Clinical trial results:
A Phase I, 2-Part, Open-label, Multiple Oral Dose Study of the Safety, Tolerability and Pharmacokinetics of up to Two Formulations of SMT C1100 in Healthy Adult Male Subjects and a Selected Formulation of SMT C1100 in Paediatric Subjects with Duchenne Muscular Dystrophy (DMD).

Summary

EudraCT number	2015-001967-38
Trial protocol	GB
Global end of trial date	28 June 2016
Results information	
Result version number	v2 (current)
This version publication date	10 March 2017
First version publication date	07 January 2017
Version creation reason	• New data added to full data set The adverse events data split by dose, and additional information is added..

Trial information

Trial identification	
Sponsor protocol code	SMTC11004
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors	
Sponsor organisation name	Summit (Oxford) Limited
Sponsor organisation address	85b Park Drive, Milton Park, Abingdon , United Kingdom, OX14 4RY
Public contact	Clinical Operations, Summit (Oxford) Limited, 0044 01235 443977, DMDphase1studies@summitplc.com
Scientific contact	Clinical Operations, Summit (Oxford) Limited, 0044 01235 443977, DMDphase1studies@summitplc.com

Notes:

Paediatric regulatory details	
Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	03 December 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 June 2016
Global end of trial reached?	Yes
Global end of trial date	28 June 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary Objectives:

Part A (Adult Subjects)
To determine the multiple dose pharmacokinetics (PK) of SMT C1100, and its dihydrodiol metabolites (DHD I and DHD III), at 2 dose levels following oral administration with up to 2 different formulations of SMT C1100 in healthy adult male subjects.

Part B (Paediatric Subjects)
To determine the multiple dose PK of SMT C1100, and its dihydrodiol metabolites (DHD I and DHD III), following oral administration of up to 3 ascending dose regimens of the formulation of SMT C1100 selected from Part A in Duchenne Muscular Dystrophy (DMD) paediatric subjects.

Protection of trial subjects:

Prior to enrolment subjects received a full explanation of the nature and purpose of the study, the safety of the drug under investigation, and discussion of any potential therapeutic benefit, and that they were free to withdraw from the study at any time without prejudice. An informed consent form approved by the IEC was signed by the subject and legal representative and the Investigator before any study-related procedures were performed. The Investigator provided copies of the signed informed consent to the subject or legal representative, and the original was retained by the Investigator.

Background therapy:

Part A:
Healthy Adult subjects were not to have prescribed medication within 14 days prior to the first dose administration until completion of the follow-up visit, and non-prescribed medication within 7 days prior to the first dose administration until completion of the follow-up visit. Use of paracetamol was permitted as clinically indicated.

Part B:
Paediatric DMD subjects were permitted systemic corticosteroids, angiotensin converting enzyme inhibitors, angiotensin-receptor blockers,
beta blockers, bisphosphonates, vitamin D and calcium supplements.
Use of inhibitors, inducers and substrates of CYP2B6, CYP1A1 and CYP1A2 was prohibited during the study and for at least 5 half-lives prior to the start of dose administration.

In the interests of subject safety and acceptable standards of medical care the Investigator was permitted to prescribe treatment(s) at his/her discretion for both the parts (A and B).

Evidence for comparator:

Not applicable; no comparators were used.

Actual start date of recruitment	02 September 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 24
Worldwide total number of subjects	24
EEA total number of subjects	24

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	8
Adolescents (12-17 years)	0
Adults (18-64 years)	16
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The first informed consent was given on 2nd September 2015, and the date of last patient last visit was 28th June 2016. The final post-study observation was made on 05 July 2016.

Pre-assignment

Screening details:

Part A: Healthy Adult Subject
Screening was performed within 28 days prior to initial dosing.

Part B: Paediatric DMD subjects
Screening was performed within 14 days prior to initial dosing.

Pre-assignment period milestones

Number of subjects started	44[1]
Number of subjects completed	24

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Failed screening criteria: 18
Reason: Number of subjects	Withdrawal of consent: 2

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: The number of subjects enrolled at the beginning of the pre-assignment period were 44; of these 18 failed screening criteria and 2 subjects withdrew consent.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A - Cohort 1 SMT C1100 oral suspension (F5)

Arm description:

SMT C1100 suspension drug product (also referred to as Formulation 5 [F5]) was supplied as a suspension for oral
administration at a dosage strength of 100 mg/g of SMT C1100.

On Days 1 to 3 subjects received oral doses of SMT C1100 suspension at 3 g SMT C1100 bid followed by 6 g SMT C1100 bid on Days 4 and 5. On Days 1 to 5 doses were administered immediately after a meal, except the morning dose on Day 5, which was administered after an overnight fast.

Arm type	Experimental
Investigational medicinal product name	SMT C1100
Investigational medicinal product code	SMT C1100
Other name	Ezutromid
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

SMT C1100 suspension drug product was supplied as a suspension for oral administration at a dosage strength of 100 mg/g of SMT C1100. The suspension was filled into glass bottles. Each dose of SMT C1100 was closely followed by consumption of full fat (whole) milk on all days; subjects consumed 100 ml of whole milk after taking their SMT C1100 dose.

Arm title	Part A Cohort 2 SMT C1100 powder for oral suspension (F6)

Arm description:

SMT C1100 powder for oral suspension (also referred to as Formulation 6 [F6]) was presented as a powder for reconstitution at a dosage strength of 250 mg/g of SMT C1100. The powder was presented in HDPE bottles and full fat (whole) milk was used as the reconstitution vehicle.

On Days 1 (first day of dosing) to 3 subjects received oral doses of SMT C1100 powder for oral suspension at 2 g bid followed by 4 g bid on Days 4 and 5. On Days 1 to 5 doses were administered immediately after a meal, except the morning dose on Day 5, which was administered after an overnight fast.

Arm type	Experimental
Investigational medicinal product name	SMT C1100
Investigational medicinal product code	SMT C1100
Other name	Ezutromid
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

SMT C1100 powder for oral suspension (F6) was presented as a powder for reconstitution at a dosage strength of 250 mg/g of SMT C1100. The powder was presented in HDPE bottles and full fat (whole) milk was used as the reconstitution vehicle.

Each dose of SMT C1100 was closely followed by consumption of full fat (whole) milk on all days; subjects consumed 100 ml of whole milk after taking their SMT C1100 dose.

Arm title	Part B SMT C1100 powder for oral suspension (F6)

Arm description:

Subjects received SMT C1100 powder for oral suspension (F6) administered bid for 7 days in Treatment Period 1 (0.25 g bid), Treatment Period 2 (0.5 g bid) and Treatment Period 3 (1.0 g bid).

Arm type	Experimental
Investigational medicinal product name	SMT C1100
Investigational medicinal product code	SMT C1100
Other name	Ezutromid
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Each bottle of SMT C1100 powder for oral suspension was reconstituted in full fat (whole) milk for oral administration.

Subjects received SMT C1100 powder for oral suspension 10 to 12-hourly, immediately following their breakfast and evening meal, closely followed by an additional 100 ml of full fat (whole) milk.

Number of subjects in period 1	Part A - Cohort 1 SMT C1100 oral suspension (F5)	Part A Cohort 2 SMT C1100 powder for oral suspension (F6)	Part B SMT C1100 powder for oral suspension (F6)
Started	8	8	8
Completed	8	7	5
Not completed	0	1	3
Adverse event, non-fatal	-	1	2
Protocol deviation	-	-	1

Baseline characteristics

Reporting groups

Reporting group title	Overall trial (overall period)

Reporting group description: -

Reporting group values	Overall trial (overall period)	Total	
Number of subjects	24	24	
Age categorical			
xx			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	8	8	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	16	16	
From 65-84 years	0	0	
85 years and over	0	0	
Not recorded	0	0	
Gender categorical Units: Subjects			
Female	0	0	
Male	24	24	
Not recorded	0	0	

Subject analysis sets

Subject analysis set title	Part A - Cohort 1, SMT C1100 , Day 1 (3g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 1 AM.

Subject analysis set title	Part A - Cohort 1, SMT C1100 , Day 1 (3g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 1 PM.

Subject analysis set title	Part A - Cohort 1, SMT C1100, Day 3 (3g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 3 AM.

Subject analysis set title	Part A - Cohort 1, SMT C1100, Day 3 (3g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 3 PM.

Subject analysis set title	Part A - Cohort 1, SMT C1100, Day 4 (6g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 4 AM.

Subject analysis set title	Part A - Cohort 1, SMT C1100, Day 4 (6g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 4 PM.

Subject analysis set title	Part A - Cohort 1, SMT C1100, Day 5 (6g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 5 AM.

Subject analysis set title	Part A - Cohort 1, SMT C1100, Day 5 (6g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 5 PM.

Subject analysis set title	Part A - Cohort 1, DHD I, Day 1 (3g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 1 AM.

Subject analysis set title	Part A - Cohort 1, DHD I, Day 1 (3g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F6 (3g) on Day 1 PM.

Subject analysis set title	Part A - Cohort 1, DHD I, Day 3 (3g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 3 AM.

Subject analysis set title	Part A - Cohort 1, DHD I, Day 3 (3g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 3 PM.

Subject analysis set title	Part A - Cohort 1, DHD I, Day 4 (6g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 4 AM.

Subject analysis set title	Part A - Cohort 1, DHD I, Day 4 (6g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 4 PM.

Subject analysis set title	Part A - Cohort 1, DHD I, Day 5 (6g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 5 AM.

Subject analysis set title	Part A - Cohort 1, DHD I, Day 5 (6g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 5 PM.

Subject analysis set title	Part A - Cohort 1, DHD III, Day 1 (3g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 1 AM.

Subject analysis set title	Part A - Cohort 1, DHD III, Day 1 (3g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 1 PM.

Subject analysis set title	Part A - Cohort 1, DHD III, Day 3 (3g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 3 AM.

Subject analysis set title	Part A - Cohort 1, DHD III, Day 3 (3g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 3 PM.

Subject analysis set title	Part A - Cohort 1, DHD III, Day 4 (6g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 4 AM.

Subject analysis set title	Part A - Cohort 1, DHD III, Day 4 (6g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 4 PM.

Subject analysis set title	Part A - Cohort 1, DHD III, Day 5 (6g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 5 AM.

Subject analysis set title	Part A - Cohort 1, DHD III, Day 5 (6g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 5 PM.

Subject analysis set title	Part A - Cohort 2, SMT C1100, Day 1 (2g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 1 AM.

Subject analysis set title	Part A - Cohort 2, SMT C1100, Day 1 (2g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 1 PM.

Subject analysis set title	Part A - Cohort 2, SMT C1100, Day 3 (2g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 3 AM.

Subject analysis set title	Part A - Cohort 2, SMT C1100, Day 3 (2g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 3 PM.

Subject analysis set title	Part A - Cohort 2, SMT C1100, Day 4 (4g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 4 AM.

Subject analysis set title	Part A - Cohort 2, SMT C1100, Day 4 (4g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 4 PM.

Subject analysis set title	Part A - Cohort 2, SMT C1100, Day 5 (4g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 5 AM.

Subject analysis set title	Part A - Cohort 2, SMT C1100, Day 5 (4g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 5 AM.

Subject analysis set title	Part A - Cohort 2, DHD I, Day 1 (2g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 1 AM.

Subject analysis set title	Part A - Cohort 2, DHD I, Day 1 (2g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 1 PM.

Subject analysis set title	Part A - Cohort 2, DHD I, Day 3 (2g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 3 AM.

Subject analysis set title	Part A - Cohort 2, DHD I, Day 3 (2g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 3 PM.

Subject analysis set title	Part A - Cohort 2, DHD I, Day 4 (4g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 4 AM.

Subject analysis set title	Part A - Cohort 2, DHD I, Day 4 (4g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 4 PM.

Subject analysis set title	Part A - Cohort 2, DHD I, Day 5 (4g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 5 AM.

Subject analysis set title	Part A - Cohort 2, DHD I, Day 5 (4g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 5 PM.

Subject analysis set title	Part A - Cohort 2, DHD III, Day 1 (2g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 1 AM.

Subject analysis set title	Part A - Cohort 2, DHD III, Day 1 (2g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 1 PM.

Subject analysis set title	Part A - Cohort 2, DHD III, Day 3 (2g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 3 AM.

Subject analysis set title	Part A - Cohort 2, DHD III, Day 3 (2g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 3 PM.

Subject analysis set title	Part A - Cohort 2, DHD III, Day 4 (4g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 4 AM.

Subject analysis set title	Part A - Cohort 2, DHD III, Day 4 (4g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 4 PM.

Subject analysis set title	Part A - Cohort 2, DHD III, Day 5 (4g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 5 AM.

Subject analysis set title	Part A - Cohort 2, DHD III, Day 5 (4g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 5 PM.

Subject analysis set title	Part B - Treatment 1, SMT C1100, Day 1 (0.25g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 1 AM.

Subject analysis set title	Part B - Treatment 1, SMT C1100, Day 1 (0.25g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 1 PM.

Subject analysis set title	Part B - Treatment 2, SMT C1100, Day 1 (0.5g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 1 AM.

Subject analysis set title	Part B - Treatment 2, SMT C1100, Day 1 (0.5g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 1 PM.

Subject analysis set title	Part B - Treatment 3, SMT C1100, Day 1 (1.0g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 1 AM.

Subject analysis set title	Part B - Treatment 3, SMT C1100, Day 1 (1.0g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 1 PM.

Subject analysis set title	Part B - Treatment 1, SMT C1100, Day 7 (0.25g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 7 AM.

Subject analysis set title	Part B - Treatment 1, SMT C1100, Day 7 (0.25g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 7 PM.

Subject analysis set title	Part B - Treatment 2, SMT C1100, Day 7 (0.5g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 7 AM.

Subject analysis set title	Part B - Treatment 2, SMT C1100, Day 7 (0.5g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 7 PM.

Subject analysis set title	Part B - Treatment 3, SMT C1100, Day 7 (1.0g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (1.0) on Day 7 AM.

Subject analysis set title	Part B - Treatment 3, SMT C1100, Day 7 (1.0g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 7 PM.

Subject analysis set title	Part B - Treatment 1, DHD I, Day 1 (0.25g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 1 AM.

Subject analysis set title	Part B - Treatment 1, DHD I, Day 1 (0.25g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 1 PM.

Subject analysis set title	Part B - Treatment 2, DHD I, Day 1 (0.5g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.5) on Day 1 AM.

Subject analysis set title	Part B - Treatment 2, DHD I, Day 1 (0.5g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 1 PM.

Subject analysis set title	Part B - Treatment 3, DHD I, Day 1 (1.0g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 1 AM.

Subject analysis set title	Part B - Treatment 3, DHD I, Day 1 (1.0g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 1 PM.

Subject analysis set title	Part B - Treatment 1, DHD I, Day 7 (0.25g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 7 AM.

Subject analysis set title	Part B - Treatment 1, DHD I, Day 7 (0.25g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 7 PM.

Subject analysis set title	Part B - Treatment 2, DHD I, Day 7 (0.5g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 7 AM.

Subject analysis set title	Part B - Treatment 2, DHD I, Day 7 (0.5g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 7 PM.

Subject analysis set title	Part B - Treatment 3, DHD I, Day 7 (1.0g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 7 AM.

Subject analysis set title	Part B - Treatment 3, DHD I, Day 7 (1.0g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 7 PM.

Subject analysis set title	Part B - Treatment 1, DHD III, Day 1 (0.25g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 1 AM.

Subject analysis set title	Part B - Treatment 1, DHD III, Day 1 (0.25g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 1 PM.

Subject analysis set title	Part B - Treatment 2, DHD III, Day 1 (0.5g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 1 AM.

Subject analysis set title	Part B - Treatment 2, DHD III, Day 1 (0.5g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 1 PM.

Subject analysis set title	Part B - Treatment 3, DHD III, Day 1 (1.0g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 1 AM.

Subject analysis set title	Part B - Treatment 3, DHD III, Day 1 (1.0g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 1 PM.

Subject analysis set title	Part B - Treatment 1, DHD III, Day 7 (0.25g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 7 AM.

Subject analysis set title	Part B - Treatment 1, DHD III, Day 7 (0.25g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 7 PM.

Subject analysis set title	Part B - Treatment 2, DHD III, Day 7 (0.5g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 7 AM.

Subject analysis set title	Part B - Treatment 2, DHD III, Day 7 (0.5g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 7 PM.

Subject analysis set title	Part B - Treatment 3, DHD III, Day 7 (1.0g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 7 AM.

Subject analysis set title	Part B - Treatment 3, DHD III, Day 7 (1.0g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 7 PM.

Reporting group values	Part A - Cohort 1, SMT C1100 , Day 1 (3g) AM	Part A - Cohort 1, SMT C1100 , Day 1 (3g) PM	Part A - Cohort 1, SMT C1100, Day 3 (3g) AM
Number of subjects	8	8	8
Age categorical			
xx			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)	8	8	8
From 65-84 years			
85 years and over			
Not recorded			
Gender categorical			
Units: Subjects			
Female	0	0	0
Male	8	8	8
Not recorded	0	0	0

Reporting group values	Part A - Cohort 1, SMT C1100, Day 3 (3g) PM	Part A - Cohort 1, SMT C1100, Day 4 (6g) AM	Part A - Cohort 1, SMT C1100, Day 4 (6g) PM
Number of subjects	8	8	8
Age categorical			
xx			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)	8	8	8
From 65-84 years			
85 years and over			
Not recorded			
Gender categorical			
Units: Subjects			
Female	0	0	0

Male	8	8	8
Not recorded	0	0	0

Reporting group values	Part A - Cohort 1, SMT C1100, Day 5 (6g) AM	Part A - Cohort 1, SMT C1100, Day 5 (6g) PM	Part A - Cohort 1, DHD I, Day 1 (3g) AM
Number of subjects	8	8	8
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	8	8	8
Gender categorical Units: Subjects			
Female	0	0	0
Male	8	8	8
Not recorded	0	0	0

Reporting group values	Part A - Cohort 1, DHD I, Day 1 (3g) PM	Part A - Cohort 1, DHD I, Day 3 (3g) AM	Part A - Cohort 1, DHD I, Day 3 (3g) PM
Number of subjects	8	8	8
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	8	8	8
Gender categorical Units: Subjects			
Female	0	0	0
Male	8	8	8
Not recorded	0	0	0

Reporting group values	Part A - Cohort 1, DHD I, Day 4 (6g) AM	Part A - Cohort 1, DHD I, Day 4 (6g) PM	Part A - Cohort 1, DHD I, Day 5 (6g) AM
Number of subjects	8	8	8
Age categorical			
xx			
Units: Subjects			
In utero	8	8	8
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Not recorded			
Gender categorical			
Units: Subjects			
Female	0	0	0
Male	8	8	8
Not recorded	0	0	0

Reporting group values	Part A - Cohort 1, DHD I, Day 5 (6g) PM	Part A - Cohort 1, DHD III, Day 1 (3g) AM	Part A - Cohort 1, DHD III, Day 1 (3g) PM
Number of subjects	8	8	8
Age categorical			
xx			
Units: Subjects			
In utero	8	8	8
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Not recorded			
Gender categorical			
Units: Subjects			
Female	0	0	0
Male	8	8	8
Not recorded	0	0	0

Reporting group values	Part A - Cohort 1, DHD III, Day 3 (3g) AM	Part A - Cohort 1, DHD III, Day 3 (3g) PM	Part A - Cohort 1, DHD III, Day 4 (6g) AM
Number of subjects	8	8	8

Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	8	8	8
Gender categorical			
Units: Subjects			
Female	0	0	0
Male	8	8	8
Not recorded	0	0	0

Reporting group values	Part A - Cohort 1, DHD III, Day 4 (6g) PM	Part A - Cohort 1, DHD III, Day 5 (6g) AM	Part A - Cohort 1, DHD III, Day 5 (6g) PM
Number of subjects	8	8	8
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	8	8	8
Gender categorical			
Units: Subjects			
Female	0	0	0
Male	8	8	8
Not recorded	0	0	0

Reporting group values	Part A - Cohort 2, SMT C1100, Day 1 (2g) AM	Part A - Cohort 2, SMT C1100, Day 1 (2g) PM	Part A - Cohort 2, SMT C1100, Day 3 (2g) AM
Number of subjects	8	8	8
Age categorical			
xx			
Units: Subjects			
In utero			

Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	8	8	8
Gender categorical Units: Subjects			
Female	0	0	0
Male	8	8	8
Not recorded	0	0	0

Reporting group values	Part A - Cohort 2, SMT C1100, Day 3 (2g) PM	Part A - Cohort 2, SMT C1100, Day 4 (4g) AM	Part A - Cohort 2, SMT C1100, Day 4 (4g) PM
Number of subjects	8	8	8
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	8	8	8
Gender categorical Units: Subjects			
Female	0	0	0
Male	8	8	8
Not recorded	0	0	0

Reporting group values	Part A - Cohort 2, SMT C1100, Day 5 (4g) AM	Part A - Cohort 2, SMT C1100, Day 5 (4g) PM	Part A - Cohort 2, DHD I, Day 1 (2g) AM
Number of subjects	7	7	8
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months)			

Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	7	7	8
Gender categorical Units: Subjects			
Female	0	0	0
Male	7	7	8
Not recorded	0	0	0

Reporting group values	Part A - Cohort 2, DHD I, Day 1 (2g) PM	Part A - Cohort 2, DHD I, Day 3 (2g) AM	Part A - Cohort 2, DHD I, Day 3 (2g) PM
Number of subjects	8	8	8
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	8	8	8
Gender categorical Units: Subjects			
Female	0	0	0
Male	8	8	8
Not recorded	0	0	0

Reporting group values	Part A - Cohort 2, DHD I, Day 4 (4g) AM	Part A - Cohort 2, DHD I, Day 4 (4g) PM	Part A - Cohort 2, DHD I, Day 5 (4g) AM
Number of subjects	8	8	7
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years	8	8	7

85 years and over Not recorded			

Gender categorical Units: Subjects			
Female	0	0	0
Male	8	8	7
Not recorded	0	0	0

Reporting group values	Part A - Cohort 2, DHD I, Day 5 (4g) PM	Part A - Cohort 2, DHD III, Day 1 (2g) AM	Part A - Cohort 2, DHD III, Day 1 (2g) PM
Number of subjects	7	8	8
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	7	8	8
Gender categorical Units: Subjects			
Female	0	0	0
Male	7	8	8
Not recorded	0	0	0

Reporting group values	Part A - Cohort 2, DHD III, Day 3 (2g) AM	Part A - Cohort 2, DHD III, Day 3 (2g) PM	Part A - Cohort 2, DHD III, Day 4 (4g) AM
Number of subjects	8	8	8
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	8	8	8

Gender categorical Units: Subjects			
Female	0	0	0
Male	8	8	8
Not recorded	0	0	0

Reporting group values	Part A - Cohort 2, DHD III, Day 4 (4g) PM	Part A - Cohort 2, DHD III, Day 5 (4g) AM	Part A - Cohort 2, DHD III, Day 5 (4g) PM
Number of subjects	8	7	7
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	8	7	7
Gender categorical Units: Subjects			
Female	0	0	0
Male	8	7	7
Not recorded	0	0	0

Reporting group values	Part B - Treatment 1, SMT C1100, Day 1 (0.25g) AM	Part B - Treatment 1, SMT C1100, Day 1 (0.25g) PM	Part B - Treatment 2, SMT C1100, Day 1 (0.5g) AM
Number of subjects	8	8	6
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	8	8	6
Gender categorical Units: Subjects			
Female	0	0	0
Male	8	8	6

Not recorded	0	0	0

Reporting group values	Part B - Treatment 2, SMT C1100, Day 1 (0.5g) PM	Part B - Treatment 3, SMT C1100, Day 1 (1.0g) AM	Part B - Treatment 3, SMT C1100, Day 1 (1.0g) PM
Number of subjects	6	6	6
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	6	6	6
Gender categorical Units: Subjects			
Female	0	0	0
Male	6	6	6
Not recorded	0	0	0

