

Dear Colleagues and AXSANA supporters,

Thanks to your support, we have successfully continued the AXSANA study as an unlimited registry since February 1, 2024. With this newsletter, we would like to inform you about the current status of the study, our study team, the ongoing 3rd data completion campaign, and upcoming scientific presentations. Many thanks to all contributors who have made the very successful course of the study possible so far and who will hopefully continue to support us in the future!

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 AXSANAplus study.

New contact persons for study coordination

- Since the spring of 2024, Ms. Jessica Wagner has been coordinating the German study sites and Ms. Katharina Jursik all international study sites. They will contact you as part of the data completion campaign. If you have any questions, please do not hesitate to contact them:

Jessica Wagner:
wagner@eubreast.com

Katharina Jursik:
k.jursik@eubreast.com



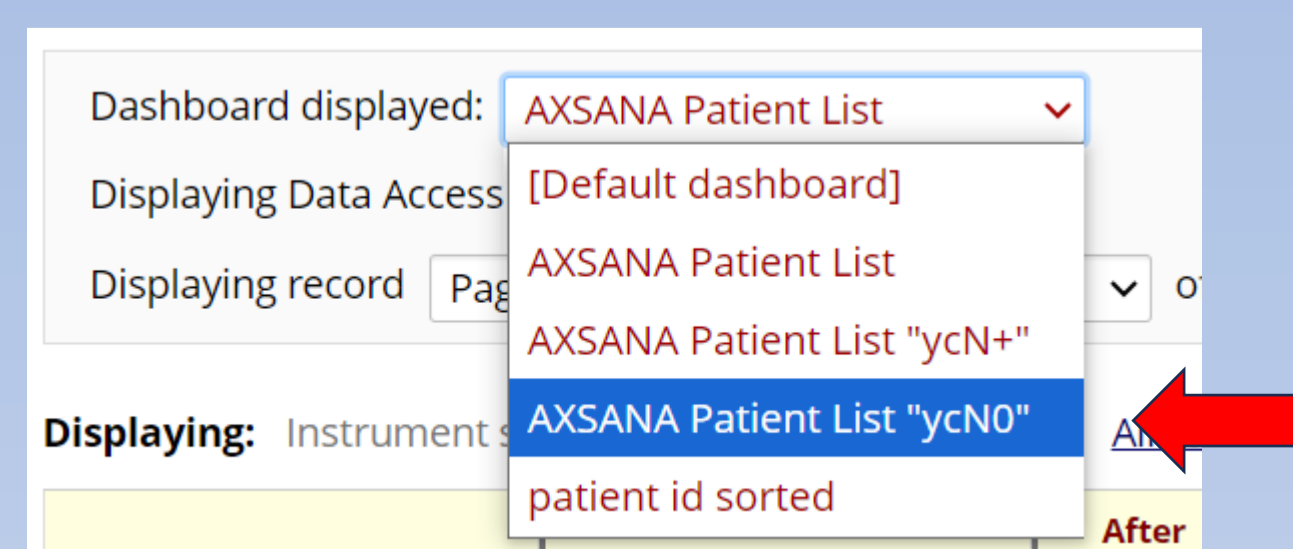
- Ms. Wagner and Ms. Jursik will continue to inform you by email about missing documentation at your study site. Please complete these promptly so that the AXSANA study can be successfully evaluated.

3rd Data Completion Campaign

- Our third data completion campaign is currently being carried out with the aim of having so many complete data sets available in 2025 that it will be possible to evaluate the primary study objectives.
- As of September 30, 2024, 4,009 locked data sets of CRF1-4 (study inclusion - postoperative histology) were already available for evaluating secondary study objectives.
- Unfortunately, the rate of missing follow-up documentation remains high:

Missing follow-ups	30/09/2024	31/01/2024
Year 1	524/2,643(19.8%)	332/1,899 (17,5%)
Year 2	546/1,468(36.7%)	211/780 (27,1%)
Year 3	273/456(59.7%)	33/54 (61,1%)
Year 4	14/15(93.3%)	

