# IMP Management and Accountability

## Sotagliflozin/Placebo

- Participants will be randomly assigned to receive one daily tablet, usually before breakfast, for a period of 16 weeks of either 200 mg Sotagliflozin or 200 mg Placebo.
- Both Sotagliflozin and Placebo will be supplied in bottles of 30 and 90 tablets.
- A total of 120 tablets must be provide per participant (i.e. participants receive one bottle of sotagliflozin/placebo 90 tablets and one bottle of sotagliflozin/placebo 30 tablets at randomisation (visit 3)).

## IMP Supply

- Clinical Trials Pharmacy will receive an initial supply of Sotagliflozin/Placebo from Sharp Clinical Services.
- The bottles and packaging will be labelled with a clinical trial label by Sharp Clinical Services.
- 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.

## IMP Storage

- Sotagliflozin/Placebo can be stored between 15-30°C, away from direct sunlight.
- 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.
- The IMP must 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.

# IMP Accountability

- Full accountability must be maintained by CTP for Sotagliflozin and Placebo using the paper IMP accountability form provided.
- The IMP accountability form must be made available for monitoring purposes.
- At the end of the trial CTP will be requested to sign the final Accountability form, file in the PSF and email a copy to the TM.
- Alternative IMP accountability forms may be used if agreed between CTP and TM.

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 |
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**Comments:**

Signed for Pharmacy Date:

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# IMP accountability

**Acknowledgement of receipt of IMP shipments**

- Each IMP shipment will be accompanied by a QP Release Certificate, temperature tracker and an Acknowledgement of Receipt.
- The Acknowledgement of Receipt must 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 paper IMP accountability form, dated and signed.
- All IMP will be referred to as packs on the paper IMP accountability form.

# IMP accountability

## Dispensing/releasing IMP

- IMP must be released for each participant on receipt of a SOPHIST Clinical Trial Request/Release Form (signed by PI or delegate doctor named on Delegation Log) and a printed copy of the randomisation email generated by TRuST. Variations to this process are allowed if agreed between CTP and TM.
- 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 the Clinical Trial Request/Release Form **and** the email notification of pack allocation.
- IMP released must 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 should be filed in the PSF.
- Where an error is noticed after dispensing the appropriate action to recall the IMP should be made. The PI and TM should be informed, and a Protocol Breach Reporting Form completed and forwarded to **tascpotentialbreach@dundee.ac.uk**.

# IMP accountability

## Recording IMP returns

- In cases where packs have been released by the Clinical Trial Pharmacy but are not dispensed to the participant, bottles **must** be unopened and returned to store at 15-30°C.
- Contact the Trial Manager to see if these can be replaced back to stock.
- Bottles returned by participants should be recorded in the SOPHIST IMP Accountability Form.

## Recall of IMP

- In the event of IMP recall, which requires 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.

# IMP accountability

## Recording IMP disposals

- The SOPHIST Clinical Trial IMP Disposal Form should be completed 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.

SOPHIST

**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): |
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| Disposed as per CTP Policy by | |
| Date of Disposal | |