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SWEET Follow Up Guidance

- SWEET Follow Up Time Points are at 6-, 12- and 18-months post-randomisation (PR).
- This is calculated in weeks by the trial team so equates to 26-, 52- and 78-weeks post-randomisation (PR).
- For each timepoint the Protocol States a +/- 4-week window to collect Follow Up data- described in the table below
- Do not forget follow up data consists of 2 items:
    - **Follow Up CRF** (to be completed by site staff at the designated timepoint)
    - **Follow Up Questionnaire** (to be completed by the participant at the designated timepoint)

Timepoint (X)	Start of Window (x- 4 weeks)	End of Window (x- 4 weeks)	Items to be completed
6 months/ 26 weeks PR	22 Weeks PR	30 Weeks PR	1) Site to complete 6 Month Follow Up CRF. 2) Site to send participant the following at the start of the window (x- 4wks): *2a. Follow Up Questionnaire with TNO, Initials and 6-month box ticked* *2b. Follow Up Cover Letter* *2c. Follow Up Postcard* *2d. Freepost Envelope*
12 months/ 52 weeks PR	48 Weeks PR	56 Weeks PR	1) Site to complete 12 Month Follow Up CRF. 2) Site to send participant the following at the start of the window (x- 4wks): *2a. Follow Up Questionnaire with TNO, Initials and 12-month box ticked* *2b. Follow Up Cover Letter* *2c. Follow Up Postcard* *2d. Freepost Envelope*
18 months/ 78 weeks PR	74 Weeks PR	82 Weeks PR	1) Site to complete 18 Month Follow Up CRF. 2) Site to send participant the following at the start of the window (x- 4wks): *2a. Follow Up Questionnaire with TNO, Initials and 18-month box ticked* *2b. Follow Up Cover Letter* *2c. Follow Up Postcard* *2d. Freepost Envelope*

SWEET

SWEET Follow Up Guidance

Specific Questionnaire Guidance

- The WCTU trial team will email you at X-4 weeks to highlight which patients are starting their follow up window. The trial team reviews this weekly- therefore if you have lots of participants in follow up you may receive an email weekly.

- At this point we ask you to
    - Complete the Follow Up CRF on the database.
    - Send the Follow Up Questionnaire to the participant.

- If at timepoint X (actual due date) we have not yet received a participants follow up questionnaire we will email and let you know. At this point we will ask you to contact the participant and
    - Make sure they have received their questionnaire.
    - Resend if they have not.
    - Gently reiterate the importance of the questionnaire. For example… ***'Thankyou <Name>, as ever we appreciate your participation in the trial. If you are able to complete the questionnaire as soon as possible and send back using the free post envelope. Your answers are really important in helping us understand if the Intervention is useful'*** …you could expand if required…for example ***'Even if you are no longer taking HT the information you provide is still really important in understanding if the intervention can support future women'*** or ***'Even if some of the questions don't feel relevant please answer as best you can or answer the questions which you feel are most relevant to you'***

- You can follow up via email, text, phone but always be cautious of impacting usual care.

- If by timepoint X+2 (a further 2 weeks later) we have not yet received a participants follow up questionnaire we will email and let you know. At this point we will ask you to contact the participant using the guidance steps noted above.

- Please don't forget to refer to the Participant Flow Document in section 8 of your ISF if required: https://warwick.ac.uk/fac/sci/med/research/ctu/trials/sweet/isf/

SWEET

SWEET Follow Up Guidance

Specific CRF Guidance

- The WCTU trial team will email you at X-4 weeks to highlight which patients are starting their follow up window. Please ensure you review your Follow Up CRF at this point.

- Please note, this CRF needs to be completed irrespective of participant response. (You do not need to wait for confirmation from the trial office that the follow up questionnaire has been returned to complete the follow up CRF)

- You do not need to contact the participant to complete the CRF, this should be completed using the information available from patients records.

- If the participant has a **new cancer event** (e.g. Breast cancer recurrence or New non-breast malignancy): ensure this is documented on the Follow Up CRF and complete an Event form CRF on the database.

- If you are aware of a new cancer event prior to the follow up time point, complete Event form CRF on the database and highlight this on the next relevant follow up CRF.

- If the participant has **died**: ensure this is documented on the Follow Up CRF and complete a Notification of Death CRF on the database.

- If you are aware of a death prior to the follow up time point, complete a Notification of Death CRF on the database and highlight this on the next relevant follow up CRF.

- Please review your Query manager frequently as the WCTU trial management with be reviewing:
    - Incomplete CRF's
    - Overdue CRF's (beyond X+4 weeks)