

## **BREAST MEDICAL ONCOLOGY PRIORITIZATION LIST**

### **HER2 POSITIVE BREAST CANCER TRIALS:**

1. [Neo-adjuvant HER2 Positive](#)
2. [Adjuvant HER2 Positive](#)
3. [Metastatic HER2 Positive](#)
4. [HER2 Positive: Tissue/Biomarkers](#)

### **HR POSITIVE BREAST CANCER TRIALS:**

1. [Neo-adjuvant HR Positive](#)
2. [Adjuvant HR Positive](#)
3. [Metastatic HR Positive \(1<sup>st</sup> Line\)](#)
4. [Metastatic HR positive \(>1<sup>st</sup> Line\)](#)
5. [Supportive Care, Biomarker/Lab-Based](#)

### **IMMUNOTHERAPY:**

1. [Neo-adjuvant TNBC](#)
2. [Neo-adjuvant HER2+](#)
3. [Adjuvant ER+](#)
4. [Adjuvant HER2+](#)
5. [Adjuvant TNBC](#)
6. [Metastatic](#)
7. [Local Recurrence](#)

### **GENOMICALLY TARGETED OR ENRICHED TRIALS:**

1. [FGFR1/2 Amplification](#)
2. [PIK3CA mutation/PTEN loss](#)
3. [HER2 mutations](#)
4. [TP53 Wild Type](#)

### **TRIPLE NEGATIVE BREAST CANCER:**

1. [Neoadjuvant TNBC](#)
2. [Neoadjuvant TNBC – Phase 2 Moonshot Trials](#)
3. [Adjuvant TNBC](#)
4. [First line Metastatic TNBC](#)
5. [Second Line Metastatic TNBC](#)
6. [≥3 Lines for mTNBC](#)

### **BREAST CANCER WITH BRAIN METASTASIS:**

1. [HER2+ \(BMO\)](#)
2. [HER2- \(BMO\)](#)

### **BRCA BREAST CANCER TRIALS:**

1. [Neoadjuvant](#)
2. [Metastatic](#)

Updated April 4th, 2024

3. [TNBC](#)

[ELDERLY ADULT:](#)

[HIGH RISK AND PREVENTION:](#)

[SYMPTOM MANAGEMENT:](#)

[INFLAMMATORY BREAST CANCER:](#)

1. [IBC Registry](#)
2. [Neoadjuvant TNIBC, HER2-/ER+, HER2+/Any HR](#)
3. [Adjuvant HR Positive IBC](#)
4. [IBC With Metastasis](#)

**HER2 POSITIVE BREAST CANCER TRIALS:**

1. [Neo-adjuvant HER2 Positive](#)

- a. [2021-0358](#): A Phase II Single-Arm Open-Label Pilot Trial Evaluating Zanidatamab (ZW25) in Patients with Early Stage HER2/neu Positive (HER2+) Breast Cancer (BC)  
PI: Vicente Valero  
SM: [Heather Alonzo](#), RN 832-728-0675 / Coverage-Shade Bambe, RN 832-729-0241
- b. [2016-0046](#) Multicenter Trial for Eliminating Breast Cancer Surgery in Exceptional Responders with Neoadjuvant Systemic Therapy  
PI: Henry Kuerer/Vicente Valero  
SM: [Cari Fiero](#) (pager 713-404-9028)
- c. [2021-1157](#) MARGetuximab or Trastuzumab (MARGOT): A phase II study comparing neoadjuvant paclitaxel/margetuximab/pertuzumab to paclitaxel/trastuzumab/pertuzumab in patients with Stage II-III HER2-positive breast cancer  
PI: Paula Pohlmann  
SM: Toni Zaayman, RN – 832-546-7723 / Coverage – Shade Bambe, RN – 832-728-0241 / Heather Alonzo, RN – 832-728-0675
- d. [2023-0100](#): TRUDI: A phase II study of neoadjuvant Trastuzumab deruxtecan and Durvalumab (MEDI4736) for stage III, Her2-expressing inflammatory Breast Cancer  
PI: Rachel Layman  
SM: Angela Marx, RN 832-450-6027

2. [Adjuvant HER2 Positive](#)

- a. [2022-0484](#): A randomized phase II trial of adjuvant trastuzumab emtansine (T-DM1) followed by subcutaneous trastuzumab versus paclitaxel in combination with subcutaneous trastuzumab for Stage I HER2-positive breast cancer (ATEMPT 2.0)  
PI: Vicente Valero, MD  
SM: Cindy Tamez (832-269-1396) / Coverage – Makeba Faniel (832-294-4690)
- b. [2021-0081](#): 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 Compared with T-DM1 and Tucatinib.

PI: Rashmi Murthy

SM: Cynthia Tamez (832-269-1396)/Makeba Faniel (713-794-3136)

- c. [2021-0792](#): A single arm phase II study of Adjuvant Endocrine therapy, subcutaneous Pertuzumab, and Trastuzumab fixed-dose combination for patients with anatomic stage I hormone receptor positive, HER2-positive breast cancer (ADEPT)

PI: Vicente Valero

SM: Cindy Tamez (832-269-1396) / Coverage – Makeba Faniel (832-294-4690)

### 3. Geriatric/Lab-Based Trials

- a. [2020-1125](#): Implementation of a Geriatric Care Survivorship Intervention in Older Adults who have Completed Curative Intent Therapy for Early-Stage Breast Cancer

PI: Meghan Karuturi

SM: Cynthia Tamez (832-269-1396)/Coverage: Makeba Faniel (713-794-3136)/Keena Woods (832-596-2985)

### 4. Metastatic HER2 Positive

#### FIRST LINE:

- a. [2022-1085](#): A Phase 1, multicenter, open-label, first-in-human study of YL202 in patients with locally advanced or metastatic non-small cell lung cancer and breast cancer

