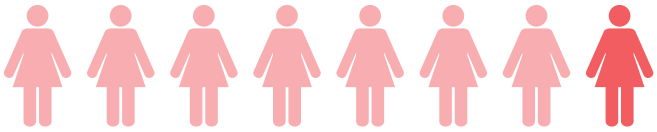
Every Woman Deserves a Unique Treatment Strategy

MammaPrint + BluePrint together help navigate the complexity of early-stage breast cancer.

AGENDIA®

PRECISION ONCOLOGY

Are you getting the whole story to make timely, informed treatment decisions?



As many as **1 in 8 women** will be diagnosed with breast cancer in their lifetime.

Informed treatment planning is critical to improving outcomes and the patient journey.

2M+
NEW CASES OF BREAST CANCER WORLDWIDE[1]

Current Challenges with Treatment Planning

- ER/PR/HER2 only provide a superficial protein-based view of a tumor and not the underlying biology driving its growth.
- Clinical factors only provide part of the story.
- Genomic information is typically not available in time for initial pre-operative consultation.

What if comprehensive information on a patient's unique tumor biology were available early in the multidisciplinary treatment-planning process?

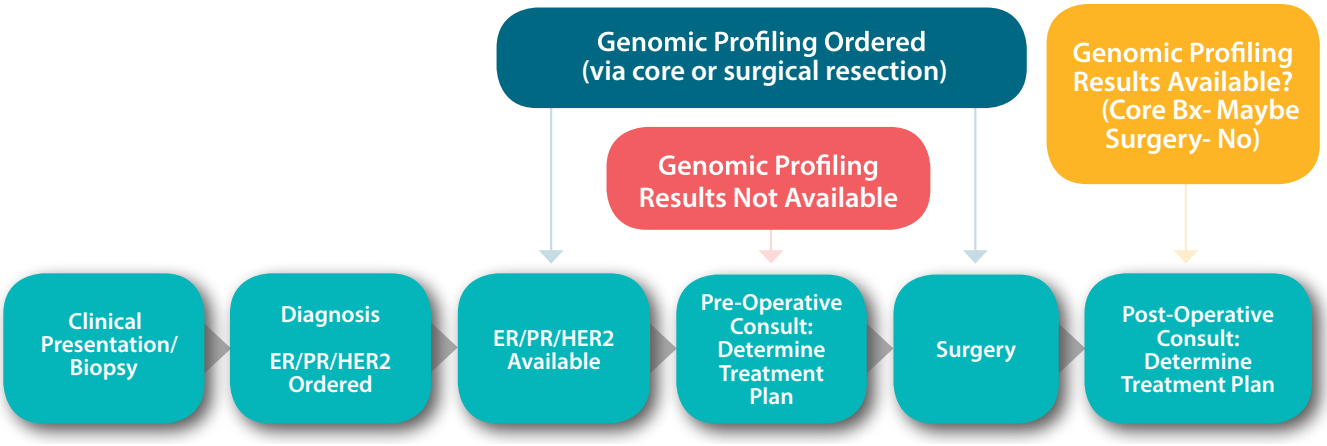
AGENDIA®
MAMMAPRINT+BLUEPRINT

Combine to provide the most comprehensive genomic profile for patients with early stage breast cancer

1 Ferlay, et al., Int J Cancer. 144, 1941–1953 (2019).

How do we improve the patient journey and support timely, effective treatment planning?

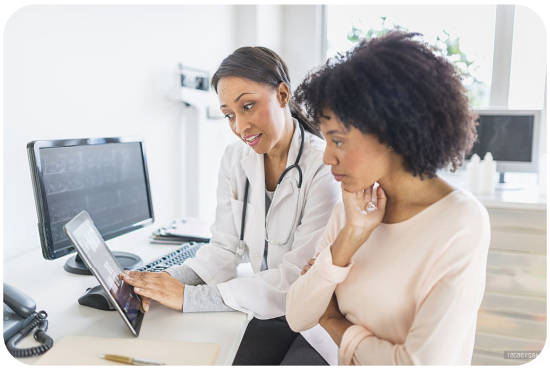
Standard Workflow Does Not Facilitate Timely Treatment Planning



How do we minimize over- and undertreatment in the pre-operative setting?

