

# Phase I trial: Quotient code QSC301152

<b>Submission date</b> 14/12/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/12/2023	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/12/2023	<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 sponsor has confirmed that the trial meets the criteria for 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

### Contact name

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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)

1008350

### Protocol serial number

IRAS 1008350, QSC301152

## Study information

### Scientific Title

Phase I trial: Quotient code QSC301152 [The full scientific title will be published within 30 months after the end of the trial]

### Study objectives

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### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 06/12/2023, London Chelsea REC (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8150; chelsea.rec@hra.nhs.uk), ref: 23/LO/0799

### Study design

First-in-man safety pharmacokinetics and pharmacodynamics trial

### Primary study design

Interventional

### Study type(s)

Safety

### 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)**

The sponsor has confirmed that the trial meets the criteria for 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.

**Key secondary outcome(s)**

The sponsor has confirmed that the trial meets the criteria for 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**

07/04/2025

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

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**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

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**Date of first enrolment**

18/12/2023

**Date of final enrolment**

07/04/2025

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

### Quotient Sciences Limited

Mere Way, Ruddington

Nottingham

United Kingdom

NG11 6JS

# Sponsor information

## Organisation

Novartis (Switzerland)

## ROR

<https://ror.org/02f9zrr09>

# Funder(s)

## Funder type

Industry

## Funder Name

Novartis Pharma

## Alternative Name(s)

Novartis Deutschland GmbH, Novartis Pharma GmbH, Novartis Deutschland

## Funding Body Type

Private sector organisation

## Funding Body Subtype

For-profit companies (industry)

## Location

Germany

# 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