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 before 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 Subject-Identification-Log and fill in the eCRF
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 before 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

To be completed only if a magnetic seed, radar marker or RFID tag was inserted into the node(s) before NACT:
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

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 =

**Intraoperative 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 only 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

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

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

**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 all 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
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  ☐ 4  ☐ 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

<table>
<thead>
<tr>
<th></th>
<th>Number of removed nodes</th>
<th>Number of nodes with:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Macro-metastasis</td>
</tr>
<tr>
<td>SLN = TLN</td>
<td></td>
<td>Micro-metastasis</td>
</tr>
<tr>
<td>Further TLN (non-SLN)</td>
<td></td>
<td>ITC</td>
</tr>
<tr>
<td>Further SLN (non-TLN)</td>
<td></td>
<td>Tumor-free</td>
</tr>
<tr>
<td>Further nodes removed during staging procedure (e.g. because of suspicious palpation or additional nodes removed during search for TLN)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALND</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Patient-ID: __ - __ - __ - __

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