# Overview of GEICAM Biobank sample collections from closed clinical studies

Biobanco GEICAM

For further information, please visit the full version of the catalogue at: https://www.geicam.org/investigacion/biobanco/Catalogo)

| Protocol ID | Type | Phase | Clinical Trials.gov ID | Description | Indication | Tumor Subtype | No. Patients Enrolled | BIOLOGICAL SAMPLES TYPE | | | | | | | | STUDY TIME-POINT |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | FFPE Tumor* | | Plasma | Serum | WB | BC | gDNA | gRNA | Vaginal cytology | |
| | | | | | | | | Primary | Metastatic | | | | | | | | |
| GEICAM/2011-02 | CT | II | NCT 01565499 | Phase II, Open-label, Non-randomized Study of Nab-paclitaxel for the Neoadjuvant Treatment of Patients With Stage II and III Luminal Breast Cancer | Neo | Luminal (ER+/HER2-) | 83 | ✓ | | ✓ | ✓ | ✓ | | | | | **Pre-tx**<br>**Post-tx** |
| GEICAM/2006-03 | CT | II | NCT 00432172 | A Randomized Multicenter Phase II Trial to Evaluate the Effectiveness of Selective Neoadjuvant Treatment According to Immunohistochemical Subtype for HER2 Negative Breast Cancer Patients | Neo | HER2- (Luminal & Basal) | 189 | ✓** | | ✓ | | | ✓ | | | | **Pre-tx**<br>**Post-tx** (tumor)<br>**FU** (plasma, BC): 18m; 24m; 36m; 42m; 48m; 54m. |
| GEICAM/2003-03 | CT | I-II | NCT 00129896 | Open-Label Phase I-II Clinical Trial to Evaluate Treatment With Myocet/Taxotere/Herceptin as Primary Chemotherapy Treatment for HER2neu Positive Breast Cancer Patients | Neo | HER2+ (HR +/-) | 72 | ✓ | | | ✓ | | | | | | **Pre-tx**<br>**Post-tx** (serum): 24m; 36m; 42m.<br>**FU:** serum |
| GEICAM/2006-14 | CT | II | NCT 00841828 | A Phase II Randomised, Multicentre Compare Epirubicine and Cyclophosphamide Treatment Plus Docetaxel and Trastuzumab Versus Epirubicine and Cyclophosphamide Treatment Plus Docetaxel and Lapatinib in Women With Primary Resectable Breast Cancer or Locally Advanced HER2+ Breast Cancer | Neo | HER2+ (HR +/-) | 102 | ✓** | | | | | | | | | **Pre-tx**<br>**Post-tx** |
| GEICAM/2002-01 | CT | II | NCT 00128856 | Phase II Pharmacogenomic and Clinical Trial for the Administration of Gemcitabine-Doxorubicin-Paclitaxel (GAT) as Neoadjuvant Treatment of Patients With Stage III Breast Cancer | Neo | All | 46 | ✓ | | | | | | | | | **Pre-tx**<br>**Post-tx** |
| GEICAM/2004-04 | CT | III | NCT 00336791 | Randomized clinical trial to evaluate the predictive accuracy of a gene expression profile-based test to select patients for preoperative taxane/anthracycline chemotherapy for stage I-III breast cancer | Neo | All | 60 | ✓ | | | | | | ✓ | | | **Pre-tx** |
| GEICAM/2014-05 | CT | II | NCT 02413008 | A Phase II Prospective, Randomized, Double-Blind, Placebo-Controlled and Multi-Centre Clinical Trial to Assess the Safety of 0.005 % Estriol Vaginal Gel in Hormone Receptor-Positive Postmenopausal Women With Early Stage Breast Cancer in Treatment With Aromatase Inhibitor in the Adjuvant Setting | Adj | HR+ | 61 | | | ✓ | ✓ | | | | | ✓ | **Pre-tx**<br>**Post-tx:** 1w; 3w; 8w; 12w; early withdrawal |
| GEICAM/2006-10 | CT | III | NCT 00543127 | A Randomized, Multicenter, Phase III Study of Parallel Groups to Compare the Efficiency and Tolerance of Fulvestrant Administered for Three Years in Combination With Anastrozol for 5 Years Versus Anastrozol for 5 Years as Adjuvant Hormonotherapy in Postmenopausal Women With Early Breast Cancer and Positive Hormone Receptors | Adj | HR+/HER2- | 872 | ✓ | | ✓ | | ✓ | ✓ | ✓ | | | **Pre-tx**<br>**FU** (plasma, serum, BC): up to 60m |
| GEICAM/2012-09 | Obs. (EPA-SP) | NA | NCT 01899079 | A Prospective Study of Clinical Outcomes for the NanoString® Technologies Breast Cancer Intrinsic Subtype Test | Adj | HR+/HER2- N- | 200 | ✓ | | | | | | | | | **Pre-tx** |
| GEICAM/2003-11 | CT | III | NCT 00130533 | Multicenter, Open-label, Randomized Phase III Trial, to Evaluate Efficacy of Maintenance Treatment With Capecitabine (X) Following Standard Adjuvant Chemotherapy, in Operable Breast Cancer Patients With Negative Hormone Receptor, Negative HER2 Tumours | Adj | TN | 871 | ✓** | | ✓ | | ✓ | | | | | **Pre-tx**<br>**FU** (plasma, WB): 3m; 4m; 6m; 12m; 24m; 42m. |
| GEICAM/9805 | CT | III | NCT 00121992 | A multicenter phase III randomized trial comparing docetaxel in combination with doxorubicin and cyclophosphamide (TAC) versus 5-Fluorouracil in combination with doxorubicin and cyclophosphamide (FAC) as adjuvant treatment of high risk operable breast cancer patients with negative axillary lymph nodes (TAX.ES1.301) | Adj | All subtypes, N- | 1060 | ✓ | | | | | | | | | **Pre-tx** |
| GEICAM/9906 | CT | III | NCT 00129922 | Multicenter Randomized Phase III Clinical Trial to Compare 6 Courses of FEC (Fluorouracil, Epirubicin and Cyclophosphamide) Vs. 4 Courses of FEC Followed by 8 Weekly Paclitaxel Administrations, as Adjuvant Treatment for Node Positive Operable Breast Cancer Patients | Adj | All subtypes, N+ | 1246 | ✓** | | | | | | | | | **Pre-tx** |
| GEICAM/2003-02 | CT | III | NCT 00129389 | Multicenter Randomized Phase III Clinical Trial to Compare 6 FAC Cycles(Fluorouracil, Doxorubicin, Cyclophosphamide) vs. 4 FAC Cycles Followed by 8 Weekly Paclitaxel Administrations, as Adjuvant Treatment for Node Negative Operable Breast Cancer Patients | Adj | All subtypes, N- | 1925 | ✓ | | | ✓ | | | | | | **Pre-tx**<br>**Post-tx** (serum): EOT<br>**FU** (serum): 6m; 12m; 18m; 24m; >24m. |
| GEICAM/2003-10 | CT | III | NCT 00129935 | Multicenter, Randomized Phase III Trial to Compare Epirubicin and Cyclophosphamide (EC) Followed by Docetaxel (T) to Epirubicin and Docetaxel (ET) Followed by Capecitabine (X) as Adjuvant Treatment for Operable, Node Positive Breast Cancer Patients | Adj | All subtypes, N+ | 1384 | ✓ | | | ✓ | ✓ | | | | | **Pre-tx**<br>**Post-tx** (serum, WB): EOT<br>**FU** (serum, WB): 6m; 12m; 18m; 24m; >24m. |
| GEICAM/2006-11 | CT | III | NCT 00545077 | Multicenter, Randomized Study to Evaluate the Efficacy and Safety of Bevacizumab in Combination With Endocrine Treatment Compared to Endocrine Treatment Alone, in Postmenopausal Women With Advanced or Metastatic Cancer With Indication of Hormonotherapy as First-line Treatment | Met | HR+/HER2- | 270 | ✓** | ✓** | ✓ | | ✓ | ✓ | | | | **Pre-tx**<br>**Post-tx** (plasma, WB, BC): at disease progression |
| GEICAM/2015-07 | CT | II | NCT 02756364 | An Open-Label Phase 2 Study of MLN0128 (A TORC1/2 Inhibitor) in Combination With Fulvestrant in Women With ER-Positive/HER2-Negative Advanced or Metastatic Breast Cancer That Has Progressed During or After Aromatase Inhibitor Therapy | Met | ER+/HER2- | 192 | | ✓ | ✓ | | ✓ | | | | | **Pre-tx**<br>**Post-tx** (plasma): C4; EOT; at progression |
| GEICAM/2011-04 | EPA-SP | NA | NCT 01733628 | Evaluation Study of Hypertension as a Predictor of Efficacy Bevacizumab (BV) in Combination With Chemotherapy (CT) in Metastatic Colorectal Cancer (MCC) and Metastatic Breast Cancer (MBC). | Met | HER2- (HR + / -) | 143 | ✓ | | ✓ | ✓ | | | ✓ | | | **Pre-tx***<br>**Post-tx** (plasma, serum, gDNA): C2D1; C4D1<br>*Additionally, **colorectal tumor** samples from 25 patients |
| GEICAM/2010-04 | CT | I-II | NCT 01306942 | A Phase I/II Trial of Dasatinib in Combination With Trastuzumab and Paclitaxel in the First Line Treatment of Her2-Positive Metastatic Breast Cancer (Mbc) Patients | Met | HER2+ (HR +/-) | 37 | ✓ | | ✓ | | | | | | | **Pre-tx***<br>**Post-tx*** (plasma): C1D1-8h<br>*Additionally, **protein extract** samples from 18 patients and **skin** FFPE samples at C1D1-pre, C1D1-8h, C1D4-8h and C2D1-8h from 7 patients |
| GEICAM/2012-12 | CT | I | NCT 02027376 | A Phase Ib Dose Escalation, Open Label, Multicenter Study Evaluating LDE225 in Combination With Docetaxel in Triple Negative (TN) Advanced Breast Cancer (ABC) Patients "EDALINE" | Met | TN | 12 | ✓ | ✓ | ✓ | | | | ✓ | ✓ | | **Pre-tx***<br>**Post-tx*** (plasma, gDNA, gRNA): C4D1; EOT<br>*Additionally, **skin** FFPE samples from 5 patients |
| GEICAM/2000-01 | CT | IV | NCT 00128297 | Randomized, Multicentric Phase IV Clinical Trial for the Administration of Pamidronate in Breast Cancer Patients With Bone Metastases | Met | All | 168 | | | | ✓ | | | | | | **Pre-tx**<br>**Post-tx:** EOT<br>**FU:** 1-6m; 7-12m; ≥13m |
| GEICAM/2000-04 | CT | III | NCT 00128310 | Randomized Phase III Trial Comparing Vinorelbine vs. Gemcitabine Plus Vinorelbine in Patients With Advanced Breast Cancer, Previously Treated With Anthracyclines and Taxanes | Met | All | 252 | | | | ✓ | | | | | | **Pre-tx**<br>**Post-tx:** EOT<br>**FU:** 1-6m; 7-12m; ≥13m |
| GEICAM/2001-05 | CT | III | NCT 00130494 | Multicenter, Open-Label, Randomized Phase III Trial for Administration of Zoledronate to Breast Cancer Metastatic Patients With Non-Symptomatic Bone Lesions | Met | All | 97 | | | | ✓ | | | | | | **Pre-tx**<br>**FU:** 1-5m; 6m; 18m |
| GEICAM/2011-07 | Obs. (EPA-OD) | NA | NCT 01598285 | A Combined Genome-Wide Association Study (GWAS) and microRNA (miRNA) Profiling Approach for the Identification of Bevacizumab Response Predictors in Metastatic Breast Cancer | Met | All | 26 | | | | | | | ✓ | ✓ | | **At study entry** |
| GEICAM/2003-08 | CT | III | NCT 00083174 | A Phase III Randomized Study of Exemestane Versus Placebo in Postmenopausal Women at Increased Risk of Developing Breast Cancer | Chem. | All subtypes | 432 | | | | | | | | | | **Pre-tx**<br>**Post-tx** (serum, gDNA): EOT<br>**FU** (serum, gDNA): 6m;1y; 2y; 3y; 4y; 5y |
| GEICAM/2011-06 | Obs. (No-EPA) | NA | NA | Evaluation of mRNA rapid in situ hybridization (RISH™) as a technique for detection of HER2 receptor over expression in breast cancer | All | All | 245 | ✓ | | | ✓ | | | ✓ | | | **At study entry** |

***FFPE blocks / slides / tissue microarray (TMA); **Tumoral DNA and/or tumoral RNA**

CT: clinical Trial; Obs.: observational study; EPA-SP: prospective drug post-authorization study; EPA-OD: retrospective/transversal drug post-authorization study; No-EPA: non drug post-authorization study; NA: not apply.

Neo: neoadjuvant; Adj: adjuvant; Met: metastatic; Chem.: chemoprevention

HER2: human epidermal growth factor receptor 2; HR: hormone receptor; ER: estrogen receptor; N: lymph node; TN: triple-negative.

WB: whole blood; BC: buffy coat; gDNA: germinal DNA; gRNA: germinal RNA.

Pre-tx: pre-treatment; Post-tx: post-treatment; FU: follow-up; m: month; w: week; EOT: end of treatment; C: cycle; D: day; h: hour; y: year.

**All GEICAM Biobank sample collections have associated clinical data collected along the study**

**Updated: January 2022**