ADDARII
ONCOLOGIA MEDICA
S.ORSOLA-MALPIGHI BOLOGNA

SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Azienda Ospedaliero - Universitaria di Bologna
IRCCS Istituto di ricovero e cura a carattere scientifico

POLICLINICO DI SANT'ORSOLA

Highlights Setting Precoce
HER2+

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Ospedale di Sant'Orsola

Disclosures

Advisory boards and/or travel accommodation

Roche, Eisai, Novartis, AstraZeneca, Pfizer, Pharmamar, Amgen, PierreFabre, Istituto Gentili, Lilly, Daiichi-Sankyo, Exact Sciences, MSD, GSK, Gilead, Seattle Genetics

Research funding to my Institution

Roche, Eisai, Novartis, AstraZeneca, Pfizer, Pharmamar, AbbVie, Medivation, Array BioPharma, Synthon, Daiichi-Sankyo, Exact Sciences, MSD, GSK, Gilead, BMS, Seattle Genetics, Takeda, Teva

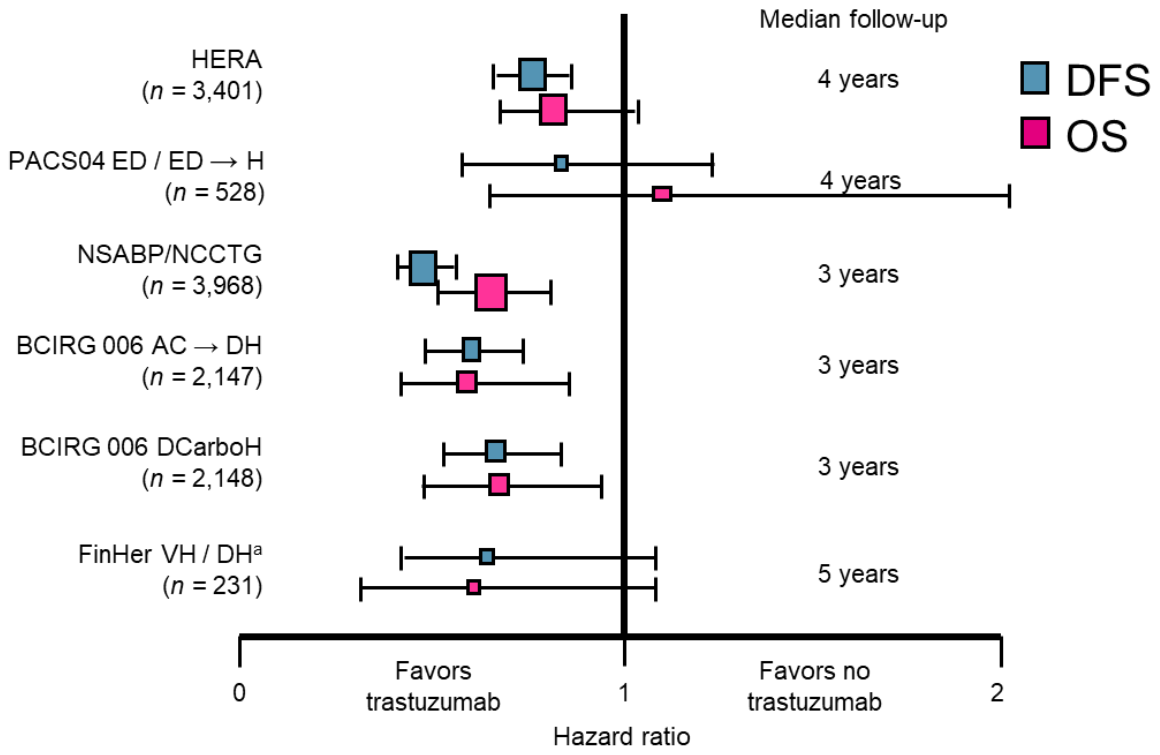
Tappe fondamentali della terapia anti HER-2

1998 l'inizio

2005 la rivoluzione

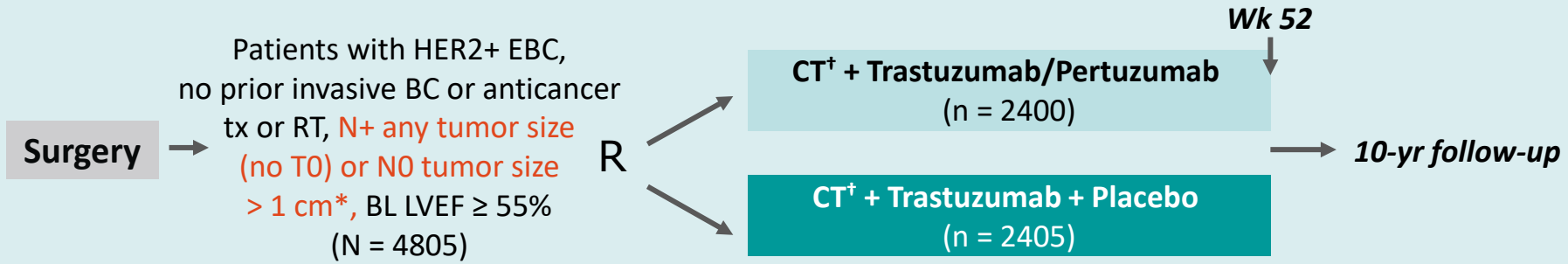
Adjuvant Trastuzumab Trials >14,000 pts

pT1a-b N0 esclusi



APHINITY: Study Design

International, randomized, double-blind, placebo-controlled phase III trial [1]

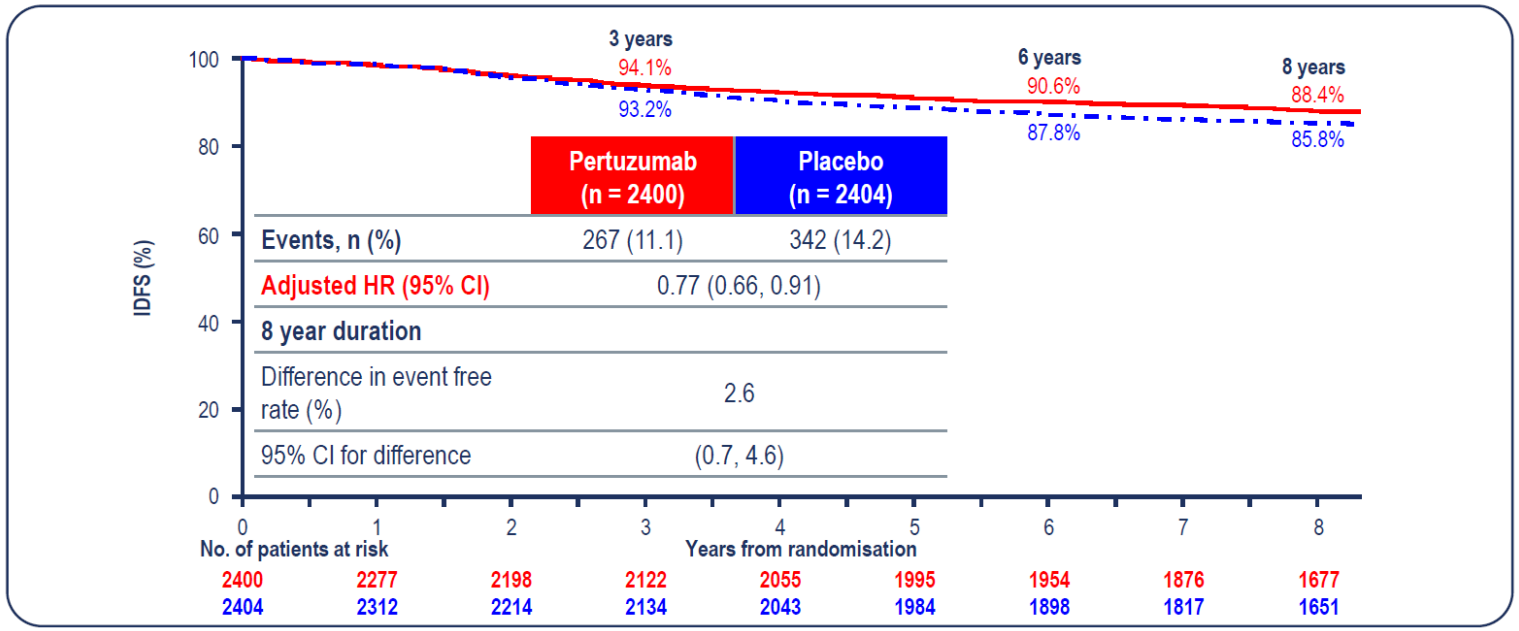


- Primary endpoint: IDFS per modified STEEP definition[2] (excludes second primary non-BC as event)
- Secondary endpoints: IDFS per STEEP definition,[2] OS, distant recurrence-free survival, DFS, recurrence-free interval, safety, cardiac safety, health-related QoL

*Or node negative with tumors > 0.5 to ≤ 1 cm + at least 1 of following: G3; ER and PgR neg; aged < 35 yrs.
Node-negative enrollment capped after first 3655 patients randomized.
†Tx initiated ≤ 8 wks post surgery. Permitted CT: standard anthracycline or nonanthracycline regimens (FEC x 3-4 → TH x 3-4; AC x 4 → TH x 4; or TCH x 6, followed by HER2-targeted therapy for total of 1 yr). Endocrine and/or radiotherapy. could be started at end of adjuvant CT.

1. von Minckwitz. NJEM. 2017;377:122.
2. Hudis. JCO. 2007;25:2127.

APHINITY Updated Descriptive IDFS Analysis at 8.4 Years Median FU by Treatment Regimen - ITT population



Node-positive Cohort

	Pertuzumab (n = 1503)	Placebo (n = 1502)
Events, n (%)	202 (13.4)	276 (18.4)
Unadjusted HR (95% CI)	0.72 (0.60, 0.87)	
8 year duration		
Difference in event free rate (%)	4.9	
95% CI for difference	(2.2, 7.6)	

Node-negative Cohort

	Pertuzumab (n = 897)	Placebo (n = 902)
Events, n (%)	65 (7.2)	66 (7.3)
Unadjusted HR (95% CI)	1.01 (0.72, 1.42)	
8 year duration		
Difference in event free rate (%)	-1.0	
95% CI for difference	(-3.5, 1.5)	

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APHINITY Updated Descriptive Analysis 8.4 year median FU, Site of First Occurrence of an IDFS Event by Nodal Status

	Node-positive Cohort		Node-negative Cohort	
	Pertuzumab N=1503	Placebo N=1502	Pertuzumab N=897	Placebo N=902
Total patients with IDFS event: n (%)	202 (13.4%)	276 (18.4%)	65 (7.2%)	66 (7.3%)
Category of IDFS event: n (%)				
• Distant recurrence	131 (8.7%)	184 (12.3%)	18 (2.0%)	20 (2.2%)
• CNS metastases	43 (2.9%)	48 (2.9%)	8 (0.9%)	5 (0.6%)
• Locoregional BC recurrence	23 (1.5%)	39 (2.6%)	9 (1.0%)	18 (2.0%)
• Contralateral invasive BC recurrence	13 (0.9%)	16 (1.1%)	15 (1.7%)	6 (0.7%)
• Death without prior event	35 (2.3%)	37 (2.5%)	23 (2.6%)	22 (2.4%)

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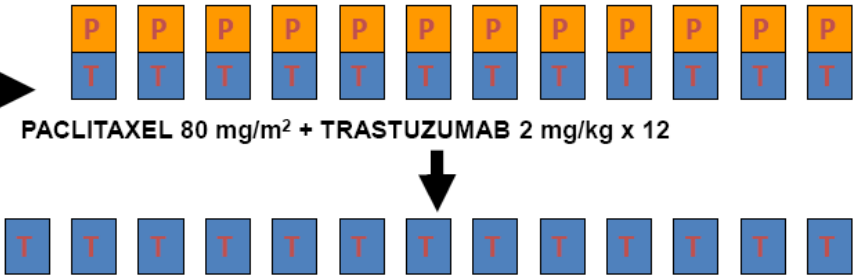
10y results of APT Chemotherapy de-escalated strategy

