

Breast Committee

Leadership

Chair: Lajos Pusztai, MD, PhD
Vice-Chair: Priyanka Sharma, MD
Executive Officer: Anne Chiang, MD, PhD
Statisticians: William E. Barlow, PhD
..... Danika Lew, MA
..... Jieling Miao, MS

Scientific Leadership

Translational Medicine: Alastair M. Thompson, MD
..... Andrew K. Godwin, PhD
Radiation Oncology: Reshma Jagsi, MD
Surgery: Joshua M.V. Mammen, MD, PhD
Imaging: Joanne E. Mortimer, MD
..... Wei Tse Yang, MBBS
Pathology: David L. Rimm, MD, PhD
Early Therapeutics: TBD

Designates

Cancer Control Liaisons: Melinda L. Irwin, PhD, MPH (Survivorship)
..... Dawn L. Hershman, MD (Cancer Care Delivery)
..... Banu Arun, MD (Prevention)
..... Helen K. Chew, MD (Symptom Control & QOL)
Digital Engagement: Sarah S. Mougalian, MD
NCORP Representative: Philip E. Lammers, MD
Data Coordinators: Iris Syquia
..... Larry Kaye
..... Ojasvi Mittal
..... Gabi Herbert
Oncology Research Professionals:
CRAs: Karyn N. Hart, CCRP
..... Avidanka Baftirovska, BS, CCRP
Nurse: TBD
Patient Advocates: Ginny Mason, RN, BSN
..... Roberta Albany
Pharmaceutical Science: Jorge G. Avila, PharmD
..... Dawud Nael Dawud Ellayan, PharmD
Protocol Project Manager: Alicia Aranda
Clinical Trials Program Manager: Michelle Maxim

Time/Location

Friday, April 8, 2022 3:30 - 6:30 pm
Room: Columbia A, Level 3

Agenda

3:30 – 3:35 pm Welcome and Introductions - Lajos Pusztai, M.D., D.Phil. (Chair) and Priyanka Sharma, M.D. (Vice-chair), and Alicia Aranda (SWOG Protocol Project Manager)

3:35 – 4:20 pm Robert Livingston lecture - “Collaborations with Bob Livingston: A Lasting Legacy” by Dr. Daniel F Hayes MD, FASCO, FACP

4:20 – 4:30 pm Publication update – William Barlow, Ph.D.

4:30 – 4:40 pm Patient Advocate update – Ginny Mason and Roberta Albany

4:40 – 5:00 pm Translational Medicine Sub-Committee update - Alastair Thompson, M.D. and Andrew K. Godwin, Ph.D.

5:00 – 5:40 pm Review of open CTSU trials

5:40 – 6:15 pm Recently approved and developing Concepts

6:15 – 6:25 pm Reports from Committee Liaisons

Radiotherapy - Reshma Jagsi, M.D.

Surgery – Joshua Mammen, M.D.

Cancer Survivorship - Melinda L. Irwin, Ph.D., M.P.H.

Cancer Care Delivery - Dawn Hershman, M.D.

Prevention – Banu Arun, M.D.

Symptom Control & QOL - Helen K. Chew, M.D.

NCORP (NCI Community Oncology Research Program) – Philip Lammers, M.D.

DEI - Gayathri Nagaraj, M.D.

6:30 pm Closing Comments and Adjourn

Proposed Breast Cancer Committee Studies

S2202, “Phase II Clinical Trial for Patients with Minimal Residual Disease Despite Therapy for Triple Negative Breast Cancer with Trop-2 Antibody Drug Conjugate, Sacituzumab Govitecan (DETECT-01).” Drs. Bardia, Kalinsky, Bhav.

S2206, “Randomized Trial of Neoadjuvant Durvalumab 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.

S2212, “TIL Adapted Neo adjuvant Chemotherapy Optimization in Triple negative breast cancer (TACT-II).” Dr. Sharma

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Active Breast Cancer Committee Studies

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, Chalasani, Moran, Speers. Activated: 09/12/18.

