



## Clinical trial results:

**A Phase 3 multicenter, randomized, double-blind, placebo-controlled, clinical study to assess the efficacy and safety of linzagolix in subjects with moderate to severe endometriosis-associated pain.**

### Summary

|                          |                         |
|--------------------------|-------------------------|
| EudraCT number           | 2019-000283-26          |
| Trial protocol           | FR HU AT CZ PL ES BG RO |
| Global end of trial date | 28 June 2022            |

### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1 (current) |
| This version publication date  | 23 July 2023 |
| First version publication date | 23 July 2023 |

### Trial information

#### Trial identification

|                       |                |
|-----------------------|----------------|
| Sponsor protocol code | 18-OBE2109-003 |
|-----------------------|----------------|

#### Additional study identifiers

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

Notes:

### Sponsors

|                              |                                                                                                |
|------------------------------|------------------------------------------------------------------------------------------------|
| Sponsor organisation name    | Kissei Pharmaceutical Co., Ltd.                                                                |
| Sponsor organisation address | 3-1-3 Koishikawa, Bunkyo-ku, Tokyo, Japan, 112-0002                                            |
| Public contact               | Kissei Pharmaceutical Co., Ltd., Clinical Projects Management, rinsyousiken@pharm.kissei.co.jp |
| Scientific contact           | Kissei Pharmaceutical Co., Ltd., Clinical Projects Management, rinsyousiken@pharm.kissei.co.jp |

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                       | 22 December 2022 |
| Is this the analysis of the primary completion data? | Yes              |
| Primary completion date                              | 01 April 2022    |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 28 June 2022     |
| Was the trial ended prematurely?                     | No               |

Notes:

## General information about the trial

Main objective of the trial:

To demonstrate the efficacy and safety of linzagolix administered orally once daily for 3 months at a dose of 75 mg alone or of 200 mg in combination with add-back therapy versus placebo, in the management of moderate to severe endometriosis-associated pain.

Protection of trial subjects:

The study was conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki and with Good Clinical Practice (GCP) rules and in line with local regulatory requirements.

Background therapy: -

Evidence for comparator: -

|                                                           |              |
|-----------------------------------------------------------|--------------|
| Actual start date of recruitment                          | 13 June 2019 |
| Long term follow-up planned                               | No           |
| Independent data monitoring committee (IDMC) involvement? | Yes          |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |                   |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | Poland: 179       |
| Country: Number of subjects enrolled | Romania: 49       |
| Country: Number of subjects enrolled | Spain: 4          |
| Country: Number of subjects enrolled | Austria: 1        |
| Country: Number of subjects enrolled | Bulgaria: 13      |
| Country: Number of subjects enrolled | Czechia: 6        |
| Country: Number of subjects enrolled | France: 1         |
| Country: Number of subjects enrolled | Hungary: 2        |
| Country: Number of subjects enrolled | Ukraine: 205      |
| Country: Number of subjects enrolled | United States: 26 |
| Worldwide total number of subjects   | 486               |
| EEA total number of subjects         | 255               |

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)                     | 486 |
| From 65 to 84 years                      | 0   |
| 85 years and over                        | 0   |

## Subject disposition

### Recruitment

Recruitment details:

The study was conducted at 71 clinical sites throughout the world, including centers in Austria, Bulgaria, Czech Republic, France, Hungary, Poland, Romania, Spain, Ukraine, and United States

### Pre-assignment

Screening details:

Number of subjects:

- 854 screened
- 486 randomized; 2 discontinued study between randomization and Day 1 due to protocol deviation
- 484 included in both of Full Analysis Set (FAS) and Safety Analysis Set (SAF)

### 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 |

### Arms

|                              |                 |
|------------------------------|-----------------|
| Are arms mutually exclusive? | Yes             |
| <b>Arm title</b>             | LGX 75 mg group |

Arm description:

Linzagolix 75 mg + Placebo ABT  
Once daily for 6 months

|                                        |                    |
|----------------------------------------|--------------------|
| Arm type                               | Experimental       |
| Investigational medicinal product name | Linzagolix         |
| Investigational medicinal product code |                    |
| Other name                             | OBE2109            |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

Dosage and administration details:

75 mg

|                  |                        |
|------------------|------------------------|
| <b>Arm title</b> | LGX 200 mg + ABT group |
|------------------|------------------------|

Arm description:

Linzagolix 200 mg + ABT  
Once daily for 6 months

|                                        |                    |
|----------------------------------------|--------------------|
| Arm type                               | Experimental       |
| Investigational medicinal product name | Linzagolix         |
| Investigational medicinal product code |                    |
| Other name                             | OBE2109            |
| Pharmaceutical forms                   | Film-coated tablet |
| Routes of administration               | Oral use           |

Dosage and administration details:

200 mg

|                                        |                                              |
|----------------------------------------|----------------------------------------------|
| Investigational medicinal product name | ESTRADIOL HEMIHYDRATE/NORETHISTERONE ACETATE |
| Investigational medicinal product code |                                              |
| Other name                             |                                              |
| Pharmaceutical forms                   | Capsule                                      |
| Routes of administration               | Oral use                                     |

Dosage and administration details:  
 ESTRADIOL HEMIHYDRATE: 1 mg  
 NORETHISTERONE ACETATE: 0.5 mg

|                                                                                 |                    |
|---------------------------------------------------------------------------------|--------------------|
| <b>Arm title</b>                                                                | Placebo group      |
| Arm description:<br>Placebo Linzagolix + Placebo ABT<br>Once daily for 6 months |                    |
| Arm type                                                                        | Placebo            |
| Investigational medicinal product name                                          | Placebo Linzagolix |
| Investigational medicinal product code                                          |                    |
| Other name                                                                      |                    |
| Pharmaceutical forms                                                            | Film-coated tablet |
| Routes of administration                                                        | Oral use           |
| Dosage and administration details:<br>0 mg                                      |                    |
| Investigational medicinal product name                                          | Placebo ABT        |
| Investigational medicinal product code                                          |                    |
| Other name                                                                      |                    |
| Pharmaceutical forms                                                            | Capsule            |
| Routes of administration                                                        | Oral use           |
| Dosage and administration details:<br>0 mg                                      |                    |

| <b>Number of subjects in period 1<sup>[1]</sup></b> | LGX 75 mg group | LGX 200 mg + ABT group | Placebo group |
|-----------------------------------------------------|-----------------|------------------------|---------------|
| Started                                             | 160             | 162                    | 162           |
| Day 1                                               | 160             | 162                    | 162           |
| Month 3                                             | 149             | 155                    | 149           |
| Month 6                                             | 140             | 143                    | 137           |
| Completed                                           | 140             | 143                    | 137           |
| Not completed                                       | 20              | 19                     | 25            |
| Consent withdrawn by subject                        | 8               | 10                     | 20            |
| Adverse event, non-fatal                            | 8               | 6                      | 3             |
| Other                                               | 1               | -                      | -             |
| Pregnancy                                           | 2               | -                      | 1             |
| Lost to follow-up                                   | -               | 1                      | 1             |
| Protocol deviation                                  | 1               | 2                      | -             |

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: The number of subjects reported to be in the baseline period are as per the Full Analysis Set (FAS). A total of 486 subjects were randomized, 484 subjects were included in the FAS. Two randomized subjects were excluded: these 2 subjects discontinued the study between randomization

and Day 1 due to protocol deviation.

## Baseline characteristics

### Reporting groups

|                                                                                             |                        |
|---------------------------------------------------------------------------------------------|------------------------|
| Reporting group title                                                                       | LGX 75 mg group        |
| Reporting group description:<br>Linzagolix 75 mg + Placebo ABT<br>Once daily for 6 months   |                        |
| Reporting group title                                                                       | LGX 200 mg + ABT group |
| Reporting group description:<br>Linzagolix 200 mg + ABT<br>Once daily for 6 months          |                        |
| Reporting group title                                                                       | Placebo group          |
| Reporting group description:<br>Placebo Linzagolix + Placebo ABT<br>Once daily for 6 months |                        |

