

62. Visit 8 - Date of Visit 8

Number	Question	Answers
62.1	Date of Visit 8	<div> <div></div> <div></div> <div></div> </div> <i>(dd-mm-yyyy)</i>
62.2	Is Date of Visit 8 between 25 and 31 days after Date of Visit 7?	Automatic Calculation on Castor

63. Visit 8 - NYHA Class

Number	Question	Answers
63.1	NYHA Class	<p><input type="radio"/> I - No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnoea (shortness of breath).</p> <p><input type="radio"/> II - Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnoea (shortness of breath).</p> <p><input type="radio"/> III - Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnoea.</p> <p><input type="radio"/> IV - Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.</p>

64. Visit 8 - Concomitant Medications

Number	Question	Answers
64.1	Concomitant Medications	
	Please complete the Concomitant Medications Log	

65. Visit 8 - Adverse Events

Number	Question	Answers
65.1	Adverse Events	
	Please complete the Adverse Events Log	

66. Visit 8 - Glucose Review

Number	Question	Answers
66.1	Was Glucose Management Assessed? <i>If Glucose Management not assessed, this is a Protocol breach</i>	<input type="radio"/> YES <input type="radio"/> NO
66.1.1	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		
66.1.1.2	Please record any level 2 or 3 hypoglycaemic events in the Hypoglycaemic Events Log	

67. Visit 8 - Ketone Review

Number	Question	Answers
Ketone Readings		
67.1	Have there been Ketone measures since the last visit?	<input type="radio"/> YES <input type="radio"/> NO
67.1.1	Number of ketone measurements taken since last visit	<input type="text"/>
67.1.2	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>		
67.1.4	Number of episodes with ketone levels greater than 1.5 mmol/L	<input type="text"/>
<i>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.</i>		
67.1.6	Have there been any DKA events since the last visit?	<input type="radio"/> YES <input type="radio"/> NO
DKA Events		
67.1.6.2	DKA Events	
If the participant has experienced any DKA events please complete the DKA Events Log		

68. Completion of Trial/Early Withdrawal - Completion of Trial/Early Withdrawal

Number	Question	Answers
68.1	Did the participant complete the trial?	<input type="radio"/> Yes <input type="radio"/> No
68.2	Date of Completion/Withdrawal	<input type="text"/> <input type="text"/> <input type="text"/> (dd-mm-yyyy)
68.3	Is Date of Completion/Withdrawal before Date of Visit 1?	
68.1.1	<p>If participant did not complete the trial, what was the main reason (tick one only)</p> <p><i>If field's value is equal to Pregnancy: a Pregnancy Notification Form must be completed.</i></p>	<p><input type="radio"/> Advice from GP/other healthcare professional</p> <p><input type="radio"/> Adverse event</p> <p><input type="radio"/> Participant's choice</p> <p><input type="radio"/> Pregnancy</p> <p><input type="radio"/> On advice of investigator</p> <p><input type="radio"/> Lost to follow-up</p> <p><input type="radio"/> Died</p> <p><input type="radio"/> Screen fail</p> <p><input type="radio"/> Other</p>
68.4	Details Calculation	
68.4.1	Please give details	<input type="text"/>

To be electronically verified by the PI once participant has completed the trial and all data entered