

Dear AXSANA study sites,

The international AXSANA family continues to grow, with 27 countries now participating. Thanks to this great commitment, more than 1,500 patients have already been included in the study since recruitment began just 20 months ago. This is a huge success, and we would sincerely like to thank all participants. For the first study patients, the follow-up phase has already begun, which is crucial for the collection of the primary study objectives on oncological outcome and quality of life. Therefore, in the current newsletter, you will find data not only on recruitment status, but also recommendations for uncomplicated study documentation.

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

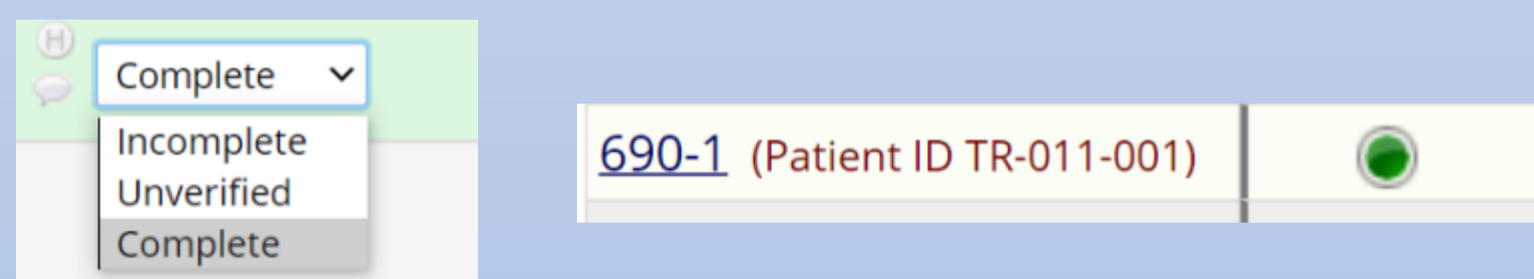
Prof. T. Kühn PD M. Banys-Paluchowski Ass. Prof. J. de Boniface Prof. E. Stickeler Dr. O. Gentilini Dr. S. Hartmann

## Reminder:

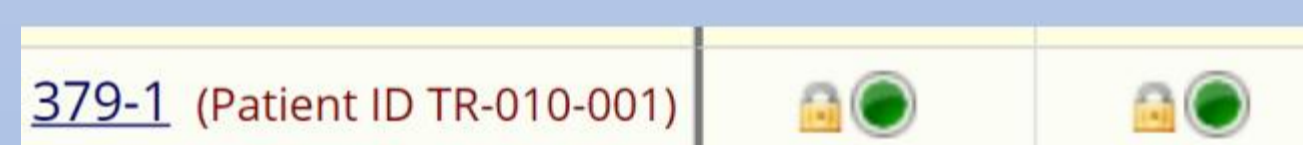
- The first follow-up should be performed one year (+/- 2 months) after surgery.

### Monitoring

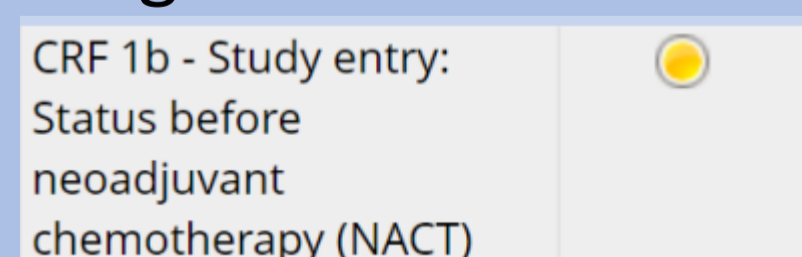
- Once you have changed the status of the CRF pages to "complete" (green), they will be checked by our monitors.



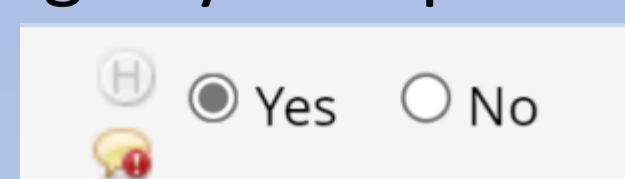
- If the CRF page is plausible and correctly filled in, a lock sign will appear after monitoring.



