



1. Visit 1 - Screening - Informed Consent

Number	Question	Answers
1.1	Date of Visit 1 - Screening	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
<p>Please remember that, as per protocol, visit 3 should be scheduled between 14-30 days after Visit 1 AND 4-10 days after Visit 2</p>		
1.2	Date of Consent	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
1.3	Is Date of Consent after Date of Visit 1?	Automatic calculation in Castor
1.4	Consent for research blood and urine samples for future use to be collected	<input type="radio"/> YES <input type="radio"/> NO
1.5	Consent to having an additional blood sample taken for future genetic analysis	<input type="radio"/> YES <input type="radio"/> NO
1.6	Consent to be contacted about future research projects	<input type="radio"/> YES <input type="radio"/> NO

2. Visit 1 - Screening - Demographics

Number	Question	Answers
2.1	Age	<input type="text"/> years
2.2	Sex at birth	<input type="radio"/> Male <input type="radio"/> Female
2.3	Ethnicity	<input type="radio"/> White - English / Welsh / Scottish / Northern Irish / British <input type="radio"/> White - Irish <input type="radio"/> White - Gypsy or Irish Traveller <input type="radio"/> White - Roma <input type="radio"/> Any other White background <input type="radio"/> Mixed or multiple ethnic groups - White and Black Caribbean <input type="radio"/> Mixed or multiple ethnic groups - White and Black African <input type="radio"/> Mixed or multiple ethnic groups - White and Asian <input type="radio"/> Any other Mixed or multiple ethnic background <input type="radio"/> Asian or Asian British - Indian <input type="radio"/> Asian or Asian British - Pakistani <input type="radio"/> Asian or Asian British - Bangladeshi <input type="radio"/> Asian or Asian British - Chinese <input type="radio"/> Any other Asian background <input type="radio"/> Black, Black British - African <input type="radio"/> Black, Black British - Caribbean <input type="radio"/> Any other Black / Black British / Caribbean background <input type="radio"/> Arab <input type="radio"/> Any other ethnic group <input type="radio"/> Unknown <input type="radio"/> Prefer not to say
2.3.1	If Any other ethnic group , specify	<input type="text"/>

3. Visit 1 - Screening - Medical History

Number	Question	Answers
3.1	Year of Diabetes Diagnosis	<input type="text"/> (yyyy)
3.2	Previous hospitalisation for Diabetic Ketoacidosis (DKA)	<input type="radio"/> YES <input type="radio"/> NO
3.2.1	Date of most recent hospitalisation for Diabetic Ketoacidosis (DKA)	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
3.2.2	Is date of most recent hospitalisation for DKA within one month of screening	Automatic Calculation on Castor
3.3	Previous hospitalisation or ambulance call-out for hypoglycaemia	<input type="radio"/> YES <input type="radio"/> NO
3.3.1	Date of most recent hospitalisation or ambulance call-out for hypoglycaemia	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
3.3.2	Is date of most recent hospitalisation or ambulance call-out for hypoglycaemia within one month of screening	Automatic calculation in Castor
3.4	Retinopathy	<input type="radio"/> YES <input type="radio"/> NO
3.5	Nephropathy	<input type="radio"/> YES <input type="radio"/> NO