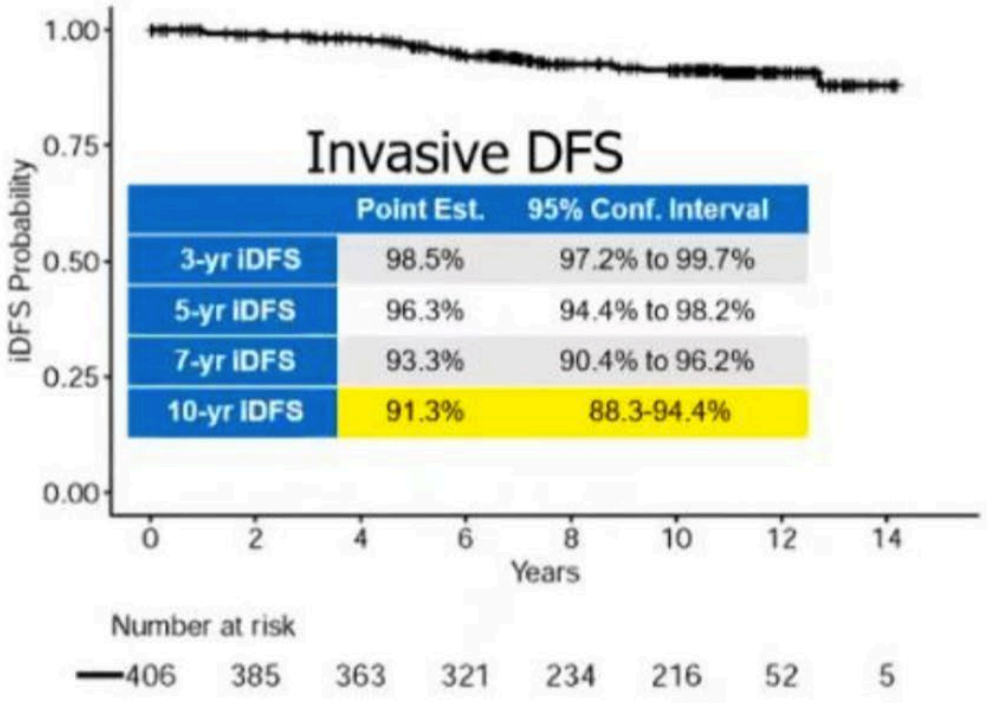
HER2+
ER+ or ER-
Node Negative
≤ 3 cm

N = 410

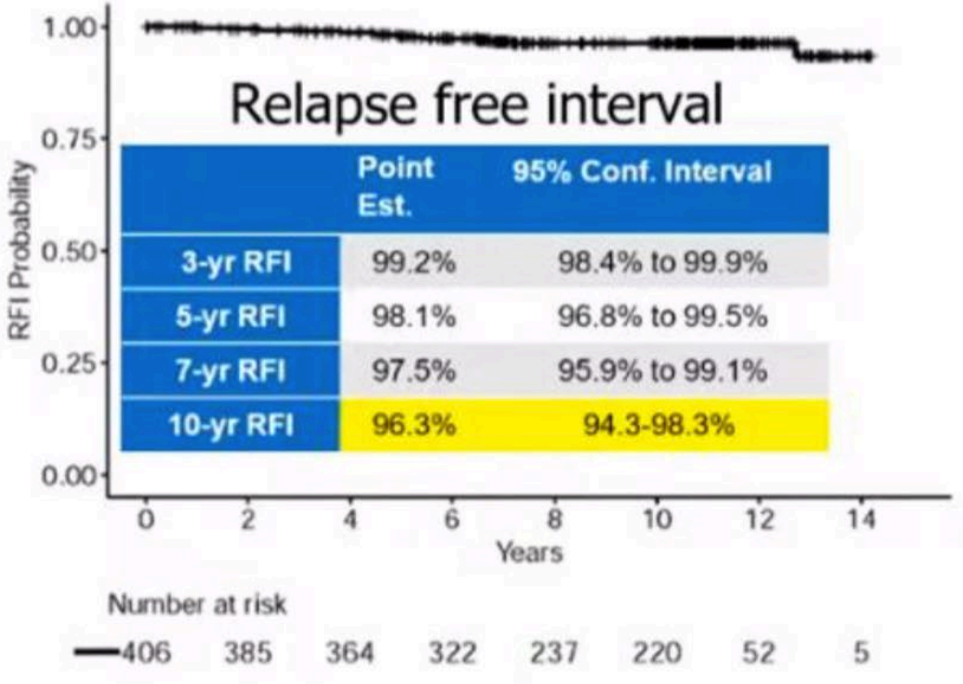
Median FU 4 years

T1a 16%, T1b 30.5%, T1c 41.6%





	Point Est.	95% Conf. Interval
3-yr iDFS	98.5%	97.2% to 99.7%
5-yr iDFS	96.3%	94.4% to 98.2%
7-yr iDFS	93.3%	90.4% to 96.2%
10-yr iDFS	91.3%	88.3-94.4%

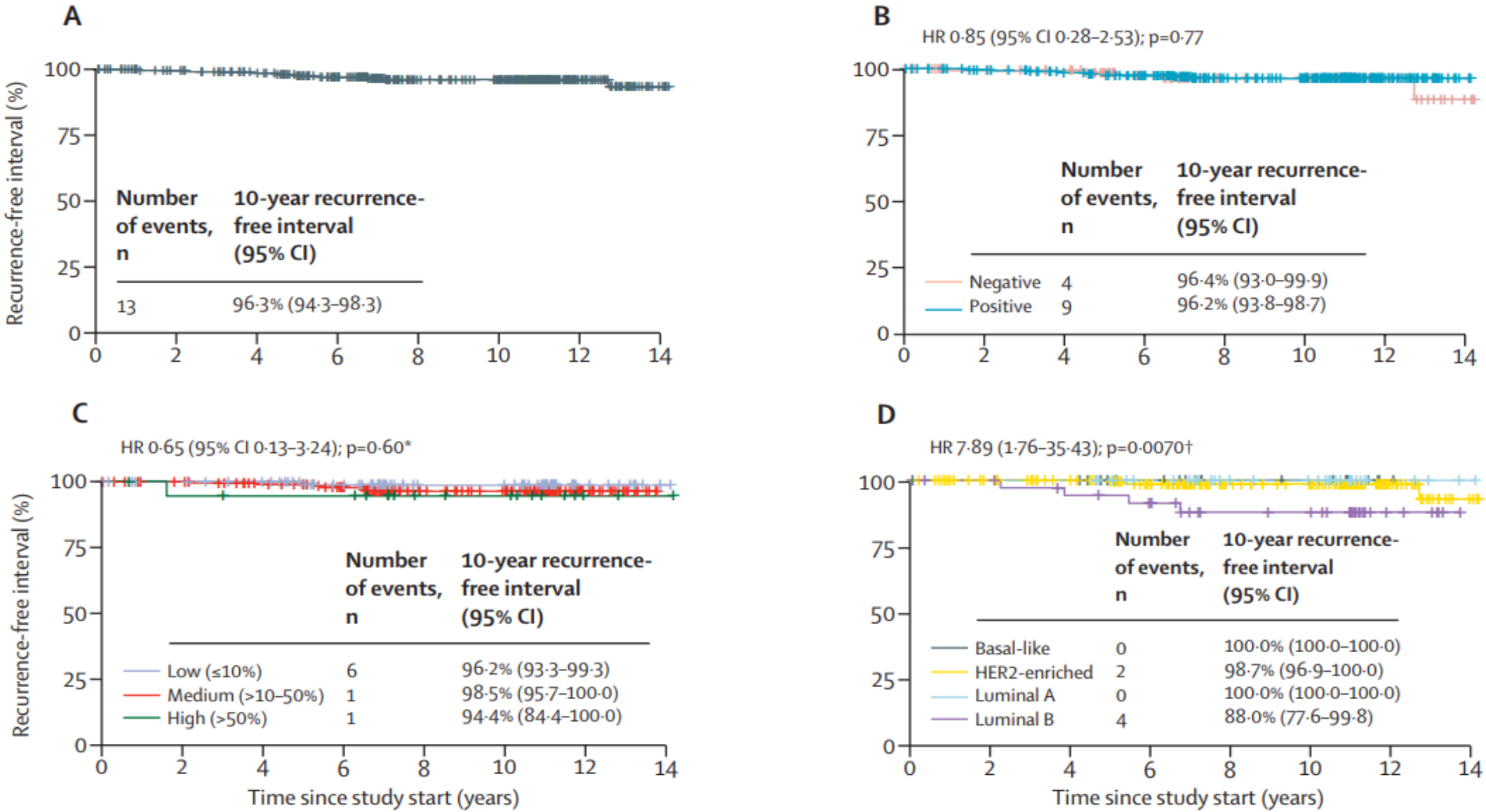


	Point Est.	95% Conf. Interval
3-yr RFI	99.2%	98.4% to 99.9%
5-yr RFI	98.1%	96.8% to 99.5%
7-yr RFI	97.5%	95.9% to 99.1%
10-yr RFI	96.3%	94.3-98.3%

Tolaney S et al , Lancet Oncol 2023

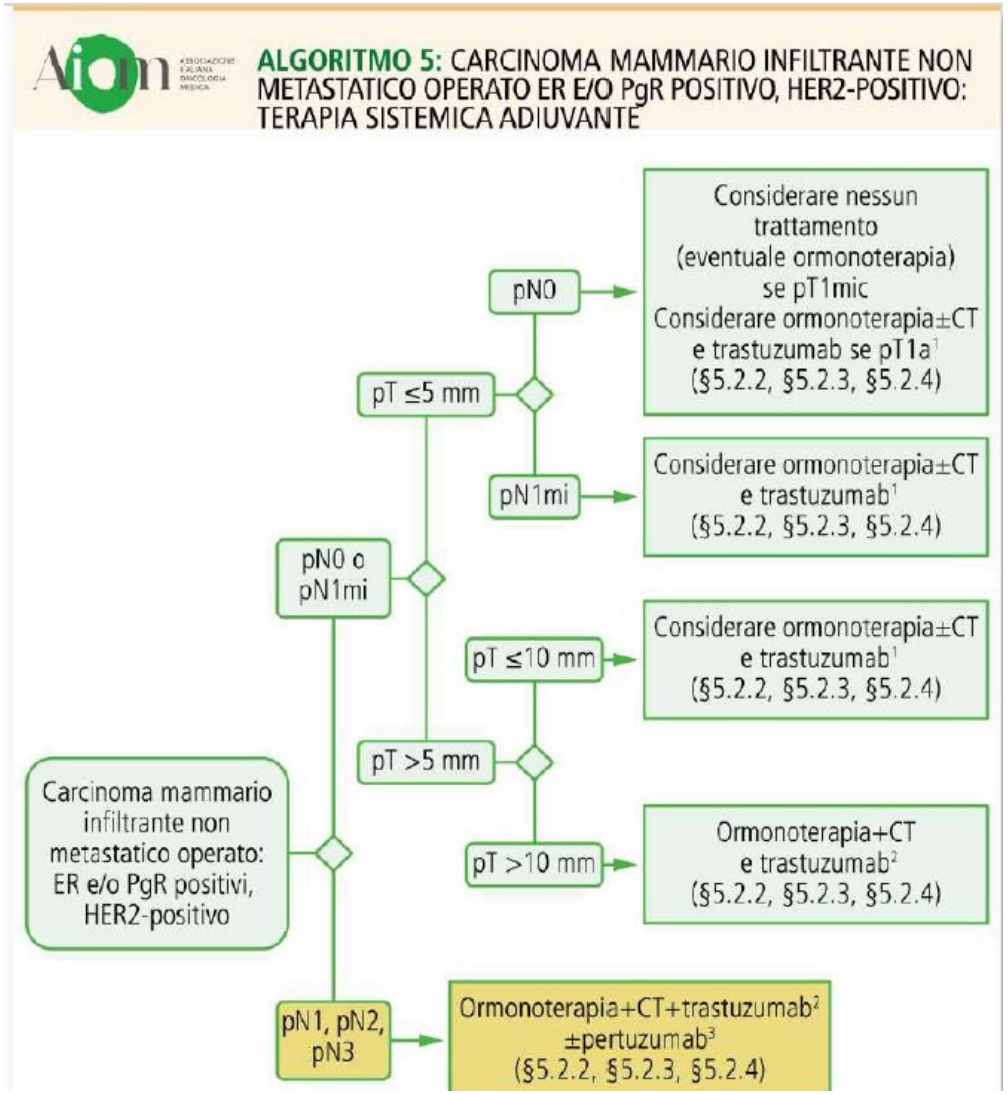
APT trial

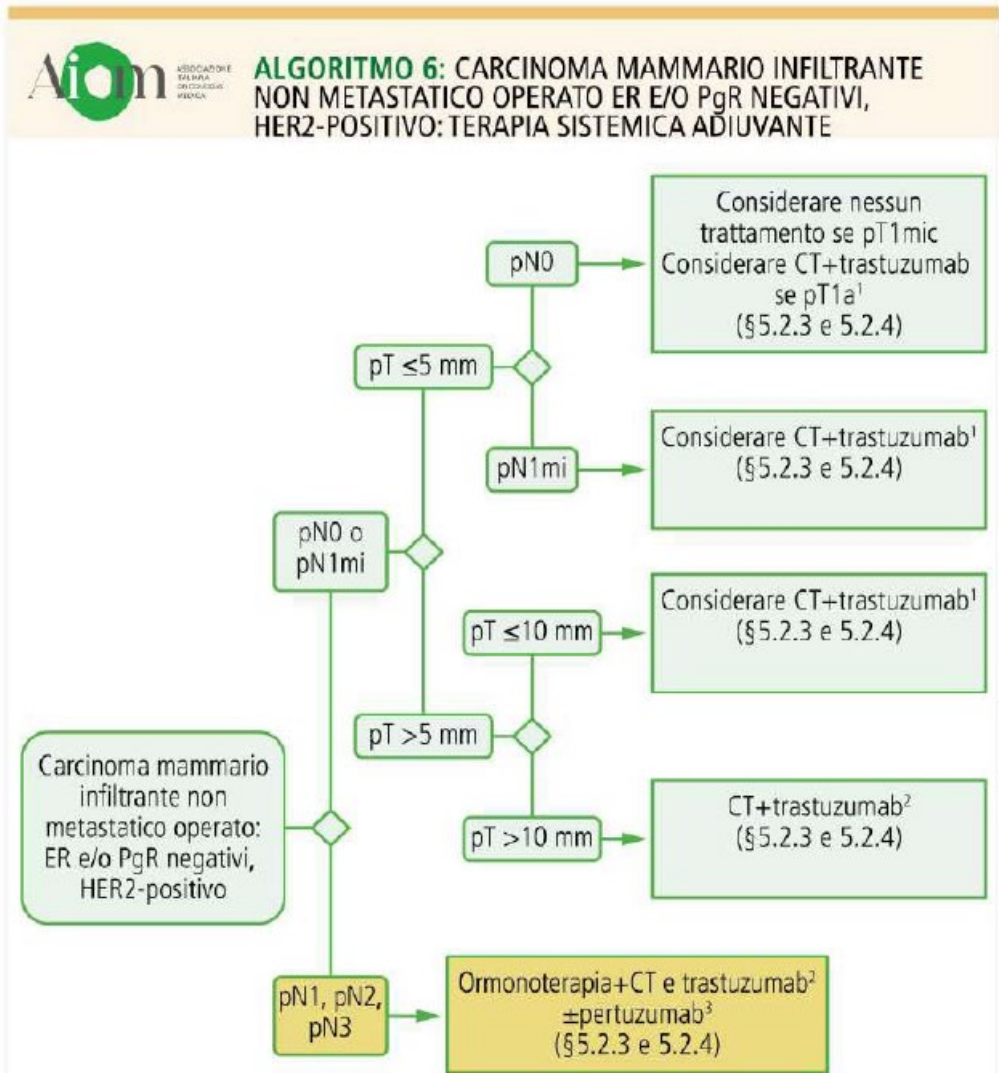
10-year recurrence-free interval overall (A) and by hormone receptor status (B), sTIL expression (C), and PAM50 subtype (D)



Tolaney S et al , Lancet Oncol 2023

eBC HER2+
Terapia adiuvante LG AIOM 2023





eBC HER2+
Terapia adiuvante 2024

Chemio + 1 anno trastuzumab*
(+ pertuzumab in N+)
(+/- ormonoterapia)

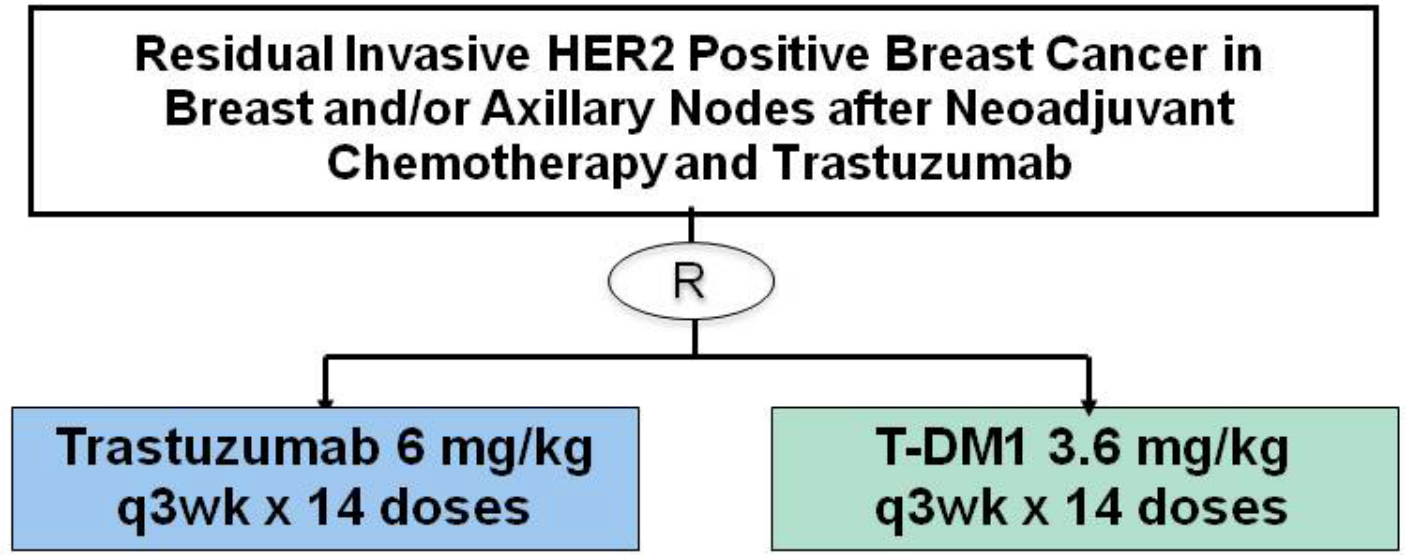
* concomitante > sequenziale

Quale chemioterapia?

$E_{90}C$ x 4 → paclitaxel 80 mg/m2/w x 12 (o docetaxel/carboplatino x 6)

Paclitaxel 80 mg/m2/w x 12 in pT1 pN0 (compresi i pT1mi diffusi)

NSABP B-50-I/GBG 77/Roche BO27938
Katherine: Study Schema



Radiation per standard guidance; hormone therapy if ER or PR pos
Accrual goal - 1484 patients
Primary Endpoint: DFS

PRESENTED AT: ASCO Annual '15 Meeting

T1-4, N0-3, M0 (T1a/bN0 not eligible)
Preoperative systemic treatment consisting of at least 6 cycles with a total duration of at least 16 weeks, including at least 9 weeks of trastuzumab and at least 9 weeks of taxane-based chemotherapy

Note: HER2-directed therapy and chemotherapy may be given concurrently; patients may have received more than one HER2-directed therapy. Patients may have received an anthracycline as part of preoperative therapy

von Minckwitz G et al ASCO 2015
von Minckwitz G et al NEJM 2019

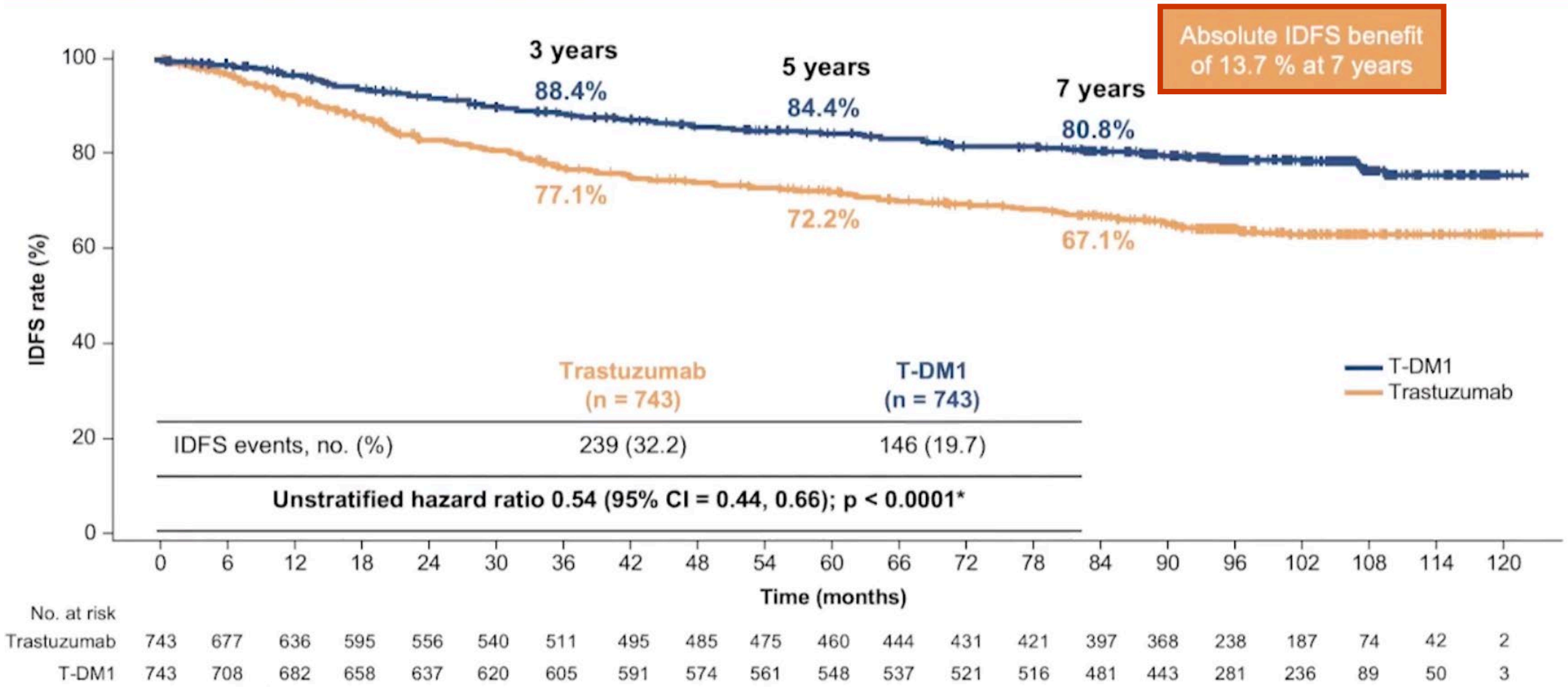
Katherine Characteristics of the Patients

Table 1. Demographic and Clinical Characteristics of the Patients at Baseline.*

Characteristic	Trastuzumab Group (N = 743)	T-DM1 Group (N = 743)
Median age (range) — yr	49 (23–80)	49 (24–79)
Race or ethnic group — no. of patients (%)†		
White	531 (71.5)	551 (74.2)
Asian	64 (8.6)	65 (8.7)
Black	19 (2.6)	21 (2.8)
American Indian or Alaska Native‡	50 (6.7)	36 (4.8)
Multiple or unknown	79 (10.6)	70 (9.4)
Clinical stage at presentation — no. of patients (%)		
Inoperable breast cancer§	190 (25.6)	185 (24.9)
Operable breast cancer¶	553 (74.4)	558 (75.1)
Hormone-receptor status — no. of patients (%)		
Estrogen-receptor–negative and progesterone-receptor–negative or status unknown	203 (27.3)	209 (28.1)
Estrogen-receptor–positive, progesterone-receptor–positive, or both	540 (72.7)	534 (71.9)
Previous use of anthracycline — no. of patients (%)	564 (75.9)	579 (77.9)
Neoadjuvant HER2-targeted therapy — no. of patients (%)		
Trastuzumab alone	596 (80.2)	600 (80.8)
Trastuzumab plus pertuzumab	139 (18.7)	133 (17.9)
Trastuzumab plus other HER2-targeted therapy‖	8 (1.1)	10 (1.3)

von Minckwitz G et al NEJM 2019

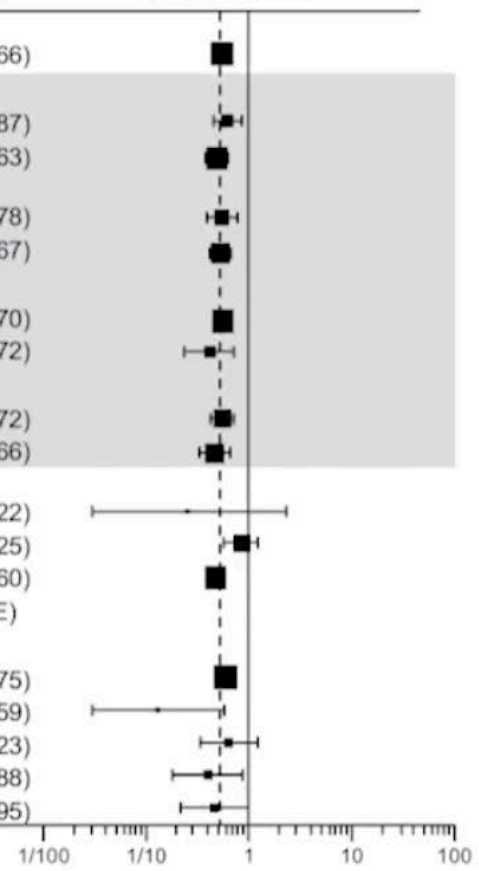
KATHERINE IDFS final analysis; median follow-up 8.4 years (101 months)



