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Brussels, January 30, 2021

SABCS
SAN ANTONIO BREAST CANCER SYMPOSIUM

An initiative of

INSTITUT JULES BORDET INSTITUUT

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Early Breast Cancer

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Disclosures

- **Board Member** : Oncolytics
- **Consultant (honoraria)** : AstraZeneca, Camel-IDS, Immutep, NBE Therapeutics, Immunomedics, Lilly, Menarini, MSD, Novartis, Odonate, Pfizer, Roche-Genentech, Seattle Genetics
- **Research grants to my Institute** : AstraZeneca, Lilly, MSD, Novartis, Pfizer, Roche-Genentech, Synthon, Servier
- **Speakers bureau/stock ownership :** none

Early Breast Cancer (BC)

- **Progress in adjuvant treatment tailoring for luminal BC…**
  … ***through the use of multigene expression signature !***

- **Adjuvant use of CDK4-6 inhibitors: not ready yet ?**
  … ***updated results of MonarchE, first results of PenelopeB***

Early Breast Cancer (SABCS 2020)

Progress in adjuvant treatment tailoring for luminal BC

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A. Baseline gene expression profiles

Clinical utility proven for

Adjuvant chemo sparing

First resuls of RX-PONDER (1)

Put in perspective with TAILOR-X/MINDACT

Extending adjuvant endocrine therapy

Level of evidence Ib for « BCI » (2)

(1) Kalinsky K et al, abst GS3-00 (2) Sgroi DC et al, abst GS4-08

Early Breast Cancer (SABCS 2020)
Progress in adjuvant treatment tailoring for luminal BC

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B. Preop endocrine treatment response guided therapy

Clinical utility not yet proven

<u>ALTERNATE</u> trial (1)

<u>ADAPT</u> HR+/HER2- trial (2)

(1) Ma CX et al, abst GS4-05
(2) Harbecq N et al, abst GS4-04

Why should we *perform GEPs* for HR+/HER2- early breast cancer?

1) To *inform* physicians and patients on the risk of recurrence

→ *Prognosis*

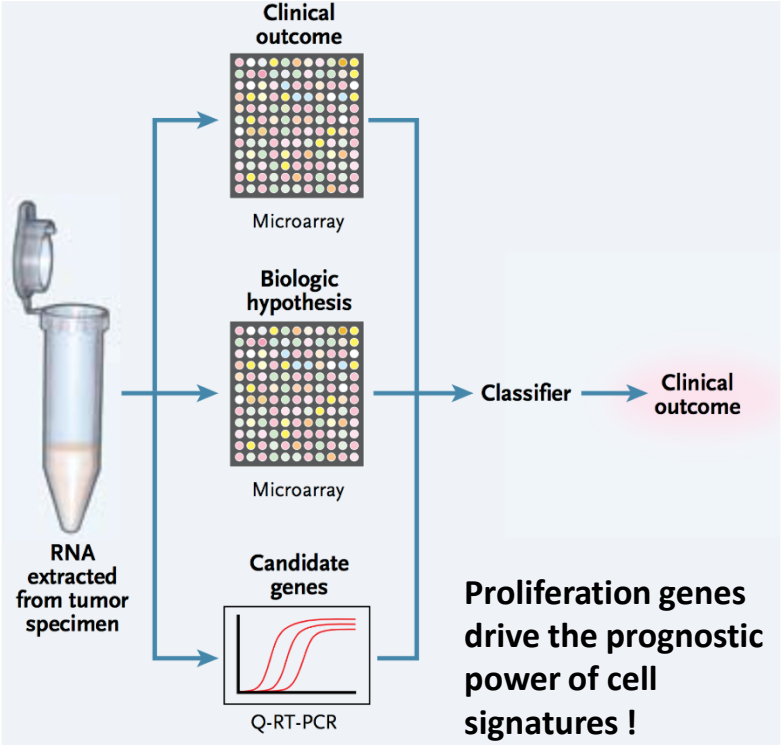
2) To *assist* physicians and patients for the best treatment options (*who will benefit from chemotherapy?*)

→ *Prediction*

→ De-scalation/Escalation of adjuvant systemic therapy

Gene expression prognostic classifiers

Top-down and bottom-up approaches



Proliferation genes drive the prognostic power of cell signatures !

mammaprint

oncotype

MINDACT

TAILOR X

RX-PONDER

PAM 50

prosigna™ Breast cancer gene signature assay

OPTIMA

EndoPredict®

BIO THERANOSTICS

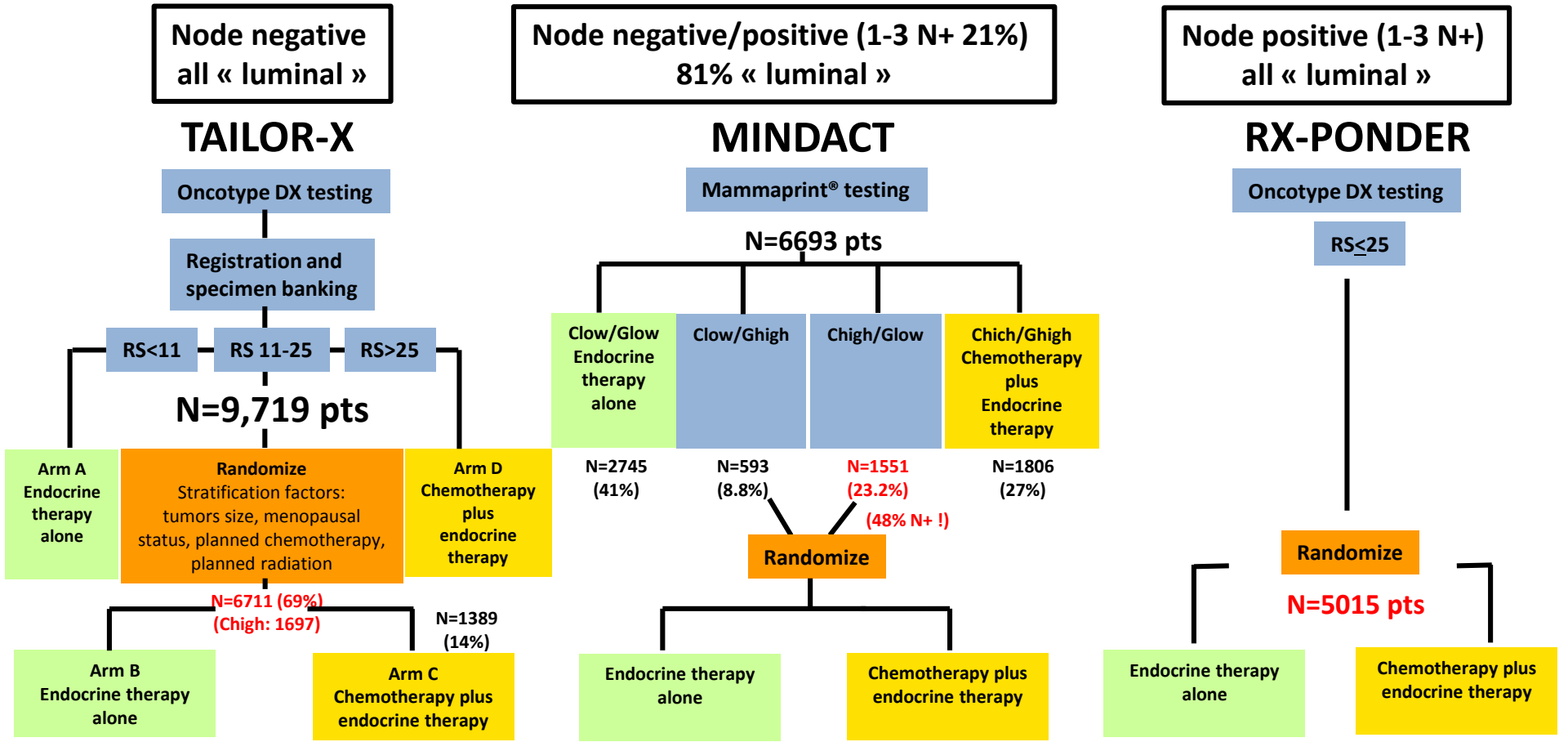
SOLUTIONS FOR METASTATIC CANCER

bci

Retrospective studies

C Sotiriou & L Pusztai, NEJM 2009

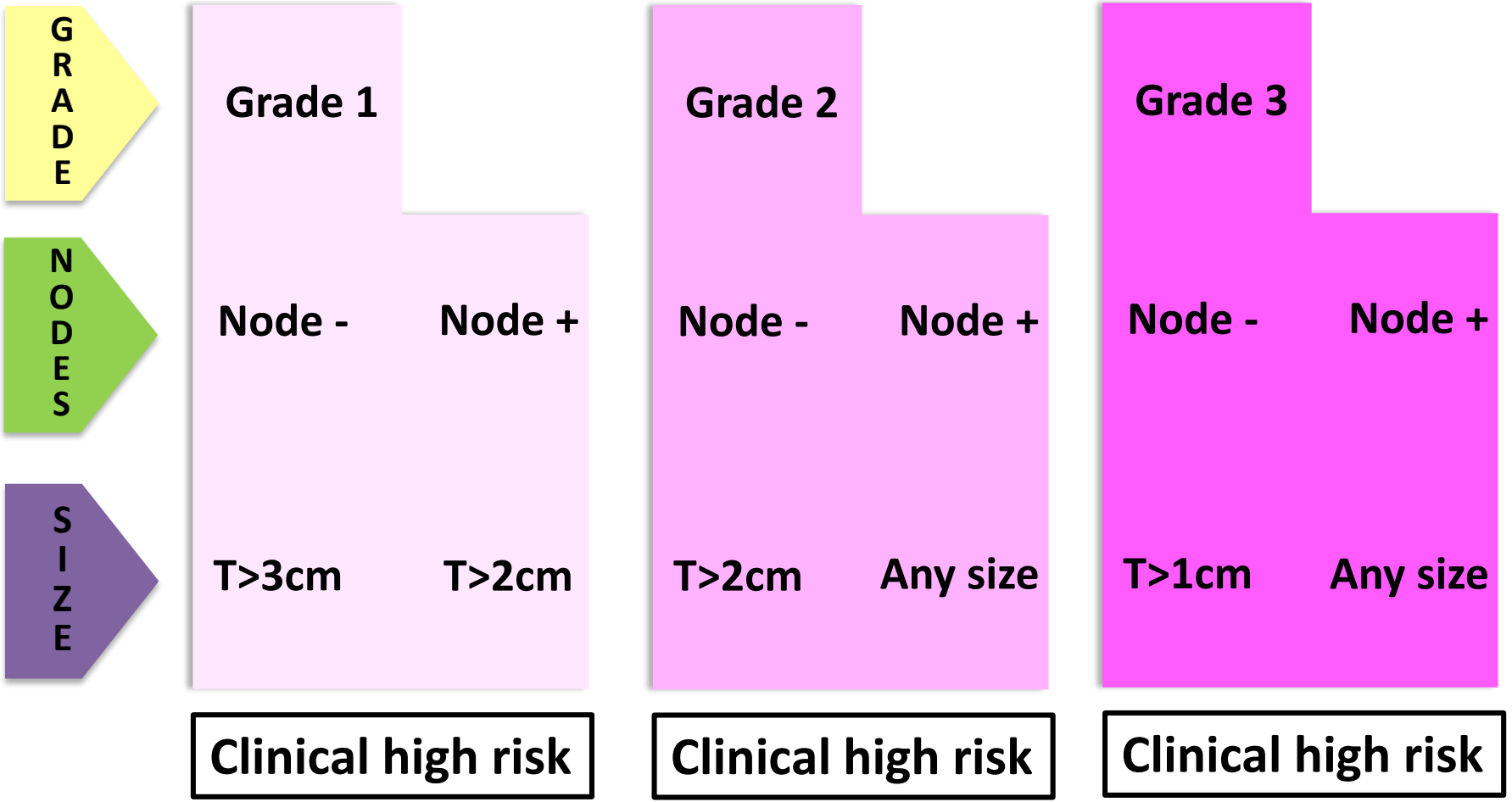
« Low risk » gene expression prognostic classifiers and chemotherapy benefit



