MINDACT Trial Results

(**M**icroarray **I**n **N**ode negative and 1-3 positive lymph node **D**isease may **A**void **C**hemo**t**herapy)

agendia® mammaprint®
70-Gene Breast Cancer Recurrence Assay

MINDACT is the first and only Phase III prospective, randomized controlled clinical trial comparing a genomic breast cancer recurrence assay to clinicopathological risk assessment (standard of care).

Baseline characteristics of the MINDACT study population

	LOW RISK (no chemo)* C= ↓ MP= ↓ n = 2,745 (41%)	OVERTREATMENT GROUP C= ↑ MP= ↓ CPFs HIGH MammaPrint LOW n = 1,550 (23%)	UNDERTREATMENT GROUP C= ↓ MP= ↑ CPFs LOW MammaPrint HIGH n = 592 (9%)	HIGH RISK (chemo)† C= ↑ MP= ↑ n= 1,806 (27%)
IHC Subtype	96% Luminal • HER2+ : 4%	91% Luminal • HER2+ : 8% • Triple Neg : 1%	79% Luminal • HER2+ : 12% • Triple Neg : 9%	50% Luminal • HER2+ :19% • Triple Neg : 31%
Grade	Grade 1 or 2 98%	Grade 2 or 3 93%	Grade 1 or 2 85%	Grade 3 76%
Node Positive	6%	48%	2%	26%
Tumor Size >2cm	4%	58%	2%	48%
5-year DMFS Distant Metastasis Free Survival	97.6% (96.9 - 98.1) - no ACT	94.7% (92.5 - 96.2) - no ACT	93.9% (89.6 - 96.5) - no ACT	90.6% (89.0 - 92.0) - CT

Primary Analysis Population

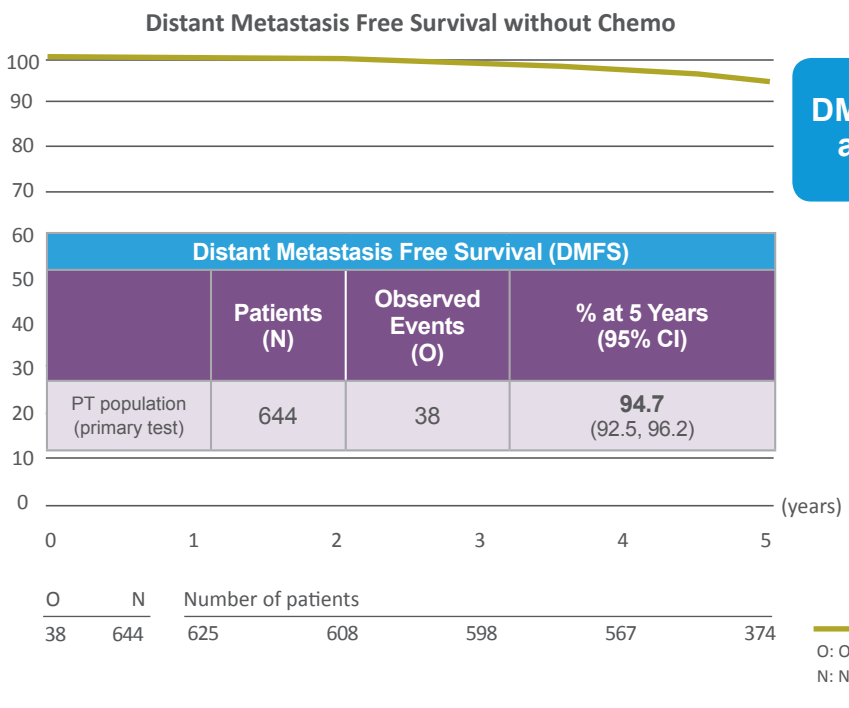
Data from the Primary Analysis: 5-year DMFS for patients with high risk clinical features identified as Low Risk by MammaPrint, without chemotherapy

C= ↑ MP= ↓
CPFs High / MammaPrint Low
no CT

48%
of patients in this group were lymph node positive.

58%
of patients in this group had a tumor size greater than 2cm.

93%
of patients in this group had tumors that were grade II or III.



