

## **DAFNEplus FAQs for Sites**

If you can't find the answer to your question here please email the DAFNEplus team:

dafneplus@sheffield.ac.uk

### **Q. Do admin staff who are assisting with data entry need to have GCP training?**

A. No- GCP training is not required for staff who are not working in a patient facing role in this trial.

### **Q. Can sites run mixed courses i.e. including research participants as well as patients who have not consented to the research?**

A. We are currently working on the basis that research and non research participants must attend separate courses. However, we recognise that this could have an impact on workload at certain sites and we plan to keep this under review when the trial opens to recruitment. If necessary we will look at submitting an amendment to the ethics committee to allow this, but it is likely that this would only be feasible for control sites that aren't involved in audio recording of sessions.

### **Q. Do participants have to use the Aviva Expert Meter?**

A. All participants in both arms should be offered the option to use the Aviva Expert Meter. However, they do not have to use this if they have a strong preference for another meter.

### **Q. Can we use the participant's DAFNE number instead of giving them a separate study ID number?**

A. Yes this has been agreed with the Central DAFNE administration team.

### **Q. What happens if a participant is recruited, and then is unable to attend all 5 sessions, e.g. through illness, or for some other reason?**

A. To be counted as having completed a DAFNE course for the purposes of statistical analyses, participants must have attended 4 days (including the first 2 days) as well as 3 of the 5 follow up sessions. Participants who don't complete these sessions will still be followed up as research participants if they agree to this. Participants who don't meet these criteria can be offered another DAFNE course if they want to attend - this can be either a research or non research course depending on availability and preference.

### **Q. What is the end recruitment date?**

A. Courses have a running period up until the end of Jan 2020

### **Q. What is the minimum and maximum number of patients needed to run a course?**

A. Minimum of 4 and maximum of 8 people.

### **Q. Do sites have to enter participant data onto both the Prospect database as well as the DAFNE database?**

A. No - sites only need to enter data onto Prospect; the team in Sheffield will send data to the DAFNE database team at study completion..

**Q. If a participant becomes pregnant during the follow-up period, would this be classed as a “clinician decision to withdraw”?**

A. No - Pregnant participants don't need to be withdrawn, unless, like any other participants, they become too unwell to continue. According to the protocol, pregnancies are reported as Serious Adverse Events, but don't need to be reported immediately (within 4 weeks instead of within 24 hours of discovery).

**Q. Do patients using the Freestyle Libre have to test and use the bolus calculator function on the Aviva Expert meter during the trial?**

Participants can use Freestyle Libre in both arms of the trial; in the intervention arm of the trial information can be downloaded onto the Glucollector site so that it is available to view with the rest of their data. In both arms of the trial participants should use the Aviva expert meter, irrespective of Libre use, to do their pre-meal BGs and before bed BG, to get the bolus advice and enable them to record their carbs, QA and BI doses.

**Q. Do you have guidance on scheduling the follow up appointments in the DAFNEplus (intervention) arm of the trial?**

The follow up dates can be flexible because in reality they need to be. Even with planning, people cancel etc. It isn't like the research appointments where they need to be within a certain window.

The essential points are - the aim is to offer 5 follow up appointments over one year with increasingly longer time periods in between. The recommended format based on the pilots are post course at 2 weeks, 6 weeks, 12 weeks, 6 months and one year. However the timing can be flexible to suit the service and the participants and cancellations and re-arrangements will be inevitable making flexibility with timing also important. Therefore for example someone may be seen at 3 weeks, 7 weeks and 11 weeks, then 6 months and 12 months. Record these dates on the appropriate data collection form.

The minimum number of follow up appointments for participants to be classed as having 'completed' the intervention is three. This may occur due to cancellations, non-attendance or because the DF and participant have agreed that not all follow up appointments are required. Follow up can be via skype or telephone as well as face to face.

**Q. I am aware that a new DAFNE curriculum and workbooks should be available soon. Do DAFNE (control sites) move to the new materials when they become available or do we wait until after the trial?**

Please start using the new DAFNE curriculum and resources when they are ready.

**Q. The SOP for using the expert meter in the control arm of the trial is not using the usual DAFNE target BG levels - are they the ones from the new curriculum?**

Yes - we had envisaged that the new DAFNE curriculum would be ready by now and therefore the targets would match those you are teaching on the course - we are working on addressing this question and will update this soon - please contact the DAFNEplus team directly if you have any questions in the meantime.

**Can the course be shared between more than 2 educators?**

It is definitely better for consistency to have just 2 facilitators, however if 3 are to deliver, at least 1 should be there for all 5 weeks and there needs to be good communication / feedback about the participants during and in between course days.

**Can the course be delivered on different days of the week in different weeks  
e.g. Monday to Friday but across 5 weeks?**

It would clearly be much better for participants to be attending the course on the same day each week; there would be the potential for confusion and drop-out if the day changes each week. If this is unavoidable (e.g. bank holidays), then there should be a minimum of 5 days and a maximum of 9 days in between course dates (similar to the 5x1 RCT).