| Reporting group values                             | LGX 75 mg group | LGX 200 mg + ABT group | Placebo group |
|----------------------------------------------------|-----------------|------------------------|---------------|
| Number of subjects                                 | 160             | 162                    | 162           |
| Age categorical<br>Units: Subjects                 |                 |                        |               |
| In utero                                           | 0               | 0                      | 0             |
| Preterm newborn infants (gestational age < 37 wks) | 0               | 0                      | 0             |
| Newborns (0-27 days)                               | 0               | 0                      | 0             |
| Infants and toddlers (28 days-23 months)           | 0               | 0                      | 0             |
| Children (2-11 years)                              | 0               | 0                      | 0             |
| Adolescents (12-17 years)                          | 0               | 0                      | 0             |
| Adults (18-64 years)                               | 160             | 162                    | 162           |
| From 65-84 years                                   | 0               | 0                      | 0             |
| 85 years and over                                  | 0               | 0                      | 0             |
| Age continuous<br>Units: years                     |                 |                        |               |
| arithmetic mean                                    | 35.1            | 34.6                   | 34.9          |
| standard deviation                                 | ± 6.4           | ± 6.8                  | ± 6.8         |
| Gender categorical<br>Units: Subjects              |                 |                        |               |
| Female                                             | 160             | 162                    | 162           |
| Male                                               | 0               | 0                      | 0             |

| Reporting group values                             | Total |  |  |
|----------------------------------------------------|-------|--|--|
| Number of subjects                                 | 484   |  |  |
| Age categorical<br>Units: Subjects                 |       |  |  |
| In utero                                           | 0     |  |  |
| Preterm newborn infants (gestational age < 37 wks) | 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)      | 484 |  |  |
| From 65-84 years          | 0   |  |  |
| 85 years and over         | 0   |  |  |
| Age continuous            |     |  |  |
| Units: years              |     |  |  |
| arithmetic mean           |     |  |  |
| standard deviation        | -   |  |  |
| Gender categorical        |     |  |  |
| Units: Subjects           |     |  |  |
| Female                    | 484 |  |  |
| Male                      | 0   |  |  |



## End points

### End points reporting groups

|                                                                                             |                        |
|---------------------------------------------------------------------------------------------|------------------------|
| Reporting group title                                                                       | LGX 75 mg group        |
| Reporting group description:<br>Linzagolix 75 mg + Placebo ABT<br>Once daily for 6 months   |                        |
| Reporting group title                                                                       | LGX 200 mg + ABT group |
| Reporting group description:<br>Linzagolix 200 mg + ABT<br>Once daily for 6 months          |                        |
| Reporting group title                                                                       | Placebo group          |
| Reporting group description:<br>Placebo Linzagolix + Placebo ABT<br>Once daily for 6 months |                        |

### Primary: Reduction of DYS at Month 3 - Proportion of responders

|                                  |                                                        |
|----------------------------------|--------------------------------------------------------|
| End point title                  | Reduction of DYS at Month 3 - Proportion of responders |
| End point description:           |                                                        |
| End point type                   | Primary                                                |
| End point timeframe:<br>3 months |                                                        |

| End point values                 | LGX 75 mg group     | LGX 200 mg + ABT group | Placebo group       |  |
|----------------------------------|---------------------|------------------------|---------------------|--|
| Subject group type               | Reporting group     | Reporting group        | Reporting group     |  |
| Number of subjects analysed      | 160                 | 162                    | 162                 |  |
| Units: percent                   |                     |                        |                     |  |
| number (confidence interval 95%) | 44.0 (36.3 to 52.0) | 72.9 (65.3 to 79.4)    | 23.5 (17.5 to 30.7) |  |

### Statistical analyses

|                                         |                                 |
|-----------------------------------------|---------------------------------|
| Statistical analysis title              | p-value of treatment effect     |
| Comparison groups                       | LGX 75 mg group v Placebo group |
| Number of subjects included in analysis | 322                             |
| Analysis specification                  | Pre-specified                   |
| Analysis type                           | other                           |
| P-value                                 | < 0.001                         |
| Method                                  | Bonferroni-corrected p-value    |

|                                         |                                        |
|-----------------------------------------|----------------------------------------|
| <b>Statistical analysis title</b>       | p-value of treatment effect            |
| Comparison groups                       | LGX 200 mg + ABT group v Placebo group |
| Number of subjects included in analysis | 324                                    |
| Analysis specification                  | Pre-specified                          |
| Analysis type                           | other                                  |
| P-value                                 | < 0.001                                |
| Method                                  | Bonferroni-corrected p-value           |

