

Riunione Annuale

GIM GRUPPO
ITALIANO
MAMMELLA



26-27 SETTEMBRE 2025 BERGAMO

HOTEL EXCELSIOR SAN MARCO

PIAZZA DELLA REPUBBLICA, 6



OSPEDALE POLICLINICO SAN MARTINO
Sistema Sanitario Regione Liguria
Istituto di Ricovero e Cura a Carattere Scientifico



Gli studi GIM come patrimonio di dati per la ricerca accademica

Eva Blondeaux, MD

*U.O. Epidemiologia Clinica
IRCCS Ospedale Policlinico San Martino*

27 settembre 2025



Disclosure

- Research support to the Institution from Gilead Science
- Speaker fee from Eli Lilly

Outline

- **The GIM trials**
 - **Early setting**
 - **Advanced setting**

- **The GIM observational studies**

- **The future of the GIM group**

Outline

- **The GIM trials**
 - Early setting
 - Advanced setting

- The GIM observational studies

- The future of the GIM group

The GIM trials and studies

Study	Patients included	Enrollment Status	Setting	Type of study
GIM1 N-	1636	Closed	Early	Trial
GIM2	2091	Closed	Early	Trial
GIM3 - FATA	3705	Closed	Early	Trial
GIM4 - LEAD	2056	Closed	Early	Trial
GIM5 - CYPLEC	488	Closed	Early	Trial
GIM8 - OVER	348	Closed	Advanced	Trial
GIM9 - NEO-ADIXERN	47	Closed	Early	Trial
GIM10 - CONSENT	1014	Closed	Early	Trial
GIM11 - BERGI	62	Closed	Advanced	Trial
GIM12 - TYPHER	62	Closed	Advanced	Trial
GIM13 - AMBRA	1063	Closed	Advanced	Observational
GIM14 - BIO-META	5041	Enrolling	Advanced	Observational
GIM15 - NEPA	147	Closed	Early	Trial
GIM16 - FEVEX	150	Closed	Advanced	Trial
GIM18 - FUMANCE	12	Closed	Advanced	Trial
GIM19 - STAR	988	Closed	Early	Observational
GIM20 - CITOHER2	46	Closed	Advanced	Observational
GIM21 - LIQERBCEPT	50	Closed	Advanced	Observational
GIM22 - ERICA	110	Closed	Advanced	Trial
GIM23 - POSTER	1140	Enrolling	Early	Observational
GIM24 - PALBO-BP	164	Closed	Advanced	Trial
GIM25 - CAPT	49	Closed	Advanced	Trial
GIM26 - TRASTHER	318	Closed	Early	Observational
GIM27 - THERAPY	12	Closed	Advanced	Observational
GIM28 - ELMER	405	Enrolling	Early	Observational
GIM29 - GIMOMIC	189	Enrolling	Early	Observational
GIM30 - RAPID	85	Closed	Advanced	Observational
GIM31 - NEO-AGILE	16	Enrolling	Early	Trial
GIM33 - TRUTH	25	Enrolling	Advanced	Observational
Total	21519			

Outline

- **The GIM trials**
 - **Early setting**
 - **Advanced setting**

- **The GIM observational studies**

- **The future of the GIM group**

The GIM trials

Study	Patients included	Enrollment Status	Setting	Type of study
GIM1 N-	1636	Closed	Early	Trial
GIM2	2091	Closed	Early	Trial
GIM3 - FATA	3705	Closed	Early	Trial
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GIM9 - NEO-ADIXERN	47	Closed	Early	Trial
GIM10 - CONSENT	1014	Closed	Early	Trial
GIM15 - NEPA	147	Closed	Early	Trial
GIM31 - NEO-AGILE	16	Enrolling	Early	Trial
Total	11184			

The GIM trials – early setting

Trial	No. of patients	Standard arm	Experimental arm	Main inclusion criteria	Stratification factors in randomization	Years of enrollment	Primary Endpoint
MIG1 ¹	1214	FEC standard interval	FEC dose dense	N+ (65%N+) <i>or</i> N- and age ≤35 years or ER/PgR negative, T>2cm, G3, high Ki67	nodal status (N- vs N+) Centre	1992-1997	OS
MIG5 ²	1055	FEC x6	EP x 4	N+	Centre	1996-2001	OS
GIM2 ³ (DD vs SI)	2003	FEC-P standard interval EC-P standard interval	FEC-P dose dense EC-P dose dense	N+	Centre	2003-2006	DFS
GIM2 ³ (EC vs FEC)	2091	EC-P standard interval EC-P dose dense interval	FEC-P standard interval FEC-P dose dense interval	N+	Centre	2003-2006	DFS
GIM3 FATA ⁴	3697	Tam for 2 yrs → Let for 3 yrs Tam for 2 yrs → Exe for 3 yrs Tam for 2 yrs → Ana for 3 yrs	Let for 5 yrs Exe for 5 yrs Ana for 5 yrs	Postmenopausal status ER+ any T / any N (35%N+)	ER and PgR status HER2 status previous CT nodal status (N0 vs N1 vs N2 vs N3)	2007-2012	DFS
GIM4 LEAD ⁵	2056	Let for 2-3 yrs (5 yrs of ET)	Let for 5 yrs (7-8 yrs of ET)	Postmenopausal status ER+ any T / any N (45%N+)	Centre	2005-2010	DFS
GIM6 PROMISE ⁶	281	CT alone	CT + GnRHa	Premenopausal candidate to CT any T / any N (55%N+)	Centre	2003-2008	CT-induced early menopause

Abbreviations: FEC, fluorouracil epirubicin, and cyclophosphamide; EC epirubicin, and cyclophosphamide; P, paclitaxel; N, nodal status; ER, estrogen receptor; PgR, progesterone receptor; OS, overall survival; DFS, disease free survival; ET, endocrine therapy; HER2, human epidermal growth factor; CT, chemotherapy; T, tumor size; Tam, tamoxifen; Let, letrozole; Exe, exemestane; Ana, anastrozole; GnRHa, Gonadotropin hormone-releasing hormone agonist.

