

GBG

GERMAN
BREAST
GROUPBIG
Breast International Group

Breast Cancer in Pregnancy



Registration form

Form 1

Prospective and Retrospective Register Study of the German Breast Group (GBG)
for Diagnosis and Treatment of Breast Cancer in Pregnancy

Demographic characteristics

Year of Birth:

Documentation for this patient is:

 prospective retrospective (informed consent not necessary)

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 noFFPE 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:

 . .

Country
Code

Center

Patient No.

Breast Cancer - Histology

Form 2

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 *

pT pN

* 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: positive negative unknown

Ki67: % 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

Form 2a

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

A. Patient and her siblings/children

No.

- a mamma carcinoma in the patient BEFORE the age of 36
- a unilateral mamma carcinoma in the patient BEFORE the age of 51
- a bilateral mamma carcinoma in the patient, the first of which occurred BEFORE the age of 51
- a unilateral or bilateral mamma carcinoma in the patient AFTER the age of 50
- a fallopian tube carcinoma or primary peritoneal carcinomatosis in the patient
- a mamma carcinoma in sisters/daughters BEFORE the age of 36
- a unilateral mamma carcinoma in sisters/daughters BEFORE the age of 51
- a bilateral mamma carcinoma in sisters/daughters, the first of which occurred BEFORE the age of 51
- a unilateral or bilateral mamma carcinoma in sisters/daughters AFTER the age of 50
- a mamma carcinoma in brothers/sons
- a fallopian tube carcinoma or primary peritoneal carcinomatosis in sisters/daughters

B. Maternal line

No.

- a mamma carcinoma in a female relative BEFORE the age of 36
- a unilateral mamma carcinoma in a female relative BEFORE the age of 51
- a bilateral mamma carcinoma in a female relative, the first of which occurred BEFORE the age of 51
- a unilateral or bilateral mamma carcinoma in a female relative AFTER the age of 50
- a mamma carcinoma in a male relative
- a fallopian tube carcinoma or primary peritoneal carcinomatosis in a female relative

C. Paternal line

No.

- a mamma carcinoma in a female relative BEFORE the age of 36
- a unilateral mamma carcinoma in a female relative BEFORE the age of 51
- a bilateral mamma carcinoma in a female relative, the first of which occurred BEFORE the age of 51
- a unilateral or bilateral mamma carcinoma in a female relative AFTER the age of 50
- a mamma carcinoma in a male relative
- a fallopian tube carcinoma or primary peritoneal carcinomatosis in a female relative

CRF comment (optional):

--

--	--	--	--

--	--	--	--	--	--

--	--	--	--	--	--	--

General Medical History

Form 2b

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

Description

Start date

--

	.		.			
--	---	--	---	--	--	--

n.k.

Current? yes no

Code*:

--	--

--

	.		.			
--	---	--	---	--	--	--

n.k.

Current? yes no

Code*:

--	--

--

	.		.			
--	---	--	---	--	--	--

n.k.

Current? yes no

Code*:

--	--

--

	.		.			
--	---	--	---	--	--	--

n.k.

Current? yes no

Code*:

--	--

--

	.		.			
--	---	--	---	--	--	--

n.k.

Current? yes no

Code*:

--	--

***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):

--

Country
Code

Center

Patient No.

Previous Pregnancy

Form 2c

Previous Pregnancy

Number of previous pregnancies

grav.

par.

Date of last
delivery/interruption:

CRF comment (optional):

Country
Code

--	--	--

Center

--	--	--	--

Patient No.

--	--	--	--

Breast Cancer - Diagnosis

Form 3

Physical examination breast

Clinical signs for cT4: none extension to chest wall (T4a)
 skin involvement (T4b) inflammation (T4d)
 not done

Assessment date:

 .

 .

Results: not suspicious suspicious led to diagnosis of carcinoma

Tumour size (largest diameters)

 X

 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 lymph nodes affected: axillary infraclavicular n.k.
 mammaia interna supraclavicular

Ultrasound of breast

Assessment date:

 .

 .

 not done

Results: not suspicious suspicious led to diagnosis of carcinoma

Tumour size (largest diameters)

 X

 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 lymph nodes affected: axillary infraclavicular n.k.
 mammaia interna supraclavicular

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)

 X

 mm not known

MRI

Assessment date:

 .