- In Redcap you can generate a list of all patients requiring follow-up:

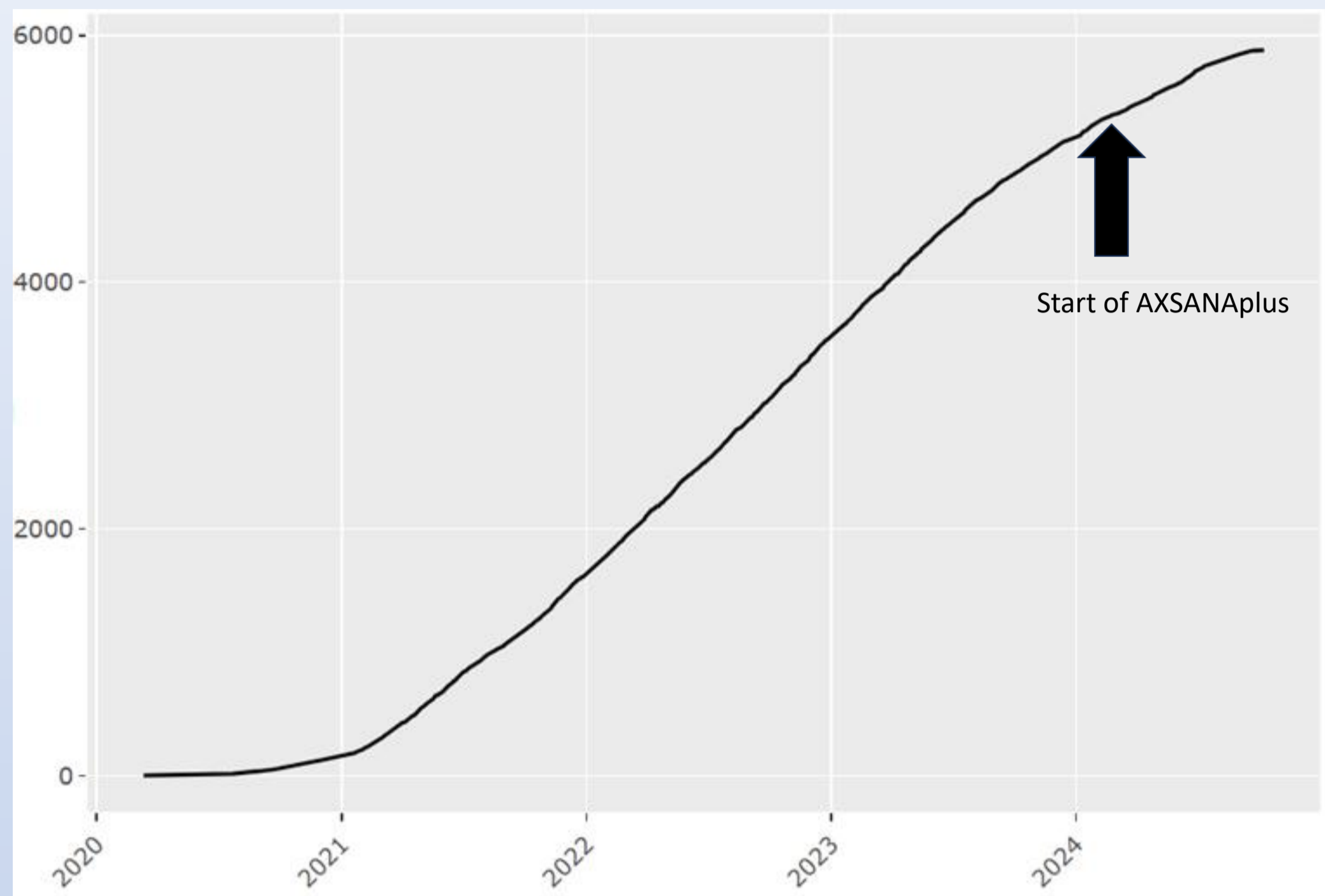


If you select „AXSANA Patient List ycN0“, all patients that need **follow-up** will be shown. If you select „AXSANA Patient List“, all patients you included are listed.

