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 modifies, 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.

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 qol-axsana@eubreast.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@eubreast.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.
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.

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

**Recruitment June 2020 – October 2022**

**country** | **no. of enrolled pat.**
--- | ---
Albania | 39
Austria | 25
Azerbaijan | 58
Czech Republic | 5
Finland | 42
Germany | 1633
Greece | 71
Hungary | 2
India | 11
Isreal | 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

**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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Dr. S. Hartmann: steffi.hartmann@kliniksued-rostock.de
International study coordination:
Ass. Prof. B. Aktas Sezen and Dr. M. Mangold
axsana@eubreast.com
Tel. +49 711 3103 3063
In case of questions do not hesitate to contact your National Steering Committee!