Clinical trial results:
A Phase 2, Long-Term Immunogenicity Follow-up Trial of Adult and Elderly Subjects who have Previously Received an Intramuscular Injection of Norovirus GI.1/GII.4 Bivalent Virus-Like Particle Vaccine

Summary

EudraCT number	2016-004288-37
Trial protocol	BE
Global end of trial date	22 July 2021

Results information

Result version number	v1 (current)
This version publication date	09 August 2022
First version publication date	09 August 2022

Trial information

Trial identification

Sponsor protocol code	NOR-213

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03039790
WHO universal trial number (UTN)	U1111-1189-7907

Notes:

Sponsors

Sponsor organisation name	HilleVax
Sponsor organisation address	Blvd Lilienthal 42, Glattpark-Opfikon (Zurich), Switzerland, 8152
Public contact	Paul Bavier, HilleVax, +1 6172063351, pbavier@hillevax.com
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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	04 July 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 July 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial is to evaluate the humoral response after at least 1 dose of NoV vaccine up to 5 years after intramuscular (IM injection as measured by histo-blood group antigen (HBGA) blocking assay.

Protection of trial subjects:

All the participants were required to read and sign the Informed Consent Form (ICF).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 February 2017
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	Belgium: 345
Country: Number of subjects enrolled	United States: 183
Worldwide total number of subjects	528
EEA total number of subjects	345

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)	405
From 65 to 84 years	86
85 years and over	37

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at 11 investigational sites in Belgium (9 sites) and the United States (2 sites) from 21 February 2017 to 22 July 2021.

Pre-assignment

Screening details:

Healthy volunteers who previously received NoV vaccine in studies NOR-107 (NCT02038907), NOR-210 (NCT02475278) and NOR-204 (NCT02661490) were assessed in this study for up to 5 years. No additional doses of vaccine were administered.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	NOR-107: GI.1/GII.4 (15/15/500) µg- MPL 50 µg,1-Dose

Arm description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, intramuscular (IM), on Day 1, followed by norovirus bivalent virus like particle (VLP) vaccine (15 µg of GI.1 norovirus virus VLP and 15 µg GII.4 norovirus VLP) adjuvanted with 50 µg monophosphoryl lipid A (MPL) and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Norovirus Bivalent Virus-Like Particle (VLP) Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Norovirus GI.1/GII.4 bivalent VLP vaccine IM injection

Investigational medicinal product name	Hepatitis A Vaccine
Investigational medicinal product code	
Other name	Havrix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Hepatitis A vaccine, intramuscular injection (IM)

Arm title	NOR-107: GI.1/GII.4 (15/50/500) µg- MPL 50 µg,1-Dose

Arm description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 50 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Hepatitis A Vaccine
Investigational medicinal product code	
Other name	Havrix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details: Hepatitis A vaccine, intramuscular injection (IM)	
Investigational medicinal product name	Norovirus Bivalent Virus-Like Particle (VLP) Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: Norovirus GI.1/GII.4 bivalent VLP vaccine IM injection	
Arm title	NOR-107: GI.1/GII.4 (50/50/500) µg- MPL 50 µg,1-Dose

Arm description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 50 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Hepatitis A Vaccine
Investigational medicinal product code	
Other name	Havrix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: Hepatitis A vaccine, intramuscular injection (IM)	
Investigational medicinal product name	Norovirus Bivalent Virus-Like Particle (VLP) Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: Norovirus GI.1/GII.4 bivalent VLP vaccine IM injection	
Arm title	NOR-107: GI.1/GII.4 (15/15/500) µg- MPL 15 µg,1-Dose

Arm description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 15 µg GII.4 norovirus VLP) adjuvanted with 15 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Hepatitis A Vaccine
Investigational medicinal product code	
Other name	Havrix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: Hepatitis A vaccine, intramuscular injection (IM)	
Investigational medicinal product name	Norovirus Bivalent Virus-Like Particle (VLP) Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: Norovirus GI.1/GII.4 bivalent VLP vaccine IM injection	
Arm title	NOR-107: GI.1/GII.4 (15/50/500) µg- MPL 15 µg,1-Dose

Arm description:

Eligible NOR-107 participants who had received IM hepatitis A vaccine on Day 1, followed by IM norovirus bivalent vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 15 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Norovirus Bivalent Virus-Like Particle (VLP) Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Norovirus GI.1/GII.4 bivalent VLP vaccine IM injection

Investigational medicinal product name	Hepatitis A Vaccine
Investigational medicinal product code	
Other name	Havrix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Hepatitis A vaccine, intramuscular injection (IM)

Arm title	NOR-107: GI.1/GII.4 (50/50/500) µg- MPL 15 µg,1-Dose

Arm description:

Eligible NOR-107 participants who received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 15 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Norovirus Bivalent Virus-Like Particle (VLP) Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Norovirus GI.1/GII.4 bivalent VLP vaccine IM injection

Investigational medicinal product name	Hepatitis A Vaccine
Investigational medicinal product code	
Other name	Havrix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Hepatitis A vaccine, intramuscular injection (IM)

Arm title	NOR-107: GI.1/GII.4 (15/15/500) µg,1-Dose

Arm description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 15 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Hepatitis A Vaccine
Investigational medicinal product code	
Other name	Havrix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Hepatitis A vaccine, intramuscular injection (IM)

Investigational medicinal product name	Norovirus Bivalent Virus-Like Particle (VLP) Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Norovirus GI.1/GII.4 bivalent VLP vaccine IM injection

Arm title	NOR-107: GI.1/GII.4 (15/50/500) µg,1-Dose

Arm description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Norovirus Bivalent Virus-Like Particle (VLP) Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Norovirus GI.1/GII.4 bivalent VLP vaccine IM injection

Investigational medicinal product name	Hepatitis A Vaccine
Investigational medicinal product code	
Other name	Havrix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Hepatitis A vaccine, intramuscular injection (IM)

Arm title	NOR-107: GI.1/GII.4 (50/50/500) µg,1-Dose

Arm description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Hepatitis A Vaccine
Investigational medicinal product code	
Other name	Havrix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Hepatitis A vaccine, intramuscular injection (IM)

Investigational medicinal product name	Norovirus Bivalent Virus-Like Particle (VLP) Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Norovirus GI.1/GII.4 bivalent VLP vaccine IM injection

Arm title	NOR-107: GI.1/GII.4 (50/150/500) µg,1-Dose

Arm description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 150 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Hepatitis A Vaccine
Investigational medicinal product code	
Other name	Havrix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Hepatitis A vaccine, intramuscular injection (IM)

Investigational medicinal product name	Norovirus Bivalent Virus-Like Particle (VLP) Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Norovirus GI.1/GII.4 bivalent VLP vaccine IM injection

Arm title	NOR-107: GI.1/GII.4 (15/50/167) µg,1-Dose

Arm description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 167 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Norovirus Bivalent Virus-Like Particle (VLP) Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Norovirus GI.1/GII.4 bivalent VLP vaccine IM injection

Investigational medicinal product name	Hepatitis A Vaccine
Investigational medicinal product code	
Other name	Havrix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Hepatitis A vaccine, intramuscular injection (IM)

Arm title	NOR-107: GI.1/GII.4 (15/50/500) µg,2-Dose

Arm description:

Eligible NOR-107 participants who had received Norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, IM, on Day 1 and Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Norovirus Bivalent Virus-Like Particle (VLP) Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Norovirus GI.1/GII.4 bivalent VLP vaccine IM injection

Arm title	NOR-107: GI.1/GII.4 (50/150/500) µg,2-Dose

Arm description:

Eligible NOR-107 participants who had received Norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 150 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, IM, on Day 1 and Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Norovirus Bivalent Virus-Like Particle (VLP) Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Norovirus GI.1/GII.4 bivalent VLP vaccine IM injection

Arm title	NOR-107: GI.1/GII.4 (15/50/167) µg,2-Dose

Arm description:

Eligible NOR-107 participants who had received Norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 167 µg aluminium hydroxide, IM, on Day 1 and Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Norovirus Bivalent Virus-Like Particle (VLP) Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Norovirus GI.1/GII.4 bivalent VLP vaccine IM injection

Arm title	NOR-210: GI.1/GII.4 (15/50/500) µg, 1-Dose

Arm description:

Eligible NOR-210 participants who had received Norovirus GI.1/GII.4 bivalent VLP vaccine NoV Vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP, adjuvanted with 500 µg aluminium hydroxide), IM injection, once on Day 1 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Norovirus Bivalent Virus-Like Particle (VLP) Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Norovirus GI.1/GII.4 bivalent VLP vaccine IM injection

Arm title	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose

Arm description:

Eligible NOR-204 participants who had received Norovirus bivalent placebo-matching vaccine, intramuscularly (IM), on Day 1, followed by norovirus (NoV) [15 µg of GI.1 and 50 µg of GII.4 bivalent virus-like particle (VLP)] adjuvanted with 500 µg aluminium hydroxide and 15 µg of monophosphoryl lipid A (MPL) (Composition B), on Day 29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Arm type	Experimental

Investigational medicinal product name	Hepatitis A Vaccine
Investigational medicinal product code	
Other name	Havrix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Hepatitis A vaccine, intramuscular injection (IM)

Arm title	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 60-94 Yrs)

Arm description:

Eligible NOR-204 participants of age 60-94 years who had received Norovirus bivalent placebo-matching vaccine, IM, on Day 1, followed by norovirus (NoV) [15 µg of GI.1 and 50 µg of GII.4 bivalent virus-like particle (VLP)] adjuvanted with 500 µg aluminium hydroxide (Composition A), on Day 29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Hepatitis A Vaccine
Investigational medicinal product code	
Other name	Havrix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Hepatitis A vaccine, intramuscular injection (IM)

Arm title	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 18-49 Yrs)

Arm description:

Eligible NOR-204 participants of age 18-49 years who had received Norovirus bivalent placebo-matching vaccine, IM, on Day 1, followed by norovirus (NoV) [15 µg of GI.1 and 50 µg of GII.4 bivalent virus-like particle (VLP)] adjuvanted with 500 µg aluminium hydroxide (Composition A), on Day 29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Hepatitis A Vaccine
Investigational medicinal product code	
Other name	Havrix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Hepatitis A vaccine, intramuscular injection (IM)

Arm title	NOR-204: GI.1/GII.4 (15/50/500/15) µg - MPL 15 µg, 2-Dose

Arm description:

