Clinical trial results:
Immunogenicity and Safety of SARS-CoV-2 Recombinant Protein Vaccines with AS03 Adjuvant in Adults 18 Years of Age and Older as a Primary Series and Immunogenicity and Safety of a Booster Dose of SARS-CoV-2 Adjuvanted Recombinant Protein Vaccines (two Monovalent and one Bivalent)

Summary

EudraCT number	2020-003370-41
Trial protocol	ES
Global end of trial date	29 June 2023

Results information

Result version number	v1 (current)
This version publication date	27 February 2025
First version publication date	27 February 2025

Trial information

Trial identification

Sponsor protocol code	VAT00002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04762680
WHO universal trial number (UTN)	U1111-1251-4616

Notes:

Sponsors

Sponsor organisation name	Sanofi Pasteur Inc
Sponsor organisation address	Discovery Drive, Swiftwater, Pennsylvania, United States, 18370-0187
Public contact	Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 September 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 June 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To assess the safety profile of all participants in each age group and in each study Intervention group.
- To assess the neutralizing antibody profile after primary series vaccination in severe acute respiratory syndrome coronavirus (SARS-CoV-2) naïve participants.
- To demonstrate that a booster dose of monovalent or bivalent SARS-CoV-2 vaccine given to participants previously vaccinated with an authorized/approved coronavirus disease (COVID-19) vaccine induces an immune response that is non-inferior to the response induced by a 2-dose priming series with the monovalent vaccine, and superior to that observed immediately before booster.

CoV2 preS dTM= SARS-CoV2 prefusion Spike delta TM, PBP= Pfizer/BioNTech Primed, MP= Moderna Primed, OUAP= Oxford University/AstraZeneca Primed, JJJP= J&J/Janssen Primed and PP= Protein Primed.

Protection of trial subjects:

Vaccinations were performed by qualified and trained study personnel. Participants with allergy to any of the vaccine components were not vaccinated. After vaccination, participants were also kept under clinical observation for 30 minutes to ensure their safety. Appropriate medical equipment were also available on site in case of any immediate allergic reactions.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 February 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 363
Country: Number of subjects enrolled	France: 375
Country: Number of subjects enrolled	Honduras: 220
Country: Number of subjects enrolled	New Zealand: 30
Country: Number of subjects enrolled	Spain: 83
Country: Number of subjects enrolled	United Kingdom: 307
Country: Number of subjects enrolled	United States: 1991
Worldwide total number of subjects	3369
EEA total number of subjects	458

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	2924
From 65 to 84 years	430
85 years and over	15

Subject disposition

Recruitment

Recruitment details:

The Phase 2 of study was conducted at 20 centers in Honduras and the United States between 24 February 2021 and 01 May 2021. The Phase 3 of study was conducted at 110 centers in Australia, France, Honduras, New Zealand, Spain, United Kingdom, and the United States between 29 July 2021 and 06 January 2023.

Pre-assignment

Screening details:

722 participants were enrolled in Phase 2 and 2647 participants (supplemental Phase 3=2617 and exploratory Phase 3=30) were enrolled in Phase 3 of the study. A total of 3159 unique participants were enrolled in the study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Carer, Data analyst, Assessor, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1

Arm description:

Participants received CoV2 preS dTM monovalent D614 antigen dose 1 with fixed dose of AS03 adjuvant intermuscular (IM) injection once daily on Days 1 and 22.

Arm type	Experimental
Investigational medicinal product name	Monovalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM monovalent D614 antigen dose 1 with fixed dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2

Arm description:

Participants received CoV2 preS dTM monovalent D614 antigen dose 2 with fixed dose of AS03 adjuvant IM injection once daily on Days 1 and 22.

Arm type	Experimental
Investigational medicinal product name	Monovalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM monovalent D614 antigen dose 2 with fixed dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3

Arm description:

Participants received CoV2 preS dTM monovalent D614 antigen dose 3 with fixed dose of AS03 adjuvant IM injection once daily on Days 1 and 22.

Arm type	Experimental
Investigational medicinal product name	Monovalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM monovalent D614 antigen dose 3 with fixed dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)

Arm description:

Participants previously vaccinated with Pfizer/BioNTech vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Arm type	Experimental
Investigational medicinal product name	Monovalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)

Arm description:

Participants previously vaccinated with Pfizer/BioNTech vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Arm type	Experimental
Investigational medicinal product name	Monovalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)

Arm description:

Participants previously vaccinated with Pfizer/BioNTech vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Arm type	Experimental
Investigational medicinal product name	Bivalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM bivalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)

Arm description:

Participants previously vaccinated with Moderna vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Arm type	Experimental
Investigational medicinal product name	Monovalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)

Arm description:

Participants previously vaccinated with Moderna vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Arm type	Experimental
Investigational medicinal product name	Monovalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)

Arm description:

Participants previously vaccinated with Moderna vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Arm type	Experimental
Investigational medicinal product name	Bivalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM bivalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)

Arm description:

Participants previously vaccinated with Oxford University/AstraZeneca vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Arm type	Experimental
Investigational medicinal product name	Monovalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant was administered to

deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)

Arm description:

Participants previously vaccinated with Oxford University/AstraZeneca vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Arm type	Experimental
Investigational medicinal product name	Monovalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)

Arm description:

Participants previously vaccinated with Oxford University/AstraZeneca vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Arm type	Experimental
Investigational medicinal product name	Bivalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM bivalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)

Arm description:

Participants previously vaccinated with J&J/Janssen vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Arm type	Experimental
Investigational medicinal product name	Monovalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)

Arm description:

Participants previously vaccinated with J&J/Janssen vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Arm type	Experimental

Investigational medicinal product name	Monovalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)

Arm description:

Participants previously vaccinated with J&J/Janssen vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Arm type	Experimental
Investigational medicinal product name	Bivalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM bivalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)

Arm description:

Participants previously vaccinated with protein based vaccine in Phase 2 of the study received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Arm type	Experimental
Investigational medicinal product name	Monovalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)

Arm description:

Participants previously vaccinated with protein based vaccine in Phase 2 of the study received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Arm type	Experimental
Investigational medicinal product name	Monovalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)

Arm description:

SARS CoV 2 naïve and unvaccinated participants received CoV2 preS dTM monovalent D614 antigen

dose 2 with full-dose of AS03 adjuvant IM injection once daily on Days 1 and 22.

Arm type	Active comparator
Investigational medicinal product name	Monovalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM monovalent D614 antigen dose 2 with full-dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Exploratory 1: PBP - CoV2 preS dTM (B.1.351)

Arm description:

Participants previously vaccinated with Pfizer mRNA vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Arm type	Experimental
Investigational medicinal product name	Monovalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM monovalent B.1.351 antigen dose 4 with full-dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Exploratory 2: PBP - CoV2 preS dTM (B.1.351)

Arm description:

Participants previously vaccinated with Pfizer mRNA vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 4 with half-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Arm type	Experimental
Investigational medicinal product name	Monovalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM monovalent B.1.351 antigen dose 4 with half-dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Exploratory 3: PBP - CoV2 preS dTM (B.1.351)

Arm description:

Participants previously vaccinated with Pfizer mRNA vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with half-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Arm type	Experimental
Investigational medicinal product name	Monovalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM monovalent B.1.351 antigen dose 1 with half-dose of AS03 adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Arm title	Phase 3: Exploratory 4: PBP - CoV2 preS dTM (B.1.351)

Arm description:

Participants previously vaccinated with Pfizer mRNA vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with no adjuvant IM injection between 4 to 10 months after priming vaccine.

Arm type	Experimental
Investigational medicinal product name	Monovalent CoV2 preS dTM-AS03 COVID-19 vaccine
Investigational medicinal product code	
Other name	SARS-CoV-2 prefusion Spike delta TM protein, recombinant
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CoV2 preS dTM monovalent B.1.351 antigen dose 1 with no adjuvant was administered to deltoid muscle in the upper arm by IM injection.

Number of subjects in period 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3
Started	241	239	242
Completed	199	204	204
Not completed	42	35	38
Consent withdrawn by subject	23	21	28
Adverse event, non-fatal	-	1	-
Lost to follow-up	14	8	9
Protocol deviation	5	5	1

Number of subjects in period 1	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Started	329	378	378
Completed	302	338	337
Not completed	27	40	41
Consent withdrawn by subject	13	17	12
Adverse event, non-fatal	1	-	-
Lost to follow-up	9	22	24
Protocol deviation	4	1	5

Number of subjects in period 1	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Started	113	112	108
Completed	102	105	100
Not completed	11	7	8
Consent withdrawn by subject	8	3	2
Adverse event, non-fatal	-	-	-
Lost to follow-up	2	4	6
Protocol deviation	1	-	-

Number of subjects in period 1	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Started	127	101	101
Completed	119	95	98
Not completed	8	6	3
Consent withdrawn by subject	4	3	1
Adverse event, non-fatal	-	-	-
Lost to follow-up	4	3	-
Protocol deviation	-	-	2

Number of subjects in period 1	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Started	105	38	38
Completed	94	32	31
Not completed	11	6	7
Consent withdrawn by subject	3	2	1
Adverse event, non-fatal	-	-	-
Lost to follow-up	5	4	6
Protocol deviation	3	-	-

Number of subjects in period 1	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)
Started	132	78	479
Completed	126	71	368
Not completed	6	7	111
Consent withdrawn by subject	4	6	32
Adverse event, non-fatal	-	-	3
Lost to follow-up	1	1	66
Protocol deviation	1	-	10

Number of subjects in period 1	Phase 3: Exploratory 1: PBP - CoV2 preS dTM (B.1.351)	Phase 3: Exploratory 2: PBP - CoV2 preS dTM (B.1.351)	Phase 3: Exploratory 3: PBP - CoV2 preS dTM (B.1.351)
Started	4	8	9
Completed	4	7	9
Not completed	0	1	0
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	1	-
Protocol deviation	-	-	-

Number of subjects in period 1	Phase 3: Exploratory 4: PBP - CoV2 preS dTM (B.1.351)

Started	9
Completed	8
Not completed	1
Consent withdrawn by subject	1
Adverse event, non-fatal	-
Lost to follow-up	-
Protocol deviation	-

Baseline characteristics

Reporting groups

Reporting group title	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1

Reporting group description:

Participants received CoV2 preS dTM monovalent D614 antigen dose 1 with fixed dose of AS03 adjuvant intermuscular (IM) injection once daily on Days 1 and 22.

Reporting group title	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2

Reporting group description:

Participants received CoV2 preS dTM monovalent D614 antigen dose 2 with fixed dose of AS03 adjuvant IM injection once daily on Days 1 and 22.

Reporting group title	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3

Reporting group description:

Participants received CoV2 preS dTM monovalent D614 antigen dose 3 with fixed dose of AS03 adjuvant IM injection once daily on Days 1 and 22.

Reporting group title	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)

Reporting group description:

Participants previously vaccinated with Pfizer/BioNTech vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)

Reporting group description:

Participants previously vaccinated with Pfizer/BioNTech vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)

Reporting group description:

Participants previously vaccinated with Pfizer/BioNTech vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)

Reporting group description:

Participants previously vaccinated with Moderna vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)

Reporting group description:

Participants previously vaccinated with Moderna vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)

Reporting group description:

Participants previously vaccinated with Moderna vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)

Reporting group description:

Participants previously vaccinated with Oxford University/AstraZeneca vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)

Reporting group description:

Participants previously vaccinated with Oxford University/AstraZeneca vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)

Reporting group description:

Participants previously vaccinated with Oxford University/AstraZeneca vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)

Reporting group description:

Participants previously vaccinated with J&J/Janssen vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)

Reporting group description:

Participants previously vaccinated with J&J/Janssen vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)

Reporting group description:

Participants previously vaccinated with J&J/Janssen vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)

Reporting group description:

Participants previously vaccinated with protein based vaccine in Phase 2 of the study received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)

Reporting group description:

Participants previously vaccinated with protein based vaccine in Phase 2 of the study received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)

Reporting group description:

SARS CoV 2 naïve and unvaccinated participants received CoV2 preS dTM monovalent D614 antigen dose 2 with full-dose of AS03 adjuvant IM injection once daily on Days 1 and 22.

Reporting group title	Phase 3: Exploratory 1: PBP - CoV2 preS dTM (B.1.351)

Reporting group description:

Participants previously vaccinated with Pfizer mRNA vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Exploratory 2: PBP - CoV2 preS dTM (B.1.351)

Reporting group description:

Participants previously vaccinated with Pfizer mRNA vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 4 with half-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Exploratory 3: PBP - CoV2 preS dTM (B.1.351)

Reporting group description:

Participants previously vaccinated with Pfizer mRNA vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with half-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Exploratory 4: PBP - CoV2 preS dTM (B.1.351)

Reporting group description:

Participants previously vaccinated with Pfizer mRNA vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with no adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3
Number of subjects	241	239	242
Age Categorical Units: participants			
Age Continuous Units: years			
arithmetic mean	53.8	53.5	53.1
standard deviation	± 15.3	± 14.9	± 15.9
Gender Categorical Units: participants			
Female	123	114	122
Male	118	125	120
Race Units: Subjects			
American Indian or Alaska Native	22	24	20
Asian	13	10	10
Black or African American	14	23	20
Multiple	5	2	4
Native Hawaiian or Other Pacific Islander	2	1	2
White	156	149	156
Not Reported	4	4	2
Unknown	25	26	28

Reporting group values	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Number of subjects	329	378	378
Age Categorical Units: participants			
Age Continuous Units: years			
arithmetic mean	49.0	40.6	40.5
standard deviation	± 15.5	± 14.0	± 13.9
Gender Categorical Units: participants			
Female	181	208	199
Male	148	170	179
Race Units: Subjects			
American Indian or Alaska Native	5	5	6
Asian	19	12	13
Black or African American	15	54	61
Multiple	1	6	6
Native Hawaiian or Other Pacific Islander	0	2	1
White	252	247	240
Not Reported	33	44	49

Unknown	4	8	2

Reporting group values	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Number of subjects	113	112	108
Age Categorical Units: participants			
Age Continuous Units: years			
arithmetic mean	47.7	44.4	46.6
standard deviation	± 16.4	± 15.8	± 13.9
Gender Categorical Units: participants			
Female	68	60	64
Male	45	52	44
Race Units: Subjects			
American Indian or Alaska Native	2	6	2
Asian	7	1	3
Black or African American	3	16	32
Multiple	1	3	1
Native Hawaiian or Other Pacific Islander	0	0	0
White	100	79	61
Not Reported	0	1	6
Unknown	0	6	3

Reporting group values	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Number of subjects	127	101	101
Age Categorical Units: participants			
Age Continuous Units: years			
arithmetic mean	54.5	51.6	51.1
standard deviation	± 12.2	± 11.7	± 13.2
Gender Categorical Units: participants			
Female	59	42	48
Male	68	59	53
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	11	4	7
Black or African American	2	3	2

Multiple	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
White	104	92	87
Not Reported	10	1	2
Unknown	0	1	2

Reporting group values	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Number of subjects	105	38	38
Age Categorical			
Units: participants			
Age Continuous			
Units: years			
arithmetic mean	46.8	47.1	47.4
standard deviation	± 13.2	± 12.0	± 12.6
Gender Categorical			
Units: participants			
Female	63	19	20
Male	42	19	18
Race			
Units: Subjects			
American Indian or Alaska Native	1	4	2
Asian	0	2	2
Black or African American	5	16	10
Multiple	0	0	0
Native Hawaiian or Other Pacific Islander	0	1	0
White	99	15	21
Not Reported	0	0	2
Unknown	0	0	1

Reporting group values	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)
Number of subjects	132	78	479
Age Categorical			
Units: participants			
Age Continuous			
Units: years			
arithmetic mean	54.9	65.9	37.6
standard deviation	± 14.8	± 11.5	± 11.3
Gender Categorical			
Units: participants			
Female	64	38	215
Male	68	40	264
Race			
Units: Subjects			
American Indian or Alaska Native	20	14	15

Asian	2	2	18
Black or African American	7	2	52
Multiple	0	1	8
Native Hawaiian or Other Pacific Islander	0	0	1
White	80	37	372
Not Reported	0	0	3
Unknown	23	22	10

Reporting group values	Phase 3: Exploratory 1: PBP - CoV2 preS dTM (B.1.351)	Phase 3: Exploratory 2: PBP - CoV2 preS dTM (B.1.351)	Phase 3: Exploratory 3: PBP - CoV2 preS dTM (B.1.351)
Number of subjects	4	8	9
Age Categorical			
Units: participants			
Age Continuous			
Units: years			
arithmetic mean	33.8	35.5	42.7
standard deviation	± 9.50	± 14.9	± 12.5
Gender Categorical			
Units: participants			
Female	3	3	8
Male	1	5	1
Race			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black or African American	0	0	0
Multiple	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
White	0	0	0
Not Reported	4	7	8
Unknown	0	1	1

Reporting group values	Phase 3: Exploratory 4: PBP - CoV2 preS dTM (B.1.351)	Total	
Number of subjects	9	3369	
Age Categorical			
Units: participants			
Age Continuous			
Units: years			
arithmetic mean	44.6		
standard deviation	± 16.9	-	
Gender Categorical			
Units: participants			
Female	6	1727	
Male	3	1642	

Race Units: Subjects			
American Indian or Alaska Native	0	148	
Asian	0	136	
Black or African American	0	337	
Multiple	0	39	
Native Hawaiian or Other Pacific Islander	0	10	
White	0	2347	
Not Reported	9	189	
Unknown	0	163	

End points reporting groups

Reporting group title	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1
Reporting group description:	
Participants received CoV2 preS dTM monovalent D614 antigen dose 1 with fixed dose of AS03 adjuvant intermuscular (IM) injection once daily on Days 1 and 22.	
Reporting group title	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2
Reporting group description:	
Participants received CoV2 preS dTM monovalent D614 antigen dose 2 with fixed dose of AS03 adjuvant IM injection once daily on Days 1 and 22.	
Reporting group title	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3
Reporting group description:	
Participants received CoV2 preS dTM monovalent D614 antigen dose 3 with fixed dose of AS03 adjuvant IM injection once daily on Days 1 and 22.	
Reporting group title	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)
Reporting group description:	
Participants previously vaccinated with Pfizer/BioNTech vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.	
Reporting group title	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)
Reporting group description:	
Participants previously vaccinated with Pfizer/BioNTech vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.	
Reporting group title	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Reporting group description:	
Participants previously vaccinated with Pfizer/BioNTech vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.	
Reporting group title	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)
Reporting group description:	
Participants previously vaccinated with Moderna vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.	
Reporting group title	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)
Reporting group description:	
Participants previously vaccinated with Moderna vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.	
Reporting group title	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Reporting group description:	
Participants previously vaccinated with Moderna vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.	
Reporting group title	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)
Reporting group description:	
Participants previously vaccinated with Oxford University/AstraZeneca vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.	
Reporting group title	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)
Reporting group description:	
Participants previously vaccinated with Oxford University/AstraZeneca vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.	

Reporting group title	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)

Reporting group description:

Participants previously vaccinated with Oxford University/AstraZeneca vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)

Reporting group description:

Participants previously vaccinated with J&J/Janssen vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)

Reporting group description:

Participants previously vaccinated with J&J/Janssen vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)

Reporting group description:

Participants previously vaccinated with J&J/Janssen vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)

Reporting group description:

Participants previously vaccinated with protein based vaccine in Phase 2 of the study received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)

Reporting group description:

Participants previously vaccinated with protein based vaccine in Phase 2 of the study received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)

Reporting group description:

SARS CoV 2 naïve and unvaccinated participants received CoV2 preS dTM monovalent D614 antigen dose 2 with full-dose of AS03 adjuvant IM injection once daily on Days 1 and 22.

