## Demographic characteristics

<table>
<thead>
<tr>
<th>Year of Birth</th>
<th>Documentation for this patient is:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>○ prospective ○ retrospective (informed consent not necessary)</td>
</tr>
</tbody>
</table>

### For registration, the inclusion criteria below must be met:

- Histopathologically confirmed breast cancer diagnosed during pregnancy or young (≤40 years) non pregnant patient? ○ pregnant ○ young non pregnant
- Karnofsky Index ≥ 80 %? ○ yes ○ no
- Course of current pregnancy without clinical findings or complications? ○ yes ○ no

## Informed consent (not necessary for retrospective documentation)

- Informed consent given? ○ yes ○ no (exclusion, if prospective)
- Date of informed consent: 
- Did the patient consent to the collection and analysis of biomaterials? ○ yes ○ no
- FFPE from primary breast tumor available? ○ yes ○ no
  - If "yes" Histo No.:

## Center information

- Country Code  Centre No.  Date of request: 
- Submitting hospital (including address)
- Name of the submitting doctor
- Phone:  Fax:  
- Email:

## GBG area (for internal use only)

- The patient has been assigned the patient number: 
- Date of registration: 

---

<table>
<thead>
<tr>
<th>GBG area (for internal use only)</th>
<th>GBG Forschungs GmbH</th>
</tr>
</thead>
<tbody>
<tr>
<td>GBG (GBG 29) :: Version 3.0 :: GBG Forschungs GmbH</td>
<td>8566243699</td>
</tr>
</tbody>
</table>
# Breast Cancer - Histology

## Physical examination

- **Ethnological origin of patient:**
  - ○ caucasian
  - ○ asian
  - ○ black-african
  - ○ oriental
  - ○ hispanic
  - ○ other

- **Date of physical examination:**
  - [ ] .
  - [ ] .
  - [ ]
  - [ ]
  - [ ]
  - [ ]
  - □ n.d.

- **Weight:** [ ] kg
- **Height:** [ ] cm
- **Blood pressure:** [ ] / [ ] mm/Hg

## Histology

- **Date of first clinical symptoms:**
  - [ ] .
  - [ ] .
  - [ ]

- **Date of histological diagnosis:**
  - [ ] .
  - [ ] .
  - [ ]
  - corresponding week of pregnancy [ ]

- **Histological method:**
  - ○ core cut biopsy
  - ○ excisional biopsy

## Tumor site

- **Localization:**
  - ○ unilateral
  - ○ bilateral

- **TNM - classification:**
  - cT [ ] [ ] [ ]
  - cN [ ] [ ] [ ]
  - M [ ] [ ] [ ]
  - □ n.
  - □ n.

  * If M=1, please specify the organ:

- **Histological type of tumour:**
  - □ ductal invasive
  - □ lobular invasive
  - □ inflammatory
  - □ other

- **Tumour grading:**
  - ○ 1
  - ○ 2
  - ○ 3
  - ○ unknown

- **Estrogen receptor status:**
  - ○ positive
  - ○ negative
  - ○ unknown

- **Progesterone receptor status:**
  - ○ positive
  - ○ negative
  - ○ unknown

- **HER-2 status**
  - ○ positive
  - ○ negative
  - ○ unknown

- **p53:** [ ] %
  - □ n.k.

- **Vascular invasion:**
  - □ yes
  - □ no
  - □ n.k.

- **Lymphatic invasion:**
  - □ yes
  - □ no
  - □ n.k.

- **BRCA1:**
  - ○ mutated
  - ○ not mutated
  - ○ not reported

- **BRCA2:**
  - ○ mutated
  - ○ not mutated
  - ○ not reported

- **Other:**
  - ○ mutated
  - ○ not mutated
  - ○ not reported

## CRF comment (optional):

[ ]
**Family History**

Checklist for determining a possible predisposition to breast and/or ovarian cancer.