 .

 not done

Results: not suspicious suspicious led to diagnosis of carcinoma

Tumour size (largest diameters)

 X

 mm not known

CRF comment (optional):

Systemic Therapy - Chemotherapy

Form 4-1

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)

	total	during pregnancy	prior to surgery
<input type="checkbox"/> EC/AC	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<input type="checkbox"/> FEC/FAC	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<input type="checkbox"/> E/A mono	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<input type="checkbox"/> Taxane: → <input type="radio"/> Paclitaxel <input type="radio"/> Docetaxel	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<input type="checkbox"/> CMF	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<input type="checkbox"/> other 1: <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<input type="checkbox"/> other 2: <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<input type="checkbox"/> target: <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

(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):

	interruption	reduction
Hematological toxicity:	<input type="checkbox"/>	<input type="checkbox"/>
Non-hematological toxicity:	<input type="checkbox"/>	<input type="checkbox"/>
Child (complications during pregnancy/delivery):	<input type="checkbox"/>	<input type="checkbox"/>
Other (please specify below):	<input type="checkbox"/>	<input type="checkbox"/>

Supportive therapy

Dexamethasone yes no G-CSF: yes no
If "yes": mg : Pegfilgrastim: yes no
5-HT3 antagonist: yes no Antibiotics: yes no
Clemastine: yes no Other: yes no
Ranitidin: yes no **If other "yes", please specify below:**

CRF comment (optional):

--	--	--	--

--	--	--	--	--	--

--	--	--	--	--	--

--

Endocrine and Targeted Therapy

Form 4-2

Endocrine therapy

Start Date:

--	--	--	--	--	--	--	--

End Date:

--	--	--	--	--	--	--	--

none

Medication

Dose

Number of months

1.

--

--

--	--

2.

--

--

--	--

Targeted therapy

Start Date:

--	--	--	--	--	--	--	--

End Date:

--	--	--	--	--	--	--	--

none

Medication

Dose

Number of
infusions/weeks

1.

--

--

--	--

2.

--

--

--	--

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

CRF comment (optional):

--

Local Therapy - Surgery

Form 4-3

Surgery

Date of surgery: . .

none

- 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?

yes no

If "yes", please give reason(s):

CRF comment (optional):

--	--	--

--	--	--	--	--

--	--	--	--	--	--

--	--

Local Therapy - Radiotherapy

Form 04-4

Radiotherapy

Start date:

		.			.				
--	--	---	--	--	---	--	--	--	--

End date:

		.			.				
--	--	---	--	--	---	--	--	--	--

none

CRF comment (optional):

--

Country
Code

--	--	--

Center

--	--	--	--

Patient No.

--	--	--	--

Adverse Events 1

Form 4a

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

Description (on the basis of CTCAE v4.0)	CTC-Grade (1)					Treatment modification (2)					Relationship	
	n.p.	1	2	3	4	1	2	3	4	5	Yes	No
Fatigue:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
Headache:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
Alopecia:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
Nausea:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
Anorexia:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
Vomiting:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
Diarrhea:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
Constipation:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
Mucositis / Esophagitis:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
PPE (HFS):	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
Allergic reaction:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
Peripheral sensory	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
Arthralgia:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
Myalgia:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
Epistaxis:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
Dyspnea:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
Fever (without neutropenia):	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
Febrile neutropenia: (ANC <1.0 x 10 /L & fever ≥38,5°C)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
Infection, please specify below:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>

(1) **CTC-Grade:** n.p.=not present; 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):

Country
Code

--	--	--

Center

--	--	--	--	--

Patient No.

--	--	--	--	--

Form 4b - Adverse Events II

Form 4b

Did any adverse event not yet documented on **Form 4a Adverse Events I** occur during neoadjuvant chemotherapy?

AE Log:

yes (please document below) no

Description:	CTC-Grade (1)				Treatment modification (2)					Relationship	
	1	2	3	4	1	2	3	4	5	Yes	No

1. Adverse Event

(on the basis of CTCAE v4.0)

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
-----------------------	-----------------------	-----------------------	-----------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	-----------------------	-----------------------

Description:

2. Adverse Event

(on the basis of CTCAE v4.0)

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
-----------------------	-----------------------	-----------------------	-----------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	-----------------------	-----------------------

Description:

3. Adverse Event

(on the basis of CTCAE v4.0):

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
-----------------------	-----------------------	-----------------------	-----------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	-----------------------	-----------------------

Description:

4. Adverse Event

Description:
(on the basis of CTCAE v4.0)

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
-----------------------	-----------------------	-----------------------	-----------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	-----------------------	-----------------------

5. Adverse Event

Description:
(on the basis of CTCAE v4.0)

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>
-----------------------	-----------------------	-----------------------	-----------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	--------------------------	-----------------------	-----------------------

(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):

Imaging neoadjuvant patients during chemotherapy

Form 4c

Breast ultrasound

Assessment date: . . n.d.

Tumor size (same lesion as at baseline, largest diameters): mm X mm not measurable
 not detectable

Were there any other suspicious findings? yes no

If "yes", please specify:

Other examination

Examination:

Assessment date: . . n.d.

Tumor size (same lesion as at baseline, largest diameters): mm X mm not measurable
 not detectable

Were there any other suspicious findings? yes no

If "yes", please specify:

CRF comment (optional):

Country
Code

--	--	--

Center

--	--	--	--

Patient No.

--	--	--	--	--

Surgery for neoadjuvant patients

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):**

yes no

--

Were additional surgeries performed?

yes no

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

number of positive

negative

stained cells in %:

--	--	--

n.k.

n.a. (pCR)

Progesterone receptor:

positive

number of positive

negative

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

mammaria interna

supraclavicular

n.d./n.k.

CRF comment (optional):

--

--	--	--

--	--	--	--

--	--	--	--	--

Pregnancy and Delivery

Form 5

Pregnancy

Pregnancy interrupted yes no Last menstrual period:

--	--

 .

--	--

 .

--	--	--	--

Complications during pregnancy no yes (please specify below)

	Diagnosis	Date of diagnosis	Relation to cancer therapy								
1.	<input style="width: 95%;" type="text"/>	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>									<input type="radio"/> none <input type="radio"/> possible <input type="radio"/> probable <input type="radio"/> unknown
2.	<input style="width: 95%;" type="text"/>	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>									<input type="radio"/> none <input type="radio"/> possible <input type="radio"/> probable <input type="radio"/> unknown
3.	<input style="width: 95%;" type="text"/>	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>									<input type="radio"/> none <input type="radio"/> possible <input type="radio"/> probable <input type="radio"/> unknown
4.	<input style="width: 95%;" type="text"/>	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>									<input type="radio"/> none <input type="radio"/> possible <input type="radio"/> probable <input type="radio"/> unknown
5.	<input style="width: 95%;" type="text"/>	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> . <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>									<input type="radio"/> none <input type="radio"/> possible <input type="radio"/> probable <input type="radio"/> unknown

Delivery

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

Date of birth:

--	--

 .

--	--

 .

--	--	--	--

 in pregnancy week no.:

--	--

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):

--

Country

Code

Center

Patient No. Child No.

--	--	--	--	--	--	--	--	--	--

Child

Form 6

Newborn

Gender: female male

arterial pH value .

Apgar number 5/10 /

venous pH value .

Release from hospital together with the mother later

If later, please specify the reasons:

Examination immediately after birth

Examination 4 weeks after birth

Body weight g

Body weight g

Body length cm

Body length cm

Hair:

- corresponding to the age
- not sufficient

Hair:

- corresponding to the age
- not sufficient

Signs of infection

- yes no

Signs of infection

- yes no

If yes, please specify

If yes, please specify

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

Haemoglobin

Leukocytes

Platelets

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

Haemoglobin

Leukocytes

Platelets

CRF comment (optional):

CRF comment (optional):

Country Code	Center	Patient No.	FU No.
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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: **yes** **no**

→ Date of first loco-regional relapse: . .

- Location(s) of relapse(s): (mark all that apply)
- ipsilateral breast - same quadrant as first primary
- ipsilateral breast - different quadrant
- axillary LN supra-/intraclavicular LN ipsilateral

Diagnosis of distant relapse: **yes** **no**

→ Date of first distant relapse: . .

- Location(s) of relapse(s): (mark all that apply)
- contralateral breast skin bone liver
- LN other than loco-regional CNS pleural lung
- other (please specify):

Diagnosis of 2nd malignancy: **yes** **no**

→ Date of diagnosis: . .

→ Diagnosis:

Patient died: **yes** **no**

→ 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):

Country
Code

--	--	--

Center

--	--	--	--	--

Patient No.

--	--	--	--	--	--

FU
No.

--	--

FU - Follow Up Patient

Pregnancy outcome

Pregnancy outcome:

- Termination
- Miscarriage
- Still birth
- Live birth

Week of pregnancy:

--	--

Date of delivery/termination:

		.			.				
--	--	---	--	--	---	--	--	--	--

CRF comment (optional):

--

Country Code	Center	Patient No.	Child No.	FU No.
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Follow Up Child

Follow-up Child

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

Child`s outcome:

- alive
 lost to follow up -> Date of last contact: . .
- dead Date of death: . . not known
- not assessed

Normal development of the Child?

- yes no, please specify:

Has an adverse event occurred?

- yes no

Date of event, if applicable

. . not known

Please specify event:

Relation to mother's cancer therapy: none possible probable unknown

CRF comment (optional):