

# Phase 1 Trial: EMP-012-1

<b>Submission date</b> 24/02/2025	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/02/2025	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/02/2026	<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)

Principal investigator

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Public, Scientific

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## Additional identifiers

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

**Integrated Research Application System (IRAS)**  
1011107

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

**Protocol serial number**  
1011107/EMP-012-1

## Study information

**Scientific Title**  
Phase 1 Trial: EMP-012-1

### 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 13/02/2025, North East-York Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8079; York.rec@hra.nhs.uk), ref: 25/NE/0004

### Study design

First-in-man safety pharmacokinetic and pharmacodynamics trial in 80 subjects including healthy volunteers and patients

**Primary study design**  
Interventional

**Study type(s)**  
Safety

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

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### 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**

18/12/2026

## **Eligibility**

### **Key inclusion criteria**

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### **Participant type(s)**

Healthy volunteer, Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Total final enrolment**

0

**Key exclusion criteria**

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**Date of first enrolment**

24/02/2025

**Date of final enrolment**

20/05/2026

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

United Kingdom

England

Australia

**Study participating centre****Medicines Evaluation Unit Limited**

The Langley Building

Southmoor Road

Wythenshawe

Manchester

England

M23 9QZ

**Sponsor information****Organisation**

Empirico Inc.

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

Industry

**Funder Name**

Empirico Inc.

# Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Data sharing statement to be made available at a later date