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

-

Registration form

Dataset established by the Domain Task Force Convention GEP.

Definition GEP target group:

Patients with early breast cancer, first diagnosis, pN0 or pN1, maximum 5 cm in greatest dimension, HER2-, ER+ and/or PR+, after primary surgery without prior neoadjuvant systemic therapy.

For all patients within this group, 2 registrations need to be performed:
➔ The specific GEP registration, irrespective of GEP request
➔ The obligatory general cancer registration (Bijlage 55 / Annexe 55)

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

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. Information on the tumour

- Detection by:
    - ❍ Screening
    - ❍ Symptomatic
    - ❍ Unknown
- Laterality:
    - ❍ Unilateral
    - ❍ Bilateral
        - Specify the laterality of the tumour for which the GEP registration is applicable:
            - ❍ 1. Left
            - ❍ 2. Right
- Multifocality:
    - ❍ Unifocal
    - ❍ Multifocal

Tumour details (related to the tumour/focus on which the decision to administer or not to administer adjuvant chemotherapy is based in case of a bilateral or multifocal tumour):

- Tumour size on resection specimen (greatest dimension): ………… (mm)
- ER:
    - Percentage of positive tumour cells: ………… (%) or Allred category: ………… (0-8)
    - Interpretation:
        - ❍ +
        - ❍ -
- PR:
    - Percentage of positive tumour cells: ………… (%) or Allred category: ………… (0-8)
    - Interpretation:
        - ❍ +
        - ❍ -

- Is Ki67 determined in the resection specimen?
  - ❍ No
  - ❍ Yes
    - Highest Ki67 value? …………... (%)
- Procedure used for lymph node analysis:
  - ❑ Sentinel lymph node biopsy
  - ❑ Axillary dissection
- Number of lymph nodes retrieved: …………
- Number of positive lymph nodes: …………
  - Size of the largest metastatic deposit on lymph node: ………… (mm)
- Tumour grade:
  - ❍ Grade 1 (total score 3 - 5)
  - ❍ Grade 2 (total score 6 - 7)
  - ❍ Grade 3 (total score 8 - 9)
  - ❍ Unknown

  Please indicate the breakdown of the tumour grade:
  - Nuclear pleomorphism: ❍ Score 1   ❍ Score 2   ❍ Score 3   ❍ Unknown
  - Tubule and gland formation: ❍ Score 1   ❍ Score 2   ❍ Score 3   ❍ Unknown
  - Mitotic score: ❍ Score 1   ❍ Score 2   ❍ Score 3   ❍ Unknown

2. At MOC/COM

- Date surgery: ………/………/………… (dd/mm/yyyy)
- Date MOC/COM: ………/………/………… (dd/mm/yyyy)
- Was a GEP test considered for this patient during the MOC/COM?
  - ❍ No
    - Reason:
      - ❍ All clinical/pathological parameters are fully concordant to indicate a (very) low risk
      - ❍ All clinical/pathological parameters are fully concordant to indicate a (very) high risk
      - ❍ Patient comorbidities would prevent chemotherapy administration
      - ❍ Clinic reached the number of reimbursements of GEP for current year
      - ❍ Other
        - Please specify: ....
  - ❍ Yes
    - Reason:
      - ❍ Clinical high risk
      - ❍ Other
        - Motivation:..
    - What would be the MOC 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
    - What does the MOC want to propose to the patient?
      - ❍ Request GEP test
      - ❍ No request GEP test

3. At postoperative consultation after MOC/COM (before request of GEP)

- Date of the postoperative consultation: ………/………/………… (dd/mm/yyyy)
- Was a request of GEP discussed with the patient during this consultation?
    - ○ No
    - ○ Yes
- Was it decided to request a GEP?
    - ○ No
        - Reason for not requesting GEP:
            - ○ MOC/COM proposal was followed
            - ○ 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: ....
        - Final treatment: Was adjuvant chemotherapy initiated (at least 1 cycle received)?
            - ○ No
            - ○ Yes
                - Which regimen?
                    - ○ Anthracycline only
                    - ○ Anthracycline and taxane
                    - ○ Docetaxel cyclophosphamide
                    - ○ Other
                        - Please specify: ....

        In case no GEP was requested, the registration ends here!

    - ○ Yes
        - Reason for requesting GEP:
            - ❑ MOC/COM proposal was followed
            - ❑ Treating physician proposal (not MOC/COM)
            - ❑ Patient request

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

- Date of GEP result available: ………/………/………… (dd/mm/yyyy)
- Which GEP test?
    - ○ Mammaprint by Agendia
        - Test result (value): ....
    - ○ Mammaprint on NGS, by UZ Leuven
        - Test result (value): ....
    - ○ Mammaprint on NGS, by Institut Jules Bordet
        - 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
  - ○ Intermediate / Borderline risk
  - ○ Low risk
  - ○ Technical failure
- What would be the treatment decision of the treating physician now that the GEP test result is available (irrespective of the preference of the patient)?
  - ○ 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
- Final treatment: Was adjuvant chemotherapy initiated (at least 1 cycle received)?
  - ○ No
    - Main reason:
      - ○ Patient does not want chemotherapy
      - ○ Proposed by the treating physician or at the MOC/COM:
        - Motivation: ....
      - ○ Other:
        - Motivation: ....
  - ○ Yes
    - Main reason:
      - ○ Patient wants chemotherapy
      - ○ Proposed by the treating physician or at the MOC/COM:
        - ○ GEP high risk and clinical high risk
        - ○ Other
          - Motivation: ....
      - ○ Other:
        - Motivation: ....
    - Which regimen?
      - ○ Anthracycline only
      - ○ Anthracycline and taxane
      - ○ Docetaxel cyclophosphamide
      - ○ Other
        - Please specify: ....
- Did the GEP result influence the confidence of the treating physician in the treatment decision?
  - ○ No impact
  - ○ More confident
  - ○ Less confident