Review and recording of Concomitant Medications

Review and recording of concomitant medications

- Taken from medical records and participant reporting.
- Reported concomitant medications must be recorded in medical records for source data verification (SDV).

Please note: Participants are expected to be on optimal heart failure therapy as judged by their treating clinician and remain on stable doses of these throughout the duration of the trial.

Visit 1

- Ask participants to bring their current prescription.
- Go through this with them and ensure it is accurate for what the participant is taking at the time of the visit, scoring off medications that the participant is not actively taking on a copy of the prescription.
- File a copy of the prescription in the medical notes for SDV.

All other visits

- Ask if there are any changes to medication since previous visit and record changes in medical notes and eCRF.

Excluded Medications

- Use of sotagliflozin within 1 month of screening or between screening and randomisation.
- Use of any other SGLT2 inhibitors or investigational drugs within five times of the elimination half-life after the last dose or within 30 days, whichever is longer.

Recording of concomitant medications in eCRF

Concomitant medications log

- Record all concomitant medications on the concomitant medications log of the trial eCRF (i.e. name of medication, class of medication, if ongoing at start/end of trial, if started/stopped during trial).
- At visit 1 all medications participant is actively taking should be ticked as ongoing at start of trial.
- Any new medications started during the trial should have a start date.
- Any medications stopped during the trial should have an end date.
- At the last visit all medications should have either an end date or ticked as ongoing at end of trial.