DMFS=94.7% at 5 years

Distant Metastasis Free Survival (DMFS)			
	Patients (N)	**Observed Events (O)**	**% at 5 Years (95% CI)**
PT population (primary test)	644	38	**94.7** (92.5, 96.2)

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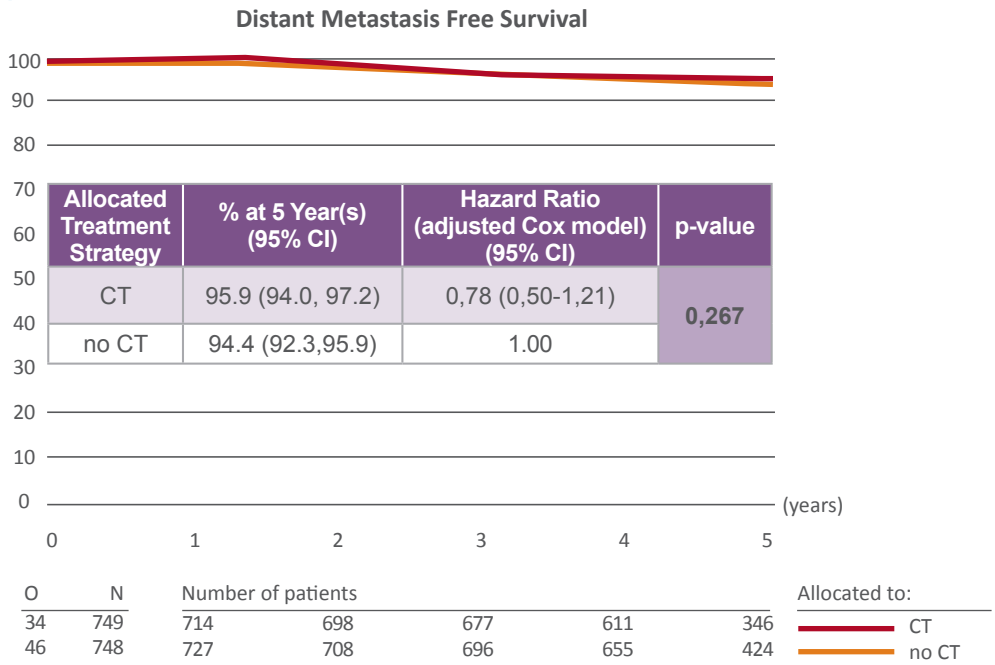
Efficacy of chemotherapy was determined by comparing DMFS at 5 years (All patients cHigh / MP Low)

OVERTREATMENT GROUP

C= ⬆ MP= ⬇

CPFs HIGH
MammaPrint LOW



Allocated Treatment Strategy	% at 5 Year(s) (95% CI)	Hazard Ratio (adjusted Cox model) (95% CI)	p-value
CT	95.9 (94.0, 97.2)	0,78 (0,50-1,21)	0,267
no CT	94.4 (92.3,95.9)	1.00	

- MINDACT data shows that in the presence of high risk clinicopathologic features, there is **no significant or clinically meaningful benefit to adding chemotherapy for MammaPrint Low Risk patients**.

MINDACT Results Summary

MammaPrint was developed independent of clinicopathologic factors so it's the only assay that provides added value to the treatment decision and can be used in conjunction with clinical factors.

MINDACT demonstrates that MammaPrint is the only breast cancer genomic assay that selectively identifies early-stage breast cancer patients with high risk features (Lymph node positivity (LN 1-3), grade II or III, size >2cm) as Low Risk with no clinically meaningful benefit of chemotherapy.

MINDACT proves that MammaPrint is superior as a standalone test to the current standard of care in predicting the benefit of chemotherapy for early-stage breast cancer patients, minimizing the risk of undertreatment.

> MINDACT provides indisputable Level 1A, phase III, randomized prospective clinical evidence that proves the superiority of MammaPrint 70-Gene Assay in predicting the benefit of chemotherapy in early-stage breast cancer patients when compared to clinicopathological risk assessment.

References

1. Cardoso, F. et al. "70-Gene Signature as an Aid to Treatment Decisions in Early-Stage Breast Cancer." N Engl J Med. 2016;375:717-29 (including Supplemental data)