Red de Programas de Cribado de Cáncer

*XVIII Reunión Red cribado*
*Donostia, 27-29 mayo 2015*

# TERAPIAS PERSONALIZADAS EN CÁNCER DE MAMA: PLATAFORMAS GENÓMICAS

## Resultados implantación en la CAPV
## - Experiencia Gipuzkoa-

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# Tratamiento adyuvante del CM localizado

- Decisión terapéutica
  - Factores pronósticos (N, T, Grado, proliferación)
  - Factores predictivos de eficacia terapéutica
    - Receptor hormonal
    - HER2
  - Factores mixtos (RH, HER2)
- Luminal (RH+) (HER2-/HER2+)
- HER2+ (RH+/RH-)
- TN

# Tratamiento adyuvante del CM localizado

- **Luminal RH+/HER2 – (Luminal A, B)**
  - FP : Grado, tamaño, N, Proliferación, IVL
  - Base del tratamiento adyuvante: Hormonoterapia
  - ¿Quién necesita QT?
    - FP clasicos
      - N/N1mi vs N+
      - T (> 2 cm?, > 5 cm?...)
      - Grado 1,2 vs 3
    - Otros factores: plataformas genómicas

# Oncotype DX – mama 21-gene RS

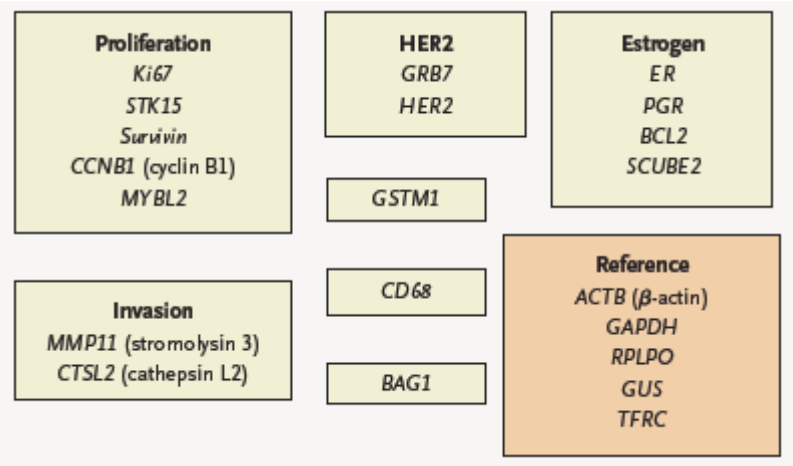
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## A Multigene Assay to Predict Recurrence of Tamoxifen-Treated, Node-Negative Breast Cancer

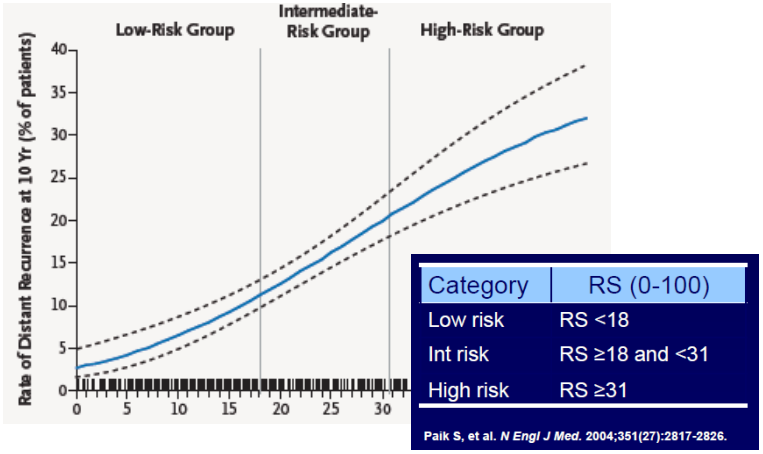
N Engl J Med 2004;351:2817-26.

onmyung Paik, M.D., Steven Shak, M.D., Gong Tang, Ph.D.,



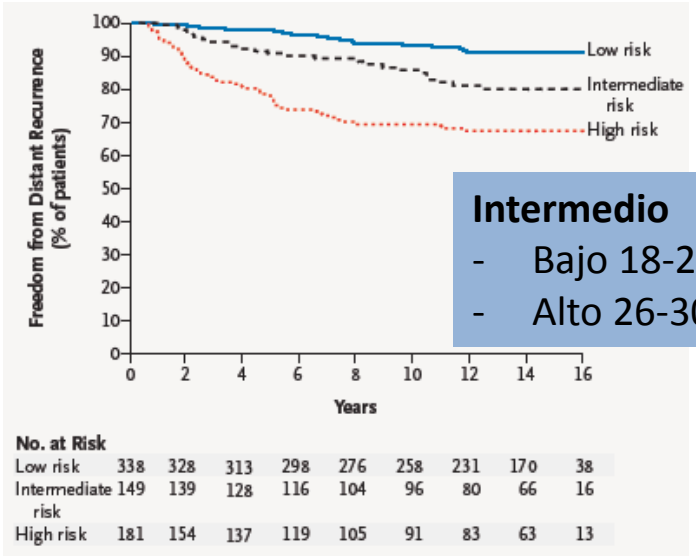

RS = + 0.47 x HER2 Group Score
- 0.34 x ER Group Score
+ 1.04 x Proliferation Group Score
+ 0.10 x Invasion Group Score
+ 0.05 x CD68
- 0.08 x GSTM1
- 0.07 x BAG1