Guidelines encourage the use of subtyping to inform neoadjuvant treatment decisions.

- BluePrint® identifies the underlying biology driving a tumor's growth enabling more accurate subtyping.
- Approximately 1 in 5 patients are reclassified from pathologically HR+ tumors into high risk Basal-Type tumors.[1-3]

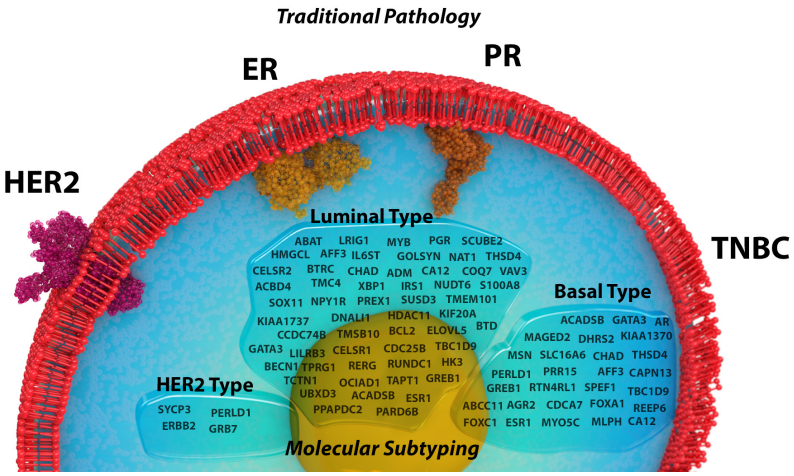


How do we optimize post-operative treatment planning?

- The prospective, randomized MINDACT trial demonstrated that MammaPrint® identifies a subset of breast cancer patients who may safely forgo chemotherapy.[4]
- MammaPrint informs endocrine treatment planning and facilitate patient counseling.[5-7]

1 Groenendijk, et al., npj Breast Cancer 5, 15 (2019).; 2 Whitworth, P., et al. Ann Surg Oncol (2017) 24: 669–675.; 3 van 't Veer L, et al. 30th EORTC-NCI-AACR Symposium, November 13-16, 2018.; 4 Cardoso, F., et al. N Engl J Med 2016;375:717-29.; 5 Esserman, L.J., et al. JAMA Oncol. 2017 Nov.; 6 Noordhoek, I., et. al, SABCS 2020, PS6-06.; 7 Opdam, M. et. al, ESMO Congress 2020, 171P

BluePrint® Functional Molecular Subtyping

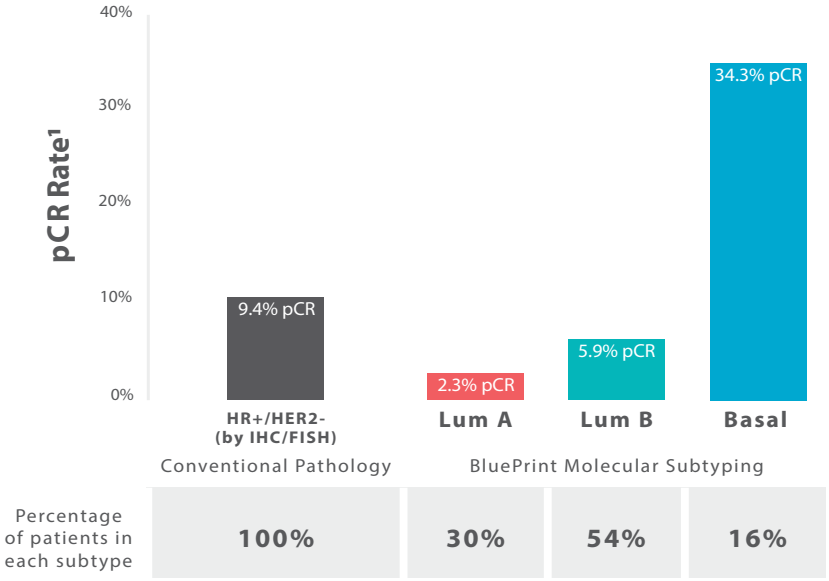


BluePrint, the 80-gene molecular subtyping assay, goes beyond the cell surface to evaluate the underlying biology of a tumor and what is driving its growth.

