



## Clinical trial results:

**Randomised, double-blind, placebo-controlled study of the, efficacy, safety and tolerability of EPA-FFA gastro-resistant capsules, in patients with familial adenomatous polyposis (FAP)**

### Summary

|                          |                      |
|--------------------------|----------------------|
| EudraCT number           | 2017-002809-34       |
| Trial protocol           | CZ NL DE IT DK PL BE |
| Global end of trial date | 25 June 2024         |

### Results information

|                                |                |
|--------------------------------|----------------|
| Result version number          | v1 (current)   |
| This version publication date  | 09 August 2026 |
| First version publication date | 09 August 2026 |

### Trial information

#### Trial identification

|                       |            |
|-----------------------|------------|
| Sponsor protocol code | EPA-POL-04 |
|-----------------------|------------|

#### Additional study identifiers

|                                    |   |
|------------------------------------|---|
| ISRCTN number                      | - |
| ClinicalTrials.gov id (NCT number) | - |
| WHO universal trial number (UTN)   | - |

Notes:

### Sponsors

|                              |                                                                 |
|------------------------------|-----------------------------------------------------------------|
| Sponsor organisation name    | SLA Pharma Ltd.                                                 |
| Sponsor organisation address | 3a Chestnut House, Farm Close, Shenley, United Kingdom, WD7 9AD |
| Public contact               | Justin Slagel, SLA Pharma (UK) Ltd., jslagel@slapharma.com      |
| Scientific contact           | Justin Slagel, SLA Pharma (UK) Ltd., jslagel@slapharma.com      |

Notes:

### Paediatric regulatory details

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

Notes:

## Results analysis stage

|                                                      |                  |
|------------------------------------------------------|------------------|
| Analysis stage                                       | Final            |
| Date of interim/final analysis                       | 19 December 2025 |
| Is this the analysis of the primary completion data? | No               |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 25 June 2024     |
| Was the trial ended prematurely?                     | No               |

Notes:

## General information about the trial

Main objective of the trial:

To determine the efficacy of eicosapentaenoic acid free fatty acid (EPA-FFA) gastro-resistant capsules in patients with FAP in reducing polypectomy.

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki and the principles of ICH Good Clinical Practice, and was approved by the competent regulatory authorities and independent ethics committees in each participating country. Written informed consent was obtained from every subject before any trial-specific procedure. The trial was categorised as risk Type B; the IMP (EPA-FFA) is an omega-3 free fatty acid generally regarded as safe when given orally, with adverse events in prior experience being predominantly minor gastrointestinal effects.

Subject safety was monitored through scheduled physical examinations and haematology/biochemistry testing, a telephone contact in week 1 and every other month thereafter to assess IMP tolerability, and a subject diary for adverse events; subjects with persistent clinically significant adverse events were seen at an additional unscheduled visit. SUSAR reporting and Development Safety Update Reports were maintained by Pharmacovigilance/the Medical Monitor.

To minimise pain and distress, sigmoidoscopy procedures were performed after bowel preparation with sedation according to local standard of care, and blood samples were taken by venepuncture; rectal polyps  $\leq 5$  mm were left in place unless clinically indicated, avoiding unnecessary intervention. Women of childbearing potential were required to use contraception and underwent urine pregnancy testing at visits, with defined pregnancy-reporting and withdrawal procedures, and subjects were free to withdraw at any time. Clinical trial insurance/indemnity was in place.