¹Blondeaux E et al. *Br J Cancer* 2020;122:1611–7; ²Del Mastro L et al. *Breast Cancer Res Treat* 2016; 155: 117–26; ³Del Mastro L et al. *Lancet Oncol* 2022; 23: 1571–82;

⁴De Placido S et al. *Lancet Oncol* 2018; 19: 474–85; ⁵Del Mastro L et al. *Lancet Oncol* 2021; 22: 1458–67; ⁶Lambertini M et al. *J Natl Cancer Inst* 2022; 114: 400–8.

The GIM trials – early setting

Blondeaux E (<40 years)

Lambertini M (<40 years)

Arecco L (<40 years)

Intermediate clinical endpoints in early-stage breast cancer: an analysis of individual patient data from the Gruppo Italiano Mammella and Mammella Intergruppo trials

Eva Blondeaux^{1,2}, Wanling Xie³, Luca Caracciolo⁴, Silvia Mura⁵, Valeria Sanna⁶, Micheline De Laurentis⁷, Roberta Caputo⁸, Anna Turletti⁹, Antonio Durando¹⁰, Sabino De Placido¹¹, Carmine De Angelis¹², Giancarlo Bisagni¹³, Elisa Gasparini¹⁴, Anita Rimanti¹⁵, Fabio Puglisi¹⁶, Mauro Mansutti¹⁷, Elisabetta Landucci¹⁸, Alessandra Fabi¹⁹, Luca Arecco²⁰, Marta Perachino²¹, Marco Bruzzone²², Luca Boni²³, Matteo Lambertini²⁴, Lucia Del Mastro²⁵ and Meredith M. Regan²⁶

Prognostic and clinical impact of the endocrine resistance/sensitivity classification according to international consensus guidelines for advanced breast cancer: an individual patient-level analysis from the Mammella InterGruppo (MIG) and Gruppo Italiano Mammella (GIM) studies

Matteo Lambertini^{1,2,3,4}, Eva Blondeaux⁵, Giancarlo Bisagni⁶, Silvia Mura⁷, Sabino De Placido⁸, Micheline De Laurentis⁹, Alessandra Fabi¹⁰, Anita Rimanti¹¹, Andrea Michelotti¹², Mauro Mansutti¹³, Antonio Russo¹⁴, Filippo Montemurro¹⁵, Antonio Frassolanti¹⁶, Antonio Durando¹⁷, Stefania Gori¹⁸, Anna Turletti¹⁹, Stefano Tambiri²⁰, Ylenia Urracci²¹, Piero Frangini²², Maria Grazia Razzetti²³, Roberta Caputo²⁴, Carmine De Angelis²⁵, Valeria Sanna²⁶, Elisa Gasparini²⁷, Evandro de Azambuja²⁸, Franca Poggio²⁹, Luca Boni³⁰ and Lucia Del Mastro³¹

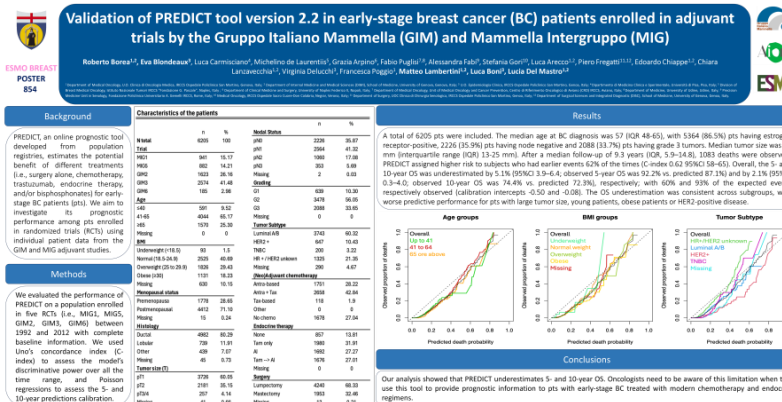
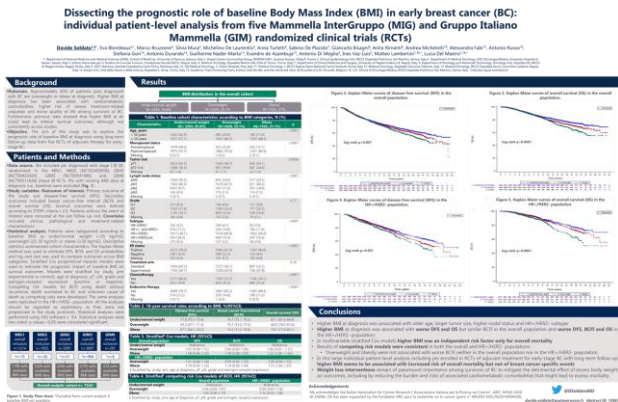
eClinicalMedicine
2024;70: 102501

eClinicalMedicine
2023;59: 101931

Soldato D (<40 years)

Borea R (<40 years)

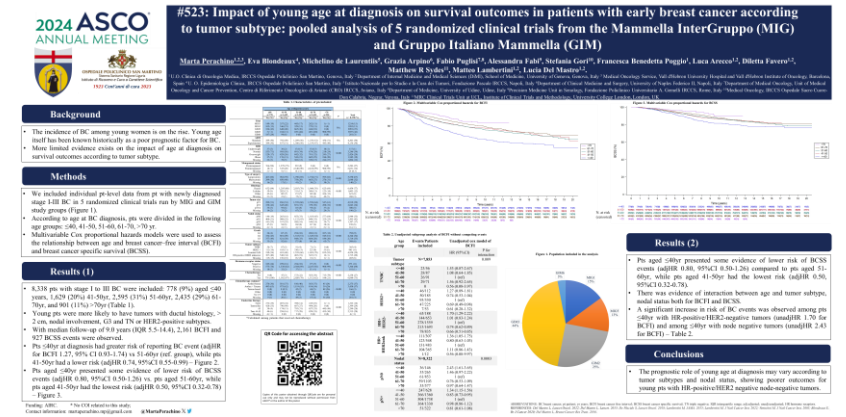
Perachino M (<40 years)