PI: Damodaran, Senthil

SM: Keena Woods ([kmwoods@mdanderson.org](mailto:kmwoods@mdanderson.org), 713-792-6679)

- b. [2019-0993](#): Outcomes and Prognostic Factors in Metastatic Breast Cancer Patients at MD Anderson Cancer Center

PI: Abbey Kaler

SM: [Makeba Faniel](#) (pager 713-404-6688)

- c. [PA13-0592](#): Establishment of Patient-derived Xenografts (PDX) Models for Solid Tumors

PI: Funda Meric-Bernstam

SC: [Bryce Kirby](#) (713-563-0834)

#### SECOND LINE:

- a. [2022-0674](#): A Phase 1 Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of ZN-A-1041 Enteric Capsules as a Single Agent or in Combination in Patients with HER2-Positive Advanced Solid Tumors

PI: Rashmi Murthy

SM: Keena Woods ([kmwoods@mdanderson.org](mailto:kmwoods@mdanderson.org), 713-792-6679)

- b. [2021-0783](#): A Global, Phase 2 Study of ARX788 in HER2-positive Metastatic Breast Cancer Patients who were previously treated with T-DXd

PI: Debu Tripathy

SM: Afolashade Bambe ([AOBambe@mdanderson.org](mailto:AOBambe@mdanderson.org), 713-792-0909)

- c. [2019-0993](#): Outcomes and Prognostic Factors in Metastatic Breast Cancer Patients at MD Anderson Cancer Center

Updated April 4th, 2024

PI: Abbey Kaler

SM: [Makeba Faniel](#) (pager 713-404-6688)

- d. [2020-0198](#): Neratinib and Capmatinib combination (phase IB/II) in metastatic breast cancer and inflammatory breast cancer patients with abnormal HER2 and c-Met pathway activity as measured by the CELsignia Signaling Analysis Test

PI: Rachel M. Layman

SM: Vivian Chiv, RN (713-859-1576)

- e. [2022-0764](#): I-SPY-Phase I/Ib (PRE-I-SPY Program) PRE-Investigation of serial studies to predict your therapeutic response with imaging and molecular analysis: A Phase I/Ib platform trial

PI: Paula Pohlmann

SC: Heather Walker (713-792-4534), Julia Moore (713-792-5199)

**THIRD LINE:**

- a. [2022-0787](#): Phase I multicenter, open-label, first-in-human study of ORM-5029 in subjects with HER2-expressing Advanced Solid Tumors

PI: Paula Pohlmann

Contact: Heather Alonzo (832-728-0675) / Coverage: Shade Bambe (832-729-0241)

- b. [2019-0993](#): Outcomes and Prognostic Factors in Metastatic Breast Cancer Patients at MD Anderson Cancer Center

PI: Abbey Kaler

SM: [Makeba Faniel](#) (pager 713-404-6688)

- c. [2020-0198](#): Neratinib and Capmatinib combination (phase IB/II) in metastatic breast cancer and inflammatory breast cancer patients with abnormal HER2 and c-Met pathway activity as measured by the CELsignia Signaling Analysis Test

PI: Rachel M. Layman

SM: Vivian Chiv, RN (713-859-1576)

- d. [2022-0764](#): I-SPY-Phase I/Ib (PRE-I-SPY Program) PRE-Investigation of serial studies to predict your therapeutic response with imaging and molecular analysis: A Phase I/Ib platform trial

PI: Paula Pohlmann

SC: Heather Walker (713-792-4534), Julia Moore (713-792-5199)

**ICT (ANY LINE):**

- a. [2021-0455](#): A Phase 1/1b Open-label, First-in-Human, Single Agent, Dose Escalation and Expansion Study for the Evaluation of Safety, Pharmacokinetics, Pharmacodynamics, and Anti-tumor Activity of SAR443216 in Participants with Relapsed/Refractory HER2 Expressing Solid Tumors (**Note: Allows non-symptomatic untreated brain mets and selects for HER2 1+, 2+ 3+ or HER2 activating mutations**)

PI: Ecaterina Dumbrava

SM: [Amber Kennon](#) (pager 713-582-3394)

Updated April 4th, 2024

- b. [2021-0298](#): A Phase 1b/2, 2-part Open-label Study to Assess the Safety and Antitumor Activity of Zanidatamab in Combination with ALX148 in Advanced HER2-expressing Cancer (\*Phase 1)  
PI: Funda Meric-Bernstam  
SM: [Noia Barreto, Carmelia Maria](#)
- c. [2017-1009](#): A Phase 1, Open-Label, Dose Escalation Study of the Safety and Pharmacokinetics of BTRC4017A administered Intravenously in Patients with Locally Advanced or Metastatic HER2-expressing cancers (Note: enrolling HR+ and TNBC patients) (\*Phase1)  
PI: Timothy Yap  
SM: [Ileana Gutierrez](#) (pager 713-404-4133)
- d. [2019-1232](#): A Phase I, Open Label, Dose Escalation Study of ACE1702 Cell Immunotherapy in Subjects with Advanced or Metastatic HER2- expressing Solid Tumors  
PI: Sarina Piha-Paul  
SM: [Xueyao Fu](#) (pager 713-606-7210)
- e. [2019-1111](#): Phase 1/2 Study of BDC-1001 as a Single Agent and in Combination with Pembrolizumab in Patients with Advanced HER2-Expressing Solid Tumors (Note: Allows HER2 2+ and 3+ FISH negative and gene amplification)  
PI: Ecaterina Dumbrava  
SM: [Amber Kennon](#) (pager 713-582-3394)
- f. [2020-0675](#): A Phase 1/2, Open-Label, Multicenter, Non-Randomized, Safety and Activity Study of HER2-Targeted Dual Switch CAR-T Cells (BPX-603) in Subjects with Previously Treated Advanced HER2-Positive Solid Tumors  
PI: Ecaterina Dumbrava  
SM: [Jeane Painter](#) (pager 713-404-1201)
- g. [2020-1161](#): A Phase I/II Trial Investigating Safety and Efficacy of Autologous TACT Cells Targeting HER2 in Relapsed or Refractory Solid Tumors (TACTIC-2) (Note: Allows HER2 1+, 2+, 3+)  
PI: Ecaterina Dumbrava  
SM: [Afzal Ahrorov](#) (pager 713-408-6453)
- h. [2020-0764](#): A Modular Phase I/IIa, Open-label, Multi-center Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Preliminary Efficacy of Ascending Doses of AZD5305 as Monotherapy and in Combination with Anti-cancer Agents in Patients with Advanced Solid Malignancies (PETRA)  
PI: Timothy Yap  
RN: [Danielle Garcia](#) (832-441-4786)  
SM: [Akosua Badu-Nkansah](#) (7133-859-5334)
- i. [2019-1175](#): A Phase 1/2, Open-Label, Two-part, Multicenter Study to Assess the Safety, Tolerability, Pharmacokinetics and Antitumor Activity of BDTX-189, an Inhibitor of Allosteric ErbB Mutations, in Patients with Advanced Solid Malignancies

