant Cancer." Drs. Algazi and Ribas. Activated: 7/1/13. Closed: 10/31/16.

Studies in Development

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

Member Funding Opportunities

APPLY BY

Virtual Grant Writing Workshop	May 1
Young Investigator Training Course	May 14
SWOG Early Exploration & Development (SEED) Fund	July 1
SWOG/Hope Foundation Impact Awards	July 1
VA Integration Support Grants	August 1
Secondary Data Analysis Projects	Ongoing

SEE ALL HOPE FUNDING PROGRAMS:
[THEHOPEFOUNDATION.ORG/RESEARCH-FUNDING](https://thehopefoundation.org/research-funding)

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Melanoma Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	S1512	S1607	S1616	S1801	EA6134	EA6141	EA6174
Arizona CC, Univ of	-	-	-	6	-	-	2
Arkansas, U of	-	-	-	-	2	-	-
Boston Medical Ctr	-	-	-	1	-	-	-
CRC West MI NCORP	-	-	4	10	-	-	-
CROWN NCORP	-	-	1	1	-	-	-
Carle CC NCORP	-	-	-	1	-	-	-
Cincinnati MC, U of	-	-	-	-	-	-	2
City of Hope Med Ctr	-	-	4	5	2	3	-
Cleveland Clinic OH	-	-	-	-	6	-	5
Colorado, U of	-	-	-	-	1	-	-
Dayton NCORP	-	-	1	-	-	2	-
Georgia NCORP	1	-	-	-	-	-	-
Greenville NCORP	-	-	-	-	1	-	-
H Lee Moffitt CC	16	-	8	-	-	-	-
Harrington CC	-	-	-	2	-	-	-
Hawaii MU-NCORP	-	-	-	1	2	-	-
Heartland NCORP	-	-	-	5	-	-	-
Henry Ford Hospital	-	4	-	-	-	-	-
Irvine, U of CA	-	-	-	-	-	-	4
Kaiser Perm NCORP	-	-	5	9	19	21	-
Kansas City NCORP	-	-	-	-	-	1	-
Kansas MU-NCORP	2	1	2	5	2	-	-
Kentucky, U of	-	-	-	1	-	-	-
Loma Linda Univ	-	-	-	1	-	-	-
Los Angeles, U of CA	4	8	6	1	7	-	-
MAVERIC	-	-	-	4	-	-	-
MD Anderson CC	-	-	-	3	-	-	-

Melanoma Committee

Cumulative Accrual by Institution and Study

Accrual from trial opening through 12/31/2020 by Institution and Study

	S1512	S1607	S1616	S1801	EA6134	EA6141	EA6174
MUSC MU-NCORP	-	-	-	1	-	-	-
Michigan CRC NCORP	-	-	-	4	-	-	-
Michigan, U of	-	-	-	10	-	-	-
Montana NCORP	-	-	1	1	-	-	-
Nevada CRF NCORP	-	-	-	-	-	-	1
New Mexico MU-NCORP	-	-	2	1	-	-	-
Northwell NCORP	-	-	-	1	-	-	-
Northwestern Univ	1	-	6	8	-	-	-
Ohio State Univ	5	4	8	5	3	-	-
PCRC NCORP	-	-	-	2	-	-	-
Rochester, Univ of	-	-	5	1	2	-	1
San Antonio, U of TX	-	-	-	-	-	1	-
San Diego, U of CA	-	-	2	-	-	-	-
So Calif, U of	4	5	-	4	-	-	1
Southeast COR NCORP	1	-	-	-	-	-	-
Sutter Cancer RC	-	-	-	-	2	5	-
Tennessee, U of	-	-	7	-	-	-	-
Utah, U of	5	10	1	12	-	-	2
Vanderbilt Univ	-	1	1	-	-	-	-
Wayne State Univ	-	-	-	-	2	-	-
Western States NCORP	1	-	-	-	-	-	-
Wisconsin NCORP	-	-	1	7	-	-	-
Yale University	-	-	-	-	-	6	-
Alliance	1	-	9	16	-	-	-
ECOG-ACRIN	1	8	7	26	-	-	-
NRG	3	2	13	26	-	-	-
Total	45	43	94	181	51	39	18

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 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 spring meeting!

DISEASE COMMITTEES

Breast



PUSZTAI

Chair: Lajos Pusztai, MD

A recently activated trial we're excited about:

Despite the horrible year of COVID, we are excited to see S2007 "Sacituzumab Govitecan for Her2 Negative Breast Cancer Brain Metastases" open to accrual in December 2020. This is an important trial for a patient population that needs better therapies.

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

On January 29, 2021, the Breast Cancer Steering Committee composed of the breast committee chairs/co-chairs/vice-chairs of each of the NCTN groups and CTEP leadership met to collectively chart the path for the next generation of large randomized trials. We placed several ideas on the table, (i) further improving outcome in post-neoadjuvant TNBC with residual disease through serial ctDNA monitoring and early intervention at the time of molecular relapse, (ii) improve chemotherapy efficacy and increase pathologic complete response rate in ER+ disease with low ER signaling and high proliferation, (RS >25 and MammaPrint UltraHigh), (iii) cure a subset of de novo oligometastatic stage IV breast cancers by

applying the same therapeutic strategy that we apply to locally advanced breast cancers, (iv) neoadjuvant chemotherapy de-escalation/treatment optimization for immune rich (i.e. TIL >30%) TNBC. Our goal for 2021 is to turn these ideas into clinical trials.

New publications or presentations:

Kudos to all breast committee members. We have changed practice again. Kevin Kalinsky, MD, MS presented the first efficacy results of the S1007/RxPONDER trial at the plenary session of the 2020 San Antonio Breast Cancer Symposium. The trial has answered an important question: Do patients with estrogen receptor positive breast cancer and 1-3 positive axillary lymph nodes with a recurrence score between 0-25 benefit from adjuvant chemotherapy? Postmenopausal patients had no improvement in invasive disease-free survival, whereas premenopausal patients experienced a statistically significant 5.2% improvement in iDFS at 5-years with chemotherapy followed by adjuvant endocrine therapy compared to endocrine therapy alone.

Priyanka Sharma, MD, presented the results of the S1416 trial as an oral presentation at the ASCO 2020 annual meeting. S1416 is the first randomized trial in breast cancer that showed benefit from a PARP inhibitor in germline BRCA normal but BRCA-like TNBC, while demonstrating no benefit in non-BRCA-like TNBC. These results expand the patient population who might benefit from PARP inhibition.

New committee members or leaders:

Congratulations to Alastair Thompson, BSc, MBChB, MD, FRCS, our translational medicine subcommittee chair, who has been elected to co-chair the NCI's Breast Oncology Local Disease (BOLD) Task Force. We also bid a bittersweet farewell and offer congratulations to Julie Gralow, MD, a long-time member of the breast committee leadership and a SWOG executive officer who has taken on a new role as chief medical officer of ASCO. We will thoroughly miss Julie!

We are also excited to welcome several new members:

Kiri A Cook, MD, Oregon Health & Science University

Kaleigh Doke, MD, UCHHealth

Chrystal A Landry, MD, Northwell Health

Evanthia T. Torres Roussos, MD, PhD,
Keck School of Medicine of USC

Dean Shumway, MD, Mayo Clinic

Neil Vasan, MD, PhD, Columbia University

Cancer Care Delivery



HERSHMAN



RAMSEY

Co-Chairs: Dawn Hershman, MD and Scott Ramsey, MD

A recently activated trial we're excited about:

S1912CD – "Addressing Cancer-Related Financial

Hardship through Delivery of Proactive Financial Navigation Intervention (CREDIT)" seeks to determine the impact of a proactive financial navigation program on development of material household financial hardship. CREDIT is led by Veena Shankaran, MD, and recently received CIRB approval. Activation is planned for early Spring of 2021. Contact Dr. Shankaran at vshank@uw.edu if your site is interested in participating.

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

S2100CD – "Randomized Comparison of an Educationally Enhanced Genomic Tumor Board (eGTB) Intervention to Usual Practice of Incorporating Genomic Test Results into Clinical Care" seeks to determine whether an eGTB intervention compared to usual practice improves physician genomic

confidence. The new concept is being prepared for NCI submission. S2100CD is led by Jens Rueter, MD (Jens.Rueter@jax.org) and Meghna S. Trivedi, MD, MS (mst2134@cumc.columbia.edu). Please contact Drs. Rueter and Trivedi if your site is interested in participating.

Cancer Survivorship



MOORE



IRWIN

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

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

We have a number of concepts in development.

One of particular interest is a study proposed by Virginia Sun, PhD and Dan Raz, MD evaluating a perioperative physical activity intervention for older adults with lung cancer. A unique aspect of this proposal is that it will include not only patients but their caregivers as well.

New publications or presentations:

The Survivorship Committee is proud to have contributed to the recent publication by Rikki Cannioto, PhD, EdD, MS et al in the *Journal of the National Cancer Institute* titled "Physical activity before, during and after chemotherapy for high-risk breast cancer: relationships with survival."