### Primary: Reduction of NMPP at Month 3 - Proportion of responders

|                        |                                                         |
|------------------------|---------------------------------------------------------|
| End point title        | Reduction of NMPP at Month 3 - Proportion of responders |
| End point description: |                                                         |
| End point type         | Primary                                                 |
| End point timeframe:   |                                                         |
| 3 months               |                                                         |

| <b>End point values</b>          | LGX 75 mg group     | LGX 200 mg + ABT group | Placebo group       |  |
|----------------------------------|---------------------|------------------------|---------------------|--|
| Subject group type               | Reporting group     | Reporting group        | Reporting group     |  |
| Number of subjects analysed      | 160                 | 162                    | 162                 |  |
| Units: percent                   |                     |                        |                     |  |
| number (confidence interval 95%) | 38.9 (31.5 to 46.9) | 47.3 (39.5 to 55.3)    | 30.9 (24.1 to 38.6) |  |

### Statistical analyses

|                                         |                                 |
|-----------------------------------------|---------------------------------|
| <b>Statistical analysis title</b>       | p-value of treatment effect     |
| Comparison groups                       | LGX 75 mg group v Placebo group |
| Number of subjects included in analysis | 322                             |
| Analysis specification                  | Pre-specified                   |
| Analysis type                           | other                           |
| P-value                                 | = 0.279                         |
| Method                                  | Bonferroni-corrected p-value    |

|                                   |                                        |
|-----------------------------------|----------------------------------------|
| <b>Statistical analysis title</b> | p-value of treatment effect            |
| Comparison groups                 | LGX 200 mg + ABT group v Placebo group |

|                                         |                              |
|-----------------------------------------|------------------------------|
| Number of subjects included in analysis | 324                          |
| Analysis specification                  | Pre-specified                |
| Analysis type                           | other                        |
| P-value                                 | = 0.007                      |
| Method                                  | Bonferroni-corrected p-value |

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Day 1 to Month 6

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 23.0 |
|--------------------|------|

### Reporting groups

|                       |                 |
|-----------------------|-----------------|
| Reporting group title | LGX 75 mg group |
|-----------------------|-----------------|

Reporting group description: -

|                       |                        |
|-----------------------|------------------------|
| Reporting group title | LGX 200 mg + ABT group |
|-----------------------|------------------------|

Reporting group description: -

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

Reporting group description: -

| Serious adverse events                            | LGX 75 mg group | LGX 200 mg + ABT group | Placebo group   |
|---------------------------------------------------|-----------------|------------------------|-----------------|
| Total subjects affected by serious adverse events |                 |                        |                 |
| subjects affected / exposed                       | 2 / 160 (1.25%) | 2 / 162 (1.23%)        | 0 / 162 (0.00%) |
| number of deaths (all causes)                     | 0               | 0                      | 0               |
| number of deaths resulting from adverse events    | 0               | 0                      | 0               |
| Gastrointestinal disorders                        |                 |                        |                 |
| Abdominal pain                                    |                 |                        |                 |
| subjects affected / exposed                       | 0 / 160 (0.00%) | 1 / 162 (0.62%)        | 0 / 162 (0.00%) |
| occurrences causally related to treatment / all   | 0 / 0           | 0 / 1                  | 0 / 0           |
| deaths causally related to treatment / all        | 0 / 0           | 0 / 0                  | 0 / 0           |
| Reproductive system and breast disorders          |                 |                        |                 |
| Endometriosis                                     |                 |                        |                 |
| subjects affected / exposed                       | 1 / 160 (0.63%) | 0 / 162 (0.00%)        | 0 / 162 (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                       |                 |                        |                 |
| Peritonitis                                       |                 |                        |                 |
| subjects affected / exposed                       | 1 / 160 (0.63%) | 0 / 162 (0.00%)        | 0 / 162 (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           |
| Pneumonia                                         |                 |                        |                 |

|                                                 |                 |                 |                 |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 160 (0.00%) | 1 / 162 (0.62%) | 0 / 162 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

