AXSANA

SOP Site management (International)

- Study sites in each country are managed by the National Steering Committee = Head of the National Steering Committee + further members.

- In case a new study site wishes to participate in the AXSANA study, they will receive contact details of the Head of their National Steering Committee. If there is no Steering Committee in the respective country, the International Steering Committee will discuss whether the contact person of the new study site may serve as National Steering Committee member.

- Heads of National Steering Committees as well as main recruiters will serve as publication authors

- Documents shared with the National Steering Committee:
    - Study protocol (English, PDF file)
    - Patient Information and Informed Consent (English, word file)
    - Contract template and Joint Controller Agreement (English)
    - Baseline Quality of Life questionnaires (all languages available, one PDF file)
    - Subject Identification Log (English, PDF file)
    - Signature & Delegation Log (English, PDF file, country-specific)
    - Feasibility Questionnaire (English, word file)
    - Excel sheet for the documentation of participating study sites in the respective countries
    - Contact information form for the participating study sites (English, word file)

- **Tasks of the National Steering Committee <u>before EC approval</u>**:
    - Translate relevant documents (if necessary)
    - Apply for the opinion of the local/national Ethics Committee
    - Choose national study sites (the Feasibility Questionnaire and Contact information form may be used)

- **Tasks of the National Steering Committee <u>after EC approval</u>:**
    - Keep the excel sheet for documentation of participating study sites in your country up to date
    - Initiation of new study sites
        - Study site may participate in an online live initiation (e.g. using zoom) or watch the initiation presentation available via www.eubreast.com/?trials
    - Send the following documents to study sites (current versions!):
        - Study protocol (PDF)
        - CRF (advise study sites that it is optional to use the PDF file but that they may use it in addition to eCRF)
        - eCRF User Manual (PDF)
        - Patient Information and Informed Consent (PDF)
        - Baseline Quality of Life questionnaires (PDF)

        - Subject Identification Log (PDF)
        - Signature & Delegation Log (PDF)
    - Send all Signature & Delegation Logs you receive to these e-mail addresses (necessary to create eCRF login credentials):
        - mangold@eubreast.com
        - jursik@eubreast.com
        - shabbir@eubreast.com
    - Coordinate study sites in case of questions/problems
    - Selective monitoring of eCRF data from your country