Participant ID				

Initials		

SOPHIST Participant Eligibility Form

Eligibility Criteria	Y	N
Inclusion Criteria		
Age 18 years to <85 years.		
Type 1 Diabetes.		
Insulin dose ≥0.5 units/kg body weight at screening **or** BMI ≥25kg/m^2 at screening.		
Using continuous glucose monitor at screening or willing to use one for the duration of the trial.		
Diagnosis of heart failure (HF) regardless of left ventricular ejection fraction (LVEF), defined as one or more of the following: Previous HF hospitalisation where HF was documented as the primary cause of hospitalisation and there was a requirement for loop diuretics **or** Impaired left ventricular (LV) function (i.e. LVEF <50% by any imaging modality) at any time **or** Preserved LV systolic function (LVEF ≥50%) with left atrial enlargement (2-dimensional measurement of left atrial width ≥3.8cm or left atrial length ≥5.0 cm or left atrial area ≥20cm^2 or left atrial volume index >29 ml/m^2) within the last 24 months. **or** Preserved LV systolic function (LVEF ≥50%) with left ventricular hypertrophy (2-dimensional measurement of end-diastolic interventricular septal diameter ≥1.2cm or end-diastolic left ventricular posterior wall diameter ≥1.2cm) within the last 24 months. **or** Preserved LV systolic function (LVEF ≥50%) with diastolic dysfunction (septal e' <7cm/sec or lateral e' <10cm/sec or average E/e' ≥15) within the last 24 months.		
New York Heart Association Class II-IV at screening.		
Elevated N-terminal pro-B-type natriuretic peptide (≥400 ng/L for those in atrial fibrillation/flutter, ≥250 ng/L for those in all other rhythms) **or** B-type natriuretic peptide (≥100 ng/L for those in atrial fibrillation/flutter, ≥75 ng/L for those in all other rhythms) within 12 months of screening.		
Kansas City Cardiomyopathy clinical summary score <85 at screening.		

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Eligibility Criteria	Y	N
Exclusion Criteria		
Cardiac surgery (coronary artery bypass graft or valve replacement), type 1 myocardial infarction, implantation of cardiac device (including biventricular pacemaker) or cardiac mechanical support implantation within 1 month of screening, or between screening and randomisation, or planned during the trial.		
End-stage heart failure requiring left ventricular assist devices, intra-aortic balloon pump, or any type of mechanical support at the time of randomisation.		
Documented primary severe valvular heart disease, amyloidosis or hypertrophic cardiomyopathy as principal cause of heart failure as judged by the local investigator.		
Respiratory disease thought to be the primary cause of dyspnoea as assessed by the local investigator.		
Chronic kidney disease with estimated glomerular filtration rate <25ml/min/1.73m^2 at screening.		
Moderate or severe hepatic impairment (e.g. Child-Pugh B and C) at screening as judged by the local investigator		
Use of sotagliflozin or any SGLT2 inhibitor within 1 month of screening or between screening and randomisation.		
Previous hypersensitivity/intolerance to SGLT2 inhibitors.		
Presence of malignancy with expected life expectancy <1 year at screening.		
Severe hypoglycaemia (hospitalisation for hypoglycaemia or episode requiring external assistance to treat) within 1 month prior to screening or between screening and randomisation.		
One episode of diabetic ketoacidosis or nonketotic hyperosmolar state within 1 month of screening or between screening and randomisation, or greater than or equal to 2 diabetic ketoacidosis or nonketotic hyperosmolar state events within 6 months of screening.		
Pregnant or lactating women		
Women of childbearing age or male partners of women of childbearing age and not practicing an acceptable method of birth control.		
On a ketogenic diet.		
Unwilling/unable to share glucose and ketone monitoring data.		
Use of any investigational drugs within five times of the elimination half-life after the last dose or within 30 days, whichever is longer. Current enrolment in non-interventional, observational studies will be allowed.		

Is the participant eligible to take part in the trial? Yes/No

Signed by Delegated Doctor: _____

Date: _____