Eligible NOR-204 participants who had received Norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide and 15 µg of MPL (Composition B), IM, on Day 1 and Day 29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Hepatitis A Vaccine
Investigational medicinal product code	
Other name	Havrix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Hepatitis A vaccine, intramuscular injection (IM)

Arm title	NOR-204: GI.1/GII.4 (15/50/500) µg, 2-Dose

Arm description:

Eligible NOR-204 participants who had received Norovirus bivalent VLP vaccine (15 µg of GI.1 50 µg of GII.4 bivalent VLP) adjuvanted with 500 µg aluminium hydroxide (Composition A) IM, on Day 1 and Day

29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Arm type	Experimental
Investigational medicinal product name	Hepatitis A Vaccine
Investigational medicinal product code	
Other name	Havrix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Hepatitis A vaccine, intramuscular injection (IM)

Number of subjects in period 1	NOR-107: GI.1/GII.4 (15/15/500) µg-	NOR-107: GI.1/GII.4 (15/50/500) µg-MPL 50 µg,1-Dose	NOR-107: GI.1/GII.4 (50/50/500) µg-
Started	25	19	27
Per Protocol Set (PPS)	25	19	27
Completed	21	19	26
Not completed	4	0	1
Withdrawal of Consent	1	-	-
Adverse event, serious fatal	-	-	-
Reason, not Specified	1	-	-
Lost to follow-up	2	-	1

Number of subjects in period 1	NOR-107: GI.1/GII.4 (15/15/500) µg-	NOR-107: GI.1/GII.4 (15/50/500) µg-MPL 15 µg,1-Dose	NOR-107: GI.1/GII.4 (50/50/500) µg-
Started	27	23	27
Per Protocol Set (PPS)	26	23	27
Completed	25	23	26
Not completed	2	0	1
Withdrawal of Consent	1	-	-
Adverse event, serious fatal	-	-	-
Reason, not Specified	-	-	-
Lost to follow-up	1	-	1

Number of subjects in period 1	NOR-107: GI.1/GII.4 (15/15/500) µg,1-	NOR-107: GI.1/GII.4 (15/50/500) µg,1-Dose	NOR-107: GI.1/GII.4 (50/50/500) µg,1-
Started	25	28	22
Per Protocol Set (PPS)	25	28	22
Completed	24	27	22
Not completed	1	1	0
Withdrawal of Consent	-	-	-
Adverse event, serious fatal	-	-	-
Reason, not Specified	-	-	-
Lost to follow-up	1	1	-

Number of subjects in period 1	NOR-107: GI.1/GII.4 (50/150/500) µg,1-	NOR-107: GI.1/GII.4 (15/50/167) µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/500) µg,2-
Started	28	21	25
Per Protocol Set (PPS)	28	19 [1]	25
Completed	26	20	25
Not completed	2	1	0
Withdrawal of Consent	1	-	-
Adverse event, serious fatal	-	-	-
Reason, not Specified	-	-	-
Lost to follow-up	1	1	-

Number of subjects in period 1	NOR-107: GI.1/GII.4 (50/150/500) µg,2-	NOR-107: GI.1/GII.4 (15/50/167) µg,2-Dose	NOR-210: GI.1/GII.4 (15/50/500) µg, 1-
Started	24	24	24
Per Protocol Set (PPS)	24	24	24
Completed	21	24	20
Not completed	3	0	4
Withdrawal of Consent	2	-	1
Adverse event, serious fatal	-	-	-
Reason, not Specified	-	-	-
Lost to follow-up	1	-	3

Number of subjects in period 1	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 60-94 Yrs)	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 18-49
Started	29	39	14
Per Protocol Set (PPS)	29	39	14
Completed	22	29	12
Not completed	7	10	2
Withdrawal of Consent	5	3	-
Adverse event, serious fatal	1	3	-
Reason, not Specified	-	2	-
Lost to follow-up	1	2	2

Number of subjects in period 1	NOR-204: GI.1/GII.4 (15/50/500/15) µg - MPL 15 µg, 2-Dose	NOR-204: GI.1/GII.4 (15/50/500) µg, 2-Dose
Started	35	42
Per Protocol Set (PPS)	35	42
Completed	29	34
Not completed	6	8
Withdrawal of Consent	2	5
Adverse event, serious fatal	2	-
Reason, not Specified	1	-

Lost to follow-up	1	3

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Per Protocol Set (PPS) included all participants in the FAS who had no major or critical protocol violations that potentially confound the primary endpoint.

Baseline characteristics

Reporting groups

Reporting group title	NOR-107: GI.1/GII.4 (15/15/500) µg- MPL 50 µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, intramuscular (IM), on Day 1, followed by norovirus bivalent virus like particle (VLP) vaccine (15 µg of GI.1 norovirus virus VLP and 15 µg GII.4 norovirus VLP) adjuvanted with 50 µg monophosphoryl lipid A (MPL) and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/50/500) µg- MPL 50 µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 50 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (50/50/500) µg- MPL 50 µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 50 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/15/500) µg- MPL 15 µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 15 µg GII.4 norovirus VLP) adjuvanted with 15 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/50/500) µg- MPL 15 µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received IM hepatitis A vaccine on Day 1, followed by IM norovirus bivalent vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 15 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (50/50/500) µg- MPL 15 µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 15 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/15/500) µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 15 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/50/500) µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (50/50/500) µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (50/150/500) µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 150 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/50/167) µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 167 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/50/500) µg,2-Dose

Reporting group description:

Eligible NOR-107 participants who had received Norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, IM, on Day 1 and Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (50/150/500) µg,2-Dose

Reporting group description:

Eligible NOR-107 participants who had received Norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 150 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, IM, on Day 1 and Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/50/167) µg,2-Dose

Reporting group description:

Eligible NOR-107 participants who had received Norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 167 µg aluminium hydroxide, IM, on Day 1 and Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-210: GI.1/GII.4 (15/50/500) µg, 1-Dose

Reporting group description:

Eligible NOR-210 participants who had received Norovirus GI.1/GII.4 bivalent VLP vaccine NoV Vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP, adjuvanted with 500 µg aluminium hydroxide), IM injection, once on Day 1 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose

Reporting group description:

Eligible NOR-204 participants who had received Norovirus bivalent placebo-matching vaccine, intramuscularly (IM), on Day 1, followed by norovirus (NoV) [15 µg of GI.1 and 50 µg of GII.4 bivalent virus-like particle (VLP)] adjuvanted with 500 µg aluminium hydroxide and 15 µg of monophosphoryl lipid A (MPL) (Composition B), on Day 29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 60-94 Yrs)

Reporting group description:

Eligible NOR-204 participants of age 60-94 years who had received Norovirus bivalent placebo-matching vaccine, IM, on Day 1, followed by norovirus (NoV) [15 µg of GI.1 and 50 µg of GII.4 bivalent virus-like particle (VLP)] adjuvanted with 500 µg aluminium hydroxide (Composition A), on Day 29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 18-49 Yrs)

Reporting group description:

Eligible NOR-204 participants of age 18-49 years who had received Norovirus bivalent placebo-matching vaccine, IM, on Day 1, followed by norovirus (NoV) [15 µg of GI.1 and 50 µg of GII.4 bivalent virus-like particle (VLP)] adjuvanted with 500 µg aluminium hydroxide (Composition A), on Day 29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-204: GI.1/GII.4 (15/50/500/15) µg - MPL 15 µg, 2-Dose

Reporting group description:

Eligible NOR-204 participants who had received Norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide and 15 µg of MPL (Composition B), IM, on Day 1 and Day 29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-204: GI.1/GII.4 (15/50/500) µg, 2-Dose

Reporting group description:

Eligible NOR-204 participants who had received Norovirus bivalent VLP vaccine (15 µg of GI.1 50 µg of

Reporting group values	NOR-107: GI.1/GII.4 (15/15/500) µg-	NOR-107: GI.1/GII.4 (15/50/500) µg-MPL 50 µg,1-Dose	NOR-107: GI.1/GII.4 (50/50/500) µg-
Number of subjects	25	19	27
Age Categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	48.1	47.9	46.8
standard deviation	± 14.24	± 14.60	± 13.39
Gender categorical			
Units: Subjects			
Female	16	13	19
Male	9	6	8
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	0	0	0
Unknown or Not Reported	25	19	27
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	25	19	27
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	NOR-107: GI.1/GII.4 (15/15/500) µg-	NOR-107: GI.1/GII.4 (15/50/500) µg-MPL 15 µg,1-Dose	NOR-107: GI.1/GII.4 (50/50/500) µg-
Number of subjects	27	23	27
Age Categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	47.5	48.0	48.0
standard deviation	± 13.96	± 13.49	± 13.13
Gender categorical			
Units: Subjects			
Female	20	14	21
Male	7	9	6

Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	0	0	0
Unknown or Not Reported	27	23	27
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	26	23	26
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	NOR-107: GI.1/GII.4 (15/15/500) µg,1-	NOR-107: GI.1/GII.4 (15/50/500) µg,1-Dose	NOR-107: GI.1/GII.4 (50/50/500) µg,1-
Number of subjects	25	28	22
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	45.4	46.8	45.5
standard deviation	± 13.63	± 13.59	± 13.23
Gender categorical Units: Subjects			
Female	12	14	16
Male	13	14	6
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	0	0	0
Unknown or Not Reported	25	28	22
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	25	28	22
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	NOR-107: GI.1/GII.4 (50/150/500) µg,1-	NOR-107: GI.1/GII.4 (15/50/167) µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/500) µg,2-
Number of subjects	28	21	25

Age Categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	44.0	41.9	42.6
standard deviation	± 15.20	± 16.17	± 13.33
Gender categorical Units: Subjects			
Female	21	12	15
Male	7	9	10
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	0	0	0
Unknown or Not Reported	28	21	25
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	27	21	25
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	NOR-107: GI.1/GII.4 (50/150/500) µg,2-	NOR-107: GI.1/GII.4 (15/50/167) µg,2-Dose	NOR-210: GI.1/GII.4 (15/50/500) µg, 1-
Number of subjects	24	24	24
Age Categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	47.3	46.3	35.0
standard deviation	± 13.98	± 15.17	± 9.44
Gender categorical Units: Subjects			
Female	18	16	10
Male	6	8	14
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	5
Not Hispanic or Latino	0	0	19
Unknown or Not Reported	24	24	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0

Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	7
White	24	24	16
More than one race	0	0	1
Unknown or Not Reported	0	0	0

Reporting group values	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 60-94 Yrs)	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 18-49
Number of subjects	29	39	14
Age Categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	73.6	77.2	35.6
standard deviation	± 8.50	± 9.48	± 7.27
Gender categorical			
Units: Subjects			
Female	20	19	7
Male	9	20	7
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1	2	1
Not Hispanic or Latino	28	37	13
Unknown or Not Reported	0	0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	0
Native Hawaiian or Other Pacific Islander	0	0	1
Black or African American	1	0	1
White	28	38	12
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	NOR-204: GI.1/GII.4 (15/50/500/15) µg - MPL 15 µg, 2-Dose	NOR-204: GI.1/GII.4 (15/50/500) µg, 2-Dose	Total
Number of subjects	35	42	528
Age Categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	76.9	76.1	
standard deviation	± 9.94	± 8.41	-
Gender categorical			
Units: Subjects			
Female	18	23	324

Male	17	19	204

Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	3	3	15
Not Hispanic or Latino	32	39	168
Unknown or Not Reported	0	0	345
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	4
Native Hawaiian or Other Pacific Islander	0	0	1
Black or African American	0	3	12
White	35	39	510
More than one race	0	0	1
Unknown or Not Reported	0	0	0

End points reporting groups

Reporting group title	NOR-107: GI.1/GII.4 (15/15/500) µg- MPL 50 µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, intramuscular (IM), on Day 1, followed by norovirus bivalent virus like particle (VLP) vaccine (15 µg of GI.1 norovirus virus VLP and 15 µg GII.4 norovirus VLP) adjuvanted with 50 µg monophosphoryl lipid A (MPL) and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/50/500) µg- MPL 50 µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 50 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (50/50/500) µg- MPL 50 µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 50 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/15/500) µg- MPL 15 µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 15 µg GII.4 norovirus VLP) adjuvanted with 15 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/50/500) µg- MPL 15 µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received IM hepatitis A vaccine on Day 1, followed by IM norovirus bivalent vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 15 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (50/50/500) µg- MPL 15 µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 15 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/15/500) µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 15 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/50/500) µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (50/50/500) µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (50/150/500) µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 150 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/50/167) µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 167 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/50/500) µg,2-Dose

Reporting group description:

Eligible NOR-107 participants who had received Norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, IM, on Day 1 and Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (50/150/500) µg,2-Dose

Reporting group description:

Eligible NOR-107 participants who had received Norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 150 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, IM, on Day 1 and Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/50/167) µg,2-Dose

Reporting group description:

Eligible NOR-107 participants who had received Norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 167 µg aluminium hydroxide, IM, on Day 1 and Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-210: GI.1/GII.4 (15/50/500) µg, 1-Dose

Reporting group description:

Eligible NOR-210 participants who had received Norovirus GI.1/GII.4 bivalent VLP vaccine NoV Vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP, adjuvanted with 500 µg aluminium hydroxide), IM injection, once on Day 1 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose

Reporting group description:

Eligible NOR-204 participants who had received Norovirus bivalent placebo-matching vaccine, intramuscularly (IM), on Day 1, followed by norovirus (NoV) [15 µg of GI.1 and 50 µg of GII.4 bivalent virus-like particle (VLP)] adjuvanted with 500 µg aluminium hydroxide and 15 µg of monophosphoryl lipid A (MPL) (Composition B), on Day 29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 60-94 Yrs)

Reporting group description:

Eligible NOR-204 participants of age 60-94 years who had received Norovirus bivalent placebo-matching vaccine, IM, on Day 1, followed by norovirus (NoV) [15 µg of GI.1 and 50 µg of GII.4 bivalent virus-like particle (VLP)] adjuvanted with 500 µg aluminium hydroxide (Composition A), on Day 29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 18-49 Yrs)

Reporting group description:

Eligible NOR-204 participants of age 18-49 years who had received Norovirus bivalent placebo-matching vaccine, IM, on Day 1, followed by norovirus (NoV) [15 µg of GI.1 and 50 µg of GII.4 bivalent virus-like particle (VLP)] adjuvanted with 500 µg aluminium hydroxide (Composition A), on Day 29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-204: GI.1/GII.4 (15/50/500/15) µg - MPL 15 µg, 2-Dose

Reporting group description:

Eligible NOR-204 participants who had received Norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide and 15 µg of MPL (Composition B), IM, on Day 1 and Day 29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-204: GI.1/GII.4 (15/50/500) µg, 2-Dose

Reporting group description:

Eligible NOR-204 participants who had received Norovirus bivalent VLP vaccine (15 µg of GI.1 50 µg of

GII.4 bivalent VLP) adjuvanted with 500 µg aluminium hydroxide (Composition A) IM, on Day 1 and Day 29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Primary: Geometric Mean Blocking Titers 50 percent (%) (GMBT50) of Anti-norovirus GI.1 VLP Antibodies as measured by Histo-Blood Group Antigen (HBGA) blocking assay

End point title	Geometric Mean Blocking Titers 50 percent (%) (GMBT50) of Anti-norovirus GI.1 VLP Antibodies as measured by Histo-Blood Group Antigen (HBGA) blocking assay[1]

End point description:

GMBT50 of anti-norovirus GI. VLP antibody titers as measured by HBGA blocking assay. Data reported for up to Year 5 was collected at Baseline,Days 28,29,36,56,57,208,211 Year 2,3,4, and 5.PPS=all participants in the FAS who had no major or critical protocol violations.n=number of participants with data available for analysis at specific timepoints.Baseline(n=25,19,27,26,23,27,25,28,22,28,19,25,24,24,24,29,39,14,35,42)D28(n=25,19,26,26,23,27,25,28,21,28,19,25,24,24)D29(n=24,29,39,14,35,42)D36(n=29,39,14,35,42)D56(n=25,19,27,26,23,27,25,28,22,28,19,25,24,24)D57(n=29,39,14,35,42)D208(n=25,19,27,26,23,27,25,28,22,28,19,25,24,24)D211(n=29,39,14,35,42)Y2(n=24,26,37,10,32,34)Y3(n=24,19,27,26,23,26,25,28,22,27,19,25,24,24,21,24,35,13,29,37)Y4(n=23,19,26,26,23,26,23,28,22,28,19,25,23,24,20,18,22,11,20,27)Y5(n=21,19,26,24,23,26,24,27,22,25,19,24,21,24,19,8,13,10,10,16).999,9999,99999=No participants were analyzed at specific timepoints in NOR-107,NOR-210,NOR-204 study respectively.

End point type	Primary

End point timeframe:

Up to 5 years post-primary 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: No statistical analysis was performed for this primary endpoint.

End point values	NOR-107: GI.1/GII.4 (15/15/500) µg- MPL 50 µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/500) µg- MPL 50 µg,1-Dose	NOR-107: GI.1/GII.4 (50/50/500) µg- MPL 50 µg,1-Dose	NOR-107: GI.1/GII.4 (15/15/500) µg- MPL 15 µg,1-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	19	27	26
Units: titer				
geometric mean (confidence interval 95%)				
Baseline	27.4 (17.5 to 42.9)	18.3 (13.4 to 24.9)	26.3 (17.4 to 39.6)	24.6 (15.5 to 38.9)
Day 28	27.7 (18.2 to 42.2)	18.1 (13.2 to 24.8)	23.8 (16.4 to 34.5)	24.0 (15.4 to 37.3)
Day 29	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 36	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 56	309.7 (168.7 to 568.4)	256.9 (136.3 to 484.0)	380.9 (227.0 to 639.2)	255.4 (132.3 to 493.1)
Day 57	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 208	143.5 (84.7 to 243.2)	109.1 (62.9 to 189.1)	154.8 (95.7 to 250.4)	125.6 (74.9 to 210.8)
Day 211	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 2	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)

Year 3	79.6 (48.9 to 129.7)	53.7 (32.8 to 88.0)	77.2 (49.1 to 121.3)	72.4 (44.0 to 119.1)
Year 4	70.5 (38.0 to 130.9)	47.5 (27.3 to 82.7)	68.6 (38.6 to 122.0)	54.0 (30.4 to 96.1)
Year 5	71.0 (37.8 to 133.6)	42.5 (25.0 to 72.4)	80.5 (45.0 to 144.0)	54.4 (30.8 to 96.2)

End point values	NOR-107: GI.1/GII.4 (15/50/500) µg- MPL 15 µg,1-Dose	NOR-107: GI.1/GII.4 (50/50/500) µg- MPL 15 µg,1-Dose	NOR-107: GI.1/GII.4 (15/15/500) µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/500) µg,1-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	27	25	28
Units: titer				
geometric mean (confidence interval 95%)				
Baseline	19.0 (15.5 to 23.2)	23.9 (17.2 to 33.2)	35.1 (21.7 to 56.9)	24.3 (16.5 to 35.8)
Day 28	17.4 (14.5 to 20.9)	21.9 (16.1 to 29.9)	29.9 (20.2 to 44.2)	24.9 (17.2 to 36.1)
Day 29	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 36	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 56	252.9 (136.7 to 468.1)	329.2 (192.9 to 561.9)	369.5 (221.0 to 617.8)	350.4 (194.5 to 631.2)
Day 57	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 208	86.4 (50.5 to 148.1)	137.9 (93.7 to 202.8)	168.9 (109.1 to 261.5)	175.4 (111.6 to 275.6)
Day 211	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 2	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 3	51.5 (33.1 to 80.1)	55.5 (35.4 to 86.8)	98.0 (65.1 to 147.5)	90.2 (60.1 to 135.5)
Year 4	54.8 (30.2 to 99.7)	49.3 (31.5 to 77.2)	84.9 (49.6 to 145.2)	67.3 (41.1 to 109.9)
Year 5	50.5 (28.7 to 89.1)	54.5 (31.0 to 96.0)	77.2 (48.4 to 123.1)	82.2 (49.0 to 137.7)

End point values	NOR-107: GI.1/GII.4 (50/50/500) µg,1-Dose	NOR-107: GI.1/GII.4 (50/150/500) µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/167) µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/500) µg,2-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	28	19	25
Units: titer				
geometric mean (confidence interval 95%)				
Baseline	26.1 (16.8 to 40.5)	23.9 (17.5 to 32.7)	33.4 (19.4 to 57.6)	23.1 (16.4 to 32.6)
Day 28	27.3 (17.2 to 43.4)	25.8 (18.3 to 36.3)	34.9 (20.8 to 58.5)	382.6 (200.9 to 728.5)

Day 29	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 36	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 56	527.0 (264.1 to 1051.5)	274.3 (171.6 to 438.4)	315.8 (154.5 to 645.2)	435.9 (288.8 to 658.0)
Day 57	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 208	214.1 (120.7 to 379.6)	125.3 (83.7 to 187.6)	115.3 (61.5 to 216.0)	208.7 (134.0 to 324.9)
Day 211	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 2	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 3	102.2 (56.4 to 185.0)	61.8 (40.5 to 94.3)	67.2 (34.5 to 131.1)	90.5 (55.4 to 147.6)
Year 4	78.2 (41.9 to 146.1)	45.5 (30.0 to 68.9)	61.2 (30.9 to 121.0)	85.8 (57.9 to 127.0)
Year 5	80.9 (43.3 to 151.1)	54.1 (32.6 to 89.7)	62.0 (32.5 to 118.5)	82.1 (50.9 to 132.4)

End point values	NOR-107: GI.1/GII.4 (50/150/500) µg,2-Dose	NOR-107: GI.1/GII.4 (15/50/167) µg,2-Dose	NOR-210: GI.1/GII.4 (15/50/500) µg, 1-Dose	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	29
Units: titer				
geometric mean (confidence interval 95%)				
Baseline	22.9 (15.9 to 32.9)	21.3 (15.4 to 29.3)	19.0 (14.1 to 25.6)	20.8 (16.4 to 26.3)
Day 28	338.0 (196.7 to 580.7)	449.4 (270.5 to 746.5)	9999 (-9999 to 9999)	99999 (-99999 to 99999)
Day 29	999 (-999 to 999)	999 (-999 to 999)	212.5 (129.9 to 347.5)	21.3 (16.9 to 26.9)
Day 36	999 (-999 to 999)	999 (-999 to 999)	9999 (-9999 to 9999)	263.3 (143.3 to 483.9)
Day 56	427.6 (300.0 to 609.6)	377.4 (251.6 to 566.0)	9999 (-9999 to 9999)	99999 (-99999 to 99999)
Day 57	999 (-999 to 999)	999 (-999 to 999)	9999 (-9999 to 9999)	228.9 (136.4 to 384.1)
Day 208	201.5 (141.3 to 287.4)	185.6 (126.9 to 271.6)	9999 (-9999 to 9999)	99999 (-99999 to 99999)
Day 211	999 (-999 to 999)	999 (-999 to 999)	9999 (-9999 to 9999)	115.9 (72.1 to 186.4)
Year 2	999 (-999 to 999)	999 (-999 to 999)	48.8 (31.2 to 76.4)	46.3 (30.7 to 69.8)
Year 3	84.9 (53.1 to 135.6)	85.7 (55.9 to 131.4)	48.2 (29.0 to 80.1)	48.8 (30.3 to 78.8)
Year 4	65.1 (39.0 to 108.8)	67.2 (42.9 to 105.2)	63.8 (35.0 to 116.2)	28.6 (17.3 to 47.2)
Year 5	69.1 (42.3 to 112.6)	74.9 (49.1 to 114.2)	52.8 (28.6 to 97.4)	34.7 (15.8 to 76.1)

End point values	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 60-94 Yrs)	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 18-49 Yrs)	NOR-204: GI.1/GII.4 (15/50/500/15) µg - MPL 15 µg, 2-Dose	NOR-204: GI.1/GII.4 (15/50/500) µg, 2-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	14	35	42
Units: titer				
geometric mean (confidence interval 95%)				
Baseline	28.9 (20.7 to 40.5)	18.7 (13.0 to 26.9)	23.9 (18.5 to 30.8)	26.4 (19.4 to 36.1)
Day 28	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Day 29	28.7 (20.6 to 40.0)	19.9 (13.5 to 29.2)	342.5 (206.3 to 568.5)	329.2 (213.3 to 508.2)
Day 36	213.4 (117.2 to 388.5)	155.3 (51.5 to 468.2)	406.4 (274.6 to 601.4)	307.2 (206.1 to 458.0)
Day 56	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Day 57	223.0 (133.9 to 371.5)	105.1 (40.9 to 270.5)	362.5 (255.9 to 513.5)	304.3 (215.6 to 429.7)
Day 208	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Day 211	96.5 (62.6 to 148.7)	43.4 (20.1 to 93.9)	132.9 (89.2 to 198.0)	126.6 (85.6 to 187.2)
Year 2	63.6 (39.6 to 102.1)	38.9 (16.7 to 90.6)	58.9 (39.8 to 87.2)	83.4 (58.2 to 119.3)
Year 3	60.7 (37.2 to 98.9)	34.0 (16.6 to 69.9)	72.5 (47.3 to 111.2)	76.1 (51.0 to 113.6)
Year 4	45.9 (25.0 to 84.3)	28.3 (14.2 to 56.2)	76.1 (45.6 to 127.2)	57.1 (34.5 to 94.3)
Year 5	41.9 (21.8 to 80.3)	31.9 (14.6 to 69.6)	59.8 (29.0 to 123.2)	65.5 (37.9 to 113.1)

Statistical analyses

No statistical analyses for this end point

Primary: Geometric mean blocking titer (GMBT50) of Anti-norovirus GII.4 VLP Antibodies as measured by HBGA blocking assay

End point title	Geometric mean blocking titer (GMBT50) of Anti-norovirus GII.4 VLP Antibodies as measured by HBGA blocking assay[2]

End point description:

GMBT50 of anti-norovirus GII. VLP antibody titers as measured by HBGA blocking assay.Data reported for up to Year 5 was collected at Baseline,Days 28,29,36,56,57,208,211 Year 2,3,4, and 5.PPS=all participants in FAS who had no major or critical protocol violations.n=number of participants with data available for analysis at specific timepoints.Baseline (n=25,19,27,26,23,27,25,28,22,28,19,25,24,24,24,29,39,14,35,42) D28 (n=25,19,26,26,23,27,25,28,21,28,19,25,24,24)D29 (n=24,29,39,14,35,42) D36 (n=29,39,14,35,42) D56 (n=25,19,27,26,23,27,25,28,22,28,19,25,24,24)D57 (n=29,39,14,35,42) D208 (n=25,19,27,26,23,27,25,28,22,28,19,25,24,24) D211 (n=29,39,14,35,42) Y2 (n=24,26,37,10,32,35) Y3 (n=24,19,27,26,23,27,25,28,22,27,19,25,24,24,21,24,35,13,29,37) Y4 (n=23,19,26,26,23,26,23,28,22,28,19,25,23,24,20,18,22,11,20,27) Y5 (n=21,19,26,24,23,26,24,27,22,25,19,24,21,24,19,8,14,10,10,17).999,9999,99999=No participants were analyzed at specific timepoints in NOR-107,NOR-210,NOR-204 respectively.

End point type	Primary

End point timeframe:

Up to 5 years post-primary vaccination

Notes:

[2] - 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: No statistical analysis was performed for this primary endpoint.

End point values	NOR-107: GI.1/GII.4 (15/15/500) µg- MPL 50 µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/500) µg- MPL 50 µg,1-Dose	NOR-107: GI.1/GII.4 (50/50/500) µg- MPL 50 µg,1-Dose	NOR-107: GI.1/GII.4 (15/15/500) µg- MPL 15 µg,1-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	19	27	26
Units: titer				
geometric mean (confidence interval 95%)				
Baseline	74.8 (38.1 to 147.0)	77.4 (41.9 to 142.8)	116.8 (65.9 to 207.2)	72.1 (41.6 to 125.1)
Day 28	80.7 (42.3 to 153.9)	67.2 (35.2 to 128.0)	128.0 (73.3 to 223.7)	71.3 (42.2 to 120.7)
Day 29	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 36	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 56	367.9 (214.8 to 630.3)	755.9 (425.6 to 1342.6)	425.1 (298.8 to 604.8)	277.9 (178.2 to 433.4)
Day 57	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 208	216.4 (132.8 to 352.6)	290.1 (182.7 to 460.7)	231.4 (152.0 to 352.4)	176.2 (116.1 to 267.4)
Day 211	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 2	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 3	122.7 (65.7 to 229.2)	177.1 (96.8 to 323.9)	117.9 (69.6 to 199.7)	104.0 (60.2 to 179.6)
Year 4	85.7 (46.7 to 157.1)	122.8 (67.4 to 223.6)	90.8 (54.4 to 151.3)	79.5 (48.3 to 130.8)
Year 5	101.1 (52.5 to 194.6)	138.3 (80.8 to 236.9)	124.4 (78.5 to 197.0)	91.2 (51.2 to 162.3)

End point values	NOR-107: GI.1/GII.4 (15/50/500) µg- MPL 15 µg,1-Dose	NOR-107: GI.1/GII.4 (50/50/500) µg- MPL 15 µg,1-Dose	NOR-107: GI.1/GII.4 (15/15/500) µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/500) µg,1-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	27	25	28
Units: titer				
geometric mean (confidence interval 95%)				
Baseline	54.6 (30.7 to 97.3)	104.2 (60.4 to 179.8)	77.5 (42.5 to 141.6)	86.3 (47.9 to 155.3)
Day 28	64.9 (36.6 to 115.3)	101.3 (57.1 to 179.6)	69.7 (40.2 to 120.9)	95.2 (49.6 to 182.6)

Day 29	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 36	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 56	584.7 (367.5 to 930.1)	593.4 (436.2 to 807.2)	201.9 (110.6 to 368.4)	810.0 (507.4 to 1293.2)
Day 57	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 208	215.9 (132.1 to 353.1)	247.4 (166.6 to 367.3)	150.4 (87.4 to 258.6)	333.2 (217.9 to 509.4)
Day 211	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 2	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 3	80.5 (45.4 to 142.9)	125.9 (74.7 to 212.3)	121.2 (71.1 to 206.7)	164.1 (97.7 to 275.5)
Year 4	61.7 (35.7 to 106.5)	106.7 (64.7 to 176.1)	108.6 (62.0 to 190.3)	131.2 (81.9 to 210.2)
Year 5	71.3 (40.0 to 126.9)	103.2 (60.6 to 175.8)	94.3 (54.4 to 163.2)	144.9 (82.9 to 253.1)