Sparano JA, NEJM 2019

Piccart MJ, Lancet Oncol, in press

Kalinsky K, SABCS 2020

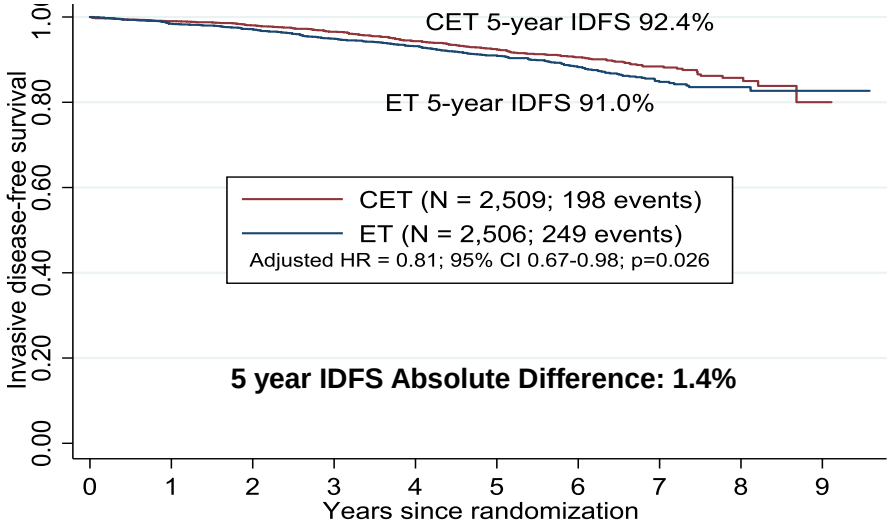


C-high risk according to « MINDACT » : expected 10 y OS < 92% with endocrine therapy alone (as per Adjuvant! Online)

“Precision medicine” prospective clinical trials in early HER2- HR+ BC

	TAILOR-X	MINDACT	RX-PONDER
Years of accrual	2006-2010	2007-2011	2011-2015
Patients recruited and eligible	9719 All node negative and HER2- HR+	6693 node- 79% 1-3 node + 21% HER2- HR+ 81%	5015 All 1-3 nodes + and HER2- HR+
Primary endpoint Median follow-up	IDFS 9 years	DMFS 8.7 years	IDFS 5 years
Primary Hypothesis	ET not inferior to CT+ET in case of RS 11-25	Threshold for 5y DMFS > 92% in Chigh/Glow risk receiving no CT	Positive interaction test of chemo benefit with increasing RS
Result	IDFS HR 1.08 (0.94-1.24) required < 1.32	5 y DMFS 95.1% (93.1-96.6) required > 92%	p interaction 0.30 5y HR .81 (95% CI 0.67-0.98) (p interaction 0.008 for CTX benefit & menopause)

IDFS in Overall Population by Treatment Arm



Number at risk

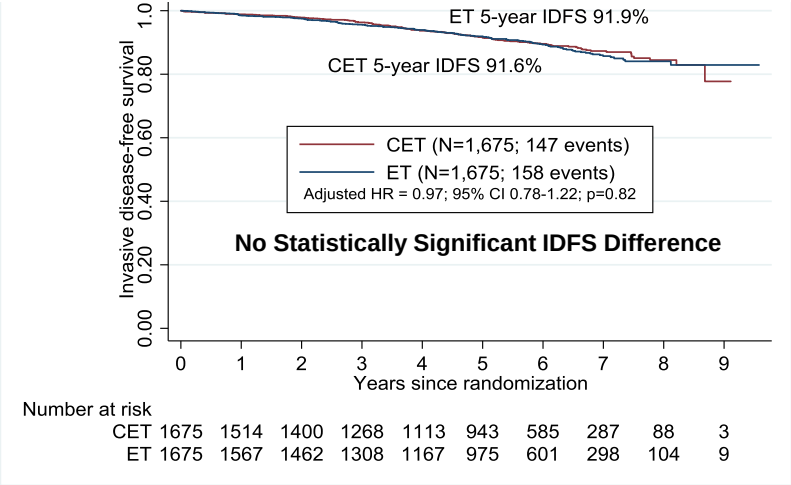
CET	2509	2277	2104	1893	1648	1397	857	403	122	4
ET	2506	2327	2161	1910	1696	1404	846	397	135	11

CET = Chemotherapy + Endocrine Therapy; ET = Endocrine Therapy Alone

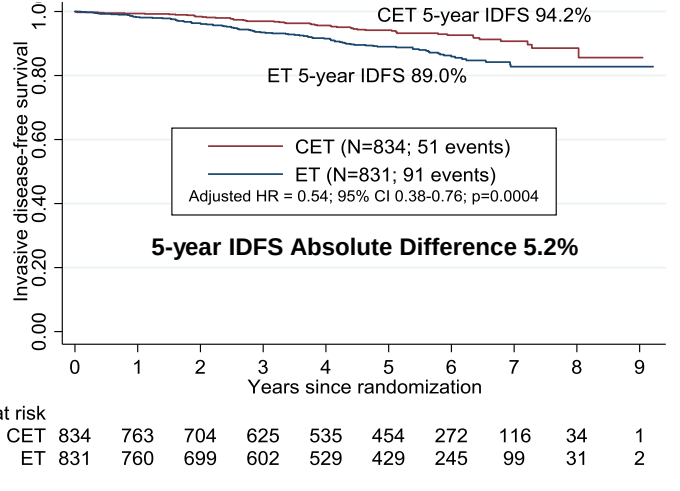
447 observed IDFS events (54% of expected at final analysis) at a median follow-up of 5.1 years

IDFS Stratified by Menopausal Status

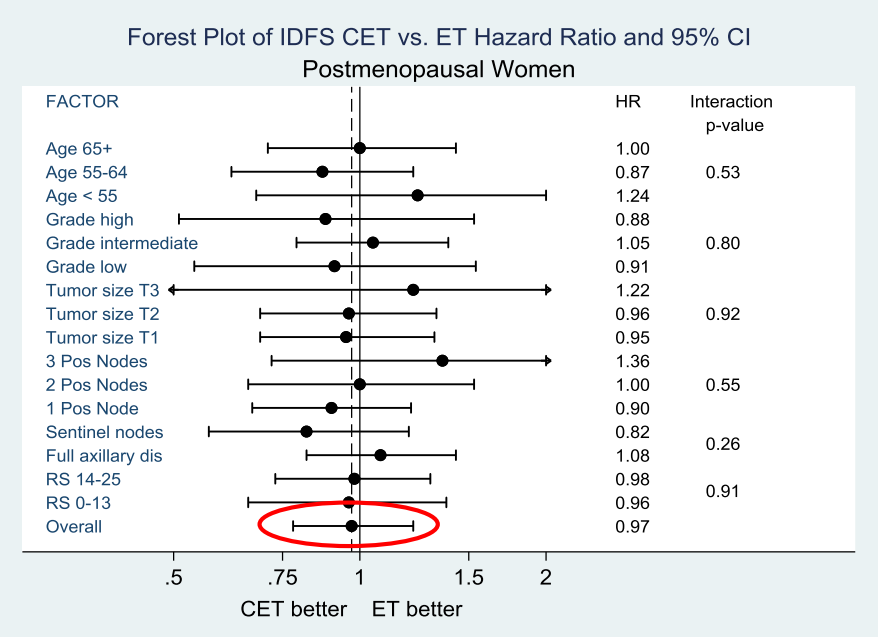
Postmenopausal

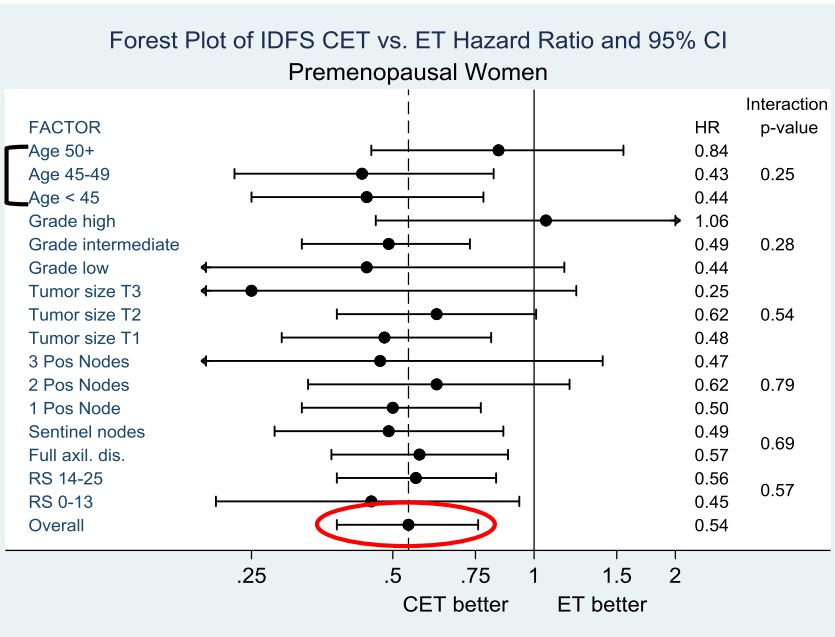


Premenopausal



Forest Plots of IDFS by Menopausal Status



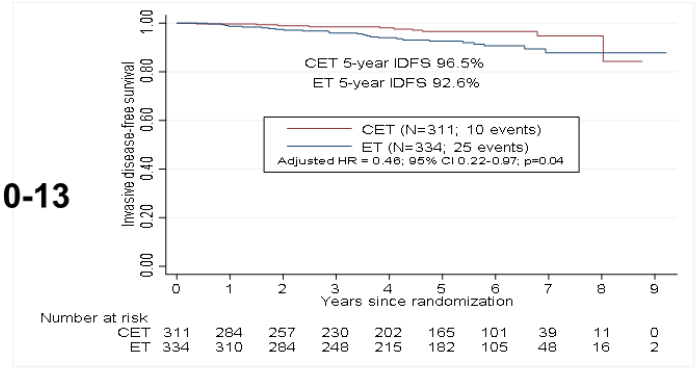


Landmarked Exploratory Analysis for IDFS in Premenopausal Women on Endocrine Therapy arm:
Ovarian Function Suppression (n=126) vs. no Ovarian Function Suppression (n=647) at 6 months: HR 0.73 (95% CI: 0.39-1.37), p=0.33