OXFORD
JNCI: Journal of the National Cancer Institute, 2025, 00(0), 1-11
https://doi.org/10.1093/jnci/djaf031
Advance Access Publication Date: February 5, 2025
Article

Prognostic implications of risk definitions from the monarchE and NATALEE trials

Luca Arecco^{1,2}, MD^{1,2}, Eva Blondeaux³, MD^{3,4}, Marco Bruzzone⁵, MSc³, Grazia Arpino⁶, MD, PhD⁴, Carmine De Angelis⁷, MD, PhD⁸, Micheline De Laurentis⁹, MD, PhD⁹, Roberta Caputo¹⁰, MD, PhD⁹, Alessandra Fabi, MD, PhD⁷, Valeria Sanna¹⁰, MD⁷, Stefania Gori¹⁰, MD, PhD^{10,11}, Luca Boni¹⁰, MD⁹, Simone Nardin¹⁰, MD^{1,12}, Irene Giannubilo¹⁰, MD^{1,12}, Marta Perachino¹⁰, MD^{1,12}, Roberto Borea¹⁰, MD^{1,12}, Elisa Agostinetto¹⁰, MD², Evandro de Azambuja¹⁰, MD, PhD², Matteo Lambertini¹⁰, MD, PhD^{1,12}, Lucia Del Mastro¹⁰, MD^{1,12}



Other analyses ongoing



The GIM trials – early setting

Arecco L (<40 years)



JNCI: Journal of the National Cancer Institute, 2025, 00(0), 1–11

<https://doi.org/10.1093/jnci/djaf031>

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Luca Arecco , MD^{1,2}, Eva Blondeaux , MD^{*3}, Marco Bruzzone , MSc³, Grazia Arpino , MD, PhD⁴, Carmine De Angelis , MD, PhD⁵, Michelino De Laurentiis , MD, PhD⁶, Roberta Caputo , MD⁵, Alessandra Fabi, MD, PhD⁷, Valeria Sanna , MD⁸, Stefania Gori , MD⁹, Fabio Puglisi , MD, PhD^{10,11}, Luca Boni , MD³, Simone Nardin , MD^{1,12}, Irene Giannubilo , MD^{1,12}, Marta Perachino , MD^{1,12}, Roberto Borea , MD^{1,12}, Elisa Agostinetto , MD², Evandro de Azambuja , MD, PhD², Matteo Lambertini , MD, PhD^{1,12}, Lucia Del Mastro , MD^{1,12}

The GIM trials – early setting

MonarchE and NATALEE patient population

Stage	T	N	Abemaciclib	Ribociclib	
I	IA	T1	N0		
	IB	T0	N1mi		
	IB	T1	N1mi	Only if G3 or Ki67≥20%	
II	IIA	T0	N1		
	IIA	T1	N1	Only if G3 or Ki67≥20%	
	IIA	T2	N0		Only if G3, or G2 with Ki67≥20%, or high genomic risk
	IIB	T2	N1	Only if G3 or Ki67≥20%	
	IIB	T3	N0		
III	IIIA	T0	N2		
	IIIA	T1	N2		
	IIIA	T2	N2		
	IIIA	T3	N1		
	IIIA	T3	N2		
	IIIB	T4	N0		
	IIIB	T4	N1		
	IIIB	T4	N2		
	IIIC	Any T	N3		

• Patients were then divided in other 3 different cohorts:

- I. **Concordant low-risk cohort** (low-risk for both trials)
- II. **Concordant high-risk cohort** (high-risk for both trials)
- III. **Discordant risk cohort** (pts considered at high-risk of recurrence for one trial but not for the other one)

Of the 4,795 pts included in the analysis:

- **28.0%** (1,343) patients were classified as **concordant high risk** → candidate to both abema and ribo
- **28.1%** (1,346) patients were classified in the **discordant risk cohort** → candidate to ribo only
- **43.9%** (2,106) patients were classified as **concordant low risk** → no adjuvant CDK4/6

Arecco L (<40 years)

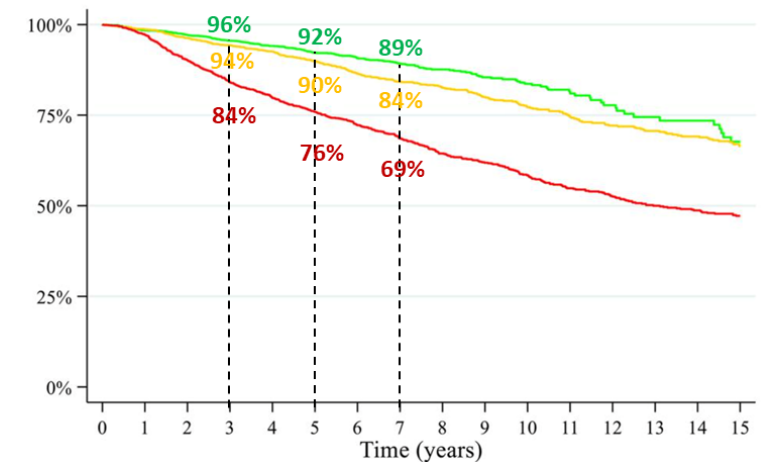


JNCI: Journal of the National Cancer Institute, 2025, 00(0), 1–11
<https://doi.org/10.1093/jnci/djaf031>
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Prognostic implications of risk definitions from the monarchE and NATALEE trials



