

40. Visit 5 - Date of Visit 5

Number	Question	Answers
40.1	Date of Visit 5	<div> <div></div> <div></div> <div></div> </div> <i>(dd-mm-yyyy)</i>
40.2	Is Visit 5 date 25 to 31 days after Visit 3 date?	Automatic Calculation on Castor

41. Visit 5 - Concomitant Medications

Number	Question	Answers
41.1	Concomitant Medications	

Please complete Concomitant Medications Log

42. Visit 5 - Adverse Events

Number	Question	Answers
42.1	Adverse Events	

Please complete Adverse Events Log

43. Visit 5 - Glucose Review

Number	Question	Answers
43.1	Was Glucose Management Assessed? <i>If Glucose Management not assessed, this is a Protocol breach</i>	<input type="radio"/> YES <input type="radio"/> NO
43.1.1	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 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	Please record any level 2 or 3 hypoglycaemic events in the Hypoglycaemic Events Log
43.1.1.2	Hypoglycaemic Events	
43.2	Insulin administration	<input type="radio"/> Subcutaneous injections <input type="radio"/> Pump
43.3	Daily basal insulin dose (average of last 7 days)	<input type="text"/> units/day
43.4	Daily bolus insulin dose (average of last 7 days)	<input type="text"/> units/day
43.5	Total daily insulin dose (average of last 7 days)	
CGM summary data from previous 2 weeks		
43.6	Are summary data from CGM readings over the 2 weeks prior to this visit available?	<input type="radio"/> YES <input type="radio"/> NO

43.6.1 Number of days CGM worn over preceding 14 days days

43.6.2 Percentage of time CGM was active over preceding 14 days %

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

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

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

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

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

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

43.6.9 Do blood glucose percentage times spent in each range add up to 100%?

43.6.10 Glycaemic variability index over preceding 14 days.

%CV

44. Visit 5 - Ketone Review

Number	Question	Answers
Ketone Readings		
44.1	Have there been Ketone measures since the last visit?	<input type="radio"/> YES <input type="radio"/> NO
44.1.1	Number of ketone measurements taken since last visit	<input type="text"/>
44.1.2	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 event.		
44.1.4	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.		
44.1.6	Have there been any DKA events since the last visit?	<input type="radio"/> YES <input type="radio"/> NO
DKA Events		
44.1.6.2	DKA Events	

If the participant has experienced any DKA events please complete the DKA Events Log

45. Visit 5 - Questionnaires

Number	Question	Answers
45.1	Has the KCCQ questionnaire been completed?	<input type="radio"/> YES <input type="radio"/> NO
If 'Has the KCCQ questionnaire been completed?' is equal to 'YES' answer this question:		
45.1.1	Add KCCQ	

Repeating Data 'Safety Bloods'

Visit 5 - Samples

Form Safety Bloods

Number	Question	Answers
1.1	Date of blood sample	<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?	
1.5	Sodium	<input type="text"/> mmol/L
1.6	Potassium	<input type="text"/> mmol/L
1.7	Urea	<input type="text"/> mmol/L
1.8	Creatinine	<input type="text"/> µmol/L
1.9	Glucose	<input type="text"/> mmol/L
1.10	eGFR	<input type="text"/> mL/min/1.73m ²

Repeating Data 'Urine Sample'

Form Urine sample

Number	Question	Answers
1.1	Date of urine sample	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
1.2	Albumin	<input type="text"/> mg/L
1.3	Albumin check	
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	<input type="text"/> mg/mmol creat
1.7	Sodium	<input type="text"/> mmol/L