### A. Patient and her siblings/children

<table>
<thead>
<tr>
<th>Event</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>a mamma carcinoma in the patient BEFORE the age of 36</td>
<td></td>
</tr>
<tr>
<td>a unilateral mamma carcinoma in the patient BEFORE the age of 51</td>
<td></td>
</tr>
<tr>
<td>a bilateral mamma carcinoma in the patient, the first of which occurred BEFORE the age of 51</td>
<td></td>
</tr>
<tr>
<td>a unilateral or bilateral mamma carcinoma in the patient AFTER the age of 50</td>
<td></td>
</tr>
<tr>
<td>a fallopian tube carcinoma or primary peritoneal carcinomatosis in the patient</td>
<td></td>
</tr>
<tr>
<td>a mamma carcinoma in sisters/daughters BEFORE the age of 36</td>
<td></td>
</tr>
<tr>
<td>a unilateral mamma carcinoma in sisters/daughters BEFORE the age of 51</td>
<td></td>
</tr>
<tr>
<td>a bilateral mamma carcinoma in sisters/daughters, the first of which occurred BEFORE the age of 51</td>
<td></td>
</tr>
<tr>
<td>a unilateral or bilateral mamma carcinoma in sisters/daughters AFTER the age of 50</td>
<td></td>
</tr>
<tr>
<td>a mamma carcinoma in brothers/sons</td>
<td></td>
</tr>
<tr>
<td>a fallopian tube carcinoma or primary peritoneal carcinomatosis in sisters/daughters</td>
<td></td>
</tr>
</tbody>
</table>

### B. Maternal line

<table>
<thead>
<tr>
<th>Event</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>a mamma carcinoma in a female relative BEFORE the age of 36</td>
<td></td>
</tr>
<tr>
<td>a unilateral mamma carcinoma in a female relative BEFORE the age of 51</td>
<td></td>
</tr>
<tr>
<td>a bilateral mamma carcinoma in a female relative, the first of which occurred BEFORE the age of 51</td>
<td></td>
</tr>
<tr>
<td>a unilateral or bilateral mamma carcinoma in a female relative AFTER the age of 50</td>
<td></td>
</tr>
<tr>
<td>a mamma carcinoma in a male relative</td>
<td></td>
</tr>
<tr>
<td>a fallopian tube carcinoma or primary peritoneal carcinomatosis in a female relative</td>
<td></td>
</tr>
</tbody>
</table>

### C. Paternal line

<table>
<thead>
<tr>
<th>Event</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>a mamma carcinoma in a female relative BEFORE the age of 36</td>
<td></td>
</tr>
<tr>
<td>a unilateral mamma carcinoma in a female relative BEFORE the age of 51</td>
<td></td>
</tr>
<tr>
<td>a bilateral mamma carcinoma in a female relative, the first of which occurred BEFORE the age of 51</td>
<td></td>
</tr>
<tr>
<td>a unilateral or bilateral mamma carcinoma in a female relative AFTER the age of 50</td>
<td></td>
</tr>
<tr>
<td>a mamma carcinoma in a male relative</td>
<td></td>
</tr>
<tr>
<td>a fallopian tube carcinoma or primary peritoneal carcinomatosis in a female relative</td>
<td></td>
</tr>
</tbody>
</table>

**CRF comment (optional):**

[Input field]
**General Medical History**

**Relevant past or current illnesses or symptoms**

Has/had the patient any relevant current or past illnesses or symptoms (including cardiac history and allergy)?  
○ yes (specify below)  ○ no