Reporting group values	Part B - Treatment 1, SMT C1100, Day 7 (0.25g) AM	Part B - Treatment 1, SMT C1100, Day 7 (0.25g) PM	Part B - Treatment 2, SMT C1100, Day 7 (0.5g) AM
Number of subjects	8	8	6
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	8	8	6
Gender categorical Units: Subjects			
Female	0	0	0
Male	8	8	6
Not recorded	0	0	0

Reporting group values	Part B - Treatment 2, SMT C1100, Day 7 (0.5g) PM	Part B - Treatment 3, SMT C1100, Day 7 (1.0g) AM	Part B - Treatment 3, SMT C1100, Day 7 (1.0g) PM
Number of subjects	6	6	4
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	6	6	4
Gender categorical			
Units: Subjects			
Female	0	0	0
Male	6	6	4
Not recorded	0	0	0

Reporting group values	Part B - Treatment 1, DHD I, Day 1 (0.25g) AM	Part B - Treatment 1, DHD I, Day 1 (0.25g) PM	Part B - Treatment 2, DHD I, Day 1 (0.5g) AM
Number of subjects	8	8	6
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	8	8	6
Gender categorical			
Units: Subjects			
Female	0	0	0
Male	8	8	6
Not recorded	0	0	0

Reporting group values	Part B - Treatment 2, DHD I, Day 1 (0.5g) PM	Part B - Treatment 3, DHD I, Day 1 (1.0g) AM	Part B - Treatment 3, DHD I, Day 1 (1.0g) PM
Number of subjects	6	6	6

Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	6	6	6
Gender categorical Units: Subjects			
Female	0	0	0
Male	6	6	6
Not recorded	0	0	0

Reporting group values	Part B - Treatment 1, DHD I, Day 7 (0.25g) AM	Part B - Treatment 1, DHD I, Day 7 (0.25g) PM	Part B - Treatment 2, DHD I, Day 7 (0.5g) AM
Number of subjects	8	8	6
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	8	8	6
Gender categorical Units: Subjects			
Female	0	0	0
Male	8	8	6
Not recorded	0	0	0

Reporting group values	Part B - Treatment 2, DHD I, Day 7 (0.5g) PM	Part B - Treatment 3, DHD I, Day 7 (1.0g) AM	Part B - Treatment 3, DHD I, Day 7 (1.0g) PM
Number of subjects	6	6	4
Age categorical			
xx			
Units: Subjects			
In utero			

Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	6	6	4
Gender categorical Units: Subjects			
Female	0	0	0
Male	6	6	4
Not recorded	0	0	0

Reporting group values	Part B - Treatment 1, DHD III, Day 1 (0.25g) AM	Part B - Treatment 1, DHD III, Day 1 (0.25g) PM	Part B - Treatment 2, DHD III, Day 1 (0.5g) AM
Number of subjects	8	8	6
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	8	8	6
Gender categorical Units: Subjects			
Female	0	0	0
Male	8	8	6
Not recorded	0	0	0

Reporting group values	Part B - Treatment 2, DHD III, Day 1 (0.5g) PM	Part B - Treatment 3, DHD III, Day 1 (1.0g) AM	Part B - Treatment 3, DHD III, Day 1 (1.0g) PM
Number of subjects	6	6	6
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months)			

Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	6	6	6
Gender categorical Units: Subjects			
Female	0	0	0
Male	6	6	6
Not recorded	0	0	0

Reporting group values	Part B - Treatment 1, DHD III, Day 7 (0.25g) AM	Part B - Treatment 1, DHD III, Day 7 (0.25g) PM	Part B - Treatment 2, DHD III, Day 7 (0.5g) AM
Number of subjects	8	8	6
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over Not recorded	8	8	6
Gender categorical Units: Subjects			
Female	0	0	0
Male	8	8	6
Not recorded	0	0	0

Reporting group values	Part B - Treatment 2, DHD III, Day 7 (0.5g) PM	Part B - Treatment 3, DHD III, Day 7 (1.0g) AM	Part B - Treatment 3, DHD III, Day 7 (1.0g) PM
Number of subjects	6	6	4
Age categorical			
xx			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years	6	6	4

85 years and over Not recorded			

Gender categorical Units: Subjects			
Female	0	0	0
Male	6	6	4
Not recorded	0	0	0

End points

End points reporting groups

Reporting group title	Part A - Cohort 1 SMT C1100 oral suspension (F5)

Reporting group description:

SMT C1100 suspension drug product (also referred to as Formulation 5 [F5]) was supplied as a suspension for oral
administration at a dosage strength of 100 mg/g of SMT C1100.

On Days 1 to 3 subjects received oral doses of SMT C1100 suspension at 3 g SMT C1100 bid followed by 6 g SMT C1100 bid on Days 4 and 5. On Days 1 to 5 doses were administered immediately after a meal, except the morning dose on Day 5, which was administered after an overnight fast.

Reporting group title	Part A Cohort 2 SMT C1100 powder for oral suspension (F6)

Reporting group description:

SMT C1100 powder for oral suspension (also referred to as Formulation 6 [F6]) was presented as a powder for reconstitution at a dosage strength of 250 mg/g of SMT C1100. The powder was presented in HDPE bottles and full fat (whole) milk was used as the reconstitution vehicle.

On Days 1 (first day of dosing) to 3 subjects received oral doses of SMT C1100 powder for oral suspension at 2 g bid followed by 4 g bid on Days 4 and 5. On Days 1 to 5 doses were administered immediately after a meal, except the morning dose on Day 5, which was administered after an overnight fast.

Reporting group title	Part B SMT C1100 powder for oral suspension (F6)

Reporting group description:

Subjects received SMT C1100 powder for oral suspension (F6) administered bid for 7 days in Treatment Period 1 (0.25 g bid), Treatment Period 2 (0.5 g bid) and Treatment Period 3 (1.0 g bid).

Subject analysis set title	Part A - Cohort 1, SMT C1100 , Day 1 (3g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 1 AM.

Subject analysis set title	Part A - Cohort 1, SMT C1100 , Day 1 (3g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 1 PM.

Subject analysis set title	Part A - Cohort 1, SMT C1100, Day 3 (3g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 3 AM.

Subject analysis set title	Part A - Cohort 1, SMT C1100, Day 3 (3g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 3 PM.

Subject analysis set title	Part A - Cohort 1, SMT C1100, Day 4 (6g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 4 AM.

Subject analysis set title	Part A - Cohort 1, SMT C1100, Day 4 (6g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 4 PM.

Subject analysis set title	Part A - Cohort 1, SMT C1100, Day 5 (6g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 5 AM.

Subject analysis set title	Part A - Cohort 1, SMT C1100, Day 5 (6g) PM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 5 PM.	
Subject analysis set title	Part A - Cohort 1, DHD I, Day 1 (3g) AM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 1 AM.	
Subject analysis set title	Part A - Cohort 1, DHD I, Day 1 (3g) PM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part A - Cohort 1 subjects were dosed with SMT C1100 F6 (3g) on Day 1 PM.	
Subject analysis set title	Part A - Cohort 1, DHD I, Day 3 (3g) AM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 3 AM.	
Subject analysis set title	Part A - Cohort 1, DHD I, Day 3 (3g) PM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 3 PM.	
Subject analysis set title	Part A - Cohort 1, DHD I, Day 4 (6g) AM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 4 AM.	
Subject analysis set title	Part A - Cohort 1, DHD I, Day 4 (6g) PM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 4 PM.	
Subject analysis set title	Part A - Cohort 1, DHD I, Day 5 (6g) AM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 5 AM.	
Subject analysis set title	Part A - Cohort 1, DHD I, Day 5 (6g) PM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 5 PM.	
Subject analysis set title	Part A - Cohort 1, DHD III, Day 1 (3g) AM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 1 AM.	
Subject analysis set title	Part A - Cohort 1, DHD III, Day 1 (3g) PM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 1 PM.	
Subject analysis set title	Part A - Cohort 1, DHD III, Day 3 (3g) AM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 3 AM.	
Subject analysis set title	Part A - Cohort 1, DHD III, Day 3 (3g) PM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (3g) on Day 3 PM.	

Subject analysis set title	Part A - Cohort 1, DHD III, Day 4 (6g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 4 AM.

Subject analysis set title	Part A - Cohort 1, DHD III, Day 4 (6g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 4 PM.

Subject analysis set title	Part A - Cohort 1, DHD III, Day 5 (6g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 5 AM.

Subject analysis set title	Part A - Cohort 1, DHD III, Day 5 (6g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 1 subjects were dosed with SMT C1100 F5 (6g) on Day 5 PM.

Subject analysis set title	Part A - Cohort 2, SMT C1100, Day 1 (2g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 1 AM.

Subject analysis set title	Part A - Cohort 2, SMT C1100, Day 1 (2g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 1 PM.

Subject analysis set title	Part A - Cohort 2, SMT C1100, Day 3 (2g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 3 AM.

Subject analysis set title	Part A - Cohort 2, SMT C1100, Day 3 (2g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 3 PM.

Subject analysis set title	Part A - Cohort 2, SMT C1100, Day 4 (4g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 4 AM.

Subject analysis set title	Part A - Cohort 2, SMT C1100, Day 4 (4g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 4 PM.

Subject analysis set title	Part A - Cohort 2, SMT C1100, Day 5 (4g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 5 AM.

Subject analysis set title	Part A - Cohort 2, SMT C1100, Day 5 (4g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 5 AM.

Subject analysis set title	Part A - Cohort 2, DHD I, Day 1 (2g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 1 AM.

Subject analysis set title	Part A - Cohort 2, DHD I, Day 1 (2g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 1 PM.

Subject analysis set title	Part A - Cohort 2, DHD I, Day 3 (2g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 3 AM.

Subject analysis set title	Part A - Cohort 2, DHD I, Day 3 (2g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 3 PM.

Subject analysis set title	Part A - Cohort 2, DHD I, Day 4 (4g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 4 AM.

Subject analysis set title	Part A - Cohort 2, DHD I, Day 4 (4g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 4 PM.

Subject analysis set title	Part A - Cohort 2, DHD I, Day 5 (4g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 5 AM.

Subject analysis set title	Part A - Cohort 2, DHD I, Day 5 (4g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 5 PM.

Subject analysis set title	Part A - Cohort 2, DHD III, Day 1 (2g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 1 AM.

Subject analysis set title	Part A - Cohort 2, DHD III, Day 1 (2g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 1 PM.

Subject analysis set title	Part A - Cohort 2, DHD III, Day 3 (2g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 3 AM.

Subject analysis set title	Part A - Cohort 2, DHD III, Day 3 (2g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (2g) on Day 3 PM.

Subject analysis set title	Part A - Cohort 2, DHD III, Day 4 (4g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 4 AM.

Subject analysis set title	Part A - Cohort 2, DHD III, Day 4 (4g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 4 PM.

Subject analysis set title	Part A - Cohort 2, DHD III, Day 5 (4g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 5 AM.

Subject analysis set title	Part A - Cohort 2, DHD III, Day 5 (4g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part A - Cohort 2 subjects were dosed with SMT C1100 F6 (4g) on Day 5 PM.

Subject analysis set title	Part B - Treatment 1, SMT C1100, Day 1 (0.25g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 1 AM.

Subject analysis set title	Part B - Treatment 1, SMT C1100, Day 1 (0.25g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 1 PM.

Subject analysis set title	Part B - Treatment 2, SMT C1100, Day 1 (0.5g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 1 AM.

Subject analysis set title	Part B - Treatment 2, SMT C1100, Day 1 (0.5g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 1 PM.

Subject analysis set title	Part B - Treatment 3, SMT C1100, Day 1 (1.0g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 1 AM.

Subject analysis set title	Part B - Treatment 3, SMT C1100, Day 1 (1.0g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 1 PM.

Subject analysis set title	Part B - Treatment 1, SMT C1100, Day 7 (0.25g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 7 AM.

Subject analysis set title	Part B - Treatment 1, SMT C1100, Day 7 (0.25g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 7 PM.

Subject analysis set title	Part B - Treatment 2, SMT C1100, Day 7 (0.5g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 7 AM.

Subject analysis set title	Part B - Treatment 2, SMT C1100, Day 7 (0.5g) PM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 7 PM.

Subject analysis set title	Part B - Treatment 3, SMT C1100, Day 7 (1.0g) AM
Subject analysis set type	Full analysis

Subject analysis set description:

Part B - Subjects were dosed with SMT C1100 F6 (1.0) on Day 7 AM.

Subject analysis set title	Part B - Treatment 3, SMT C1100, Day 7 (1.0g) PM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 7 PM.	
Subject analysis set title	Part B - Treatment 1, DHD I, Day 1 (0.25g) AM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 1 AM.	
Subject analysis set title	Part B - Treatment 1, DHD I, Day 1 (0.25g) PM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 1 PM.	
Subject analysis set title	Part B - Treatment 2, DHD I, Day 1 (0.5g) AM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part B - Subjects were dosed with SMT C1100 F6 (0.5) on Day 1 AM.	
Subject analysis set title	Part B - Treatment 2, DHD I, Day 1 (0.5g) PM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 1 PM.	
Subject analysis set title	Part B - Treatment 3, DHD I, Day 1 (1.0g) AM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 1 AM.	
Subject analysis set title	Part B - Treatment 3, DHD I, Day 1 (1.0g) PM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 1 PM.	
Subject analysis set title	Part B - Treatment 1, DHD I, Day 7 (0.25g) AM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 7 AM.	
Subject analysis set title	Part B - Treatment 1, DHD I, Day 7 (0.25g) PM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 7 PM.	
Subject analysis set title	Part B - Treatment 2, DHD I, Day 7 (0.5g) AM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 7 AM.	
Subject analysis set title	Part B - Treatment 2, DHD I, Day 7 (0.5g) PM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 7 PM.	
Subject analysis set title	Part B - Treatment 3, DHD I, Day 7 (1.0g) AM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 7 AM.	
Subject analysis set title	Part B - Treatment 3, DHD I, Day 7 (1.0g) PM
Subject analysis set type	Full analysis
Subject analysis set description:	
Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 7 PM.	

Subject analysis set title	Part B - Treatment 1, DHD III, Day 1 (0.25g) AM
Subject analysis set type	Full analysis
Subject analysis set description: Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 1 AM.	
Subject analysis set title	Part B - Treatment 1, DHD III, Day 1 (0.25g) PM
Subject analysis set type	Full analysis
Subject analysis set description: Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 1 PM.	
Subject analysis set title	Part B - Treatment 2, DHD III, Day 1 (0.5g) AM
Subject analysis set type	Full analysis
Subject analysis set description: Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 1 AM.	
Subject analysis set title	Part B - Treatment 2, DHD III, Day 1 (0.5g) PM
Subject analysis set type	Full analysis
Subject analysis set description: Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 1 PM.	
Subject analysis set title	Part B - Treatment 3, DHD III, Day 1 (1.0g) AM
Subject analysis set type	Full analysis
Subject analysis set description: Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 1 AM.	
Subject analysis set title	Part B - Treatment 3, DHD III, Day 1 (1.0g) PM
Subject analysis set type	Full analysis
Subject analysis set description: Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 1 PM.	
Subject analysis set title	Part B - Treatment 1, DHD III, Day 7 (0.25g) AM
Subject analysis set type	Full analysis
Subject analysis set description: Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 7 AM.	
Subject analysis set title	Part B - Treatment 1, DHD III, Day 7 (0.25g) PM
Subject analysis set type	Full analysis
Subject analysis set description: Part B - Subjects were dosed with SMT C1100 F6 (0.25g) on Day 7 PM.	
Subject analysis set title	Part B - Treatment 2, DHD III, Day 7 (0.5g) AM
Subject analysis set type	Full analysis
Subject analysis set description: Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 7 AM.	
Subject analysis set title	Part B - Treatment 2, DHD III, Day 7 (0.5g) PM
Subject analysis set type	Full analysis
Subject analysis set description: Part B - Subjects were dosed with SMT C1100 F6 (0.5g) on Day 7 PM.	
Subject analysis set title	Part B - Treatment 3, DHD III, Day 7 (1.0g) AM
Subject analysis set type	Full analysis
Subject analysis set description: Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 7 AM.	
Subject analysis set title	Part B - Treatment 3, DHD III, Day 7 (1.0g) PM
Subject analysis set type	Full analysis
Subject analysis set description: Part B - Subjects were dosed with SMT C1100 F6 (1.0g) on Day 7 PM.	