End point values	NOR-107: GI.1/GII.4 (50/50/500) µg,1-Dose	NOR-107: GI.1/GII.4 (50/150/500) µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/167) µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/500) µg,2-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	28	19	25
Units: titer				
geometric mean (confidence interval 95%)				
Baseline	97.1 (55.8 to 169.0)	106.1 (66.7 to 168.8)	124.3 (69.0 to 223.9)	65.8 (39.6 to 109.1)
Day 28	84.1 (46.7 to 151.3)	129.9 (83.4 to 202.4)	112.4 (63.0 to 200.5)	607.7 (379.2 to 974.0)
Day 29	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 36	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 56	328.5 (173.8 to 620.8)	886.3 (562.3 to 1397.0)	746.6 (456.8 to 1220.3)	458.4 (290.9 to 722.3)
Day 57	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 208	173.0 (94.8 to 315.8)	352.9 (242.4 to 513.8)	274.9 (151.4 to 499.2)	277.2 (186.5 to 412.0)
Day 211	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 2	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 3	125.3 (67.9 to 230.9)	167.0 (111.3 to 250.4)	142.2 (76.9 to 263.1)	149.2 (83.1 to 267.9)
Year 4	101.9 (60.1 to 172.7)	113.9 (73.3 to 177.1)	130.1 (70.0 to 241.9)	98.1 (55.0 to 175.1)
Year 5	105.1 (57.8 to 191.1)	147.2 (92.4 to 234.4)	118.0 (66.8 to 208.6)	118.3 (71.4 to 195.8)

End point values	NOR-107: GI.1/GII.4 (50/150/500) µg,2-Dose	NOR-107: GI.1/GII.4 (15/50/167) µg,2-Dose	NOR-210: GI.1/GII.4 (15/50/500) µg, 1-Dose	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	29
Units: titer				
geometric mean (confidence interval 95%)				
Baseline	97.2 (53.8 to 175.9)	127.3 (70.2 to 231.0)	42.7 (25.6 to 71.1)	140.5 (78.5 to 251.6)
Day 28	668.3 (397.3 to 1124.0)	893.6 (578.4 to 1380.5)	9999 (-9999 to 9999)	99999 (-99999 to 99999)
Day 29	999 (-999 to 999)	999 (-999 to 999)	665.9 (408.2 to 1086.2)	118.3 (66.7 to 210.0)
Day 36	999 (-999 to 999)	999 (-999 to 999)	9999 (-9999 to 9999)	920.9 (521.8 to 1625.4)
Day 56	575.5 (358.1 to 924.8)	594.2 (369.2 to 956.2)	9999 (-9999 to 9999)	99999 (-99999 to 99999)
Day 57	999 (-999 to 999)	999 (-999 to 999)	9999 (-9999 to 9999)	1133.2 (682.7 to 1881.0)
Day 208	342.5 (233.2 to 503.1)	308.7 (198.5 to 480.0)	9999 (-9999 to 9999)	99999 (-99999 to 99999)
Day 211	999 (-999 to 999)	999 (-999 to 999)	9999 (-9999 to 9999)	417.6 (252.8 to 689.6)
Year 2	999 (-999 to 999)	999 (-999 to 999)	105.2 (58.7 to 188.3)	223.2 (120.7 to 412.9)
Year 3	144.7 (83.1 to 251.7)	173.8 (104.6 to 288.8)	87.5 (43.9 to 174.5)	172.0 (100.1 to 295.5)
Year 4	104.4 (58.4 to 186.5)	120.3 (72.6 to 199.3)	84.1 (44.2 to 160.3)	116.0 (54.0 to 249.4)
Year 5	115.7 (57.7 to 232.0)	132.0 (79.7 to 218.5)	94.2 (49.1 to 180.7)	123.4 (26.5 to 574.3)

End point values	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 60-94 Yrs)	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 18-49 Yrs)	NOR-204: GI.1/GII.4 (15/50/500/15) µg - MPL 15 µg, 2-Dose	NOR-204: GI.1/GII.4 (15/50/500) µg, 2-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	14	35	42
Units: titer				
geometric mean (confidence interval 95%)				
Baseline	71.8 (45.7 to 113.0)	97.5 (40.3 to 235.8)	104.9 (64.2 to 171.5)	111.0 (72.0 to 171.1)
Day 28	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Day 29	63.5 (41.0 to 98.4)	83.2 (34.3 to 201.9)	1134.4 (784.6 to 1640.1)	824.2 (493.4 to 1376.8)
Day 36	518.7 (273.0 to 985.2)	1037.4 (448.1 to 2401.9)	1016.2 (719.4 to 1435.4)	766.8 (483.1 to 1216.9)
Day 56	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Day 57	471.8 (285.2 to 780.5)	663.8 (304.5 to 1447.1)	740.2 (549.0 to 998.0)	589.1 (359.7 to 964.6)

Day 208	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Day 211	195.2 (120.2 to 316.8)	274.7 (135.3 to 557.8)	374.7 (262.6 to 534.6)	265.3 (157.4 to 447.2)
Year 2	122.5 (74.8 to 200.5)	250.5 (80.8 to 776.7)	220.9 (137.2 to 355.7)	243.0 (149.6 to 394.7)
Year 3	94.9 (59.4 to 151.3)	133.8 (56.2 to 318.9)	153.3 (100.1 to 234.8)	162.4 (102.5 to 257.3)
Year 4	80.9 (42.1 to 155.4)	131.1 (57.6 to 298.6)	241.9 (140.2 to 417.5)	136.7 (75.7 to 246.9)
Year 5	66.8 (32.2 to 138.6)	107.4 (43.5 to 265.1)	202.2 (110.2 to 370.9)	187.3 (105.6 to 332.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers (GMT) of Anti-norovirus GI.1 VLP Antibodies as measured by Total Immunoglobulin (pan-Ig) Enzyme-linked Immunosorbent Assay (ELISA)

End point title	Geometric Mean Titers (GMT) of Anti-norovirus GI.1 VLP Antibodies as measured by Total Immunoglobulin (pan-Ig) Enzyme-linked Immunosorbent Assay (ELISA)

End point description:

GMT of anti-norovirus GI.1 VLP antibody titers as measured by pan-Ig ELISA.Data reported for up to Year 5 was collected at Baseline,Days 28,29,36,56,57,208,211 Year 2,3,4, and 5.PPS=all participants in FAS who had no major or critical protocol violations.n=number of participants with data available for analysis at specific timepoints.Baseline
(n=25,19,27,26,23,27,25,28,22,28,19,25,24,24,24,29,39,14,35,42) D28
(n=25,19,26,26,23,27,25,28,21,28,19,25,24,24)
D29 (n=24,29,39,14,35,42) D36 (n=29,39,14,35,42) D56
(n=25,19,27,26,23,27,25,28,22,28,19,25,24,24)
D57 (n=29,39,14,35,42 D208 (n=25,19,27,26,23,27,25,28,22,28,19,25,24,24) D211
(n=29,39,14,35,42)
Y2 (n=24,26,37,10,32,35) Y3 (n=24,19,27,26,23,27,25,28,22,27,19,25,24,24,21,24,35,13,29,37) Y4
(n=23,19,26,26,23,26,23,28,22,28,19,25,23,24,20,18,22,11,20,27) Y5
(n=21,19,26,24,23,26,24,27,22,25,19,24,21,24,19,8,15,10,10,16).999,9999,99999=No participants were analyzed at specific timepoints in NOR-107,NOR-210,NOR-204 respectively.

End point type	Secondary

End point timeframe:

Up to 5 years post-primary vaccination

End point values	NOR-107: GI.1/GII.4 (15/15/500) µg- MPL 50 µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/500) µg- MPL 50 µg,1-Dose	NOR-107: GI.1/GII.4 (50/50/500) µg- MPL 50 µg,1-Dose	NOR-107: GI.1/GII.4 (15/15/500) µg- MPL 15 µg,1-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	19	27	26
Units: titer				
geometric mean (confidence interval 95%)				
Baseline	1030.5 (543.6 to 1953.7)	689.8 (295.3 to 1611.4)	646.2 (354.3 to 1178.4)	620.9 (326.7 to 1180.1)

Day 28	975.2 (508.7 to 1869.6)	649.3 (285.2 to 1478.2)	544.9 (297.5 to 998.3)	648.7 (324.3 to 1297.5)
Day 29	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 36	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 56	15032.5 (10033.4 to 22522.2)	12246.2 (7488.7 to 20025.9)	16739.1 (11460.0 to 24450.0)	13673.2 (8411.3 to 22226.9)
Day 57	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 208	6015.9 (4271.9 to 8471.9)	4784.5 (3114.9 to 7349.0)	6231.0 (4321.0 to 8985.3)	5675.5 (3783.7 to 8513.4)
Day 211	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 2	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 3	2229.0 (1481.3 to 3354.1)	1493.3 (987.8 to 2257.6)	2058.7 (1538.0 to 2755.7)	2227.0 (1581.4 to 3136.2)
Year 4	2095.5 (1272.0 to 3452.2)	1727.7 (1016.1 to 2937.8)	2541.1 (1618.3 to 3990.1)	1958.2 (1363.0 to 2813.3)
Year 5	1732.3 (1133.8 to 2646.8)	1563.6 (957.9 to 2552.6)	2345.8 (1566.6 to 3512.7)	2009.8 (1396.6 to 2892.2)

End point values	NOR-107: GI.1/GII.4 (15/50/500) µg- MPL 15 µg,1-Dose	NOR-107: GI.1/GII.4 (50/50/500) µg- MPL 15 µg,1-Dose	NOR-107: GI.1/GII.4 (15/15/500) µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/500) µg,1-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	27	25	28
Units: titer				
geometric mean (confidence interval 95%)				
Baseline	547.4 (334.5 to 895.6)	539.6 (293.3 to 992.5)	1089.2 (599.9 to 1977.6)	856.1 (471.5 to 1554.3)
Day 28	475.4 (284.8 to 793.4)	535.4 (287.5 to 997.1)	1086.1 (613.7 to 1922.0)	839.1 (469.7 to 1499.0)
Day 29	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 36	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 56	12847.2 (9036.9 to 18264.2)	18464.0 (14207.7 to 23995.3)	15242.3 (11298.2 to 20563.2)	15071.0 (9104.8 to 24946.5)
Day 57	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 208	4212.3 (3065.0 to 5789.1)	4997.4 (3748.7 to 6662.0)	5577.8 (4072.7 to 7639.2)	6686.7 (4766.4 to 9380.5)
Day 211	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 2	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)