Reporting group title	Phase 3: Exploratory 1: PBP - CoV2 preS dTM (B.1.351)

Reporting group description:

Participants previously vaccinated with Pfizer mRNA vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Exploratory 2: PBP - CoV2 preS dTM (B.1.351)

Reporting group description:

Participants previously vaccinated with Pfizer mRNA vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 4 with half-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Exploratory 3: PBP - CoV2 preS dTM (B.1.351)

Reporting group description:

Participants previously vaccinated with Pfizer mRNA vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with half-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Exploratory 4: PBP - CoV2 preS dTM (B.1.351)

Reporting group description:

Participants previously vaccinated with Pfizer mRNA vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with no adjuvant IM injection between 4 to 10 months after priming vaccine.

Subject analysis set title	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received CoV2 preS dTM monovalent D614 antigen dose 2 with fixed dose of AS03 adjuvant IM injection once daily on Days 1 and 22.

Primary: Number of Participants With Immediate Unsolicited Adverse Events (AEs)

End point title	Number of Participants With Immediate Unsolicited Adverse Events (AEs)[1][2]

End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Immediate events were recorded to capture medically relevant unsolicited systemic AEs which occurred within the first 30 minutes after vaccination. An unsolicited AE was an observed AE that did not fulfill the conditions of solicited reactions, that is, pre-listed in the case report form (CRF) in terms of diagnosis and onset window post-vaccination. The Safety analysis set included participants randomized and who had received at least 1 dose of the study vaccines. Safety analysis was performed according to the actual study vaccine received by the participants.

End point type	Primary

End point timeframe:

Up to 30 minutes after each vaccination

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Participants treated in Phase 3 exploratory reporting groups were not analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	240	241	328	378
Units: participants	2	1	0	0

End point values	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	375	113	111	108
Units: participants	0	0	0	0

End point values	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	127	100	100	103
Units: participants	0	0	0	0

End point values	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	132	78
Units: participants	0	0	0	0

End point values	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	473	240		
Units: participants	9	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Solicited Injection Site Reactions and Systemic Reactions

End point title	Number of Participants With Solicited Injection Site Reactions and Systemic Reactions[3][4]

End point description:

A solicited reaction was an "expected" adverse reaction (AR) (sign or symptom) observed and reported under the conditions (nature and onset) pre-listed in the protocol and CRF, and were considered to be related to the study vaccine administered. An injection site reaction was an AR at and around the injection site of the study vaccine. Systemic AR were all ARs that were not injection site reactions. The Safety analysis set included participants randomized and who had received at least 1 dose of the study vaccines. Safety analysis was performed according to the actual study vaccine received by the participants.

End point type	Primary

End point timeframe:

Up to 7 days after each vaccination

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Participants treated in Phase 3 exploratory reporting groups were not analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	238	239	326	367
Units: participants				
Injection site reaction	201	200	262	300
Systemic reaction	191	185	198	238

End point values	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	370	113	110	108
Units: participants				
Injection site reaction	303	90	82	74
Systemic reaction	242	67	67	65

End point values	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	127	100	100	102
Units: participants				
Injection site reaction	104	87	87	81
Systemic reaction	75	61	75	62

End point values	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	132	78
Units: participants				
Injection site reaction	19	19	98	46
Systemic reaction	14	17	88	36

End point values	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	460	237		
Units: participants				
Injection site reaction	375	196		
Systemic reaction	359	191		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Unsolicited Adverse Events

End point title	Number of Participants With Unsolicited Adverse Events[5][6]

End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An unsolicited AE was an observed AE that did not fulfill the conditions of solicited reactions, that is, pre-listed in the CRF in terms of diagnosis and onset window post-vaccination. The Safety analysis set included participants randomized and who had received at least 1 dose of the study vaccines. Safety analysis was performed according to the actual study vaccine received by the participants.

End point type	Primary

End point timeframe:

Up to 21 days after each vaccination

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Participants treated in Phase 3 exploratory reporting groups were not analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	240	241	328	378
Units: participants	88	91	76	106

End point values	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	375	113	111	108

Units: participants	96	29	18	22

End point values	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	127	100	100	103
Units: participants	34	27	35	16

End point values	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	132	78
Units: participants	7	7	25	11

End point values	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	473	240		
Units: participants	199	81		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Serious Adverse Events (SAEs), Adverse Events of Special Interest (AESIs) and Medically Attended Adverse Events (MAAEs)

End point title	Number of Participants With Serious Adverse Events (SAEs), Adverse Events of Special Interest (AESIs) and Medically Attended Adverse Events (MAAEs)[7][8]

End point description:

An SAE was defined as any AE that at any dose resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, was a congenital anomaly/birth defect, or was an important medical event. An AESI (serious or non-serious) was 1 of scientific and medical concern specific to the Sponsor's study intervention or program, for which ongoing monitoring and rapid communication by the Investigator to the Sponsor could be appropriate. An MAAE was a new onset or a worsening of a condition that prompted the participant or participant's parent/guardian to seek unplanned medical advice at a

physician’s office or Emergency Department. The Safety analysis set included participants randomized and who had received at least 1 dose of the study vaccines. Safety analysis was performed according to the actual study vaccine received by the participants.

End point type	Primary

End point timeframe:

Phase 2 and Phase 3 Comparator: From first dose of study vaccine administration (Day 1) up to 387 days.
Phase 3 Cohorts 1 and 2: From first dose of study vaccine administration (Day 1) up to 366 days.

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Participants treated in Phase 3 exploratory reporting groups were not analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	240	241	328	378
Units: participants				
SAE	2	4	8	9
AESI	0	0	2	0
MAAE	42	59	80	106

End point values	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	375	113	111	108
Units: participants				
SAE	11	3	1	4
AESI	1	1	0	0
MAAE	117	28	25	19

End point values	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	127	100	100	103
Units: participants				
SAE	3	4	0	1
AESI	0	0	1	0

MAAE	31	24	29	19

End point values	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	132	78
Units: participants				
SAE	2	3	3	3
AESI	0	0	0	1
MAAE	7	7	42	32

End point values	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	473	240		
Units: participants				
SAE	14	6		
AESI	1	0		
MAAE	110	48		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2: Geometric Mean Titers (GMTs) of Neutralizing Antibodies Against Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) D614G Strain at Day 1

End point title	Phase 2: Geometric Mean Titers (GMTs) of Neutralizing Antibodies Against Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2) D614G Strain at Day 1[9][10]

End point description:

Neutralizing antibodies activity against SARS-CoV-2 D614G strain was measured with the neutralization assay (monogram assay) and the results were expressed as geometric mean titers. The per-protocol analysis set (PPAS) Naïve-D01+D22 is a subset of the FAS. Here, -99999 and 99999= The upper and lower limits of 95% confidence interval was not calculable.

End point type	Primary

End point timeframe:

Pre-vaccination on Day 1

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 2 of the study were analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	167	170	171	
Units: titers				
geometric mean (confidence interval 95%)	20.0 (-99999 to 99999)	20.0 (-99999 to 99999)	20.0 (-99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2: Geometric Mean Titers of Neutralizing Antibodies Against SARS-CoV-2 D614G Strain at Day 36

End point title	Phase 2: Geometric Mean Titers of Neutralizing Antibodies Against SARS-CoV-2 D614G Strain at Day 36[11][12]

End point description:

Neutralizing antibodies activity against SARS-CoV-2 D614G strain was measured with the neutralization assay (monogram assay) and the results were expressed as geometric mean titers. The PPAS Naïve-D01+D22 is a subset of the FAS.

End point type	Primary

End point timeframe:

Day 36

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 2 of the study were analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	162	163	167	
Units: titers				
geometric mean (confidence interval 95%)	2132 (1690 to 2688)	2376 (1873 to 3015)	2903 (2289 to 3683)	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2: Number of Participants With >=2-Fold and >=4-Fold Rise in Serum Neutralization Antibody Titers Against SARS-CoV-2 D614G Strain at Day 36

End point title	Phase 2: Number of Participants With >=2-Fold and >=4-Fold Rise in Serum Neutralization Antibody Titers Against SARS-CoV-2 D614G Strain at Day 36[13][14]

End point description:

Neutralizing antibodies activity against SARS-CoV-2 D614G strain was measured with serum neutralization assay (monogram assay). Participants with neutralization antibody titers >=2-fold and >=4-fold increase from baseline (pre-vaccination) were analyzed. The PPAS Naïve-D01+D22 is a subset of the FAS.

End point type	Primary

End point timeframe:

Day 1 (pre-vaccination) and Day 36

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 2 of the study were analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	159	158	161	
Units: participants				
>=2-fold rise	155	156	158	
>=4-fold rise	154	154	157	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2: Number of Responders as Determined by Neutralizing Antibody Titers Against SARS-CoV-2 D614G Strain at Day 36

End point title	Phase 2: Number of Responders as Determined by Neutralizing Antibody Titers Against SARS-CoV-2 D614G Strain at Day 36[15][16]

End point description:

Responders were participants who had baseline values below lower limit of quantification (LLOQ) with

detectable neutralization titer above assay LLOQ at each pre-defined post-vaccination time point and participants with baseline values above LLOQ with a 4-fold increase in neutralizing antibody titers at each pre-defined post-vaccination time point. The PPAS Naïve-D01+D22 is a subset of the FAS.

End point type	Primary

End point timeframe:

Day 36

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 2 of the study were analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	159	158	161	
Units: participants	155	156	158	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 3: Cohorts 1 and 2: Geometric Mean Titers of Neutralizing Antibodies Against SARS-CoV-2 D614G Strain and B.1.351 Variant at Day 1

End point title	Phase 3: Cohorts 1 and 2: Geometric Mean Titers of Neutralizing Antibodies Against SARS-CoV-2 D614G Strain and B.1.351 Variant at Day 1[17][18]

End point description:

Neutralizing antibodies activity against SARS-CoV-2 D614G strain and B.1.351 variant was measured with the neutralization assay (monogram assay) and the results were expressed as geometric mean titers. The PPAS is a subset of the FAS. Here, n= number of participants analyzed for each parameter.

End point type	Primary

End point timeframe:

Pre-vaccination on Day 1

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 3 Cohorts 1 and 2 reporting groups were analyzed in this endpoint.

End point values	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	301[19]	348[20]	345[21]	107[22]
Units: titers				
geometric mean (confidence interval 95%)				
D614G	320 (275 to 373)	678 (558 to 824)	579 (478 to 701)	668 (537 to 830)
B.1.351	70.1 (60.3 to 81.4)	176 (142 to 217)	149 (120 to 184)	122 (95.4 to 157)

Notes:

[19] - D614G (n=301)
B.1.351 (n=290)
[20] - D614G (n=348)
B.1.351 (n=336)
[21] - D614G (n=345)
B.1.351 (n=324)
[22] - D614G (n=107)
B.1.351 (n=88)

End point values	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	107[23]	101[24]	120[25]	90[26]
Units: titers				
geometric mean (confidence interval 95%)				
D614G	1107 (816 to 1503)	1347 (977 to 1858)	265 (190 to 369)	137 (98.0 to 193)
B.1.351	258 (182 to 364)	296 (207 to 424)	54.1 (41.4 to 70.7)	43.3 (32.0 to 58.5)

Notes:

[23] - D614G (n=107)
B.1.351 (n=97)
[24] - D614G (n=101)
B.1.351 (n=94)
[25] - D614G (n=107)
B.1.351 (n=120)
[26] - D614G (n=89)
B.1.351 (n=90)

End point values	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	97[27]	89[28]	36[29]	36[30]
Units: titers				
geometric mean (confidence interval 95%)				

D614G	134 (95.7 to 186)	222 (155 to 318)	1188 (567 to 2490)	447 (217 to 921)
B.1.351	36.8 (28.8 to 47.1)	42.6 (32.5 to 55.7)	345 (167 to 714)	122 (55.3 to 268)

Notes:

[27] - D614G (n=93)
B.1.351 (n=97)
[28] - D614G (n=82)
B.1.351 (n=89)
[29] - D614G (n=36)
B.1.351 (n=36)
[30] - D614G (n=36)
B.1.351 (n=34)

End point values	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	108[31]	68[32]		
Units: titers				
geometric mean (confidence interval 95%)				
D614G	274 (182 to 413)	159 (97.4 to 260)		
B.1.351	97.7 (68.0 to 140)	70.3 (47.9 to 103)		

Notes:

[31] - D614G (n=107)
B.1.351 (n=108)
[32] - D614G (n=67)
B.1.351 (n=68)

Statistical analyses

No statistical analyses for this end point

Primary: Phase 3: Cohorts 1, 2 and Comparator: Geometric Mean Titers of Neutralizing Antibodies Against SARS-CoV-2 D614G Strain and B.1.351 Variant at 14 Days Post-Vaccination

End point title	Phase 3: Cohorts 1, 2 and Comparator: Geometric Mean Titers of Neutralizing Antibodies Against SARS-CoV-2 D614G Strain and B.1.351 Variant at 14 Days Post-Vaccination[33][34]

End point description:

Neutralizing antibodies activity against SARS-CoV-2 D614G strain and B.1.351 variant was measured with the neutralization assay (monogram assay) and the results were expressed as geometric mean titers. The PPAS is a subset of the FAS. Here, n= number of participants analyzed for each parameter.

End point type	Primary

End point timeframe:

Cohorts 1 and 2: 14 days post-vaccination on Day 1, Day 15;
Comparator: 14 days post-vaccination on Day 22, Day 36

Notes:

[33] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[34] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 3 Cohorts 1, 2 and comparator reporting groups were analyzed in this endpoint.

End point values	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	301[35]	325[36]	334[37]	101[38]
Units: titers				
geometric mean (confidence interval 95%)				
D614G	6964 (6268 to 7737)	9995 (8976 to 11129)	8430 (7572 to 9386)	6347 (5207 to 7736)
B.1.351	2610 (2316 to 2942)	7021 (6262 to 7873)	4900 (4370 to 5494)	2222 (1754 to 2814)

Notes:

[35] - D614G (n=301)
B.1.351 (n=299)
[36] - D614G (n=325)
B.1.351 (n=325)
[37] - D614G (n=334)
B.1.351 (n=334)
[38] - D614G (n=101)
B.1.351 (n=98)

End point values	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93[39]	96[40]	118[41]	94[42]
Units: titers				
geometric mean (confidence interval 95%)				
D614G	14240 (11257 to 18013)	12522 (10368 to 15123)	6257 (5313 to 7369)	5536 (4436 to 6910)
B.1.351	9449 (7376 to 12104)	6581 (5340 to 8111)	2062 (1708 to 2489)	4610 (3689 to 5760)

Notes:

[39] - D614G (n=93)
B.1.351 (n=93)
[40] - D614G (n=96)
B.1.351 (n=95)
[41] - D614G (n=118)
B.1.351 (n=118)
[42] - D614G (n=94)
B.1.351 (n=94)

End point values	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93[43]	91[44]	31[45]	34[46]
Units: titers				
geometric mean (confidence interval 95%)				

D614G	5855 (4669 to 7344)	6875 (5587 to 8460)	11005 (7533 to 16078)	11624 (8086 to 16710)
B.1.351	3099 (2386 to 4026)	2054 (1642 to 2568)	6872 (4482 to 10537)	5057 (3416 to 7488)

Notes:

[43] - D614G (n=93)
B.1.351 (n=93)
[44] - D614G (n=91)
B.1.351 (n=89)
[45] - D614G (n=31)
B.1.351 (n=30)
[46] - D614G (n=34)
B.1.351 (n=34)

End point values	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	119[47]	72[48]	307[49]	
Units: titers				
geometric mean (confidence interval 95%)				
D614G	22457 (19123 to 26374)	25002 (18441 to 33897)	3611 (3086 to 4224)	
B.1.351	7452 (6212 to 8939)	13300 (9817 to 18018)	413 (346 to 493)	

Notes:

[47] - D614G (n=119)
B.1.351 (n=119)
[48] - D614G (n=72)
B.1.351 (n=72)
[49] - D614G (n=307)
B.1.351 (n=296)

Statistical analyses

No statistical analyses for this end point

Primary: Phase 3: Comparator: Percentage of Responders as Determined by Neutralizing Antibody Titers Against SARS-CoV-2 D614G Strain and B.1.351 Variant at Day 36

End point title	Phase 3: Comparator: Percentage of Responders as Determined by Neutralizing Antibody Titers Against SARS-CoV-2 D614G Strain and B.1.351 Variant at Day 36[50][51]

End point description:

Responders were participants who had baseline values below LLOQ with detectable neutralization titer above assay LLOQ at each pre-defined post-vaccination time point and participants with baseline values above LLOQ with a 4-fold increase in neutralizing antibody titers at each pre-defined post-vaccination time point. The PPAS is a subset of the FAS. Here, n= number of participants analyzed for each parameter. Percentages are rounded off to the tenth decimal place.

End point type	Primary

End point timeframe:

Day 36

Notes:

[50] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[51] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all

the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 3 comparator reporting group were analyzed in this endpoint.

End point values	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)			
Subject group type	Reporting group			
Number of subjects analysed	301			
Units: percentage of participants				
number (confidence interval 95%)				
D614G (n=301)	99.3 (97.6 to 99.9)			
B.1.351 (n=290)	91.0 (87.1 to 94.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Geometric Mean Titers of Neutralizing Antibodies Against SARS-CoV-2 D614G Strain at Days 22, 78, 134, 202, 292, and 387

End point title	Phase 2: Geometric Mean Titers of Neutralizing Antibodies Against SARS-CoV-2 D614G Strain at Days 22, 78, 134, 202, 292, and 387[52]

End point description:

Neutralizing antibodies activity against SARS-CoV-2 D614G strain was measured with the neutralization assay (monogram assay) and the results were expressed as geometric mean titers. The PPAS Naïve-D01+D22 is a subset of the FAS. Here, n= number of participants analyzed at specific timepoint.

End point type	Secondary

End point timeframe:

Post-vaccination on Days 22, 78, 134, 202, 292, and 387

Notes:

[52] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 2 of the study were analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	159[53]	160[54]	160[55]	
Units: titers				
geometric mean (confidence interval 95%)				
Day 22	36.0 (29.4 to 44.2)	39.6 (32.3 to 48.6)	47.3 (37.8 to 59.1)	
Day 78	467 (361 to 606)	558 (438 to 711)	569 (458 to 707)	
Day 134	225 (160 to 318)	249 (182 to 340)	260 (190 to 358)	

Day 202	254 (158 to 408)	344 (208 to 570)	259 (159 to 421)	
Day 292	12145 (3643 to 40491)	2518 (335 to 18928)	804 (108 to 6014)	
Day 387	17837 (9491 to 33522)	46305 (24179 to 88677)	8353 (1414 to 49336)	

Notes:

[53] - Day 22 (n=159)
Day 78 (n=118)
Day 134 (n=99)
Day 202 (n=73)
Day 292 (n=11)
Day 387 (n=11)

[54] - Day 22 (n=160)
Day 78 (n=124)
Day 134 (n=103)
Day 202 (n=76)
Day 292 (n=11)
Day 387 (n=9)

[55] - Day 22 (n=160)
Day 78 (n=121)
Day 134 (n=94)
Day 202 (n=77)
Day 292 (n=13)
Day 387 (n=12)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Number of Participants With >=2-Fold and >=4-Fold Rise in Serum Neutralization Antibody Titers Against SARS-CoV-2 D614G Strain at Days 22, 78, 134, 202, 292, and 387

End point title	Phase 2: Number of Participants With >=2-Fold and >=4-Fold Rise in Serum Neutralization Antibody Titers Against SARS-CoV-2 D614G Strain at Days 22, 78, 134, 202, 292, and 387[56]

End point description:

Neutralizing antibodies activity against SARS-CoV-2 D614G strain was measured with serum neutralization assay (monogram assay). Participants with neutralization antibody titers >=2-fold and >=4-fold increase from baseline (pre-vaccination) were analyzed. The PPAS Naïve-D01+D22 is a subset of the FAS. Here, n= number of participants analyzed at specific timepoint.

