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 (1st Line)
4. Metastatic HR positive (>1st 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
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**
      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
   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)

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, 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, 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, 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/II (PRE-I-SPY Program) PRE-Investigation of serial studies to predict your therapeutic response with imaging and molecular analysis: A Phase I/II 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/II (PRE-I-SPY Program) PRE-Investigation of serial studies to predict your therapeutic response with imaging and molecular analysis: A Phase I/II 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)
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) (*Phase 1*)
   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
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 (1st 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, 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, 713-792-6679)* **ON HOLD**

4. **Metastatic HR Positive (>1st 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, 713-834-6567)*

   c. **2023-0691**: A phase 1b, 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, 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, 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, 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, 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)
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: Nuhad 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-HER2antibody 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
**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
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, 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, 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
Updated April 4th, 2024

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, 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: Nuhad Ibrahim
      SM: Alyson Clayborn, Sr. RN (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, 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, 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
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)

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**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, 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, 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 ([EIMontazari@mdanderson.org](mailto:EIMontazari@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: Nuhad 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: Nuhad 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
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 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. 2022-0764: 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)