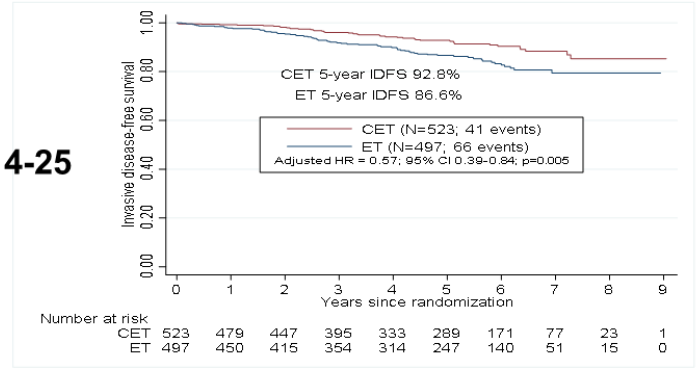
IDFS Stratified by Recurrence Score in premenopausal women

Premenopausal

RS 0-13



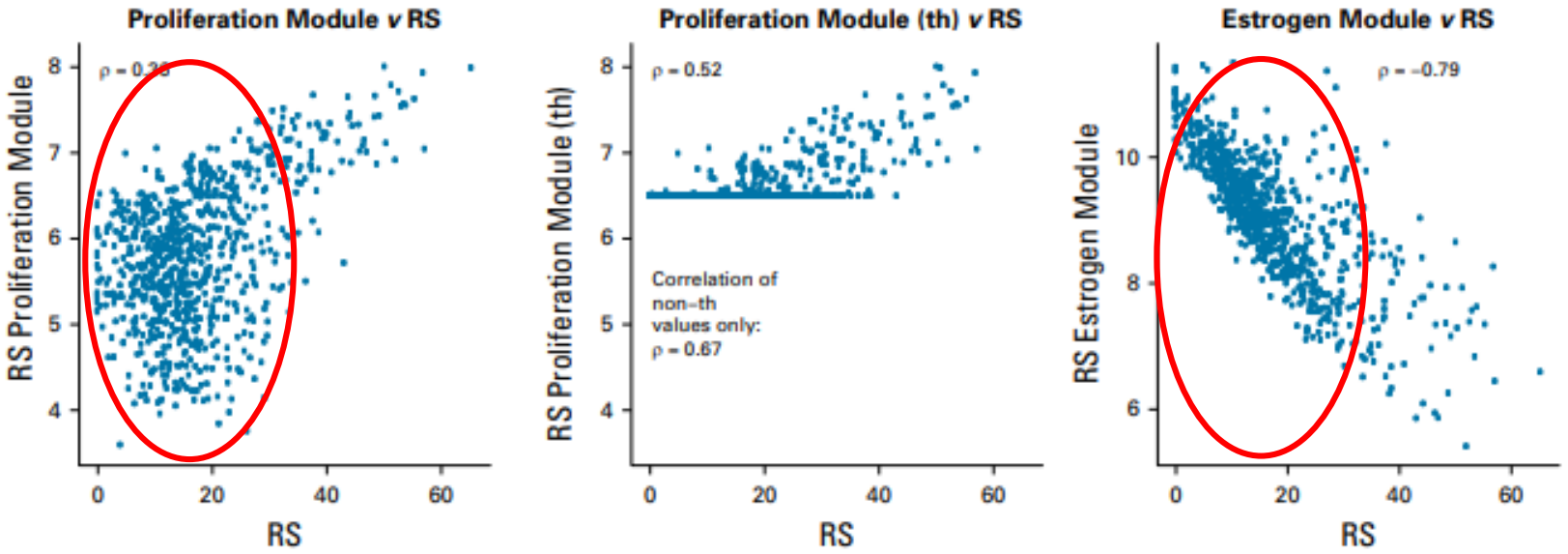
RS 14-25



No indication of a smaller benefit if RS 0-13 !!!

Kalinsky K. et al, SABCS 2020

Why did RX-PONDER fail to show an increasing chemotherapy benefit with an increasing RS up to RS 25 ?

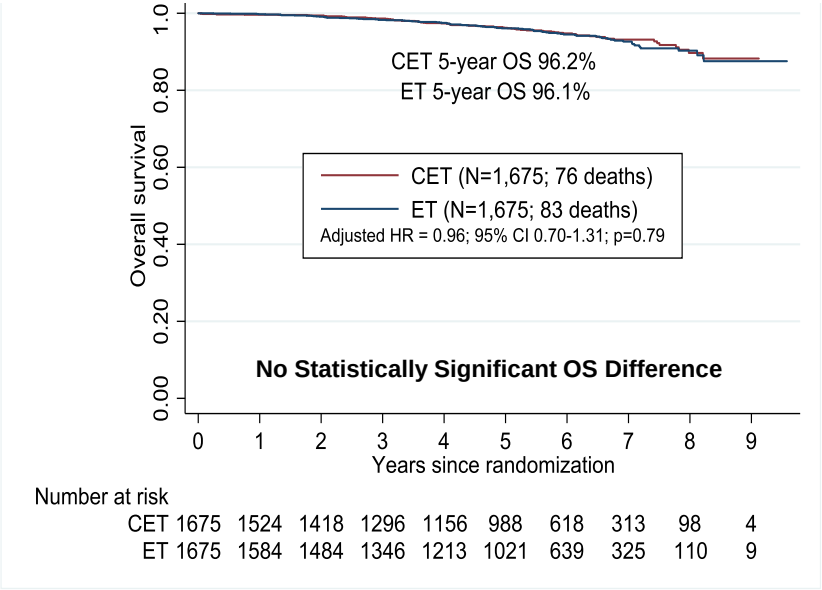


- **RS is determined more strongly by its estrogen module than its proliferation module**
- **The score from the proliferation module is thresholded !**

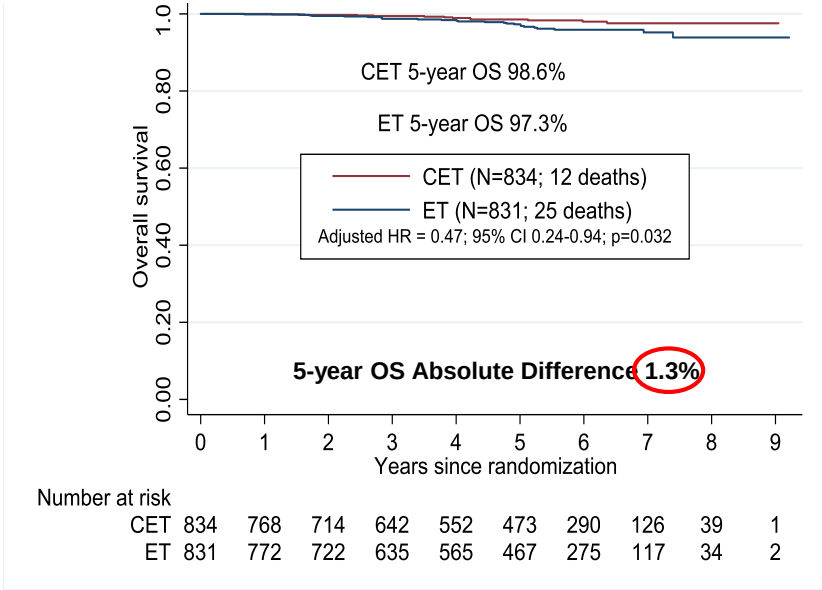
Buus R. et al, JCO 2020

Overall Survival by Menopausal Status

Postmenopausal



Premenopausal



RxPONDER Conclusions

- At this interim analysis with 54% of anticipated IDFS events in the overall population, the 21-gene RS 0-25 was prognostic but did not show a treatment interaction with chemotherapy
  - Relative benefit of chemotherapy was similar across RS 0-25
- Postmenopausal women with RS 0-25 did not benefit from adjuvant chemotherapy in any subgroup
- Premenopausal women with RS 0-25 had benefit from the addition of chemotherapy to endocrine therapy
  - 46% decrease in IDFS events; benefit was observed across premenopausal subgroups
  - 53% decrease in deaths, leading to a 5-year OS absolute improvement of 1.3%
- Additional follow-up is ongoing, and future analyses will also include QOL and other outcomes

“Precision medicine” prospective clinical trials in early HER2- HR+ BC (2)

	TAILOR-X	MINDACT	RX-PONDER
Chemotherapy (CT) benefit	Primary endpoint	Secondary endpoint	Subprimary endpoint
- Populations tested	> 50 y N= 4353 (1180 Chigh) ≤ 50 y N= 2143 (517 Chigh)	> 50 y N= 1016 (Chigh) ≤ 50 y N= 535 (Chigh)	Postmenopausal N= 3350 Premenopausal N= 1665
- Type of CT	TC 56% A (± T) based 36%	T based 24% A (± T) based 64%	TC 50% A (± T) based 50%
- Non-adherence to rand. therapy	≈ 12%	≈ 13%	≈ 5%
- OFS in premenopause	13%	20%	16% (in ET arm) and 3% in CTX arm

Chemotherapy benefit among patients with “low risk” genomic signatures

	TAILOR-X	MINDACT	RX-PONDER
	Distant recurrence	DMFS	IDFS
> 50y or postmen Clin low risk	1,13 (0,71 – 1,74)	0,82 (0,55 – 1,24)	0,97 (0,78 – 1,22)
> 50y or postmen Clin high risk	1,07 (0,65 – 1,62)		
≤ 50y or premen Clin low risk	0,76 (0,44 – 1,41)		
≤ 50y or premen Clin high risk	0,57 (0,28 – 1,11)	0,54 (0,30 – 0,98)	0,54 (0,38 – 0,76)

0.30 1.00 2.00 4.00

CT+ET better ET better

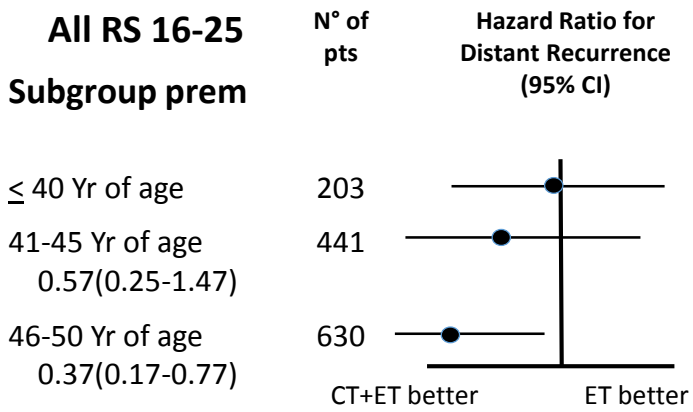
	Distant recurrence at 9y	DMFS at 8y	IDFS at 5y
> 50y or postmen Clin high risk	8.3% vs 9.3%	90.2% vs 90%	91.6% vs 91.9%
≤ 50y or premen Clin high risk	6.1% vs 12.3%	93.6% vs 88.6%	94.2% vs 89%
	chemo benefit 6.2%	chemo benefit 5%	chemo benefit 5.2%
			2.9% for dist.rec. 1.3% for OS

Could an ovarian function suppression effect explain the chemo benefit in younger women with “low risk” gene expression signatures ?

