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breast
Journal
Club

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L'IMPORTANZA DELLA RICERCA IN ONCOLOGIA

**7-8 MARZO 2025
NAPOLI**

Hotel Royal Continental
Via Partenope, 38



**UNIVERSITÀ
DEGLI STUDI
DI UDINE**
hic sunt futura



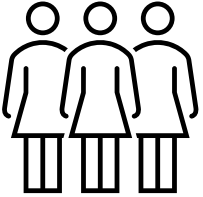
PROTOCOL: GIM 14 - BIO-META

A Retrospective-prospective observational study to evaluate medical treatments (chemotherapy, hormonal therapy and biological therapies) in metastatic breast cancer patients according to biologic subtype and line of treatment

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

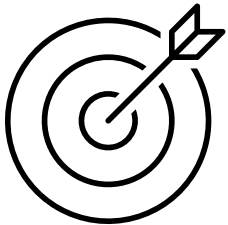
Linda Cucciniello, Eva Blondeaux, Claudia Bighin, Simona Gasparro, Stefania Russo, Arianna Dri, Palma Pugliese, Andrea Fontana, Enrico Cortesi, Antonella Ferzi, Ferdinando Riccardi, Valentina Sini, Luca Boni, Alessandra Fabi, Filippo Montemurro, Michelino De Laurentiis, Grazia Arpino, Lucia Del Mastro, Lorenzo Gerratana, Fabio Puglisi

Target population



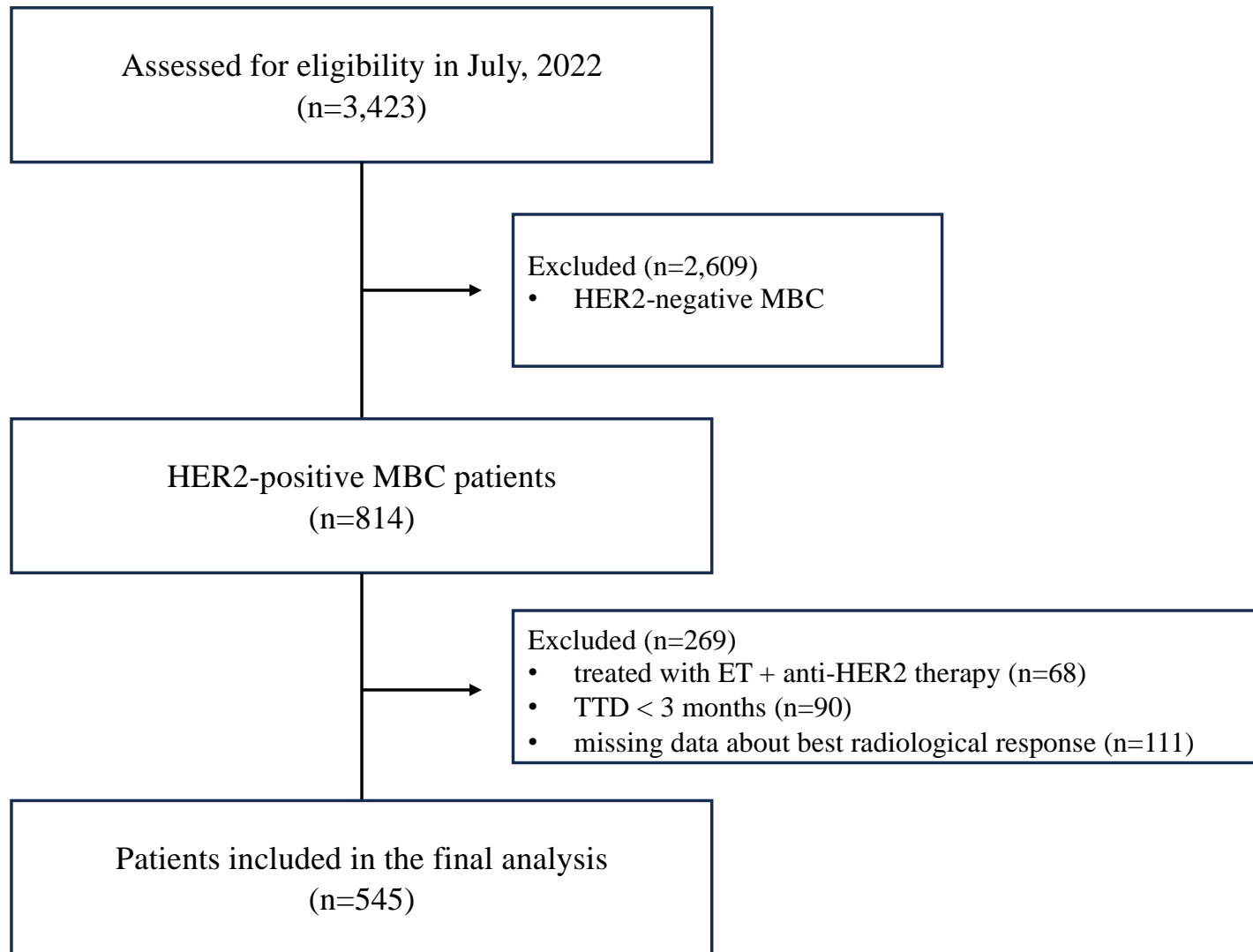
- Patients with HER2-positive metastatic breast cancer treated with 1st line anti-HER2 based therapy from year 2000 to 2021

