DATA OF THE PROSPECTIVE, INTERSECTORAL RESEARCH PLATFORM OPAL

ROUTINE CARE OF EARLY BREAST CANCER (STAGE I-III) IN GERMANY

INTRODUCTION
The registry platform OPAL started 2017 with the recruitment of patients with advanced breast cancer. Since May 2021, patients with early breast cancer (EBC, stage I-III) receiving systemic therapy have been recruited. OPAL provides insight into treatment and outcome in routine practice where patients’ sociodemographic and medical characteristics often differ from those treated in clinical trials.

METHODS
OPAL is a prospective, observational, open, multicenter clinical registry (NETZ2015512). 500 patients with EBC will be recruited in 3 cohorts: 500 patients with hormone receptor (HR) positive, HER2-negative, 750 patients with HER2-positive and 750 patients with triple-negative breast cancer. OPAL is conducted at more than 250 sites throughout Germany. Over 100 sites are participating. All patients are recruited at start of their first systemic treatment. There is no treatment specification.

OPAL collects detailed information on neoadjuvant, post-neoadjuvant, and adjuvant treatments, patient and tumor characteristics, physician-reported factors potentially influencing treatment decision, biomarker testing and additional treatments (surgery, radiotherapy).

RESULTS
By March 31, 2022 (database cut for the first interim analysis) 1175 pts had been recruited by over 100 sites.

HR-positive, HER2-negative cohort
Patients with HR-positive, HER2-negative EBC (n=215) were median 56 years old, 20% were premenopausal and overall in a good general condition (ECOG 0-1), no comorbidities, according to the Charlson Comorbidity Index (CCI 0-1) (Table 2).

HER2-positive cohort
Patients with HER2-positive EBC (n=210) had a median age of 56 years, 29% of patients were premenopausal and most patients were in a good condition (ECOG 0-1), CCI 0 (Table 2).

Triple-negative cohort
Similar to patients with HER2-positive EBC, patients with triple-negative EBC (n=217) were median 56 years, 30% premenopausal. 80% ECOG 0 and 80% CCI 0. 57% of patients were diagnosed with a UICC stage II (Table 1).

CONCLUSION
OPAL-EBC displays inter-sectoral and prospectively collected data on the treatment reality of patients with EBC in Germany. Further analysis will show the implementation of newly approved drugs, their effectiveness (e.g. disease-free survival) and PROs in a “real world” setting.

Figure 1
Figure 2
Figure 3
Figure 4