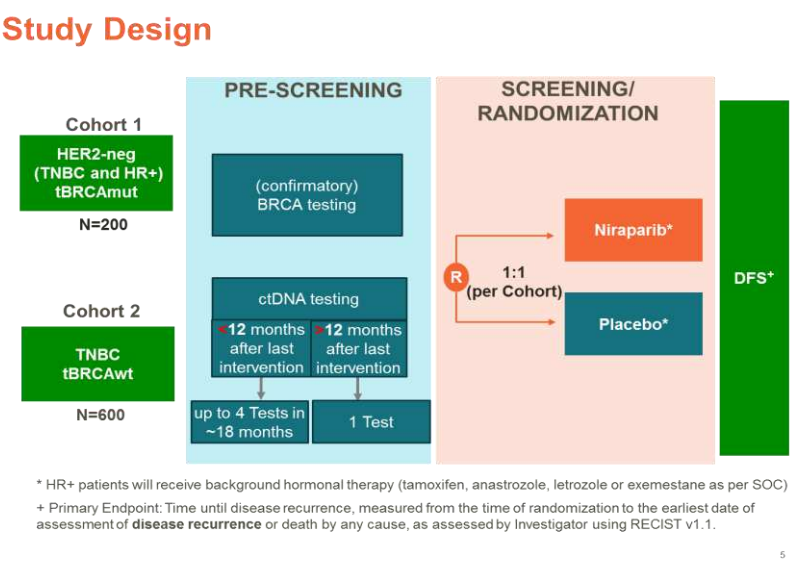
Studienname	**ZEST:** A Randomized Phase 3 Double-blinded Study Comparing The Efficacy And Safety of Niraparib To Placebo In Participants With Either HER2-negative BRCA-mutated Or Triple-negative Breast Cancer With Molecular Disease Based On Presence Of Circulating Tumor DNA After Definitive Therapy
Sponsor	GSK, Phase 3
Studiendesign	
Einschlusskriterien (Auswahl)	1. Stage I to III breast cancer 2. TNBC, irrespective of *BRCA* status 3. HR+/HER2− breast cancer with a known and documented t*BRCA* mutation 4. Completed prior standard therapy for curative intent, including all of the following, if indicated: neoadjuvant treatment, surgery, adjuvant radiotherapy, and adjuvant chemotherapy. 5. Participants with HR+ breast cancer must be on a stable regimen of endocrine therapy, if indicated, for at least 3 months prior to enrollment. Ovarian suppression, if indicated, must also have been started at least 3 months prior to enrollment. 6. Detectable ctDNA → Wird im Rahmen des Screenings am Studienzentrum bestimmt. 7. An archival tumor tissue specimen of the primary tumor sufficient in quality and quantity for ctDNA assay design and t*BRCA* and HRD testing (a minimum of fifteen 5-µm sections or 1 FFPE tumor block for ctDNA assay design and t*BRCA* testing and a minimum of 1 FFPE tumor block for HRD testing) is required
Ausschlusskriterien (Auswahl)	1. Prior treatment with a PARP inhibitor. 2. Current treatment with a CDK4/6 inhibitor or endocrine therapy other than anastrozole, letrozole, exemestane, and tamoxifen. 3. Participants have any sign of metastasis or local recurrence after comprehensive assessment conducted per protocol. 4. Participants have shown no definitive response to preoperative chemotherapy by pathologic or radiological evaluation, in cases where preoperative chemotherapy was administered.

	5. Participants have systolic BP >140 mmHg or diastolic BP >90 mmHg that has not been adequately treated or controlled. 6. Participants have previously or are currently participating in a treatment study of an investigational agent within 4 weeks of the first dose of therapy preceding the study. 7. Participants have a second primary malignancy. Exceptions are the following: • Adequately treated non-melanoma skin cancer, curatively treated in situ cancer of the cervix, ductal carcinoma in situ (DCIS) of the breast, Stage I Grade 1 endometrial carcinoma • Other solid tumors and lymphomas (without bone marrow involvement) diagnosed ≥5 years prior to randomization and treated with no evidence of disease recurrence and for whom no more than 1 line of chemotherapy was applied 8. Participants have current active pneumonitis or any history of pneumonitis requiring steroids (any dose) or immunomodulatory treatment within 90 days of planned start of the study.
Teilnehmende Zentren (Kontakt siehe hier)	Kliniken Essen-Mitte: Prof. Kümmel, Dr. Reinisch