Year 3	1465.7 (1056.7 to 2032.8)	1568.0 (1188.6 to 2068.5)	2156.1 (1527.7 to 3042.9)	1913.2 (1386.8 to 2639.4)
Year 4	1802.9 (1185.9 to 2740.8)	1565.5 (1181.0 to 2075.1)	2934.1 (1993.0 to 4319.7)	2107.0 (1384.3 to 3207.0)
Year 5	1664.8 (1100.7 to 2518.1)	1781.2 (1102.5 to 2877.7)	2116.5 (1597.7 to 2803.7)	2270.3 (1536.1 to 3355.5)

End point values	NOR-107: GI.1/GII.4 (50/50/500) µg,1-Dose	NOR-107: GI.1/GII.4 (50/150/500) µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/167) µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/500) µg,2-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	28	19	25
Units: titer				
geometric mean (confidence interval 95%)				
Baseline	749.7 (406.6 to 1382.5)	770.6 (413.5 to 1436.2)	925.3 (366.0 to 2339.3)	777.3 (413.1 to 1462.8)
Day 28	729.3 (380.1 to 1399.5)	731.0 (382.7 to 1396.2)	932.8 (402.0 to 2164.8)	16822.8 (11052.9 to 25604.9)
Day 29	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 36	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 56	25738.6 (16696.8 to 39676.9)	14709.3 (10110.9 to 21399.2)	12428.4 (6942.7 to 22248.5)	14302.9 (10081.6 to 20291.8)
Day 57	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 208	7761.2 (5226.5 to 11525.1)	5274.3 (3746.7 to 7424.6)	4978.7 (3275.4 to 7567.6)	7082.7 (5051.7 to 9930.2)
Day 211	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 2	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 3	2063.1 (1370.8 to 3105.0)	1702.4 (1165.5 to 2486.6)	1579.5 (977.5 to 2552.2)	2422.7 (1732.0 to 3388.9)
Year 4	1965.0 (1287.9 to 2997.9)	1679.0 (1208.0 to 2333.5)	2025.2 (1254.9 to 3268.3)	2335.8 (1724.4 to 3163.8)
Year 5	2181.9 (1360.4 to 3499.2)	1811.9 (1173.5 to 2797.8)	1434.9 (956.9 to 2151.6)	2036.9 (1475.0 to 2812.9)

End point values	NOR-107: GI.1/GII.4 (50/150/500) µg,2-Dose	NOR-107: GI.1/GII.4 (15/50/167) µg,2-Dose	NOR-210: GI.1/GII.4 (15/50/500) µg, 1-Dose	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	29

Units: titer				
geometric mean (confidence interval 95%)				
Baseline	908.6 (501.0 to 1647.8)	640.4 (378.5 to 1083.5)	160.1 (78.6 to 326.1)	671.5 (432.5 to 1042.4)
Day 28	21215.2 (15921.0 to 28269.9)	14102.7 (9666.5 to 20574.8)	9999 (-9999 to 9999)	99999 (-99999 to 99999)
Day 29	999 (-999 to 999)	999 (-999 to 999)	10798.6 (7482.3 to 15584.8)	630.6 (407.9 to 974.8)
Day 36	999 (-999 to 999)	999 (-999 to 999)	9999 (-9999 to 9999)	6915.9 (4770.3 to 10026.5)
Day 56	18086.8 (13594.7 to 24063.2)	11282.4 (8142.8 to 15632.5)	9999 (-9999 to 9999)	99999 (-99999 to 99999)
Day 57	999 (-999 to 999)	999 (-999 to 999)	9999 (-9999 to 9999)	10684.3 (8532.4 to 13378.9)
Day 208	7469.9 (5874.5 to 9498.6)	5355.9 (4082.7 to 7026.2)	9999 (-9999 to 9999)	99999 (-99999 to 99999)
Day 211	999 (-999 to 999)	999 (-999 to 999)	9999 (-9999 to 9999)	5970.0 (4586.1 to 7771.7)
Year 2	999 (-999 to 999)	999 (-999 to 999)	1662.0 (1203.1 to 2296.0)	1804.4 (1405.6 to 2316.4)
Year 3	2914.8 (2270.4 to 3742.1)	2077.8 (1523.3 to 2834.1)	1500.9 (1031.3 to 2184.2)	2006.4 (1373.3 to 2931.3)
Year 4	2635.7 (1936.2 to 3587.9)	2016.6 (1500.0 to 2711.1)	1627.4 (1127.0 to 2350.1)	1512.1 (1032.5 to 2214.6)
Year 5	2405.4 (1763.1 to 3281.8)	1817.7 (1256.1 to 2630.5)	1803.8 (1205.4 to 2699.1)	1937.4 (1141.5 to 3288.2)

End point values	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 60-94 Yrs)	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 18-49 Yrs)	NOR-204: GI.1/GII.4 (15/50/500/15) µg - MPL 15 µg, 2-Dose	NOR-204: GI.1/GII.4 (15/50/500) µg, 2-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	14	35	42
Units: titer				
geometric mean (confidence interval 95%)				
Baseline	769.8 (559.5 to 1059.0)	493.1 (170.7 to 1424.8)	683.8 (460.7 to 1014.9)	851.8 (534.3 to 1357.9)
Day 28	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Day 29	734.8 (544.2 to 992.1)	694.7 (249.8 to 1931.4)	10862.2 (8363.3 to 14107.7)	8286.7 (6204.3 to 11068.0)
Day 36	3909.4 (2555.3 to 5981.0)	7407.6 (3545.0 to 15479.0)	10851.2 (8549.3 to 13772.9)	8143.0 (6132.6 to 10812.4)

Day 56	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Day 57	5646.8 (4043.4 to 7886.1)	7944.8 (4570.2 to 13811.2)	9388.2 (7285.3 to 12098.2)	7316.3 (5685.6 to 9414.7)
Day 208	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Day 211	4137.3 (3176.2 to 5389.2)	3745.8 (1975.8 to 7101.5)	5320.5 (4169.4 to 6789.4)	5020.4 (3878.5 to 6498.6)
Year 2	1477.4 (1016.3 to 2147.7)	1672.4 (656.0 to 4263.7)	1770.6 (1310.4 to 2392.3)	1635.0 (1194.2 to 2238.4)
Year 3	1932.8 (1245.7 to 2998.7)	1254.9 (701.7 to 2244.2)	1670.1 (1258.5 to 2216.4)	1700.5 (1224.7 to 2361.3)
Year 4	1441.7 (926.9 to 2242.4)	1238.3 (841.5 to 1822.1)	1585.6 (1101.6 to 2282.3)	1392.4 (917.6 to 2112.9)
Year 5	1255.5 (709.1 to 2223.1)	1048.6 (566.7 to 1940.4)	2060.5 (1422.7 to 2984.3)	1687.2 (1031.7 to 2759.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers (GMT) of Anti-norovirus GII.4 VLP Antibodies as measured by pan-Ig ELISA

End point title	Geometric Mean Titers (GMT) of Anti-norovirus GII.4 VLP Antibodies as measured by pan-Ig ELISA

End point description:

GMT of anti-norovirus GII.4 VLP antibody titers as measured by pan-Ig ELISA.Data reported for up to Year 5 was collected at Baseline,Days 28,29,36,56,57,208,211 Year 2,3,4, and 5.PPS=all participants in FAS who had no major or critical protocol violations.n=number of participants with data available for analysis at specific timepoints. Baseline
(n=25,19,27,26,23,27,25,28,22,28,19,25,24,24,24,29,39,14,35,42)
D28 (n=25,19,26,26,23,27,25,28,21,28,19,25,24,24) D29 (n=24,29,39,14,35,42) D36 (n=29,39,14,35,42) D56 (n=25,19,27,26,23,27,25,28,22,28,19,25,24,24) D57 (n=29,39,14,35,42) D208 (n=25,19,27,26,23,27,25,28,22,28,19,25,24,24) D211 (n=29,39,14,35,42) Y2 (n=24,26,37,10,32,35)
Y3 (n=24,19,27,26,23,27,25,28,22,27,19,25,24,24,21,24,35,13,29,37)
Y4 (n=23,19,26,26,23,26,23,28,22,28,19,25,23,24,20,18,22,11,20,27)
Y5 (n=21,19,26,24,23,26,24,27,22,25,19,24,21,24,19,8,15,10,10,17). 999,9999,99999=No participants were analyzed at specific timepoints in NOR-107,NOR-210,NOR-204 respectively.

End point type	Secondary

End point timeframe:

Up to 5 years post-primary vaccination

End point values	NOR-107: GI.1/GII.4 (15/15/500) µg- MPL 50 µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/500) µg- MPL 50 µg,1-Dose	NOR-107: GI.1/GII.4 (50/50/500) µg- MPL 50 µg,1-Dose	NOR-107: GI.1/GII.4 (15/15/500) µg- MPL 15 µg,1-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	19	27	26
Units: titer				
geometric mean (confidence interval 95%)				
Baseline	1209.8 (617.2 to 2371.5)	1248.3 (665.1 to 2343.0)	1423.3 (799.5 to 2533.7)	954.0 (530.1 to 1716.8)
Day 28	1218.3 (609.8 to 2433.7)	1233.2 (658.4 to 2309.7)	1471.1 (841.2 to 2572.7)	953.8 (549.5 to 1655.4)
Day 29	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 36	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 56	5051.3 (3144.0 to 8115.7)	8644.5 (6368.1 to 11734.7)	5651.7 (4159.3 to 7679.4)	3909.2 (2620.5 to 5831.7)
Day 57	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 208	2805.0 (1665.3 to 4724.8)	3797.7 (2654.3 to 5433.8)	2757.9 (1631.0 to 4663.4)	2575.3 (1695.6 to 3911.3)
Day 211	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 2	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 3	1643.9 (850.8 to 3176.6)	1874.7 (1066.5 to 3295.6)	1756.7 (1193.6 to 2585.3)	1159.4 (731.0 to 1838.7)
Year 4	1580.2 (856.2 to 2916.6)	2128.6 (1214.1 to 3732.0)	1828.6 (1183.6 to 2825.2)	1234.2 (791.8 to 1923.6)
Year 5	1159.9 (587.5 to 2289.8)	2232.6 (1270.8 to 3922.1)	1702.6 (1091.4 to 2656.0)	1135.0 (709.5 to 1815.7)

