TRENDS IN PHASE 3 CLINICAL TRIALS IN OVARIAN CANCER FROM 2001–2021

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10.1136/ijgc-2022-igcs.77

Objectives To determine the trends and progress of clinical trials on ovarian cancer over the last 20 years.

Methods From 2001 to 2021, all phase 3 clinical trials were identified from clinicaltrials.gov. Demographics and characteristics were analyzed for comparison and trends using chi square analysis.

Results Of 43,641 ovarian cancer patients enrolled in 58 clinical trials, 19 were based in the US and 39 were based internationally. There were 35 (60%) government sponsored trials vs. 23 (40%) industry trials. 18 (31%) trials studied chemotherapies vs. 40 (69%) targeted therapies; 17 (30%) trials incorporated biomarkers. The median number of patients per trial was 581 (range 50–1952), and those using PFS vs. OS was 35 (60%) vs. 14 (24%). To evaluate trends, we studied two time periods, 2001–2010 and 2011–2021. There was an increase in industry sponsored trials (5% (2001–2010) vs. 49% (2011–2021); p-value<.05), targeted therapy trials (10% to 43%; p-value<.05), biomarker use (BRCA, HRD, PDL1) (67% to 89%; p-value<.05), and incorporation of PFS endpoint (57% to 70%; p-value=.3). There was a decrease in the median number of patients enrolled per trial (n= 820 to 426) and in the proportion of patients with comorbidities (ECOG>2) (17% to 7%; p-value=.2).

Conclusions Over the past 20 years, targeted therapy trials incorporating biomarker use has increased, but the number of patients enrolled and those with comorbidities has decreased. These trends in trial design and enrollment are important in understanding the applicability of their results to our patients.