# Phase I Study: Quotient Code QSC300759

Submission date	Recruitment status	[X] Prospectively registered
30/10/2025	Recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
31/10/2025	Deferred	Results
Last Edited	Condition category	Individual participant data
31/10/2025	Other	[X] 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. 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

Dr Litza McKenzie

#### Contact details

Quotient Sciences Limited
Mere Way
Ruddington Fields
Ruddington
Nottingham
United Kingdom
NG11 6JS
+44 (0)330 303 1000
recruitment@weneedyou.co.uk

#### Type(s)

Public, Scientific

#### Contact name

Dr Novartis Study Director

#### Contact details

Lichtstrasse 35 Basel Switzerland

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

#### Integrated Research Application System (IRAS)

1010366

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

Quotient code QSC300759

# Study information

#### Scientific Title

Phase I Study: Quotient Code QSC300759 [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)

submitted 01/09/2025, London - Harrow REC (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048357; harrow.rec@hra.nhs.uk), ref: 25/LO/0485

## Study design

Relative bioavailability study in healthy volunteers

## Primary study design

Interventional

## Study type(s)

Other

## 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)

The sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the trial. 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. Full details will be added to the study record within 30 months after the trial has ended.

### Completion date

22/02/2026

# **Eligibility**

### Key inclusion criteria

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## Participant type(s)

Healthy volunteer

## Healthy volunteers allowed

No

## Age group

Adult

#### Lower age limit

18 years

## Upper age limit

#### Sex

All

### Key exclusion criteria

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### Date of first enrolment

05/11/2025

#### Date of final enrolment

22/02/2026

## Locations

#### Countries of recruitment

United Kingdom

England

### Study participating centre Quotient Sciences Limited

Mere Way Ruddington Fields Ruddington Nottingham United Kingdom NG11 6JS

# Sponsor information

### Organisation

Novartis Pharmaceuticals UK Limited

# Funder(s)

## Funder type

Industry

### **Funder Name**

Novartis Pharmaceuticals UK Limited

#### Alternative Name(s)

Novartis UK, NOVARTIS UK LIMITED

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

For-profit companies (industry)

#### Location

United Kingdom

## **Results and Publications**

### Individual participant data (IPD) sharing plan

Not expected to be made available

### IPD sharing plan summary

Not expected to be made available

### **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No Yes