Safety and immunogenicity of heterologous boosting with BNT162b2 following a primary immunisation course with NVX-CoV2373: a sub-study of the COV-BOOST phase 2 randomised controlled trial of third dose booster vaccines for COVID-19

Supplementary Appendix

Contents

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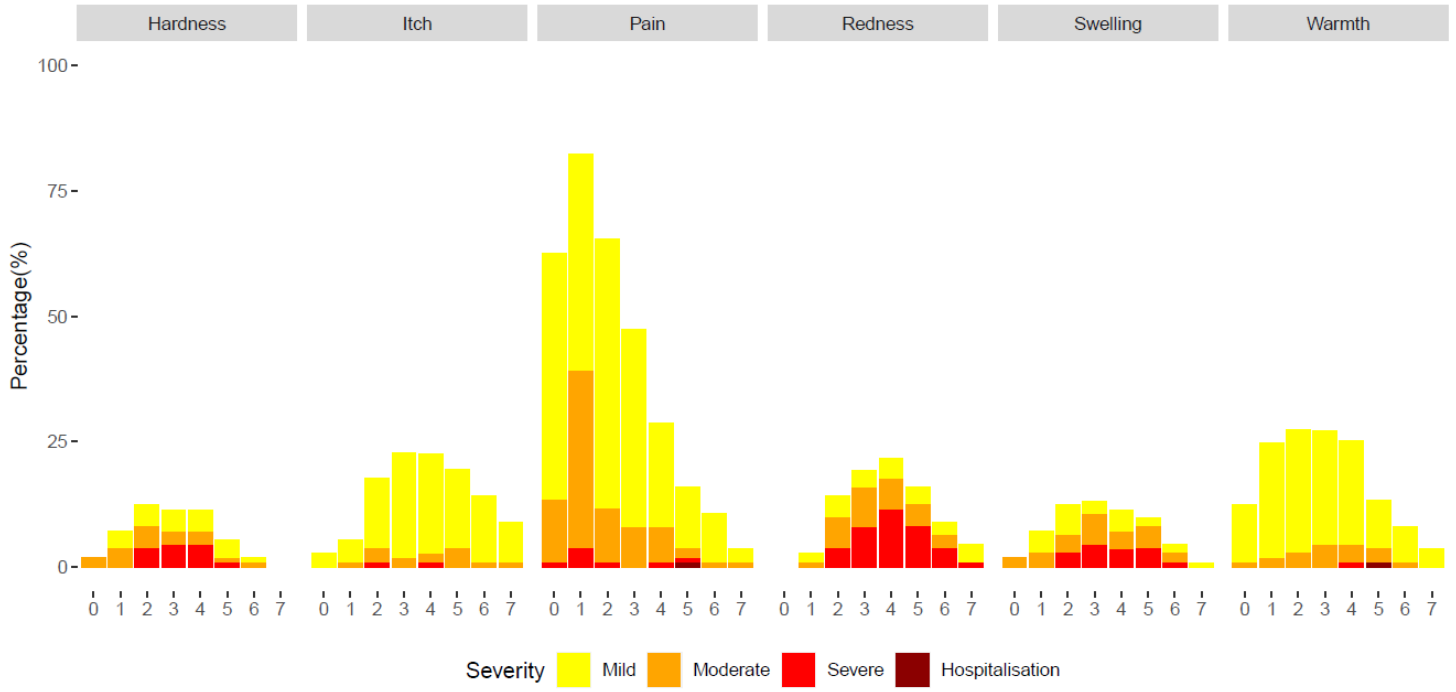
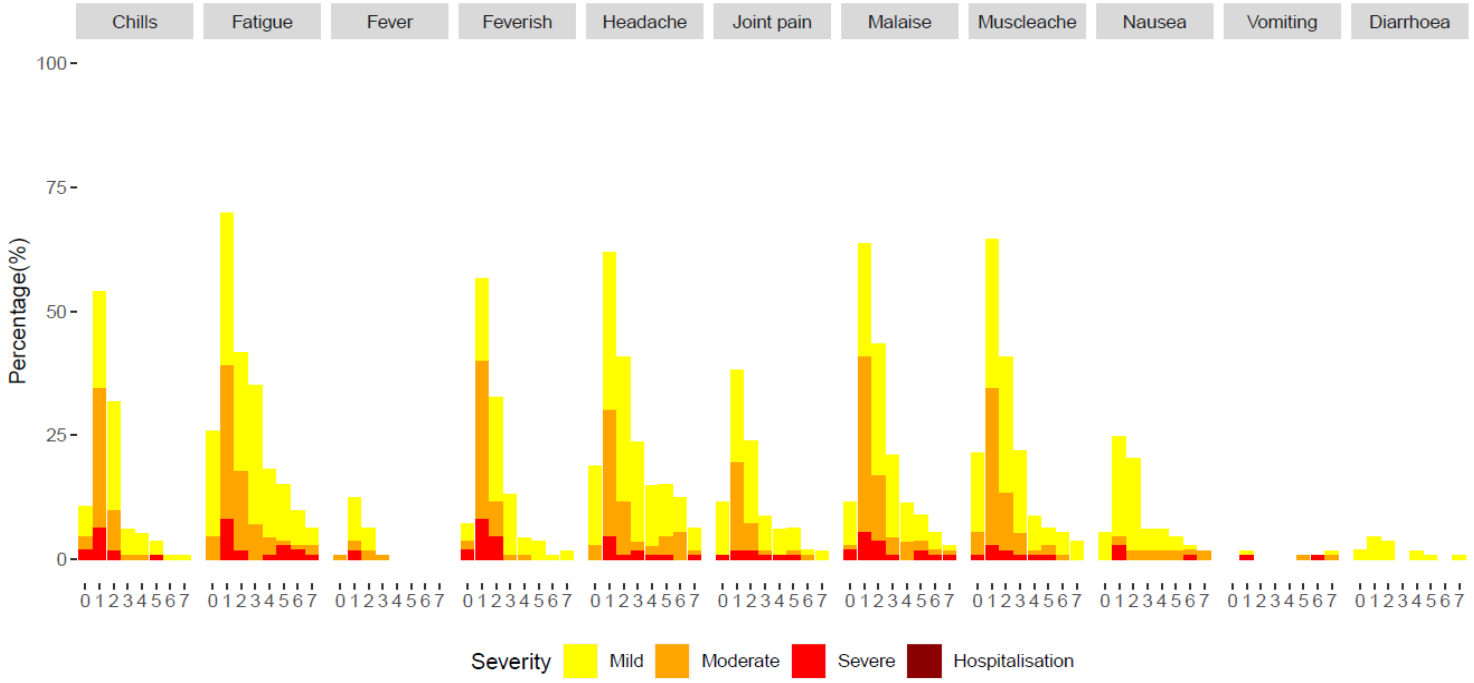
Supplementary Figure 1: Severity of solicited local adverse events in days 0-7 following booster vaccination

