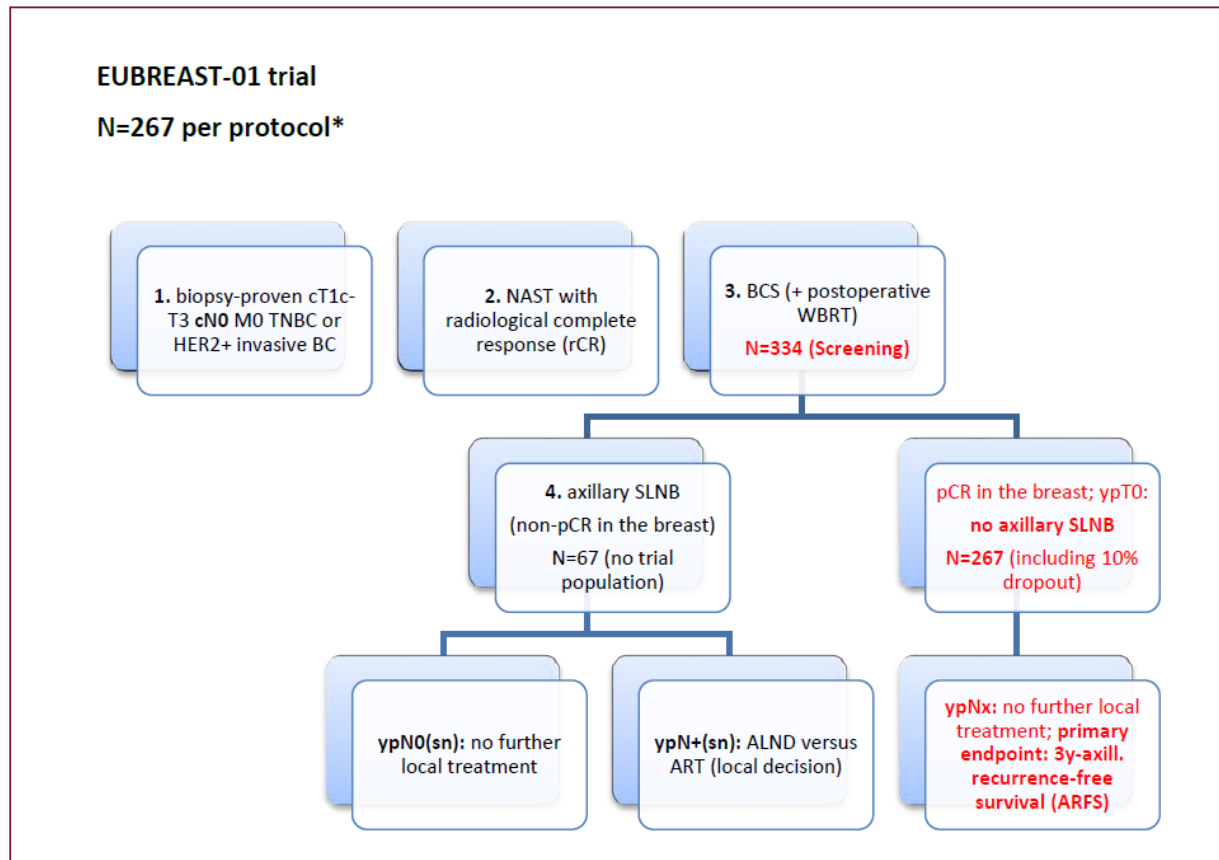


EUBREAST-01 trial (NCT04101851)

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EUBREAST-01 flow chart (Amendment#1)



Current status EUBREAST-01 trial

- Sponsor: University Medicine Rostock (UMR; for Germany and Austria)
- Approved Funding (Germany):
 - Else Kröner-Fresenius-Foundation: 260,000.-€
 - German Society of Senology: 40,000.-€
 - Women's Hospital Rostock: 40,000(-90,000).-€
 - Pfizer Germany: 40,000.-€ (**pending**)
- Feasibility of German study sites (N=55)
 - N=32 with positive feedback
- Protocol version Amendment#1 and ICFs available for EC submission

Open questions (I)

- Decision regarding central data management (for all) and monitoring (Germany)
 - CRO ALCEDIS (Gießen, Germany)
 - CRO Kottmann (Hamm, Germany)
 - NOGGO CRO (Hospital North-West, Frankfurt/Main, Germany)
 - German Breast Group (Neu-Isenburg, Germany)
- Decision regarding patient's insurance (Germany, Austria)
- Legal contract for scientific cooperation between UMR and sponsor outside from Germany-Austria („Co-lead trial“)

Open questions (II)

- Pre-recruitment status in Austria, Italy, Spain, and Sweden
 - Sponsor
 - Patient's insurance
 - Monitoring (local)
 - Contracts with national study sites
 - Submission to local ECs
 - Approval of national budget

Ongoing topics

- After selection of central data management/monitoring and insurance company completing of updated protocol version (Amend#1) and ICFs
- Submission to local EC in Rostock
- Signing of study site contracts (Germany, Austria)

>>> Planned first-patient-in (FPI) in SEP or OCT, 2020