TAILOR-X

All RS 16-25

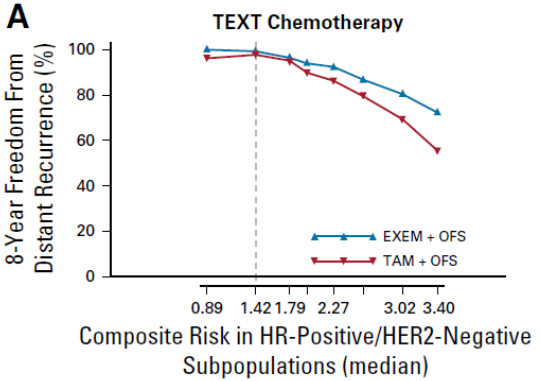
Subgroup prem



MAYBE

…

SOFT & TEXT

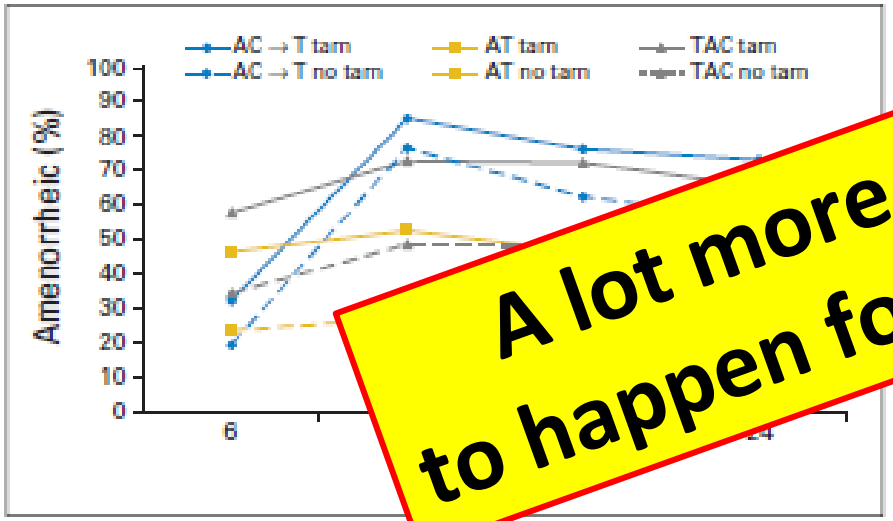


RX – PONDER

more data to be generated since menopausal status <u>after</u> chemotherapy was recorded in young women !

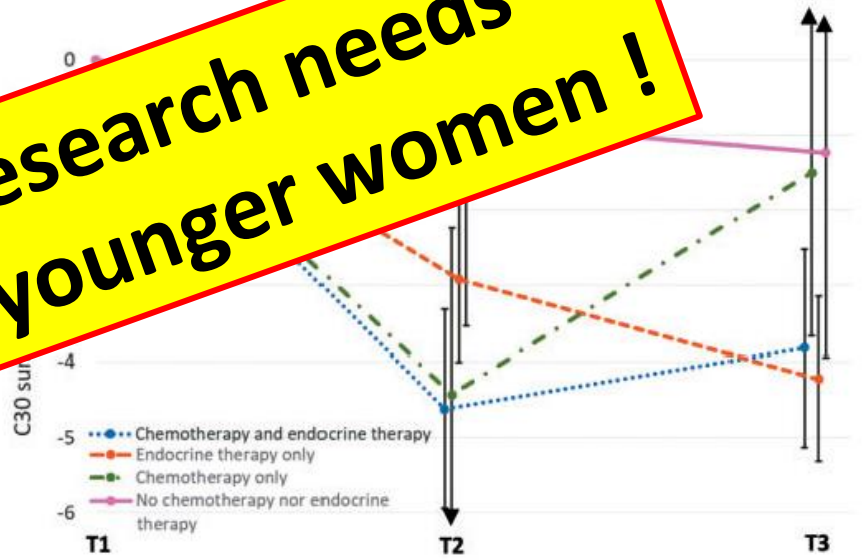
Premenopausal women Chigh/Glow

Which chemotherapy ?
Amenorrhea rates differ significantly by chemotherapy regimen



P. Ganz et al, JCO, 2011

Endocrine therapy: better QofLife ?
Different trajectories by treatment receiv… …n women)



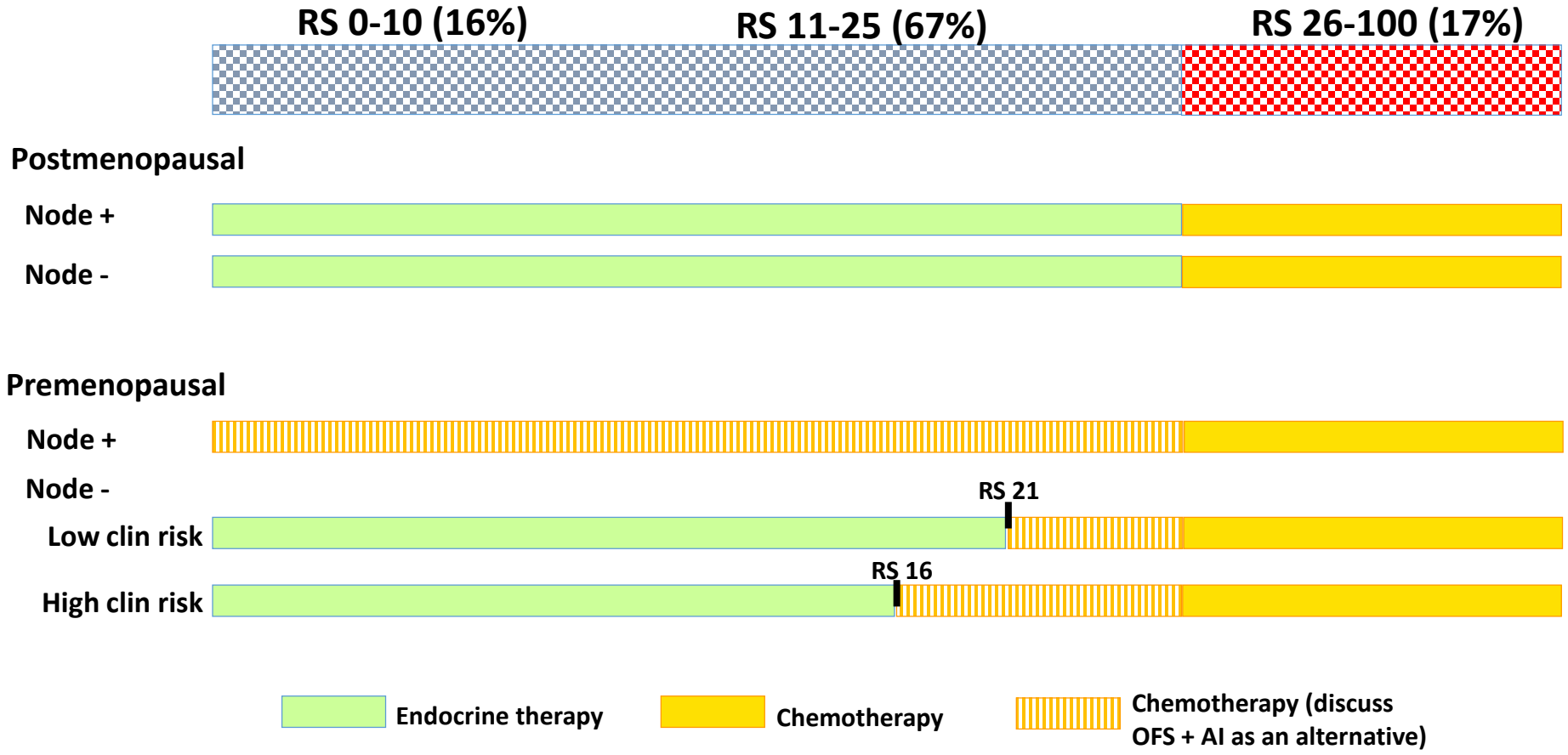
A.R. Ferreira et al, Annals of Oncol, 2019 (CANTO trial)

A lot more research needs to happen for younger women !

Message to clinicians

« What am I going to advise my patients ? »

Adjuvant chemotherapy decision making in “luminal BC” with up to 3 positive nodes
What will I do on Monday ?



Adjuvant chemotherapy decision making in “luminal BC” with up to 3 positive nodes
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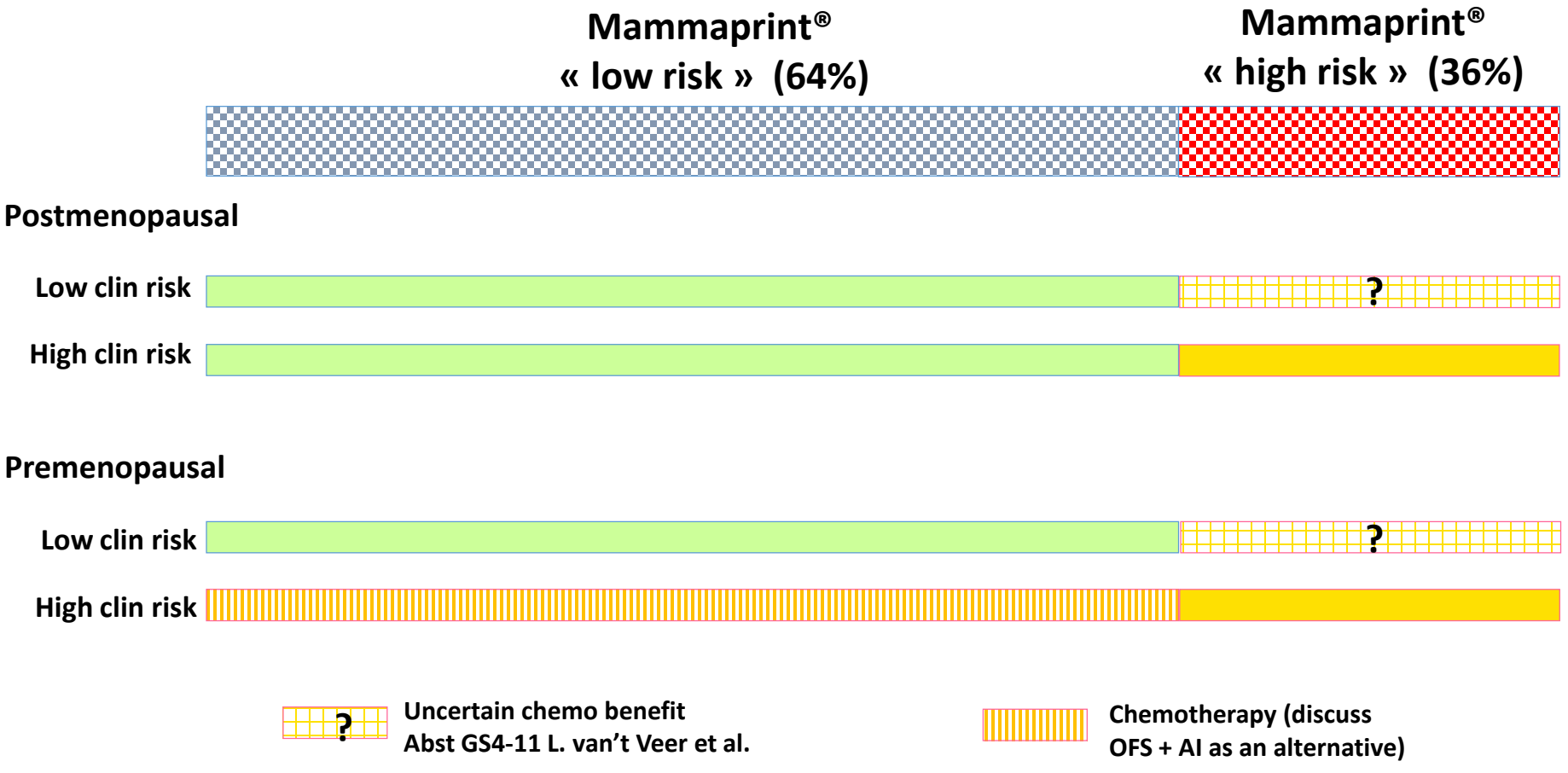


Could “Clinical” low risk/”Genomic” high risk patients benefit from chemotherapy ?

