

CRF 1 – Study entry

Signed written informed consent: ☐ yes, date: _____
☐ not applicable (retrospective data collection)

Sex: ☐ female ☐ male Age at the time of diagnosis: _____ years

Height: _____ cm Weight: _____ kg

Inclusion and exclusion criteria checked and fulfilled: ☐ yes ☐ no

Histological diagnosis:

☐ Idiopathic granulomatous mastitis

☐ Cystic neutrophilic granulomatous mastitis

Exclusion of tuberculosis performed by:

☐ Histopathology (e.g. Ziehl-Neelsen staining)

☐ Microbiological testing of breast tissue/aspirate (PCR/culture)

☐ Skin or blood test (e.g., tuberculin skin test or IGRA)

☐ Chest X-ray

☐ Other: _____

☐ none of the above

Other diagnostics:

☐ microbiological tests for *Corynebacterium* species (specifically the *C. kroppenstedtii* complex) in breast tissue/aspirate performed ☐ yes ☐ no

☐ exclusion of sarcoidosis performed ☐ yes ☐ no

☐ exclusion of fungal infection (e.g. PAS staining) performed ☐ yes ☐ no

Race / ethnic group

U.S. categories:

☐ White: Not Arab ☐ White: Arab ☐ Asian

☐ Black / African American ☐ Amer. Indian / Alaska Native ☐ Hispanic / Latino

☐ Native Hawaiian / Pacific Islander ☐ other: _____

☐ unknown

Obstetric and gynecologic history

History of pregnancy ☐ yes ☐ no

If yes, pregnancy at the time of IGM diagnosis ☐ yes ☐ no

Number of previous pregnancies (including current pregnancy): _____

Number of births: _____

Last birth (year): _____

History of breastfeeding: ☐ yes ☐ no ☐ unknownIf yes, breastfeeding at the time of diagnosis: ☐ yes ☐ no

If yes, duration of lactation (incl. all breastfed children):

☐ < 3 months ☐ 3-6 months ☐ > 6 months

If yes, last lactation until: _____ (year)

History of milk stasis: ☐ yes ☐ no ☐ unknownIf yes: ☐ right ☐ left ☐ bothHistory of birth control pill use: ☐ yes, duration: ____ years ☐ noBirth control pill at the time of diagnosis: ☐ yes ☐ noHistory of hormone replacement therapy: ☐ yes, duration: ____ years ☐ noHormone replacement therapy at the time of diagnosis ☐ yes ☐ no**Medical history**History of tuberculosis: ☐ yes, first diagnosed: ____ (year) ☐ noHistory of sarcoidosis: ☐ yes, first diagnosed: ____ (year) ☐ noHistory of vasculitis: ☐ yes, first diagnosed: ____ (year) ☐ no

If yes, type of vasculitis: _____

History of autoimmune diseases: ☐ yes, first diagnosed: ____ (year) ☐ no

If yes, which: _____

History of Diabetes mellitus:

☐ yes, first diagnosed: ____ (year) ☐ noMedication at the time of diagnosis: ☐ yes, which: _____ ☐ noSmoking at the time of diagnosis: ☐ yes, ____ packyears ☐ noIf no, history of smoking: ☐ yes, ____ packyears ☐ no**History of previous breast conditions**

Has the patient had an episode of idiopathic granulomatous mastitis (IGM) before?

☐ no ☐ yes, date: ____ (year) side: ☐ right ☐ leftHistory of any other breast condition: ☐ yes ☐ no

If yes: [multiple selection possible]

☐ puerperal mastitis, year: ____ side: ☐ right ☐ left☐ nonpuerperal mastitis, year: ____ side: ☐ right ☐ left

☐ breast surgery, year: _____	side: ☐ right ☐ left
If yes, type of surgery: _____	
If yes, indication for surgery: _____	
☐ breast implant, year of first implantation: _____	side: ☐ right ☐ left
If yes, does the patient still have a breast implant?	☐ yes ☐ no
If yes:	side: ☐ right ☐ left
☐ breast cancer, year: _____	side: ☐ right ☐ left
☐ breast irradiation, year: _____	side: ☐ right ☐ left
☐ other: _____	

CRF 2a – Onset of current episodeSide: ☐ left ☐ right ☐ bilateralIf bilateral, simultaneous onset: ☐ yes ☐ no, details: _____

If bilateral, questions in this CRF refer to the side with earlier onset of symptoms or, in case of simultaneous onset, stronger symptoms; this corresponds to:

☐ left side ☐ right side*Please fill out an additional CRF 2b for the contralateral breast.*

Date of first symptoms: _____ [day, month, year]

Date of first patient visit at your institution: _____

Has the patient consulted other physicians before presentation at your institution?