Loibl S et al SABCS 2023

Final IDFS analysis: Subgroups (1/2)

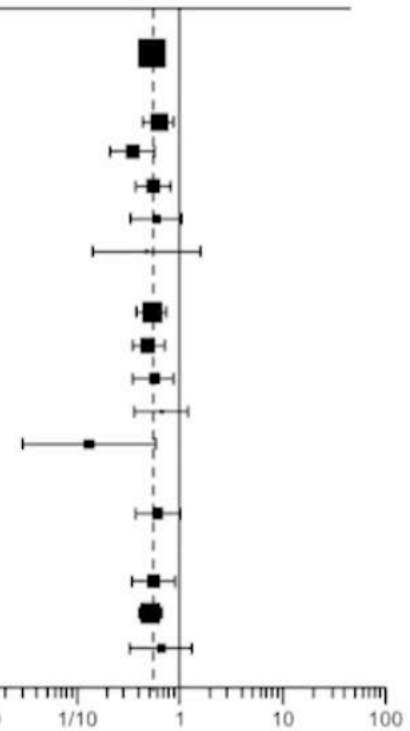
Baseline risk factors	Total n	Trastuzumab (n = 743) Patients per group	Trastuzumab (n = 743) n events	Trastuzumab (n = 743) 7-year IDFS	T-DM1 (n = 743) Patients per group	T-DM1 (n = 743) n events	T-DM1 (n = 743) 7-year IDFS	Hazard ratio	95% CI
All	1486	743	239	67.1	743	146	80.8	0.54	(0.44, 0.66)
Clinical stage at presentation									
Inoperable	375	190	87	51.3	185	62	66.7	0.63	(0.45, 0.87)
Operable	1111	553	152	72.3	558	84	85.4	0.48	(0.37, 0.63)
Hormone receptor status									
Negative (ER-negative and PgR-negative/-unknown)	412	203	75	59.4	209	53	75.0	0.55	(0.39, 0.78)
Positive (ER- and/or PgR-positive)	1074	540	164	69.8	534	93	83.1	0.52	(0.40, 0.67)
Preoperative HER2-directed therapy									
Trastuzumab alone	1196	596	198	66.4	600	128	79.5	0.56	(0.45, 0.70)
Trastuzumab plus additional HER2-directed agent(s)	290	147	41	69.8	143	18	87.2	0.42	(0.24, 0.72)
Pathologic nodal status after preoperative therapy									
Node-positive	688	345	142	57.7	343	96	71.6	0.56	(0.43, 0.72)
Node-negative/not done	798	398	97	74.8	400	50	88.8	0.47	(0.34, 0.66)
Central HER2 status by IHC									
0/1+	25	13	4	67.1	12	1	100.0	0.25	(0.03, 2.22)
2+	326	168	52	68.8	158	44	72.4	0.84	(0.56, 1.25)
3+	1132	559	183	66.5	573	101	82.8	0.47	(0.37, 0.60)
Unknown	3	3	0	100.0				NE	(NE, NE)
Race									
White	1081	530	158	69.3	551	110	80.7	0.59	(0.46, 0.75)
Black or African American	40	19	11	51.3	21	2	88.9	0.13	(0.03, 0.59)
Asian	129	64	22	62.9	65	16	75.3	0.65	(0.34, 1.23)
American Indian or Alaska Native	86	50	25	50.2	36	8	75.8	0.40	(0.18, 0.88)
Other or multiple or unknown	150	80	23	71.0	70	10	86.8	0.45	(0.22, 0.95)



Loibl S et al SABCS 2023

Final IDFS analysis: Subgroups (2/2)

Baseline risk factors	Total n	Trastuzumab (n = 743) Patients per group	Trastuzumab (n = 743) n events	Trastuzumab (n = 743) 7-year IDFS	T-DM1 (n = 743) Patients per group	T-DM1 (n = 743) n events	T-DM1 (n = 743) 7-year IDFS	Hazard ratio	95% CI
All	1486	743	239	67.1	743	146	80.8	0.54	(0.44, 0.66)
Primary tumor stage (at definitive surgery)									
ypT0, ypT1a, ypT1b, ypT1mic, ypTis	637	306	78	74.6	331	59	82.0	0.65	(0.46, 0.90)
ypT1, ypT1c	359	184	60	66.8	175	22	87.4	0.35	(0.21, 0.56)
ypT2	359	185	67	62.9	174	41	78.4	0.55	(0.37, 0.80)
ypT3	108	57	28	46.4	51	19	62.0	0.59	(0.33, 1.06)
ypT4*	23	11	6	33.8	12	5	70.0	0.49	(0.15, 1.61)
Regional lymph node stage (at definitive surgery)									
ypN0	673	332	83	74.0	341	48	87.1	0.53	(0.37,0.75)
ypN1	432	212	76	63.6	220	47	78.0	0.50	(0.35, 0.72)
ypN2	189	103	47	52.4	86	28	69.5	0.56	(0.35, 0.89)
ypN3	67	30	19	32.1	37	21	38.6	0.67	(0.36, 1.24)
ypNX	125	66	14	79.1	59	2	98.2	0.13	(0.03, 0.59)
Residual disease ≤1 cm with negative axillary lymph nodes									
ypT1a, ypT1b or ypT1mic and ypN0	328	160	36	76.7	168	25	85.7	0.62	(0.37, 1.03)
Age group (years)									
<40	296	153	46	67.2	143	28	81.2	0.56	(0.35, 0.90)
40–64	1064	522	170	66.7	542	104	80.9	0.52	(0.41, 0.66)
≥65	126	68	23	69.4	58	14	78.6	0.67	(0.34, 1.30)



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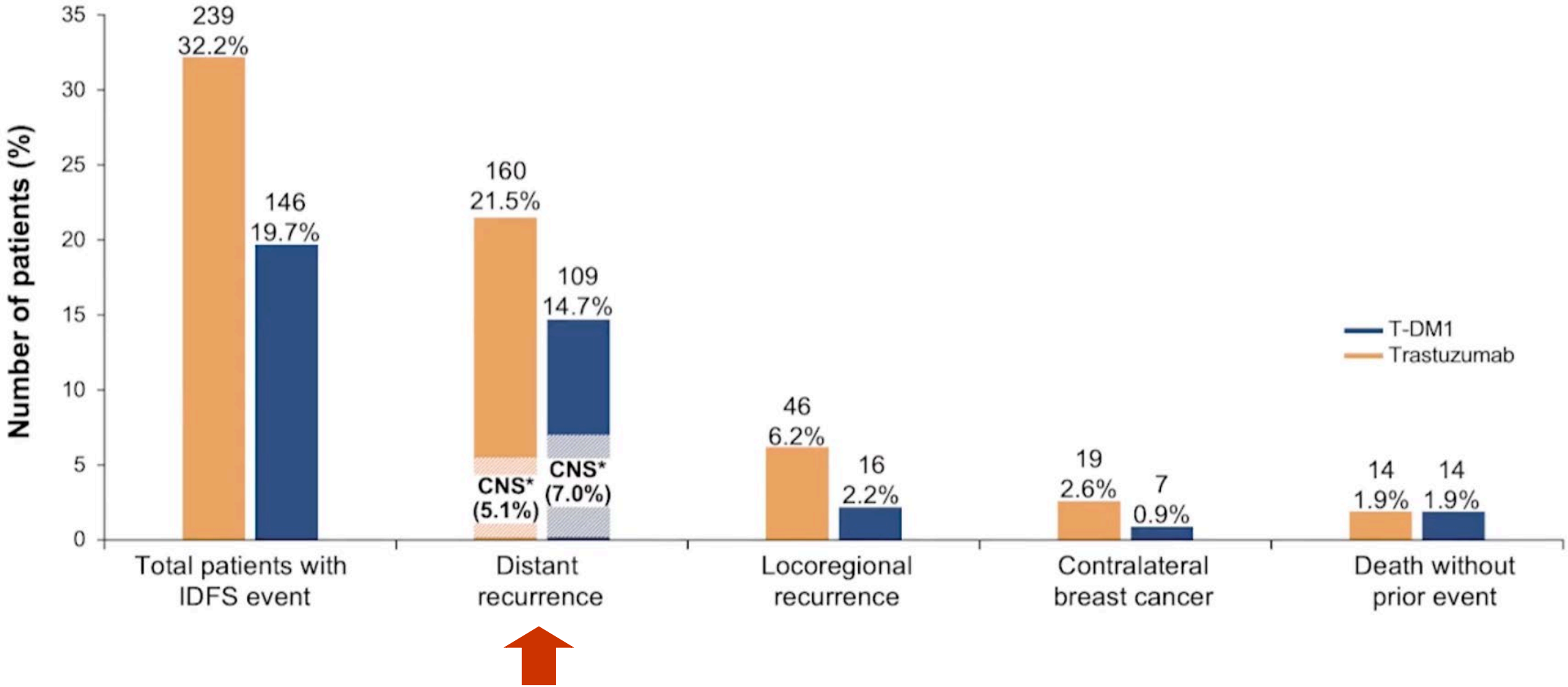
Site of first occurrence of an IDFS event



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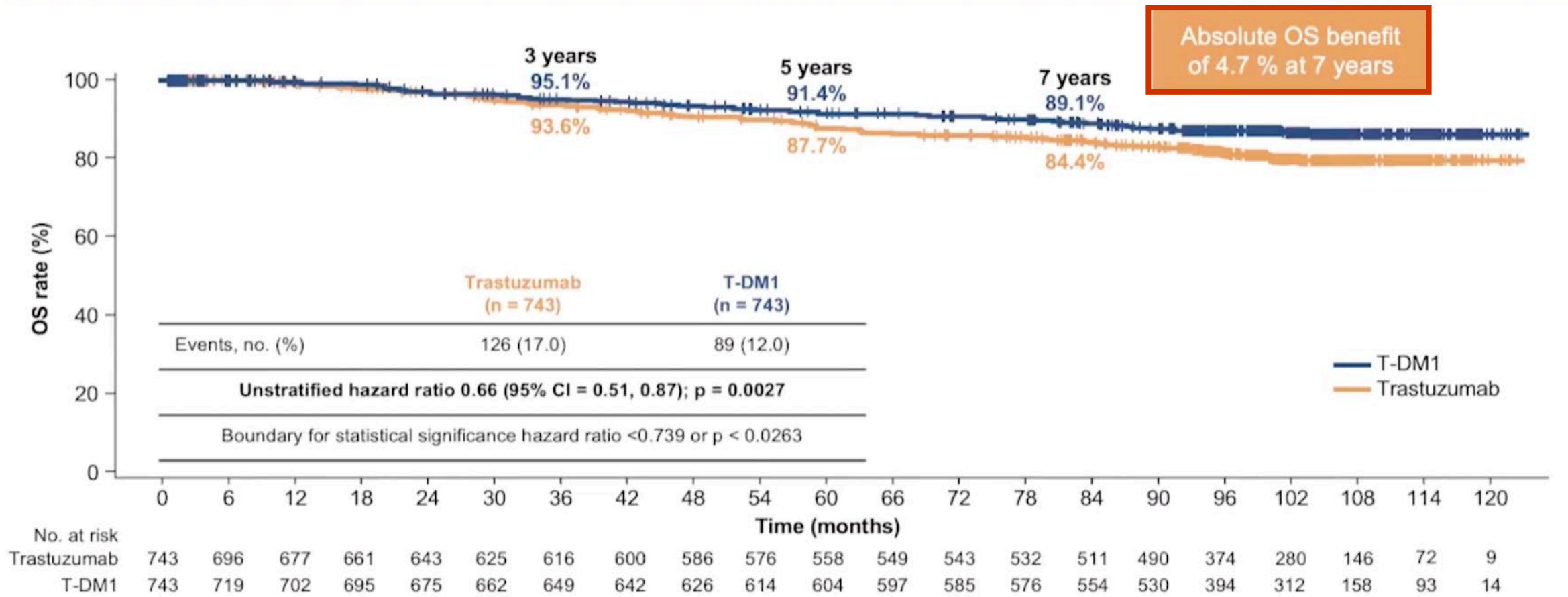
KATHERINE 2nd OS interim analysis; median follow-up 8.4 years (101 months)



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Implicazione chiave dello studio Katherine

L’ottenimento della pCR assume importanza di per sé, indipendentemente dal suo valore come end-point surrogato di outcome

ADIUVANTE ⟷ NEOADIUVANTE

NeoSphere: Study design and main results

TH (n=107)
docetaxel (75→100 mg/m^2)
trastuzumab (8→6 mg/kg)