Updated April 4th, 2024

PI: Jordi Rodon

SM: [Uyen Vu](#) (pager 713-404-4987)

- j. [2019-0993](#): Outcomes and Prognostic Factors in Metastatic Breast Cancer Patients at MD Anderson Cancer Center

PI: Abbey Kaler

SM: [Makeba Faniel](#) (pager 713-404-6688)

- n. [2020-0198](#): Neratinib and Capmatinib combination (phase IB/II) in metastatic breast cancer and inflammatory breast cancer patients with abnormal HER2 and c-Met pathway activity as measured by the CELsignia Signaling Analysis Test

PI: Rachel M. Layman

SM: Vivian Chiv, RN (713-859-1576)

## 5. [HER2 Positive: Tissue/Biomarkers](#)

### **HR POSITIVE BREAST CANCER TRIALS:**

#### 1. [Neo-adjuvant HR Positive](#)

- a. [2023-0568](#): ETHAN: A phase II study comparing different Endocrine Therapies for male breast cancer

PI: Jasmine Sukumar

SM: Heather Alonzo, Sr. RN (832-728-0675)/Alyson Clayborn, Sr. RN (713-745-8748)

#### 2. [Adjuvant HR Positive](#)

- a. [NRG-BR007](#): De-Escalation of Breast Radiation Trial for Hormone Sensitive, HER-2 Negative, Oncotype Recurrence Score Less Than or Equal to 18 Breast Cancer (DEBRA)  
PI: Shaitelman. BMO Collaborator: Layman  
SC: [Lynn Isales](#) (281-814-6535)
- b. [2020-1125](#): Implementation of a Geriatric Care Survivorship Intervention in Older Adults who have Completed Curative Intent Therapy for Early-Stage Breast Cancer

PI: Meghan Karuturi

SM: Cynthia Tamez (832-269-1396)/Coverage: Makeba Faniel (713-794-3136)/Keena Woods (832-596-2985)

#### 3. [Metastatic HR Positive \(1<sup>st</sup> Line\)](#)

- a. [2023-0691](#): A phase 1b/2, open-label umbrella study to evaluate safety and efficacy of Elacestrant in various combinations in patients with Metastatic Breast Cancer (ELEVATE)  
PI: Vicente Valero  
RN: Alyson Clayborn ([ARClayborn@mdanderson.org](mailto:ARClayborn@mdanderson.org), 713-75-8748)
- b. [2019-0993](#): Outcomes and Prognostic Factors in Metastatic Breast Cancer Patients at MD Anderson Cancer Center

PI: Abbey Kaler

SM: [Makeba Faniel](#) (pager 713-404-6688)

- c. [2022-0315](#): Phase 1b study of EZH1/2 inhibitor valemetostat in combination with trastuzumab deruxtecan in subjects with HER2 low/ultra-low/null metastatic breast cancer  
PI: Senthil Damodaran  
SM: Angela Marx, RN (832-450-6027)
- d. [PA19-0047](#): Biomarkers of Resistance to Hormonal Therapy in Hormone Receptor (HR) Positive Breast Cancer (for new patients starting on any CDK)  
RN: [Jill Schwartz-Gomez](#) (RN 713-729-6453, Cell 832-829-6453)  
SM: Maggie Zarate (713-563-5779)
- e. [2023-0260](#): A phase 1b open-label multicenter study of OP-1250 in combination with the CDK4/6 Inhibitor Ribociclib or with the PI3K Inhibitor Alpelisib in adult subjects with advanced and/or metastatic HR positive, HR2 negative breast cancer  
PI: Jason Mouabbi  
SC: Keena Woods ([kmwoods@mdanderson.org](mailto:kmwoods@mdanderson.org), 713-792-6679) **ON HOLD**