Primary: AUC 0-tau (Part A: F5 - SMT C1100; DHD I; DHD III)

End point title	AUC 0-tau (Part A: F5 - SMT C1100; DHD I; DHD III)[1]

End point description:

End point type	Primary

End point timeframe:

Area under the plasma concentration versus time curve over a dosing interval.

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive statistical analyses for the PK data are reported here.

End point values	Part A - Cohort 1, SMT C1100, Day 1 (3g) AM	Part A - Cohort 1, SMT C1100, Day 1 (3g) PM	Part A - Cohort 1, SMT C1100, Day 3 (3g) AM	Part A - Cohort 1, SMT C1100, Day 3 (3g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	8	8
Units: ng.h/ml				
geometric mean (geometric coefficient of variation)	2048 (± 73.7)	2376 (± 92)	2066 (± 85.5)	2681 (± 109.4)

End point values	Part A - Cohort 1, SMT C1100, Day 4 (6g) AM	Part A - Cohort 1, SMT C1100, Day 4 (6g) PM	Part A - Cohort 1, SMT C1100, Day 5 (6g) AM	Part A - Cohort 1, SMT C1100, Day 5 (6g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	8	8
Units: ng.h/ml				
geometric mean (geometric coefficient of variation)	2646 (± 121.9)	3436 (± 113.8)	1850 (± 133.1)	2844 (± 105.4)

End point values	Part A - Cohort 1, DHD I, Day 1 (3g) AM	Part A - Cohort 1, DHD I, Day 1 (3g) PM	Part A - Cohort 1, DHD I, Day 3 (3g) AM	Part A - Cohort 1, DHD I, Day 3 (3g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	8	8
Units: ng.h/ml				
geometric mean (geometric coefficient of variation)	6510 (± 15.5)	9093 (± 29)	7796 (± 12.9)	9640 (± 16)

End point values	Part A - Cohort 1, DHD I, Day 4 (6g) AM	Part A - Cohort 1, DHD I, Day 4 (6g) PM	Part A - Cohort 1, DHD I, Day 5 (6g) AM	Part A - Cohort 1, DHD I, Day 5 (6g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	8	8
Units: ng.h/ml				
geometric mean (geometric coefficient of variation)	9915 (± 21)	12340 (± 19.5)	7544 (± 23.7)	11190 (± 12.9)

End point values	Part A - Cohort 1, DHD III, Day 1 (3g) AM	Part A - Cohort 1, DHD III, Day 1 (3g) PM	Part A - Cohort 1, DHD III, Day 3 (3g) AM	Part A - Cohort 1, DHD III, Day 3 (3g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	8	8
Units: ng.h/ml				
geometric mean (geometric coefficient of variation)	14790 (± 22.7)	22180 (± 26.7)	23610 (± 25.3)	21160 (± 19.9)

End point values	Part A - Cohort 1, DHD III, Day 4 (6g) AM	Part A - Cohort 1, DHD III, Day 4 (6g) PM	Part A - Cohort 1, DHD III, Day 5 (6g) AM	Part A - Cohort 1, DHD III, Day 5 (6g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	8	8
Units: ng.h/ml				
geometric mean (geometric coefficient of variation)	29210 (± 23.6)	28930 (± 18.1)	23680 (± 25.7)	25550 (± 21.6)

End point values	Part A - Cohort 2, SMT C1100, Day 1 (2g) AM	Part A - Cohort 2, SMT C1100, Day 1 (2g) PM	Part A - Cohort 2, SMT C1100, Day 3 (2g) AM	Part A - Cohort 2, SMT C1100, Day 3 (2g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	8	8
Units: ng.h/ml				
geometric mean (geometric coefficient of variation)	2268 (± 89.9)	3281 (± 84.6)	3784 (± 132.2)	3870 (± 97.6)

End point values	Part A - Cohort 2, SMT C1100, Day 4 (4g) AM	Part A - Cohort 2, SMT C1100, Day 4 (4g) PM	Part A - Cohort 2, SMT C1100, Day 5 (4g) AM	Part A - Cohort 2, SMT C1100, Day 5 (4g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	7	7
Units: ng.h/ml				
geometric mean (geometric coefficient of variation)	7823 (± 73.6)	7428 (± 79.4)	11010 (± 92)	10890 (± 104)

End point values	Part A - Cohort 2, DHD I, Day 1 (2g) AM	Part A - Cohort 2, DHD I, Day 1 (2g) PM	Part A - Cohort 2, DHD I, Day 3 (2g) AM	Part A - Cohort 2, DHD I, Day 3 (2g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	8	8
Units: ng.h/ml				

geometric mean (geometric coefficient of variation)	8784 (± 17.2)	10740 (± 21.3)	11670 (± 21.5)	12320 (± 19.7)

End point values	Part A - Cohort 2, DHD I, Day 4 (4g) AM	Part A - Cohort 2, DHD I, Day 4 (4g) PM	Part A - Cohort 2, DHD I, Day 5 (4g) AM	Part A - Cohort 2, DHD I, Day 5 (4g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	7	7
Units: ng.h/ml				
geometric mean (geometric coefficient of variation)	15420 (± 24)	15970 (± 25.9)	17030 (± 24.3)	16760 (± 16.2)

End point values	Part A - Cohort 2, DHD III, Day 1 (2g) AM	Part A - Cohort 2, DHD III, Day 1 (2g) PM	Part A - Cohort 2, DHD III, Day 3 (2g) AM	Part A - Cohort 2, DHD III, Day 3 (2g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	8	8
Units: ng.h/ml				
geometric mean (geometric coefficient of variation)	21210 (± 24.4)	29290 (± 36.2)	41750 (± 27.4)	40730 (± 31.1)

End point values	Part A - Cohort 2, DHD III, Day 4 (4g) AM	Part A - Cohort 2, DHD III, Day 4 (4g) PM	Part A - Cohort 2, DHD III, Day 5 (4g) AM	Part A - Cohort 2, DHD III, Day 5 (4g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	7	7
Units: ng.h/ml				
geometric mean (geometric coefficient of variation)	46430 (± 24.8)	48740 (± 32.2)	58160 (± 24.6)	53870 (± 21.5)

Statistical analyses

No statistical analyses for this end point

Primary: AUC 0-24 (Part B - F6; SMT C1100)

End point title	AUC 0-24 (Part B - F6; SMT C1100)[2]

End point description:

End point type	Primary

End point timeframe:

Area under the plasma concentration versus time curve from time zero to 24 hours.

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only exploratory statistical analyses done for this point.

End point values	Part B - Treatment 1, SMT C1100, Day 1 (0.25g) AM	Part B - Treatment 2, SMT C1100, Day 1 (0.5g) AM	Part B - Treatment 3, SMT C1100, Day 1 (1.0g) AM	Part B - Treatment 1, SMT C1100, Day 7 (0.25g) AM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	5	5	7
Units: ng.h/ml				
geometric mean (geometric coefficient of variation)	625.1 (± 26)	1258 (± 76.7)	2601 (± 66.2)	528.6 (± 25.7)

End point values	Part B - Treatment 2, SMT C1100, Day 7 (0.5g) AM	Part B - Treatment 3, SMT C1100, Day 7 (1.0g) AM	Part B - Treatment 1, DHD I, Day 1 (0.25g) AM	Part B - Treatment 2, DHD I, Day 1 (0.5g) AM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	4	7	5
Units: ng.h/ml				
geometric mean (geometric coefficient of variation)	1015 (± 30.5)	3855 (± 42.9)	8289 (± 33.9)	12110 (± 51.3)

End point values	Part B - Treatment 3, DHD I, Day 1 (1.0g) AM	Part B - Treatment 1, DHD I, Day 7 (0.25g) AM	Part B - Treatment 2, DHD I, Day 7 (0.5g) AM	Part B - Treatment 3, DHD I, Day 7 (1.0g) AM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	7	5	4
Units: ng.h/ml				
geometric mean (geometric coefficient of variation)	24810 (± 28.6)	7483 (± 21.9)	11720 (± 33)	28240 (± 28.5)

End point values	Part B - Treatment 1, DHD III, Day 1 (0.25g) AM	Part B - Treatment 2, DHD III, Day 1 (0.5g) AM	Part B - Treatment 3, DHD III, Day 1 (1.0g) AM	Part B - Treatment 1, DHD III, Day 7 (0.25g) AM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	5	5	7
Units: ng.h/ml				
geometric mean (geometric coefficient of variation)	20130 (± 37.4)	31710 (± 36.3)	60970 (± 29.9)	23800 (± 36.2)

End point values	Part B - Treatment 2, DHD III, Day 7 (0.5g) AM	Part B - Treatment 3, DHD III, Day 7 (1.0g) AM		

Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	5	4		
Units: ng.h/ml				
geometric mean (geometric coefficient of variation)	34190 (± 29.7)	92850 (± 12.1)		

Statistical analyses

No statistical analyses for this end point

Primary: Cmax (Parts A & B - SMT C100; DHD I; DHD III)

End point title	Cmax (Parts A & B - SMT C100; DHD I; DHD III)[3]

End point description:

End point type	Primary

End point timeframe:

Maximum observed concentration.

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive statistical analyses for the PK data are reported here.

End point values	Part A - Cohort 1, SMT C1100, Day 1 (3g) AM	Part A - Cohort 1, SMT C1100, Day 1 (3g) PM	Part A - Cohort 1, SMT C1100, Day 3 (3g) AM	Part A - Cohort 1, SMT C1100, Day 3 (3g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	8	8
Units: ng/ml				
geometric mean (geometric coefficient of variation)	397.4 (± 81.3)	312.3 (± 98.1)	346.6 (± 87.7)	389.2 (± 100.5)

End point values	Part A - Cohort 1, SMT C1100, Day 4 (6g) AM	Part A - Cohort 1, SMT C1100, Day 4 (6g) PM	Part A - Cohort 1, SMT C1100, Day 5 (6g) AM	Part A - Cohort 1, SMT C1100, Day 5 (6g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	8	8
Units: ng/ml				
geometric mean (geometric coefficient of variation)	489.1 (± 117.3)	445.3 (± 114.8)	345.2 (± 134.8)	371.5 (± 109.6)

End point values	Part A - Cohort 1, DHD I, Day 1 (3g) AM	Part A - Cohort 1, DHD I, Day 1 (3g) PM	Part A - Cohort 1, DHD I, Day 3 (3g) AM	Part A - Cohort 1, DHD I, Day 3 (3g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	8	8
Units: ng/ml				

geometric mean (geometric coefficient of variation)	1053 (± 17.2)	1093 (± 27.5)	1174 (± 18.2)	1251 (± 18.7)

End point values	Part A - Cohort 1, DHD I, Day 4 (6g) AM	Part A - Cohort 1, DHD I, Day 4 (6g) PM	Part A - Cohort 1, DHD I, Day 5 (6g) AM	Part A - Cohort 1, DHD I, Day 5 (6g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	8	8
Units: ng/ml				
geometric mean (geometric coefficient of variation)	1556 (± 21.6)	1429 (± 23.6)	1245 (± 19.1)	1262 (± 12.7)

End point values	Part A - Cohort 1, DHD III, Day 1 (3g) AM	Part A - Cohort 1, DHD III, Day 1 (3g) PM	Part A - Cohort 1, DHD III, Day 3 (3g) AM	Part A - Cohort 1, DHD III, Day 3 (3g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	8	8
Units: ng/ml				
geometric mean (geometric coefficient of variation)	1923 (± 24.3)	2590 (± 25.9)	3037 (± 19.3)	2645 (± 19.5)

End point values	Part A - Cohort 1, DHD III, Day 4 (6g) AM	Part A - Cohort 1, DHD III, Day 4 (6g) PM	Part A - Cohort 1, DHD III, Day 5 (6g) AM	Part A - Cohort 1, DHD III, Day 5 (6g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	8	8
Units: ng/ml				
geometric mean (geometric coefficient of variation)	3641 (± 25.8)	3066 (± 15.2)	3054 (± 21.5)	2624 (± 18.9)

End point values	Part A - Cohort 2, SMT C1100, Day 1 (2g) AM	Part A - Cohort 2, SMT C1100, Day 1 (2g) PM	Part A - Cohort 2, SMT C1100, Day 3 (2g) AM	Part A - Cohort 2, SMT C1100, Day 3 (2g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	8	8
Units: ng/ml				
geometric mean (geometric coefficient of variation)	459 (± 96.4)	714.6 (± 69.1)	683.6 (± 120.6)	746.1 (± 81.7)

End point values	Part A - Cohort 2, SMT C1100, Day 4 (4g) AM	Part A - Cohort 2, SMT C1100, Day 4 (4g) PM	Part A - Cohort 2, SMT C1100, Day 5 (4g) AM	Part A - Cohort 2, SMT C1100, Day 5 (4g) PM

Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	7	7
Units: ng/ml				
geometric mean (geometric coefficient of variation)	1563 (± 55.6)	1556 (± 63.8)	2125 (± 71.1)	2279 (± 104.7)

End point values	Part A - Cohort 2, DHD I, Day 1 (2g) AM	Part A - Cohort 2, DHD I, Day 1 (2g) PM	Part A - Cohort 2, DHD I, Day 3 (2g) AM	Part A - Cohort 2, DHD I, Day 3 (2g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	8	8
Units: ng/ml				
geometric mean (geometric coefficient of variation)	1376 (± 27.2)	1400 (± 27.3)	1654 (± 19.6)	1471 (± 10.4)

End point values	Part A - Cohort 2, DHD I, Day 4 (4g) AM	Part A - Cohort 2, DHD I, Day 4 (4g) PM	Part A - Cohort 2, DHD I, Day 5 (4g) AM	Part A - Cohort 2, DHD I, Day 5 (4g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	7	7
Units: ng/ml				
geometric mean (geometric coefficient of variation)	2050 (± 22.3)	1804 (± 16.8)	2443 (± 21.7)	1947 (± 15)

End point values	Part A - Cohort 2, DHD III, Day 1 (2g) AM	Part A - Cohort 2, DHD III, Day 1 (2g) PM	Part A - Cohort 2, DHD III, Day 3 (2g) AM	Part A - Cohort 2, DHD III, Day 3 (2g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	8	8
Units: ng/ml				
geometric mean (geometric coefficient of variation)	2766 (± 23)	3602 (± 34)	4485 (± 24.7)	4193 (± 29.7)

End point values	Part A - Cohort 2, DHD III, Day 4 (4g) AM	Part A - Cohort 2, DHD III, Day 4 (4g) PM	Part A - Cohort 2, DHD III, Day 5 (4g) AM	Part A - Cohort 2, DHD III, Day 5 (4g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	8	8	7	7
Units: ng/ml				
geometric mean (geometric coefficient of variation)	5064 (± 26.4)	5129 (± 27.2)	6344 (± 27)	5741 (± 22.1)

End point values	Part B - Treatment 1, SMT C1100, Day 1 (0.25g) AM	Part B - Treatment 1, SMT C1100, Day 1 (0.25g) PM	Part B - Treatment 2, SMT C1100, Day 1 (0.5g) AM	Part B - Treatment 2, SMT C1100, Day 1 (0.5g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	7	5	5
Units: ng/ml				
geometric mean (geometric coefficient of variation)	93.16 (± 28.2)	43.74 (± 51.8)	176.6 (± 108.1)	113.6 (± 201.2)

End point values	Part B - Treatment 3, SMT C1100, Day 1 (1.0g) AM	Part B - Treatment 3, SMT C1100, Day 1 (1.0g) PM	Part B - Treatment 1, SMT C1100, Day 7 (0.25g) AM	Part B - Treatment 1, SMT C1100, Day 7 (0.25g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	5	7	7
Units: ng/ml				
geometric mean (geometric coefficient of variation)	265.5 (± 102.4)	212.9 (± 86.6)	49.64 (± 43.1)	39.03 (± 52.6)

End point values	Part B - Treatment 2, SMT C1100, Day 7 (0.5g) AM	Part B - Treatment 2, SMT C1100, Day 7 (0.5g) PM	Part B - Treatment 3, SMT C1100, Day 7 (1.0g) AM	Part B - Treatment 3, SMT C1100, Day 7 (1.0g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	5	5	4
Units: ng/ml				
geometric mean (geometric coefficient of variation)	114.6 (± 67.3)	78.98 (± 55)	282.8 (± 49.1)	415.6 (± 67.6)

End point values	Part B - Treatment 1, DHD I, Day 1 (0.25g) AM	Part B - Treatment 1, DHD I, Day 1 (0.25g) PM	Part B - Treatment 2, DHD I, Day 1 (0.5g) AM	Part B - Treatment 2, DHD I, Day 1 (0.5g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	7	5	5
Units: ng/ml				
geometric mean (geometric coefficient of variation)	726.2 (± 20.1)	596.8 (± 29.8)	1175 (± 43.9)	831.9 (± 84.8)

End point values	Part B - Treatment 3, DHD I, Day 1 (1.0g) AM	Part B - Treatment 3, DHD I, Day 1 (1.0g) PM	Part B - Treatment 1, DHD I, Day 7 (0.25g) AM	Part B - Treatment 1, DHD I, Day 7 (0.25g) PM

Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	5	7	7
Units: ng/ml				
geometric mean (geometric coefficient of variation)	1711 (± 37)	1555 (± 26)	606.3 (± 36.3)	585.3 (± 16.9)

End point values	Part B - Treatment 2, DHD I, Day 7 (0.5g) AM	Part B - Treatment 2, DHD I, Day 7 (0.5g) PM	Part B - Treatment 3, DHD I, Day 7 (1.0g) AM	Part B - Treatment 3, DHD I, Day 7 (1.0g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	5	5	4
Units: ng/ml				
geometric mean (geometric coefficient of variation)	1087 (± 44.7)	820.3 (± 23.5)	1799 (± 48.6)	2038 (± 24.8)

End point values	Part B - Treatment 1, DHD III, Day 1 (0.25g) AM	Part B - Treatment 1, DHD III, Day 1 (0.25g) PM	Part B - Treatment 2, DHD III, Day 1 (0.5g) AM	Part B - Treatment 2, DHD III, Day 1 (0.5g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	7	5	5
Units: ng/ml				
geometric mean (geometric coefficient of variation)	1625 (± 29.2)	1170 (± 29.8)	2439 (± 33.5)	1971 (± 59.2)

End point values	Part B - Treatment 3, DHD III, Day 1 (1.0g) AM	Part B - Treatment 3, DHD III, Day 1 (1.0g) PM	Part B - Treatment 1, DHD III, Day 7 (0.25g) AM	Part B - Treatment 1, DHD III, Day 7 (0.25g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	5	7	7
Units: ng/ml				
geometric mean (geometric coefficient of variation)	3647 (± 22.7)	3641 (± 28.1)	1859 (± 25.5)	1501 (± 34.6)

End point values	Part B - Treatment 2, DHD III, Day 7 (0.5g) AM	Part B - Treatment 2, DHD III, Day 7 (0.5g) PM	Part B - Treatment 3, DHD III, Day 7 (1.0g) AM	Part B - Treatment 3, DHD III, Day 7 (1.0g) PM
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	5	5	4
Units: ng/ml				
geometric mean (geometric coefficient of variation)	2626 (± 41.6)	2039 (± 20.2)	5012 (± 33.9)	5088 (± 8)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Duration of the study.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18

Reporting groups

Reporting group title	Part A Cohort 1 SMT C1100 oral suspension

Reporting group description:

On Days 1 to 3 subjects received oral doses of SMT C1100 suspension at 3 g SMT C1100 bid followed by 6 g SMT C1100 bid on Days 4 and 5.
On Days 1 to 5 doses were administered immediately after a meal, except the morning dose on Day 5, which was administered after an overnight fast.

Reporting group title	Part A Cohort 2 SMT C1100 powder for oral suspension

Reporting group description:

On Days 1 to 3 subjects received oral doses of SMT C1100 powder for oral suspension at 2 g SMT C1100 bid followed by 4 g SMT C1100 bid on Days 4 and 5.

On Days 1 to 5 doses were administered immediately after a meal, except the morning dose on Day 5, which was administered after an overnight fast.

Reporting group title	Part B SMT C1100 powder for oral suspension-0.25g bid

Reporting group description:

Subjects received SMT C1100 powder for oral suspension (F6) administered 0.25 g bid for 7 days in Treatment Period 1.

Reporting group title	Part B SMT C1100 powder for oral suspension-0.5g bid

Reporting group description:

Subjects received SMT C1100 powder for oral suspension (F6) administered 0.5 g bid for 7 days in Treatment Period 2.

Reporting group title	Part B SMT C1100 powder for oral suspension-1.0g bid

Reporting group description:

Subjects received SMT C1100 powder for oral suspension (F6) administered 1.0 g bid for 7 days in Treatment Period 3.

Serious adverse events	Part A Cohort 1 SMT C1100 oral suspension	Part A Cohort 2 SMT C1100 powder for oral suspension	Part B SMT C1100 powder for oral suspension-0.25g bid
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Liver function test abnormal			

subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part B SMT C1100 powder for oral suspension-0.5g bid	Part B SMT C1100 powder for oral suspension-1.0g bid	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Investigations			
Liver function test abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Part A Cohort 1 SMT C1100 oral suspension	Part A Cohort 2 SMT C1100 powder for oral suspension	Part B SMT C1100 powder for oral suspension-0.25g bid
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	8 / 8 (100.00%)	5 / 8 (62.50%)
Injury, poisoning and procedural complications			
Road traffic accident			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 8 (12.50%)	2 / 8 (25.00%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Presyncope			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Catheter site related reaction			

subjects affected / exposed	0 / 8 (0.00%)	2 / 8 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Fatigue			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Medical device site reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Change of bowel habit			
subjects affected / exposed	0 / 8 (0.00%)	5 / 8 (62.50%)	0 / 8 (0.00%)
occurrences (all)	0	5	0
Faeces discoloured			
subjects affected / exposed	8 / 8 (100.00%)	4 / 8 (50.00%)	0 / 8 (0.00%)
occurrences (all)	8	4	0
Abdominal discomfort			
subjects affected / exposed	0 / 8 (0.00%)	2 / 8 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Faeces pale			
subjects affected / exposed	0 / 8 (0.00%)	2 / 8 (25.00%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Abdominal pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Diarrhoea			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Dyspepsia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0

Nausea			
subjects affected / exposed	1 / 8 (12.50%)	1 / 8 (12.50%)	1 / 8 (12.50%)
occurrences (all)	1	1	1
Abdominal pain upper			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Haemorrhoids			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Dry throat			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 8 (12.50%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			

subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Rhinitis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 8 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 8 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Non-serious adverse events	Part B SMT C1100 powder for oral suspension-0.5g bid	Part B SMT C1100 powder for oral suspension-1.0g bid	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 6 (66.67%)	2 / 6 (33.33%)	
Injury, poisoning and procedural complications			
Road traffic accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Catheter site related reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Medical device site reaction			

subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Change of bowel habit			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Faeces discoloured			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Faeces pale			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	2 / 6 (33.33%)	1 / 6 (16.67%)	
occurrences (all)	2	1	
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Haemorrhoids			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	
occurrences (all)	1	0	

Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Dry throat			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Infections and infestations			
Rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Nil

Notes: