

Breast Committee

Leadership

Chair: Lajos Pusztai, MD, PhD
 Vice-Chair: Priyanka Sharma, MD
 Executive Officer: Anne Chiang, MD, PhD
 Statisticians: Allison Meisner, PhD
 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: Joshua M.V. Mammen, MD, PhD
 Imaging: Joanne E. Mortimer, MD
 Wei Tse Yang, MBBS
 Pathology: David L. Rimm, MD, PhD
 Early Therapeutics: Stephanie L. Graff, 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)
 DEI Champion: Gayathri Nagaraj, MD
 Digital Engagement: Sarah S. Mougalian, MD
 NCORP Representative: Philip E. Lammers, MD
 Veterans Affairs: Sarah V. Colonna, MD
 Data Coordinators: Aubrey Gilmore, BA
 Gabi Herbert, MS, BS
 Kevin Moralda, BS
 Larry G. Kaye
 Oncology Research Professionals:
 CRAs: Karyn N. Hart, CCRP
 Avidanka Baftirovska, BS, CCRP
 Nurse: Cameo Windham, BSN, RN
 Patient Advocates: Roberta A. Albany
 Ginny Mason, RN, BSN
 Pharmaceutical Science: Jorge G. Avila, PharmD
 Dawud Nael Dawud Ellayan, Pharm D
 Protocol Project Manager: Alicia Aranda
 Clinical Trials Program Manager: Crystal Miwa

Time/Location

Friday, October 13, 2023 3:30 p.m. - 6:30 p.m.
 Room: Regency A (Ballroom Level, West Tower)

Agenda

3:30 - 3:35 pm Welcome and Introductions - Lajos Pusztai, MD, DPhil (Chair) and Priyanka Sharma, MD (Vice-chair)

Mini symposium: New horizons in Neoadjuvant systemic therapy for breast cancer

3:35-3:50 pm Pathological response and long-term outcomes across breast cancer subtypes - Fraser Symmans MD, Professor, Department of Pathology, Division of Pathology/Lab Medicine, The University of Texas MD Anderson Cancer Center

3:50-4:05 pm Neoadjuvant chemo-immunotherapy for Hormone positive breast cancer: Patient selection and trial end points - Erin Cobain MD, Assistant Professor, Department of Internal Medicine Rogel Cancer Center, Michigan

4:05-4:20 pm Neo and adjuvant chemo-immunotherapy for TNBC. Right Sizing the treatment - Zahi Mitri MD, MS, Associate Professor of Medicine, Department of Medicine British Columbia Cancer Agency, Vancouver

4:20 - 4:35 pm Q&A and Panel Discussion

4:35 - 4:45 pm Publication update – William Barlow, PhD

4:45 - 5:00 pm Patient Advocate update – Ginny Mason and Roberta Albany

5:00 - 5:10 pm Translational Medicine Subcommittee update - Alastair Thompson, MD and Andrew K. Godwin, PhD

5:10 - 5:50 pm Review of open CTSU trials

5:50 - 6:10 pm Recently approved and developing Concepts

6:10 - 6:30 pm Reports from Committee Liaisons

Radiotherapy: Reshma Jagsi, MD
 Surgery: Joshua Mammen, MD
 Survivorship: Melinda L. Irwin, PhD, MPH
 Cancer Care Delivery: Dawn Hershman, MD
 Prevention: Banu Arun, MD
 Symptom Control & QOL: Helen K. Chew, MD
 NCORP: Philip Lammers, MD
 DEI: Gayathri Nagaraj, MD

6:30 pm Closing Comments and Adjourn

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Developing Studies

S2206, "Phase III Trial of Neoadjuvant Durvalumab (NSC 778709) plus Chemotherapy versus Chemotherapy Alone for MammaPrint Ultrahigh (MP2) Hormone Receptor (HR) Positive / Human Epidermal Growth Factor Receptor (HER2) Negative Stage II-III Breast Cancer." Drs. Cobain and Pusztai.

Active Studies

S2212, "Shorter Anthracycline-Free Chemo Immunotherapy Adapted to Pathological Response in Early Triple Negative Breast Cancer (SCARLET), A Randomized Phase III Study." Drs. Sharma and Mitri. Activated: 07/21/23.

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

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

CTSUA011801, "The COMPASSHER2 Trials (COMprehensive Use of Pathologic Response ASSESSment to Optimize Therapy in HER2-Positive Breast Cancer): COMPASSHER2 Residual Disease (RD), A Double-Blinded, Phase III Randomized Trial of T-DM1 and Placebo Compared with T-DM1 and Tucatinib." Dr. O'Sullivan. SWOG Champion: Dr. Murthy. Activated: 01/06/21.

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

CTSUEA1181, "(CompassHER2-pCR): Preoperative THP and Postoperative HP in Patients Who Achieve a Pathologic Complete Response Part 1 Component of: The CompassHER2 Trials (COMprehensive Use of Pathologic Response ASSESSment to Optimize Therapy in HER2-Positive Breast Cancer)" Dr. Tung. SWOG Champions: Breast Committee: Dr. Tang, Imaging Committee: Dr. Lu. Activated: 02/11/20.

CTSUEA1183, "FDG PET to Assess Therapeutic Response in Patients with Bone-Dominant Metastatic Breast Cancer, FEATURE." Dr. Specht. SWOG Champions: Breast Committee: Dr. Linden, Imaging Committee: Dr. Wright. Activated: 04/02/20.

CTSNRG-BR007, "A Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER2-Negative, Oncotype Recurrence Score Less Than or Equal

to 18 Breast Cancer (DEBRA)." Dr. White. SWOG Champion: Dr. Shumway. Activated: 06/07/21.

Closed Studies

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

S1207, "Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer. e³ Breast Cancer Study-Evaluating Everolimus with Endocrine Therapy." Drs. Chavez-MacGregor and Pusztai. Activated: 09/04/13. Permanently closed: 05/01/19.

CTSUA011202, "A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy." Dr. Boughey. SWOG Champion: Dr. Mammen. Activated: 02/07/14. Permanently closed: 07/01/22.

CTSNRG-BR002, "A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer." Drs. Chmura and White. SWOG Champion: Dr. Jagsi. Activated: 12/24/14. Permanently closed: 05/27/22.

CTSNRG-BR003, "A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer." Dr. Valero. SWOG Champion: Dr. Makhoul. Activated: 06/26/15. Permanently closed: 04/22/22.

CTSNRG-BR004, "A Randomized, Double-Blind, Phase III Trial of Taxane/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer." Dr. Geyer. SWOG Champion: Dr. Cobain. Activated: 03/12/19. Permanently closed: 07/01/22.

CTSNRG-BR005, "A Phase II Trial Assessing the Accuracy of Tumor Bed Biopsies in Predicting Pathologic Response in Patients with Clinical/Radiologic Complete Response after Neoadjuvant Chemotherapy in Order to Explore the Feasibility of Breast Conserving Treatment without Surgery." Dr. Basik. SWOG Champion: Dr. Thompson. Activated: 04/13/17. Permanently closed: 12/02/22.

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Active Cancer Survivorship Study

S1501, "Prospective Evaluation of Carvedilol in Prevention of Cardiac Toxicity in Patients with Metastatic HER-2+ Breast Cancer, Phase III." Drs. Floyd and Leja. Activated: 09/15/17.

Closed Symptom Control and Quality of Life Studies

S1614, "A Phase III Randomized Trial of Prophylactic Antiviral Therapy in Patients with Current or Past Hepatitis B Virus (HBV) Infection Receiving Anti-Cancer Therapy for Solid Tumors." Drs. Hwang and Lok. Activated: 02/21/19. Permanently closed: 11/15/22.

S1714, "A Prospective Observational Cohort Study to Develop a Predictive Model of Taxane-Induced Peripheral Neuropathy in Cancer Patients." Drs. Trivedi and Hershman. Activated 03/01/19. Permanently closed: 11/15/21.

Active Cancer Care Delivery Studies

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

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

Active Cancer Prevention Study

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

Closed Early Therapeutics and Rare Cancers Studies

S1609, "DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors." Drs. Patel and Chae. Activated 01/13/17. Permanently closed: 03/15/23.

CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)". Dr. Flaherty. Activated 08/12/15. Permanently closed: 12/30/22.

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Accrual from trial opening through 6/30/2023 by Institution and Study

	S1706	S2007	A011202	A011801	EA1181	EA1183	MA39	NRGBR002
Ascension Providence Hospitals - Southfield	2	-	4	1	5	-	1	-
Banner MD Anderson Cancer Center	-	-	-	3	-	-	-	-
Banner University Medical Center - Tucson	1	-	1	-	10	-	-	-
Baptist Memorial Health Care/Mid South Minority Underserved	3	-	1	-	1	-	-	-
Baylor University Medical Center	-	-	1	-	-	-	-	-
Boston Medical Center	-	-	-	5	14	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	1	-	-	3	-	1	-
Cancer Research for the Ozarks NCORP	1	-	-	1	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	-	2	-	-	-	-	-	-
Columbia University Minority Underserved NCORP	4	-	-	-	3	-	-	-
CommonSpirit Health Research Institute	1	-	-	-	-	-	1	-
Cotton O'Neil Cancer Center / Stormont Vail Health	-	-	1	-	-	-	-	-
Dayton NCI Community Oncology Research Program	-	1	-	-	7	2	-	-
Desert Regional Medical Center	-	-	7	-	2	-	1	-
Essentia Health NCI Community Oncology Research Program	-	-	-	1	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	4	-	-	-	-	-	-	-
Georgia NCI Community Oncology Research Program	2	-	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	1	-	-	-	2	-	-	-
Heartland Cancer Research NCORP	3	-	-	1	-	-	-	-
Houston Methodist Hospital	-	-	-	1	-	-	2	-
Kaiser Permanente NCI Community Oncology Research Program	-	-	1	-	-	-	-	-
Lahey Hospital and Medical Center	-	-	-	-	6	-	-	-
Loma Linda University Medical Center	-	-	3	-	-	-	-	-
Loyola University Medical Center	-	-	-	-	1	-	-	-
Medical University of South Carolina Minority Underserved NCORP	1	-	-	-	-	3	-	-
Meharry Medical College	-	-	-	-	-	-	-	-
Michigan Cancer Research Consortium NCORP	2	-	-	-	-	-	-	-
Moffitt Cancer Center	-	-	1	-	-	-	-	-
Montana Cancer Consortium NCORP	3	-	-	-	-	-	-	-
Mount Sinai Hospital	-	-	-	-	1	-	-	-
New Mexico Minority Underserved NCORP	4	1	-	-	-	-	-	-
Northwell Health NCORP	-	1	-	-	-	-	-	-
Northwestern University LAPS	1	1	-	-	4	1	-	-

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Accrual from trial opening through 6/30/2023 by Institution and Study

	S1706	S2007	A011202	A011801	EA1181	EA1183	MA39	NRGBR002
Ohio State University Comprehensive Cancer Center LAPS	3	-	-	-	1	-	-	-
Oregon Health and Science University	-	-	-	-	-	3	-	-
Pacific Cancer Research Consortium NCORP	-	-	-	-	-	-	-	-
Salem Hospital	-	-	4	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	1	-	1	-	-	-	-
Sutter Cancer Research Consortium	-	-	-	2	5	-	-	-
The Don and Sybil Harrington Cancer Center	3	-	11	2	-	-	-	-
The James Graham Brown Cancer Center at University of Louisville	-	-	2	-	-	-	-	-
The West Clinic - Wolf River	-	-	9	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	6	-	2	-	4	-	-	-
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	1	3	-	-	-	-	-
UC San Diego Moores Cancer Center	-	-	-	-	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS	-	-	4	1	-	-	2	-
U of Alabama at Birmingham / Deep South Research Consortium LAPS	-	1	-	-	-	-	-	-
University of Arkansas for Medical Sciences	2	-	-	2	-	-	-	-
University of Colorado Cancer Center LAPS	1	-	42	1	11	-	1	-
University of Kansas Cancer Center - MCA Rural MU NCORP	4	-	4	-	-	-	1	-
University of Michigan Comprehensive Cancer Center LAPS	2	-	-	1	1	-	7	-
University of Mississippi Medical Center	-	-	-	-	1	-	-	-
University of Rochester LAPS	1	-	-	-	1	-	-	-
University of Texas Health Science Center at San Antonio	-	1	6	-	-	-	-	-
University of Texas MD Anderson Cancer Center LAPS	1	1	-	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	4	-	-	1	7	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	11	2	14	4	1	-
William Beaumont Hospital-Royal Oak	-	-	6	-	-	-	-	1
Wisconsin NCI Community Oncology Research Program	1	-	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	-	5	3	10	-	-	-
ALLIANCE	16	6	-	-	-	-	-	-
CCTG	6	-	-	-	-	-	-	-
ECOG-ACRIN	6	2	-	-	-	-	-	-
NRG	42	-	-	-	-	-	-	-
Total	131	20	129	29	114	13	18	1

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Accrual from trial opening through 6/30/2023 by Institution and Study

	NRGBR003	NRGBR004	NRGBR005	NRGBR007
Ascension Providence Hospitals - Southfield	3	1	-	-
Banner MD Anderson Cancer Center	-	-	-	-
Banner University Medical Center - Tucson	-	-	-	-
Baptist Memorial Health Care/Mid South Minority Underserved	-	1	-	-
Baylor University Medical Center	-	-	-	-
Boston Medical Center	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	9	1	-	-
Cancer Research for the Ozarks NCORP	3	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	-	-	-	-
Columbia University Minority Underserved NCORP	-	-	-	-
CommonSpirit Health Research Institute	-	-	-	-
Cotton O'Neil Cancer Center / Stormont Vail Health	1	-	-	-
Dayton NCI Community Oncology Research Program	-	-	-	-
Desert Regional Medical Center	-	-	-	-
Essentia Health NCI Community Oncology Research Program	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	-	-	-	-
Georgia NCI Community Oncology Research Program	1	-	-	-
Gulf South Minority Underserved NCORP	4	-	-	-
Heartland Cancer Research NCORP	-	-	-	-
Houston Methodist Hospital	-	-	1	-
Kaiser Permanente NCI Community Oncology Research Program	25	1	-	-
Lahey Hospital and Medical Center	-	1	-	-
Loma Linda University Medical Center	-	-	-	-
Loyola University Medical Center	-	-	-	-
Medical University of South Carolina Minority Underserved NCORP	-	-	-	-
Meharry Medical College	1	-	-	-
Michigan Cancer Research Consortium NCORP	-	-	-	-
Moffitt Cancer Center	-	-	-	-
Montana Cancer Consortium NCORP	-	-	-	-
Mount Sinai Hospital	-	-	-	-
New Mexico Minority Underserved NCORP	-	-	-	-
Northwell Health NCORP	-	-	-	2
Northwestern University LAPS	1	-	-	-

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Accrual from trial opening through 6/30/2023 by Institution and Study

	NRGBR003	NRGBR004	NRGBR005	NRGBR007
Ohio State University Comprehensive Cancer Center LAPS	-	-	-	-
Oregon Health and Science University	3	-	-	-
Pacific Cancer Research Consortium NCORP	2	-	-	-
Salem Hospital	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	-	-	-
Sutter Cancer Research Consortium	4	2	-	-
The Don and Sybil Harrington Cancer Center	-	-	-	-
The James Graham Brown Cancer Center at University of Louisville	-	-	-	-
The West Clinic - Wolf River	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	-	1	-	1
UC Irvine Health/Chao Family Comprehensive Cancer Center	1	-	-	-
UC San Diego Moores Cancer Center	1	-	-	-
USC Norris Comprehensive Cancer Center LAPS	-	-	-	-
U of Alabama at Birmingham / Deep South Research Consortium LAPS	-	-	-	-
University of Arkansas for Medical Sciences	-	-	-	-
University of Colorado Cancer Center LAPS	-	-	2	-
University of Kansas Cancer Center - MCA Rural MU NCORP	-	-	1	-
University of Michigan Comprehensive Cancer Center LAPS	3	-	-	-
University of Mississippi Medical Center	-	-	-	-
University of Rochester LAPS	9	-	-	1
University of Texas Health Science Center at San Antonio	4	-	-	-
University of Texas MD Anderson Cancer Center LAPS	-	-	3	-
University of Utah - Huntsman Cancer Institute LAPS	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	6	-	-	-
William Beaumont Hospital-Royal Oak	-	-	-	-
Wisconsin NCI Community Oncology Research Program	-	-	-	-
Yale University - Yale Cancer Center LAPS	9	1	-	-
ALLIANCE	-	-	-	-
CCTG	-	-	-	-
ECOG-ACRIN	-	-	-	-
NRG	-	-	-	-
Total	90	9	7	4