

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

<b>Submission date</b> 02/07/2025	<b>Recruitment status</b> 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> 03/07/2025	<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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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

1010113

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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

### Secondary study design

Randomised parallel trial

### Study setting(s)

Other

**Study type(s)**

Safety

**Participant information sheet**

Not available in web format, please use the contact details to request a participant information sheet

**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 measure**

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**Secondary outcome measures**

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.

**Overall study start date**

01/07/2024

**Completion date**

20/08/2025

**Eligibility****Key inclusion criteria**

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**Participant type(s)**

Healthy volunteer, Other

**Age group**

Adult

**Sex**

Both

**Target number of participants**

165

**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**

England

United Kingdom

**Study participating centre****Fortrea Clinical Research Unit Limited**

Draper's Yard Marshall Street

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**Sponsor information****Organisation**

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**Sponsor type**

Industry

**Website**

<https://www.sudobio.com/>

**Funder(s)****Funder type**

Industry

**Funder Name**

Sudo Biosciences Limited

**Results and Publications****Publication and dissemination plan**

Full trial details will be published up to 30 months after the end of the trial. Publication of some trial details is deferred because of the high commercial sensitivity of this Phase I study and the negligible benefit to the public of Phase I information. Results may be posted on or after the date of publication of full trial details.

**Intention to publish date**

20/02/2028

**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