Background therapy: -

Evidence for comparator: -

|                                                           |             |
|-----------------------------------------------------------|-------------|
| Actual start date of recruitment                          | 12 May 2018 |
| 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 | Netherlands: 5 |
| Country: Number of subjects enrolled | Poland: 3      |
| Country: Number of subjects enrolled | Spain: 8       |
| Country: Number of subjects enrolled | Czechia: 9     |
| Country: Number of subjects enrolled | Denmark: 4     |
| Country: Number of subjects enrolled | Germany: 6     |
| Country: Number of subjects enrolled | Italy: 68      |
| Country: Number of subjects enrolled | France: 13     |
| Country: Number of subjects enrolled | Israel: 4      |

|                                    |     |
|------------------------------------|-----|
| Worldwide total number of subjects | 120 |
| EEA total number of subjects       | 116 |

Notes:

| <b>Subjects enrolled per age group</b>    |     |
|-------------------------------------------|-----|
| 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)                      | 120 |
| From 65 to 84 years                       | 0   |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details:

Subjects with FAP were recruited at specialist gastroenterology sites in Belgium, Czech Republic, Denmark, France, Germany, Israel, Italy, Netherlands, Poland and Spain (a Swedish site was initiated but recruited none). Recruitment ran 05 Dec 2018 (first consent) to 17 Jul 2023 (last randomised).

### Pre-assignment

Screening details:

Subjects were screened at Visit 1 (Day -14±7) for FAP eligibility (APC mutation, prior colectomy, IPSS stage 1-3). No run-in; fish-oil required a 2-month wash-out and NSAIDs stopped ≥3 months pre-entry (low-dose aspirin allowed).

### Period 1

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

Blinding implementation details:

Double-blind. Randomisation, labelling and packaging were done by an independent contractor, so subjects, investigators and the Sponsor stayed blinded. Active and placebo capsules were identical in appearance and packs, assigned 1:1 via IWRS. Emergency code-breaks were available 24h via the e-CRF, only for medical emergencies or SUSAR reporting.

### Arms

|                              |         |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes     |
| <b>Arm title</b>             | EPA-FFA |

Arm description:

EPA-FFA 500 mg gastro-resistant capsules, 2 g/day taken as two capsules twice daily, orally, for up to 24 months.

|                                        |                                                                           |
|----------------------------------------|---------------------------------------------------------------------------|
| Arm type                               | Experimental                                                              |
| Investigational medicinal product name | Eicosapentaenoic acid free fatty acid (EPA-FFA) gastro-resistant capsules |
| Investigational medicinal product code |                                                                           |
| Other name                             |                                                                           |
| Pharmaceutical forms                   | Gastro-resistant capsule, soft                                            |
| Routes of administration               | Oral use                                                                  |

Dosage and administration details:

Each capsule contains 500 mg EPA-FFA. Dose 2 g/day, taken as two 500 mg capsules twice daily (4 capsules/day), for up to 24 months. Capsule shell: gelatin, glycerol, sorbitol, titanium dioxide, FD&C Blue No. 1, hypromellose phthalate, dibutyl sebacate.

|                  |         |
|------------------|---------|
| <b>Arm title</b> | Placebo |
|------------------|---------|

Arm description:

Matching placebo gastro-resistant capsules (identical in appearance), two capsules twice daily, orally, for up to 24 months.

|                                        |                                |
|----------------------------------------|--------------------------------|
| Arm type                               | Placebo                        |
| Investigational medicinal product name | Placebo                        |
| Investigational medicinal product code |                                |
| Other name                             |                                |
| Pharmaceutical forms                   | Gastro-resistant capsule, soft |
| Routes of administration               | Oral use                       |

Dosage and administration details:

Each capsule contains 500 mg mixed-chain triglycerides (placebo). Regimen matched to active: two

capsules twice daily (4 capsules/day), for up to 24 months. Identical in appearance to the active IMP.  
 Capsule shell: gelatin, glycerol, sorbitol, titanium dioxide, FD&C Blue No. 1, hypromellose phthalate, dibutyl sebacate.

| <b>Number of subjects in period 1</b> | <b>EPA-FFA</b> | <b>Placebo</b> |
|---------------------------------------|----------------|----------------|
| Started                               | 61             | 59             |
| Completed                             | 41             | 38             |
| Not completed                         | 20             | 21             |
| Consent withdrawn by subject          | 6              | 2              |
| Physician decision                    | -              | 1              |
| Adverse event, non-fatal              | 4              | 3              |
| Other                                 | 1              | 7              |
| Pregnancy                             | -              | 1              |
| Non-compliance with study drug        | 1              | 2              |
| Use of prohibited medication          | 1              | -              |
| Lost to follow-up                     | 3              | 2              |
| Study ended (sponsor close-out)       | 4              | 3              |

