Pharmacy Manual	
SOPHIST - SOtagliflozin in **P**atients with **H**eart fa**i**lure **S**ymptoms and **T**ype 1 Diabetes A phase 2 double-blind randomised controlled trial studying the effect of sotagliflozin 200mg once daily versus placebo in individuals with heart failure and type 1 diabetes on quality of life measured using the Kansas City Cardiomyopathy Questionnaire.	
IRAS ID: 1007807	**Protocol Version:** V5
Sponsor: University of Dundee & NHS Tayside	Chief Investigator: Dr Ify Mordi

This document describes the process for Investigational Medicinal Product (IMP) and placebo management at site.

Abbreviations / terms used:

CTP	Clinical Trial Pharmacy
IMP	Investigational Medicinal Product
PSF	Pharmacy Site File
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre
TM	Trial Manager
TRuST	Tayside Randomisation System

Contents

1. Treatment Overview

Participants will be randomly assigned to receive one daily tablet for a period of 16 weeks of either:

- 200mg Sotagliflozin
- 200mg Placebo

2. IMP description

Description	Packaging	Storage conditions	Supplier
Sotagliflozin/placebo 200mg per tablet	30 or 90 tablets in each high-density polyethylene (HDPE) bottle with a child-resistant cap with an induction seal liner.	15 -30°C	Sharp Clinical Services Ltd

Both Sotagliflozin/placebo tablets will be supplied in bottles of 90 and 30.

Participants will receive one bottle of sotagliflozin/placebo 90 tablets and one bottle of sotagliflozin/placebo 30 tablets at randomisation (visit 3), total of 120 tablets per participant.

Participants should take one tablet only per day, usually before breakfast.

Each bottle is identified by a pack ID number.

See Appendix 1 for IMP label details.

3. Investigational Medicinal Product (IMP) supply

3.1. Initial IMP supply

The Clinical Trial Pharmacy (CTP) will receive an initial supply from Sharp Clinical Services of:

10 bottles of Sotagliflozin/placebo 90 tablets

10 bottles of Sotagliflozin/placebo 30 tablets

The initial supply may be different with agreement of the CTP/TM. The bottles and packaging will be labelled with a clinical trial label by Sharp Clinical Services.

3.2. Re-supply

The Trial Manager (TM) will manage stock, contacting Sharp Clinical Services to arrange further shipments as required according to recruitment. The CTP will be informed by email when new supplies are expected.

Pharmacy should contact the Trial Manager if stock levels are causing concern.

4. IMP storage

Sotagliflozin/placebo should be stored between 15 - 30°C, away from direct sunlight.

Do not use beyond expiry date.

A daily temperature log will be required (paper/electronic); this should be available for review as requested for monitoring purposes. A file note detailing the location of the temperature log should be held in the PSF.

4.1. Temperature excursions

The IMP should be quarantined and reported to the TM if exposed to temperatures outside 15 - 30°C for more than 24 hours at any one time, or if the maximum temperature exceeds 32°C at any point.

Temperature excursions reported to the TM will be discussed with Lexicon Pharmaceuticals, and Sponsor to identify what action is necessary. TM will inform CTP of any action required.

5. Drug accountability

Full accountability must be maintained by CTP for Sotagliflozin and placebo. A paper IMP accountability form is provided (Appendix 2) which must be made available for monitoring purposes. Alternative IMP accountability forms may be used if agreed between CTP and TM.

At the end of the trial CTP will be requested to sign the final Accountability Log, file in the PSF and email a copy to the TM.

5.1. Acknowledge receipt of shipments on arrival

The CTP at each site will receive shipments from Sharp Clinical Services. Each shipment will be accompanied by a QP Release Certificate, temperature tracker and an Acknowledgement of Receipt. The Acknowledgement of Receipt will be emailed back to Sharp Clinical Services and copied to the TM to confirm delivery. A copy of the QP Release Certificate and Acknowledgement of Receipt should be filed in the PSF.

On receipt, each IMP pack ID number must be recorded in the IMP accountability form, dated and signed.

All IMP will be referred to as packs on the paper IMP accountability form.

5.2. Dispensing/releasing IMP

IMP will be released for each participant as defined by visit schedule (Appendix 3), on receipt of a SOPHIST Clinical Trial Request/Release Form (Appendix 4) and a printed copy of the randomisation email generated by TRuST. Variations to this process are allowed if agreed between CTP and TM.

