

GBG

GERMAN
BREAST
GROUP



in person

2.- 3. März 2023

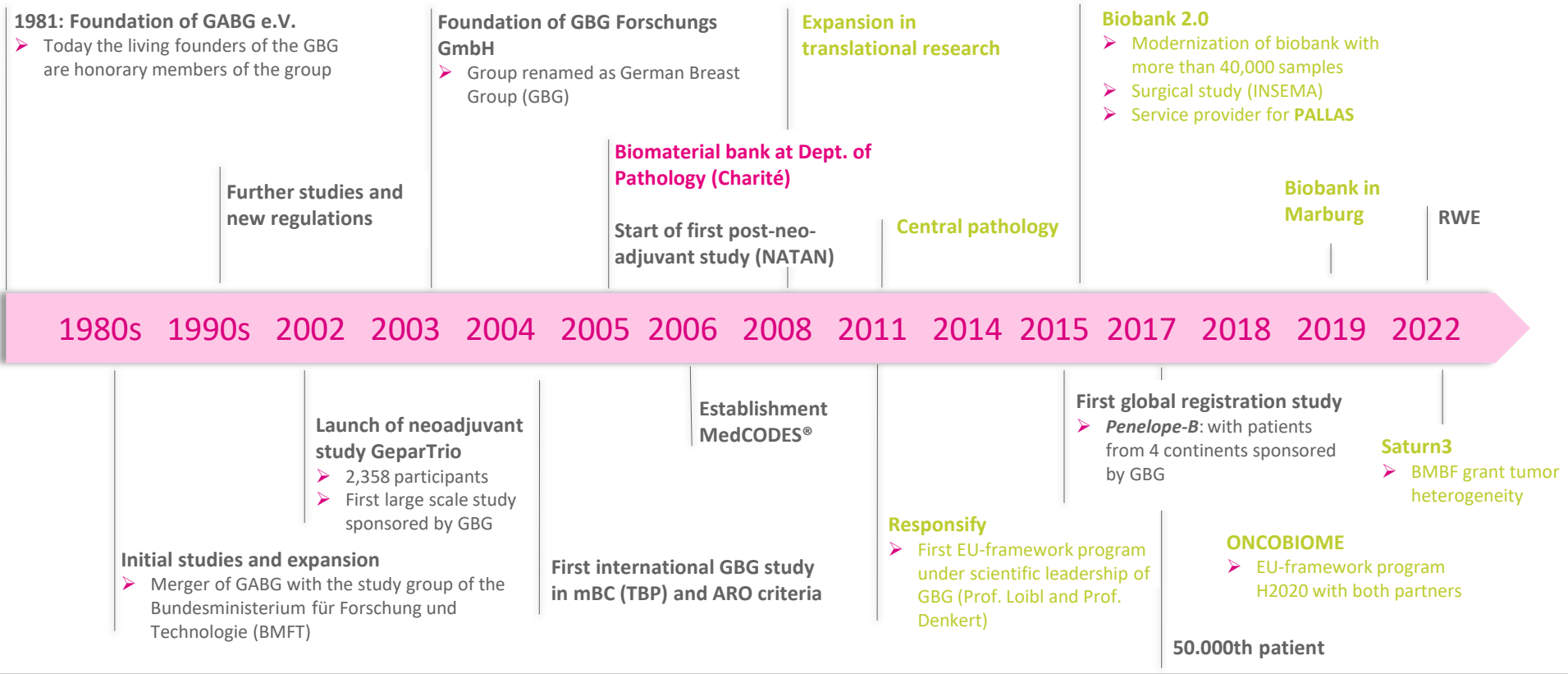
GBG Jahrestreffen

20 YEARS
ANNIVERSARY

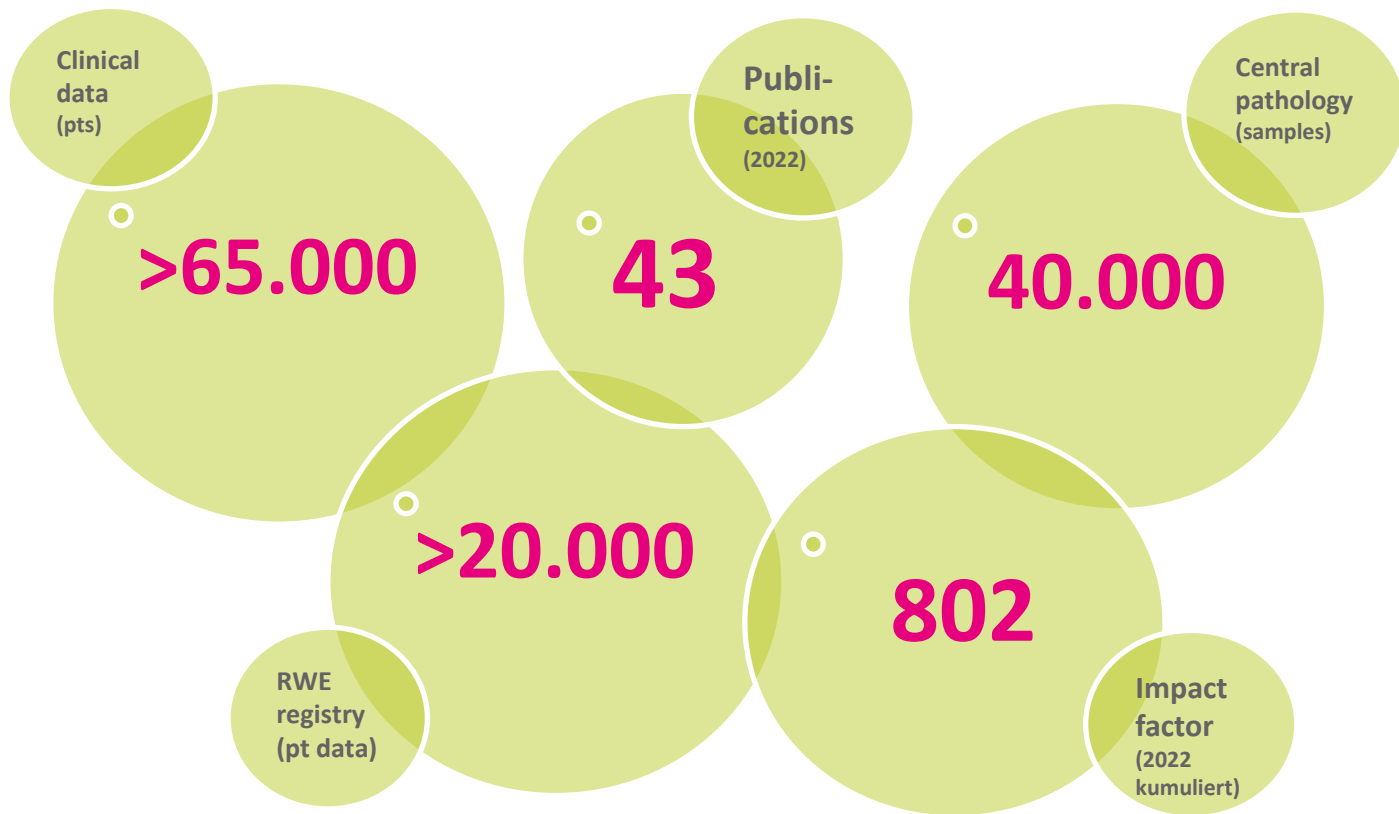
Prof. Dr. med. Sibylle Loibl
Chair of the GBG
CEO GBG Forschungs GmbH

Über 40 Jahre Brustkrebsforschung auf höchstem Niveau

Where we got started – more than 40 years ago

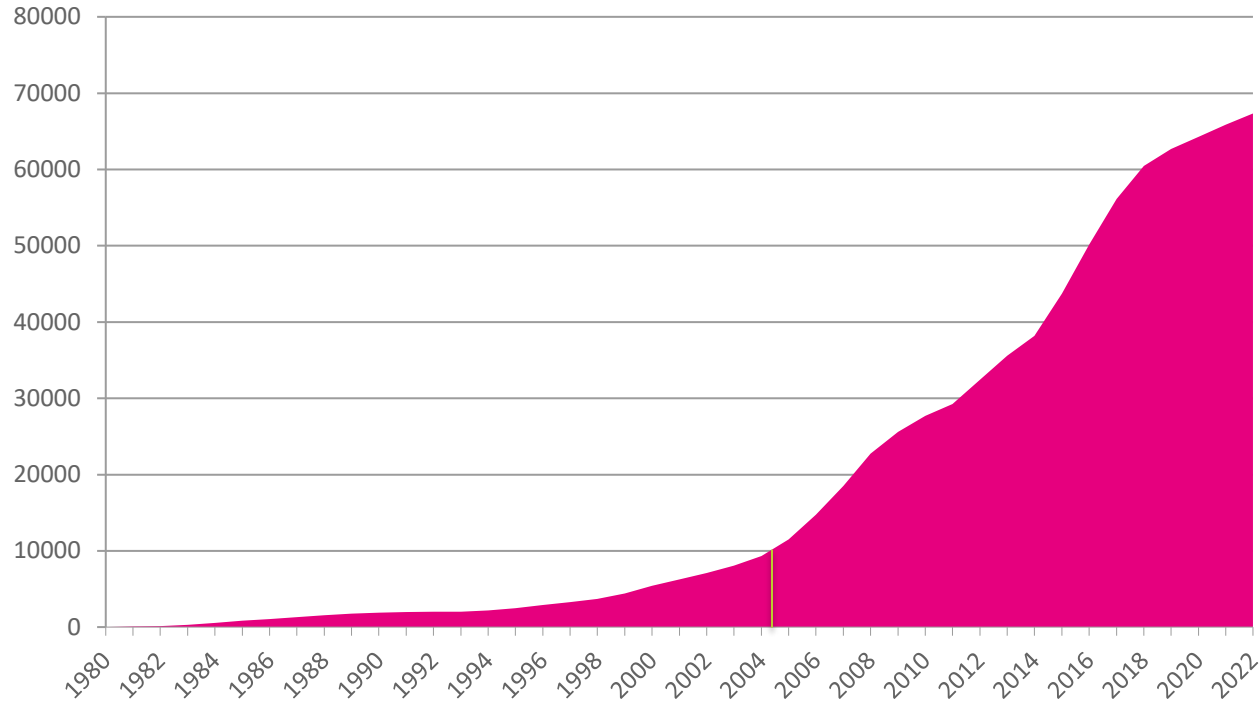


Facts & figures

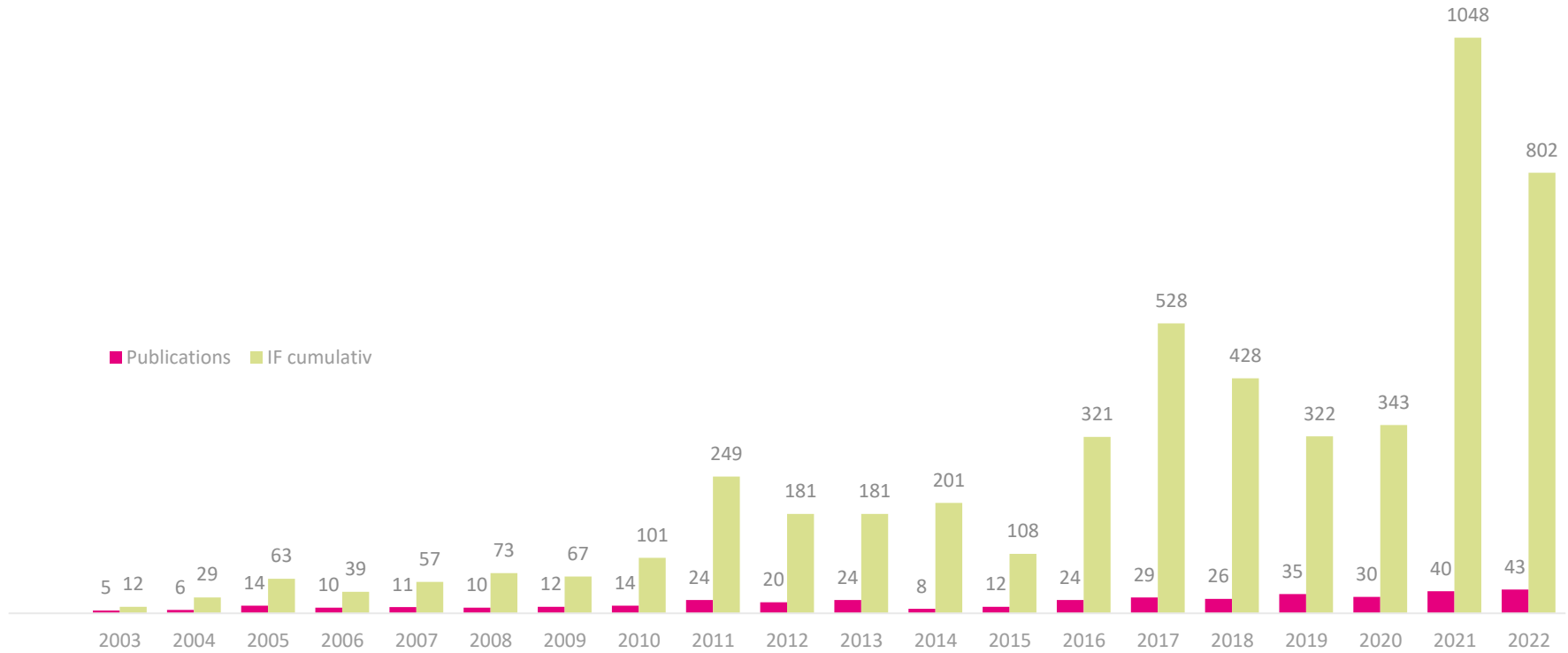


Rekrutierung über 20 Jahre 65.000 Patientinnen

patients cummulative



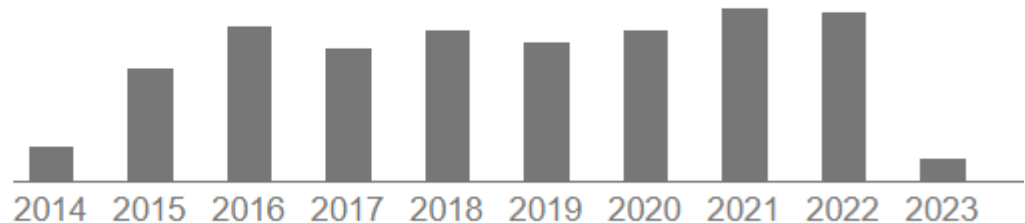
Publikationen über die Zeit



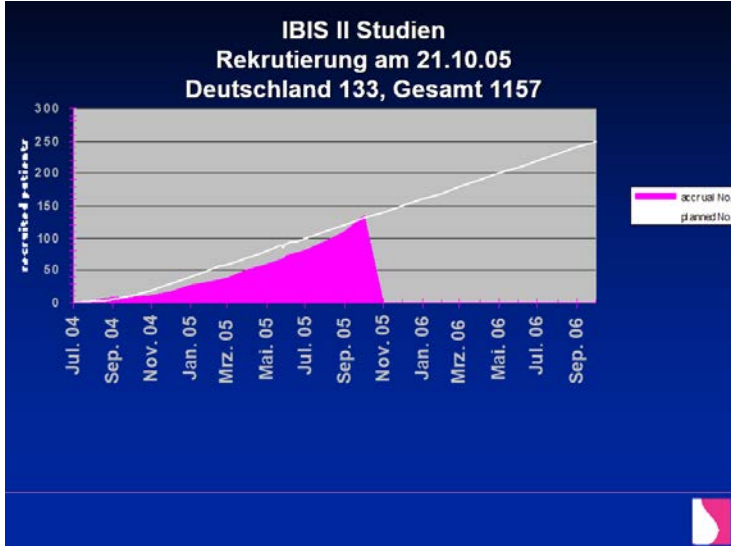


GeparSixto – am häufigsten zitierte GBG eigene Studie

Zitate insgesamt Zitiert von: 975

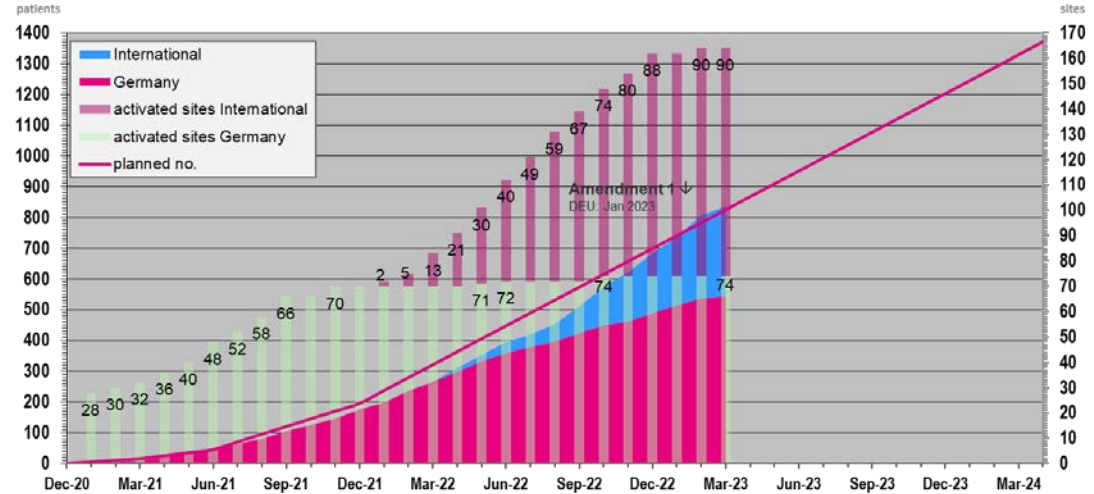


Rekrutierung früher und heute



SASCIA - Recruitment on 15.02.2023

n = 838 (↑31)



Der Vorstand der GABG



Foto: H. Maass, W. Jonat, M. Kaufmann, F. Kubli



Studienleitkommission v. Subboards

Studienleitkommission

- **Mitglieder:** Die Studienleitkommission kann aus bis zu 13 Mitgliedern inkl. je einem Vertreter des Methodischen Zentrums und der Studienkoordination sowie Referenzzentren bestehen; vorwiegend Oberärzte der Mitgliedskliniken.
- **Aufgaben:** Erarbeitung künftiger Studienkonzepte, Überwachung des Verlaufs und der Durchführung der GABG - Studien, aktive Werbung für die Aufnahme von Patientinnen in die GABG-Studien, Entscheidung über Vorgehensweisen bei Problemen. Die Studienleitkommission tagt ca. vier - bis fünfmal jährlich.

Bisherige Mitglieder der Studienleitkommission



J. Bishmer (seit 1997), Charité, Berlin



S. Braun (seit 2001), Klinikum Rechts der Isar, München



A. Caputo (2000/2001), Universitätsklinikum, Freiburg



H. Meisinger/Biehl (1997/2000), Kreiskrankenhaus Eggenfelden



G. v. Minckwitz (seit 1997), Vorsitzender, Universitätsklinikum Frankfurt



G. Raab, (seit 2001), Rot Kreuz Krankenhaus, München



B. Conrad (seit 1997), Elisabeth Hospital, Kassel



A. Diehl (seit 1997), GABG Studienkoordination, Frankfurt



A. du Bois (seit 2001), Dr. Hoss-Schmid Kliniken GmbH, Wiesbaden



A. von der Assen (1997/2000), Franziskus Hospital, Georgsmarienhütte



H. Wolf, (seit 1997), Kreiskrankenhaus Leonberg



H. Eidmann (seit 1997), Universitätsklinikum Kiel



M. Geberth (seit 2001), Universitätsklinikum Heidelberg



B. Gerber (seit 1997), Universitätsklinikum Rostock



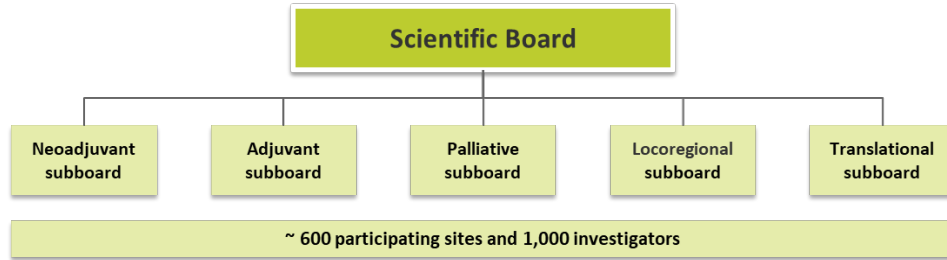
E. Graf (seit 1997), Universitätsklinikum Freiburg



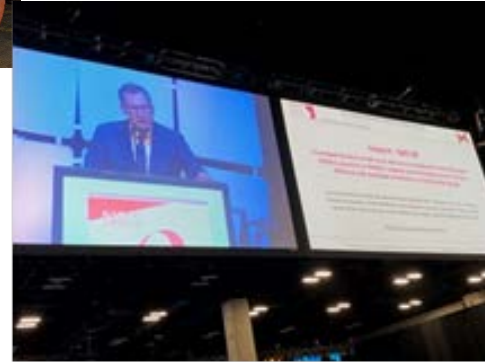
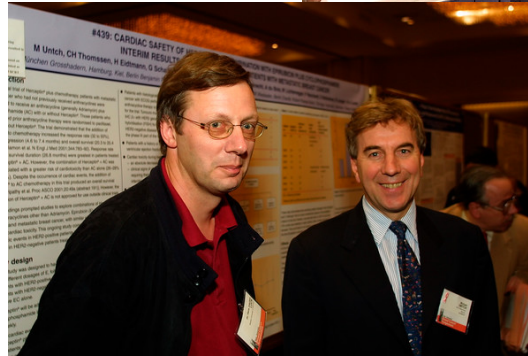
E. Grischke (bis 2000), Krankenhaus Schwabing



Ch. Jackisch (seit 2001), Universitätsklinikum Münster



Subboard in action



GABG IV

CMF versus goserelin as adjuvant therapy for node-negative, hormone-receptor-positive breast cancer in premenopausal patients: a randomised trial (GABG trial IV-A-93).

von Minckwitz G, Graf E, Geberth M, Eiermann W, Jonat W, Conrad B, Brunnert K, Gerber B, Vescia S, Wollert J, Kaufmann M.

Eur J Cancer. 2006 Aug;42(12):1780-8. doi: 10.1016/j.ejca.2006.04.006. Epub 2006 Jun 12.

Studienschemata der GABG IV im Überblick

STAND: AUGUST 1999

G A B G
GERMAN
ADJUVANT
BREAST
CANCER
GROUP

THERAPIEZUTEILUNGEN ANHAND PROGNOSTISCHER FAKTOREN

	REZEPTOR POSITIV	ANZAHL BEFALLENER LYMPHKNOTEN			
		0	1-3	4-9	10+
PRÄMENOPAUSAL	REZEPTOR POSITIV	A	B	B*	E
	REZEPTOR NEGATIV	B	B	B*	E
POSTMENOPAUSAL BIS 70 JAHRE	REZEPTOR POSITIV	ARNO	ARNO	ARNO	E
	REZEPTOR NEGATIV	D	D	D*	E

STUDIE THERAPIE

G A B G - IV

POSTOPERATIVE THERAPIEENTSCHEIDUNG

A-93 \leftarrow CMF x 3
ZOLADEX* 2 J.

B-93 \leftarrow CMF x 3 \leftarrow \emptyset
ZOLADEX* 2 J.

B-93* \leftarrow EC x 4 \rightarrow CMF x 3 \leftarrow \emptyset
ZOLADEX* 2 J.

D-93 \leftarrow CMF x 3 \leftarrow \emptyset
TAMOXIFEN 5 J.

D-93* \leftarrow EC x 4 \rightarrow CMF x 3 \leftarrow \emptyset
TAMOXIFEN 5 J.

E-93 \leftarrow EC x 4 \rightarrow CMF x 3
(SIMULTAN: PRÄM. + ZOLADEX* 2 J.; POSTM. + TAMOXIFEN 5 J.)
 \leftarrow E 120 x 4
(SIMULTAN: PRÄM. + ZOLADEX* 2 J.; POSTM. + TAMOXIFEN 5 J.)

ARNO-95 \leftarrow TAMOXIFEN 2 J. \rightarrow NOLVADEX* 3 J.
TAMOXIFEN 2 J. \rightarrow ARIMIDEX* 3 J.

PRÄOPERATIVE THERAPIEENTSCHEIDUNG

G-93 \leftarrow OPERATION MIT AXILLADISSEKTION \rightarrow
TAMOXIFEN 5 J.
 \leftarrow OPERATION OHNE AXILLADISSEKTION \rightarrow
TAMOXIFEN 5 J.
(> 70 J., KLIN N0, T < 3 CM)

Studie	Sollzahl	Anzahl Patientinnen	Prozent
A-93:	770	771	100,1 %
B/B*-93:	700	776	110,8 %
D/D*-93:	700	829	118,4 %
E-93:	320	411	128,4 %
ARNO-95:	1000	742	74,2 %
G-93:	keine Sollvorgabe	94	

Stand: Oktober 01

Dose-intensified epirubicin versus standard-dose epirubicin/cyclophosphamide followed by CMF in breast cancer patients with 10 or more positive lymph nodes: results of a randomised trial (GABG-IV E-93) - the German Adjuvant Breast Cancer Group.

Eiermann W, Graf E, Ataseven B, Conrad B, Hilfrich J, Massinger-Biebl H, Vescia S, Loibl S, von Minckwitz G, Schumacher M, Kaufmann M: German Adjuvant Breast Cancer Group.
Eur J Cancer. 2010 Jan;46(1):84-94. doi: 10.1016/j.ejca.2009.10.001.

A randomised trial of goserelin versus control after adjuvant, risk-adapted chemotherapy in premenopausal patients with primary breast cancer - GABG-IV B-93.

Kaufmann M, Graf E, Jonat W, Eiermann W, Vescia S, Geberth M, Conrad B, Gademann G, Albert U, Loibl S, von Minckwitz G, Schumacher M: German Adjuvant Breast Cancer Study Group (GABG).
Eur J Cancer. 2007 Nov;43(16):2351-8. doi: 10.1016/j.ejca.2007.08.012. Epub 2007 Sep 25.

VOLUME 23 - NUMBER 31 - NOVEMBER 1 2005

JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Tamoxifen Versus Control After Adjuvant, Risk-Adapted Chemotherapy in Postmenopausal, Receptor-Negative Patients With Breast Cancer: A Randomized Trial (GABG-IV D-93)—The German Adjuvant Breast Cancer Group

Manfred Kaufmann, Erika Graf, Walter Jonas, Wolfgang Eiermann, Matthias Geberth, Ute-Susanne Albers, Günther Gademann, Bettina Conrad, Karin Stuhl, Gunter von Minckwitz, and Martin Schumacher

Switching of postmenopausal women with endocrine-responsive early breast cancer to anastrozole after 2 years' adjuvant tamoxifen: combined results of ABCSG trial 8 and ARNO 95 trial

Raimund Jakesz, Walter Jonas, Michal Gnant, Martina Mittlboeck, Richard Greil, Christoph Tausch, Joern Hilfrich, Werner Kwasny, Christian Menzel, Hellmut Samonigg, Michal Seifert, Guenther Gademann, Manfred Kaufmann, on behalf of the ABCSG and the GABG

Summary

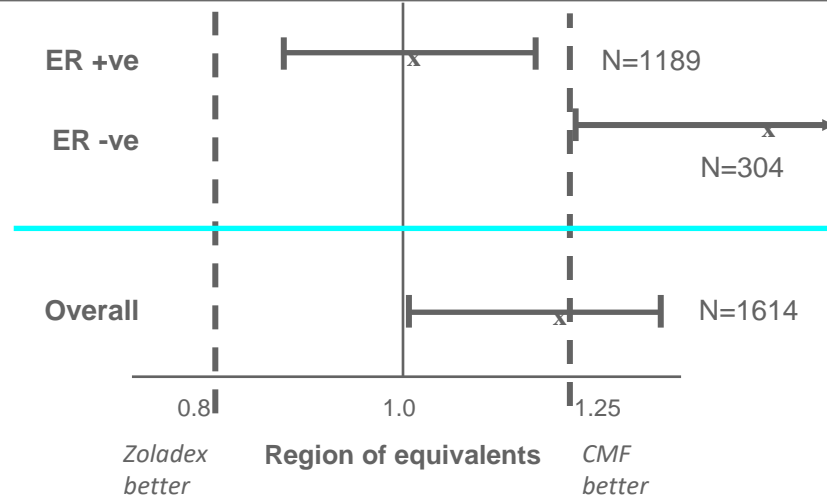
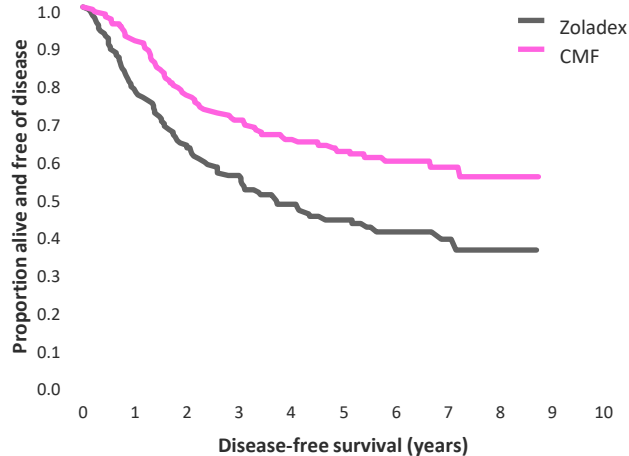
Background Tamoxifen has been the standard adjuvant treatment for postmenopausal women with hormone-
Lancet 2005; 366: 455-62

ZEBRA Studie – die erste internationale Kooperation

Das Studiendesign der Zebra - Studie

OP $\left\{ \begin{array}{l} \text{Zoladex 3,6 mg/28 Tage, 2 Jahre} \\ 6 \times \text{CMF} \end{array} \right.$

Kaplan-Meier DFS: ER-ve



Interaction test, $p=0.0016$



PERGAMON

European Journal of Cancer 39 (2003) 1711–1717

European
Journal of
Cancer
www.ejconline.com

Survival analyses from the ZEBRA study: goserelin (Zoladex™) versus CMF in premenopausal women with node-positive breast cancer

M. Kaufmann^{a,*}, W. Jonat^b, R. Blamey^c, J. Czick^d, M. Namer^e, I. Fogelman^f, J.C. de Haes^g, M. Schumacher^h, W. Sauerbrei^h on behalf of the Zoladex Early Breast Cancer Research Association (ZEBRA) Trialists' Group

Neoadjuvante Therapie - die Anfänge






JCO 1999, JCO 2001

The German GeparD

 JCO 2001, JCO 2005


 JNCI 2008, JNCI 2008, JCO 2013

 JCO 2010; JCO 2010; Ann Oncol 2013

 NEJM 2012; Lancet Oncol 2012; Eru J Cancer 2013;
Ann Oncol 2014; JCO 2018

 Lancet Oncol 2014; Annals Oncol 2019

 Lancet Onc 2016; J Clin Oncol 2019

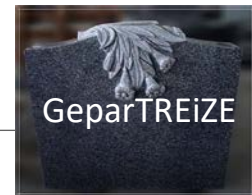
 Eur J Cancer 2019; Eur J Cancer
Annals Oncol 2019; Annals Oncol 2022

 Annals Oncol 2020; SABCS 2021

 JAMA Oncol 2022

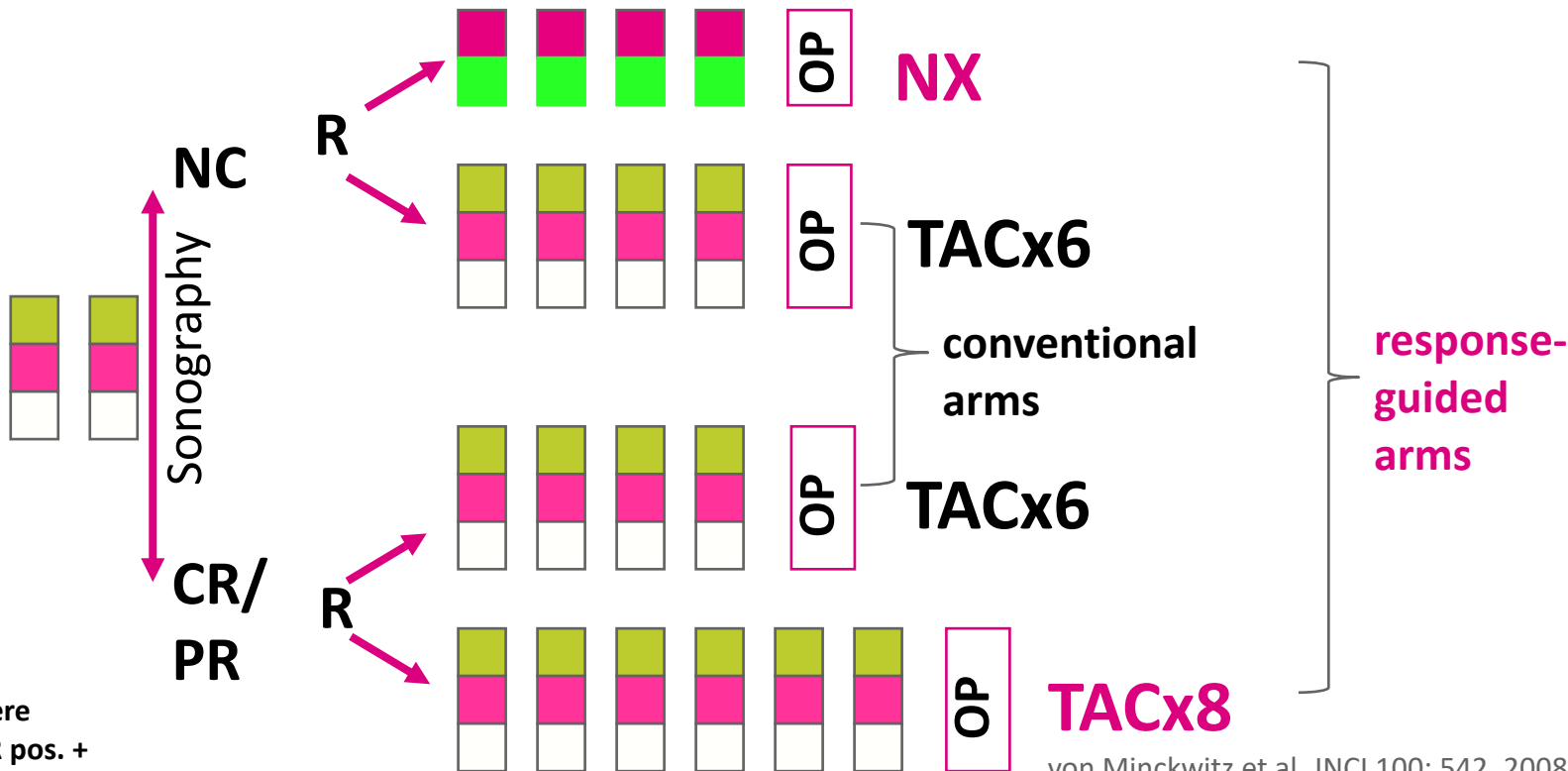
 GeparELEVEN → Impassion 50

 ESMO 2023



N=2072

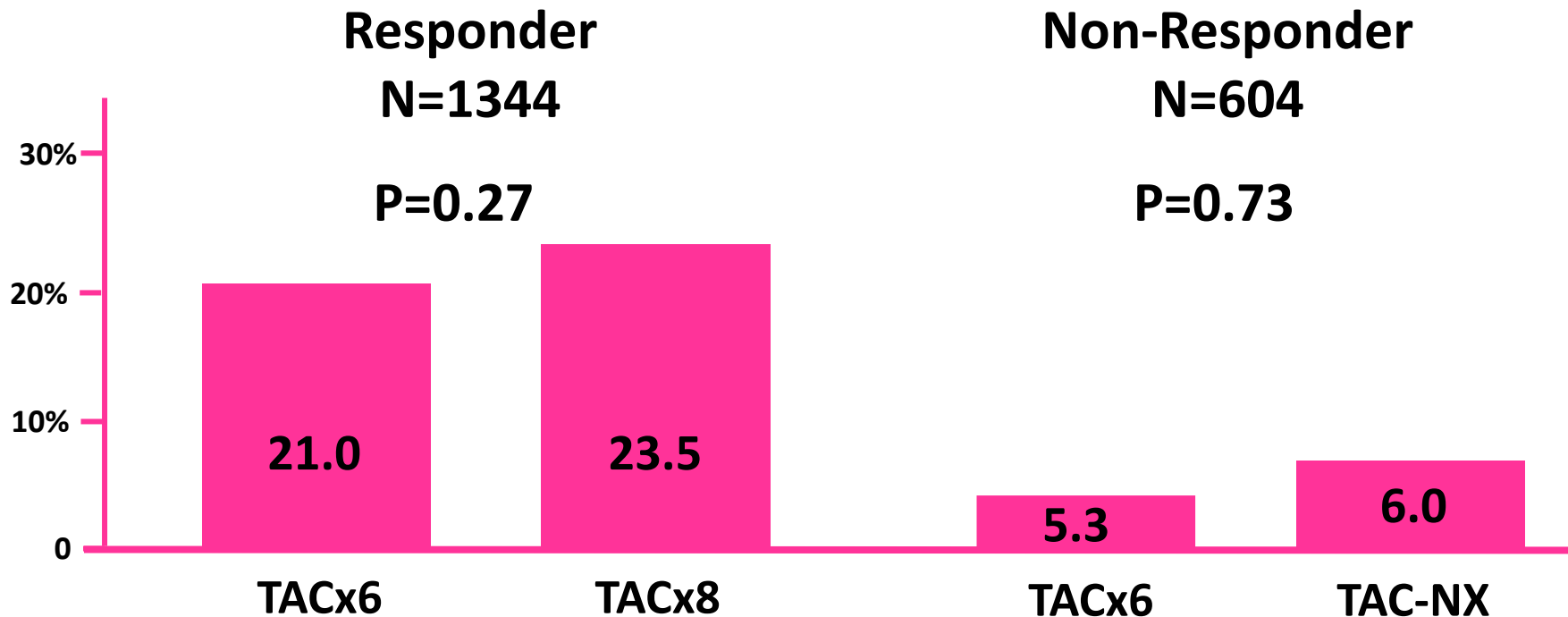
**Core biopsy:
uni/bilateral
cT2-4a-d
cN0-3
size ≥ 2 cm***

