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This is the official meeting book of the 2016 Alliance for Clinical Trials in Oncology (Alliance) Spring Group Meeting held May 12-14 in Chicago, IL. This book is for internal use by Alliance members and contains a directory of Alliance programs, committees and staff, along with accrual data and protocol listings for Alliance studies. Content in this book contains the most current information available at publication. Not for publication or citation.

For more information about the Alliance, visit www.AllianceforClinicalTrialsinOncology.org

Welcome 2016 Alliance Spring Group Meeting



Dear Alliance Members and Colleagues,

It has been exciting to see how our meetings have evolved over the past few years, transitioning from many new program-building activities to our current state of exceptional research productivity. Each Alliance meeting attempts to pack the three days allotted with many important sessions, including ongoing study review, new idea generation, networking to increase collaboration, member education, and new policy development. With each successive meeting, Alliance researchers are increasing their capability to accomplish highest impact cancer clinical and translational research.

This spring meeting includes a wide variety of educational and networking activities that promise to be valuable for our members. For example, one of our most important goals is to provide talented young oncologists with the skills and support required to become active Alliance researchers. To this end, a new feature of the meeting is a program specifically designed for junior investigators, including fellows, junior associates in community practices, and junior faculty members who have not previously been associated with Alliance research. The agenda has been organized by prominent Alliance members who have been past recipients of Alliance Foundation clinical research awards. The Clinical Research Professionals Committee is once again hosting its highly acclaimed educational sessions, with new topics including “Meet Your Data Manager,” updates on specimen submission via BioMS and several study-specific training sessions. Finally, the Member Services Enhancement Task Force continues its work to understand and respond to the specific needs of our members. The Alliance will be conducting a post-meeting survey to explore ways to make each Group Meeting better than the last.

My sincere thanks to all of you for attending this meeting. Your participation is essential for our success, and it is also a great inspiration to the staff who work so hard to make our meetings interesting and productive.

Enjoy the meeting!

Handwritten signature of Monica M. Bertagnolli, MD, in black ink.

Monica M. Bertagnolli, MD, Group Chair

About | The Alliance

The **Alliance for Clinical Trials in Oncology** is a multi-institutional cancer research consortium that conducts high-impact multidisciplinary cancer control, prevention, and treatment trials. The Alliance was formed in 2011 by the merger of three National Cancer Institute (NCI)-funded cooperative groups, the American College of Surgeons Oncology Group (ACOSOG), the Cancer and Leukemia Group B (CALGB), and the North Central Cancer Treatment Group (NCCTG). Through these legacy groups, the Alliance brings a 60-year history of cancer clinical trials experience to meet the research challenges of 2016.

The mission of the Alliance is to reduce the impact of cancer by:

- ▲ conducting high quality multidisciplinary cancer control, prevention, and treatment trials that engage a comprehensive research network;
- ▲ furthering our understanding of the biological basis of the cancer process and its treatment, from discovery, to validation, to clinical practice; and
- ▲ providing a scientific and operational infrastructure for innovative clinical and translational research in the academic and community settings.

The Alliance is comprised of an outstanding scientific team, where its studies are designed by disease and modality committees populated by U.S. leaders in clinical oncology, cancer control and prevention, and translational research. Central to this work, a network of member clinical sites are distributed throughout North America, with almost equal representation by community oncology and academic institutions. The activities of these researchers are coordinated by an infrastructure that provides central administration, protocol operations, statistics and data management, translational research expertise and biorepository resources. In order to achieve its mission, the Alliance is supported by two distinct and complementary operations teams. The first, dating to 1956, manages Alliance participation in the U.S. National Cancer Institute-sponsored National Clinical Trials Network (NCTN) and NCI Community Oncology Research Program (NCORP). Through this mechanism, the Alliance joins ECOG-ACRIN, NRG Oncology, SWOG, the National Cancer Institute of Canada (NCIC) and the Children's Oncology Group (COG) to conduct a comprehensive portfolio of research funded through the NCI. In addition, Alliance Foundation Trials, LLC (AFT), a not-for-profit corporation, allows Alliance researchers and institutions to lead and participate in cancer clinical trials supported by organizations outside of the NCI. Current AFT studies are funded by a number of pharmaceutical company collaborators and the Patient-Centered Outcomes Research Institute (PCORI).



About | The Foundation

The **Alliance for Clinical Trials in Oncology Foundation** is a nonprofit, tax-exempt foundation that raises funds to help the Alliance for Clinical Trials in Oncology answer important treatment questions through large-scale clinical trials. Through efforts of the Foundation in support of Alliance clinical trials and laboratory research, donors can help find new ways to prevent, treat and cure many types of cancer, and help educate the medical community on methods of cancer diagnosis, treatment and prevention.

Some recent initiatives supported by the Foundation include: new chemotherapy treatments for breast, prostate, lung and colorectal cancer; new surgical techniques for breast and colon cancer; genetic studies of breast cancer risk; molecular determinants of response to therapy for breast, colorectal and lung cancers, and leukemia; and research that improves the quality of life for cancer patients and their caregivers. For more information about the Foundation or to donate, visit the *Support Research* page on the Alliance website at www.AllianceforClinicalTrialsinOncology.org.



ALLIANCE AWARDS

The Alliance for Clinical Trials in Oncology Foundation supports Alliance researchers and their work through two annual awards: Richard L. Schilsky CALGB Achievement Award, which identifies and honors “unsung heroes” of the Alliance, and the Alliance Scholar Award, which supports oncology junior faculty working at Alliance institutions. The Moertel Lecture Endowment Fund also supports Alliance researchers and their work through the annual Charles G. Moertel Lecturer award, which honors an investigator whose work impacts community cancer practices. The Alliance NCORP Research Base, which is supported by the NCI Division of Cancer Prevention (DCP), supports Alliance researchers and junior investigators and their work through two annual awards: Alliance Cancer Control Program Pilot Project Award, which supports pilot projects in the Alliance Cancer Control Program, and the Alliance Cancer Control Program Junior Faculty Award, which supports training and research initiatives for junior faculty and post-doctoral fellows in the Alliance. Visit the *Support Research* page on the Alliance website at www.AllianceforClinicalTrialsinOncology.org to learn more about these awards.

About | Alliance Foundation Trials

**ALLIANCE
FOUNDATION TRIALS, LLC**

Alliance Foundation Trials, LLC (AFT) is a research organization that develops and conducts cancer clinical trials, working closely with the Alliance for Clinical Trials in Oncology scientific investigators and institutional member network, research collaborators, and non-NCI funding sources. AFT seeks to fulfill the vision of the Alliance for Clinical Trials in Oncology to reduce the impact of cancer on people by uniting a broad community of scientists and clinicians from many disciplines committed to discovering, validating and disseminating effective strategies for the prevention and treatment of cancer. Established in 2014 as a limited liability corporation, AFT is managed by the Alliance for Clinical Trials in Oncology Foundation, which is its sole member. For more information about developing an AFT study, contact the AFT Project Manager at Info@AllianceFoundationTrials.org.

Group Meeting | Highlights

PLENARY SESSION

Friday, May 13 | 11 am-1 pm

Introduction – Monica M. Bertagnolli, MD

The Alliance Breast Committee: Where Do We Come From? Who Are We? Where Are We Going? – Clifford A. Hudis, MD and Eric P. Winer, MD

Co-Chairs Clifford A. Hudis, MD, and Eric P. Winer, MD, will present a thorough history of the Alliance Breast Committee, including the committee's evolution over the years, its current portfolio and plans for the future. Dr. Hudis is Chief of the Breast Cancer Medicine Service, Vice President for Government Relations and Chief Advocacy Officer at Memorial Sloan-Kettering Cancer Center and Professor of Medicine at the Weill Medical College of Cornell University. Dr. Winer is Chief of the Division of Women's Cancers, the Thompson Senior Investigator in Breast Cancer Research and Director of the Breast Oncology Center at the Dana-Farber Cancer Institute, and Professor of Medicine at Harvard Medical School. Both have served as co-chairs since 2003.

Annual Charles G. Moertel Lecture – Jan C. Buckner, MD

The recipient of this year's lectureship is Jan C. Buckner, MD. Dr. Buckner is Chair of Mayo Clinic's Department of Oncology in Rochester, MN; Chair for the Enterprise Mayo Clinic Cancer Center; and Betty J. Foust, MD, and Parents' Professor in Oncology at the Mayo Clinic College of Medicine. He is also Program Director of the Alliance Cancer Control Program and Contact Principal Investigator for the Alliance NCI Community Oncology Research Program (NCORP) Research Base. Dr. Buckner specializes in the research and treatment of cancers affecting the brain and nervous system. He has authored and co-authored more than 500 articles and abstracts. The Moertel Lecturer is an investigator whose research within the NCI National Clinical Trials Network (NCTN) results in a major impact on community cancer practice. Dr. Buckner's lecture is entitled "Diagnosing and Treating Lower-Grade Glioma Patients: A Journey in Team Science."



Mastering Breast Cancer Initiative: Opportunities for Collaboration between NCTN and AFT – Monica M. Bertagnolli, MD

Women with metastatic breast cancer are living longer due to better therapy, and researchers are learning a great deal about the disease, especially how tumors evolve in response to different treatments. A number of factors demonstrate an urgent need to adopt a coordinated approach to drug development for metastatic breast cancer. In the clinical setting, researchers now can identify numerous metastatic breast cancer genomic categories, and many promising therapeutics are emerging that may effectively target different disease subtypes. The genomic profile of metastatic breast cancer changes throughout lines of therapy, indicating the need to understand how to best sequence or combine different therapeutics. Given the diversity of disease and multiplicity of therapeutic possibilities, it is clear that large, centrally coordinated clinical trials are required to achieve the goal of improving treatment for women with metastatic breast cancer. Dr. Bertagnolli will discuss a new metastatic breast cancer collaborative initiative between clinical trial groups in the U.S., Canada and Europe to achieve this aim.



A SPECIAL THANK YOU!

Thirteen Years of Service as Co-Chairs of the Alliance Breast Committee

The **Board of Directors of the Alliance for Clinical Trials in Oncology** proudly acknowledge **Clifford A. Hudis, MD**, and **Eric P. Winer, MD**, for more than a decade of dedicated service to the Alliance Breast Committee. Dr. Hudis is one of the nation's leading specialists in breast cancer treatment and a recognized expert in studies of cancer prevention. Dr. Winer has devoted his professional career to the treatment of individuals with breast cancer and breast cancer research. Through the Alliance and the Alliance Breast Committee, both have led, mentored and collaborated with teams of talented researchers to improve care and the quality of life for patients with breast cancer through new drug treatments developed in numerous clinical trials. Their leadership efforts will leave an indelible impression on the Alliance and all other researchers who pick up the mantle and follow in their path.

CLINICAL RESEARCH PROFESSIONAL LEARNING OPPORTUNITIES

The **Clinical Research Professionals (CRP) Committee** will provide 11 learning sessions for CRPs and other research professionals at this meeting. The sessions will include information and education sessions, along with special CRP study coordinator training sessions for specific Alliance trials, CRP administrator sessions for regulatory topics, and CRP data manager sessions to engage with colleagues assigned to Alliance trials. Several sessions will be repeated at least once to allow all interested meeting attendees to participate.

The **CRP Information Session** (Thursday, May 12 | 3 pm–5 pm) will provide information to CRPs, including data managers and nurses, regarding Alliance updates and resources. Presentations will include Alliance administrative, protocol, data and statistical center updates. **Alicia Quirke**, Site Manager for Alliance Foundation Trials, LLC (AFT), will present *AFT Study Start up*; **Kathi Celii**, Cancer Trials Support Unit (CTSU) Westat, will discuss CTSU updates; and **Michael Kelly, MA**, Alliance Director of Protocol Operations, will present *Where To Find It? Alliance Protocol Template Review*.

The **CRP Education Session** (Friday, May 13 | 3:30 pm–5:30 pm) will offer presentations on *Pharmacy and Oral Pill Compliance*, *AFT vs NCTN Trials* and *A151216/ALCHEMIST Consent Process*. Presenters will include **Barbara K. Barrett, MS, CCRP**, Alliance Audit Program Director; **Brenda Gebhart, RPh**, Pharmacist, Missouri Baptist Medical Center; **Trini Ajazi, MM**, Alliance Chief Administrative Officer; and **Peg Reamer, RN**, University of Pittsburgh Cancer Center.

CRP Learning Sessions

Thursday, May 12

5 pm–6 pm & 6 pm–7 pm
5 pm–6 pm & 6 pm–7 pm
5 pm–6 pm
5 pm–7 pm
6 pm–7 pm

CRP Data Manager: Meet Your Data Manager
CRP Specimen Submission: BioMS Training and Update 2.0
CRP Study Coordinator: A221405 (Breast) Study Training
CRP Study Coordinator: A031102 (GU) Study Training
CRP Study Coordinator: A021302 (GI) Study Training

Friday, May 13

8 am–9:30 am
9 am–10 am & 10 am–11 am
9 am–10 am & 10 am–11 am
9 am–10 am & 10 am–11 am

CRP Study Coordinator: A011203 (Breast) Study Training
CRP Administrator: IPEC Reports
CRP Administrator/Study Coordinator: Prepping Pharmacy for Audit
CRP Administrator/Regulatory: NCI Site Codes

OTHER EDUCATIONAL SESSIONS

Oncology Nursing Education Session – Friday, May 13 | 1 pm–3 pm

The A-ONC Education Session will focus on various aspects of CAR-T cell therapy. Presenters will include **Yi Lin, MD, PhD**, Consultant, Department of Hematology at Mayo Clinic (*CART Cell Therapy Overview*); **Sarah Nikiforow, MD, PhD**, Instructor in Medicine at Dana-Farber Cancer Institute (*ASH Update on CAR-T Cell Therapy and Medical Management of Patients on CAR-T Cell Therapy*); and **Ilene Galinsky, MSN, ANP-C**, Senior Leukemia Research Program Nurse Practitioner at Dana-Farber Cancer Institute (*Clinical Nursing Assessment and Interventions to Monitor and Manage Patients on CAR-T Cell Therapy*).

Oncology Nursing Open Forum – Friday, May 13 | 3 pm–3:30 pm

The A-OCN Open Forum is a session that will encourage open dialogue between Alliance oncology nurses. The session is designed as an opportunity for Alliance nurses to network with other Alliance nurses; to ask questions of A-OCN chairs and disease-specific committee nursing liaisons; and to openly discuss and seek advice on various issues regarding Alliance protocols.

Alliance Foundation Trials Information Session – Friday, May 13 | 5:30 pm–6:30 pm

Alliance Foundation Trials, LLC (AFT) is a limited liability corporation managed by the Alliance for Clinical Trials in Oncology Foundation. AFT develops and conducts cancer clinical trials, working closely with the Alliance for Clinical Trials in Oncology scientific investigators and institutional member network, research collaborators, and non-NCI funding sources. This session will provide an opportunity to ask questions and learn more about participating in AFT studies.

Alliance Main Member Institutions

Allan Blair Cancer Centre
Altru Cancer Center
Aurora NCI Community Oncology Research Program
Baptist Health Cancer Research Network
Bay Area Tumor Institute NCORP
Baylor University Medical Center
Beaumont NCI Community Oncology Research Program
Cancer Research Consortium of West Michigan NCORP
Cancer Research for the Ozarks NCORP
Carle Cancer Center NCI Community Oncology Research Program
Carolinas Medical Center/Levine Cancer Institute
Cedars-Sinai Medical Center
Coborn Cancer Center at Saint Cloud Hospital
Colorado Cancer Research Program NCORP
Columbia University Minority Underserved NCORP
Columbus NCI Community Oncology Research Program
Dana-Farber/Partners CancerCare LAPS
Dartmouth College-Norris Cotton Cancer Center LAPS
Dayton NCI Community Oncology Research Program
Delaware/Christiana Care NCI Community Oncology Research Program
Doctor's Hospital of Laredo
Duke University-Duke Cancer Institute LAPS
Eastern Maine Medical Center Cancer Care
Edwards Comprehensive Cancer Center
Essentia Health NCI Community Oncology Research Program
Florida Hospital Orlando
Fox Valley Surgical Associates Limited
Franciscan Saint Francis Health-Indianapolis
Froedtert and the Medical College of Wisconsin
Fundacion De Investigacion de Diego
Geisinger Cancer Institute NCI Community Oncology Research Program
Georgia Regents University Minority Underserved NCORP
Hackensack University Medical Center
Hawaii Minority Underserved NCORP
Heartland Cancer Research NCORP
Hematology Oncology Associates of Central New York-East Syracuse
Henry Ford Hospital
Indiana University-Melvin and Bren Simon Cancer Center LAPS
Inova Fairfax Hospital
Iowa-Wide Oncology Research Coalition NCORP
JHU Sidney Kimmel Comprehensive Cancer Center LAPS
Kansas City NCI Community Oncology Research Program
Lakeland Regional Cancer Center

Legacy Good Samaritan Hospital and Medical Center
Lehigh Valley Hospital-Cedar Crest
London Regional Cancer Program
Loyola University Medical Center
Main Line Health NCORP
Mayo Clinic LAPS
Medical University of South Carolina Minority Underserved NCORP
MedStar Georgetown University Hospital
Memorial Regional Hospital/Joe DiMaggio Children's Hospital
Memorial Sloan-Kettering Cancer Center LAPS
Metro-Minnesota NCI Community Oncology Research Program
Michigan Cancer Research Consortium NCORP
Missouri Valley Cancer Consortium
Montana Cancer Consortium NCORP
Montefiore Minority Underserved NCORP
Morton Plant Hospital
Mount Sinai Medical Center (Florida)
Mount Sinai Medical Center (New York)
NCORP of the Carolinas (Greenville Health System NCORP)
Nevada Cancer Research Foundation NCORP
New Hampshire Oncology Hematology PA-Hooksett
New Mexico Minority Underserved NCORP
North Shore-LIJ Health System NCORP
NorthShore University HealthSystem-Evanston Hospital
Northwest NCI Community Oncology Research Program
Northwestern University
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Ohio State University Comprehensive Cancer Center LAPS
Oregon Health and Science University
Pacific Cancer Research Consortium NCORP
Phoebe Putney Memorial Hospital
Princeton Community Hospital
Queens Hospital Center
Rapid City Regional Hospital
Rhode Island Hospital
Roswell Park Cancer Institute LAPS
Rush University Medical Center
Rutgers New Jersey Medical School
Saint Elizabeth Medical Center South
Saint Joseph Hospital - Orange
Sanford NCI Community Oncology Research Program of the North Central Plains
Sentara Hospitals

Sharp Memorial Hospital
Sinai Hospital of Baltimore
Southeast Clinical Oncology Research Consortium NCORP
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Stony Brook University Medical Center
Swiss Group for Clinical Cancer Research
The James Graham Brown Cancer Center at University of Louisville
Toledo Clinic Cancer Centers-Toledo
UC San Diego Moores Cancer Center
UCLA/Jonsson Comprehensive Cancer Center
UCSF Medical Center-Mount Zion
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University of Arkansas for Medical Sciences
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University of Maryland/Greenebaum Cancer Center
University of Miami Miller School of Medicine-Sylvester Cancer Center
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Accrual Data | Protocol Listings

Accrual by Institution/Network and Committee

Accrual reporting from March 1, 2015 to February 28, 2016

Alliance Member Networks	Total	Breast	GI	GU	Leukemia	Lymphoma	Myeloma	Neuro-Oncology	Respiratory	Experimental Therapeutics	Cancer Control	CTSU*
Altru Cancer Center	11	-	-	-	-	-	-	1	1	-	6	3
Aurora NCI Community Oncology Research Program	17	5	-	4	-	-	-	2	-	-	6	-
Baptist Health Cancer Research Network	9	-	-	-	-	-	-	-	-	-	4	5
Bay Area Tumor Institute NCORP	8	3	1	-	-	-	-	-	-	-	4	-
Beaumont NCI Community Oncology Research Program	9	9	-	-	-	-	-	-	-	-	-	-
Cancer Research Consortium of West Michigan NCORP	16	-	4	5	1	-	-	2	-	-	4	-
Cancer Research for the Ozarks NCORP	16	1	1	2	2	2	-	-	-	-	8	-
Carle Cancer Center NCI Community Oncology Research Program	6	1	1	-	-	-	-	-	-	-	-	4
Carolinas Medical Center/Levine Cancer Institute	20	14	6	-	-	-	-	-	-	-	-	-
Cedars-Sinai Medical Center	26	23	-	-	-	-	-	-	-	-	3	-
Coborn Cancer Center at Saint Cloud Hospital	9	-	3	1	1	-	-	-	-	-	1	3
Colorado Cancer Research Program NCORP	26	2	5	-	2	-	-	1	1	1	4	10
Columbia University Minority Underserved NCORP	34	2	-	2	2	-	-	1	-	7	17	3
Columbus NCI Community Oncology Research Program	6	1	1	1	1	-	-	1	-	-	1	-
Dana-Farber / Partners CancerCare LAPS	102	14	14	4	7	5	6	1	1	-	15	35
Dartmouth College - Norris Cotton Cancer Center LAPS	34	4	5	5	2	-	-	3	1	-	4	10
Dayton NCI Community Oncology Research Program	35	1	5	3	4	-	-	1	-	-	2	19
Delaware/Christiana Care NCI Community Oncology Research Program	42	8	4	-	2	-	-	2	-	1	8	17
Doctor's Hospital of Laredo	25	18	-	-	-	-	-	-	-	-	-	7
Duke University - Duke Cancer Institute LAPS	66	6	2	14	11	-	-	-	-	4	8	21
Eastern Maine Medical Center Cancer Care	26	1	1	3	1	-	-	-	1	-	-	19
Edwards Comprehensive Cancer Center	5	-	-	-	-	-	-	-	-	1	1	3
Essentia Health NCI Community Oncology Research Program	11	1	1	2	-	-	-	2	-	-	1	4
Florida Hospital Orlando	7	-	4	1	-	-	-	-	-	-	-	2
Fox Valley Surgical Associates Limited	4	1	-	-	-	-	-	-	-	-	-	3
Franciscan Saint Francis Health-Indianapolis	8	-	3	-	-	-	-	-	-	-	-	5
Froedtert and the Medical College of Wisconsin	23	6	4	4	-	-	-	2	-	1	2	4

Source: Alliance Statistics and Data Center.

* Alliance institution accrual to CTSU studies

	Total	Breast	GI	GU	Leukemia	Lymphoma	Myeloma	Neuro-Oncology	Respiratory	Experimental Therapeutics	Cancer Control	CTSU*
Geisinger Cancer Institute NCI Community Oncology Research Program	10	-	1	1	1	-	-	-	1	-	5	1
Georgia Regents University Minority Underserved NCORP	5	2	2	-	-	-	-	-	-	-	-	1
Hackensack University Medical Center	13	-	-	7	-	-	-	3	-	3	-	-
Hawaii Minority Underserved NCORP	28	-	2	5	-	-	-	-	-	-	5	16
Heartland Cancer Research NCORP	76	3	9	18	1	2	-	4	1	2	21	15
Hematology Oncology Associates of Central New York-East Syracuse	8	-	3	-	-	-	-	-	-	-	-	5
Indiana University - Melvin and Bren Simon Cancer Center LAPS	7	7	-	-	-	-	-	-	-	-	-	-
Inova Fairfax Hospital	18	6	1	-	-	-	-	2	-	-	-	9
Iowa-Wide Oncology Research Coalition NCORP	48	2	9	6	2	1	-	-	-	-	5	23
JHU Sidney Kimmel Comprehensive Cancer Center LAPS	16	1	-	10	-	-	-	-	1	-	-	4
Kansas City NCI Community Oncology Research Program	16	1	5	4	2	-	-	2	1	-	-	1
Lakeland Regional Cancer Center	8	1	-	6	-	-	-	-	-	-	1	-
Legacy Good Samaritan Hospital and Medical Center	9	6	1	2	-	-	-	-	-	-	-	-
Lehigh Valley Hospital-Cedar Crest	11	-	3	1	-	-	-	2	-	-	-	5
Loyola University Medical Center	3	-	-	1	1	-	-	-	-	1	-	-
Main Line Health NCORP	11	-	4	-	1	-	-	-	5	-	-	1
Mayo Clinic LAPS	108	26	6	12	2	1	-	6	12	13	15	15
Medical University of South Carolina Minority Underserved NCORP	14	5	-	-	-	-	-	1	1	-	4	3
MedStar Georgetown University Hospital	39	5	3	1	-	-	-	-	-	2	2	26
Memorial Regional Hospital/Joe DiMaggio Children's Hospital	13	-	1	-	-	-	-	2	-	-	7	3
Memorial Sloan-Kettering Cancer Center LAPS	90	19	7	23	-	-	3	-	9	24	3	2
Metro Minnesota Community Oncology Research Consortium	110	6	16	20	6	6	-	8	4	-	21	23
Michigan Cancer Research Consortium NCORP	57	12	14	7	2	1	-	4	-	-	11	6
Missouri Valley Cancer Consortium	15	-	5	6	-	-	-	1	1	-	-	2
Montana Cancer Consortium NCORP	18	1	5	5	2	3	-	-	-	-	1	1
Montefiore Minority Underserved NCORP	7	1	1	3	-	-	-	-	-	-	-	2
Morton Plant Hospital	19	13	-	-	-	-	-	-	-	-	4	2
Mount Sinai Medical Center (Florida)	20	1	2	3	2	-	-	-	-	-	1	11
Mount Sinai Medical Center (New York)	60	9	5	4	1	-	-	6	3	-	-	32
NCORP of the Carolinas (Greenville Health System NCORP)	33	3	9	6	4	-	-	1	-	2	7	1
Nevada Cancer Research Foundation NCORP	7	-	4	-	-	-	-	-	-	1	2	-
New Hampshire Oncology Hematology PA-Hooksett	19	-	-	9	2	-	-	2	-	-	-	6
New Mexico Minority Underserved NCORP	25	12	4	5	3	-	-	-	-	1	-	-
North Shore-LIJ Health System NCORP	20	1	-	2	2	-	-	-	-	-	3	12
NorthShore University HealthSystem-Evanston Hospital	29	4	1	3	6	-	-	1	-	1	10	3

	Total	Breast	GI	GU	Leukemia	Lymphoma	Myeloma	Neuro-Oncology	Respiratory	Experimental Therapeutics	Cancer Control	CTSU*
Northwest NCI Community Oncology Research Program	8	2	2	-	-	-	-	2	-	-	2	-
Northwestern University	13	-	-	-	-	-	-	12	-	1	-	-
Ochsner NCI Community Oncology Research Program	16	1	9	4	-	-	-	-	1	-	-	1
Ohio State University Comprehensive Cancer Center LAPS	91	10	7	12	3	3	2	-	-	3	2	49
Oregon Health and Science University	1	1	-	-	-	-	-	-	-	-	-	-
Pacific Cancer Research Consortium NCORP	26	1	5	6	3	-	-	-	2	-	2	7
Phoebe Putney Memorial Hospital	3	-	-	-	-	-	-	-	-	-	-	3
Princeton Community Hospital	1	-	1	-	-	-	-	-	-	-	-	-
Queens Hospital Center	2	-	-	-	-	-	-	-	-	-	-	2
Rapid City Regional Hospital	4	-	-	-	1	-	-	-	-	-	1	2
Rhode Island Hospital	21	3	2	-	2	-	-	1	2	-	-	11
Roswell Park Cancer Institute LAPS	101	7	7	10	1	-	-	-	6	-	26	44
Rush University Medical Center	1	-	-	-	-	-	-	-	-	-	-	1
Saint Elizabeth Medical Center South	24	20	-	-	-	-	-	-	-	-	-	4
Saint Joseph Hospital - Orange	6	-	4	-	-	-	-	1	-	-	-	1
Sanford NCI Community Oncology Research Program of the North Central Plains	32	1	1	1	-	-	-	2	-	-	16	11
Sentara Hospitals	18	9	-	-	-	-	-	-	-	-	-	9
Sharp Memorial Hospital	4	1	-	2	-	-	-	-	-	-	-	1
Sinai Hospital of Baltimore	12	4	1	2	1	1	-	-	1	-	-	2
Southeast Clinical Oncology Research (SCOR) Consortium NCORP	141	5	13	25	9	4	-	2	2	5	35	41
Southern Cancer Center PC-Providence	6	-	5	-	-	-	-	-	-	-	-	1
State University of New York Upstate Medical University	15	-	2	1	1	1	-	2	2	-	1	5
Stony Brook University Medical Center	4	1	-	-	3	-	-	-	-	-	-	-
Swiss Group for Clinical Cancer Research	7	-	7	-	-	-	-	-	-	-	-	-
The James Graham Brown Cancer Center at University of Louisville	2	2	-	-	-	-	-	-	-	-	-	-
Toledo Clinic Cancer Centers-Toledo	19	-	1	1	-	3	-	1	-	-	1	12
UC San Diego Moores Cancer Center	35	3	-	4	-	2	-	-	1	-	20	5
UCSF Medical Center-Mount Zion	53	4	10	6	1	2	-	12	1	-	-	17
UNC Lineberger Comprehensive Cancer Center LAPS	37	1	6	1	3	1	-	1	-	-	3	21
University of Arkansas for Medical Sciences	23	13	-	4	2	-	-	3	-	1	-	-
University of Chicago Comprehensive Cancer Center LAPS	63	1	5	13	1	1	-	-	1	8	3	30
University of Illinois	11	-	2	2	1	-	-	-	-	-	-	6
University of Iowa/Holden Comprehensive Cancer Center	46	1	-	7	-	-	-	2	-	8	10	18
University of Kentucky/Markey Cancer Center	14	-	-	-	-	-	-	4	1	-	7	2

* Alliance institution accrual to CTSU studies

	Total	Breast	GI	GU	Leukemia	Lymphoma	Myeloma	Neuro-Oncology	Respiratory	Experimental Therapeutics	Cancer Control	CTSU*
University of Maryland/Greenebaum Cancer Center	21	-	-	1	-	-	-	-	2	-	-	18
University of Miami Miller School of Medicine-Sylvester Cancer Center	13	1	4	-	2	-	-	3	-	-	3	-
University of Minnesota/Masonic Cancer Center	15	-	2	7	3	-	-	-	-	-	-	3
University of Missouri - Ellis Fischel	3	1	-	-	-	2	-	-	-	-	-	-
University of Nebraska Medical Center	18	1	-	-	-	4	-	4	-	2	-	7
University of Oklahoma Health Sciences Center LAPS	37	3	5	5	-	3	-	5	1	-	11	4
University of Pittsburgh Cancer Institute LAPS	33	5	3	7	4	1	-	2	3	-	-	8
University of Rochester	4	3	-	1	-	-	-	-	-	-	-	-
University of Texas MD Anderson Cancer Center LAPS	64	42	4	-	-	-	-	-	1	8	-	9
University of Texas Southwestern Medical Center LAPS	46	33	-	5	-	-	-	4	2	-	-	2
University of Utah - Huntsman Cancer Institute LAPS	17	4	2	-	-	3	-	4	-	1	-	3
University of Vermont College of Medicine	15	-	5	2	-	1	-	-	1	-	-	6
University of Virginia Cancer Center	19	1	-	3	1	-	-	10	3	-	-	1
University of Wisconsin Carbone Cancer Center LAPS	18	3	3	-	-	-	-	1	-	-	1	10
VCU Massey Cancer Center Minority Underserved NCORP	47	2	3	10	5	-	-	-	1	-	6	20
Wake Forest University Health Sciences	58	6	2	12	1	-	-	3	2	-	-	32
Walter Reed National Military Medical Center	8	-	-	-	-	-	-	-	-	-	1	7
Washington University - Siteman Cancer Center LAPS	207	11	12	15	8	10	-	11	1	42	19	78
Weill Medical College of Cornell University	28	-	3	3	-	1	-	-	-	-	-	21
WellSpan Health-York Cancer Center	15	-	-	1	1	-	-	-	-	-	1	12
West Penn Hospital	17	-	7	-	-	-	-	-	10	-	-	-
Wichita NCI Community Oncology Research Program	62	4	5	2	4	-	-	9	2	-	36	-
Wisconsin NCI Community Oncology Research Program	36	3	5	6	2	1	-	2	2	-	15	-
Other - Inactive Networks	20	1	2	-	3	-	-	3	-	-	5	6
ALLIANCE MEMBER NETWORK TOTALS	3,274	485	345	402	142	65	11	170	95	144	454	961
Non-Alliance Groups												
ECOG-ACRIN	304	48	107	44	34	3	-	14	21	11	22	-
NRG	348	78	111	41	16	1	-	38	42	3	18	-
SWOG	433	35	131	147	55	2	-	16	12	9	26	-
NCIC-CTG	283	-	82	50	56	-	-	7	25	14	49	-
NON-ALLIANCE GROUP TOTALS	1,368	161	431	282	161	6	0	75	100	37	115	-
GRAND TOTALS	4,642	646	776	684	303	71	11	245	195	181	569	961

* Alliance institution accrual to CTSU studies

Protocol Status by Program, Committee and Study

Program: Office of the Group Chair

Reporting period for all studies through February 28, 2016

Breast Committee

Co-Chairs: Clifford A. Hudis, MD, Memorial Sloan Kettering Cancer Center and Eric P. Winer, MD, Dana-Farber Cancer Institute

PENDING		Phase	Chair	Status
A011401	Randomized phase III trial evaluating the role of weight loss in adjuvant treatment of overweight and obese women with early breast cancer	Phase III	J. Ligibel	In Development
A011502	A randomized phase III double blinded placebo controlled trial of aspirin as adjuvant therapy of node positive HER2 negative breast cancer: The ABC trial	Phase III	W. Chen	In Development

ACTIVE		Phase	Chair	Date Open	Target Accrual	Current Accrual
A011104	Effect of preoperative breast MRI on surgical outcomes, costs and quality of life of women with breast cancer	Phase III	I. Bedrosian	02/21/14	536	91
A011104	Prospective assessment of clinical-pathologic and molecular predictors of ipsilateral breast cancer recurrence-free survival, recurrence-free survival and distant recurrence free survival	Ancillary	I. Bedrosian	02/21/14	488	27
A011106	Alternate approaches for clinical stage II or III estrogen receptor, positive breast cancer neoadjuvant treatment (ALTERNATE) in postmenopausal women: A phase III study	Phase III	C. Ma	12/13/13	2,820	360
A011106-ST1	Alternate approaches for clinical stage II or III estrogen receptor, positive breast cancer neoadjuvant treatment (ALTERNATE) in postmenopausal women: A phase III study - Translational component	Ancillary	M. Ellis	12/13/13	2,820	318
A011202	A randomized phase III trial evaluating the role of axillary lymph node dissection in breast cancer patients (cT1-3 N1) who have positive sentinel lymph node disease after neoadjuvant chemotherapy	Phase III	J. Boughey	02/07/14	1,576	314
A011202-S1	Optional assessments to determine the incidence of arm and breast lymphedema	Ancillary	J. Armer	02/07/14	900	461
A011203	A randomized phase II trial of tamoxifen versus Z-endoxifen in postmenopausal women with metastatic estrogen receptor positive, HER2 negative breast cancer	Phase II	M. Goetz	03/06/15	94	22
A011203-PP1	Z-endoxifen and tamoxifen pharmacokinetics and pharmacogenetics (Alliance A011203-PP1)	Ancillary	J. Reid	03/06/15	-	28
A011203-ST1	Evaluation of ESR1 alterations and marker of endocrine resistance in patients treated with either tamoxifen or endoxifen (Alliance A011203-ST1)	Ancillary	J. Hawse	03/06/15	38	30
A011203-ST2	DNA alterations in patients treated with either tamoxifen or Z-endoxifen: Circulating tumor cells and circulating cell free DNA (Alliance A011203-ST2)	Ancillary	M. Liu	03/06/15	-	28
A011203-ST3	Biochemical markers of bone turnover (Alliance A011203-ST3)	Ancillary	M. Goetz	03/06/15	-	28
C151008	Correlative science for 40903	Ancillary	F. Waldman	02/15/12	106	101
N9831C-ICSC	Round-robin clinico-pathological review of HER2 testing in the context of adjuvant therapy for breast cancer (N9831, BCIRG 006, and BCIRG 005)	Ancillary	E. Perez	09/01/09	135	263
N9831D-ICSC	Adjuvant chemotherapy combined with trastuzumab in the randomized phase III trial N9831 actively immunizes patients against tumor antigens	Ancillary	K. Knutson	02/28/12	1,390	-
Z11102	Impact of breast conservation surgery on surgical outcomes and cosmesis in patients with multiple ipsilateral breast cancers (MIBC)	Phase II	J. Boughey	07/23/12	230	206
Z11102	Protein and gene expression and concordance between the two in breast tumor tissue	Ancillary	J. Filho	07/23/12	230	206

Source: Alliance Statistics and Data Center.

NCTN						
9876	Phase Ib study of HSP90 inhibitor, AT13387 in combination with paclitaxel in patients with advanced, triple negative breast cancer	Phase I	R. Wesolowski	01/15/16	24	0
E1211	A cohort study to evaluate genetic predictors of aromatase inhibitor musculoskeletal symptoms (AIMSS)	Other	V. Stearns	05/21/13	1,000	934
E2112	A randomized phase III trial of endocrine therapy plus entinostat/placebo in postmenopausal patients with hormone receptor-positive advanced breast cancer	Phase III	R. Connolly	03/29/14	600	203
E4112	Prospective study of magnetic resonance imaging (MRI) and multiparameter gene expression assay in ductal carcinoma in situ (DCIS)	Other	C. Lehman	02/17/15	350	300
EA1131	A randomized phase III post-operative trial of platinum based chemotherapy vs. observation in patients with residual triple-negative basal-like breast cancer following neoadjuvant chemotherapy	Phase III	I. Mayer	04/29/15	558	5
EAI142	[18F] fluoroestradiol (FES) PET as a predictive measure for endocrine therapy in patients with newly diagnosed metastatic breast cancer	Phase II	F. Dehdashti	02/02/16	99	0
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	Phase II-III	S. Chmura	12/24/14	402	7
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	Phase III	V. Valero	06/26/15	990	89
NSABP-B-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	Phase III	E. Mamounas	08/22/13	1,636	288
NSABP-B-55	A randomised, double-blind, parallel group, placebo-controlled multi-centre phase III study to assess the efficacy and safety of olaparib versus placebo as adjuvant treatment in patients with germline BRCA1/2 mutations and high risk HER2 negative primary breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy	Phase III	C. Geyer	07/03/14	1,500	50
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.	Phase III	K. Kalinsky	01/15/11	4,000	4,246
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	Phase III	M. Chavez Mac Gregor	09/04/13	1,900	672
SCUSF-1102	A cluster randomized controlled trial comparing interventions to enhance utilization of genetics services among breast cancer patients	Other	R. Sutphen		3,780	0

CLOSED		Phase	Chair	Date Open	Date Closed
C40903	Phase II study of neoadjuvant letrozole for postmenopausal women with estrogen receptor positive ductal carcinoma in situ (DCIS)	Phase II	E. Hwang	02/15/12	01/25/16

Experimental Therapeutics Committee

Co-Chairs: Charles Erlichman, MD, Mayo Clinic and Gary K. Schwartz, MD, Columbia University Medical Center

Reporting period for all studies through February 28, 2016

PENDING		Phase	Chair	Status
A091404	A phase II study of enzalutamide (NSC #766085) for patients with androgen receptor positive salivary cancers	Phase II	A. Ho	In Development
A091404-ST1	DNA and RNA analysis of archival and flash frozen tissue from androgen receptor-positive salivary gland cancers	Ancillary	T. Chan	In Development
A091502	Reversing resistance to pazopanib with histone deacetylase inhibition: A randomized phase II study	Phase II	P. Munster	SCRC
A091602	Randomized phase III clinical trial of adjuvant anti-PD-1 therapy in patients with high risk stage IB-IIIC melanoma	Phase III	L. Geskin	NCI Concept Submitted

ACTIVE		Phase	Chair	Date Open	Target Accrual	Current Accrual
A091101	Carboplatin-paclitaxel induction chemotherapy and ABT-888 (Velaparib) - A phase I/randomized phase 2 study in patients with locoregionally advanced squamous cell carcinoma of the head and neck	Phase I-II	J. de Souza	10/22/12	110	11
A091105	A phase III, double blind, randomized, placebo-controlled trial of sorafenib in desmoid tumors or aggressive fibromatosis (DT/DF)	Phase III	M. Gounder	03/21/14	83	87
A091105-HO1	Quality of life study	Ancillary	M. Gounder	03/21/14	83	65
A091105-ST1	Analysis of archival tissue and pre-treatment and 8 day tumor biopsy and blood samples	Ancillary	M. Gounder	03/21/14	50	49
A091201	Randomized phase II study comparing the MET inhibitor cabozantinib to temozolomide/dacarbazine in ocular melanoma	Phase II	J. Luke	07/31/13	69	40
A091201-ST1	Solid tumor correlative studies in Alliance A091201	Ancillary	J. Luke	07/31/13	69	31
A091202	A phase II randomized double blinded study of the peroxisome proliferator-activated receptor gamma agonist, efatutazone versus placebo in patients with previously treated, unresectable myxoid liposarcoma	Phase II	M. Pishvaian	01/15/15	36	4
A091202-ST1	Analysis of cell cycle regulated proteins and markers of differentiation	Ancillary	P. Furth	01/15/15	36	3
A091302	Randomized phase II study of sorafenib with or without everolimus in patients with radioactive iodine refractory Hurthle cell thyroid cancer	Phase II	E. Sherman	10/01/14	56	8
A091304	A phase I/randomized phase II study of MLN0128 vs pazopanib in patients with locally advanced/unresectable and/or metastatic sarcoma	Phase I-II	W. Tap	11/30/15	134	2
A091305	A phase 2 randomized study of efatutazone, an oral PPAR agonist in combination with paclitaxel versus paclitaxel alone in patients with advanced anaplastic thyroid cancer	Phase II	R. Smallridge	09/01/14	50	3
A091305-ST1	Tissue biomarkers as predictors of response in paclitaxel +/- efatutazone anaplastic thyroid carcinoma protocol	Ancillary	J. Copland	09/01/14	50	3
A091401	Randomized phase II study of nivolumab with or without ipilimumab in patients with metastatic or unresectable sarcoma	Phase II	S. D'Angelo	07/30/15	84	71
A091401-ST1	Correlative science in A091401	Ancillary	S. D'Angelo	07/30/15	84	21
N1153	Study of sorafenib + TH-302: Phase I in advanced renal cell carcinoma (RCC) and advanced hepatocellular carcinoma (HCC) and phase II in 1st line advanced HCC	Phase I-II	M. Borad	05/11/12	48	24

Gastrointestinal Committee

Reporting period for all studies through February 28, 2016

Co-Chairs: Jeffrey A. Meyerhardt, MD, MPH, Dana-Farber Cancer Institute and Eileen M. O'Reilly, MD, Memorial Sloan Kettering Cancer Center

PENDING		Phase	Chair	Status		
A021501	Preoperative extended chemotherapy vs chemotherapy plus hypofractionated radiation therapy for borderline resectable adenocarcinoma of the head of the pancreas	Phase II	M. Katz	In Development		
A021502	Randomized trial of FOLFOX alone or combined with a PD-L1 inhibitor as adjuvant therapy of patients with stage III deficient mismatch repair colon cancer	Phase III	F. Sinicrope	NCI Concept Submitted		

ACTIVE		Phase	Chair	Date Open	Target Accrual	Current Accrual
A021202	Prospective randomized phase II trial of pazopanib (NSC #737754, IND 75648) versus placebo in patients with progressive carcinoid tumors	Phase II	E. Bergsland	06/21/13	165	171
A021202-HO1	Quality of life studies in A021202	Ancillary	J. Sloan	06/21/13	165	145
A021302	Impact of early FDG-PET directed intervention on preoperative therapy for locally advanced gastric cancer: A random assignment phase II study	Phase II	M. Shah	08/01/15	162	2
C150705	Correlative science studies in colon cancer: a companion study to 9581 and 89803	Ancillary	M. Bertagnolli	07/15/07	1,260	-
C150806	Correlative science studies in untreated metastatic adenocarcinoma of the colon or rectum	Ancillary	M. Bertagnolli	09/15/09	238	-
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	Phase II-III	D. Schrag	01/13/12	1,060	510
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 - Translational component	Phase II-III	D. Schrag	01/13/12	1,060	509

