

52. Visit 7 - Date of Visit 7

Number	Question	Answers
52.1	Date of Visit 7	<div> <div></div> <div></div> <div></div> </div> <i>(dd-mm-yyyy)</i>
52.2	Is Visit 7 date 109 to 115 days after Visit 3 date?	Automatic Calculation on Castor

54. Visit 7 - NYHA Class

Number	Question	Answers
54.1	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>

55. Visit 7 - Concomitant Medications

Number	Question	Answers
55.1	Concomitant Medications	
	Please complete Concomitant Medications Log	

56. Visit 7 - Adverse Events

Number	Question	Answers
56.1	Adverse Events	

Please complete Adverse Events Log

57. Visit 7 - Glucose Review

Number	Question	Answers
57.1	Was Glucose Management Assessed? If Glucose Management not assessed, this is a Protocol breach	<input type="radio"/> YES <input type="radio"/> NO
57.2	Insulin administration	<input type="radio"/> Subcutaneous injections <input type="radio"/> Pump
57.3	Daily basal insulin dose (average of last 7 days)	<input type="text"/> units/day
57.4	Daily bolus insulin dose (average of last 7 days)	<input type="text"/> units/day
57.5	Total daily insulin dose (average of last 7 days)	Automatic Calculation on Castor
CGM summary data from previous 2 weeks		
57.6	Are summary data from CGM readings over the 2 weeks prior to this visit available?	<input type="radio"/> YES <input type="radio"/> NO
57.6.1	Number of days CGM worn over preceding 14 days	<input type="text"/> days
57.6.2	Percentage of time CGM was active over preceding 14 days	<input type="text"/> %

57.6.3	Mean blood glucose level over preceding 14 days	<input type="text"/>	mmol/L
57.6.4	Blood glucose percentage time above 13.9 mmol/L over preceding 14 days	<input type="text"/>	%
57.6.5	Blood glucose percentage time from 10.1 to 13.9mmol/L over preceding 14 days	<input type="text"/>	%
57.6.6	Blood glucose percentage time from 3.9 to 10.0 mmol/L over preceding 14 days	<input type="text"/>	%
57.6.7	Blood glucose percentage time from 3.0 to 3.8 mmol/L over preceding 14 days	<input type="text"/>	%
57.6.8	Blood glucose percentage time below 3.0 mmol/L over preceding 14 days	<input type="text"/>	%
57.6.9	Do blood glucose percentage times spent in each range add up to 100%?	Automatic Calculation on Castor	
57.6.10	Glycaemic variability index over preceding 14 days <i>Warning</i>	<input type="text"/>	%CV
57.1.1	Does the participant report any level 2 or level 3 hypoglycaemic events since last visit?	<input type="radio"/> YES <input type="radio"/> NO	

Level 3 hypoglycaemic event is defined as requiring hospitalisation and/or assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions. These episodes may be associated with sufficient neuroglycopaenia to induce seizure or coma. Plasma glucose measurements may not be available during such an event, but neurological recovery attributable to the restoration of plasma glucose to normal is considered sufficient evidence that the event was induced by a low plasma glucose concentration

Hypoglycaemic Events Please record any level 2 or 3 hypoglycaemic events in the Hypoglycaemic Events Log

57.1.1.2 Hypoglycaemic Events

57.1.3 Does the participant report any other symptomatic hypoglycaemic events in the last 2 weeks?

☐ YES

☐ NO

57.1.3.1 If Yes, specify

58. Visit 7 - Ketone Review

Number	Question	Answers
Ketone Readings		
58.1	Have there been Ketone measures since the last visit?	<input type="radio"/> YES <input type="radio"/> NO
58.1.1	Number of ketone measurements taken since last visit	<input type="text"/>
58.1.2	Number of episodes with ketone levels between 0.6 and 1.5 mmol/L (inclusive of endpoints).	<input type="text"/>
A distinct episode is a period where ketones have gone above the threshold (0.6mmol/L) and then come down below this. If it then went up again that would be a new distinct even		
58.1.4	Number of episodes with ketone levels greater than 1.5 mmol/L	<input type="text"/>
A distinct episode is a period where ketones have gone above the threshold (1.5mmol/L) and then come down below this. If it then went up again that would be a new distinct event.		
58.1.6	Have there been any DKA events since the last visit?	<input type="radio"/> YES <input type="radio"/> NO
DKA Events		
58.1.6.2	DKA Events	
If the participant has experienced any DKA events please complete the DKA Events Log		

Repeating Data 'Vital Signs'

Form Vital Signs

Number	Question	Answers
	Complete Vital Signs form	
1.1	Blood Pressure - Systolic	<input type="text"/> mmHg
1.2	Blood Pressure - Diastolic	<input type="text"/> mmHg
1.3	Pulse	<input type="text"/> bpm

60. Visit 7 - Physical Examination

Number	Question	Answers
60.1	Weight	<input type="text"/> kg
60.2	Cardiovascular	<input type="radio"/> Normal <input type="radio"/> Abnormal
60.2.1	If abnormal, provide details	<input type="text"/>
60.3	Respiratory	<input type="radio"/> Normal <input type="radio"/> Abnormal
60.3.1	If abnormal, provide details	<input type="text"/>
60.4	Gastrointestinal	<input type="radio"/> Normal <input type="radio"/> Abnormal
60.4.1	If abnormal, provide details	<input type="text"/>
60.5	Neurological	<input type="radio"/> Normal <input type="radio"/> Abnormal
60.5.1	If abnormal, provide details	<input type="text"/>
60.6	Other Abnormalities?	<input type="radio"/> YES <input type="radio"/> NO

60.6.1

If Other Abnormalities, specify

61. Visit 7 - Questionnaires

Number	Question	Answers
61.1	Has the KCCQ questionnaire been completed?	<input type="radio"/> YES <input type="radio"/> NO
61.1.1	Add KCCQ	Performed in Castor
61.2	Has the DTSQs questionnaire been completed?	<input type="radio"/> YES <input type="radio"/> NO
61.2.1	Add DTSQs	Performed in Castor
61.3	Has the DTSQc questionnaire been completed?	<input type="radio"/> YES <input type="radio"/> NO
61.3.1	Add DTSQc	Performed in Castor
61.4	Has the EQ-5D-5L questionnaire been completed?	<input type="radio"/> YES <input type="radio"/> NO
61.4.1	Add EQ-5D-5L	Performed in Castor

62. Visit 7 - 6-Minute Walk Test

Number	Question	Answers
	Please complete 6-Minute Walk Test	
62.1	Was 6-Minute Walk Test completed?	<input type="radio"/> YES <input type="radio"/> NO
62.1.1	Distance walked in 6 minutes?	<input type="text"/> m
62.1.2	Number of stops?	<input type="text"/>

63. Visit 7 - Samples

Number	Question Safety Bloods	Answers
Safety Bloods - please complete Safety Bloods Results Sheet Urine Sample		
63.1	Urine Sample - please complete Urine Sample Results Sheet	
63.2		
63.3	Were research bloods taken and processed as per laboratory manual?	<input type="radio"/> YES <input type="radio"/> NO
63.3.1	If answered No, give reason	<div></div>
63.4	HbA1c performed?	<input type="radio"/> YES <input type="radio"/> NO
63.4.1	HbA1c units used?	<input type="radio"/> mmol/mol <input type="radio"/> %
63.4.1.1	HbA1c level	<div></div> mmol/mol
63.4.1.2	HbA1c level	<div></div> %

Repeating Data 'Safety Bloods'

Form Safety Bloods

Number	Question	Answers
1.1	Date of blood sample <i>Warning shown if field's value is larger than NOW: 'Date of blood sample cannot be in the future.'</i>	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
1.2	Haemoglobin	<input type="text"/>
1.3	Haemoglobin Unit	<input type="radio"/> g/L <input type="radio"/> g/dL
1.4	Is the haemoglobin value within the expected range? <i>Warning shown if field's value is equal to NO: 'Haemoglobin value should be between 50 and 200 g/L OR between 7 and 20 g/dL.'</i>	
1.5	Sodium <i>Warning shown if field's value is smaller than 120: 'Sodium value should be between 120 and 150 mmol/L.'</i> <i>Warning shown if field's value is larger than 150: 'Sodium value should be between 120 and 150 mmol/L.'</i>	<input type="text"/> mmol/L
1.6	Potassium <i>Warning shown if field's value is smaller than 2.5: 'Potassium value should be between 2.5 and 6.5 mmol/L.'</i> <i>Warning shown if field's value is larger than 6.5: 'Potassium value should be between 2.5 and 6.5 mmol/L.'</i>	<input type="text"/> mmol/L
1.7	Urea <i>Warning shown if field's value is smaller than 1: 'Urea value should be between 1 and 30 mmol/L.'</i> <i>Warning shown if field's value is larger than 30: 'Urea value should be between 1 and 30 mmol/L.'</i>	<input type="text"/> mmol/L
1.8	Creatinine <i>Warning shown if field's value is smaller than 20: 'Creatinine value should be between 20 and 400 µmol/L.'</i> <i>Warning shown if field's value is larger than 400: 'Creatinine value should be between 20 and 400 µmol/L.'</i>	<input type="text"/> µmol/L
1.9	Glucose <i>Warning shown if field's value is smaller than 3: 'Glucose value should be between 3 and 30 mmol/L.'</i> <i>Warning shown if field's value is larger than 30: 'Glucose value should be between 3 and 30 mmol/L.'</i>	<input type="text"/> mmol/L
1.10	eGFR	<input type="text"/> mL/min/1.73m ²
1.11	Has eGFR been reported in the correct range/format? <i>Warning shown if field's value is equal to NO: 'eGFR: Value should be an integer between 0 and 100. Values between this range can also be written with a ">" in front of the value'</i>	

Repeating Data 'Urine Sample'

Form Urine sample

Number	Question	Answers
1.1	Date of urine sample <i>Warning shown if field's value is larger than NOW: 'Date of urine sample cannot be in the future.'</i>	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
1.2	Albumin	<input type="text"/> mg/L
1.3	Albumin check <i>Warning shown if field's value is equal to NO: 'Urine albumin must be in the range 0-3000 mg/L or <3 mg/L'</i>	
1.4	Creatinine	<input type="text"/>
1.5	Creatinine Units	<input type="radio"/> μ mol/L <input type="radio"/> mmol/L
1.6	Urine albumin/creatinine ratio <i>Warning shown if field's value is smaller than 0: 'Urine albumin/creatinine ratio must be between 0 and 2000 mg/mmol creat.'</i> <i>Warning shown if field's value is larger than 2000: 'Urine albumin/creatinine ratio must be between 0 and 2000 mg/mmol creat.'</i>	<input type="text"/> mg/mmol creat
1.7	Sodium <i>Warning shown if field's value is smaller than 5: 'Sodium value should be between 5 and 130 mmol/L.'</i> <i>Warning shown if field's value is larger than 130: 'Sodium value should be between 5 and 130 mmol/L.'</i>	<input type="text"/> mmol/L