End point type	Secondary

End point timeframe:

Pre-vaccination on Day 1 and Post-vaccination on Days 22, 78, 134, 202, 292, and 387

Notes:

[56] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 2 of the study were analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	159[57]	160[58]	159[59]	
Units: participants				
Day 22: >=2-fold rise	35	44	53	
Day 22: >=4-fold rise	28	36	44	
Day 78: >=2-fold rise	108	116	113	
Day 78: >=4-fold rise	105	115	110	

Day 134: >=2-fold rise	85	87	82	
Day 134: >=4-fold rise	75	83	76	
Day 202: >=2-fold rise	57	62	62	
Day 202: >=4-fold rise	53	57	60	
Day 292: >=2-fold rise	10	10	11	
Day 292: >=4-fold rise	10	9	8	
Day 387: >=2-fold rise	10	9	11	
Day 387: >=4-fold rise	10	9	11	

Notes:

[57] - Day 22 (n=159)
Day 78 (n=116)
Day 134 (n=98)
Day 202 (n=72)
Day 292 (n=10)
Day 387 (n=10)
[58] - Day 22 (n=160)
Day 78 (n=123)
Day 134 (n=102)
Day 202 (n=75)
Day 292 (n=11)
Day 387 (n=9)
[59] - Day 22 (n=159)
Day 78 (n=117)
Day 134 (n=93)
Day 202 (n=77)
Day 292 (n=13)
Day 387 (n=12)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Number of Responders as Determined by Neutralizing Antibody Titers Against SARS-CoV-2 D614G Strain at Days 22, 78, 134, 202, 292, and 387

End point title	Phase 2: Number of Responders as Determined by Neutralizing Antibody Titers Against SARS-CoV-2 D614G Strain at Days 22, 78, 134, 202, 292, and 387[60]

End point description:

Responders were participants who had baseline values below LLOQ with detectable neutralization titer above assay LLOQ at each pre-defined post-vaccination time point and participants with baseline values above LLOQ with a 4-fold increase in neutralizing antibody titers at each pre-defined post-vaccination time point. Neutralizing antibodies activity against SARS-CoV-2 D614G strain was measured with serum neutralization assay (monogram assay). The PPAS Naïve-D01+D22 is a subset of the FAS. Here, n= number of participants analyzed at specific timepoint.

End point type	Secondary

End point timeframe:

Post-vaccination on Days 22, 78, 134, 202, 292, and 387

Notes:

[60] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 2 of the study were analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	159[61]	160[62]	159[63]	
Units: participants				

Day 22	35	44	53	
Day 78	108	116	113	
Day 134	85	87	82	
Day 202	57	62	62	
Day 292	10	10	11	
Day 387	10	9	11	

Notes:

[61] - Day 22 (n=159)
Day 78 (n=116)
Day 134 (n=98)
Day 202 (n=72)
Day 292 (n=10)
Day 387 (n=10)

[62] - Day 22 (n=160)
Day 78 (n=123)
Day 134 (n=102)
Day 202 (n=75)
Day 292 (n=11)
Day 387 (n=9)

[63] - Day 22 (n=159)
Day 78 (n=117)
Day 134 (n=93)
Day 202 (n=77)
Day 292 (n=13)
Day 387 (n=12)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Geometric Mean Concentration (GMC) of Binding Antibodies Against SARS-CoV-2 D614G Strain at Days 1, 22, 36, 78, 134, 202, 292, and 387

End point title	Phase 2: Geometric Mean Concentration (GMC) of Binding Antibodies Against SARS-CoV-2 D614G Strain at Days 1, 22, 36, 78, 134, 202, 292, and 387[64]

End point description:

Binding antibodies activity against SARS-CoV-2 D614G strain was measured with Nexelis GCN4 S-enzyme-linked immunosorbent assay (ELISA) and the results were expressed as geometric mean concentrations. The PPAS Naïve-D01+D22 is a subset of the FAS. Here, n= number of participants analyzed at specific timepoint.

End point type	Secondary

End point timeframe:

Pre-vaccination on Day 1 and post-vaccination on Days 22, 36, 78, 134, 202, 292, and 387

Notes:

[64] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 2 of the study were analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	169	172	176	
Units: titers				
geometric mean (confidence interval 95%)				
Day 1 (n=166,170,175)	10.3 (9.54 to 11.1)	9.99 (9.52 to 10.5)	10.2 (9.77 to 10.7)	

Day 22 (n=169,172,176)	103 (80.6 to 131)	149 (119 to 187)	228 (182 to 285)	
Day 36 (n=165,167,171)	15533 (13000 to 18560)	17176 (14468 to 20390)	18003 (15039 to 21550)	
Day 78 (n=126,127,127)	6572 (5469 to 7897)	7526 (6112 to 9267)	7133 (5848 to 8700)	
Day 134 (n=105,111,100)	2750 (2104 to 3594)	2977 (2305 to 3846)	2696 (2064 to 3521)	
Day 202 (n=87,93,87)	1414 (983 to 2033)	1961 (1369 to 2809)	1438 (978 to 2113)	
Day 292 (n=12,12,14)	40589 (10633 to 155000)	9247 (1625 to 52615)	5557 (1183 to 26116)	
Day 387 (n=11,10,13)	61087 (40242 to 92728)	58674 (12370 to 278000)	16234 (3146 to 83760)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Number of Participants With >=2-Fold and >=4-Fold Rise in Binding Antibody Concentration Against SARS-CoV-2 D614G Strain at Days 22, 36, 78, 134, 202, 292, and 387

End point title	Phase 2: Number of Participants With >=2-Fold and >=4-Fold Rise in Binding Antibody Concentration Against SARS-CoV-2 D614G Strain at Days 22, 36, 78, 134, 202, 292, and 387[65]

End point description:

Binding antibodies concentration against SARS-CoV-2 D614G strain was measured with Nexelis GCN4 S-ELISA assay. Participants with binding antibodies concentration >=2-fold and >=4-fold increase from baseline (pre-vaccination) were analyzed. The PPAS Naïve-D01+D22 is a subset of the FAS. Here, n= number of participants analyzed at specific timepoint.

End point type	Secondary

End point timeframe:

Pre-vaccination on Day 1 and Post-vaccination on Days 22, 36, 78, 134, 202, 292, and 387

Notes:

[65] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 2 of the study were analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	166[66]	170[67]	175[68]	
Units: participants				
Day 22: >=2-fold rise	141	155	161	
Day 22: >=4-fold rise	117	136	156	
Day 36: >=2-fold rise	159	160	165	
Day 36: >=4-fold rise	158	160	165	
Day 78: >=2-fold rise	121	124	124	
Day 78: >=4-fold rise	121	124	124	
Day 134: >=2-fold rise	101	109	100	
Day 134: >=4-fold rise	101	109	100	
Day 202: >=2-fold rise	85	91	86	

Day 202: >=4-fold rise	85	91	85	
Day 292: >=2-fold rise	11	12	14	
Day 292: >=4-fold rise	11	12	14	
Day 387: >=2-fold rise	10	10	13	
Day 387: >=4-fold rise	10	10	13	

Notes:

[66] - Day 22(n=166)
Day 36(n=159)
Day 78(n=121)
Day 134(n=101)
Day 202(n=85)
Day 292(n=11)
Day 387(n=10)
[67] - Day 22(n=170)
Day 36(n=161)
Day 78(n=125)
Day 134(n=110)
Day 202(n=92)
Day 292(n=12)
Day 387(n=10)
[68] - Day 22(n=175)
Day 36(n=166)
Day 78(n=124)
Day 134(n=100)
Day 202(n=87)
Day 292(n=14)
Day 387(n=13)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Number of Responders as Determined by Binding Antibody Concentration Against SARS-CoV-2 D614G Strain at Days 22, 36, 78, 134, 202, 292, and 387

End point title	Phase 2: Number of Responders as Determined by Binding Antibody Concentration Against SARS-CoV-2 D614G Strain at Days 22, 36, 78, 134, 202, 292, and 387[69]

End point description:

Responders were participants who had baseline values below LLOQ with detectable antibody concentration above assay LLOQ at each pre-defined post-vaccination time point and participants with baseline values above LLOQ with a 4-fold increase in neutralizing antibody titers at each pre-defined post-vaccination time point. Binding antibodies concentration against SARS-CoV-2 D614G strain was measured with Nexelis GCN4 S-ELISA assay. The PPAS Naïve-D01+D22 is a subset of the FAS. Here, n= number of participants analyzed at specific timepoint.

End point type	Secondary

End point timeframe:

Post-vaccination on Days 22, 36, 78, 134, 202, 292, and 387

Notes:

[69] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 2 of the study were analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	166[70]	170[71]	175[72]	
Units: participants				

Day 22	139	154	161	
Day 36	159	160	165	
Day 78	121	124	124	
Day 134	101	109	100	
Day 202	85	91	86	
Day 292	11	12	14	
Day 387	10	10	13	

Notes:

[70] - Day 22(n=166)
Day 36(n=159)
Day 78(n=121)
Day 134(n=101)
Day 202(n=85)
Day 292(n=11)
Day 387(n=10)

[71] - Day 22(n=170)
Day 36(n=161)
Day 78(n=125)
Day 134(n=110)
Day 202(n=92)
Day 292(n=12)
Day 387(n=10)

[72] - Day 22(n=175)
Day 36(n=166)
Day 78(n=124)
Day 134(n=100)
Day 202(n=87)
Day 292(n=14)
Day 387(n=13)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3: Cohort 1: Geometric Mean Titers of Neutralizing Antibodies Against SARS-CoV-2 D614G Strain and B.1.351 Variant at Days 29, 91, 181, and 366

End point title	Phase 3: Cohort 1: Geometric Mean Titers of Neutralizing Antibodies Against SARS-CoV-2 D614G Strain and B.1.351 Variant at Days 29, 91, 181, and 366[73]

End point description:

Neutralizing antibodies activity against SARS-CoV-2 D614G strain and B.1.351 variant was measured with the neutralization assay (monogram assay) and the results were expressed as geometric mean titers. The PPAS is a subset of the FAS. Here, n= number of participants analyzed for each parameter at specific timepoint.

End point type	Secondary

End point timeframe:

Post-vaccination on Days 29, 91, 181, and 366

Notes:

[73] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 3 Cohort 1 reporting groups were analyzed in this endpoint.

End point values	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	311	106	117	96
Units: titers				
geometric mean (confidence interval 95%)				
Day 29: D614G (n=311,106,117,96)	5795 (5222 to 6432)	5743 (4668 to 7065)	4869 (4113 to 5764)	4400 (3566 to 5430)
Day 29: B.1.351 (n=307,104,117,96)	2078 (1844 to 2342)	1726 (1355 to 2198)	1790 (1452 to 2207)	1390 (1095 to 1764)
Day 91: D614G (n=249,91,86,84)	4623 (4037 to 5295)	4879 (3774 to 6308)	2704 (2065 to 3541)	2509 (1954 to 3223)
Day 91: B.1.351 (n=248,90,83,83)	1522 (1304 to 1776)	1254 (920 to 1711)	949 (702 to 1281)	711 (540 to 936)
Day 181: D614G (n=197,59,74,66)	7502 (6161 to 9135)	10068 (6940 to 14605)	2658 (1834 to 3852)	5649 (3695 to 8635)
Day 181: B.1.351 (n=196,56,70,64)	2328 (1827 to 2966)	3217 (2073 to 4992)	1035 (650 to 1648)	1853 (1095 to 3134)
Day 366: D614G (n=161,47,46,42)	10224 (8101 to 12903)	10567 (6608 to 16898)	2940 (1779 to 4858)	6314 (3847 to 10361)
Day 366: B.1.351 (n=162,47,46,41)	3419 (2572 to 4545)	3349 (1929 to 5812)	942 (533 to 1664)	2233 (1267 to 3937)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3: Cohort 1: Number of Participants With >=2-Fold and >=4-Fold Rise in Serum Neutralization Antibody Titers Against SARS-CoV-2 D614G Strain and B.1.351 Variant at Days 15, 29, 91, 181, and 366

End point title	Phase 3: Cohort 1: Number of Participants With >=2-Fold and >=4-Fold Rise in Serum Neutralization Antibody Titers Against SARS-CoV-2 D614G Strain and B.1.351 Variant at Days 15, 29, 91, 181, and 366[74]

End point description:

Neutralizing antibodies activity against SARS-CoV-2 D614G strain and B.1.351 variant was measured with serum neutralization assay (monogram assay). Participants with neutralization antibody titers >=2-fold and >=4-fold increase from baseline (pre-vaccination) were analyzed. The PPAS is a subset of the FAS. Here, n= number of participants analyzed for each parameter at specific timepoint.

End point type	Secondary

End point timeframe:

Pre-vaccination on Day 1 and Post-vaccination on Days 15, 29, 91, 181, and 366

Notes:

[74] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 3 Cohort 1 reporting groups were analyzed in this endpoint.

End point values	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	290	104	114	87
Units: participants				
D614G; Day 15: >=2-fold rise (n=278,98,101,75)	263	86	95	70
D614G; Day 15: >=4-fold rise (n=278,98,101,75)	252	70	87	66
D614G; Day 29: >=2-fold rise (n=290,104,102,80)	266	91	97	73
D614G; Day 29: >=4-fold rise (n=290,104,102,80)	250	79	87	68
D614G; Day 91: >=2-fold rise (n=233,89,74,72)	208	74	67	62
D614G; Day 91: >=4-fold rise (n=233,89,74,72)	187	57	58	56
D614G; Day 181: >=2-fold rise (n=182,58,63,55)	167	50	54	51
D614G; Day 181: >=4-fold rise (n=182,58,63,55)	149	44	42	41
D614G; Day 366: >=2-fold rise (n=152,45,37,37)	141	38	33	31
D614G; Day 366: >=4-fold rise (n=152,45,37,37)	129	34	28	31
B.1.351; Day 15: >=2-fold rise (n=266,79,114,81)	258	76	109	78
B.1.351; Day 15: >=4-fold rise (n=266,79,114,81)	246	67	103	76
B.1.351; Day 29: >=2-fold rise (n=273,85,113,87)	261	79	109	83
B.1.351; Day 29: >=4-fold rise (n=273,85,113,87)	245	70	103	80
B.1.351; Day 91: >=2-fold rise (n=224,74,79,75)	203	64	75	68
B.1.351; Day 91: >=4-fold rise (n=224,74,79,75)	189	54	67	66
B.1.351; Day 181: >=2-fold rise (n=173,44,68,58)	162	38	59	54
B.1.351; Day 181: >=4-fold rise (n=173,44,68,58)	145	38	51	46
B.1.351; Day 366: >=2-fold rise (n=147,35,43,36)	137	32	36	34
B.1.351; Day 366: >=4-fold rise (n=147,35,43,36)	127	30	34	30

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3: Cohorts 1, 2 and Comparator: Percentage of Participants With Seroresponse Against SARS-CoV-2 D614G Strain and B.1.351 Variant at 14 Days Post-Vaccination

End point title	Phase 3: Cohorts 1, 2 and Comparator: Percentage of Participants With Seroresponse Against SARS-CoV-2 D614G

	Strain and B.1.351 Variant at 14 Days Post-Vaccination[75]

End point description:

Seroresponse was defined as a >=4-fold rise in serum neutralization titer against SARS-CoV-2 D614G strain and B.1.351 variant (post/pre) at Day 15 or Day 36 relative to Day 0 or Day 22. Neutralizing antibodies activity against SARS-CoV-2 D614G strain and B.1.351 variant was measured with serum neutralization assay (monogram assay). The PPAS is a subset of the FAS. Here, n= number of participants analyzed for each parameter at specific timepoint. Percentages are rounded off to the tenth decimal place.

End point type	Secondary

End point timeframe:

Cohorts 1 and 2: 14 days post-vaccination on Day 1 (Day 15);
Comparator: 14 days post-vaccination on Day 22 (Day 36)

Notes:

[75] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 3 Cohorts 1, 2 and comparator reporting groups were analyzed in this endpoint.

End point values	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	278[76]	315[77]	320[78]	98[79]
Units: percentage of participants				
number (confidence interval 95%)				
D614G	90.6 (86.6 to 93.8)	73.7 (68.4 to 78.4)	75.6 (70.5 to 80.2)	71.4 (61.4 to 80.1)
B.1.351	92.5 (88.6 to 95.3)	83.3 (78.6 to 87.3)	82.9 (78.1 to 87.0)	84.8 (75.0 to 91.9)

Notes:

[76] - D614G (n=278)
B.1.351 (n=266)
[77] - D614G (n=315)
B.1.351 (n=299)
[78] - D614G (n=320)
B.1.351 (n=298)
[79] - D614G (n=98)
B.1.351 (n=79)

End point values	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92[80]	91[81]	114[82]	87[83]
Units: percentage of participants				
number (confidence interval 95%)				
D614G	72.8 (62.6 to 81.6)	63.7 (53.0 to 73.6)	86.1 (77.8 to 92.2)	89.7 (81.3 to 95.2)
B.1.351	83.3 (73.6 to 90.6)	80.0 (69.9 to 87.9)	90.4 (83.4 to 95.1)	95.4 (88.6 to 98.7)

Notes:

[80] - D614G (n=92)
B.1.351 (n=84)

[81] - D614G (n=91)
B.1.351 (n=85)
[82] - D614G (n=101)
B.1.351 (n=114)
[83] - D614G (n=87)
B.1.351 (n=87)

End point values	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	91[84]	81[85]	31[86]	33[87]
Units: percentage of participants				
number (confidence interval 95%)				
D614G	89.8 (81.5 to 95.2)	88.0 (78.4 to 94.4)	58.1 (39.1 to 75.5)	78.8 (61.1 to 91.0)
B.1.351	96.7 (90.7 to 99.3)	93.8 (86.2 to 98.0)	75.9 (56.5 to 89.7)	77.4 (58.9 to 90.4)

Notes:
[84] - D614G (n=88)
B.1.351 (n=91)
[85] - D614G (n=75)
B.1.351 (n=81)
[86] - D614G (n=31)
B.1.351 (n=29)
[87] - D614G (n=33)
B.1.351 (n=31)

End point values	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	99[88]	64[89]	301[90]	
Units: percentage of participants				
number (confidence interval 95%)				
D614G	84.8 (76.2 to 91.3)	90.6 (80.7 to 96.5)	99.0 (97.1 to 99.8)	
B.1.351	85.9 (77.4 to 92.0)	90.6 (80.7 to 96.5)	86.6 (82.1 to 90.3)	

Notes:
[88] - D614G (n=99)
B.1.351 (n=99)
[89] - D614G (n=64)
B.1.351 (n=64)
[90] - D614G (n=301)
B.1.351 (n=290)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3: Cohorts 1 and 2: Geometric Mean Concentration of Binding Antibodies Against SARS-CoV-2 D614G Strain at Days 1, 15, 29, 91, 181, and 366

End point title	Phase 3: Cohorts 1 and 2: Geometric Mean Concentration of Binding Antibodies Against SARS-CoV-2 D614G Strain at Days 1, 15, 29, 91, 181, and 366[91]

End point description:

Binding antibodies activity against SARS-CoV-2 D614G strain was measured with Nexelis GCN4 S-ELISA and the results were expressed as geometric mean concentrations. The PPAS is a subset of the FAS. Here, n= number of participants analyzed at specific timepoint and 99999= no participants were analyzed.

