2023年8月10日NRG Oncology Japan meeting

NRGで実施中の乳腺関係の試験

兵庫県立がんセンター
腫瘍内科
松本光史

NRG Oncology-Japan

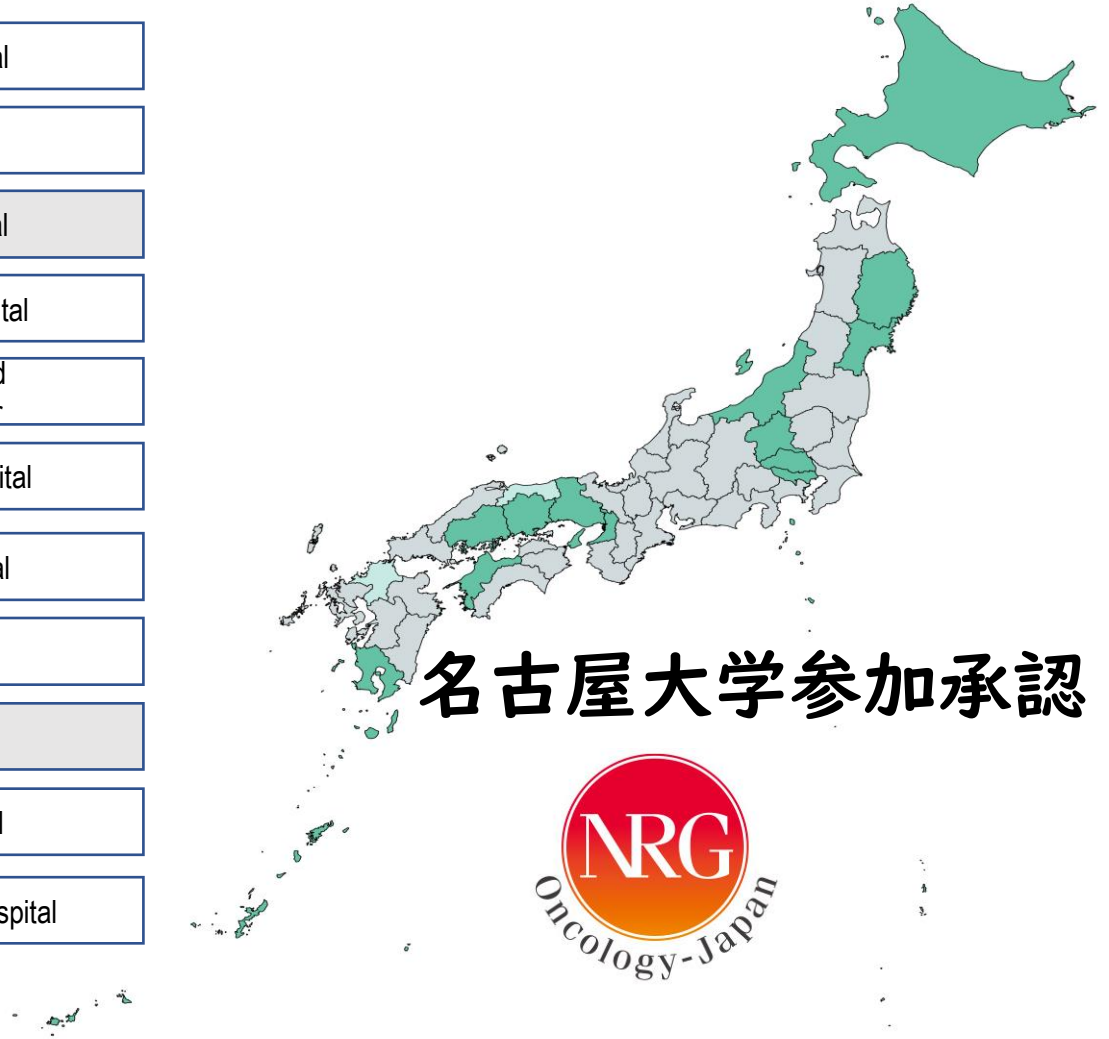
as of Dec 2022

Main Member Institution 1

Affiliate Member Institution 18

Followup Only Institution 3

- Kindai University Hospital
- Hyogo Cancer Center
- Tottori University Hospital
- Okayama University Hospital
- Kure Medical Center and Chugoku Cancer Center
- Hiroshima University Hospital
- Ehime University Hospital
- Shikoku Cancer Center
- Kyushu Cancer Center
- Kagoshima City Hospital
- University of The Ryukus Hospital



名古屋大学参加承認！

NRG Oncology-Japan

- Hokkaido University Hospital
- Tohoku University Hospital
- Iwate Medical University Hospital
- Niigata University Medical & Dental Hospital
- Gunma University Hospital
- Saitama Medical University International Medical Center
- Keio University Hospital
- National Cancer Center Hospital
- Cancer Institute Hospital
- Kyorin University Hospital
- The Jikei University Hospital

International member Working groupにて

NRGで実施中の乳腺関係の試験

1. BR007 (DEBRA); 50yo+ pT1 & low RSでBp後RT省略 P3
2. BR008 (HERO); HER2 low risk RT省略 P3
3. BR009 (OFSET Chemo); 閉経前low RSでOFS+AI時ケモ省略P3
4. 検討中コンセプト
   - ABCD
   - CRISP
   - Optimize RT
5. 提案中コンセプト
   - Nipple neurotization
   - Post CDK4/6i T-Dxd
   - NSABP B-64

Breast Cancer Workshop Agenda

Date:	July 22, 2023
Start and End Time:	9:45 am – 11:45 am
Chair:	Eleftherios Mamounas, MD
Co-Chairs:	Julia White, MD; Charles Geyer, MD; Mothaffar Rimawi, MD

Learning Objectives
Following this activity, participants will be better able to:

1. Identify and describe the design and status of new breast cancer clinical trials.
2. Identify and describe the status of ongoing breast cancer clinical trials.
3. Identify and describe new forms of radiotherapy delivery and their use in breast cancer trials.
4. Identify and describe systemic therapies, including chemotherapeutic drugs, hormonal strategies, biologic agents, new classes of targeted therapies, and immunotherapy that may be used in breast cancer treatment clinical trials.

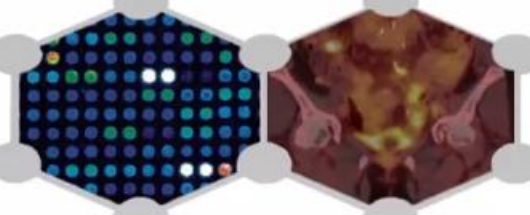
WORKSHOP AGENDA

9:45 – 10:15	**Report from the Breast Working Group Meeting**	Eleftherios Mamounas, MD Julia White, MD
10:15 – 10:30	**ctDNA Breast Cancer Platform Trial in Early Breast Cancer**	Emilia Diego, MD Mark Basik, MD
10:30 – 10:45	**BR007:** A Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER2-Negative, Breast Cancer with a Low Oncotype Recurrence Score	Julia White, MD
10:45 – 11:00	**BR008:** A Phase III Randomized Trial Evaluating Omission of Breast Radiotherapy for Low-Risk HER2-Positive Breast Cancer	Lior Braunstein, MD Melissa Mitchell, MD, PHD
11:00– 11:15	**BR009:** Chemotherapy plus ET vs. Ovarian Ablation plus ET in Early-Stage Hormone-Positive Premenopausal Women with Oncotype ≤ 25 (OFSET CHEMO)	Shannon Puhalla, MD Eleftherios Mamounas, M
11:15 – 11:30	**COMPASS HER2-RD:** Postneoadjuvant T-DM-1 + Tucatinib or Placebo in HER2-Positive Patients with Residual Disease Following Preoperative Therapy	Virginia Borges, MD
11:30 - 11:45	***DESTINY* BREAST-05 (NSABP B-60):** DS-8201a vs. T-DM-1 for High-Risk Patients with HER2-Positive Residual Invasive Cancer Following Preoperative Therapy	Jame Abraham, MD

