

Oklahoma State University College of Osteopathic Medicine

Assessing Patient Risk, Benefit, and Outcomes in Drug Development: A Decade of Pertuzumab Clinical Trials



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Background

Breast cancer is the most prevalent cancer among women, and its diagnosis leads to financial and health burdens. Pertuzumab is an anti-*HER2* drug FDA approved for breast cancer, yet it is used for off-label indications. In order to better understand its off-label use, a drug development profile must be established for pertuzumab.

Results

Table 2a. Overall Trial Characteristics and Outcomes by Indication

Indication	# of Trials	# of Randomized Trials (n (%))	# of Participants	# of Males	# of Females	# of GRADE 3-5 Events	Median PFS (months)	Median OS (months)	Median Age	Median Partial Response Rate	Median Complete Response Rate	Median ORR*
Breast Cancer	31	11 (35.5)	6762	11	6749	4712	13.4	39.2	53	49.8%	7.9%	68.3%
Colorectal Cancer	1	-**	31	24	7	2	4.1	-	60	9.7%	0.0%	9.7%
Gastric and Gastric	2	2 (100)	810	641	163	1071	7.8	15.9	62.3	62.5%	0.0%	57.5%
Lung Cancer	1	-	15	11	4	12	9.3	-	61	20.0%	-	20.0%
Ovarian Cancer	2	2 (100)	305	0	305	347	19.2	9.1	61.1	43.3%	0.0%	43.3%
Totals/Medians	37	15	7923	687	7228	6144	12.1	34.1	61	42.3%	9.4%	51.7%

*Response rate median calculations for those indications using RECIST or mRECIST only

**Did not measure outcome, failed to report outcomes, or failed to report outcome measure for all enrolled patients

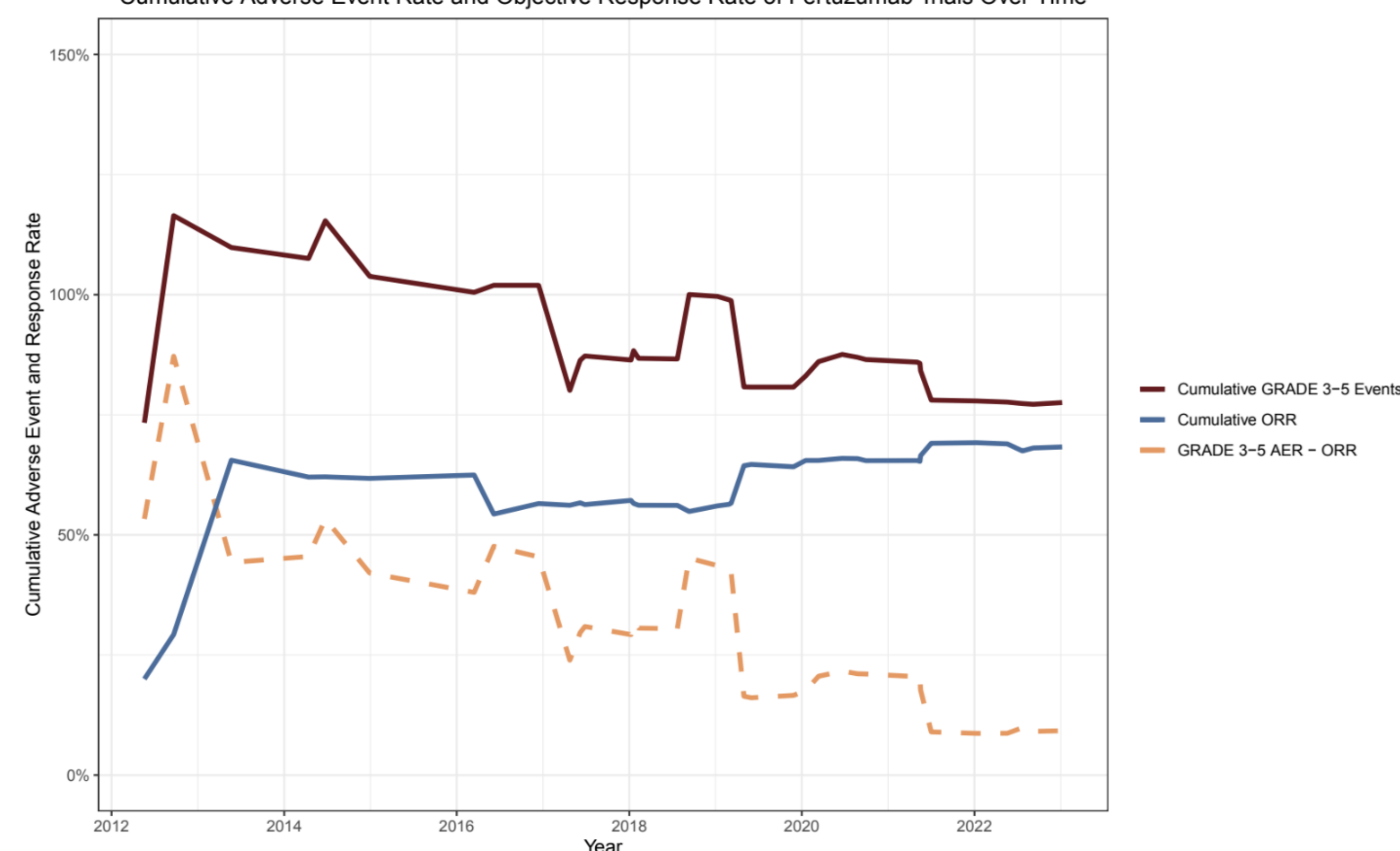
Discussion

Pertuzumab first received US FDA approval in 2012 for the treatment of metastatic *HER2* positive breast cancer, based on the results of the CLEOPATRA trial. CLEOPATRA found an increased overall survival with the addition of pertuzumab. Since then, the drug has enjoyed two more supplementary approvals, such as use for neoadjuvant treatment for locally advanced, inflammatory, or early stage breast cancer, and for adjuvant treatment with early *HER2* positive breast cancer with high risk of recurrence.¹⁹ Among tumor types, pertuzumab is currently only approved for use in breast tissues. Here we sought to explore the broader clinical trials portfolio of pertuzumab since its FDA approval in 2012.

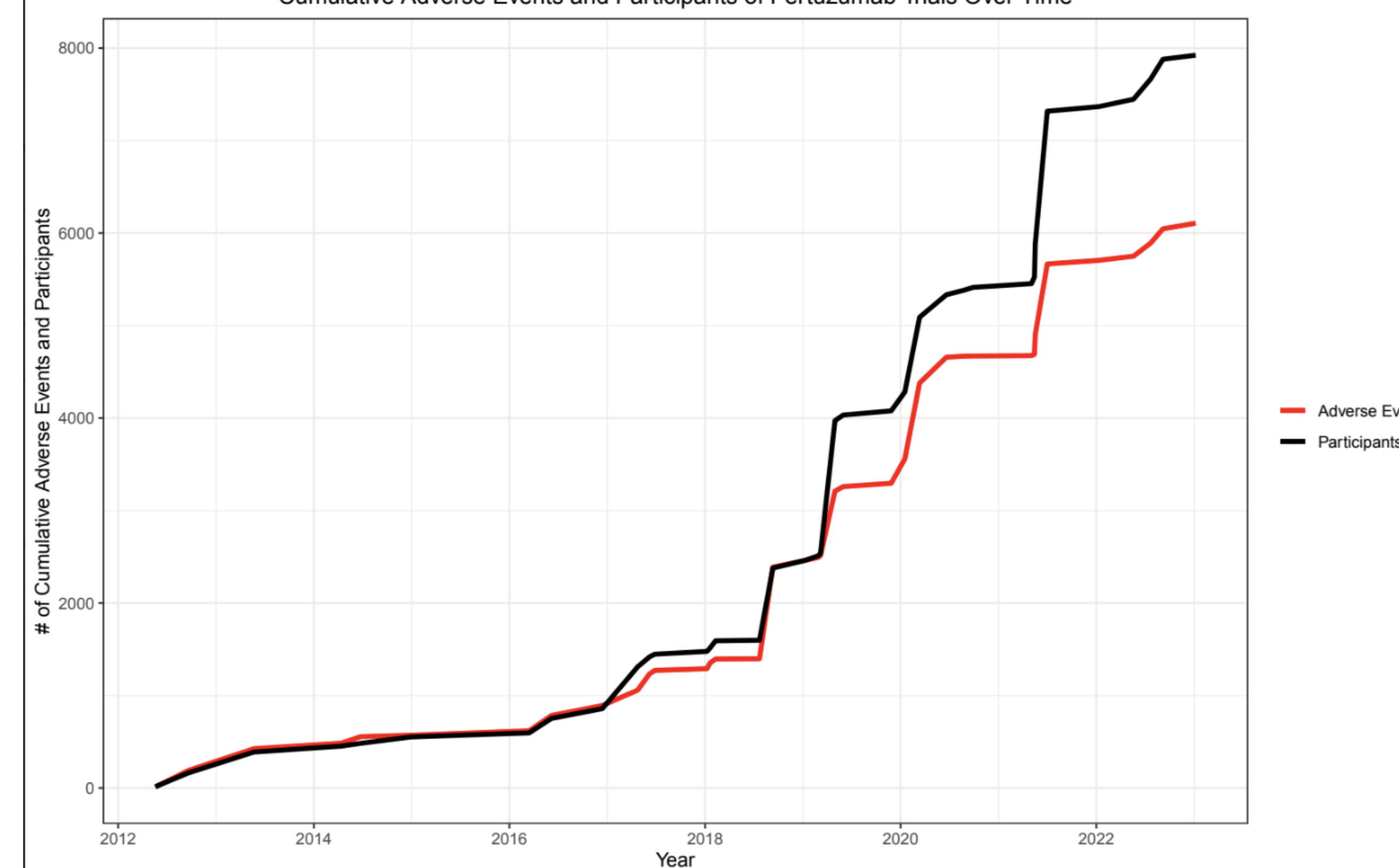
Methods

On May 25, 2023, a search through Pubmed/MEDLINE, Embase, Cochrane CENTRAL, and ClinicalTrials.gov was completed to gather clinical trials evaluating pertuzumab. Studies meeting inclusion criteria were screened in a masked duplicate fashion, followed by a full-text screen. Final included studies were evaluated for adverse events, trial characteristics, and endpoints such as objective response rate, progression-free survival, and overall survival.

Cumulative Adverse Event Rate and Objective Response Rate of Pertuzumab Trials Over Time



Cumulative Adverse Events and Participants of Pertuzumab Trials Over Time



References



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