AGENDIA WEBSITE COPY - PHASE 1

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Precision oncology
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Precision oncology

<H1>

We believe the fight against cancer is being won through precision oncology

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Breast cancer patients and their families deserve precision answers to help give them the longest and healthiest time together possible.

We bring precision oncology to routine clinical practice, with genomic tests that help patients and their physicians make the most informed and personalized treatment decisions. Who would benefit from chemotherapy? Who wouldn't?

In avoiding overtreatment, we spare thousands of cancer patients from unnecessary chemo, while reassuring those who need it that it's the right path for them.

<patient quote>

"I wanted a test that was going to tell me, yes you need chemo or no you don't. That's what I got with MammaPrint." Cari

<Our tests>

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Genomic tests

<H1>

We believe patients deserve definitive answers about their cancer

<body copy>

Our breast cancer tests analyze the genes in a patient's tumor to provide a unique insight that may help physicians assess the risk of cancer recurring.

Armed with this information, patients and their physicians can make informed, personalized treatment decisions with confidence.

Is this patient's cancer likely to come back? Is she likely to benefit from chemo? Or would she do just as well with other, less arduous therapies?

<patient quote>

"I want to choose chemo, not have chemo choose me. MammaPrint empowers you to know you have a choice." Angie

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Precision answers

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Our breast cancer tests, MammaPrint and BluePrint, can be run at the same time on the same tissue sample, and deliver clear 'low risk' or 'high risk' of recurrence results in less than ten days.

Both tests are designed for women of all ages, who are newly diagnosed with invasive early-stage breast cancer – stage I or II, with a tumor size up to 5cm, and either lymph node negative or 1-3 positive lymph node disease.

<data graphic>

More than 75,000 women have benefited from the peace of mind provided by MammaPrint.

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Best-in-class genomic testing

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Genomic and genetic testing sound similar but they analyze different things.

Genomic testing looks at specific genes in a tumor to find out what's driving its growth and behavior, whether a person's cancer is likely to come back, and which treatment will be most effective.

Genetic testing looks at the genes a person is born with to determine whether there's an inherited risk or hereditary predisposition for cancer, such as the BRCA gene.

MammaPrint is a genomic test that helps predict the risk of breast cancer recurring in the future. BluePrint is a genomic test that helps inform how a tumor may respond to chemotherapy.

<patient quote>

"MammaPrint gives me peace of mind, and has very likely saved my life." Nicole

Historically, physicians have relied on clinical and pathological factors - like patient age, tumor size, tumor grade, lymph node involvement, hormone receptor status, and HER2 status - to assess the risk of breast cancer coming back.

Our genomic tests look deeper. They analyze the genes of a tumor itself to uncover its unique biology, and to specifically examine those genes most associated with cancer recurrence.

Combining clinical, pathological, and genomic information about a patient's tumor gives a clear picture from which she and her physician can make more informed, more confident treatment decisions.

<data graphic>

The MINDACT study[1] found that 46% of patients who were identified as high risk for recurrence based on clinical and pathological factors alone (and therefore usual candidates for chemotherapy) were in fact classified as genomic low risk according to MammaPrint results and not likely to benefit from chemo.

<scientist testimonial>

"By looking at the genes, we get a far deeper insight into the biology of a breast tumor, so we can make much better predictions as to how that tumor is going to respond to therapy, and whether it needs therapy to begin with." Prof René Bernards

[1]Cardoso F, van't Veer LJ, Bogaerts J, et al. 70-Gene Signature as an Aid to Treatment Decisions in Early-Stage Breast Cancer. *N Engl J Med*. 2016; 375(8):717-29

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MammaPrint

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We believe that, when it comes to cancer, “maybe” is not an answer

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MammaPrint®

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A test to predict risk of cancer recurrence

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MammaPrint is a genomic test that examines the 70 most important genes associated with breast cancer recurrence - more than any other test.

It’s the first and only test of its kind that gives a definitive ‘low risk’ or ‘high risk’ result for cancer coming back. Unlike other tests, there’s no ‘intermediate’ score and no ambiguity.

This element of clarity helps both patients and their physicians make the most informed and confident treatment decisions.

MammaPrint is also the only test of its kind that’s both CE-marked (Europe) and FDA-cleared (US) for women of all ages. It is validated by a wealth of data and supported by the highest level of evidence from a landmark randomized, prospective, phase III clinical trial known as MINDACT.