End point type	Secondary

End point timeframe:

Pre-vaccination on Day 1 and post-vaccination on Days 15, 29, 91, 181, and 366

Notes:

[91] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 3 Cohorts 1 and 2 reporting groups were analyzed in this endpoint.

End point values	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	326[92]	362[93]	361[94]	110[95]
Units: titers				
geometric mean (confidence interval 95%)				
Day 1	1888 (1687 to 2114)	3032 (2621 to 3507)	2580 (2228 to 2987)	3236 (2729 to 3839)
Day 15	26710 (24337 to 29314)	36428 (33227 to 39938)	30892 (27925 to 34174)	27390 (23220 to 32309)
Day 29	20212 (18487 to 22097)	33416 (30407 to 36723)	27083 (24480 to 29964)	23079 (19417 to 27431)
Day 91	18845 (16780 to 21165)	29384 (25972 to 33244)	23908 (20860 to 27402)	20758 (16506 to 26107)
Day 181	20073 (17076 to 23596)	20450 (18029 to 23195)	18628 (16117 to 21530)	25701 (17854 to 36998)
Day 366	41232 (28233 to 60218)	19545 (17037 to 22422)	19989 (17351 to 23028)	32368 (16026 to 65374)

Notes:

[92] - Day 1 (n=326)
Day 15 (n=302)
Day 29 (n=312)
Day 91 (n=251)
Day 181 (n=198)
Day 366 (n=28)
[93] - Day 1 (n=362)
Day 15 (n=323)
Day 29 (n=334)
Day 91 (n=267)
Day 181 (n=257)
Day 366 (n=234)
[94] - Day 1 (n=361)
Day 15 (n=335)
Day 29 (n=341)
Day 91 (n=280)
Day 181 (n=269)
Day 366 (n=241)
[95] - Day 1 (n=110)
Day 15 (n=102)
Day 29 (n=107)
Day 91 (n=92)
Day 181 (n=59)

Day 366 (n=20)

End point values	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	108[96]	107[97]	125[98]	97[99]
Units: titers				
geometric mean (confidence interval 95%)				
Day 1	3285 (2534 to 4259)	3505 (2747 to 4471)	993 (781 to 1262)	564 (427 to 747)
Day 15	43611 (35852 to 53049)	34704 (29398 to 40968)	21654 (18927 to 24775)	23775 (19137 to 29537)
Day 29	48428 (39336 to 59623)	41018 (34290 to 49065)	13305 (11657 to 15186)	16401 (13253 to 20296)
Day 91	37791 (29062 to 49140)	35363 (28656 to 43639)	9792 (8093 to 11849)	10365 (8105 to 13255)
Day 181	25615 (20346 to 32248)	24500 (19714 to 30448)	7281 (5366 to 9880)	8665 (6100 to 12311)
Day 366	25800 (20031 to 33232)	19848 (15543 to 25345)	99999 (99999 to 99999)	10382 (6531 to 16505)

Notes:

[96] - Day 1 (n=108)
Day 15 (n=93)
Day 29 (n=98)
Day 91 (n=84)
Day 181 (n=85)
Day 366 (n=81)
[97] - Day 1 (n=107)
Day 15 (n=98)
Day 29 (n=101)
Day 91 (n=91)
Day 181 (n=83)
Day 366 (n=72)
[98] - Day 1 (n=125)
Day 15 (n=119)
Day 29 (n=118)
Day 91 (n=87)
Day 181 (n=74)
Day 366 (n=0)
[99] - Day 1 (n=97)
Day 15 (n=94)
Day 29 (n=94)
Day 91 (n=61)
Day 181 (n=57)
Day 366 (n=30)

End point values	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	99[100]	99[101]	37[102]	37[103]
Units: titers				
geometric mean (confidence interval 95%)				

Day 1	537 (420 to 687)	608 (457 to 809)	2290 (1068 to 4908)	996 (491 to 2021)
Day 15	28783 (24417 to 33930)	21758 (18254 to 25935)	31067 (24221 to 39849)	34534 (26146 to 45614)
Day 29	17729 (14944 to 21034)	14014 (11798 to 16647)	29315 (22236 to 38647)	24388 (17369 to 34243)
Day 91	13189 (10078 to 17261)	9032 (7387 to 11043)	18463 (13497 to 25255)	16236 (9684 to 27219)
Day 181	10649 (7312 to 15510)	12342 (8420 to 18092)	11275 (7727 to 16451)	19231 (12448 to 29712)
Day 366	10937 (6565 to 18220)	14545 (4542 to 46582)	12176 (8897 to 16664)	12002 (8266 to 17425)

Notes:

[100] - Day 1 (n=99)
Day 15 (n=93)
Day 29 (n=92)
Day 91 (n=60)
Day 181 (n=51)
Day 366 (n=32)
[101] - Day 1 (n=99)
Day 15 (n=92)
Day 29 (n=97)
Day 91 (n=87)
Day 181 (n=66)
Day 366 (n=10)
[102] - Day 1 (n=37)
Day 15 (n=31)
Day 29 (n=34)
Day 91 (n=29)
Day 181 (n=25)
Day 366 (n=22)
[103] - Day 1 (n=37)
Day 15 (n=34)
Day 29 (n=31)
Day 91 (n=26)
Day 181 (n=25)
Day 366 (n=22)

End point values	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	130[104]	77[105]		
Units: titers				
geometric mean (confidence interval 95%)				
Day 1	1357 (1004 to 1834)	969 (688 to 1365)		
Day 15	65824 (57576 to 75254)	77057 (61772 to 96125)		
Day 29	60707 (52764 to 69845)	65974 (53800 to 80902)		
Day 91	41282 (34967 to 48736)	40566 (32032 to 51373)		
Day 181	21387 (17825 to 25661)	20803 (16151 to 26794)		
Day 366	32168 (25602 to 40417)	33194 (24774 to 44476)		

Notes:

[104] - Day 1 (n=130)
Day 15 (n=120)
Day 29 (n=124)

Day 91 (n=114)
Day 181 (n=116)
Day 366 (n=99)
[105] - Day 1 (n=77)
Day 15 (n=72)
Day 29 (n=71)
Day 91 (n=69)
Day 181 (n=68)
Day 366 (n=57)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3: Cohorts 1 and 2: Number of Participants With >=2-Fold and >=4-Fold Rise in Binding Antibody Concentration Against SARS-CoV-2 D614G Strain at Days 15, 29, 91, 181, and 366

End point title	Phase 3: Cohorts 1 and 2: Number of Participants With >=2-Fold and >=4-Fold Rise in Binding Antibody Concentration Against SARS-CoV-2 D614G Strain at Days 15, 29, 91, 181, and 366[106]

End point description:

Binding antibodies concentration against SARS-CoV-2 D614G strain was measured with Nexelis GCN4 S-ELISA assay. Participants with binding antibodies concentration >=2-fold and >=4-fold increase from baseline (pre-vaccination) were analyzed. The PPAS is a subset of the FAS. Here, n= number of participants analyzed for each parameter at specific timepoint and 99999= no participants were analyzed.

End point type	Secondary

End point timeframe:

Pre-vaccination on Day 1 and Post-vaccination on Days 15, 29, 91, 181, and 366

Notes:

[106] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 3 Cohorts 1 and 2 reporting groups were analyzed in this endpoint.

End point values	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	312[107]	332[108]	340[109]	106[110]
Units: participants				
Day 15: >=2-fold rise	287	276	292	94
Day 15: >=4-fold rise	265	234	265	72
Day 29: >=2-fold rise	285	278	285	93
Day 29: >=4-fold rise	253	243	254	71
Day 91: >=2-fold rise	227	210	217	73
Day 91: >=4-fold rise	197	183	184	60
Day 181: >=2-fold rise	175	189	193	43
Day 181: >=4-fold rise	146	160	167	38
Day 366: >=2-fold rise	27	174	184	15
Day 366: >=4-fold rise	26	147	165	13

Notes:

[107] - Day 15 (n=302)
Day 29 (n=312)
Day 91 (n=251)
Day 181 (n=198)
Day 366 (n=28)
[108] - Day 15 (n=322)
Day 29 (n=332)
Day 91 (n=266)
Day 181 (n=255)
Day 366 (n=232)
[109] - Day 15 (n=334)
Day 29 (n=340)
Day 91 (n=279)
Day 181 (n=269)
Day 366 (n=240)
[110] - Day 15 (n=101)
Day 29 (n=106)
Day 91 (n=91)
Day 181 (n=59)
Day 366 (n=19)

End point values	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98[111]	101[112]	119[113]	94[114]
Units: participants				
Day 15: >=2-fold rise	84	87	114	92
Day 15: >=4-fold rise	73	69	106	85
Day 29: >=2-fold rise	87	87	111	92
Day 29: >=4-fold rise	75	74	96	85
Day 91: >=2-fold rise	70	76	82	61
Day 91: >=4-fold rise	62	58	69	57
Day 181: >=2-fold rise	63	59	59	53
Day 181: >=4-fold rise	55	48	45	45
Day 366: >=2-fold rise	62	49	99999	26
Day 366: >=4-fold rise	56	37	99999	23

Notes:

[111] - Day 15 (n=93)
Day 29 (n=98)
Day 91 (n=84)
Day 181 (n=85)
Day 366 (n=81)
[112] - Day 15 (n=98)
Day 29 (n=101)
Day 91 (n=91)
Day 181 (n=83)
Day 366 (n=72)
[113] - Day 15 (n=119)
Day 29 (n=118)
Day 91 (n=87)
Day 181 (n=74)
Day 366 (n=0)
[114] - Day 15 (n=94)
Day 29 (n=94)
Day 91 (n=61)
Day 181 (n=57)
Day 366 (n=30)

End point values	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93[115]	96[116]	34[117]	34[118]
Units: participants				
Day 15: >=2-fold rise	92	88	24	29
Day 15: >=4-fold rise	90	84	19	28
Day 29: >=2-fold rise	90	91	24	27
Day 29: >=4-fold rise	86	84	19	27
Day 91: >=2-fold rise	59	79	17	23
Day 91: >=4-fold rise	56	72	14	22
Day 181: >=2-fold rise	49	56	14	20
Day 181: >=4-fold rise	40	51	11	17
Day 366: >=2-fold rise	27	9	12	17
Day 366: >=4-fold rise	23	7	11	14

Notes:

[115] - Day 15 (n=93)
Day 29 (n=92)
Day 91 (n=60)
Day 181 (n=51)
Day 366 (n=32)
[116] - Day 15 (n=91)
Day 29 (n=96)
Day 91 (n=86)
Day 181 (n=65)
Day 366 (n=10)
[117] - Day 15 (n=31)
Day 29 (n=34)
Day 91 (n=29)
Day 181 (n=25)
Day 366 (n=22)
[118] - Day 15 (n=34)
Day 29 (n=31)
Day 91 (n=26)
Day 181 (n=25)
Day 366 (n=22)

End point values	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	124[119]	72[120]		
Units: participants				
Day 15: >=2-fold rise	108	69		
Day 15: >=4-fold rise	103	67		
Day 29: >=2-fold rise	115	69		
Day 29: >=4-fold rise	109	66		
Day 91: >=2-fold rise	105	65		
Day 91: >=4-fold rise	98	62		
Day 181: >=2-fold rise	98	62		
Day 181: >=4-fold rise	89	59		
Day 366: >=2-fold rise	83	53		
Day 366: >=4-fold rise	77	52		

Notes:

[119] - Day 15 (n=120)
Day 29 (n=124)
Day 91 (n=114)
Day 181 (n=116)
Day 366 (n=99)
[120] - Day 15 (n=72)
Day 29 (n=71)
Day 91 (n=69)
Day 181 (n=68)
Day 366 (n=57)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3: Cohort 2: Geometric Mean Titers of Neutralizing Antibodies Against SARS-CoV-2 D614G Strain and B.1.351 Variant at Days 1, 15, 29, 91, 181, and 366

End point title	Phase 3: Cohort 2: Geometric Mean Titers of Neutralizing Antibodies Against SARS-CoV-2 D614G Strain and B.1.351 Variant at Days 1, 15, 29, 91, 181, and 366[121]

End point description:

Neutralizing antibodies activity against SARS-CoV-2 D614G strain and B.1.351 variant was measured with the neutralization assay (monogram assay) and the results were expressed as geometric mean titers. The PPAS is a subset of the FAS. Here, n= number of participants analyzed for each parameter at specific timepoint and 99999= no participants were analyzed.

End point type	Secondary

End point timeframe:

Pre-vaccination on Day 1 and post-vaccination on Days 15, 29, 91, 181, and 366

Notes:

[121] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 3 Cohort 2 reporting groups were analyzed in this endpoint.

End point values	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	348	345	107	101
Units: titers				
geometric mean (confidence interval 95%)				
Day 1: D614G(n=348,345,107,101,89,93,36,3	678 (558 to 824)	579 (478 to 701)	1107 (816 to 1503)	1347 (977 to 1858)
Day 1: B.1.351(n=336,324,97,94,90,97,36,34,	176 (142 to 217)	149 (120 to 184)	258 (182 to 364)	296 (207 to 424)
Day 15: D614G (n=325,334,93,96,94,93,31,34,119,72)	9995 (8976 to 11129)	8430 (7572 to 9386)	14240 (11257 to 18013)	12522 (10368 to 15123)
Day 15:B.1.351(n=325,334,93,95,94,93,30,	7021 (6262 to 7873)	4900 (4370 to 5494)	9449 (7376 to 12104)	6581 (5340 to 8111)
Day 29: D614G(n=333,341,99,100,93,92,34,31,	14065 (12399 to 15954)	10885 (9664 to 12261)	16286 (12808 to 20710)	16874 (13763 to 20688)
Day 29:B.1.351(n=333,340,99,98,93,92,34,	8947 (7845 to 10203)	6045 (5307 to 6886)	10264 (7924 to 13296)	8139 (6470 to 10239)

Day 91: D614G (n=264,279,84,89,61,60,29,26,112,69)	11037 (9530 to 12782)	8523 (7284 to 9973)	13701 (10206 to 18392)	12424 (9586 to 16103)
Day 91:B.1.351(n=264,279,84,89,61,60,29,	6557 (5617 to 7654)	4359 (3673 to 5172)	8141 (5982 to 11080)	5474 (4176 to 7175)
Day 181: D614G (n=0,0,0,0,0,0,0,0,0,0)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
Day 181: B.1.351 (n=0,0,0,0,0,0,0,0,0,0)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
Day 366: D614G (n=0,0,0,0,0,0,0,0,0,0)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
Day 366: B.1.351 (n=0,0,0,0,0,0,0,0,0,0)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	94	97	36	36
Units: titers				
geometric mean (confidence interval 95%)				
Day 1: D614G(n=348,345,107,101,89,93,36,3	137 (98.0 to 193)	134 (95.7 to 186)	1188 (567 to 2490)	447 (217 to 921)
Day 1: B.1.351(n=336,324,97,94,90,97,36,34,	43.3 (32.0 to 58.5)	36.8 (28.8 to 47.1)	345 (167 to 714)	122 (55.3 to 268)
Day 15: D614G (n=325,334,93,96,94,93,31,34,119,72)	5536 (4436 to 6910)	5855 (4669 to 7344)	11005 (7533 to 16078)	11624 (8086 to 16710)
Day 15:B.1.351(n=325,334,93,95,94,93,30,	4610 (3689 to 5760)	3099 (2386 to 4026)	6872 (4482 to 10537)	5057 (3416 to 7488)
Day 29: D614G(n=333,341,99,100,93,92,34,31,	6320 (4941 to 8083)	6370 (5014 to 8093)	9711 (6526 to 14450)	9521 (6555 to 13828)
Day 29:B.1.351(n=333,340,99,98,93,92,34,	4736 (3680 to 6096)	3103 (2340 to 4115)	6028 (3889 to 9342)	4007 (2553 to 6290)
Day 91: D614G (n=264,279,84,89,61,60,29,26,112,69)	3620 (2680 to 4891)	3981 (2812 to 5637)	5797 (3725 to 9024)	5880 (3125 to 11064)
Day 91:B.1.351(n=264,279,84,89,61,60,29,	2456 (1792 to 3364)	2029 (1376 to 2993)	3374 (2161 to 5269)	2405 (1093 to 5295)
Day 181: D614G (n=0,0,0,0,0,0,0,0,0,0)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
Day 181: B.1.351 (n=0,0,0,0,0,0,0,0,0,0)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
Day 366: D614G (n=0,0,0,0,0,0,0,0,0,0)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
Day 366: B.1.351 (n=0,0,0,0,0,0,0,0,0,0)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	123	72		
Units: titers				
geometric mean (confidence interval 95%)				
Day 1: D614G(n=348,345,107,101,89,93,36,3	274 (182 to 413)	159 (97.4 to 260)		
Day 1: B.1.351(n=336,324,97,94,90,97,36,34,	97.7 (68.0 to 140)	70.3 (47.9 to 103)		
Day 15: D614G (n=325,334,93,96,94,93,31,34,119,72)	22457 (19123 to 26374)	25002 (18441 to 33897)		
Day 15:B.1.351(n=325,334,93,95,94,93,30,	7452 (6212 to 8939)	13300 (9817 to 18018)		
Day 29: D614G(n=333,341,99,100,93,92,34,31,	16032 (13535 to 18989)	16425 (12103 to 22291)		
Day 29:B.1.351(n=333,340,99,98,93,92,34,	7185 (5841 to 8838)	12712 (9376 to 17234)		
Day 91: D614G (n=264,279,84,89,61,60,29,26,112,69)	14498 (11931 to 17618)	13641 (9766 to 19055)		
Day 91:B.1.351(n=264,279,84,89,61,60,29,	6455 (5117 to 8143)	8990 (6284 to 12861)		
Day 181: D614G (n=0,0,0,0,0,0,0,0,0,0)	99999 (99999 to 99999)	99999 (99999 to 99999)		
Day 181: B.1.351 (n=0,0,0,0,0,0,0,0,0,0)	99999 (99999 to 99999)	99999 (99999 to 99999)		
Day 366: D614G (n=0,0,0,0,0,0,0,0,0,0)	99999 (99999 to 99999)	99999 (99999 to 99999)		
Day 366: B.1.351 (n=0,0,0,0,0,0,0,0,0,0)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3: Cohort 2: Number of Participants With >=2-Fold and >=4-Fold Rise in Serum Neutralization Antibody Titers Against SARS-CoV-2 D614G Strain and B.1.351 Variant at Days 15, 29, 91, 181, and 366

End point title	Phase 3: Cohort 2: Number of Participants With >=2-Fold and >=4-Fold Rise in Serum Neutralization Antibody Titers Against SARS-CoV-2 D614G Strain and B.1.351 Variant at Days 15, 29, 91, 181, and 366[122]

End point description:

Neutralizing antibodies activity against SARS-CoV-2 D614G strain and B.1.351 variant was measured with serum neutralization assay (monogram assay). Participants with neutralization antibody titers >=2-fold and >=4-fold increase from baseline (pre-vaccination) were analyzed. The PPAS is a subset of the FAS. Here, n= number of participants analyzed for each parameter at specific timepoint, 99999= no participants were analyzed, and D=Day.

