

SPRING GROUP MEETING

Seattle

Breast Committee

APRIL 3-6, 2024 | SEATTLE, WASHINGTON

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

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: Mariya Rozenblit, MD (Cancer 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

Saturday, April 6, 2024 9:15 a.m. - 12:15 p.m.
 Room: Columbia D (Level 3)

Agenda

9:15 - 9:20 am Welcome and Introductions - Lajos Pusztai, MD, DPhil (Chair) and Priyanka Sharma, MD (Vice-chair)

9:20 - 9:50 am Robert Livingston lecture: "Building a Better Biomarker: Lessons Learned from TAILORx and RxPONDER"
 Dr. Joseph Sparano MD, FACP, Chief, Division of Hematology/Oncology, Icahn School of Medicine at Mt. Sinai, Deputy Director, Tisch Cancer Institute

9:50 - 10:00 am Q&A

10:00 - 10:10 am Publication update – Allison Meisner, PhD

10:10 - 10:25 am Patient Advocate update – Ginny Mason and Roberta Albany

10:25 - 10:35 am Translational Medicine Subcommittee update - Alastair Thompson, MD and Andrew K. Godwin, PhD

10:35- 11:30 am Review of open CTSU trials

11:30 - 11:50 am Recently approved and developing concepts.

11:50 - 12:10 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

12:15 pm Closing Comments and Adjour

Developing Breast Cancer Committee 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.

Active Breast Cancer Committee 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. Activated: 10/30/23.

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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.

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 Breast Cancer Committee 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: 06/30/21.

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

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.

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; Permanently closed: 10/19/23.

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; Permanently closed: 12/22/23.

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.

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; Temporary closure: 02/01/24.

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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. Accordino and Hershman. Activated: 07/16/18.

CTS/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.

CTS/EA1131, "Molecular Analysis for Therapy Choice (MATCH)". Dr. Flaherty. Activated 08/12/15; 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 Fall 2023 Group Meeting. Conference abstracts are not included.

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

Published/Accepted Manuscripts

S0221 Vitamin D Insufficiency as a Risk Factor for Paclitaxel-Induced Peripheral Neuropathy in SWOG S0221 Chen C, Zirpoli G, McCann S, Barlow W, Budd GT, Puztai L, Henry NL, Godwin A, Thompson

A, Ambrosone C, Stringer K, Hertz D. *Journal of the National Comprehensive Cancer Network* Nov;21(11):1172-1180.e3, 2023. <https://pubmed.ncbi.nlm.nih.gov/37935109/> [see also SCQL and Pharmaceutical Sciences Committees]

S0307 Evaluating the Utility and Privacy of Synthetic Breast Cancer Clinical Trial Data Sets. El Kababji S, Mitsakakis N, Fang X, Beltran-Bless AA, Pond G, Vandermeer L, Radhakrishnan D, Mosquera L, Paterson A, Shepherd L, Chen B, Barlow WE, Gralow J, Savard MF, Clemons M, El Emam K. *JCO Clin Cancer Inform*. 2023 Sep;7:e2300116. doi: 10.1200/CCI.23.00116. <https://pubmed.ncbi.nlm.nih.gov/38011617/>

S9313 Dual Prognostic Classification of Triple-Negative Breast Cancer by DNA Damage Immune Response and Homologous Recombination Deficiency. Stecklein S, Barlow W, Puztai L, Timms K, Kennedy R, Logan G, Seitz R, Badve S, Gökmen-Polar Y, Porter P, Linden H, Tripathy D, Hortobagyi G, Godwin A, Thompson A, Hayes D, Sharma P. *JCO Precis Oncol* Sep;7:e2300197. doi: 10.1200/PO.23.00197. .2023. <https://pubmed.ncbi.nlm.nih.gov/37972336/>

Multiple Studies* Cell State and Cell Type: Deconvoluting Circulating Tumor Cell Populations in Liquid Biopsies by Multi-Omics. Welter L, Zheng S, Setayesh S, Morikado M, Agrawal A, Nevarez R, Naghdloo A, Pore M, Higa N, Kolatar A, Sharma P, Moore H, Richer J, Elias A, Pienta K, Zurita A, Gross M, Shishido S, Hicks J, Velasco C, Kuhn P. *Cancers (Basel)* Aug 3;15(15):3949, 2023. [*S1222,S1416,OTHER] <https://pubmed.ncbi.nlm.nih.gov/37568766/>

Submitted Manuscripts

S1207 Results from a phase III randomized, placebo-controlled clinical trial evaluating adjuvant endocrine therapy +/- 1 year of everolimus in patients with high-risk hormone receptor-positive, HER2-negative breast cancer: SWOG S1207. 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. Submitted, 2024.

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Accrual from trials that are open as of 12/31/2023 or have closed in the prior 18 Months by Institution and Study

	S1706	S2007	S2212	A011202	A011801	A012103	EA1181	EA1183	MA39	NRGBR005	NRGBR007
Ascension Providence Hospitals - Southfield	2	-	-	4	2	2	5	-	1	-	-
Banner MD Anderson Cancer Center	-	-	-	-	7	-	-	-	-	-	-
Banner University Medical Center - Tucson	1	-	-	1	-	-	10	-	-	-	-
Baptist Mem Health Care/Mid South Minority Underserved NCORP	3	-	-	1	-	-	1	-	-	-	-
Baylor University Medical Center	-	-	-	1	-	-	-	-	-	-	-
Boston Medical Center	-	-	-	-	5	-	15	-	-	-	-
CWRU Case Comprehensive Cancer Center LAPS	-	1	-	-	-	-	4	-	1	-	-
Cancer Research Consortium of West Michigan NCORP	1	-	-	-	-	-	-	-	-	-	-
Cancer Research for the Ozarks NCORP	2	-	-	-	1	-	-	-	-	-	-
Carle Cancer Center NCI Community Oncology Research Program	-	2	-	-	-	-	-	-	-	-	-
Columbia University Minority Underserved NCORP	4	-	-	-	-	-	3	-	-	-	-
CommonSpirit Health Research Institute	1	-	3	-	-	-	-	-	1	-	-
Cotton O'Neil Cancer Center / Stormont Vail Health	-	-	-	1	-	-	-	-	-	-	-
Dayton NCI Community Oncology Research Program	-	1	-	-	-	-	6	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	-	1	-	-	-	2	-	-	-	-
Heartland Cancer Research NCORP	4	-	4	-	1	-	-	-	-	-	-
Houston Methodist Hospital	-	-	-	-	1	-	-	-	2	1	-
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 Univ of South Carolina Minority Underserved NCORP	1	-	-	-	-	-	-	3	-	-	-
Michigan Cancer Research Consortium NCORP	2	-	4	-	-	-	-	-	-	-	-
Moffitt Cancer Center	-	-	-	1	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	3	-	-	-	-	-	-	-	-	-	-
Mount Sinai Hospital	-	-	-	-	-	-	1	-	-	-	-
New Mexico Minority Underserved NCORP	5	1	-	-	-	-	-	-	-	-	-
Northwell Health NCORP	-	1	-	-	-	-	-	-	-	-	2
Northwestern University LAPS	1	2	1	-	1	-	4	1	-	-	-

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	S1706	S2007	S2212	A011202	A011801	A012103	EA1181	EA1183	MA39	NRGBR005	NRGBR007
Ohio State University Comprehensive Cancer Center LAPS	3	-	-	-	-	-	1	-	-	-	-
Oregon Health and Science University	-	-	-	-	-	-	-	3	-	-	1
Pacific Cancer Research Consortium NCORP	2	-	-	-	-	-	-	-	2	-	-
Salem Hospital	-	-	-	4	-	-	-	-	-	-	-
Southeast Clinical Oncology Research Consortium NCORP	-	1	1	-	1	-	-	-	-	-	-
Sutter Cancer Research Consortium	-	-	1	-	2	-	5	-	-	-	-
The Don and Sybil Harrington Cancer Center	3	-	-	11	3	-	-	-	-	-	-
The James Graham Brown Cancer Cntr at University of Louisville	-	-	-	2	-	-	-	-	-	-	-
The West Clinic - Wolf River	-	-	-	9	-	-	-	-	-	-	-
UC Davis Comprehensive Cancer Center LAPS	7	-	-	2	-	-	4	-	-	-	1
UC Irvine Health/Chao Family Comprehensive Cancer Center	-	1	-	3	2	-	-	-	-	-	-
USC Norris Comprehensive Cancer Center LAPS	-	-	-	4	1	-	-	-	2	-	-
U of Alabama at Birmingham/Deep South Rsrch Consortium LAPS	-	2	-	-	-	-	-	-	-	-	-
University of Arkansas for Medical Sciences	2	-	-	-	2	2	-	-	-	-	-
University of Colorado Cancer Center LAPS	1	-	-	42	1	-	11	-	1	2	1
University of Kansas Cancer Center - MCA Rural MU NCORP	4	-	2	4	-	-	-	-	1	1	-
University of Michigan Comprehensive Cancer Center LAPS	3	-	-	-	1	-	1	-	9	-	-
University of Mississippi Medical Center	-	-	-	-	-	-	1	-	-	-	-
University of Rochester LAPS	1	-	-	-	-	-	1	-	-	-	1
University of Texas Health Science Center at San Antonio	-	1	-	6	-	-	-	-	-	-	2
University of Texas MD Anderson Cancer Center LAPS	1	1	-	-	-	-	-	-	-	3	-
University of Utah - Huntsman Cancer Institute LAPS	4	-	-	-	1	-	7	-	-	-	-
Vanderbilt University - Ingram Cancer Center LAPS	-	-	-	-	1	-	-	-	-	-	-
Wayne State University - Karmanos Cancer Institute LAPS	-	-	-	11	2	-	14	4	1	-	-
Western States Cancer Research NCORP	-	-	-	-	-	-	2	-	-	-	-
William Beaumont Hospital-Royal Oak	-	-	-	6	-	-	-	-	-	-	-
Wisconsin NCI Community Oncology Research Program	1	-	-	-	-	-	-	-	-	-	-
Yale University - Yale Cancer Center LAPS	-	-	-	5	3	-	13	-	-	-	-
ALLIANCE	17	7	2	-	-	-	-	-	-	-	-
CCTG	6	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	8	2	1	-	-	-	-	-	-	-	-
NRG	43	-	5	-	-	-	-	-	-	-	-
Total	143	23	25	129	39	4	120	13	22	7	8

