

# Phase 1 trial: Labcorp code 8501022

<b>Submission date</b> 21/03/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 23/03/2023	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 30/10/2023	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data
		<input 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)**  
Scientific

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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
1006499

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
IRAS 1006499, Labcorp code: 8501022

## **Study information**

**Scientific Title**  
Phase 1 trial: Labcorp code 8501022

**Study objectives**  
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**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

1. Approved 21/12/2022, North East - York Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0) 207 104 8079; york.rec@hra.nhs.uk), ref: 22/NE/0185
2. Approved 17/01/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, UK; +44 (0) 20 3080 6000; info@mhra.gov.uk), ref: CTA 36216/0012/001-0001

The HRA has approved deferral of publication of trial details.

### **Study design**

Safety and tolerability study in 108 healthy volunteers.

### **Primary study design**

Interventional

### **Study type(s)**

Other

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

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)**

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

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### **Completion date**

26/09/2023

## **Eligibility**

**Key inclusion criteria**

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**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

76

**Key exclusion criteria**

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**Date of first enrolment**

06/02/2023

**Date of final enrolment**

26/09/2023

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Labcorp CRU Ltd

Springfield House

Hyde Street

Leeds

United Kingdom

LS2 9LH

**Study participating centre**  
**Labcorp CRU Ltd**  
Drapers Yard, Marshall Street  
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## Sponsor information

**Organisation**  
Albireo (Sweden)

**ROR**  
<https://ror.org/02py10784>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Albireo AB

## 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			26/07/2023	No	No