

34. Visit 4 - Date of Visit 4

Name	Question	Answers
34.1	Date of Visit 4	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
34.2	Is Date of Visit 4 between 4 and 10 days after Date of Visit 3?	Automatic Calculation on Castor

35. Visit 4 - Concomitant Medications

Name	Question	Answers
35.1	Concomitant Medications	
	Please complete Concomitant Medications Log	

36. Visit 4 - Adverse Events

Number	Question	Answers
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36.1	Adverse Events	
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Please complete Adverse Events Log

37. Visit 4 - Glucose Review

Number	Question	Answers
37.1	Was Glucose Management Assessed? <i>If Glucose Management not assessed, this is a Protocol breach</i>	<input type="radio"/> YES <input type="radio"/> NO
37.1.1	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		
37.1.1.2	Please record any level 2 or 3 hypoglycaemic events in the Hypoglycaemic Events Log	

38. Visit 4 - Ketone Review

Number	Question	Answers
Ketone Readings		
38.1	Have there been Ketone measures since the last visit?	<input type="radio"/> YES <input type="radio"/> NO
38.1.1	Number of ketone measurements taken since last visit	<input type="text"/>
38.1.2	Number of episodes with ketone levels between 0.6 and 1.5 mmol/L (inclusive of endpoints).	<input type="text"/>
<p>A distinct episode is a period where ketones have gone above that threshold (0.6 mmol/L) and then come down below this. If it then went up again that would be a new distinct event.</p>		
38.1.4	Number of episodes with ketone levels greater than 1.5 mmol/L	<input type="text"/>
<p>A distinct episode is a period where ketones have gone above the threshold (1.5 mmol/L) and then come down below this. If it then went up again that would be a new distinct event.</p>		
38.1.6	Have there been any DKA events since the last visit?	<input type="radio"/> YES <input type="radio"/> NO
38.1.6.2	DKA Events	
Please report any level 2 or 3 events in the Hypoglycaemic Events Log		