AXSANA-CRF **Patient-ID: _ _ - _ _ _ - _ _ _**

CRF 1a – Study entry

Status before neoadjuvant chemotherapy (NACT)

Patient data

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

Side of breast cancer: ☐ left ☐ right Height: ___ cm Weight: ___ kg

Signed written informed consent: ☐ yes, date: _____

Bilateral breast cancer: ☐ yes ☐ no

Distant metastasis: ☐ yes ☐ no

Recurrent breast cancer: ☐ yes ☐ no

Inflammatory breast cancer: ☐ yes ☐ no

Extramammary breast cancer: ☐ yes ☐ no

History of any invasive cancer or DCIS: ☐ yes ☐ no

Supraclavicular lymph node metastasis: ☐ yes ☐ no

Parasternal lymph node metastasis: ☐ yes ☐ no

Axillary surgery before NACT: ☐ yes ☐ no

Pregnancy: ☐ yes ☐ no

Patient suitable for surgical treatment after NACT: ☐ yes ☐ no

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

Scheduled for neoadjuvant chemotherapy: ☐ yes ☐ no

Has NACT already begun? ☐ yes ☐ no

Histology – core biopsy of the breast

Subtype: ☐ NST/ductal ☐ lobular ☐ mixed ductal-lobular ☐ other: _____

ER: _____ % or ____ IRS PgR: _____ % or ____ IRS

HER2 status: ☐ positive ☐ negative

Lymphovascular invasion: ☐ yes ☐ no ☐ not reported

Grading: ☐ 1 ☐ 2 ☐ 3 ☐ 4

Ki-67: _____ % ☐ unknown

Pretherapeutic T stage (before NACT)

Max. tumor size: _____ mm, based on:

☐ Mammography ☐ Ultrasound ☐ MRI ☐ PET

cT: ☐ 1 ☐ 2 ☐ 3 ☐ 4

Focality: ☐ unifocal ☐ bifocal ☐ ≥ 3 tumors

Multicentricity: ☐ yes ☐ no

CRF 1b – Study entry

Status before neoadjuvant chemotherapy (NACT)

Pretherapeutic N stage (before NACT)

Suspicious nodes on palpation: ☐ yes ☐ no

Suspicious nodes on ultrasound: ☐ yes ☐ no

Suspicious nodes on MRI: ☐ yes ☐ no ☐ not performed

Suspicious nodes on PET: ☐ yes ☐ no ☐ not performed

Max. number of suspicious nodes: ☐ 1 ☐ 2 ☐ 3 ☐ ≥ 4

Minimally invasive node biopsy: ☐ Not performed ☐ FNA ☐ Core biopsy

Date: _____

Number of nodes biopsied: ☐ 0 ☐ 1 ☐ 2 ☐ ≥ 3, of these: Positive: _____

Negative: _____

Inconclusive: _____

Max. size of the largest suspicious lymph node: _____ mm

Final classification: ☐ cN+ ☐ cN0

Marking of the target lymph node (TLN): ☐ yes ☐ no Date: _____

Lymph node metastasis confirmed by biopsy/FNA before marking (i.e. cytological/ pathological report available <u>before</u> inserting the marker): ☐ yes ☐ no

Number of marked lymph nodes: ☐ 1 ☐ 2 ☐ ≥ 3

Max. size of the largest marked node: _____ mm

Type of marker: ☐ Carbon ink ☐ Radioactive seed ☐ Magnetic seed ☐ Radar marker

☐ Clip/Coil (Manufacturer und type: _____)

☐ other: _____

Under what guidance was the marker inserted? ☐ Ultrasound ☐ Mammography ☐ MRI

☐ PET-CT ☐ other: _____

Please enter the patient into the <u>Subject-Identification-Log</u> and fill in the <u>eCRF</u> so that the study patient can be registered.

This printed form is for internal documentation. Its use is optional.

CRF 2
= to be completed after neoadjuvant therapy =

Remember that Quality of life questionnaires must be completed by the patient within 4 weeks <u>before</u> surgery!

