

# SOPHIST worksheet



## 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)
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?	<b>Automatic Calculation on Castor</b>
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  <i>Participant not eligible for trial if date of most recent hospitalisation for DKA is within one month of screening.</i>	<b>Automatic Calculation on Castor</b>
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  <i>Participant not eligible for trial if date of most recent hospitalisation or ambulance call-out for hypoglycaemia is within one month of screening.</i>	<b>Automatic Calculation on Castor</b>
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 **Automatic Calculation on Castor**

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

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3.14	Stroke	<input type="radio"/> YES
		<input type="radio"/> NO

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3.15	Atrial Fibrillation/flutter	<input type="radio"/> YES
		<input type="radio"/> NO

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3.16	Chronic Kidney Disease (eGFR less than 60 ml/min/1.73m2)	<input type="radio"/> YES
		<input type="radio"/> NO

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3.17	Chronic Obstructive Pulmonary Disease	<input type="radio"/> YES
		<input type="radio"/> NO

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3.18	Amputation (non-traumatic)	<input type="radio"/> YES
		<input type="radio"/> NO

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3.19	Peripheral Vascular Disease	<input type="radio"/> YES
		<input type="radio"/> NO

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3.20	Other relevant medical history	<input type="radio"/> YES
		<input type="radio"/> NO

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3.20.1	Specify other relevant medical history
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## 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 on 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 on Castor
6.8	Insulin (units/kg)	Automatic Calculation on Castor
6.9	Insulin dose units per kg body weight <i>If insulin dose is not greater than or equal to 0.5units/kg body weight and BMI is not greater than 25 participant not eligible for trial</i>	Automatic Calculation on 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

# Repeating Data 'Vital Signs'



## Form Vital Signs

Question	Answers
Blood Pressure - Systolic	<div></div> mmHg
Blood Pressure - Diastolic	<div></div> mmHg
Pulse	<div></div> 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	<div style="border: 1px solid black; width: 150px; height: 20px; display: inline-block;"></div> 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	If Other Rhythm, please specify	<div style="border: 1px solid black; width: 200px; height: 80px; display: inline-block;"></div>

## 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?	<b>Automatic Calculation on Castor</b>														
9.3	LVEF	<input type="text"/> %														
<p><b>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</b></p>																
9.4	LVEF Table	<table border="1"> <thead> <tr> <th>Documented LVEF</th> <th>Numerical LVEF equivalent (%)</th> </tr> </thead> <tbody> <tr> <td>Normal/preserved</td> <td>55</td> </tr> <tr> <td>Mildly reduced</td> <td>50</td> </tr> <tr> <td>Mild/moderate</td> <td>45</td> </tr> <tr> <td>Moderate</td> <td>40</td> </tr> <tr> <td>Moderate/severe</td> <td>35</td> </tr> <tr> <td>Severe</td> <td>30</td> </tr> </tbody> </table>	Documented LVEF	Numerical LVEF equivalent (%)	Normal/preserved	55	Mildly reduced	50	Mild/moderate	45	Moderate	40	Moderate/severe	35	Severe	30
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														
<p>Preserved LV systolic function (LVEF <math>\geq 50\%</math>) with left atrial enlargement (2-dimensional measurement of left atrial width <math>\geq 3.8</math> cm or left atrial length <math>\geq 5.0</math> cm or left atrial area <math>\geq 20</math> cm<sup>2</sup> or left atrial volume index <math>&gt; 29</math> ml/m<sup>2</sup>) within the last 24 months.</p>																
9.6	Left Ventricular Hypertrophy	<input type="radio"/> YES <input type="radio"/> NO														
<p>Defined as: 2-dimensional measurement of end-diastolic interventricular septal diameter <math>\geq 1.2</math> cm or end-diastolic left ventricular posterior wall diameter <math>\geq 1.2</math> cm</p>																
9.7	Diastolic dysfunction	<input type="radio"/> YES <input type="radio"/> NO														
<p>Defined as: septal e' <math>&lt; 7</math> cm/sec or lateral e' <math>&lt; 10</math> cm/sec or average E/e' <math>\geq 15</math></p>																

# 10. Visit 1 - Screening - Cardiomyopathy Questionnaire (Kansas City) (KCCQ) - Screening

Please Complete KCCQ

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## 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 <sup>2</sup>

## 11. Visit 1 - Screening - Samples

Number	Question	Answers
<b>Other Tests</b>		
11.2	Pregnancy test performed	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> N/A
11.2.1	Pregnancy test result	<input type="radio"/> Positive <input type="radio"/> Negative
11.2.2	Is the participant either permanently sterilized or post-menopausal?	<input type="radio"/> YES <input type="radio"/> NO
11.3	N-terminal pro-B-type natriuretic peptide or B-type natriuretic peptide measurement available within 12 months of Visit 1 Screening?	<input type="radio"/> YES <input type="radio"/> NO
11.3.1	Date of N-terminal pro-B-type natriuretic peptide or B-type natriuretic peptide measurement	<input type="text"/> <input type="text"/> <input type="text"/> (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?	<b>Automatic Calculation on Castor</b>

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

11.3.3.1 N-terminal pro-B-type natriuretic peptide  ng/L

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
12.1	Age 18 years to <85 years	<b>Automatic Calculation on Castor</b>
12.2	Type 1 diabetes	<input type="radio"/> YES <input type="radio"/> NO
12.3	Insulin dose greater than or equal to 0.5 units/kg body weight at screening or BMI equal to or greater than 25kg/m2 at screening	<b>Automatic Calculation on Castor</b>
12.4	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
12.5	Diagnosis of heart failure (HF), defined as one or more of the following:	<input type="radio"/> YES <input type="radio"/> NO
	Previous HF hospitalisation where HF was documented as the primary cause of hospitalisation and there was a requirement for loop diuretics.	
	Impaired left ventricular function (i.e. LVEF <50% by any imaging modality) at any time.	
	Preserved LV systolic function (LVEF ≥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 <sup>2</sup> or left atrial volume index >29 ml/m <sup>2</sup> ) within the last 24 months.	
	Preserved LV systolic function (LVEF ≥50%) with left ventricular hypertrophy (2-dimensional measurement of end-diastolic interventricular septal diameter ≥1.2 cm or end-diastolic left ventricular posterior wall diameter ≥1.2 cm) within the last 24 months.	
	Preserved LV systolic function (LVEF ≥50%) with diastolic dysfunction (septal e' <7 cm/sec or lateral e' <10 cm/sec or average E/e' ≥15) within the last 24 months.	
12.6	New York Heart Association Class II-IV at screening	<b>Automatic Calculation on Castor</b>
12.7	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.	<input type="radio"/> YES <input type="radio"/> NO

12.8

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 <sup>2</sup> 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	<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