- If the monitor has created a query, the color of the CRF page turns yellow and the status changes to "unverified" (only the monitors use this status).



- You can recognize the query in the CRF page by the speech bubble with the red exclamation mark.



- **Please do not change the status of the CRF after answering the query**, it should remain yellow ("unverified").
- **Note:** You can keep the PDF version of the CRF pages in the patient file for timely documentation and transfer the data to the online CRFs later.

### Quality of life (QoL)

- Currently, the online version of the QoL system is available in Austria, Germany, Greece, Italy, Poland, Romania, Spain, Turkey and Sweden. The version for Norway is in progress.
- We kindly ask you to use the online questionnaires as first choice if possible, once they are available for your country.
- If the patient has completed the paper version, please scan it and send it via email to Ms. Shabbir in the study office: [shabbir@eubreast.com](mailto:shabbir@eubreast.com). **Please do not transfer the data from the QoL paper version into the online system yourself.**

### Initiation and eCRF-Training

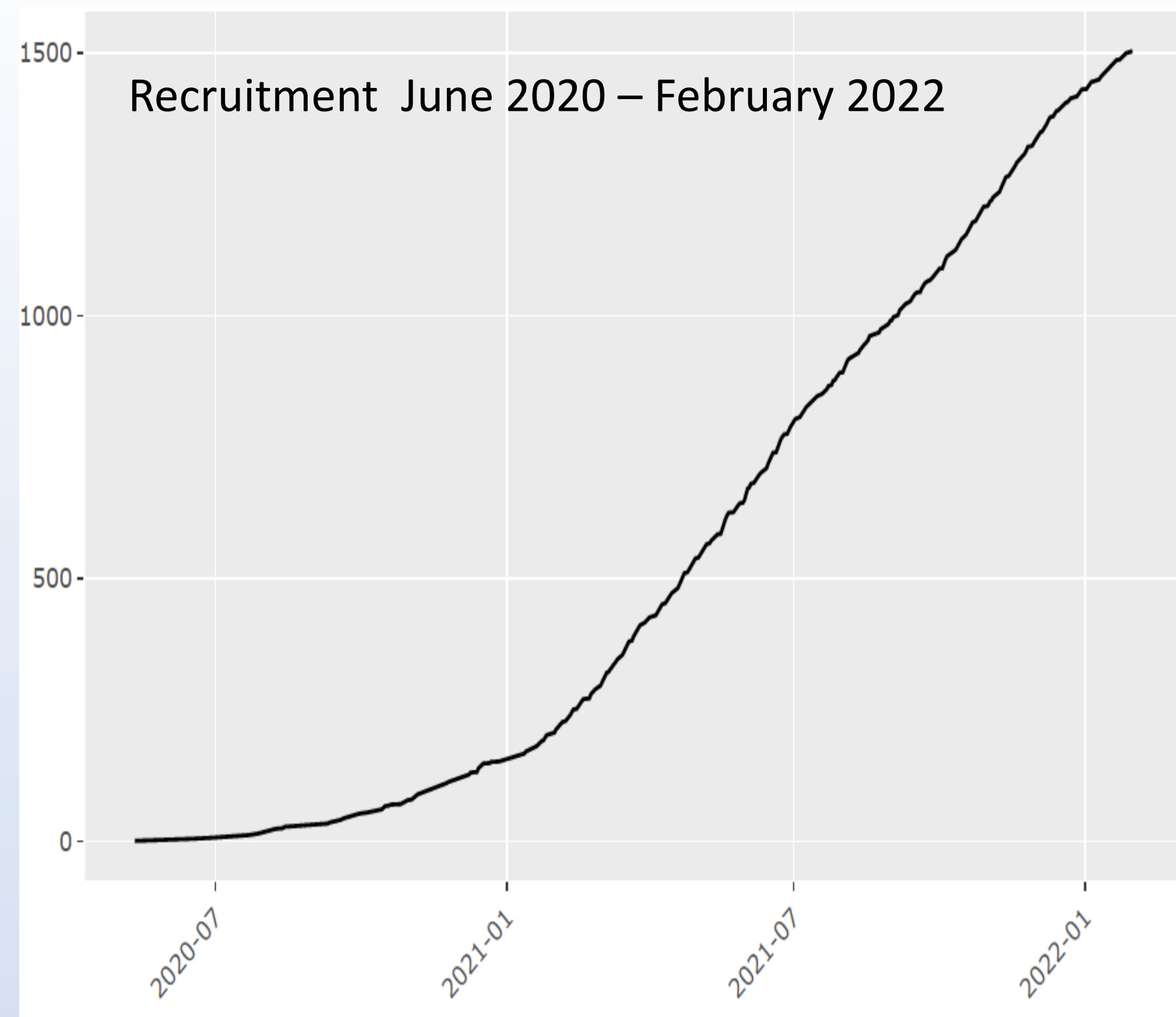
- To refresh your knowledge of the AXSANA study and of the eCRF documentation system in particular, you can watch the video recording of the most recent initiation at any time on the AXSANA homepage: <https://eubreast.com/?Trials/AXSANA#Video>.
- We also would like to invite you to participate in the next international live initiation presentation in English, which will take place on February 28, 2022 at 1 p.m. CET (Time Zone Berlin, Paris, Madrid, Rome). Zoomlink: <https://us02web.zoom.us/j/85901622623?pwd=R09iRDc3TEhWc2w1c01EdWtrZEVcZz09>