Study objectives



- To identify clinico-pathological characteristics predictive of achieving a rCR (CR with TTD > 3 months) to a 1st line anti-HER2 based therapy
- To assess the impact of rCR on overall survival (OS)

Patient selection



Strobe diagram summarizing the process for the identification of eligible patients.

- 3423 patients enrolled in GIM14 study at the moment of data cut-off
- After excluding patients not respecting inclusion criteria, **545 patients were included in this analysis.**

Results

clinico-pathological characteristics and best response outcome

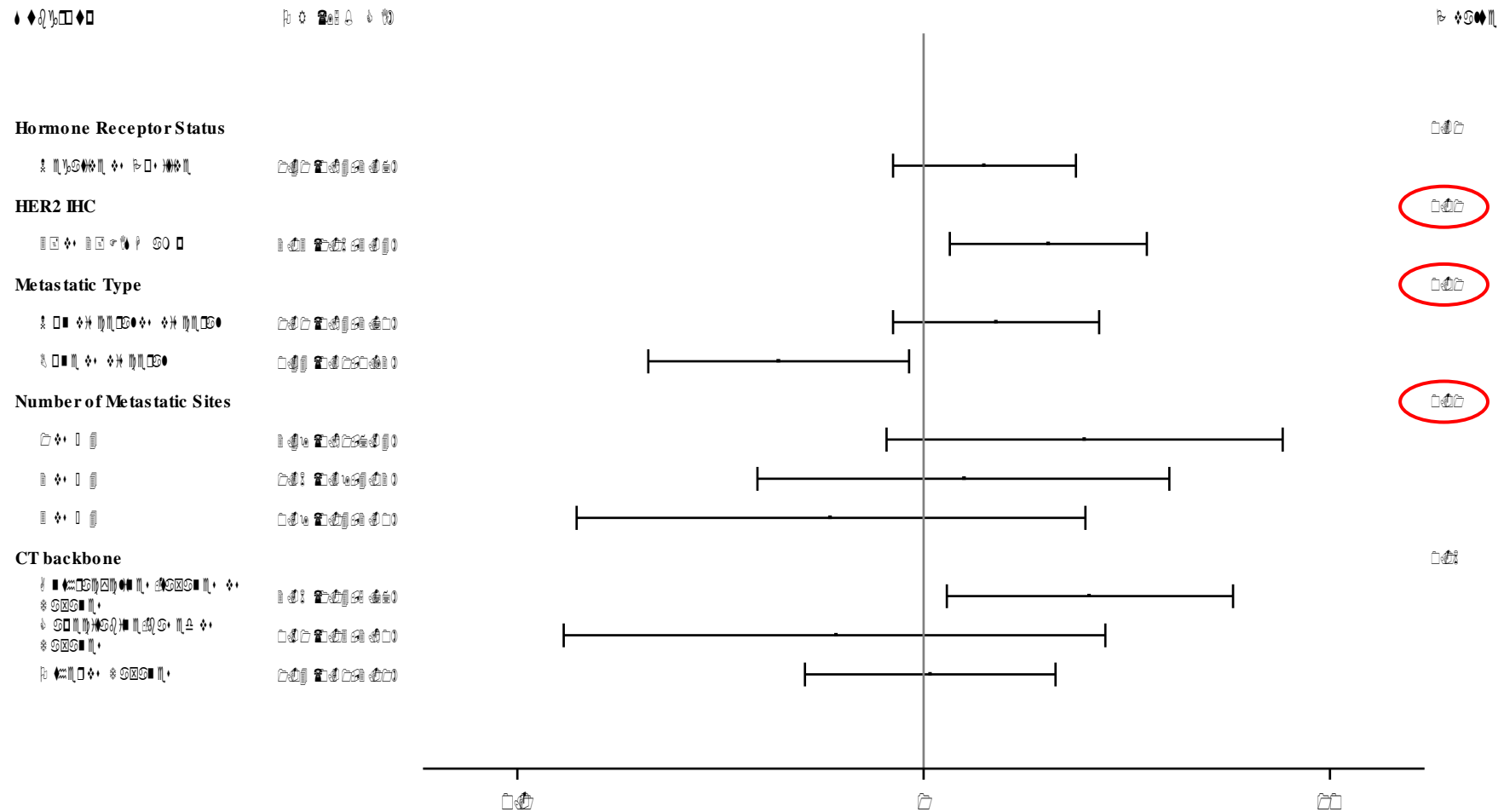
- median age was 53 years old and most patients were in **post-menopause**
- 68% were **HR+** and 59% had **HER2 IHC score 3+**
- 60% had **recurrent MBC**
- 58% presented **visceral metastases**
- 47% had **1 metastatic site**
- 93% had **no CNS involvement**

- **Taxanes** were the main CT backbone (73%) and 54% of patients received the **trastuzumab-pertuzumab doublet**.

Type of Response	No. of patients	Percentage (%)
CR	80	15
RP	250	46
SD	181	33
PD	34	6
TOTAL	545	100

Results

Association amongst clinico-pathological variables and rCR



At multivariable analysis, **HER2 IHC score 3+** (OR 2.03, p-value = 0.01), the **presence of non-visceral metastases** (OR 1.51, p-value=0.01) and **1 metastatic site** (OR 2.49, p-value=0.01) were **significantly associated with higher odds of obtaining a rCR.**

Results

Subpopulation with sustained response (TTD > 18 months)

- most patients were in **post-menopause**
- 50% were **HR+** and 79% had **HER2 IHC score 3+**
- 50% presented **visceral metastases**
- 66% had **1 metastatic site**
- 95% had **no CNS involvement**