<table>
<thead>
<tr>
<th>Description</th>
<th>Start date</th>
<th>Current?</th>
<th>Current?</th>
<th>Code*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Code for SOC MedDRA-terms:
01 = Infections and infestations; 02 = Neoplasms benign and malignant (including cysts and polyps); 03 = Blood and the lymphatic system disorders; 04 = Immune system disorders; 05 = Endocrine disorders; 06 = Metabolism and nutrition; 07 = Psychiatric disorders; 08 = Nervous system disorders; 09 = Eye disorders; 10 = Ear and labyrinth disorders; 11 = Cardiac disorders; 12 = Vascular disorders; 13 = Respiratory, thoracic and mediastinal disorders; 14 = Gastrointestinal disorders; 15 = Hepato-biliary disorders; 16 = Skin and subcutaneous tissue disorders; 17 = Musculoskeletal, connective tissue and bone disorders; 18 = Renal and urinary disorders; 19 = Pregnancy, puerperium and prenatal conditions; 20 = Reproductive system and breast disorders; 21 = Congenital and familial/genetic disorders; 22 = General disorders and administration site conditions; 23 = Investigations; 24 = Injury and poisoning; 25 = Surgical and medical procedures; 26 = Social circumstances

**CRF comment (optional):**
Previous Pregnancy

Number of previous pregnancies

Date of last delivery/interruption:

CRF comment (optional):
### Breast Cancer - Diagnosis

#### Physical examination breast

- **Clinical signs for cT4:**
  - □ none
  - □ extension to chest wall (T4a)
  - □ skin involvement (T4b)
  - □ inflammation (T4d)

- **Assessment date:**
  - [ ] [ ] [ ] [ ] [ ] [ ]
  - □ not done

- **Results:**
  - ○ not suspicious
  - ○ suspicious
  - ○ led to diagnosis of carcinoma

- **Tumour size** (largest diameters)
  - □ □ □ □ □ □ □ □ □ □ □ □ □ mm
  - □ not known
  - □ not measurable

- **Tumor site:**
  - ○ unilateral right
  - ○ unilateral left
  - ○ bilateral

  **If bilateral,** state site of largest indicator lesion:
  - ○ left
  - ○ right

- **The tumor is:**
  - ○ unifocal
  - ○ multifocal
  - ○ multicentric

- **Nodal status:**
  - ○ cN0
  - ○ cN1
  - ○ cN2
  - ○ cN3
  - ○ n.d.

  **If cN>0** please indicate
  - □ axillary
  - □ infraclavicular
  - □ supraclavicular

- **lymph nodes affected:**
  - □ mammaria interna
  - □ n.k.

#### Ultrasound of breast

- **Assessment date:**
  - [ ] [ ] [ ] [ ] [ ] [ ]
  - □ not done

- **Results:**
  - ○ not suspicious
  - ○ suspicious
  - ○ led to diagnosis of carcinoma

- **Tumour size** (largest diameters)
  - □ □ □ □ □ □ □ □ □ □ □ □ □ mm
  - □ not measurable
  - □ not detectable
  - □ not known

- **The tumor is:**
  - ○ unifocal
  - ○ multifocal
  - ○ multicentric

- **Nodal status:**
  - ○ cN0
  - ○ cN1
  - ○ cN2
  - ○ cN3
  - ○ n.d.

  **If CN>0** please indicate
  - □ axillary
  - □ infraclavicular

- **lymph nodes affected:**
  - □ mammaria interna
  - □ supraclavicular

- **n.k.**

- **Were there any other suspicious findings?**
  - ○ yes
  - ○ no

  **If "yes", please specify:**

#### Mammography

- **Assessment date:**
  - [ ] [ ] [ ] [ ] [ ] [ ]
  - □ not done

- **Results:**
  - ○ not suspicious
  - ○ suspicious
  - ○ led to diagnosis of carcinoma

- **Tumour size** (largest diameters)
  - □ □ □ □ □ □ □ □ □ □ □ □ □ mm
  - □ not known

#### MRI

- **Assessment date:**
  - [ ] [ ] [ ] [ ] [ ] [ ]
  - □ not done

- **Results:**
  - ○ not suspicious
  - ○ suspicious
  - ○ led to diagnosis of carcinoma

- **Tumour size** (largest diameters)
  - □ □ □ □ □ □ □ □ □ □ □ □ □ mm
  - □ not known

#### CRF comment (optional):
Systemic Therapy - Chemotherapy

Chemotherapy and concomitant targeted therapy

- neo-adjuvant
- adjuvant
- palliative
- none

Start Date: __________________________  End Date: __________________________

Regimen: __________________________

Number of cycles

(please document number of cycles, not number of infusions)

- EC/AC
- FEC/FAC
- E/A mono
- Taxane: → ○ Paclitaxel  ○ Docetaxel
- CMF
- other 1: __________________________
- other 2: __________________________
- target: __________________________

(please document further targeted therapy on Form 4-2)

Has the treatment been interrupted? ○ yes  ○ no
Has the dose been reduced? ○ yes  ○ no

In case of treatment interruption or dose reduction please give the reason(s):

<table>
<thead>
<tr>
<th>Hematological toxicity</th>
<th>interruption</th>
<th>reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-hematological toxicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child (complications during pregnancy/delivery)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (please specify below):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Supportive therapy

- Dexamethasone: ○ yes  ○ no
  If "yes": mg:

- G-CSF: ○ yes  ○ no
- Pegfilgrastim: ○ yes  ○ no
- Antibiotics: ○ yes  ○ no
- Other: ○ yes  ○ no

If other "yes", please specify below:

5-HT3 antagonist: ○ yes  ○ no
- Clemastine: ○ yes  ○ no
- Ranitidin: ○ yes  ○ no

CRF comment (optional):

______________________________

______________________________
**Endocrine and Targeted Therapy**

### Endocrine therapy

<table>
<thead>
<tr>
<th>Start Date</th>
<th>End Date</th>
<th>Medication</th>
<th>Dose</th>
<th>Number of months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Start Date</th>
<th>End Date</th>
<th>Medication</th>
<th>Dose</th>
<th>Number of months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Please notice targeted therapy given during chemotherapy has to be documented on Form 4-1.*

### Targeted therapy

<table>
<thead>
<tr>
<th>Start Date</th>
<th>End Date</th>
<th>Medication</th>
<th>Dose</th>
<th>Number of infusions/weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Start Date</th>
<th>End Date</th>
<th>Medication</th>
<th>Dose</th>
<th>Number of infusions/weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Local Therapy - Surgery

Surgery

Date of surgery: ___. ____. ___

☐ breast conserving surgery
☐ mastectomy
☐ sentinel node biopsy (SNB), please specify below
☐ axillary node dissection, please specify below

If "sentinel node biopsy" was performed:

Number of lymph nodes dissected for SNB: ___
Number of positive sentinel nodes: ___

Sentinal node procedure:
○ 99 TC sulphur colloid
○ Blue dye
○ n.k.

If "axilla node dissection" was performed:

Number of lymph nodes dissected: ___
Number of positive nodes: ___

Were there postoperative complications?
If "yes", please give reason(s):

☐ yes  ☐ no

CRF comment (optional):
Local Therapy - Radiotherapy

Radiotherapy

Start date: 

End date: 

☐ none

CRF comment (optional):
### Adverse Events 1

If AE description is not mentioned below, please document on Form 4b.

Did any adverse event listed below occur during neoadjuvant chemotherapy?

- Yes (please document below)
- No

<table>
<thead>
<tr>
<th>Description</th>
<th>CTC-Grade (1)</th>
<th>Treatment modification (2)</th>
<th>Relationship</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n.p. 1 2 3 4</td>
<td>1 2 3 4 5</td>
<td>Yes No</td>
</tr>
<tr>
<td>Fatigue:</td>
<td>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Headache:</td>
<td>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Alopecia:</td>
<td>☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Nausea:</td>
<td>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Anorexia:</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Vomiting:</td>
<td>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Diarrhea:</td>
<td>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Constipation:</td>
<td>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Mucositis / Esophagitis:</td>
<td>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>PPE (HFS):</td>
<td>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Allergic reaction:</td>
<td>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Peripheral sensory</td>
<td>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Arthralgia:</td>
<td>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Myalgia:</td>
<td>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Epistaxis:</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Dyspnea:</td>
<td>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Fever (without neutropenia):</td>
<td>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Febrile neutropenia:</td>
<td>☐ ☐ ☐ ☐</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
<tr>
<td></td>
<td>ANC &lt; 1.0 x 10 /L &amp; fever&gt; = 38,5°C</td>
<td>☐ ☐ ☐ ☐ ☐</td>
<td>☐ ☐</td>
</tr>
</tbody>
</table>

Infection, please specify below:

CRF comment (optional):

---

(1) CTC-Grade: n.p. = not present; maximum CTC-Grade, using the Common Terminology Criteria for Adverse Events (CTCAE v4.0)
(2) Treatment mod: 1 = no action taken / 2 = Dose delay / 3 = Dose reduction / 4 = Interruption / 5 = Permanent discontinuation
Did any adverse event not yet documented on Form 4a Adverse Events I occur during neoadjuvant chemotherapy?  

<table>
<thead>
<tr>
<th>Description:</th>
<th>CTC-Grade (1)</th>
<th>Treatment modification (2)</th>
<th>Relationship</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Adverse Event</td>
<td>4 3 2 1</td>
<td>5 4 3 2 1</td>
<td>Yes No</td>
</tr>
<tr>
<td>(on the basis of CTCAE v4.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Adverse Event</td>
<td>4 3 2 1</td>
<td>5 4 3 2 1</td>
<td>Yes No</td>
</tr>
<tr>
<td>(on the basis of CTCAE v4.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Adverse Event</td>
<td>4 3 2 1</td>
<td>5 4 3 2 1</td>
<td>Yes No</td>
</tr>
<tr>
<td>(on the basis of CTCAE v4.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Adverse Event</td>
<td>4 3 2 1</td>
<td>5 4 3 2 1</td>
<td>Yes No</td>
</tr>
<tr>
<td>(on the basis of CTCAE v4.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Adverse Event</td>
<td>4 3 2 1</td>
<td>5 4 3 2 1</td>
<td>Yes No</td>
</tr>
<tr>
<td>(on the basis of CTCAE v4.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. CTC-Grade: maximum CTC-Grade, using the Common Terminology Criteria for Adverse Events (CTCAE v4.0)  
2. Treatm. mod: 1 = no action taken / 2 = Dose delay / 3 = Dose reduction / 4 = Interruption / 5 = Permanent discontinuation  

CRF comment (optional):
## Breast ultrasound

<table>
<thead>
<tr>
<th>Assessment date:</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>□ n.d.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumor size (same lesion as at baseline, largest diameters):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were there any other suspicious findings?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If &quot;yes&quot;, please specify:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Other examination

<table>
<thead>
<tr>
<th>Examination:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment date:</td>
<td></td>
</tr>
<tr>
<td>Tumor size (same lesion as at baseline, largest diameters):</td>
<td></td>
</tr>
<tr>
<td>Were there any other suspicious findings?</td>
<td></td>
</tr>
<tr>
<td>If &quot;yes&quot;, please specify:</td>
<td></td>
</tr>
</tbody>
</table>
**Primary breast surgery**

Date of the first breast surgery:  

Was the surgery performed within 1-14 days after the completion of the last chemotherapy cycle? If "no", please give reason(s):  

Were additional surgeries performed?  

If "yes" → a total of additional surgeries were performed.  

Date of last surgery:  

**Histology**

Date of histology:  

Histological tumor type:  

- ductal or ductal-lobular invasive  
- lobular invasive  
- DCIS  
- LCIS  
- pCR  
- other (please specify):  

Tumor grading:  

- 1  
- 2  
- 3  
- n.k.  
- pCR  

Vascular Invasion:  

- yes  
- no  
- pCR  

Lymphatic Invasion:  

- yes  
- no  
- pCR  

Estrogen receptor:  

- positive  
- negative  
- number of positive stained cells in %:  
- n.k.  
- n.a. (pCR)  

Progestereone receptor:  

- positive  
- negative  
- number of positive stained cells in %:  
- n.k.  
- n.a. (pCR)  

HER-2/neu status:  

- negative  
- IHC+++  
- FISH+  
- n.k.  
- n.a. (pCR)  

Ki-67 status:  

- %  

TNM-Classification:  

- ypT  
- ypN  

If pN>0, please indicate lymph nodes affected:  

- axillary  
- infraclavicular  
- mammra interna  
- supraclavicular  
- n.d./n.k.  

