



nº 6 (03/2023)

Dear AXSANA study sites,

More than two and a half years after the initiation of the AXSANA study, we can still report a high recruitment rate. For this we would like to thank all participating study centers sincerely. If recruitment continues to be so successful, we will reach the recruitment target already this year and thus ahead of schedule. Therefore, we ask all of you to continue to enroll your patients in the study. With this newsletter we would like to inform you about the results of the recently finished first data completing campaign, the current recruitment status and scientific activities.

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 PD S. Hartmann

# Important:

Please consistently perform and document annual follow-ups beginning
 1 year after surgery in all ycN0-patients.

## Data-completing campaign

- Thanks to your dedicated help, we were able to successfully complete our first data-completing campaign on January 31, 2023.
- One result of the campaign is that records are available for 92% of patients up to and including CRF 5 (planned adjuvant treatment). For 81% of the patients, these data sets are already complete, i.e. no more queries need to be answered.
- However, data for the first follow-up one year after surgery are currently missing for 21% of the study participants.
- Therefore, we ask you not only to consistently continue to complete the data for all patients up to and including CRF 5, but also to be strictly sure to perform and document the annual follow-up (CRF6a/b, CRF7a-d, years 1-5 after surgery) for all ycN0-patients.
- A second data-completing campaign is planned for the upcoming autumn after the recruitment target of 4500 study participants has been reached. We ask for your support again, because for the evaluation of the AXSANA study objectives only data sets of completely documented patients (including follow-up) can be used.

## Quality of life (QoL)

- A high response rate of the QoL questionnaires is crucial for the reliability of QoL data evaluation.
- About 400 baseline questionnaires, confirmed completed in CRF 2 are still missing. If you have completed paper questionnaires at your site, please send them immediately to <a href="mailto:qol-axsana@eubreast.com">qol-axsana@eubreast.com</a>. Do not transfer the data from the paper forms to the online forms independently.
- Please use postal reminder if questionnaires are not answered within one month of sending the one-year post surgery follow-up questionnaire to the participant.

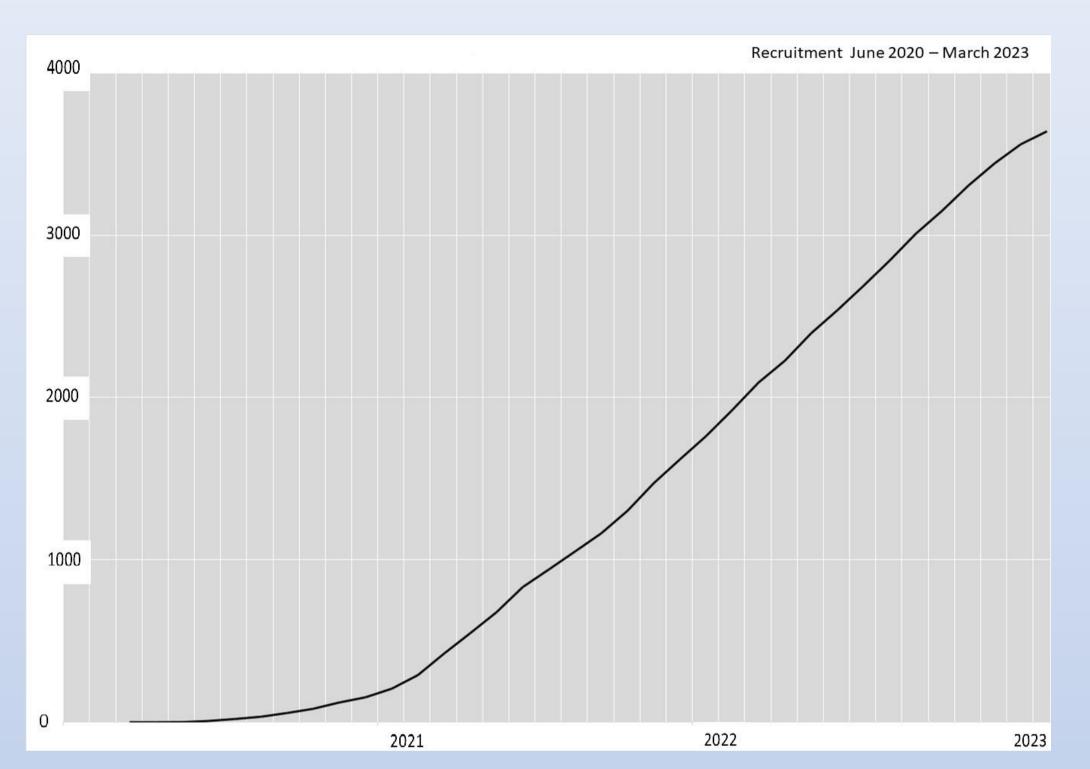
Contact for QoL questionnaires: matilda.appelgren@ki.se

#### Scientific Activities

- You can find all previous full-text publications and congress papers of the AXSANA Study Group at <a href="https://www.eubreast.com/?Trials/AXSANA#Publications">https://www.eubreast.com/?Trials/AXSANA#Publications</a>.
- The current status of the AXSANA study has been presented recently in the Ongoing Trials session at the SABCS 2022.
- This year we are also planning presentations at national and international congresses and publications of initial interim analyses.

