



## **REPOSE SOP Number 16: End of trial for pump participants**

### **1) Purpose**

This guideline describes the process for managing pump participants at the end of the REPOSE trial.

### **2) Background**

The insulin pumps being used by REPOSE participants have been provided free of charge by Medtronic and were supplied with a two year warranty. The pump consumables are being paid for by DoH/CSO/PCT and funding of these is also limited to the 2 year duration of the trial

### **3) Procedure**

#### **3.1 Decision whether to continue on the pump**

Local staff will make a clinical decision with the participant as to whether they would benefit from continued use of a pump. Such discussions and any final decision **should not be taken until the participant has completed data collection for the trial** (i.e. after the 24 month follow up data collection). This is to ensure that any decision does not impact on a participant's behaviour during the trial which could affect REPOSE outcomes. In cases where continued use of a pump is considered appropriate, funding will need to be sought locally.

#### **3.2 Timing of the 24 month follow-up visit and the use of pumps to trial completion**

All REPOSE participants' 24 month visits should be booked in the first half of the data collection window if possible, regardless of which arm they are in (i.e. up to 6 weeks prior to the exact 24 month date).

Medtronic have agreed a 2 month extension of the pump warranties. This will allow participants who have to attend the 24 month follow-up in the second half of the 12 week data collection window to continue using the pump until the end of their participation in the trial. The agreements for the funding of pump consumables are for a fixed amount and cannot be changed. Therefore any continued use of pump consumables during this time may need to be funded locally. In practice however, we do not expect this to be required, as those participants who complete the trial early should offset any who are followed up late.

#### **3.3 Post-trial arrangements**

It will be up to local diabetes teams to determine how the transition between trial completion and continued pump use is managed. The ordering systems used for REPOSE are trial specific and will not be valid for non-REPOSE participants, normal local procedures should be used.

If the decision is that the patient is continuing on pump therapy, Medtronic can accommodate one of the following two options:

1. A new pump with 4 year warranty can be purchased for the patient with access to full training and resources.
2. An extension to the warranty of 1 year 10 months resulting in cumulative 4 year warranty for the existing pump can be purchased (this option should be discussed and agreed in advance of the 2 year 2 month warranty period ending).

Where no longer required, pumps should be disposed of at site or returned to Medtronic clearly marked as a REPOSE study pump.