Recruitment

- By September 30, 2024, 5,881 patients had been enrolled in the study.
- Patients from 26 countries have been recruited.
- 177 study sites from 20 countries are taking part in the AXSANAplus study and are continuing to recruit.
- Since the continuation of AXSANA as an unlimited registry from February 1, 2024, 591 patients have been recruited at these sites.

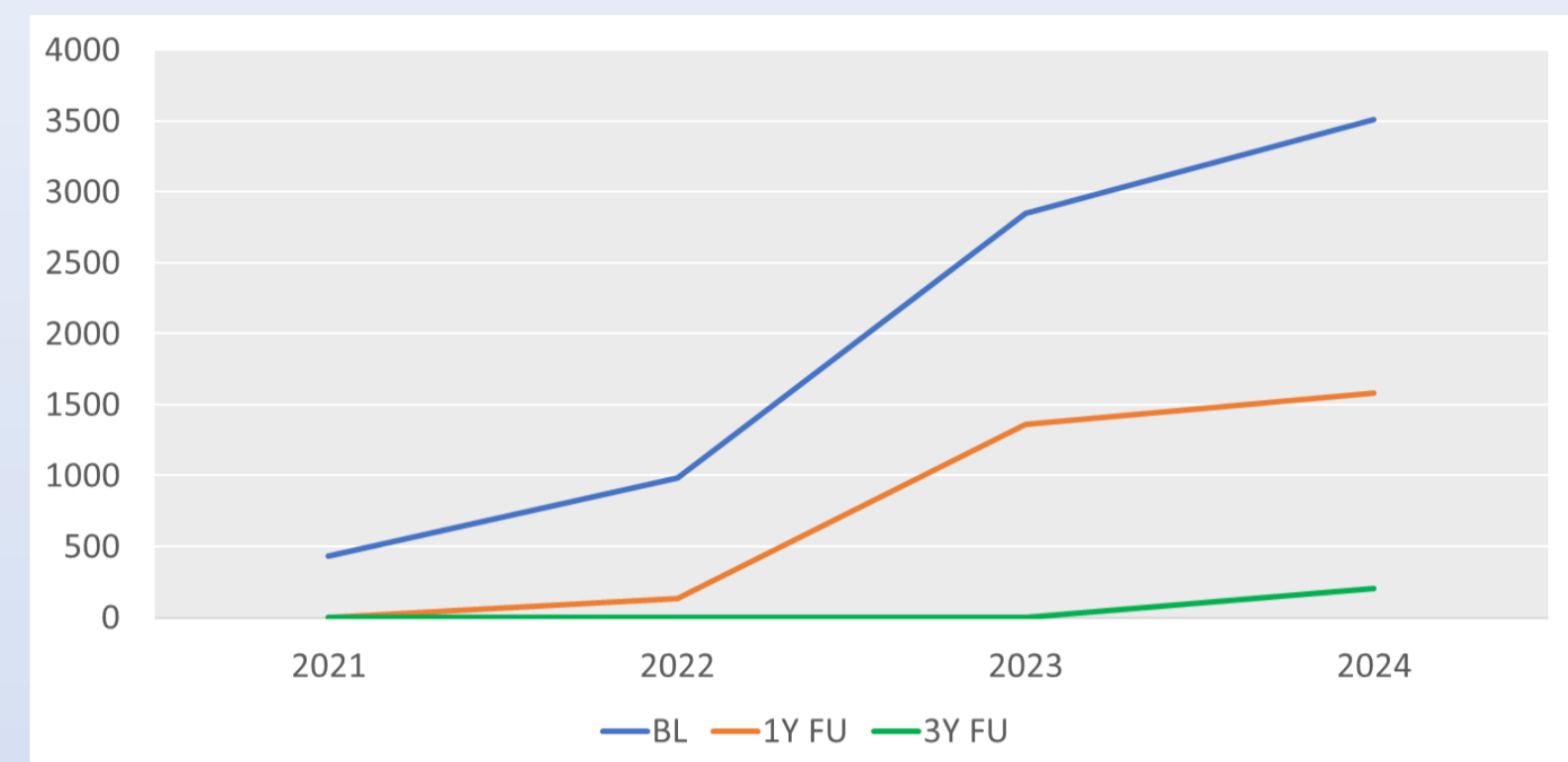
Recruitment June 2020 – September 2024



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	75
Azerbaijan	Ass. Prof. Hagigat Valiyeva Qanimat	1	72
Belgium	Prof. Dr. Marian Vanhoeij	4	55
Bulgaria	Dr. Tsvetomir Ivanov	1	8
Czech Republic	Dr. Lukas Dostalek	1	5
Finland	Dr. Laura Niinikoski	1	106
Germany	Prof. Dr. Maggie Banys-Paluchowski PD Dr. Steffi Hartmann	164	3245
Greece	Prof. Dr. Michalis Kontos	6	140
Hungary	Dr. Zoltan Matrai	1	2
India	Dr. Geeta Kadayaprath	2	83
Israel	Dr. Douglas Zippel	2	35
Italy	Prof. Oreste D. Gentilini	24	392
N.N.	N.N.	1	25
Norway	Dr. Ellen Schlichting	5	65
Peru	Dr. Lía Pamela Rebaza	1	79
Poland	Prof. Dr. Dawid Murawa	11	185
Portugal	Dr. David Pinto	11	118
Romania	Dr. Eduard-Alexandru Bonci	2	53
Slowenia	Dr. Andraž Perhavec	1	13
Spain	Dr. Isabel Rubio	9	185
Sweden	Prof. Jana de Boniface	7	236
Switzerland	Dr. Maria Luisa Gasparri	9	65
Thailand	Dr. Sarun Thongvitokomarn	1	20
Turkey	Prof. Dr. Guldeniz Karadeniz Cakmak	14	492
United Kingdom	Prof. Ashutosh Kothari and Dr. Elina Shaari	1	20

Quality of life (QoL)

- More than 3,500 baseline (BL) and close to 1,600 one-year follow-up questionnaires have been collected.
- Response rate for BL is > 85% - excellent!