Accrual to Breast Protocols
(AS OF 7/20/22)

2

Protocol	Open Date	Total Accrual	Target Accrual	Projected Closure
BR007	6-21	515	1714	TBD
BR008 (HERO)	2-23	1	1300	TBD
COMPASS RD	1-21	447	1031	4Q2024
DESTINY 05 (B-60)	12-20	1249	1600	4Q2023
IidERA (B-61)	7-21	3913	4100	3Q2023
CAMBRIA (B-62)	5-23	11	4300	TBD
EAY191-N2:	6/23	0	95	TBD



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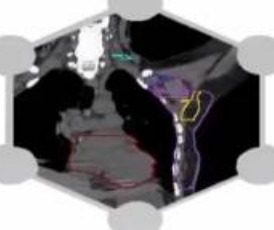
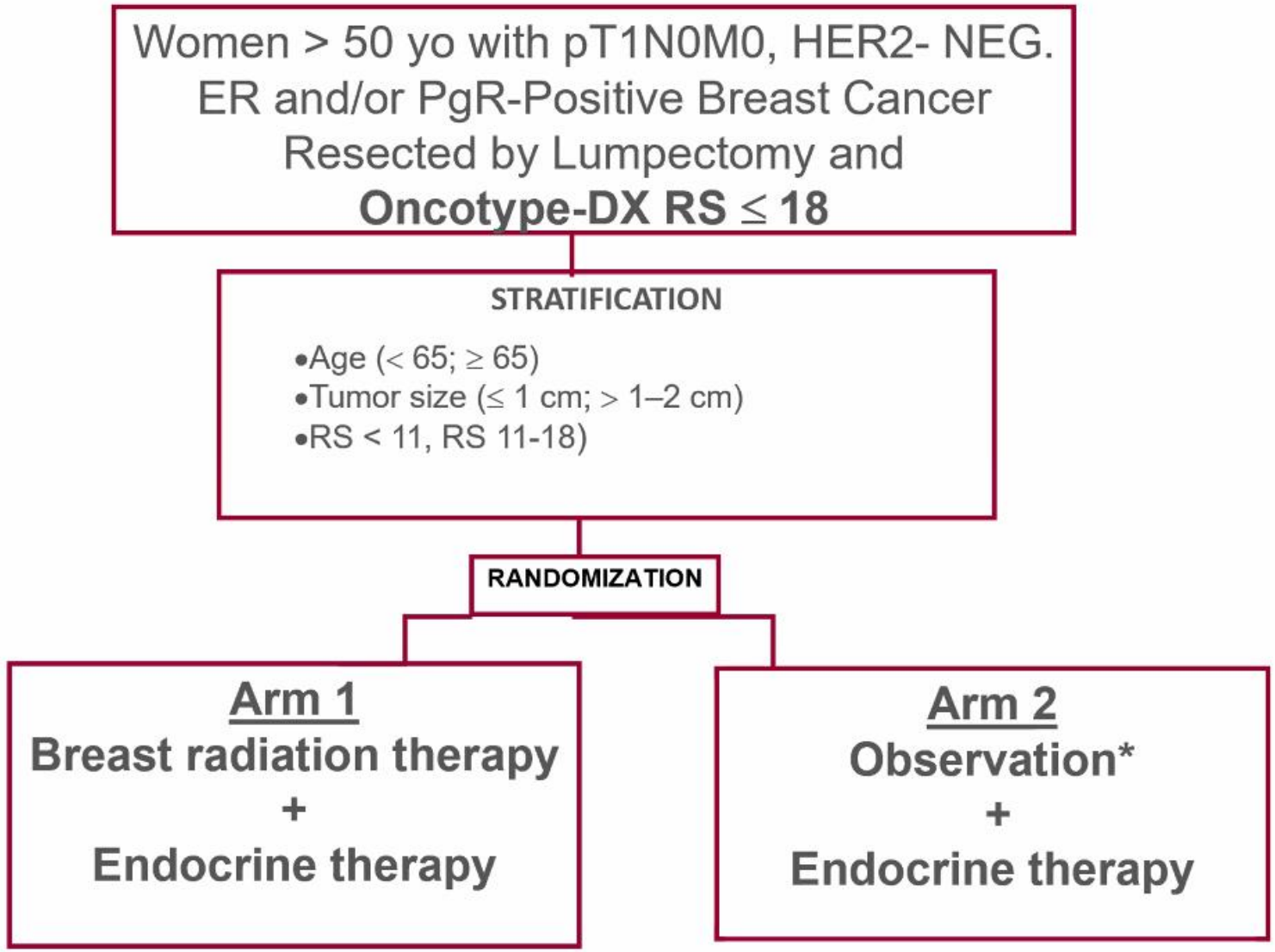
Advancing Research. Improving Lives.™



BR007

Phase III: Evaluating **De**-escalation of **Br**east **Ra**diation (**DEBRA**) for Conservative Treatment of Stage 1, HR+, HER2-, RS ≤ 18 Breast Cancer

BR007 Schema



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BQ1．StageⅠ—Ⅱ乳癌に対する乳房温存手術後の放射線療法として全乳房照射は勧められるか？

ステートメント

・全乳房照射を行うことが標準治療である。

解　説

乳房温存手術後の乳房照射の有用性は，これまでのいくつかのランダム化比較試験とそれらを解析したEBCTCGによるメタアナリシスによって証明された[1]。それぞれのランダム化比較試験で対象症例，治療法などが多少異なるが，多くは4 cm以下の腫瘍に対して腫瘍摘出術を行い，放射線療法（50 Gy前後の全乳房照射と一部は10 Gy程度の追加照射）の有無でランダム化割付けを行っている。このメタアナリシスでは，乳房温存手術後に放射線療法を加えることで10年での乳癌再発の絶対リスクが15.7%減少（35.0%→19.3%，2p<0.00001）するとしている。

一方，早期乳癌患者のうち，温存乳房内再発リスクが低いホルモン受容体陽性の高齢患者については，放射線療法が省略できるのではないかとの検討も行われてきた。70歳以上，かつエストロゲン受容体陽性の患者に対してタモキシフェンのみとタモキシフェン＋放射線療法を比較したランダム化比較試験では，10年全生存率には有意差がなかったが（66% vs 67%），10年の局所・領域リンパ節無再発率はそれぞれ90%，98%で有意差が認められた（p<0.001）[2]。65歳以上の低リスク（ホルモン受容体陽性，腋窩リンパ節転移なし，腫瘍径3 cm以下，断端陰性，「G3かつ脈管侵襲あり」ではない，などの条件で判定）の乳癌患者に対するランダム化比較試験でも，放射線療法により中央値5年の経過観察で温存乳房内再発はわずかに減少（1.3% vs 4.1%，p＝0.0002）したが，生存率に差はみられなかった[3]。このよ