Luca Arecco^{1,2}, MD^{1,2}, Eva Blondeaux^{1,2}, MD^{*,3}, Marco Bruzzone^{1,2}, MSc³, Grazia Arpino^{1,2}, MD, PhD⁴, Carmine De Angelis^{1,2}, MD, PhD⁵, Michelino De Laurentiis^{1,2}, MD, PhD⁶, Roberta Caputo^{1,2}, MD⁶, Alessandra Fabi, MD, PhD⁷, Valeria Sanna^{1,2}, MD⁸, Stefania Gori^{1,2}, MD⁹, Fabio Puglisi^{1,2}, MD, PhD^{10,11}, Luca Boni^{1,2}, MD⁹, Simone Nardin^{1,2}, MD^{1,12}, Irene Giannubilo^{1,2}, MD^{1,12}, Marta Perachino^{1,2}, MD^{1,12}, Roberto Borea^{1,2}, MD^{1,12}, Elisa Agostinetti^{1,2}, MD², Evandro de Azambuja^{1,2}, MD, PhD², Matteo Lambertini^{1,2}, MD, PhD^{1,12}, Lucia Del Mastro^{1,2}, MD^{1,12}

DFS estimate



The GIM trials – early setting

Borea R (<40 years)

Validation of PREDICT tool version 2.2 in early-stage breast cancer (BC) patients enrolled in adjuvant trials by the Gruppo Italiano Mammella (GIM) and Mammella Intergruppo (MIG)

Roberto Borea^{1,2}, Eva Blondeaux³, Luca Carmisiano⁴, Michellino de Laurentis⁵, Grazia Argiro⁶, Fabio Puglisi⁷, Alessandra Fabi⁸, Stefania Gori⁹, Luca Arecco¹⁰, Piero Fregatti^{11,12}, Edoardo Chiappesi¹³, Chiara Lanzavecchia¹⁴, Virginia Delucchi¹⁵, Francesca Poggio¹⁶, Matteo Lambertini¹⁷, Luca Boni¹⁸, Lucia Del Mastro¹⁹

Poster 854

Background

PREDICT, an online prognostic tool developed from population registries, estimates the potential benefit of different treatments (i.e., surgery alone, chemotherapy, trastuzumab, endocrine therapy, and/or bisphosphonates) for early-stage BC patients (pts). We aim to investigate its prognostic performance among pts enrolled in randomized trials (RCTs) using individual patient data from the GIM and MIG adjuvant studies.

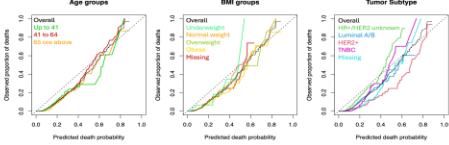
Methods

We evaluated the performance of PREDICT on a population enrolled in five RCTs (i.e., MIG1, MIG5, GIM2, GIM3, GIM6) between 2002 and 2012 with complete baseline information. We used Uno's concordance index (C-index) to assess the model's discriminative power over all the time range, and Poisson regressions to assess the 5- and 10-year predictions calibration.

Characteristics of the patients			
	n	%	Node Status
Total	6205	100	
Stage			
Ia	541	8.7	2326
Ib	541	8.7	2564
II	882	14.2	3960
III	1923	31.1	303
IV	2974	47.8	2
Missing	185	2.98	629
Age			
≤40	581	9.37	2473
41-65	4844	78.17	2888
≥66	1930	31.16	35
Missing	0	0	0
Missing	0	0	0
Tumor Subtype			
Luminal A/B	3742	60.32	
HER2	647	10.43	
TNBC	200	3.23	
Missing	3200	51.68	
Adjuvant Chemotherapy			
Adjuvant	731	11.78	
Adjuv + Tax	2858	46.06	
Tax-based	118	1.9	
Other	0	0	
Missing	1678	27.04	
Endocrine Therapy			
None	107	1.73	
Tam only	1983	31.95	
Tam + A	1682	27.27	
Tam + H	926	14.92	
Missing	0	0	
Stage			
I/II	4243	68.39	
Lumpectomy	440	7.1	
Mastectomy	1993	32.1	
Missing	13	0.21	

Results

A total of 6205 pts were included. The median age at BC diagnosis was 57 (IQR 48-65), with 5364 (86.5%) pts having estrogen receptor-positive, 2226 (35.9%) pts having node-negative and 2088 (33.7%) pts having grade 3 tumors. Median tumor size was 18 mm (interquartile range (IQR) 13-25 mm). After a median follow-up of 9.3 years (IQR, 5.9-14.8), 1083 deaths were observed. PREDICT assigned higher risk to subjects who had earlier events 62% of the times (C-index 0.62 95%CI 0.58-0.65). Overall, the 5- and 10-year OS was underestimated by 5.1% (95%CI 3.9-6.4), observed 5-year OS was 92.2% vs. predicted 87.1% and by 2.1% (95%CI 0.3-4.0), observed 10-year OS was 74.4% vs. predicted 72.3%, respectively, with 60% and 93% of the expected events respectively observed (calibration intercepts -0.50 and -0.08). The OS underestimation was consistent across subgroups, with worse predictive performance for pts with large tumor size, young patients, obese patients or HER2-positive disease.



Conclusions

Our analysis showed that PREDICT underestimates 5- and 10-year OS. Oncologists need to be aware of this limitation when they use this tool to provide prognostic information to pts with early-stage BC treated with modern chemotherapy and endocrine regimens.

* All COI related to this study. Contact information: roby.borea@gim.com @RobertoBorea

The GIM trials – early setting

Borea R (<40 years)

Characteristics of the patients		n	%
N total		6205	100
Trial			
MIG1		941	15.17
MIG5		882	14.21
GIM2		1623	26.16
GIM3		2574	41.48
GIM6		185	2.98
Age			
≤40		591	9.52
41-65		4044	65.17
≥65		1570	25.30
Missing		0	0
BMI			
Underweight (<18.5)		93	1.5
Normal (18.5-24.9)		2525	40.69
Overweight (25 to 29.9)		1826	29.43
Obese (≥30)		1131	18.23
Missing		630	10.15
Menopausal status			
Premenopausa		1778	28.65
Postmenopausal		4412	71.10
Missing		15	0.24
Histology			
Ductal		4982	80.29
Lobular		739	11.91
Other		439	7.07
Missing		45	0.73
Tumor size (T)			
pT1		3726	60.05
pT2		2181	35.15
pT3/4		257	4.14
Missing		41	0.66
Nodal Status			
pN0		2226	35.87
pN1		2564	41.32
pN2		1060	17.08
pN3		353	5.69
Missing		2	0.03
Grading			
G1		639	10.30
G2		3478	56.05
G3		2088	33.65
Missing		0	0
Tumor Subtype			
Luminal A/B		3743	60.32
HER2 +		647	10.43
TNBC		200	3.22
HR + / HER2 unknown		1325	21.35
Missing		290	4.67
(Neo)Adjuvant chemotherapy			
Antra-based		1751	28.22
Antra + Tax		2658	42.84
Tax-based		118	1.9
Other		0	0
No chemo		1678	27.04
Endocrine therapy			
None		857	13.81
Tam only		1980	31.91
AI		1692	27.27
Tam --> AI		1676	27.01
Missing		0	0
Surgery			
Lumpectomy		4240	68.33
Mastectomy		1953	32.46
Missing		13	0.21