New committee leaders or members:

We have a number of new members interested in sarcopenia and cancer outcomes. Recently, three concepts were presented by Drs. William Evans, Grant Williams and Vickie Baracos. We look forward to moving these concepts forward and facilitating other survivorship-related research with our members.

Early Therapeutics



KURZROCK

Chair: Razelle Kurzrock, MD

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

Young Kwang Chae, MD, MPH, MBA, is leading a collaboration with the NCI's Cancer Immune Monitoring and Analysis Centers, or CIMAC, to interrogate at a multi-omic level rare cancers

from S1609 or DART (Dual Anti-CTLA-4 & Anti-PD1 blockade in Rare Tumors) immunotherapy study.

New publications and presentations:

Sylvia Adams et al., "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)" To be submitted shortly.

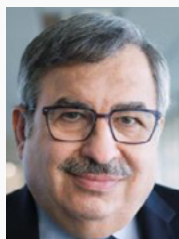
Michael J. Wagner et al., "A Multicenter Phase II Trial (SWOG S1609, Cohort 51) of Ipilimumab and Nivolumab in Metastatic or Unresectable Angiosarcoma: A Sub-Study of Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (DART)," Submitted pending acceptance.

New leaders and members:

Lara Davis, MD, leader of the Sarcoma Working Group, Early Therapeutics and Rare Cancers Committee

Manmeet Ahluwalia, MD, MBA, leader of CNS Working Group, Early Therapeutics and Rare Cancers Committee

Gastrointestinal



PHILIP

Chair: Philip Philip, MD

A recently activated trial we're excited about:

S2001, "Randomized Phase II Clinical Trial of Olaparib + Pembrolizumab vs. Olaparib Alone as Maintenance Therapy in Metastatic Pancreatic Cancer Patients with Germline

BRCA1 or 2 Mutations." Principal investigators: Vincent Chung, MD, and Michael Pishvaian, MD, PhD. S2001 is an innovative study that builds on the recent POLO phase III trial that established the role of olaparib in pancreatic cancer and preclinical data demonstrating the benefit of combining PARP inhibition with immunotherapy. The goal is to extend the benefit of olaparib and more importantly to develop immunotherapy in this disease, which so far did not respond to immunotherapy. Patients must have germline mutation in *BRCA1* or *BRCA2* and have completed at least four months of platinum-based therapy without progression.

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

S2107, "Randomized phase II trial of encorafenib and cetuximab

with or without nivolumab for patients with microsatellite stable, *BRAF*V^{600E} metastatic colorectal cancer." Principal investigator: Van Morris, MD. This concept extends SWOG's contribution in the treatment of *BRAF* mutated colorectal cancer (S1406) by the incorporation of immunotherapy based on strong preclinical evidence of synergy and pilot clinical data that demonstrate clinical antitumor benefit and safety of such a combination. This is a very unmet area of a subgroup of metastatic colorectal cancers with poor prognosis. We are hoping for activation in the fourth quarter of 2021. Eligible patients would have received frontline therapy and have tumors that are *BRAF*V^{600E} mutated/microsatellite stable.

New publications or presentations:

Ahmad S, et al. "Surgical Outcome Results from SWOG S1505: A Randomized Clinical Trial of mFOLFIRINOX vs. Gemcitabine/nab-Paclitaxel for Perioperative Treatment of Resectable Pancreatic Ductal Adenocarcinoma (PDA)." *Annals of Surgery* Sep 1;272(3):481-486, 2020. PMID32740235; PMC7856053. <https://pubmed.ncbi.nlm.nih.gov/32740235/>

Kopetz S, et al. "Randomized trial of irinotecan and cetuximab with or without vemurafenib in BRAF-mutant metastatic colorectal cancer (SWOG S1406)." *Journal of Clinical Oncology* Feb 1;39(4):285-294, 2021. PMID33356422; PMC journal in process. <https://pubmed.ncbi.nlm.nih.gov/33356422/>

Sohal D, et al. "Efficacy of Perioperative Chemotherapy for Resectable Pancreatic Adenocarcinoma: A Phase 2 Randomized Clinical Trial." *JAMA Oncology* Jan 21; e207328. doi: 10.1001/jamaoncol.2020.7328. Online ahead of print, 2021. PMID33475684; PMC7821078. <https://pubmed.ncbi.nlm.nih.gov/33475684/>

Innocenti F, et al. "Genomic analysis of germline variation associated with survival of colorectal cancer patients treated with chemotherapy plus biologics in CALGB/SWOG 80405 (Alliance)." *Clinical Cancer Research* Jan 1;27(1):267-275, 2021. PMID32958699; PMC7785628. <https://pubmed.ncbi.nlm.nih.gov/32958699/>

Andre T, et al. "Duration of Adjuvant Chemotherapy for Stage III Colon Cancer: Final results from the IDEA (International Duration Evaluation of Adjuvant chemotherapy) Collaboration." *Lancet Oncology* 2020 Dec;21(12):1620-1629, 2021. PMID33271092; PMC7786835. [*C80702, MULTIPLE] <https://pubmed.ncbi.nlm.nih.gov/33271092/>

Sohal D, et al. "Immunologic Predictors of Therapeutic Response to Neoadjuvant Therapy for Pancreatic Adenocarcinoma (PDA) in SWOG S1505." J Clin Oncol 39, 2021 (suppl 3; abstr 419); ASCO GI Cancers Symposium (January 15-17, 2021, virtual), poster presentation & poster highlights session, 2021.

<https://meetinglibrary.asco.org/record/194466/abstract>

Chung V, et al. "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." J Clin Oncol 39, 2021 (suppl 3; abstr TPS447); ASCO GI Cancers Symposium (January 15-17, 2021, virtual), poster session, 2021. <https://meetinglibrary.asco.org/record/194473/abstract>

New committee members or leaders:

Behrman, Stephen W., MD, FACS, surgical oncologist,
University of Tennessee

Catenacci, Daniel, MD, PhD, medical oncologist,
University of Chicago

Genitourinary



THOMPSON

Chair: Ian Thompson, MD

A recently activated trial we're excited about:

S1931 is a cutting-edge study, activated in November 2020, that builds on the results of the original SWOG trial published in 2001 in the *New England Journal of Medicine* in

2001 showing the benefit of cytoreductive nephrectomy for metastatic kidney cancer in the interferon era. With the advent of immunotherapy, the question is whether cytoreductive nephrectomy remains beneficial – a question critically-important to our patients. Our committee is uniquely positioned to answer this question. We are also delighted that, S1937, a Phase III trial of eribulin + gemcitabine vs standard of care for metastatic urothelial cancer refractory to Immunotherapy, has just activated. This is an important niche for us to develop improved care for our patients.

New publications or presentations:

Pal SK, Tangen C, et al. in *The Lancet*, February 2021: "A comparison of sunitinib with cabozantinib, crizotinib, and

savolitinib for treatment of advanced papillary renal cell carcinoma: a randomised, open-label, phase 2 trial." Monty Pal, MD, did a superb job conceiving this multi-arm trial comparing three MET inhibitors with sunitinib and working with the amazing investigators at 65 centers across the U.S. and Canada. The upshot of the trial is that cabozantinib significantly improved progression-free survival when compared to sunitinib and should be considered the new standard of care for advanced papillary renal cell carcinoma. We also anticipate that results of our COXEN trial for bladder cancer will be published by the time of the spring meeting in *Clinical Cancer Research*.

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

Success of S1500 allows our committee to build on the positive study outcomes. Ben Maughan, MD, PharmD, attended the SWOG Young Investigator Course in 2019 and is building the follow-on study: "Cabozantinib with or without atezolizumab in metastatic papillary renal cell carcinoma."

Lung



KELLY

Chair: Karen Kelly, MD

A recently activated trial we're excited about:

S1929 is a randomized trial of maintenance atezolizumab versus atezolizumab plus talazoparib in patients with SLNFN11 positive extensive stage SCLC. Forward progress

has been made in the treatment of SCLC, but we need to build upon it using biology as our guide. Nagla Karim, MD, is leading our first biomarker driven trial in SCLC. The rationale for the study is based on work from SWOG member Lauren A. Byers, MD, and her team at MD Anderson Cancer Center. Her group developed and validated the SLNFN11 IHC assay used in the study. We urge everyone to participate in the Lung Committee Main Session and listen to Dr. Byers' presentation on transforming SCLC into a molecularly targeted disease.

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

We are excited about the upcoming S1934 study "NASSIST: NeoAdjuvant chemoradiation +/- Immunotherapy before Surgery for Superior Sulcus Tumors." Ray Osarogiagbon, MD,

leads the trial, which incorporates every treatment modality and more! Investigators from surgery, radiation oncology, medical oncology, translational medicine, pathology, imaging and our stellar patient advocate have come together to modernize treatment for this orphan disease. A perfect example of SWOG team science at its best.