AGENDIA® BLUEPRINT

Informs treatment planning in the pre-operative setting

Standard Pathologic Subtyping vs. BluePrint Molecular Subtyping[1]



- Further subdivides pathologically luminal tumors (HR+) into low risk Luminal A and high risk Luminal B subtypes.
- Reclassifies as many as 1 in 5 patients' pathologically HR+ tumors into high risk Basal-Type tumors.[1-3]

- As expected, pCR rates in high risk Basal-Type patients correlate with long-term outcomes.[4]
- The subtyping information that BluePrint provides enables physicians to better tailor pre-operative treatment and the timing of surgery to individual patients.[4]

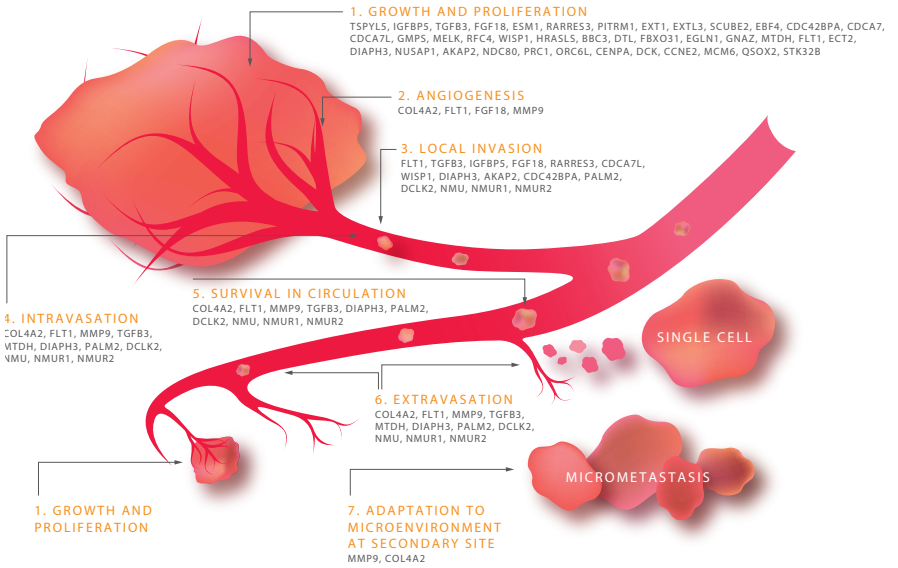
BluePrint Subtyping	pCR Rate (%)	5-Year DMFS by Response		
Luminal A-Type	9/172 (5%)	pCR no pCR	100% 91%	p= N.S.
Luminal B-Type	27/355 (8%)	pCR no pCR	82% 75%	p= N.S.
HER2-Type	102/174 (59%)	pCR no pCR	90% 83%	p= N.S.
Basal-Type	136/371 (37%)	pCR no pCR	94% 58%	p<0.001

1 Groenendijk, et al. npj Breast Cancer 5, 15 (2019).; 2 Whitworth, P., et al. Ann Surg Oncol (2017) 24: 669–675.; 3 van 't Veer L, et al. 30th EORTC-NCI-AACR Symposium, November 13-16, 2018.; 4 Data on file

MammaPrint® Risk of Recurrence Testing

MammaPrint, the 70-gene breast cancer recurrence assay, is the first FDA-cleared and CE-marked risk-of-recurrence test backed by peer-reviewed, prospective outcome data and included in major treatment guidelines.[1]