# International Recruitment

- By February 1, 2022, 1,503 patients had been enrolled in the study.
- Patients from 18 countries have been recruited.
- Belgium, Bulgaria, Great Britain, Hungary, India, Israel, Mexico, Slovenia and Thailand are the newest members of the AXSANA study group and will start recruiting soon.

country	national coordinator	top-recruiter - PI	pat.
Albania	Prof. Nina Helidon	Oncological Hospital Tirana – Prof. Helidon	8
Austria	Univ.-Prof. Florentia Peintinger	LKH Hochsteiermark – Prof. Peintinger	5
Azerbaijan	Ass. Prof. Hagigat Valiyeva	Medical University Baku – Prof. Valiyeva	15
Czech Republic	Dr. Lukas Dostalek	Charles University, General University Hospital, Prague – Dr. Dostalek	5
Finland	Dr. Laura Niinikoski	Helsinki University Hospital – Dr. Niinikoski	32
Germany	PD Maggie Banys-Paluchowski	University of Rostock – Dr. Hartmann University of Tuebingen – Prof. Hahn	37
Greece	Prof. Michalis Kontos	Interbalkan Medical Center of Thessaloniki – Dr. Natsiopoulos	15
Italy	Dr. Oreste Gentilini	IRCCS Ospedale San Raffaele, Milano – Dr. Gentilini	19
Norway	Dr. Ellen Schlichting	Oslo University Hospital – Dr. Schlichting	13
Peru	Dr. Lia Rebaza Vasquez	Oncosalud-AUNA Clinic Lima – Dr. Vasquez	12
Poland	Prof. Dawid Murawa	Clinic of General and Oncological Surgery of the Karol Marcinkowski University Hospital, Zielona Góra – Prof. Murawa	18
Portugal	Dr. David Pinto	Hospital do Litoral Alentejano – Dr. Cruz Champalimaud Clinical Center Lisboa – Dr. Pinto	4
Romania	Dr. Eduard-Alexandru Bonci	„Prof. Dr. Ion Chiricuta“ Institute of Oncology, Cluj Napoca – Dr. Bonci	15
Russia	Prof. Petr Krivorotko	N.N. Petrov NMRC of Oncology St. Petersburg – Prof. Krivorotko	10
Spain	Dr. Isabel Rubio	Hospital Clinic Barcelona – Dr. Vargas	14
Sweden	Ass. Prof. Jana de Boniface	St. Görans sjukhus – Dr. Zetterlund	24
Switzerland	Dr. Maria Luisa Gasparri	University of the Italian Switzerland, Lugano – Dr. Gasparri	5
Turkey	Prof. Guldeniz Karadeniz Cakmak	Zonguldak Bulent Ecevit University, The School of Medicine – Prof. Karadeniz Cakmak	46



country	no. of enrolled pat.
all	1,503
Albania	8
Austria	8
Azerbaijan	15
Czech Republic	5
Finland	32
Germany	1,003
Greece	35
Italy	27
Norway	13
Peru	12
Poland	33
Portugal	9
Romania	22
Russia	10
Spain	48
Sweden	52
Switzerland	6
Turkey	165

## San Antonio Breast Cancer Symposium 2021

- The concept and current status of the AXSANA study has been presented at several national conferences and most recently in the Ongoing Trials session at the SABCS 2021.