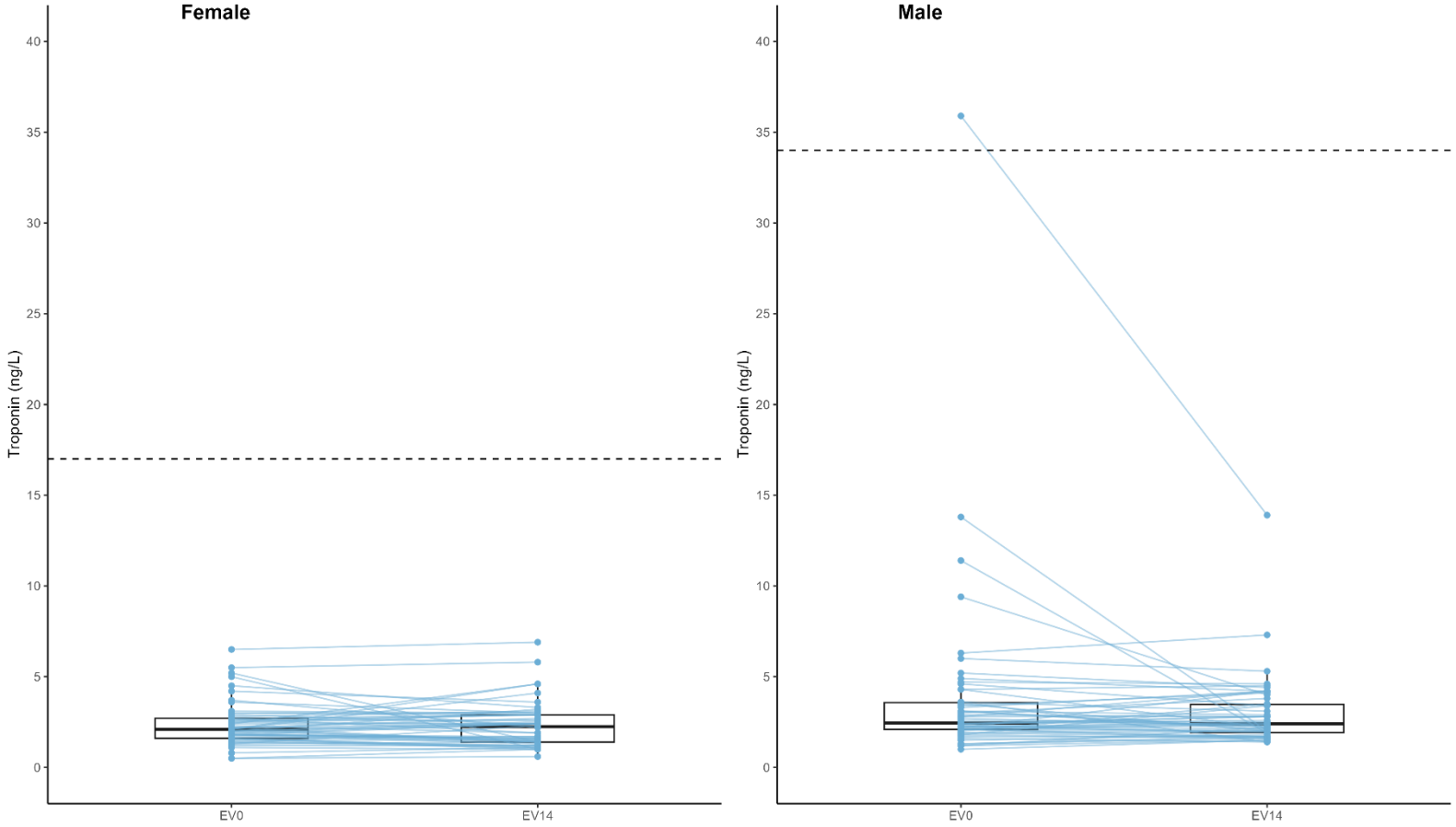


Supplementary Figure 2: Severity of solicited systemic reactions in days 0-7 following booster vaccination

