

Dear Colleagues and AXSANA supporters,

Thanks to your great support, the preplanned target accrual for the AXSANA study was reached earlier than expected. However, due to an unexpected high rate of drop-outs and missing follow-up data, the International Steering Committee has decided to continue recruitment to achieve the required statistical power and improve patient numbers for secondary endpoints. We therefore successfully amended our protocol and received ethical approval to continue the study (as AXSANAplus). This newsletter aims to inform you about the AXSANAplus project, the current data-completing campaign, as well as the scientific activities. Much gratitude to all participating sites which contributed to the great success of the AXSANA study!

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

Prof. T. Kühn

Prof. M. Banys-Paluchowski

Ass. Prof. J. de Boniface

Prof. E. Stickeler

Prof. O.D. Gentilini

Prof. G. Karadeniz Çakmak

PD S. Hartmann

Important Notice:

Please remember to perform and document annual follow-ups in a consistent manner starting 1 year after surgery in all ycN0-patients, even if your study site will not participate in the AXSANAplus study.

AXSANAplus

- As the recruitment target of the **AXSANA** study has been reached, the inclusion of new patients in the study will be **stopped by no later than January 31, 2024**. However, recruitment into the **AXSANAplus** study can **continue from February 1, 2024**.
- Your national steering committee will inform you whether your country is participating in the AXSANAplus study.
- If your country opts to participate in AXSANAplus, you can **choose between 2 options**:
 - Continue recruitment for AXSANAplus or**
 - Stop recruitment, complete datasets and provide follow-up data (over 5 years).**
- If you are participating in AXSANAplus, you can continue to recruit using the AXSANA-redcap database after January 31, 2024, provided that you have a positive ethics committee decision and that you are using the updated patient information. The only difference from the AXSANA study is that the number of participants in AXSANAplus is unlimited. The patient information and consent form for AXSANAplus will be available in the respective national languages at : <https://www.eubreast.org/axsana/>
- Please inform your national steering committee if you would like to participate in AXSANAplus.

Second Data-Completing Campaign

- Following the great success of the first data-completing campaign, we launched a second campaign in September 2023. Our study coordinators, Dr. Bilge Aktas Sezen and Ms. Jana Shabbir, will be contacting all study sites with open documentation until the end of the 2023 and asking them to complete the data as soon as possible.
- Despite best efforts, the rate of missing follow-up documentation is still over 20 percent. However, follow-up data are essential for the primary study objectives of the AXSANA study.
- Therefore, we ask you not only to continue to complete the **data for all patients (ycN0 and ycN+)** up to and **including CRF 5**, but also to be sure to consistently perform and document the annual **follow-up** (CRF6a/b, CRF7a-d, years 1-5 after surgery) for all **ycN0-patients**.
- Please complete all data sets including follow-up even if you are not participating in the AXSANAplus study.**

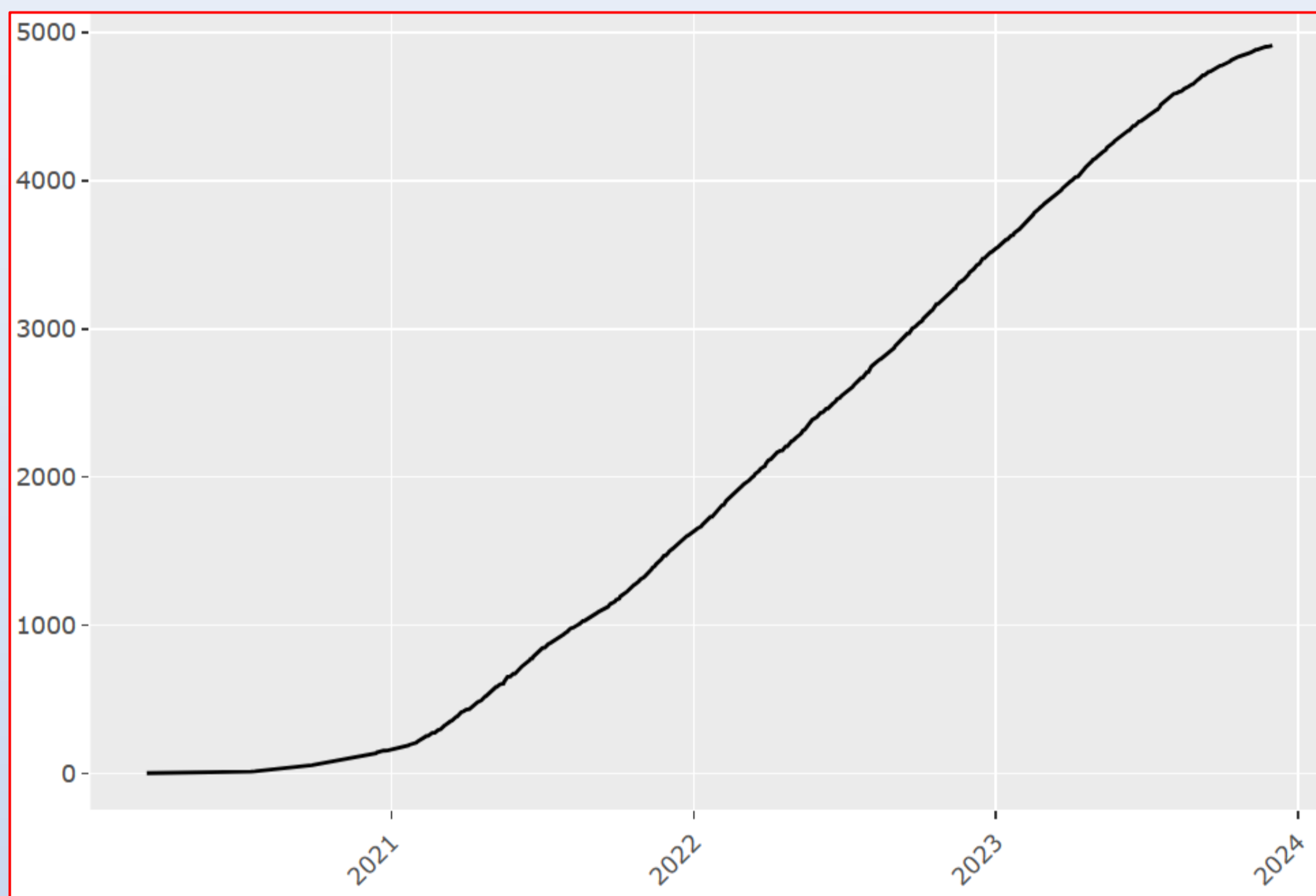
Data Collection Instrument	Study entry	After neoadj. therapy	After surgery	Postop. histopathology	Planned adjuvant treatment	Adj. Treatment and FU1	FU 2-5 years after surgery	End of Observation
Completed after surgery								
CRF 3b - to be completed after surgery								
CRF 4 - Postoperative histopathology								
CRF 5 - Planned adjuvant treatment								
CRF 6b - Adjuvant treatment after surgery								
CRF 6a - Follow up 1 year after surgery								
CRF 7a - Follow up 2 years after surgery								
CRF 7b - Follow up 3 years after surgery								
CRF 7c - Follow up 4 years after surgery								
CRF 7d - Follow up 5 years after surgery								
CRF 8 End Of Observation								

ycN0:
Please document follow-up year 1-5!

Recruitment

- By December 1, 2023, 4.907 patients had been enrolled in the study.
- Patients from 26 countries have been recruited.
- Recruitment in the AXSANA study is planned to end on January 31, 2024. The study sites participating in AXSANAplus can continue to recruit patients starting February 1, 2024, using the updated patient information.

Recruitment June 2020 – December 2023



country	Head of National Steering Committee	No. of study sites	No. of enrolled patients
Albania	Prof. Helidon Nina	1	86
Austria	Univ.-Prof. Dr. Florentia Peintinger	7	60
Azerbaijan	Ass. Prof. Hagigat Valiyeva Qanimat	1	72
Belgium	Prof. Dr. Marian Vanhoeij	4	30
Bulgaria	Dr. Tsvetomir Ivanov	1	1
Czech Republic	Dr. Lukas Dostalek	1	5
Finland	Dr. Laura Niinikoski	1	84
Germany	Prof. Dr. Maggie Banys-Paluchowski	162	2715
Greece	Prof. Dr. Michalis Kontos	6	125
Hungary	Dr. Zoltan Matrai	1	2
India	Dr. Geeta Kadayaprath	2	56
Israel	Dr. Douglas Zippel	2	27
Italy	Prof. Oreste D. Gentilini	24	264
N.N.	N.N.	1	25
Norway	Dr. Ellen Schlichting	5	62
Peru	Dr. Lía Pamela Rebaza	1	64
Poland	Prof. Dr. Dawid Murawa	11	160
Portugal	Dr. David Pinto	11	106
Romania	Dr. Eduard-Alexandru Bonci	2	53
Slowenia	Dr. Andraž Perhavec	1	13
Spain	Dr. Isabel Rubio	9	180
Sweden	Ass. Prof. Jana de Boniface	7	201
Switzerland	Dr. Maria Luisa Gasparri	8	38
Thailand	Dr. Sarun Thongvitokomarn	1	20
Turkey	Prof. Dr. Guldeniz Karadeniz Cakmak	14	438
United Kingdom	Prof. Ashutosh Kothari and Dr. Elina Shaari	1	20

Quality of life (QoL)

- More than 2500 baseline and almost 800 1-year follow-up questionnaires have already been submitted by the study sites participating in the QoL part of the AXSANA study. Thank you for all the effort!
- Please send follow-up questionnaires at 1, 3 and 5-year follow-up to only ycN0, one reminder if necessary.
- Questionnaire cover letters are available for sites with online questionnaires at: <https://data.dynareg.se/axsana>
- The first one-year evaluation will begin in 2024 and a high response rate is crucial for a reliable evaluation. Please scan and email completed paper questionnaires regularly.
- Contact for questionnaires: matilda.appelgren@ki.se
- **Online questionnaires:** Austria, Germany, Greece, Italy, Norway, Peru, Poland, Romania, Spain, Sweden, Turkey. **Paper questionnaires only:** Belgium, Czech Republic, Israel, Portugal, Switzerland, United Kingdom.

Scientific Activities

- You can find all previous full-text publications and congress papers of the AXSANA Study Group at: <https://www.eubreast.org/axsana/#Publications>
- Three posters from the AXSANA Study Group were presented at SABCS 2023:
 1. AXSANA – EUBREAST-3: An international prospective multicenter cohort study to evaluate different surgical methods of axillary staging in clinically node-positive breast cancer patients treated with neoadjuvant chemotherapy
 2. Radar reflectors for marking of target lymph nodes in patients receiving neoadjuvant chemotherapy for breast cancer: a subgroup analysis of the prospective AXSANA (EUBREAST-03) trial
 3. Magnetic seeds used for the detection of target lymph nodes after neoadjuvant therapy for early breast cancer – a subgroup analysis of the prospective AXSANA(EUBREAST-03) trial
- A current full-text publication on the feasibility of magnetic seeds for TLNB can be found at: <https://doi.org/10.1007/s10549-023-07100-0>

IMPRESSUM

EUBREAST Study Group

International Steering and Organizing Committee:

Prof. T. Kühn (Chair)

Prof. E. Stickeler

Prof. J. de Boniface

Prof. M. Banys-Paluchowski

Prof. O. Gentilini

Prof. G. Karadeniz Çakmak

PD S. Hartmann

Study coordination:

Ass. Prof. B. Aktas Sezen, Ms. J. Shabbir, and Dr. M. Mangold

axsana@eubreast.com

In case of questions do not hesitate to contact your National Steering Committee!

AGO-B
BREAST STUDY GROUP

AWOgyn

EUBREAST

CLAUDIA VON SCHILLING FOUNDATION
FOR BREAST CANCER RESEARCH

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MERITMEDICA

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NOGGO
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