**San Antonio Breast Cancer Symposium® - December 7-11, 2021**

**AXSANA** AWOgyn

**AXillary Surgery After NeoAdjuvant treatment: an international prospective multicenter cohort study of the EUBREAST study group to evaluate different surgical methods of axillary staging in clinically node-positive breast cancer patients treated with neoadjuvant chemotherapy (NCT 04373655)**

**BACKGROUND**

The optimal surgical staging procedure of the axilla in patients who convert from a clinically positive (cN+) to a clinically negative node status (yN0) through neoadjuvant chemotherapy is still controversial. Widely diverse techniques such as full Axillary Lymph Node Dissection (ALND), Targeted Axillary Dissection (TAD), Targeted Lymph Node Biopsy (TLNB) and Sentinel Lymph Node Biopsy alone (SLNB) are given preference in different international guidelines. So far, no comparative data on the oncological outcome or the morbidity of the different procedures are available. Further research is needed to safely de-escalate the extent of axillary surgery in this patient group.

**TRIAL DESIGN**

Prospective multicenter cohort study  
Target accrual: 3000 pts.  
Study duration: 5 years (enrollment) + 5 years (follow up)  
Primary endpoints  
• 5-year invasive disease-free survival  
• 3-year axillary recurrence rate  
• HRQL (EORTC QLQ-C 30, BR 23, Lymph ICF and SOC-13) (baseline, year1,3,5)  
Inclusion criteria  
• Primary invasive breast cancer (confirmed by core biopsy)  
• cN+ (confirmed by core biopsy or FNA)  
• cT1-3  
• Scheduled for NACT  
• Female / male pts. ≥ 18 years old  
Exclusion criteria  
• Distant metastasis  
• Recurrent or inflammatory BC  
• Estrogen/anti-estrogen therapy  
• Pregnancy  
• < 4 cycles of NACT administered

**CURRENT STATUS**

PI: Thorsten Kühn, Germany  
Heads of National Steering Committees  
Albania: Nina Helidon  
Austria: Florentia Peintinger  
Azerbaijan: Hagigat Valiyeva  
Belgium: Magali D'Amico  
Canada: Carol O'Connell  
France: Jean-Marc Claret  
Germany: Maggie Banys-Paluchowski  
Greece: Michalis Kontos  
Hungary: Csilla Mészáros  
India: Geeta Kulkarni  
Israel: Orna Sidiropoulos  
Italy: Oreste Gentilini  
Japan: Masahito Nishida  
Korea: David Park  
Norway: Ellen Schlichting  
Peru: Lia Rebaza Vasquez  
Poland: Dawid Murawa  
Portugal: David Pinto  
Romania: Eduard-Alexandru Bonci  
Russia: Petr Krivorotko  
Spain: Isabel Rubio  
Sweden: Jana de Boniface  
Switzerland: Maria Luisa Gasparri  
Turkey: Guldeniz Karadeniz Cakmak

First patient recruited: June 2020  
Current accrual (Nov 2021): 1177 pts.  
Open study sites: 150  
Participating countries: 21  
100% of datasets are monitored for privacy (remote monitoring).

**Variability of Axillary Staging Techniques**

**Distribution of techniques – all patients**

### IMPRESSUM

EUBREAST Study Group

Chairs and Co-Chairs: EUBREAST

Prof. T. Kühn, Prof. E. Stickeler,

Prof. J. de Boniface, Dr. O. Gentilini

Organizing Committee:

Prof. T. Kühn: t.kuehn@klinikum-esslingen.de

PD Dr. M. Banys-Paluchowski: m.banys@outlook.com

Dr. S. Hartmann: steffi.hartmann@klinikusued-rostock.de

International study coordination:

Ms. A. Jursik, Ms. J. Shabbir und Dr. M. Mangold

axsana@eubreast.com

Tel. +49 711 3103 3063

In case of questions do not hesitate to

contact your National Steering Committee!