Our analysis showed that PREDICT underestimates 5- and 10-year OS. Oncologists need to be aware of this limitation when they use this tool to provide prognostic information to pts with early-stage BC treated with modern chemotherapy and endocrine regimens.

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Background

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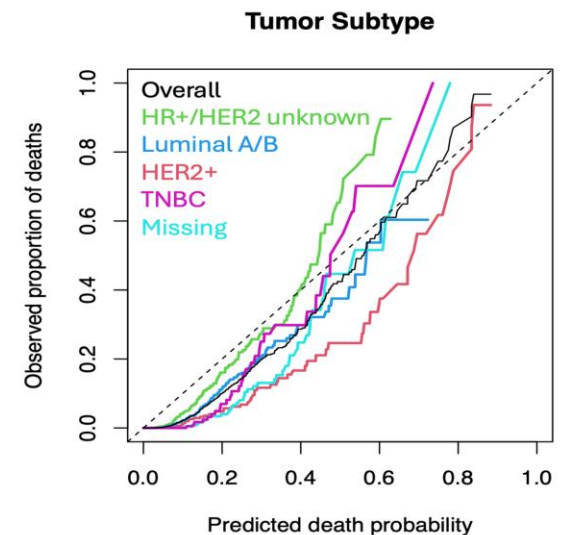
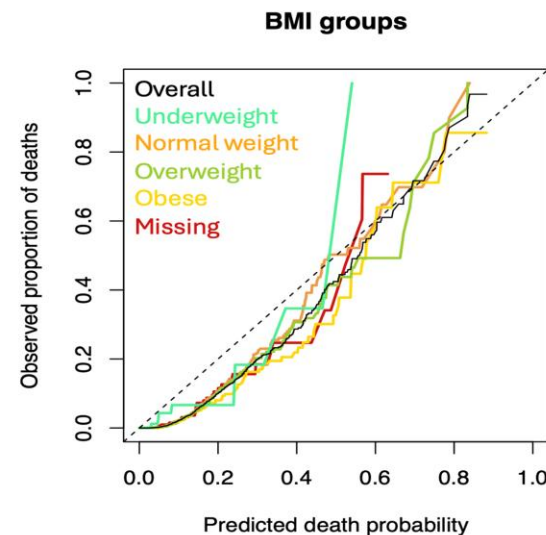
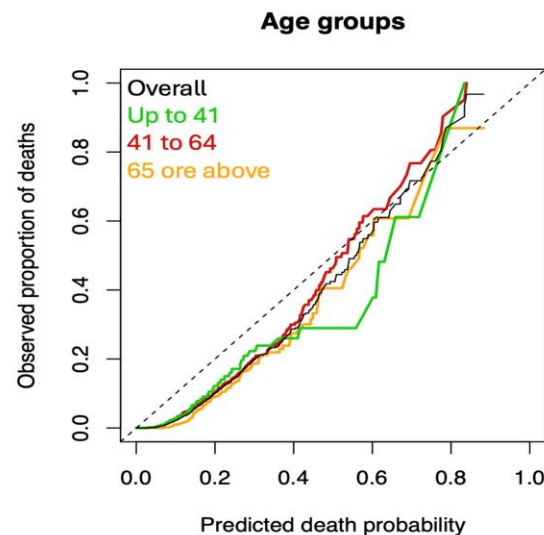
We evaluated the performance of PREDICT on a population enrolled in five RCTs (i.e., MIG1, MIG5, GIM2, GIM3, GIM6) between 1992 and 2012 with complete baseline information. We used Uno's concordance index (C-index) to assess the model's discriminative power over all the time range, and Poisson regressions to assess the 5- and 10-year predictions calibration.

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 - Early setting
 - **Advanced setting**

- The GIM observational studies

- The future of the GIM group

The GIM trials – advanced setting

GIM 11 BERGI

De Angelis C (<40 years)



ORIGINAL RESEARCH

Eribulin in combination with bevacizumab as second-line treatment for HER2-negative metastatic breast cancer progressing after first-line therapy with paclitaxel and bevacizumab: a multicenter, phase II, single arm trial (GIM11-BERGI)

C. De Angelis¹, D. Bruzzese², A. Bernardo³, E. Baldini⁴, L. Leo⁵, A. Fabi⁶, T. Gamucci⁷, P. De Placido¹, F. Poggio⁸, S. Russo⁹, V. Forestieri¹, R. Lauria¹, I. De Santo¹, A. Michelotti¹⁰, L. Del Mastro^{8,11}, M. De Laurentiis¹², M. Giuliano¹⁴, S. De Placido² & G. Arpino¹

GIM12 TYPHER

De Angelis C (<40 years)

The Oncologist, 2025, 30, oya200
<https://doi.org/10.1093/oncolo/oyaf200>
 Advance access publication 16 July 2025
 Clinical Trial Results



Trastuzumab plus lapatinib or chemotherapy in patients with HER2-overexpressed advanced breast cancer: a randomized, phase II trial (GIM12-TYPHER)