New publications or presentations:

LUNGMAP is first public-private partnership to develop better therapies for lung cancer. Over the years, the program has evolved. Spearheaded by Mary Redman, PhD, the LUNGMAP team published an article in *Lancet Oncology* entitled "On the Design, Conduct, and Lessons Learned from Lung-MAP (SWOG S1400): A Biomarker-Driven Master Protocol to Evaluate Biomarker-Driven Therapies for Previously-Treated Squamous Lung Cancer." The article provides investigators and stakeholders around the world a blueprint for the development of future platform trials.

New committee members or leaders:

Sukhhmani K Padda, MD, recently left Stanford to joined Cedars-Sinai as an assistant professor of medicine and the director of medical thoracic oncology. She is co-chair for the upcoming LUNGMAP sub-study S1900E "A phase II study of AMG 510 in previously treated patients with KRAS G12C mutated nonsquamous lung cancer."

Lymphoma



FRIEDBERG

Chair: Jonathan Friedberg, MD

A recently activated trial we're excited about:

S1918 will be the first randomized prospective multicenter trial conducted specifically in older patients. This is a phase II/III study of R-mini-CHOP with or without oral azacitidine (CC-486) in patients 75 years and older with newly diagnosed diffuse large B-cell lymphoma. There are integrated geriatric assessment components to determine the impact of baseline frailty/fitness on outcome as well as embedded quality of life studies to determine longitudinal impact on function.

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

The lymphoma committee is highly interested in improving the

outcomes of patients with aggressive B-cell lymphomas, with two concepts in development. The success of cellular therapy with CAR-T in relapsed/refractory aggressive lymphomas is limited to approximately 40 percent of eligible patients. The remaining patients have limited options and constitute a new unmet need. Building on our interest in diffuse large B-cell lymphoma (DLBCL), we are designing a trial for patients with a suboptimal early response. However, some patients are ineligible for aggressive therapies, and we are also designing a trial for patients with relapsed/refractory DLBCL who are not transplant-eligible. There are a number of new and emerging targeted agents that hold promise and may be active in both of these patient groups.

New committee members or leaders:

Marc Hoffman, MD, University of Kansas Medical Center

Melanoma



GROSSMANN

Chair: Ken Grossmann, MD

A recently activated trial we're excited about:

S2000 recently activated, and when completed it will be the first NCI-sponsored study focused on brain metastasis from melanoma. The concept is exploring the use of a three-drug combination (encorafenib/benimetinib/pembrolizumab) which targets BRAF/MEK and PD-1 respectively. Triplet therapies in melanoma have shown improved response rates, with manageable toxicity, and for patients with brain metastasis they represent a possible improvement over the standard of care, nivolumab ipilimumab, as the response kinetics are also improved. The trial activated in September 2020, and has now accrued three patients. Zeynep Eroglu, MD, is the principal investigator and has been awarded a Coltman Fellowship from The Hope Foundation for Cancer Research for her consistent contributions in SWOG both from a study design point of view, and from her efforts at accruing patients across multiple studies in the melanoma portfolio. She accrued the first patient to this trial on January 6.

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

Tanner Johanns, MD, has completed capsule development of a study aiming to establish a combination of MEK inhibitor (trametinib), and hydroxychloroquine (which activates

autophagy), in patients with NRAS mutated melanoma. The concept is highly innovative, and based on promising preclinical data from Martin McMahon's lab at the Huntsman Cancer Institute. Dr. Johanns completed the SWOG Young Investigator Training Course this year, and we anticipate moving this through the next steps of approval soon. Patients with NRAS mutations presently lack a targeted therapeutic option, so if successful this will fill a critical need in our treatment arsenal.

New publications and presentations:

Alain Algazi, Nature Med. 2020 – This publication showed that intermittent dosing of dabrafenib and trametinib was not superior to continuous dosing. Though preclinical models have suggested the interruption of drug would improve outcomes, it may be that human tumors are more heterogenous than the mouse model systems making it difficult to know pre-treatment which patients would benefit, and which may not. Future work will be exploring interruptions with potentially alternative treatments inserted into drug interruption, and so as a foundational study, this work is highly impactful.

New leaders and members:

Camille Stewart, MD, University of Colorado

Prevention & Epidemiology



ARUN



NEUHOUSER

Co-Chairs: Banu Arun, MD, and Marian Neuhouwer, PhD, RD

A recently activated trial we're excited about:

S1823, "A Prospective Observational Cohort Study

to Assess miRNA 371 for Outcome Prediction in Patients with Newly Diagnosed Germ Cell Tumors" Principal investigators: Craig Nichols, MD, and Lucia Nappi, MD, PhD

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." Principal investigator: Katherine Crew, MD

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

"Effects of Chemoprevention and Adjuvant Endocrine Therapy on a Convolutional Neural Network-Based Breast Cancer Risk

Model Using Mammographic Datasets from [S0812](#) and [S1007](#)." Principal investigators: Richard Ha, MD, and Katherine Crew, MD, with co-investigators Kevin Kalinsky, MD, and Lawrence Schwartz MD

"Evaluating Mammographic Density Changes in Patients Receiving Pembrolizumab." Substudy to S1418 led by Banu Arun, MD

Both of these exciting studies use mammographic density both to explore risk with a novel approach to using existing mammography data and to explore potential chemoprevention in contralateral breast tissue that remains at risk for women undergoing treatment.

Symptom Control & Quality of Life



FISCH



HENRY

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

A recently activated trial we're excited about:

We eagerly await activation of our trial led by Krishna Gunturu, MD, of the Lahey

Clinic, *S2013-Immune Checkpoint Inhibitor Toxicity (I-CHECKIT): A Prospective Observational Study*, as the study protocol is now approved by the NCI. We anticipate that this trial will inform us about immune related adverse events that occur in patients treated with immunotherapy, either single agent or in combination (but without chemotherapy). Importantly, the goal is to enroll patients receiving standard of care treatment, because we want it to be as representative of typical patients with cancer as possible.

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

We are working on 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 publications or presentations:

Our S0702 study led by Cathy Van Poznak, MD, and Joe Unger, PhD, was recently published in *JAMA Oncology*. The findings are important because the treatment, zoledronic acid, is prescribed to tens of thousands of patients whose cancer has spread to the bone. In this prospective observational study of nearly 3,500 patients, we found that 2.8 percent of patients on average develop osteonecrosis of the jaw, or ONJ, within three years of starting receiving zoledronic acid.

New committee members or leaders:

Risa Wong, MD, hematology/oncology fellow,
University of Washington

Noel Arring, DNP, PhD, RN, OCN, assistant professor,
University of Michigan

Hayder Saeed, MD, assistant member, Moffitt Cancer Center

RESEARCH SUPPORT COMMITTEES

Adolescent & Young Adult



JOHNSON

Chairs: Rebecca Johnson, MD

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

Development of a website to connect AYA investigators and facilitate collaborations within the NCTN

New publications and presentations:

"Enrollment of adolescents and young adults onto SWOG cancer research network clinical trials: A comparative analysis by treatment site and era." Roth ME, Unger JM, O'Mara AM, Lewis MA, Budd T, Johnson RH, Pollock BH, Blanke C, Freyer DR. *Cancer Med*. 2020: 2146-2152.

"SWOG AYA Committee Activities" presentation to the COG Outcomes and Health Services Working Group. Rebecca Johnson, MD, 11/20/20.

New committee members or leaders:

Lucia Nappi, MD, PhD, vice-chair of SWOG AYA committee

Digital Engagement



DIZON

Chair: Don Dizon, MD

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

We continue to work to introduce new technologies to SWOG and to see what we can do with it. We are excited to continue the very early development of a concept in the myeloma committee, led by Saad Usmani, MD, to evaluate the Aura ring in a prospective, exploratory, non-interventional study that would offer subjects on planned SWOG trials to opt-in for the Aura ring during the course of their treatment. It would be aimed at exploring whether passively collected biometric data might predict clinical endpoints of interest, such as neuropathy or febrile neutropenia.

New publications or presentations:

Gunturu KS, Dizon DS, Johnson J, Mercurio AM, Mason G, Sparks DB, Lawton W, Klemp JR. "Clinical Trials in the Era of Digital Engagement: A SWOG Call to Action." *JCO Clin Cancer Inform*. 2020 Mar; 4:254-258. doi: 10.1200/CCI.19.00128. PMID: 32191544; PMCID: PMC7113134.

Sedrak MS, Sun CL, Hershman DL, Unger JM, Liu J, Dale W, Dizon DS. "Investigator Use of Social Media for Recruitment of Patients for Cancer Clinical Trials." *JAMA Netw Open*. 2020 Dec 1; 3(12):e2031202.