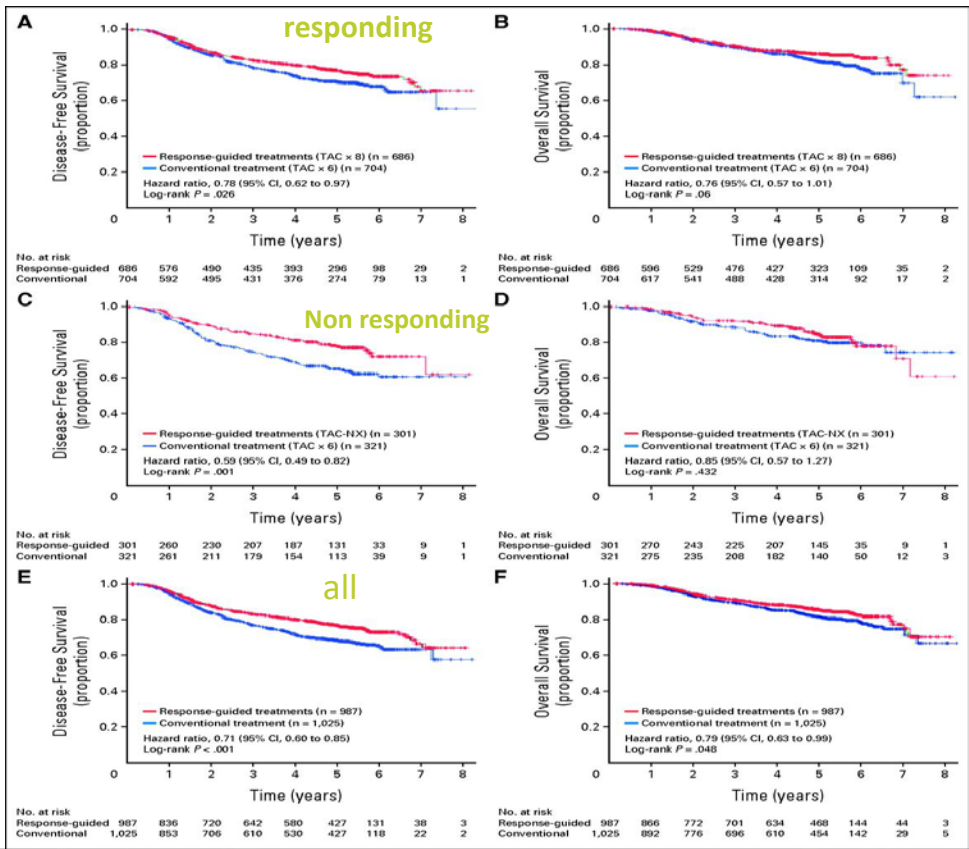


*low risk patients were excluded (T2 + ER/PR pos. + cN0 + G1/2 + > 35 yrs)

von Minckwitz et al, JNCI 100: 542, 2008
von Minckwitz et al. JNCI 100; 552, 2008

Short Term Efficacy (pCR = ypT0 ypN0)





VOLUME 31 · NUMBER 29 · OCTOBER 10 2013

JOURNAL OF CLINICAL ONCOLOGY

EDITORIAL

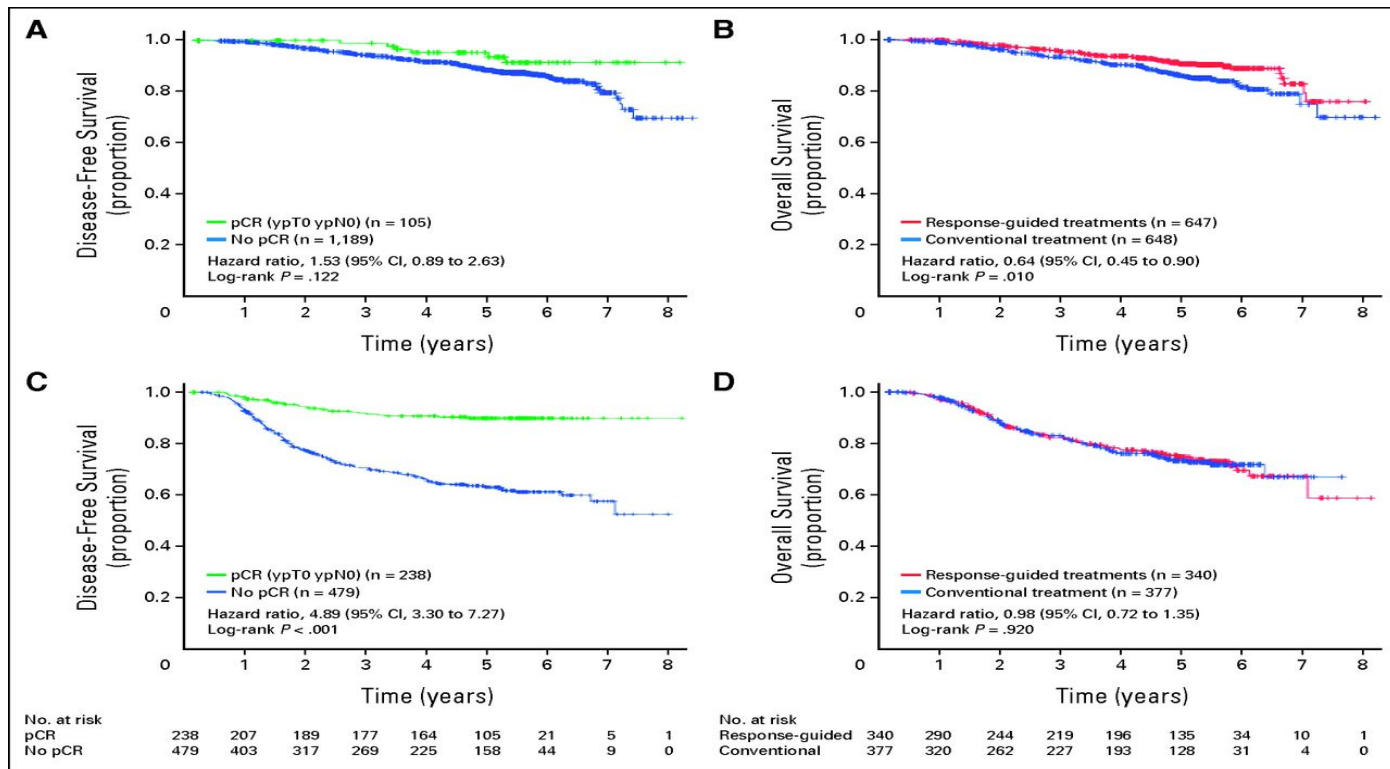
Insight or Confusion: Survival After Response-Guided Neoadjuvant Chemotherapy in Breast Cancer

 Melinda L. Telli, *Stanford University School of Medicine, Stanford, CA*

See accompanying article on page 3623

hormone
receptor-positive

hormone
receptor-negative



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

JANUARY 26, 2012

VOL. 366 NO. 4

Noadjuvant Chemotherapy and Bevacizumab for HER2-Negative Breast Cancer

Gunter von Minckwitz, M.D., Holger Eidtmann, M.D., Mahdi Rezaei, M.D., Peter A. Fasching, M.D., Hans Tesch, M.D., Holm Eggemann, M.D., Iris Schrader, M.D., Kornelia Kittel, M.D., Claus Hanusch, M.D., Rolf Kreienberg, M.D., Christine Solbach, M.D., Bernd Gerber, M.D., Christian Jackisch, M.D., Georg Kunz, M.D., Jens-Uwe Blohmer, M.D., Jens Huober, M.D., Maik Hauschild, M.D., Tanja Fehm, M.D., Berit Maria Müller, M.D., Carsten Denkert, M.D., Sibylle Loibl, M.D., Valentina Nekljudova, Ph.D., and Michael Untch, M.D., for the German Breast Group and the Arbeitsgemeinschaft Gynäkologische Onkologie–Breast Study Groups

EDITORIAL



Fighting Fire with Fire: Rekindling the Bevacizumab Debate

Alberto J. Montero, M.D., and Charles Vogel, M.D.

In/ Exclusion criteria fulfilled?

yes

Her-2 positive?

yes

EC-Doc: H vs. L

no

EC vs. EC + Bev

Response assessment after 4xEC+/-Bev

no

2nd randomisation:
Pw vs. Pw + RAD001

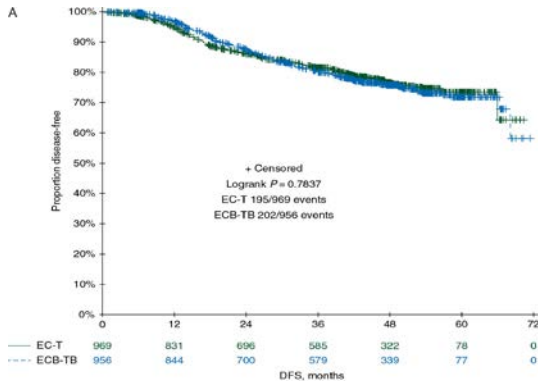
yes

Doc vs. Doc + Bev

Main results GeparQuinto n=2560

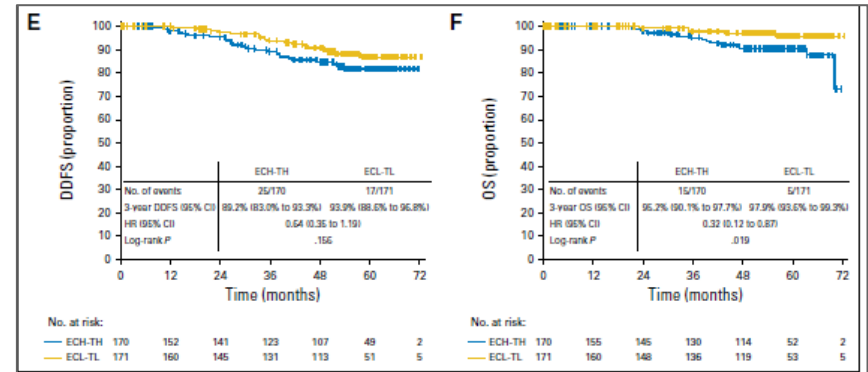
HER2-negative n=1948

- Bev erhöht pCR rate von 14.9-18.4%
- Kein Unterschied im DFS und OS
- non Responders: Everolimus vs nil
3.6% vs 5.6%



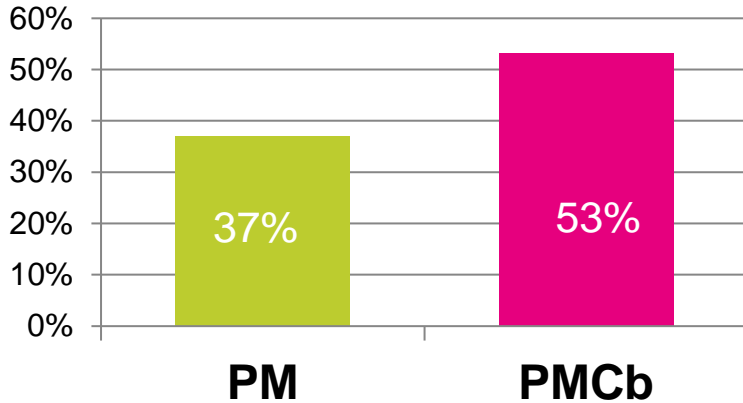
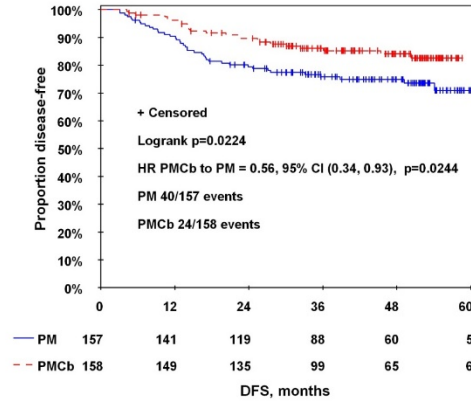
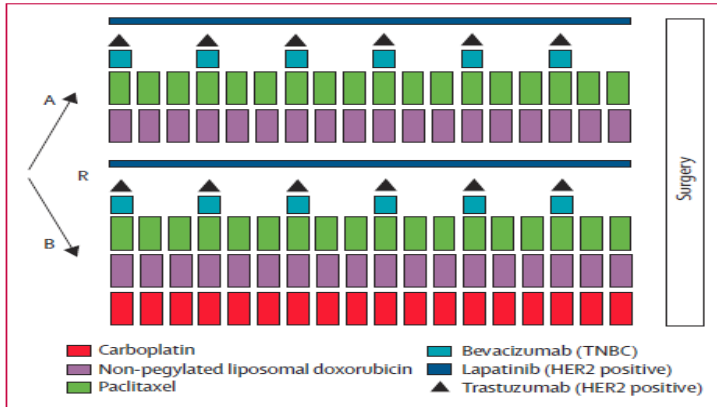
HER2-positive n=620