CRF comment (optional):
**Pregnancy and Delivery**

### Pregnancy

**Pregnancy interrupted**  ○ yes  ○ no  
**Last menstrual period**:  

**Complications during pregnancy**  ○ no  ○ yes (please specify below)

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Date of diagnosis</th>
<th>Relation to cancer therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Delivery

**Multiple birth**:  ○ yes  ○ no  
(please fill in Form 6 for each baby.)  
**Date of birth**:  

**Type of birth**  ○ spontaneous  ○ operative vaginal delivery  ○ caesarean section

### Histology of Placenta

**Metastasis to placenta?**  ○ yes  ○ no  ○ not done

**FFPE from placenta available?**  ○ yes  ○ no

If "yes"  
**Histo No.**:  

**CRF comment (optional)**:
**Newborn**

- Gender: ○ female ○ male
- Apgar number 5/10
- Release from hospital ○ together with the mother ○ later
- If later, please specify the reasons:

**Examination immediately after birth**

- Body weight
- Body length
- Hair: ○ corresponding to the age ○ not sufficient
- Signs of infection ○ yes ○ no
- If yes, please specify

**Examination 4 weeks after birth**

- Body weight
- Body length
- Hair: ○ corresponding to the age ○ not sufficient
- Signs of infection ○ yes ○ no
- If yes, please specify

**Haematology**

- Haemoglobin
- Leukocytes
- Platelets

Please enter the decimal point/comma in a separate field. Unit (or n.d.)

**CRF comment (optional):**
FU - Follow Up Patient

Date of Follow up Report / Date of last contact

Date of follow up report: [ ] [ ] [ ] [ ] [ ] [ ] [ ] Date of last contact: [ ] [ ] [ ] [ ] [ ] [ ]

Patient status

Patient is alive and healthy: (if "no", please specify below) ○ yes ○ no

Diagnosis of local relapse:
- Date of first loco-regional relapse: [ ] [ ] [ ]
- Location(s) of relapse(s): □ ipsilateral breast - same quadrant as first primary
  □ ipsilateral breast - different quadrant
  □ axillary LN □ supra-/intraclavicular LN ipsilateral

Diagnosis of distant relapse:
- Date of first distant relapse: [ ] [ ] [ ]
- Location(s) of relapse(s): □ contralateral breast □ skin □ bone □ liver
  □ LN other than loco-regional □ CNS □ pleural □ lung
  □ other (please specify):

Diagnosis of 2nd malignancy:
- Date of diagnosis: [ ] [ ] [ ] [ ]
- Diagnosis:

Patient died:
- Date of death: [ ] [ ] [ ] [ ] [ ] [ ]
- Primary cause of death: ○ due to breast cancer
  ○ due to the following adverse event:
  ○ other (specify):
  ○ unknown

Has the patient become pregnant?: ○ yes ○ no
  if "yes", please fill in the section below "Pregnancy outcome"

CRF comment (optional):

[ ] [ ] [ ] [ ] [ ] [ ] [ ]
### FU - Follow Up Patient

#### Pregnancy outcome

**Pregnancy outcome:**
- [ ] Termination
- [ ] Miscarriage
- [ ] Still birth
- [ ] Live birth

**Week of pregnancy:**

**Date of delivery/termination:**

---

**CRF comment (optional):**
Follow Up Child

In case of multiple birth, please fill in this CRF for each child.

Child’s outcome:
- alive
- lost to follow up
- dead
- not assessed

Date of last contact:

Date of death:

Normal development of the Child?
- yes
- no, please specify:

Has an adverse event occurred?
- yes
- no

Date of event, if applicable:

Relation to mother’s cancer therapy:
- none
- possible
- probable
- unknown

Please specify event:

CRF comment (optional):