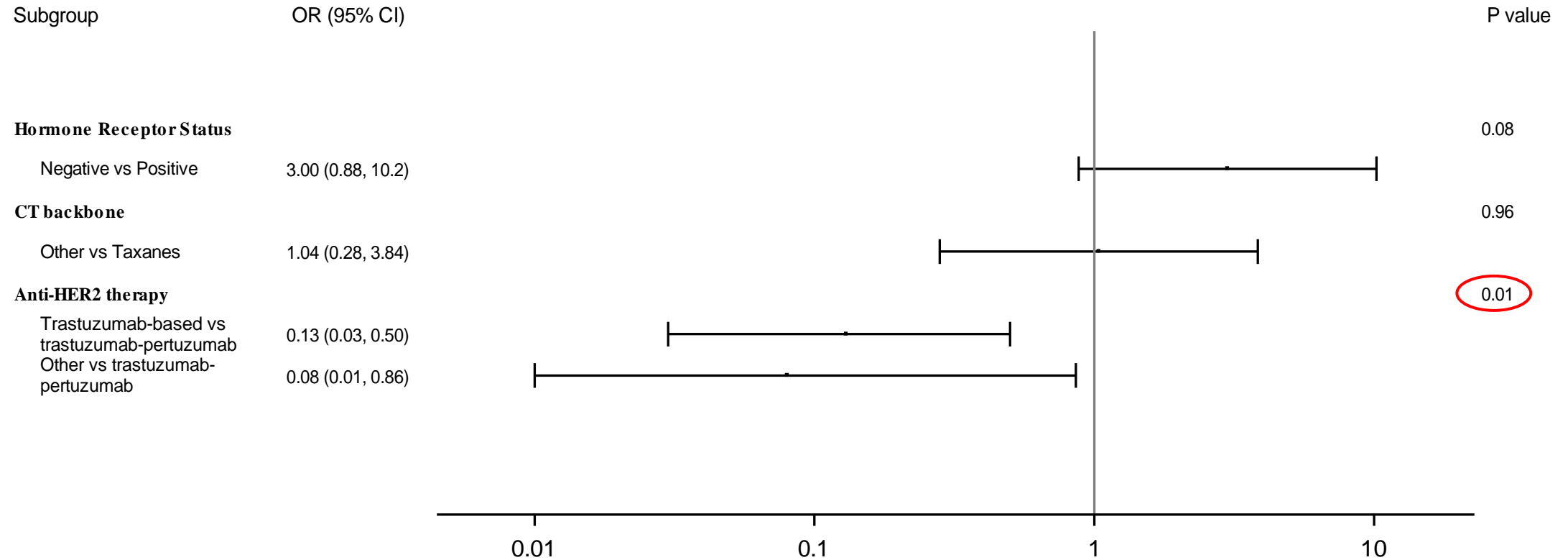
- **Taxanes** were the main CT backbone (73%) and 58% of patients received the **trastuzumab-pertuzumab doublet**.



Type of Response	TTD < 18 months		TTD > 18 months		TOTAL
	No. of patients	Percentage %	No. of patients	Percentage %	
CR	21	8	56	24	
RP	139	49	96	41	
SD	87	31	83	35	
PD	34	12	0	0	
TOTAL	281	52	235	43	516 + 29 incomplete observation = 545

Results

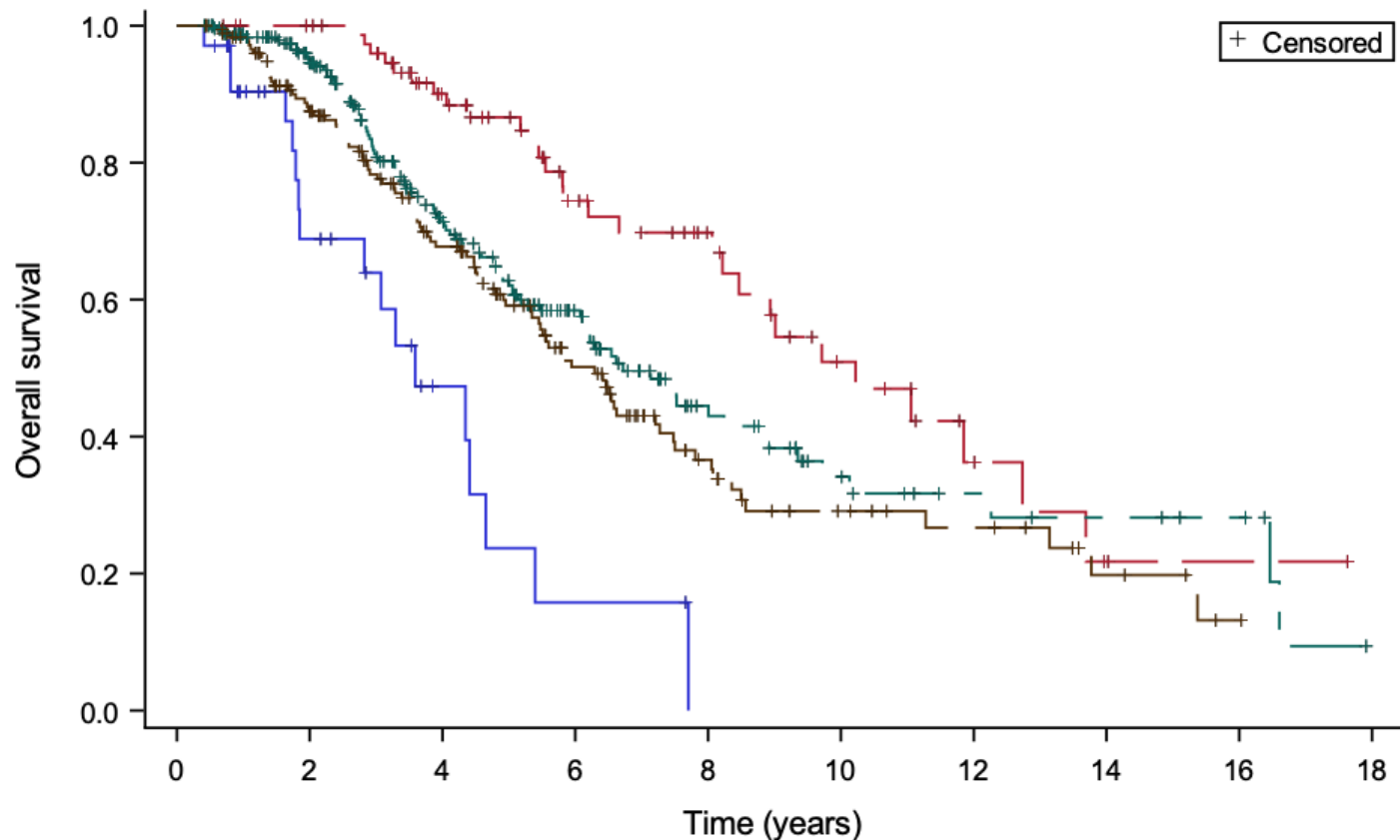
Association amongst clinico-pathological variables CR with TTD > 18 months



At multivariable analysis, only **type of anti-HER2 therapy** (OR 0.13 p-value < 0.01 for trastuzumab-based therapy and OR 0.08, p-value = 0.04 for other anti-HER2 therapy) was found to be related to a **higher probability of achieving a CR with a TTD > 18 months**.

Results

Survival outcomes in all patients with TTD > 3 months

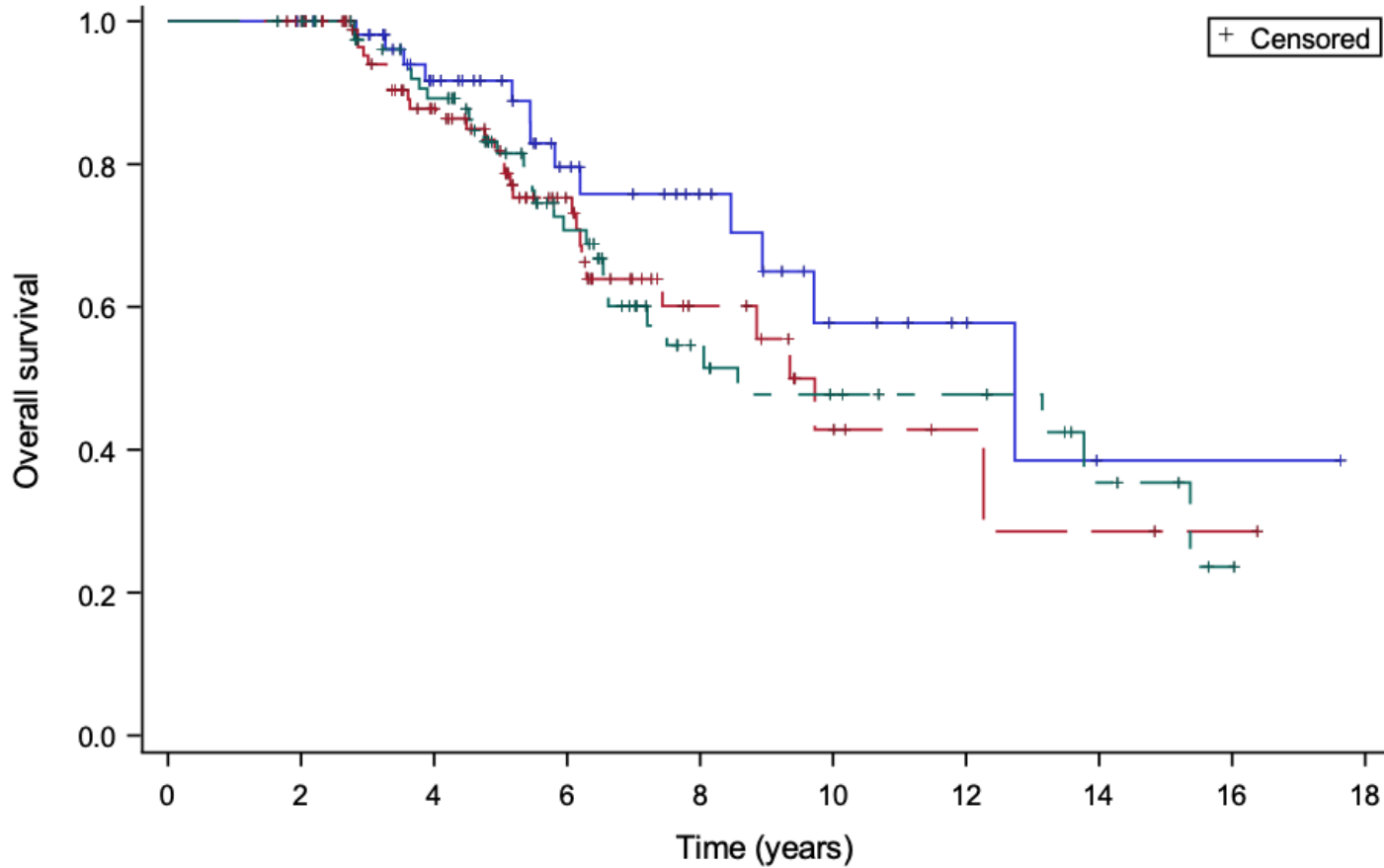


- median OS of **10.22 years** for patients with **CR**
- median OS of **6.71 years** for patients with **PR**
- median OS of **6.29 years** for patients with **SD**

PD	34	16	6	2	0					
RC	80	76	54	34	24	13	6	2	1	0
RP	250	196	114	64	30	15	9	7	5	0
SD	181	141	94	53	26	15	11	5	1	0

Results

Survival outcome in patients with TTD > 18 months



- median OS of **12.73 years** for patients with **CR**
- median OS of **9.35 years** for patients with **PR**
- median OS of **8.56 years** for patients with **SD**

RC	56	55	38	23	15	7	4	1	1	0
RP	96	94	65	35	14	6	3	2	1	0
SD	83	82	65	37	17	12	10	5	1	0

Conclusions

In our experience **higher odds of achieving a complete response** to a 1st line anti-HER2 therapy **with a TTD > 3 months** were present in case of

- **HER2 IHC score 3+**
- **non-visceral metastases**
- **single metastatic site.**

A sustained complete response was observed in the subset of patients that had been exposed to a **trastuzumab-based therapy.**

Study limits



- retrospective, multicentric study

- patients treated in different historical times



- higher percentage of oligometastatic patients

- not applicable with respect to novel anti-HER2 regimens



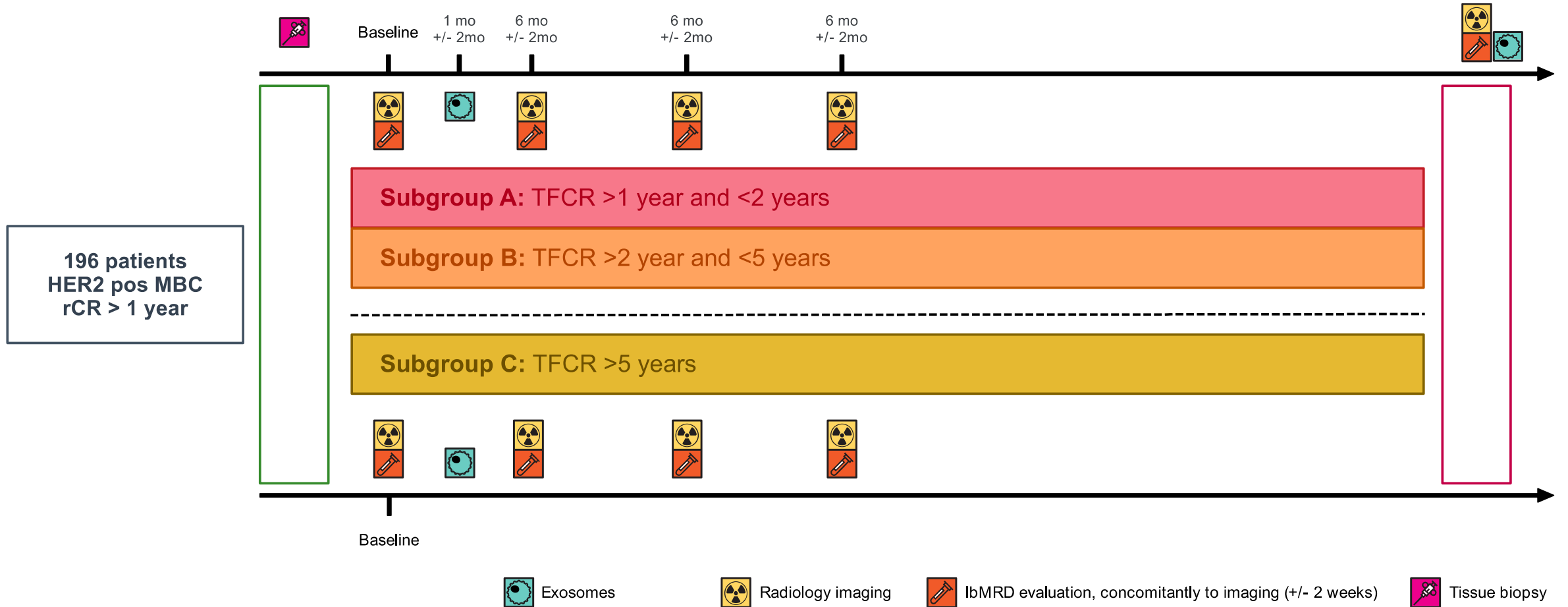
What we know now...

standard first-line therapy for HER2-positive MBC consists of **taxane + pertuzumab-trastuzumab** for 6-8 cycles, **followed by maintenance treatment...**

... but for how long?

... and what about the future?

GIM36/INSPIRE.1





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***Thank you for
your attention!***

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