一方，早期乳癌患者のうち，温存乳房内再発リスクが低いホルモン受容体陽性の高齢患者については，放射線療法が省略できるのではないかとの検討も行われてきた。70歳以上，かつエストロゲン受容体陽性の患者に対してタモキシフェンのみとタモキシフェン＋放射線療法を比較したランダム化比較試験では，10年全生存率には有意差がなかったが（66% vs 67%），10年の局所・領域リンパ節無再発率はそれぞれ90%，98%で有意差が認められた（p<0.001）[2]。65歳以上の低リスク（ホルモン受容体陽性，腋窩リンパ節転移なし，腫瘍径3 cm以下，断端陰性，「G3かつ脈管侵襲あり」ではない，などの条件で判定）の乳癌患者に対するランダム化比較試験でも，放射線療法により中央値5年の経過観察で温存乳房内再発はわずかに減少（1.3% vs 4.1%，p＝0.0002）したが，生存率に差はみられなかった[3]。このよ

のようなランダム化比較試験の結果を受けて，早期乳癌患者のうち，ホルモン受容体陽性の高齢患者に対しては，放射線療法を省略して内分泌療法のみを行うことも容認し得るという意見もある。しかし，高齢の低リスク乳癌患者に関する最近のシステマティック・レビューでは，内分泌療法に放射線療法を加えることにより，生存率は改善しないが，温存乳房内再発は有意に減少するという結果が出ている[4) 5)]。現時点では，温存乳房内再発リスクが低いと考えられる患者についても，原則として放射線療法を行うべきと考えたほうがよい。

乳房温存手術後の放射線療法によって生存率が有意に向上したとする個々の臨床試験はない。しかし，Vinh—Hungらは1976～2000年に行われた13の臨床試験データを解析した結果，放射線療法の省略により死亡の相対リスクが1.086倍（95%CI　1.003-1.175）になることを示した[6]。また，EBCTCGのメタアナリシスでは，17の臨床試験において，放射線療法により，15年での乳癌死の絶対リスクが3.8%減少（25.2%→21.4%，2p<0.00005）することが示された。このメタアナリシスの結果から，乳房温存手術後の放射線療法は，乳癌の再発を半減させ，乳癌死を約6分の1減少させると見積もられている。また，10年までの乳癌再発を4例予防することにより，15年までの乳癌死を1例予防できるということもできる[1]。

乳房温存手術後の全乳房照射により，乳癌再発，乳癌死のリスクが低減でき，さらに，現時点では全乳房照射を安全に省略できる患者も明らかではないことから，乳房温存手術後には全乳房照射を行うことが標準治療である。

Background

- Roughly 50% of newly diagnosed breast cancer is stage 1
- The majority of this is ER / PR positive, Her2 Negative.
- Local regional recurrence rates have steadily reduced
- Genomic Assays like Oncotype RS have identified patients with reduced DM and lack of CT benefit allowing patients to avoid excess toxicity
- Multiple studies have demonstrated that genomic assays like the RS is prognostic for local regional recurrence.
- De-escalation of therapy is a of interest to patients, providers, and payers

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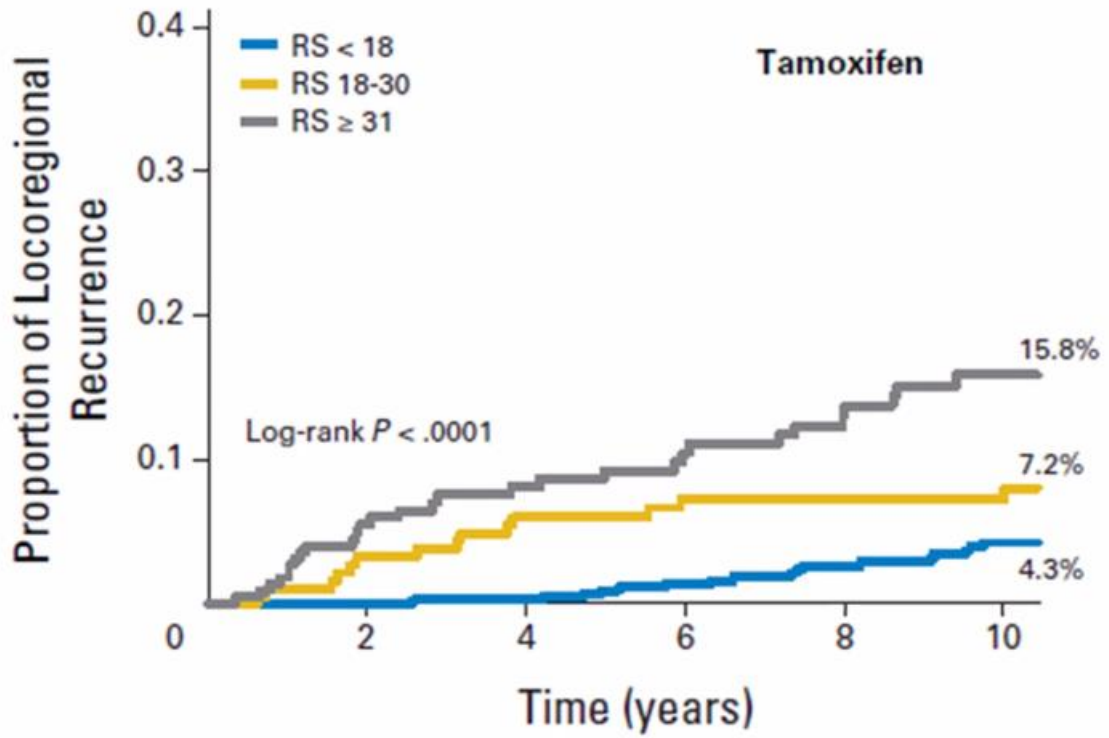
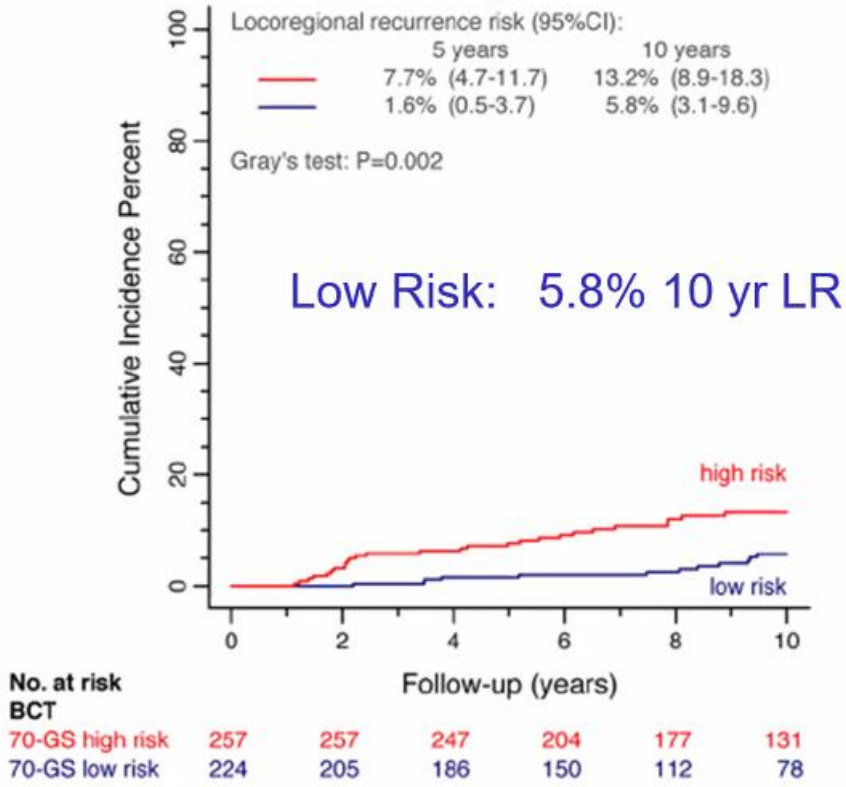
“Low risk” by Multi-gene Assay Associated with Low LRR after Lumpectomy and WBI