## Baseline characteristics

### Reporting groups

|                                |               |
|--------------------------------|---------------|
| Reporting group title          | Overall trial |
| Reporting group description: - |               |

| Reporting group values                                                                                                                                                                                                                             | Overall trial | Total |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-------|--|
| Number of subjects                                                                                                                                                                                                                                 | 120           | 120   |  |
| Age categorical                                                                                                                                                                                                                                    |               |       |  |
| Age was recorded in years and categorised into the standard age bands. All subjects were adults ( $\geq 18$ years) with familial adenomatous polyposis (FAP); no subjects under 18 were enrolled. Values are reported for all randomised subjects. |               |       |  |
| Units: Subjects                                                                                                                                                                                                                                    |               |       |  |
| Adults (18-64 years)                                                                                                                                                                                                                               | 120           | 120   |  |
| Age continuous                                                                                                                                                                                                                                     |               |       |  |
| Age was recorded in years and categorised into the standard age bands. All subjects were adults ( $\geq 18$ years) with familial adenomatous polyposis (FAP); no subjects under 18 were enrolled. Values are reported for all randomised subjects. |               |       |  |
| Units: years                                                                                                                                                                                                                                       |               |       |  |
| arithmetic mean                                                                                                                                                                                                                                    | 41.5          |       |  |
| standard deviation                                                                                                                                                                                                                                 | $\pm 12.9$    | -     |  |
| Gender categorical                                                                                                                                                                                                                                 |               |       |  |
| Gender was recorded at baseline as reported by the subject/investigator and categorised as female or male. All subjects were adults with familial adenomatous polyposis (FAP). Values are reported for all randomised subjects.                    |               |       |  |
| Units: Subjects                                                                                                                                                                                                                                    |               |       |  |
| Female                                                                                                                                                                                                                                             | 52            | 52    |  |
| Male                                                                                                                                                                                                                                               | 68            | 68    |  |

### Subject analysis sets

|                            |                                       |
|----------------------------|---------------------------------------|
| Subject analysis set title | Intention-to-treat (ITT) analysis set |
| Subject analysis set type  | Intention-to-treat                    |

Subject analysis set description:

The intention-to-treat (ITT) analysis set is defined as all randomised subjects. Subjects are analysed according to their planned (randomised) treatment. The ITT set comprises 120 subjects (61 EPA-FFA, 59 placebo) and was the primary analysis set for efficacy.

| Reporting group values                                                                                                                                                                                                                             | Intention-to-treat (ITT) analysis set |  |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|--|--|
| Number of subjects                                                                                                                                                                                                                                 | 120                                   |  |  |
| Age categorical                                                                                                                                                                                                                                    |                                       |  |  |
| Age was recorded in years and categorised into the standard age bands. All subjects were adults ( $\geq 18$ years) with familial adenomatous polyposis (FAP); no subjects under 18 were enrolled. Values are reported for all randomised subjects. |                                       |  |  |
| Units: Subjects                                                                                                                                                                                                                                    |                                       |  |  |
| Adults (18-64 years)                                                                                                                                                                                                                               | 120                                   |  |  |
| Age continuous                                                                                                                                                                                                                                     |                                       |  |  |
| Age was recorded in years and categorised into the standard age bands. All subjects were adults ( $\geq 18$ years) with familial adenomatous polyposis (FAP); no subjects under 18 were enrolled. Values are reported for all randomised subjects. |                                       |  |  |
| Units: years                                                                                                                                                                                                                                       |                                       |  |  |
| arithmetic mean                                                                                                                                                                                                                                    | 41.5                                  |  |  |

|                    |        |  |  |
|--------------------|--------|--|--|
| standard deviation | ± 12.9 |  |  |
|--------------------|--------|--|--|

|                                                                                                                                                                                                                                 |    |  |  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|--|--|
| Gender categorical                                                                                                                                                                                                              |    |  |  |
| Gender was recorded at baseline as reported by the subject/investigator and categorised as female or male. All subjects were adults with familial adenomatous polyposis (FAP). Values are reported for all randomised subjects. |    |  |  |
| Units: Subjects                                                                                                                                                                                                                 |    |  |  |
| Female                                                                                                                                                                                                                          | 52 |  |  |
| Male                                                                                                                                                                                                                            | 68 |  |  |