NSABP 14 RE+/N0 TMX vs nada



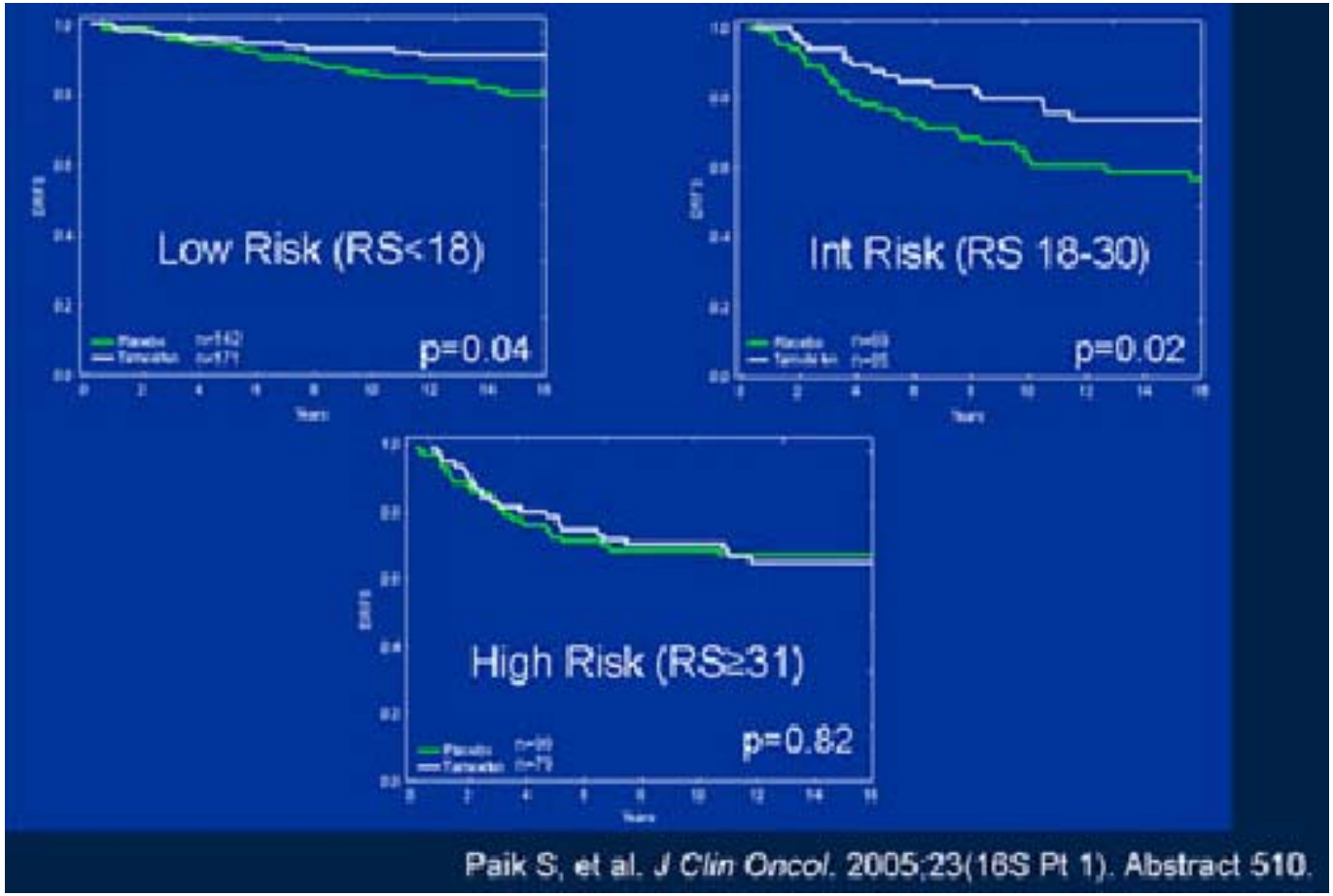

| Category | RS (0-100) |
|---|---|
| Low risk | RS <18 |
| Int risk | RS ≥18 and <31 |
| High risk | RS ≥31 |

Paik S, et al. *N Engl J Med.* 2004;351(27):2817-2826.

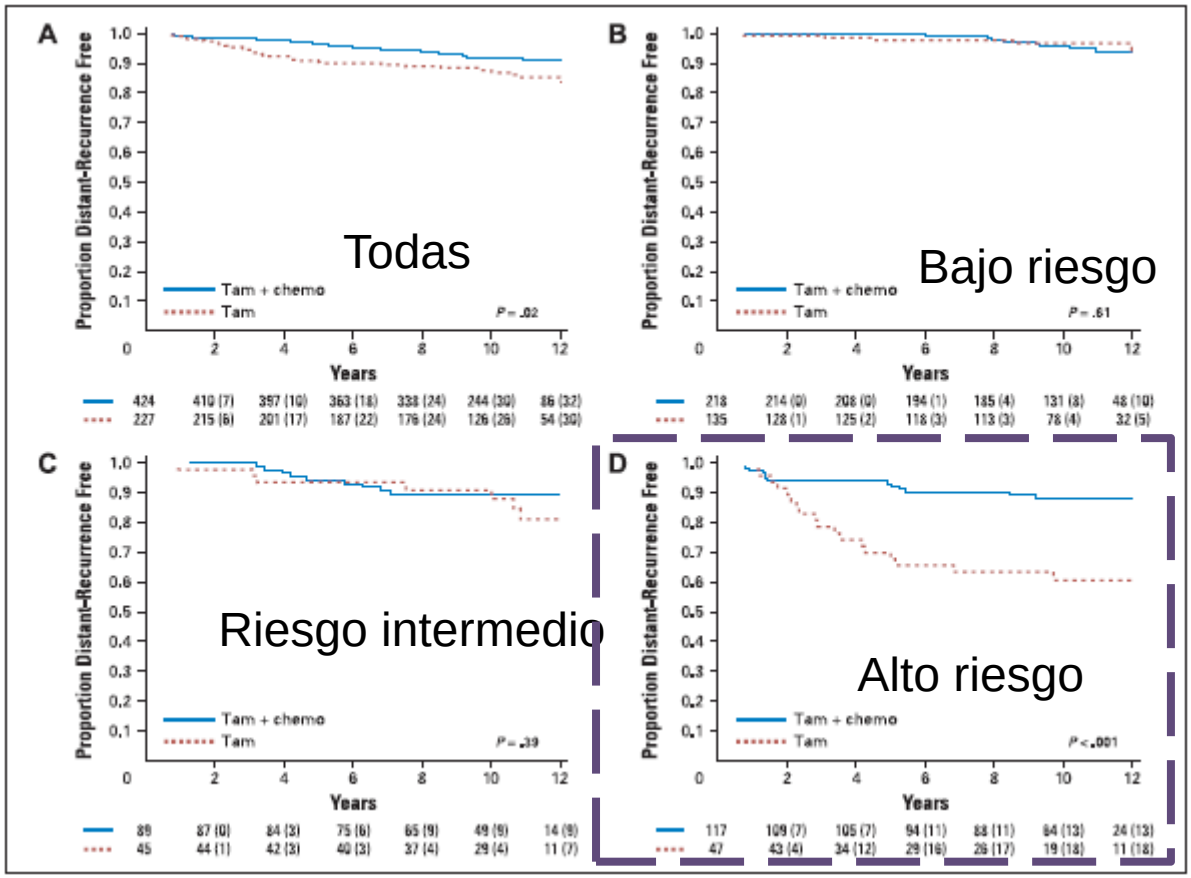



**Intermedio**
- Bajo 18-25
- Alto 26-30

# Oncotype DX- Beneficio de TMX (vs nada) (N0)

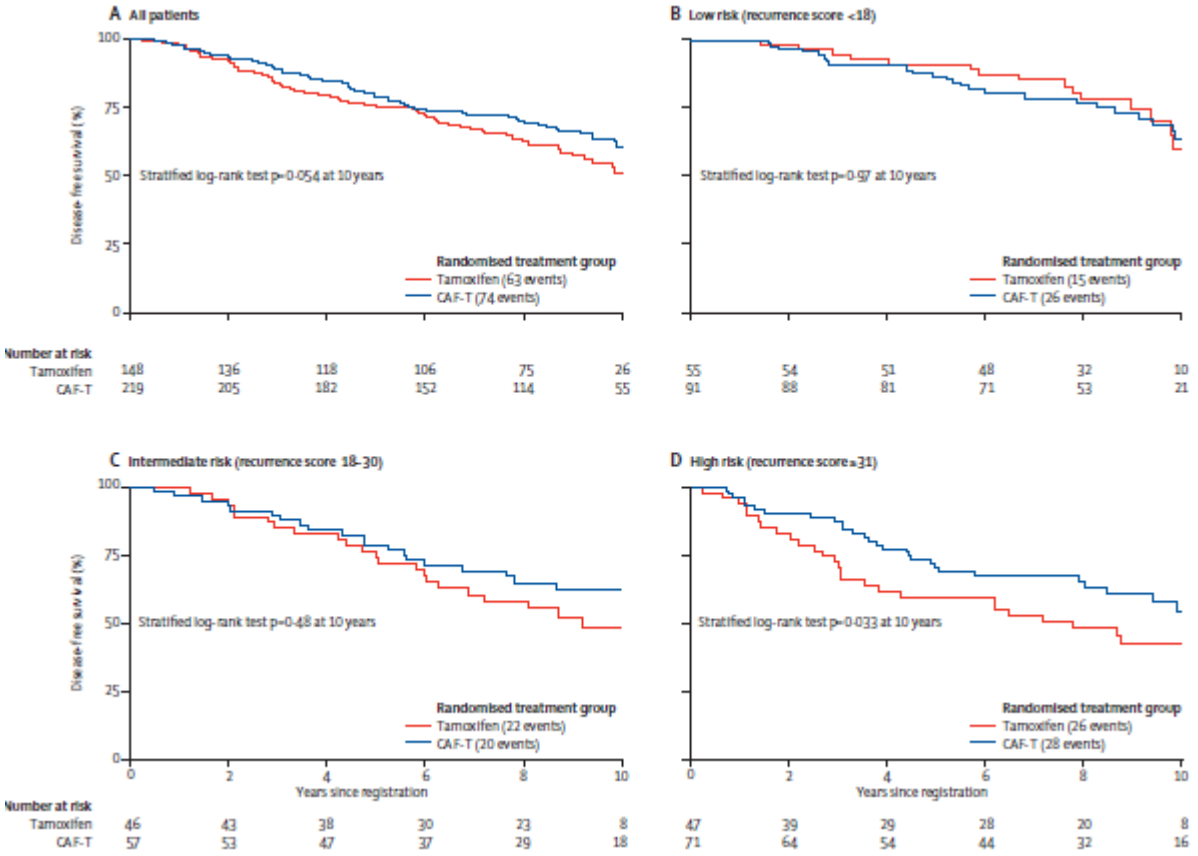


# Oncotype DX- Beneficio de QT
# NSABP B20 (TvsT+QT-CMFMF)(N0)



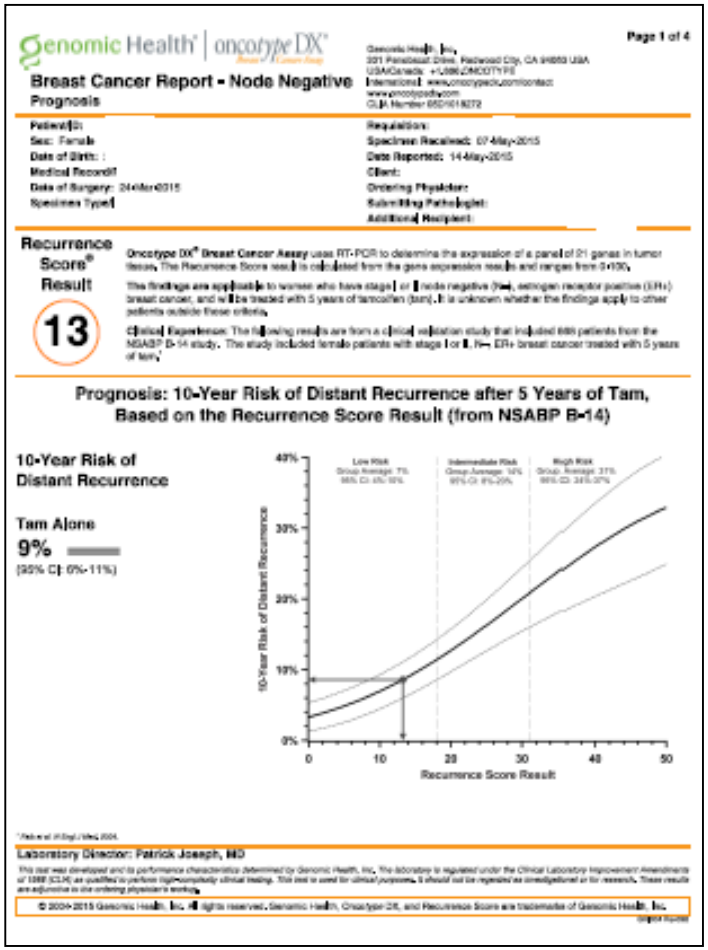

*Paik S. JCO 2006*

# Oncotype DX- Beneficio de QT
# SWOG 8814(TvsT+QT-FAC)(N+)




*Albain K Lancet Onc 2009*

# Oncotype DX – Informe de resultado - 1



Genomic Health | oncotype DX

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**Breast Cancer Report - Node Negative**
**Prognosis**

Genomic Health, Inc.
301 Penobscot Drive, Redwood City, CA 94063 USA
USA/Canada: +1.866.ONCOTYPE
International: www.oncotypedx.com/contact
www.oncotypedx.com
CLIA Number 05D1018272

Patient ID:
Sex: Female
Date of Birth:
Medical Record#
Date of Surgery: 24-Mar-2015
Specimen Type:

Requisition:
Specimen Received: 07-May-2015
Date Reported: 14-May-2015
Client:
Ordering Physician:
Submitting Pathologist:
Additional Recipient:

**Recurrence Score® Result**

**13**

**Oncotype DX® Breast Cancer Assay** uses RT-PCR to determine the expression of a panel of 21 genes in tumor tissue. The Recurrence Score result is calculated from the gene expression results and ranges from 0-100.

The findings are applicable to women who have stage I or II node negative (N0), estrogen receptor positive (ER+) breast cancer, and will be treated with 5 years of tamoxifen (tam). It is unknown whether the findings apply to other patients outside these criteria.

**Clinical Experience:** The following results are from a clinical validation study that included 668 patients from the NSABP B-14 study. The study included female patients with stage I or II, N0, ER+ breast cancer treated with 5 years of tam.[1]

**Prognosis: 10-Year Risk of Distant Recurrence after 5 Years of Tam, Based on the Recurrence Score Result (from NSABP B-14)**

**10-Year Risk of Distant Recurrence**

**Tam Alone**
**9%**
(95% CI: 6%-11%)

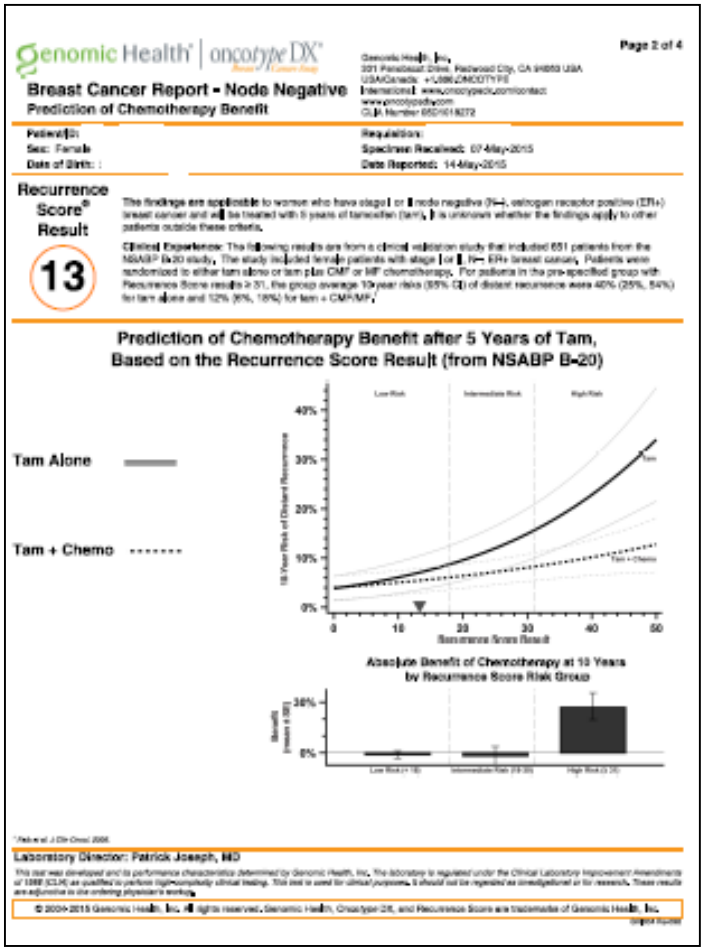


[1] Paik et al. N Engl J Med. 2004.

**Laboratory Director: Patrick Joseph, MD**

This test was developed and its performance characteristics determined by Genomic Health, Inc. The laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing. This test is used for clinical purposes. It should not be regarded as investigational or for research. These results are adjunctive to the ordering physician's working.





Genomic Health | oncotype DX

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**Breast Cancer Report - Node Negative**
**Prediction of Chemotherapy Benefit**

Genomic Health, Inc.
301 Penobscot Drive, Redwood City, CA 94063 USA
USA/Canada: +1.866.ONCOTYPE
International: www.oncotypedx.com/contact
www.oncotypedx.com
CLIA Number 05D1018272

Patient ID:
Sex: Female
Date of Birth:

Requisition:
Specimen Received: 07-May-2015
Date Reported: 14-May-2015

**Recurrence Score® Result**

**13**

The findings are applicable to women who have stage I or II node negative (N0), estrogen receptor positive (ER+) breast cancer and will be treated with 5 years of tamoxifen (tam). It is unknown whether the findings apply to other patients outside these criteria.

**Clinical Experience:** The following results are from a clinical validation study that included 651 patients from the NSABP B-20 study. The study included female patients with stage I or II, N0, ER+ breast cancer. Patients were randomized to either tam alone or tam plus CMF or MF chemotherapy. For patients in the pre-specified group with Recurrence Score results in 31. The group average 10-year risks (95% CI) of distant recurrence were 40% (25%, 54%) for tam alone and 12% (6%, 18%) for tam + CMF/MF.[1]

**Prediction of Chemotherapy Benefit after 5 Years of Tam, Based on the Recurrence Score Result (from NSABP B-20)**

**Tam Alone**

**Tam + Chemo**



**Absolute Benefit of Chemotherapy at 10 Years by Recurrence Score Risk Group**

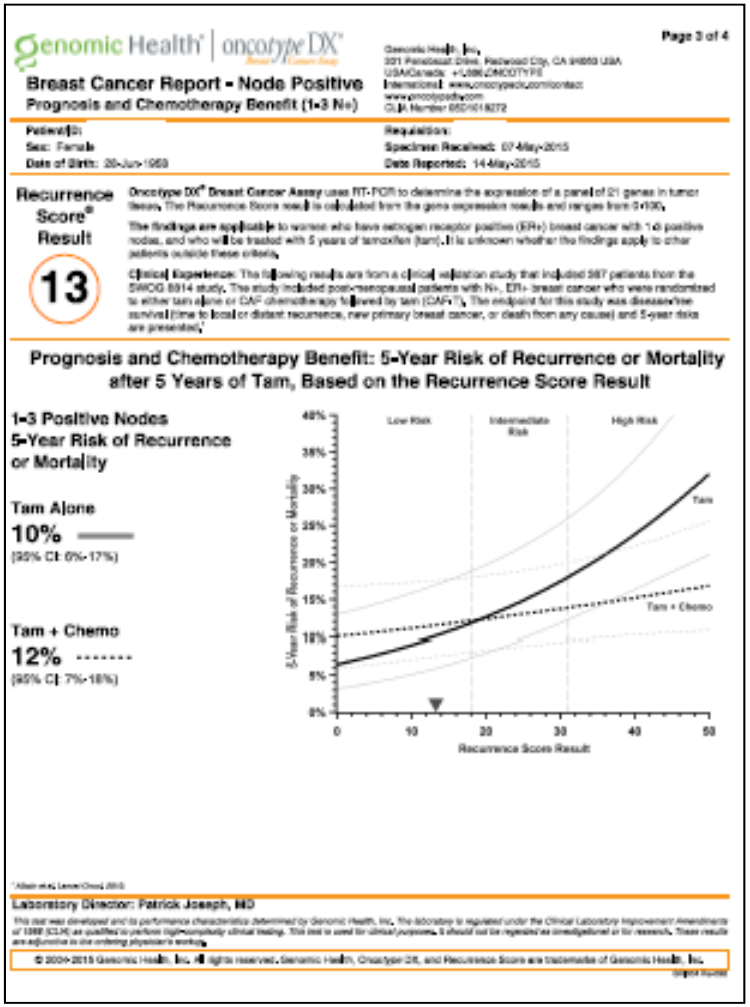


[1] Paik et al. J Clin Oncol. 2006.

**Laboratory Director: Patrick Joseph, MD**

This test was developed and its performance characteristics determined by Genomic Health, Inc. The laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing. This test is used for clinical purposes. It should not be regarded as investigational or for research. These results are adjunctive to the ordering physician's working.

# Oncotype DX – Informe de resultado - 2



Genomic Health | oncotype DX

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**Breast Cancer Report - Node Positive**
**Prognosis and Chemotherapy Benefit (1-3 N+)**

Genomic Health, Inc.
301 Penobscot Drive, Redwood City, CA 94063 USA
USA/Canada: +1.866.ONCOTYPE
International: www.oncotypedx.com/contact
www.oncotypedx.com
CLIA Number 05D1018272

Patient ID:
Sex: Female
Date of Birth: 20-Jun-1959

Requisition:
Specimen Received: 07-May-2015
Date Reported: 14-May-2015

**Recurrence Score® Result**

**13**

Oncotype DX® Breast Cancer Assay uses RT-PCR to determine the expression of a panel of 21 genes in tumor tissue. The Recurrence Score result is calculated from the gene expression results and ranges from 0-100.

The findings are applicable to women who have estrogen receptor positive (ER+) breast cancer with 1-3 positive nodes, and who will be treated with 5 years of tamoxifen (tam). It is unknown whether the findings apply to other patients outside these criteria.

Clinical Experience: The following results are from a clinical validation study that included 667 patients from the SWOG 8814 study. The study included post-menopausal patients with N+, ER+ breast cancer who were randomized to either tam alone or CAF chemotherapy followed by tam (CAF/T). The endpoint for this study was disease-free survival (time to local or distant recurrence, new primary breast cancer, or death from any cause) and 5-year risks are presented.

**Prognosis and Chemotherapy Benefit: 5-Year Risk of Recurrence or Mortality after 5 Years of Tam, Based on the Recurrence Score Result**

**1-3 Positive Nodes**
**5-Year Risk of Recurrence or Mortality**

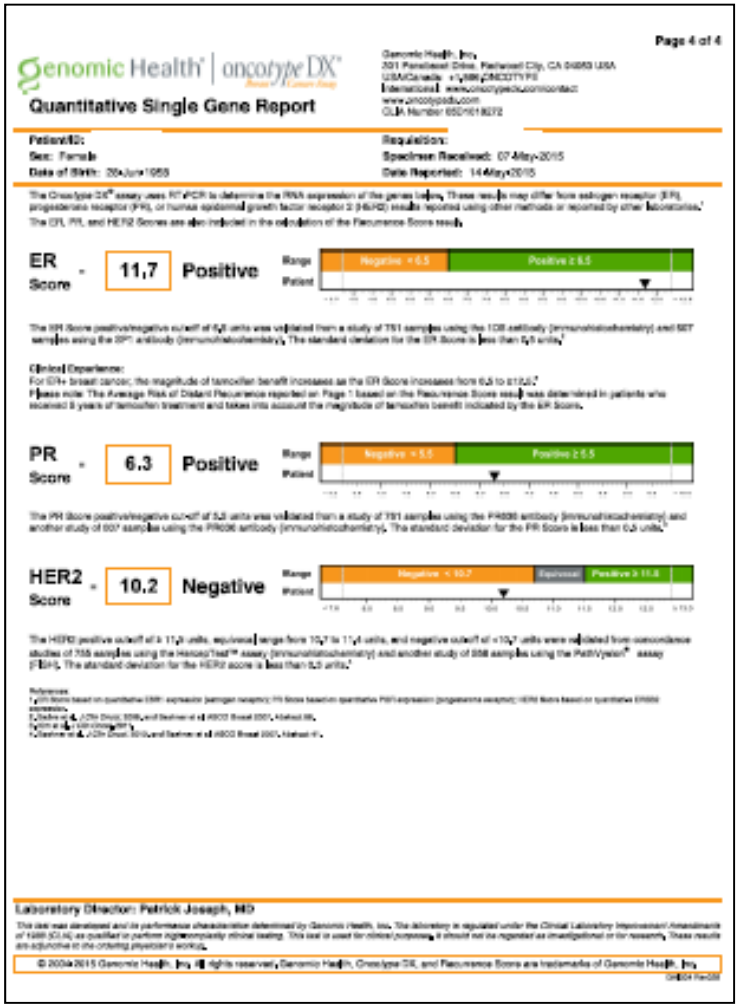
**Tam Alone**
**10%**
(95% CI: 6%-17%)

**Tam + Chemo**
**12%**
(95% CI: 7%-18%)




Laboratory Director: Patrick Joseph, MD





Genomic Health | oncotype DX

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**Quantitative Single Gene Report**

Genomic Health, Inc.
301 Penobscot Drive, Redwood City, CA 94063 USA
USA/Canada: +1.866.ONCOTYPE
International: www.oncotypedx.com/contact
www.oncotypedx.com
CLIA Number 05D1018272

Patient ID:
Sex: Female
Date of Birth: 20-Jun-1959

Requisition:
Specimen Received: 07-May-2015
Date Reported: 14-May-2015

The Oncotype DX® assay uses RT-PCR to determine the RNA expression of the genes below. These results may differ from estrogen receptor (ER), progesterone receptor (PR), or human epidermal growth factor receptor 2 (HER2) results reported using other methods or reported by other laboratories.[1]
The ER, PR, and HER2 Scores are also included in the calculation of the Recurrence Score result.

**ER Score** - **11.7** **Positive**




The ER Score positive/negative cutoff of 6.5 units was validated from a study of 751 samples using the 1D5 antibody (immunohistochemistry) and 607 samples using the ER1 antibody (immunohistochemistry). The standard deviation for the ER Score is less than 0.5 units.[1]

Clinical Experience:
For ER+ breast cancer, the magnitude of tamoxifen benefit increases as the ER Score increases from 6.5 to 11.7.[2]
Please note: The Average Risk of Distant Recurrence reported on Page 1 based on the Recurrence Score result was determined in patients who received 5 years of tamoxifen treatment and takes into account the magnitude of tamoxifen benefit indicated by the ER Score.

**PR Score** - **6.3** **Positive**




The PR Score positive/negative cut-off of 5.5 units was validated from a study of 791 samples using the PR636 antibody (immunohistochemistry) and another study of 607 samples using the PR636 antibody (immunohistochemistry). The standard deviation for the PR Score is less than 0.5 units.[1]

**HER2 Score** - **10.2** **Negative**




The HER2 positive cutoff of ≥ 11.0 units, equivocal range from 10.7 to 11.0 units, and negative cutoff of <10.7 units were validated from concordance studies of 758 samples using the HercepTest™ assay (immunohistochemistry) and another study of 658 samples using the PathVysion® assay (FISH). The standard deviation for the HER2 score is less than 0.5 units.[1]

References
1. [illegible]
2. [illegible]
3. [illegible]

Laboratory Director: Patrick Joseph, MD

# Cáncer de mama localizado – Plataformas genómicas – Oncotype DX - Osakidetza

- Fase piloto
  - HU Donostia (Donostia)
  - HU Araba (Gasteiz)
  - 30 pacientes  (HUD 15 pacientes)
  - Abril 2012 – Mayo 2012

- Implantación Osakidetza – Septiembre 2012

# Evolución del proceso

**PILOTO (ABR-MAY 2012)**

RE+ y/o RP+; HER2 (-)
N0 y N1mic
Tamaño tumoral ≤ 2 cm

- T <1cm. si 1 de: G3, IVL, Ki67 > 13%.
- p T1c : 1cm – 2cm, (todos)

Sept 2012-
Extension Osakidetza,
incluye T2

**CRITERIOS 29.7.2013**

RE+ y/o RP+; HER2 (-)
N0 y N1mic
Tamaño tumoral ≤ 5 cm

- T <1cm. si 1 de: G3, IVL, Ki67 > 13%.
- p T1c : 1cm – 2cm
  (excepto G1+Ki67 < 14%)
- pT2 (2-5 cm)
  (excepto G3)

No contraindicación para recibir QT (comorbilidad, edad)
Que el resultado del test influya en la decisión de tratamiento de la paciente

# Variables

- Edad, estatus menopáusico, programa cribado
- Tipo de cirugía (CC vs mast; GC vs LA)
- T, N, Grado, IVL, Ki 67, RE, RP.
- Oncotype Dx: RS valor y subgrupo
- Propuesta terapéutica pre y propuesta y decisión post-test

# Oncotype DX – Osakidetza - Gipuzkoa

- Periodo 2012-2014
- Centros
  - HUDonostia: 103 casos
    - Fase piloto + Implantación Osakidetza
  - Onkologikoa: 28 casos

# Criterios QT --RH+/HER2-/T1-2_N0-1mi

- < 70 años
  - T1a-b: HT solo
  - T1c-T2 – propuesta si al menos 1
    - G3
    - Ki 67 elevado
    - ≥ 2 cm
- ≥ 70 años: Individualización teniendo en cuenta además: comorbilidad, PS, dependencia…

# Propuesta post-test

- RS bajo:  HT sólo
- RS alto:   HT + QT
- RS intermedio
  - la misma propuesta que la previa
  - Valoración conjunta con la paciente en función del RS (int bajo, intermedio alto…)

# Características -1

| | N | % | Media - Mediana | Min-max |
|---|---|---|---|---|
| **Total** | 131 | | | |
| **Edad (años)** | | | 56 - 56 | 38-76 |
| **< 50** | 38 | 29 | | |
| **≥ 50** | **93** | **71** | | |
| **Estatus menopáusico** | | | | |
| **Pre** | 48 | 36,6 | | |
| **Post** | **83** | **63,4** | | |
| **PDP Osakidetza** | | | | |
| **No** | 63 | 48 | | |
| **Si – Detección en PDP** | 56 | 43 | | |
| **Si – Ca de intervalo** | 12 | 9 | | |

# Características -2

| | N | % |
|---|---|---|
| **Total** | 131 | |
| **Cirugía** | | |
| **Conservadora** | **121** | **92** |
| **Mastectomía** | 10 | 8 |
| **Estudio axilar** | | |
| **Ganglio centinela** | **125** | **95** |
| **Linfadenectomía** | 6 | 5 |

# Características -3

| | N | % | Media - Mediana | Min-max |
|---|---|---|---|---|
| **Total** | 131 | | | |
| **Tamaño tumoral (mm)** | | | 16,8 - 15 | 6-40 |
| **pT** | | | | |
| **pT1b** | 19 | 14,5 | | |
| **pT1c** | 82 | 62,6 | | |
| **pT2** | 30 | 22,9 | | |
| **pN** | | | | |
| **pN0** | 116 | 88,5 | | |
| **pN1mi** | 15 | 11,5 | | |

# Características -4

| | N | % |
|---|---|---|
| **Total** | 131 | |
| **Grado** | | |
| **1** | 37 | 28 |
| **2** | **72** | **55** |
| **3** | 22 | 17 |
| **Ki 67 (%)** | | |
| **< 14%** | 24 | 18 |
| **≥ 14%** | **107** | **82** |
| **RE** | | |
| **1-10%** | 1 | 0,8 |
| **≥10-50%** | - | |
| **≥50%** | **130** | **99,2** |
| **RP** | | |
| **0** | 12 | 9,2 |
| **1-20%** | 8 | 6,1 |
| **≥ 20%** | **111** | **84,7** |

| | N | % |
|---|---|---|
| **Total** | 131 | |
| **Inmunofenotipo (St Gallen 2013)** | | |
| **Luminal A** | 23 | 17,6 |
| **Luminal B** | 108 | 82,4 |

**'Luminal A-like'** all of:
ER and PgR positive (PgR cut-point of ≥20%)
HER2 negative
Ki-67 'low' (< 14%)

**'Luminal B-like (HER2 negative)'**
ER positive
HER2 negative
and at least one of:
Ki-67 'high' (≥ 14%
PgR 'negative or low' (PgR < 20%)

*Annals of Oncology 24: 2206–2223, 2013*

# Resultados - RS

| | N | % |
|---|---|---|
| **Total** | 131 | |
| **Risk Score** | | |
| **Bajo (< 18)** | 72 | 55 |
| **Intermedio bajo (18-25)** | 35 | 26,7 |
| **Intermedio alto (>25-30)** | 13 | 9,9 |
| **Alto (≥ 31)** | 11 | 8,4 |

} 48 – 36,6%

**1 caso Triple negativo por Oncotype DX**

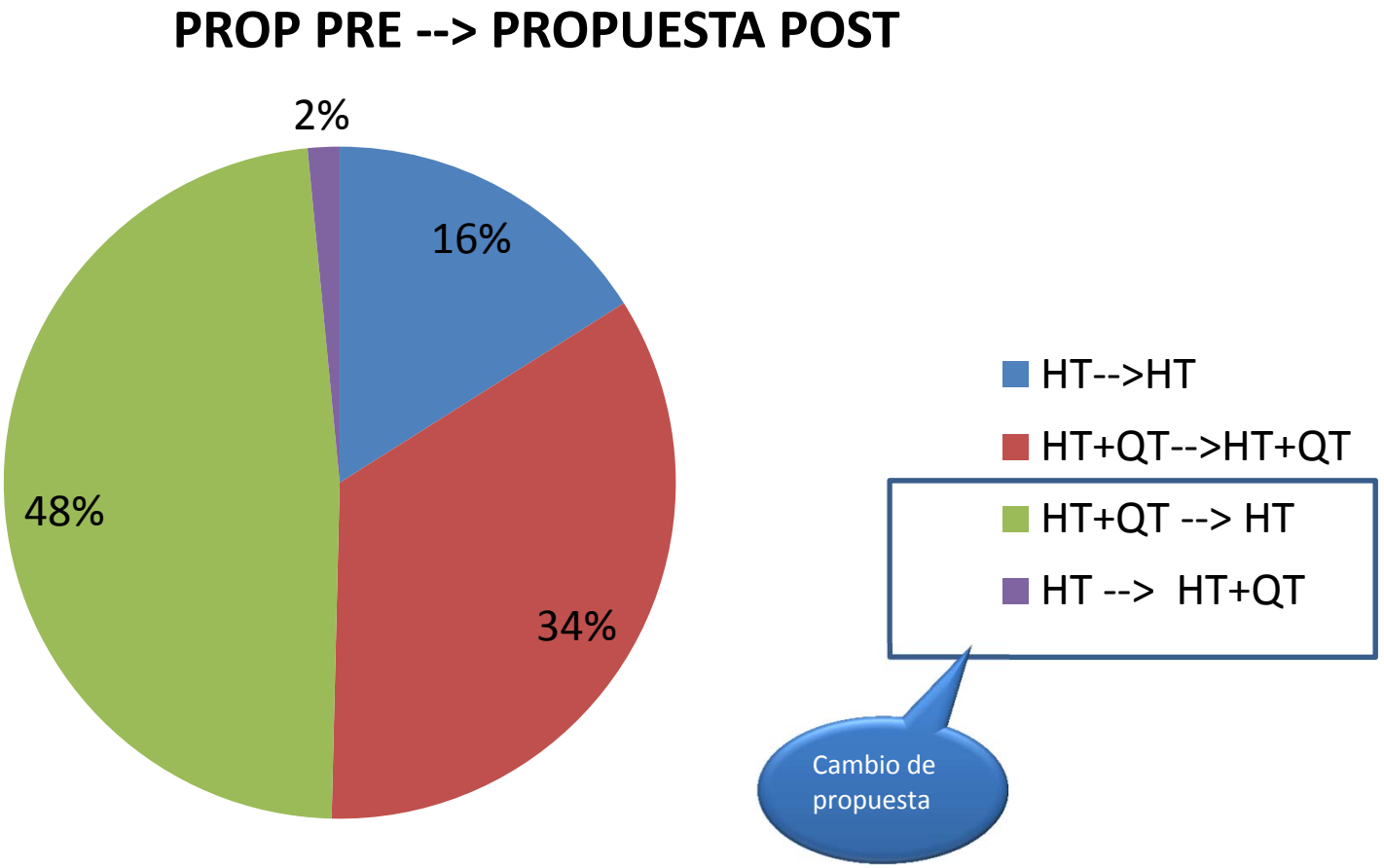
| TAMAÑO T (mm) | ESTADIO N | grado | kI 67 | INF VL | RE | RP | score ONCOTYPE | RISK |
|---|---|---|---|---|---|---|---|---|
| 11 | 1mi | III | 91 | NO | 8 | 0 | 38 | Alto |

# Cambio de propuesta terapéutica-1

| PROP_PRE*PROP_POST | | | | |
|---|---|---|---|---|
| | | PROP_POST | | |
| | | HT | HT+QT | Total |
| PROP_PRE | HT | 21 | ***2*** | 23 |
| | HT+QT | ***63*** | 45 | 108 |
| Total | | 84 | 47 | 131 |

| | |
|---|---|
| **No** | 66/ 131= 50,38% |
| **Si** | 65/131= 49,62% |

# Cambio de propuesta terapéutica-1



# Cambio de propuesta terapéutica-2

| | |
|---|---|
| **No** | 66/ 131= 50,38% |
| **Si** | 65/131= 49,62% (30,9-44,9) |

| | | | | |
|---|---|---|---|---|
| **HT+ QT → HT** | 63/108 | 58% | (46-62) |
| **HT →HT+QT** | 2/23 | 8,7% | (2-26) |

**Cambio: 65 casos**

| | | |
|---|---|---|
| 63 | → | **no QT 97%** |
| 2 | → | sí QT 3% |

# Cambio de propuesta terapéutica-3

| **PILOTO** | **15p** | | |
|---|---|---|---|
| 7/15 | 46,7% | | |
| HT+ QT | → HT | 7/10 | 70% |
| HT | →HT+QT | 0 | 0 |

| **GENERAL** | **116p** | | |
|---|---|---|---|
| 58/116 | 50% | | |
| HT+ QT | → HT | 56/98 | 57,1% |
| HT | →HT+QT | 2/18 | 11,1% |

# Correlaciones

- No correlación RS con
  - Edad, estatus menopáusico, T, grado de expresion del RH
- Correlación significativa RS
  - Grado
  - Ki 67 (variable continua, subgrupos)
  - Luminal A vs Luminal B

# % cambio según “risk score”

| | | | PROP_POST | | |
|---|---|---|---|---|---|
| | | | HT | HT+QT | Total |
| | | HT | 11 | 0 | 11 |
| | **PROP_PRE** | HT+QT | 59 | 2 | 61 |
| **BAJO** | Total | | 70 | 2 | 72 |
| | | HT | | 2 | 2 |
| | **PROP_PRE** | HT+QT | | 9 | 9 |
| **ALTO** | Total | | | 11 | 11 |
| | | HT | 9 | 0 | 9 |
| | **PROP_PRE** | HT+QT | 4 | 22 | 26 |
| **INT BAJO** | Total | | 13 | 22 | 35 |
| | | HT | 1 | 0 | 1 |
| | **PROP_PRE** | HT+QT | 0 | 12 | 12 |
| **INT ALTO** | Total | | 1 | 12 | 13 |
| | | HT | 21 | 2 | 23 |
| | PROP_PRE | HT+QT | 63 | 45 | 108 |
| Total | Total | | 84 | 47 | 131 |

**% cambio**

**59/72= 82%**
**100% No QT**

**2/11=18%**
**100% QT+HT**

**4/35=11%**
**100% No QT**

**0 – no cambios**
***Total Intermedio***
***4/48= 8%***
***100% no QT***

# % cambio - edad

| EDAD | | | PROP_POST | | Total |
|---|---|---|---|---|---|
| | | | HT | HT+QT | |
| < 50 | PROP_PRE | HT | 5 | 0 | 5 |
| | | HT+QT | 21 | 12 | 33 |
| | Total | | 26 | 12 | 38 |
| ≥ 50 | PROP_PRE | HT | 16 | 2 | 18 |
| | | HT+QT | 42 | 33 | 75 |
| | Total | | 58 | 35 | 93 |

**% cambio**

**21/38= 55%**
**100% no QT**

**44/93= 47%**
**95% no QT**
**5% HT+QT**

# % cambio - T

| T | | | PROP_POST | | Total |
|---|---|---|---|---|---|
| | | | HT | HT+QT | |
| 1b | PROP_PRE | HT | 7 | 2 | 9 |
| | | HT+QT | 5 | 5 | 10 |
| | Total | | 12 | 7 | 19 |
| 1c | PROP_PRE | HT | 13 | 0 | 13 |
| | | HT+QT | 36 | 33 | 69 |
| | Total | | 49 | 33 | 82 |
| 2 | PROP_PRE | HT | 1 | 0 | 1 |
| | | HT+QT | 22 | 7 | 29 |
| | Total | | 23 | 7 | 30 |

**% cambio**

**7/19**
**71% no QT**
**11% HT+QT**

**36/82= 44%**
**100% no QT**

**22/30= 73%**
**100% no QT**

# 5 cambio- grado

| GRADO | | | PROP_POST | | Total |
|---|---|---|---|---|---|
| | | | HT | HT+QT | |
| 1 | PROP_PRE | HT | 7 | 0 | 7 |
| | | HT+QT | 20 | 10 | 30 |
| | Total | | 27 | 10 | 37 |
| 2 | PROP_PRE | HT | 12 | 2 | 14 |
| | | HT+QT | 40 | 18 | 58 |
| | Total | | 52 | 20 | 72 |
| 3 | PROP_PRE | HT | 2 | 0 | 2 |
| | | HT+QT | 3 | 17 | 20 |
| | Total | | 5 | 17 | 22 |

**% cambio**

**20/37=54%**
**100% no QT**

**42/72=58%**
**95% no QT**
**5% HT+QT**

**3/22= 14%**
**100% no QT**

# % cambio – Ki 67

| KI67 % | | | PROP_POST | | Total |
|---|---|---|---|---|---|
| | | | HT | HT+QT | |
| **<14** | PROP_PRE | HT | 14 | 0 | 14 |
| | | HT+QT | 9 | 1 | 10 |
| | Total | | 23 | 1 | 24 |
| **14-20** | PROP_PRE | HT | 0 | 1 | 1 |
| | | HT+QT | 27 | 12 | 39 |
| | Total | | 27 | 13 | 40 |
| **>20** | PROP_PRE | HT | 7 | 1 | 8 |
| | | HT+QT | 27 | 32 | 59 |
| | Total | | 34 | 33 | 67 |

**% cambio**

**9/24= 36%**
**100% no QT**

**28/40=70%**
**96% no QT**
**4% QT + HT**

**28/59= 47%**
**96% no QT**
**4% HT+QT**

# % cambio – subtipo luminal

| LUMINAL | | | PROP_POST | | Total |
|---|---|---|---|---|---|
| | | | HT | HT+QT | |
| A | PROP_PRE | HT | 13 | 0 | 13 |
| | | HT+QT | 9 | 1 | 10 |
| | Total | | 22 | 1 | 23 |
| B | PROP_PRE | HT | 8 | 2 | 10 |
| | | HT+QT | 54 | 44 | 98 |
| | Total | | 62 | 46 | 108 |

**% cambio**

**9/23= 39%**
**100% no QT**

**56/108= 52%**
**96% no QT**
**4% HT + QT**

# % cambio “Ki 67-grado-T”

| GRADO_KI_T | | | PROP_POST HT | PROP_POST HT+QT | Total |
|---|---|---|---|---|---|
| KI <14, G1 , > 2 CM | PROP_PRE | HT | 1 | 0 | 1 |
| | | HT+QT | 22 | 7 | 29 |
| | Total | | 23 | 7 | 30 |
| KI <14, G1 , ≤ 2 cm | PROP_PRE | HT | 6 | | 6 |
| | Total | | 6 | | 6 |
| KI ≥ 14 y/o G= 2,3, T cualquiera | PROP_PRE | HT | 14 | 2 | 16 |
| | | HT+QT | 41 | 38 | 79 |
| | Total | | 55 | 40 | 95 |

**% cambio**

**22/30=73%**
**100% no QT**

**No cambio**

**43/95= 45%**
**95% no QT**
**5% HT+QT**

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# Prospective transGEICAM study of the impact of the 21-gene Recurrence Score assay and traditional clinicopathological factors on adjuvant clinical decision making in women with estrogen receptor-positive (ER+) node-negative breast cancer

J. Albanell[1,2,3*], A. González[4], M. Ruiz-Borrego[5], E. Alba[6], J. A. García-Saenz[7], J. M. Corominas[2,3,8], O. Burgues[9], V. Furio[10], A. Rojo[11], J. Palacios[12], B. Bermejo[13], M. Martínez-García[1,2], M. L. Limon[5], A. S. Muñoz[6], M. Martín[14], I. Tusquets[1,2], F. Rojo[2,15], R. Colomer[4], I. Faull[16] & A. Lluch[13]