Carmine De Angelis^{1,5,10}, Martina Pagliuca^{1,2,5,10}, Emanuela Magnolfi³, Mauro Mansutti⁴, Zelmira Ballatore⁵, Michelino De Laurentiis⁶, Roberto Bordonaro⁷, Vita Leonardi^{8,11}, Dario Bruzzese^{9,10}, Roberta Caputo^{6,10}, Anna Maria Mosconi¹⁰, Saverio Cinieri¹¹, Alessandra Fabi¹², Lucia Del Mastro^{13,14}, Fabio Puglisi^{15,16,10}, Sabino De Placido¹⁷, Mario Giuliano¹⁷, Grazia Arpino^{17,18,10}

Study	Patients included	Enrollment Status	Setting	Type of study
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GIM22 - ERICA	110	Closed	Advanced	Trial
GIM24 - PALBO-BP	164	Closed	Advanced	Trial
GIM25 - CAPT	49	Closed	Advanced	Trial
Total	957			

Outline

- The GIM trials
 - Early setting
 - Advanced setting
- **The GIM observational studies**
- The future of the GIM group

The GIM observational studies – early and advanced setting

Early setting

Study	Patients included	Enrollment Status	Setting	Type of study
GIM19 – STAR	988	Closed	Early	Observational
GIM23 – POSTER	1140	Enrolling	Early	Observational
GIM26 – TRASTHER	318	Closed	Early	Observational
GIM28 – ELMER	405	Enrolling	Early	Observational
GIM29 – GIMOMIC	189	Enrolling	Early	Observational
Total	3040			

Advanced setting

Study	Patients included	Enrollment Status	Setting	Type of study
GIM13 - AMBRA	1.063	Closed	Advanced	Observational
GIM14 - BIO-META	5.041	Enrolling	Advanced	Observational
GIM20 - CITOHER2	46	Closed	Advanced	Observational
GIM21 - LIQERBCEPT	50	Closed	Advanced	Observational
GIM27 - THERAPY	12	Closed	Advanced	Observational
GIM30 – RAPID	85	Closed	Advanced	Observational
GIM33 – TRUTH	25	Enrolling	Advanced	Observational
Total	6322			

The GIM observational studies

GIM23 - POSTER

Arecco L (<40 years)

The Breast 77 (2024) 103769

Contents lists available at ScienceDirect

The Breast

journal homepage: www.journals.elsevier.com/the-breast



Adjuvant endocrine therapy choices in premenopausal patients with hormone receptor-positive early breast cancer: Insights from the prospective GIM23-POSTER study

Luca Arecco^{a,b,*}, Maria Maddalena Latocca^a, Eva Blondeaux^c, Ferdinando Riccardi^d, Carmela Mocerino^d, Valentina Guarneri^{e,f}, Eleonora Mioranza^f, Giancarlo Bisagni^g, Elisa Gasparini^g, Fabio Puglisi^{h,i}, Alexandro Membrino^{h,i}, Antonella Ferro^j, Vincenzo Adamo^k, Filippo Giovanardi^g, Stefano Tamberi^l, Sara Donati^m, Elisabetta Landucciⁿ, Laura Biganzoli^o, Sara Piccinini^a, Simona Pastorino^a, Evandro de Azambuja^b, Francesca Poggio^a, Matteo Lambertini^{a,p}, Lucia Del Mastro^{a,p}

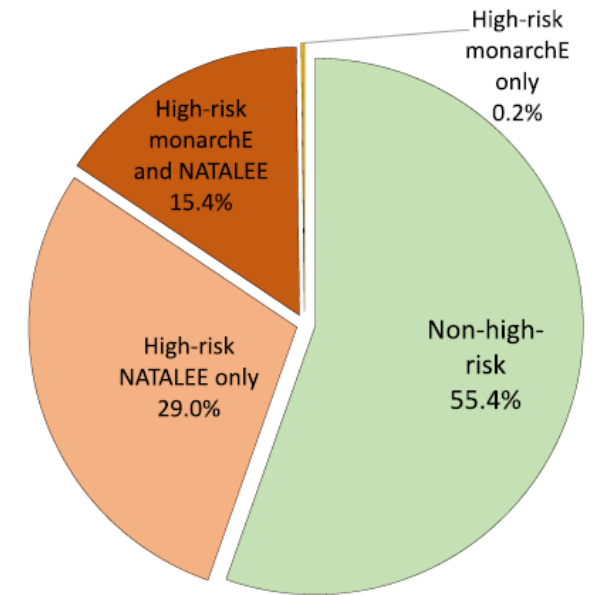
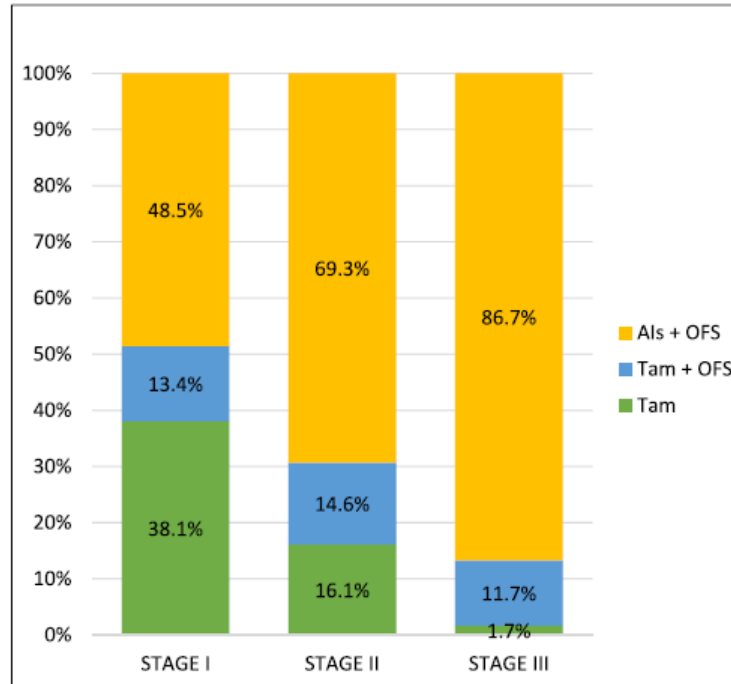
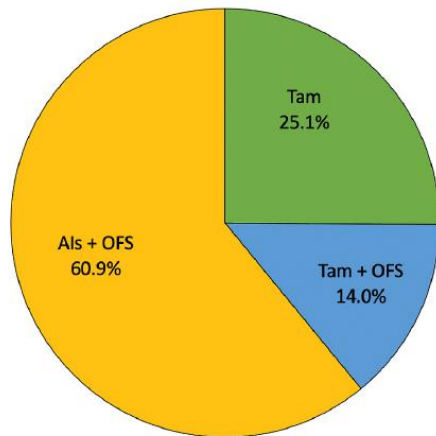


Fig. 1. Adjuvant endocrine therapy prescribed in the overall population.

