

46. Visit 6 - Date of Visit 6

Number	Question	Answers
46.1	Date of Visit 6	<div><div></div><div></div><div></div></div> (dd-mm-yyyy)
46.2	Is Date of Visit 6 between 39 and 45 days after Date of Visit 5?	Automatic Calculation on Castor

47. Visit 6 - Concomitant Medications

Number	Question	Answers
47.1	Concomitant Medications	
	Please complete Concomitant Medications Log	

48. Visit 6 - Adverse Events

Number	Question	Answers
48.1	Adverse Events	
	Please complete Adverse Events Log	

49. Visit 6 - Glucose Review

Number	Question	Answers
49.1	Was Glucose Management Assessed? <i>If Glucose Management not assessed, this is a Protocol breach</i>	<input type="radio"/> YES <input type="radio"/> NO
49.1.1	Does the participant report any level 2 or level 3 hypoglycaemic events since last visit?	<input type="radio"/> YES <input type="radio"/> NO
<p>Does the participant report any level 2 or level 3 hypoglycaemic events since last visit?” to “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</p>		
<p>Hypoglycaemic Events</p>		
49.1.1.2	Please record any level 2 or 3 hypoglycaemic events in the Hypoglycaemic Events Log	

50. Visit 6 - Ketone Review

Number	Question	Answers
Ketone Readings		
50.1	Have there been Ketone measures since the last visit?	<input type="radio"/> YES <input type="radio"/> NO
50.1.1	Number of ketone measurements taken since last visit	<input type="text"/>
50.1.2	Number of episodes with ketone levels between 0.6 and 1.5 mmol/L (inclusive of endpoints).	<input type="text"/>
<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>		
50.1.4	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.		
50.1.6	Have there been any DKA events since the last visit?	<input type="radio"/> YES <input type="radio"/> NO
DKA Events		
50.1.6.2	DKA Events	
If the participant has experienced any DKA events please complete the DKA Events Log		