Early Metastatic Process

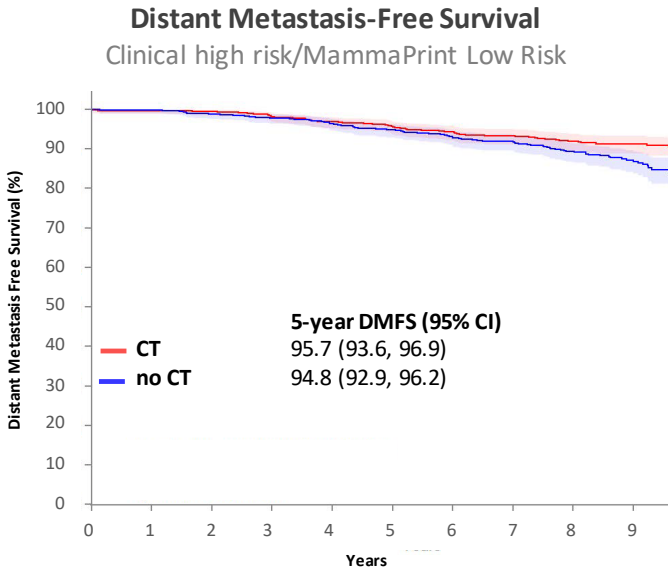


- Interrogates genes involved in every step of the metastatic cascade.
- Results are independent of and complementary to standard IHC/FISH testing.

AGENDIA®
MAMMAPRINT

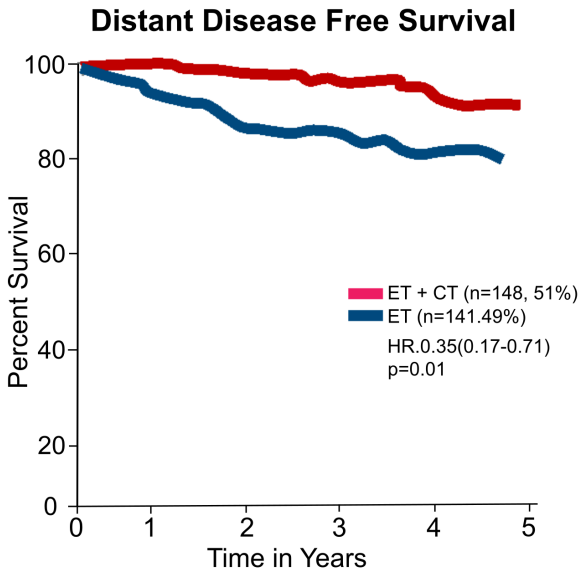
Provides insight into the benefit of post-operative treatment

Adjuvant Chemotherapy Planning[2]



MammaPrint Low Risk patients may safely forego adjuvant chemotherapy.

Chemotherapy Prediction[3]



MammaPrint High Risk patients have significantly better outcomes with chemotherapy.

1 In 2007, MammaPrint became the first IVDMIA to gain 510(k) clearance from the FDA. In 2018, The MammaPrint and BluePrint Kit attained the CE mark.
2 Cardoso, F., et al. N Engl J Med 2016;375:717-29.; 3 Knauer, M., et al. Breast Cancer Res Treat. 2010 Apr;120(3):655-61.

PRE-OPERATIVE TRE

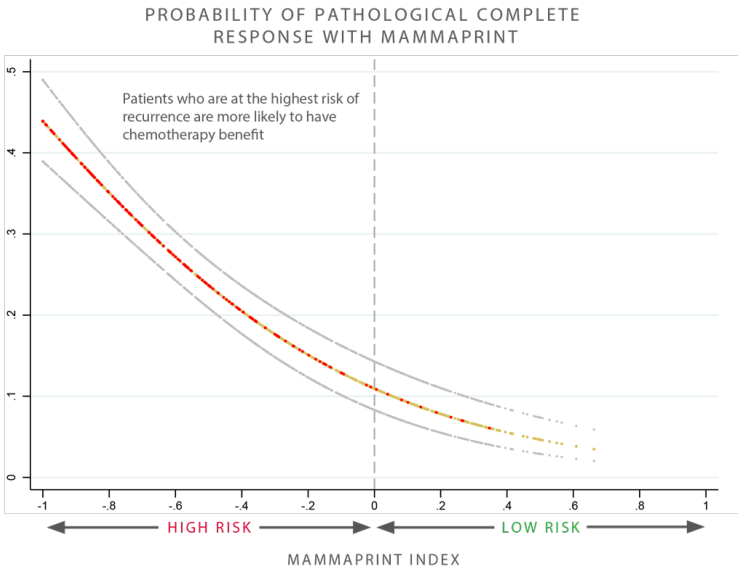
"As clinicians, our aim is to utilize the most comprehensive genomic tools available to u

How do we minimize over- and undertr

Case Study: Patient Presents with a Large HR+ Tumor[1]

Clinical Characteristics	Genomic Results
61-year-old patient	BluePrint® Luminal A-Type
4.5 cm invasive ductal tumor	MammaPrint® Low Risk
ER+ 90%, PR+ 80% via IHC	
HER2 negative via IHC and FISH	
Clinically node positive	
Grade 2	

Probability of Pathological Complete Response (pCR) with MammaPrint[2]



- MammaPrint indices correlate with likelihood of pCR, enabling physicians to identify patients most likely to benefit from neoadjuvant chemotherapy.
- With the additional information of BluePrint, multidisciplinary care teams can minimize over- and undertreatment.
- Guidelines suggest neoadjuvant endocrine therapy may be considered for breast cancer patients with low-risk luminal biology.

1 Beatty, J., et al. Miami Breast Conference 2020.; 2 Data on file.

ATMENT PLANNING

s to optimize treatment planning and improve patient outcomes." – *Joyce O'Shaughnessy, MD*

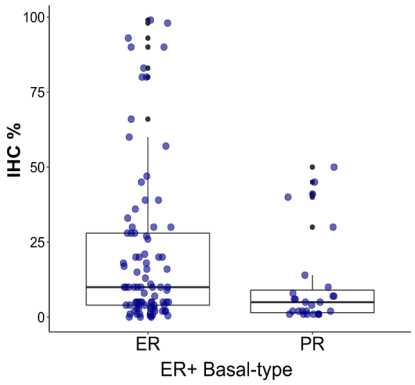
reatment in the pre-operative setting?

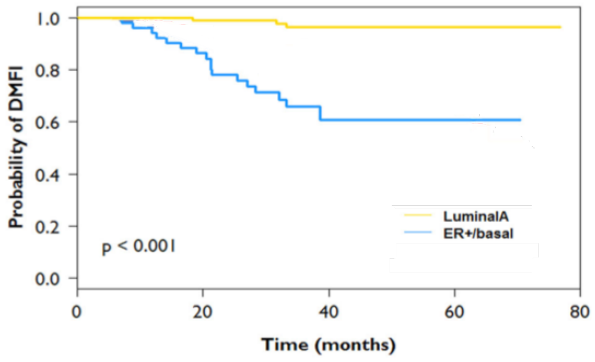
Case Study: Patient Presents with a Smaller HR+ Tumor[1]

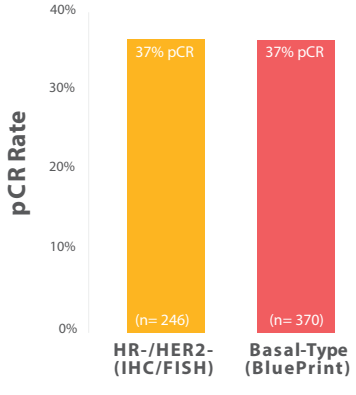
Clinical Characteristics	Genomic Results
31-year-old patient	BluePrint® Basal-Type
1.8 cm tumor	MammaPrint® High Risk
ER+ 90%, PR- via IHC	
HER2 negative via IHC and FISH	
Clinically node negative	
Grade 2	

**Patient going on 2-month long vacation and would like to postpone her cancer management if possible.*

Comparing Molecular and Pathological Subtypes







- The ER+/Basal phenotype is seen at all levels of ER/PR expression, not just in tumors with low HR staining[2]
- ER+ patients classified as Basal-Type have significantly worse outcomes than patients classified as Luminal A-Type[3]
- When ER+Basal-Type patients are treated with NAC, they respond to treatment similar to triple negative breast cancer patients[3]

1 Beatty, J., et al. Miami Breast Conference 2020.; 2 Whitworth, P., et al. . J Clin Oncol. 36, no. 15_suppl (May 20, 2018) 590-590.; 3 Whitworth, P., et al. Ann Surg Oncol (2014) 21: 3261–3267.

