

# Evaluating the benefit of Gene Expression Profiling (GEP) in early breast cancer

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## Registration form

*Dataset established by the Domain Task Force Convention GEP.*

### Definition GEP target group:

- Early primary breast cancer,
- pN0 or pN1,
- maximum 5 cm in greatest dimension,
- HER2-, ER+ and/or PR+,
- menopausal or at least 45 years old,
- clinical high risk based on for example the algorithm used in the MINDACT study<sup>1</sup> or the Magee score<sup>2</sup>.

For all patients for whom a GEP-test is **proposed by the MOC/COM**, the specific GEP registration needs to be completed.

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<sup>1</sup> This risk can for example be determined on <http://www.mymammaprint.com/>

<sup>2</sup> This risk can for example be determined on <https://path.upmc.edu/onlineTools/MageeEquations.html>



All variables are required to be filled out unless stated otherwise.

Single-select variables: only one answer can be selected

Multi-select variables: one or more answers can be selected

### **Administrative patient data**

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Hospital: .....

Health insurance institution: .....

National number for social security (INSZ/NISS)\*: .....

*\* if filled out in the online WBCR application, the following variables will be completed automatically:*

Last name: .....

First name: .....

Postal code: .....

City: .....

Country: .....

Health insurance number: ..... (if possible)

Date of birth: ...../...../..... (dd/mm/yyyy)

Date of death: ...../...../..... (dd/mm/yyyy) (if applicable)

Sex:  Male

Female

### **1. For all patients for whom a GEP test is proposed by the MOC/COM**

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- Was surgery performed?

Yes: date surgery: ...../...../..... (dd/mm/yyyy)

No surgery was performed prior to request of GEP

- Date MOC/COM: ...../...../..... (dd/mm/yyyy)

- Woman in menopause:

Yes

No

Unknown

Not applicable (male patient)

- Indication:
  - Patient **belongs** to the target group of the convention (all of the following: early primary breast cancer, pN0 or pN1, maximum 5 cm in greatest dimension, HER2-, ER+ and/or PR+, menopausal or at least 45 years old, without prior neoadjuvant systemic therapy, clinical high risk based on the MINDACT criteria or Magee score)
  - Patient **does not belong** to the target group, but MOC/COM decides that a GEP-test is justified. Deviation from the target population:
    - Not primary cancer
    - Not first diagnosis
    - Not pN0 or pN1
    - HER2+
    - Tumour > 5cm
    - Not menopausal/not 45 years old
    - Doubtful clinical low risk:
      - Motivation: .....
    - Other (explain):.....
- What would be the MOC/COM treatment decision without knowledge of the GEP?
  - Strong recommendation to administer adjuvant chemotherapy
  - Weak recommendation to administer adjuvant chemotherapy
  - Strong recommendation not to administer any chemotherapy
  - Weak recommendation not to administer any chemotherapy

## 2. At consultation after MOC/COM (before request of GEP)

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- Was a GEP test ordered after positive advice from MOC/COM?
  - Yes
  - No
    - Reason for not requesting GEP:
      - Patient wants chemotherapy anyhow, despite advise of MOC/COM to request GEP and await results
      - Patient does not want chemotherapy, despite advise of MOC/COM to request GEP and await results
      - Other
        - Please specify: .....

*In case no GEP was ordered, the registration ends here!*

**3. Only if GEP was requested: GEP result (final situation) and adjuvant chemotherapy initiated**

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- Which GEP test?
  - Mammaprint by Agendia
    - Test result (value): .....
  - Mammaprint on NGS, by UZ Leuven
    - Test result (value): .....
  - Oncotype DX by Genomic Health
    - Test result (value): .....
  - Other
    - Name of the test: .....
    - Test result (value): .....
  
- Interpretation of GEP result (as stated on the report):
  - High risk
  - Borderline risk
  - Low risk
  - Technical failure
  
- Final treatment: Was adjuvant chemotherapy initiated (at least 1 cycle received)?
  - No
    - Main reason:
      - GEP low risk
      - Patient does not want chemotherapy, despite advise of MOC/COM for chemotherapy
      - Other:
        - Motivation: .....
  - Yes
    - Main reason:
      - GEP high risk
      - Patient wants chemotherapy, despite advice of MOC/COM not to initiate chemotherapy
      - Other:
        - Motivation: .....