☐ yes ☐ no ☐ unknown

Date of first histological confirmation: _____

Type of first histological confirmation: ☐ core needle biopsy ☐ open surgery
☐ fine needle aspiration ☐ other: _____

Symptoms at the onset of disease [multiple selection possible]:

☐ pain if yes, VAS pain intensity (1-10): _____
☐ palpable mass ☐ skin redness ☐ skin ulceration
☐ abscess ☐ fever ☐ fatigue ☐ nipple discharge
☐ galactorrhea ☐ nipple retraction ☐ skin retraction ☐ other: _____

Size of the lesion / skin change upon clinical examination: _____ cm

Location of local symptoms: ____ o'clock

or quadrant (multiple selection possible):☐ upper outer ☐ upper inner ☐ lower outer ☐ lower inner ☐ centralLocation in relation to the nipple: ☐ periareolar ☐ peripheral ☐ diffuseBlood sample(s) examined at least once: ☐ yes ☐ noIf yes, highest white blood cells count: _____ x 1000/ μ l or x 10⁹/L ☐ not assessed

If yes, highest C-reactive protein level: _____ mg/dL or _____ mg/l

☐ not assessedProlactin level: _____ μ g/L _____ mIU/L ☐ not assessed☐ other: _____**Breast imaging at the onset of current condition:**

Imaging performed [multiple selection possible]:

☐ Breast ultrasound	☐ Mammography	☐ Breast MRI
☐ Breast CT	☐ PET-CT	☐ no breast imaging performed

Presentation at breast imaging
Some questions below refer to the lesion size. If only one or two dimensions are available, fill in only those. It is not necessary to measure additional dimensions outside of clinical routine.

Ultrasound

Lesion visible: ☐ yes, clearly visible ☐ yes, but not clearly ☐ no

Number of lesions: ☐ 1 ☐ 2 ☐ 3 ☐ ≥ 4

If > 1 lesion, size of all lesions together: ____ x ____ x ____ mm

Size of the largest lesion: ____ x ____ x ____ mm

DEGUM / BIRADS (if known): ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Morphology of the main lesion on ultrasound:

Shape: ☐ irregular ☐ oval ☐ round

Orientation ☐ parallel ☐ not parallel

Margins: ☐ well defined (circumscribed) ☐ ill defined (not circumscribed)

If ill defined, please specify (indistinct, spiculated, angular, microlobulated): _____

hyperechogenic rim: ☐ yes ☐ no

Echogenicity: ☐ anechoic ☐ hypoechoic ☐ hyperechoic ☐ heterogenous

☐ complex (cystic/solid) ☐ isoechoic

Posterior acoustic features: ☐ Indifferent ☐ Acoustic enhancement

☐ Attenuation or shadowing ☐ Combined pattern/complex behavior

Co-existing findings on ultrasound:

☐ cyst ☐ benign lesion: _____ ☐ duct ectasia ☐ skin oedema

☐ floating debris

☐ abnormal axillary lymph nodes: ☐ yes ☐ no

if yes ☐ ipsilateral ☐ contralateral

if yes please specify: cortical thickness of > 3.0mm ☐ yes ☐ no

Size of the largest lymph node in mm: longitudinal diameter: ____ transverse diameter: ____

☐ other: _____ ☐ none

Mammography ☐ not performed

Contrast-enhanced: ☐ yes ☐ no Tomosynthesis: ☐ yes ☐ no

Lesion visible: ☐ yes, clearly visible ☐ yes, but not clearly ☐ no

Number of lesions: ☐ 1 ☐ 2 ☐ 3 ☐ ≥ 4

If > 1 lesion, size of all lesions together: __ x __ x __ mm

Size of the largest lesion: __ x __ x __ mm

Microcalcifications: ☐ yes, size: __ x __ x __ mm ☐ noBIRADS (if known): ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5Breast MRI ☐ not performedLesion visible: ☐ yes, clearly visible ☐ yes, but not clearly ☐ noif visible, visible as: ☐ mass ☐ non-mass enhancementNumber of lesions: ☐ 1 ☐ 2 ☐ 3 ☐ ≥ 4