POST-OPERATIVE TR

"Reports indicate that only 40% to 60% of patients with breast cancer finish their recommended courses of hormonal therapy..."

– Hershman, D., et al. J Clin Oncol[1]

How do we make more informed endocrine therapy decisions?

Case Study: Patient Presents with HR+ Tumor[2]

Clinical Characteristics

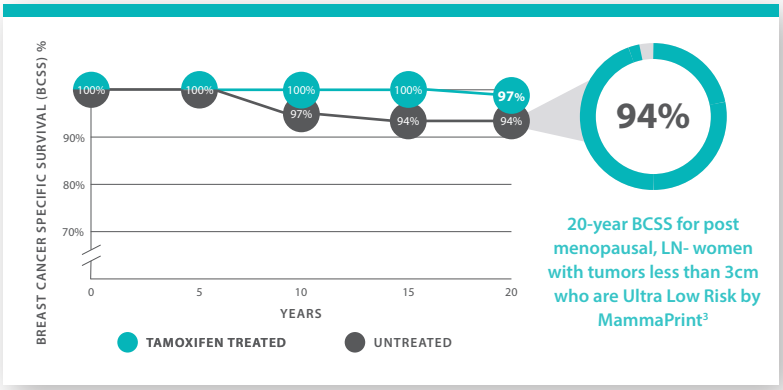
- 57-year-old patient
- 2.1 cm tumor
- ER+ 100%, PR+ 85% via IHC
- HER2 negative via IHC and FISH
- Clinically node negative
- Grade 1

Genomic Results

- BluePrint® Luminal A-Type
- MammaPrint® Ultra Low Risk

**Patient is struggling with side effects and would like to discontinue endocrine therapy.*

Prediction of Endocrine Therapy (ET) Benefit in MammaPrint Ultra Low Patients



20-year BCSS for post menopausal, LN- women with tumors less than 3cm who are Ultra Low Risk by MammaPrint[3]

- MammaPrint Ultra Low status identifies patients with extremely indolent cancers that are unlikely to recur[3]
- Data from several prospective trials demonstrate that patients with an Ultra Low MammaPrint status have excellent outcomes with little or no ET.[3-5]

1 Hershman, D., et al. J Clin Oncol. 28:4120-4128.; 2 Beatty, J., et al. Miami Breast Conference 2020.; 3 Esserman, L.J., et al. JAMA Oncol. 2017 Nov.; 4 Noordhoek, I., et. al, SABCS 2020, PS6-06.; 5 Opdam, M. et. al, ESMO Congress 2020, 171P

EATMENT PLANNING

MammaPrint is the only genomic test with prospective, randomized data for lymph node positive breast cancer patients.[1]

How do we help patients with node positive disease?

Case Study: Patient Presents with LN+ Breast Cancer

Clinical Characteristics
55-year-old patient
3 cm tumor
ER+ 90%, PR+ 90% via IHC
HER2 negative via IHC and FISH
Node positive
Grade 2

Genomic Results
BluePrint® Luminal A-Type
MammaPrint® Low Risk

MINDACT[1]