End point type	Secondary

End point timeframe:

Pre-vaccination on Day 1 and Post-vaccination on Days 15, 29, 91, 181, and 366

Notes:

[122] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 3 Cohort 2 reporting groups were analyzed in this endpoint.

End point values	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	318[123]	324[124]	99[125]	95[126]
Units: participants				
D614G; Day 15: >=2-fold rise	267	269	79	77
D614G; Day 15: >=4-fold rise	232	242	67	58
D614G; Day 29: >=2-fold rise	272	283	83	76
D614G; Day 29: >=4-fold rise	240	251	74	67
D614G; Day 91: >=2-fold rise	199	208	69	70
D614G; Day 91: >=4-fold rise	175	187	57	54
D614G; Day 181: >=2-fold rise	99999	99999	99999	99999
D614G; Day 181: >=4-fold rise	99999	99999	99999	99999
D614G; Day 366: >=2-fold rise	99999	99999	99999	99999
D614G; Day 366: >=4-fold rise	99999	99999	99999	99999
B.1.351; Day 15: >=2-fold rise	275	269	77	79
B.1.351; Day 15: >=4-fold rise	249	247	70	68
B.1.351; Day 29: >=2-fold rise	278	277	81	79
B.1.351; Day 29: >=4-fold rise	258	261	75	70
B.1.351; Day 91: >=2-fold rise	212	207	69	68
B.1.351; Day 91: >=4-fold rise	195	197	62	60
B.1.351; Day 181: >=2-fold rise	99999	99999	99999	99999
B.1.351; Day 181: >=4-fold rise	99999	99999	99999	99999
B.1.351; Day 366: >=2-fold rise	99999	99999	99999	99999
B.1.351; Day 366: >=4-fold rise	99999	99999	99999	99999

Notes:

[123] - D614G:D15(n=315),D29(n=318),D91(n=251);B.1.351:D15(n=299),D29(n=306),D91(n=246); D181:(n=0),D366:(n=0

[124] - D614G:D15(n=320),D29(n=324),D91(n=265);B.1.351:D15(n=298),D29(n=304),D91(n=252); D181:(n=0),D366:(n=0

[125] - D614G:D15(n=92),D29(n=99),D91(n=84);B.1.351:D15(n=84),D29(n=90),D91(n=76);D181: (n=0),D366:(n=0)

[126] - D614G:D15(n=91),D29(n=95),D91(n=86);B.1.351:D15(n=85),D29(n=88),D91(n=82);D181: (n=0),D366:(n=0)

End point values	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	87[127]	91[128]	33[129]	33[130]
Units: participants				
D614G; Day 15: >=2-fold rise	85	84	26	30
D614G; Day 15: >=4-fold rise	78	79	18	26
D614G; Day 29: >=2-fold rise	84	83	22	28
D614G; Day 29: >=4-fold rise	80	80	15	23
D614G; Day 91: >=2-fold rise	57	51	16	20
D614G; Day 91: >=4-fold rise	55	48	12	16
D614G; Day 181: >=2-fold rise	99999	99999	99999	99999
D614G; Day 181: >=4-fold rise	99999	99999	99999	99999

D614G; Day 366: >=2-fold rise	99999	99999	99999	99999
D614G; Day 366: >=4-fold rise	99999	99999	99999	99999
B.1.351; Day 15: >=2-fold rise	85	88	28	28
B.1.351; Day 15: >=4-fold rise	83	88	22	24
B.1.351; Day 29: >=2-fold rise	86	87	28	26
B.1.351; Day 29: >=4-fold rise	84	87	20	25
B.1.351; Day 91: >=2-fold rise	56	56	22	21
B.1.351; Day 91: >=4-fold rise	56	53	16	17
B.1.351; Day 181: >=2-fold rise	99999	99999	99999	99999
B.1.351; Day 181: >=4-fold rise	99999	99999	99999	99999
B.1.351; Day 366: >=2-fold rise	99999	99999	99999	99999
B.1.351; Day 366: >=4-fold rise	99999	99999	99999	99999

Notes:

[127] - D614G:D15(n=87),D29(n=86),D91(n=58);B.1.351:D15(n=87),D29(n=87),D91(n=56);D181:(n=0),D366:(n=0)
[128] - D614G:D15(n=88),D29(n=86),D91(n=55);B.1.351:D15(n=91),D29(n=90),D91(n=58);D181:(n=0),D366:(n=0)
[129] - D614G:D15(n=31),D29(n=33),D91(n=28);B.1.351:D15(n=29),D29(n=33),D91(n=29);D181:(n=0),D366:(n=0)
[130] - D614G:D15(n=33),D29(n=30),D91(n=25);B.1.351:D15(n=31),D29(n=28),D91(n=25);D181:(n=0),D366:(n=0)

End point values	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103[131]	64[132]		
Units: participants				
D614G; Day 15: >=2-fold rise	86	60		
D614G; Day 15: >=4-fold rise	84	58		
D614G; Day 29: >=2-fold rise	89	58		
D614G; Day 29: >=4-fold rise	85	56		
D614G; Day 91: >=2-fold rise	81	57		
D614G; Day 91: >=4-fold rise	78	53		
D614G; Day 181: >=2-fold rise	99999	99999		
D614G; Day 181: >=4-fold rise	99999	99999		
D614G; Day 366: >=2-fold rise	99999	99999		
D614G; Day 366: >=4-fold rise	99999	99999		
B.1.351; Day 15: >=2-fold rise	88	62		
B.1.351; Day 15: >=4-fold rise	85	58		
B.1.351; Day 29: >=2-fold rise	95	62		
B.1.351; Day 29: >=4-fold rise	92	58		
B.1.351; Day 91: >=2-fold rise	87	58		
B.1.351; Day 91: >=4-fold rise	80	55		
B.1.351; Day 181: >=2-fold rise	99999	99999		
B.1.351; Day 181: >=4-fold rise	99999	99999		
B.1.351; Day 366: >=2-fold rise	99999	99999		
B.1.351; Day 366: >=4-fold rise	99999	99999		

Notes:

[131] - D614G:D15(n=99),D29(n=101),D91(n=93);B.1.351:D15(n=99),D29(n=103),D91(n=94);D181:(n=0),D366:(n=0)
[132] - D614G:D15(n=64),D29(n=62),D91(n=61);B.1.351:D15(n=64),D29(n=64),D91(n=62);D181:(n=0),D366:(n=0)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3: Comparator: Geometric Mean Titers of Neutralizing Antibodies Against SARS-CoV-2 D614G Strain and B.1.351 Variant at Days 1, 22, 36, 134, 202, 292, and 387

End point title	Phase 3: Comparator: Geometric Mean Titers of Neutralizing Antibodies Against SARS-CoV-2 D614G Strain and B.1.351 Variant at Days 1, 22, 36, 134, 202, 292, and 387[133]

End point description:

Neutralizing antibodies activity against SARS-CoV-2 D614G strain and B.1.351 variant was measured with the neutralization assay (monogram assay) and the results were expressed as geometric mean titers. The PPAS is a subset of the FAS. Here, n= number of participants analyzed for each parameter at specific timepoint.

End point type	Secondary

End point timeframe:

Pre-vaccination on Day 1 and post-vaccination on Days 22, 36, 134, 202, 292, and 387

Notes:

[133] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 3 comparator reporting group were analyzed in this endpoint.

End point values	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)			
Subject group type	Reporting group			
Number of subjects analysed	330			
Units: titers				
geometric mean (confidence interval 95%)				
D614G: Day 1 (n=330)	20.3 (19.7 to 21.0)			
D614G: Day 22 (n=281)	53.3 (44.6 to 63.8)			
D614G: Day 36 (n=302)	3658 (3123 to 4286)			
D614G: Day 134 (n=143)	1050 (743 to 1486)			
D614G: Day 202 (n=128)	1685 (1142 to 2487)			
D614G: Day 292 (n=117)	1943 (1294 to 2918)			
D614G: Day 387 (n=112)	1973 (1344 to 2897)			
B.1.351: Day 1 (n=329)	20.3 (19.7 to 20.8)			
B.1.351: Day 22 (n=326)	29.4 (25.7 to 33.5)			
B.1.351: Day 36 (n=291)	413 (346 to 493)			
B.1.351: Day 134 (n=113)	496 (330 to 745)			
B.1.351: Day 202 (n=123)	671 (441 to 1022)			

B.1.351: Day 292 (n=120)	867 (560 to 1342)			
B.1.351: Day 387 (n=112)	1033 (686 to 1555)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3: Comparator: Number of Participants With >=2-Fold and >=4-Fold Rise in Serum Neutralization Antibody Titers Against SARS-CoV-2 D614G Strain and B.1.351 Variant at Days 22, 36, 134, 202, 292, and 387

End point title	Phase 3: Comparator: Number of Participants With >=2-Fold and >=4-Fold Rise in Serum Neutralization Antibody Titers Against SARS-CoV-2 D614G Strain and B.1.351 Variant at Days 22, 36, 134, 202, 292, and 387[134]

End point description:

Neutralizing antibodies activity against SARS-CoV-2 D614G strain and B.1.351 variant was measured with serum neutralization assay (monogram assay). Participants with neutralization antibody titers >=2-fold and >=4-fold increase from baseline (pre-vaccination) were analyzed. The PPAS is a subset of the FAS. Here, n= number of participants analyzed for each parameter at specific timepoint.

End point type	Secondary

End point timeframe:

Pre-vaccination on Day 1 and Post-vaccination on Days 22, 36, 134, 202, 292, and 387

Notes:

[134] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 3 comparator reporting group were analyzed in this endpoint.

End point values	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)			
Subject group type	Reporting group			
Number of subjects analysed	325			
Units: participants				
D614G; Day 22: >=2-fold rise (n=281)	99			
D614G; Day 22: >=4-fold rise (n=281)	88			
D614G; Day 36: >=2-fold rise (n=301)	299			
D614G; Day 36: >=4-fold rise (n=301)	298			
D614G; Day 134: >=2-fold rise (n=143)	134			
D614G; Day 134: >=4-fold rise (n=143)	131			
D614G; Day 202: >=2-fold rise (n=127)	120			
D614G; Day 202: >=4-fold rise (n=127)	119			
D614G; Day 292: >=2-fold rise (n=117)	108			
D614G; Day 292: >=4-fold rise (n=117)	105			

D614G; Day 387: >=2-fold rise (n=111)	105			
D614G; Day 387: >=4-fold rise (n=111)	101			
B.1.351; Day 22: >=2-fold rise (n=325)	39			
B.1.351; Day 22: >=4-fold rise (n=325)	32			
B.1.351; Day 36: >=2-fold rise (n=290)	264			
B.1.351; Day 36: >=4-fold rise (n=290)	251			
B.1.351; Day 134: >=2-fold rise (n=112)	99			
B.1.351; Day 134: >=4-fold rise (n=112)	89			
B.1.351; Day 202: >=2-fold rise (n=122)	100			
B.1.351; Day 202: >=4-fold rise (n=122)	97			
B.1.351; Day 292: >=2-fold rise (n=119)	98			
B.1.351; Day 292: >=4-fold rise (n=119)	91			
B.1.351; Day 387: >=2-fold rise (n=111)	96			
B.1.351; Day 387: >=4-fold rise (n=111)	94			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3: Comparator: Geometric Mean Concentration of Binding Antibodies Against SARS-CoV-2 D614G Strain at Days 1, 22, 36, 134, 202, 292, and 387

End point title	Phase 3: Comparator: Geometric Mean Concentration of Binding Antibodies Against SARS-CoV-2 D614G Strain at Days 1, 22, 36, 134, 202, 292, and 387[135]

End point description:

Binding antibodies activity against SARS-CoV-2 D614G strain was measured with Nexelis GCN4 S-ELISA and the results were expressed as geometric mean concentrations. The PPAS is a subset of the FAS. Here, n= number of participants analyzed at specific timepoint.

End point type	Secondary

End point timeframe:

Pre-vaccination on Day 1 and post-vaccination on Days 22, 36, 134, 202, 292, and 387

Notes:

[135] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only participants treated in Phase 3 comparator reporting group were analyzed in this endpoint.

End point values	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)			
Subject group type	Reporting group			
Number of subjects analysed	330			
Units: titers				
geometric mean (confidence interval 95%)				
Day 1 (n=326)	10.7 (9.91 to 11.6)			
Day 22 (n=330)	212 (183 to 246)			
Day 36 (n=303)	24278 (21681 to 27185)			
Day 134 (n=147)	6593 (4952 to 8779)			
Day 202 (n=132)	6667 (4833 to 9197)			
Day 292 (n=122)	6868 (4919 to 9587)			
Day 387 (n=115)	7112 (5216 to 9697)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3: Comparator: Number of Participants With >=2-Fold and >=4-Fold Rise in Binding Antibody Concentration Against SARS-CoV-2 D614G Strain at Days 22, 36, 134, 202, 292, and 387

End point title	Phase 3: Comparator: Number of Participants With >=2-Fold and >=4-Fold Rise in Binding Antibody Concentration Against SARS-CoV-2 D614G Strain at Days 22, 36, 134, 202, 292, and 387[136]

End point description:

Binding antibodies concentration against SARS-CoV-2 D614G strain was measured with Nexelis GCN4 S-ELISA assay. Participants with binding antibodies concentration >=2-fold and >=4-fold increase from baseline (pre-vaccination) were analyzed. The PPAS is a subset of the FAS. Here, n= number of participants analyzed for each parameter at specific timepoint.

End point type	Secondary

End point timeframe:

Pre-vaccination on Day 1 and Post-vaccination on Days 22, 36, 134, 202, 292, and 387

Notes:

[136] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 3 comparator reporting group were analyzed in this endpoint.

End point values	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)			
Subject group type	Reporting group			
Number of subjects analysed	331			
Units: participants				
Day 22: >=2-fold rise (n=331)	312			
Day 22: >=4-fold rise (n=331)	290			
Day 36: >=2-fold rise (n=303)	302			
Day 36: >=4-fold rise (n=303)	302			
Day 134: >=2-fold rise (n=150)	149			
Day 134: >=4-fold rise (n=150)	148			
Day 202: >=2-fold rise (n=134)	133			
Day 202: >=4-fold rise (n=134)	133			
Day 292: >=2-fold rise (n=124)	123			
Day 292: >=4-fold rise (n=124)	123			
Day 387: >=2-fold rise (n=118)	117			
Day 387: >=4-fold rise (n=118)	117			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 3: Comparator: Percentage of Responders as Determined by Binding Antibody Concentration Against SARS-CoV-2 D614G Strain at Days 22, 36, 134, 202, 292, and 387

End point title	Phase 3: Comparator: Percentage of Responders as Determined by Binding Antibody Concentration Against SARS-CoV-2 D614G Strain at Days 22, 36, 134, 202, 292, and 387[137]

End point description:

Responders were participants who had baseline values below LLOQ with detectable antibody concentration above assay LLOQ at each pre-defined post-vaccination time point and participants with baseline values above LLOQ with a 4-fold increase in neutralizing antibody titers at each pre-defined post-vaccination time point. Binding antibodies activity against SARS-CoV-2 D614G strain was measured with Nexelis GCN4 S-ELISA. The PPAS is a subset of the FAS. Here, n= number of participants analyzed at specific timepoint. Percentages are rounded off to the tenth decimal place.

End point type	Secondary

End point timeframe:

Post-vaccination on Days 22, 36, 134, 202, 292, and 387

Notes:

[137] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 3 comparator reporting group were analyzed in this endpoint.

End point values	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)			
Subject group type	Reporting group			
Number of subjects analysed	331			
Units: percentage of participants				
number (confidence interval 95%)				
Day 22 (n=331)	94.3 (91.2 to 96.5)			
Day 36 (n=325)	99.7 (98.3 to 100)			
Day 134 (n=159)	98.7 (95.5 to 99.8)			
Day 202 (n=141)	99.3 (96.1 to 100)			
Day 292 (n=134)	99.3 (95.9 to 100)			
Day 387 (n=127)	99.2 (95.7 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Laboratory-Confirmed Symptomatic COVID-19

End point title	Percentage of Participants With Laboratory-Confirmed Symptomatic COVID-19[138]

End point description:

Laboratory-confirmed SARS-CoV-2 infection was defined as a positive result for SARS-CoV-2 by nucleic acid amplification test (done by the central laboratory or locally) on at least 1 respiratory sample. The Safety analysis set included participants randomized and who had received at least 1 dose of the study vaccines. Safety analysis was performed according to the actual study vaccine received by the participants. Percentages are rounded off to the tenth decimal place.

End point type	Secondary

End point timeframe:

Phase 2 and Phase 3 Comparator: From first dose of study vaccine administration (Day 1) up to 387 days.
Phase 3 Cohorts 1 and 2: From first dose of study vaccine administration (Day 1) up to 366 days.

Notes:

[138] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Participants treated in Phase 3 exploratory reporting groups were not analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	240	241	328	378
Units: percentage of participants				
number (confidence interval 95%)	3.3 (1.4 to 6.5)	5.4 (2.9 to 9.0)	14.0 (10.5 to	20.9 (16.9 to

	18.3)	25.4)		

End point values	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	375	113	111	108
Units: percentage of participants				
number (confidence interval 95%)	23.5 (19.3 to 28.1)	12.4 (6.9 to 19.9)	10.8 (5.7 to 18.1)	10.2 (5.2 to 17.5)

End point values	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	127	100	100	103
Units: percentage of participants				
number (confidence interval 95%)	24.4 (17.2 to 32.8)	25.0 (16.9 to 34.7)	29.0 (20.4 to 38.9)	9.7 (4.8 to 17.1)

End point values	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	132	78
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 9.3)	18.4 (7.7 to 34.3)	18.9 (12.6 to 26.7)	19.2 (11.2 to 29.7)

End point values	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	473	240		
Units: percentage of participants				
number (confidence interval 95%)	8.2 (5.9 to 11.1)	1.7 (0.5 to 4.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Percentage of Participants With Serologically-Confirmed SARS-CoV-2 Infection

End point title	Phase 2: Percentage of Participants With Serologically-Confirmed SARS-CoV-2 Infection[139]

End point description:

Blood samples collected from participants were used for serological assessments in the study. Serologically-confirmed SARS-CoV-2 infection was defined as a positive result in a serum sample for antibodies specific to the nucleocapsid of SARS-CoV-2 detected by electrochemiluminescence immunoassay. The Safety analysis set included participants randomized and who had received at least 1 dose of the study vaccines. Percentages are rounded off to the tenth decimal place.

End point type	Secondary

End point timeframe:

From first dose of study vaccine administration (Day 1) up to 387 days

Notes:

[139] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants treated in Phase 2 of the study were analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	240	241	240	
Units: percentage of participants				
number (confidence interval 95%)	12.1 (8.2 to 16.9)	14.1 (10.0 to 19.2)	10.8 (7.2 to 15.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Symptomatic COVID-19 Episodes Associated With Hospitalization

End point title	Percentage of Participants With Symptomatic COVID-19 Episodes Associated With Hospitalization[140]

End point description:

Symptomatic COVID-19 was defined as laboratory-confirmed SARS-CoV-2 infection accompanied by protocol-defined COVID-19-like illness. The Safety analysis set included participants randomized and who had received at least 1 dose of the study vaccines. Safety analysis was performed according to the actual study vaccine received by the participants. Percentages are rounded off to the tenth decimal place.

End point type	Secondary

End point timeframe:

Phase 2 and Phase 3 Comparator: From first dose of study vaccine administration (Day 1) up to 387 days.
Phase 3 Cohorts 1 and 2: From first dose of study vaccine administration (Day 1) up to 366 days.

Notes:

[140] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Participants treated in Phase 3 exploratory reporting groups were not analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	240	241	328	378
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 1.5)	0 (0 to 1.5)	0 (0 to 1.1)	0 (0 to 1.0)

End point values	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	375	113	111	108
Units: percentage of participants				
number (confidence interval 95%)	0.3 (0 to 1.5)	0 (0 to 3.2)	0 (0 to 3.3)	0 (0 to 3.4)

End point values	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	127	100	100	103
Units: percentage of participants				
number (confidence interval 95%)	0.8 (0 to 4.3)	0 (0 to 3.6)	0 (0 to 3.6)	0 (0 to 3.5)

End point values	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	132	78

Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 9.3)	0 (0 to 9.3)	0 (0 to 2.8)	0 (0 to 4.6)

End point values	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	473	240		
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 0.8)	0 (0 to 1.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Severe Symptomatic COVID-19

End point title	Percentage of Participants With Severe Symptomatic COVID-

End point description:

Severe COVID-19 was defined as COVID-19 with any 1: Any clinical signs of severe illness measured at least on 2 occasions separated by 30 minutes, supplemental oxygen administration for >1 hour, use of invasive or non-invasive ventilation or Extracorporeal Membrane Oxygenation, clinical diagnosis of respiratory failure, significant acute renal, hepatic, or neurologic dysfunction, shock (defined by systolic blood pressure 90 mm Hg, or diastolic blood pressure 60 mm Hg or requiring vasopressors), admission to an intensive care unit, or death. Symptomatic COVID-19 was defined as laboratory-confirmed SARS-CoV-2 infection accompanied by protocol-defined COVID-19-like illness. The Safety analysis set included participants randomized and who had received at least 1 dose of the study vaccines. Safety analysis was performed according to the actual study vaccine received by the participants. Percentages are rounded off to the tenth decimal place.

End point type	Secondary

End point timeframe:

Phase 2 and Phase 3 Comparator: From first dose of study vaccine administration (Day 1) up to 387 days.
Phase 3 Cohorts 1 and 2: From first dose of study vaccine administration (Day 1) up to 366 days.

Notes:

[141] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Participants treated in Phase 3 exploratory reporting groups were not analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	240	241	328	378
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 1.5)	0 (0 to 1.5)	0 (0 to 1.1)	0 (0 to 1.0)

End point values	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	375	113	111	108
Units: percentage of participants				
number (confidence interval 95%)	0.3 (0 to 1.5)	0 (0 to 3.2)	0 (0 to 3.3)	0 (0 to 3.4)

End point values	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	127	100	100	103
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 2.9)	0 (0 to 3.6)	0 (0 to 3.6)	0 (0 to 3.5)

End point values	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	132	78
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 9.3)	0 (0 to 9.3)	0.8 (0 to 4.1)	0 (0 to 4.6)

End point values	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	473	240		
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 0.8)	0 (0 to 1.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Death Associated With Symptomatic COVID-19

End point title	Percentage of Participants With Death Associated With Symptomatic COVID-19[142]

End point description:

Death associated with COVID-19 was defined as death in a participant with COVID-19 who died within 28 days of the first positive specimen date OR died more than 28 days after the first specimen date and COVID-19 was mentioned as an immediate or underlying cause of death on the death certificate. Symptomatic COVID-19 was defined as laboratory-confirmed SARS-CoV-2 infection accompanied by protocol-defined COVID-19-like illness. The Safety analysis set included participants randomized and who had received at least 1 dose of the study vaccines. Safety analysis was performed according to the actual study vaccine received by the participants. Percentages are rounded off to the tenth decimal place.

End point type	Secondary

End point timeframe:

Phase 2 and Phase 3 Comparator: From first dose of study vaccine administration (Day 1) up to 387 days.
Phase 3 Cohorts 1 and 2: From first dose of study vaccine administration (Day 1) up to 366 days.

Notes:

[142] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Participants treated in Phase 3 exploratory reporting groups were not analyzed in this endpoint.

End point values	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	240	241	328	378
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 1.5)	0 (0 to 1.5)	0 (0 to 1.1)	0 (0 to 1.0)

End point values	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	375	113	111	108
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 1.0)	0 (0 to 3.2)	0 (0 to 3.3)	0 (0 to 3.4)

End point values	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03

	(D614)	(B.1.351)	(D614 + B.1.351)	(D614)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	127	100	100	103
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 2.9)	0 (0 to 3.6)	0 (0 to 3.6)	0 (0 to 3.5)

End point values	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	38	132	78
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 9.3)	0 (0 to 9.3)	0 (0 to 2.8)	0 (0 to 4.6)

End point values	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	473	240		
Units: percentage of participants				
number (confidence interval 95%)	0 (0 to 0.8)	0 (0 to 1.5)		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Phase 2 and Phase 3 Comparator: AEs data was collected from first dose of study vaccine administration (Day 1) up to 387 days.
Phase 3 Cohorts 1 and 2: AEs data was collected from first dose of study vaccine administration (Day 1) up to 366 days.

Adverse event reporting additional description:

Analysis was performed on the safety analysis set. Safety analysis was performed according to the actual study vaccine received by the participants.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1

Reporting group description:

Participants received CoV2 preS dTM monovalent D614 antigen dose 1 with fixed dose of AS03 adjuvant IM injection once daily on Days 1 and 22.

Reporting group title	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)

Reporting group description:

Participants previously vaccinated with Pfizer/BioNTech vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3

Reporting group description:

Participants received CoV2 preS dTM monovalent D614 antigen dose 3 with fixed dose of AS03 adjuvant IM injection once daily on Days 1 and 22.

Reporting group title	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2

Reporting group description:

Participants received CoV2 preS dTM monovalent D614 antigen dose 2 with fixed dose of AS03 adjuvant IM injection once daily on Days 1 and 22.

Reporting group title	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)

Reporting group description:

Participants previously vaccinated with Pfizer/BioNTech vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)

Reporting group description:

Participants previously vaccinated with Pfizer/BioNTech vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)

Reporting group description:

Participants previously vaccinated with Oxford University/AstraZeneca vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)

Reporting group description:

Participants previously vaccinated with Moderna vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)

Reporting group description:

Participants previously vaccinated with Moderna vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)

Reporting group description:

Participants previously vaccinated with Moderna vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)

Reporting group description:

Participants previously vaccinated with Oxford University/AstraZeneca vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)

Reporting group description:

Participants previously vaccinated with protein based vaccine in Phase 2 of the study received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)

Reporting group description:

Participants previously vaccinated with protein based vaccine in Phase 2 of the study received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)

Reporting group description:

Participants previously vaccinated with J&J/Janssen vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)

Reporting group description:

Participants previously vaccinated with J&J/Janssen vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)

Reporting group description:

Participants previously vaccinated with Oxford University/AstraZeneca vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 4 plus B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)

Reporting group description:

Participants previously vaccinated with J&J/Janssen vaccine received a single booster dose of CoV2 preS dTM monovalent D614 antigen dose 1 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Exploratory 1: PBP - CoV2 preS dTM (B.1.351)

Reporting group description:

Participants previously vaccinated with Pfizer mRNA vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 4 with full-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)

Reporting group description:

SARS CoV 2 naïve and unvaccinated participants received CoV2 preS dTM monovalent D614 antigen dose 2 with full-dose of AS03 adjuvant IM injection once daily on Days 1 and 22.

Reporting group title	Phase 3: Exploratory 3: PBP - CoV2 preS dTM (B.1.351)

Reporting group description:

Participants previously vaccinated with Pfizer mRNA vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with half-dose of AS03 adjuvant IM injection between 4 to 10

months after priming vaccine.

Reporting group title	Phase 3: Exploratory 2: PBP - CoV2 preS dTM (B.1.351)

Reporting group description:

Participants previously vaccinated with Pfizer mRNA vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 4 with half-dose of AS03 adjuvant IM injection between 4 to 10 months after priming vaccine.

Reporting group title	Phase 3: Exploratory 4: PBP - CoV2 preS dTM (B.1.351)

Reporting group description:

Participants previously vaccinated with Pfizer mRNA vaccine received a single booster dose of CoV2 preS dTM monovalent B.1.351 antigen dose 1 with no adjuvant IM injection between 4 to 10 months after priming vaccine.

Serious adverse events	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 240 (0.83%)	8 / 328 (2.44%)	4 / 241 (1.66%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal Neoplasm			

subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive Breast Carcinoma			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Ectopic Pregnancy			
subjects affected / exposed	0 / 240 (0.00%)	1 / 328 (0.30%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Antidepressant Discontinuation Syndrome			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Serum Sickness-Like Reaction			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Loss Of Personal Independence In Daily Activities			
subjects affected / exposed	0 / 240 (0.00%)	1 / 328 (0.30%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 240 (0.00%)	1 / 328 (0.30%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 240 (0.00%)	1 / 328 (0.30%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional State			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Animal Bite			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Stoma Complication			

subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand Fracture			
subjects affected / exposed	0 / 240 (0.00%)	1 / 328 (0.30%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head Injury			
subjects affected / exposed	0 / 240 (0.00%)	1 / 328 (0.30%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional Overdose			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Fractures			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Injuries			
subjects affected / exposed	0 / 240 (0.00%)	1 / 328 (0.30%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pain			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road Traffic Accident			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			

subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma Site Pain			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	1 / 240 (0.42%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular Tachycardia			

subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Alcoholic Seizure			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular Accident			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicobrachial Syndrome			
subjects affected / exposed	0 / 240 (0.00%)	1 / 328 (0.30%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss Of Consciousness			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor Neurone Disease			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	1 / 241 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Iron Deficiency Anaemia			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Blindness Unilateral			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Acute			
subjects affected / exposed	0 / 240 (0.00%)	1 / 328 (0.30%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	1 / 241 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis Chronic			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	1 / 241 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Urinary			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Obstruction			
subjects affected / exposed	1 / 240 (0.42%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nephrolithiasis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Inappropriate Antidiuretic Hormone Secretion			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Disorder			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Degeneration			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Abscess			

subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised Infection			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising Fasciitis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Abscess			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological Infection			

subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Abscess			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periumbilical Abscess			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal Disease			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Acute			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes Mellitus			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Ketoacidosis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	1 / 241 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte Imbalance			

subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 240 (2.50%)	9 / 378 (2.38%)	11 / 375 (2.93%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	1 / 375 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			
subjects affected / exposed	0 / 240 (0.00%)	1 / 378 (0.26%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal Neoplasm			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive Breast Carcinoma			

subjects affected / exposed	1 / 240 (0.42%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Ectopic Pregnancy			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Antidepressant Discontinuation Syndrome			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Serum Sickness-Like Reaction			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Loss Of Personal Independence In Daily Activities			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary Embolism			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional State			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	1 / 375 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Animal Bite			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Stoma Complication			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand Fracture			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Head Injury			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional Overdose			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Fractures			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	1 / 375 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Injuries			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pain			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	1 / 375 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road Traffic Accident			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	0 / 240 (0.00%)	1 / 378 (0.26%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma Site Pain			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			

subjects affected / exposed	0 / 240 (0.00%)	1 / 378 (0.26%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular Tachycardia			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Alcoholic Seizure			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular Accident			

subjects affected / exposed	1 / 240 (0.42%)	1 / 378 (0.26%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicobrachial Syndrome			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss Of Consciousness			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor Neurone Disease			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Blindness Unilateral			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	1 / 375 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal Pain			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 240 (0.00%)	1 / 378 (0.26%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	1 / 375 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Acute			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	1 / 375 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			

subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	1 / 375 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis Chronic			
subjects affected / exposed	0 / 240 (0.00%)	1 / 378 (0.26%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	1 / 240 (0.42%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Urinary			
subjects affected / exposed	1 / 240 (0.42%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Obstruction			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	1 / 240 (0.42%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Inappropriate Antidiuretic Hormone Secretion			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	1 / 375 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 240 (0.00%)	2 / 378 (0.53%)	1 / 375 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Disorder			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	1 / 375 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Degeneration			
subjects affected / exposed	1 / 240 (0.42%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Abscess			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 240 (0.00%)	1 / 378 (0.26%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			
subjects affected / exposed	1 / 240 (0.42%)	0 / 378 (0.00%)	1 / 375 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cellulitis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	1 / 375 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised Infection			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising Fasciitis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Abscess			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological Infection			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Abscess			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periumbilical Abscess			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal Disease			

subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	1 / 375 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Acute			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	1 / 240 (0.42%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes Mellitus			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Ketoacidosis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte Imbalance			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 127 (2.36%)	4 / 108 (3.70%)	1 / 111 (0.90%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			

subjects affected / exposed	1 / 127 (0.79%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal Neoplasm			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive Breast Carcinoma			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Ectopic Pregnancy			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General disorders and administration site conditions			
Antidepressant Discontinuation Syndrome			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Serum Sickness-Like Reaction			
subjects affected / exposed	0 / 127 (0.00%)	1 / 108 (0.93%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Loss Of Personal Independence In Daily Activities			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 127 (0.00%)	1 / 108 (0.93%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional State			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Suicidal Ideation			
subjects affected / exposed	1 / 127 (0.79%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Animal Bite			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 127 (0.00%)	1 / 108 (0.93%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Stoma Complication			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand Fracture			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head Injury			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional Overdose			
subjects affected / exposed	1 / 127 (0.79%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Fractures			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Multiple Injuries			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pain			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road Traffic Accident			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma Site Pain			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 127 (0.00%)	1 / 108 (0.93%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			

subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular Tachycardia			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Alcoholic Seizure			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular Accident			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicobrachial Syndrome			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss Of Consciousness			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor Neurone Disease			

subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Blindness Unilateral			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pancreatitis Acute			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis Chronic			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Acute Kidney Injury			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Urinary			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Obstruction			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Inappropriate Antidiuretic Hormone Secretion			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Disorder			

subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Degeneration			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Abscess			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			
subjects affected / exposed	1 / 127 (0.79%)	1 / 108 (0.93%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised Infection			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising Fasciitis			

subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Abscess			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological Infection			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Abscess			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periumbilical Abscess			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal Disease			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Acute			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			

subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes Mellitus			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Ketoacidosis			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte Imbalance			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 113 (2.65%)	4 / 100 (4.00%)	3 / 78 (3.85%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 113 (0.00%)	1 / 100 (1.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			

subjects affected / exposed	0 / 113 (0.00%)	1 / 100 (1.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal Neoplasm			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive Breast Carcinoma			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Ectopic Pregnancy			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Antidepressant Discontinuation Syndrome			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Serum Sickness-Like Reaction			

subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Loss Of Personal Independence In Daily Activities			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional State			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Animal Bite			

subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Stoma Complication			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand Fracture			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head Injury			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional Overdose			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Fractures			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Injuries			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pain			

subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road Traffic Accident			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma Site Pain			
subjects affected / exposed	1 / 113 (0.88%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			

subjects affected / exposed	0 / 113 (0.00%)	1 / 100 (1.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular Tachycardia			
subjects affected / exposed	1 / 113 (0.88%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Alcoholic Seizure			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular Accident			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicobrachial Syndrome			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss Of Consciousness			
subjects affected / exposed	0 / 113 (0.00%)	1 / 100 (1.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor Neurone Disease			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigeminal Neuralgia			

subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Blindness Unilateral			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	1 / 113 (0.88%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Acute			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Small Intestinal Obstruction			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 113 (0.88%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis Chronic			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Calculus Urinary			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Obstruction			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Inappropriate Antidiuretic Hormone Secretion			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Disorder			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Degeneration			

subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Abscess			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	1 / 78 (1.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised Infection			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising Fasciitis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Abscess			

subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological Infection			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Abscess			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periumbilical Abscess			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal Disease			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Acute			
subjects affected / exposed	1 / 113 (0.88%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes Mellitus			

subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Ketoacidosis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte Imbalance			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 132 (2.27%)	3 / 38 (7.89%)	2 / 38 (5.26%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			

subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal Neoplasm			
subjects affected / exposed	1 / 132 (0.76%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive Breast Carcinoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 132 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Ectopic Pregnancy			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Antidepressant Discontinuation Syndrome			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Serum Sickness-Like Reaction			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Loss Of Personal Independence In Daily Activities			

subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional State			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Animal Bite			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			

subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Stoma Complication			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand Fracture			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head Injury			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional Overdose			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Fractures			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Injuries			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pain			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road Traffic Accident			

subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma Site Pain			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
subjects affected / exposed	0 / 132 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	1 / 132 (0.76%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			

subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular Tachycardia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Alcoholic Seizure			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular Accident			
subjects affected / exposed	0 / 132 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicobrachial Syndrome			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss Of Consciousness			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor Neurone Disease			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			

subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Blindness Unilateral			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Acute			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vomiting			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis Chronic			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Urinary			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Urinary Tract Obstruction			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Inappropriate Antidiuretic Hormone Secretion			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Disorder			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Degeneration			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess			

subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Abscess			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised Infection			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising Fasciitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Abscess			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			

subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological Infection			
subjects affected / exposed	1 / 132 (0.76%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Abscess			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periumbilical Abscess			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal Disease			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Acute			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes Mellitus			
subjects affected / exposed	0 / 132 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Ketoacidosis			

subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte Imbalance			
subjects affected / exposed	1 / 132 (0.76%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)	Phase 3: Exploratory 1: PBP - CoV2 preS dTM (B.1.351)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 100 (0.00%)	1 / 103 (0.97%)	2 / 4 (50.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal Neoplasm			

subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive Breast Carcinoma			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Ectopic Pregnancy			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Antidepressant Discontinuation Syndrome			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Serum Sickness-Like Reaction			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Loss Of Personal Independence In Daily Activities			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional State			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Animal Bite			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Stoma Complication			

subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand Fracture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head Injury			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional Overdose			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Fractures			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Injuries			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road Traffic Accident			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			

subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma Site Pain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular Tachycardia			

subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Alcoholic Seizure			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular Accident			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicobrachial Syndrome			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss Of Consciousness			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor Neurone Disease			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Iron Deficiency Anaemia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Blindness Unilateral			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Acute			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 100 (0.00%)	1 / 103 (0.97%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis Chronic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Urinary			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Obstruction			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nephrolithiasis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Inappropriate Antidiuretic Hormone Secretion			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Disorder			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Degeneration			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Abscess			

subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised Infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising Fasciitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Abscess			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological Infection			

subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Abscess			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periumbilical Abscess			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal Disease			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Acute			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes Mellitus			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Ketoacidosis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte Imbalance			

subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)	Phase 3: Exploratory 3: PBP - CoV2 preS dTM (B.1.351)	Phase 3: Exploratory 2: PBP - CoV2 preS dTM (B.1.351)
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 473 (2.96%)	1 / 9 (11.11%)	0 / 8 (0.00%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	1 / 473 (0.21%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal Neoplasm			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive Breast Carcinoma			

subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Ectopic Pregnancy			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Antidepressant Discontinuation Syndrome			
subjects affected / exposed	1 / 473 (0.21%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Serum Sickness-Like Reaction			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Loss Of Personal Independence In Daily Activities			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary Embolism			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional State			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			
subjects affected / exposed	1 / 473 (0.21%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Animal Bite			
subjects affected / exposed	1 / 473 (0.21%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Stoma Complication			
subjects affected / exposed	1 / 473 (0.21%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand Fracture			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Head Injury			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional Overdose			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Fractures			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Injuries			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pain			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road Traffic Accident			
subjects affected / exposed	1 / 473 (0.21%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma Site Pain			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			

subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	1 / 473 (0.21%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular Tachycardia			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Alcoholic Seizure			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular Accident			

subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicobrachial Syndrome			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss Of Consciousness			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor Neurone Disease			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Iron Deficiency Anaemia			
subjects affected / exposed	1 / 473 (0.21%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Blindness Unilateral			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal Pain			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Acute			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	1 / 473 (0.21%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			

subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis Chronic			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Urinary			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Obstruction			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Inappropriate Antidiuretic Hormone Secretion			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Disorder			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Degeneration			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 473 (0.00%)	1 / 9 (11.11%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Abscess			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cellulitis			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised Infection			
subjects affected / exposed	1 / 473 (0.21%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising Fasciitis			
subjects affected / exposed	1 / 473 (0.21%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Abscess			
subjects affected / exposed	1 / 473 (0.21%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	1 / 473 (0.21%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological Infection			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Abscess			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periumbilical Abscess			
subjects affected / exposed	0 / 473 (0.00%)	1 / 9 (11.11%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal Disease			

subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Acute			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes Mellitus			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Ketoacidosis			
subjects affected / exposed	1 / 473 (0.21%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte Imbalance			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 3: Exploratory 4: PBP - CoV2 preS dTM (B.1.351)		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 9 (11.11%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			

subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast Cancer				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant Melanoma				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostate Cancer				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritoneal Neoplasm				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Invasive Breast Carcinoma				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Hypertension				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pregnancy, puerperium and perinatal conditions				
Ectopic Pregnancy				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

General disorders and administration site conditions			
Antidepressant Discontinuation Syndrome			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Serum Sickness-Like Reaction			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Social circumstances			
Loss Of Personal Independence In Daily Activities			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary Embolism			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Confusional State			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Suicidal Ideation				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Animal Bite				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal Stoma Complication				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hand Fracture				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Head Injury				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intentional Overdose				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple Fractures				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Multiple Injuries				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Procedural Pain				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Road Traffic Accident				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal Compression Fracture				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stoma Site Pain				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femur Fracture				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Acute Myocardial Infarction				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Angina Pectoris				

subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial Fibrillation				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Palpitations				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Supraventricular Tachycardia				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Alcoholic Seizure				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular Accident				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervicobrachial Syndrome				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Loss Of Consciousness				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Motor Neurone Disease				

subjects affected / exposed	1 / 9 (11.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Trigeminal Neuralgia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sciatica			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Blindness Unilateral			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Pancreatitis Acute			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small Intestinal Obstruction			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis Chronic			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			

Acute Kidney Injury				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Calculus Urinary				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary Tract Obstruction				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nephrolithiasis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocrine disorders				
Inappropriate Antidiuretic Hormone Secretion				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Arthralgia				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral Disc Disorder				

subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral Disc Degeneration				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Abscess				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anal Abscess				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Covid-19				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Localised Infection				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Necrotising Fasciitis				

subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung Abscess				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neurological Infection				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian Abscess				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Periumbilical Abscess				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pilonidal Disease				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis Acute				
subjects affected / exposed	0 / 9 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary Tract Infection				

subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Diabetes Mellitus			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetic Ketoacidosis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Electrolyte Imbalance			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 1	Phase 3: Cohort 1: PBP - CoV2 preS dTM-AS03 (D614)	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	217 / 240 (90.42%)	281 / 328 (85.67%)	219 / 241 (90.87%)
General disorders and administration site conditions			
Injection Site Pain			
subjects affected / exposed	199 / 240 (82.92%)	259 / 328 (78.96%)	200 / 241 (82.99%)
occurrences (all)	336	260	339
Injection Site Erythema			
subjects affected / exposed	28 / 240 (11.67%)	32 / 328 (9.76%)	26 / 241 (10.79%)
occurrences (all)	31	32	29
Fatigue			
subjects affected / exposed	22 / 240 (9.17%)	9 / 328 (2.74%)	17 / 241 (7.05%)
occurrences (all)	25	9	19
Injection Site Swelling			

subjects affected / exposed	40 / 240 (16.67%)	32 / 328 (9.76%)	37 / 241 (15.35%)
occurrences (all)	42	33	41
Chills			
subjects affected / exposed	97 / 240 (40.42%)	50 / 328 (15.24%)	77 / 241 (31.95%)
occurrences (all)	113	50	90
Malaise			
subjects affected / exposed	138 / 240 (57.50%)	101 / 328 (30.79%)	146 / 241 (60.58%)
occurrences (all)	189	101	190
Pyrexia			
subjects affected / exposed	34 / 240 (14.17%)	15 / 328 (4.57%)	29 / 241 (12.03%)
occurrences (all)	35	16	29
Injection Site Pruritus			
subjects affected / exposed	7 / 240 (2.92%)	4 / 328 (1.22%)	6 / 241 (2.49%)
occurrences (all)	7	4	8
Immune system disorders			
Dust Allergy			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	1 / 240 (0.42%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 240 (1.67%)	8 / 328 (2.44%)	2 / 241 (0.83%)
occurrences (all)	4	8	2
Dyspnoea			
subjects affected / exposed	1 / 240 (0.42%)	2 / 328 (0.61%)	0 / 241 (0.00%)
occurrences (all)	1	2	0
Rhinorrhoea			
subjects affected / exposed	4 / 240 (1.67%)	6 / 328 (1.83%)	1 / 241 (0.41%)
occurrences (all)	4	6	1
Nasal Congestion			
subjects affected / exposed	0 / 240 (0.00%)	4 / 328 (1.22%)	4 / 241 (1.66%)
occurrences (all)	0	4	4
Psychiatric disorders			

Depression			
subjects affected / exposed	1 / 240 (0.42%)	1 / 328 (0.30%)	1 / 241 (0.41%)
occurrences (all)	1	1	1
Injury, poisoning and procedural complications			
Foot Fracture			
subjects affected / exposed	1 / 240 (0.42%)	1 / 328 (0.30%)	0 / 241 (0.00%)
occurrences (all)	2	1	0
Muscle Strain			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences (all)	0	0	0
Skin Laceration			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	141 / 240 (58.75%)	130 / 328 (39.63%)	134 / 241 (55.60%)
occurrences (all)	195	133	198
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	2 / 240 (0.83%)	2 / 328 (0.61%)	3 / 241 (1.24%)
occurrences (all)	3	2	3
Gastrointestinal disorders			
Dental Caries			
subjects affected / exposed	0 / 240 (0.00%)	1 / 328 (0.30%)	0 / 241 (0.00%)
occurrences (all)	0	1	0
Abdominal Pain Lower			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	11 / 240 (4.58%)	2 / 328 (0.61%)	8 / 241 (3.32%)
occurrences (all)	11	2	9
Tooth Impacted			

subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Biliary Colic			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Skin Reaction			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	107 / 240 (44.58%)	91 / 328 (27.74%)	104 / 241 (43.15%)
occurrences (all)	132	94	131
Myalgia			
subjects affected / exposed	143 / 240 (59.58%)	123 / 328 (37.50%)	123 / 241 (51.04%)
occurrences (all)	196	124	166
Infections and infestations			
Breast Abscess			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences (all)	0	0	0
Covid-19			
subjects affected / exposed	5 / 240 (2.08%)	16 / 328 (4.88%)	7 / 241 (2.90%)
occurrences (all)	5	16	7
Nasopharyngitis			
subjects affected / exposed	2 / 240 (0.83%)	3 / 328 (0.91%)	0 / 241 (0.00%)
occurrences (all)	2	3	0
Otitis Externa			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 240 (0.42%)	2 / 328 (0.61%)	3 / 241 (1.24%)
occurrences (all)	1	2	3
Sinusitis			
subjects affected / exposed	2 / 240 (0.83%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences (all)	2	0	0

Post-Acute Covid-19 Syndrome			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences (all)	0	0	0
Suspected Covid-19			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences (all)	0	0	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 240 (0.00%)	0 / 328 (0.00%)	0 / 241 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
subjects affected / exposed	4 / 240 (1.67%)	2 / 328 (0.61%)	2 / 241 (0.83%)
occurrences (all)	4	2	2
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 240 (0.00%)	3 / 328 (0.91%)	3 / 241 (1.24%)
occurrences (all)	0	4	3

Non-serious adverse events	Phase 2: CoV2 preS dTM-AS03 (D614) Formulation 2	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: PBP - CoV2 preS dTM-AS03 (D614 + B.1.351)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	215 / 240 (89.58%)	328 / 378 (86.77%)	331 / 375 (88.27%)
General disorders and administration site conditions			
Injection Site Pain			
subjects affected / exposed	194 / 240 (80.83%)	297 / 378 (78.57%)	301 / 375 (80.27%)
occurrences (all)	331	298	302
Injection Site Erythema			
subjects affected / exposed	41 / 240 (17.08%)	23 / 378 (6.08%)	19 / 375 (5.07%)
occurrences (all)	46	23	19
Fatigue			
subjects affected / exposed	9 / 240 (3.75%)	17 / 378 (4.50%)	13 / 375 (3.47%)
occurrences (all)	11	18	13
Injection Site Swelling			

subjects affected / exposed	39 / 240 (16.25%)	37 / 378 (9.79%)	25 / 375 (6.67%)
occurrences (all)	46	37	25
Chills			
subjects affected / exposed	93 / 240 (38.75%)	74 / 378 (19.58%)	77 / 375 (20.53%)
occurrences (all)	103	75	77
Malaise			
subjects affected / exposed	142 / 240 (59.17%)	122 / 378 (32.28%)	122 / 375 (32.53%)
occurrences (all)	183	124	126
Pyrexia			
subjects affected / exposed	35 / 240 (14.58%)	12 / 378 (3.17%)	18 / 375 (4.80%)
occurrences (all)	36	12	19
Injection Site Pruritus			
subjects affected / exposed	14 / 240 (5.83%)	4 / 378 (1.06%)	2 / 375 (0.53%)
occurrences (all)	15	4	2
Immune system disorders			
Dust Allergy			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 240 (0.00%)	1 / 378 (0.26%)	2 / 375 (0.53%)
occurrences (all)	0	1	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 240 (1.25%)	13 / 378 (3.44%)	12 / 375 (3.20%)
occurrences (all)	4	14	12
Dyspnoea			
subjects affected / exposed	2 / 240 (0.83%)	3 / 378 (0.79%)	1 / 375 (0.27%)
occurrences (all)	2	3	1
Rhinorrhoea			
subjects affected / exposed	4 / 240 (1.67%)	9 / 378 (2.38%)	11 / 375 (2.93%)
occurrences (all)	4	10	11
Nasal Congestion			
subjects affected / exposed	2 / 240 (0.83%)	6 / 378 (1.59%)	5 / 375 (1.33%)
occurrences (all)	2	6	5
Psychiatric disorders			

Depression			
subjects affected / exposed	0 / 240 (0.00%)	3 / 378 (0.79%)	1 / 375 (0.27%)
occurrences (all)	0	3	1
Injury, poisoning and procedural complications			
Foot Fracture			
subjects affected / exposed	0 / 240 (0.00%)	1 / 378 (0.26%)	0 / 375 (0.00%)
occurrences (all)	0	1	0
Muscle Strain			
subjects affected / exposed	0 / 240 (0.00%)	2 / 378 (0.53%)	0 / 375 (0.00%)
occurrences (all)	0	2	0
Skin Laceration			
subjects affected / exposed	0 / 240 (0.00%)	2 / 378 (0.53%)	0 / 375 (0.00%)
occurrences (all)	0	2	0
Nervous system disorders			
Headache			
subjects affected / exposed	134 / 240 (55.83%)	167 / 378 (44.18%)	165 / 375 (44.00%)
occurrences (all)	187	176	179
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	1 / 240 (0.42%)	5 / 378 (1.32%)	4 / 375 (1.07%)
occurrences (all)	1	5	5
Gastrointestinal disorders			
Dental Caries			
subjects affected / exposed	1 / 240 (0.42%)	1 / 378 (0.26%)	2 / 375 (0.53%)
occurrences (all)	1	1	2
Abdominal Pain Lower			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	7 / 240 (2.92%)	9 / 378 (2.38%)	8 / 375 (2.13%)
occurrences (all)	8	9	8
Tooth Impacted			

subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	1 / 375 (0.27%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Biliary Colic			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	1 / 375 (0.27%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Skin Reaction			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	102 / 240 (42.50%)	110 / 378 (29.10%)	114 / 375 (30.40%)
occurrences (all)	134	113	115
Myalgia			
subjects affected / exposed	135 / 240 (56.25%)	145 / 378 (38.36%)	153 / 375 (40.80%)
occurrences (all)	176	148	153
Infections and infestations			
Breast Abscess			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences (all)	0	0	0
Covid-19			
subjects affected / exposed	3 / 240 (1.25%)	34 / 378 (8.99%)	37 / 375 (9.87%)
occurrences (all)	3	35	38
Nasopharyngitis			
subjects affected / exposed	1 / 240 (0.42%)	7 / 378 (1.85%)	2 / 375 (0.53%)
occurrences (all)	1	9	2
Otitis Externa			
subjects affected / exposed	0 / 240 (0.00%)	1 / 378 (0.26%)	0 / 375 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	3 / 240 (1.25%)	7 / 378 (1.85%)	4 / 375 (1.07%)
occurrences (all)	3	7	4
Sinusitis			
subjects affected / exposed	1 / 240 (0.42%)	4 / 378 (1.06%)	7 / 375 (1.87%)
occurrences (all)	1	4	8

Post-Acute Covid-19 Syndrome			
subjects affected / exposed	1 / 240 (0.42%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences (all)	1	0	0
Suspected Covid-19			
subjects affected / exposed	0 / 240 (0.00%)	2 / 378 (0.53%)	3 / 375 (0.80%)
occurrences (all)	0	3	3
Tonsillitis			
subjects affected / exposed	0 / 240 (0.00%)	1 / 378 (0.26%)	3 / 375 (0.80%)
occurrences (all)	0	1	3
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 240 (0.00%)	0 / 378 (0.00%)	0 / 375 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
subjects affected / exposed	3 / 240 (1.25%)	6 / 378 (1.59%)	5 / 375 (1.33%)
occurrences (all)	3	6	6
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 240 (0.42%)	5 / 378 (1.32%)	2 / 375 (0.53%)
occurrences (all)	1	5	2

Non-serious adverse events	Phase 3: Cohort 1: OUAP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 2: MP - CoV2 preS dTM-AS03 (B.1.351)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	115 / 127 (90.55%)	83 / 108 (76.85%)	88 / 111 (79.28%)
General disorders and administration site conditions			
Injection Site Pain			
subjects affected / exposed	100 / 127 (78.74%)	75 / 108 (69.44%)	81 / 111 (72.97%)
occurrences (all)	100	75	81
Injection Site Erythema			
subjects affected / exposed	22 / 127 (17.32%)	4 / 108 (3.70%)	7 / 111 (6.31%)
occurrences (all)	22	4	7
Fatigue			
subjects affected / exposed	4 / 127 (3.15%)	3 / 108 (2.78%)	3 / 111 (2.70%)
occurrences (all)	4	3	3
Injection Site Swelling			

subjects affected / exposed	24 / 127 (18.90%)	4 / 108 (3.70%)	7 / 111 (6.31%)
occurrences (all)	24	4	7
Chills			
subjects affected / exposed	23 / 127 (18.11%)	23 / 108 (21.30%)	23 / 111 (20.72%)
occurrences (all)	23	23	23
Malaise			
subjects affected / exposed	40 / 127 (31.50%)	33 / 108 (30.56%)	39 / 111 (35.14%)
occurrences (all)	40	33	39
Pyrexia			
subjects affected / exposed	3 / 127 (2.36%)	6 / 108 (5.56%)	5 / 111 (4.50%)
occurrences (all)	3	6	5
Injection Site Pruritus			
subjects affected / exposed	1 / 127 (0.79%)	3 / 108 (2.78%)	1 / 111 (0.90%)
occurrences (all)	1	3	1
Immune system disorders			
Dust Allergy			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	7 / 127 (5.51%)	4 / 108 (3.70%)	3 / 111 (2.70%)
occurrences (all)	7	4	3
Dyspnoea			
subjects affected / exposed	1 / 127 (0.79%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	2 / 127 (1.57%)	3 / 108 (2.78%)	3 / 111 (2.70%)
occurrences (all)	2	3	3
Nasal Congestion			
subjects affected / exposed	2 / 127 (1.57%)	2 / 108 (1.85%)	1 / 111 (0.90%)
occurrences (all)	2	2	1
Psychiatric disorders			

Depression			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Foot Fracture			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Muscle Strain			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Skin Laceration			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	45 / 127 (35.43%)	39 / 108 (36.11%)	50 / 111 (45.05%)
occurrences (all)	46	39	51
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Dental Caries			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain Lower			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Tooth Impacted			

subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Biliary Colic			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Skin Reaction			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	22 / 127 (17.32%)	31 / 108 (28.70%)	39 / 111 (35.14%)
occurrences (all)	22	31	40
Myalgia			
subjects affected / exposed	40 / 127 (31.50%)	43 / 108 (39.81%)	48 / 111 (43.24%)
occurrences (all)	41	43	51
Infections and infestations			
Breast Abscess			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Covid-19			
subjects affected / exposed	2 / 127 (1.57%)	9 / 108 (8.33%)	4 / 111 (3.60%)
occurrences (all)	2	9	4
Nasopharyngitis			
subjects affected / exposed	5 / 127 (3.94%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	5	0	0
Otitis Externa			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	2 / 127 (1.57%)	1 / 108 (0.93%)	3 / 111 (2.70%)
occurrences (all)	2	1	3
Sinusitis			
subjects affected / exposed	1 / 127 (0.79%)	0 / 108 (0.00%)	3 / 111 (2.70%)
occurrences (all)	1	0	3

Post-Acute Covid-19 Syndrome			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Suspected Covid-19			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 127 (0.00%)	0 / 108 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 127 (0.00%)	1 / 108 (0.93%)	0 / 111 (0.00%)
occurrences (all)	0	1	0
Urinary Tract Infection			
subjects affected / exposed	3 / 127 (2.36%)	0 / 108 (0.00%)	0 / 111 (0.00%)
occurrences (all)	3	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 127 (0.00%)	4 / 108 (3.70%)	1 / 111 (0.90%)
occurrences (all)	0	4	1

Non-serious adverse events	Phase 3: Cohort 1: MP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (B.1.351)	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (B.1.351)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	97 / 113 (85.84%)	92 / 100 (92.00%)	59 / 78 (75.64%)
General disorders and administration site conditions			
Injection Site Pain			
subjects affected / exposed	89 / 113 (78.76%)	86 / 100 (86.00%)	46 / 78 (58.97%)
occurrences (all)	89	86	46
Injection Site Erythema			
subjects affected / exposed	8 / 113 (7.08%)	8 / 100 (8.00%)	2 / 78 (2.56%)
occurrences (all)	8	8	2
Fatigue			
subjects affected / exposed	2 / 113 (1.77%)	1 / 100 (1.00%)	0 / 78 (0.00%)
occurrences (all)	2	1	0
Injection Site Swelling			
subjects affected / exposed	10 / 113 (8.85%)	8 / 100 (8.00%)	3 / 78 (3.85%)
occurrences (all)	10	8	3