S1007, "A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and Her2-Negative Breast Cancer with Recurrence Score (Rs) of 25 or Less. Rxponder: A Clinical Trial Rx Fnr Positive Node, Endocrine Responsive Breast Cancer." Drs. Kalinsky, Meric-Bernstam. Step 3 open to accrual 07/22/2021.

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.

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.

CTSUNRG-BR002, "A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer." Drs. Chmura and White. SWOG

Champion: Dr. Jagsi. Activated: 12/24/14. Temporarily closed: 09/13/19.

CTSUNRG-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.

CTSUNRG-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.

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: 04/13/17. Temporarily closed: 07/02/19.

CTSUNRG-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, Mammen, Henry, Jagsi. Activated: 11/15/16. Permanently closed: 06/30/21.

S1416, "Phase II Randomized Placebo-Controlled Trial of Cisplatin with or Without ABT-888 (Veliparib) in Metastatic Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer, with or Without Brain Metastases." Drs. Rodler, Sharma, Hicks, and Gralow. Activated 07/07/2016. Closed: 6/16/2019.

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.

S1222, "Fulvestrant Alone Versus Fulvestrant and Everolimus Versus Fulvestrant, Everolimus and Anastrozole: A Phase III Randomized

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Accrual from trial opening through 12/31/2021 by Institution and Study

	S1418	S1706	S2007	A011202	A011401	A011502	A011801	B51	EAT131	EAT181	EAT183	MA39	NRGBR003	NRGBR004
Ascension Prov Hospitals - Southfield	6	2	-	4	10	8	-	8	1	1	-	1	3	1
Ascension Via Christi Hospitals Wichita	9	-	-	-	-	-	-	-	-	-	-	-	-	-
Banner MD Anderson CC	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Banner U Med Ctr - Tucson	4	1	-	1	6	-	-	-	-	2	-	-	-	-
Baptist Mem HC/Mid South MU NCORP	9	3	-	1	4	-	-	-	-	-	-	-	-	1
Bay Area Tumor Inst NCORP	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Baylor U Med Ctr	-	-	-	1	-	-	-	2	-	-	-	-	-	-
Boston Med Ctr	-	-	-	-	3	-	-	-	-	2	-	-	-	-
CWRU Case CCC LAPS	12	-	-	-	2	-	-	5	-	-	-	1	9	1
Ca Res Consortium West Mich NCORP	24	-	-	-	1	-	-	-	-	-	-	-	-	-
Ca Res for the Ozarks NCORP	9	1	-	-	1	-	1	-	-	-	-	-	3	-
Ca Res of Wisconsin & N Mich Consort	7	-	-	-	-	-	-	-	-	-	-	-	-	-
Carle CC NCORP	3	-	1	-	-	-	-	-	-	-	-	-	-	-
City of Hope CCC	9	-	-	-	-	-	-	-	-	-	-	-	-	-
Columbia U MU NCORP	8	1	-	-	-	-	-	-	-	1	-	-	-	-
Columbus NCORP	13	-	-	-	-	-	-	-	-	-	-	-	-	-
CommonSpirit Health Research Inst	19	1	-	-	2	-	-	2	-	-	-	-	-	-
Cotton O'Neil CC / Stormont Vail Hlth	-	-	-	1	1	-	-	-	-	-	-	-	1	-
Dayton NCORP	3	-	-	-	1	-	-	-	1	2	-	-	-	-
Desert Regional Med Ctr	1	-	-	7	4	-	-	4	-	-	-	-	-	-
Essentia Health NCORP	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Fred Hutchinson Ca Res Ctr LAPS	10	2	-	-	12	9	-	-	-	-	-	-	-	-
Georgia NCORP	23	2	-	-	2	1	-	-	4	-	-	-	1	-
Gulf South MU NCORP	5	1	-	-	-	-	-	-	-	2	-	-	4	-
Hawaii MU NCORP	5	-	-	-	-	-	-	-	-	-	-	-	-	-
Heartland Ca Res NCORP	19	3	-	-	-	1	-	-	-	-	-	-	-	-
Henry Ford Hospital	1	-	-	-	-	-	-	-	1	-	-	-	-	-
Houston Methodist Hospital	-	-	-	-	-	-	1	1	-	-	-	-	-	-
Kaiser Permanente NCORP	51	-	-	1	55	25	-	-	-	-	-	-	25	1
Lahey Hospital & Med Ctr	3	-	-	-	9	5	-	-	1	4	-	-	-	1
Loma Linda U Med Ctr	1	-	-	3	-	-	-	3	-	-	-	-	-	-
Loyola U Med Ctr	3	-	-	-	6	7	-	1	2	1	-	-	-	-
Massachusetts Veterans ERIC	-	-	-	-	-	1	-	-	-	-	-	-	-	-
Medical U South Carolina MU NCORP	11	-	-	-	-	-	-	-	-	-	3	-	-	-
Meharry Medical College	-	-	-	-	3	-	-	-	-	-	-	-	1	-
Michigan Ca Res Consortium NCORP	21	1	-	-	-	-	-	-	-	-	-	-	-	-
Moffitt CC	-	-	-	1	3	2	-	-	-	-	-	-	-	-
Montana Cancer Consortium NCORP	2	3	-	-	-	-	-	-	-	-	-	-	-	-
Mount Sinai Hospital	3	-	-	-	-	-	-	-	-	-	-	-	-	-
NCORP Carolinas (Prisma Hlth NCORP)	4	-	-	-	-	-	-	-	-	-	-	-	-	-
Nevada Ca Res Foundation NCORP	11	-	-	-	-	-	-	-	-	-	-	-	-	-
New Mexico MU NCORP	19	4	-	-	-	-	-	-	-	-	-	-	-	-

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Accrual from trial opening through 12/31/2021 by Institution and Study

	S1418	S1706	S2007	A011202	A011401	A011502	A011801	B51	EA1731	EA1781	EA1783	MA39	NRGBR003	NRGBR004
Northwell Health NCORP	-	-	1	-	-	-	-	-	-	-	-	-	-	-
Northwestern U LAPS	2	1	-	-	-	-	-	-	-	2	1	-	1	-
Ohio State U CCC LAPS	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Oregon Health & Science U	19	-	-	-	-	-	-	1	-	-	3	-	3	-
Orlando Health Ca Inst	1	-	-	-	1	-	-	-	-	-	-	-	-	-
Pacific Ca Res Consortium NCORP	19	-	-	-	3	1	-	-	-	-	-	-	1	-
SCL Health Saint Joseph Hospital	-	-	-	-	1	-	-	-	-	-	-	-	-	-
Salem Hospital	-	-	-	4	-	-	-	-	-	-	-	-	-	-
Scott & White Mem Hospital	-	-	-	-	4	-	-	-	-	-	-	-	-	-
Southeast Clin Onc Res Consort NCORP	46	-	-	-	-	6	-	-	-	-	-	-	-	-
Sutter Ca Res Consortium	3	-	-	-	8	2	2	2	1	3	-	-	4	2
Don & Sybil Harrington CC	7	3	-	11	8	-	1	1	-	-	-	-	-	-
James Graham Brown CC at U Louisville	-	-	-	2	-	-	-	-	-	-	-	-	-	-
West Clinic - Wolf River	-	-	-	9	-	-	-	4	-	-	-	-	-	-
UC Davis CCC LAPS	8	4	-	2	4	17	-	-	-	-	-	-	-	-
UC Irvine Health/Chao Family CCC	6	-	-	3	2	2	-	1	-	-	-	-	1	-
UC San Diego Moores CC	-	-	-	-	2	3	-	-	-	-	-	-	1	-
USC Norris CCC LAPS	3	-	-	4	-	6	-	-	-	-	-	2	-	-
U Arkansas for Medical Sciences	17	2	-	-	3	22	-	-	-	-	-	-	-	-
U Cincinnati CC-UC Med Ctr	-	-	-	-	-	-	-	1	-	-	-	-	-	-
U Colorado CC LAPS	11	1	-	42	27	7	1	3	-	10	-	-	-	-
U Kansas CC - MCA Rural MU NCORP	22	2	-	4	23	9	-	-	-	-	-	-	-	-
U Kentucky/Markey CC	-	-	-	-	-	3	-	1	-	-	-	-	-	-
U Michigan CCC LAPS	13	2	-	-	14	11	-	-	-	1	-	4	3	-
U Mississippi Med Ctr	-	-	-	-	-	-	-	-	-	1	-	-	-	-
U Oklahoma Health Sciences Ctr LAPS	2	-	-	-	-	-	-	-	-	-	-	-	-	-
U Rochester LAPS	2	1	-	-	-	15	-	-	7	1	-	-	9	-
U Texas HSC at San Antonio	5	-	1	6	2	1	-	5	-	-	-	-	4	-
U Texas MD Anderson CC LAPS	21	1	-	-	-	-	-	-	-	-	-	-	-	-
U Utah - Huntsman Ca Inst LAPS	6	2	-	-	7	-	1	-	-	2	-	-	-	-
Upstate Carolina Consortium NCORP	8	-	-	-	1	-	-	-	-	-	-	-	-	-
Virginia Mason Med Ctr	1	-	-	-	-	-	-	1	-	-	-	-	-	-
Wayne State U - Karmanos Ca Inst LAPS	3	-	-	11	12	9	-	-	6	9	2	-	6	-
Western States Ca Res NCORP	4	-	-	-	-	-	-	-	-	-	-	-	-	-
William Beaumont Hosp-Royal Oak	1	-	-	6	5	2	-	1	-	-	-	-	-	-
Wisconsin NCORP	2	1	-	-	-	-	-	-	-	-	-	-	-	-
Yale U - Yale CC LAPS	8	-	-	5	81	31	-	-	6	1	-	-	9	-
ALLIANCE	144	10	-	-	-	-	-	-	-	-	-	-	-	-
CCTG	39	3	-	-	-	-	-	-	-	-	-	-	-	-
ECOG-ACRIN	129	5	1	-	-	-	-	-	-	-	-	-	-	-
NRG	307	33	-	-	-	-	-	-	-	-	-	-	-	-
Total	1,195	97	4	129	333	206	7	47	30	45	9	8	89	7

Breast Committee

Placebo-Controlled Trial in Postmenopausal Patients with Hormone-Receptor-Positive Stage IV Breast Cancer.” Drs. Moore, Somlo, Hayes, Kuhn, and Hicks. Activated 05/09/2014. Permanently Closed 10/15/2015.

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, Leja, Fabian, Godwin. Activated: 09/15/17.

Active 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, Lok, Gehring, Feld. Activated: 02/21/19.

S1714, “A Prospective Observational Cohort Study to Develop a Predictive Model of Taxane-Induced Peripheral Neuropathy in Cancer Patients.” Drs. Trivedi, Hershman, Brannagan, Hertz. Activated 03/01/19.

Active Cancer Care Delivery Studies

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

Active Cancer Prevention Studies

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, Kukafka, Hershman, Thomas, Caban-Holt. Activated: 09/01/20.

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

Active Early Therapeutics and Rare Cancers Studies

S1609, “DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors.” Drs. Patel, Chae, Kurzrock. Activated 01/13/17.

CTSU/EAY131, “Molecular Analysis for Therapy Choice (MATCH).” Dr. Flaherty. Activated 08/12/15.