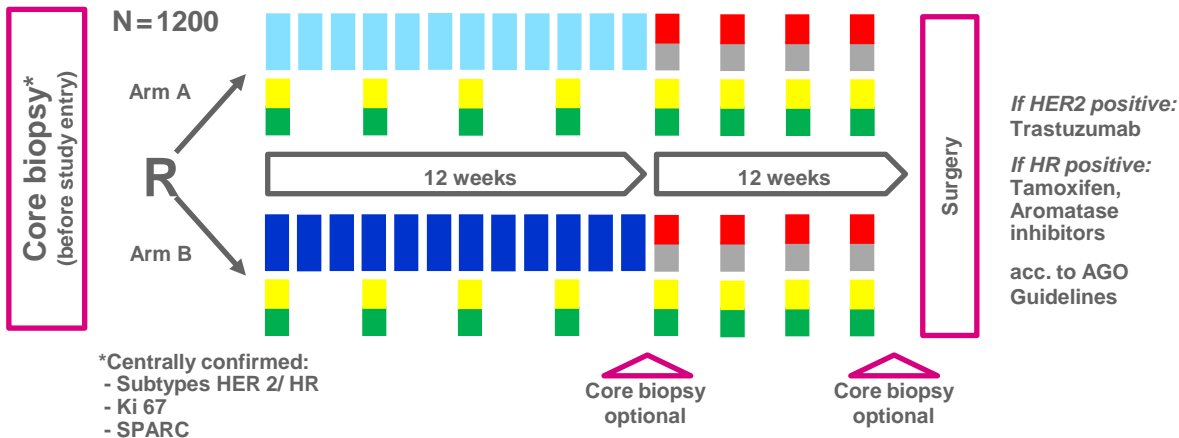
- Lap vs Trastuzumab: 22.75 vs 30.3% sign
 - Kein Unterschied im DFS und OS
 - Alle Pat erhalten 1 Jahr Trastuzumab
- HR-positive; HER2+; DDFS and OS





Die Platine: GeparSIXTO



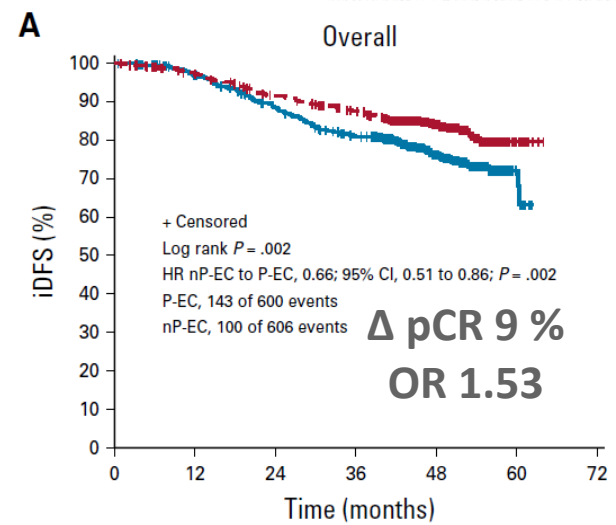


- Core biopsy
- Paclitaxel 80 mg/m² weekly
- nab-Paclitaxel 125 mg/ m² weekly
- Epirubicin 90 mg/m²
- Cyclophosphamide 600 mg/m²
- If HER2 positive:*
Trastuzumab 8 mg/kg (loading dose) followed by 6 mg/kg
- Pertuzumab (absolute dose per application) 840 mg (loading dose) followed by 420 mg

editorial

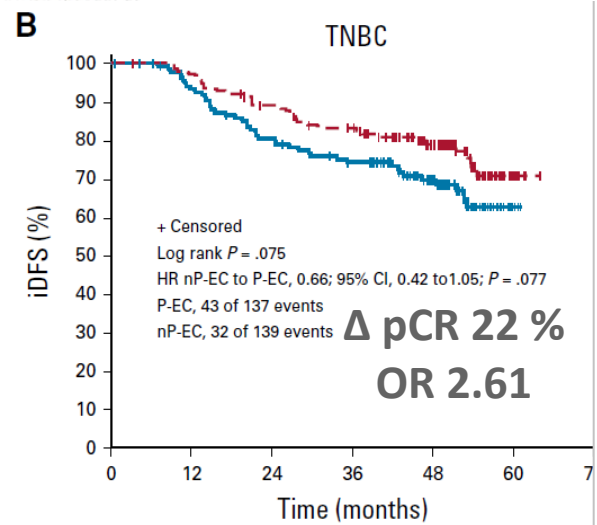
Nab-Paclitaxel: A New Standard of Care in Neoadjuvant Therapy of High-Risk Early Breast Cancer?

Masey Ross, MD, MS¹ and Charles E. Geyer Jr, MD, FACP²



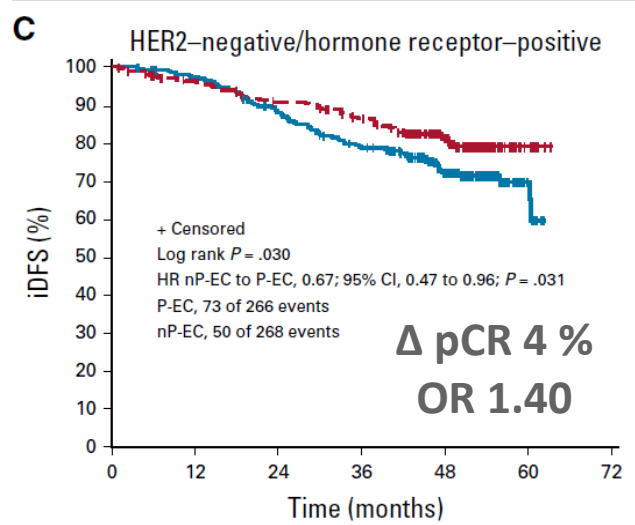
No at risk:

— P-EC	600	565	507	453	295	18	0
- - nP-EC	606	574	530	497	315	21	0



No at risk:

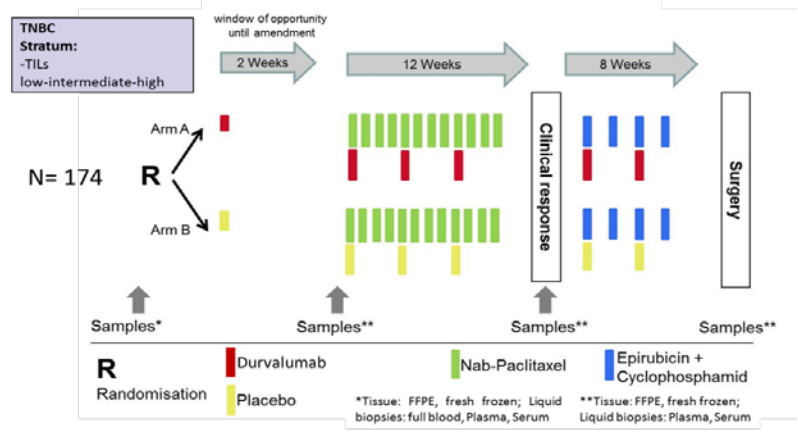
— P-EC	137	124	106	95	61	3	0
- - nP-EC	139	134	120	109	73	8	0



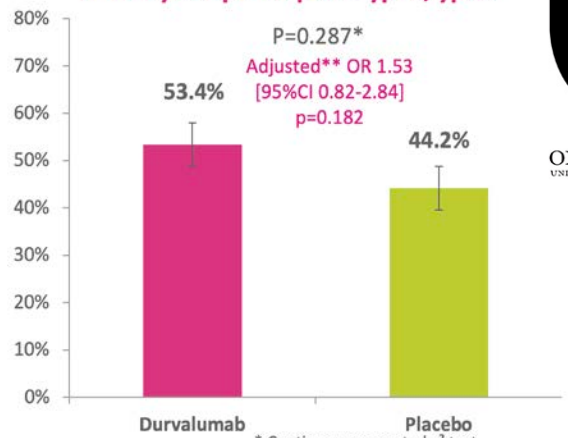
No at risk:

— P-EC	266	253	225	198	131	15	0
- - nP-EC	268	247	230	214	133	11	0

Gepar Nuevo Die NEUNTE: GeparNUEVO



Primary endpoint: pCR – ypT0, ypN0

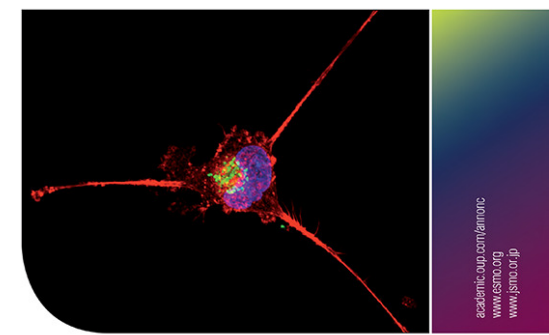


Loibl S, et al. Ann Oncol 2019

* Continuous corrected χ^2 test

** For stratification factor (TIL groups)

Triple-negative breast cancer - clinical results and biomarker analysis of GeparNuevo study



OXFORD UNIVERSITY PRESS

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www.esmo.org
www.jsmo.jp

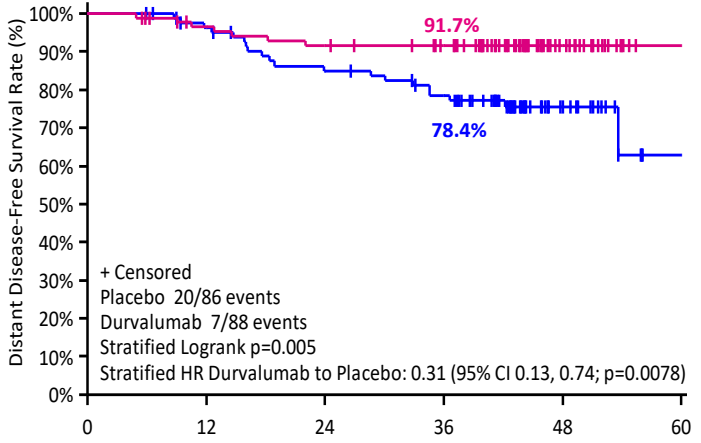




GeparNUEVO clinical results



DDFS



Patients at risk:

	Time (months)					
	0	12	24	36	48	60
Placebo	86	78	67	59	16	0
Durvalumab	88	80	76	70	20	0

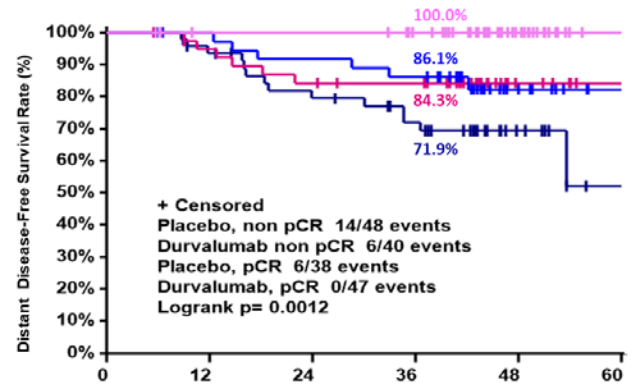
EDITORIAL

Neoadjuvant immunotherapy in triple-negative breast cancer: lesson learnt, remaining questions

In this issue of the *Annals of Oncology*, Loibl et al.¹ report the analysis of the secondary time-to-event endpoints of the GeparNuevo trial. GeparNuevo is a small phase II study (n = 174) investigating the addition of the programmed

capcitabine and, in patients with germline *BRCA1/2*, olaparib,^{5,6} but there are no data comparing the efficacy of these drugs with adjuvant pembrolizumab, and their combinations have not been tested. In addition, in the adjuvant

DDFS by pCR

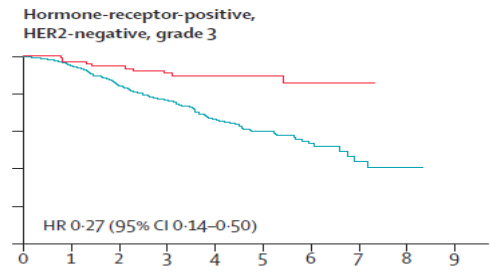
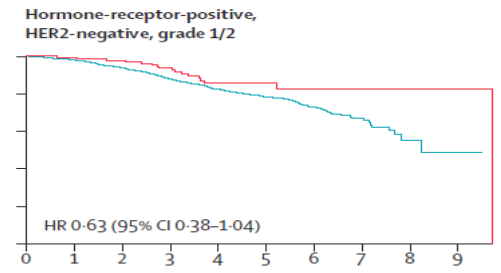
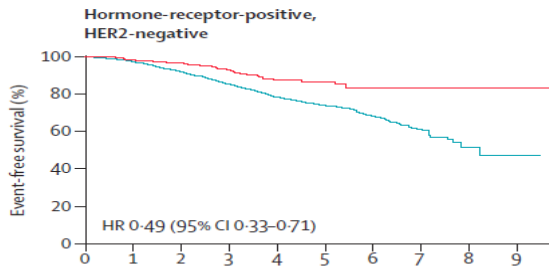


Patients at risk:

	Time (months)					
	0	12	24	36	48	60
Placebo, non pCR	48	42	34	28	8	0
Durvalumab non pCR	40	36	32	30	5	0
Placebo, pCR	38	36	33	31	8	0
Durvalumab, pCR	47	44	44	40	15	0



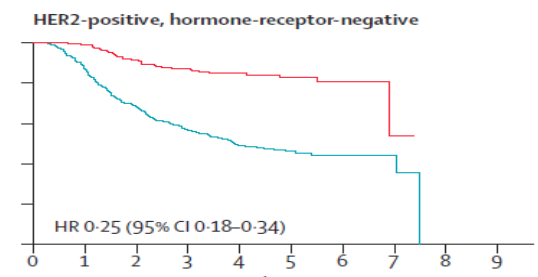
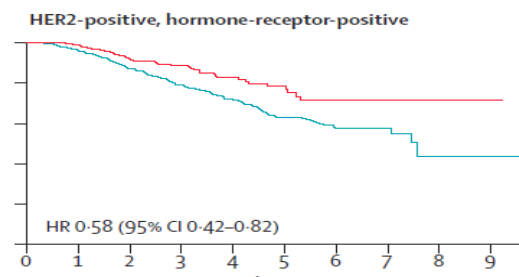
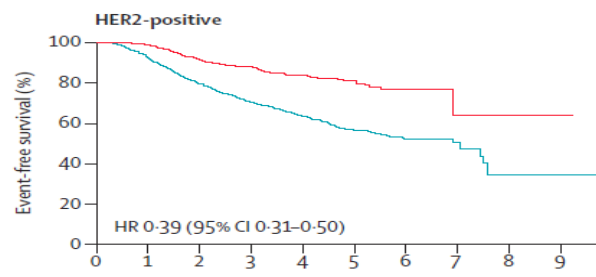
Postneoadjuvante Therapie



— pCR
— No pCR

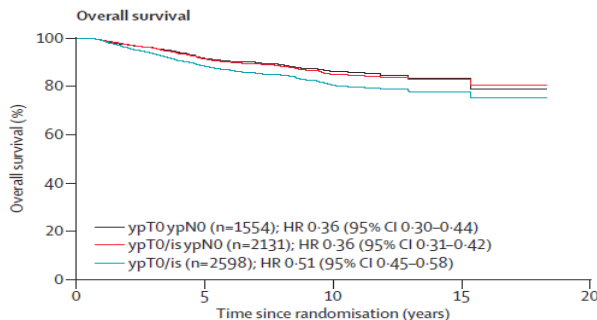
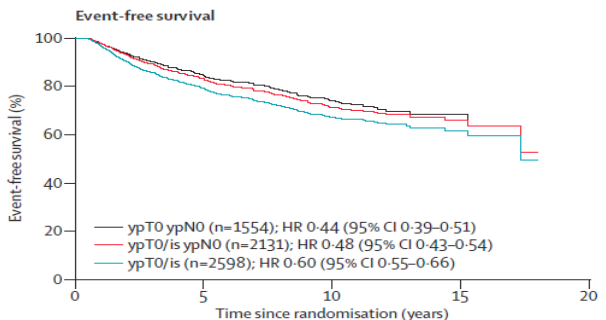
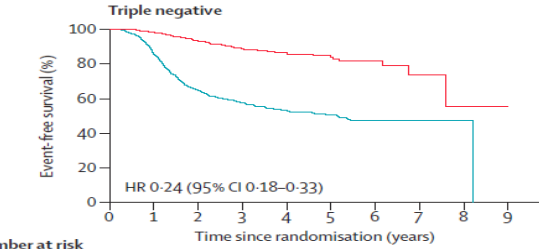
Number at risk

	pCR	270	244	224	184	113	69	21	6	2	2	148	134	123	102	55	33	10	5	2	2	102	92	83	71	49	30	9	1	0
	No pCR	2491	2226	1978	1616	1017	658	247	84	20	1	1838	1653	1493	1236	790	517	198	68	15	1	528	458	376	290	173	111	38	14	5



Number at risk

	pCR	586	527	454	371	212	120	37	4	2	1	247	224	194	157	91	50	17	2	2	1	325	293	250	205	115	65	19	2
	No pCR	1403	1157	918	713	436	269	106	33	3	1	839	723	617	484	306	198	79	24	3	1	510	392	269	200	111	59	22	6



Number at risk

	pCR	389	349	310	250	166	88	29	11	1
	No pCR	768	604	429	317	198	125	50	13	1

NaTaN: Disease-free survival

Stratification factors

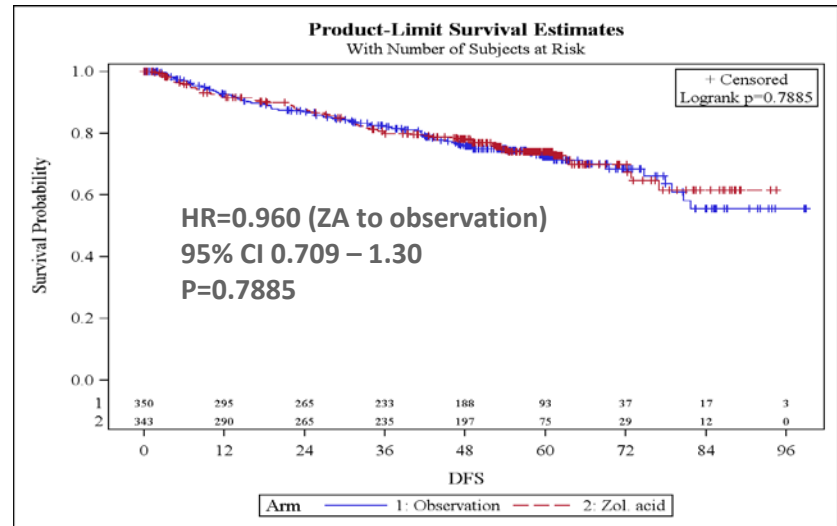
- > Center
- > Hormone receptor status (<10 or ≥ 10 % ER or PgR)
- > Age (<50 / ≥50 years)
- > Time since surgery (within 3 months, 1 year, 2 years, or 3 years)

RANDOMIZATION

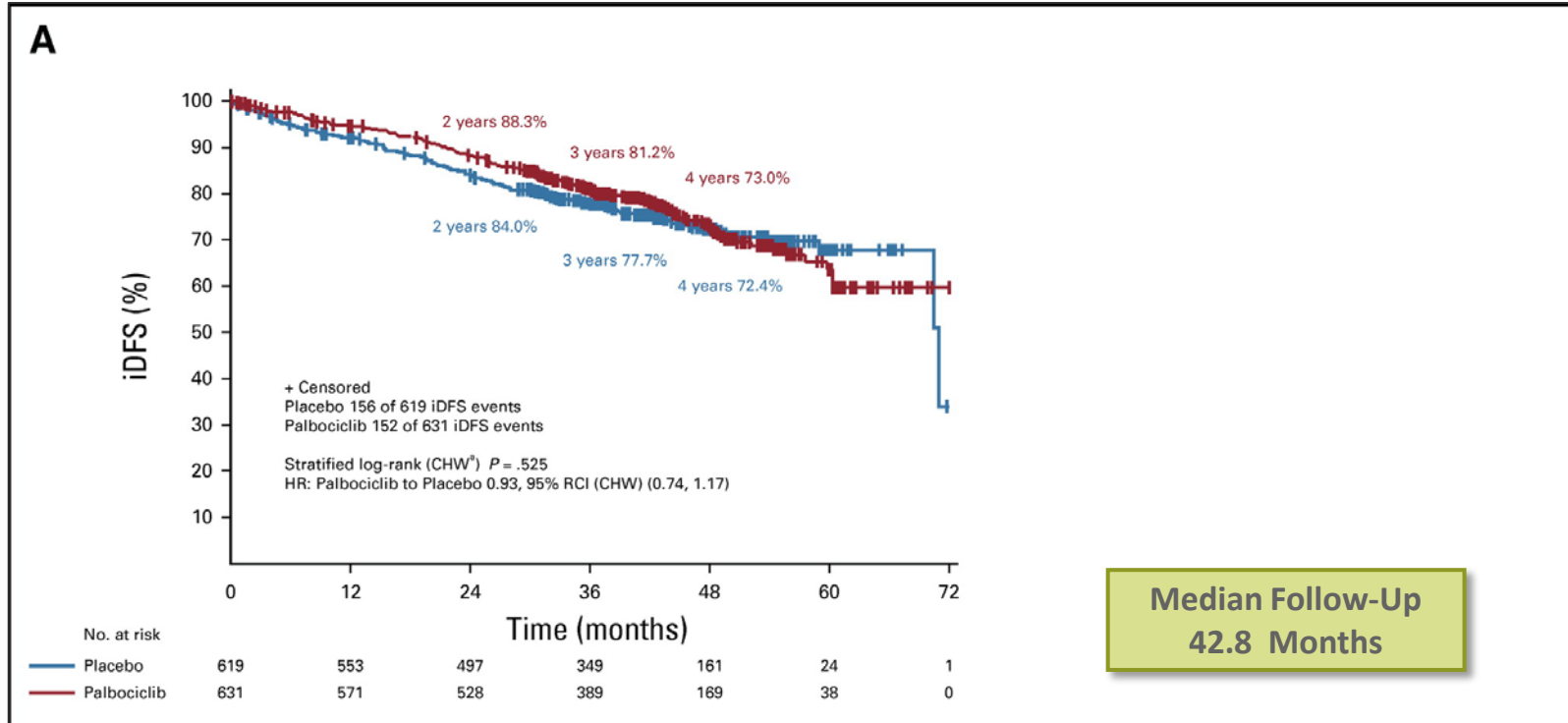
Observation

Zoledronate 4 mg iv.

- Every 4 weeks for the first 6 doses (year 0- 0.5)
- Every 3 months for 8 doses (year 0.5-2.5)
- Every 6 months for 5 doses (year 2.5- 5.0)



Penelope-B: Primärer Endpunkt



KATHERINE Study Design

- cT1-4/N0-3/M0 at presentation (cT1a-b/N0 excluded)
- Centrally confirmed HER2-positive breast cancer
- Neoadjuvant therapy must have consisted of
 - Minimum of 6 cycles of chemotherapy
 - Minimum of 9 weeks of taxane
 - Anthracyclines and alkylating agents allowed
 - All chemotherapy prior to surgery
 - Minimum of 9 weeks of trastuzumab
 - Second HER2-targeted agent allowed
- Residual invasive tumor in breast or axillary nodes
- Randomization within 12 weeks of surgery

R
1:1

N=1486

T-DM1
3.6 mg/kg IV Q3W
14 cycles

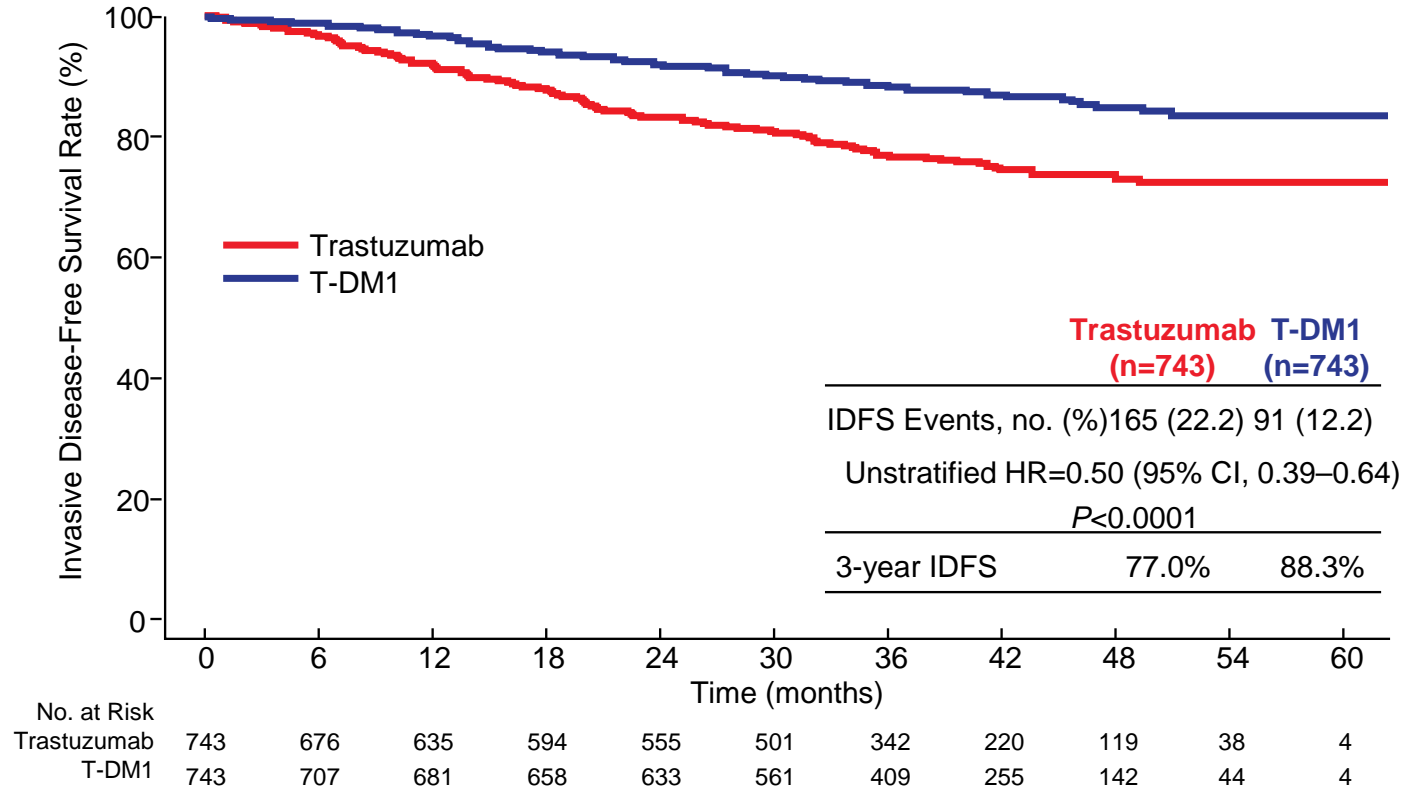
Trastuzumab
6 mg/kg IV Q3W
14 cycles

Radiation and endocrine therapy
per protocol and local guidelines

Stratification factors:

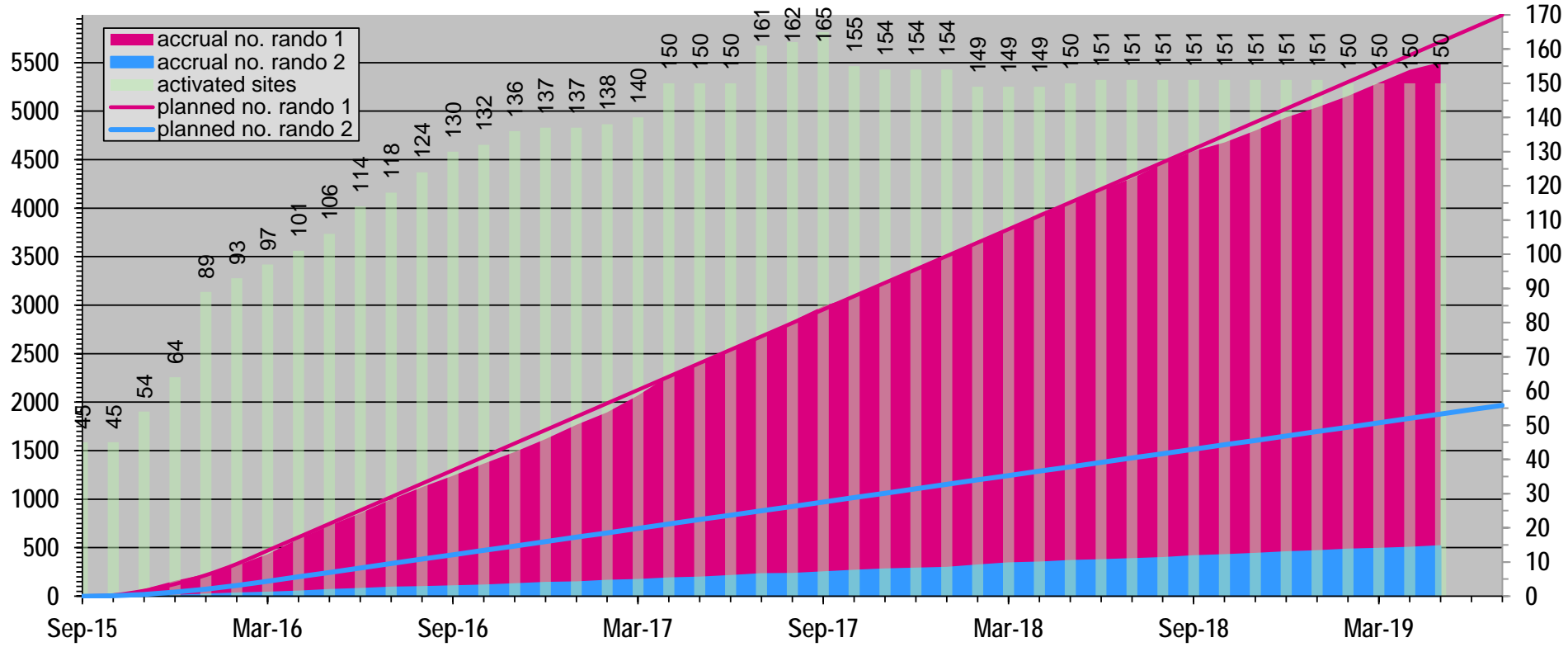
- Clinical presentation: Inoperable (stage cT4 or cN2–3) vs operable (stages cT1-3N0-1)
- Hormone receptor: ER or PR positive vs ER negative and PR negative/unknown
- Preoperative therapy: Trastuzumab vs trastuzumab plus other HER2-targeted therapy
- Pathological nodal status after neoadjuvant therapy: Positive vs negative/not done

Invasive Disease-Free Survival



Insema – Recruitment on 01.05.2019

rando 1 = 5505 / rando 2 = 517



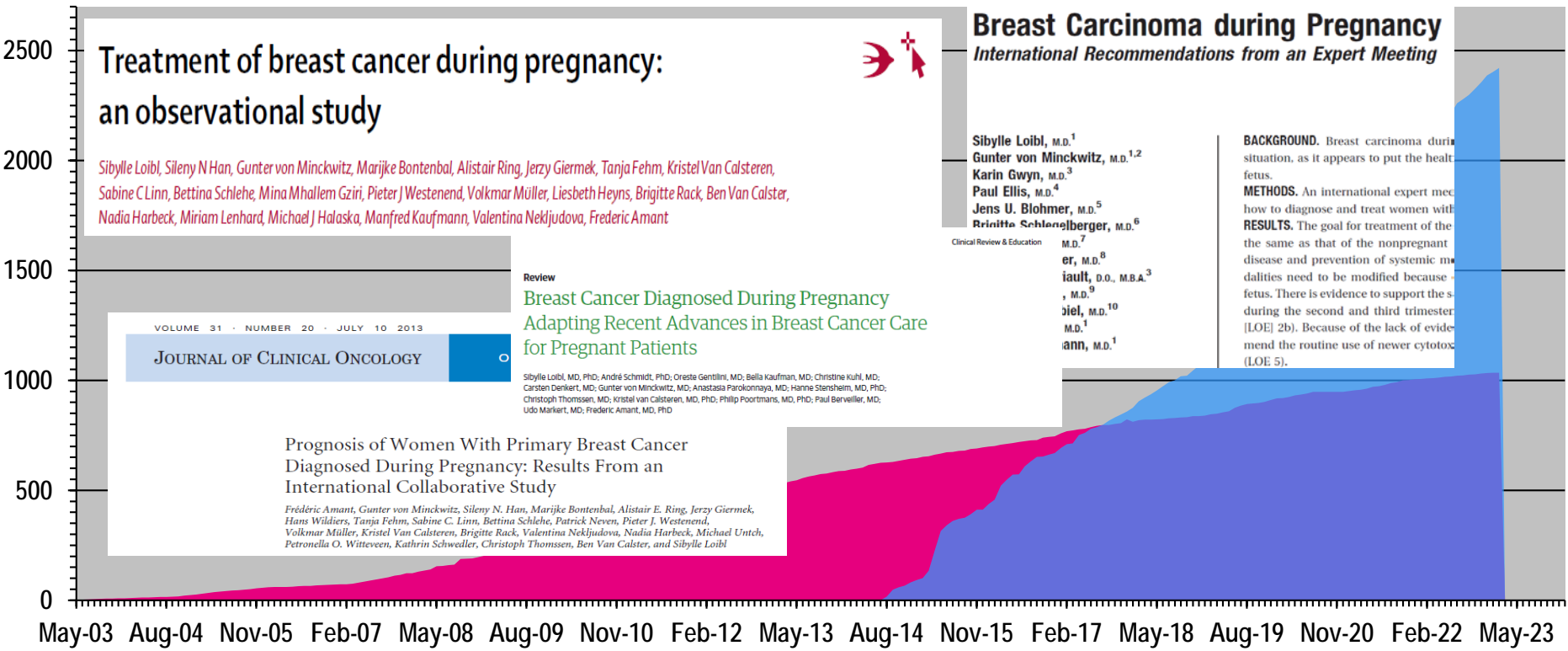


BCP - Recruitment on 01.02.2023

n = 3456 (↑19)

Germany n = 3081 (total)
Foreign countries n = 375 (total)

n = 702 (pregnant) n = 2379 (not pregnant)
n = 333 (pregnant) n = 42 (not pregnant)



Treatment of breast cancer during pregnancy: an observational study

Sibylle Loibl, Sileny N Han, Gunter von Minckwitz, Marijke Bontenbal, Alistair Ring, Jerzy Giermek, Tanja Fehm, Kristel Van Calsteren, Sabine C Linn, Bettina Schlehe, Mina Mhallet Gziri, Pieter J Westenend, Volkmar Müller, Liesbeth Heyns, Brigitte Rack, Ben Van Calster, Nadia Harbeck, Miriam Lenhard, Michael J Halaska, Manfred Kaufmann, Valentina Nekjudova, Frederic Amant



Breast Carcinoma during Pregnancy International Recommendations from an Expert Meeting

Sibylle Loibl, M.D.¹
Gunter von Minckwitz, M.D.^{1,2}
Karin Gwyn, M.D.³
Paul Ellis, M.D.⁴
Jens U. Blohmer, M.D.⁵
Rinitta Schlangelberger, M.D.⁶
Clinical Review & Education
M.D.⁷
er, M.D.⁸
iault, D.O., M.B.A.³
, M.D.⁹
biel, M.D.¹⁰
M.D.¹
ann, M.D.¹

BACKGROUND. Breast carcinoma during pregnancy is a challenging situation, as it appears to put the health of the fetus at risk.
METHODS. An international expert meeting was convened to discuss how to diagnose and treat women with breast cancer during pregnancy.
RESULTS. The goal for treatment of breast cancer during pregnancy is the same as that of the nonpregnant patient. Systemic therapies need to be modified because of the potential for fetal toxicity. There is evidence to support the use of tamoxifen during the second and third trimester (LOE 2b). Because of the lack of evidence, the routine use of newer cytotoxic agents is not recommended (LOE 5).

Review Breast Cancer Diagnosed During Pregnancy Adapting Recent Advances in Breast Cancer Care for Pregnant Patients

Sibylle Loibl, MD, PhD; André Schmidt, PhD; Orreste Gentilini, MD; Bella Kaufman, MD; Christine Kuhl, MD; Carsten Denkert, MD; Gunter von Minckwitz, MD; Anastasia Parokonnaya, MD; Hanne Stensheim, MD, PhD; Christoph Thomssen, MD; Kristel van Calsteren, MD, PhD; Philipp Poortmans, MD, PhD; Paul Berviller, MD; Udo Markert, MD; Frederic Amant, MD, PhD

Prognosis of Women With Primary Breast Cancer Diagnosed During Pregnancy: Results From an International Collaborative Study

Frédéric Amant, Gunter von Minckwitz, Sileny N. Han, Marijke Bontenbal, Alistair E. Ring, Jerzy Giermek, Hans Wildiers, Tanja Fehm, Sabine C. Linn, Bettina Schlehe, Patrick Neven, Pieter J. Westenend, Volkmar Müller, Kristel Van Calsteren, Brigitte Rack, Valentina Nekjudova, Nadia Harbeck, Michael Untch, Petronella O. Witteveen, Kathrin Schwedler, Christoph Thomssen, Ben Van Calster, and Sibylle Loibl

May-03 Aug-04 Nov-05 Feb-07 May-08 Aug-09 Nov-10 Feb-12 May-13 Aug-14 Nov-15 Feb-17 May-18 Aug-19 Nov-20 Feb-22 May-23

Male

JAMA Oncology

Research

JAMA Oncology | Original Investigation

Efficacy of Endocrine Therapy for the Treatment of Breast Cancer in Men Results from the MALE Phase 2 Randomized Clinical Trial