End point values	NOR-107: GI.1/GII.4 (15/50/500) µg- MPL 15 µg,1-Dose	NOR-107: GI.1/GII.4 (50/50/500) µg- MPL 15 µg,1-Dose	NOR-107: GI.1/GII.4 (15/15/500) µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/500) µg,1-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	27	25	28
Units: titer				
geometric mean (confidence interval 95%)				
Baseline	838.8 (507.6 to 1386.1)	1239.7 (705.8 to 2177.4)	1373.7 (792.4 to 2381.6)	1179.5 (677.5 to 2053.4)
Day 28	754.4 (464.2 to 1226.0)	1198.8 (688.3 to 2088.0)	1310.7 (797.3 to 2154.5)	1246.3 (710.3 to 2187.0)
Day 29	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 36	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)

Day 56	6655.7 (4670.1 to 9485.5)	7585.7 (5687.6 to 10117.3)	3296.3 (2075.7 to 5234.7)	9110.9 (5865.5 to 14152.2)
Day 57	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 208	2861.7 (2000.7 to 4093.2)	3086.6 (2194.7 to 4341.0)	2239.3 (1451.7 to 3454.4)	4668.9 (3069.6 to 7101.4)
Day 211	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 2	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 3	1193.5 (780.4 to 1825.4)	1385.2 (946.0 to 2028.2)	1425.3 (844.2 to 2406.6)	1705.3 (1024.2 to 2839.3)
Year 4	1283.8 (870.2 to 1894.0)	1714.5 (1133.1 to 2594.2)	2114.3 (1369.8 to 3263.4)	1858.2 (1107.6 to 3117.5)
Year 5	1177.1 (774.7 to 1788.5)	1545.6 (952.6 to 2507.9)	1410.6 (927.5 to 2145.5)	2047.9 (1097.6 to 3821.1)

End point values	NOR-107: GI.1/GII.4 (50/50/500) µg,1-Dose	NOR-107: GI.1/GII.4 (50/150/500) µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/167) µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/500) µg,2-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	28	19	25
Units: titer				
geometric mean (confidence interval 95%)				
Baseline	1133.9 (648.4 to 1982.8)	1442.1 (864.3 to 2406.1)	2069.2 (1362.0 to 3143.7)	1078.9 (678.4 to 1715.6)
Day 28	1086.0 (619.5 to 1903.7)	1491.7 (983.7 to 2262.0)	1940.6 (1259.0 to 2991.2)	8866.0 (6415.5 to 12252.6)
Day 29	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 36	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 56	4762.7 (2918.8 to 7771.4)	10733.0 (7902.0 to 14578.1)	9544.8 (6846.7 to 13306.1)	7083.6 (5125.3 to 9790.1)
Day 57	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Day 208	2349.9 (1405.2 to 3929.8)	4661.9 (3401.9 to 6388.5)	4450.1 (2994.6 to 6613.0)	4004.2 (2834.4 to 5656.7)
Day 211	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 2	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)	999 (-999 to 999)
Year 3	1166.5 (608.1 to 2237.6)	1775.4 (1208.6 to 2608.1)	1783.7 (1093.8 to 2909.0)	1880.8 (1254.3 to 2820.4)
Year 4	1115.2 (597.5 to 2081.7)	1762.5 (1170.1 to 2655.0)	2173.9 (1287.5 to 3670.6)	1702.1 (976.9 to 2965.5)

Year 5	1265.5 (682.2 to 2347.3)	2037.4 (1364.0 to 3043.1)	1648.1 (989.0 to 2746.2)	1746.6 (1149.0 to 2655.0)

End point values	NOR-107: GI.1/GII.4 (50/150/500) µg,2-Dose	NOR-107: GI.1/GII.4 (15/50/167) µg,2-Dose	NOR-210: GI.1/GII.4 (15/50/500) µg, 1-Dose	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	29
Units: titer				
geometric mean (confidence interval 95%)				
Baseline	1308.9 (779.3 to 2198.4)	1598.5 (952.6 to 2682.3)	93.1 (58.8 to 147.3)	1213.2 (658.2 to 2236.1)
Day 28	13710.2 (10111.0 to 18590.5)	10202.3 (6715.1 to 15500.5)	9999 (-9999 to 9999)	99999 (-99999 to 99999)
Day 29	999 (-999 to 999)	999 (-999 to 999)	10170.0 (7301.6 to 14165.2)	1172.6 (630.4 to 2181.1)
Day 36	999 (-999 to 999)	999 (-999 to 999)	9999 (-9999 to 9999)	5938.0 (3771.8 to 9348.2)
Day 56	10333.3 (7485.5 to 14264.4)	7801.7 (5379.1 to 11315.4)	9999 (-9999 to 9999)	99999 (-99999 to 99999)
Day 57	999 (-999 to 999)	999 (-999 to 999)	9999 (-9999 to 9999)	9761.9 (6487.9 to 14688.1)
Day 208	4807.4 (3225.4 to 7165.3)	4177.3 (2914.0 to 5988.2)	9999 (-9999 to 9999)	99999 (-99999 to 99999)
Day 211	999 (-999 to 999)	999 (-999 to 999)	9999 (-9999 to 9999)	5710.0 (3654.0 to 8922.7)
Year 2	999 (-999 to 999)	999 (-999 to 999)	1513.3 (897.0 to 2553.2)	2344.8 (1508.6 to 3644.5)
Year 3	2079.5 (1465.2 to 2951.4)	1946.0 (1303.7 to 2904.8)	1202.9 (682.0 to 2121.6)	2200.3 (1284.6 to 3768.8)
Year 4	2766.1 (1630.1 to 4694.0)	2044.1 (1416.3 to 2950.2)	1254.0 (743.5 to 2115.0)	1514.3 (895.9 to 2559.5)
Year 5	2225.0 (1305.9 to 3791.0)	1624.0 (1073.2 to 2457.7)	1241.5 (726.4 to 2121.8)	1076.0 (406.2 to 2850.3)

End point values	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 60-94 Yrs)	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 18-49 Yrs)	NOR-204: GI.1/GII.4 (15/50/500/15) µg - MPL 15 µg, 2-Dose	NOR-204: GI.1/GII.4 (15/50/500) µg, 2-Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	14	35	42

Units: titer				
geometric mean (confidence interval 95%)				
Baseline	826.1 (508.7 to 1341.7)	1288.0 (570.8 to 2906.4)	1263.5 (794.7 to 2009.0)	1149.0 (672.9 to 1961.8)
Day 28	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Day 29	818.6 (510.4 to 1313.0)	1251.3 (563.1 to 2780.5)	9284.7 (6772.0 to 12729.9)	8508.2 (5798.6 to 12484.1)
Day 36	4248.1 (2787.2 to 6474.8)	8348.3 (5370.9 to 12976.3)	9415.5 (7120.6 to 12450.1)	8518.7 (5970.1 to 12155.2)
Day 56	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Day 57	5961.1 (4365.7 to 8139.7)	8689.8 (6309.5 to 11968.1)	7673.7 (5733.9 to 10269.7)	7610.5 (5336.3 to 10854.0)
Day 208	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Day 211	3949.0 (2991.2 to 5213.6)	4825.8 (3063.2 to 7602.6)	5389.0 (4070.1 to 7135.2)	5415.4 (3633.4 to 8071.3)
Year 2	1465.5 (1039.9 to 2065.3)	4160.4 (1968.6 to 8792.4)	2244.0 (1462.9 to 3442.1)	2380.4 (1507.4 to 3759.2)
Year 3	1771.1 (1276.4 to 2457.6)	2155.0 (1293.4 to 3590.8)	2297.5 (1422.8 to 3709.9)	2304.2 (1369.0 to 3878.4)
Year 4	1267.2 (788.9 to 2035.5)	1806.5 (1032.7 to 3160.1)	2466.9 (1489.0 to 4086.9)	1823.5 (1089.5 to 3052.0)
Year 5	912.7 (529.7 to 1572.6)	1187.7 (680.8 to 2071.8)	1522.7 (936.1 to 2476.8)	2097.3 (1285.7 to 3421.1)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

From the time of informed consent signed up to end of the study (Up to approximately 5 years)

Adverse event reporting additional description:

At each visit the investigator had to document any occurrence of adverse events and abnormal laboratory findings. Any event spontaneously reported by the participant or observed by the investigator was recorded, irrespective of the relation to study treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	NOR-107: GI.1/GII.4 (15/50/500) µg- MPL 50 µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 50 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/15/500) µg- MPL 50 µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, intramuscular (IM), on Day 1, followed by norovirus bivalent virus like particle (VLP) vaccine (15 µg of GI.1 norovirus virus VLP and 15 µg GII.4 norovirus VLP) adjuvanted with 50 µg monophosphoryl lipid A (MPL) and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (50/50/500) µg- MPL 50 µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 50 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/15/500) µg- MPL 15 µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 15 µg GII.4 norovirus VLP) adjuvanted with 15 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/50/500) µg- MPL 15 µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received IM hepatitis A vaccine on Day 1, followed by IM norovirus bivalent vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 15 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (50/50/500) µg- MPL 15 µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 15 µg MLP and 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/15/500) µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 15 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (50/50/500) µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/50/500) µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (50/150/500) µg,1-Dose

Reporting group description:

Eligible NOR-217 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 150 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/50/167) µg,1-Dose

Reporting group description:

Eligible NOR-107 participants who had received Hepatitis A vaccine, IM, on Day 1, followed by norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 167 µg aluminium hydroxide, on Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/50/500) µg,2-Dose

Reporting group description:

Eligible NOR-107 participants who had received Norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, IM, on Day 1 and Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (50/150/500) µg,2-Dose

Reporting group description:

Eligible NOR-107 participants who had received Norovirus bivalent VLP vaccine (50 µg of GI.1 norovirus VLP and 150 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide, IM, on Day 1 and Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-107: GI.1/GII.4 (15/50/167) µg,1-Dose

Reporting group description:

Eligible NOR-217 participants who had received Norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 167 µg aluminium hydroxide, IM, on Day 1 and Day 28 were enrolled at 3rd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-210: GI.1/GII.4 (15/50/500) µg, 1-Dose

Reporting group description:

Eligible NOR-210 participants who had received Norovirus GI.1/GII.4 bivalent VLP vaccine NoV Vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP, adjuvanted with 500 µg aluminium hydroxide), IM injection, once on Day 1 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-204: GI.1/GII.4 (15/50/500/15) µg, 1-Dose

Reporting group description:

Eligible NOR-204 participants who had received Norovirus bivalent placebo-matching vaccine, intramuscularly (IM), on Day 1, followed by norovirus (NoV) [15 µg of GI.1 and 50 µg of GII.4 bivalent virus-like particle (VLP)] adjuvanted with 500 µg aluminium hydroxide and 15 µg of monophosphoryl lipid A (MPL) (Composition B), on Day 29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 60-94 Yrs)

Reporting group description:

Eligible NOR-204 participants of age 60-94 years who had received Norovirus bivalent placebo-matching vaccine, IM, on Day 1, followed by norovirus (NoV) [15 µg of GI.1 and 50 µg of GII.4 bivalent virus-like particle (VLP)] adjuvanted with 500 µg aluminium hydroxide (Composition A), on Day 29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 18-49 Yrs)

Reporting group description:

Eligible NOR-204 participants of age 18-49 years who had received Norovirus bivalent placebo-matching

vaccine, IM, on Day 1, followed by norovirus (NoV) [15 µg of GI.1 and 50 µg of GII.4 bivalent virus-like particle (VLP)] adjuvanted with 500 µg aluminium hydroxide (Composition A), on Day 29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-204: GI.1/GII.4 (15/50/500/15) µg - MPL 15 µg, 2-Dose

Reporting group description:

Eligible NOR-204 participants who had received Norovirus bivalent VLP vaccine (15 µg of GI.1 norovirus VLP and 50 µg GII.4 norovirus VLP) adjuvanted with 500 µg aluminium hydroxide and 15 µg of MPL (Composition B), IM, on Day 1 and Day 29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Reporting group title	NOR-204: GI.1/GII.4 (15/50/500) µg, 2-Dose

Reporting group description:

Eligible NOR-204 participants who had received Norovirus bivalent VLP vaccine (15 µg of GI.1 50 µg of GII.4 bivalent VLP) adjuvanted with 500 µg aluminium hydroxide (Composition A) IM, on Day 1 and Day 29 were enrolled at 2nd year post-primary vaccination in NOR-213 study.

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No non-serious adverse events were reported in this study.

Serious adverse events	NOR-107: GI.1/GII.4 (15/50/500) µg-	NOR-107: GI.1/GII.4 (15/15/500) µg- MPL 50 µg,1-Dose	NOR-107: GI.1/GII.4 (50/50/500) µg-
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 27 (3.70%)	0 / 25 (0.00%)	1 / 19 (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)			
Metastases to lung			
subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)
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			
Fall			

subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)
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			
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)
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 failure congestive			
subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)
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			
Neurodegenerative disorder			
subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)
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			
Amaurosis fugax			
subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Episcleritis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)
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			
Colitis ulcerative			
subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)
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			
Pulmonary embolism			
subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)
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 failure			
subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)
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			
Polymyalgia rheumatica			
subjects affected / exposed	1 / 27 (3.70%)	0 / 25 (0.00%)	0 / 19 (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			
Appendicitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)
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			
Adult failure to thrive			
subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)
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	NOR-107: GI.1/GII.4 (15/15/500) µg-	NOR-107: GI.1/GII.4 (15/50/500) µg-MPL 15 µg,1-Dose	NOR-107: GI.1/GII.4 (50/50/500) µg-
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 27 (3.70%)	0 / 23 (0.00%)	0 / 27 (0.00%)
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)			
Metastases to lung			
subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			

subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
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			
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
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 failure congestive			
subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
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			
Neurodegenerative disorder			
subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
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			
Amaurosis fugax			
subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Episcleritis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
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			
Colitis ulcerative			

subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	1 / 27 (3.70%)	0 / 23 (0.00%)	0 / 27 (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
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
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 failure			
subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
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			
Polymyalgia rheumatica			
subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
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			
Adult failure to thrive			
subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)
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	NOR-107: GI.1/GII.4 (15/15/500) µg,1-	NOR-107: GI.1/GII.4 (50/50/500) µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/500) µg,1-
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
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)			
Metastases to lung			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			

subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
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			
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
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 failure congestive			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
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			
Neurodegenerative disorder			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
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			
Amaurosis fugax			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Episcleritis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
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			
Colitis ulcerative			

subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
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			
Pulmonary embolism			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
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 failure			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
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			
Polymyalgia rheumatica			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
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			
Adult failure to thrive			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)
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	NOR-107: GI.1/GII.4 (50/150/500) µg,1-	NOR-107: GI.1/GII.4 (15/50/167) µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/500) µg,2-
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
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)			
Metastases to lung			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			

subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
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			
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
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 failure congestive			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
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			
Neurodegenerative disorder			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
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			
Amaurosis fugax			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Episcleritis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
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			
Colitis ulcerative			

subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
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			
Pulmonary embolism			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
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 failure			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
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			
Polymyalgia rheumatica			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
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			
Adult failure to thrive			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)
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	NOR-107: GI.1/GII.4 (50/150/500) µg,2-	NOR-107: GI.1/GII.4 (15/50/167) µg,1-Dose	NOR-210: GI.1/GII.4 (15/50/500) µg, 1-
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	1 / 24 (4.17%)
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)			
Metastases to lung			
subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			

subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
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			
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
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 failure congestive			
subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
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			
Neurodegenerative disorder			
subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
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			
Amaurosis fugax			
subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Episcleritis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	1 / 24 (4.17%)
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			
Colitis ulcerative			

subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
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			
Pulmonary embolism			
subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
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 failure			
subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
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			
Polymyalgia rheumatica			
subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
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			
Adult failure to thrive			
subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)
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	NOR-204: GI.1/GII.4 (15/50/500/15) µg,	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 60-94 Yrs)	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 18-49
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 35 (5.71%)	0 / 14 (0.00%)	5 / 39 (12.82%)
number of deaths (all causes)	2	0	3
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to lung			
subjects affected / exposed	0 / 35 (0.00%)	0 / 14 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 35 (0.00%)	0 / 14 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 35 (0.00%)	0 / 14 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 35 (0.00%)	0 / 14 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			

subjects affected / exposed	1 / 35 (2.86%)	0 / 14 (0.00%)	0 / 39 (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			
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 35 (0.00%)	0 / 14 (0.00%)	0 / 39 (0.00%)
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 failure congestive			
subjects affected / exposed	0 / 35 (0.00%)	0 / 14 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 35 (0.00%)	0 / 14 (0.00%)	0 / 39 (0.00%)
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			
Neurodegenerative disorder			
subjects affected / exposed	0 / 35 (0.00%)	0 / 14 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	0 / 35 (0.00%)	0 / 14 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Episcleritis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 14 (0.00%)	0 / 39 (0.00%)
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			
Colitis ulcerative			

subjects affected / exposed	0 / 35 (0.00%)	0 / 14 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 35 (0.00%)	0 / 14 (0.00%)	0 / 39 (0.00%)
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			
Pulmonary embolism			
subjects affected / exposed	0 / 35 (0.00%)	0 / 14 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 35 (2.86%)	0 / 14 (0.00%)	0 / 39 (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
Musculoskeletal and connective tissue disorders			
Polymyalgia rheumatica			
subjects affected / exposed	0 / 35 (0.00%)	0 / 14 (0.00%)	0 / 39 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 14 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 35 (2.86%)	0 / 14 (0.00%)	0 / 39 (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
Sepsis			

subjects affected / exposed	0 / 35 (0.00%)	0 / 14 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Adult failure to thrive			
subjects affected / exposed	1 / 35 (2.86%)	0 / 14 (0.00%)	0 / 39 (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	NOR-204: GI.1/GII.4 (15/50/500/15) µg - MPL 15 µg, 2-Dose	NOR-204: GI.1/GII.4 (15/50/500) µg, 2-Dose	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 29 (6.90%)	2 / 42 (4.76%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to lung			
subjects affected / exposed	1 / 29 (3.45%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic renal cell carcinoma			
subjects affected / exposed	1 / 29 (3.45%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 29 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 29 (0.00%)	1 / 42 (2.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			

subjects affected / exposed	0 / 29 (0.00%)	1 / 42 (2.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 29 (0.00%)	1 / 42 (2.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	0 / 29 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	0 / 29 (0.00%)	1 / 42 (2.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Neurodegenerative disorder			
subjects affected / exposed	0 / 29 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	1 / 29 (3.45%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Episcleritis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Colitis ulcerative			

subjects affected / exposed	0 / 29 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crohn's disease			
subjects affected / exposed	0 / 29 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 29 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	0 / 29 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Polymyalgia rheumatica			
subjects affected / exposed	0 / 29 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 29 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			

subjects affected / exposed	0 / 29 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Adult failure to thrive			
subjects affected / exposed	0 / 29 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	NOR-107: GI.1/GII.4 (15/50/500) µg-	NOR-107: GI.1/GII.4 (15/15/500) µg-MPL 50 µg,1-Dose	NOR-107: GI.1/GII.4 (50/50/500) µg-
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 19 (0.00%)

Non-serious adverse events	NOR-107: GI.1/GII.4 (15/15/500) µg-	NOR-107: GI.1/GII.4 (15/50/500) µg-MPL 15 µg,1-Dose	NOR-107: GI.1/GII.4 (50/50/500) µg-
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 27 (0.00%)	0 / 23 (0.00%)	0 / 27 (0.00%)

Non-serious adverse events	NOR-107: GI.1/GII.4 (15/15/500) µg,1-	NOR-107: GI.1/GII.4 (50/50/500) µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/500) µg,1-
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 22 (0.00%)	0 / 25 (0.00%)	0 / 28 (0.00%)

Non-serious adverse events	NOR-107: GI.1/GII.4 (50/150/500) µg,1-	NOR-107: GI.1/GII.4 (15/50/167) µg,1-Dose	NOR-107: GI.1/GII.4 (15/50/500) µg,2-
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	0 / 24 (0.00%)

Non-serious adverse events	NOR-107: GI.1/GII.4 (50/150/500) µg,2-	NOR-107: GI.1/GII.4 (15/50/167) µg,1-Dose	NOR-210: GI.1/GII.4 (15/50/500) µg, 1-

Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 25 (0.00%)	0 / 21 (0.00%)	0 / 24 (0.00%)

Non-serious adverse events	NOR-204: GI.1/GII.4 (15/50/500/15) µg,	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 60-94 Yrs)	NOR-204: GI.1/GII.4 (15/50/500) µg, 1-Dose (Age: 18-49
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 35 (0.00%)	0 / 14 (0.00%)	0 / 39 (0.00%)

Non-serious adverse events	NOR-204: GI.1/GII.4 (15/50/500/15) µg - MPL 15 µg, 2-Dose	NOR-204: GI.1/GII.4 (15/50/500) µg, 2-Dose	
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 29 (0.00%)	0 / 42 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported