6521 **Poster Session**

Representation of women in clinical trials supporting the FDA-approval of contemporary anticancer therapies.

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Background: Contemporary anticancer drugs frequently have different efficacy and side effects in men and women. Yet, whether women are well-represented in pivotal trials supporting contemporary anticancer drugs is unknown. The objective of this study was to characterize the representation of women in trials supporting the use of contemporary anticancer drugs. **Methods:** We retrospectively evaluated all pivotal (phase II and III) trials supporting FDA-approval of anticancer drugs from 1998 to 2018, derived from Drugs@FDA, clinicaltrials.gov, MEDLINE, and publicly available FDA-drug reviews. Expected population rates were derived from the National Cancer Institute Surveillance, Epidemiology, and End Results (SEER) program, and US Census databases. The primary outcome was the report of any gender-specific analysis of efficacy and/or safety, irrespective of treatment-arm. The secondary outcome was the proportional representation of women across trials, evaluated by a participation-to-prevalence ratio (PPR) of 0.85, according to cancer-type. Female representation was also assessed as change across time. Differences in pooled binary endpoint hazard ratios, by the presence or absence of adequate female representation, were also assessed. **Results:** In total, there were 97,566 participants, enrolled in 189 clinical trials, evaluating 123 anticancer therapies. Gender was reported in 182 (96.3%) clinical trials, of which 43.4% (42,299) were women, compared to 55.6% (55,267) men ($P < 0.01$). Overall, women were under-represented in clinical trials of anticancer therapies by a mean of 16.5% compared to the proportional incidence of all cancers in women. Women were the most under-represented in gastric (PPR = 0.821) and liver (PPR = 0.619) cancer trials. Sex-based drug efficacy analysis was only published in 36.8% of trials. Over time, the trend of percentage women recruited into clinical trials increased, but not at a rate comparable to prevalence (-5.0 to -5.5% of prevalence), and the gap in under-representation of women in anticancer therapy clinical trials is widening. **Conclusions:** Among pivotal clinical trials supporting contemporary FDA-approved cancer drugs, women were frequently under-represented. Additional studies are needed to understand the impact of under-representation on contemporary anticancer therapy outcomes. Research Sponsor: None.