**4. [Metastatic HR Positive \(>1<sup>st</sup> Line\)](#)**

- a. [2022-0357](#): Phase 1b/2 Study of the Addition of STAT3 inhibitor TTI-101 to Reverse Resistance on First-Line Palbociclib Plus Aromatase Inhibitor Therapy for Metastatic Hormone Receptor-Positive and Her2-Negative Breast Cancer  
PI: Debu Tripathy  
SM: Cindy Tamez (832-269-1396) / Coverage – Makeba Faniel (832-294-4690)
- b. [2023-0316](#): An open label, randomized, multicenter study comparing the efficacy and safety of the combination of Lasofoxifene and Abemaciclib to the combination of Fulvestrant and Abemaciclib for the treatment of pre-and postmenopausal women and men with locally advanced or metastatic ER+/HER2- breast cancer with an ESR1 mutation  
PI: Senthil Damodaran  
RN: Toni Zaayman ([TLZaayman@mdanderson.org](mailto:TLZaayman@mdanderson.org), 713-834-6567)
- c. [2023-0691](#): A phase 1b/2, open-label umbrella study to evaluate safety and efficacy of Elacestrant in various combinations in patients with Metastatic Breast Cancer (ELEVATE)  
PI: Vicente Valero  
RN: Alyson Clayborn ([ARClayborn@mdanderson.org](mailto:ARClayborn@mdanderson.org), 713-75-8748)
- d. [2022-0623](#): A Phase 3, Open-Label, Randomized, Two-Part Study Comparing Gedatolisib in Combination with Palbociclib and Fulvestrant to Standard-of-Care Therapies in Patients with HR-Positive, Her2-Negative Advanced Breast Cancer Previously Treated with a CDK4/6 Inhibitor in Combination with Non-Steroidal Aromatase Inhibitor Therapy (VIKTORIA-1)  
PI: Rachel Layman  
SM: Makeba Faniel (832-294-4690) / Coverage: Cindy Tamez (832-269-1396)

- e. [2022-0638](#): An Open-label Multicenter Phase 1b-2 Study of Elacestrant as Monotherapy and in Combination with Abemaciclib in Women and Men with Brain Metastasis from Estrogen Receptor Positive, Her2-Negative Breast Cancer (ELECTRA)  
PI: Nuhad Ibrahim  
SM: Shade Bambe (713-792-0909)/Coverage: Heather Alonzo (832-728-0675)/Toni Zaayman (832-546-7723)
- f. [2023-0009](#): Tactive-U: An interventional safety and efficacy phase 1b/2, open label umbrella study to investigate tolerability, Pk, and antitumor activity of ARV-471 (PF-07850327), an oral proteolysis targeting chimera, in combination with other anticancer treatments in participants aged 18 years and over with ER+ advanced or metastatic breast cancer, sub-study a (ARV-471 in combination with Abemaciclib)  
PI: Rachel Layman  
SM: Lamiae Sahnoune ([LSahnoune@mdanderson.org](mailto:LSahnoune@mdanderson.org), 713-792-7173)
- g. [2023-0130](#): TACTIVE-U: an interventional safety and efficacy phase 1b/2, open-label umbrella study to investigate tolerability, pk, and antitumor activity of ARV-471 (pf-07850327), an oral proteolysis targeting chimera, in combination with other anticancer treatments in participants aged 18 years and over with er+ advanced or metastatic breast cancer, sub-study b (ARV-471 in combination with Ribociclib)  
PI: Rachel Layman  
SM: Lamiae Sahnoune ([LSahnoune@mdanderson.org](mailto:LSahnoune@mdanderson.org), 713-792-7173)
- h. [2021-0875](#): A Phase 1 Dose Escalation and Expansion Study to Evaluate Safety, Tolerability, Pharmacokinetic, Pharmacodynamic, and Anti-Tumor Activity of PF-07248144 in Participants with Advanced or Metastatic Solid Tumors  
PI: [Rachel Layman](#)  
SM: Heather Alonzo, RN (832-728-0675) / Coverage – Shade Bambe, RN (832-729-0241)
- i. [2023-0266](#): A phase I clinical study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary anti-tumor activity of AC699 in patients with estrogen receptor positive/human epidermal growth factor receptor 2 negative (ER+/HER2-) locally advanced or metastatic Breast Cancer  
PI: Rachel Layman  
SM: Makeba Faniel ([MNFaniel@mdanderson.org](mailto:MNFaniel@mdanderson.org), 713-794-3136)
- j. [2021-0033](#): Evaluation of Talazoparib, a PARP Inhibitor, in Patients with Somatic BRCA Mutant Metastatic Breast Cancer: Genotyping Based Clinical Trial  
PI: Senthil Damodaran  
SM: Makeba Faniel (832-294-4690 / Cindy Tamez (832-269-1396)
- k. [2020-0198](#): Neratinib and Capmatinib combination (phase IB/II) in metastatic breast cancer and inflammatory breast cancer patients with abnormal HER2 and c-Met pathway activity as measured by the CELsignia Signaling Analysis Test  
PI: Rachel M. Layman  
SM: Vivian Chiv, RN (713-859-1576)

Updated April 4th, 2024

- l. [2023-0263](#): AIPAC-003: A randomized, double-blind, placebo-controlled Phase 3 trial testing eftilagimod alpha (soluble LAG-3) in HER2-neg/low metastatic breast cancer patients receiving paclitaxel, following an open-label dose optimization  
PI: Nuha Ibrahim  
SM: Alyson Clayborn, Sr. RN ([ARClayborn@mdanderson.org](mailto:ARClayborn@mdanderson.org), 713-745-8748)
- m. [2022-0397](#): A Phase 1/2a, Multicenter, Open-Label, Non-Randomized First in Human Study to Assess the Safety, Tolerability, Pharmacokinetics, and Preliminary Antitumor Activity of DB-1305 in Subjects with Advanced/Metastatic Solid Tumors.  
PI: Senthil Damodaran  
SM: Keena Woods (832-596-2985) / Coverage: Olaia Kizzee (832-450-0990)
- m. [2019-0993](#): Outcomes and Prognostic Factors in Metastatic Breast Cancer Patients at MD Anderson Cancer Center  
PI: Abbey Kaler  
SM: [Makeba Faniel](#) (pager 713-404-6688)
- n. [PA19-0047](#): Biomarkers of Resistance to Hormonal Therapy in Hormone Receptor (HR) Positive Breast Cancer (for all CDK inhibitors progressions)  
RN: [Jill Schwartz-Gomez](#) (RN 713-729-6453, Cell 832-829-6453)  
SM: Maggie Zarate (713-563-5779)