The GIM observational studies

GIM14 - BIOMETA

Cucciniello L (<40 years)

npj | breast cancer

Article

Published in partnership with the Breast Cancer Research Foundation



<https://doi.org/10.1038/s41523-024-00713-8>

Clinico-pathological predictors of radiologic complete response to first-line anti-HER2 therapy in metastatic breast cancer

Check for updates

Linda Cucciniello^{1,2}, Eva Blondeaux³, Claudia Bighin⁴, Simona Gasparro⁵, Stefania Russo⁶, Arianna Dri^{1,2}, Palma Pugliese⁷, Andrea Fontana⁸, Enrico Cortesi⁹, Antonella Ferzi¹⁰, Ferdinando Riccardi¹¹, Valentina Sini¹², Luca Boni³, Alessandra Fabi^{5,13}, Filippo Montemurro^{14,15}, Michelino De Laurentiis¹⁶, Grazia Arpino¹⁷, Lucia Del Mastro^{18,19}, Lorenzo Gerrata^{1,2,19} & Fabio Puglisi^{1,2,19}

Conte B (<40 years)

Original Study

Check for updates

T-DM1 Efficacy in Patients With HER2-positive Metastatic Breast Cancer Progressing After a Taxane Plus Pertuzumab and Trastuzumab: An Italian Multicenter Observational Study

Benedetta Conte¹, Alessandra Fabi², Francesca Poggio¹, Eva Blondeaux¹, Chiara Dellepiane¹, Alessia D'Alonzo¹, Giuseppe Buono³, Grazia Arpino³, Valentina Magri⁴, Giuseppe Naso⁴, Daniele Presti⁵, Silvia Mura⁶, Andrea Fontana⁷, Francesco Cognetti⁸, Chiara Molinelli¹, Simona Pastorino¹, Claudia Bighin¹, Loredana Miglietta¹, Francesco Boccardo^{9,10}, Matteo Lambertini^{9,10}, Lucia Del Mastro^{1,9} on behalf of the Gruppo Italiano Mammella (GIM) study group



N = 5041

Blondeaux E (<40 years)



ORIGINAL ARTICLE

Factors associated with first-to-second-line attrition among patients with metastatic breast cancer in the real world

E. Blondeaux^{1,9}, L. Boni¹, G. Chilà², A. Dri^{3,4}, R. Caputo⁵, F. Poggio⁶, A. Fabi^{7,8}, G. Arpino⁹, F. Pravisano^{3,4}, E. Geuna², V. Delucchi¹, T. Ruelle^{6,10}, I. Giannubilo^{6,10}, M. De Laurentiis⁵, F. Puglisi^{9,11}, C. Bighin⁶, M. Lambertini^{10,12}, F. Montemurro¹³ & L. Del Mastro^{10,12}

Other analyses ongoing

Molinelli C (<40 years)

European Journal of Cancer 213 (2024) 115113



Contents lists available at ScienceDirect
European Journal of Cancer

journal homepage: www.ejancer.com



Original research

The journey of patients affected by metastatic hormone receptor-positive/HER2-negative breast cancer from CDK 4/6 inhibitors to second-line treatment: A real-world analysis of 701 patients enrolled in the GIM14/BIOMETA study

Chiara Molinelli^{1,4}, Marco Bruzzone⁵, Eva Blondeaux⁶, Tommaso Ruelle^{4,7}, Chiara Lanzavecchia^{4,8}, Michelino De Laurentiis⁴, Stefania Russo⁹, Ferdinando Riccardi¹, Valentina Sini⁸, Francesco Cognetti⁸, Grazia Arpino¹, Alessandra Fabi¹, Palma Pugliese⁸, Elena Collova¹, Andrea Fontana¹⁰, Fabio Puglisi^{10,11}, Claudia Bighin¹, Matteo Lambertini^{10,11}, Lucia Del Mastro^{10,11}

Di Maio M

The Breast 72 (2023) 103583



Contents lists available at ScienceDirect
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journal homepage: www.journals.elsevier.com/the-breast



Evolving treatments and outcomes in HER2-Positive metastatic breast cancer: Data from the GIM14/BIOMETA study

Massimo Di Maio¹, Claudia Bighin², Francesco Schettini^{3,4,5}, Tommaso Ruelle⁶, Laura Marandino⁸, Alessandra Fabi¹, Carmine De Angelis¹, Mario Giuliano¹, Pietro De Placido¹, Michelino De Laurentiis¹, Ferdinando Riccardi¹, Caterina Picotto⁸, Fabio Puglisi^{1,10}, Lucia Del Mastro^{6,7,11}, Grazia Arpino^{6,7,11}, on behalf of the Gruppo Italiano Mammella (GIM) Study Group



