

Dear AXSANA study sites,

We are proud to present to you the first international AXSANA newsletter. With this newsletter, we will inform you regularly about the current state of the study.

You can also find important information and files for download at our website: <http://axsana.eubreast.com>

We wish you all the best for the New Year 2021!

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



Prof. T. Kühn



PD Dr. M. Banys-Paluchowski



Ass. Prof. J. de Boniface



Prof. E. Stickeler



Dr. O. Gentilini



Dr. S. Hartmann

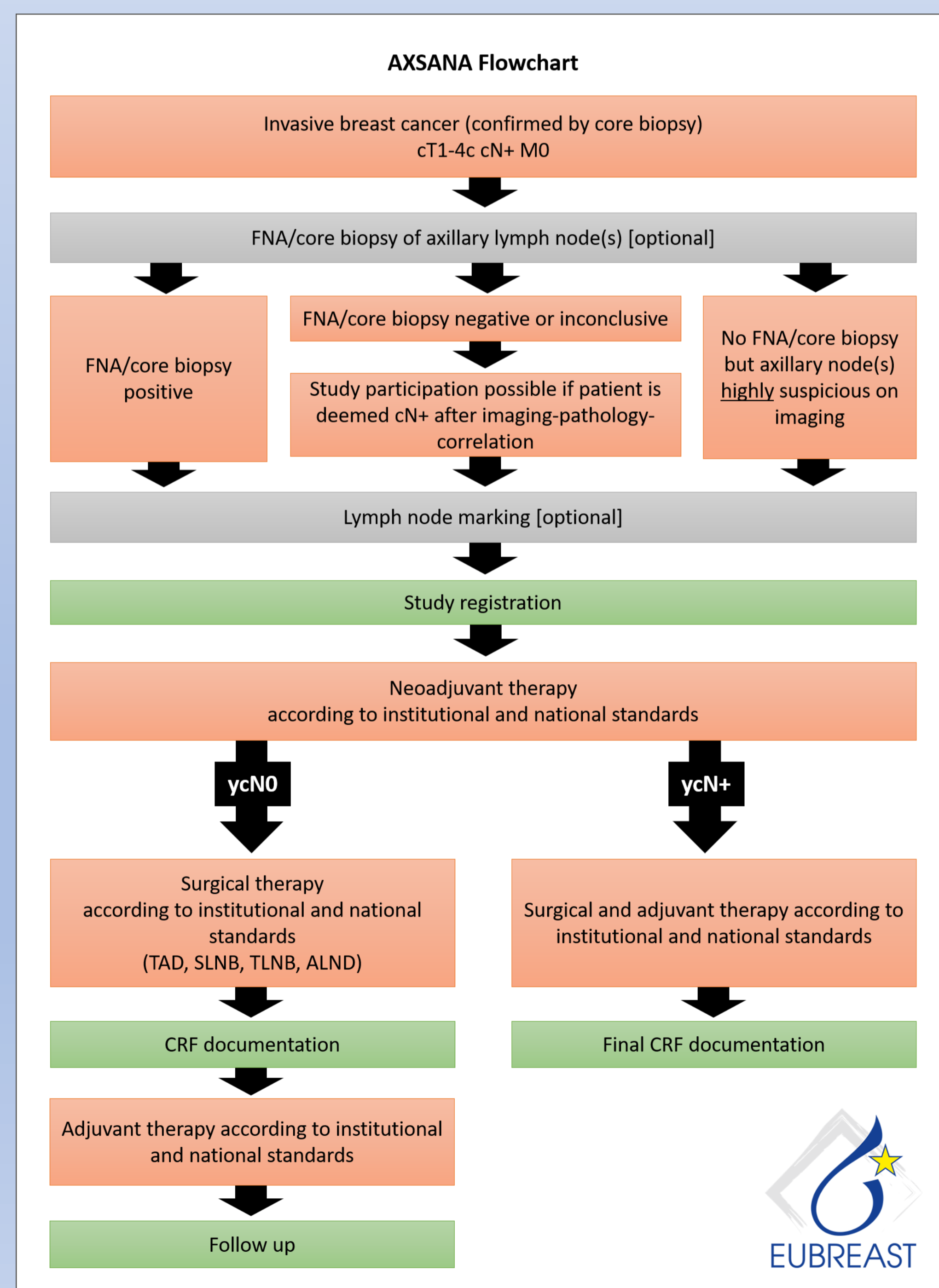
## Protocol amendment

Initially, only patients with histologically or cytologically confirmed lymph node metastasis were allowed to participate in AXSANA. Since core biopsy/FNA of suspicious nodes is standard in some countries but not in others, an amendment has been prepared after discussing this issue in the International Steering Board meeting. Now, patients with highly suspicious nodes upon imaging can be enrolled in AXSANA even if they have not received a minimally invasive biopsy of the node(s).

The amended protocol has been submitted to ethical committees and already approved in some countries (Greece, Romania, Switzerland). Your National Steering Committee will provide you with the current version of the protocol approved in your country.

