

Dear AXSANA study sites,

Since the publication of our last newsletter eight months ago, more than 1200 additional patients have been enrolled and several study sites have been opened in four additional countries. This is a great success for the AXSANA project, and we thank all dedicated contributors! In addition to a continuous recruitment, the success of the trial requires the collection of complete data sets. In the upcoming weeks, we will therefore intensify our efforts to complete missing data and contact all study sites in this regard. In the current newsletter, we present not only the current recruitment status but also a change in the CRF system and introduce the contact persons of the AXSANA organizational team.

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, then once a year until 5 years after surgery.

### CRF 6

- There was a modification in the eCRF system for CRF 6. This was renamed (formerly "FU 1 year after surgery") to "Adj. Treatment and FU1" and CRF6b now precedes CRF 6a.
- Only the name and order of the sheets have modified, not the content. All previously documented data remain unchanged.
- Please assess the postoperative treatment performed in CRF6b as promptly as possible. You do not have to wait until the first follow-up after one year postoperatively.

Adj. Treatment and FU1	
	CRF 6a
	-
CRF 6b - Adjuvant treatment after surgery	Follow up 1 year after surgery
<input type="radio"/>	<input type="radio"/>

### Team International Study Coordination



*The entire AXSANA team mourns the loss of its longtime study coordinator Ms. Angelika Jursik, who supported this study project until the end with a lot of engagement and competence.*

### Quality of life (QoL)

- Please remember to have patients complete the QoL questionnaire within **four weeks before surgery** and as part of the follow-up **one, three and five years after surgery**.
- If available for your country, the online version of the questionnaire should preferably be used. If you do use the paper version, please send it to [gol-axsana@eubrest.com](mailto:gol-axsana@eubrest.com). Please do not transfer the data from the paper forms to the online forms independently.

- We welcome Ass. Prof. Bilge Aktas Sezen to our team. She is responsible for the administrative coordination of the international study sites. During the next two months, she will contact all study sites where data sets need to be completed. If you have any organizational questions, please contact Ms. Aktas Sezen via [aktas@eubrest.com](mailto:aktas@eubrest.com).
- The monitoring team (Franziska Ruf, Angelika Rief, Guldeniz Karadeniz Cakmak, Steffi Hartmann, Timo Basali) will be working more intensively on completing the CRF datasets in the upcoming weeks and we would appreciate timely responses to the queries.

# International Recruitment

- By October 1, 2022, 2.738 patients had been enrolled in the study.
- Patients from 23 countries have been recruited.
- Belgium, Bulgaria, Great Britain, Hongkong, and Mexico are the newest members of the AXSANA study group and will start recruiting soon.
- To evaluate 3000 ycN0 patients, a total of 4500 patients need to be recruited, given the current rate of ycN0 cases of 68%. As more than 100 patients per month are currently enrolled in the study, the recruitment target is achievable by 2025 as planned.



country	no. of enrolled pat.
Albania	39
Austria	25
Azerbaijan	58
Czech Republic	5
Finland	42
Germany	1633
Greece	71
Hungary	2
India	11
Israel	3
Italy	98
Norway	27
Peru	27
Poland	86
Portugal	38
Romania	45
Russia	25
Slowenia	13
Spain	109
Sweden	103
Switzerland	13
Thailand	8
Turkey	257

country	national coordinator	top-recruiter - PI	pat.
Albania	Prof. Nina Helidon	Oncological Hospital Tirana – Prof. Helidon	39
Austria	Univ.-Prof. Florentia Peintinger	LKH University of Graz – Prof. Peintinger	13
Azerbaijan	Ass. Prof. Hagigat Valiyeva	Medical University Baku – Prof. Valiyeva	58
Czech Republic	Dr. Lukas Dostalek	Charles University, General University Hospital, Prague – Dr. Dostalek	5
Finland	Dr. Laura Niinikoski	Helsinki University Hospital – Dr. Niinikoski	42
Germany	PD Maggie Banys-Paluchowski	University of Tuebingen – Prof. Hahn	70
Greece	Prof. Michalis Kontos	Anticancer Hospital Theageneio Thessaloniki – Dr. Iosifidou	22
Hungary	Dr. Zoltan Matrai	National Institut of Oncology, Budapest	2
India	Dr. Geeta Kadayaprath	MAX Hospital, Patparganj, New Delhi – Dr. Geeta Kadayaprath	7
Israel	Dr. Dov Zippel	Sheba Medical Centre Tel Aviv – Dr. Zippel	3
Italy	Dr. Oreste Gentilini	Breast Unit S. Anna Hospital Torino – Italy – Dr. Porpiglia	29
Norway	Dr. Ellen Schlichting	Oslo University Hospital – Dr. Schlichting	25
Peru	Dr. Lia Rebaza Vasquez	Oncosalud-AUNA Clinic Lima – Dr. Vasquez	27
Poland	Prof. Dawid Murawa	Clinic of General and Oncological Surgery of the Karol Marcinkowski University Hospital, Zielona Góra – Prof. Murawa	33
Portugal	Dr. David Pinto	Hospital do Litoral Alentejano – Dr. Cruz Chamalimaud Clinical Center Lisboa – Dr. Pinto	16
Romania	Dr. Eduard-Alexandru Bonci	„Prof. Dr. Ion Chiricuta“ Institute of Oncology, Cluj Napoca – Dr. Bonci	30
Russia	Prof. Petr Krivorotko	N.N. Petrov NMRC of Oncology St. Petersburg – Prof. Krivorotko	25
Slowenia	Dr. Andraz Perhavec	Institute of Oncology Ljubljana – Dr. Perhavec	13
Spain	Dr. Isabel Rubio	Unidad de Patologia Mamaria, Hospital San Cecilio, Granada – Dr. Sanchez Barron	35
Sweden	Ass. Prof. Jana de Boniface	St. Görans sjukhus – Dr. Zetterlund	36
Switzerland	Dr. Maria Luisa Gasparri	University of the Italian Switzerland, Lugano – Dr. Gasparri	8
Thailand	Dr. Sarun Thongvitokomarn	Queen Sirikit Centre for Breast Cancer Bangkok – Dr. Thongvitokomarn	8
Turkey	Prof. Guldeniz Karadeniz Cakmak	Zonguldak Bulent Ecevit University, The School of Medicine – Prof. Karadeniz Cakmak	70

## IMPRESSUM

EUBREAST Study Group

Chairs and Co-Chairs:

Prof. T. Kühn, Prof. E. Stickeler,

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

Organizing Committee:

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International study coordination:

Ass. Prof. B. Aktas Sezen and Dr. M. Mangold

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

