SOPHIST

Participant name:	
Hospital ID:	
CHI/Date of Birth:	

SOPHIST - SOtagliflozin in Patients with Heart failure Symptoms and Type 1 Diabetes

Sponsor	University of Dundee-NHS Tayside
Chief Investigator	Dr Ify Mordi
IRAS number	1007807

Principal Investigator	
Contact number	
Contact email	

Visit 3 – Baseline & Randomisation

Date of visit: | | Participant trial ID: | | | | | |

Please tick to indicate the following have been completed:

Confirmed participant's identity	
Participant has verbally given their consent to continue in the trial	
Concomitant medications have been reviewed	
Adverse events have been reviewed	
Education/review of glucose and ketone management undertaken including hypoglycaemic and DKA events, glucose/ketone readings, and insulin doses	
Six-minute walk test	
Urine pregnancy test, if women of childbearing potential	
Urine albumin, creatinine and sodium	
Full blood count, urea & electrolytes, liver function tests and glucose	
Research blood and urine samples, according to participant consent	
Participant was randomised as per protocol	
Participant has been given trial medication	

Physical characteristics and vital signs

Weight	kg		
Systolic/Diastolic BP	mmHg	Pulse	bpm

Insulin dose reduction (ONLY applicable for participants with HbA1c at screening lower than 58 mmol/mol or 7.5%)

Was insulin dose reduced by 10%? yes ☐ no ☐

The following should be filed in the participant's medical notes:

- Eligibility criteria confirmation signed and dated by doctor on delegation log
- Changes to concomitant medications since last visit

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- Any adverse events since last visit
- Details of review of diabetes management including any changes to insulin or other diabetes medication
- Any hypoglycaemic and DKA events since last visit
- Any other notable findings and actions taken
- Copy of all laboratory test printouts signed and dated by doctor on delegation log
- Pregnancy test results, if applicable, signed and dated by doctor on delegation log
- If the participant was withdrawn from the trial at this visit, document reason

Any further information of note:

The visit has been carried out as per protocol.

Signature:	
Name:	
Job title:	
Date:	