## End points

### End points reporting groups

|                                                                                                                                                                                                                                                                                                           |                                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| Reporting group title                                                                                                                                                                                                                                                                                     | EPA-FFA                               |
| Reporting group description:<br>EPA-FFA 500 mg gastro-resistant capsules, 2 g/day taken as two capsules twice daily, orally, for up to 24 months.                                                                                                                                                         |                                       |
| Reporting group title                                                                                                                                                                                                                                                                                     | Placebo                               |
| Reporting group description:<br>Matching placebo gastro-resistant capsules (identical in appearance), two capsules twice daily, orally, for up to 24 months.                                                                                                                                              |                                       |
| Subject analysis set title                                                                                                                                                                                                                                                                                | Intention-to-treat (ITT) analysis set |
| Subject analysis set type                                                                                                                                                                                                                                                                                 | Intention-to-treat                    |
| Subject analysis set description:<br>The intention-to-treat (ITT) analysis set is defined as all randomised subjects. Subjects are analysed according to their planned (randomised) treatment. The ITT set comprises 120 subjects (61 EPA-FFA, 59 placebo) and was the primary analysis set for efficacy. |                                       |

### Primary: Total number of polypectomies (polyps >5 mm in the rectum) over the 24-month study period

|                                                                                    |                                                                                           |
|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| End point title                                                                    | Total number of polypectomies (polyps >5 mm in the rectum) over the 24-month study period |
| End point description:                                                             |                                                                                           |
| End point type                                                                     | Primary                                                                                   |
| End point timeframe:<br>From start of treatment to the Month-24 visit (cumulative) |                                                                                           |

| End point values                 | EPA-FFA             | Placebo             |  |  |
|----------------------------------|---------------------|---------------------|--|--|
| Subject group type               | Reporting group     | Reporting group     |  |  |
| Number of subjects analysed      | 56                  | 52                  |  |  |
| Units: Polypectomy               |                     |                     |  |  |
| number (confidence interval 95%) | 3.06 (2.14 to 4.38) | 4.54 (2.80 to 7.37) |  |  |

### Statistical analyses

|                                         |                               |
|-----------------------------------------|-------------------------------|
| Statistical analysis title              | EPA-FFA vs Placebo (arms) ITT |
| Comparison groups                       | EPA-FFA v Placebo             |
| Number of subjects included in analysis | 108                           |
| Analysis specification                  | Pre-specified                 |
| Analysis type                           | superiority                   |
| P-value                                 | = 0.1825                      |
| Method                                  | GEE negative binomial         |
| Parameter estimate                      | Mean ratio                    |
| Point estimate                          | 0.67                          |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.38    |
| upper limit         | 1.2     |

## Secondary: Change in polyp number from baseline to Month 24 (blinded video review)

|                        |                                                                         |
|------------------------|-------------------------------------------------------------------------|
| End point title        | Change in polyp number from baseline to Month 24 (blinded video review) |
| End point description: |                                                                         |
| End point type         | Secondary                                                               |
| End point timeframe:   |                                                                         |
| Baseline to Month 24   |                                                                         |

| End point values                             | EPA-FFA               | Placebo               |  |  |
|----------------------------------------------|-----------------------|-----------------------|--|--|
| Subject group type                           | Reporting group       | Reporting group       |  |  |
| Number of subjects analysed                  | 54                    | 52                    |  |  |
| Units: Polyps                                |                       |                       |  |  |
| least squares mean (confidence interval 95%) | 6.45 (-1.25 to 14.15) | 10.33 (2.60 to 18.06) |  |  |

## Statistical analyses

|                                         |                                |
|-----------------------------------------|--------------------------------|
| Statistical analysis title              | EPA-FFA vs Placebo (arm) ITT   |
| Comparison groups                       | EPA-FFA v Placebo              |
| Number of subjects included in analysis | 106                            |
| Analysis specification                  | Pre-specified                  |
| Analysis type                           | superiority                    |
| P-value                                 | = 0.4794                       |
| Method                                  | Mixed models analysis          |
| Parameter estimate                      | Mean difference (final values) |
| Point estimate                          | -3.87                          |
| Confidence interval                     |                                |
| level                                   | 95 %                           |
| sides                                   | 2-sided                        |
| lower limit                             | -14.73                         |
| upper limit                             | 6.98                           |

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent: first dose to the Month-24 visit (or early withdrawal +1 day)

|                 |            |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 25.1 |
|--------------------|------|

### Reporting groups

|                       |         |
|-----------------------|---------|
| Reporting group title | EPA-FFA |
|-----------------------|---------|

Reporting group description:

EPA-FFA 500 mg gastro-resistant capsules, 2 g/day taken as two capsules twice daily, orally, for up to 24 months.

|                       |         |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Matching placebo gastro-resistant capsules (identical in appearance), two capsules twice daily, orally, for up to 24 months.

| Serious adverse events                                              | EPA-FFA        | Placebo         |  |
|---------------------------------------------------------------------|----------------|-----------------|--|
| Total subjects affected by serious adverse events                   |                |                 |  |
| subjects affected / exposed                                         | 5 / 60 (8.33%) | 6 / 58 (10.34%) |  |
| number of deaths (all causes)                                       | 0              | 1               |  |
| number of deaths resulting from adverse events                      | 0              | 1               |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                |                 |  |
| Rectal neoplasm                                                     |                |                 |  |
| subjects affected / exposed                                         | 1 / 60 (1.67%) | 0 / 58 (0.00%)  |  |
| occurrences causally related to treatment / all                     | 0 / 1          | 0 / 0           |  |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0           |  |
| Injury, poisoning and procedural complications                      |                |                 |  |
| Ankle fracture                                                      |                |                 |  |
| subjects affected / exposed                                         | 1 / 60 (1.67%) | 0 / 58 (0.00%)  |  |
| occurrences causally related to treatment / all                     | 0 / 1          | 0 / 0           |  |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0           |  |
| Joint dislocation                                                   |                |                 |  |
| subjects affected / exposed                                         | 1 / 60 (1.67%) | 0 / 58 (0.00%)  |  |
| occurrences causally related to treatment / all                     | 0 / 1          | 0 / 0           |  |
| deaths causally related to treatment / all                          | 0 / 0          | 0 / 0           |  |
| Vascular disorders                                                  |                |                 |  |

|                                                      |                |                |  |
|------------------------------------------------------|----------------|----------------|--|
| Vascular occlusion                                   |                |                |  |
| subjects affected / exposed                          | 1 / 60 (1.67%) | 0 / 58 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| General disorders and administration site conditions |                |                |  |
| Condition aggravated                                 |                |                |  |
| subjects affected / exposed                          | 1 / 60 (1.67%) | 0 / 58 (0.00%) |  |
| occurrences causally related to treatment / all      | 0 / 1          | 0 / 0          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Gastrointestinal disorders                           |                |                |  |
| Abdominal pain upper                                 |                |                |  |
| subjects affected / exposed                          | 0 / 60 (0.00%) | 1 / 58 (1.72%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Diarrhoea                                            |                |                |  |
| subjects affected / exposed                          | 0 / 60 (0.00%) | 1 / 58 (1.72%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Hepatobiliary disorders                              |                |                |  |
| Biliary colic                                        |                |                |  |
| subjects affected / exposed                          | 0 / 60 (0.00%) | 1 / 58 (1.72%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Respiratory, thoracic and mediastinal disorders      |                |                |  |
| Dyspnoea                                             |                |                |  |
| subjects affected / exposed                          | 0 / 60 (0.00%) | 1 / 58 (1.72%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Renal and urinary disorders                          |                |                |  |
| Renal colic                                          |                |                |  |
| subjects affected / exposed                          | 0 / 60 (0.00%) | 1 / 58 (1.72%) |  |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          |  |
| Infections and infestations                          |                |                |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| COVID-19                                        |                |                |  |
| subjects affected / exposed                     | 0 / 60 (0.00%) | 1 / 58 (1.72%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 1          |  |

