

## 14. Visit 2 - Date of Visit 2

Number	Question	Answers
14.1	Date of Visit 2	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
14.2	Is Date of Visit 2 between 4 and 26 days after Date of Visit 1?	<b>Automatic Calculation on Castor</b>

## 15. Visit 2 - Concomitant Medications

Number	Question	Answers
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15.1	Concomitant Medications	
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**Please complete Concomitant Medications Log**

## 16. Visit 2 - Adverse Events

Number	Question	Answers
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16.1	Adverse Events	
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**Please complete Adverse Events Log**

## 17. Visit 2 - Glucose Review

Number	Question	Answers
17.1	Was Glucose Management Assessed? <i>If Glucose Management not assessed, this is a Protocol breach</i>	<input type="radio"/> YES <input type="radio"/> NO
17.1.1	Does the participant report any level 2 or level 3 hypoglycaemic events since last visit? <i>If there has been a level 3 hypoglycaemic event since last visit, participant is ineligible for trial. Complete the hypoglycaemic repeating data.</i>	<input type="radio"/> YES <input type="radio"/> NO
<p><b>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.</b></p>		
<p><b>Hypoglycaemic Events</b></p>		
17.1.1.2	Hypoglycaemic Events  <b>Please complete Hypoglycaemic Events Log</b>	
17.1.3	Has the participant registered with a CGM diabetes management device, e.g. Libreview or Dexcom?	<input type="radio"/> YES <input type="radio"/> NO

## 18. Visit 2 - Ketone Review

Number	Question	Answers
18.1	Have there been any Ketone measures taken since the last visit?	<input type="radio"/> YES <input type="radio"/> NO
18.1.1	Number of ketone measurements taken since last visit	<input type="text"/>
18.1.2	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 the 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>		
18.1.4	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>		
18.1.6	Have there been any DKA events since the last visit?	<input type="radio"/> YES <input type="radio"/> NO
<p><i>If there has been a DKA event since last visit, participant is ineligible for trial. Complete the DKA repeating data.</i></p>		
<p><b>DKA Events</b></p>		
18.1.6.2	<b>Please complete DKA Log</b>	