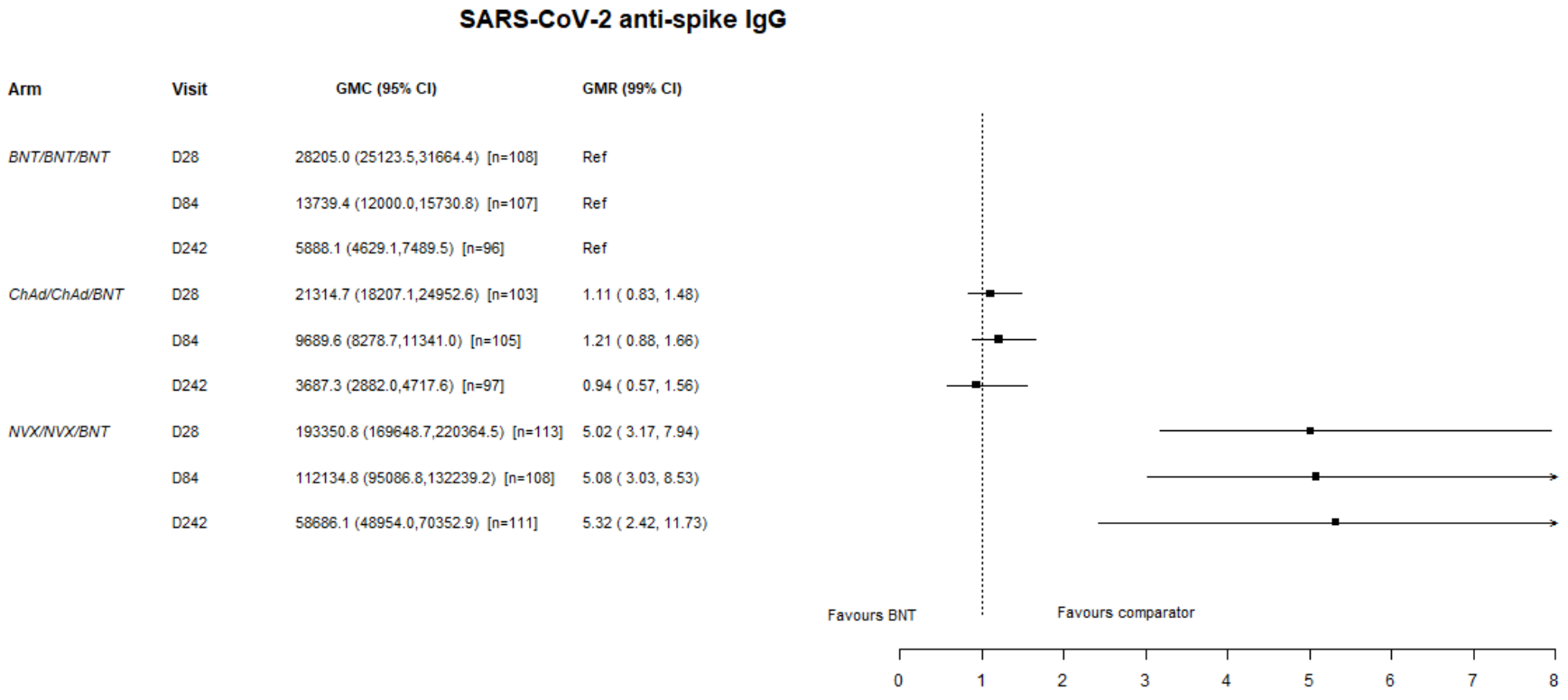


Supplementary Figure 3: Troponin levels in A) Females and B) Males at day 0 prior to booster vaccination and at day 14 post vaccination.

Troponin adult ranges are 0-17 ng/L in females (dotted line) and 0-34 ng/L in males (dashed line). Male adult who is above the range at the baseline is aged 54, white, with no comorbidities.



Supplementary Figure 4: Immune responses (SARS-CoV-2 anti-spike IgG, ELU/ml) of participants from the current study (NVX-COV2373/NVX-COV2373/BNT162b2) in comparison to cohorts who received BNT162b2/BNT162b2/BNT162b and ChAdOx1-nCoV19/ChAdOx1-nCoV19/BNT162bin the original COV-BOOST study.



Supplementary Table 1: The most severe category of local solicited adverse events experienced over first 7 days (severe events are highlighted in bold).

N= 115		**Count**	**Percent (%)**
Hardness	**Grade 1**	4	3.5
	Grade 2	6	5.2
	Grade 3	**8**	**7.0**
	Grade 4	0	0.0
Itch	**Grade 1**	34	29.6
	Grade 2	7	6.1
	Grade 3	1	0.9
	Grade 4	0	0.0
Pain	**Grade 1**	53	46.1
	Grade 2	45	39.1
	Grade 3	4	3.5
	Grade 4	**1**	**0.9**
Redness	**Grade 1**	4	3.5
	Grade 2	10	8.7
	Grade 3	**17**	**14.8**
	Grade 4	0	0.0
Swelling	**Grade 1**	5	4.3
	Grade 2	8	7.0

	Grade 3	**6**	**5.2**
	Grade 4	0	0.0
Warmth	**Grade 1**	41	35.7
	Grade 2	8	7.0
	Grade 3	0	0.0
	Grade 4	**1**	**0.9**

Supplementary Table 2: The most severe category of systemic solicited adverse events experienced over first 7 days (severe events are highlighted in bold)

N= 115		**Count**	**Percent%**
Chills	**Grade 1**	24	20.9
	Grade 2	35	30.4
	Grade 3	**10**	**8.7**
	Grade 4	0	0.0
Fatigue	**Grade 1**	30	26.1
	Grade 2	42	36.5
	Grade 3	**13**	**11.3**
	Grade 4	0	0.0
Fever	**Grade 1**	12	10.4
	Grade 2	3	2.6
	Grade 3	**2**	**1.7**
	Grade 4	0	0.0
Feverish	**Grade 1**	16	13.9
	Grade 2	38	33.0
	Grade 3	**14**	**12.2**
	Grade 4	0	0.0
Headache	**Grade 1**	35	30.4
	Grade 2	36	31.3
	Grade 3	**7**	**6.1**
	Grade 4	0	0.0
Joint Pain	**Grade 1**	27	23.5

	Grade 2	21	18.3
	Grade 3	**5**	**4.3**
	Grade 4	0	0.0
Malaise	**Grade 1**	23	20.0
	Grade 2	43	37.4
	Grade 3	**13**	**11.3**
	Grade 4	0	0.0
Muscle Ache	**Grade 1**	38	33.0
	Grade 2	39	33.9
	Grade 3	**6**	**5.2**
	Grade 4	0	0.0
Nausea	**Grade 1**	34	29.6
	Grade 2	4	3.5
	Grade 3	**3**	**2.6**
	Grade 4	0	0.0
Vomiting	**Grade 1**	2	1.7
	Grade 2	0	0.0
	Grade 3	1	0.9
	Grade 4	0	0.0
Diarrhoea	**Grade 1**	13	11.3
	Grade 2	0	0.0
	Grade 3	0	0.0
	Grade 4	0	0.0

Supplementary Table 3: Summary of adverse events

N=Number of vaccinated participants	**(N=115)**
Number of unique participants with at least one adverse event	68
Number of adverse events	120
Adverse events with special interest	
No	81 (67.5%)
Yes	39 (32.5%)
Serious adverse events	
No	118 (98.3%)
Yes - an important medical event	1 (0.8%)
Yes - hospitalisation	1 (0.8%)
Severity	
Grade 1	73 (60.8%)
Grade 2	40 (33.3%)
Grade 3	6 (5.0%)
Grade 4	1 (0.8%)
Causality	
No relationship	64 (53.3%)
Unlikely	22 (18.3%)
Possible	15 (12.5%)
Probable	13 (10.8%)
Definite	6 (5.0%)
System Organ Classes (SOC)	

Blood and lymphatic system disorders	10 (8.3%)
Cardiac disorders	3 (2.5%)
Congenital, familial and genetic disorders	0 (0.0%)
Ear and labyrinth disorders	0 (0.0%)
Endocrine disorders	0 (0.0%)
Eye disorders	2 (1.7%)
Gastrointestinal disorders	4 (3.3%)
General disorders and administration site conditions	3 (2.5%)
Hepatobiliary disorders	4 (3.3%)
Immune system disorders	0 (0.0%)
Infections and infestations	53 (44.2%)
Injury, poisoning and procedural complications	0 (0.0%)
Investigations	3 (2.5%)
Metabolism and nutrition disorders	4 (3.3%)
Musculoskeletal and connective tissue disorders	8 (6.7%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0 (0.0%)
Nervous system disorders	9 (7.5%)
Pregnancy, puerperium and perinatal conditions	0 (0.0%)
Product issues	0 (0.0%)
Psychiatric disorders	1 (0.8%)

Renal and urinary disorders	0 (0.0%)
Reproductive system and breast disorders	4 (3.3%)
Respiratory, thoracic and mediastinal disorders	6 (5.0%)
Skin and subcutaneous tissue disorders	2 (1.7%)
Social circumstances	0 (0.0%)
Surgical and medical procedures	1 (0.8%)
Vascular disorders	3 (2.5%)
Menstrual disorder	
Yes	0 (0.0%)

Supplementary Table 4: Troponin levels at Day 0 before booster dose and at day 14 after booster, split by gender

Troponin ng/L		**Male N=58**	**Female N=57**	**Total N=115**
Day 0	**Mean (SD)**	3.8 (4.9) [n=58]	2.3 (1.2) [n=57]	3.1 (3.61) [n=115]
	Median (Q1-Q3)	2.5 [2.1, 3.6] [n=58]	2.1 [1.6, 2.7] [n=57]	2.3 [1.8, 3.1] [n=115]
Day 14	**Mean (SD)**	3.0 (1.9) [n=54]	2.3 (1.2) [n=56]	2.6 (1.6) [n=110]
	Median (Q1-Q3)	2.4 [1.9, 3.5] [n=54]	2.3 [1.4, 2.9] [n=56]	2.4 [1.6, 3.0] [n=110]

Supplementary Table 5: Sup-group analysis of Immune response (SARS-CoV-2 anti-spike IgG, ELU/ml) by gender and baseline serostatus at Day 0 and Days 14, 28,84 and 242 after NVX-CoV2373 booster vaccine

SARS-CoV-2 anti-spike IgG, ELU/ml		Visit					Fold Change		
		Day 0	**Day 14**	**Day 28**	**Day 84**	**Day 242**	**Day 28 to Day 0**	**Day 84 to Day 28**	**Day 242 to Day 84**
Gender	**Male**	904 (626,1306) (n=58)	181777 (151503,218101) (n=54)	175657 (143918,214396) (n=56)	101496 (77933,132183) (n=54)	53712 (39826-72439) (n=54)	186.2 (120.3-288.1) (n=56)	0.59 (0.52-0.67) (n=53)	0.53 (0.48-0.59) (n=53)
	Female	1389 (771,2503) (n=57)	255682 (218437,299277) (n=56)	212469 (179594,251361) (n=57)	123888 (101794,150778) (n=54)	63823 (516783-78821) (n=57)	152.9 (86.0-271.8) (n=57)	0.57 (0.51-0.64) (n=54)	0.52 (0.47-0.58) (n=54)
Serostatus at the baseline	**Seronegative**	662 (526-834) (n=99)	214226 (188591-243346) (n=94)	195410 (170563-223876) (n=97)	116385 (97912-138344) (n=96)	61495 (50745-74522) (n=97)	289.8 (224.4-374.2) (n=97)	0.61 (0.55-0.66) (n=95)	0.53 (0.49-0.58) (n=96)
	Seropositive	28694 (9305-88488) (n=16)	228570 (150893-346234) (n=16)	181324 (118204-278148) (n=16)	83268 (48955-141631) (n=12)	42447 (24974-72145) (n=14)	6.3 (2.2-18.1) (n=16)	0.42 (0.34-0.52) (n=12)	0.45 (0.39-0.52) (n=11)

Supplementary Table6: Exploratory analysis of Immune response (SARS-CoV-2 anti-spike IgG, ELU/ml) by reactogenicity severity at Day 0 and Days 14 and 28 after NVX-CoV2373 booster vaccine

SARS-CoV-2 anti-spike IgG, ELU/ml		Visit			Fold Change	
		Day 0	Day 14	Day 28	Day 14 to Day 0	Day 28 to Day 0
Reactogenicity Severity	Severe	1134 (632-2037) (n=42)	261428(222473-307205) (n=42)	250558 (212602-295290) (n=42)	230.5(131.0-405.6) (n=42)	220.9(120.9-403.7) (n=42)
	Mild/Moderate	1110(720-1710) (n=73)	192345.2(162515-227651) (n=68)	165867.1(139196-197648) (n=71)	167.5(105.9-265.0) (n=68)	143.7(91.-225.1) (n=71)

Supplementary Table7: Immune response (SARS-CoV-2 anti-spike IgG, ELU/ml for the original test and the re-run test conducted on five participants from both the Novavax substudy and the main COV-BOOST study

Visits	Original Test Results			Rerun Results		
	D28	D84	D242	D28	D84	D242
Novavax	230967.4 (127025,419963.8) (n=5)	102081.9 (44304.5,235206.5) (n=5)	50382.0 (14199.3,178765.7) (n=5)	136659.0 (58920,316967) (n=5)	64828.7 (22944,183174.2) (n=5)	27987.1 (7345.1,106640.1) (n=5)
Main Study	28814.5 (15565.6,53340.3) (n=5	14029.8 (7949.6,24760.3) (n=5	7775.2 (2084.0,29009.2) (n=5)	15669.7 (7168.6,34252.1) (n=5)	7012.3 (4340.8,11328) (n=5)	4043.3 (992.1,16478.8) (n=5)