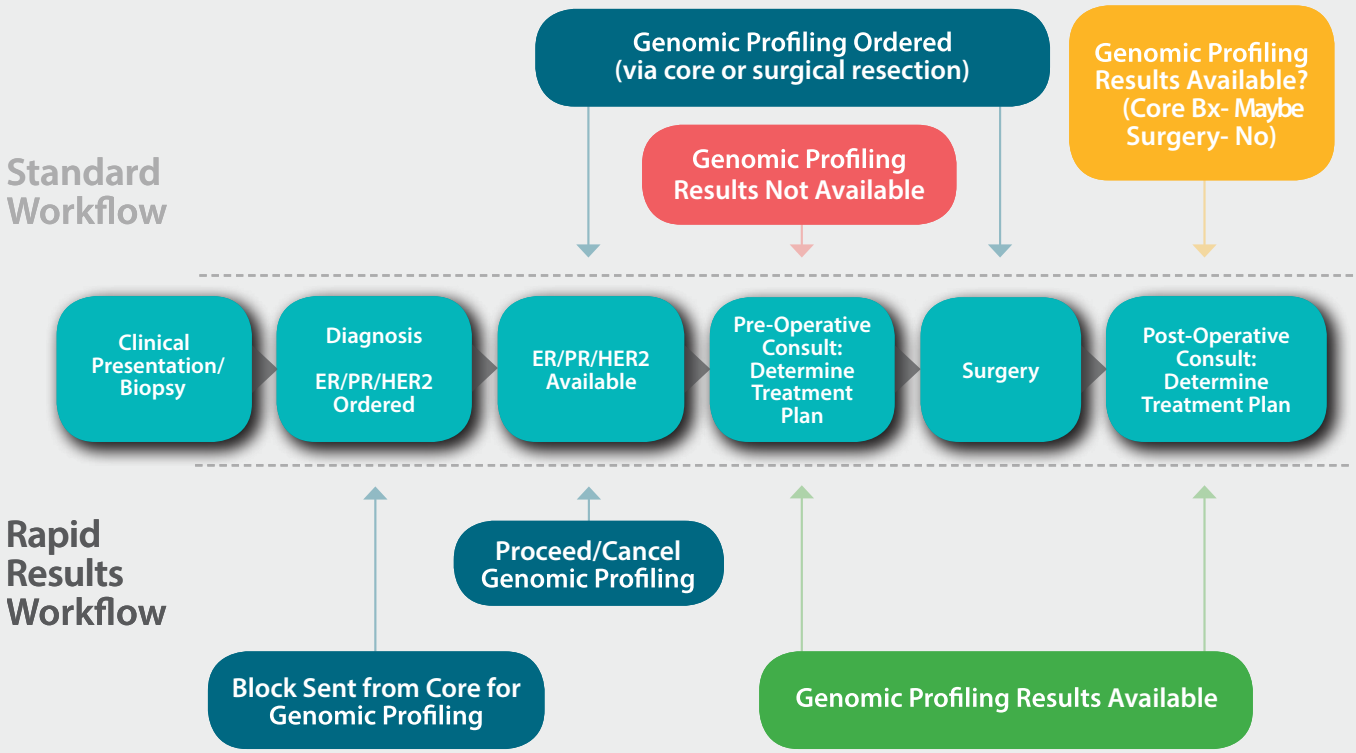
96%
5 year DMFS for clinically high risk, MammaPrint Low Risk patients with 1-3+ lymph nodes treated with endocrine therapy alone.

65%
of LN+ patients in MINDACT were MammaPrint Low Risk and had excellent outcomes without chemotherapy.

46%
of patients who would have received chemotherapy were able to avoid it with no impact on their outcomes