#### 5. [Supportive Care, Biomarker/Lab-Based](#)

- a. [2020-1125](#): Implementation of a Geriatric Care Survivorship Intervention in Older Adults who have Completed Curative Intent Therapy for Early-Stage Breast Cancer  
PI: Meghan Karuturi  
SM: Cynthia Tamez (832-269-1396)/Coverage: Makeba Faniel (713-794-3136)/Keena Woods (832-596-2985)
- b. [PA19-0047](#): Biomarkers of Resistance to Hormonal Therapy in Hormone Receptor (HR) Positive Breast Cancer  
RN: [Jill Schwartz-Gomez](#) (RN 713-729-6453, Cell 832-829-6453)  
SM: Maggie Zarate (713-563-5779)
- c. [PA15-1026](#): Department of Breast Medical Oncology Universal blood biorepository  
PI: Carlos Barcenas  
SM: [Angela Alexander](#) (cell #832596-2958)
- d. [PA18-1100](#): Biomarker discovery study of DS-8201A, an anti-HER2 antibody drug conjugate, in randomized phase III trials (DS-8201A-U301, U302, U303) in unresectable and/or metastatic breast cancer and in patients receiving DS-8201A as standard of care treatment  
PI: Azadeh Nasrazadani  
SM: [Angela Alexander](#) (cell #832-450-5265)
- e. [2022-0150](#): A Feasibility and Acceptability Pilot Study Evaluating a Patient-Specific Targeted Intervention Using Patient Navigators or Routine Clinical Care  
PI: Mariana Chavez Mac Gregor, MD

Updated April 4th, 2024

Coordinator: Catalina Malinowski, [CMalinowski@mdanderson.org](mailto:CMalinowski@mdanderson.org), 713-516-2406

## **IMMUNOTHERAPY**

1. [Neo-adjuvant TNBC](#)
2. [Neo-adjuvant HER2+](#)
3. [Neo-adjuvant ER+](#)
4. [Adjuvant ER+](#)
5. [Adjuvant ER+ IBC](#)
6. [Adjuvant HER2+](#)
7. [Adjuvant TNBC](#)
8. [Metastatic ER+](#)
9. [Metastatic – IBC/TNBC](#)
  - a. [2019-0993](#): Outcomes and Prognostic Factors in Metastatic Breast Cancer Patients at MD Anderson Cancer Center  
PI: Abbey Kaler  
SM: [Makeba Faniel](#) (pager 713-404-6688)
  - b. PA19-0047: Biomarkers of Resistance to Hormonal Therapy in Hormone Receptor (HR) Positive Breast Cancer (for all CDK inhibitors progressions)  
RN: [Jill Schwartz-Gomez](#) (RN 713-729-6453, Cell 832-829-6453)  
SM: Maggie Zarate (713-563-5779)
10. [Local Recurrence](#)

## **GENOMICALLY TARGETED OR ENRICHED TRIALS**

1. [FGFR1/2 Amplification](#)
2. [PIK3CA Mutation/PTEN Loss](#)
3. [HER2 Mutations](#)
  - a. [2013-0904](#): An Open-Label, Phase 2 Study of Neratinib in Patients with Solid Tumors with Somatic Human Epidermal Growth Factor Receptor (EGFR, HER2, HER3) mutations or EGFR Gene Amplification  
PI: Sarina Piha-Paul  
SM: [Rabia Khan](#) (pager 713-404-4901)
4. [TP53 Wild Type](#)
5. [ESR1 Mutation](#)
  - b. [2023-0316](#): An open label, randomized, multicenter study comparing the efficacy and safety of the combination of Lasofoxifene and Abemaciclib to the combination of Fulvestrant and Abemaciclib for the treatment of pre-and postmenopausal women and men with locally advanced or metastatic ER+/HER2- breast cancer with an ESR1 mutation  
PI: Senthil Damodaran

Updated April 4th, 2024

RN: Toni Zaayman ([TLZaayman@mdanderson.org](mailto:TLZaayman@mdanderson.org), 713-834-6567)

**6. Androgen Receptor Positive**

**7. Somatic BRCA Mutation**

- a. [2021-0033](#): Evaluation of Talazoparib, a PARP Inhibitor, in Patients with Somatic BRCA Mutant Metastatic Breast Cancer: Genotyping Based Clinical Trial  
PI: Senthil Damodaran  
SM: Makeba Faniel (832-294-4690 / Cindy Tamez (832-269-1396)

**TRIPLE NEGATIVE BREAST CANCER**

**1. Neoadjuvant TNBC**

- a. [2022-0439](#): P-RAD: A randomized study of preoperative chemotherapy, pembrolizumab and No, low or high dose radiation in node-positive, HER2-negative breast cancer  
PI: Haven Garber  
SM: Afolashade Bambe ([AObambe@mdanderson.org](mailto:AObambe@mdanderson.org), 713-792-0909)
- b. [2014-0185](#): Improving Outcomes in Triple-Negative Breast Cancer Using Molecular Triaging and Diagnostic Imaging to Guide Neoadjuvant Therapy (Moonshot Platform) (**INTERNAL HOLD; not enrolling**)  
PI: Clinton Yam  
SM: Alyson Clayborn, RN (713-606-7540)/Coverage: Courtney Bevel (832-729-2458)
- c. [2022-0431](#): A Phase II study of neoadjuvant sacituzumab govitecan and pembrolizumab therapy for immunochemotherapy-resistant early-stage triple-negative breast cancer (TNBC)  
PI: Yam, Clinton  
SM: Alfoshade Bambe ([AObambe@mdanderson.org](mailto:AObambe@mdanderson.org), 713-792-0909)
- d. [2020-1125](#): Implementation of Geriatric Care Survivorship Intervention in Older Adults who have Completed Curative Intent Therapy for Early-Stage Breast Cancer  
PI: Meghan Karuturi  
SM: Cynthia Tamez (832-269-1396)/Coverage: Makeba Faniel (713-794-3136)/Keena Woods (832-596-2985)
- e. [2019-1237](#): Precision Performance Status Assessment in Early Stage Triple-Negative Breast Cancer Patients Receiving Neoadjuvant Therapy **"Observational"**  
PI: Meghan Karuturi  
Manager: [Sanda Tin](#) (832-829-5199)

**2. Neoadjuvant TNBC – Phase 2 Moonshot Trials**

**3. Neoadjuvant TNBC –BRCA+**

**4. Adjuvant TNBC**

- a. [2020-1125](#): Implementation of a Geriatric Care Survivorship Intervention in Older Adults who have Completed Curative Intent Therapy for Early-Stage Breast Cancer  
PI: Meghan Karuturi

SM: Cynthia Tamez (832-269-1396)/Coverage: Makeba Faniel (713-794-3136)/Keena Woods (832-596-2985)

- b. [2023-0157](#): A randomized, open-label, phase 3 study of adjuvant Sacituzumab Govitecan and Pembrolizumab versus treatment of physician's choice in patients with triple negative breast cancer who have residual invasive disease after surgery and neoadjuvant therapy

PI: Clinton Yam

SM: Alfoshade Bambe ([AOBambe@mdanderson.org](mailto:AOBambe@mdanderson.org), 713-792-0909)

#### 5. First line Metastatic TNBC

- a. [2023-0263](#): AIPAC-003: A randomized, double-blind, placebo-controlled Phase 3 trial testing eftilagimod alpha (soluble LAG-3) in HER2-neg/low metastatic breast cancer patients receiving paclitaxel, following an open-label dose optimization

PI: Nuha Ibrahim

SM: Alyson Clayborn, Sr. RN ([ARClayborn@mdanderson.org](mailto:ARClayborn@mdanderson.org), 713-745-8748)

- b. [2022-0353](#): A Phase 3, Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) Versus Investigator's Choice of Chemotherapy in Patients who are not Candidates for PD-1/PD-L1 Inhibitor Therapy in First-Line Locally Recurrent Inoperable or Metastatic Triple-Negative Breast Cancer (TROPION-Breast02)

PI: Senthil Damodaran

SC: Afolashade (Shade) Bambe, [AOBambe@mdanderson.org](mailto:AOBambe@mdanderson.org), 713-792-0909

- c. [2022-0315](#): Phase 1b study of EZH1/2 inhibitor valemetostat in combination with trastuzumab deruxtecan in subjects with HER2 low/ultra-low/null metastatic breast cancer

PI: Senthil Damodaran

SM: Angela Marx, RN (832-450-6027)

- d. [2022-0204](#): A Randomized, Open-label, Phase 3 Study of Sacituzumab Govitecan and Pembrolizumab Versus Treatment of Physician's Choice and Pembrolizumab in Patients With Previously Untreated, Locally Advanced, Inoperable, or Metastatic Triple-Negative Breast Cancer (ASCENT04)

PI: Clinton Yam

SM: Toni Zaayman, RN (832-546-7723) / Coverage: Shade Bambe, RN (832-728-0241) & Heather Alonzo, RN (832-728-0675)

- e. [2021-0611](#): A Phase II Study of Pembrolizumab in Combination with Lenvatinib in Patients with TNBC, NSCLC, and Other Tumor Types and Brain Metastasis

PI: Jordi Rodon

SM: [Caitlin Creasy](#) (office mobile 832-728-5851)

- f. [2019-0993](#): Outcomes and Prognostic Factors in Metastatic Breast Cancer Patients at MD Anderson Cancer Center

PI: Abbey Kaler

SM: [Makeba Faniel](#) (pager 713-404-6688)

**6. Second Line Metastatic TNBC**

- a. [2022-0397](#): A Phase 1/2a, Multicenter, Open-Label, Non-Randomized First in Human Study to Assess the Safety, Tolerability, Pharmacokinetics, and Preliminary Antitumor Activity of DB-1305 in Subjects with Advanced/Metastatic Solid Tumors.  
PI: Senthil Damodaran  
SM: Keena Woods (832-596-2985) / Coverage: Olaia Kizzee (832-450-0990)
- b. [2021-0033](#): Evaluation of Talazoparib, a PARP Inhibitor, in Patients with Somatic BRCA Mutant Metastatic Breast Cancer: Genotyping Based Clinical Trial  
PI: Senthil Damodaran  
SM: Makeba Faniel (832-294-4690) / Cindy Tamez (832-269-1396)
- c. [2021-0611](#): A Phase II Study of Pembrolizumab in Combination with Lenvatinib in Patients with TNBC, NSCLC, and Other Tumor Types and Brain Metastasis  
PI: Jordi Rodon  
SM: [Caitlin Creasy](#) (office mobile 832-728-5851)
- d. [2019-0993](#): Outcomes and Prognostic Factors in Metastatic Breast Cancer Patients at MD Anderson Cancer Center  
PI: Abbey Kaler  
SM: [Makeba Faniel](#) (pager 713-404-6688)
- e. [2020-0198](#): Neratinib and Capmatinib combination (phase IB/II) in metastatic breast cancer and inflammatory breast cancer patients with abnormal HER2 and c-Met pathway activity as measured by the CELSignia Signaling Analysis Test  
PI: Rachel M. Layman  
SM: Vivian Chiv, RN (713-859-1576)
- f. [2022-0764](#): I-SPY-Phase I/Ib (PRE-I-SPY Program) PRE-Investigation of serial studies to predict your therapeutic response with imaging and molecular analysis: A Phase I/Ib platform trial  
PI: Paula Pohlmann  
SC: Heather Walker (713-792-4534), Julia Moore (713-792-5199)