New committee members or leaders:

Allison Rosen, MS, SWOG community advocate, adolescent and young adult community

Nagla Karin, MD, SWOG liaison from the lung cancer committee, Augusta University

Immunotherapeutics



POLITI



HU-LIESKOVAN

Co-Chairs: Katerina Politi, PhD, and Siwen Hu-Lieskovan, MD, PhD

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

Our committee has been leading the efforts for the biomarker driven immunoMATCH (iMATCH) trial, a part of the MATCH series by NCI. This is a clinical trial platform that tests combination immunotherapy strategies in biomarker defined biological groups. We are currently developing a pilot protocol (S2101 BICAZO trial) using this biomarker stratification to test cabozantinib plus nivolumab in patients with melanoma or HNSCC after progression on PD-1 checkpoint inhibitor-based therapies. Stay tuned! The protocol will be activated towards the end of the year, and iMATCH platform is expected to be activated in the next year.

New committee members or leaders:

Join us for our IO committee monthly meeting! Please email Alene.Schwei@hci.utah.edu to be invited to participate and discuss any brilliant ideas and concepts.

Oncology Research Professionals



SZCZEPANEK

Chair: Connie Szczepanek, RN, BSN, CCRP

New publications or presentations:

Committee chair Connie Szczepanek was an author of ASCO's "Road to Recovery" report, outlining lessons from the COVID-19 pandemic for cancer clinical trials. "American Society of Clinical Oncology Road to

Recovery Report: Learning From the COVID-19 Experience to Improve Clinical Research and Cancer Care," *Journal of Clinical Oncology*, Volume 39, Issue 2, 155-169. January 10, 2021

Patient Advocates



BANGS

Chair: Rick Bangs, MBA

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

TeamScience@SWOG Module 6, *Improving Diversity and Representativeness in Clinical Trial Participants*, is complete! The Module 6 training focuses on actions that SWOG study

teams can take to improve the diversity and representativeness of our clinical trial participants. Training is targeted to SWOG study chairs, patient advocates, biostatisticians, and leadership. Other SWOG members are encouraged to take the course. An implementation guide is included, offering practical guidance

on improving diversity and representativeness. Module 6 and the methodology are a partnership between the patient advocate and recruitment and retention committees.

New publications or presentations:

Advocate names are in **bold**.

Ginny Mason and **Elda Railey** presented the patient perspective on the RXPonder trial for a virtual advocacy seminar for Exact Sciences, (formerly Genomic Health).

"Clinical Trials in the Era of Digital Engagement: A SWOG Call to Action" JCO Clinical Cancer Informatics March 2020 Krishna S. Gunturu, MD; Don S. Dizon, MD; **Judy Johnson, MBA; Anne Marie Mercurio, PA; Ginny Mason, BSN;** Dana B. Sparks, MAT; Wendy Lawton, MA; and Jennifer R. Klemp, PhD

"Effective Stakeholder Engagement: Design and Implementation of a Clinical Trial (SWOG S1415CD) to Improve Cancer Care" *BMC Medical Research Methodology* March 2019 Sarah Barger, Sean D. Sullivan, Ari Bell-Brown, Brad Bott, **Anne Marie Ciccarella**, John Golenski, Mark Gorman, Judy Johnson, Karma Kreizenbeck, **Florence Kurttila, Ginny Mason**, Jamie Myers, **Carole Seigel**, James L. Wade III, Guneet Walia, Kate Watabayashi, Gary H. Lyman and Scott D. Ramsey

New committee members or leaders:

This spring, we plan to onboard up to four additional community advocates representing the metastatic/advanced cancer; LGBTQ; rural; and caregiver communities. Look for an announcement soon.

Pharmaceutical Sciences



WONG

Chair: Siu-Fun Wong, PharmD

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

The committee continues to make good progress in the development of the electronic drug-drug interaction (DDI) platform. We submitted a manuscript confirming high rates of drug-drug interactions in patients enrolling on SWOG clinical trials (Under Review, *BMC Cancer*). We published a manuscript describing the development of our DDI platform (Publication #2 below). We received a SEED grant from The Hope Foundation for Cancer Research to conduct a prospective SWOG study in which sites use our screening tool so we can determine its effectiveness and efficiency. Any staff involved

in eligibility screening who are interested in participating in our study should contact committee member Dan Hertz at DLHertz@umich.edu.

New publications or presentations:

Wong SF, Unger J, Arnold K, Moinpour C. "S1013 A Phase II Prospective Study of Epidermal Growth Factor Receptor (Her-1/EGFR) Inhibitor-Induced Dermatologic Toxicity: Validation of the Functional Assessment of Cancer Therapy – EGFR18 (FACT-EGFR18) Questionnaire for EGFR1-induced skin toxicities." *Journal of Patient Reported Outcomes* 2020 Jul8;4(1):54.

Marcath LA, Coe TD, Shakeel F, Reynolds E, Bayuk M, Haas S, Redman BG, Wong SF, Hertz DL. "Improvement Initiative to Develop and Implement a Tool for Detecting Drug-Drug Interactions During Oncology Clinical Trial Enrollment Eligibility Screening" *J Patient Safety*. 2020 Sep 29. doi: 10.1097/PTS.0000000000000772. Online ahead of print.

Ryan-Wolf J, Nabiee R, Candela B, Nassairirad S, Mehvar R, Montezeeri H, Wong SF. "Safety evaluations of topical vitamin K1 for epidermal growth factor inhibitor-induced rash." *Journal of Drug Research and Development* (In Press)

New committee members or leaders:

Aida Ulloa, PhD, drug information subcommittee chair, UCHHealth

Mathew Eng, PharmD, SWOG Statistics and Data Management Center liaison, Cancer Research And Biostatistics

Jane Rogers, PharmD, GI committee liaison, University of Texas M.D. Anderson Cancer Center

Mahta Mahmoudieh, PharmD, lymphoma committee liaison, Banner Health, AZ

U of Michigan Drug Information Team: Kim Redic, PharmD, manager, research pharmacy; Andrew Smith, PharmD, PGY2 investigational drugs and research pharmacy resident

Johns Hopkins Drug Information Team: Janet Mighty, BS Pharm, MBA, director, investigational drug services; Michelle Yu, PharmD, PGY2 investigational drugs and research pharmacy resident

Recruitment & Retention



CABAN-HOLT

Chair: Allison Caban-Holt, PhD

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

The Diversity, Inclusion, and Belonging Strategic (DIBS) Working Group in our committee is an interdisciplinary team that aims to promote diversity, equity, and inclusion (DEI) at all levels of SWOG membership and leadership and provide guidance for the implementation of accountability metrics for SWOG leaders in ensuring DEI. DIBS will also provide a voice for DEI strategic planning for SWOG.

DIBS aims to:

- Ensure diversity of SWOG leaders and members
- Ensure improved DEI awareness, knowledge, and advocacy among SWOG leaders and members
- Develop and document best practices for increasing DEI in SWOG (research and publication)

New publications or presentations:

Several committee members contributed to the Feb. 5, 2021 "Crucial Conversations" webinar on diversity, equity and inclusion efforts sponsored by The Hope Foundation for Cancer Research. Committee chair Allison Caban-Holt moderated the one-hour panel, which included three recruitment and retention committee members as panelists: Lucy Gansauer, MSN, RN, OCN, CCRP; Lynne Nguyen, MPH; and Desiree A.H. Walker.

New committee members or leaders:

Jeremy Kilburn, MD, Gibbs Cancer Center & Research Institute, Spartanburg Regional Healthcare System

Surgery



AHMAD

Chair: Syed A. Ahmad, MD

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

We have helped with the design and approval of S2104 "Randomized Phase II trial of postoperative adjuvant capecitabine and temozolomide versus observation in high-risk

pancreatic neuroendocrine tumors” led by Sy Ahmad, MD, and Heloisa Soares, MD.

We are designing a trial that will evaluate neoadjuvant chemotherapy and cytoreduction and HIPEC for high grade appendiceal carcinoma (NOTH Trial) led by Sameer Patel, MD

We are working on a platform trial to study immune augmenting treatment strategies for MSS colorectal liver metastases, to be led by Sepideh Gholami, MD

We have completed two secondary analysis of SWOG 0809, both submitted to ASCO

New publications or presentations:

“Efficacy of Perioperative Chemotherapy for Resectable Pancreatic Adenocarcinoma: A Phase 2 Randomized Clinical Trial” Sohal DPS, Duong M, Ahmad SA, Gandhi NS, Beg MS, Wang-Gillam A, Wade JL 3rd, Chiorean EG, Guthrie KA, Lowy AM, Philip PA, Hochster HS. JAMA Oncol. 2021

New committee members or leaders:

Gary Deutsch, MD, Northwell Health
Jonathon Sham, MD, University of Washington
Flavio Rocha, MD, Oregon Health & Science University
David Horowitz, MD, Columbia University
Val Simianu, MD, MPH, Virginia Mason

Publication List by Committee

The publications listed below were received by the Group Chair's Office as published, accepted, and submitted or reflect change in status since the SWOG Fall 2020 SWOG Virtual Group Meeting. Conference abstracts are not included.

ADOLESCENT AND YOUNG ADULT (AYA) COMMITTEE

Published/Accepted Manuscripts

C10403 Comparison of CALGB 10403 (Alliance) and COG AALL0232 toxicity results in young adults with acute lymphoblastic leukemia, Advani A, Larsen E, Laumann K, Luger S, Liedtke M, Devidas M, Chen Z, Chen Z, Yen J, Foster M, Claxton D, Coffan K, Tallman M, Appelbaum F, Erba H, Erba H, Stone R, Hunger S, McNeer J, Loh M, Raetz E, Winick N, Carroll W, Larson R, Stock W. *Blood Advances*, Jan 26;5(2):504-512, 2021. [see also Leukemia Committee] <https://pubmed.ncbi.nlm.nih.gov/33496745/>

Submitted Manuscripts

(none this cycle)

BARLOGIE-SALMON MYELOMA COMMITTEE

Published/Accepted Manuscripts

S1211 Bortezomib, Lenalidomide, Dexamethasone with or without Elotuzumab for Untreated, High-Risk Myeloma: Primary Analysis of the SWOG-1211 Randomized Phase II Trial. Usmani S, Hoering A, Ailawadhi S, Sexton R, Lipe B, Hita S, Valent J, Rosenzweig M, Zonder J, Dhodapkar M, Callander N, Zimmerman T, Voorhees P, Durie B, Rajkumar V, Richardson P, Orlowski R. *Lancet Haematology*, Jan;8(1):e45-e54, 2021. <https://pubmed.ncbi.nlm.nih.gov/33357482/>

E1A11 Carfilzomib, Lenalidomide and Dexamethasone versus Bortezomib, Lenalidomide and Dexamethasone for Initial Therapy of Newly Diagnosed Multiple Myeloma (Endurance): A Phase 3 Trial of the ECOG-ACRIN Cancer Research Group (E1A11). Kumar S, Jacobus S, Cohen A, Weiss M, Callander N, Singh A, Parker T, Menter A, Yang A, Parsons B, Kumar P, Kapoor P, Rosenberg A, Zonder J, Faber E, Lonial S, Richardson P, Orlowski R, Wagner L, Rajkumar S. *Lancet Oncology* Oct;21(10):1317-1330, 2020. <https://pubmed.ncbi.nlm.nih.gov/32866432/>

Submitted Manuscripts

(none this cycle)

BREAST COMMITTEE

Published/Accepted Manuscripts

S0307 Risk factors for bisphosphonate-associated osteonecrosis of the jaw in the prospective randomized trial of adjuvant bisphosphonates for early-stage breast cancer (SWOG 0307). Kizub D, Miao J, Schubert M, Paterson A, Clemons M, Dees E, Ingle J, Falkson C, Barlow W,

Hortobagyi G, Gralow J. *Supportive Care in Cancer*, Sep 15. doi:10.1007/s00520-020-05748-8. Online ahead of print, 2020. <https://pubmed.ncbi.nlm.nih.gov/32929540/>

C40601 Survival, Pathologic Response, and Genomics in CALGB 40601 (Alliance), a Neoadjuvant Phase III Trial of Paclitaxel-Trastuzumab With or Without Lapatinib in HER2-Positive Breast Cancer. Fernandez-Martinez A, Kropf J, Hillman D, M-Yin, Parker J, Huebner L, Hoadley K, Sheperd J, Tolane S, Henry NL, Dang C, Harris L, Berry D, Hahn O, Hudis C, Winer E, Partridge A, Perou C, Carey L. *Journal of Clinical Oncology* Dec 10;38(35):4184-4193, 2020. <https://pubmed.ncbi.nlm.nih.gov/33095682/>

C40503 Clinical significance of circulating tumor cells in hormone receptor-positive metastatic breast cancer patients who received letrozole with or without bevacizumab. Magbanua M, Savenkov O, Asmus E, Ballman K, Scott J, Park J, Dickler M, Partridge A, Carey L, Winer E, Rugo H. [note: D. Tripathy in acknowledgements as SWOG study champion]. *Clinical Cancer Research* Sep 15;26(18):4911-4920, 2020. <https://pubmed.ncbi.nlm.nih.gov/32586939/>

N9831 Impact of Adjuvant Trastuzumab on Locoregional Failure Rates in the NCCTG N9831 (Alliance) Study. Vargas C, Thorpe C, Dueck A, Tenner K, Perez E, Hwang E, Halyard M, Pisansky T, Davidson N, Martino S, Pockaj B. *Cancer* Dec 15;126(24):5239-5246, 2020. <https://pubmed.ncbi.nlm.nih.gov/32931029/>

PACCT-1 Race, ethnicity and clinical outcomes in hormone receptor-positive, HER2-negative, node-negative breast cancer: results from the TAILORx trial. Albain K, Gray R, Makower D, Faghih A, Hayes DF, Geyer C, Dees E, Goetz M, Olson J, Lively T, Bavde S, Saphner T, Wagner L, Whelan T, Ellis M, Paik S, Wood W, Ravdin P, Keane M, Gomez H, Reddy P, Goggins T, Mayer I, Brufsky A, Toppmeyer D, Kaklamani V, Berenberg J, Abrams J, Sledge G, Sparano J. *Journal of the National Cancer Institute* Sep 28;djaa148. doi: 10.1093/jnci/djaa148. Online ahead of print., 2020. <https://pubmed.ncbi.nlm.nih.gov/32986828/>

Submitted 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, Puzstai L, Sharma P, Godwin A, Thompson A, Hayes D, Rae J. *Annals of Oncology*, submitted 2021.

Publication List by Committee

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*, submitted 2021.

CANCER CONTROL & PREVENTION

Cancer Care Delivery Committee

Published/Accepted Manuscripts

S1105 Patient Reported Outcomes and Long-Term Non-Adherence to Aromatase Inhibitors. Hershman D, Neugut A, Moseley A, Arnold K, Gralow J, Henry NL, Clarke Hillyer G, Ramsey S, Unger J. *Journal of the National Cancer Institute*, Feb 25:djab022, 2021. doi: 10.1093/jnci/djab022. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/33629114/>

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*, accepted 2021. [see also Lung Committee]

Multiple Studies Investigator Use of Social Media for Recruitment of Patients for Cancer Clinical Trials. Sedrak MS, Sun C-L, Hershman DL, Unger JM, Liu J, Dale W, Dizon DS. *JAMA Network Open* Dec 1;3(12):e2031202, 2020. <https://pubmed.ncbi.nlm.nih.gov/33369658/> [see also Digital Engagement Committee]

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*, accepted 2021.

Multiple Studies "When offered to participate:" A systematic review and meta-analysis of patient agreement to participate in cancer clinical trials. Unger J, Hershman D, Till C, Minasian L, Osarogiagbon R, Fleury M, Vaidya R. *Journal of the National Cancer Institute* Mar 1;113(3):244-257, 2021. <https://pubmed.ncbi.nlm.nih.gov/33022716/>

Multiple Studies What Keeps Patients Out of Clinical Trials? [Editorial]. Minasian L, Unger J. *JCO Oncology Practice* Mar;16(3):125-127, 2020. <https://pubmed.ncbi.nlm.nih.gov/32074016/>

Multiple Studies* Economic evaluations in NCI-sponsored network cancer clinical trials. Nghiem VT, Vaidya R, Lyman GH, Hershman DL, Ramsey SD, Unger JM. *Value in Health*, Dec;23(12):1653-1661, 2020. [*E2100, E4494, IBCSG25, JMA17, N9741, N9831, S8494, S8710, S8794, S8797, S9031, S9412, S9509] <https://pubmed.ncbi.nlm.nih.gov/33248521/>

Multiple Studies Moving Beyond the Momentum: Innovative Approaches to Clinical Trial Implementation. Eng C, Chen E, Rogers J, Lewis M, Strosberg J, Thota R, Krishnamurthi S, Oberstein P, Govindarajan R, Buchschacher G, Patel S, Sohal D, Al-Toubah T, Philip P, Dasari NA, Kennecke H, Stein S. *JCO Oncology Practice* Feb 3;OP2000701. doi: 10.1200/OP.20.00701. Online ahead of print., 2021. <https://pubmed.ncbi.nlm.nih.gov/33534616/>

Submitted Manuscripts

(none this cycle)

Cancer Survivorship Committee

Published/Accepted Manuscripts

C80405 Coffee Intake and Survival in Patients with Advanced or Metastatic Colorectal Cancer: Results from Cancer and Leukemia Group B/SWOG 80405 (Alliance). Mackintosh C, Yuan C, Ou F-S, Zhang S, Niedzwiecki D, Chang I-W, O'Neil B, Mullen B, Lenz H-J, Blanke CD, Venook A, Mayer R, Fuchs C, Innocenzi F, Nixon A, Goldberg R, O'Reilly E, Meyerhardt J, Ng K. *JAMA Oncology* Sep 17; 6(11):1713-1721, 2020. <https://pubmed.ncbi.nlm.nih.gov/33022716/> [see also GI Committee]

C80405 Association of diet quality with survival among people with metastatic colorectal cancer: data from CALGB/SWOG 80405 (Alliance). Van Blarigan E, Zhang S, Ou F-S, Venook A, Ng K, Atreya C, Van Loon K, Niedzwiecki D, Giovannucci E, Wolfe E, Lenz H-J, Innocenti F, O'Neil B, Shaw J, Polite B, Hochster H, Atkins J, Goldberg R, Mayer R, Blanke CD, O'Reilly E, Fuchs C, Meyerhardt J. *JAMA Network Open* Oct 1;3(10):e2023500, 2020. <https://pubmed.ncbi.nlm.nih.gov/33125497/> [see also GI Committee]

Submitted Manuscripts

(none this cycle)

Palliative & End of Life Care Committee

Published/Accepted Manuscripts

(none this cycle)

Submitted Manuscripts

Publication List by Committee

(AIMS-RC): Feasibility of a Diet Modification Intervention for Post-Treatment Bowel Dysfunction. 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, submitted.

Multiple Studies* 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. The Association of Patient Fatigue and Journal of Clinical Oncology, resubmitted. [*S0027,S0421,S9509,S9916]

Prevention & Epidemiology Committee

Published/Accepted Manuscripts

S0000 A Latent Disease Model to Reduce Detection Bias in Cancer Risk Prediction Studies. Aleshin-Guendel S, Lange J, Goodman P, Weiss N, Etzioni R. Evaluation and the Health Professions Mar;44(1):42-49, 2021. <https://pubmed.ncbi.nlm.nih.gov/33506704/>

S0000/Other Genetic architectures of proximal and distal colorectal cancer are partly distinct. Huyghe J, Harrison T, Bien S, Hampel H, Figueriedo, Schmit S, Albanes D, Goodman P, Tangen C, Gruber S, Hsu L, Moreno V, Hayes R, Newcomb P, Ulrike P. Gut Feb 25;gutjnl-2020-321534. doi: 10.1136/gutjnl-2020-321534. Online ahead of print, 2021. <https://pubmed.ncbi.nlm.nih.gov/33632709/>

S0000/Other Adiposity, metabolites, and colorectal cancer risk: Mendelian randomization study. Bull CJ, Bell JA, Murphy N, Sanderson E, Smith G, Timpson N, Albanes D, Platz E, Tangen CM, Wu A, Campbell P, Zheng W, Peters U, Vincent E, Gunter M. BMC Med Dec 17;18(1):396, 2020. <https://pubmed.ncbi.nlm.nih.gov/33327948/>

S0000/Other Circulating adipokine concentrations and risk of five obesity-related cancers: A Mendelian randomization study. Dimou N, Papadimitriou N, Mariosa D, Johansson M, Brennan P, Peters U, Chanock S, Purdue M, Bishop D, Gago-Dominquez M, Giles G, Moreno V, Platz EA, Tangen CM, Wolk A, Zheng W, Wu X, Campbell P, Giovannucci E, Lin Y, Gunter M, Murphy N. International Journal of Cancer Apr 1; 148(7): 1625–1636, 2021. <https://pubmed.ncbi.nlm.nih.gov/33038280/>

S0000/Other Smoking modifies pancreatic cancer risk loci on 2q21.3. Mocci E, Kundu P, Wheeler W, Arslan A, Beane Freeman L, Bracchi P, Brennan P, Canzian F, Du M, Gallinger S, Giles G, Goodman P, Albanes D, Fuchs C, Gaziano J, Thompson I, Chatterjee N, Klein A, Stolzenberg-Solomon R. Cancer Research Feb 11;canres.3267.2020. doi: 10.1158/0008-5472.CAN-20-3267. Online ahead of print., 2021. <https://pubmed.ncbi.nlm.nih.gov/33574088/>

S0000/Other Identifying novel susceptibility genes for colorectal cancer

risk from a transcriptome-wide association study of 125,478 subjects. Guo X, Lin W, Wen W, Bien S, Qu C, Huyghe J, Abecasis G, Albanes D, Berndt S, Bezieu S, Bishop DT, Brenner H, Buch S, Burnett-Hartman A, Campbell PT, Castellvi Bel S, Chan AT, Chang-Claude J, Chanock S, Cho SH, Conti D, de la Chapelle A, Feskens E, Gallinger S, Giles G, Goodman P, Gsur A, Guinter M, Gunter M, Hampe J, Hampel H, Harrison T, Hayes R, Hoffmeister M, Jenkins MA, Kampman E, Kang HM, Keku T, Kim HR, Le Marchand L, Lee SC, Lee CI, Li L, Lindbom A, Milne RL, Moreno V, Newcomb P, Nickerson D, Offir K, Peters U. Gastroenterology Oct 12;S0016-5085(20)35243-4. doi: 10.1053/j.gastro.2020.08.062. Online ahead of print, 2020. <https://pubmed.ncbi.nlm.nih.gov/33058866/>

S0000A Mental Component Score (MCS) from Health-related Quality of Life Predicts Incidence of Dementia in U.S. Males. Ding X, Abner E, Schmitt F, Crowley J, Goodman P, Kryscio R. Journal of Prevention of Alzheimer's Disease p8(2):169-174, 2021. <https://pubmed.ncbi.nlm.nih.gov/33569563/>

S9217 Association of Serum Carotenoids and Retinoids with Intraprostatic Inflammation in Men without Prostate Cancer or Clinical Indication for Biopsy in the Placebo Arm of the Prostate Cancer Prevention Trial. Chadid S, Song X, Schenk J, Gurel B, Lucia MS, Thompson I, Jr., Neuhauser M, Goodman P, Parnes H, Lippman S, Nelson W, De Marzo A, Platz E. Nutrition and Cancer Jan 29;1-8. doi: 10.1080/01635581.2021.1879879. Online ahead of print., 2021. <https://pubmed.ncbi.nlm.nih.gov/33511883/>

Multiple Studies* Polygenic hazard score is associated with prostate cancer in multi-ethnic populations. Huynh-Le M, Fan C, Karunamuni R, Thompson W, Martinez ME, Eeles R, Tangen C, Albanes D, Parent M-E, Hu J, Mills I, Andreassen O, Dale A, Seibert T. Nature Communications, Feb 23;12(1):1236, 2021. [*S0000, S9217, OTHER] <https://pubmed.ncbi.nlm.nih.gov/33623038/>

Multiple Studies* A multilayered post-GWAS assessment on genetic susceptibility to pancreatic cancer. Lopez de Maturana E, Rodriguez J, Alonso L, Lao O, Molina-Montes E, Gomez-Rubio P, Lawlor R, Albanes D, Gaziano JM, Goodman P, Marti-Renom M, Real F, Malats N. Genome Medicine Feb 1;13(1):15. 2021. [*S0000, S9217, OTHER] <https://pubmed.ncbi.nlm.nih.gov/33517887/>

Multiple Studies* African-specific improvement of a polygenic hazard score for age at diagnosis of prostate cancer. Karunamuni R, Huynh-Le MP, Fan C, Thompson W, Eeles R, Kote-Jarai Z, Tangen C, Goodman P, Thompson IM Jr., Andreassen O, Dale A, Seibert T. Journal of Cancer Jan 1;148(1):99-105, 2021. [*S0000, S9217, OTHER] <https://pubmed.ncbi.nlm.nih.gov/32930425/>

Publication List by Committee

Multiple Studies* Additional SNPs improve the performance of a polygenic hazard score for prostate cancer. Karunamuni R, Huynh-Le M, Fan C, Thompson W, Eeles R, Kote-Jarai Z, Muir K, Lophatananon A, UKGPCS collaborators, Schleutker J, Pashayan N, Batra J, APCB BioResource (Australian Prostate Cancer BioResource), Grönberg H, Walsh E, Turner E, Lane A, Martin R, Neal D, Donovan J, Hamdy F, Nordestgaard B, Tangen C, MacInnis R, Wolk A, Albanes D, Mills I, Andreassen O, Dale A, Seibert T, The PRACTICAL Consortium. *Prostate Cancer and Prostatic Diseases* Jan 8, 2021. doi: 10.1038/s41391-020-00311-2. Online ahead of print. [*S0000, S9217, OTHER] <https://pubmed.ncbi.nlm.nih.gov/33420416/>

Multiple Studies* Mendelian randomization analysis of n-6 polyunsaturated fatty acid levels and pancreatic cancer risk. Ghoneim D, Zhu J, Zheng W, Long J, Murff H, Ye F, Goodman P, Albanes D, Fuchs C, Gaziano JM, Thompson I, Amundadottir L, Kraft P, Klein A, Stolzenberg-Solomon R, Shu X-O, Wu L. *Cancer Epidemiology, Biomarkers & Prevention*, Sep 23;cebp.0651.2020. Online ahead of Print:doi: 10.1158/1055-9965.EPI-20-0651, 2020. [*S0000, S9217, OTHER] <https://pubmed.ncbi.nlm.nih.gov/32967863/>

Multiple Studies* Trans-ancestry genome-wide association meta-analysis of prostate cancer identifies new susceptibility loci and informs genetic risk prediction. Conti D, Darst B, Saunders EJ, Sheng X, Chou A, Schumacher F, Albanes D, Tangen C, Goodman P, Thompson IM, Klein EA, Hsing A, Eeles R, Kote-Jarai Z, Haiman C. *Nature Genetics* Jan 4. doi: 10.1038/s41588-020-00748-0, Online ahead of print, 2021. <https://pubmed.ncbi.nlm.nih.gov/33398198/> [*S0000, S9217, OTHER].