Oncotype RS



NSABP B14 (+/- Tam)

Mamma print



Low Risk: 5.8% 10 yr LR

Netherlands Registry

Lump + WBI

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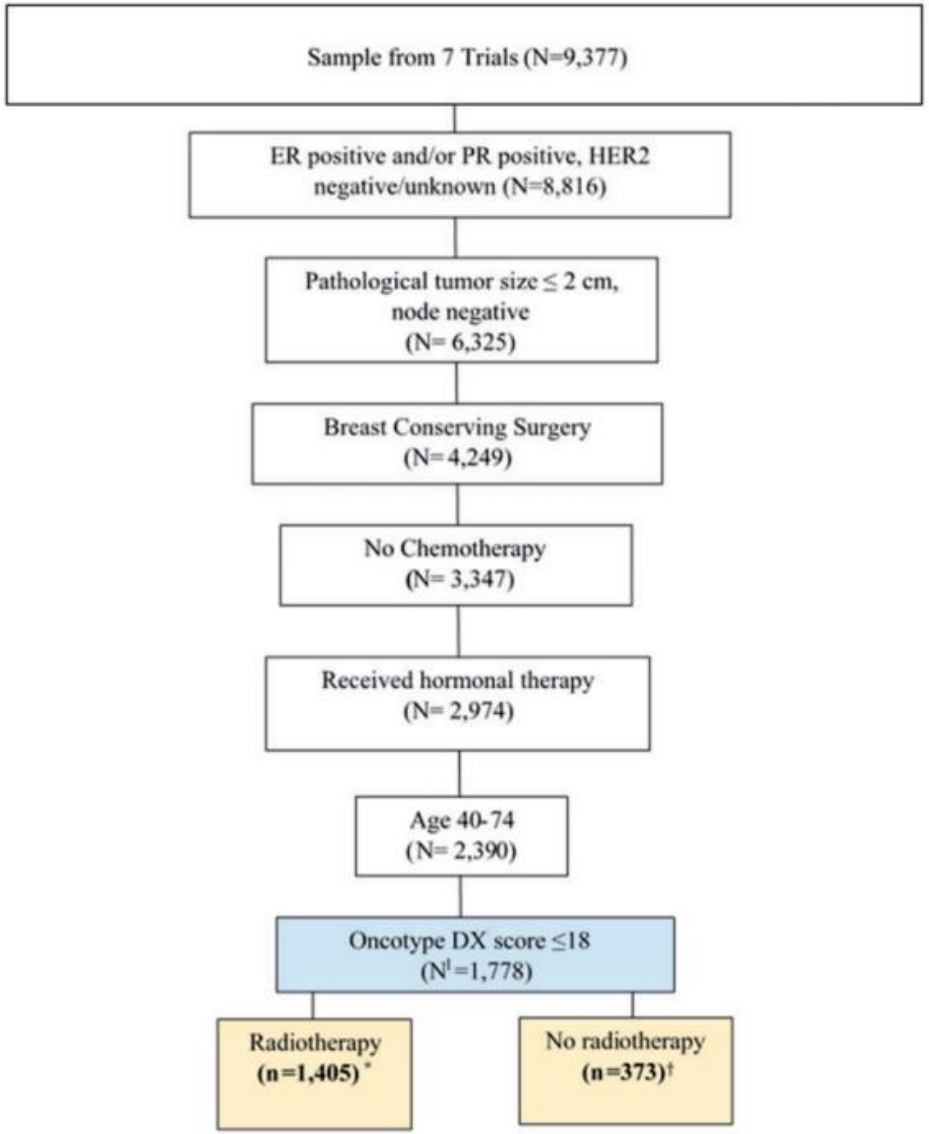
Mamounas et al, JCO 2010

Drukker et al, Breast Cancer Res Treat 2014

低RSでBp後照射省略時の再発リスク

低RS集団でBp後のRT省略時再発リスク

7試験 1778名
CALGB9343
NSABP B21
Tront/Vancouver
GBSG-V
TAILORx
NSABP B14
NSABP B20



Jayasekera et al. JNCI2018 djy12

局所再発のみ増え遠隔/生存は増えない

Table 2. Hazard ratios for recurrence-free interval and overall and breast cancer–specific survival for omission vs receipt of radiotherapy

Study endpoints	No.	No. of events/Total No. of women		HR (95% CI)	P*
		No RT	RT		
RFI					
Unweighted (no RT vs RT)†	1778	53/373	91/1405	2.59 (1.38 to 4.89)	.003
Propensity weighted (no RT vs RT) ‡	1778			2.75 (1.67 to 4.54)	<.001
Competing risk model (no RT vs RT)†	1778			2.63 (1.40 to 4.92)	.003
Locoregional RFI§					
Unweighted (no RT vs RT) †	1741	38/366	30/1375	3.91 (1.81 to 8.45)	.001
Propensity weighted (no RT vs RT) ‡	1741			3.92 (1.87 to 8.20)	<.001
Competing risk model (no RT vs RT) †	1741			3.97 (1.85 to 8.50)	<.001
Distant RFI‖					
Unweighted (no RT vs RT) †	1710	7/335	30/1375	0.90 (0.26 to 3.10)	.90
Propensity weighted (no RT vs RT)‡	1710			0.84 (0.30 to 2.34)	.81
Competing risk model (no RT vs RT) †	1710			0.82 (0.24 to 2.75)	.75
Mortality outcomes					
All-cause mortality †	1778	44/373	104/1405	0.88 (0.53 to 1.44)	.61
Breast cancer–specific mortality †	1778	6/373	19/1405	1.14 (0.30 to 4.43)	.85

*Two-sided P values are based on Student t test. RFI = recurrence-free interval; CI = confidence interval; RT = radiotherapy.

†Adjusted for patient age, tumor grade (low, moderate, high, or unknown), ER/PR status (ER+ and PR+ or other), HER2 (negative or unknown), initial hormonal treatment (tamoxifen, aromatase inhibitors or other), tumor size, trial, and Oncotype DX recurrence score.