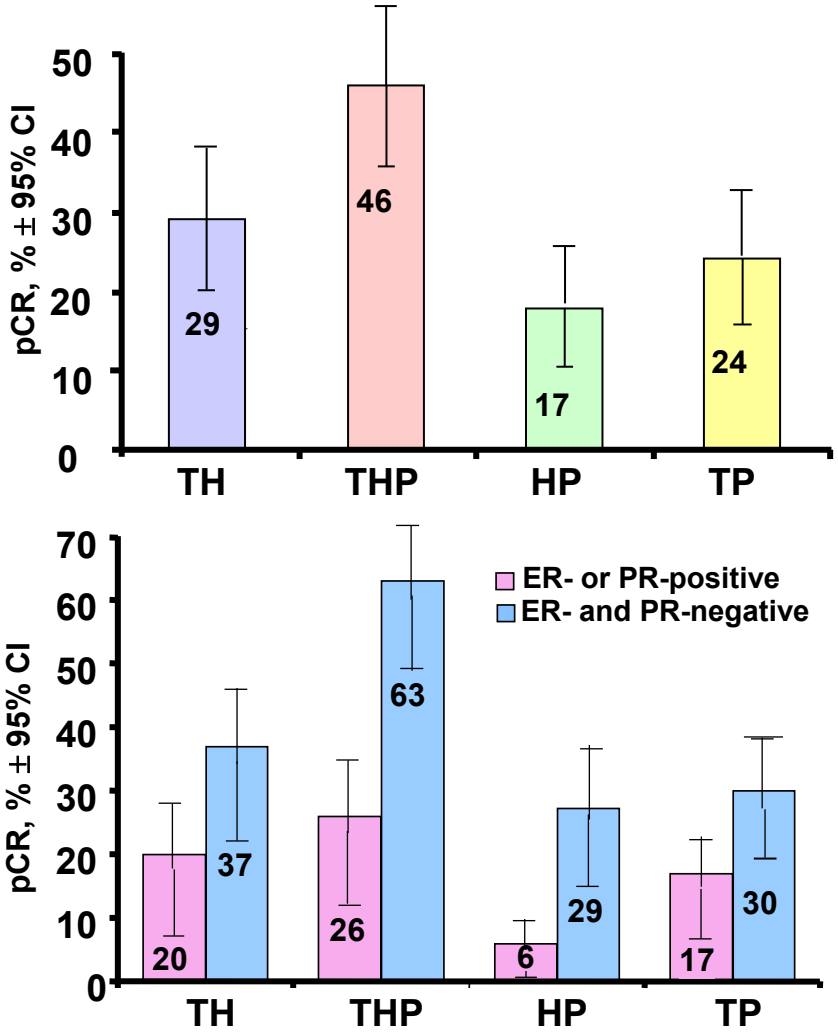
THP (n=107)
docetaxel (75→100 mg/m^2)
trastuzumab (8→6 mg/kg)
pertuzumab (840→420 mg)

HP (n=107)
trastuzumab (8→6 mg/kg)
pertuzumab (840→420 mg)

TP (n=96)
docetaxel (75→100 mg/m^2)
pertuzumab (840→420 mg)

SURGERY

Study dosing: q3w x 4



Gianni L, *et al. Lancet Oncol* 2012; **13**:25–32

Trastuzumab/pertuzumab *vs* trastuzumab
pCR gain without incremental toxicity

Summary of the ten most common adverse events (any grade)

	Trastuzumab plus docetaxel (group A; n=107)	Pertuzumab, trastuzumab, and docetaxel (group B; n=107)
Alopecia	70 (65%)	68 (64%)
Neutropenia	67 (63%)	54 (50%)
Diarrhoea	36 (34%)	49 (46%)
Nausea	39 (36%)	41 (38%)
Fatigue	29 (27%)	28 (26%)
Rash	23 (21%)	28 (26%)
Mucosal inflammation	23 (21%)	28 (26%)
Myalgia	24 (22%)	24 (22%)
Asthenia	19 (18%)	22 (21%)
Headache	12 (11%)	12 (11%)

Data are n (%).

Most common adverse events of grade 3 or higher and serious adverse events

	Trastuzumab plus docetaxel (group A; n=107)	Pertuzumab, trastuzumab, and docetaxel (group B; n=107)
Neutropenia	61 (57%)	48 (45%)
Febrile neutropenia	8 (7%)	9 (8%)
Leucopenia	13 (12%)	5 (5%)
Diarrhoea	4 (4%)	6 (6%)
Asthenia	0	2 (2%)
Granulocytopenia	1 (1%)	1 (1%)
Rash	2 (2%)	2 (2%)
Menstruation irregular	1 (1%)	1 (1%)
Drug hypersensitivity	0	1 (1%)
ALT increased	3 (3%)	0
Total number of serious adverse events	20	15
Number of patients with ≥1 serious adverse events	18 (17%)	11 (10%)
Neutropenia	1 (1%)	4 (4%)
Febrile neutropenia	7 (7%)	6 (6%)
Neutropenic infection	0	1 (1%)
Neutropenic sepsis	1 (1%)	0
Pyrexia	1 (1%)	1 (1%)
Diarrhoea	2 (2%)	0
Congestive heart failure	0	0
Fulminant hepatitis	0	1 (1%)*
Other	8 (7%)	2 (2%)
Deaths	0	1 (1%)†‡

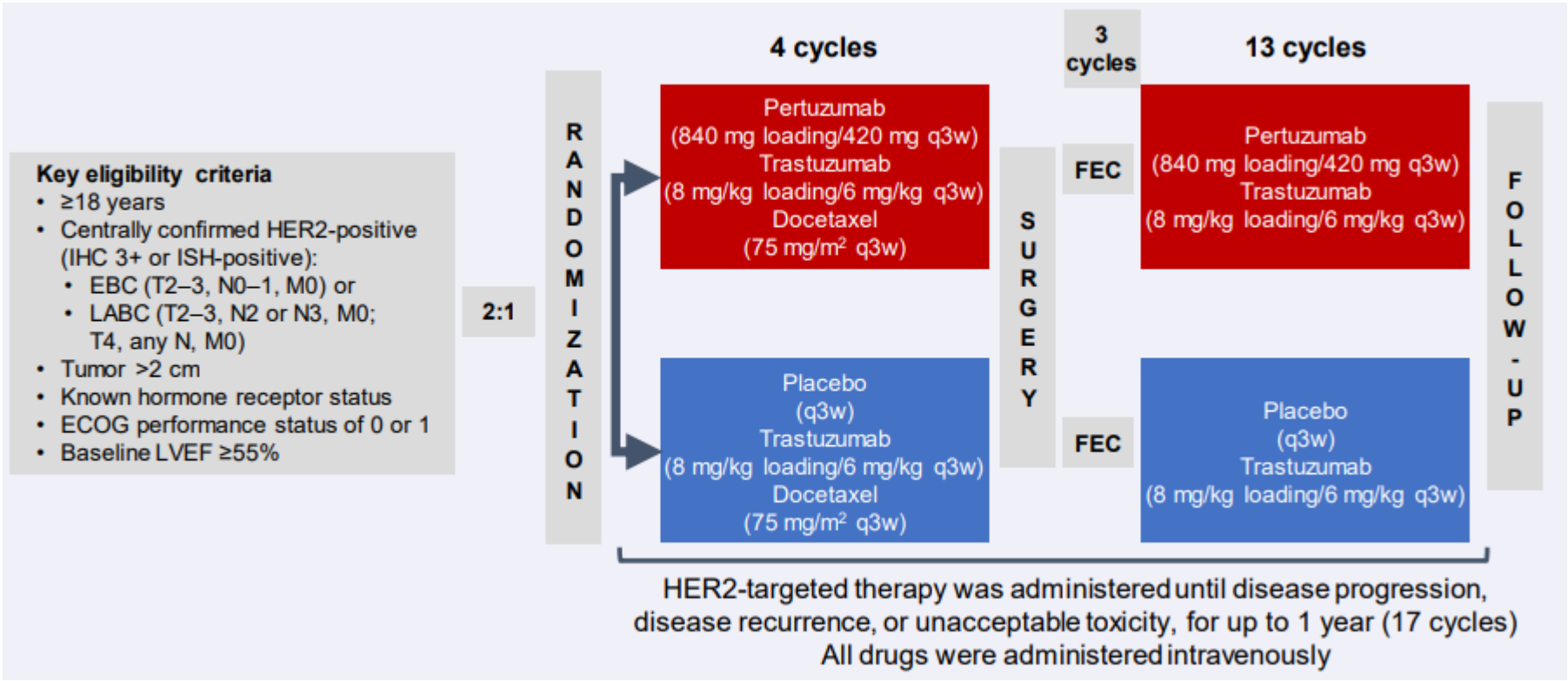
Gianni L, *et al. Lancet Oncol* 2012; **13**:25–32

JAMA Oncology | Brief Report

Efficacy, Safety, and Tolerability of Pertuzumab, Trastuzumab, and Docetaxel for Patients With Early or Locally Advanced ERBB2-Positive Breast Cancer in Asia

The PEONY Phase 3 Randomized Clinical Trial

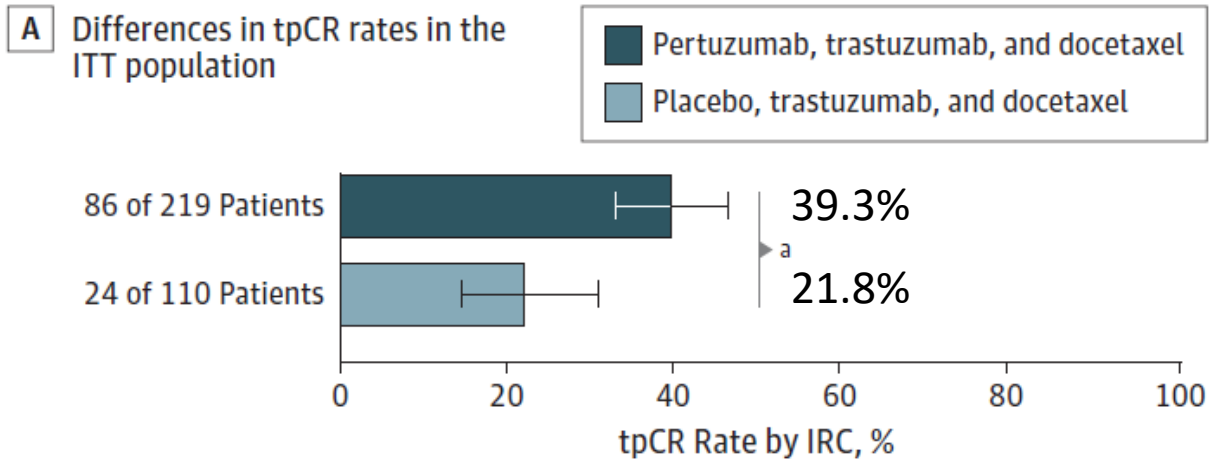
Zhimin Shao, MD; Da Pang, MD; Hongjian Yang, MD; Wei Li, MD; Shusen Wang, MD; Shude Cui, MD; Ning Liao, MD; Yongsheng Wang, MD; Chuan Wang, MD; Yuan-Ching Chang, MD; Hweichung Wang, MD; Seok Yun Kang, MD; Jae Hong Seo, MD; Kunwei Shen, MD; Suphawat Laohawiriyakamol, MD; Zefei Jiang, MD; Junjie Li, MD; Julian Zhou, PhD; Betsy Althaus, PharmD; Yixiang Mao, MD; Jennifer Eng-Wong, MD

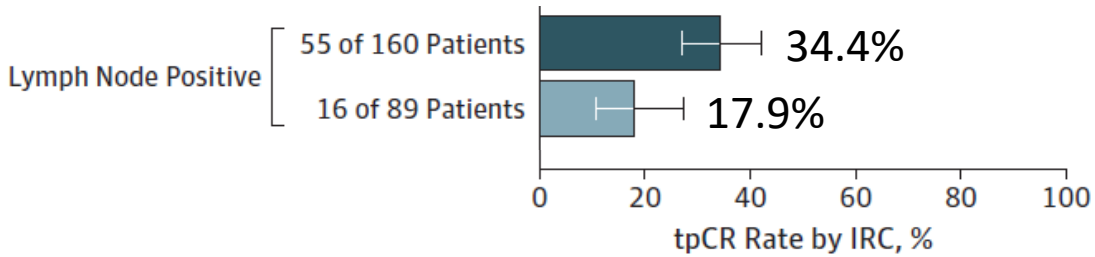


Shao Z et al JAMA Oncol 2020

Primary endpoint of the Phase III PEONY trial: pCR

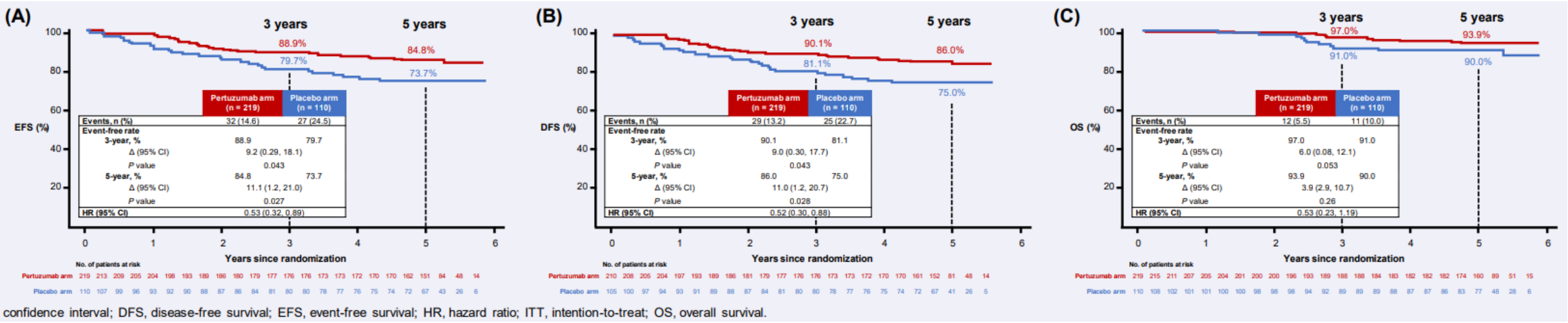
Figure 2. Efficacy Data





Shao Z et al JAMA Oncol 2020

Final analysis of the Phase III PEONY trial: long-term efficacy (ITT population)



CI, confidence interval; DFS, disease-free survival; EFS, event-free survival; HR, hazard ratio; ITT, intention-to-treat; OS, overall survival.

