

Overview of GEICAM Biobank sample collections from ongoing clinical studies

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		Other	
								Primary	Metastatic									
GEICAM/2014-09	Obs. (No-EPA)	NA	NCT 03860740	Effect of Exercise on Ki-67 Levels in Women With HR+/HER2- Operable Breast Cancer. (EFIK)	Neo	HR+/HER2-Ki67 ≥14%	10***	✓			✓							Pre-tx Post-tx FU (serum): 6m
GEICAM/2019-01	CT	II	NCT 04293393	Phase II, randomized, open-label, international, multicenter study to compare efficacy of standard chemotherapy vs. letrozole plus abemaciclib as neoadjuvant therapy in HR-positive/HER2-negative high/intermediate risk breast cancer patients	Neo	HR+/HER2-Ki67 >20%	135***	✓		✓		✓						Pre-tx Post-tx (tumor: 2w; at surgery) (plasma, WB: 2w; 12w; 6m; 12m; 4w post-surgery; at disease progression) FU (plasma, WB): every 6m for 5y and every 12m for the following 5y Other samples: fresh tumor (pre- and post-tx) for PDX and organoid-based model generation
GEICAM/2011-03	CT	III	NCT 01272037	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 for Positive Node, Endocrine Responsive Breast Cancer	Adj	HR+/HER2-N+	792	✓		✓	✓		✓					Pre-tx Other samples: affected and non-affected lymph nodes samples
GEICAM/2009-03	No-EPA	NA	NCT 01377363	Evaluation of Degree of Conversion of HER2 Receptor Between Primary Breast Cancer and Metastasis	Adj / Met	All subtypes	184	✓	✓									At study entry
GEICAM/2013-02	CT	III	NCT 02028507	Phase III study of Palbociclib (PD-0332991) in combination with Endocrine therapy (exemestane or fulvestrant) versus chemotherapy (capecitabine) in Hormonal Receptor (HR) positive/HER2 negative Metastatic Breast Cancer (MBC) patients with Resistance to non-steroidal Aromatase inhibitors	Met	ER+/HER2-	601	✓	✓	✓			✓					Pre-tx Post-tx (plasma): C1D1; C1D15; C2D15; EOT; at disease progression
GEICAM/2014-12	CT	II	NCT 02690480	A randomized, double-blind, parallel-group, multicentre, phase II study to compare the efficacy and tolerability of fulvestrant (Faslodex™) 500mg with placebo and fulvestrant (Faslodex™) 500mg in combination with PD-0332991 (Palbociclib) as first line treatment for postmenopausal women with hormone receptor-positive metastatic breast cancer, who have completed at least 5 years of adjuvant endocrine therapy and remained disease free for more than 12 months following its completion or have "de novo" metastatic disease.	Met	ER+/HER2-	189	✓	✓	✓			✓					Pre-tx Post-tx FU (plasma): 12w; 24w; 36w; 48w; at disease progression
GEICAM/2018-03	Obs. (NO-EPA)	NA	NCT 04370522	The NIKOLE study: Characterization of innate immune system in patients with luminal advanced breast cancer	Met	HR+/HER2-	13***	✓	✓	✓			✓					Pre-tx Post-tx (plasma, PBMCs): 6w; 3m; EOT/at disease progression; at disease progression after EOT Other samples: peripheral blood mononuclear cells (PBMCs)
GEICAM/2017-01	CT	III	NCT 05063786	A randomized phase III trial of trastuzumab + Alpelisib +/- fulvestrant versus trastuzumab + chemotherapy in patients with PIK3CA mutated previously treated HER2+ Advanced BrEasT cancer. "ALPHABET Study"	Met	HER2+ (HR +/-) PIK3CA mutated	2***	✓	✓	✓			✓					Pre-tx Post-tx (plasma, WB): 9w; EOT/at disease progression; at disease progression after EOT
GEICAM/2017-04	Obs. NO-EPA	NA	NCT 03829306	Unraveling Kadcyla (Trastuzumab emtansine; T-DM1) resistance In HER2-positive Advanced breast cancer (ABC): a prospective GEICAM study	Met	HER2+	32	✓	✓	✓								Pre-tx Post-tx (tumor: 5d post-tx and at progression) (plasma: C2; C4; every 3 cycles until C16; EOT; at disease progression) Other samples: pre- and post-tx tumor after ex-vivo culture with Kadcyla
GEICAM/2015-04	CT	II	NCT 03025880	A Multicenter Phase II Trial to Evaluate the Efficacy and Safety of Pembrolizumab and Gemcitabine in Patients With HER2-negative Advanced Breast Cancer (ABC)	Met	HER2- (Luminal A & B / TN)	36		✓			✓				✓		Pre-tx Post-tx: C3; C6 (serum, gRNA); at disease progression
GEICAM/2015-06	CT	II	NCT 03205761	A Phase II Clinical Trial to Analyse Olaparib Response in Patients With BRCA1 and/or 2 Promoter Methylation Diagnosed of Advanced Breast Cancer (COMETA-Breast Study)	Met	TN	11	✓**	✓**	✓			✓				✓	Pre-tx Post-tx: (tumor: at disease progression) (plasma, WB, gRNA: 4-6w; EOT/at disease progression; at disease progression after EOT)
GEICAM/2014-03	Registry Obs. (NO-EPA)	NA	NCT 02819882	A Prospective Registry Study in Patients With Unresectable Locally Advanced or Metastatic Breast Cancer (MBC)	Met	All subtypes	1900***	✓	✓	✓	✓			✓				At registration At disease progression (tumor, plasma, serum)
GEICAM/2012-03	Obs. (NO-EPA)	NA	Not registered	Molecular characterization of Gestational Breast Cancer	All	All subtypes	73	✓**	✓**									At study entry
EPIGEICAM	Obs. (NO-EPA)	NA	Not registered	Lifestyle and Breast Cancer Risk in Spain	All	All subtypes	2374			✓	✓		✓	✓			✓	At study entry (samples from breast cancer patients and healthy women) Other samples: saliva
Health-epiGEICAM	Obs. (NO-EPA)	NA	NCT 04379908	Healthy lifestyles and quality of life in women with breast cancer	All	All subtypes	1257	✓	✓									At study entry
GEICAM/2016-04	Registry Obs. (NO-EPA)	NA	NCT 03800355	An observational, retrospective study on the progress of breast cancer cases in males and the assessment of relapse risk through gene sequencing	All	All subtypes	541***	✓	✓			✓						At study entry At disease progression
GEICAM/2017-07	Registry Obs. (NO-EPA)	NA	NCT 04603820	An ambispective observational registry study of pregnancy and breast cancer. EMBARCAM Study.	All	All subtypes	185***	✓	✓	✓			✓					At study entry

*FFPE blocks / slides; **Tumoral DNA and/or tumoral RNA; ***On recruitment

CT: clinical trial; Obs.: observational study; No-EPA: non drug post-authorization study.

NA: not apply.

Neo: neoadjuvant; Adj: adjuvant; Met: metastatic

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; w: week; m: month; y: year; C: cycle; D: day; EOT: end of treatment.

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