Mattea Reinisch, MD; Sabine Seiler, MD; Tanja Hauzenberger, MD; Axel Kamischke, MD, PhD; Sabine Schmatloch, MD; Hans-Joachim Strittmatter, MD, PhD; Dirk-Michael Zahm, MD; Christian Thode, MD; Jenny Furlanetto, MD; Dominika Strik, MD; Volker Möbus, MD, PhD; Toralf Reimer, MD, PhD; Bruno Valentin Sinn, MD; Elmar Stickeler, MD, PhD; Frederik Marmé, MD, PhD; Wolfgang Janni, MD, PhD; Marcus Schmidt, MD, PhD; Christian Rudlowski, MD, PhD; Michael Untch, MD, PhD; Valentina Nekljudova, PhD; Sibylle Loibl, MD, PhD

RCT Efficacy of Endocrine Therapy for the Treatment of Breast Cancer in Men

POPULATION

56 Men



Men with hormone receptor-positive breast cancer

Median age, 61.5 y
(range 37-83 y)

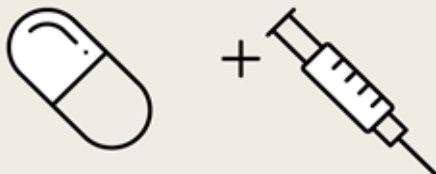
SETTINGS / LOCATIONS



24 Breast units or medical centers, Germany

INTERVENTION

50 Men randomized and analyzed for primary outcome



17 Tamoxifen alone:
Oral tamoxifen 20 mg daily

15 Tamoxifen + GnRHs: Oral tamoxifen 20 mg daily and subcutaneous gonadotropin-releasing hormone analogue (GnRHs) every 3 mo

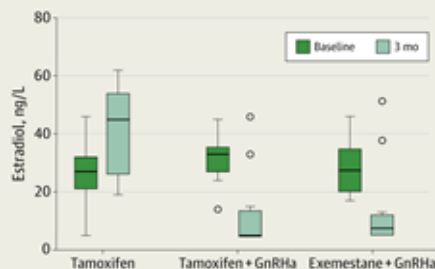
18 Exemestane + GnRHs: Oral exemestane 25 mg daily and subcutaneous GnRHs at baseline and after 3 mo

PRIMARY OUTCOME

The primary outcome was the change of estradiol levels after 3 months of therapy (normal range of estradiol was between 27-52 ng/L, the threshold of detection was below 5 ng/L)

FINDINGS

Estradiol levels significantly decreased in men receiving either tamoxifen + GnRHs or exemestane + GnRHs but significantly increased in men receiving tamoxifen alone



% Change in median estradiol level, baseline to 3 mo

Tamoxifen alone: 67% increase (+17.0 ng/L)

Tamoxifen + GnRHs: 85% decrease (-23.0 ng/L)

Exemestane + GnRHs: 72% decrease (-18.5 ng/L)

GBG 2006 und 2023





Translational Research

2015



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META cancer



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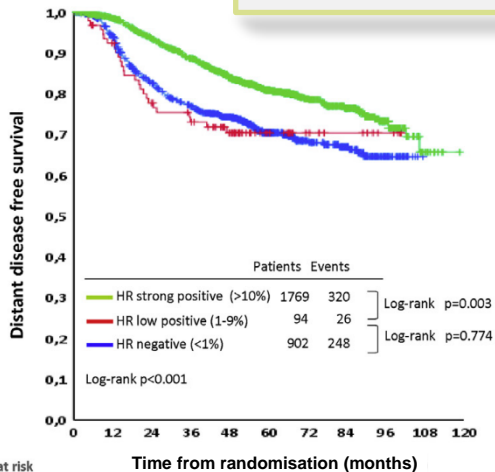


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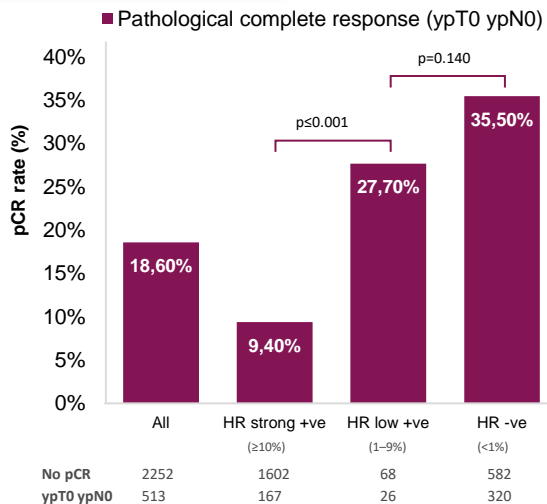


TNBC definition and outcome

GBG neoadjuvant study cohort¹

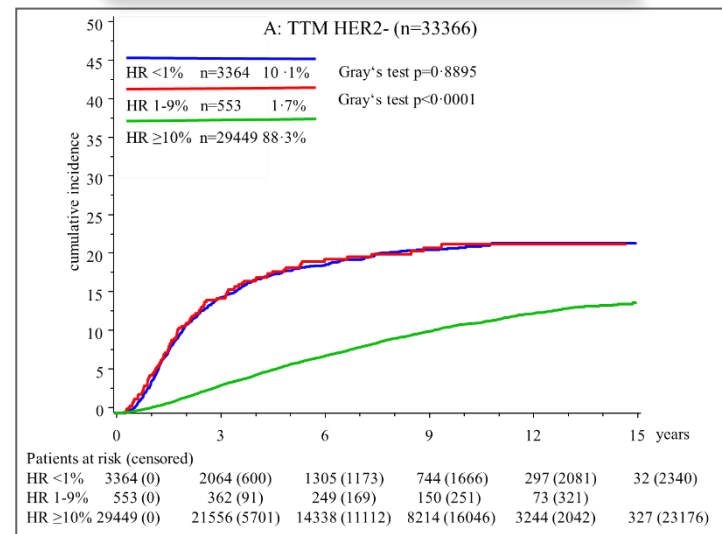


	1769	1634	1479	1339	1108	740	392	275	97	12
HR strong positive	1769	1634	1479	1339	1108	740	392	275	97	12
HR negative	902	811	684	608	507	295	155	102	32	
HR low positive	94	83	68	62	46	23	12	9	5	



	All	HR strong +ve (≥10%)	HR low +ve (1-9%)	HR -ve (<1%)
No pCR	2252	1602	68	582
ypT0 ypN0	513	167	26	320

Munich Cancer Registry cohort²



ER=oestrogen receptor; GBG=German Breast Group; HER2=human epidermal growth factor receptor 2; HR=hormone receptor; pCR=pathological complete response; PR=progesterone receptor; TTM=time to metastasis; TNBC=triple-negative breast cancer.

TNBCs also include tumours with low ER and PR expressions and tumours

1. Villegas-Salazar et al. *Front J Cancer* 2021;148:159-170. 2. Schrodi S, et al. *Ann Oncol* 2021;

What are HER2 negative

HER2-low

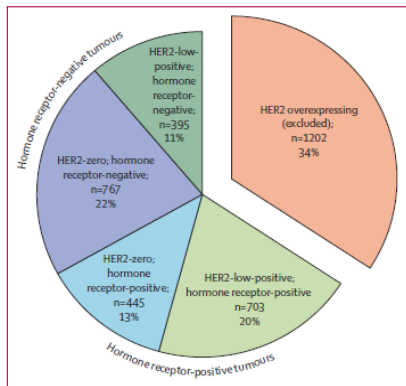
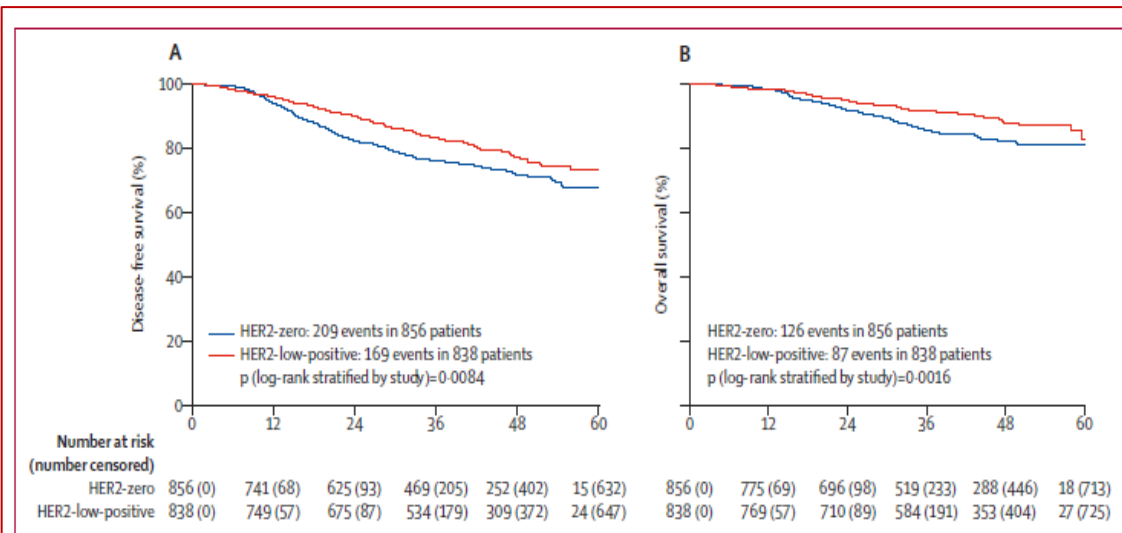
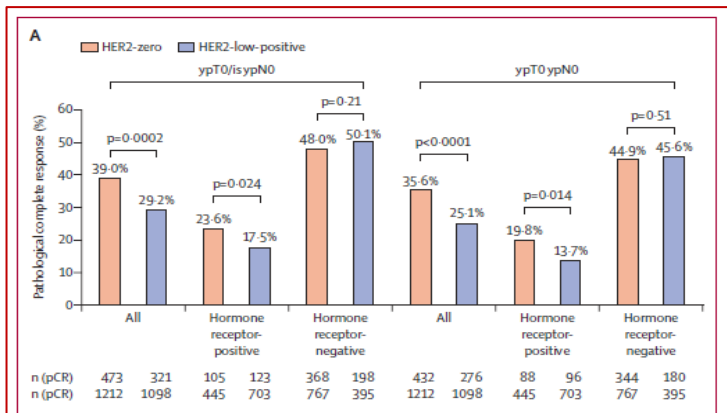


Figure 1: Modified classification of breast cancer based on a combination of hormone-receptor expression and HER2 expression

Clinical and molecular characteristics of HER2-low-positive breast cancer: pooled analysis of individual patient data from four prospective, neoadjuvant clinical trials



Carsten Denkert, Fenja Seither, Andreas Schneeweiss, Theresa Link, Jens-Uwe Blohmer, Marianne Just, Pauline Wimberger, Almuth Forberger, Hans Tesch, Christian Jackisch, Sabine Schmatloch, Mattea Reinisch, Erich F Solomayer, Wolfgang D Schmitt, Claus Hanusch, Peter A Fasching, Kristina Lübke, Christine Solbach, Jens Huober, Kerstin Rhiem, Frederik Marmé, Toralf Reimer, Marcus Schmidt, Bruno V Sinn, Wolfgang Janni, Elmar Stickeler, Laura Michel, Oliver Stötzer, Eric Hahnen, Jenny Furlanetto, Sabine Seiler, Valentina Nekljudova, Michael Untch, Sibylle Loibl



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BIG Breast International Group

SOLTI INNOVATIVE BREAST CANCER RESEARCH

French breast cancer intergroup UNICANCER

UCBG

ABCSG AUSTRIAN BREAST & COLORECTAL CANCER STUDY GROUP

SBG

CIRG Cancer International Research Group

IKP STUTTGART

NRG ONCOLOGY Advancing Research. Improving Lives.™

GEICAM investigación en cáncer de mama

BOOG

UZ LEUVEN

WSG WOMEN'S HEALTHCARE STUDY GROUP

cancer trials ireland

Grupo Espanol de Investigacion del Cancer de Mama

IBCSG International Breast Cancer Study Group

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

BREAST CANCER TRIALS

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FONDAZIONE MICHELANGELO avanzamento dello studio + cura dei tumori

ALLIANCE FOUNDATION TRIAL

Japan Breast Cancer Research Group

一般社団法人 JBCRG Japan Breast Cancer Research Group

LACOG Latin American Cooperative Oncology Group

PRECOG

nadian Cancer Trials Group

Groupes canadien des essais sur le cancer

NSABP National Surgical Adjuvant Breast and Bowel Project PARTNERS IN CANCER RESEARCH

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, Karn, Loibl,
Stickeler, van

Vielen Dank an alle für die
GUTE ZUSAMMENARBEIT

AGO-B

Fasching, Fehm, Jackisch, Janni, Kühn,
Lück, Möbus, Müller, Rack, Schmidt,
Schneeweiss, Stickeler, Thomssen, Untch
u.v.a.

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Collaborating Partners

Cooperating partners



Carsten Denkert
Paul Jank



Thomas Karn



Michael Untch
Peter Fasching
Volkmar Müller



Rita Schmutzler
Kerstin Rhiem
Eric Hahnen

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DANKE!

Wir bedanken uns bei den Sponsoren der GBG Jahrestagung 2. – 3. März 2023

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