If > 1 lesion, size of all lesions together: __ x __ x __ mm

Size of the largest lesion: __ x __ x __ mm

BIRADS (if known): ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5☐ Breast CT ☐ not performedLesion visible: ☐ yes, clearly visible ☐ yes, but not clearly ☐ noNumber of lesions: ☐ 1 ☐ 2 ☐ 3 ☐ ≥ 4

If > 1 lesion, size of all lesions together: __ x __ x __ mm

Size of the largest lesion: __ x __ x __ mm

☐ PET-CT ☐ not performedLesion visible: ☐ yes, clearly visible ☐ yes, but not clearly ☐ noNumber of lesions: ☐ 1 ☐ 2 ☐ 3 ☐ ≥ 4

If > 1 lesion, size of all lesions together: __ x __ x __ mm

Size of the largest lesion: __ x __ x __ mm

CRF 3 – Treatment

Watch and wait

Patient first treated with watch and wait

☐ yes☐ no

If yes, start of observation _____ [day, month, year]

End of observation: _____ [day, month, year]

Systemic treatment

Antibiotics administered: ☐ yes ☐ no

If yes, start of treatment: _____ [day, month, year]

How many antibiotic regimens have been used: ☐ 1 ☐ 2 ☐ ≥ 3

First antibiotic: _____ Duration: _____ weeks

Second antibiotic: _____ Duration: _____ weeks

Third antibiotic: _____ Duration: _____ weeks

Further: _____ Duration: _____ weeks

*[The duration of therapy should be rounded up to full weeks if the treatment exceeds 3 days]*Application of antibiotics before histologic diagnosis of IGM: ☐ yes ☐ noApplication of antibiotics after histologic diagnosis of IGM: ☐ yes ☐ noSteroids administered: ☐ yes ☐ no

If yes, start of treatment: _____ [day, month, year]

Application of steroid before histologic diagnosis of IGM: ☐ yes ☐ noApplication of steroids after histologic diagnosis of IGM: ☐ yes ☐ no

First steroid:

☐ Prednisolone ☐ Methylprednisolone ☐ Prednisone ☐ Dexamethasone☐ Hydrocortisone ☐ Triamcinolone ☐ other: _____Administration: ☐ systemic Initial dose: _____ mg. per day☐ topic Initial dose: _____ % _____ per day☐ local depot steroid injection: Initial dose: _____ mg. _____ per week

Duration in weeks: _____

*[The duration of therapy should be rounded up to full weeks if the treatment exceeds 3 days]*First steroid scheme: _____ *[in case of dose reductions or weaning, please document here as well]*

Second steroid:

☐ Prednisolone ☐ Methylprednisolone ☐ Prednisone ☐ Dexamethasone

☐ Hydrocortisone ☐ Triamcinolone ☐ other: _____

Administration: ☐ systemic Initial dose: _____ mg. per day

☐ topic Initial dose: _____ % _____ per day

☐ local depot steroid injection: Initial dose: _____ mg. _____ per week

Second steroid duration in weeks: _____

[The duration of therapy should be rounded up to full weeks if the treatment exceeds 3 days]

Second steroid scheme: _____ *[in case of dose reductions or weaning, please document here as well]*

Further steroid therapy (details): _____

Steroids side effects:

☐ Weight gain ☐ Osteoporosis ☐ Diabetes ☐ Hypertension

☐ Skin problems ☐ Cushing syndrome ☐ other _____ ☐ none

NSAIDs administered: ☐ yes ☐ no

Name of the agent (if known): _____

Duration in weeks: _____

[The duration of therapy should be rounded up to full weeks if the treatment exceeds 3 days]