3.6 Neuropathy YES
 NO

3.7 Heart Failure YES
 NO

3.7.1 Year of Heart Failure diagnosis (yyyy)

3.7.2 Heart Failure Aetiology Ischaemic
 Non-ischaemic

3.8 Previous Heart Failure Hospitalisation YES
 NO

3.8.1 Heart Failure Check

3.8.2 Date of most recent Heart Failure hospitalisation (dd-mm-yyyy)

3.9 Implantable Cardioverter Defibrillator YES
 NO

3.10 Cardiac Resynchronisation Therapy Device (with or without defibrillator) YES
 NO

3.11 Myocardial Infarction YES
 NO

3.12 Angina YES
 NO

3.13 Coronary Artery Bypass Graft YES
 NO

3.14 Stroke YES
 NO

3.15 Atrial Fibrillation/flutter YES
 NO

3.16 Chronic Kidney Disease (eGFR less than 60 ml/min/1.73m²) YES
 NO

3.17 Chronic Obstructive Pulmonary Disease YES
 NO

3.18 Amputation (non-traumatic) YES
 NO

3.19 Peripheral Vascular Disease YES
 NO

3.20 Other relevant medical history YES
 NO

3.20.1 Specify other relevant medical history



4. Visit 1 - Screening - NYHA Class

Number	Question	Answers
4.1	NYHA Class	<p><input type="radio"/> I - No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnoea (shortness of breath).</p> <p><input type="radio"/> II - Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnoea (shortness of breath).</p> <p><input type="radio"/> III - Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnoea.</p> <p><input type="radio"/> IV - Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.</p>

5. Visit 1 - Screening - Concomitant Medications

Number	Question	Answers
5.1	Concomitant Medications	

Please complete concomitant medications log

6. Visit 1 - Screening - Physical Examination

Number	Question	Answers
6.1	Height	<input type="text"/> cm
6.2	Weight	<input type="text"/> kg
6.3	BMI	Automatic calculation in Castor
6.4	Insulin administration	<input type="radio"/> Subcutaneous injections <input type="radio"/> Pump
6.5	Daily basal insulin dose (average of last 7 days)	<input type="text"/> units/day
6.6	Daily bolus insulin dose (average of last 7 days)	<input type="text"/> units/day
6.7	Total daily insulin dose (average of last 7 days)	Automatic calculation in Castor
6.8	Insulin (units/kg)	Automatic Calculation on Castor
6.9	Insulin dose units per kg body weight	Automatic calculation in Castor
6.10	Waist circumference	<input type="text"/> cm
6.11	Hip circumference	<input type="text"/> cm

6.12 Cardiovascular

- Normal
- Abnormal

6.12.1 If abnormal, provide details

6.13 Respiratory

- Normal
- Abnormal

6.13.1 If abnormal, provide details

6.14 Gastrointestinal

- Normal
- Abnormal

6.14.1 If abnormal, provide details

6.15 Neurological

- Normal
- Abnormal

6.15.1 If abnormal, provide details

6.16 Other abnormalities?

- YES
- NO

6.16.1 Other abnormality, specify

Vital Signs

Question	Answers
Blood Pressure - Systolic	<input data-bbox="952 454 1321 499" type="text"/> mmHg
Blood Pressure - Diastolic	<input data-bbox="952 656 1321 701" type="text"/> mmHg
Pulse	<input data-bbox="952 864 1321 909" type="text"/> bpm

8. Visit 1 - Screening - Electrocardiogram (ECG)

Number	Question	Answers
8.1	ECG Performed/Not performed	<input type="radio"/> Performed <input type="radio"/> Not performed
8.1.1	ECG Result	<input type="radio"/> Normal <input type="radio"/> Abnormal - not clinically significant <input type="radio"/> Abnormal - clinically significant
8.1.2	Was the ECG reviewed by a delegated doctor prior to randomisation?	<input type="radio"/> YES <input type="radio"/> NO
8.1.3	Heart rate	<input style="width: 150px; height: 20px; border: 1px dashed black;" type="text"/> beats/min
8.1.4	Rhythm	<input type="radio"/> Sinus rhythm <input type="radio"/> Atrial fibrillation / Flutter <input type="radio"/> Paced <input type="radio"/> Other
8.1.4.1	Other, please specify	<input style="width: 200px; height: 60px; border: 1px dashed black;" type="text"/>

9. Visit 1 - Screening - Imaging Test (LVEF)

Number	Question	Answers
9.1	Date of Imaging Test	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
9.2	Has Imaging Test been performed within 24 months of Screening?	Automatic Calculation on Castor
9.3	LVEF	<input type="text"/> %

Where numerical assessment is not available and there is a need to convert the qualitative documented LVEF to the equivalent numerical LVEF as a %, refer to the table below

9.4 LVEF Table

Documented LVEF	Numerical LVEF equivalent (%)
Normal/preserved	55
Mildly reduced	50
Mild/moderate	45
Moderate	40
Moderate/severe	35
Severe	30

9.5	Left Atrial Enlargement	<input type="radio"/> YES <input type="radio"/> NO
Preserved LV systolic function (LVEF $\geq 50\%$) with left atrial enlargement (2-dimensional measurement of left atrial width ≥ 3.8 cm or left atrial length ≥ 5.0 cm or left atrial area ≥ 20 cm ² or left atrial volume index > 29 ml/m ²) within the last 24 months.		
9.6	Left Ventricular Hypertrophy	<input type="radio"/> YES <input type="radio"/> NO
Defined as: 2-dimensional measurement of end-diastolic interventricular septal diameter ≥ 1.2 cm or end-diastolic left ventricular posterior wall diameter ≥ 1.2 cm		
9.7	Diastolic dysfunction	<input type="radio"/> YES <input type="radio"/> NO

Defined as: septal e' < 7 cm/sec or lateral e' < 10 cm/sec or average E/e' ≥ 15

10. Visit 1 - Screening - Cardiomyopathy Questionnaire (KansasCity) (KCCQ) - Screening

Please Complete KCCQ

11. Visit 1 - Screening - Samples

Number	Question	Answers
11.1	Safety Bloods	
	Date of blood sample	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
	Haemoglobin	<input type="text"/>
	Haemoglobin Unit	<input type="radio"/> g/L <input type="radio"/> g/dL
	Sodium	<input type="text"/> mmol/L
	Potassium	<input type="text"/> mmol/L
	Urea	<input type="text"/> mmol/L
	Creatinine	<input type="text"/> µmol/L
	Glucose	<input type="text"/> mmol/L
	eGFR	<input type="text"/> mL/min/1.73m ²

11. Visit 1 - Screening - Samples

Number Question

Other Tests

11.2 Pregnancy test performed

YES
 NO
 N/A

11.2.1 Pregnancy test result

Positive
 Negative

11.2.2 Is the participant either permanently sterilized or post-menopausal?

YES
 NO

11.3 N-terminal pro-B-type natriuretic peptide or B-type natriuretic peptide measurement available within 12 months of Visit 1 Screening?

YES
 NO

11.3.1 Date of N-terminal pro-B-type natriuretic peptide or B-type natriuretic peptide measurement

(dd-mm-yyyy)

11.3.2 N-terminal pro-B-type natriuretic peptide or B-type natriuretic peptide available within 12 months prior to screening?

11.3.3 N-terminal pro-B-type natriuretic peptide or B-type peptide peptide

Automatic Calculation on Castor
 natriureticN-terminal pro-B-type natriuretic
 B-type natriuretic peptide

11.3.3.1 N-terminal pro-B-type natriuretic peptide

ng/L

Answers

11.3.3.2 B-type natriuretic peptide

 ng/L

11.4 HbA1c performed?

 YES
 NO

11.4.1 HbA1c units used?

 mmol/mol
 %

11.4.1.1 HbA1c level

 mmol/mol

11.4.1.2 HbA1c level

 %

12. Visit 1 - Screening - Inclusion Criteria

Number	Question	Answers
12.2	Age 18 years to less than 85 years	Automatic Calculation on Castor
12.3	Type 1 Diabetes	<input type="radio"/> YES <input type="radio"/> NO
12.4	Insulin dose greater than or equal to 0.5 units/kg body weight at screening or BMI greater than or equal to 25kg/m2 at screening	Automatic Calculation on Castor
12.5	Using continuous glucose monitor at screening or willing to use one for the duration of the trial	<input type="radio"/> YES <input type="radio"/> NO
12.1.1	Diagnosis of heart failure (HF) or high risk for HF defined as any of the following: NT-pro-BNP greater than or equal to 250 ng/L for those in atrial fibrillation/flutter, greater than or equal to 125 ng/L for those in all other rhythms <u>or</u> Previous HF hospitalisation where HF was documented as the primary cause of hospitalisation and there was a requirement for loop diuretics. <u>or</u> Impaired left ventricular function (i.e. LVEF less than 50% by any imaging modality) at any time <u>or</u> Preserved LV systolic function (LVEF greater than or equal to 50%) with left atrial enlargement (2-dimensional measurement of left atrial width greater than or equal to 3.8 cm or left atrial length greater than or equal to 5.0 cm or left atrial area greater than or equal to 20 cm2 or left atrial volume index greater than 29 ml/m2) within the last 24 months. <u>or</u>	<input type="radio"/> YES <input type="radio"/> NO

Preserved LV systolic function (LVEF greater than or equal to 50%) with left ventricular hypertrophy (2-dimensional measurement of end-diastolic interventricular septal diameter greater than or equal to 1.2 cm or end-diastolic left ventricular posterior wall diameter greater than or equal to 1.2 cm) within the last 24 months

or

Preserved LV systolic function (LVEF greater than or equal to 50%) with diastolic dysfunction (septal e' less than 7 cm/sec or lateral e' less than 10 cm/sec or average E/e' greater than or equal to 15) within the last 24 months

12.6 New York Heart Association Class II-IV at screening Automatic Calculation on Castor

12.7 Kansas City Cardiomyopathy clinical summary score less than 85 at screening. Automatic Calculation on Castor

13. Visit 1 - Screening - Exclusion Criteria

Number	Question	Answers
13.1	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.	<input type="radio"/> YES <input type="radio"/> NO
13.2	End-stage heart failure requiring left ventricular assist devices, intra-aortic balloon pump, or any type of mechanical support.	<input type="radio"/> YES <input type="radio"/> NO
13.3	Documented primary severe valvular heart disease, amyloidosis or hypertrophic cardiomyopathy as principal cause of heart failure as judged by the local investigator.	<input type="radio"/> YES <input type="radio"/> NO
13.4	Respiratory disease thought to be the primary cause of dyspnoea as assessed by the local investigator.	<input type="radio"/> YES <input type="radio"/> NO
13.5	Chronic kidney disease with estimated glomerular filtration rate <25ml/min/1.73m ² at screening.	<input type="radio"/> YES <input type="radio"/> NO
13.6	Moderate or severe hepatic impairment (e.g. Child-Pugh B and C) at screening as judged by the local investigator.	<input type="radio"/> YES <input type="radio"/> NO
13.7	Use of sotagliflozin or any SGLT2 inhibitor within 1 month of screening.	<input type="radio"/> YES <input type="radio"/> NO
13.8	Previous hypersensitivity/intolerance to SGLT2 inhibitors.	<input type="radio"/> YES <input type="radio"/> NO
13.9	Presence of malignancy with expected life expectancy less than 1 year at screening	<input type="radio"/> YES <input type="radio"/> NO
13.10	Severe hypoglycaemia (hospitalisation for hypoglycaemia or episode requiring external assistance to treat) within 1 month prior to screening.	<input type="radio"/> YES <input type="radio"/> NO

13.11 One episode of diabetic ketoacidosis or nonketotic hyperosmolar state within 1 month of screening or greater than or equal to 2 diabetic ketoacidosis or nonketotic hyperosmolar state events within 6 months of screening.

YES
 NO

13.12 Pregnant or lactating women

YES
 NO

13.13 Women of childbearing age or male partners of women of childbearing age and not practicing a method of acceptable birth control

YES
 NO

13.14 On a ketogenic diet.

YES
 NO

13.15 Unwilling/unable to share glucose and ketone monitoring data.

YES
 NO

13.16 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.

YES
 NO

13.17 Is participant eligible to continue to visits 2 and 3?

YES
 NO