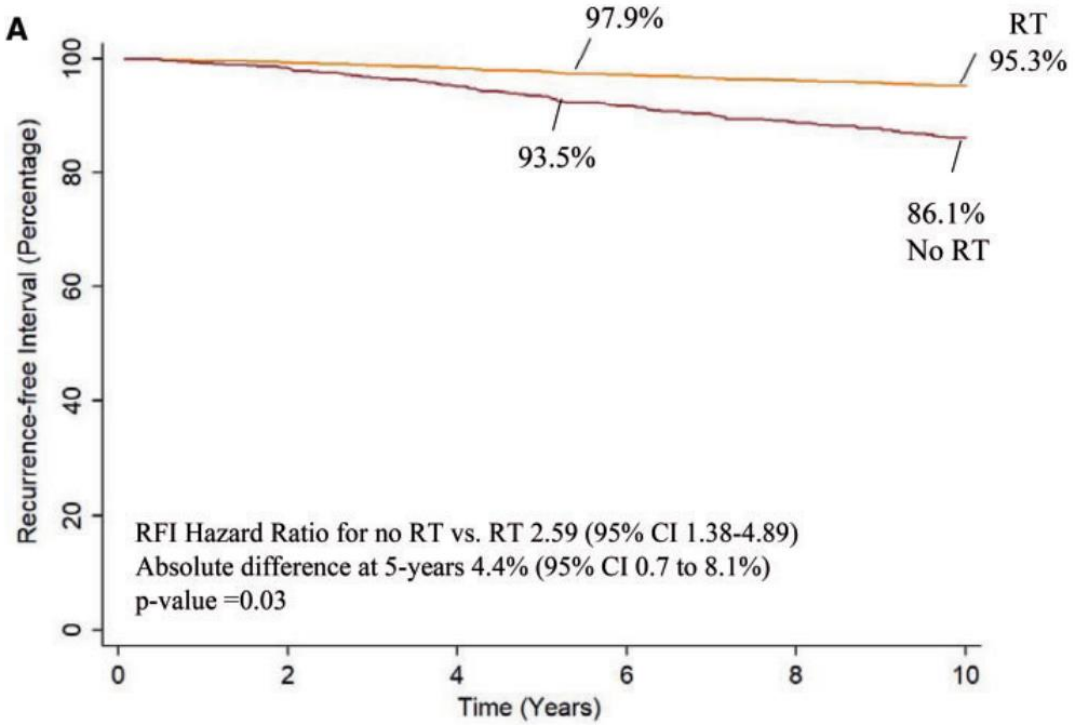
‡Inverse probability of treatment weighted (IPTW) analysis.

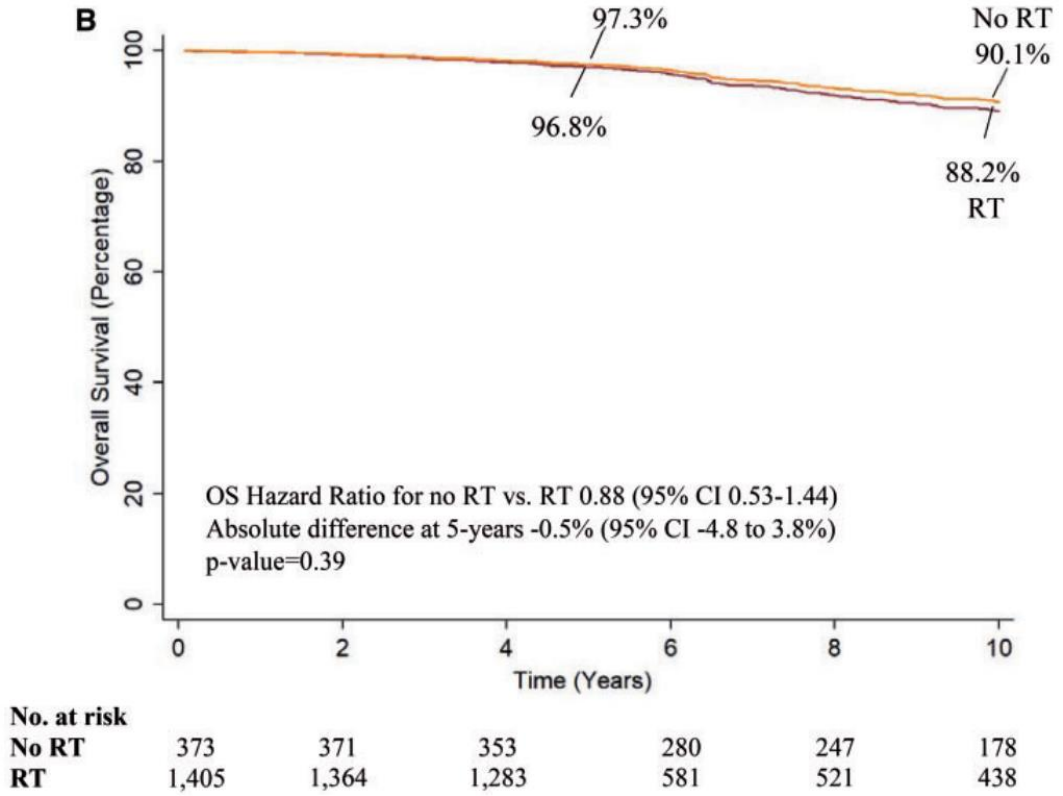
§Excluding distant recurrence events.

‖Excluding locoregional recurrence events.

Jayasekera et al. JNCI2018 djy12

局所再発は増えるが生存には影響せず





No. at risk						
No RT	373	371	353	280	247	178
RT	1,405	1,364	1,283	581	521	438

Jayasekera et al. JNCI2018 djy12

モデル研究のlimitationとそれを踏まえた NRG BR-007のデザイン

- 40-49歳の女性は少ない→BR007試験から除外
- HER2 unknownが44%→HER2陰性に限定
- 60歳未満の女性の64%がTamoxifenを使用→基本はAIを使用

Statistics

- Using TAILORx 10-year local regional recurrence free survival by recurrence score 2% for RS< 11 and 2.5% 11-18 for IBTR at 9 years adjusted to a study done for 10 years.
- We assume that a clinically acceptable difference in IBTR at 10 years to judge omission of RT as non-inferior is 4% (10-year event-free survival for RT group is 97.8% versus 93.8% for the omission of RT group).
- To be able to detect non-inferiority as defined with 80% power and a one sided $\alpha = 0.025$ and assuming a 5 year accrual (ramp up: Year 1 ~ 12/mo; Year 2 ~ 23 / mo, Years 3 – 5 ~ 35/ mo), **a total accrual of 1670 (835 per arm) is required.** This conservatively assumes loss to follow-up will be 1% per year

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Hypothesis

That breast conserving surgery alone is non-inferior to breast conserving surgery and radiation for in-breast cancer control and breast preservation for women intending appropriate endocrine therapy for Stage 1 breast cancer, that is ER and/ or PR Positive, HER2-negative and Oncotype DX Recurrence Score low.

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Eligibility (Key)

- Age ≥ 50 years and < 70 years of age
- Pathologic T1 (≤ 2 cm), N0
- Oncotype DX Recurrence Score of ≤ 18 on core biopsy or resected specimen
- ER and/or PgR positive by ASCO/CAP
- HER2-negative by ASCO/CAP
- ≤ 70 Days from Surgery to Study Entry

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Pre-Entry: T1a Tumors

- ***T1a tumor (≤0.5 cm in size)*** who do **not** have an Oncotype DX Recurrence Score
- Tissue sample sent to Genomic Health for a Recurrence Score to determine eligibility. For these patients, Genomic Health will cover the cost of the test.
- Sample to be sent for central Oncotype DX Recurrence Score testing
- When a Recurrence Score result of ≤ 18 is received on central testing for patients with a ***T1a tumor (≤ 0.5 cm in size)***, the patient should be randomized. Patients who do **not** have a Recurrence Score result of ≤ 18 by central testing will not be randomized, will be treated per investigator discretion, and will not be followed on BR007.

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Treatment Arms

Arm 1:

- Post lumpectomy breast radiation using standard methods. (Hypo or conventional fractionated whole breast irradiation with or without boost, Accelerated Partial Breast Irradiation).

- At least 5 years of endocrine therapy (tamoxifen or aromatase inhibitor). The specific regimen of endocrine therapy is at the treating physician's discretion.

Arm 2:

- At least 5 years of endocrine therapy (tamoxifen or aromatase inhibitor). The specific regimen of endocrine therapy is at the treating physician's discretion.

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Endpoints

Primary:

- To evaluate whether breast conservation surgery alone results in a non-inferior rate of in-breast tumor recurrence (IBTR) compared to breast conservation with lumpectomy and breast radiation in eligible breast cancer patients.

Secondary:

- Overall breast conservation rate (Rate of second breast conserving)
- Endocrine therapy adherence
- Cosmetic outcome (Cosmesis)
- QOL (Breast Pain and Worry for Recurrence
- Invasive-DCIS Recurrence-free Interval (IRFI)
- Distant disease free Interval (DDFI)
- Disease Free Survival
- Overall survival (OS)

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Statistics

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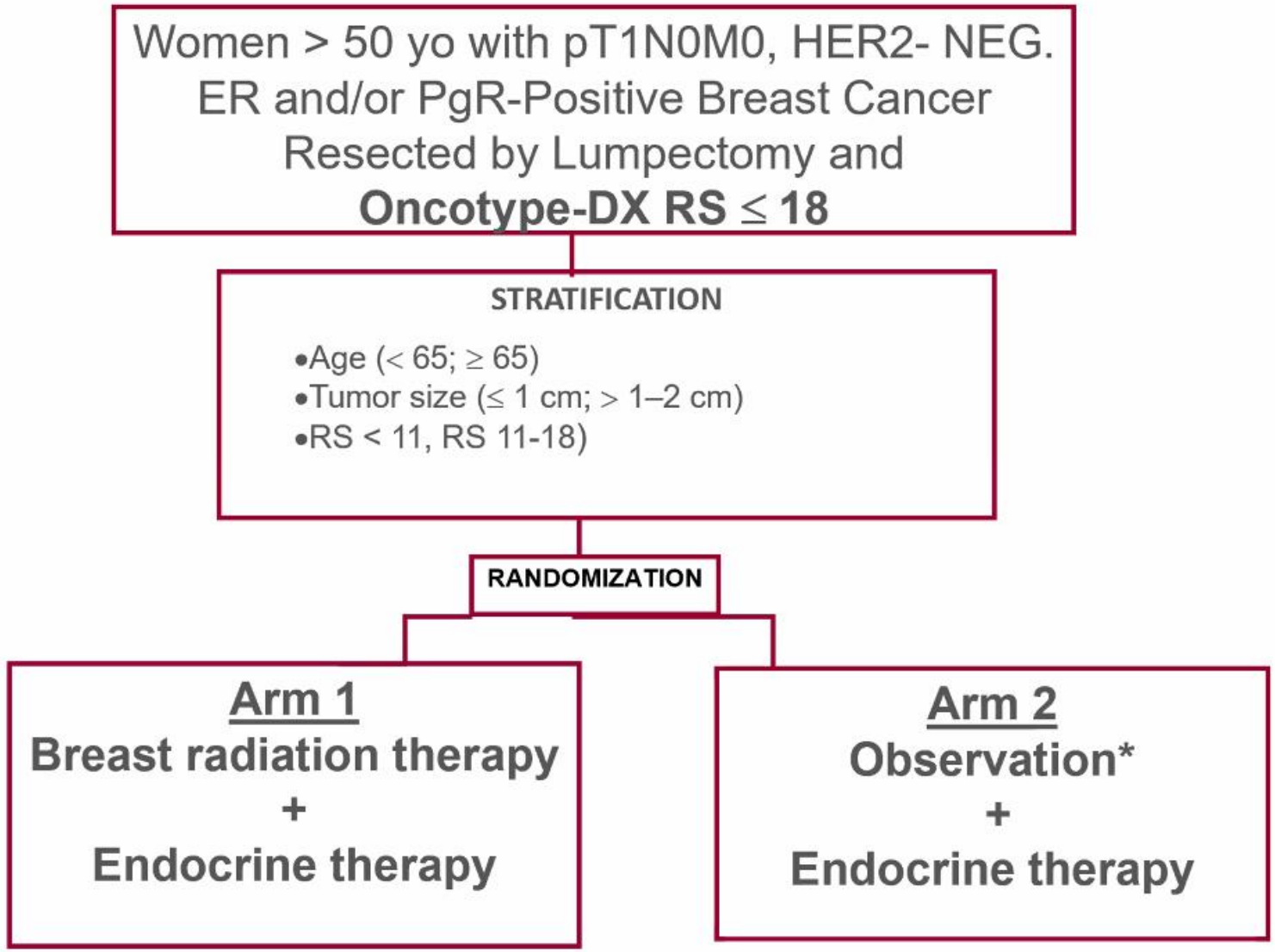
BR007 Schema



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2023年3月のアンケート結果
(ご協力、ありがとうございました！！)

- 13施設中、11施設から回答
- 年間手術件数は総合計 3903件
- 年間のOncotypeDx出検数は総合計500件程度(割合は3-30%)

相談事項

- OncotypeDxの出検体制と適応(pT1a/b/c)

→

- 放射線治療科の協力体制(責任者/担当者お名前？)

→

- 競合試験の有無

→

- IRBのタイムライン(プロトコル日本語版fixから何ヶ月程度？)

→

乳癌学会で数人の先生に個別にご相談
(ご協力、ありがとうございました！！)

	笹田先生(広大)	須藤先生(国がん中)	青儀先生(四国がん)	増田先生(名大)
実地臨床での pT1abcのODx適応	pT1c(Ki67高め)	pT2が主 pT1cは交渉の余地	pT1cが中心 pT1bは高リスクなら	practiceでは pT2が中心
放射線治療科の 協力体制 責任者/担当者	協力的 村上先生 西渕先生	腫瘍内科内で プレゼン後、依頼 井垣先生/高橋先生	OK 浜本先生	OK 川村先生
プロトコルfix後 IRBまで	2-3ヶ月	2ヶ月程度	1-2ヶ月	2-3ヶ月
競合試験	なし	なし	なし	なし

