

# Phase I Trial: 36414 (SUDO-550-102)

<b>Submission date</b> 16/01/2026	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/01/2026	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/01/2026	<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)

Public, Scientific

### Contact name

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### Type(s)

Principal investigator

### Contact name

Dr Annelize Koch

### Contact details

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# Additional identifiers

## Study information

### Scientific Title

Phase I Trial: 36414 (SUDO-550-102)

### 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

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### Ethics approval(s)

1. approved 20/11/2025, Wales Research Ethics Committee 2 (Health and Care Research Wales, Floor 4, Crown Building, Cathays Park, Cardiff, CF10 3NQ, United Kingdom; N/A; Wales. REC2@wales.nhs.uk), ref: 25/WA/0247
2. approved 01/12/2025, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; N/A; info@mhra.gov.uk), ref: CTA 59625/0003/001-0001

### Primary study design

Interventional

### Allocation

N/A: single arm study

### Masking

Open (masking not used)

### Control

Uncontrolled

### Assignment

Single

### Purpose

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### Study type(s)

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

N/A - healthy volunteers

### Interventions

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### **Intervention Type**

Drug

### **Phase**

Phase I

### **Drug/device/biological/vaccine name(s)**

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### **Primary outcome(s)**

1. 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. measured using - at -

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

### **Completion date**

09/03/2026

## **Eligibility**

### **Key inclusion criteria**

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### **Healthy volunteers allowed**

Yes

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

55 years

### **Sex**

Female

### **Total final enrolment**

0

## Key exclusion criteria

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## Date of first enrolment

08/12/2025

## Date of final enrolment

08/02/2026

## Locations

### Countries of recruitment

United Kingdom

Wales

### Study participating centre

**Simbec-Orion Clinical Pharmacology (AKA Simbec Research Ltd)**

Simbec-Orion Clinical Pharmacology, Merthyr Tydfil Industrial Park, Cardiff Road

Merthyr Tydfil

Wales

CF48 4DR

## Sponsor information

### Organisation

Sudo Biosciences Ltd

## Funder(s)

### Funder type

### Funder Name

Sudo Biosciences Ltd

## Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not expected to be made available