Further analgetic therapy (details): _____

MTX administered: ☐ yes ☐ no

If yes, was MTX administered simultaneously with steroids ☐ yes ☐ no

How many MTX regimens have been administered ☐ 1 ☐ 2 ☐ ≥ 3

First MTX regimen: ☐ 7.5mg/week ☐ 10mg/week ☐ 15mg/week ☐ other: _____

Start of treatment: _____ [day, month, year]

Duration in weeks: _____

[The duration of therapy should be rounded up to full weeks if the treatment exceeds 3 days]

Second MTX regimen: ☐ 7.5mg/week ☐ 10mg/week ☐ 15mg/week ☐ other: _____

Start of treatment: _____ [day, month, year]

Duration in weeks: _____

[The duration of therapy should be rounded up to full weeks if the treatment exceeds 3 days]

Further MTX therapy (details): _____

MTX side effects:

☐ Nausea ☐ Hair loss ☐ Liver function disorders ☐ other _____ ☐ none

Other Immunosuppressants administered: ☐ yes ☐ no

If yes, start of treatment: _____ [day, month, year]

First regimen: _____

Duration in weeks: _____

[The duration of therapy should be rounded up to full weeks if the treatment exceeds 3 days]

Dose: _____

Second regimen: _____

Duration in weeks: _____

[The duration of therapy should be rounded up to full weeks if the treatment exceeds 3 days]

Dose: _____

Further therapy (details): _____

Other systemic treatment: ☐ yes ☐ no If yes:☐ Colchicine ☐ Hydrochloroquine ☐ Other: _____

In case of more than one therapy line

Reason for treatment escalation /treatment switch (Multiple answers possible)

☐ No response ☐ Partial response ☐ Persistent pain ☐ Persistent findings on imaging☐ Side effects of the treatment ☐ Other: _____ ☐ Not applicable**Local interventions**Needle puncture with aspiration ☐ yes, ☐ no*[This field refers to a puncture with a needle, not an incision using a scalpel. If an incision with a scalpel was performed, please document this under Local Interventions-Open Surgery]*

If yes: date of first intervention: _____

☐ local anaesthesia ☐ general anaesthesia ☐ no anaesthesiaClinical appearance: ☐ pus ☐ serous ☐ blood ☐ other: _____Instillation of an active substance: ☐ yes, details: _____ ☐ noDrain placed: ☐ yes, duration in days: _____ ☐ noIntervention performed under ultrasound guidance: ☐ yes ☐ noMicrobiological analysis performed: ☐ yes ☐ noIf yes: ☐ standard microbiological stain ☐ standard microbiological culture ☐ specialized microbiological culture for *Corynebacterium kroppenstedtii* complex ☐ 16S rRNA gene sequencing☐ microbiological culture for tuberculosis ☐ PCR for tuberculosis (MTB-PCR)☐ other (please specify): _____If yes, result: ☐ sterile ☐ positive (specify pathogen): _____☐ Staphylococcus species ☐ Streptococcus species ☐ MRSA ☐ *Corynebacterium kroppenstedtii* complex ☐ Gram-negative species ☐ other: _____

Further drainage / puncture:	☐ yes, how many: _____ ☐ no
Further details: _____	
Open surgery: ☐ yes, date of first surgery: _____ ☐ no	
If yes: Type of surgery	
☐ incision ☐ partial excision ☐ complete excision ☐ mastectomy ☐ other: _____	
Wound healing: ☐ primary ☐ secondary	
If yes: ☐ local anaesthesia ☐ general anaesthesia ☐ no anaesthesia	
Clinical appearance: ☐ pus ☐ serous ☐ blood ☐ other: _____	
Instillation of an active substance: ☐ yes, details: _____ ☐ no	
Drain placed: ☐ yes, duration in days: _____ ☐ no	
Microbiological analysis performed: ☐ yes ☐ no	
If yes: ☐ standard microbiological stain ☐ standard microbiological culture ☐ specialized microbiological culture for <i>Corynebacterium kroppenstedtii</i> complex ☐ 16S rRNA gene sequencing	
☐ microbiological culture for tuberculosis ☐ PCR for tuberculosis (MTB-PCR)	
☐ other (please specify): _____	
If yes, result: ☐ sterile ☐ positive (specify pathogen): _____	
☐ Staphylococcus species ☐ Streptococcus species ☐ MRSA ☐ Corynebacterium species ☐ Gram-negative species ☐ other: _____	
Further surgeries: ☐ yes, how many: _____ ☐ no	
If yes, details: _____	
Type of surgery [multiple selection possible]:	
☐ incision, date: _____	
☐ partial excision, date: _____	
☐ complete excision, date: _____	
☐ mastectomy, date: _____	
Wound healing: ☐ primary ☐ secondary	
Further details: _____	
Local interventions side effects	
Which side effects have you observed with local interventions?	
(Multiple answers possible)	

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(Required only for prospective cohort)

- ☐ Secondary infections ☐ Disfiguring scarring ☐ Delayed wound healing
- ☐ Long-term pain ☐ Ensuing breast deformity ☐ Recurrences
- Other: _____ ☐ None

CRF 4 – End of treatment

Duration of clinical symptoms:

☐ < 1 month☐ 1-3 months☐ 3-6 months☐ > 6 monthsDid the clinical symptoms resolve completely? ☐ yes ☐ noIf no, type of symptoms at the end of treatment [*multiple selection possible*]:☐ pain if yes, VAS pain intensity (1-10): _____☐ palpable mass ☐ skin redness ☐ skin ulceration☐ abscess ☐ fever ☐ fatigue ☐ nipple discharge☐ galactorrhea ☐ nipple retraction ☐ skin retraction ☐ other: _____

Size of the lesion / skin change upon clinical examination: _____ cm

Location of local symptoms: ____ o'clock

or quadrant (multiple selection possible):☐ upper outer☐ upper inner☐ lower outer☐ lower inner☐ centralLocation in relation to the nipple: ☐ periareolar ☐ peripheral ☐ diffuse**Breast imaging at the end of the treatment**

*This question refers to breast imaging after the IGM treatment, not to the initial breast imaging. Some questions below refer to the lesion size. If only one or two dimensions are available, fill in only those. It is **not necessary** to measure additional dimensions outside of clinical routine.*

Breast imaging performed at the end of the treatment ☐ yes ☐ noIf yes: Residual lesion visible upon imaging: ☐ yes ☐ noNumber of lesions: ☐ 1 ☐ 2 ☐ 3 ☐ ≥ 4

If > 1 lesion, size of all residual lesions together: ____ x ____ x ____ mm

Size of the largest residual lesion: ____ x ____ x ____ mm

Lesion seen upon: [*multiple selection possible*]:☐ Breast ultrasound☐ Mammography☐ Breast MRI☐ Breast CT☐ PET-CT

CRF 5 – Follow up after 1 year

☐ not available / not applicable (retrospective data collection)

Did the clinical symptoms of the first episode resolve completely?

☐ yes, when: _____ [month / year] ☐ no

If no, type of symptoms at 1 year follow up [multiple selection possible]:

- ☐ pain if yes, VAS pain intensity (1-10): _____
- ☐ palpable mass ☐ skin redness ☐ skin ulceration
- ☐ abscess ☐ fever ☐ fatigue ☐ nipple discharge
- ☐ galactorrhea ☐ nipple retraction ☐ skin retraction ☐ other: _____

Breast imaging after 1 year

*This question refers to breast imaging 1 year after the end of IGM treatment, not to the initial breast imaging. Some questions below refer to the lesion size. If only one or two dimensions are available, fill in only those. It is **not necessary** to measure additional dimensions outside of clinical routine.*

Breast imaging performed ☐ yes ☐ noIf yes, Residual lesion visible upon imaging: ☐ yes ☐ noNumber of lesions: ☐ 1 ☐ 2 ☐ 3 ☐ ≥ 4

If > 1 lesion, size of all residual lesions together: ____ x ____ x ____ mm

Size of the largest residual lesion: ____ x ____ x ____ mm

Lesion seen upon: [multiple selection possible]:

- ☐ Breast ultrasound ☐ Mammography ☐ Breast MRI
- ☐ Breast CT ☐ PET-CT

New episode of IGM after the end of treatment?

☐ yes, date of recurrence: _____ [month / year] ☐ noIf yes: Side: ☐ right ☐ left

If yes: Treatment (if known): _____

Did further events of interest occur?

☐ right-sided breast cancer, if yes: date of diagnosis: _____☐ left-sided breast cancer, if yes: date of diagnosis: _____☐ other (e.g., other breast disease, autoimmune disease, sarcoidosis, tuberculosis...)If yes: details _____ date of diagnosis: _____ ☐ no

CRF 6 – Follow up after 3 years☐ not available / not applicable (retrospective data collection)

Did the patient experience another episode of IGM after the end of treatment, that has not been documented in CRF 5?

☐ yes, date of recurrence: _____ [month / year] ☐ noIf yes: Side: ☐ right ☐ left

If yes: Treatment (if known): _____

If no, did clinical symptoms of the first episode resolve completely?

☐ yes, when: _____ [month / year] ☐ no

If no, type of symptoms at 3 years follow up [multiple selection possible]:

☐ pain if yes VAS pain intensity (1-10): _____☐ palpable mass ☐ skin redness ☐ skin ulceration☐ abscess ☐ fever ☐ fatigue ☐ nipple discharge☐ galactorrhea ☐ nipple retraction ☐ skin retraction ☐ other: _____**Breast imaging after 3 years***This question refers to breast imaging 3 years after the end of IGM treatment, not to the initial breast imaging. Some questions below refer to the lesion size. If only one or two dimensions are available, fill in only those. It is **not necessary** to measure additional dimensions outside of clinical routine.*Breast imaging performed ☐ yes ☐ noIf yes Residual lesion visible upon imaging: ☐ yes ☐ noNumber of lesions: ☐ 1 ☐ 2 ☐ 3 ☐ ≥ 4

If > 1 lesion, size of all residual lesions together: ____ x ____ x ____ mm

Size of the largest residual lesion: ____ x ____ x ____ mm

Lesion seen upon: [multiple selection possible]:

☐ Breast ultrasound ☐ Mammography ☐ Breast MRI☐ Breast CT ☐ PET-CT

Did further events of interest occur?

☐ right-sided breast cancer, if yes: date of diagnosis: _____☐ left-sided breast cancer, if yes: date of diagnosis: _____☐ other (e.g., other breast disease, autoimmune disease, sarcoidosis, tuberculosis...)If yes: details _____ date of diagnosis: _____ ☐ no

CRF 7 – Follow up after 5 years

☐ not available / not applicable (retrospective data collection)

Did the patient experience another episode of IGM after the end of treatment, that has not been documented in CRF 6?

☐ yes, date of recurrence: _____ [month / year] ☐ noIf yes: Side: ☐ right ☐ left

If yes: Treatment (if known): _____

If no, did clinical symptoms of the first episode resolve completely?

☐ yes, when: _____ [month / year] ☐ no

If no, type of symptoms at 5 years follow up [multiple selection possible]:

☐ pain if yes VAS pain intensity (1-10): _____☐ palpable mass ☐ skin redness ☐ skin ulceration☐ abscess ☐ fever ☐ fatigue ☐ nipple discharge☐ galactorrhea ☐ nipple retraction ☐ skin retraction ☐ other: _____**Breast imaging after 5 years***This question refers to breast imaging 5 years after the end of IGM treatment, not to the initial breast imaging. Some questions below refer to the lesion size. If only one or two dimensions are available, fill in only those. It is **not necessary** to measure additional dimensions outside of clinical routine.*Breast imaging performed: ☐ yes ☐ noResidual lesion visible upon imaging: ☐ yes ☐ noNumber of lesions: ☐ 1 ☐ 2 ☐ 3 ☐ ≥ 4

If > 1 lesion, size of all residual lesions together: ____ x ____ x ____ mm

Size of the largest residual lesion: ____ x ____ x ____ mm

Lesion seen upon: [multiple selection possible]:

☐ Breast ultrasound ☐ Mammography ☐ Breast MRI☐ Breast CT ☐ PET-CT

Did further events of interest occur?

☐ right-sided breast cancer, if yes: date of diagnosis: _____☐ left-sided breast cancer, if yes: date of diagnosis: _____☐ other (e.g., other breast disease, autoimmune disease, sarcoidosis, tuberculosis...)If yes: details _____ date of diagnosis: _____ ☐ no

CRF 2b – Onset of symptoms on the contralateral breast in case of bilateral IGM

In case of bilateral IGM, questions in this CRF refer to the side with later onset of symptoms or, in case of simultaneous onset, weaker symptoms; this corresponds to:

☐ left side ☐ right side

Date of first symptoms: _____ [day, month, year]

Date of first patient visit at your institution: _____

Has the patient consulted other physicians before presentation at your institution?

☐ yes ☐ no ☐ unknown

Date of first histological confirmation: _____

Type of first histological confirmation: ☐ core needle biopsy ☐ open surgery
☐ fine needle aspiration ☐ other: _____

Symptoms at the onset of disease [multiple selection possible]:

☐ pain ☐ palpable mass ☐ skin redness ☐ skin ulceration
☐ abscess ☐ fever ☐ fatigue ☐ nipple discharge
☐ galactorrhea ☐ nipple retraction ☐ skin retraction ☐ other: _____

Size of the lesion / skin change upon clinical examination: _____ cm

Location of local symptoms: ____ o'clock

or quadrant (multiple selection possible):

☐ upper outer ☐ upper inner ☐ lower outer ☐ lower inner ☐ central

Location in relation to the nipple: ☐ periareolar ☐ peripheral ☐ diffuse

Breast imaging at the onset of current condition:

Imaging performed [multiple selection possible]:

☐ Breast ultrasound ☐ Mammography ☐ Breast MRI
☐ Breast CT ☐ PET-CT ☐ no breast imaging performed

Presentation at breast imaging

Some questions below refer to the lesion size. If only one or two dimensions are available, fill in only those. It is not necessary to measure additional dimensions outside of clinical routine.

Ultrasound

Lesion visible: ☐ yes, clearly visible ☐ yes, but not clearly ☐ no

Number of lesions: ☐ 1 ☐ 2 ☐ 3 ☐ ≥ 4

If > 1 lesion, size of all lesions together: __ x __ x __ mm

Size of the largest lesion: __ x __ x __ mm

BIRADS / DEGUM (if known): ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Morphology of the main lesion on ultrasound:

Shape: ☐ irregular ☐ oval ☐ roundOrientation ☐ parallel ☐ not parallelMargins: ☐ well defined (circumscribed) ☐ ill defined (not circumscribed)

If ill defined, please specify (indistinct, spiculated, angular, microlobulated): _____

Hyperechogenic rim: ☐ yes ☐ noEchogenicity: ☐ anechoic ☐ hypoechoic ☐ hyperechoic ☐ heterogenous☐ complex (cystic/solid) ☐ isoechoicPosterior acoustic features: ☐ Indifferent ☐ Acoustic enhancement☐ Attenuation or shadowing ☐ Combined pattern/complex behavior☐ abnormal axillary lymph nodes ☐ yes ☐ noif yes ☐ ipsilateral ☐ contralateralif yes please specify: cortical thickness of > 3.0mm ☐ yes ☐ no

Size of the largest lymph node in mm: longitudinal diameter: __ transverse diameter: __

Co-existing findings on ultrasound: ☐ cyst ☐ benign lesion: _____☐ duct ectasia ☐ skin oedema ☐ floating debris☐ other: _____ ☐ noneMammographyContrast-enhanced: ☐ yes ☐ no Tomosynthesis: ☐ yes ☐ noLesion visible: ☐ yes, clearly visible ☐ yes, but not clearly ☐ noNumber of lesions: ☐ 1 ☐ 2 ☐ 3 ☐ ≥ 4

If > 1 lesion, size of all lesions together: __ x __ x __ mm

Size of the largest lesion: __ x __ x __ mm

Microcalcifications: ☐ yes, size: __ x __ x __ mm ☐ noBIRADS (if known): ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5Breast MRILesion visible: ☐ yes, clearly visible ☐ yes, but not clearly ☐ noif visible, visible as: ☐ mass ☐ non-mass enhancementNumber of lesions: ☐ 1 ☐ 2 ☐ 3 ☐ ≥ 4

If > 1 lesion, size of all lesions together: __ x __ x __ mm

Size of the largest lesion: __ x __ x __ mm

GRAMAREG - CRF**Patient-ID:** __ - __ - __ - __ - __
(Required only for prospective cohort)

BIRADS (if known):		☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
☐ Breast CT	☐ not performed						
Lesion visible:	☐ yes, clearly visible	☐ yes, but not clearly	☐ no				
Number of lesions:	☐ 1	☐ 2	☐ 3	☐ ≥ 4			
If > 1 lesion, size of all lesions together: ____ x ____ x ____ mm							
Size of the largest lesion: ____ x ____ x ____ mm							
☐ PET-CT	☐ not performed						
Lesion visible:	☐ yes, clearly visible	☐ yes, but not clearly	☐ no				
Number of lesions:	☐ 1	☐ 2	☐ 3	☐ ≥ 4			
If > 1 lesion, size of all lesions together: ____ x ____ x ____ mm							
Size of the largest lesion: ____ x ____ x ____ mm							

CRF 5a – Post-treatment Outcome**Retrospective study arm only****General Instructions**

This CRF is intended to document the latest available information on the outcome after the end of treatment of the initial IGM episode, as available from the medical records. No additional follow-up visit, examination, or imaging is required for the purpose of this study.

Clinical assessment and breast imaging may have been performed at different time points. Please document the date corresponding to each assessment.

If a new IGM episode occurred, the clinical and imaging information below should refer to the initial IGM episode and not to the new episode.

Is any information on the patient's outcome after the end of treatment of the initial IGM episode available (e.g., clinical assessment, breast imaging, potential IGM recurrence, or other events of interest)?

☐ yes ☐ no

If no – End of CRF

If yes, date of the latest available clinical assessment: ____ / ____ [month / year]

If more than one clinical assessment is available, please document the latest available assessment relating to the initial IGM episode.

At the latest available clinical assessment, did the clinical symptoms of the initial IGM episode resolve completely?

☐ yes, when: ____ [month / year] ☐ no ☐ unknown / not documented

If no, which symptoms were still present at the latest available clinical assessment?

[multiple selections possible]

☐ pain	if yes, VAS pain intensity (1-10): _____		
☐ palpable mass	☐ skin redness	☐ skin ulceration	
☐ abscess	☐ fever	☐ fatigue	☐ nipple discharge
☐ galactorrhea	☐ nipple retraction	☐ skin retraction	☐ other: _____

Breast imaging

*This question refers to breast imaging after the end of IGM treatment, not to the initial breast imaging. Some questions below refer to the lesion size. If only one or two dimensions are available, fill in only those. It is **not necessary** to measure additional dimensions outside of clinical routine.*

Breast imaging performed after the end of treatment ☐ yes ☐ no

If yes, date of imaging: ____ / ____ [month / year]

If more than one imaging examination is available, please document the latest available imaging examination relating to the initial IGM episode.

Residual lesion visible upon imaging: ☐ yes ☐ no

Number of lesions: ☐ 1 ☐ 2 ☐ 3 ☐ ≥ 4

If > 1 lesion, size of all residual lesions together: ____ x ____ x ____ mm

Size of the largest residual lesion: ____ x ____ x ____ mm

Lesion seen upon: [multiple selection possible]:

- ☐ Breast ultrasound ☐ Mammography ☐ Breast MRI
☐ Breast CT ☐ PET-CT

New episode / Recurrence

IGM recurrence refers to newly documented signs or symptoms of IGM after a period of clinical resolution of the initial IGM episode. Persistent disease without an intervening period of clinical resolution should not be considered a recurrence.

New episode of IGM after the end of treatment?

☐ yes, date of recurrence: ____ [month / year] ☐ no

If yes: side: ☐ right ☐ left

If yes: treatment (if known): _____

Did complete clinical resolution of the initial IGM episode occur before the recurrence?

☐ yes ☐ no ☐ unknown / not documented

Did complete imaging resolution of the initial IGM episode occur before the recurrence?

☐ yes ☐ no ☐ no imaging performed ☐ unknown / not documented

Did further events of interest occur?

☐ right breast cancer, if yes: date of diagnosis: _____

☐ left breast cancer, if yes: date of diagnosis: _____

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Patient-ID: __ - __ - __
(Required only for prospective cohort)

☐ other (e.g., other breast disease, autoimmune disease, sarcoidosis, tuberculosis...)

If yes: details _____ date of diagnosis: _____ ☐ no