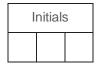
Participant ID						





SOPHIST Participant Eligibility Form

Eligibility Criteria	Υ	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 ≥20cm2 or left atrial volume index >29 ml/m2)		
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.		
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?
Is the participant eligible to take part in the trial? Yes/No

Is the participant eligible to take part i	Yes/No	
Signed by Delegated Doctor:		
Date:		