MINDACT RESULTS All Clinical Low risk

	C-Low/G-Low N=2744	C-Low/G-High N=593
Tumor size T1 (<2 cm)	2623 (96%)	528 (98%)
Grade 1	1242 (45%)	92 (16%)
Grade 2	1456 (53%)	415 (70%)
LN negative	2571 (94%)	578 (97%)
HR+/HER2-	2637 (96%)	468 (79%
HR+/HER+	96 (3%)	68
Triple negative	3 (0.1%)	

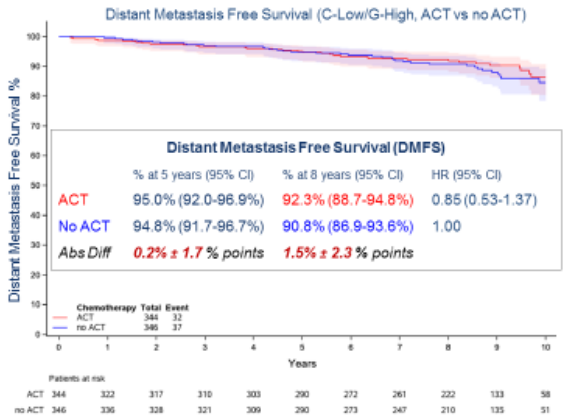
Small group … ated »
by Tri… patients

Uncertain CTX benefit

HR CT vs no CT :
0.85 (95% CI 0,53 – 1,37)

econdary MINDACT RESULTS C-Low/G-High

December 8-11, 2020



ACT vs no ACT by randomization to follow clinical or genomic status (ITT population) 1.5% improvement

Of note: Analyses ACT vs no ACT is considerably underpowered, small series (n=690)

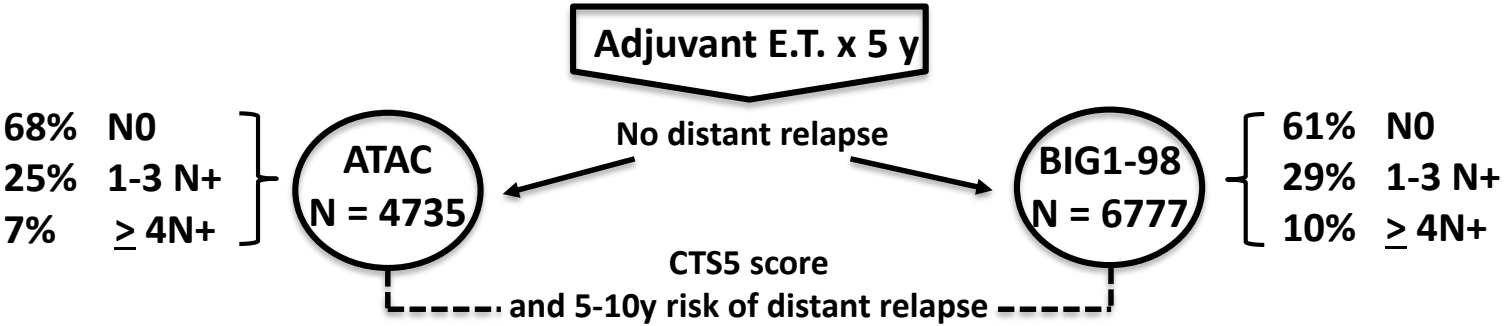
L. van’t Veer, SABCS 2020

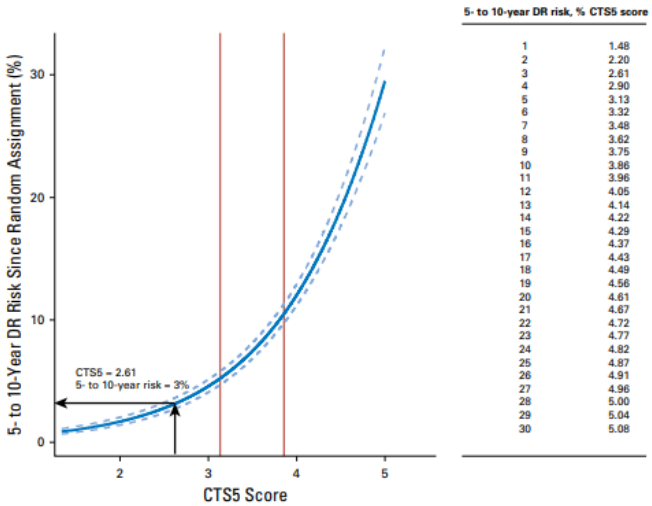
Luminal Breast Cancers

- **WHO is at very low or very high risk of recurrence after 5 y of adjuvant E.T. ?**

- **WHO will benefit from extended adjuvant endocrine therapy ?**

Luminal Breast Cancers
Prediction of late distant relapses in ATAC/BIG1-98





5- to 10-year DR risk, %	CTS5 score
1	1.48
2	2.20
3	2.61
4	2.90
5	3.13
6	3.32
7	3.48
8	3.62
9	3.75
10	3.86
11	3.96
12	4.05
13	4.14
14	4.22
15	4.29
16	4.37
17	4.43
18	4.49
19	4.56
20	4.61
21	4.67
22	4.72
23	4.77
24	4.82
25	4.87
26	4.91
27	4.96
28	5.00
29	5.04
30	5.08

60% of N- pts, 15% of pts 1-3 N+ and < 1% pts with ≥ 4 N+ have a low score and derive little benefit from extended ET

Dowsett M et al, JCO 2018

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Extending adjuvant endocrine therapy in a high risk patient does not mean that she will derive a benefit !

↓

Breast Cancer Index (BCI) and benefit from extended hormonal therapy

DC Sgroi et al, abst GS4-08
SABCS 2020

Background
Breast Cancer Index (BCI) Biomarker

- The Breast Cancer Index (BCI) is a gene expression-based signature comprised of two functional biomarker panels:
  - *HOXB13* and *IL17BR* (H/I) – 2 gene ratio measuring estrogen signaling
  - Molecular Grade Index (MGI) – 5 genes measuring tumor proliferative status

- The BCI test reports both a prognostic and a predictive result:
  - The prognostic component consists of the integration of MGI and H/I into a score that quantifies the risk of both late (5–10 y) and overall (0–10 y) distant recurrence[1,2,4]

  - The predictive component of BCI **[BCI (H/I)]** has been shown to predict endocrine benefit across multiple different endocrine therapeutic scenarios including extended endocrine therapy.[1-3]

1. Sgroi DC et al. *J Natl Cancer Inst* 2013;105:1036–42. **2.** Zhang Y et al. *Clin Cancer Res* 2013;19:4196–205. **3.** Bartlett JMS et al. *Ann Oncol* 2019;30:1776–83. **4.** Sgroi DC et al. *Lancet Oncol* 2013;14(11):1067-76.

BCI reaches level I_B for its utility in predicting benefit from extended ET

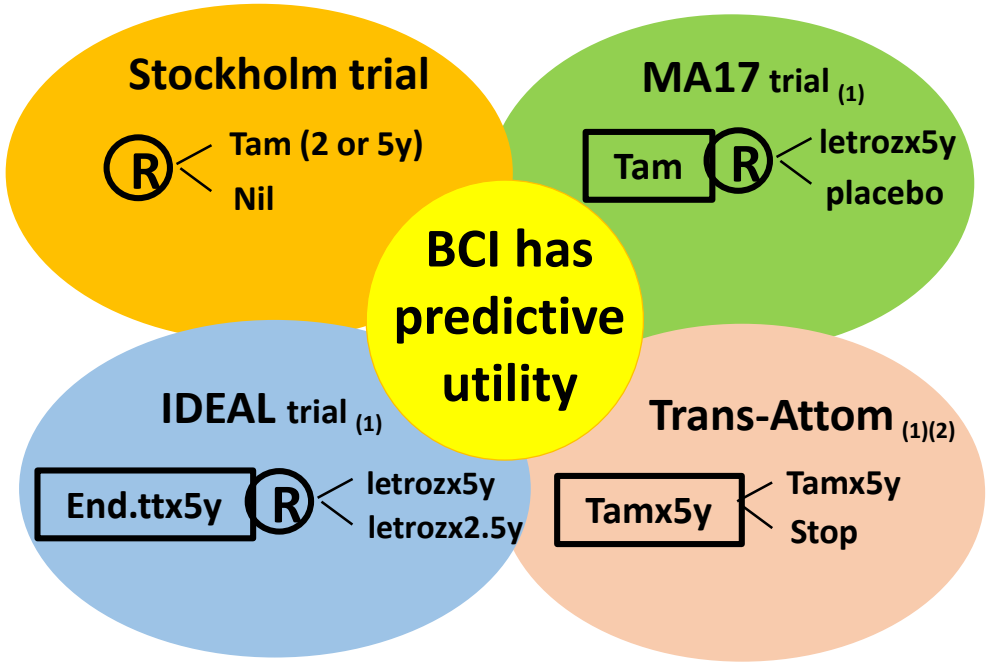
Tumor marker studies
Levels of evidence

Level I_A Prospective randomized controlled trial designed to address the tumor marker utility

Level I_B Prospective trial not designed to address tumor marker but design accommodates tumor marker utility

⚠ For a predictive marker the trial must be a R̄ controlled trial

\+ ≥ 1 validation study



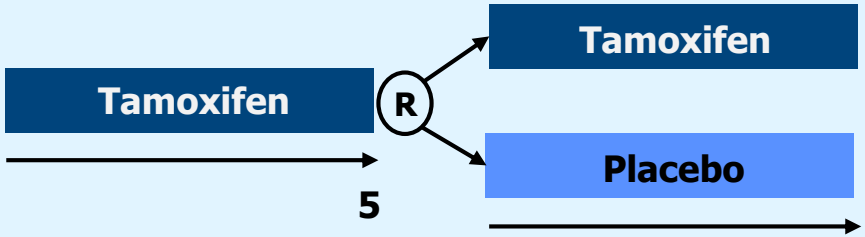
(1) Statistical significant interaction between extended endocrine therapy benefit and BCI (N=1946 biosamples)

(2) SABCS 2020: updated data showing lack of predictive value of ER, PgR, AR, Ki67 and confirming BCI utility

Background

Adjuvant Tamoxifen – To Offer More? (**aTTom**) Trial: Extended Endocrine Therapy