- The one-year data evaluation of arm morbidity will take place soon, and a response rate > 80% is of utmost importance for the quality of the study results.
- We kindly prompt sites who have not completed CRF 6a or have not emailed their returned paper questionnaires at the one-year follow-up, to do so by October 30, 2024.



Scientific Activities

- You can find all previous full-text publications and congress papers of the AXSANA Study Group at: <https://www.eubrest.org/axsana/#Publications>
- Three abstracts from the AXSANA study have been accepted for presentation at this year's San Antonio Breast Cancer Symposium:

“Upstage of N-Stage by diagnostic axillary lymph node dissection in patients with isolated tumor cells or micrometastases in the sentinel/target lymph node after neoadjuvant chemotherapy - results from the prospective multicenter AXSANA / EUBREAST 3 Study (NCT04373655)” – poster spotlight presentation Thu, Dec 12, 7:00-8:30am

“Diagnostic performance of axillary ultrasound after neoadjuvant chemotherapy in initially node-positive breast cancer patients – results from the prospective AXSANA registry trial (NCT04373655)” - rapid fire presentation Thu, Dec 12, 12:00-12:50pm

“Status of the international prospective multicenter cohort study evaluating different surgical methods of axillary staging in clinically node-positive breast cancer patients treated with neoadjuvant chemotherapy (NCT04373655)” – poster presentation Wed, Dec 11, 5:30-7:00pm

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@eubrest.com

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