The SOPHIST Clinical Trial Request/Release Form must be signed by the PI or their delegate named on the Delegation Log. The participant will be randomised to receive 120 tablets of either Sotagliflozin/placebo 200mg. Visual confirmation of the correct pack ID number on each bottle should be checked against Clinical Trial Request/Release Form and the email notification of pack allocation.

NB. Each participant should receive one bottle of 90 tablets and one bottle of 30 tablets at randomisation (visit 3) according to the pack allocation information received.

IMP released will be recorded in the IMP accountability form by entering date, participant ID and signing for each pack ID released. The pharmacist or delegate should also sign and date the release section of the SOPHIST Clinical Trial Request/Release form.

The completed SOPHIST Clinical Trial Request/Release Forms (Appendix 4) should be filed in the PSF.

Where an error is noticed after dispensing the appropriate action to recall the IMP should be made. The Principal Investigator and TM should be informed, and a Protocol Breach Reporting Form completed and forwarded to **tascpotentialbreach@dundee.ac.uk**.

5.3. Recording drug returns

If bottles have been released by CTP but are not dispensed to the participant, bottles **must** be unopened, return to store at 15-30ºC and contact the Trial Manager to see if these can be replaced back to stock.

Bottles returned by participants should be recorded in the IMP accountability form.

5.4. Recording drug disposals

The SOPHIST Clinical Trial IMP Disposal Form should be completed (Appendix 5) and the SOPHIST IMP accountability form updated**.**

Disposal of any returned or expired IMP should be undertaken as per local Standard Operating Procedure (SOP), no approval from Sponsor is required.

Disposal of unused bottles at the end of trial should only be carried out **after** Sponsor has approved after which they should be disposed of as per local SOP.

5.5. Recording quarantined drugs

If requested to by the Sponsor, the IMP must be removed from the stock shelf and placed in a separate area at 15-30ºC. The IMP must be clearly marked as in quarantine and not to be dispensed. This should be recorded on the comments section of the IMP accountability form. The IMP must remain in quarantine until the Sponsor has notified CTP whether the IMP can be returned to the stock shelf and dispensed as usual or whether the IMP must be disposed of.

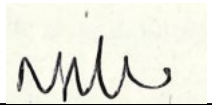
5.6. Recall of IMP

In the event of IMP recall, which necessitates the return of Sotagliflozin/placebo supplies, sites will be given further information on this as required. Label the stock as ‘quarantined’, record on the comments section of the IMP accountability form and hold in a quarantine area, ideally at 15 to 30°C, until further information is received.

6. Emergency Unblinding

Emergency unblinding will be carried out by the PI or delegate.

Any clinician requiring the emergency unblinding of a participant should, where possible, discuss this with the Principal Investigator, however, this should not stall or delay in any way the unblinding of trial participant treatment in emergency situations. If unblinding is required, the clinician should contact the local PI or delegate. TRuST access will be provided to the local PI which will permit individual participant unblinding in the event of a medical emergency. An emergency unblinding form (Appendix 6) should be printed and signed by person performing the unblinding. It is the responsibility of the local PI to ensure that adequate training and instructions are given for anyone delegated this role to enable them to access and perform the emergency unblinding procedure. For additional details of the emergency unblinding procedure see Appendix 7.

Signed  Date 11-12-2025

Neil Reynolds

Clinical Trials Pharmacist, Clinical Trial Pharmacy, Ninewells Hospital, Dundee

Clinical Trial Manager	sophist-trial@dundee.ac.uk	01382 388596
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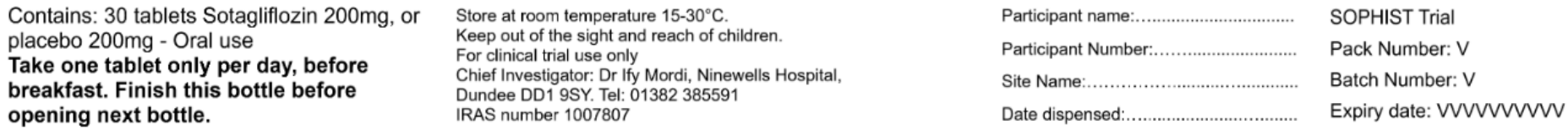
Lead Clinical Trial Pharmacist (Tayside)	neil.reynolds@nhs.scot	01382 632969
Sharp Clinical Services	SCSUK-ShipmentRequests@sharpclinical.com	

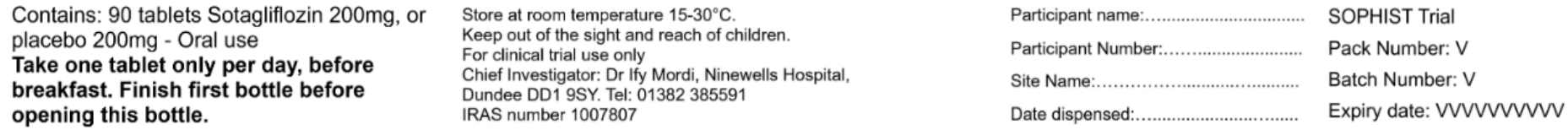
Appendices

Appendix 1 IMP Labels

Sotagliflozin/placebo 30 tablets/bottle label



Sotagliflozin/placebo 90 tablets/bottle label



The letter V in the sample labels represents where the variable data will be printed (i.e. Pack number, batch number and expiry date).

Appendix 2 IMP accountability form

SOPHIST (**SO**tagliflozin in **P**atients with **H**eart fa**i**lure **S**ymptoms and **T**ype 1 Diabetes)

IMP ACCOUNTABILITY FORM FOR PHARMACY

IRAS	1007807			Local CTP ID	
Chief Investigator	Dr Ify Mordi	**Principal Investigator**		Tel No	

Batch Number		Expiry date		Sotagliflozin 200mg or Placebo tablets

PACKS		**RECEIVED**		**ISSUED**			**RETURNED**			**DISPOSED OF**	
Pack ID	Quantity (tablets)	Date	Signature	Date	Participant ID	Signature	Date	Quantity (tablets)	Signature	Date	signature

Comments:

Signed for Pharmacy Date:

Appendix 3 SOPHIST Visit Schedule

	Visit 1 (Screening)	**Visit 2**	**Visit 3 (Baseline)**	**Visit 4**	**Visit 5**	**Visit 6**	**Visit 7**	**Visit 8**
	-30 days to -14 days	**-7 days +/- 3 days**	**Day 0**	**Week 1 +/- 3 days**	**Week 4 +/- 3 days**	**Week 10 +/- 3 days**	**Week 16 +/- 3 days**	**Week 20 +/-3 days**
	Research Site	Research Site	Research Site	Remote/ Research Site	Research Site	Remote/ Research Site	Research Site	Remote/ Research Site
Randomisation			X					
Dispensing of IMP			X					
Compliance to IMP (Research Nurse)				X	X	X	X	
IMP Accountability			X				X	

Appendix 4 SOPHIST IMP Request/Release Form

SOPHIST (**SO**tagliflozin in **P**atients with **H**eart fa**i**lure **S**ymptoms and **T**ype 1 Diabetes)

CLINICAL TRIAL REQUEST/RELEASE FORM FOR PHARMACY

IRAS	**1007807**	Sponsor	**University of Dundee and NHS Tayside**
Protocol No.		Local CTP ID	

Chief Investigator	**Dr Ify Mordi**	Tel No	**01382385591**
Principal Investigator		Tel No	

Participant trial ID:			
Participant Name:			
Date of Birth:		CHI/hospital number:	
Visit Number:		Visit Date:	

Sotagliflozin 200mg or Placebo 200mg	
Total number of tablets:	**120 (one bottle of 90 tablets and one bottle of 30 tablets)**
Pack ID:	
Pack ID:	
Dosage schedule:	**1 tablet per day for a total of 16 weeks**

PI or delegate doctor's signature:	Date:
Print name:	

Released By:	Date:
Checked By:	Date:
Collected By:	Date:

Appendix 5 SOPHIST IMP Disposal Form

SOPHIST (**SO**tagliflozin in **P**atients with **H**eart fa**i**lure **S**ymptoms and **T**ype 1 Diabetes)

CLINICAL TRIAL IMP DISPOSAL FORM

Sponsor	**University of Dundee and NHS Tayside**
IRAS	**1007807**
Local CTP ID	

Chief Investigator	**Dr Ify Mordi**	Tel No	**01382385591**
Principal Investigator		Tel No	

FOR PHARMACY USE:				
Pack ID:	Quantity (tablets):		Pack ID:	Quantity (tablets):

Disposed as per CTP Policy by	
Date of Disposal	

Appendix 6 Emergency Unblinding Form

EMERGENCY UNBLINDING FORM

Unblinding should only occur when patient safety is compromised. Ensure there is a genuine need to perform unblinding