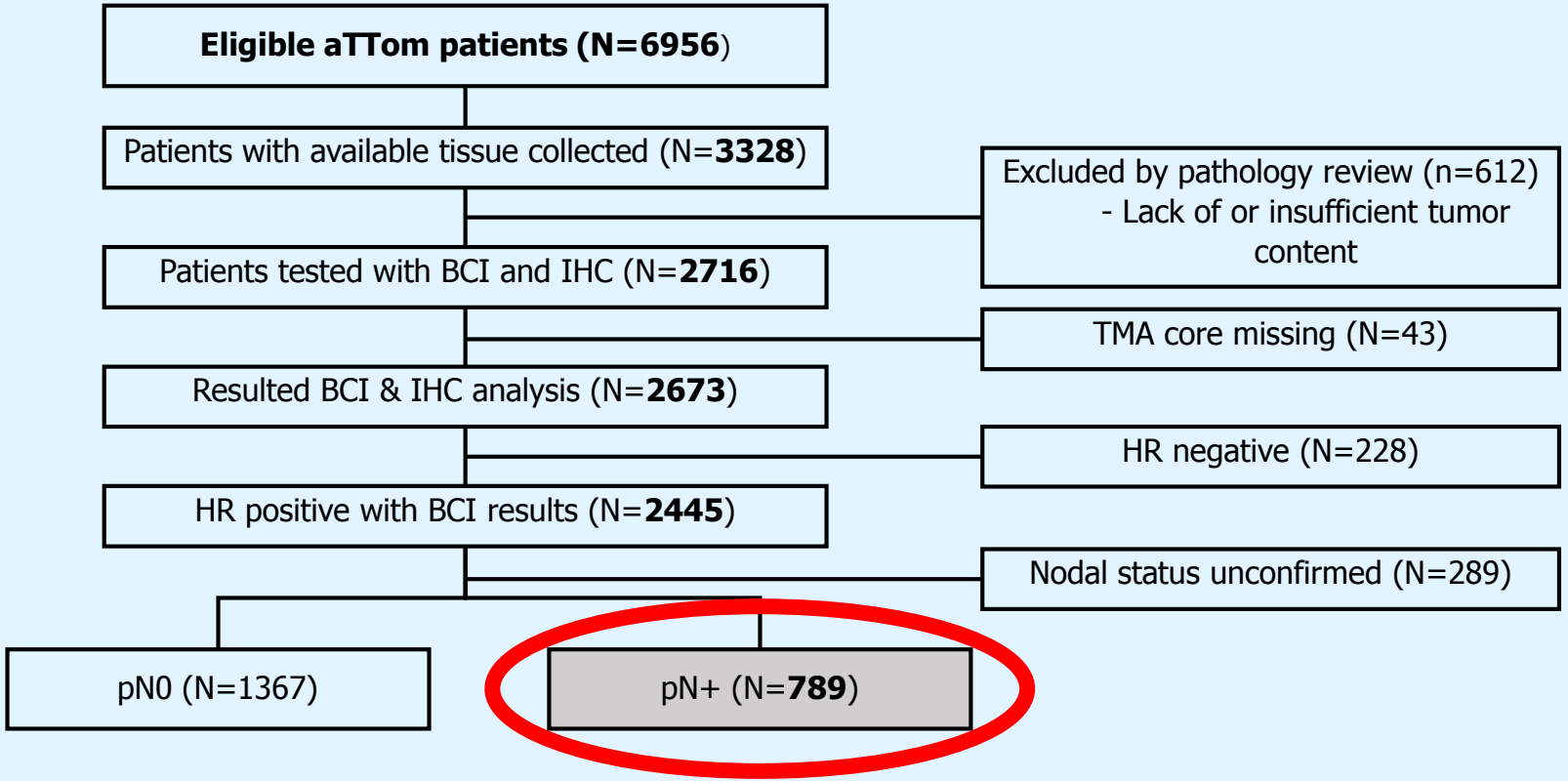
- Prospective phase III trial of 6956 early stage patients who completed at least 4 years of tamoxifen randomized to either stop or continue tamoxifen for an additional 5 years
- Data available to 12.6 years median follow-up (2017)
- **Demonstrated benefit from 10 vs 5 years of tamoxifen with a HR HR: 0.86, 95% CI 0.77-0.96, (p=0.006) and a median follow-up of 8.9 years**



(78% ≥ 55 years old, 50% T1, 38% T2, 31% node-positive)

Gray RG et al. *J Clin Oncol* 2013;31:5–5.

Patient Case Flow



Background

BCI (H/I) Predicts Benefits from Extended Tamoxifen in Trans-aTTom

	Groups	No. Patients (%)	Absolute Be	
Primary Endpoint	Unselected	789 (100%)		
RFI	BCI (H/I)-High	404 (51		.75)
	BCI (H/I)-Low			.11 (0.76-1.64)
Secondary Endpoints	Unselec			0.87 (0.68-1.12)
DFI			10.4%	**0.43 (0.20-0.92)**
			-0.8%	1.08 (0.74-1.57)
		(100%)	4.1%	0.90 (0.70-1.15)
		404 (51%)	8.8%	**0.48 (0.24-0.99)**
	(H/I)-Low	385 (49%)	-0.4%	1.07 (0.74-1.55)

SABCS 2020 : traditional biomarkers (ER, PgR, Ki67, androg receptor) are not able to predict benefit from extended TAM

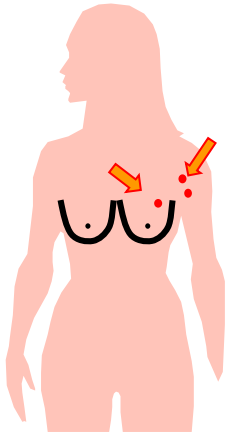
Re erval (RFI): time from randomization to first local, regional, or distant recurrence
Dis nterval (DFI): time from randomization to first local, regional, distant recurrence or new breast primary
Dise ree Survival (DFS): time from randomization to first local, regional, distant recurrence, new breast primary or breast cancer death

Reference for RFI: Bartlett JMS et al. *SABCS* 2019; DFI and DFS: manuscript in preparation

Using BCI to assist with extended ET decision

Sequencing tested in trials

Tam x 5y → AI x 5y



- 52 year old, postmenopausal
- T size 25 mm
- 2 node +
- Grade 2
- Side effects + (+)

CTS_5 score 4,17

Distant relapse risk 13,4% at 10y

Encourage to switch if BCI high

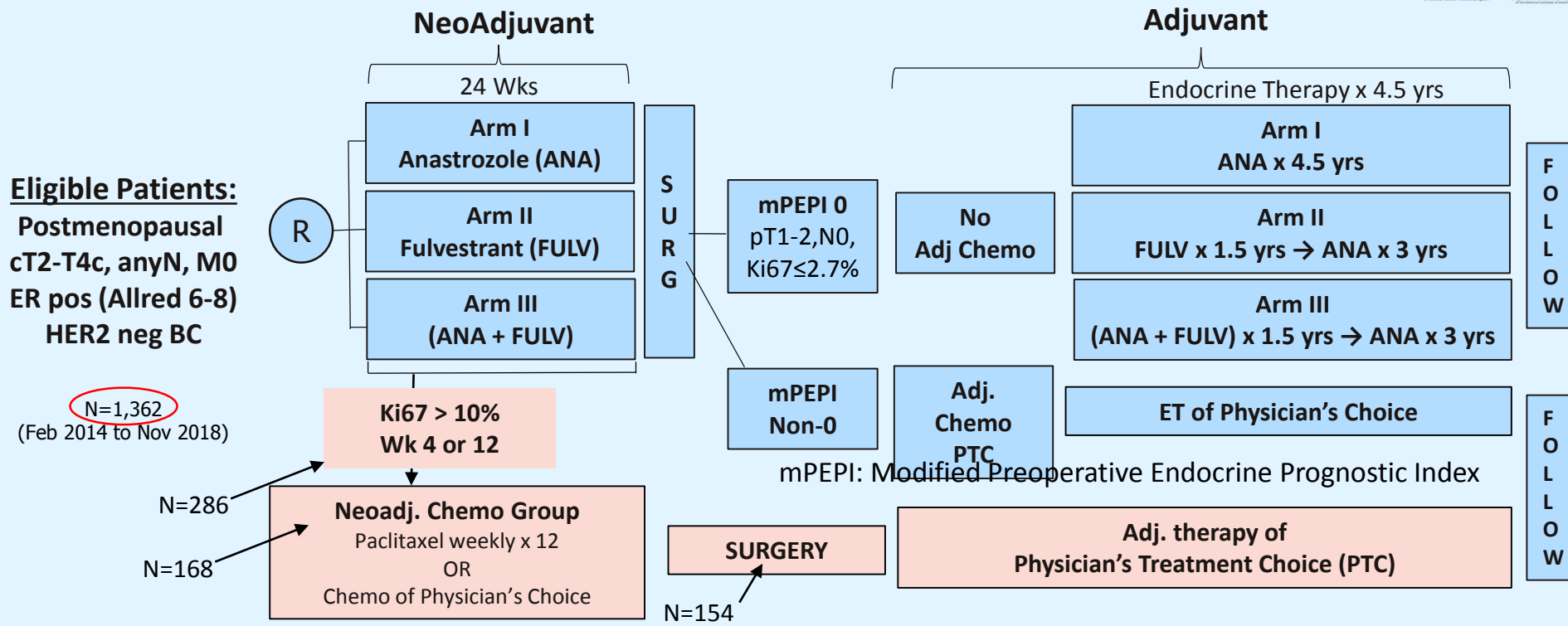
Preoperative endocrine treatment response guided therapy

- **ALTERNATE (1)**
- **ADAPT HR+/HER2- (2)**

Elegant trials… but clinical utility NOT demonstrated

(1) Abst GS4-05, SABCS 2020
(2) Abst GS4-04, SABCS 2020

ALTERNATE



The Primary Endpoint: The Endocrine Sensitive Disease (ESD: pCR + mPEPI 0) rate in FULV or FULV + ANA arm was not significantly higher than that of the ANA arm (Ma, C et al ASCO 2020).