Chills			
subjects affected / exposed	16 / 113 (14.16%)	23 / 100 (23.00%)	15 / 78 (19.23%)
occurrences (all)	16	23	15
Malaise			
subjects affected / exposed	42 / 113 (37.17%)	35 / 100 (35.00%)	25 / 78 (32.05%)
occurrences (all)	43	38	25
Pyrexia			
subjects affected / exposed	1 / 113 (0.88%)	4 / 100 (4.00%)	3 / 78 (3.85%)
occurrences (all)	1	4	3
Injection Site Pruritus			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Immune system disorders			
Dust Allergy			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 113 (3.54%)	4 / 100 (4.00%)	1 / 78 (1.28%)
occurrences (all)	4	4	1
Dyspnoea			
subjects affected / exposed	0 / 113 (0.00%)	1 / 100 (1.00%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	4 / 113 (3.54%)	5 / 100 (5.00%)	0 / 78 (0.00%)
occurrences (all)	4	5	0
Nasal Congestion			
subjects affected / exposed	1 / 113 (0.88%)	3 / 100 (3.00%)	0 / 78 (0.00%)
occurrences (all)	1	3	0
Psychiatric disorders			
Depression			

subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Foot Fracture			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Muscle Strain			
subjects affected / exposed	1 / 113 (0.88%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Skin Laceration			
subjects affected / exposed	1 / 113 (0.88%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	47 / 113 (41.59%)	48 / 100 (48.00%)	20 / 78 (25.64%)
occurrences (all)	49	51	20
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Dental Caries			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain Lower			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 113 (0.88%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Tooth Impacted			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0

Hepatobiliary disorders			
Biliary Colic			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Skin Reaction			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	31 / 113 (27.43%)	30 / 100 (30.00%)	18 / 78 (23.08%)
occurrences (all)	32	30	18
Myalgia			
subjects affected / exposed	41 / 113 (36.28%)	36 / 100 (36.00%)	27 / 78 (34.62%)
occurrences (all)	41	38	27
Infections and infestations			
Breast Abscess			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Covid-19			
subjects affected / exposed	6 / 113 (5.31%)	9 / 100 (9.00%)	13 / 78 (16.67%)
occurrences (all)	6	9	13
Nasopharyngitis			
subjects affected / exposed	0 / 113 (0.00%)	1 / 100 (1.00%)	6 / 78 (7.69%)
occurrences (all)	0	1	6
Otitis Externa			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	2 / 113 (1.77%)	2 / 100 (2.00%)	0 / 78 (0.00%)
occurrences (all)	2	2	0
Sinusitis			
subjects affected / exposed	3 / 113 (2.65%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	3	0	0
Post-Acute Covid-19 Syndrome			

subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Suspected Covid-19			
subjects affected / exposed	0 / 113 (0.00%)	2 / 100 (2.00%)	2 / 78 (2.56%)
occurrences (all)	0	2	2
Tonsillitis			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 113 (0.00%)	0 / 100 (0.00%)	0 / 78 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
subjects affected / exposed	1 / 113 (0.88%)	1 / 100 (1.00%)	1 / 78 (1.28%)
occurrences (all)	1	1	1
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 113 (1.77%)	0 / 100 (0.00%)	2 / 78 (2.56%)
occurrences (all)	2	0	3

Non-serious adverse events	Phase 3: Cohort 2: PP - CoV2 preS dTM-AS03 (D614)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 2: JJJP - CoV2 preS dTM-AS03 (B.1.351)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	112 / 132 (84.85%)	24 / 38 (63.16%)	21 / 38 (55.26%)
General disorders and administration site conditions			
Injection Site Pain			
subjects affected / exposed	96 / 132 (72.73%)	19 / 38 (50.00%)	18 / 38 (47.37%)
occurrences (all)	96	19	18
Injection Site Erythema			
subjects affected / exposed	9 / 132 (6.82%)	3 / 38 (7.89%)	1 / 38 (2.63%)
occurrences (all)	9	3	1
Fatigue			
subjects affected / exposed	4 / 132 (3.03%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	4	0	1
Injection Site Swelling			
subjects affected / exposed	11 / 132 (8.33%)	3 / 38 (7.89%)	0 / 38 (0.00%)
occurrences (all)	11	3	0

Chills			
subjects affected / exposed	38 / 132 (28.79%)	5 / 38 (13.16%)	5 / 38 (13.16%)
occurrences (all)	38	5	5
Malaise			
subjects affected / exposed	61 / 132 (46.21%)	7 / 38 (18.42%)	8 / 38 (21.05%)
occurrences (all)	61	7	8
Pyrexia			
subjects affected / exposed	11 / 132 (8.33%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	11	1	0
Injection Site Pruritus			
subjects affected / exposed	3 / 132 (2.27%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	3	1	0
Immune system disorders			
Dust Allergy			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 132 (3.03%)	2 / 38 (5.26%)	1 / 38 (2.63%)
occurrences (all)	4	2	1
Dyspnoea			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 132 (0.76%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Nasal Congestion			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			

subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Foot Fracture			
subjects affected / exposed	0 / 132 (0.00%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Muscle Strain			
subjects affected / exposed	1 / 132 (0.76%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Skin Laceration			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	51 / 132 (38.64%)	10 / 38 (26.32%)	10 / 38 (26.32%)
occurrences (all)	52	10	10
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	1 / 132 (0.76%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	1 / 132 (0.76%)	1 / 38 (2.63%)	1 / 38 (2.63%)
occurrences (all)	1	1	1
Gastrointestinal disorders			
Dental Caries			
subjects affected / exposed	2 / 132 (1.52%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	2	0	0
Abdominal Pain Lower			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 132 (0.76%)	0 / 38 (0.00%)	3 / 38 (7.89%)
occurrences (all)	1	0	3
Tooth Impacted			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0

Hepatobiliary disorders			
Biliary Colic			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Skin Reaction			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	42 / 132 (31.82%)	7 / 38 (18.42%)	6 / 38 (15.79%)
occurrences (all)	42	7	6
Myalgia			
subjects affected / exposed	61 / 132 (46.21%)	11 / 38 (28.95%)	9 / 38 (23.68%)
occurrences (all)	61	11	9
Infections and infestations			
Breast Abscess			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Covid-19			
subjects affected / exposed	20 / 132 (15.15%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	20	1	0
Nasopharyngitis			
subjects affected / exposed	3 / 132 (2.27%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	4	0	0
Otitis Externa			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	2 / 132 (1.52%)	1 / 38 (2.63%)	0 / 38 (0.00%)
occurrences (all)	2	1	0
Sinusitis			
subjects affected / exposed	1 / 132 (0.76%)	0 / 38 (0.00%)	1 / 38 (2.63%)
occurrences (all)	1	0	1
Post-Acute Covid-19 Syndrome			

subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Suspected Covid-19			
subjects affected / exposed	4 / 132 (3.03%)	2 / 38 (5.26%)	0 / 38 (0.00%)
occurrences (all)	4	2	0
Tonsillitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
subjects affected / exposed	0 / 132 (0.00%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 132 (0.76%)	0 / 38 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Phase 3: Cohort 2: OUAP - CoV2 preS dTM-AS03 (D614 + B.1.351)	Phase 3: Cohort 1: JJJP - CoV2 preS dTM-AS03 (D614)	Phase 3: Exploratory 1: PBP - CoV2 preS dTM (B.1.351)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	97 / 100 (97.00%)	89 / 103 (86.41%)	4 / 4 (100.00%)
General disorders and administration site conditions			
Injection Site Pain			
subjects affected / exposed	85 / 100 (85.00%)	80 / 103 (77.67%)	4 / 4 (100.00%)
occurrences (all)	85	80	4
Injection Site Erythema			
subjects affected / exposed	9 / 100 (9.00%)	5 / 103 (4.85%)	0 / 4 (0.00%)
occurrences (all)	9	5	0
Fatigue			
subjects affected / exposed	6 / 100 (6.00%)	4 / 103 (3.88%)	0 / 4 (0.00%)
occurrences (all)	6	4	0
Injection Site Swelling			
subjects affected / exposed	5 / 100 (5.00%)	6 / 103 (5.83%)	0 / 4 (0.00%)
occurrences (all)	5	6	0

Chills			
subjects affected / exposed	31 / 100 (31.00%)	10 / 103 (9.71%)	0 / 4 (0.00%)
occurrences (all)	31	10	0
Malaise			
subjects affected / exposed	43 / 100 (43.00%)	31 / 103 (30.10%)	1 / 4 (25.00%)
occurrences (all)	43	31	1
Pyrexia			
subjects affected / exposed	7 / 100 (7.00%)	2 / 103 (1.94%)	0 / 4 (0.00%)
occurrences (all)	7	2	0
Injection Site Pruritus			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Dust Allergy			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	1 / 100 (1.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 100 (4.00%)	1 / 103 (0.97%)	0 / 4 (0.00%)
occurrences (all)	4	1	0
Dyspnoea			
subjects affected / exposed	2 / 100 (2.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Rhinorrhoea			
subjects affected / exposed	2 / 100 (2.00%)	1 / 103 (0.97%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Nasal Congestion			
subjects affected / exposed	4 / 100 (4.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	0	0
Psychiatric disorders			
Depression			

subjects affected / exposed	1 / 100 (1.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Foot Fracture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle Strain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin Laceration			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	55 / 100 (55.00%)	37 / 103 (35.92%)	2 / 4 (50.00%)
occurrences (all)	56	37	2
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	1 / 100 (1.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Dental Caries			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain Lower			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 100 (2.00%)	1 / 103 (0.97%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Tooth Impacted			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Hepatobiliary disorders			
Biliary Colic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Skin Reaction			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	35 / 100 (35.00%)	24 / 103 (23.30%)	0 / 4 (0.00%)
occurrences (all)	36	24	0
Myalgia			
subjects affected / exposed	54 / 100 (54.00%)	33 / 103 (32.04%)	2 / 4 (50.00%)
occurrences (all)	54	33	2
Infections and infestations			
Breast Abscess			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Covid-19			
subjects affected / exposed	6 / 100 (6.00%)	5 / 103 (4.85%)	0 / 4 (0.00%)
occurrences (all)	6	5	0
Nasopharyngitis			
subjects affected / exposed	2 / 100 (2.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Otitis Externa			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	2 / 100 (2.00%)	1 / 103 (0.97%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Sinusitis			
subjects affected / exposed	0 / 100 (0.00%)	2 / 103 (1.94%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Post-Acute Covid-19 Syndrome			

subjects affected / exposed	1 / 100 (1.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Suspected Covid-19			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 103 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
subjects affected / exposed	1 / 100 (1.00%)	1 / 103 (0.97%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 100 (1.00%)	3 / 103 (2.91%)	0 / 4 (0.00%)
occurrences (all)	1	3	0

Non-serious adverse events	Phase 3: Comparator: CoV2 preS dTM-AS03 (D614)	Phase 3: Exploratory 3: PBP - CoV2 preS dTM (B.1.351)	Phase 3: Exploratory 2: PBP - CoV2 preS dTM (B.1.351)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	421 / 473 (89.01%)	8 / 9 (88.89%)	7 / 8 (87.50%)
General disorders and administration site conditions			
Injection Site Pain			
subjects affected / exposed	372 / 473 (78.65%)	7 / 9 (77.78%)	5 / 8 (62.50%)
occurrences (all)	590	7	5
Injection Site Erythema			
subjects affected / exposed	77 / 473 (16.28%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	92	0	0
Fatigue			
subjects affected / exposed	40 / 473 (8.46%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	46	0	0
Injection Site Swelling			
subjects affected / exposed	72 / 473 (15.22%)	0 / 9 (0.00%)	1 / 8 (12.50%)
occurrences (all)	86	0	1

Chills			
subjects affected / exposed	160 / 473 (33.83%)	1 / 9 (11.11%)	1 / 8 (12.50%)
occurrences (all)	193	1	1
Malaise			
subjects affected / exposed	241 / 473 (50.95%)	2 / 9 (22.22%)	3 / 8 (37.50%)
occurrences (all)	331	2	4
Pyrexia			
subjects affected / exposed	42 / 473 (8.88%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	44	0	0
Injection Site Pruritus			
subjects affected / exposed	13 / 473 (2.75%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	15	0	0
Immune system disorders			
Dust Allergy			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	3 / 473 (0.63%)	1 / 9 (11.11%)	0 / 8 (0.00%)
occurrences (all)	3	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	33 / 473 (6.98%)	0 / 9 (0.00%)	1 / 8 (12.50%)
occurrences (all)	36	0	1
Dyspnoea			
subjects affected / exposed	7 / 473 (1.48%)	0 / 9 (0.00%)	1 / 8 (12.50%)
occurrences (all)	7	0	1
Rhinorrhoea			
subjects affected / exposed	22 / 473 (4.65%)	0 / 9 (0.00%)	1 / 8 (12.50%)
occurrences (all)	24	0	1
Nasal Congestion			
subjects affected / exposed	13 / 473 (2.75%)	0 / 9 (0.00%)	1 / 8 (12.50%)
occurrences (all)	14	0	1
Psychiatric disorders			
Depression			

subjects affected / exposed	1 / 473 (0.21%)	0 / 9 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Injury, poisoning and procedural complications			
Foot Fracture			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscle Strain			
subjects affected / exposed	0 / 473 (0.00%)	1 / 9 (11.11%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Skin Laceration			
subjects affected / exposed	2 / 473 (0.42%)	1 / 9 (11.11%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	278 / 473 (58.77%)	6 / 9 (66.67%)	3 / 8 (37.50%)
occurrences (all)	406	6	3
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	5 / 473 (1.06%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	6	0	0
Gastrointestinal disorders			
Dental Caries			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Abdominal Pain Lower			
subjects affected / exposed	2 / 473 (0.42%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Nausea			
subjects affected / exposed	26 / 473 (5.50%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	30	0	0
Tooth Impacted			
subjects affected / exposed	0 / 473 (0.00%)	1 / 9 (11.11%)	0 / 8 (0.00%)
occurrences (all)	0	1	0

Hepatobiliary disorders			
Biliary Colic			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Skin Reaction			
subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	228 / 473 (48.20%)	1 / 9 (11.11%)	1 / 8 (12.50%)
occurrences (all)	308	1	1
Myalgia			
subjects affected / exposed	275 / 473 (58.14%)	4 / 9 (44.44%)	2 / 8 (25.00%)
occurrences (all)	371	4	2
Infections and infestations			
Breast Abscess			
subjects affected / exposed	0 / 473 (0.00%)	1 / 9 (11.11%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Covid-19			
subjects affected / exposed	21 / 473 (4.44%)	1 / 9 (11.11%)	0 / 8 (0.00%)
occurrences (all)	21	1	0
Nasopharyngitis			
subjects affected / exposed	2 / 473 (0.42%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Otitis Externa			
subjects affected / exposed	0 / 473 (0.00%)	1 / 9 (11.11%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	7 / 473 (1.48%)	0 / 9 (0.00%)	1 / 8 (12.50%)
occurrences (all)	7	0	1
Sinusitis			
subjects affected / exposed	3 / 473 (0.63%)	1 / 9 (11.11%)	0 / 8 (0.00%)
occurrences (all)	3	2	0
Post-Acute Covid-19 Syndrome			

subjects affected / exposed	0 / 473 (0.00%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Suspected Covid-19			
subjects affected / exposed	1 / 473 (0.21%)	1 / 9 (11.11%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Tonsillitis			
subjects affected / exposed	4 / 473 (0.85%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	5	0	0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 473 (0.00%)	1 / 9 (11.11%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Urinary Tract Infection			
subjects affected / exposed	5 / 473 (1.06%)	0 / 9 (0.00%)	0 / 8 (0.00%)
occurrences (all)	5	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	4 / 473 (0.85%)	0 / 9 (0.00%)	1 / 8 (12.50%)
occurrences (all)	4	0	1

Non-serious adverse events	Phase 3: Exploratory 4: PBP - CoV2 preS dTM (B.1.351)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 9 (66.67%)		
General disorders and administration site conditions			
Injection Site Pain			
subjects affected / exposed	3 / 9 (33.33%)		
occurrences (all)	3		
Injection Site Erythema			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Injection Site Swelling			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Chills			

subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Malaise			
subjects affected / exposed	3 / 9 (33.33%)		
occurrences (all)	3		
Pyrexia			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Injection Site Pruritus			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Dust Allergy			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Nasal Congestion			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		

Injury, poisoning and procedural complications			
Foot Fracture			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Muscle Strain			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Skin Laceration			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 9 (33.33%)		
occurrences (all)	3		
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Lymphadenopathy			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Gastrointestinal disorders			
Dental Caries			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Abdominal Pain Lower			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Nausea			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Tooth Impacted			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			

Biliary Colic			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Skin Reaction			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Myalgia			
subjects affected / exposed	4 / 9 (44.44%)		
occurrences (all)	4		
Infections and infestations			
Breast Abscess			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Covid-19			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Otitis Externa			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Sinusitis			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Post-Acute Covid-19 Syndrome			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		

Suspected Covid-19			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Tonsillitis			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 9 (0.00%)		
occurrences (all)	0		
Urinary Tract Infection			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 April 2021	Amended to clarify that safety, reactogenicity, and immunogenicity data from the Phase 2 study used to determine progression to a Phase 3 and inform dose selection. Revised text to clarify the onset of COVID-like-illness. Halting rule added per Center for Biologics Evaluation and Research non-hold comment.
10 June 2021	The study design changed to add a Supplemental Phase 3 Cohorts (Booster Study 1). Study phase changed. Study name changed to add Supplemental Phase 3 Cohorts. Titles changed to add Supplemental Phase 3 Cohorts. New formulations added for the Supplemental Phase 3 Cohorts. Study Design changed to add the Supplemental Phase 3 Cohorts. Objectives and Endpoints added for the Supplemental Phase 3 Cohorts. Schemas added for the Supplemental Phase 3 Cohorts. Schedule of Activities added for the Supplemental Phase 3 Cohorts.
31 August 2021	Shortened names of vaccine candidates changed. Greek letter names for the virus variants was added, that is Alpha (B.1.1.7), Beta (B.1.351), Delta (B.1.617). Text added to replace pandemic scope text in previous versions. Nonclinical studies text added for monovalent and bivalent vaccine data. Additional objectives for Supplemental Cohorts 1 and 2 added. Modified participant numbers for Cohort 3 subset to 87. Dose formulation text updated. Updated inclusion and exclusion criteria. Removed text for SARS-CoV-2 Virus Neutralization Assays.
12 October 2021	Clarification added to protein-primed dosing groups only. Seroresponse included as conditional secondary endpoint for powered comparisons. New subsection "A Pooled Primary Series Cohort as Supplemental Cohorts 1 and 2 Comparator Group" was added.
19 November 2021	Removed bivalent vaccine candidate arm from Variant Prime Cohort 3. Participants numbers changed in monovalent arms. Total participant numbers changed due to no bivalent arm in Variant Prime Cohort 3. Definition of COVID-19 was changed. Updated the Section "Variant Prime Cohort 3 statistical analysis".
20 January 2022	Removed Supplemental Variant Prime Cohort 3. Total participant numbers changed for removal of Variant Prime Cohort 3 participants. Updated the Section "List of potential immune-mediated diseases".

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported