

Dear Colleagues and AXSANA supporters,

Thanks to your great support, the recruitment target for the AXSANA study has already been reached ahead of schedule. Since February 1, 2024, we have therefore continued the study as AXSANApplus. With this newsletter, we would like to inform you about the progress of the AXSANApplus study, the results of the second data completion campaign, and upcoming scientific activities. We would like to thank everyone for the very successful and engaged collaboration!

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 Notice:

**Please perform annual follow-ups starting 1 year after surgery in all ycN0-patients (CRF2), even if your study site does not participate in the AXSANApplus study.**

### AXSANApplus

- After reaching the original recruitment target of the AXSANA study, it is now being continued as the AXSANApplus study. The information for AXSANApplus differs from the information for the AXSANA study only in reference to the unlimited number of participants. The prerequisite for this is the consent of the responsible ethics committee to our amendment and the use of the new patient information.
- Study sites participating in the AXSANApplus study can continue with recruitment, registration, and documentation as usual.
- Since February 1, 2024, 182 patients have already been included in the AXSANApplus study.
- Important for all study sites: Please continue the annual postoperative **follow-up** over 5 years for all ycN0-patients previously included in the AXSANA study and the AXSANApplus study in the future, **even if your study site is not participating in the AXSANApplus study.**

CRF2:

Final classification 👤  ycN0  ycN+

\* must provide value

➔ complete:

Adj. Treatment and FU1	FU 2-5 years after surgery				
	CRF 6a	CRF 7a	CRF 7b	CRF 7c	CRF 7d
CRF 6b - Adjuvant treatment after surgery	Follow up 1 year after surgery	Follow up 2 years after surgery	Follow up 3 years after surgery	Follow up 4 years after surgery	Follow up 5 years after surgery
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

### Data Completion Campaign

- We performed our second data completion campaign from September 1, 2023, to January 31, 2024. Thanks to your support, this was very successful.
- The proportion of complete and locked data sets for CRF1-4 was increased from 76.2% after the first data completion campaign to 84.2%. Therefore, we already have data from more than 3600 study participants available for the evaluation of secondary study objectives.
- The proportion of missing follow-up documentation was also reduced compared to the first data completion campaign. Nevertheless, we ask you to carry out the follow-ups consistently, as the proportion of missing documented follow-ups is still relatively high:

Missing follow-ups	31/01/2024	
Year 1	332/1899	(17,5%)
Year 2	211/780	(27,1%)
Year 3	33/54	(61,1%)

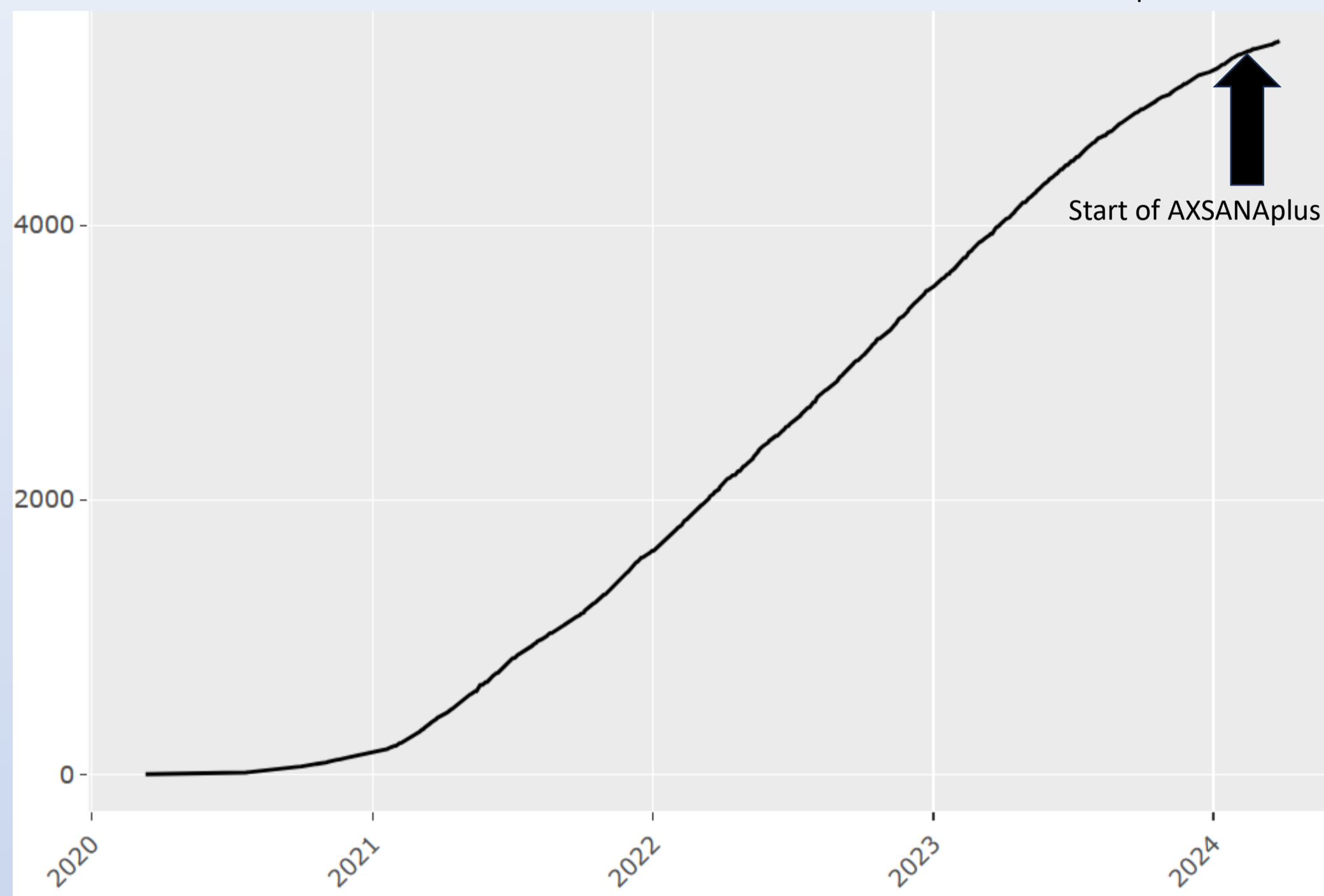
- In the future, we will check the documentation status at your study site once a year. Our study coordinators Ms. Shabbir and Ms. Aktas Sezen will inform you of any documentation gaps. We kindly ask you to eliminate these as soon as possible.



