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Improving quality of life of patients with HER2-positive breast cancer: the DEFINITIVE trial

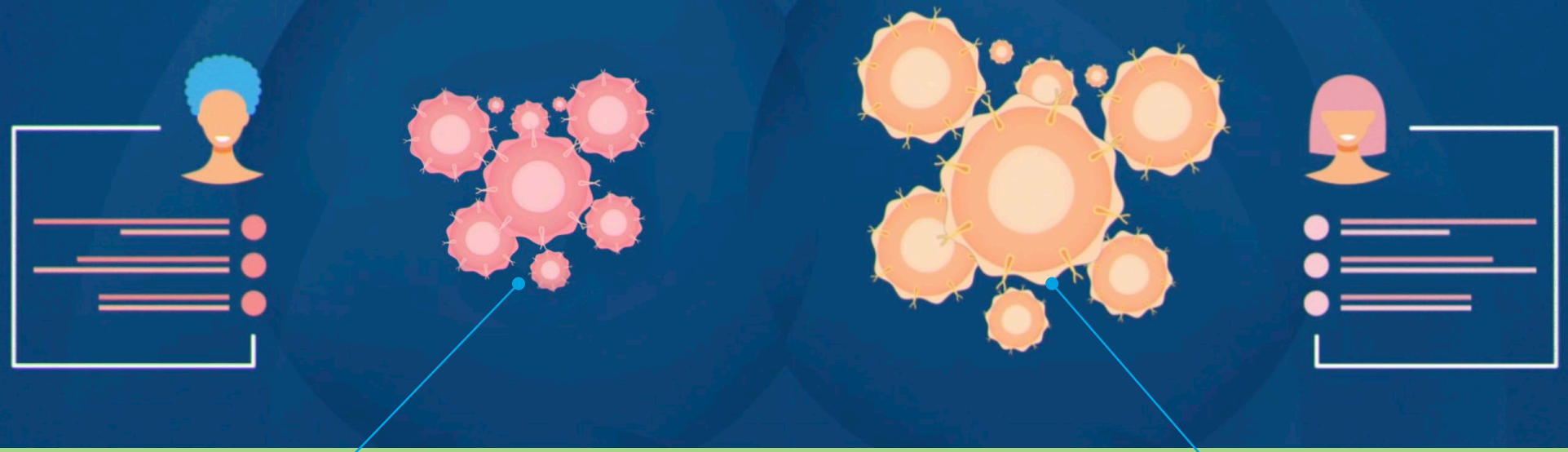
October 1st, 2026
Patricia Villagrasa, PhD
CEO & Co-Founder at REVEAL GENOMICS, S.L.

5 years Cancer Mission:
Stronger Through Connection

BRUSSELS
29 SEPTEMBER – 01 OCTOBER

5 years Cancer Mission:
Stronger Through Connection





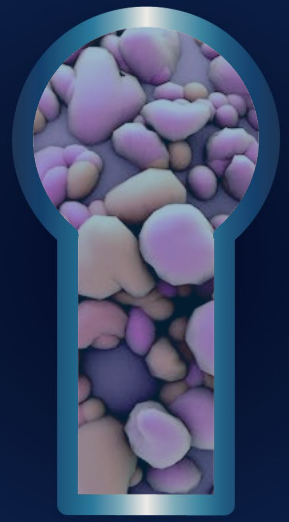
SMALL TUMOR

LARGE TUMOR

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There's no way to find out

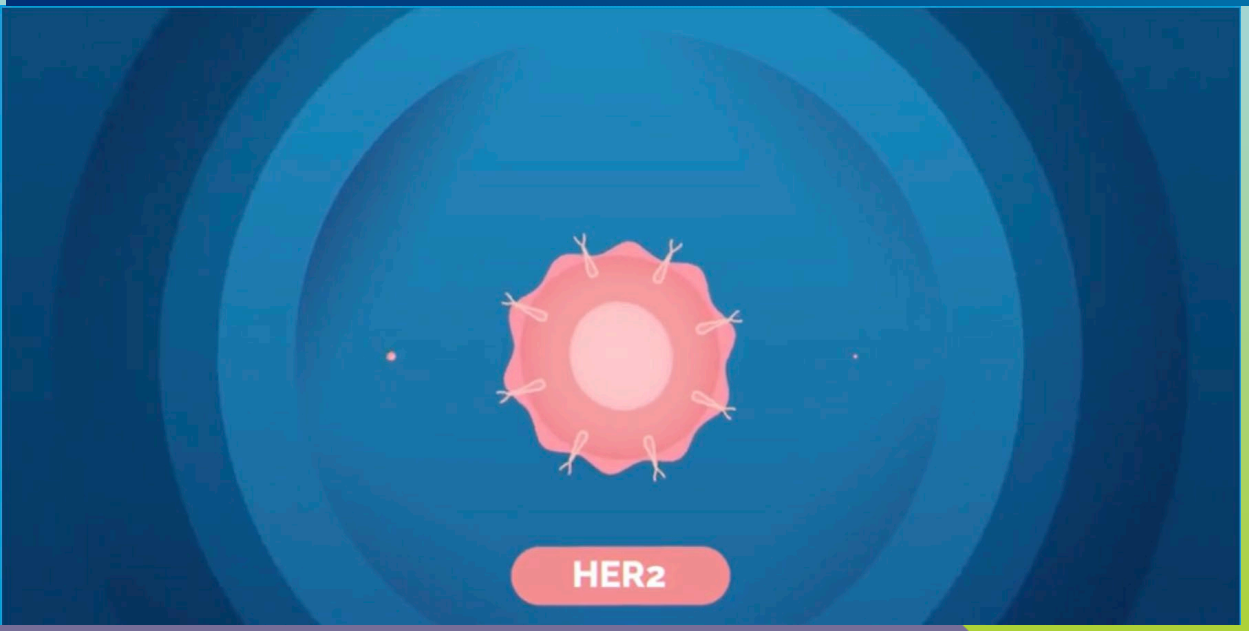


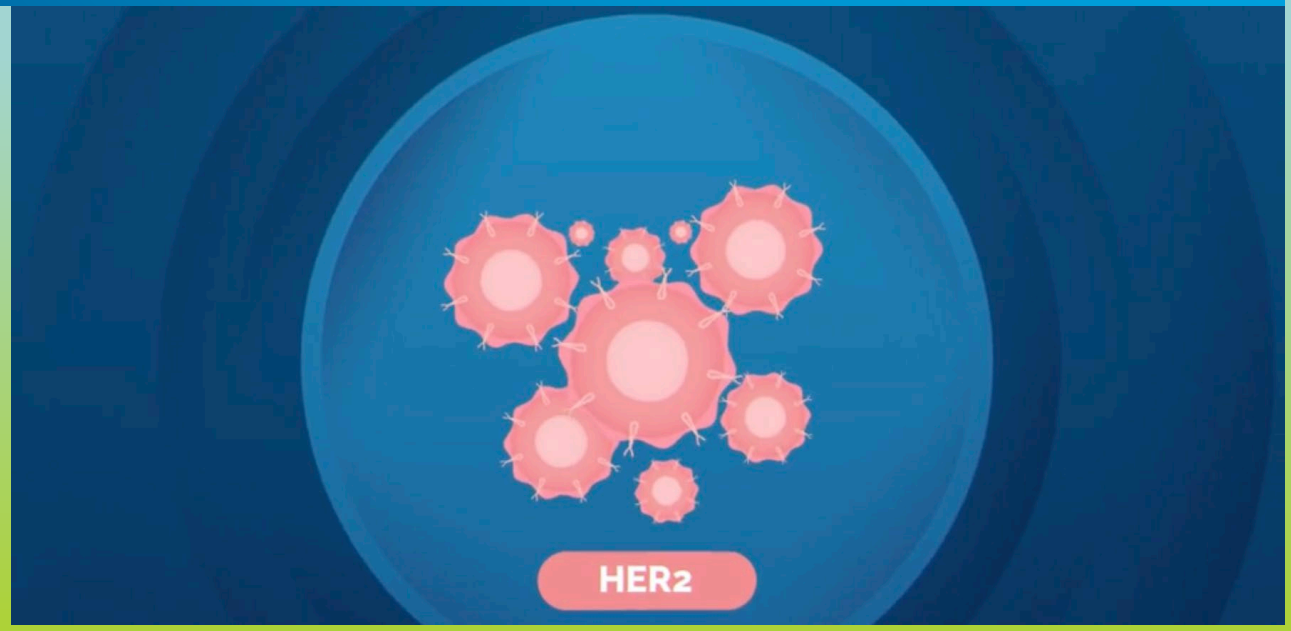
5 years Cancer Mission:
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400.000

patients a year





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Stronger Through Connection



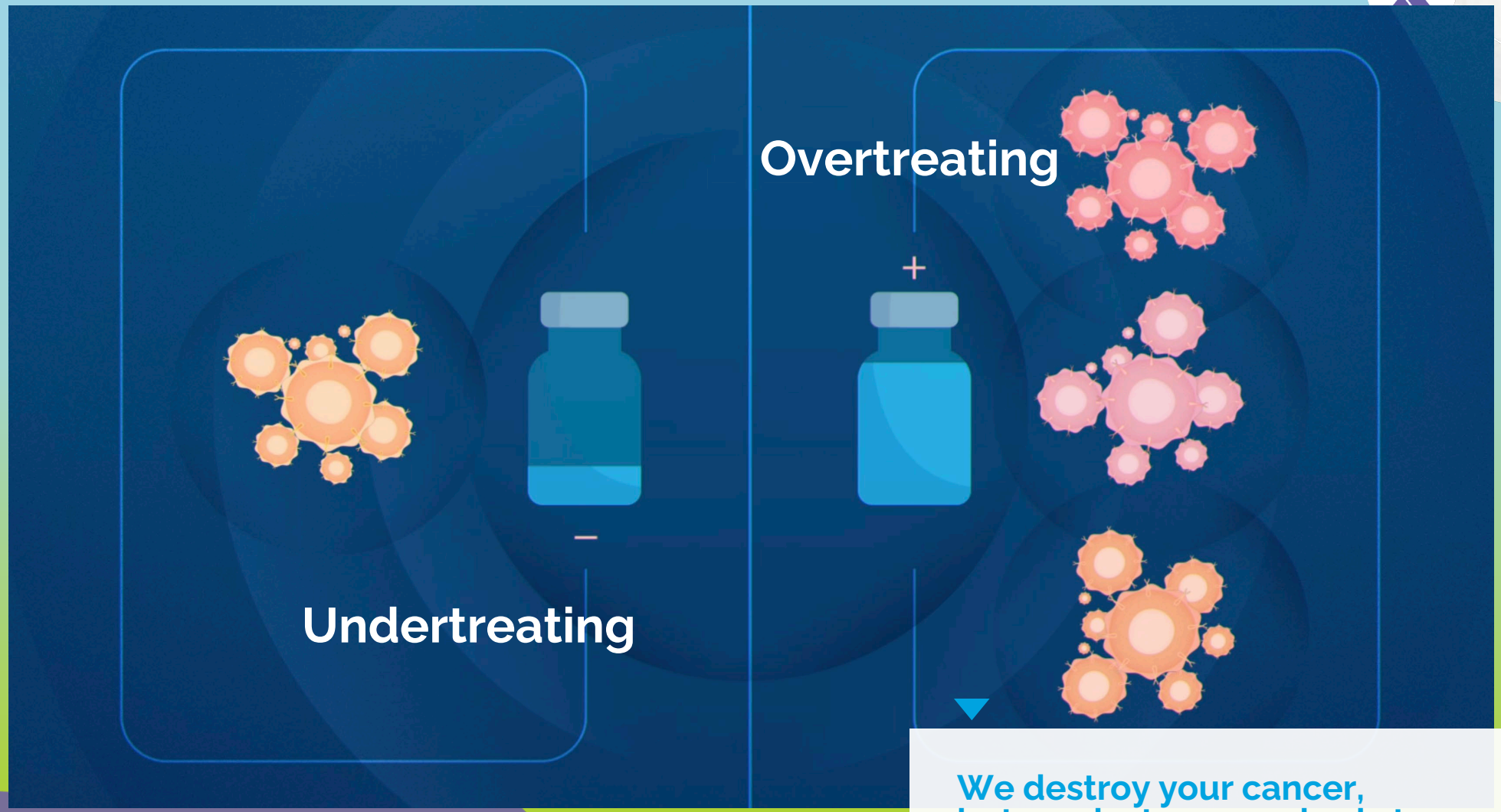


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5 years Cancer Mission:
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We destroy your cancer,
but we destroy your body too

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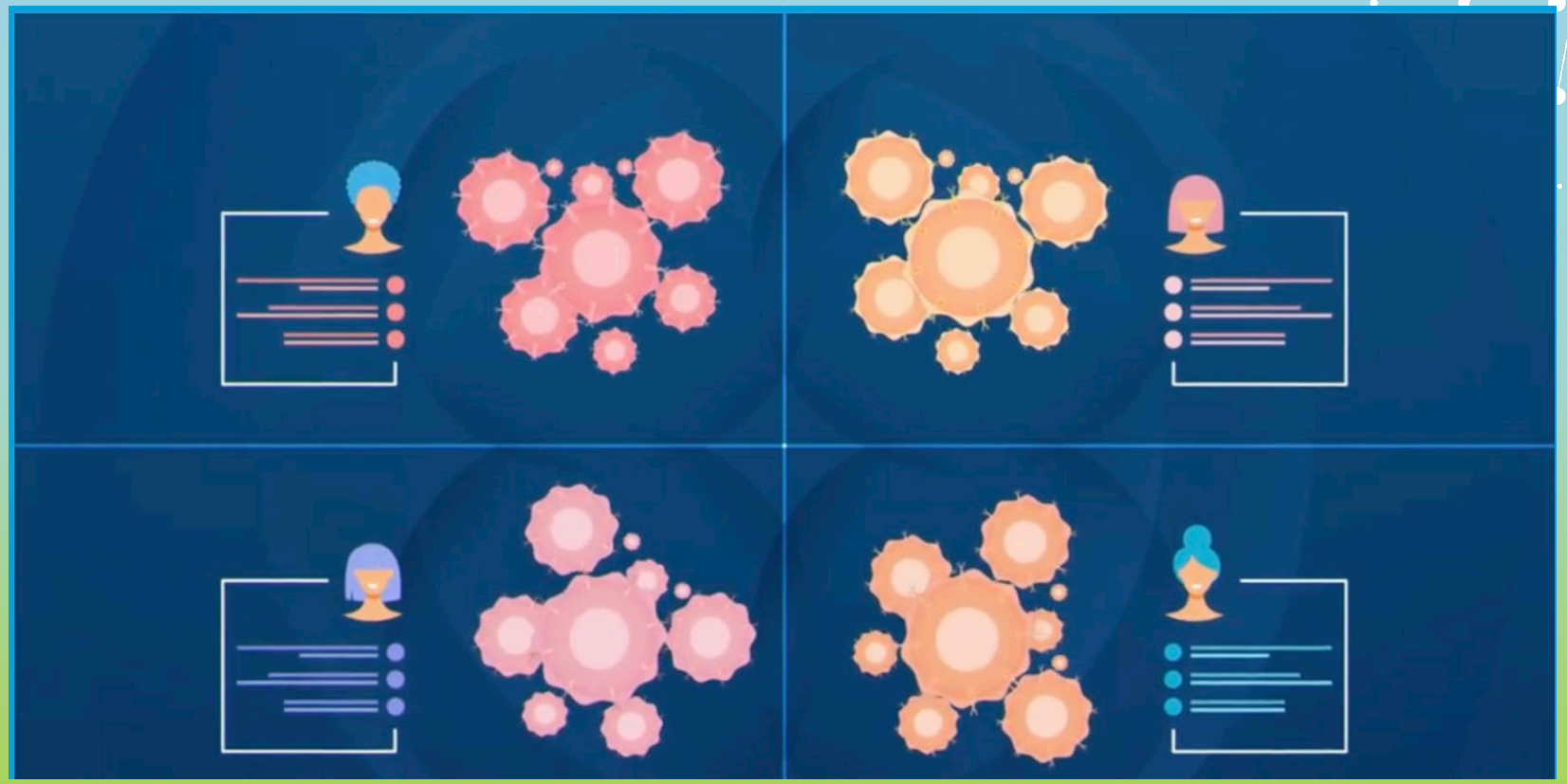
Bad news for the healthcare system!

The costs of wasted treatment

The costs of treating the new problems we've created



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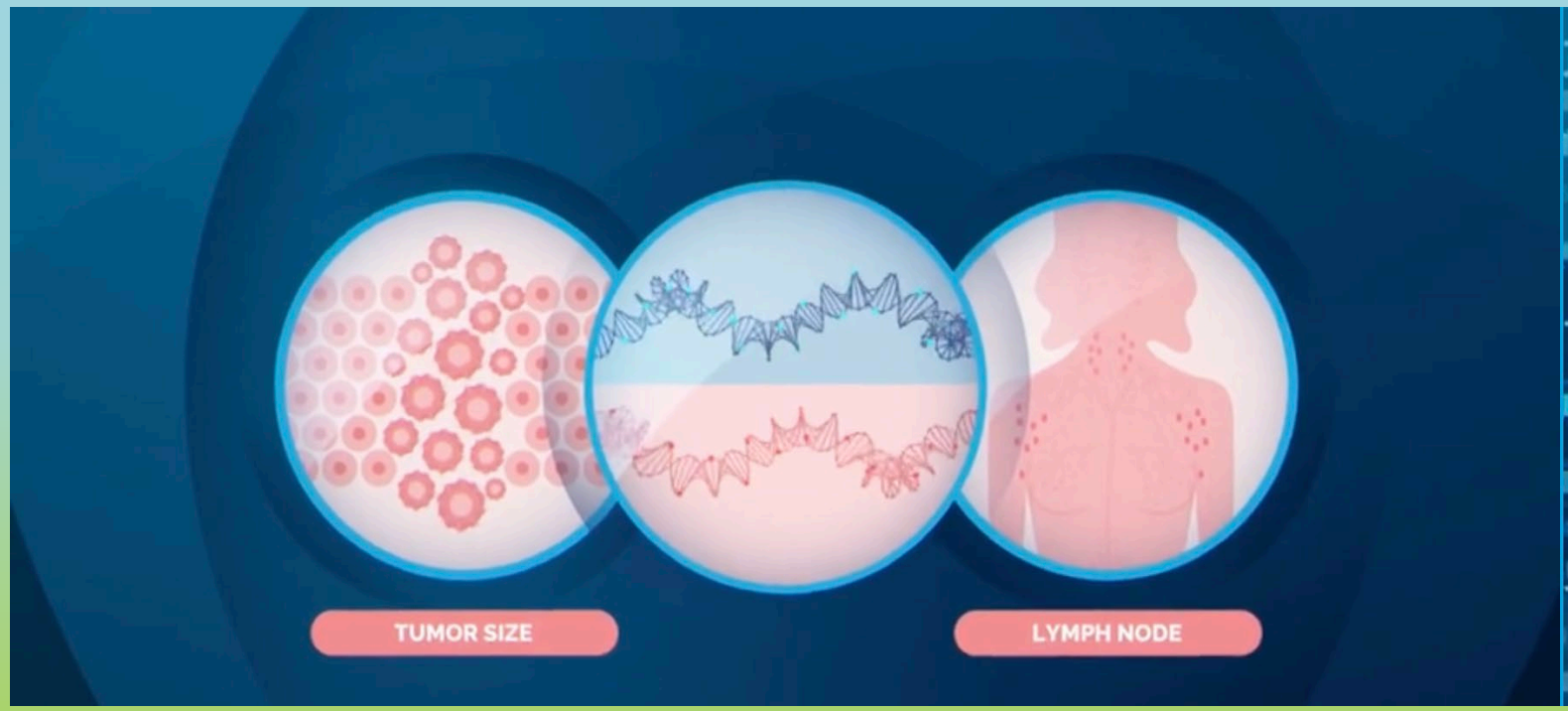
27 genes

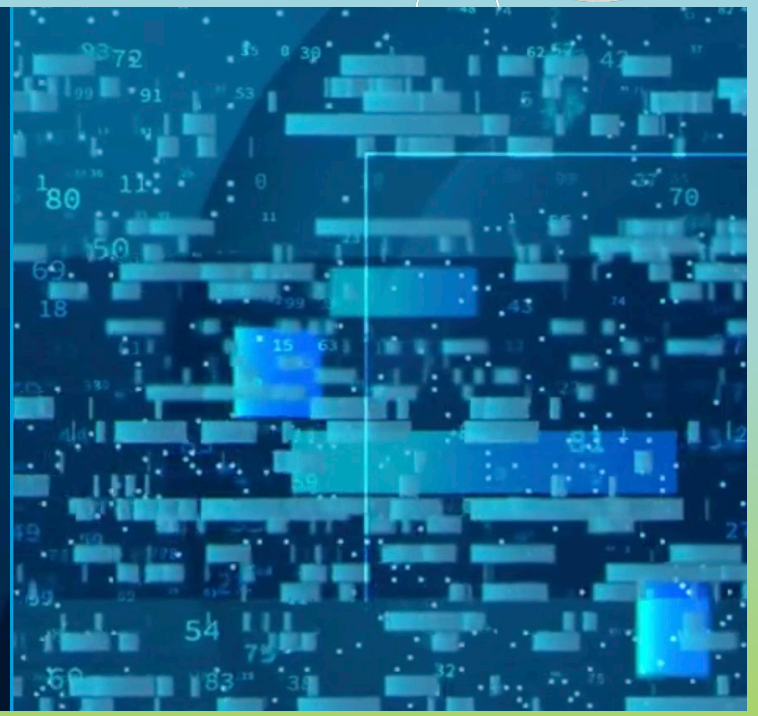
with 4 gene signatures:

- Immune activation
- Proliferation
- Luminal differentiation
- HER2 amplicon expression

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- **Validated in >5000 samples**
- **TIME 2022**
- **Included in the Spanish and German clinical guidelines**
- **Practice changing St Gallen guidelines**
- **Early adoption ex-EU**

> TO TRANSFORM BREAST CANCER TREATMENT

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41 sites in 7 countries





304 patients enrolled

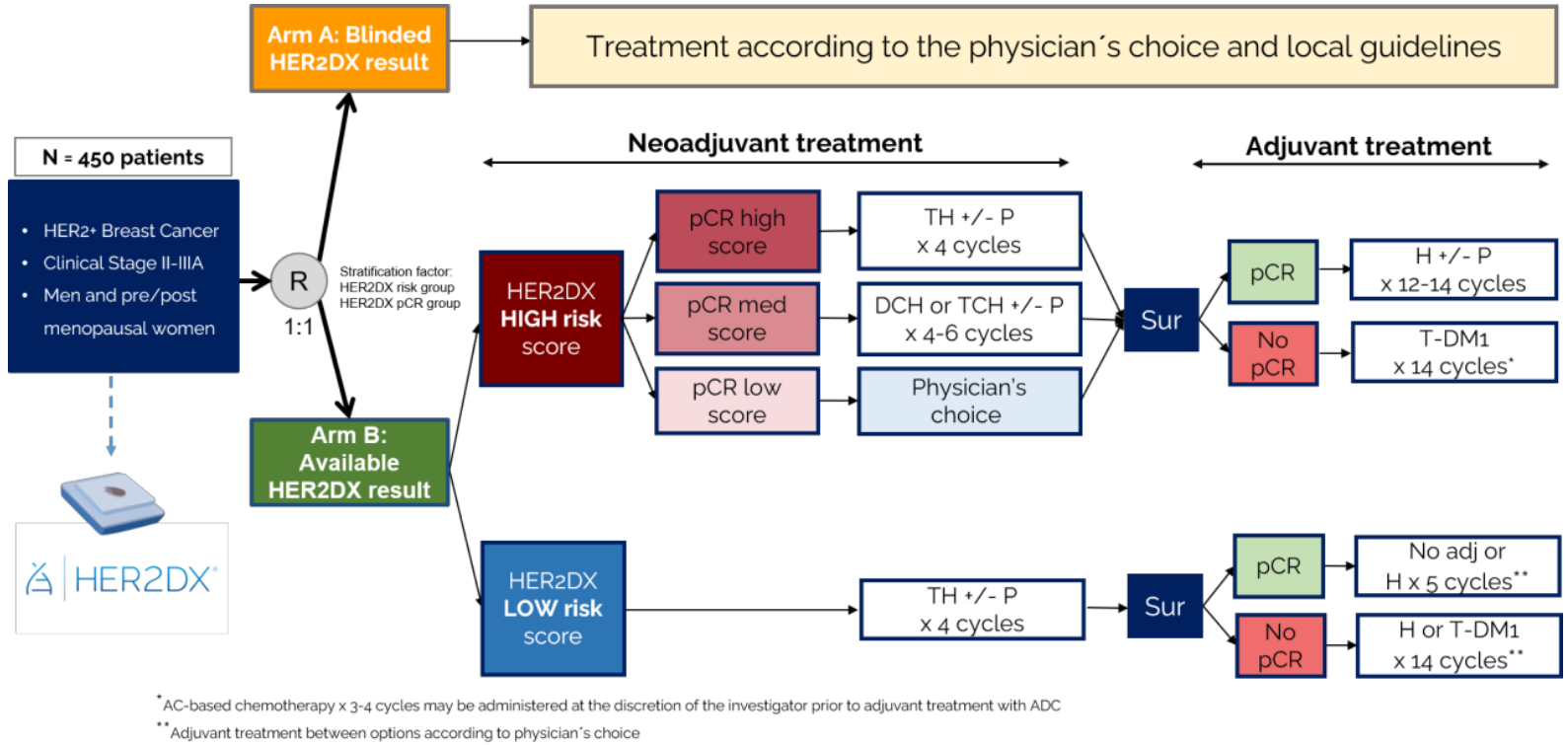
of 450 planned

Target expanded from 304 in protocol v3.0 (July 2026) to add pCR as a co-primary endpoint

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Trial design: can HER2DX safely de-escalate treatment?



AC: anthracyclines and cyclophosphamide; C: carboplatin; D: docetaxel; H: trastuzumab; P: pertuzumab; pCR: pathologic complete response; Sur: surgery; T: paclitaxel; T-DM1: trastuzumab emtansine.

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HER2DX Implementation roadmap

REVEAL GENOMICS

SIOG

Market analysis

Guidelines review and HER2DX inclusion

HTA analysis

Policy recommendations

ICO Institut Català d'Oncologia

Data analysis

MEDIZINISCHE UNIVERSITÄT WIEN

Trainings for professionals and patients

Sharing Progress in Cancer Care

EUROPA DONNA

Data collection

Patient inclusion

UCC

Università degli Studi di Padova

IEO

ABCSG

Istituto Oncologico Veneto I.R.C.C.S.

SHEBA Tel HaShomer City of Health

WSG

SOLTI

unicancer

Operational set up

Trial design

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What the next phase needs: one roadmap for Europe

Recommendations of the Cancer Mission Diagnostics Cluster, Policy Brief no. 1 (2026)

1

Harmonise approvals

Approved in one country, recognised in all.

2

Harmonise reimbursement

Reimbursed in one country, reimbursed in all.

3

Harmonise care

Every patient, wherever they live, gets the same cancer care.

Live longer. Live better.

Our contribution to the Cancer Mission goal of 3 million lives by 2030.

DEFINITIVE



Learn more at www.thedefinitivetrial.eu

Diagnostic HER2DX-guided treatment for patients with early-stage HER2-positive breast cancer

This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement No 101136953.

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Clínic Barcelona
REVEAL GENOMICS
SOLTI
EUROPA DONNA
Università degli Studi di Padova
IEO Istituto Europeo di Oncologia
SIOG
UCC
SHEBA Tel HaShomer City of Health
Medizinische Universität Wien
unicancer
WSG Women's Cancer Study Group
ICO Institut Català d'Oncologia
ABCSG Austrian Breast & Colorectal Cancer Study Group
Sharing Progress in Cancer Care
I.O.V. Istituto Oncologico Veneto I.R.C.C.S.
Erasmus