Sponsor	**University of Dundee and NHS Tayside**		
Protocol No.		EudraCT	
Chief Investigator	**Dr Ify Mordi**	IRAS	**1007807**

Person Performing the Unblinding:	
Person Requesting the Unblinding:	
Role:	
Contact Number:	
Email:	
Reason for Unblinding Request:	
Date of Request:	

Study Participant ID:			Site:		
Pack ID:					
Date of birth:		Initials:		Gender:	

Unblinding Result

Sotagliflozin/Placebo	

TRuST Unblinding Performed by:

Name:		Designation:	
Signature:		Date:	

Download Date:

Appendix 7 Emergency Unblinding Procedure

- Emergency unblinding should only be carried out where a physician considers that it is necessary for participants clinical safety/medical emergency (e.g. a severe adverse event where it is necessary for the PI or treating health care professional to know which treatment the patient is receiving before the patient can be treated).

- If emergency unblinding is required, the clinician should contact the local PI or delegate that will have a login to the interactive web-based randomisation system, TRuST, for 24-hour emergency unblinding (only for their site). CI is also able to unblind all participants across all sites if required.

- The date, reason and result must be documented and signed by the person carrying out the unblinding. This must be stored in a sealed envelope in the ISF.

- Disclosure of the unblinding result should be to individuals involved in the participant's care only and, where possible, the participant should remain blinded and continue with trial visits.

1. TRuST Unblinding Login Details

Username:…….

Password:…….

The password will be emailed to the PI/delegate and this should be changed on first login with the new password written here.

- If TRuST is not working during normal working hours the PI or delegate should inform the Clinical Trial Manager and contact the NHS Tayside Clinical Trial Pharmacy for emergency unblinding.

- If, TRuST is not working outside normal working hours please contact NHS Tayside On-call Pharmacist for emergency unblinding.

2. Local Contact Details

	PI name / Delegate:	Contact details:
Principal Investigator		
Delegate		
Delegate		

3. Other contact Details

- Clinical Trial Manager: Susan Long 07386657801 SOPHIST-trial@dundee.ac.uk
- Chief Investigator: Ify Mordi 01382 385591 i.mordi@dundee.ac.uk
- NHS Tayside Clinical Trial Pharmacy: 01382 632969 Tay.clinicaltrials@nhs.scot
- NHS Tayside On-Call Pharmacist (Ninewells Hospital): Call switchboard on 01382 660111 and ask for on call Pharmacist.

4. Emergency unblinding procedure

- The PI will have responsibility for carrying out the unblinding procedure. This role may be delegated to appropriate staff to allow for 24-hour access to unblinding.
- A label will be put on the inside cover of the patient's medical notes on randomisation detailing the name of the trial, participant trial number, trial medication, PI details and contact for emergency unblinding. An alert sticker will be put on the outside of the participants' medical notes to alert readers the patient is in a clinical trial. Where electronic records only are kept, local practice for alerting healthcare professionals to the fact that the patient is in a clinical trial will be followed. Details of this practice should be filed in the ISF.
- The treating healthcare professional will contact the PI or delegate to request unblinding.
- The PI will be provided with login details (see above) for TRuST (Tayside Randomisation System) which will give access for unblinding.
- The PI or delegate will log on to TRuST and complete the unblinding procedure, see SOPHIST Training Presentation 4-Emergency Unblinding document. It is the responsibility of the PI to ensure that adequate training and instructions are given to delegates to access and perform the emergency unblinding procedure.
- Unblinding requires gender, date of birth and initials of the participant to be unblinded. Participant ID and a Pack ID should also be used but emergency unblinding is still possible if latter two are not known (unless there is more than one participant at your site with the same details).
- An Emergency Unblinding Form should be completed by the PI/delegate performing the unblinding. This is generated from TRuST and can then be printed and signed, a blank copy can also be found in the ISF. Where it is not possible to print an unblinding form immediately the PI or delegate should log on to TRuST and print and sign the form within 24 hours. The unblinding form should be sealed in an envelope and filed in the ISF.
- On receipt of the treatment allocation details the treating health care professional will deal with the participants' medical emergency as appropriate.
- The web-based system will email the PI, the CI, the Sponsor and the Clinical Trial Manager that unblinding has taken place but not of the treatment allocation details.
- The participant should remain in the study where possible.