## Recruitment

- By April 1, 2024, 5346 patients had been enrolled in the study.
- Patients from 26 countries have been recruited.
- Study sites from 17 countries are already taking part in the AXSANApplus study and are continuing to recruit. However, we are still awaiting the ethics approval from additional countries, so that the number of AXSANApplus sites will further increase.

Recruitment June 2020 – April 2024



country	Head of National Steering Committee	No. of study sites	No. of enrolled patients
Albania	Prof. Helidon Nina	1	100
Austria	Univ.-Prof. Dr. Florentia Peintinger	7	73
Azerbaijan	Ass. Prof. Hagigat Valiyeva Qanimat	1	72
Belgium	Prof. Dr. Marian Vanhoeij	4	40
Bulgaria	Dr. Tsvetomir Ivanov	1	2
Czech Republic	Dr. Lukas Dostalek	1	5
Finland	Dr. Laura Niinikoski	1	95
Germany	Prof. Dr. Maggie Banys-Paluchowski PD Dr. Steffi Hartmann	163	2942
Greece	Prof. Dr. Michalis Kontos	6	129
Hungary	Dr. Zoltan Matrai	1	2
India	Dr. Geeta Kadayaprath	2	78
Israel	Dr. Douglas Zippel	2	34
Italy	Prof. Oreste D. Gentilini	24	319
N.N.	N.N.	1	25
Norway	Dr. Ellen Schlichting	5	63
Peru	Dr. Lía Pamela Rebaza	1	67
Poland	Prof. Dr. Dawid Murawa	11	168
Portugal	Dr. David Pinto	11	117
Romania	Dr. Eduard-Alexandru Bonci	2	53
Slowenia	Dr. Andraž Perhavec	1	13
Spain	Dr. Isabel Rubio	9	184
Sweden	Prof. Jana de Boniface	7	216
Switzerland	Dr. Maria Luisa Gasparri	8	49
Thailand	Dr. Sarun Thongvitokomarn	1	20
Turkey	Prof. Dr. Guldeniz Karadeniz Cakmak	14	460
United Kingdom	Prof. Ashutosh Kothari and Dr. Elina Shaari	1	20

## Quality of life (QoL)

The baseline response rate is 82%, which is excellent! The response rate for the one-year follow-up forms is 71%, which is a bit low, but there are still many paper questionnaires that have not yet been returned from sites.

We will soon conduct the first one-year arm morbidity and quality of life evaluation, and response rate above 80% is crucial for a reliable result. Therefore, we ask you to:

- Please scan and email us all your completed one-year paper questionnaires, with date and patient-ID, as soon as possible to [gol-axsana@eubreast.com](mailto:gol-axsana@eubreast.com)
- If the participant has not answered the questionnaire within a month, please send a reminder letter.
- Follow-up questionnaires should be distributed after 1, 3, and 5 years, not annually.
- If questionnaires have not been distributed from site, please register this in RedCap.

Please, do not hesitate to email [matilda.appelgren@ki.se](mailto:matilda.appelgren@ki.se) if any questions.

## 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>
- The following abstracts were accepted as presentations for the conference of the German Society of Senology (June 6-8, 2024 Dresden, Germany):
  - “Marking of target lymph nodes with clips/coils in breast cancer patients undergoing neoadjuvant chemotherapy” (oral presentation and honored with the Klaus-Dieter Schulz Supply Research Award)
  - “Marking of Target Lymph Nodes with carbon suspension in breast cancer patients undergoing neoadjuvant chemotherapy” (oral presentation)
  - “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” (poster presentation)

### 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 Cakmak

Prof. N. Ditsch

PD S. Hartmann

Study coordination:

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

[axsana@eubreast.com](mailto: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

EHMANN-STIFTUNG SAVOGNIN

MERITMEDICAL

endomag+

Mammotome

NOGGO  
e.v.

GBG  
GERMAN BREAST GROUP