

35. Visit 4 - Date of Visit 4

Number	Question	Answers
35.1	Date of Visit 4	<div> <div></div> <div></div> <div></div> </div> (dd-mm-yyyy)
35.2	Is Visit 4 date 4 to 10 days after Visit 3 date?	Automatic Calculation on Castor

36. Visit 4 - Concomitant Medications

Number	Question	Answers
36.1	Concomitant Medications	
	Please complete Concomitant Medications Log	

37. Visit 4 - Adverse Events

Number	Question	Answers
37.1	Adverse Events	
	Please complete Adverse Events Log	

38. Visit 4 - Glucose Review

Number	Question	Answers
38.1	Was Glucose Management Assessed? <i>If Glucose Management not assessed, this is a Protocol breach</i>	<input type="radio"/> YES <input type="radio"/> NO
38.1.1	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		
38.1.1.2	Hypoglycaemic Events	
Please record any level 2 or 3 hypoglycaemic events in the Hypoglycaemic Events Log		

39. Visit 4 - Ketone Review

Number	Question	Answers
Ketone Readings		
39.1	Have there been Ketone measures since the last visit?	<input type="radio"/> YES <input type="radio"/> NO
39.1.1	Number of ketone measurements taken since last visit	<input type="text"/>
39.1.2	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.		
39.1.4	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.		
39.1.6	Have there been any DKA events since the last visit?	<input type="radio"/> YES <input type="radio"/> NO
DKA Events		
39.1.6.2	DKA Events	
Please report any level 2 or 3 events in the Hypoglycaemic Events Log		