AXSANA

(AXillary Surgery After NeoAdjuvant Treatment)

-EUBREAST 3-

A prospective multicenter cohort study 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

Protocol changes:

English Version:

Version	Changes
5.0.15	Head of National Steering Committee of Hong Kong added
5.0.14	Head of National Steering Committee of Bulgaria added
5.0.13	Head of National Steering Committee of Belgium added
5.0.12	Head of National Steering Committee of Thailand added and affiliation of Head of Steering Committee of Germany updated
5.0.11	Head of National Steering Committee of Mexico, United Kingdom and Slovenia added; affiliation of Organizing Committee member updated
5.0.10	Head of National Steering Committee of Israel added
5.0.9	Head of National Steering Committee of Peru added
5.0.8	Head of National Steering Committee of Azerbaijan added
5.0.7	Head of National Steering Committee of Albania added
5.0.6	Heads of National Steering Committee of India and Czech Republic added
5.0.5	Timepoint of baseline QoL evaluation specified

5.0.4	International Steering Committee and International Steering Board defined Statistician added
5.0.3	Head of National Steering Committee of France corrected Organizing Committee added
5.0.2	Head of National Steering Committee of Finland and Norway added
5.0.1	Head of National Steering Committee of Turkey added
5.0	Amendment 26.10.20
4.6.5	Address of Dr. Isabel Rubio corrected
4.6.4	Head of National Steering Committee of Romania added Denmark removed (not participating)
4.6.3	Follow up intervals corrected (old: year 1, 3, 5; new and CRF-conform: yearly in the first 5 years)
4.6.2	Head of National Steering Committee of Portugal added
4.6.1	Head of National Steering Committee of Switzerland added
previous versions	redactional changes only

German Version:

Version	Changes
5.1	Changes requested by the Ethical Committee Aachen implemented
5.0	Amendment 26.10.20
4.6.1	Follow up intervals described in more detail and in alignment with CRF. 4.6: „Die Rückmeldung der Daten zum Status der Patientin sowie die Erfassung der Armmorbidität und der Lebensqualität erfolgt zu Beginn der Studie und nach 1, 3 und 5 Jahren.“ 4.6.1: „Die Rückmeldung der Daten zum Status der Patientin erfolgt jährlich in den ersten 5 Jahren nach Operation. Die Erfassung der Armmorbidität und der Lebensqualität erfolgt zu Beginn der Studie und nach 1, 3 und 5 Jahren.“
4.6	NCT number added Data management corrected (4.3: Prof. Fasching, 4.6: EUBREAST) Protocol version number harmonized with the current English version (4.6)
4.3	First final version (submitted for review to the Ethical Committee of the University of Aachen)
previous versions	drafts only