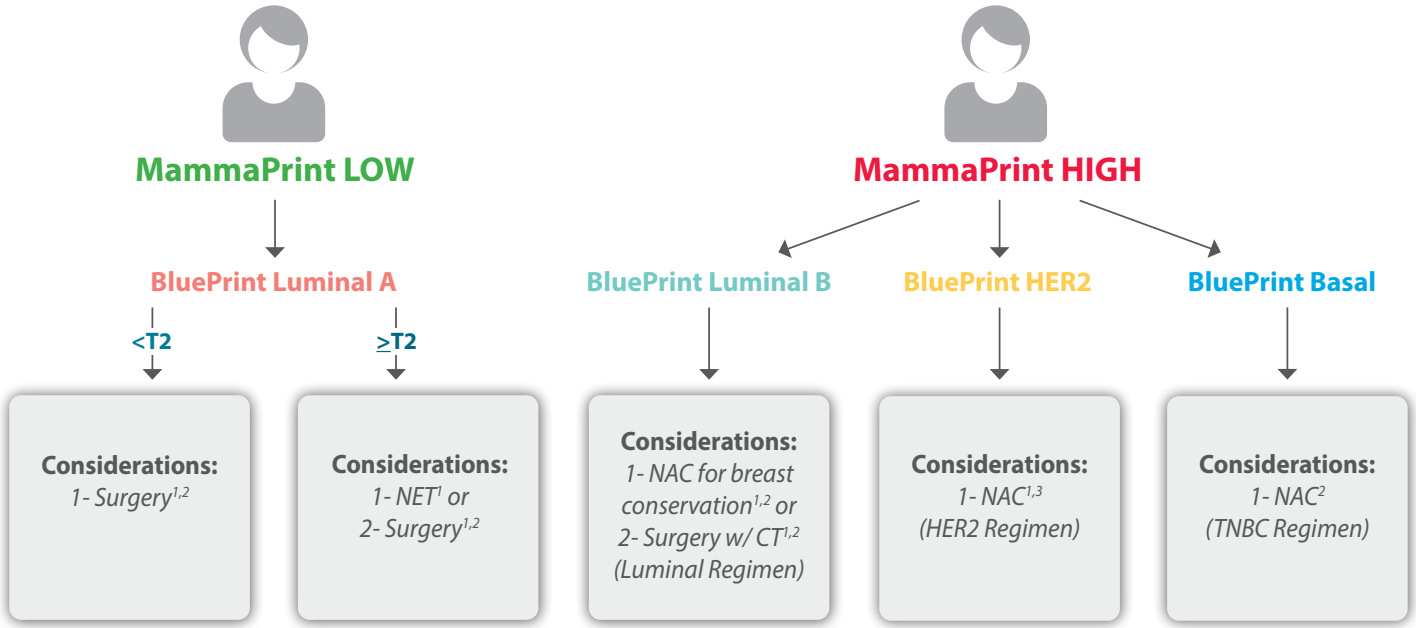
1 Cardoso, F., et al. N Engl J Med 2016;375:717-29,. doi: 10.1056/NEJMoa1602253, Supp. Appx, Figure S2

Optimizing the patient journey through effective testing processes



Pre-operative Treatment Algorithm Utilizing Agendia Results

For ER+ Early Stage Breast Cancer Patients



Abbreviations: NET- Neoadjuvant Endocrine Therapy; NAC= Neoadjuvant Chemotherapy; CT= Chemotherapy; TNBC= Triple Negative Breast Cancer

1 Whitworth, P., et al. Ann Surg Oncol (2017) 24: 669–675.; 2 Groenendijk, et al., npj Breast Cancer 5, 15 (2019).; 3 Beitsch, P., et al. Ann Surg Oncol. 2017 Sep;24(9):2539-2546.

Agendia works with insurance companies to ensure patients have access to genomic testing

REIMBURSEMENT

For patients in the US: We are dedicated to working with patients and their insurance plans to do all we can to help maximize their coverage.

- MammaPrint is reimbursed by most health plans in the USA and Puerto Rico, including Medicare.
- MammaPrint is the only risk of recurrence test approved by many BlueCross BlueShield plans for lymph node positive patients.
- If your patients have no insurance or thier health plan doesn't cover Agendia tests, they may be eligible for one of our financial support programs.

For patients outside of the US:

- MammaPrint and BluePrint are covered by selected public healthcare systems across the world, including several in Europe.
- To find out if MammaPrint and BluePrint are covered in your country, or for more information on the reimbursement status or private insurance options, please contact our customer care team at customercare@agendia.com.

MammaPrint + BluePrint integrate easily into diagnostic workups

Agendia's assays can be ordered on core biopsies or surgical specimens with results provided in as little as 5 days to inform pre- and post-operative treatment decisions.

DIAGNOSIS

Leverage the power of our comprehensive genomic profiling at the time of diagnosis

RESULTS

Obtain rapid results to improve time to treatment and multi-disciplinary treatment planning

TREATMENT PLANNING

Empower more informed patient care decisions to minimize under- and over-treatment

#EXPLORE THE 150

How to order

We're committed to ensuring easy access to our tests and the highest level of support for patients and their physicians.

Order online or by fax. Once you and your patient have decided that MammaPrint and BluePrint are right for her, tests can be ordered online or by fax:

https://agendia.secure.force.com/
Fax (844) 711-9132

Or contact our Customer Care team and they will gladly assist you:

customercare@agendia.com
Tel (888) 321-2732

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