## Quality of life (QoL)

- **IMPORTANT:** Keep in mind that patients need to complete their baseline QoL questionnaires within 4 weeks before surgery. Example: surgery is scheduled for Jan, 14th → baseline questionnaires should be completed between Dec, 17th and Jan, 13th.
- The Swedish QoL team led by Jana de Boniface (Matilda Appelgren, Cristofer Lagerros, Helena Sackey) is working at full speed to establish the online QoL tool. We hope that AXSANA patients will be able to use the tool in February 2021. From then on, study sites will only have to print the QoL access data and give them to the patient. We will inform you as soon as we are online!



## Enrollment status



	Enrolled patients	First site open
Total	123	August 2020

## International AXSANA Teams

Country	National Steering Committee (Head of the NSC underlined in case of more than one member)
Austria	Prof. <u>Florentia Peintinger</u>
Finland	<u>Dr. Laura Niinikoski</u> , Dr. Tuomo Meretoja, Dr. Marjut Leidenius
France	<u>Prof. Jean-Marc Classe</u> , Prof. Emmanuel Barranger
Germany	<u>PD Dr. M. Banys-Paluchowski</u> , Dr. S. Hartmann, Prof. M. Thill
Greece	<u>Prof. Michalis Kontos</u> , Dr. Makis Kanavidis
Hungary	Dr. habil. Zoltan Matrai
Italy	<u>Dr. Oreste Gentilini</u> , Dr. Rosa di Micco
Norway	Dr. Ellen Schlichting
Poland	Prof. Dawid Murawa
Portugal	<u>Dr. David Pinto</u> , Prof. Maria Joao Cardoso
Romania	Dr. Eduard-Alexandru Bonci
Russia	<u>Prof. Petr Krivorotko</u> , Dr. A. S. Emelyanov
Spain	<u>Dr. Isabel Rubio</u> , Dr. Antonio Esgueva
Sweden	<u>Prof. Jana de Boniface</u> , Hanna Karlsson, Matilda Appelgren
Switzerland	Dr. Maria Luisa Gasparri
Turkey	<u>Prof. Guldeniz Karadeniz Cakmak</u> , Dr. U. Ugurlu, Dr. A. Sezer

## AXSANA Initiation presentation

The study sites are kindly asked to participate in an initiation presentation. The next international initiation presentation in English will take place on **January, 25th 2021 (Monday) at 4 p.m. CET** (Time Zone Berlin, Paris, Madrid, Rome).

Zoom link: <https://us02web.zoom.us/j/86193865170>

You can also visit our website to see the recorded initiation videoconference at: <http://axsana.eubreast.com>

## San Antonio Breast Cancer Symposium 2020

The concept of the AXSANA study has been presented at several national conferences and recently in the „Ongoing Trials“ session at the SABCS 2020:

**BACKGROUND**

The optimal surgical staging of the axilla in breast cancer (BC) patients who convert from a clinically positive to a clinically negative node status (cN+ → cN0, Fig. 1) through neoadjuvant chemotherapy (NACT) is still unclear. For many decades, axillary lymph node dissection (ALND) has been considered standard of care in this setting. However, ALND is associated with high morbidity and may therefore lead to reduced quality of life in BC patients (Fig. 2).

Various forms of axillary staging surgery after NACT are currently in use internationally with the aim to ensure oncological safety and to avoid over-therapy (ALND, TLNB, TAD, SLNB) [1]. The choice of the appropriate technique generally depends on the national and international recommendations and surgeon's preference. 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.

**STUDY DESIGN (NCT04373655)**

**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
- 5-year axillary recurrence rate
- HRQL (evaluated using 4 standardized questionnaires [EORTC QLQ-C30, BR-23, Lymph ICF and SOC-13] at baseline and 1, 3, 5 years after surgery)

**Secondary endpoints** are the feasibility and performance of different axillary staging techniques (detection rate, number of removed lymph nodes and association with complications, arm morbidity and quality of life, operating time and use of clinical and economic resources), impact of learning curve, and the detailed mapping of surgical and oncological treatment standards in different countries.

**KEY ELIGIBILITY CRITERIA**

**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
- Recurrence or inflammatory BC
- Extremity breast cancer
- Pregnancy
- < 4 cycles of NACT administered
- PIs, not suitable for surgical treatment

**CURRENT STATUS**

First patient recruited: June 2020  
Current accrual (Oct 2020): 70 pts.  
Open study sites: 39

**Head of National Steering Committees**

- Austria: Florentia Peintinger
- Germany: Maggie Banys-Paluchowski
- Greece: Michalis Kontos
- Hungary: Zoltan Matrai
- Italy: O. Gentilini, R. di Micco
- Poland: Dawid Murawa
- Portugal: David Pinto
- Romania: Eduard Alexandru Bonci
- Russia: Petr Krivorotko
- Spain: Isabel Rubio
- Sweden: Jana de Boniface
- Switzerland: Maria Luisa Gasparri

**REFERENCES**

1. Banys-Paluchowski M et al. Arch Oncol 2020. Axillary assessment for prediction of response to neoadjuvant therapy in the context of surgical strategies to axillary dissection.

**Affiliations**

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## IMPRESSUM

EUBREAST Study Group

**Chairs and Co-Chairs:**

Prof. T. Kühn, Prof. E. Stickeler,

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

**Organizing Committee:**

PD Dr. M. Banys-Paluchowski: [m.banys@outlook.com](mailto:m.banys@outlook.com)

Dr. S. Hartmann: [steffi.hartmann@kliniksued-rostock.de](mailto:steffi.hartmann@kliniksued-rostock.de)

Prof. T. Kühn: [t.kuehn@klinikum-esslingen.de](mailto:t.kuehn@klinikum-esslingen.de)

**International study coordination:**

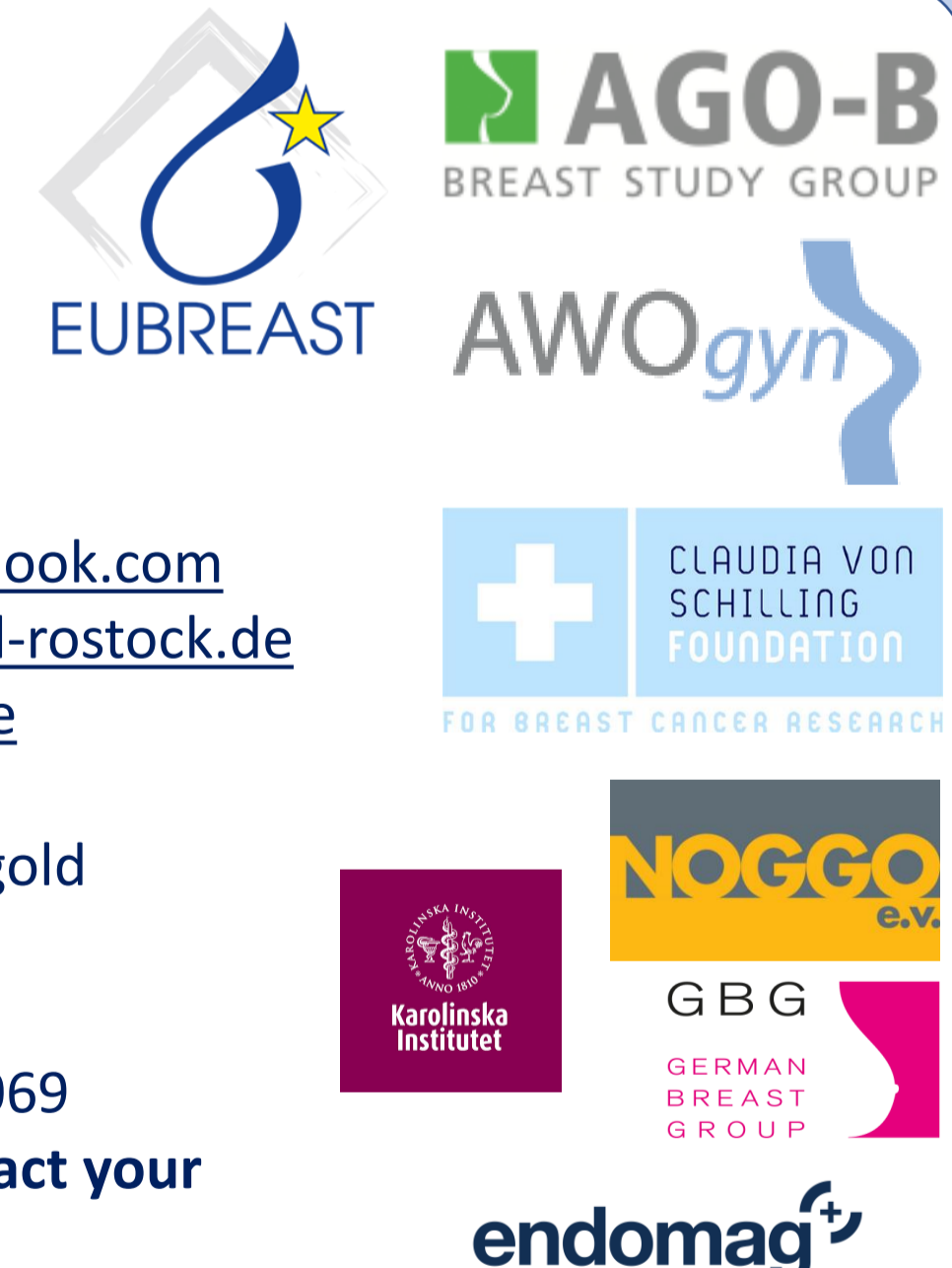
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**In case of questions do not hesitate to contact your National Steering Committee!**



<http://axsana.eubreast.com>