

51. Visit 7 - Date of Visit 7

Number	Question	Answers
51.1	Date of Visit 7	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
51.2	Is Date of Visit 7 between 39 and 45 days after Date of Visit 6?	Automatic Calculation on Castor

52. Visit 7 - NYHA Class

Number	Question	Answers
52.1	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>

53. Visit 7 - Concomitant Medications

Number	Question	Answers
53.1	Concomitant Medications Please complete Concomitant Medications Log	

54. Visit 7 - Adverse Events

Number	Question	Answers
54.1	Adverse Events Please complete Adverse Events Log	

55. Visit 7 - Glucose Review

Number	Question	Answers
55.1	Was Glucose Management Assessed? <i>If Glucose Management not assessed, this is a Protocol breach</i>	<input type="radio"/> YES <input type="radio"/> NO
55.2	Insulin administration	<input type="radio"/> Subcutaneous injections <input type="radio"/> Pump
55.3	Daily basal insulin dose (average of last 7 days)	<input type="text"/> units/day
55.4	Daily bolus insulin dose (average of last 7 days)	<input type="text"/> units/day
55.5	Total daily insulin dose (average of last 7 days)	Automatic Calculation on CaStar
CGM summary data from previous 2 weeks		
55.6	Are summary data from CGM readings over the 2 weeks prior to this visit available?	<input type="radio"/> YES <input type="radio"/> NO
55.6.1	Number of days CGM worn over preceding 14 days	<input type="text"/> days
55.6.2	Percentage of time CGM was active over preceding 14 days	<input type="text"/> %

55.6.3 Mean blood glucose level over preceding 14 days mmol/L

55.6.4 Blood glucose percentage time above 13.9 mmol/L over preceding 14 days %

55.6.5 Blood glucose percentage time from 10.1 to 13.9mmol/L over preceding 14 days %

55.6.6 Blood glucose percentage time from 3.9 to 10.0 mmol/L over preceding 14 days %

55.6.7 Blood glucose percentage time from 3.0 to 3.8 mmol/L over preceding 14 days %

55.6.8 Blood glucose percentage time below 3.0 mmol/L over preceding 14 days %

55.6.9 Do blood glucose percentage times spent in each range add up to 100%? **Automatic Calculation on Castor**

55.6.10 Glycaemic variability index over preceding 14 days %CV

55.1.1 Does the participant report any level 2 or level 3 hypoglycaemic events since last visit?
 YES
 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 neuroglycopenia 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

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

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

YES

NO

55.1.3.1 If Yes, specify



56. Visit 7 - Ketone Review

Number	Question	Answers
Ketone Readings		
56.1	Have there been Ketone measures since the last visit?	<input type="radio"/> YES <input type="radio"/> NO
56.1.1	Number of ketone measurements taken since last visit	<input style="width: 150px; height: 20px;" type="text"/>
56.1.2	Number of episodes with ketone levels between 0.6 and 1.5 mmol/L (inclusive of endpoints).	<input style="width: 150px; height: 20px;" type="text"/>
<p><i>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 event.</i></p>		
56.1.4	Number of episodes with ketone levels greater than 1.5 mmol/L	<input style="width: 150px; height: 20px;" type="text"/>
<p>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.</p>		
56.1.6	Have there been any DKA events since the last visit?	<input type="radio"/> YES <input type="radio"/> NO
DKA Events		
56.1.6.2	DKA Events	
<p>If the participant has experienced any DKA events please complete the DKA Events Log</p>		

Repeating Data 'Vital Signs'

Form Vital Signs



Question	Answers
Complete Vital Signs form	
Blood Pressure - Systolic	<input data-bbox="951 499 1318 539" type="text"/> mmHg
Blood Pressure - Diastolic	<input data-bbox="951 701 1318 741" type="text"/> mmHg
Pulse	<input data-bbox="951 902 1318 943" type="text"/> bpm

58. Visit 7 - Physical Examination

Number	Question	Answers
58.1	Weight	<input type="text"/> kg
58.2	Cardiovascular	<input type="radio"/> Normal <input type="radio"/> Abnormal
58.2.1	If abnormal, provide details	<input type="text"/>
58.3	Respiratory	<input type="radio"/> Normal <input type="radio"/> Abnormal
58.3.1	If abnormal, provide details	<input type="text"/>
58.4	Gastrointestinal	<input type="radio"/> Normal <input type="radio"/> Abnormal
58.4.1	If abnormal, provide details	<input type="text"/>
58.5	Neurological	<input type="radio"/> Normal <input type="radio"/> Abnormal
58.5.1	If abnormal, provide details	<input type="text"/>
58.6	Other Abnormalities?	<input type="radio"/> YES <input type="radio"/> NO

58.6.1 If Other Abnormalities, specify



59. Visit 7 - Questionnaires

Number	Question	Answers
59.1	Has the KCCQ questionnaire been completed?	<input type="radio"/> YES <input type="radio"/> NO
59.1.1	Add KCCQ	Performed in Castor
59.2	Has the DTSQs questionnaire been completed?	<input type="radio"/> YES <input type="radio"/> NO
59.2.1	Add DTSQs	Performed in Castor
59.3	Has the DTSQc questionnaire been completed?	<input type="radio"/> YES <input type="radio"/> NO
59.3.1	Add DTSQc	Performed in Castor
59.4	Has the EQ-5D-5L questionnaire been completed?	<input type="radio"/> YES <input type="radio"/> NO
59.4.1	Add EQ-5D-5L	Performed in Castor

60. Visit 7 - 6-Minute Walk Test

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

61. Visit 7 - Samples

Number	Question	Answers
Safety Bloods		
61.1	Safety Bloods - please complete Safety Bloods Results Sheet	
Urine Sample		
61.2	Urine Sample - please complete Urine Sample Results Sheet	
61.3	Were research bloods taken and processed as per laboratory manual?	<input type="radio"/> YES <input type="radio"/> NO
61.3.1	If answered No, give reason	<div style="border: 1px dotted black; height: 80px; width: 100%;"></div>
61.4	HbA1c performed?	<input type="radio"/> YES <input type="radio"/> NO
61.4.1	HbA1c units used?	<input type="radio"/> mmol/mol <input type="radio"/> %
61.4.1.1	If 'HbA1c units used?' is 'mmol/mol' answer this question: HbA1c level	<div style="border: 1px dotted black; width: 150px; height: 20px;"></div> mmol/mol
61.4.1.2	If 'HbA1c units used?' is '%' answer this question: HbA1c level	<div style="border: 1px dotted black; width: 150px; height: 20px;"></div> %

61. Visit 7 - Samples

Number	Question	Answers
61.1	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

Repeating Data 'Urine Sample'

Form Urine sample



Question	Answers
Date of urine sample	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
Albumin	<input type="text"/> mg/L
Creatinine	<input type="text"/> <input type="text"/> μmol/L or mmol/L
Urine albumin/creatinine ratio	<input type="text"/> mg/mmol
Sodium	<input type="text"/> mmol/L