Multiple Studies* The CHEK2 Variant C.349A>G Is Associated with Prostate Cancer Risk and Carriers Share a Common Ancestor. Brandao A, Paulo P, Maia S, Pinheiro M, Peixoto A, Cardoso M, Tangen C, Albanes D, Roobol M, Study Steering Cmte Profile, Consortium PRACTICAL, Teixeira M. *Cancers (Basel)* Nov 4;12(11):3254. doi: 10.3390/cancers12113254, 2020. [*S0000, S9217, OTHER] <https://pubmed.ncbi.nlm.nih.gov/33158149/>

Submitted Manuscripts

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. *JAMA*, submitted 2020.

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.

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

S9217 Obesity-related Biomarkers Mediating the Association Between Obesity and Prostate Cancer Risk: Results from the Prostate Cancer Prevention Trial. Chau C, Till C, Price D, Goodman P, Tangen C, Thompson I, Figg W. *British Journal of Cancer*, submitted.

Multiple Studies* A functional variation in PSA that confers lower risk is also associated with more aggressive disease and lower survival in men with prostate cancer. 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, Eeles R, Clements J, Batra J. *Nature Genetics*, submitted. [*S0000, S9217, OTHER]

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*, submitted 2021. [*S0000, S9217, OTHER]

Symptom Control & Quality of Life Committee

Published/Accepted Manuscripts

S0702 Osteonecrosis of the jaw in patients with cancer receiving zoledronic acid for bone metastases: SWOG S0702, NCT00874211. Van Poznak C, Unger J, Darke A, Moynour C, Bagramian R, Schubert M, Hansen L, Floyd J, Dakhil S, Lew D, Wade J, Fisch M, Henry NL, Hershman D, Gralow J. *JAMA Oncology* Feb 1;7(2):246-254, 2021. <https://pubmed.ncbi.nlm.nih.gov/33331905/>

Submitted Manuscripts

S1202 Relationship of Adverse Events to Patient Perception of Benefit from Duloxetine for Treating Aromatase Inhibitor-Associated Arthralgias. Schnell P, Lustberg M, Henry NL. *JNCI Spectrum*, in press.

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. *Journal of Clinical Oncology*, 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).

Publication List by Committee

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

Multiple Studies Investigator Use of Social Media for Recruitment of Patients for Cancer Clinical Trials. Sedrak MS, Sun C-L, Hershman DL, Unger JM, Liu J, Dale W, Dizon DS. *JAMA Network Open* Dec 1;3(12):e2031202, 2020. <https://pubmed.ncbi.nlm.nih.gov/33369658/> [see also CCD Committee]

Submitted Manuscripts

(none this cycle)

EARLY THERAPEUTICS & RARE CANCERS COMMITTEE

Published/Accepted Manuscripts

S1609 Dual Checkpoint Blockade in a Neuroendocrine Carcinoma with Dual PD-L1/PD-L2 Amplification and High Tumor Mutational Burden [case report]. Gong J, Adashek D, Frishberg D, Guan M, Placencio-Hickock V, Gangi A, Gresham G, Tuli R, Othus M, Chae YK, Kurzrock R, Hendifar A. *JCO Precision Oncology* May 15;4:PO.18.00391, 2020. <https://pubmed.ncbi.nlm.nih.gov/33215052/>

Submitted Manuscripts

S1609 A Multicenter Phase II Trial (SWOG S1609, Cohort 51) 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 Clinical Oncology*, 2021.

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 SP, Othus M, Chae YK, J Strosberg J, Wang J, Konda B, Hayward J, McLeod C, Chen H, Sharon E, Mayerson E, Ryan C, Plets M, Blanke CD, Kurzrock R. *JAMA Oncology*, submitted.

EXECUTIVE COMMITTEE

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NONE What happened to the US cancer cooperative groups? A status update ten years after the Institute of Medicine report. Bertagnolli M, Blanke C, Curran W, Hawkins D, Mannel R, O'Dwyer P, Schnall M, Wolmark N. *Cancer* Dec 1;126(23):5022-5029, 2020. <https://pubmed.ncbi.nlm.nih.gov/33369658/>

[ncbi.nlm.nih.gov/32970346/](https://pubmed.ncbi.nlm.nih.gov/32970346/)

GASTROINTESTINAL COMMITTEE

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S1406 Randomized trial of irinotecan an cetuximab with or without vemurafenib in BRAF-mutant metastatic colorectal cancer (SWOG S1406). Kopetz S, Guthrie KA, Morris VK, Lenz H-J, Magliocco AM, Maru D, Yan Y, Lanman R, Manyam G, Hong DS, Sorokin A, Atreya CE, Allegra C, Raghav KP, Wang SE, Lieu CH, McDonough SL, Philip PA, Hochster HS. *Journal of Clinical Oncology* Feb 1;39(4):285-294, 2021. <https://pubmed.ncbi.nlm.nih.gov/33356422/>

S1505 Surgical Outcome Results from SWOG S1505: A Randomized Clinical Trial of mFOLFIRINOX vs. Gemcitabine/nab-Paclitaxel for Perioperative Treatment of Resectable Pancreatic Ductal Adenocarcinoma (PDA). Ahmad SA, Duong M, Sohal DPS, Gandhi NS, Beg MS, Wang-Gillam A, Wade JL 3rd, Chiorean EG, Guthrie KA, Lowy AM, Philip PA, Hochster HS. *Annals of Surgery* Sep 1;272(3):481-486, 2020. <https://pubmed.ncbi.nlm.nih.gov/32740235/>

S1505 Efficacy of Perioperative Chemotherapy for Resectable Pancreatic Adenocarcinoma: A Phase 2 Randomized Clinical Trial. Sohal DPS, Duong M, Ahmad SA, Gandhi NS, Beg MS, Wang-Gillam A, Wade JL, Chiorean EG, Guthrie KA, Lowy AM, Philip PA, Hochster HS. *JAMA Oncology* Jan 21;e207328. doi: 10.1001/jamaoncol. 2020. 7328. Online ahead of print, 2021. <https://pubmed.ncbi.nlm.nih.gov/33475684/>

C80405 Association of diet quality with survival among people with metastatic colorectal cancer: data from CALGB/SWOG 80405 (Alliance). Van Blarigan E, Zhang S, Ou F-S, Venook A, Ng K, Atreya C, Van Loon K, Niedzwiecki D, Giovannucci E, Wolfe E, Lenz H-J, Innocenti F, O'Neil B, Shaw J, Polite B, Hochster H, Atkins J, Goldberg R, Mayer R, Blanke CD, O'Reilly E, Fuchs C, Meyerhardt J. *JAMA Network Open* Oct 1;3(10):e2023500, 2020. <https://pubmed.ncbi.nlm.nih.gov/33125497/> [see also Cancer Survivorship Committee]

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C80405 Genomic analysis of germline variation associated with survival

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C80405 IGF-binding proteins, adiponectin and survival in metastatic colorectal cancer: results from CALGB (Alliance)/SWOG 80405. Guercio B, Zhang S, Ou F-S, Venook A, Niedzwiecki D, Lenz H-J, Innocenti F, Pollak M, Nixon A, Mullen B, O'Neil B, Shaw J, Polite B, Benson A, Atkins J, Goldberg R, Brown J, O'Reilly EM, Mayer R, Blanke CD, Fuchs C, Meyerhardt J. *JNCI Cancer Spectrum* Aug 27;5(1):5(1):pkaa074, 2020. <https://pubmed.ncbi.nlm.nih.gov/33426464/>

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Multiple Studies* Effect of duration of adjuvant chemotherapy for patients with stage III colon cancer (IDEA collaboration): final results from a prospective, pooled analysis of six randomised, phase 3 trials Andre T, Meyerhardt J, Iveson T, Sobrero A, Yoshino T, Souglakos I, Niedzwiecki D, Saunders M, Labianca R, Yamanaka T, Boukovinas I, Vernerey D, Meyers J, Harkin A, Torri V, Georgoulas E, Oki E, Taieb J, Shields AF, Shi Q. *Lancet Oncology* 2020 Dec;21(12):1620-1629, 2021. [*C80702,MULTIPLE] <https://pubmed.ncbi.nlm.nih.gov/33271092/>

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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 SCQOL Cmtc]

