

AXSANA – EUBREAST3 (AXillary Surgery After NeoAdjuvant Treatment)

An international prospective multicenter cohort study of the EUBREAST study group to evaluate different surgical methods of axillary staging (sentinel lymph node biopsy, targeted axillary dissection, axillary dissection) in clinically node-positive breast cancer patients treated with neoadjuvant chemotherapy

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Background:

The surgical staging procedure of the axilla in patients who convert from clinically positive (cN+) to clinically negative node status (ycN0) through neoadjuvant chemotherapy is still controversial. In different international guidelines diverse techniques are recommended such as Axillary Lymph Node Dissection (ALND), Targeted Axillary Dissection (TAD), Target Lymph Node Biopsy (TLNB) and Sentinel Lymph Node Biopsy (SLNB). Comparative data on outcome and morbidity are still not available and further research is needed.

Methods:

AXSANA is an international prospective cohort study including patients who are clinically node positive and scheduled to receive neoadjuvant chemotherapy. The surgical staging procedure is performed according to the standard at their treating institution. Primary aims are invasive disease-free survival, axillary recurrence rate and health-related quality of life (QoL). Patients undergo a 5 year-follow-up including oncological outcomes and QOL questionnaires.

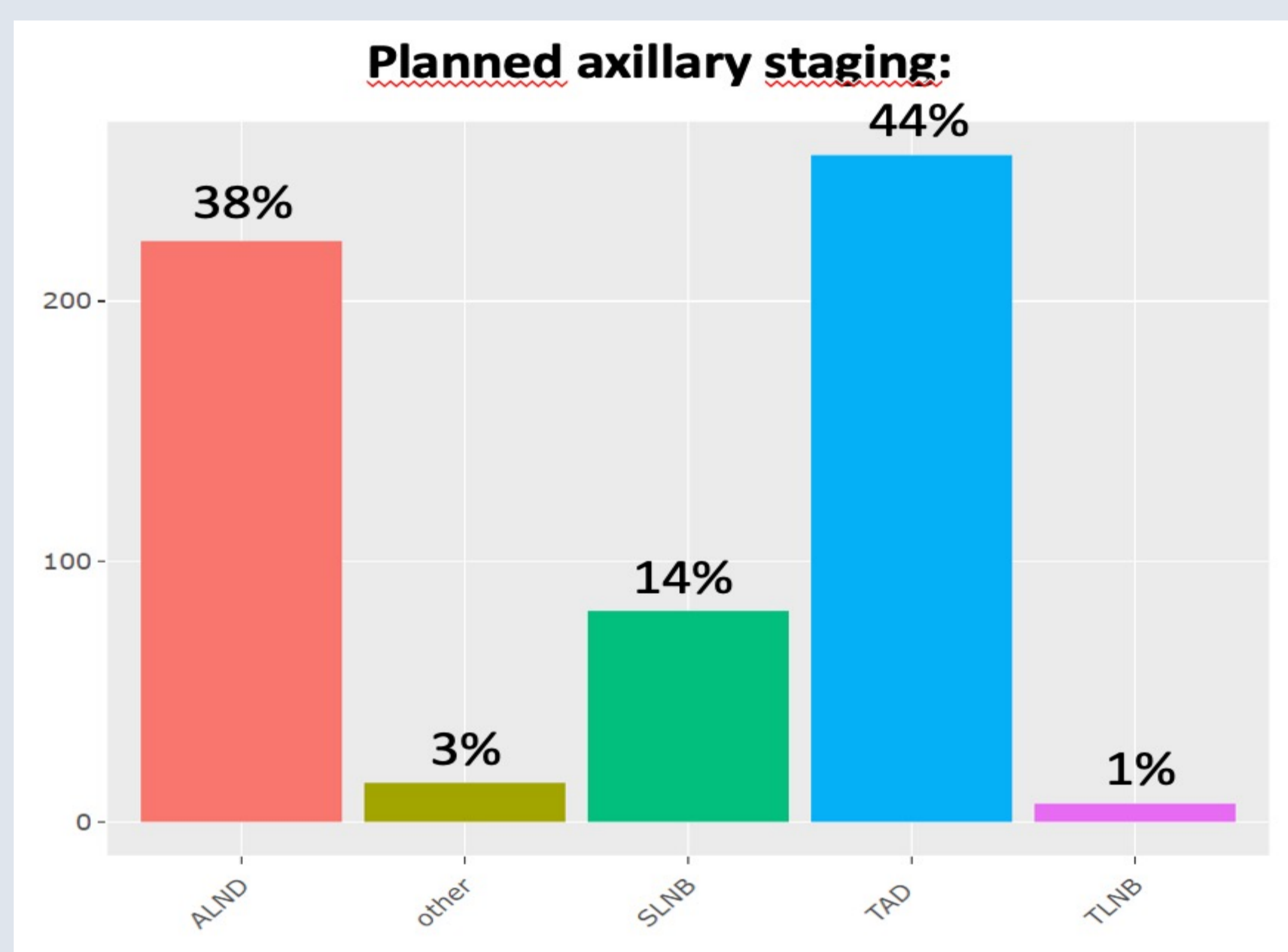


Fig. 1. Planned axillary staging.

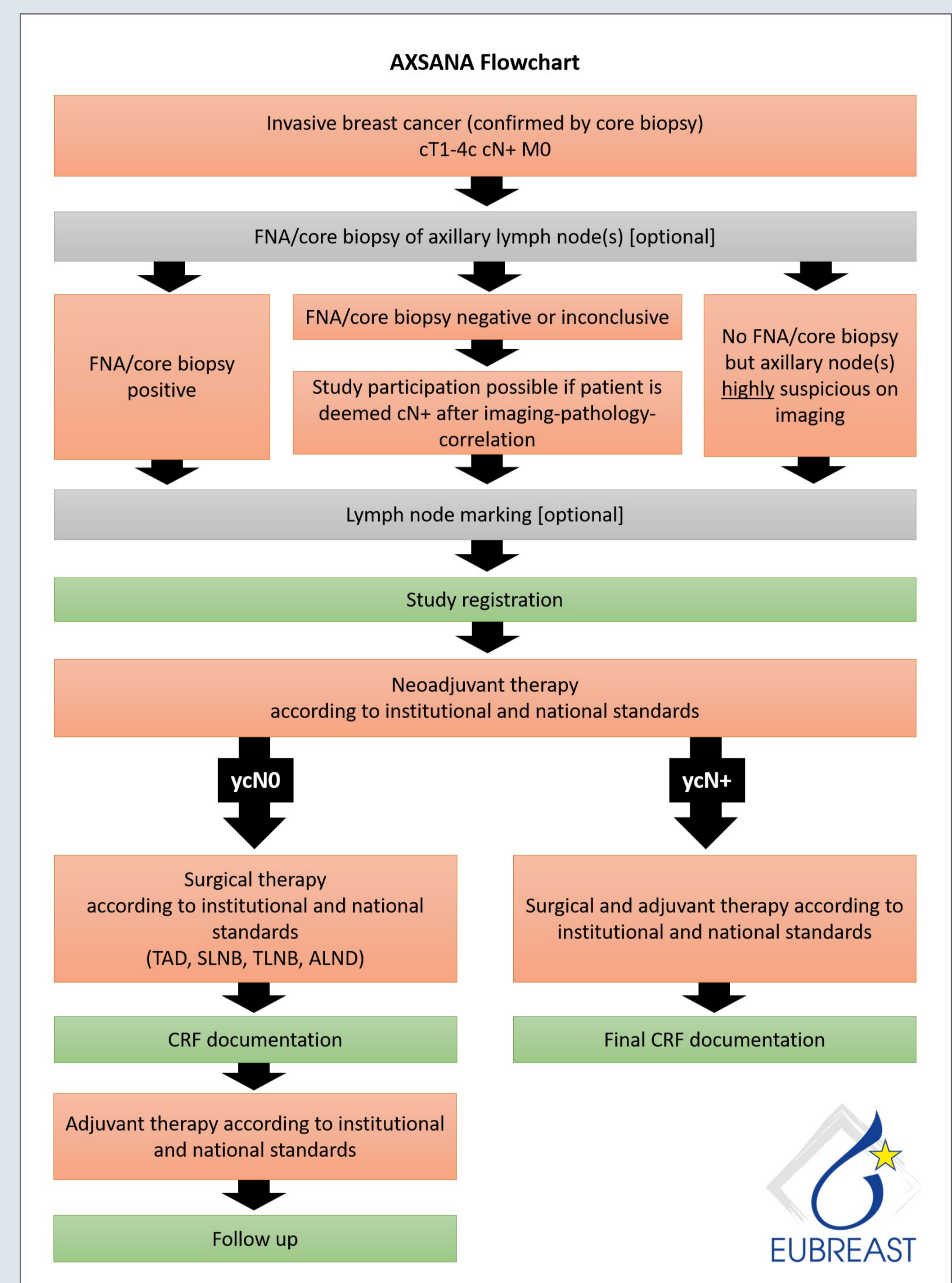


Fig. 2. Study flow chart

Current status of the study:

So far 885 cN+ patients from 13 countries were recruited. Median age was 52 years. In 39% of patients, only one node was suspicious upon imaging, followed by 21% with two suspicious nodes and 40% with at least 3 suspicious nodes. 58% of patients received marker placement into at least one suspicious node; in 10% more than one node was marked. The most frequently used marker was clip/coil in 80% of patients, followed by carbon ink (12%) and magnetic seed (9%). 71% of patients reached ycN0 status. TAD was planned in 44% of cases, ALND in 38%, SLNB in 14% and TLNB in 1%.