NCTN		Phase	Chair	Date Open	Target Accrual	Current Accrual
9742	Multicenter phase II study of nivolumab in previously treated patients with recurrent and metastatic nasopharyngeal carcinoma	Phase II	B. Ma	07/21/15	40	24
9824	A phase I study of alisertib (MLN8237) in combination with mFOLFOX in gastrointestinal tumors	Phase I	L. Goff	08/27/15	30	7
9874	A phase I trial of AT13387 in patients with locoregionally advanced squamous cell carcinoma of the head and neck (LA-SCCHN) receiving concurrent radiation and cisplatin	Phase I	A. Hope	09/21/15	36	1
CITN11-01	Phase I study of preoperative gemcitabine plus CP-870,893 followed by addition of CP-870,893 to standard-of-care adjuvant chemoradiation for patients with newly diagnosed resectable pancreatic carcinoma	Phase I	R. Vonderheide	09/24/12	20	0
E3311	Phase II randomized trial of transoral surgical resection followed by low-dose or standard-dose IMRT in resectable p16+ locally advanced oropharynx cancer	Phase II	R. Ferris	08/08/13	377	277
E7208	A randomized phase II study of irinotecan and cetuximab with or without the anti-angiogenic antibody, ramucirumab (IMC-1121B), in advanced, K-ras wild-type colorectal cancer following progression on bevacizumab-containing chemotherapy	Phase II	H. Hochster	10/08/10	147	91
EA2133	InterAACT - an international multicentre open label randomised phase II advanced anal cancer trial comparing cisplatin plus 5-fluorouracil versus carboplatin plus weekly paclitaxel in patients with inoperable locally recurrent or metastatic disease	Phase II	C. Eng	01/29/16	80	0
EA2142	Randomized phase II study of cisplatin and etoposide versus temozolomide and capecitabine in patients with advanced G3 non-small cell gastroenteropancreatic neuroendocrine carcinomas	Phase II	J. Eads	11/06/15	126	0
NRG-GI001	Randomized phase III study of focal radiation therapy for unresectable, localized intrahepatic cholangiocarcinoma	Phase III	T. Hong	09/29/14	146	0
NRG-HN001	Randomized phase II and phase III studies of individualized treatment for nasopharyngeal carcinoma based on biomarker epstein barr virus (EBV) deoxyribonucleic acid (DNA)	Phase II-III	N. Lee	04/21/14	758	62
NRG-HN002	A randomized phase II trial for patients with p16 positive, non-smoking associated, locoregionally advanced oropharyngeal cancer	Phase II	S. Yom	10/27/14	296	130

Gastrointestinal Committee *continued*

NCTN						
RTOG-0848	A phase III trial evaluating both erlotinib and chemoradiation as adjuvant treatment for patients with resected head of pancreas adenocarcinoma	Phase III	R. Abrams	11/17/09	950	458
RTOG-0912	A randomized phase II study of concurrent intensity modulated radiation therapy (IMRT), paclitaxel and pazopanib (NSC 737754)/ placebo, for the treatment of anaplastic thyroid cancer	Phase II	E. Sherman	10/28/10	121	74
RTOG-0920	A phase III study of postoperative radiation therapy (IMRT) +/- cetuximab for locally-advanced resected head and neck cancer	Phase III	M. Machtay	11/05/09	700	522
RTOG-1008	A randomized phase II/III study of adjuvant concurrent radiation and chemotherapy versus radiation alone in resected high-risk malignant salivary gland tumors	Phase II	C. Rodriguez	11/03/10	252	124
RTOG-1112	Randomized phase III study of sorafenib versus stereotactic body radiation therapy followed by sorafenib in hepatocellular carcinoma	Phase III	L. Dawson	04/24/13	368	70
RTOG-1201	A phase II randomized trial evaluating the addition of high or standard intensity radiation to gemcitabine and nab-paclitaxel for locally advanced pancreatic cancer	Phase II	E. Ben-Josef	08/14/13	288	8
RTOG-1216	Randomized phase II/III trial of surgery and postoperative radiation delivered with concurrent cisplatin versus docetaxel versus docetaxel and cetuximab for high-risk squamous cell cancer of the head and neck	Phase II-III	P. Harari	03/18/13	660	237
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 cancer, phase III - preventing adenomas of the colon with eflornithine and sulindac (PACES)	Phase III	J. Zell	03/01/13	1,488	76
S1316	Prospective comparative effectiveness trial for malignant bowel obstruction	Phase III	R. Krouse	03/09/15	200	19
S1406	Randomized phase II study of irinotecan and cetuximab with or without vemurafenib in BRAF mutant metastatic colorectal cancer	Phase II	E. Kopetz	11/13/14	105	97
S1505	A randomized phase II study of perioperative mFOLFIRINOX versus gemcitabine/nab-paclitaxel as therapy for resectable pancreatic adenocarcinoma	Phase II	D. Sohal	10/12/15	112	5

CLOSED		Phase	Chair	Date Open	Date Closed
C80702	A phase III trial of 6 versus 12 treatments of adjuvant FOLFOX plus celecoxib or placebo for patients with resected stage III colon cancer	Phase III	J. Meyerhardt	06/15/10	11/20/15
C80803	Randomized phase II trial of PET scan-directed combined modality therapy in esophageal cancer	Phase II	K. Goodman	07/15/11	05/11/15

Genitourinary Committee

Chair: Michael J. Morris, MD, Memorial Sloan Kettering Cancer Center

Reporting period for all studies through February 28, 2016

PENDING		Phase	Chair	Status		
A031501	Phase III randomized "Adjuvant study of pembrolizumab in muscle invasive and locally advanced urothelial carcinoma" (AMBASSADOR) versus placebo	Phase III	A. Apolo	In Development		

ACTIVE		Phase	Chair	Date Open	Target Accrual	Current Accrual
A031102	A randomized phase III trial comparing conventional-dose chemotherapy using paclitaxel, ifosfamide, and cisplatin (TIP) with high-dose chemotherapy using mobilizing paclitaxel plus ifosfamide followed by high-dose carboplatin and etoposide (TI-CE) as first salvage treatment in relapse/refractory germ cell tumors (TIGER)	Phase III	D. Feldman	07/01/15	420	6
A031102-HO1	Quality of life studies in A031102	Ancillary	R. Chen	07/01/15	332	6
A031102-PP1	Pharmacogenomic correlative study	Ancillary	P. O'Donnell	07/01/15	303	6
A031201	Phase III trial of enzalutamide (NSC#766085) versus enzalutamide, abiraterone and prednisone for castration resistant metastatic prostate cancer	Phase III	M. Morris	01/22/14	1,224	896
A031201-IM1	Biomarker development/validation of technetium bone scintigraphy and sodium fluoride (NaF) PET/CT for CPRC	Ancillary	L. Schwartz	01/22/14	1,224	896
A031201-PP1	Pharmacogenomic studies in Alliance A031201	Ancillary	H. McLeod	01/22/14	1,224	742
A031201-PP2	Population pharmacokinetics of abiraterone and enzalutamide	Ancillary	L. Lewis	01/22/14	1,224	741
A031201-ST1	Correlative science studies in Alliance A031201	Ancillary	A. Armstrong	01/22/14	1,224	741
C150201	Laboratory studies in hormone refractory prostate cancer	Phase II	D. George	07/15/03	-	-
C150412	Tumor RNA and DNA analyses in men enrolled on CALGB 90203	Ancillary	M. Taplin	12/15/06	750	473
C150413	Tumor and serum protein correlative studies in men enrolled on 90203	Ancillary	M. Taplin	12/15/06	750	659
C150603	Laboratory studies in metastatic renal cell carcinoma	Ancillary	F. Waldman	03/15/10	500	-
C150609	Correlative companion study to 90601: Association of baseline plasma and urine VEGF levels with response and survival in metastatic bladder cancer	Ancillary	M. Taplin	07/15/09	500	446
C151003	Evaluating the effect of tobacco on prostate cancer outcomes	Ancillary	A. Harzstark	09/15/11	827	-

NCTN		Phase	Chair	Date Open	Target Accrual	Current Accrual
9653	Phase II trial of gemcitabine-eribulin (GE) in cisplatin ineligible patients with advanced or unresectable urothelial carcinoma of the bladder	Phase II	S. Sadeghi	12/11/14	21	11
9681	A phase 1 study of (Cabozantinib) plus nivolumab (CaboNivo) alone or in combination with ipilimumab (Cabinivoli) in patients with advanced/metastatic urothelial carcinoma and other genitourinary tumors	Phase I	A. Apolo	07/09/15	66	20
CITN12-03	A phase 2 study of recombinant glycosylated human interleukin-7 (CYT107) after completion of standard FDA approved therapy with sipuleucel-T (Provenge) for patients with asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer (mCRPC)	Phase II	L. Fong	09/10/13	80	16
E2810	Randomized, double-blind phase III study of pazopanib vs. placebo in subjects with metastatic renal cell carcinoma who have no evidence of disease following metastasectomy	Phase III	L. Appleman	08/08/12	180	97
EA8141	A prospective phase II trial of neoadjuvant systemic chemotherapy followed by extirpative surgery for patients with high grade upper tract urothelial carcinoma	Phase II	V. Margulis	04/10/15	60	10
NRG-GU001	Randomized phase II trial of postoperative adjuvant IMRT following cystectomy for pT3/pT4 urothelial bladder cancer	Phase II	L. Eapen	02/23/15	185	3

Genitourinary Committee *continued*

NCTN						
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	Phase III	M. Roach	07/07/11	2,580	1,066
S0931	Everest: Everolimus for renal cancer ensuing surgical therapy, a phase III study	Phase III	C. Ryan	04/01/11	1,537	1,360
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	Phase III	S. Lerner	08/01/11	620	560
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	Phase III	N. Agarwal	03/06/13	1,636	942
S1314	A randomized phase II study of co-expression extrapolation (COXEN) with neoadjuvant chemotherapy for localized, muscle-invasive bladder cancer	Phase II	T. Flaig	07/11/14	212	63

CLOSED		Phase	Chair	Date Open	Date Closed
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	Phase III	J. Eastham	12/15/06	10/02/15

Leukemia Committee

Chair: Richard M. Stone, MD, Dana-Farber Cancer Institute

Reporting period for all studies through February 28, 2016

PENDING		Phase	Chair	Status		
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 16-39 years) with newly diagnosed precursor B-Cell ALL	Phase III	D. DeAngelo	In Development		
NCTN						
9706	Randomized phase II study to assess the role of nivolumab as single agent to eliminate minimal residual disease and maintain remission in acute myelogenous leukemia (AML) patients after chemotherapy	Phase II	H. Liu	05/27/15	80	15
9853	A phase 1 study of AZD1775 in combination with belinostat in relapsed and refractory myeloid malignancies and selected untreated patients with acute myeloid leukemia	Phase I	D. Shafer	08/18/15	30	6
E1910	A phase III randomized trial of blinatumomab for newly diagnosed BCR-ABLI-negative B lineage acute lymphoblastic leukemia in adults	Phase III	M. Litzow	12/23/13	360	102
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)	Phase III	T. Shanafelt	02/20/14	519	455
E2905	Randomized phase III trial comparing the frequency of major erythroid response (MER) to treatment with lenalidomide (Revlimid) alone and in combination with epoetin alfa (procrit) in subjects with low- or intermediate-1 risk MDS and symptomatic anemia	Phase III	A. List	01/29/09	252	237
E2906	Phase III trial of clofarabine as induction and post-remission therapy vs. standard daunorubicin & cytosine arabinoside induction and intermediate dose cytosine arabinoside post-remission therapy, followed by decitabine maintenance vs. observation in newly-diagnosed acute myeloid leukemia in older adults (age greater than or equal to 60 years)	Phase III	J. Foran	12/28/10	747	718
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-chromo-some positive (Ph+) ALL	Phase II	A. Advani	01/12/15	44	5