Frequency threshold for reporting non-serious adverse events: 3 %

| <b>Non-serious adverse events</b>                     | LGX 75 mg group   | LGX 200 mg + ABT group | Placebo group     |
|-------------------------------------------------------|-------------------|------------------------|-------------------|
| Total subjects affected by non-serious adverse events |                   |                        |                   |
| subjects affected / exposed                           | 83 / 160 (51.88%) | 94 / 162 (58.02%)      | 69 / 162 (42.59%) |
| Vascular disorders                                    |                   |                        |                   |
| Hot flush                                             |                   |                        |                   |
| subjects affected / exposed                           | 12 / 160 (7.50%)  | 11 / 162 (6.79%)       | 4 / 162 (2.47%)   |
| occurrences (all)                                     | 15                | 11                     | 4                 |
| Nervous system disorders                              |                   |                        |                   |
| Headache                                              |                   |                        |                   |
| subjects affected / exposed                           | 13 / 160 (8.13%)  | 17 / 162 (10.49%)      | 13 / 162 (8.02%)  |
| occurrences (all)                                     | 17                | 24                     | 25                |
| General disorders and administration site conditions  |                   |                        |                   |
| Fatigue                                               |                   |                        |                   |
| subjects affected / exposed                           | 6 / 160 (3.75%)   | 11 / 162 (6.79%)       | 4 / 162 (2.47%)   |
| occurrences (all)                                     | 6                 | 11                     | 4                 |
| Blood and lymphatic system disorders                  |                   |                        |                   |
| Anaemia                                               |                   |                        |                   |
| subjects affected / exposed                           | 5 / 160 (3.13%)   | 4 / 162 (2.47%)        | 10 / 162 (6.17%)  |
| occurrences (all)                                     | 5                 | 4                      | 13                |
| Gastrointestinal disorders                            |                   |                        |                   |
| Nausea                                                |                   |                        |                   |
| subjects affected / exposed                           | 6 / 160 (3.75%)   | 6 / 162 (3.70%)        | 7 / 162 (4.32%)   |
| occurrences (all)                                     | 6                 | 6                      | 7                 |
| Abdominal distension                                  |                   |                        |                   |
| subjects affected / exposed                           | 4 / 160 (2.50%)   | 6 / 162 (3.70%)        | 3 / 162 (1.85%)   |
| occurrences (all)                                     | 4                 | 6                      | 4                 |
| Diarrhoea                                             |                   |                        |                   |
| subjects affected / exposed                           | 4 / 160 (2.50%)   | 2 / 162 (1.23%)        | 5 / 162 (3.09%)   |
| occurrences (all)                                     | 4                 | 2                      | 5                 |
| Constipation                                          |                   |                        |                   |

|                                                  |                      |                      |                      |
|--------------------------------------------------|----------------------|----------------------|----------------------|
| subjects affected / exposed<br>occurrences (all) | 3 / 160 (1.88%)<br>3 | 5 / 162 (3.09%)<br>5 | 2 / 162 (1.23%)<br>2 |
| Reproductive system and breast disorders         |                      |                      |                      |
| Vaginal haemorrhage                              |                      |                      |                      |
| subjects affected / exposed                      | 4 / 160 (2.50%)      | 6 / 162 (3.70%)      | 1 / 162 (0.62%)      |
| occurrences (all)                                | 5                    | 7                    | 1                    |
| Breast pain                                      |                      |                      |                      |
| subjects affected / exposed                      | 1 / 160 (0.63%)      | 2 / 162 (1.23%)      | 5 / 162 (3.09%)      |
| occurrences (all)                                | 1                    | 2                    | 5                    |
| Skin and subcutaneous tissue disorders           |                      |                      |                      |
| Acne                                             |                      |                      |                      |
| subjects affected / exposed                      | 1 / 160 (0.63%)      | 3 / 162 (1.85%)      | 5 / 162 (3.09%)      |
| occurrences (all)                                | 1                    | 3                    | 5                    |
| Psychiatric disorders                            |                      |                      |                      |
| Mood swings                                      |                      |                      |                      |
| subjects affected / exposed                      | 8 / 160 (5.00%)      | 5 / 162 (3.09%)      | 3 / 162 (1.85%)      |
| occurrences (all)                                | 8                    | 6                    | 3                    |
| Musculoskeletal and connective tissue disorders  |                      |                      |                      |
| Arthralgia                                       |                      |                      |                      |
| subjects affected / exposed                      | 8 / 160 (5.00%)      | 3 / 162 (1.85%)      | 2 / 162 (1.23%)      |
| occurrences (all)                                | 8                    | 3                    | 2                    |
| Infections and infestations                      |                      |                      |                      |
| COVID-19                                         |                      |                      |                      |
| subjects affected / exposed                      | 5 / 160 (3.13%)      | 6 / 162 (3.70%)      | 5 / 162 (3.09%)      |
| occurrences (all)                                | 5                    | 6                    | 5                    |
| Urinary tract infection                          |                      |                      |                      |
| subjects affected / exposed                      | 3 / 160 (1.88%)      | 7 / 162 (4.32%)      | 0 / 162 (0.00%)      |
| occurrences (all)                                | 3                    | 7                    | 0                    |

## 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