! **Have the questionnaires been distributed to the patient either electronically or in paper version?** ☐ yes ☐ no
Have the questionnaires been completed by the patient? ☐ yes ☐ no

Neoadjuvant systemic therapy administered: ☐ yes ☐ no
Anthracycline administered: ☐ yes ☐ no Taxane administered: ☐ yes ☐ no
HER2-targeted therapy administered: ☐ yes ☐ no
if yes: ☐ Trastuzumab ☐ Pertuzumab ☐ other: _____
Number of planned chemotherapy cycles: ___, Number of administered cycles: ___

T stage after neoadjuvant therapy (before surgery)
Max. tumor size: _____ mm, based on:

	☐ Mammography	☐ Ultrasound	☐ MRI	☐ PET
ycT:	☐ 0 ☐ 1	☐ 2	☐ 3	☐ 4

N stage after neoadjuvant therapy (before surgery)
Suspicious nodes on palpation: ☐ yes ☐ no
Suspicious nodes on ultrasound: ☐ yes ☐ no ☐ unclear ☐ not performed
Suspicious nodes on MRI: ☐ yes ☐ no ☐ unclear ☐ not performed
Suspicious nodes on PET: ☐ yes ☐ no ☐ unclear ☐ not performed
Preoperative minimally invasive biopsy (after NACT):
☐ not done ☐ FNA ☐ core biopsy, if performed: ☐ malignant ☐ benign
Imaging-pathology-concordance: ☐ yes ☐ no
Final classification: ☐ ycN0 ☐ ycN+

Planned axillary staging:
☐ ALND (Axillary lymph node dissection)
☐ TAD (Targeted axillary dissection = SLNB + TLNB)
☐ SLNB (Sentinel lymph node biopsy)
☐ SLNB + radiography of the SLN but without specific search for the TLN
☐ TLNB (Target lymph node biopsy)
☐ Other: _____

In case of TAD: How many TAD procedures using the marking technique used in this patient have already been performed at your site? ☐ < 30 ☐ ≥ 30

<u>To be completed only if a magnetic seed, radar marker or RFID tag was inserted into the node(s) before NACT:</u>
MRI performed between marker placement and surgery? ☐ Yes, date: _____ ☐ No
if yes, artifacts visible? ☐ Yes ☐ No
if yes, assessment of MRI limited due to artifacts? ☐ Yes ☐ No

CRF 3a
= to be completed after surgery =

Date of surgery: _____

Total time from incision to skin closure: _____ min.

Breast surgery: ☐ Breast-conserving surgery ☐ Mastectomy

Reconstruction: ☐ yes ☐ no

Surgery of the other breast during the same procedure? ☐ yes ☐ no

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Axillary surgery:

Sentinel lymph node (SLN) tracer injection: ☐ yes ☐ no

if yes:

Technique (multiple selection possible): ☐ Dye ☐ Technetium ☐ ICG (indocyanine green)
☐ SPIO (for example MagTrace) ☐ Other: _____

Lymphoscintigraphy performed: ☐ yes ☐ no

if yes: SLN identified on scintigraphy: ☐ yes ☐ no

SLN removed: ☐ yes, number: _____ ☐ no

if yes: Frozen section performed? ☐ no ☐ yes, result:

☐ Macrometastasis (> 2 mm) ☐ Micrometastasis (≤ 2 mm) ☐ ITC ☐ tumor-free

Radiography of the SLN performed: ☐ yes ☐ no

if yes: Marker detected in the SLN: ☐ yes ☐ no

Has/have the TLN been marked before neoadjuvant therapy? ☐ yes ☐ no

if yes:

Preoperative (post-NACT) localization of the target lymph node performed: ☐ yes ☐ no

(CAUTION: the question refers not to marking of the node before NACT!)

if yes: ☐ Wire ☐ Radioactive seed ☐ Magnetic seed ☐ Skin marking
☐ Ink ☐ Radar marker ☐ other: _____

Imaging-guided localization: ☐ ultrasound ☐ mammography ☐ MRT ☐ PET-CT
☐ CT ☐ other: _____

Number of preoperatively localized target lymph nodes: _____

TLN localization: ☐ successful ☐ questionable

if no: why has the preoperative localization not been performed?

☐ initially planned but marker not visible

☐ not planned

☐ unnecessary due to planned intraoperative localization

☐ other reasons: _____

CRF 3b
= to be completed after surgery =

<u>Intraoperative</u> localization of the target lymph node attempted: ☐ yes ☐ no

(CAUTION: the question refers to intraoperative localization = intraoperative search for the marker inserted into the node[s] before NACT, not to SLN search; choose gamma probe <u>only</u> in case of radioactive seeds used as TLN marker!)

if yes: ☐ Intraoperative ultrasound ☐ Ink visualization ☐ Gamma probe
☐ Radar probe ☐ Magnetic probe ☐ Palpation ☐ other: _____

TLN removed: ☐ yes, during TAD/TLNB/SLNB, number of TLNs: __
☐ yes, during ALND, number of TLNs: __
☐ no ☐ not applicable (no marker used)

if yes: Frozen section of the TLN performed? ☐ no ☐ yes, result:
☐ Macrometastasis (> 2 mm) ☐ Micrometastasis (≤ 2 mm) ☐ ITC ☐ tumor-free

Marker detected in the TLN: ☐ yes ☐ no

Radiography of the TLN performed: ☐ yes ☐ no

if yes: marker visible on radiography: ☐ yes ☐ no

Ultrasound of the TLN performed: ☐ yes ☐ no

if yes: marker visible on ultrasound: ☐ yes ☐ no

<u>To be completed only in case a clip/coil marker was inserted before NACT:</u>

Pre-/intraoperative ultrasound visualization of the clip/coil attempted? ☐ yes ☐ no
if yes, TLN visible on ultrasound? ☐ yes ☐ no
if TLN visible on ultrasound: ☐ clearly visible ☐ not clearly visible

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ALND performed: ☐ yes ☐ no

if yes: ☐ as one procedure ☐ as a secondary procedure, date: _____

Radiography of the ALND specimen performed: ☐ yes ☐ no

Marker detected in the ALND specimen but not in the TLN specimen: ☐ yes ☐ no

Further oncological breast surgeries performed: ☐ yes ☐ no

Final result: ☐ Breast conservation ☐ Mastectomy

Have <u>all</u> markers inserted before NACT been removed during SLNB/TAD/TLNB/ALND?

☐ yes ☐ no ☐ not applicable (no markers inserted before NACT)

if no: is one of the markers still in the patient? ☐ yes ☐ no ☐ unclear

Additional imaging to identify lost marker(s) performed: ☐ yes, specify: _____ ☐ no

Was an additional procedure necessary to remove lost marker(s) or is it planned?

☐ yes, please specify: _____ ☐ no

AXSANA-CRF **Patient-ID: _ _ - _ _ _ - _ _ _**

CRF 4

= Postoperative histopathology =

Tumor stage after NACT: ypT _____ ypN _____

Resection margin after completion of surgical therapy:

☐ negative (R0) ☐ positive (R1/R2)

Residual Cancer Burden (RCB): ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ not performed

Sinn's regression score: ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ not performed

Other classifications / Result: _____

_____

Summarized lymph node status after NACT (final histopathology):

Was at least one node both SLN and TLN (SLN = TLN)?

☐ yes, how many? _____ ☐ no

	Number of removed nodes	Number of nodes with:			
		Macro-metastasis	Micro-metastasis	ITC	Tumor-free
SLN = TLN					
Further TLN (non-SLN)					
Further SLN (non-TLN)					
Further nodes removed during staging procedure (e.g. because of suspicious palpation or additional nodes removed during search for TLN)					
ALND					
Total					

Please complete the table with numbers in all categories!

Extracapsular metastatic growth: ☐ yes ☐ no

Max. size of the largest node metastasis: ___ mm ☐ not reported / not applicable

CRF 5
= Planned adjuvant treatment =

Planned systemic therapy after the surgery:

Endocrine therapy: ☐ yes ☐ no

Chemotherapy: ☐ yes ☐ no

if yes: ☐ Capecitabine ☐ other: _____

HER2-targeted therapy: ☐ yes ☐ no

if yes: ☐ Trastuzumab ☐ Pertuzumab ☐ T-DM1

☐ other: _____

Other: ☐ yes ☐ no, if yes, specify: _____

Planned radiation therapy after the surgery:

Breast: ☐ yes ☐ no, if yes: ☐ with Boost ☐ without Boost

Thoracic wall: ☐ yes ☐ no

Supra-/infraclavicular: ☐ yes ☐ no

Parasternal/mediastinal: ☐ yes ☐ no

Axilla: ☐ yes ☐ no

if yes (multiple selection possible): ☐ level I ☐ level II ☐ level III

Axillary complications after the surgery (multiple selection possible):

- ☐ None
- ☐ Bleeding/hematoma requiring surgical intervention
- ☐ Infection requiring antibiotics
- ☐ Infection requiring surgical intervention
- ☐ Seroma requiring puncture/evacuation
- ☐ Other: _____

AXSANA-CRF 6a

= Follow up 1 year after surgery =

Date: _____

! **Have the Quality of life questionnaires been distributed to the patient either electronically or in paper version?** ☐ yes ☐ no

The patient is alive: ☐ yes ☐ no

Date of death: _____

Cause of death: ☐ breast cancer ☐ other malignancy ☐ cardiovascular
☐ treatment toxicity ☐ infection ☐ unknown
☐ other, specify:_____

Distant metastasis: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Site: ☐ lung ☐ pleura ☐ brain ☐ skin ☐ bone marrow ☐ liver
☐ bone ☐ peritoneum ☐ distant lymph nodes ☐ adrenal glands
☐ other: _____

Ipsilateral breast / chest wall recurrence: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Invasive: ☐ yes ☐ no

Carcinoma of the contralateral breast: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Invasive: ☐ yes ☐ no

Lymph node recurrence: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Location (multiple selection possible): ☐ Axilla Level I ☐ Axilla Level II
☐ Axilla Level III ☐ Parasternal ☐ Supra-/infraclavicular
☐ Other: _____

AXSANA-CRF 6b

= Follow up 1 year after surgery =

Radiation therapy performed:

☐ yes ☐ discontinued ☐ not performed

Breast: ☐ yes ☐ no, if yes: ☐ with Boost ☐ without Boost

Thoracic wall: ☐ yes ☐ no

Supra-/infraclavicular: ☐ yes ☐ no

Parasternal/mediastinal: ☐ yes ☐ no

Axilla: ☐ yes ☐ no

if yes (multiple selection possible): ☐ level I ☐ level II ☐ level III

Received adjuvant systemic therapy:

Endocrine therapy: ☐ yes ☐ no

Chemotherapy: ☐ yes ☐ no

if yes: ☐ Capecitabine ☐ other: _____

HER2-targeted therapy: ☐ yes ☐ no

if yes: ☐ Trastuzumab ☐ Pertuzumab ☐ T-DM1

☐ other: _____

Other: ☐ yes ☐ no, if yes, specify: _____

Is the patient currently receiving endocrine therapy? ☐ yes ☐ no

AXSANA-CRF 7a

= Follow up 2 years after surgery =

Date: _____

The patient is alive: ☐ yes ☐ no

Date of death: _____

Cause of death: ☐ breast cancer ☐ other malignancy ☐ cardiovascular
☐ treatment toxicity ☐ infection ☐ unknown
☐ other, specify:_____

Distant metastasis: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Site: ☐ lung ☐ pleura ☐ brain ☐ skin ☐ bone marrow ☐ liver
☐ bone ☐ peritoneum ☐ distant lymph nodes ☐ adrenal glands
☐ other: _____