CLOSED		Phase	Chair	Date Open	Date Closed
A041202	A randomized phase III study of bendamustine plus rituximab versus ibrutinib plus rituximab versus ibrutinib alone in untreated older patients (\geq 65 years of age) with chronic lymphocytic leukemia (CLL)	Phase III	J. Woyach	12/09/13	12/28/15
A041202-EL1	Geriatric assessment in Alliance A041202	Ancillary	A. Hurria	12/09/13	12/28/15
A041202-LC1	Leukemia correlative science in A041202	Ancillary	J. Byrd	12/09/13	12/28/15
A041202-PP1	Evaluation of candidate pharmacogenetic determinants of ibrutinib or ibrutinib/rituximab response	Ancillary	K. Richards	12/09/13	12/28/15

Lymphoma Committee

Chair: John P. Leonard, MD, Weill Medical College of Cornell University

Reporting period for all studies through February 28, 2016

PENDING		Phase	Chair	Status
A051301	A randomized 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	Phase III	C. Andreadis	In Development
A051301-PP1	Pharmacogenetics of high-dose chemotherapy and treatment efficacy in relapsed/refractory DLBCL	Ancillary	K. Richards	In Development
A051301-ST1	Biomarker studies in A051301	Ancillary	E. Hsi T. Kelley	In Development

ACTIVE		Phase	Chair	Date Open	Target Accrual	Current Accrual
C50801	Phase II trial of response-adapted therapy based on positron emission tomograph (PET) for bulky stage I and stage II classical Hodgkin lymphom (HL)	Phase II	A. LaCasce	05/15/10	123	79
C50904	A randomized phase II trial of ofatumumab-bendamustine vs. ofatumumab, bortezomib, and bendamustine in patients with untreated follicular lymphoma	Phase II	K. Blum	04/08/11	130	128
C150903	Correlative science in 50801	Ancillary	E. Hsi	05/15/10	99	72
C151005	Correlative science in 50904	Ancillary	E. Hsi	04/08/11	130	118
C151113	Exploratory analyses of biomarkers as potential predictors of outcome for primary CNS B-cell lymphoma	Phase II	E. Hsi	06/15/12	120	3
C51101	A randomized phase II trial of myeloablative versus non-myeloablative consolidation chemotherapy for newly diagnosed primary CNS B-cell lymphoma	Phase II	T. Batchelor	06/15/12	160	62
NCTN						
9177	Phase II study of dose-adjusted epoch+/- rituximab in adults with untreated Burkitt lymphoma, C-Myc positive diffuse large B-cell lymphoma and plasmablastic lymphoma	Phase II	K. Dunleavy	04/13/12	194	140
E1411	Intergroup randomized phase II four arm study in patients with previously untreated mantle cell lymphoma of therapy with: Arm A = rituximab+ bendamustine followed by rituximab consolidation (RB -> R); Arm B = rituximab + bendamustine + bortezomib followed by rituximab consolidation (RBV -> R), Arm C = rituximab + bendamustine followed by lenalidomide + rituximab consolidation (RB -> LR) or Arm D = rituximab + bendamustine + bortezomib followed by lenalidomide + rituximab consolidation RBV -> LR)	Phase II	M. Smith	05/22/12	332	314
E1412	Randomized phase II open label study of lenalidomide R-CHOP (R2CHOP) vs RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone) in patients with newly diagnosed diffuse large B cell lymphoma	Phase II	G. Nowakowski	08/27/13	345	255
S1001	A phase II trial of pet-directed therapy for limited stage diffuse large B-cell lymphoma (DLBCL)	Phase II	D. Persky	07/18/11	155	149

Myeloma Committee

Chair: Paul G. Richardson, MD, Dana-Farber Cancer Institute

Reporting period for all studies through February 28, 2016

ACTIVE		Phase	Chair	Date Open	Target Accrual	Current Accrual
A061202	A phase I/II study of pomalidomide, dexamethasone and ixazomib vs. pomalidomide and dexamethasone for patients with multiple myeloma refractory to lenalidomide and proteasome inhibitor-based therapy	Phase I-II	P. Voorhees	02/07/14	132	23
A061202-ST1	Evaluation of the cereblon/1RF-41/c-Myc pathway in resistance to pomalidomide based therapy	Ancillary	T. Kelley	02/07/14	108	0
A061402	Solitary plasmacytoma of bone: Randomized phase III trial to evaluate treatment with adjuvant systemic treatment and zoledronic acid versus zoledronic acid after definite radiation therapy	Phase III	A. Mahindra	12/23/15	100	0
A061402-ST1	Minimal residual disease monitoring	Ancillary	S. Holstein	12/23/15		0
NCTN						
E1A11	Randomized phase III trial of bortezomib, lenalidomide and dexamethasone (VRD) versus carfilzomib, lenalidomide and dexamethasone (CRD) followed by limited or indefinite lenalidomide maintenance in patients with newly diagnosed symptomatic multiple myeloma	Phase III	S. Kumar	12/02/13	756	280
E3A06	Randomized phase III trial of lenalidomide versus observation alone in patients with asymptomatic smoldering multiple myeloma	Phase III	S. Lonial	10/05/10	180	168
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)	Phase I-II	S. Usmani	11/09/12	130	122
S1304	A phase II randomized study comparing two doses of carfilzomib (NSC-756640) with dexamethasone for multiple myeloma patients with relapsed or refractory	Phase II	S. Ailawadhi	10/18/13	140	143

Neuro-Oncology Committee

Chair: Evanthia Galanis, MD, Mayo Clinic

Reporting period for all studies through February 28, 2016

ACTIVE		Phase	Chair	Date Open	Target Accrual	Current Accrual
A071101	A phase II randomized trial comparing the efficacy of heat shock protein-peptide complex-96 (HSPPC-96) (NSC #725085, Alliance IND# 15380) vaccine given with bevacizumab versus bevacizumab alone in the treatment of surgically resectable recurrent glioblastoma multiforme (GBM)	Phase II	I. Parney O. Bloch	05/22/13	165	65
A071101-ST1	Correlative science in A071101	Ancillary	P. Srivastava	05/22/13	80	60
A071102	A phase II/III randomized trial of veliparib or placebo in combination with adjuvant temozolomide in newly diagnosed glioblastoma with MGMT promoter hypermethylation	Phase II-III	J. Sarkaria	12/15/14	440	116
A071102-IM1	Analysis of advanced MR imaging	Ancillary	L. Hu	12/15/14	400	91
A071102-ST1	DNA extraction from tissue	Ancillary	E. Sulman	12/15/14	400	398
A071102-ST2	DNA extraction from blood	Ancillary	J. Sarkaria	12/15/14	400	104
A071401	Phase II trial of SMO/AKT/NF2 inhibitors in progressive meningiomas with SMO/AKT/NF2 mutations	Phase II	P. Brastianos	08/28/15	56	1
A071401-IM1	Imaging biomarkers of response	Ancillary	E. Gerstner	08/28/15	56	11
A071401-ST1	Identification of molecular biomarkers of response	Ancillary	S. Santagata	08/28/15	56	17
N0577	Phase III intergroup study of temozolomide alone versus radiotherapy with concomitant and adjuvant temozolomide versus radiotherapy with adjuvant PCV chemotherapy in patients with 1p/19q codeleted anaplastic glioma	Phase III	K. Jaeckle	09/22/09	488	59
N0577	MGMT promoter methylation status in tissue	Ancillary	R. Jenkins	09/22/09	488	59
NCTN						
E3F05	Phase III study of radiation therapy with or without temozolomide for symptomatic or progressive low-grade gliomas	Phase III	D. Schiff	09/11/09	540	168
NRG-BN001	Randomized phase II trial of hypofractionated dose-escalated photon IMRT or proton beam therapy versus conventional photon irradiation with concomitant and adjuvant temozolomide in patients with newly diagnosed glioblastoma	Phase II	M. Mehta	10/27/14	576	137
RTOG-1205	Randomized phase II trial of concurrent bevacizumab and re-irradiation versus bevacizumab alone as treatment for recurrent glioblastoma	Phase II	C. Tsien	12/20/12	178	167
CLOSED		Phase	Chair	Date Open	Date Closed	
N107C	A phase III trial of post-surgical stereotactic radiosurgery (SRS) compared with whole brain radiotherapy (WBRT) for resected metastatic brain disease	Phase III	P. Brown	07/08/11	01/22/16	
N107C	To determine if Apo E (i.e., Apo E2, Apo E3, and Apo E4) genotyping may prove to be a predictor of radiation induced neurocognitive decline (or neuroprotection) (DNA)	Ancillary	P. Brown	07/08/11	01/22/16	
N1174	Phase I/comparative randomized phase II trial of TRC105 plus bevacizumab versus bevacizumab in bevacizumab-naïve patients with recurrent glioblastoma multiforme	Phase I-II	E. Galanis	11/09/12	09/22/15	
N1174	Phase I comparative randomized phase II trial of bevacizumab with or without TRC105 in patients with recurrent glioblastoma multiforme - Translational component	Ancillary	S. Kumar	11/09/12	09/22/15	

Respiratory Committee

Chair: Everett E. Vokes, MD, University of Chicago Comprehensive Cancer Center

Reporting period for all studies through February 28, 2016

PENDING		Phase	Chair	Status
A081601	Evaluation of Nivolumab in compromised populations with advanced non-small cell lung cancer	Phase I	M. Edelman	SCRC

ACTIVE		Phase	Chair	Date Open	Target Accrual	Current Accrual
A081105	Randomized double blind placebo controlled study of erlotinib or placebo in patients with completely resected epidermal growth factor receptor (EGFR) mutant non-small cell lung cancer (NSCLC)	Phase III	R. Govindan	08/18/14	450	43
A151216	Adjuvant lung cancer enrichment marker identification and sequencing trial	Screening	G. Oxnard	08/18/14	8,000	-
C140503	A phase III randomized trial of lobectomy versus sublobar resection for small (≤ 2 cm) peripheral non-small cell lung cancer	Phase III	N. Altorki	06/15/07	692	616
C30610	Phase III comparison of thoracic radiotherapy regimens in patients with limited small cell lung cancer also receiving cisplatin or carboplatin and etoposide	Phase III	J. Bogart	03/15/08	729	499
C30901	Randomized phase II study of maintenance pemetrexed versus observation for patients with malignant pleural mesothelioma without progression after first-line chemotherapy	Phase II	A. Dudek	04/15/10	94	67
C150607	A pilot project to study the expression of C-MET and p53 in resected lung adenocarcinoma specimens	Ancillary	R. Salgia	09/15/08	280	-
C150712	Correlative science studies in CALGB 30610	Ancillary	R. Kratzke	03/15/08	690	358
C150802	Participation in the lung adjuvant cisplatin evaluation biological program (LACE-Bio)	Ancillary	S. Graziano	07/15/08	241	-
C150807	Validation of molecular prognostic tests in NSCLC: A companion study to CALGB 140202	Ancillary	R. Bueno	01/15/12	270	-
C150809	Multi-analyte serum test validation for NSCLC: Pre-operative nodal status	Ancillary	R. Kratzke	05/15/10	230	-
C150901	MicroRNA profiling using an updated microarray to prognosticate early lung cancer	Ancillary	S. Yendamuri	07/15/09	80	4
C150908	Correlation of urinary PGE-M determination with COX-2 expression, COX-2 inhibition and outcome	Ancillary	R. Kratzke	02/15/10	297	260
C150912	SMRP and osteopontin levels in blood and tumor tissue expression of thymidylate synthase in patients on CALGB 30901	Ancillary	A. Dudek	04/15/10	96	52
C151107	Molecular characterization of lung cancer: A collaboration with The Cancer Genome Atlas Project (TCGA)	Ancillary	R. Govindan	10/15/11	200	248
C151111	Genomics of small cell lung cancer: A companion to CALGB 140202	Ancillary	P. Janne	01/15/12	50	-

Respiratory Committee *continued*

NCTN							
9878	A phase I/II trial of erlotinib and onalespib lactate in EGFR-mutant non-small cell lung cancer	Phase I-II	J. Riess	01/21/16	24	0	
E4512	A phase III double-blind trial for surgically resected early stage non-small cell lung cancer: crizotinib versus placebo for patients with tumors harboring the anaplastic lymphoma kinase (ALK) fusion protein	Phase III	D. Gerber	08/18/14	378	14	
EA5123	Role of early 18F-FDG-PET/CT scan in predicting mediastinal downstaging with neoadjuvant chemotherapy in resectable stage III A NSCLC	Phase II	L. Horn	11/20/15	68	0	
NRG-CC003	Randomized phase II/III trial of prophylactic cranial irradiation with or without hippocampal avoidance for small cell lung cancer	Phase II-III	V. Gondi	12/07/15	302	7	
RTOG-1306	A randomized phase II study of individualized combined modality therapy for stage III non-small cell lung cancer (NSCLC)	Phase II	R. Govindan	11/04/13	234	28	
RTOG-1308	Phase III randomized trial comparing overall survival after photon versus proton chemoradiotherapy for inoperable stage II-IIIB NSCLC	Phase III	Z. Liao	02/03/14	560	66	
S1300	A randomized, phase II trial of crizotinib plus pemetrexed versus pemetrexed monotherapy in ALK-positive non-squamous NSCLC patients who have progressed systemically after previous clinical benefit from crizotinib monotherapy	Phase II	D. Camidge	08/01/14	114	1	
S1400	Phase II/III biomarker-driven master protocol for second line therapy of squamous cell lung cancer	Phase II-III	V. Papadimitrakopoulou	06/16/14	10,000	606	
S1400B	A phase II/III randomized study of GDC-0032 versus chemotherapy as second line therapy for biomarker selected patients with squamous cell lung cancer	Phase II-III	V. Papadimitrakopoulou	06/16/14	59	17	
S1400C	A phase II/III randomized study of palbociclib versus chemotherapy as second line therapy for biomarker selected patients with squamous cell lung cancer	Phase II-III	V. Papadimitrakopoulou	06/16/14	42	38	
S1400D	A phase II/III randomized study of AZD4547 versus chemotherapy as second line therapy for biomarker selected patients with squamous cell lung cancer	Phase II-III	V. Papadimitrakopoulou	06/16/14	42	24	
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)	Phase III	V. Papadimitrakopoulou	12/18/15	350	16	
S1403	A randomized phase II/III trial of afatinib plus cetuximab versus afatinib alone in treatment-naïve patients with advanced, EGFR mutation positive non-small cell lung cancer (NSCLC)(BI 1200.124)	Phase II-III	S. Goldberg	03/25/15	605	34	
WF-01414	Improving resection rates among African Americans with NSCLC ("Southern Lung Cancer Study")	Phase III	K. Weaver	01/21/15	200	0	

Program: Translational Research

Reporting period for all studies through February 28, 2016

Imaging Committee

Chair: Lawrence Schwartz, MD, Columbia University Medical Center

ACTIVE		Phase	Chair	Date Open	Target Accrual	Current Accrual
C580602	Imaging substudy in CALGB 140503	Ancillary	E. Scalzetti	06/15/07	692	621
C580903	Volumetric tumor measurements in patients on CALGB 30901	Ancillary	E. Scalzetti	04/15/10	96	66
C581101	Imaging markers of outcome after chemotherapy in patients with newly diagnosed PCNSL	Phase II	H. Schoder	06/15/12	50	0

Pharmacogenomics and Population Pharmacology Committee

Chair: Mark J. Ratain, MD, University of Chicago Comprehensive Cancer Center

ACTIVE		Phase	Chair	Date Open	Target Accrual	Current Accrual
C60705	VEGF haplotypes in patients on CALGB 30704	Ancillary	R. Kratzke	04/15/08	225	111
C60707	Pharmacogenomic companion study to CALGB 90601	Ancillary	H. McLeod	07/15/09	500	448
C60901	Pharmacogenomic studies in 80802	Ancillary	F. Innocenti	02/15/10	480	241
C60905	Pharmacogenetic companion studies for CALGB/SWOG 80702	Ancillary	H. McLeod	06/15/10	2,500	2,085
C61004	Dasatinib pharmacokinetic study in CALGB 10701	Ancillary	J. Beumer	12/15/10	66	49
C61102	DNA Analyses in AVITA	Ancillary	F. Innocenti	11/09/12	150	-
C61105	Exploration of the correlaton between the host genetic polymorphisms of interest, specifically 4 SNPs on chromosome 14 recently identified by GWAS (rs7158782, rs7159713, rs2369049 and rs11849538) and incidence of letrozole induced musculoskeletal adverse events	Ancillary	E. Dees	02/15/12	106	94

Translational Research

Reporting period for all studies through February 28, 2016

PENDING		Phase	Chair	Status
A151304	Whole exome genotyping of tumors and patients with stage III colon cancer: Identifying genomic markers associated with recurrence and poor outcomes	Ancillary	R. Goldberg	NCI Approved
A151307	Evaluation of the predictive value of the expression of EpCAM and EpCAM variants in colorectal patients treated with the EpCAM-specific antibody edrecolomab	Ancillary	G. Gastri	In Development
A151308	Genetic contributions to symptom reports: A proposed pilot project	Ancillary	J. Sloan	NCI Approved
A151310	Germline, somatic mutation of POLE, POLD1 and CRC prognosis	Ancillary	F. Innocenti	In Development
A151315	An analysis of baseline serum NTx and BAP as independent predictors of overall survival and risk of SREs	Ancillary	P. Saylor	NCI Approved
A151410	Association of CEP72 SNP (rs924607) and vincristine-induced peripheral neuropathy in adults with acute lymphoblastic leukemia (ALL)	Ancillary	W. Stock	NCI Approved
A151414	The relationship of peripheral blood leukocyte mitochondrial (mt) DNA copy number with disease free survival, molecular tumor profiles and peripheral blood telomere length	Ancillary	L. Boardman	In Development
A151427	Examining the potential of gene expression profiling for guiding adjuvant radiotherapy decision-making for elderly women with early stage breast cancer	Ancillary	C. Rutter	In Development
A151428	The relationship of normal and tumor telomere length and telomere maintenance mechanisms with disease free survival, molecular tumor profiles and blood telomere profiles	Ancillary	L. Boardman	In Development
A151431	TRP: Identifying oncogenic drivers in small cell lung cancer associated with response to sunitinib on CALGB 30504	Ancillary	N. Ready	In Development
A151432	TRP: Homologous recombination deficiency biomarker to predict pCR to platinum-based therapy in patients with TNBC in CALGB 40603	Ancillary	L. Carey	NCI Approved
A151517	Circulating tumor DNA as a marker of minimal residual disease in resected stage III colon cancer	Ancillary	A. Grothey	In Development
A151522	Immunomodulatory effects of epigenetic therapy	Ancillary	S. Chumsri	In Development
A151523	Plan for completion of NCCTG N0147 pharmacogenomic correlative studies	Ancillary	R. Diasio	In Development
A151529	Gene signatures associated with risk of brain metastases in early stage non-small cell lung cancer	Ancillary	N. Ready	In Development
A151532	Analysis of IKZF1 and IKZF3 variants in association with secondary acute lymphoblastic leukemia diagnosed after exposure to autologous hematopoietic cell transplantation and lenalidomide maintenance for multiple myeloma	Ancillary	P. McCarthy	In Development

ACTIVE		Phase	Chair	Date Open	Target Accrual	Current Accrual
A151202	Development of predictive and prognostic blood-based biomarkers in men with castration-resistant prostate cancer from CALGB 90401	Ancillary	D. George	11/05/14	-	-
A151205	Analysis of the association between HSP110 (delta) E9 and prognosis in patients with stage III colon cancers with microsatellite instability	Ancillary	R. Goldberg	12/29/14	-	-
A151214	Genetic predictors of bevacizumab toxicity in CALGB 80405	Ancillary	D. Kroetz	05/22/13	-	-
A151215	Immunogenicity response to cetuximab (LY293777) at different sampling intervals using a validated immunogenicity assay in patients randomized to arm B in study CALGB 80405	Ancillary	F. Innocenti	11/20/13	-	-
A151220	Evaluating BRAF, PIK3CA, NRAS, and KRAS Q61 mutations as predictors of efficacy in cetuximab, or bevacizumab-treated colorectal cancer patients	Ancillary	C. Atreya	06/21/13	-	-
A151316	Generation of adaptive HER2-specific immunity in breast cancer patients as a predictor of response to trastuzumab-based neoadjuvant chemotherapy (ACOSOG Z1041)	Ancillary	E. Mittendorf	09/14/15	-	-
A151407	Detection of VE cadherin in plasma samples from CALGB 30504	Ancillary	M. Maitland	01/14/15	-	-
A151425	Large correlative science study using 80405 samples	Ancillary	A. Venook	08/10/15	-	-

**Program: Cancer Control
Health Disparities Committee**

Chair: Electra D. Paskett, PhD, Ohio State University Comprehensive Cancer Center

Reporting period for all studies through February 28, 2016

PENDING		Phase	Chair	Status
A191402	Testing decision aids to improve prostate cancer decisions for minority men	Other	J. Tilburt	In Development

ACTIVE		Phase	Chair	Date Open	Target Accrual	Current Accrual
A191401	The ALLIANCE patient questionnaire: A pilot study to determine questionnaire feasibility	Pilot	E. Paskett	03/16/15	240	31

Health Outcomes Committee

Co-Chairs: Ethan M. Basch, MD, University of North Carolina at Chapel Hill and Jeffrey A. Sloan, PhD, Mayo Clinic

Reporting period for all studies through September 1, 2015

ACTIVE		Phase	Chair	Date Open	Target Accrual	Current Accrual
C70702	Quality of life studies in CALGB 30610	Ancillary	S. Fleishman	03/15/08	415	372
C71105	Neurocognitive function and quality of life in patients with primary CNS B-cell lymphoma	Ancillary	D. Correa	06/15/12	160	2
N0392	Assessment of patient satisfaction with participation in phase II/III NCCTG clinical trials	Ancillary	J. Sloan	06/07/06	3,870	672

Prevention Committee

Chair: James R. Marshall, PhD, Roswell Park Cancer Institute

Reporting period for all studies through February 28, 2016

PENDING		Phase	Chair	Status
A211401	Reducing surgical complications in newly diagnosed lung cancer patients who smoke cigarettes	Other	I. Croghan	In Development
A211402	Effect of aspirin on breast cancer risk	Other	M. Wood	SCRC

ACTIVE		Phase	Chair	Date Open	Target Accrual	Current Accrual
A211102	Testing for atypia in random periareolar fine needle aspiration (RPFNA) cytology after 12 months metformin (1,1-dimethylbiguanide hydrochloride) chemoprevention versus placebo control in premenopausal women	Other	V. Seewaldt	02/01/15	400	3
A211201	Change in mammographic density with metformin use: A companion study to NCIC study MA.32	Ancillary	M. Wood	08/22/12	458	148

CLOSED		Phase	Chair	Date Open	Date Closed
C70807	The men's eating and living (MEAL) study: A randomized trial of diet to alter disease progression in prostate cancer patients on active surveillance	Phase III	J. Parsons	12/01/10	10/01/15
C71002	Cancer prevention companion studies for CALGB/SWOG C80702	Ancillary	J. Meyerhardt	11/01/10	10/20/15
C151105	Carotenoid and polymorphism analysis of patients enrolled to 70807	Ancillary	C. Rock	06/15/11	10/01/15

Symptom Intervention Committee

Chair: Charles L. Loprinzi, MD, Mayo Clinic

PENDING		Phase	Chair	Status
A221208	Randomized phase II study: Corticosteroids + bevacizumab vs. corticosteroids + placebo (BeSt) for radionecrosis after radiosurgery for brain metastases	Phase II	C. Chung	Pre-Activated
A221208-IM1	Evaluation of imaging biomarkers of radionecrosis response to corticosteroid and bevacizumab therapy in Alliance A221208	Ancillary	T. Kaufmann	Pre-Activated
A221208-ST1	Evaluation of biofluid biomarkers of radiation necrosis in Alliance A221208	Ancillary	C. Chung, E. Sulman	Pre-Activated
A221502	Pulmonary rehabilitation before lung cancer resection	Other	R. Benzo	In Development
A221503	A phase III, randomized, double-blind placebo controlled study of the probiotic lactobacillus rhamnosus GG (Culturelle) versus placebo in the prevention of acute enteritis in patients receiving concurrent chemotherapy and pelvic radiation therapy	Phase II	C. Hallemeier	SCRC
A221504	A randomized, double-blind, placebo-controlled pilot study of an oral, selective peripheral opioid receptor antagonist in advanced non-small cell lung cancer (adenocarcinoma)	Pilot	P. Gupta	In Development
A221505	Phase III randomized trial of hypofractionated post mastectomy radiation with breast reconstruction	Phase III	M. Poppe	NCI Concept Submitted
A221601	A randomized, double-blinded, placebo-controlled trial of a 10% urea-based topical cream to decrease the incidence of sorafenib- or sunitinib- or regorafenib-induced hand-foot skin reaction	Phase III	A. Jatoi	SCRC

Symptom Intervention Committee *continued*

ACTIVE		Phase	Chair	Date Open	Target Accrual	Current Accrual
A221101	A phase III randomized, double-blind placebo controlled study of armodafinil (Nuvigil) to reduce cancer-related fatigue in patients with high grade glioma	Phase III	A. Umphrey, S. Kohli	06/03/13	330	121
A221102	Randomized double-blind placebo controlled study of testosterone in the adjuvant treatment of postmenopausal women with aromatase inhibitor induced arthralgias	Phase III	C. Loprinzi S. Birrell	09/07/12	224	57
A221102	Correlative science in A221102	Ancillary	C. Loprinzi	09/07/12	224	57
A221303	Randomized study of early palliative care integrated with standard oncology care versus standard oncology care alone in patients with incurable lung or non-colorectal gastrointestinal malignancies	Phase III	J. Temel	05/15/15	400	115
A221304	A phase III placebo-controlled, randomized three-arm study of doxepin and a topical rinse in the treatment of acute oral mucositis pain in patients receiving radiotherapy with or without chemotherapy	Phase III	R. Miller	11/01/14	270	224
A221501	A study evaluating the pregnancy outcomes and safety of interrupting endocrine therapy for young women with endocrine responsive breast cancer who desire pregnancy	Other	A. Partridge	10/15/15	500	0
A221501	Preventing anthracycline cardiovascular toxicity with statins (PREVENT)	Other	K. Ruddy	07/15/15	250	0

ALLIANCE FOUNDATION TRIALS, LLC

Reporting period for all studies through February 28, 2016

ACTIVE		Phase	AFT PI	Date Open	Target Accrual	Current Accrual
AFT-01	Post-treatment surveillance in breast cancer: Bringing CER to the Alliance	N/A	C. Greenberg	03/01/14	N/A	N/A
AFT-02	Patient centered, risk stratified surveillance after curative resection of colorectal cancer	N/A	G. Chang	03/01/14	N/A	N/A
AFT-03	Improving the effectiveness of routine surveillance following lung cancer resection	N/A	B. Kozower	07/01/14	N/A	N/A
AFT-04/M14-011	A randomized, placebo-controlled, double-blind phase 3 study evaluating the safety and efficacy of the addition of veliparib plus carboplatin versus the addition of carboplatin to standard neoadjuvant chemotherapy in subjects with early stage triple negative breast cancer (TNBC)	Phase III	M. Golshan	08/19/14	624	634
AFT-05/PALLAS	Palbociclib collaborative adjuvant study: A randomized phase 3 trial of palbociclib with adjuvant endocrine therapy versus endocrine therapy alone for hormone receptor positive/HER2-negative breast cancer	Phase III	E. Mayer	08/25/15	2,300	39
AFT-07/M14-360	A phase 1 dose escalation and phase 2 randomized, placebo-controlled study of the efficacy and tolerability of veliparib in combination with paclitaxel/carboplatin-based chemoradiotherapy followed by veliparib and paclitaxel/carboplatin consolidation in subjects with stage III non-small cell lung cancer (NSCLC)	Phase I/II	J. Salama T. Stinchcombe	12/29/14	Phase 1: 18, Phase 2: 150	P1: 16
AFT-08/CC-486-DLBCL-001	A phase I, open-label, multi-center trial of oral azacitidine (CC-486) plus R-CHOP in subjects with high risk (IPI 3 or more) previously untreated diffuse large B-cell lymphoma or grade 3B follicular lymphoma	Phase I	P. Martin	01/28/15	Up to 25 in the MTD determination phase; plus an additional 25 in the expansion phase	14
AFT-09/Pembrolizumab	A randomized phase II trial evaluating the optimal sequencing of PD-1 inhibition with pembrolizumab (MK-3475) and standard platinum-based chemotherapy in patients with chemotherapy naive stage IV non-small cell lung cancer	Phase III	T. Hensing	03/17/16	90	1
AFT-23/ICT-107	A phase III randomized double-blind, controlled study of ICT-107 with maintenance temozolomide (TMZ) in newly diagnosed glioblastoma following resection and concomitant TMZ chemoradiotherapy	Phase III	P. Wen	12/18/15	414	3

In Memoriam 2016



Egbert C. Brown

Member, Alliance Patient Advocate Committee
Board of Directors, Central Ohio Men Against Prostate Cancer
Peer Reviewer, U.S. Army Medical Research and Material Command
Prostate Cancer Research Program
Affiliate Member, Professor, American Association for Cancer Research



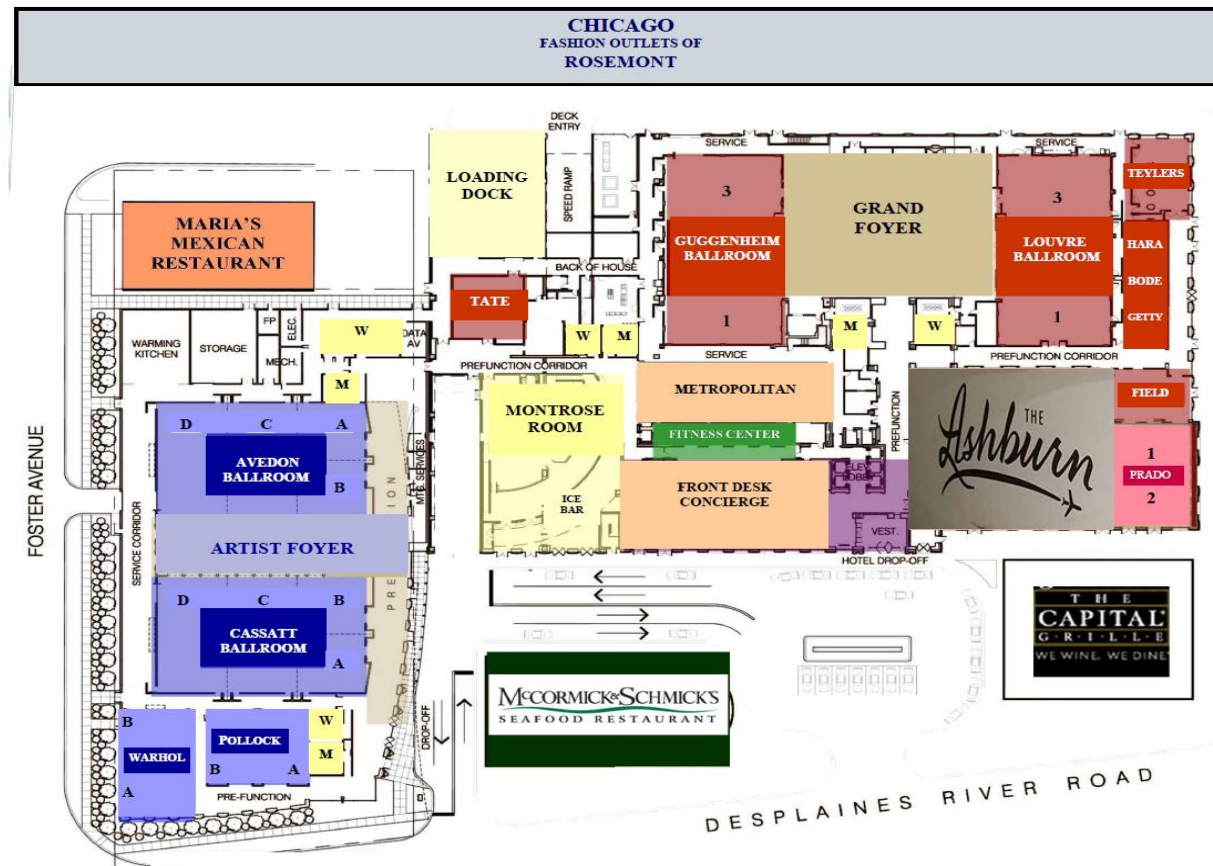
Kathleen W. Rao, PhD, FACWG

Member, Alliance Karyotype Review Committee
Professor, Departments of Pediatrics / Pathology and Laboratory Medicine
University of North Carolina at Chapel Hill School of Medicine
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Hotel Floor Plan

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