Objective of this analysis

To determine the rate of pCR and residual cancer burden (RCB) following NCT for patients triaged to NCT due to Ki67 >10% at Wk 4 or 12

Results

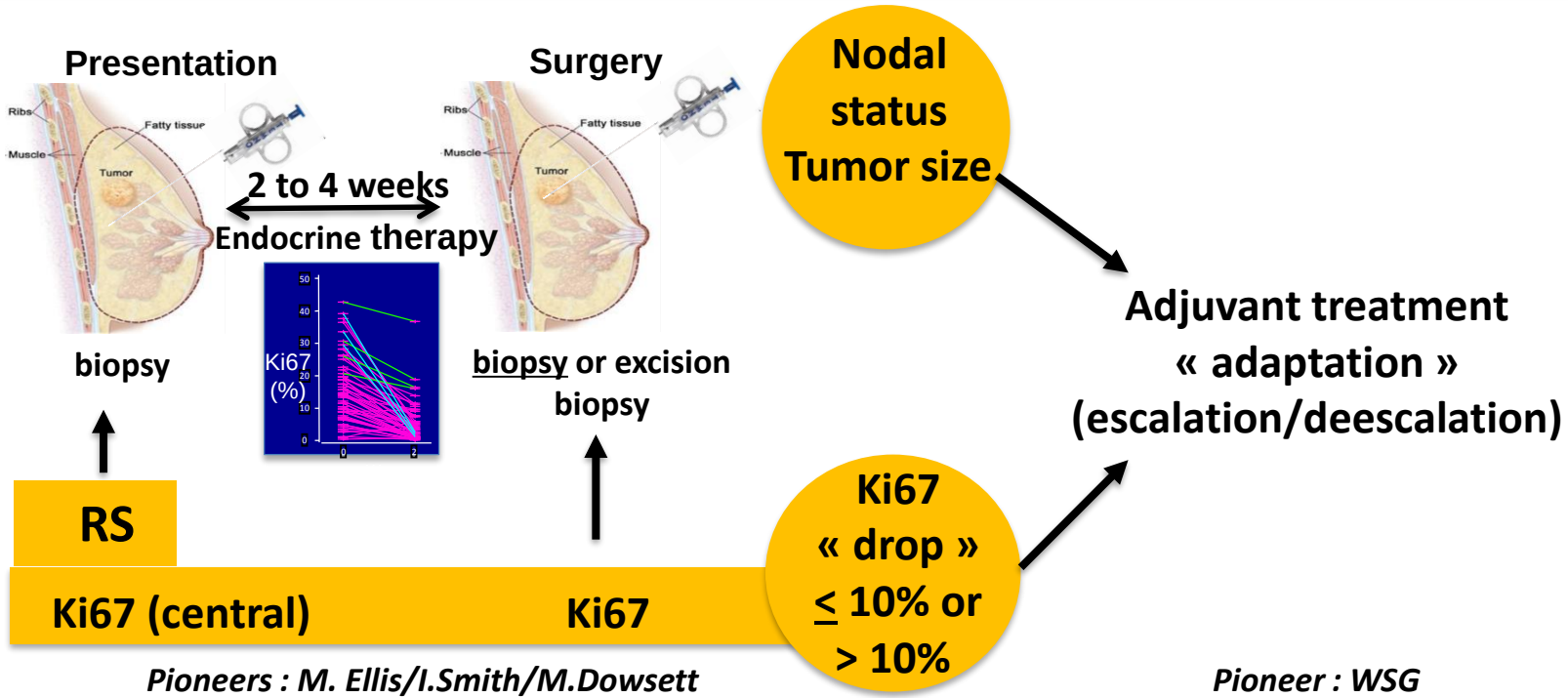
pCR rate	4.8%	Chemotherapy is NOT an attractive option !
RCB II and III	74% !!	

Question

What is the underlying biology of these high risk BCs ?

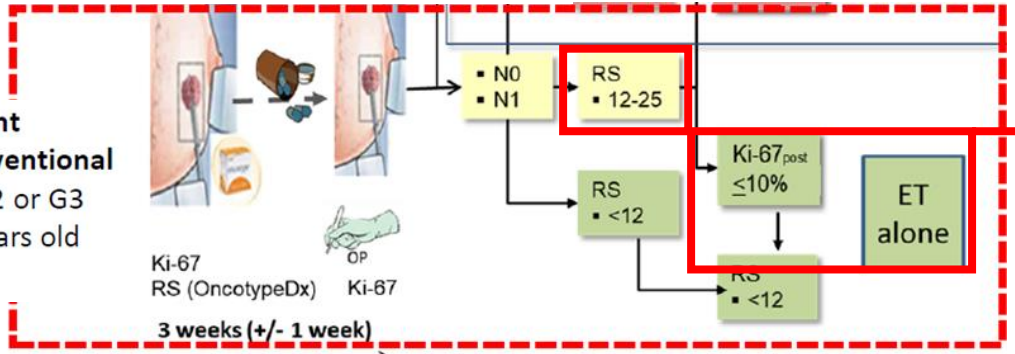
Philosophy of the "ADAPT" trials by the West German Study Group

Integration of baseline and dynamic biomarkers, measured in a short window of drug exposure, with tumor burden in order to "adapt" adjuvant systemic therapy



ADAPT HR+/HER2-
Study design

- **Candidates for adjuvant chemotherapy by conventional prognostic criteria:** cT2 or G3 or Ki67≥15% or <35 years old or cN+



- **Trial hypothesis :**
  Non inferior IDFS compared to RS O-11
- **Pt characteristics :**
  - **premenopausal 26%**
  - **pN1 27%**
  - **grade 3 21%**

Clinical high risk

Genomic low/ Intermediate risk

Sensitivity to Endocrine therapy (ET)

Chemotherapy sparing strategy

N. Harbeck et al, SABCS 2020

ADAPT HR+/HER2- chemotherapy de-escalation (N=2290)
5 year results

RS 0-11 group N=868 women		RS 12-25/ET responders N=1422 women
93.9% (95% CI 91.8-95.4)	5y IDFS*	92.6% (95% CI 90.8-94)
96.3%	5y dDFS	95.6%
98%	5y OS	97.3%

… and no difference according to age (≤ 50 vs > 50), or to nodal status (N0 or 1-3 N+)

but poor outcome for 3+ Nodes (dDFS 76% only)

* Non inferiority margin respected (≤ 3.3%) : difference is 1.3% with a 95% CI [-3.3% + 0.6%]

N. Harbeck et al, SABCS 2020

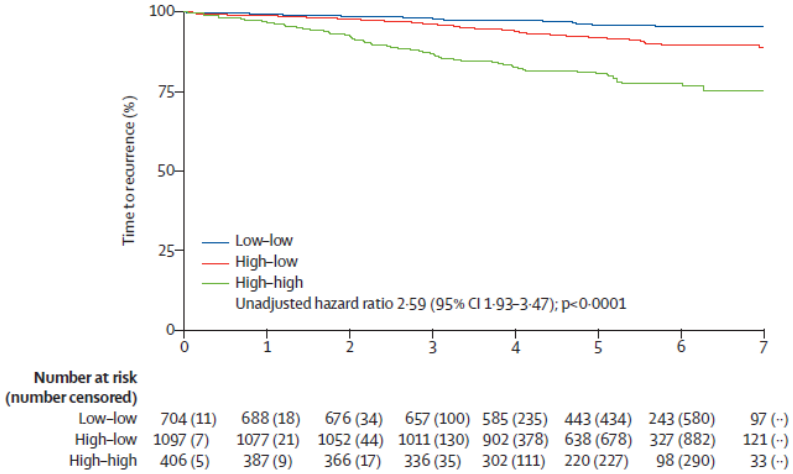
ADAPT HR+/HER2- chemotherapy de-escalation Discussion

- **My worries**
- **My reluctance to use ADAPT HR+/HER2- on Monday morning**

Dynamic proliferation response to preoperative endocrine therapy is linked to long term outcome

POETIC (1)

Short term presurgical AI

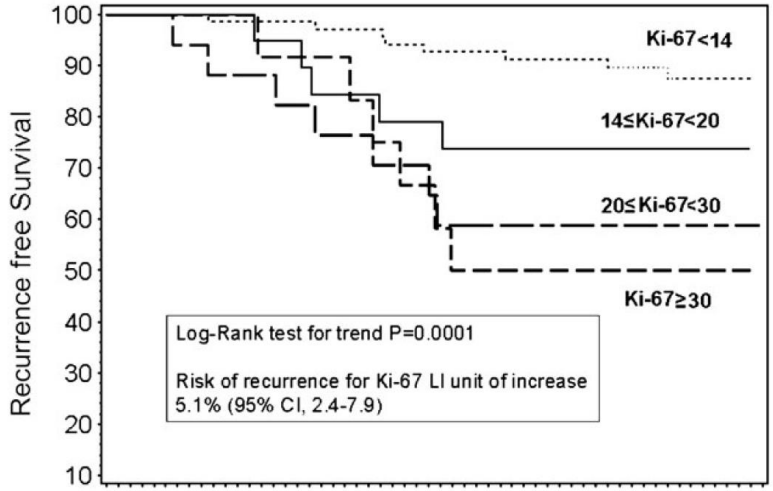


N = 2207 postmenopausal women

SOLID DATA for aromatase inhibitor

DeCensi (2)

Short term presurgical TAM



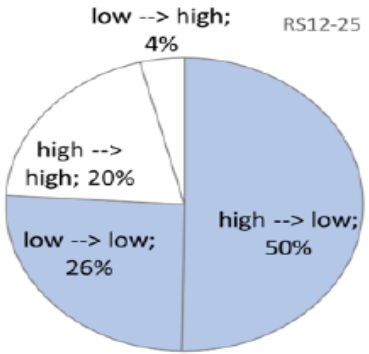
N = 86 postmen + 30 premen women

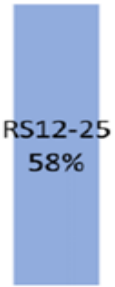
VERY WEAK DATA for tamoxifen

Particularly in premenopausal women

(1) Smith I et al, The Lancet Oncol, 2020 – (2) DeCensi et al, Annals of Oncol, 2011

Using ADAPT HR+/HER2- on Monday morning ?





(1)

RS 12-25, up to 3N+
and
Adding the Ki67 centrally measured dynamic response
(3)

- **24% women will not show a Ki67 drop and might no longer be candidates for ET alone !**
- **Logistics and financial hurdles**

RS 12-25, up to 3N+
(2)

- **Postmenopausal women ET only (TAILOR-X/RX-PONDER)**
- **Premenopausal women RS ≥ 16 if N- and RS ≥ 0 if 1-3 N+ CT brings a benefit ! (TAILOR-X/RX-PONDER)**

(1) Nitz et al, Ther Adv Med Oncol, 2020 (2) Sparano, NEJM, 2019 – Kalinsky, SABCS 2020 (3) Harbeck, SABCS 2020

SAN ANTONIO Breast Cancer Conference 2020

Further results from the incorporation of CDK4-6 inhibitors into the adjuvant treatment strategy for high risk luminal BC

- **First results of Penelope B** (1)
- **Updated results of Monarch E** (2)

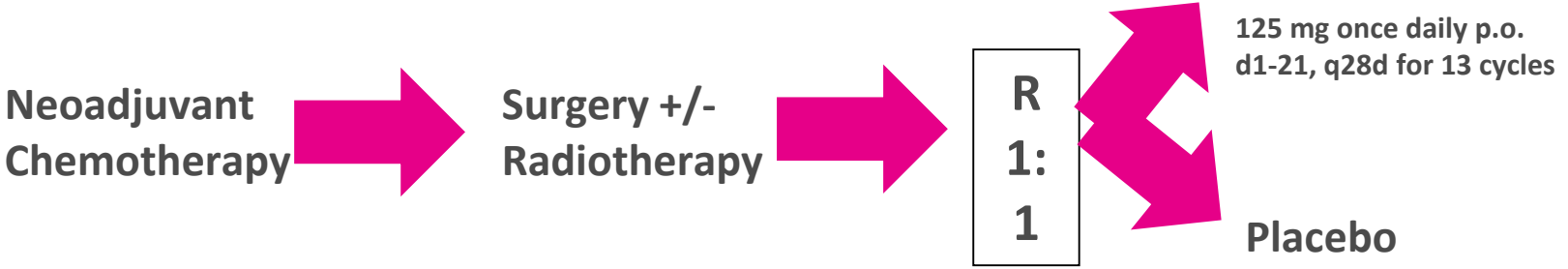
(1) Loibl S et al, abst GS1-02 *(2) O' Shaughnessy JA, abst GS1-01*

Study Design

N=1250
- HR+/HER2- breast cancer
- no pCR after NACT
- CPS-EG score ≥3 or ≥2 with ypN+