### International Recruitment

- By March 1, 2023, 3.647 patients had been enrolled in the study.
- Patients from 24 countries have been recruited.
- Belgium, Great Britain, Hongkong and Mexico are the newest members of the AXSANA study group and will start recruiting soon.
- As more than 100 patients per month are currently enrolled in the study, the recruitment target is achievable before 2025 (as initially planned).
- Therefore, please continue to maintain the high recruitment rate!



| country        | no. of enrolled patients |
|----------------|--------------------------|
| Albania        | 62                       |
| Austria        | 40                       |
| Azerbaijan     | 66                       |
| Bulgaria       | 1                        |
| Czech Republic | 5                        |
| Finland        | 49                       |
| Germany        | 2037                     |
| Greece         | 97                       |
| Hungary        | 2                        |
| India          | 26                       |
| Israel         | 18                       |
| Italy          | 175                      |
| N.N.           | 25                       |
| Norway         | 44                       |
| Peru           | 43                       |
| Poland         | 131                      |
| Portugal       | 63                       |
| Romania        | 53                       |
| Slowenia       | 13                       |
| Spain          | 156                      |
| Sweden         | 146                      |
| Switzerland    | 21                       |
| Thailand       | 14                       |
| Turkey         | 360                      |
|                |                          |

| country        | national coordinator            | top-recruiter - PI   | pat. |
|----------------|---------------------------------|--|------|
| Albania        | Prof. Nina Helidon              | Oncological Hospital Tirana – Prof. Helidon  | 62   |
| Austria        | UnivProf. Florentia Peintinger  | LKH University of Graz – Prof. Peintinger  | 23   |
| Azerbaijan     | Ass. Prof. Hagigat Valiyeva     | Medical University Baku – Prof. Valiyeva   | 66   |
| Bulgaria       | Dr. Tsvetomir Ivanov, Ph.D.     | Heart and Brain Hospital Pleven – Dr. Tsvetomir  | 1    |
| Czech Republic | Dr. Lukas Dostalek              | Charles University, General University Hospital, Prague – Dr. Dostalek                 | 5    |
| Finland        | Dr. Laura Niinikoski            | Helsinki University Hospital – Dr. Niinikoski  | 49   |
| Germany        | PD Maggie Banys-Paluchowski     | University of Tuebingen – Prof. Hahn   | 88   |
| Greece         | Prof. Michalis Kontos           | Anticancer Hospital Theageneio Thessaloniki – Dr. Iosifidou                            | 27   |
| Hungary        | Dr. Zoltan Matrai               | National Institut of Oncology, Budapest  | 2    |
| India          | Dr. Geeta Kadayaprath           | MAX Hospital, Vaishali, New Delhi – Dr. Arun Kumar Goel                                | 16   |
| Isreal         | Dr. Dov Zippel                  | Sheba Medical Centre Tel Aviv – Dr. Zippel   | 16   |
| Italy          | Dr. Oreste Gentilini            | Breast Unit S. Anna Hospital Torino – Italy – Dr. Porpiglia                            | 48   |
| Norway         | Dr. Ellen Schlichting           | Oslo University Hospital – Dr. Schlichting   | 29   |
| Peru           | Dr. Lia Rebaza Vasquez          | Oncosalud-AUNA Clinic Lima – Dr. Vasquez   | 43   |
| Poland         | Prof. Dawid Murawa              | Greater Poland Cancer Centre Poznan – Dr. Adamczyk                                     | 53   |
| Portugal       | Dr. David Pinto                 | Champalimaud Clinical Center Lisboa – Dr. Pinto  | 20   |
| Romania        | Dr. Eduard-Alexandru Bonci      | "Prof. Dr. Ion Chiricuta" Institute of Oncology, Cluj Napoca<br>– Dr. Bonci            | 34   |
| Slowenia       | Dr. Andraz Perhavec             | Institute of Oncology Ljubljana – Dr. Perhavec   | 13   |
| Spain          | Dr. Isabel Rubio                | Unidad de Patologia Mamaria, Hospital San Cecilio,<br>Granada – Dr. Sanchez Barron     | 51   |
| Sweden         | Ass. Prof. Jana de Boniface     | St. Görans Sjukhus – Dr. Zetterlund  | 45   |
| Switzerland    | Dr. Maria Luisa Gasparri        | University of the Italian Switzerland, Lugano – Dr. Gasparri                           | 9    |
| Thailand       | Dr. Sarun Thongvitokomarn       | Queen Sirikit Centre for Breast Cancer Bangkok  – Dr. Thongvitokomarn                  | 14   |
| Turkey         | Prof. Guldeniz Karadeniz Cakmak | Zonguldak Bulent Ecevit University, The School of Medicine<br>– Prof. Karadeniz Cakmak | 94   |

#### **IMPRESSUM**

**EUBREAST Study Group Chairs and Co-Chairs:** Prof. T. Kühn, Prof. E. Stickeler, Prof. J. de Boniface, Dr. O. Gentilini **Organizing Committee:** 

Prof. T. Kühn: t.kuehn@filderklinik.de

PD Dr. M. Banys-Paluchowski: m.banys@outlook..com PD Dr. S. Hartmann: steffi.hartmann@kliniksued-rostock.de

**EUBREAST** 

**International study coordination:** 

Ass. Prof. B. Aktas and Dr. M. Mangold axsana@eubreast.com

Tel. +49 711 3103 3063

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









