Discontinuation of Trial Medication
Withdrawal from Trial
Completion of Trial

Permanent discontinuation of trial medication

The trial drug must be discontinued permanently in the following circumstances:

- Recurrent (more than 2) level 3 hypoglycaemia events with no other contributing factors, e.g. diet or exercise.
- DKA requiring hospitalisation.
- Renal failure requiring dialysis.
- Pregnancy.
- Diagnosed Fournier's gangrene.
- Circumstances where the PI feels that continuation of trial drug will be detrimental to the participant's wellbeing.

Where the participant, for whatever reason, permanently discontinues the trial drug they should be encouraged to remain in the trial completing all follow-up visits and calls.

Temporary discontinuation of trial medication

The trial drug must be temporary discontinued in the following circumstances:

- Potential DKA: Participants will be instructed to stop their trial drug if blood ketones are >1.5mmol/L. Restarting of the trial drug is at the discretion of the local investigator, however we would anticipate that this it is not restarted until ketones are <0.6mmol/l and symptoms (if present) have resolved.
- Clinically significant volume depletion (as judged by the local investigator) or intercurrent illness may necessitate a temporary cessation of trial drug, although additional steps should be taken initially as appropriate such as increasing fluid intake and adjusting loop diuretic dose.
- Suspected Fournier's gangrene.
- If the patient has stopped trial drug for >5 consecutive days, the PI should be notified to confirm that it is appropriate to restart the trial drug on a case-by-case basis.

Withdrawal from trial

- Participants are free to withdraw at any time and are not obliged to give reason(s).
- Discuss with the participant the value to the trial of discontinuing trial medication but continuing with trial follow up rather than withdrawing completely.
- Make a reasonable effort to ascertain the reason(s), both for those who express their right to withdraw and for those lost to follow up, while fully respecting the individual's rights.
- The investigator may also withdraw a participant at any time if it is in the best interest of the participant and treatment continuation would be detrimental to the participant's wellbeing.
- The participant should be offered an end-of-trial assessment.
- If a participant withdraws and does not remain on the study, the Completion of Trial/Early Withdrawal should be completed on the eCRF.

Completion of Trial

- Once a participant has completed all trial visits, the Completion of Trial/Early Withdrawal Visit must be completed on the eCRF.