Primary Endpoint: iDFS

Stratification factors
- Nodal status: ypN 0-1 vs ypN2-3
- Age: ≤50 vs >50 yrs
- Ki-67: >15% vs ≤ 15%
- Region: Asian vs non Asian
- CPS-EG Score: ≥3 vs 2 and ypN+



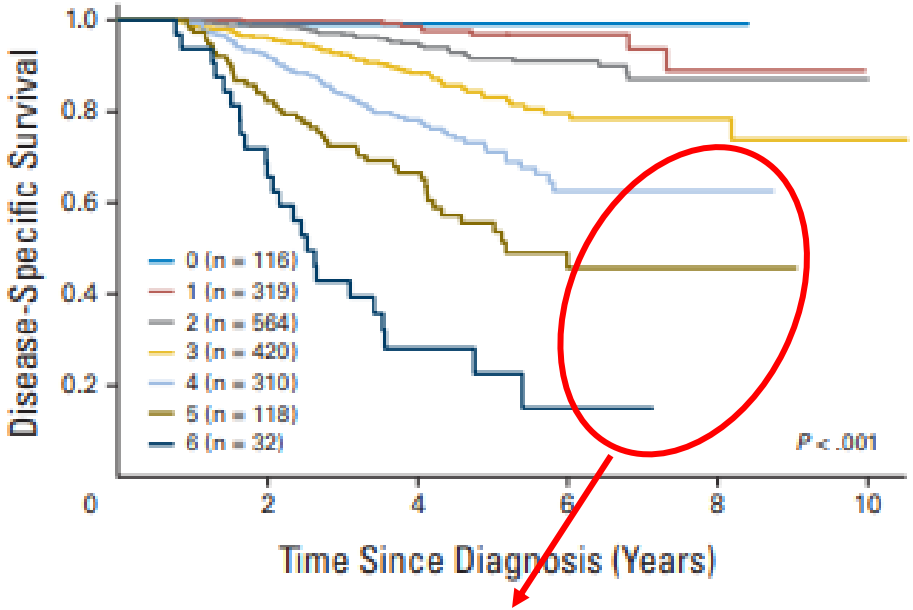
All patients will receive concomitantly endocrine therapy according to local standards

Penelope-B: ClinicalTrials.gov NCT01864746

A novel staging system (CPS-EG) predicts disease specific survival after neoadjuvant chemotherapy

Stage	Points
Clinical stage	
I	0
IIA	0
IIB	1
IIIA	1
IIIB	2
IIIC	2
Pathologic stage	
0	0
I	0
IIA	1
IIB	1
IIIA	1
IIIB	1
IIIC	2
Tumor marker	
ER negative	1
Nuclear grade 3	1

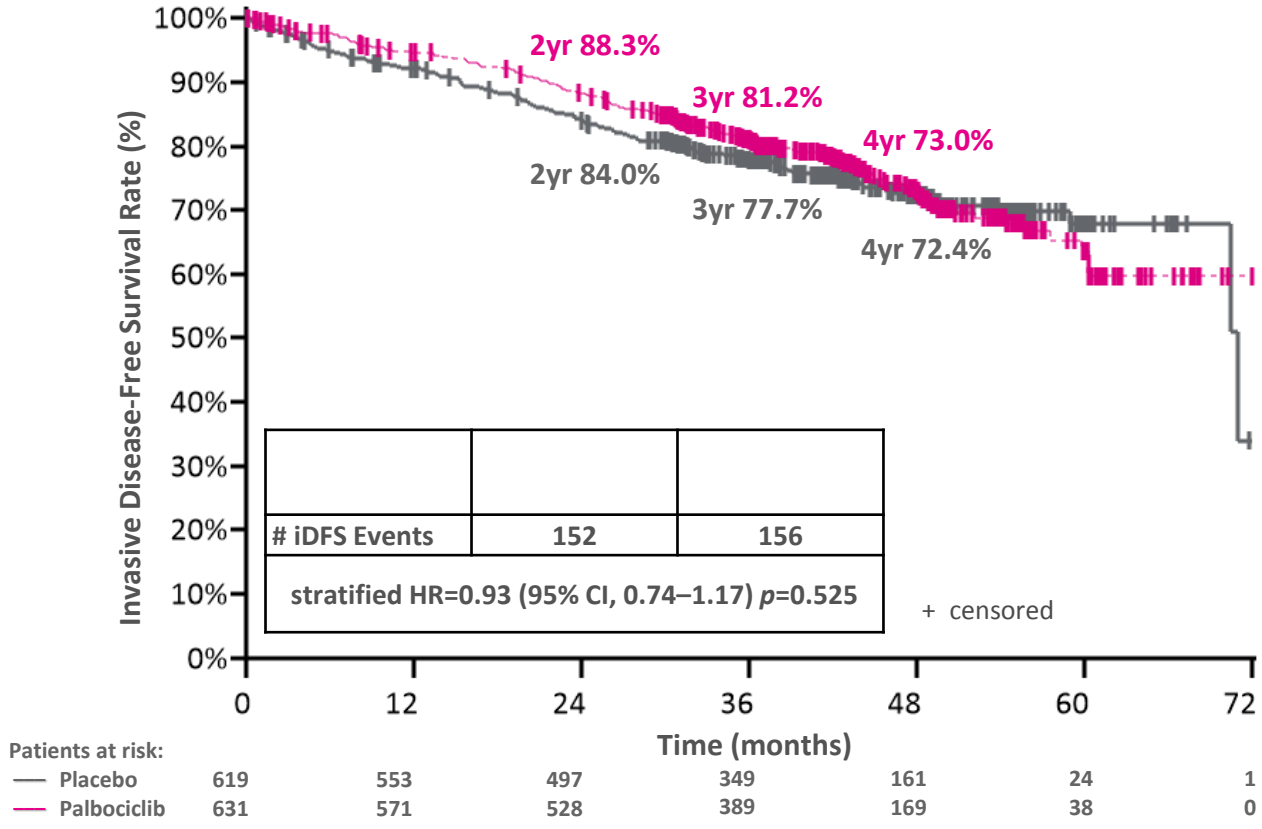
Abbreviations: CPS + EG, clinical-pathologic staging system incorporating ER-negative disease and nuclear grade 3 tumor pathology; ER, estrogen receptor.



Selected in Penelope B

E. Mittendorf et al, JCO 2011

Results Primary Endpoint iDFS



Median Follow-Up
42.8 Months

* Weighted log-rank test based on the CHW method, taking into account the adaptive sample size re-estimation and group-sequential nature of the design

CDK4-6 inhibitors in early HR+/HER2- BC

	Penelope B	Pallas	Monarch-E
	N = 1250 Median age 49y Very high risk postneoadj CTX CPS EG score ≥ 3 60% pN2/pN3 50% pN+ 95%	N = 5600 Median age 52y High risk ≥ 4N+ 49%	N = 5637 Median age 51y Very high risk cohort 1 ≥ 4N+ → 60% 1-3N+ & gr 3 or ≥ T3 cohort 2 1-3 N+ and Ki67 ≥ 20%
CDK4-6 inhibitor therapy	Palbo x 1 year intermittent dosing	Palbo x 2 years intermittent dosing	Abema x 2 years continuous dosing
Endocrine therapy	AI 50% Tam 50% LHRH≈10%	AI 67% Tam 32% LHRH≈20%	AI 69% Tam 31% LHRH≈21%
Chemotherapy exposure	100%	83%	95%

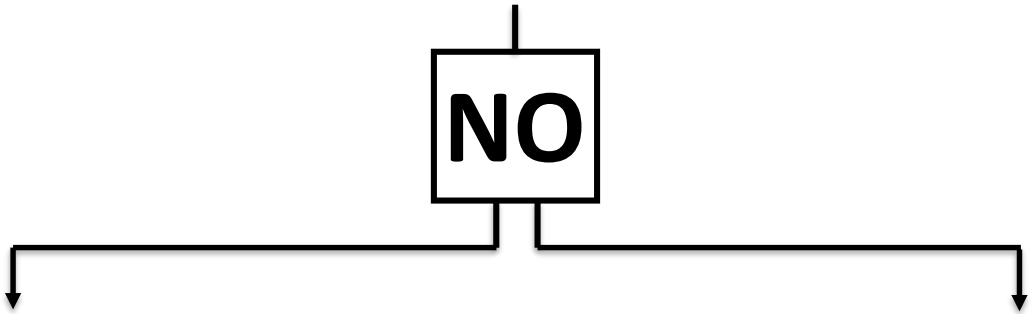
CDK4-6 inhibitors in early HR+/HER2- BC

	Penelope B	Pallas	Monarch-E
Primary endpoint	IDFS	IDFS	IDFS
Secondary endpoint	DRFS	DRFS	DRFS
Analysis	« final » N=308 events	2nd interim N=351 events	2nd interim N=323 events / SABCS N=390 events
Median F-up	43 months	24 months	15.5 → 19.1 months
Results IDFS	HR 0.93 (95% CI 0.74-1.17) p 0.52	HR 0.93 (0.76-1.15)	HR 0.74 → HR 0.71 (0.58-0.87) p 0.0009
2y IDFS 3 y IDFS	88.3% vs 84% 81.2% vs 77.7%	88.2% vs 88.5%	92.3% vs 89.3% NA
DRFS	NA	- 0.3% benefit HR 1.00 (0.79-1.27)	3% absolute benefit HR 0.68 (0.55-0.85)
Remarks	⚠ there was a 4% benefit at 24 m !		Possible greater benefit in patients with Ki67 ≥ 20%

CDK4-6 inhibitors in early HR+/HER2- BC

	Penelope B	Pallas	Monarch-E
Still on therapy	0%	26%	58% (!)
Premature treatment discontinuation	20%	42%	28%
Side effect profile			
• Neutropenia gr 3-4	70%	61%	44%
• Diarrhea gr 3-4	N.A.	0.7%	7.6%
• Fatigue	N.A.	40%	38%
• Arthralgia	N.A.	34%	20%
• Hot flushes	N.A.	24%	14%
• VTE	?	?	2,3%

Are we ready to treat our « high risk » HR+/HER2- early BC patients with Abemaciclib ?



Demonstration of « robust » efficacy awaits a longer follow-up
… hoping that we are not just treating OCCULT METASTATIC DISEASE

Full demonstration of tolerability and safety awaits all patients to be off protocol therapy

SABCS 2020 Early BC

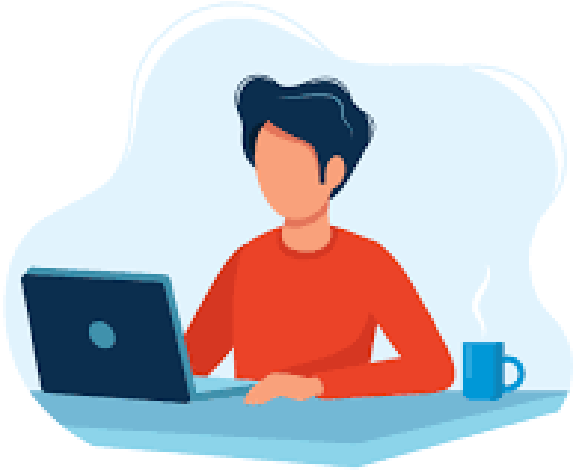
Most important take-home message

↓

Luminal BC, high clinical risk (up to 2-3 N+) and low genomic risk

=

No adjuvant CT for postmenopausal women



We missed the atmosfeer…

… but we learned a lot !

THANK YOU