Shao Z et al JAMA et al SABCS 2022

Neoadjuvant chemotherapy with or without anthracyclines in the presence of dual HER2 blockade for HER2-positive breast cancer (TRAIN-2): a multicentre, open-label, randomised, phase 3 trial

Lancet Oncol 2018; 19: 1630–40

Mette S van Ramshorst, Anna van der Voort, Erik D van Werkhoven, Ingrid A Mandjes, Inge Kemper, Vincent O Dezentjé, Irma M Oving, Aafke H Honkoop, Lidwine W Tick, Agnes J van de Wouw, Caroline M Mandigers, Laurence J van Warmerdam, Jelle Wesseling, Marie-Jeanne T Vrancken Peeters, Sabine C Linn, Gabe S Sonke, on behalf of the Dutch Breast Cancer Research Group (BOOG)

Stage II-III
HER2+

LVEF ≥50%
Age ≥ 18y
N = 438

R

$FE_{90}C$ x 3 → Cb AUC6 q3w (or AUC 3 d1-8)
+ Pac80 d1-8 x 6

Cb AUC6 q3w (or AUC 3 d1-8)
+ Pac80 d1-8 x 9

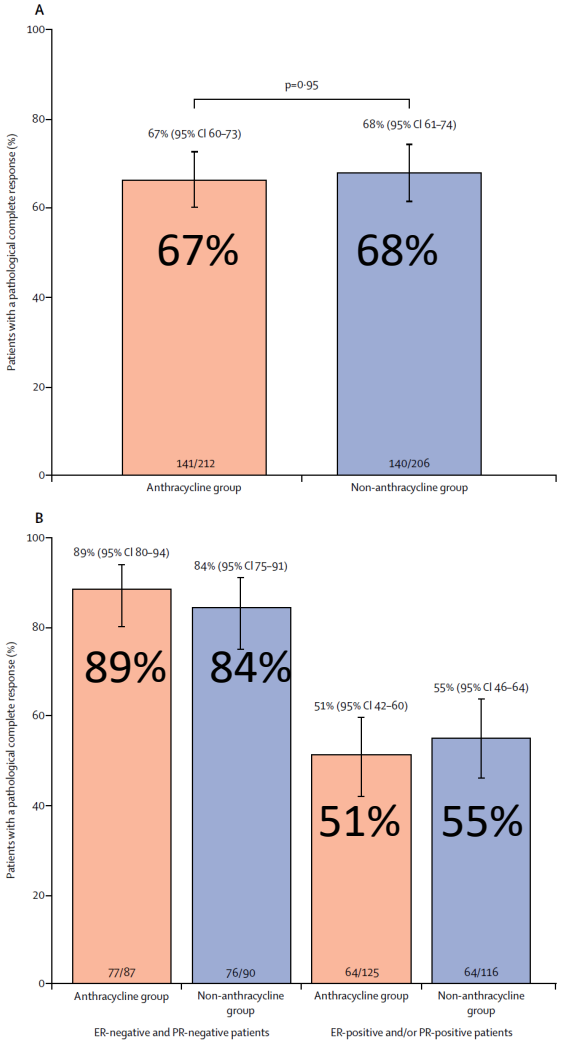
Trastuzumab + Pertuzumab at standard doses q 3w x 9 in both arms

→ **Surgery within 6 weeks**

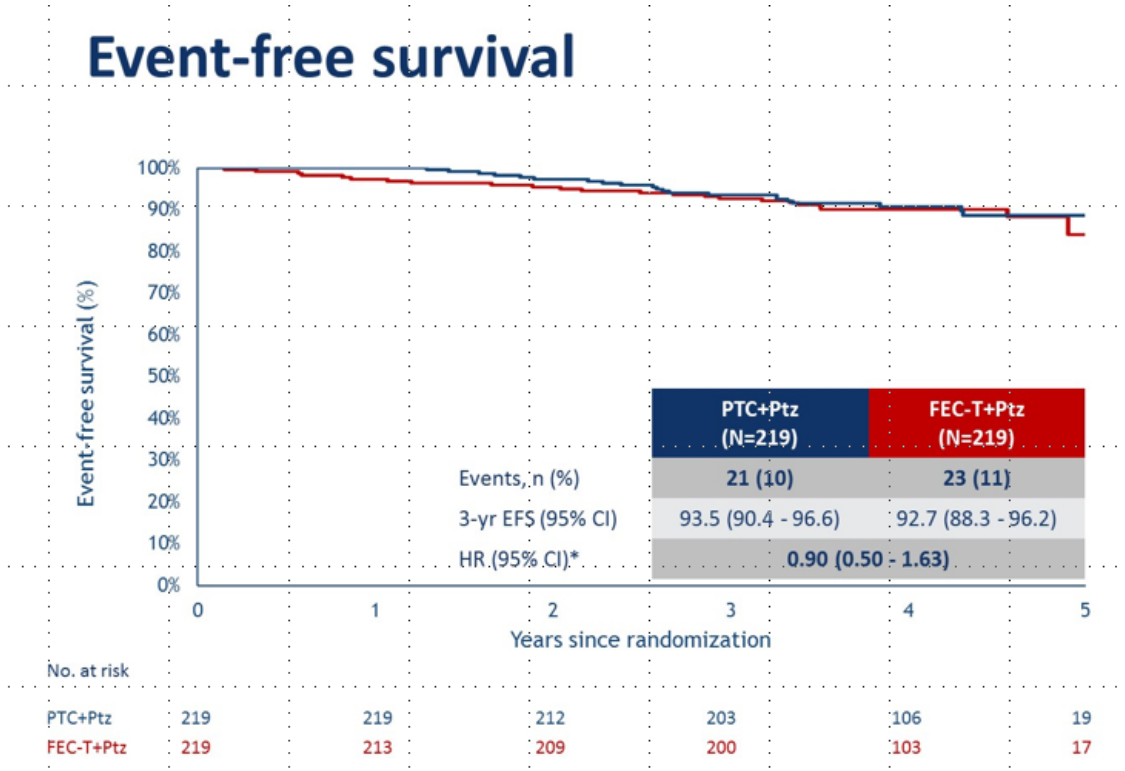
Primary endpoint
pCR (ypT0/is, ypN0) by local assessment

Secondary endpoints
Toxicity
RFS, BCSS, OS

TRAIN-2 Trial: pCR (ypT0/is ypN0) according to treatment and ER-PR status, and EFS



van Ramshorst MS et al Lancet Oncol 2018



Anna van der Voort ASCO 2020

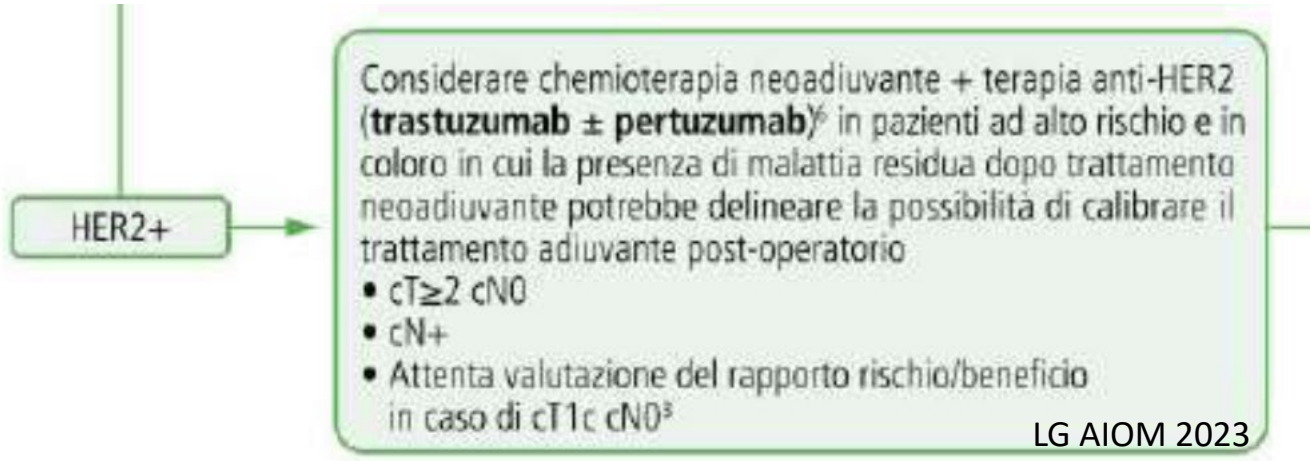
eBC HER2+ nel 2024 (opinione personale)

Approccio **neoadiuvante** in tutti gli stadi (esclusi cT1N0?parliamone!)

Tutta la chemioterapia* prima dell'intervento

*EC/AC→ taxani *oppure* Platino/taxani

Trastuzumab e pertuzumab in neoadiuvante
Trastuzumab adiuvante nelle pCR; TDM1 se malattia residua (T e/o N)



LG AIOM 2023

eBC HER2+ : prospettive future
De-escalation

Possiamo ottenere **gli stessi risultati**,
riducendo il carico di effetti sfavorevoli?

Neoadjuvant treatment with trastuzumab and pertuzumab plus palbociclib and fulvestrant in HER2-positive, ER-positive breast cancer (NA-PHER2): an exploratory, open-label, phase 2 study

Luca Gianni, Giancarlo Bisagni, Marco Colleoni, Lucia Del Mastro, Claudio Zamagni, Mauro Mansutti, Milvia Zambetti, Antonio Frassoldati, Raffaella De Fato, Pinuccia Valagussa, Giuseppe Viale

	Eligible patients (n=30)
Overall clinical response	29 (97% [83–100])
Complete clinical response	15 (50% [31–69])
Partial clinical response	14 (47% [28–64])
Stable disease	1 (3% [0–17])
Pathological complete response (no invasive cells in breast and axillary lymph nodes)	8 (27% [12–46])

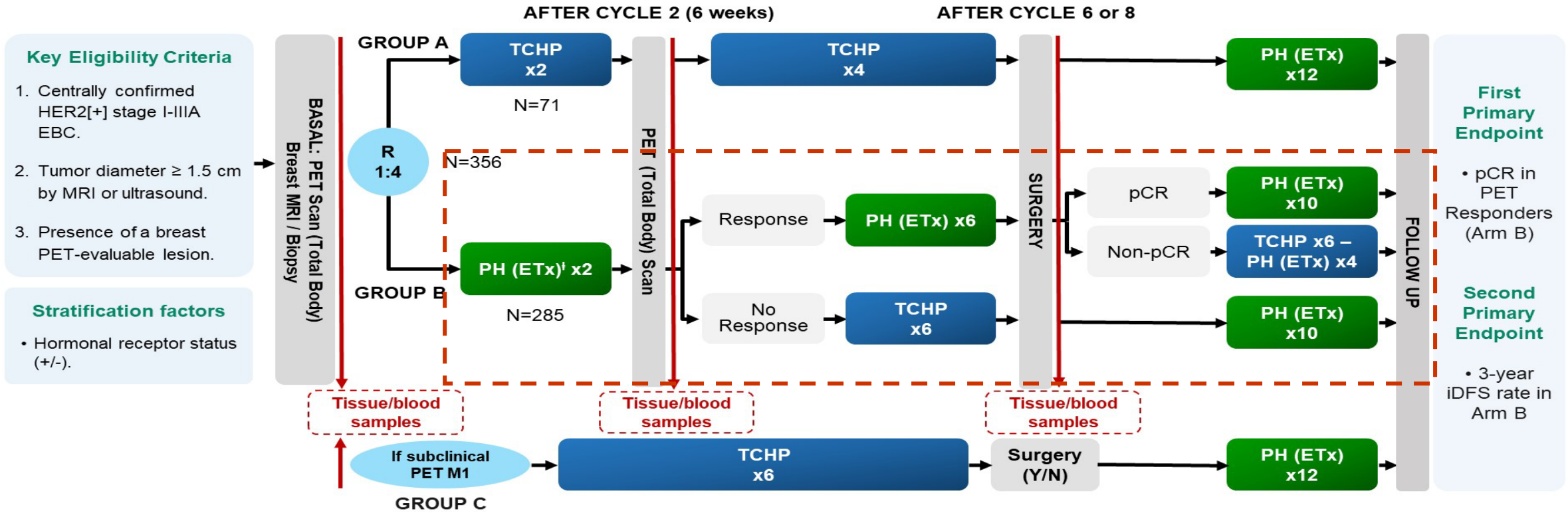
Data are n (% [95% CI]).

Table 2: **Clinical and pathological response**

Lancet Oncol 2018; 19: 249–56

Early response evaluation to modulate the treatment strategy

PHERGain Study Design

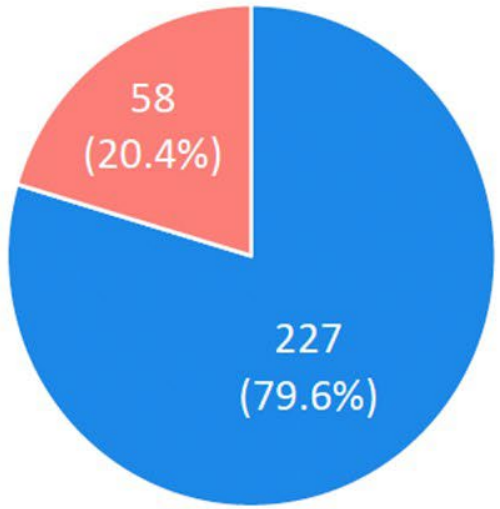


C: Carboplatin; D: Docetaxel; EBC: Early breast cancer; ETx: Endocrine therapy (letrozole post-menopausal/tamoxifen pre-menopausal), Adjuvant ETx up to 3 years from surgery; PET: ^{18}F-fluorodeoxyglucose positron emission tomography/computed tomography; H: Trastuzumab SC; HER2: Human Epidermal Growth Factor Receptor 2; iDFS: Invasive disease-free survival; MRI: Magnetic resonance Imaging; P: Pertuzumab IV; R: Randomization; TCHP: Trastuzumab, pertuzumab, docetaxel, and carboplatin. [I] All hormonal receptor-positive patients received ETx concomitantly with PH (except on chemotherapy).

- PET RESPONDERS: RECIST responders after cycle 2 with SUV_{max} reduction ≥40%.
- pCR, Pathological complete response (ypT0/isN0)

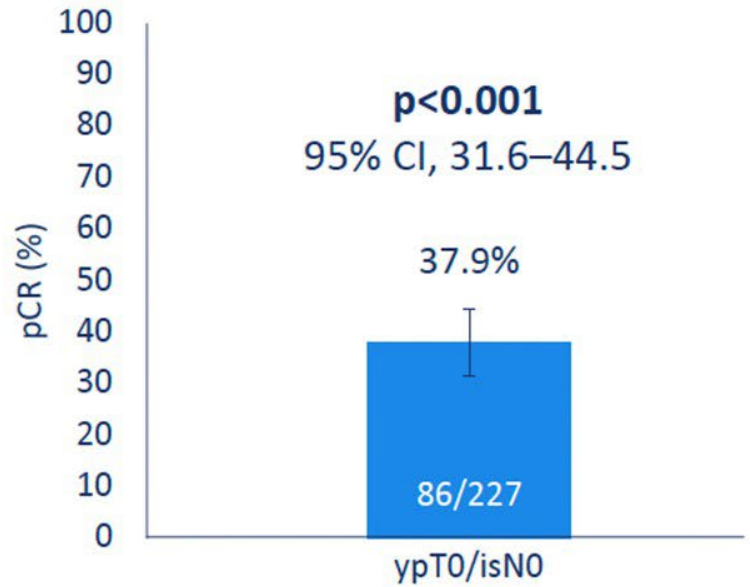
Primary Endpoint: pCR in ^{18}F-FDG-PET responders in group B

PET Responders and Non-Responders



PET Responder PET Non-Responder

pCR rate



Null hypothesis: pCR ≤20%

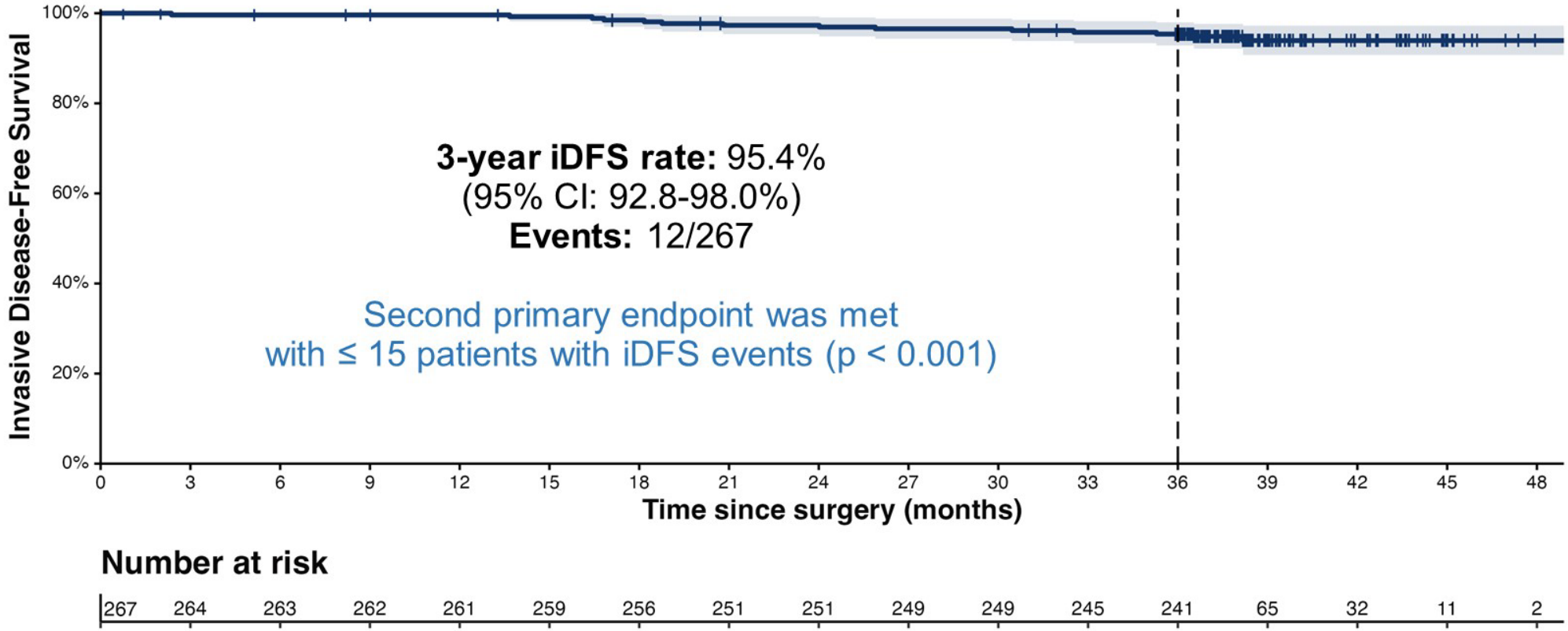
pCR was observed in patients with both HER2++ and HER2+++, pts with stage II and stage III, and pts ER+ and ER-.

Pérez-García, JM, et al. (2021). *Lancet Oncol*, 22(6), 858-871.

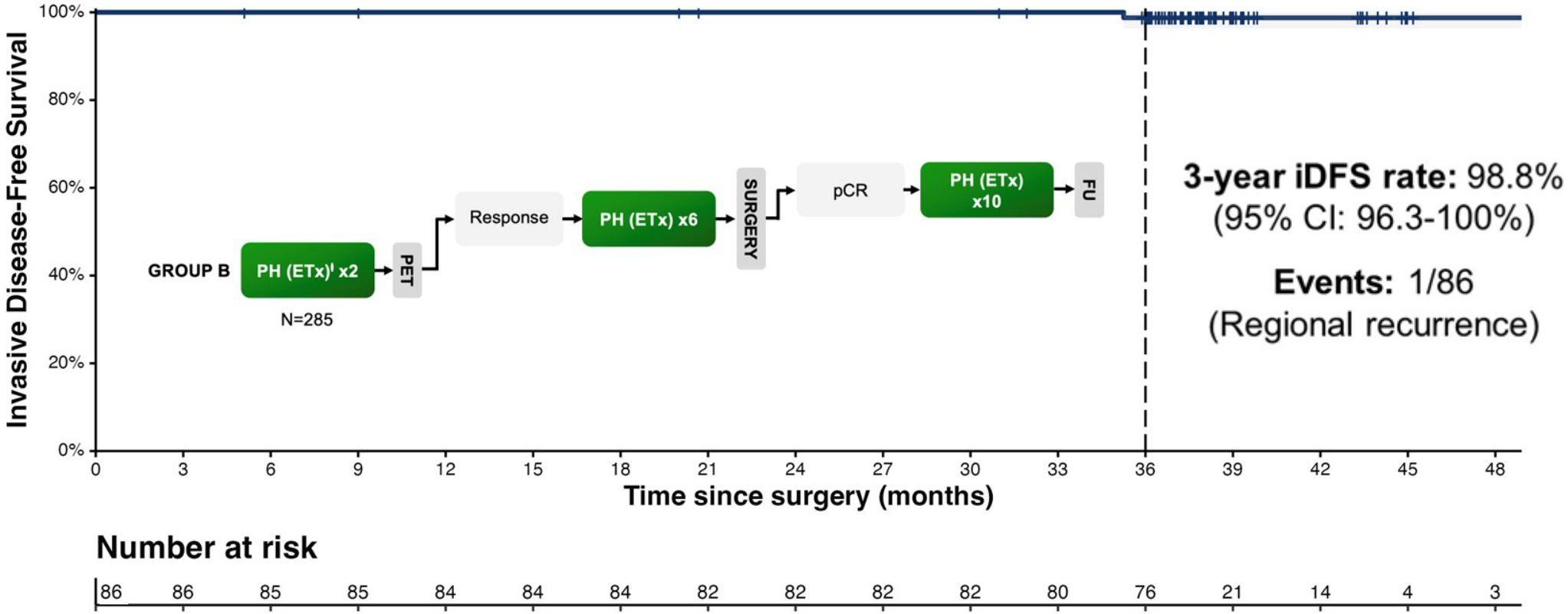
CI: Confidence interval; PET: ^{18}F-fluorodeoxyglucose positron emission tomography/computed tomography; pCR: Pathological complete response (ypT0/isN0).

Primary Endpoint: 3-year iDFS rate in group B

ITT population



Subgroup analysis:
3-year iDFS rate without CT in PET responders with pCR (n=86)



How to move toward escalated or de-escalated strategy at single patient level?

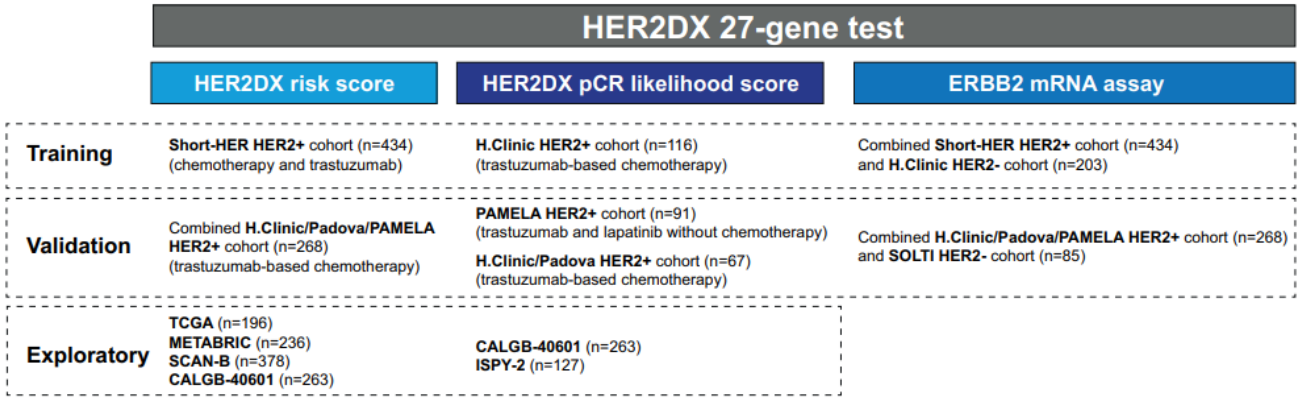
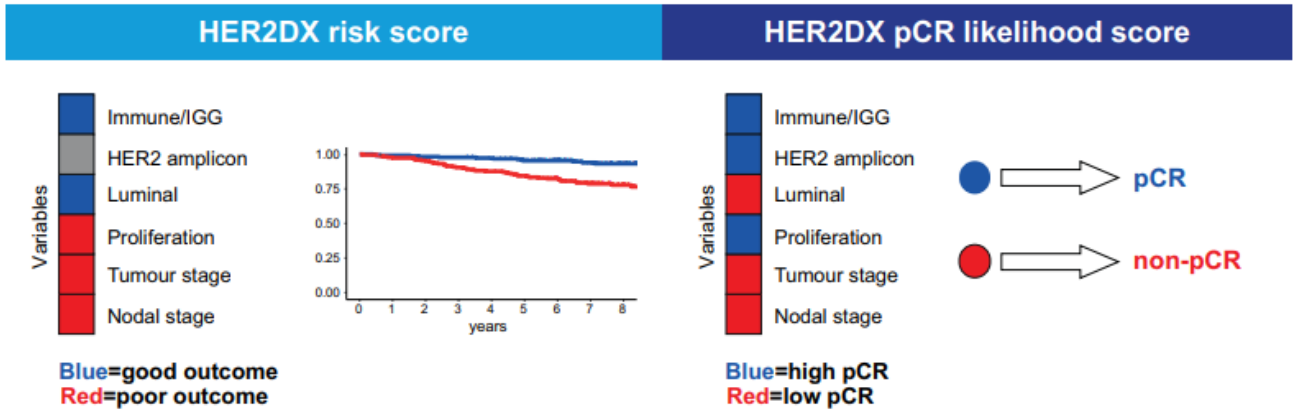


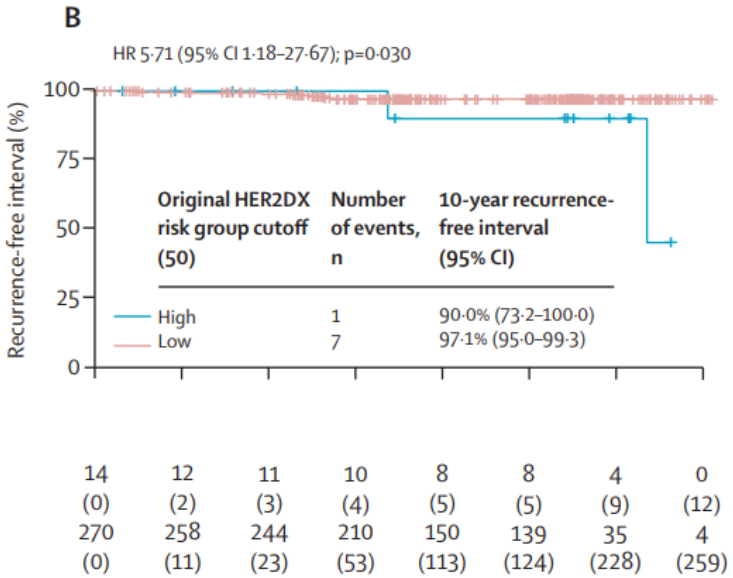
Figure 1. Summary of the different cohorts of patients evaluated during HER2DX development and validation.

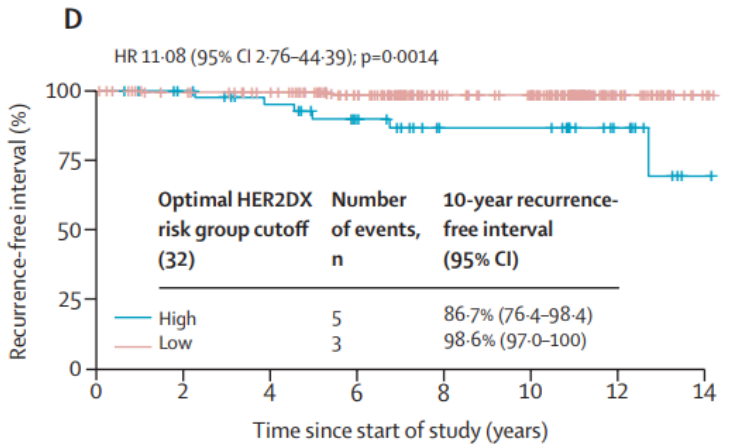


Prat A, et al. Ebiomedicine 2021; Prat A, et al. Lancet Oncol 2020

APT trial

10-year recurrence free survival (B, D), stratified by HER2DX risk group





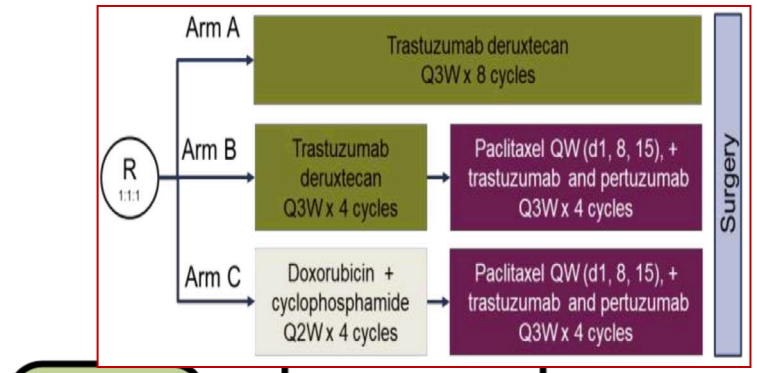
Tolaney S et al , Lancet Oncol 2023

eBC HER2+ : prospettive future

Escalation

Moving forward in treatment strategy personalization

DESTINY-Breast 11



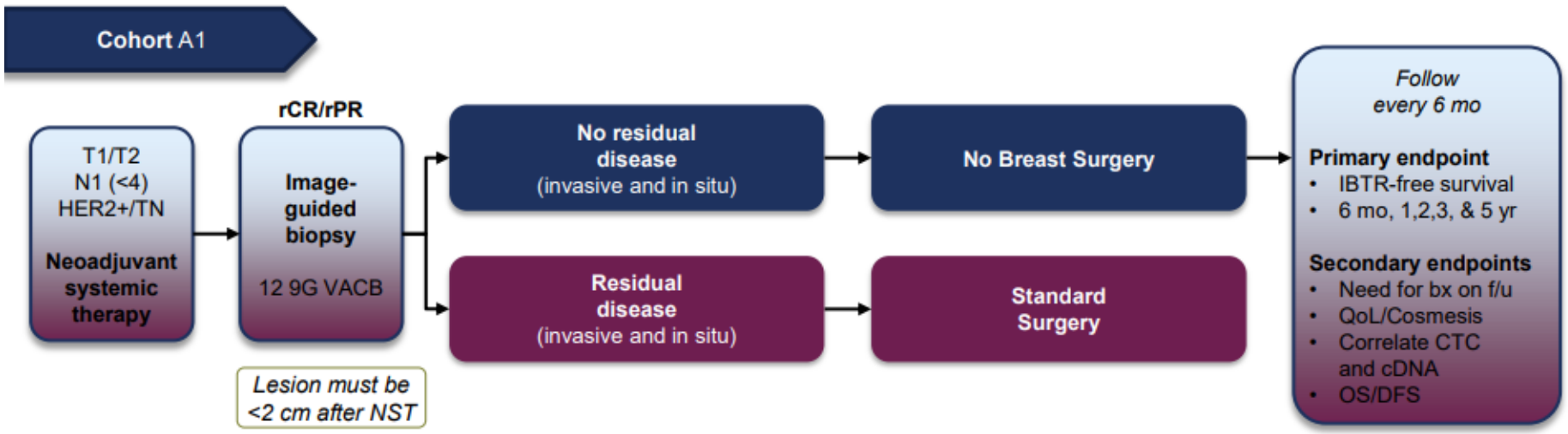
ph III - CompassHER2 RD, TDM1+ Tucatinib in residual disease after NAT

Eliminating breast surgery for invasive breast cancer in exceptional responders to neoadjuvant systemic therapy: a multicentre, single-arm, phase 2 trial

*Henry M Kuerer, Benjamin D Smith, Savitri Krishnamurthy, Wei T Yang, Vicente Valero, Yu Shen, Heather Lin, Anthony Lucci, Judy C Boughey, Richard L White, Emilia J Diego, Gaiane M Rauch, on behalf of the Exceptional Responders Clinical Trials Group**

MD Anderson Multicenter Phase 2 Treatment Trial

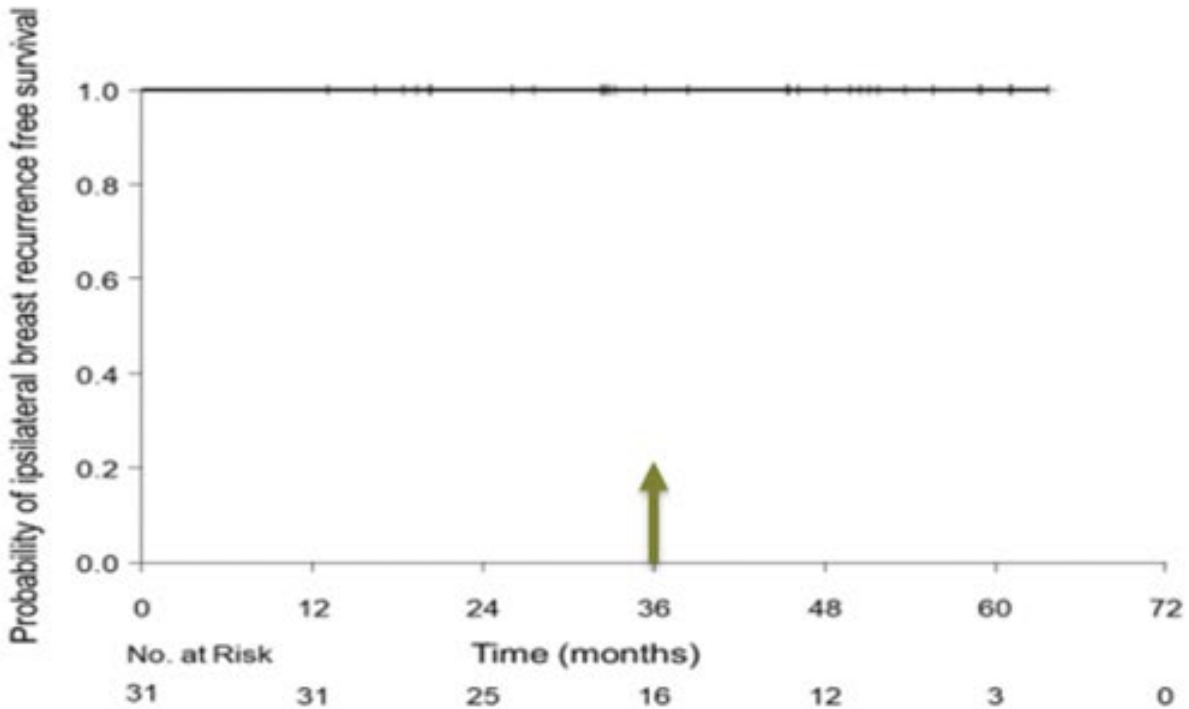
- Multicenter trial 2016-0046: *Eliminating Breast Cancer Surgery in Exceptional Responders With Neoadjuvant Systemic Therapy*
- MD Anderson Cancer Network, UPMC, Mayo Clinic, and Levine Cancer Institute



https://clinicaltrials.gov/ct2/show/NCT02945579

Kuerer *et al*, *Lancet Oncol* 2022

RESULTS: Primary objective IBTR-free survival among patients who did not undergo breast surgery 3-year planned analysis



100% IBTRFS

Secondary
100% OS/DFS

Median follow-up 38.4 months (IQR 27.6–51.8)

Henry M. Kuerer, MD, PhD; hkuerer@mdanderson.org

HER2+ eBC Highlights

Neoadiuvante > Adiuvante

- nella pratica clinica
- nella ricerca di strategie di potenziamento/depotenziamento (terapia sistemica & locale)

Definizione della risposta patologica

- ancora dicotomica, quindi margini di ulteriore miglioramento

Qualità/organizzazione Breast Unit

- imprescindibile per neoadiuvante