



Dear Colleagues and AXSANA supporters,

Thanks to your great support, the success story of the AXSANA study continues. Recent highlights were the presentations at the San Antonio Breast Cancer Symposium in December 2024 on the value of axillary ultrasound after neoadjuvant chemotherapy and the clinical impact of minimal residual axillary tumor burden. The latter was classified as practice-changing! You can find all previous full-text publications and congress papers of the AXSANA Study Group at: <https://www.eubreast.org/axsana/#Publications>. We look forward to continuing our successful teamwork with you.

In the name of the International Steering Committee and the Organizing Committee,

Prof. T. Kühn Prof. M. Banyas-Paluchowski Prof. J. de Boniface Prof. O.D. Gentilini Prof. E. Stickeler

Prof. G. Karadeniz Çakmak Prof. N. Ditsch PD S. Hartmann

Important:

Please perform and document follow-up for all ycN0 patients 1, 2, 3, 4, and 5 years after the surgery as specified in the study protocol.

Scientific Activities

Upcoming oral presentations:

- Comparison of marking techniques for target lymph nodes in 2,596 patients with node-positive breast cancer treated with neoadjuvant chemotherapy - Results from the prospective multicenter AXSANA / EUBREAST-03 / AGO-B-053 study (NCT04373655) – **ASCO** annual meeting May 30 - June 3, 2025, Chicago, USA
- Surgical axillary staging in elderly patients with initially node-positive breast cancer after neoadjuvant chemotherapy - data from the prospective AXSANA study (NCT04373655 / EUBREAST-03 / AGO-B-053 study) – annual meeting of the **German Society of Senology** June 26-28, 2025, Stuttgart, Germany
- Consequences of lost axillary markers after neoadjuvant chemotherapy in breast cancer patients - data from the prospective international AXSANA cohort study (NCT04373655) – annual meeting of the **German Society of Senology** June 26-28, 2025, Stuttgart, Germany

Latest full-text publication:

- Radar reflectors for marking of target lymph nodes in initially node-positive patients receiving neoadjuvant chemotherapy for breast cancer-a subgroup analysis of the prospective AXSANA (EUBREAST-03) trial. Breast Cancer Res Treat 2025;211(1):203-211.

Quality of Life

Thanks to your important and solid work, we have collected approximately 4,500 baseline questionnaires to date, which will give us sufficient statistical power for future analyses of QoL and arm morbidity, under the condition that you continue collecting questionnaires from the patients already enrolled.

Please follow the updated instructions below:

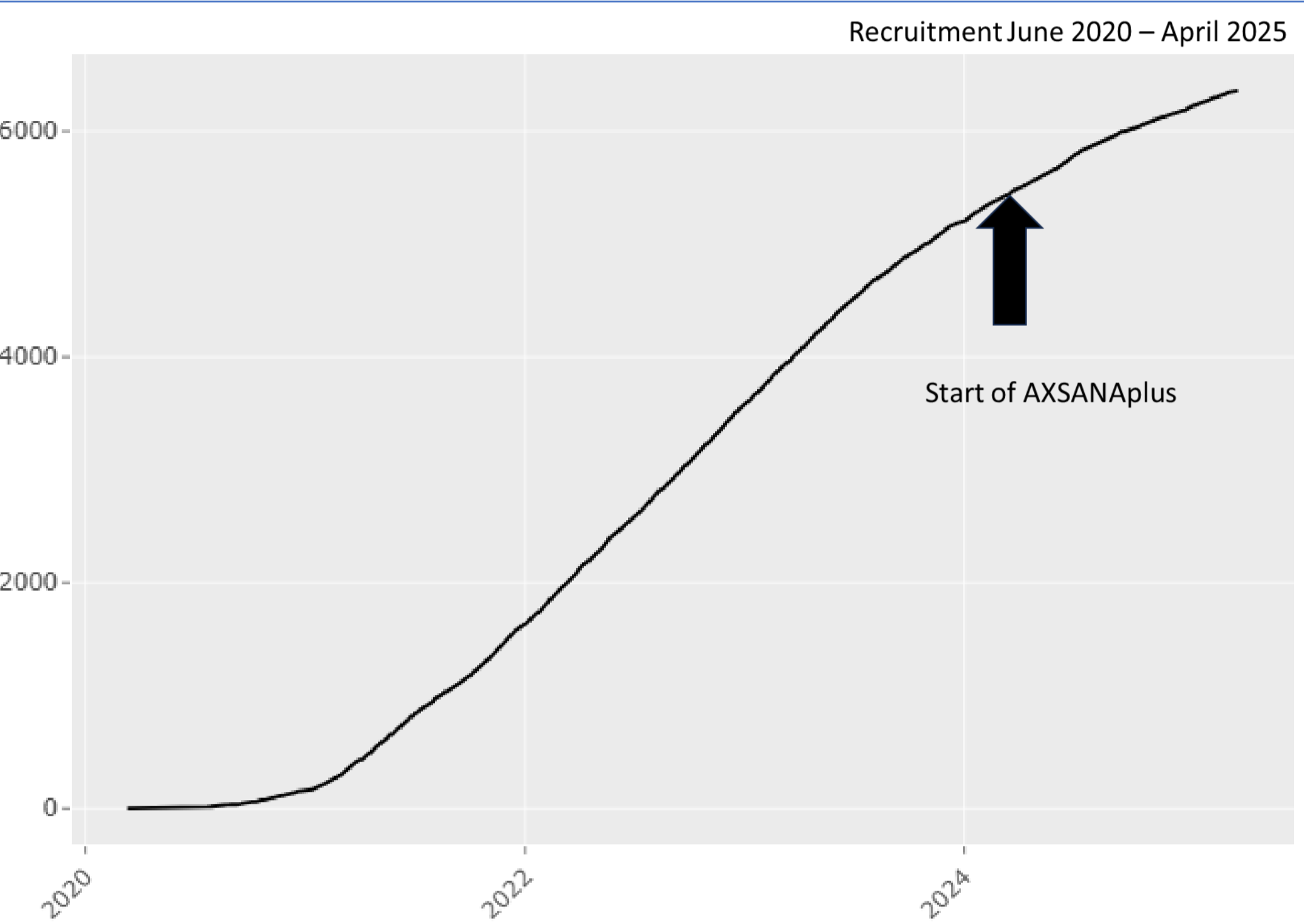
- Patients recruited after March 30, 2025, should not complete any QoL questionnaires at all.
- Patients recruited before March 30, 2025, should still complete questionnaires at baseline (within 4 weeks before surgery) and at follow-up 1, 3, and 5 years after surgery.
- Use electronic questionnaires whenever possible.
- Send a reminder if no response is received. To maintain a high response rate of over 80% even at longer follow-up, participants may need extra reminders and motivation to continue answering the questionnaires.

Your efforts are enormously important and appreciated.

If you have any questions about the QoL questionnaires, do not hesitate to contact Matilda Appelgren at matilda.appelgren@ki.se

Recruitment

- By April 01, 2025, 6,351 patients had been enrolled in the study.
- Patients from 26 countries have been recruited.
- Since the continuation of AXSANA as an unlimited registry from February 1, 2024, 1,197 patients have been recruited at the 179 still participating sites.



country	Head of National Steering Committee	No. of study sites	No. of enrolled patients
Albania	Prof. Helidon Nina	1	107
Austria	Univ.-Prof. Dr. Florentia Peintinger	7	76
Azerbaijan	Ass. Prof. Hagigat Valiyeva Qanimat	1	75
Belgium	Prof. Dr. Marian Vanhoeij	4	61
Bulgaria	Dr. Tsvetomir Ivanov	1	14
Czech Republic	Dr. Lukas Dostalek	1	5
Finland	Dr. Laura Niinikoski	1	113
Germany	Prof. Dr. Maggie Banys-Paluchowski PD Dr. Steffi Hartmann	164	3547
Greece	Prof. Dr. Michalis Kontos	6	145
Hungary	Dr. Zoltan Matrai	1	2
India	Dr. Geeta Kadayaprath	2	83
Israel	Dr. Douglas Zippel	2	39
Italy	Prof. Oreste D. Gentilini	24	442
N.N.	N.N.	1	25
Norway	Dr. Ellen Schlichting	5	68
Peru	Dr. Lía Pamela Rebaza	1	97
Poland	Prof. Dr. Dawid Murawa	11	200
Portugal	Dr. David Pinto	11	123
Romania	Dr. Eduard-Alexandru Bonci	2	53
Slowenia	Dr. Andraž Perhavec	1	13
Spain	Dr. Isabel Rubio	9	188
Sweden	Prof. Jana de Boniface	7	252
Switzerland	Prof. Maria Luisa Gasparri	9	73
Thailand	Dr. Sarun Thongvitokomarn	1	23
Turkey	Prof. Dr. Guldeniz Karadeniz Cakmak	14	517
United Kingdom	Prof. Ashutosh Kothari and Dr. Elina Shaari	1	20

Update CRF

- You can now select “Sirius Pintuition” as an additional option among the marking techniques for the axillary lymph node in the CRF:

CRF 2
(marking before neoadjuvant therapy)

CRF 3a
(marking before surgery)

Type of marker

Type of marker
* must provide value

☐ Carbon ink
☐ Radioactive seed
☐ Magseed
☐ Radar marker
☒ Sirius Pintuition
☐ Clip/Coil
☐ other

Preoperative (post NACT) localization of the target lymph node performed?

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

* must provide value

☒ Yes ☐ No

If yes, please specify

* must provide value

☐ Wire
☐ Radioactive seed
☐ MagSeed
☒ Sirius Pintuition
☐ Skin marking
☐ Ink
☐ Radar marker
☐ other

Data Completing Campaign

- Our third data completion campaign is currently being carried out to have so many complete data sets available in 2025 that it will be possible to start evaluating the primary study objectives.
- We have already resolved more than 15,000 queries in cooperation with you.
- Unfortunately, the number of missing follow-up documentation remains high:

Number of missing follow-ups April 1, 2025:

Year 1	n=370
Year 2	n=427
Year 3	n=245
Year 4	n=73

- However, only data sets with fully completed documentation, **including follow-up**, can be used for the evaluation of the primary study objectives.
- All study participants with a documented ycN0 status in CRF2 should have an annual follow-up documentation 1-5 years after surgery.

IMPRESSUM

EUBREAST Study Group
International Steering and Organizing Committee:
Prof. T. Kühn (Chair)
Prof. M. Banys-Paluchowski
Prof. E. Stickeler
Prof. J. de Boniface
Prof. O. Gentilini
Prof. G. Karadeniz Çakmak
Prof. N. Ditsch
PD S. Hartmann

Study coordination:
Ms. Katharina Jursik, Ms. Jessica Wagner, and Dr. M. Mangold
axsana@eubreast.com
In case of questions do not hesitate to contact your National Steering Committee!