26-27 SETTEMBRE 2025 BERGAMO

The GIM observational studies

GIM14 - BIOMETA

N = 5041

Cucciniello L (<40 years)

npj | breast cancer

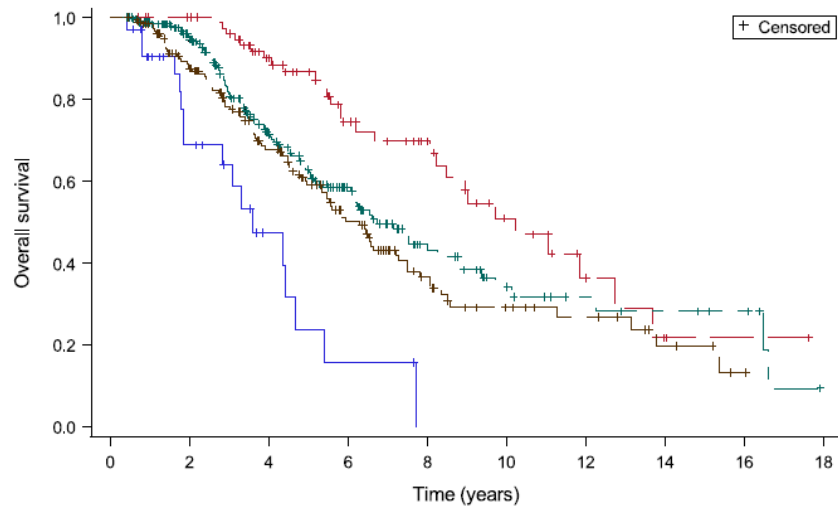
Article

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Clinico-pathological predictors of radiologic complete response to first-line anti-HER2 therapy in metastatic breast cancer



	PD	RC	RP	SD
PD	34	16	6	2
RC	80	76	54	34
RP	250	196	114	64
SD	181	141	94	53



Molinelli C (<40 years)

European Journal of Cancer 213 (2024) 115113

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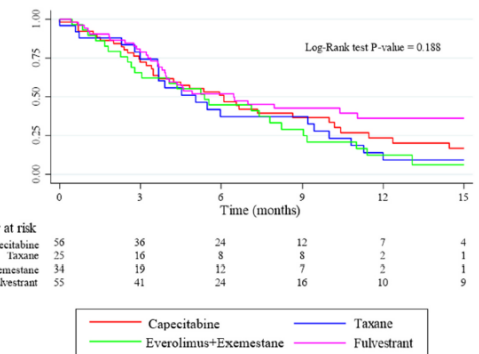
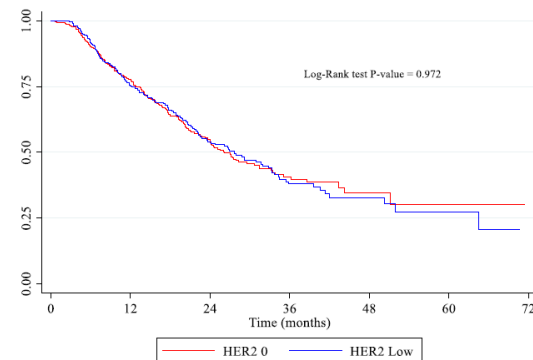
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Original research

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Chiara Molinelli ^{a,b}, Marco Bruzzone ^c, Eva Blondeaux ^c, Tommaso Ruelle ^{a,b}, Chiara Lanzavecchia ^{a,b}, Michelino De Laurentis ^d, Stefania Russo ^e, Ferdinando Riccardi ^f, Valentina Sini ^g, Francesco Cognetti ^h, Grazia Arpino ⁱ, Alessandra Fabi ^j, Palma Pugliese ^k, Elena Collovà ^l, Andrea Fontana ^m, Fabio Puglisi ^{n,o}, Claudia Bighin ^p, Matteo Lambertini ^{a,b}, Lucia Del Mastro ^{a,b}



26-27 SETTEMBRE 2025 BERGAMO

The GIM observational studies

GIM14 – BIOMETA - Other analyses ongoing

- Prevalence and predictors of early progression in first-line CDK4/6 inhibitors (Pagliuca M)
- Survival outcomes of patients relapsing after adjuvant CDK4/6 inhibitors (gruppo Genova)
- Effectiveness of sacituzumab in patients with TNBC and HR+ (Caputo R)
- Effectiveness of CDK4/6 and ADCs in patients with HER2-low (Di Lauro V)
- Overall survival according to different follow up strategies (Blondeaux E)
- Survival outcomes of triple negative breast cancer patients treated with immunotherapy (Cerbone L/Ruelle T)
- Brain metastasis (Fabi A et al)
- Lobular breast cancer (Carbogin L and Fabi A)
- Inflammatory indexes as prognostic biomarkers in advanced triple negative breast cancer patients (De Giorgi U et al – submitted)

Outline

- The GIM trials
 - Early setting
 - Advanced setting
- The GIM observational studies
- **The future of the GIM group**

The future of the GIM group

GIM36 - VOICE

Assessing prevalence of financial burden and impact of cancer on financial toxicity in patients with early-stage breast cancer

Acronym/study code: VOICE – GIM36

Sponsor no-profit:	National Cancer Institute, Napoli, Italy
Principal Investigators:	Martina Pagliuca, Clinical and Translational Oncology, Scuola Superiore Meridionale, Napoli, Italy Maria Carmela Piccirillo, Clinical Trials Unit, National Cancer Institute, Napoli, Italy

GIM37 - INSPIRE.1

A prospective observational study on the incidence of liquid biopsy-detectable minimal residual disease (lbMRD) in HER2 positive metastatic breast cancer after radiological complete response (rCR): GIM37 - INSPIRE.1

Principal Investigator of the Coordinating Center:

Prof. Lorenzo Gerratana

Co-Principal Investigator of the Coordinating Center and Chair of the Steering Committee:

Prof. Fabio Puglisi

GIM38 - interSECT

A translational observational study on the incidence of targetable mutations in HR-positive, HER2-negative metastatic breast cancer and their impact on prognosis and attrition rate: GIM38/interSECT

Principal Investigator of the Coordinating Center:

Prof. Lorenzo Gerratana

Co-Principal Investigator of the Coordinating Center and Chair of the Steering Committee:

Prof. Fabio Puglisi



OSPEDALE POLICLINICO SAN MARTINO
Sistema Sanitario Regione Liguria
Istituto di Ricovero e Cura a Carattere Scientifico



Thank you for the attention

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*U.O. Epidemiologia Clinica
IRCCS Ospedale Policlinico San Martino*



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