Ipsilateral breast / chest wall recurrence: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Invasive: ☐ yes ☐ no

Carcinoma of the contralateral breast: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Invasive: ☐ yes ☐ no

Lymph node recurrence: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Location (multiple selection possible): ☐ Axilla Level I ☐ Axilla Level II
☐ Axilla Level III ☐ Parasternal ☐ Supra-/infraclavicular
☐ Other: _____

Is the patient currently receiving endocrine therapy? ☐ yes ☐ no

AXSANA-CRF 7b
= Follow up 3 years after surgery =

Date: _____

! **Have the Quality of life questionnaires been distributed to the patient either electronically or in paper version?** ☐ yes ☐ no

The patient is alive: ☐ yes ☐ no

Date of death: _____

Cause of death: ☐ breast cancer ☐ other malignancy ☐ cardiovascular
☐ treatment toxicity ☐ infection ☐ unknown
☐ other, specify:_____

Distant metastasis: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Site: ☐ lung ☐ pleura ☐ brain ☐ skin ☐ bone marrow ☐ liver
☐ bone ☐ peritoneum ☐ distant lymph nodes ☐ adrenal glands
☐ other: _____

Ipsilateral breast / chest wall recurrence: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Invasive: ☐ yes ☐ no

Carcinoma of the contralateral breast: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Invasive: ☐ yes ☐ no

Lymph node recurrence: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Location (multiple selection possible): ☐ Axilla Level I ☐ Axilla Level II
☐ Axilla Level III ☐ Parasternal ☐ Supra-/infraclavicular
☐ Other: _____

Is the patient currently receiving endocrine therapy? ☐ yes ☐ no

AXSANA-CRF 7c

= Follow up 4 years after surgery =

Date: _____

The patient is alive: ☐ yes ☐ no

Date of death: _____

Cause of death: ☐ breast cancer ☐ other malignancy ☐ cardiovascular

☐ treatment toxicity ☐ infection ☐ unknown

☐ other, specify:_____

Distant metastasis: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Site: ☐ lung ☐ pleura ☐ brain ☐ skin ☐ bone marrow ☐ liver

☐ bone ☐ peritoneum ☐ distant lymph nodes ☐ adrenal glands

☐ other: _____

Ipsilateral breast / chest wall recurrence: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Invasive: ☐ yes ☐ no

Carcinoma of the contralateral breast: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Invasive: ☐ yes ☐ no

Lymph node recurrence: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Location (multiple selection possible): ☐ Axilla Level I ☐ Axilla Level II

☐ Axilla Level III ☐ Parasternal ☐ Supra-/infraclavicular

☐ Other: _____

Is the patient currently receiving endocrine therapy? ☐ yes ☐ no

AXSANA-CRF 7d
= Follow up 5 years after surgery =

Date: _____

! **Have the Quality of life questionnaires been distributed to the patient either electronically or in paper version?** ☐ yes ☐ no

The patient is alive: ☐ yes ☐ no

Date of death: _____

Cause of death: ☐ breast cancer ☐ other malignancy ☐ cardiovascular
☐ treatment toxicity ☐ infection ☐ unknown
☐ other, specify:_____

Distant metastasis: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Site: ☐ lung ☐ pleura ☐ brain ☐ skin ☐ bone marrow ☐ liver
☐ bone ☐ peritoneum ☐ distant lymph nodes ☐ adrenal glands
☐ other: _____

Ipsilateral breast / chest wall recurrence: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Invasive: ☐ yes ☐ no

Carcinoma of the contralateral breast: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Invasive: ☐ yes ☐ no

Lymph node recurrence: ☐ yes ☐ no Date: _____

if yes, histologically confirmed: ☐ yes ☐ no

Location (multiple selection possible): ☐ Axilla Level I ☐ Axilla Level II
☐ Axilla Level III ☐ Parasternal ☐ Supra-/infraclavicular
☐ Other: _____

Is the patient currently receiving endocrine therapy? ☐ yes ☐ no