頂いたご質問

- pT1b/pT1cで先に同意取得、その後ODx提出は許容されるか
- 院内でCRCに依頼するに足る費用は配分されるか

BR007 Accrual

Targeted Accrual for Screening 1,714

Targeted Sample Size 1,670

Projected monthly accrual in Year 1: 14

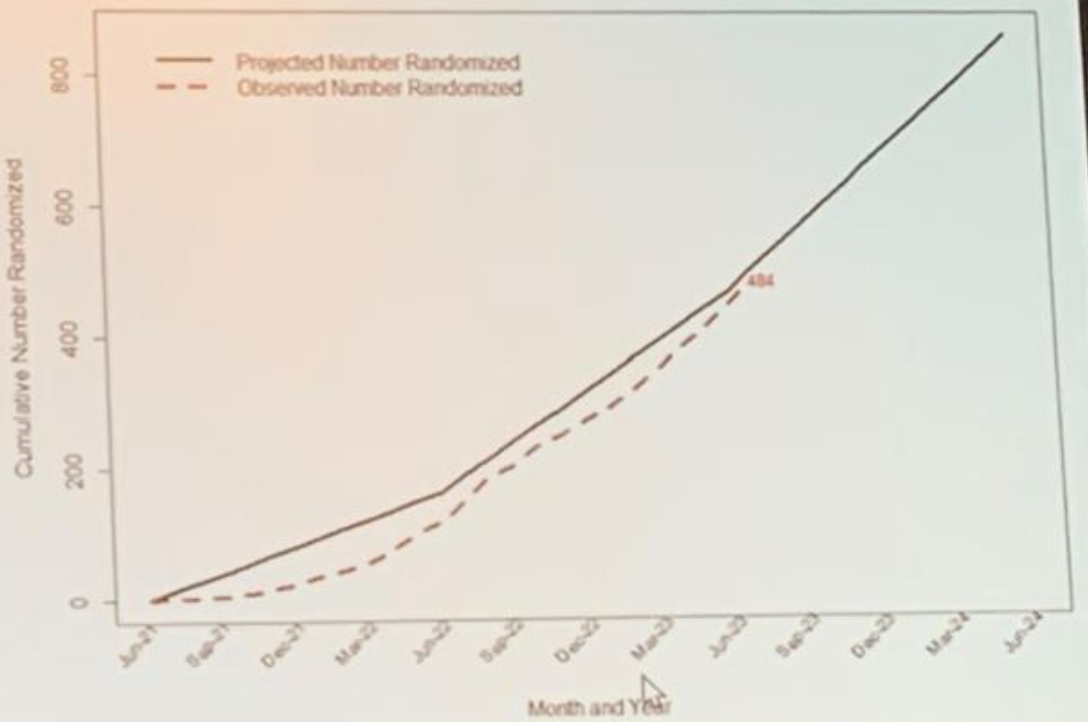
Projected monthly accrual in Year 2: 25

Projected monthly accrual in Year 3: 35

Average monthly accrual over last 6 months: 33

Number Screened as of 7/20/2023: 579

Number Randomized as of 7/20/2023: 515



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Characteristics of the Patient Population Enrolled (6/30/2023)

Variable		%
Age	Median	62 years
	% >60 yrs.	67
Race/Ethnicity	White	83.7%
	Black	7.2%
	Hispanic	6.4%
	Asian	4.1%
Tumor size	> 10 mm	45.2%
Oncotype RS	> 11	55%
Breast Radiation Type	WBI	42.6%
	APBI	15.3%
	PBI (15 F)	19.1%

n = 484

NRG ONCOLOGY™

Amendment

- Eligibility:

3.2.9 Oncotype DX Recurrence Score of ≤ 18 on diagnostic core biopsy or resected specimen.**, ###

** For patients with a ***T1a tumor (≤ 0.5 cm in size)*** who do not already have an Oncotype DX Recurrence Score at study entry, a specimen (unstained blocks or slides) must be sent to the Genomic Health centralized laboratory._

The Oncotype RS can be run on the biopsy core or final surgical specimen. The patient cannot have already been on endocrine therapy when the tissue was collected.

- Patients whose tumor already underwent MammaPrint testing as part of usual care and is in the binary "Low "Genomic Score category meet this eligibility criteria and an Oncotype RS does not need to be done for eligibility

NRG ONCOLOGY™

Amendment

5.4.1: Dose Recommendations

- Whole breast with concomitant boost:
  - Breast 4000 cGy in 15 fractions of 2.67 Gy q day
  - Concomitant Boost 800 cGy in 15 fractions of 0.53 Gy q day
- Whole breast c/w Fast Forward Trial
  - Breast 2600 cGy in 5 fractions of 520 cGy q day
  - Sequential boost 1000 cGy in 5 fractions of 200 cGy q day

Accelerated Partial Breast Irradiation:

- 30 Gy in 5 fractions of 6 Gy delivered every other day or daily
- 28 Gy in 5 fractions of 5.6 Gy delivered every other day or daily
- 27 Gy in 5 fractions of 5.4 Gy delivered every other day or daily

NRG ONCOLOGY™

Julia

BR007のtimeline

1. 立ち上げ資金獲得 (delete C)　2023年1月
2. 米国側の参加承認　2023年2月
3. CRO (A2ヘルスケア)と契約　2023年5月
4. プロトコル翻訳　←現在作業中
5. キックオフ　←TBD!

NRG BR009
A Randomized Phase III Adjuvant Trial of Ovarian Function Suppression + Endocrine Therapy +/- Adjuvant Chemotherapy in Premenopausal Patients with pN0-1, ER+/HER2-Negative Breast Cancer and RS < 25

(OFSET Chemo)

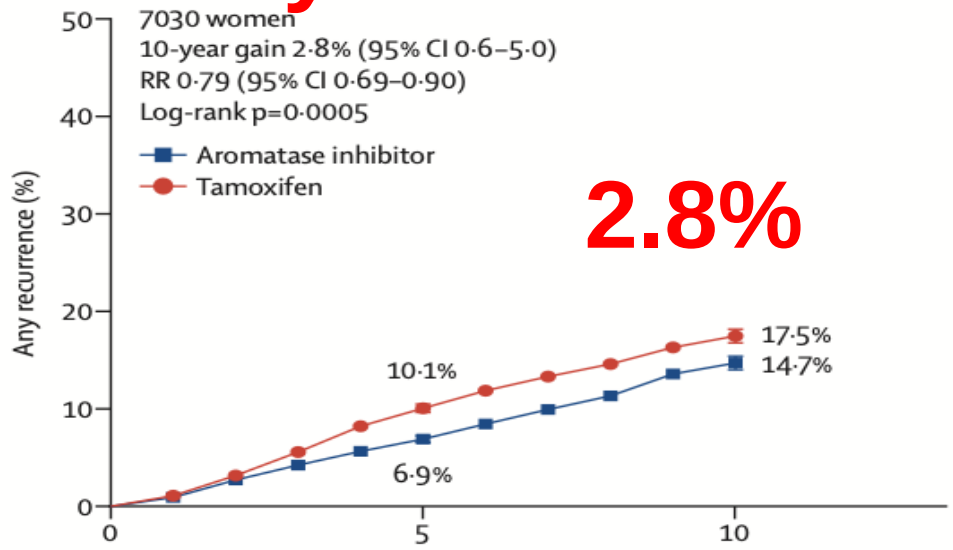
Background/Rationale

- **TAILORx: Node negative**
  - **No benefit with CET vs. ET in postmenopausal pts with pN0/RS 11-25**
  - **Significant benefit with CET vs. ET in premenopausal pts with pN0/RS 16-20 (and high clinical risk) or RS 21-25**
- **RxPONDER: Node positive**
  - **No benefit with CET vs. ET in postmenopausal pts with pN1/RS 0-25**
  - **Significant benefit with CET vs. ET in premenopausal pts with pN1/RS 0-25 (high clinical risk by definition)**
- **SOFT:**
  - **Significant benefit with OFS + Exemestane vs. Tamoxifen Alone in high-risk premenopausal patients who also received adjuvant chemotherapy**
- **Neoadjuvant Chemo Studies in ER+/HER2- pts:**
  - **Low pCR in pts with RS <25 irrespective of menopausal status (ADAPT SABCS 2020)**

TAILORx (Sparano 2019)