<HCP testimonial>

“The results come back cut and dried, it’s very black and white. You’re going to have either a high risk or a low risk result. I think that’s very important.” Dr Samira Khera, MD

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An end to overtreatment and undertreatment

<body copy>

In the MINDACT study[1] [link to published trials page], MammaPrint identified that 46% of women who would usually have been classified as high risk for recurrence, and therefore candidates for chemotherapy, were actually found low risk when tested using MammaPrint and would see no significant benefit from chemo.

Applied on a global scale, this amounts to more than 600,000 women who could potentially avoid the toxicity and side effects of unnecessary chemo.

This could save global healthcare systems some 4.7 billion US dollars (4 billion euro[2]) a year in chemotherapy costs.

Around 75% of patients with the most commonly diagnosed breast cancer (ER+, HER2-) are genomically low risk and will receive no significant benefit from chemotherapy.[1] Without MammaPrint, many of these patients may be wrongly deemed clinically high risk and advised treatment they don't need.

<data graphic>

MINDACT found that clinically high risk patients reclassified by MammaPrint as low risk had 95% five-year distant metastasis-free survival without chemo.[1]

[1]Cardoso F, van't Veer LJ, Bogaerts J, et al. 70-Gene Signature as an Aid to Treatment Decisions in Early-Stage Breast Cancer. *N Engl J Med*. 2016; 375(8):717-29
[2]Agendia's corporate profile pdf

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Recommended by prestigious guidelines

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MammaPrint is included in numerous clinical practice guidelines by world-recognized cancer care organizations. It is the only test endorsed (by ASCO) for lymph node-positive patients.

- American Society of Clinical Oncology (ASCO) [link to guidelines]
- St Gallen International Breast Cancer Consensus [link to guidelines]
- European Group on Tumor Markers (EGTM) [link to guidelines]
- German Gynecological Oncology Group (AGO) [link to guidelines]
- American Joint Committee on Cancer (AJJC) [link to guidelines]
- European Society of Medical Oncology (ESMO) [link to guidelines]
- National Borstkanker Overleg Nederland (NABON) [link to guidelines]

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MammaPrint test report

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A MammaPrint test report includes both a detailed results page and a summary page [link to sample summary page: http://www.agendia.com/media/June2017_LR-Luminal_A-Summary-Pages_PATIENT.pdf], which shows additional clinical information to help physicians explain and discuss a patient's results.

MammaPrint provides a definitive result – low risk or high risk - which correlates with probability of metastasis-free survival.

- **A low risk result** means that a patient has ~10% chance that her cancer will recur within 10 years without any additional treatment, either hormonal therapy or chemo.[1]

- **A high risk result** means that a patient has ~29% chance that her cancer will recur within 10 years without any additional treatment, either hormonal therapy or chemo.[1]

When combined with traditional risk factors, if a patient is classified as low risk by MammaPrint, endocrine therapy (e.g. tamoxifen) alone may be sufficient to further reduce her recurrence risk. Conversely, if a patient is found high risk by MammaPrint and has additional risk factors, she may benefit from more aggressive treatment including chemotherapy.

"I kept thinking maybe I'd made the wrong decision, maybe I should have had a mastectomy. MammaPrint allowed me to calm down, refer back to my results, and return to the faith I had in my treatment." Mary

<data graphic>

79% of physicians reported more confidence in their treatment recommendation after receiving MammaPrint results, as compared to other tests.[2]

[1]Personalized Medicine, November 1, 2013, Leonie JM Delahaye, Diederik Wehkamp, Arno N Floore, Rene Bernards, Laura J van't Veer1 & Annuska M Glas

[2]Tsai M, Lo S, Audeh W, et al. Association of 70-Gene Signature Assay Findings With Physicians' Treatment Guidance for Patients With Early Breast Cancer Classified as Intermediate Risk by the 21-Gene Assay. *JAMA Oncol*. 2018; 4(1):e173470

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BluePrint

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We believe every breast cancer patient deserves a treatment as unique as she is

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BluePrint®

<H3>

A test to predict likely tumor behavior

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BluePrint is a genomic test that analyzes 80 different genes to classify a breast cancer patient's tumor into four molecular subtypes: luminal A, luminal B, basal, or HER2.

Each subtype has marked differences in its aggressive nature, long-term outcome, and response to chemotherapy.

BluePrint helps physicians make decisions about a patient's specific treatment options, thereby personalizing her treatment.

<HCP testimonial>

"BluePrint is very important to us as clinicians because it's the new classification of breast cancer. It allows us to choose our targeted therapies, which are sometimes quite toxic, for the appropriate women that they will help." Dr John Link, MD

<body copy>

While traditional subtyping methods assess a tumor by looking at genetic copies or cell surface characteristics, BluePrint looks at a more comprehensive set of genes to see what's driving a tumor's behavior – known as its 'gene expression'.

In a 2013 study[2] by Glück *et al* [phase 2 link to 'Clinical trials'], adding BluePrint molecular subtyping to MammaPrint helped to improve prognostic estimation and choice of therapy versus traditional methods (i.e. IHC* and FISH† [links to pop-up definitions]).

21% of patients were reclassified as low risk luminal-type A and showed little, if any, benefit from chemotherapy.[2]

*IHC = immunohistochemistry

†FISH = fluorescence in situ hybridization

[1]Whitworth P, Stork-Sloots L, de Snoo F, et al. *Ann Surg Oncol* (2014) 21:3261-7

[2]Glück S, de Snoo F, Peeters J, Stork-Sloots L, Somlo G. Molecular subtyping of early-stage breast cancer identifies a group of patients who do not benefit from neoadjuvant chemotherapy. *Breast Cancer Res Treat*. 2013; 139(3):759-67

<patient quote>

"I knew this is about **my** *specific biology,* **my** *specific tumor, and this is the best way to treat it. The test gave me peace."* Anna

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How to order our tests

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We believe in empowering patients

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How to order our tests

<body copy>

Once a patient and her physician have decided that MammaPrint and BluePrint are right for her, the physician can place an order by submitting a test request form [link to order form].

For patients in the US, our doctor finder [link to tool] can help you find local centers offering our tests. You can also contact our customer care team [link to contact us page].

MammaPrint can be ordered alone, or in combination with BluePrint as a complementary test. BluePrint is not available independently.

If a patient has already had another type of genomic test, received an 'intermediate' result (which has been shown to be the case for 39% to 67% of patients[1,2]), and is dissatisfied with the ambiguous result, her physician can always order MammaPrint for more definitive answers.

<insert CTA boxes/buttons>

<patient quote>

"Before these tests were available, so many women would be overtreated or undertreated. Now having this profile of **my** *specific cancer that's unique to* **me***…well, it's so much better for women."* Mary

[1]Carlson JJ, Roth JA. The impact of the Oncotype Dx breast cancer assay in clinical practice: a systematic review and meta-analysis. Breast Cancer Res Treat. 2013; 141(1):13-22

[2]Sparano JA, Gray RJ, Makower DF, et al. Prospective Validation of a 21-Gene Expression Assay in Breast Cancer. N Engl J Med. 2015; 373(21):2005-14

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Reimbursement & financial support

<H1>

We believe patients shouldn't have to choose between bankruptcy and survival

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Our reimbursement coverage

<body copy>

In the US and Puerto Rico, Agendia is contracted with Medicare and many other large national and regional health plans, covering over 200 million lives.

If a patient has insurance, we'll bill her insurance company directly. Based on her benefit level, the insurance company may choose to pay a portion or all of the cost of the tests that we run. The patient may be responsible for any co-insurance, co-pay, or deductible expenditure per her health insurance plan.

For any questions about insurance coverage or the cost of our tests, please get in touch with one of our patient advocate teams:

- For the US, please contact us at billing@agendia.com [email link] or 888-363-7868.
- For Canada, Latin America, and Oceania, please contact us in the US at customercare@agendia.com [email link] or (+001) 888-321-2732.
- For Europe, Asia, or South Africa, please contact us in The Netherlands at customerservice@agendia.com [email link] or +31 20 462 1500.

If a patient has no insurance, or her health plan doesn't cover Agendia tests, she may be eligible for one of our financial support programs [link to financial support programs].

<patient quote>

"I called Agendia about my financials, and the person I spoke to was great. She answered all my questions, explained the process, and told me what the steps were." Angie

<H2>

Our financial support programs

<body copy>

We're pleased to offer comprehensive financial support to all eligible US patients and their families who encounter difficulties in affording the precision answers we deliver.

We have four programs to help reduce out-of-pocket costs:

- Uninsured patient assistance
- Indigent patient assistance
- Underinsured patient assistance
- Interest-free payment plans

To find out if you're eligible, please email billing@agendia.com [email link] or call 888-363-7868.

<Clinical trials>

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Clinical trials

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We believe in providing peace of mind

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Our published clinical trials

<body copy>

Over the past decade, we've carried out extensive clinical trials and research collaborations resulting in hundreds of publications that demonstrate the prognostic ability and clinical utility of MammaPrint and BluePrint.

Here are just some of our key trials and findings.

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MINDACT trial

<body copy>

MammaPrint is supported by the highest level of clinical evidence (level 1A) from MINDACT[1], a landmark independent trial published in the New England Journal of Medicine in 2016.

MINDACT stands for **M**icroarray **I**n **N**ode-negative (or 1-3 positive lymph node) **D**isease may **A**void **C**hemo**T**herapy. It is the only phase III, prospective, randomized, clinical study for a breast cancer recurrence test.

The trial investigates the clinical utility of MammaPrint, when compared to (or used in conjunction with) standard pathological criteria for the selection of patients unlikely to benefit from adjuvant chemotherapy.

Taking place from 2007 to 2011, the study involved 6,693 women, across 112 centers in nine countries, who had undergone surgery for early-stage breast cancer.

Participants were categorized as low or high risk for cancer recurrence in two ways: first, through analysis of tumor tissue using MammaPrint; and second, using Adjuvant! Online, a tool that calculates risk of breast cancer recurrence based on common clinicopathological factors (CPFs).

Patients characterized as low risk with both clinical and genomic assessments were spared chemotherapy, while patients characterized as high risk with both were advised chemotherapy. Those with discordant results were randomized to use either clinical or genomic (MammaPrint) risk evaluation to decide on chemotherapy treatment.

[1]Cardoso F, van't Veer LJ, Bogaerts J, et al. 70-Gene Signature as an Aid to Treatment Decisions in Early-Stage Breast Cancer. N Engl J Med. 2016; 375(8):717-29

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MINDACT findings

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MINDACT[1] found that 46% of patients who were identified as clinically high risk for recurrence (according to routine assessment), and who therefore would be usual candidates for adjuvant chemotherapy, were in fact classified as genomic low risk (according to MammaPrint results) and not likely to benefit from chemo.

Furthermore, the trial showed that those clinically high risk patients who were reclassified by MammaPrint as genomic low risk had 95% five-year distant metastasis-free survival (DMFS) without chemo.

It also found patients with 1-3 affected lymph nodes (again, clinically high risk but reclassified by MammaPrint as genomic low risk) had five-year survival of 96% without chemo.

[1]Cardoso F, van't Veer LJ, Bogaerts J, et al. 70-Gene Signature as an Aid to Treatment Decisions in Early-Stage Breast Cancer. N Engl J Med. 2016; 375(8):717-29

Learn more about the MINDACT study >
[link to download]

<patient quote>

"Chemo is toxic, but I was fine with it **as long as** *I knew it was going to help me. With MammaPrint, I had the science to back me up."* Margot

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PROMIS trial

<body copy>

In 2015, PROMIS[1] (**Pro**spective Study of **M**ammaPrint in Breast Cancer Patients With an **I**ntermediate Recurrence **S**core) evaluated 840 patients with early-stage breast cancer who had received an 'intermediate'

recurrence result from a 21-gene genomic test. The aim was to assess the change in physician treatment decisions before versus after receiving a MammaPrint result.

MammaPrint reclassified the intermediate patients as low risk in 44.5% of cases and high risk in 55.5% of cases, and this was associated with a significant change in adjuvant treatment.

When analyzing the subgroup of 368 patients for whom the original treatment recommendation (based on the intermediate result) conflicted with that indicated by MammaPrint, 75.8% of patients had their treatment plan changed, with chemotherapy either added or removed.

The study's authors concluded that MammaPrint provides clinically actionable information on patients classified as intermediate risk by the 21-gene test, and that physicians may consider ordering MammaPrint to help with treatment decisions for these patients.

Furthermore, in 78.6% of cases, physicians reported greater confidence in their treatment recommendation based on MammaPrint results.

[1]Tsai M, Lo S, Audeh W, et al. Association of 70-Gene Signature Assay Findings With Physicians' Treatment Guidance for Patients With Early Breast Cancer Classified as Intermediate Risk by the 21-Gene Assay. JAMA Oncol. 2018; 4(1):e173470

Learn more about the PROMIS study >
[link to download]

<patient quote>

"I scored lower-intermediate with a 21-gene test. I would have liked something clearer." Liz

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Late Recurrence (20yr) Low Risk result

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In a study[1] published in 2017, MammaPrint was used to analyze 652 patient samples with 20-year follow-up data from the prospective, randomized Stockholm Tamoxifen Trial.

It demonstrated that MammaPrint's late recurrence (20yr) low risk result could identify a sub-group of patients with exceedingly low risk of cancer recurrence 20 years after diagnosis. These patients, most of whom received only two years of hormonal therapy, had an observed 20-year breast cancer specific survival of 97%.

This information is helpful to physicians in deciding whether to recommend extended, standard, or limited hormone therapy for some patients. It gives both physicians and their patients more options for better treatment and management of the disease.

[1]Esserman LJ, Yau C, Thompson CK, et al. Use of Molecular Tools to Identify Patients With Indolent Breast Cancers With Ultralow Risk Over 2 Decades. JAMA Oncol. 2017; 3(11):1503-1510

Learn more about the Late Recurrence (20yr) Low Risk result >
[link to download]

"I trusted the MammaPrint test. Even if my results came back high risk, at least there was no maybe, no mystery." Margaret

Go to our new and ongoing studies >
[link]

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Our ongoing studies

<H1>

We believe that precision oncology saves lives

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Our new and ongoing studies

<body copy>

As one of the world's leaders in precision oncology, we're constantly driving innovation with challenging new studies on genomics and genomic testing.

These are just some of the clinical trials that we're involved with right now.

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I-SPY2 trial

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We're proud to be part of the groundbreaking I-SPY2 trial, which looks at neoadjuvant treatment for locally advanced breast cancer.

Findings so far support the use of residual cancer burden (RCB) as a prognostic indicator for long-term outcomes in patients pre-selected as high risk for recurrence, and the importance of MammaPrint in identifying these patients.

The trial also shows the role of MammaPrint in achieving international cost savings, and in adding to the limited evidence available for younger breast cancer patients.

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I-SPY2: a next-gen adaptive platform

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I-SPY2 breaks from the traditional randomized form of trial, employing an 'adaptive' model that allows multiple treatments (up to five different agents) to be studied in parallel. This master framework also allows new agents to

enter and leave the study without having to halt enrollment or resubmit the entire clinical trial protocol for regulatory review.

I-SPY2's innovative design sets a new benchmark for efficiency in phase II clinical trials, by minimizing the number of participants and time required to evaluate each experimental agent.

Widely regarded as a pioneer of the 'platform' trial, I-SPY2 is a major influence on the development of next-generation trial designs in oncology and beyond.

Learn more about I-SPY2 >
[link to download]

"Chemo or no chemo is one of the biggest topics of conversation in our Facebook group." Stephany

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FLEX Registry

<body copy>

We're excited to have launched a new ten-year clinical trial, known as the FLEX Registry - MammaPrint, BluePrint, and **F**ull-genome Data **L**inked with Clinical Data to Evaluate New Gene **Ex**pression Profiles: An Adaptable Registry.

At full registration, FLEX will involve some 2,000 patients in the US – both men and women – with stage I to III breast cancer who have received MammaPrint and BluePrint testing on a primary breast tumor.

Launched in 2017, the study is being implemented as a large-scale, population-based, prospective registry of full genome expression data, as well as clinical data, to investigate new gene associations with prognostic and/or predictive value.

FLEX's infrastructure will be shared to enable researchers to examine smaller groups of interest and generate hypotheses for targeted sub-studies, which can be added throughout the duration of the trial.

Learn more about the FLEX Registry >
[link to download]

<patient quote>

"To be in the gray zone is the worst - to have chemo, the whole time thinking, do I really need this?" Susan

<H2>

Horizon 2020

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We're thrilled to have received funding of €4 million from Horizon 2020, the biggest research and innovation program in the European Union.

We're using our grant to fund a three-year project whose goal is to achieve final evidence for the clinical utility of MammaPrint.

Our objective is to meet the reimbursement requirements in each targeted market and thereby gain comprehensive uptake by international clinical guidelines and reimbursement bodies. As a result, many more breast cancer patients will potentially have access to the MammaPrint test.

Learn more about our Horizon 2020 project >
[link to Horizon 2020 page]

<see separate doc for Horizon 2020 copy>

Go to our published clinical trials >
[link]

<About us>

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About us

H1>

We believe it's our collective responsibility to deliver precision oncology

<body copy>

We believe in a world where cancer has lost its power to terrify.

We believe that every cancer patient deserves answers - definitive answers - that can confidently lead them to the best treatment decisions.

We believe that using state-of-the-art precision oncology tools can help guide physicians to make the best and most personalized treatment decisions for their patients.

We believe it is the collective responsibility of every stakeholder in the cancer-care ecosystem to deliver precision oncology so we can minimize suffering for every cancer patient to enable them to live the longest and healthiest life possible.

<patient quote>

"I highly recommend MammaPrint. Everyone is scared, and says 'Doctor, give me all the treatment'. But you might go through treatment you don't need, when in fact you have many options." Julieta

<H2>

Our story so far

<body copy>

Agendia was founded in 2003 as a spin-out of the Netherlands Cancer Institute in Amsterdam – our focus to improve quality of life for cancer patients through a suite of genomic tests, while also helping to lower costs to the healthcare system.

We launched our flagship test, MammaPrint, in Europe in 2004 and in the US in 2007. It became the first IVDMIA* [link to pop-up definition] to gain 510(k) clearance from the FDA† [link], and has since received six additional FDA clearances.

In 2008, the Dutch Institute CBO Guidelines selected MammaPrint to be included for breast cancer treatment, followed a year later by the St Gallen's International Oncology Guidelines. MammaPrint now features in six major global guidelines.

We introduced our second test, BluePrint, in 2010. This was supported in 2013 by the Glück et al study[1], which showed BluePrint to have better prognostic accuracy than traditional subtyping methods (i.e. IHC[‡] [link] and FISH[§] [link]).

In 2016, the landmark MINDACT trial[2] published its results confirming MammaPrint's ability to reclassify patients as high or low risk for cancer recurrence, and to help physicians and patients make more informed treatment decisions.

In 2018, MammaPrint and BluePrint attained the CE mark, which allows cancer centers across Europe to run the tests in their own labs using their existing next-generation sequencing (NGS) instruments.

Today, both our tests have a broad and growing global customer base, including many major hospitals and clinical institutions.

<Patient quote>

"I was thinking, oh no, chemo will make me so sick, I won't be able to work, I have to work! My test result came back low risk. It was a gift." Lisa

*IVDMIA = *in vitro* diagnostic multivariate index assay
[†]FDA = Food & Drug Administration (US)
[‡]IHC = immunohistochemistry
[§]FISH = fluorescence in situ hybridization

[1]Glück S, Snoo FD, Peeters J, Stork-Sloots L, Somlo G. Molecular subtyping of early-stage breast cancer identifies a group of patients who do not benefit from neoadjuvant chemotherapy. *Breast Cancer Res Treat*. 2013;139(3):759-767
[2]Cardoso F, van't Veer LJ, Bogaerts J, et al. 70-Gene Signature as an Aid to Treatment Decisions in Early-Stage Breast Cancer. *N Engl J Med*. 2016; 375(8):717-29

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Our vision for the future

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We have an exciting pipeline of other genomic products in development, which include additional predictive signatures for breast cancer, as well as full genome analysis. These feature 'big data' population health management opportunities, based on a growing data set of 30,000 patients.

Having recently launched our NGS solution in Europe, we plan to expand this decentralized offering to a wider range of markets so that many more labs can use our tests in-house.

As for research, we collaborate with pharmaceutical companies, academic institutions, and some of the world's leading cancer centers to continue our studies in genomics and genomic testing. Right now, we're a critical partner in the ongoing I-SPY2 and FLEX Registry [links] trials.

<patient quote>

"My MammaPrint result was a great relief. So, when I declined chemo, my doctor agreed with my decision because she understood I was low risk for recurrence." Sandra