

# A Phase 1 trial: Fortrea Phase 1 Leeds Clinic: SUDO-550-101

<b>Submission date</b> 02/07/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/07/2025	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/08/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

## Contact information

### Type(s)

Principal investigator

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### Type(s)

Public, Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

1010113

### Protocol serial number

8535365

## Study information

### Scientific Title

A Phase 1 trial: Fortrea Phase 1 Leeds Clinic: SUDO-550-101

### Study objectives

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 20/09/2024, London Chelsea Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8141; chelsea.rec@hra.nhs.uk), ref: 24/LO/0575

### Study design

Interventional single-centre partially blinded randomized study

### Primary study design

Interventional

### Study type(s)

Safety

### Health condition(s) or problem(s) studied

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## **Interventions**

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

## **Intervention Type**

Other

## **Primary outcome(s)**

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## **Key secondary outcome(s)**

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

## **Completion date**

20/08/2025

# **Eligibility**

## **Key inclusion criteria**

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## **Participant type(s)**

Healthy volunteer, Other

## **Healthy volunteers allowed**

No

## **Age group**

Adult

## **Sex**

All

## **Key exclusion criteria**

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## **Date of first enrolment**

03/10/2024

## **Date of final enrolment**

20/08/2025

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

#### Fortrea Clinical Research Unit Limited

Draper's Yard Marshall Street

Holbeck

Leeds

United Kingdom

LS11 9EH

## Sponsor information

### Organisation

Sudo Biosciences Limited

## Funder(s)

### Funder type

Industry

### Funder Name

Sudo Biosciences Limited

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are not expected to be made available because of their high commercial sensitivity and the negligible benefit to the public of publication of results of non-therapeutic clinical trials.

### IPD sharing plan summary

Not expected to be made available