

OCTOBER 16-19, 2024
CHICAGO, ILLINOIS



Chicago Specials

Fall Group Meeting

Breast Committee

Breast Committee

Leadership

Chair: Lajos Pusztai, MD, PhD
 Vice-Chair:Priyanka Sharma, MD
 Executive Officer:..... Anne Chiang, MD, PhD
 Statisticians:Allison Meisner, PhD
 Danika Lew, MA
 Jieling Miao, MS
 Allison Hayes, BS

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: TBD
 Pathology:..... David L. Rimm, MD, PhD
 Early Therapeutics:.....Stephanie L. Graff, MD

Designates

Cancer Control Liaisons: Mariya Rozenblit, MD (Survivorship)
 Dawn L. Hershman, MD (Cancer Care Delivery)
 Banu Arun, MD (Prevention)
Helen K. Chew, MD (Symptom Management)
 DEI Champion:.....Gayathri Nagaraj, MD
 Digital Engagement:..... TBD
 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
 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: TBD
 Clinical Trials Program Manager:Sharon Palmer

Time/Location

Friday, October 18, 2024 8:30 a.m. - 11:30 a.m.
 Room: Regency A (Ballroom Level, West Tower)

Agenda

8:30 - 8:35 am Welcome and Introductions - Lajos Pusztai, MD, DPhil (Chair) and Priyanka Sharma, MD (Vice-chair)

CME Session

“Optimization of endocrine therapy for advanced hormone positive breast cancer”
 8:35 - 8:50 am Current treatment landscape of second line endocrine therapy - Christos Vakilavas, MD
 8:50 - 9:05 am Emerging role of molecular response/ctDNA dynamics in treatment sequencing - Kevin Kalinsky MD
 9:05 - 9:20 am Androgen Receptors in Luminal Breast Cancer: Effects on Response to Endocrine Therapy and an Immune-Suppressive Tumor Immune Microenvironment - Anthony Elias MD
 9:20 - 9:50 am Q&A

Committee Business and Updates

9:50 - 10:00 am Publication update – Allison Meisner, PhD
 10:00 - 10:10 am Patient Advocate update – Ginny Mason and Roberta Albany
 10:10 - 10:20 am Translational Medicine Sub-Committee update - Alastair Thompson, MD and Andrew K. Godwin, PhD
 10:20 - 11:00 am Review of open CTSU trials
 11:00 - 11:10 am Recently approved concepts
 11:10 - 11:25 am Reports from Committee Liaisons
 Radiotherapy: Reshma Jagsi, MD
 Surgery: Joshua Mammen, MD
 Survivorship: Mariya Rozenblit, MD
 Cancer Care Delivery: Dawn Hershman, MD
 Prevention: Banu Arun, MD
 Symptom Management: Helen K. Chew, MD
 NCORP: Philip Lammers, MD
 11:25 am Closing Comments and Adjourn

Breast Committee

Developing Studies

S2428, "Randomized Phase III trials of multimodality therapy versus palliative therapy in triple negative (TNBC) and HER2 positive (HER2+) de novo (AJCC stage IV) oligometastatic breast cancer." Drs. Rozenblit, Stecklein, and Lin.

S2501, "ARIA: A Randomized Phase III Trial of Abemaciclib Versus Ribociclib In the Adjuvant Treatment of High-Risk, Hormone-Receptor Positive Early-Stage Breast Cancer." Drs. McGuinness, Sharma, Cobain, and Rozenblit.

Active Studies

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 Puztai. Activated: 10/30/23.

S2212, "Shorter Anthracycline-Free Chemo Immunotherapy Adapted to Pathological Response in Early Triple Negative Breast Cancer (SCARLET), A Randomized Phase III Study." Drs. Sharma and Mitri. Activated: 7/21/23.

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

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

CTSU/CCTG MA.39, "Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive and T3N0 Breast Cancer." Dr. Whelan. SWOG Champion: Dr. Jagsi. Activated: 5/30/18.

CTSU/NRG-BR007, "A Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER2-Negative, Oncotype Recurrence Score Less Than or Equal to 18 Breast Cancer (DEBRA)." Dr. White. SWOG Champion: Dr. Shumway. Activated: 6/7/21.

Closed Studies

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

Lymph Nodes (ypN1mi, ypN1-3) after Neoadjuvant Chemotherapy." Drs. Puztai and Mammen. Activated: 11/15/16; Permanently closed: 6/30/21.

S1207, "Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer. e³ Breast Cancer Study-Evaluating Everolimus with Endocrine Therapy." Drs. Chavez-MacGregor and Puztai. Activated: 9/4/13; Permanently closed: 5/1/19.

S1706, "A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy Alone for Inflammatory Breast Cancer." Drs. Jagsi and Chalasani. Activated: 9/12/18. Permanently closed: 7/1/24.

CTSU/A011202, "A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy." Dr. Boughey. SWOG Champion: Dr. Mammen. Activated: 2/7/14; Permanently closed: 7/1/22.

CTSU/EA1181, "(CompassHER2-pCR): Preoperative THP and Postoperative HP in Patients Who Achieve a Pathologic Complete Response Part 1 Component of: The CompassHER2 Trials (COMprehensive Use of Pathologic Response ASSESSment to Optimize Therapy in HER2-Positive Breast Cancer)" Dr. Tung. SWOG Champions: Breast Committee: Dr. Tang, Imaging Committee: Dr. Lu. Activated: 2/11/20; Permanently closed: 10/19/23.

CTSU/EA1183, "FDG PET to Assess Therapeutic Response in Patients with Bone-Dominant Metastatic Breast Cancer, FEATURE." Dr. Specht. SWOG Champions: Breast Committee: Dr. Linden, Imaging Committee: Dr. Wright. Activated: 4/2/20; Permanently closed: 12/22/23.

CTSU/NRG-BR002, "A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer." Drs. Chmura and White. SWOG Champion: Dr. Jagsi. Activated: 12/24/14; Permanently closed: 5/27/22.

CTSU/NRG-BR003, "A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer." Dr. Valero. SWOG Champion: Dr. Makhoul. Activated: 6/26/15; Permanently closed: 4/22/22.

CTSU/NRG-BR004, "A Randomized, Double-Blind, Phase III Trial of Taxane/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line

Breast Committee

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

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

Active Palliative Care Study

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

Closed Symptom Management & Survivorship Studies

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

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

Active Cancer Care Delivery Studies

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

CTSUEA1151, "Tomosynthesis Mammographic Imaging Screening Trial (TMIST)." Dr. Pisano. SWOG Champion: Dr. Arun. Activated: 7/6/17.

Closed Prevention, Screening & Surveillance 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: 9/1/20. Permanently closed: 6/14/24.

Closed Early Therapeutics and Rare Cancers Studies

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

CTSUEAY131, "Molecular Analysis for Therapy Choice (MATCH)". Dr. Flaherty. Activated 8/12/15; Permanently closed: 12/30/22.

Publications

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

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

Published/Accepted Manuscripts

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

S0221 Pre-treatment Amino Acids and Risk of Paclitaxel-induced Peripheral Neuropathy in SWOG S0221. Chen C, Zirpoli G, Barlow W, Budd GT, Puztai L, Hortobagyi G, Albain K, Godwin A, Thompson A, Henry NL, Ambrosone C, Stringer K, Hertz D. *Cancer Chemotherapy and Pharmacology* May 30. doi: 10.1007/s00280-024-04680-6. Online ahead of print, 2024. <https://pubmed.ncbi.nlm.nih.gov/38814343/>

S1207 Phase III Randomized, Placebo-Controlled Trial of Endocrine Therapy ± 1 Year of Everolimus in Patients With High-Risk, Hormone Receptor-Positive, Early-Stage Breast Cancer. Chavez MacGregor M, Miao J, Puztai L, Goetz M, Rastogi P, Ganz P, Mamounas E, Paik S, Bandox H, Razaq W, O'Dea A, Kaklamani V, Silber A, Flaum L, Andreopoulou E, Wendt A, Carney J, Sharma P, Gralow J, Lew D, Barlow W, Hortobagyi G. *Journal of Clinical Oncology* Jun 4;JCO2302344. doi: 10.1200/JCO.23.02344. Online ahead of print, 2024. <https://pubmed.ncbi.nlm.nih.gov/38833643/>

E1105 A randomized phase III double-blind placebo-controlled trial of first line chemotherapy and trastuzumab with or without bevacizumab for patients with HER2/neu over-expressing metastatic breast cancer: a trial of the ECOG-ACRIN Cancer Research Group (E1105). Mezzanotte-Sharpe J, O'Neill A, Mayer I, Arteaga C, Yang X, Wagner L, Celia D,

Breast Committee

Meropol N, Alpaugh R, Saphner T, Swaney R, Hoelzer K, Gradishar W, Abramson V, Sundaram K, Jilani S, Perez E, Lin N, Jahanzeb M, Sledge G, Reid S. *Breast Cancer Research and Treatment* Sep;207(2):275-282, 2024. <https://pubmed.ncbi.nlm.nih.gov/38967884/>

Submitted Manuscripts

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

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

Breast Committee

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

	S1706	S2007	S2206	S2212	A011801	A012103	EA1181	EA1183	EA1211	MA39	NRGBR007	NRGBR009
Ascension Providence Hospitals - Southfield	2	-	-	-	2	2	5	-	-	1	-	1
Banner MD Anderson Cancer Center	-	-	-	-	9	-	-	-	-	-	-	-
Banner University Medical Center - Tucson	1	-	-	-	-	-	10	-	-	-	-	-
Baptist Mem Health Care/Mid South MU-NCORP	3	-	1	2	-	-	1	-	-	-	-	-
Boston Medical Center	-	-	-	-	5	-	15	-	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	1	-	-	-	-	4	-	-	1	-	-
Cancer Research Consortium of West Michigan NCORP	1	-	-	2	-	-	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	3	-	-	1	1	-	-	-	-	-	-	-
Ca Research of Wisconsin and N Michigan Consort	-	-	-	2	-	-	-	-	-	-	-	-
Carle Cancer Center NCI Comm Oncology Research Prgm	-	2	-	8	-	-	-	-	-	-	-	-
Cedars-Sinai Medical Center	-	-	1	-	1	1	-	-	-	-	-	-
City of Hope Comprehensive Cancer Center	-	-	-	1	-	-	-	-	-	-	-	-
Columbia University Minority Underserved NCORP	4	-	-	-	-	-	3	-	-	-	-	-
CommonSpirit Health Research Institute	2	-	-	6	-	-	-	-	-	2	-	-
Dayton NCI Community Oncology Research Program	-	1	-	-	-	-	6	2	-	-	-	-
Desert Regional Medical Center	1	-	-	-	-	-	2	-	-	1	-	-
Essentia Health NCI Comm Oncology Research Program	-	-	-	-	1	-	-	-	-	-	-	-
Fred Hutchinson Cancer Research Center LAPS	5	-	-	-	-	-	-	-	-	-	-	-
Georgia NCI Community Oncology Research Program	2	-	-	-	-	-	-	-	-	-	-	-
Gulf South Minority Underserved NCORP	1	-	2	2	-	-	2	-	-	-	-	-
Heartland Cancer Research NCORP	4	-	2	9	1	-	-	-	-	-	-	-
Henry Ford Hospital	-	-	-	-	-	1	-	-	-	-	-	-
Houston Methodist Hospital	-	-	-	-	1	-	-	-	-	3	-	-
Lahey Hospital and Medical Center	-	-	-	1	-	-	6	-	-	-	-	-
Loma Linda University Medical Center	-	-	-	3	-	-	-	-	-	-	-	-
Loyola University Medical Center	-	-	-	-	-	-	1	-	-	-	-	-
Med U of South Carolina Minority Underserved NCORP	1	-	-	-	-	-	-	3	-	-	-	-
Michigan Cancer Research Consortium NCORP	2	-	2	4	-	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	3	-	-	1	-	-	-	-	-	-	-	-
Mount Sinai Hospital	-	-	-	-	-	-	1	-	-	-	-	-
MultiCare Tacoma General Hospital	-	-	3	-	-	-	-	-	-	-	-	-
NCORP of the Carolinas (Prisma Health NCORP)	-	-	-	2	-	-	-	-	-	-	-	-
New Mexico Minority Underserved NCORP	6	1	-	-	-	-	-	-	-	-	-	-
Northwell Health NCORP	-	1	-	-	-	-	-	-	-	-	2	-
Northwestern University LAPS	1	2	-	11	1	-	4	1	-	-	-	-

Breast Committee

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

	S1706	S2007	S2206	S2212	A011801	A012103	EA1181	EA1183	EA1211	MA39	NRGBR007	NRGBR009
Ohio State U Comprehensive Cancer Center LAPS	3	-	-	-	-	-	1	-	-	-	-	-
Oregon Health and Science University	-	-	1	-	-	-	-	3	-	-	1	-
Pacific Cancer Research Consortium NCORP	2	-	-	7	-	-	-	-	-	2	-	-
Rhode Island Hospital	-	-	-	1	-	-	-	-	-	-	-	-
SCL Health Saint Joseph Hospital	-	-	-	5	-	-	-	-	-	-	-	-
Southeast Clinical Oncology Research Consort NCORP	-	1	-	11	1	-	-	-	-	-	-	-
Sutter Cancer Research Consortium	-	-	-	1	2	-	5	-	-	-	-	1
The Don and Sybil Harrington Cancer Center	3	-	-	-	3	-	-	-	-	-	-	-
The West Clinic - Wolf River	-	-	-	6	-	-	-	-	-	-	-	1
UC Davis Comprehensive Cancer Center LAPS	7	-	-	-	-	1	4	-	-	-	1	-
UC Irvine Health/Chao Comprehensive Cancer Center	-	1	-	-	2	-	-	-	-	-	-	-
UPMC Hillman Cancer Center LAPS	1	-	-	-	-	-	-	-	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS	-	-	-	-	1	-	-	-	-	2	-	-
U of Alabama at Birm/Deep South Res Cnsrt LAPS	-	2	-	-	-	-	-	-	-	-	-	-
University of Arkansas for Medical Sciences	2	-	-	1	2	3	-	-	-	-	-	-
University of Colorado Cancer Center LAPS	1	-	1	-	1	-	11	-	-	1	1	-
U of Kansas Cancer Center - MCA Rural MU NCORP	4	-	-	5	1	-	-	-	-	1	-	-
U of Michigan Comprehensive Cancer Center LAPS	3	-	1	-	2	-	1	-	-	14	-	-
University of Mississippi Medical Center	-	-	-	-	-	-	1	-	-	-	-	-
University of Oklahoma Health Sciences Center LAPS	1	-	1	1	-	-	-	-	1	-	-	-
University of Rochester LAPS	1	-	-	-	-	-	1	-	-	-	1	-
University of Texas Health Science Center at San Antonio	-	1	1	-	-	-	-	-	-	-	3	-
University of Texas MD Anderson Cancer Center LAPS	1	1	-	-	-	-	-	-	-	-	-	-
University of Utah - Huntsman Cancer Institute LAPS	5	-	-	-	1	-	7	-	-	-	-	-
Vanderbilt University - Ingram Cancer Center LAPS	-	-	-	-	1	-	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	-	-	2	-	14	4	-	1	-	-
Western States Cancer Research NCORP	-	-	-	-	-	-	2	-	-	-	-	-
Wisconsin NCI Community Oncology Research Program	1	-	-	-	-	-	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	-	1	6	3	-	13	-	-	-	-	-
ALLIANCE	18	7	4	38	-	-	-	-	-	-	-	-
CCTG	6	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	11	3	4	30	-	-	-	-	-	-	-	-
NRG	48	-	3	25	-	-	-	-	-	-	-	-
Total	160	24	28	192	44	8	120	13	1	29	9	3