GENITOURINARY COMMITTEE

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

Published/Accepted Manuscripts

S1216 Baseline circulating tumor cell count as a prognostic marker of PSA response and disease progression in metastatic castrate sensitive

prostate cancer (SWOG S1216). Goldkorn A, Tangen C, Plets M, Morrison GJ, Cunha A, Xu T, Pinski JK, Ingles SA, Triche T, Harzstark AL, Kohli M, MacVicar GR, Vaena DA, Crispino AW, McConkey DJ, Lara PN Jr., Hussain MHA, Quinn DI, Vogelzang NJ, Thompson IM Jr., Agarwal N. *Clin Cancer Res*. 2021 Jan 26. doi: 10.1158/1078-0432.CCR-20-3587. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/33500355/>

S1314 A randomized phase II study of coexpression extrapolation (COXEN) with neoadjuvant chemotherapy for bladder cancer (SWOG S1314; NCT02177695). Flaig TW, Tangen CM, Daneshmand S, Alva AS, Lerner SP, Lucia MS, McConkey DJ, Theodorescu D, Goldkorn A, Milowsky MI, Bangs R, MacVicar GR, Bastos BR, Fowler J, Gustafson D, Plets M, Thompson IM. *Clinical Cancer Research* Feb 10;clincanres.2409.2020. doi: 10.1158/1078-0432.CCR-20-2409. Online ahead of print, 2021. <https://pubmed.ncbi.nlm.nih.gov/33568346/>

S1500 A comparison of sunitinib with cabozantinib, crizotinib, and savolitinib for treatment of advanced papillary renal cell carcinoma: a randomised, open-label, phase 2 trial. Pal S, Tangen C, Thompson I, Balzer-Haas N, George D, Heng D, Shuch B, Stein M, Tretiakova M, Humphrey P, Adeniran A, Narayan V, Bjarnason G, Vaishampayan U, Alva A, Zhang T, Cole S, Plets M, Wright J, Lara P. *Lancet*, Feb 20;397(10275):695-703, 2021. <https://pubmed.ncbi.nlm.nih.gov/33592176/>

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LEUKEMIA COMMITTEE

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N, Carroll W, Larson R, Stock W. *Blood Advances*, Jan 26;5(2):504-512, 2021. [see also AYA Committee] <https://pubmed.ncbi.nlm.nih.gov/33496745/>

C10603 Midostaurin reduces the cumulative incidence of relapse and is tolerable for maintenance in FLT3-mutant acute myeloid leukemia (CALGB 10603). Larson RA, Mandrekar S, Huebner L, Sanford B, Laumann C, Geyer S, Bloomfield C, Thiede C, Prior T, Dohner K, Marcucci G, Voso M, Klisovic R, Galinsky I, Wei A, Sierra J, Sanz M, Brandwein J, de Witte T, Niederwieser D, Appelbaum F, Medeiros B, Tallman M, Krauter J, Schlenk R, Ganser R, Serve H, Ehninger G, Amadori S, Gathmann I, Dohner H, Stone R. *Blood*, Mar 2. doi: 10.1038/s41375-021-01179-4. Online ahead of print, 2021. <https://pubmed.ncbi.nlm.nih.gov/33654204/>

E2905 Lenalidomide-Epoetin Alfa Versus Lenalidomide Monotherapy in Myelodysplastic Syndromes Refractory to Recombinant Erythropoietin. List A, Sun Z, Verma A, Bennett J, Komrokji R, McGraw K, Nardelli L, Maciejewski J, Altman J, Cheema P, Claxton D, Luger S, Mattison R, Wassenaar T, Artz A, Schiffer C, Litzow M, Tallman M. *Journal of Clinical Oncology* Jan 13;JCO2001691.doi: 10.1200/JCO.20.01691. Online ahead of print., 2021. <https://pubmed.ncbi.nlm.nih.gov/33439748/>

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Multiple Studies* Bias in mean survival from fitting cure models with limited follow-up. Othus M, Bansal A, Erba H, Ramsey S. *Value in Health*, Aug;23(8):1034-1039, 2020. [*S0106, S0325, S0703, S0805, S1117, S1203] <https://pubmed.ncbi.nlm.nih.gov/32828215/>

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LUNG COMMITTEE

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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*, accepted 2021.

S1400 Biomarker-driven therapies for previously treated squamous non-small-cell lung cancer (Lung-MAP SWOG S1400): a biomarker-driven master protocol. Redman M, Papadimitrakopoulou V, Minichiello K, Hirsch F, Mack P, Schwartz L, Vokes E, Ramalingam S, Leighl N, Bradley J, Miao J, Moon J, Highleyman L, Miwa C, LeBlanc M, Malik S, Miller V, Sigal E, Adam S, Wholley D, Blanke CD, Kelly K, Gandara D, Herbst RS. *Lancet Oncology* Dec;21(12):1589-1601, 2020. <https://pubmed.ncbi.nlm.nih.gov/33125909/>

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S1400G A Phase II Study of Talazoparib in Patients with Homologous Recombination Repair Deficiency (HRRD) Positive Stage IV Squamous Cell Lung Cancer (Lung-MAP Sub-Study S1400G). Owonikoko T, Redman M, Byers L, Hirsch F, Mack P, Schwartz L, Bradley J, Stinchcombe T, Leighl N, Al Baghdadi T, Lara P, Miao J, Kelly K, Ramalingam S, Herbst RS, Papadimitrakopoulou V, Gandara D. *Clinical Lung Cancer* Jan 10;S1525-7304(21)00004-8. doi: 10.1016/j.clcc.2021.01.001. Online ahead of print. 2021, 2021. <https://pubmed.ncbi.nlm.nih.gov/33583720/>

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S1400K A Phase II Study of Telisotuzumab Vedotin (Teliso-V, Abbv-399) in Patients with C-Met Positive Stage I or Recurrent Squamous Cell Lung Cancer (Lung-MAP Sub-Study SWOG S1400K, NCT03574753). Waqar S, Redman M, Arnold SM, Hirsch FR, Mack PC, Schwartz LH, Gandara D,

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Stinchcombe T, Ramalingam S, Tanna S, Raddin R, Minichiello K, Kelly K, Bradley JD, Herbst RS, Papadimitrakopoulou V. Clinical Lung Cancer Oct 14; doi: 10.1016/j.clcc.2020.09.013. [Epub ahead of print], 2020. <https://pubmed.ncbi.nlm.nih.gov/33221175/>

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LYMPHOMA COMMITTEE

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S1001 Reply to Hawkes et al. [Correspondence]. Persky D, Smith S, LeBlanc M, Friedberg J. Journal of Clinical Oncology Oct 26;JCO2002856. Online ahead of print, 2020. PMID33104437. <https://pubmed.ncbi.nlm.nih.gov/33104437/>

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 (SWOG Intergroup S1826). Herrera A, Kahl B. Hematologist [Clinical Trials Corner] Sept 1 Vol 17, Issue 5, 2020. <https://ashpublications.org/thehematologist/article/464062/S1826-U-S-Intergroup-Trial-for-Advanced-Stage>

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Submitted Manuscripts

(none this cycle)

MELANOMA COMMITTEE

Published/Accepted Manuscripts

S1320 Continuous compared to intermittent therapy for BRAF mutated melanoma. Algazi A, Othus M, Othus M, Daud A, Lo R, Mehnert J, Truong T-G, Conry R, Kendra K, Doolittle G, Clark J, Messino M, Moore D, Lao C, Faller B, Govindarajan R, Harker-Murray A, Dreisbach L, Moon J, Grossmann K, Ribas A. Nature Medicine Oct;26(10):1564-1568, 2020. <https://pubmed.ncbi.nlm.nih.gov/33020646/>

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E1609 Immune adverse events (irAEs) with adjuvant ipilimumab in melanoma, use of hormone replacement and immunosuppressants and association with outcome: ECOG-ACRIN E1609 study analysis. Tarhini A, Kang N, Lee S, Hodi F, Rao U, Cohen G, Hamid O, Hutchins L, Sosman J, Kluger H, Eroglu Z, Koon H, Lawrence D, Kendra K, Minor D, Lee C, Albertini M, Flaherty L, Petrella T, Streicher H, Sondak V, Kirwood J. Journal for ImmunoTherapy of Cancer, submitted.

PHARMACEUTICAL SCIENCES COMMITTEE

Published/Accepted Manuscripts

Multiple Studies Improvement Initiative to Develop and Implement a Tool for Detecting Drug-Drug Interactions During Oncology Clinical Trial Enrollment Eligibility Screening Marcath LA, Coe T, Shakeel F, Reynolds E, Bayuk M, Haas S, Redman BG, Wong S-F, Hertz DL. Journal of Patient Safety Jan 1;17(1):e28-e34, 2021. <https://pubmed.ncbi.nlm.nih.gov/33003175/>

Submitted Manuscripts

Multiple Studies Drug-drug interactions in subjects enrolled in SWOG trials of oral chemotherapy. Marcath LA, Finley C, Wong S-F, Hertz DL. BMC Cancer, under review.

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