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

| <b>Non-serious adverse events</b>                     | EPA-FFA          | Placebo          |  |
|-------------------------------------------------------|------------------|------------------|--|
| Total subjects affected by non-serious adverse events |                  |                  |  |
| subjects affected / exposed                           | 43 / 60 (71.67%) | 43 / 58 (74.14%) |  |
| Nervous system disorders                              |                  |                  |  |
| Headache                                              |                  |                  |  |
| subjects affected / exposed                           | 9 / 60 (15.00%)  | 10 / 58 (17.24%) |  |
| occurrences (all)                                     | 21               | 37               |  |
| General disorders and administration site conditions  |                  |                  |  |
| Pyrexia                                               |                  |                  |  |
| subjects affected / exposed                           | 2 / 60 (3.33%)   | 4 / 58 (6.90%)   |  |
| occurrences (all)                                     | 2                | 6                |  |
| Gastrointestinal disorders                            |                  |                  |  |
| Diarrhoea                                             |                  |                  |  |
| subjects affected / exposed                           | 12 / 60 (20.00%) | 16 / 58 (27.59%) |  |
| occurrences (all)                                     | 20               | 36               |  |
| Abdominal pain                                        |                  |                  |  |
| subjects affected / exposed                           | 6 / 60 (10.00%)  | 6 / 58 (10.34%)  |  |
| occurrences (all)                                     | 8                | 14               |  |
| Toothache                                             |                  |                  |  |
| subjects affected / exposed                           | 5 / 60 (8.33%)   | 6 / 58 (10.34%)  |  |
| occurrences (all)                                     | 6                | 6                |  |
| Abdominal pain upper                                  |                  |                  |  |
| subjects affected / exposed                           | 5 / 60 (8.33%)   | 3 / 58 (5.17%)   |  |
| occurrences (all)                                     | 6                | 4                |  |
| Dyspepsia                                             |                  |                  |  |
| subjects affected / exposed                           | 3 / 60 (5.00%)   | 4 / 58 (6.90%)   |  |
| occurrences (all)                                     | 4                | 4                |  |
| Nausea                                                |                  |                  |  |

|                                                                                                                          |                     |                      |  |
|--------------------------------------------------------------------------------------------------------------------------|---------------------|----------------------|--|
| subjects affected / exposed<br>occurrences (all)                                                                         | 5 / 60 (8.33%)<br>5 | 1 / 58 (1.72%)<br>1  |  |
| Abdominal distension<br>subjects affected / exposed<br>occurrences (all)                                                 | 0 / 60 (0.00%)<br>0 | 5 / 58 (8.62%)<br>6  |  |
| Musculoskeletal and connective tissue disorders<br>Pain in extremity<br>subjects affected / exposed<br>occurrences (all) | 1 / 60 (1.67%)<br>1 | 5 / 58 (8.62%)<br>5  |  |
| Infections and infestations<br>Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all)                       | 2 / 60 (3.33%)<br>2 | 6 / 58 (10.34%)<br>8 |  |
| Influenza<br>subjects affected / exposed<br>occurrences (all)                                                            | 5 / 60 (8.33%)<br>7 | 2 / 58 (3.45%)<br>4  |  |
| COVID-19<br>subjects affected / exposed<br>occurrences (all)                                                             | 5 / 60 (8.33%)<br>5 | 7 / 58 (12.07%)<br>7 |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported