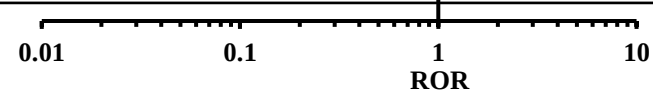
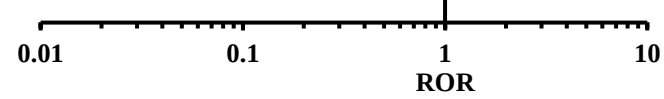
a

Seriousness	Without pertuzumab (n = 18,910)	With pertuzumab (n = 8,537)	ROR (95% CI)
Serious total	10,407	4,536	0.93 (0.88 – 0.98)
Death	826	285	0.76 (0.66 – 0.87)
Life-threatening	499	207	0.92 (0.78 – 1.08)
Caused/Prolonged Hospitalization	3,141	1,700	1.25 (1.17 – 1.33)
Disabling/Incapacitating	305	117	0.85 (0.68 – 1.05)
Congenital anomaly/Birth defect	3	1	0.74 (0.08 – 7.10)
Other	5,633	2,226	0.83 (0.78 – 0.88)



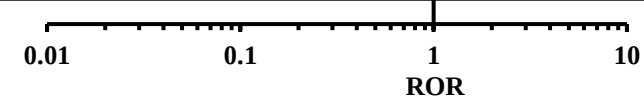
b

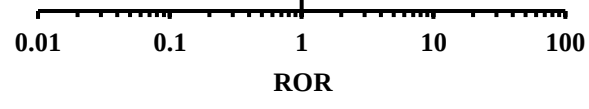
Seriousness	Trastuzumab only (n = 6,173)	Trastuzumab + Pertuzumab (n = 1,586)	ROR (95% CI)
Serious total	2,814	744	1.05 (0.94 – 1.18)
Death	287	58	0.78 (0.58 – 1.04)
Life-threatening	156	25	0.62 (0.40 – 0.95)
Caused/Prolonged Hospitalization	788	233	1.18 (1.00 – 1.38)
Disabling/Incapacitating	80	14	0.68 (0.38 – 1.20)
Congenital anomaly/Birth defect	1	0	-
Other	1,502	414	1.10 (0.97 – 1.25)



c

Seriousness	Trastuzumab + Docetaxel (n = 1,307)	Trastuzumab + Docetaxel + Pertuzumab (n = 1,993)	ROR (95% CI)
Serious total	734	1,013	0.81 (0.70 – 0.93)
Death	46	54	0.76 (0.51 – 1.14)
Life-threatening	48	57	0.77 (0.52 – 1.14)
Caused/Prolonged Hospitalization	315	434	0.88 (0.74 – 1.03)
Disabling/Incapacitating	19	20	0.69 (0.37 – 1.29)
Congenital anomaly/Birth defect	0	1	-
Other	306	447	0.95 (0.80 – 1.12)



d

SOC	Trastuzumab only (n = 788)	Trastuzumab + Pertuzumab (n = 233)	ROR (95% CI)
Blood and lymphatic system disorders	29	15	1.80 (0.95 – 3.42)
Cardiac disorders	145	42	0.98 (0.67 – 1.43)
Congenital, familial and genetic disorders	0	0	-
Ear and labyrinth disorders	4	1	0.84 (0.09 – 7.60)
Endocrine disorders	1	0	-
Eye disorders	16	3	0.63 (0.18 – 2.18)
Gastrointestinal disorders	155	63	1.51 (1.08 – 2.12)
General disorders and administration site conditions	276	86	1.09 (0.80 – 1.47)
Hepatobiliary disorders	10	1	0.34 (0.04 – 2.63)
Immune system disorders	51	17	1.14 (0.64 – 2.01)
Infections and infestations	83	31	1.30 (0.84 – 2.03)
Injury, poisoning and procedural complications	77	27	1.21 (0.76 – 1.93)
Investigations	107	44	1.48 (1.01 – 2.18)
Metabolism and nutrition disorders	33	18	1.92 (1.06 – 3.47)
Musculoskeletal and connective tissue disorders	83	16	0.63 (0.36 – 1.09)
Neoplasms benign, malignant and unspecified (including cysts and polyps)	22	11	1.73 (0.82 – 3.61)
Nervous system disorders	148	37	0.82 (0.55 – 1.21)
Pregnancy, puerperium and perinatal conditions	1	0	-
Psychiatric disorders	30	5	0.55 (0.21 – 1.44)
Renal and urinary disorders	18	4	0.75 (0.25 – 2.23)
Reproductive system and breast disorders	6	4	2.28 (0.64 – 8.14)
Respiratory, thoracic and mediastinal disorders	174	49	0.94 (0.66 – 1.34)
Skin and subcutaneous tissue disorders	89	21	0.78 (0.47 – 1.28)
Social circumstances	3	1	1.13 (0.12 – 10.89)
Surgical and medical procedures	18	1	0.18 (0.02 – 1.39)
Vascular disorders	85	23	0.91 (0.56 – 1.47)
Product issues	2	1	1.69 (0.15 – 18.77)