Conclusions:

The preliminary data show a strong heterogeneity of axillary staging among countries. Despite the lack of long-term data regarding oncological safety, TAD is a widely used technique. The results of the AXSANA study will clarify whether de-escalation of axillary surgery is a feasible option that should be recommended to patients converting from cN+ to ycN0.

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First patient recruited:

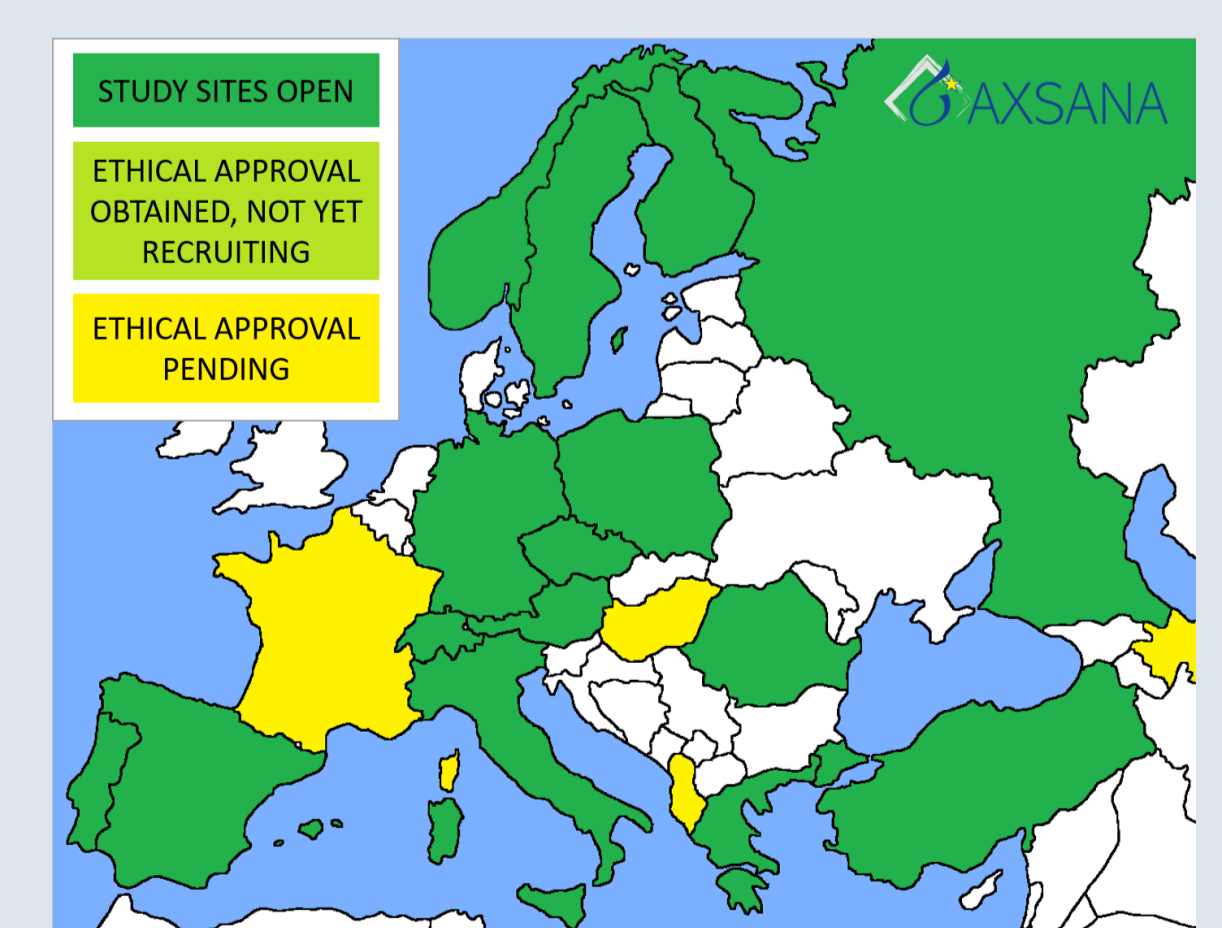
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Current accrual (Sep 21):

885 pts.

Target accrual: 3000 pts.

Open study sites: 185



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