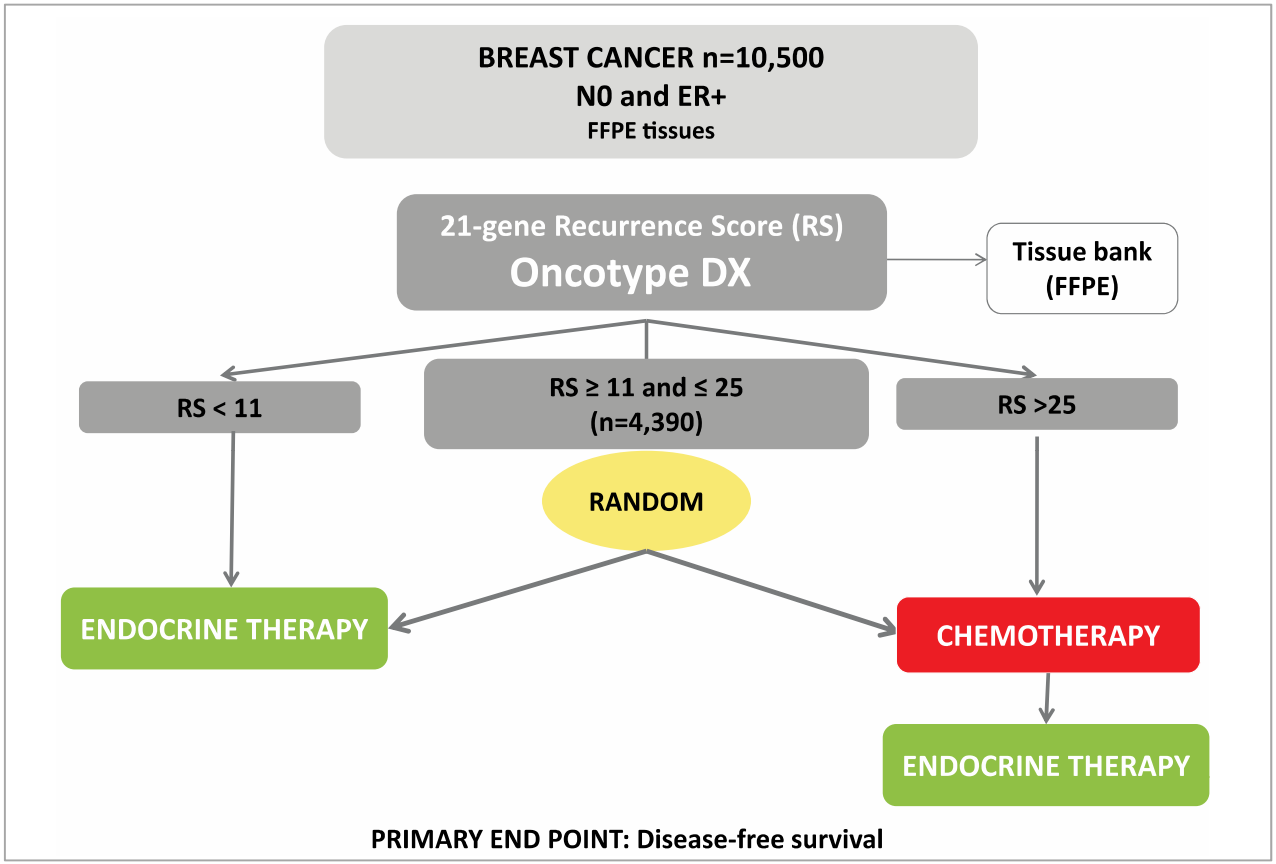
| Pre- to post-RS treatment recommendation | Low RS (<18) $N = 62$, $n$ (%) | Intermediate RS (18–30) $N = 35$, $n$ (%) | High RS (>30) $N = 10$, $n$ (%) | Total $N = 107$, $n$ (%) |
|---|---|---|---|---|
| Treatment plan changed | 20 (59) | 12 (35) | 2 (6) | 34 (32) |
| HT to CHT | 0 (0) | 10 (83) | 2 (17) | 12 (11) |
| CHT to HT | 20 (91) | 2 (9) | 0 (0) | 22 (21) |
| Treatment plan not changed | 42 (58) | 23 (32) | 8 (11) | 73 (68) |
| CHT to CHT | 2 (12) | 7 (41) | 8 (11) | 17 (16) |
| HT to HT | 40 (71) | 16 (29) | 0 (0) | 56 (52) |

# Conclusiones

Serie HUD-Onkologikoa

- % cambio 49% (series internacionales 30-50%)
- 97% de los casos que cambian es a no recibir QT
  - 58% casos propuestos para QT → no QT
  - 8,7% casos propuestos para no QT → QT
- Selección previa (eliminación grupos extremos)

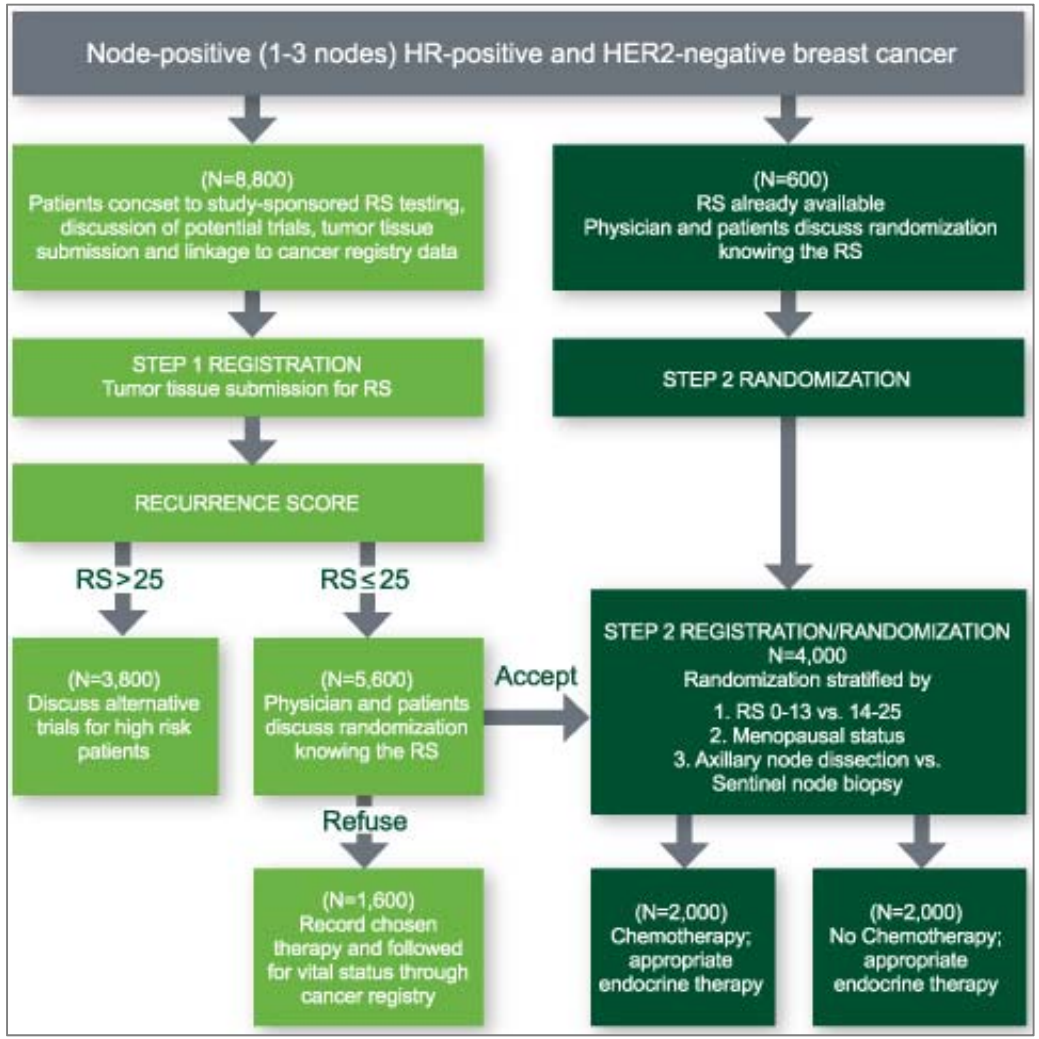
# TAYLOR – RH+/HER2(-) – N0




ECOG

Reclutamiento cerrado, pendiente de resultados

# RxPONDER – RH+/HER2(-) – N1-3




SWOG, NSABP, NCCTG, CALGB, ECOG, NCIC CTG, GEICAM y UNICANCER.

GEICAM
- 21 Centros
- HUDonostia y Onkologikoa
  - 105 registros
  - 60 incluidas

En fase de reclutamiento