

Supplementary Table 3: Summary of Adverse Events by Treatment Group (Safety Population).

	PHH-1V (N=513)	BNT162b2 (N=252)	OR (95% CI)	p value
Total Adverse Events	1581 [458 (89.3)]	1061 [238 (94.4)]	0.49 [0.26, 0.91]	0.0219
Injection site pain	748 [409 (79.7)]	466 [225 (89.3)]	0.47 [0.30, 0.75]	0.0010
Headache	193 [160 (31.2)]	122 [101 (40.1)]	0.68 [0.49, 0.94]	0.0190
Fatigue	166 [141 (27.5)]	115 [106 (42.1)]	0.52 [0.38, 0.72]	0.0001
Myalgia	107 [100 (19.5)]	93 [86 (34.1)]	0.47 [0.33, 0.66]	0
Injection site induration	45 [44 (8.6)]	44 [43 (17.1)]	0.46 [0.29, 0.72]	0.001
Injection site erythema	33 [33 (6.4)]	37 [36 (14.3)]	0.41 [0.25, 0.70]	0.0007
Intensity				
Mild	1382 [342 (66.7)]	885 [146 (57.9)]	1.45 [1.06, 1.98]	0.02
Moderate	187 [108 (21.1)]	165 [85 (33.7)]	0.52 [0.37, 0.74]	0.0002
Severe	12 [8 (1.6)]	11 [7 (2.8)]	0.55 [0.20, 1.74]	0.27
Treatment-related Adverse Events	1384 [434 (84.6)]	975 [231 (91.7)]	0.5 [0.29, 0.83]	0.0061
Serious Adverse Events (SAEs)	1 [1 (0.2)]	0 [0 (0.0)]	∞ [0.03, ∞]	1
COVID-19 cases				
≥ 14 days post-booster	52 [52 (10.14)]	31 [30 (11.9)]	0.83 [0.51, 1.36]	0.45

Data are shown as the “total number of events [subjects (percentage)]” in relation to the safety population. For the total adverse events, is shown those events with a frequency $\geq 10\%$ of treated patients, and as the system organ class preferred term. For comparison of dichotomous variables between groups, the OR of the corresponding proportions of affected individuals were estimated and tested against the null hypothesis $H_0: OR = 1$ using Fisher's Exact test. CI=Confidence Interval; OR=Odds ratio.