

## 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? | <b>Automatic Calculation on Castor</b>                                      |

## 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  |
|--------|----------------|--|
| 36.1   | Adverse Events | <p><b>Please complete Adverse Events Log</b></p> |

## 37. Visit 4 - Glucose Review

| Number   | Question   | Answers   |
|--|--|---|
| 37.1   | Was Glucose Management Assessed?<br><i>If Glucose Management not assessed, this is a Protocol breach</i> | <input type="radio"/> YES<br><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<br><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>   |  |   |
| 37.1.1.2   | <p><b>Please record any level 2 or 3 hypoglycaemic events in the Hypoglycaemic Events Log</b></p>        |   |

## 38. Visit 4 - Ketone Review

| Number   | Question   | Answers   |
|--|--|---|
| <b>Ketone Readings</b>   |  |   |
| 38.1   | Have there been Ketone measures since the last visit?                                      | <input type="radio"/> YES<br><input type="radio"/> NO |
| 38.1.1   | Number of ketone measurements taken since last visit                                       | .....   |
| 38.1.2   | Number of episodes with ketone levels between 0.6 and 1.5 mmol/L (inclusive of endpoints). | .....   |
| <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> |  |   |
| 38.1.4   | Number of episodes with ketone levels greater than 1.5 mmol/L                              | .....   |
| <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<br><input type="radio"/> NO |
| 38.1.6.2   | DKA Events   |   |
| <p><b>Please report any level 2 or 3 events in the Hypoglycaemic Events Log</b></p>  |  |   |