**6. ≥3 Lines for mTNBC**

- a. [2022-0688](#): A phase I study to assess the safety and efficacy of LyL797, ROR1-targeting CAR T cells, in adults with relapsed and/or refractory solid tumor malignancies  
PI: Haven Garber  
SM: Heather Alonzo ([HRAlonzo@mdanderson.org](mailto:HRAlonzo@mdanderson.org), 832-728-0675)
- b. [2022-0397](#): A Phase 1/2a, Multicenter, Open-Label, Non-Randomized First in Human Study to Assess the Safety, Tolerability, Pharmacokinetics, and Preliminary Antitumor Activity of DB-1305 in Subjects with Advanced/Metastatic Solid Tumors.  
PI: Senthil Damodaran  
SM: Keena Woods (832-596-2985) / Coverage: Olaia Kizzee (832-450-0990)
- c. [2021-0033](#): Evaluation of Talazoparib, a PARP Inhibitor, in Patients with Somatic BRCA Mutant Metastatic Breast Cancer: Genotyping Based Clinical Trial

Updated April 4th, 2024

PI: Senthil Damodaran

SM: Makeba Faniel (832-294-4690 / Cindy Tamez (832-269-1396)

- d. [2019-0993](#): Outcomes and Prognostic Factors in Metastatic Breast Cancer Patients at MD Anderson Cancer Center

PI: Abbey Kaler

SM: [Makeba Faniel](#) (pager 713-404-6688)

- e. [2021-0611](#): A Phase II Study of Pembrolizumab in Combination with Lenvatinib in Patients with TNBC, NSCLC, and Other Tumor Types and Brain Metastasis

PI: Jordi Rodon

SM: [Caitlin Creasy](#) (office mobile 832-728-5851)

- f. [2020-0198](#): Neratinib and Capmatinib combination (phase IB/II) in metastatic breast cancer and inflammatory breast cancer patients with abnormal HER2 and c-Met pathway activity as measured by the CELsignia Signaling Analysis Test

PI: Rachel M. Layman

SM: Vivian Chiv, RN (713-859-1576)

- g. [2022-0764](#): I-SPY-Phase I/Ib (PRE-I-SPY Program) PRE-Investigation of serial studies to predict your therapeutic response with imaging and molecular analysis: A Phase I/Ib platform trial

PI: Paula Pohlmann

SC: Heather Walker (713-792-4534), Julia Moore (713-792-5199)

**8. [Metastatic TNBC and Chest wall Metastasis](#)**

- a. [2019-0993](#): Outcomes and Prognostic Factors in Metastatic Breast Cancer Patients at MD Anderson Cancer Center

PI: Abbey Kaler

SM: [Makeba Faniel](#) (pager 713-404-6688)

**BREAST CANCER WITH BRAIN METASTASIS**

**1. [HER2+ \(BMO\)](#)**

- a. [2022-0910](#): BRIDGET: Secondary BRain metastases prevention after Isolated intracranial progression on Trastuzumab/Pertuzumab or T-DM1 in patients with aDvanced human epidermal Growth factor receptor 2+ brEast cancer with the addition of Tucatinib

PI: Rashmi Murthy

SM: Afolashade Bambe ([AObambe@mdanderson.org](mailto:AObambe@mdanderson.org), 713-792-0909)

- b. [2022-0674](#): A Phase 1 Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of ZN-A-1041 Enteric Capsules as a Single Agent or in Combination in Patients with HER2-Positive Advanced Solid Tumors

PI: Rashmi Murthy

SM: Keena Woods ([kmwoods@mdanderson.org](mailto:kmwoods@mdanderson.org), 713-792-6679) **ON HOLD**

- c. [2021-0899](#): A phase II study of Tucatinib and Ado-trastuzumab eEmtansine (T-DM1) in patients with HER2-positive metastatic solid tumors and metastases to brain (TUCATEMEB)  
PI: Ecaterina Dumbrava  
SC: Emma Montazari, Sr. RN ([EJMontazari@mdanderson.org](mailto:EJMontazari@mdanderson.org), 281-813-1402)
- d. [2019-0993](#): Outcomes and Prognostic Factors in Metastatic Breast Cancer Patients at MD Anderson Cancer Center  
PI: Abbey Kaler  
SM: [Makeba Faniel](#) (pager 713-404-6688)

## 2. [HER2- \(BMO\)](#)

- a. [2021-0836](#) ([SWOGS2007](#)): A Phase II Trial of Sacituzumab Govitecan (IMMU-132) (NSC#820016) for Patients with Her2-Negative Breast Cancer and Brain Metastases  
PI: Nuha Ibrahim  
SM: Heather Alonzo, RN (832-728-0675)/Coverage: Shade Bambe, RN (832-729-0241)
- b. [2021-0611](#): A Phase II Study of Pembrolizumab in Combination with Lenvatinib in Patients with TNBC, NSCLC, and Other Tumor Types and Brain Metastasis  
PI: Jordi Rodon  
SM: [Caitlin Creasy](#) (office mobile 832-728-5851)
- c. [2019-0993](#): Outcomes and Prognostic Factors in Metastatic Breast Cancer Patients at MD Anderson Cancer Center  
PI: Abbey Kaler  
SM: [Makeba Faniel](#) (Pager 713-404-6688)

## 3. [ER+ \(BMO\)](#)

- a. [2022-0638](#): An Open-label Multicenter Phase 1b-2 Study of Elacestrant as Monotherapy and in Combination with Abemaciclib in Women and Men with Brain Metastasis from Estrogen Receptor Positive, Her2-Negative Breast Cancer (ELECTRA)  
PI: Nuha Ibrahim  
SM: Shade Bambe (713-792-0909)/Coverage: Heather Alonzo (832-728-0675)/Toni Zaayman (832-546-7723)

## **BRCA germline + BREAST CANCER TRIALS**

### 1. [Neoadjuvant](#)

- a. [2020-1125](#): Implementation of a Geriatric Care Survivorship Intervention in Older Adults who have Completed Curative Intent Therapy for Early-Stage Breast Cancer  
PI: Meghan Karuturi  
SM: Cynthia Tamez (832-269-1396)/Coverage: Makeba Faniel (713-794-3136)/Keena Woods (832-596-2985)

### 2. [Metastatic](#)

Updated April 4th, 2024

- a. [2018-0062](#): Overcoming PARP Inhibitor Resistance in BRCA Germline Mutation Positive Advanced Breast Cancer  
PI: Banu Arun  
SM: Cindy Tamez (832-269-1396 / Coverage – Makeba Faniel (832-294-4690)
- h. [2019-0993](#): Outcomes and Prognostic Factors in Metastatic Breast Cancer Patients at MD Anderson Cancer Center  
PI: Abbey Kaler  
SM: [Makeba Faniel](#) (pager 713-404-6688)

### **3. TNBC**

#### **ELDERLY ADULT**

- a. [2020-1125](#): Implementation of a Geriatric Care Survivorship Intervention in Older Adults who have Completed Curative Intent Therapy for Early-Stage Breast Cancer  
PI: Meghan Karuturi  
SM: Cynthia Tamez (832-269-1396)/Coverage: Makeba Faniel (713-794-3136)/Keena Woods (832-596-2985)
- b. [2016-0055](#): Identifying Decision Making Needs for Older Adult Women with Breast Cancer Considering Neoadjuvant or Adjuvant Chemotherapy  
PI: Meghan Karuturi  
SM: Cynthia Tamez (832-269-1396) / Coverage: Makeba Faniel (832-294-4690)

#### **HIGH RISK AND PREVENTION**

- a. [LAB03-0479](#): A Prospective Follow-up of High-Risk Patients  
PI: Banu Arun  
SM: [Angelica Gutierrez-Barrera](#) (pager 713-606-2663)
- b. [2020-0182](#): A Randomized Phase II Window-of-opportunity Trial of Ruxolitinib in Patients with High Risk and Premalignant Breast Conditions  
PI: Parijatham Thomas

#### **SYMPTOM MANAGEMENT**

#### **INFLAMMATORY BREAST CANCER**

##### **1. IBC Registry**

- a. [2006-1072](#): IBC Registry  
PI: Vicente Valero  
SM: [Angela Alexander](#) (Cell #832-450-5265)

##### **2. Neoadjuvant HER2-/ER+, HER2+/Any HR**

- a. [2020-1125](#): Implementation of a Geriatric Care Survivorship Intervention in Older Adults who have Completed Curative Intent Therapy for Early-Stage Breast Cancer  
PI: Meghan Karuturi

SM: Cynthia Tamez (832-269-1396)/Coverage: Makeba Faniel (713-794-3136)/Keena Woods (832-596-2985)

- b. [2023-0100](#): TRUDI: A phase II study of neoadjuvant Trastuzumab deruxtecan and Durvalumab (MEDI4736) for stage III, Her2-expressing inflammatory Breast Cancer  
PI: Rachel Layman  
SM: Angela Marx, RN 832-450-6027

### 3. [Neoadjuvant TN-IBC](#)

- a. [2020-1125](#): Implementation of a Geriatric Care Survivorship Intervention in Older Adults who have Completed Curative Intent Therapy for Early-Stage Breast Cancer  
PI: Meghan Karuturi  
SM: Cynthia Tamez (832-269-1396)/Coverage: Makeba Faniel (713-794-3136)/Keena Woods (832-596-2985)

### 4. [Adjuvant HR Positive IBC](#)

- a. [2020-1125](#): Implementation of a Geriatric Care Survivorship Intervention in Older Adults who have Completed Curative Intent Therapy for Early-Stage Breast Cancer  
PI: Meghan Karuturi  
SM: Cynthia Tamez (832-269-1396)/Coverage: Makeba Faniel (713-794-3136)/Keena Woods (832-596-2985)

### 5. [Adjuvant TNIBC](#)

- a. [2020-1125](#): Implementation of a Geriatric Care Survivorship Intervention in Older Adults who have Completed Curative Intent Therapy for Early-Stage Breast Cancer  
PI: Meghan Karuturi  
SM: Cynthia Tamez (832-269-1396)/Coverage: Makeba Faniel (713-794-3136)/Keena Woods (832-596-2985)

### 6. [IBC With Metastasis](#)

- a. [2019-0993](#): Outcomes and Prognostic Factors in Metastatic Breast Cancer Patients at MD Anderson Cancer Center  
PI: Abbey Kaler  
SM: [Makeba Faniel](#) (pager 713-404-6688)
- b. [2020-0198](#): Neratinib and Capmatinib combination (phase IB/II) in metastatic breast cancer and inflammatory breast cancer patients with abnormal HER2 and c-Met pathway activity as measured by the CELsignia Signaling Analysis Test  
PI: Rachel M. Layman  
SM: Vivian Chiv, RN (713-859-1576)
- c. [2022-0315](#): Phase 1b study of EZH1/2 inhibitor valemestostat in combination with trastuzumab deruxtecan in subjects with HER2 low/ultra-low/null metastatic breast cancer  
PI: Senthil Damodaran  
SM: Angela Marx, RN (832-450-6027)

Updated April 4th, 2024

- d. [2022-0764](#): I-SPY-Phase I/Ib (PRE-I-SPY Program) PRE-Investigation of serial studies to predict your therapeutic response with imaging and molecular analysis: A Phase I/Ib platform trial

PI: Paula Pohlmann

SC: Heather Walker (713-792-4534), Julia Moore (713-792-5199)

**DCIS (BREAST SURGICAL ONCOLOGY)**

- a. [ALLIANCE AFT-25](#) Comparison of Operative to Monitoring and Endocrine Therapy (COMET) Trial for Low-Risk DCIS: A Phase III Prospective Randomized Trial

PI: Nina Tamirisa

SM: [Anthony Jones](#) (pager 713-404-3603)