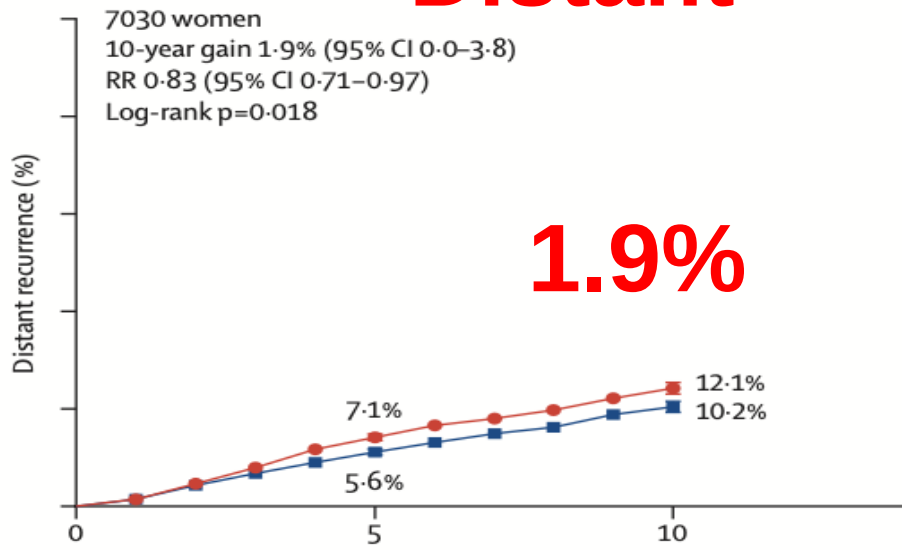
	Adjuvant Chemo	Clinical Risk	No.	Distant Recurrence Rate	HR for Distant Recurrence by Chemo Use (No vs. Yes)	Estimated Absolute Chemo Benefit
RS 16-20	No	Low	328	4.6 ± 1.5%	1.00 (0.44, 2.28)	Δ +1.6%
	Yes	Low	343	4.8 ± 1.5%		
	No	High	107	11.9 ± 3.9%	2.26 (0.70, 7.34)	
	Yes	High	108	5.5 ± 344.0%		
RS 21-25	No	Low	158	11.4 ± 3.9%	3.16 (1.01, 9.94)	Δ +6.4% (±SE 4.9%)
	Yes	Low	161	5.0 ± 3.0%		
	No	High	75	18.8 ± 5.0%	1.86 (0.73, 4.74)	Δ +8.7% (±SE 6.2%)
	Yes	High	82	10.1 ± 3.7%		

Aromatase inhibitors versus tamoxifen in premenopausal women with ER+ EBC treated with ovarian suppression: a patient-level meta-analysis of 7030 women from four randomised trials



Recurrence rates per year (% [events/women-years]) and log-rank analyses

	Years 0–4	Years 5–9	Years ≥10
Aromatase inhibitor	1·46 (237/16 276)	1·76 (158/8999)	1·89 (9/476)
Tamoxifen	2·08 (332/15 958)	1·74 (150/8639)	0·44 (2/459)
RR (95% CI)	0·68 (0·58–0·80)	0·98 (0·78–1·23)	3·31 (0·99–11·06)
from (o–e)/v	–52·9/137·2	–1·2/74·5	3·2/2·6

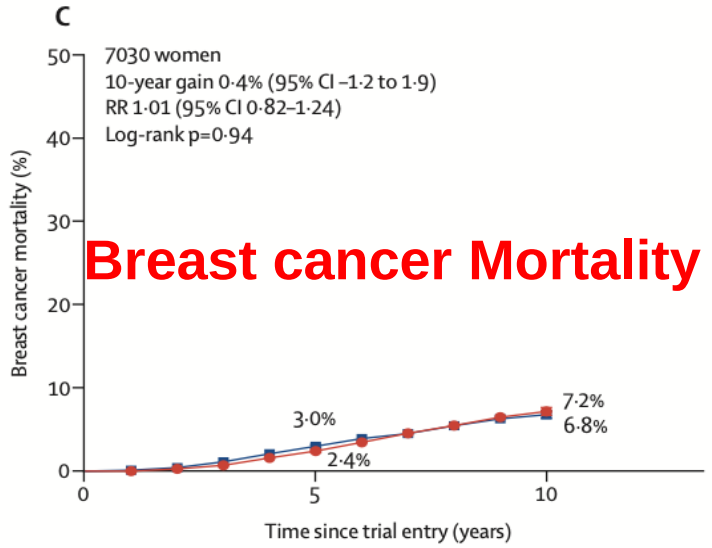


Distant recurrence rates per year (% [events/women-years]) and log-rank analyses

Years 0–4	Years 5–9	Years ≥10
1·16 (190/16 386)	1·01 (93/9222)	0·60 (3/502)
1·44 (233/16 169)	1·08 (97/9016)	0·00 (0/490)
0·78 (0·65–0·95)	0·91 (0·68–1·22)	7·86 (0·72–85·91)
–24·8/101·8	–4·3/45·8	1·4/0·7

EBCTCG *Lancet Onc* 2022

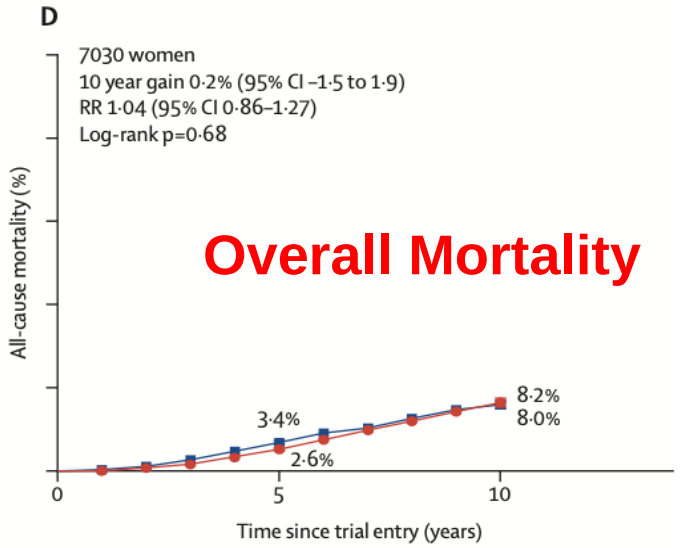
Aromatase inhibitors versus tamoxifen in premenopausal women with ER+ EBC treated with ovarian suppression: a patient-level meta-analysis of 7030 women from four randomised trials



Breast cancer Mortality

Death rates in women without recurrence, per year (% [95% CI]) and log-rank analyses

	Years 0–4	Years 5–9	Years ≥10
Aromatase inhibitor	0·60 (0·48–0·72)	0·85 (0·66–1·03)	0·76 (0·02–1·51)
Tamoxifen	0·47 (0·37–0·57)	1·03 (0·82–1·23)	0·57 (0·08–1·22)
RR (95% CI)	1·25 (0·93–1·68)	0·80 (0·60–1·08)	1·45 (0·33–6·44)
from (o–e)/v	9·7/43·4	−9·6/43·5	0·6/1·7



Overall Mortality

Death rates per year (% [events/women-years]) and log-rank analyses

Years 0–4	Years 5–9	Years ≥10
0·69 (115/16 663)	1·01 (96/9515)	0·76 (4/525)
0·51 (85/16 573)	1·17 (111/9481)	1·33 (7/525)
1·33 (1·00–1·76)	0·84 (0·64–1·11)	0·64 (0·18–2·24)
13·8/48·9	−8·6/50·2	−1·1/2·5

EBCTCG *Lancet Oncol* 2022

BR009: Schema

- Premenopausal; HR+/HER2- BC
- pN0 with RS 16-20 (high clinical risk) or RS 21-25
- pN1 with RS 0-25

Stratification

Nodal Status (pN0 vs. pN1)

RS (0-15 vs. 16-25)

Age > 40 and ≤40

Randomization

Chemotherapy + Ovarian Function Suppression + Aromatase Inhibitor* X 5 Years	Ovarian Function Suppression + Aromatase Inhibitor* X 5 Years

N = 3960

参加へ向け交渉中

SWOG

* Tamoxifen can be used if AI is not tolerated

Community Oncology Research Program


10 Years
NRG
ONCOLOGY
2023 SUMMER MEETING


THE BARNES FOUNDATION


次回：2024年2月 15-17日Orland World Center Marriot
次々回：2024年7月25-27日 Sheraton Denver Downtown
皆様と現地参加できるのを楽しみにしております！