

Guideline for obtaining 180-day follow-up

There are three outcomes to be obtained at follow-up 180 days after randomisation:

- Mortality
- Health-Related Quality of Life (HRQoL)
 - EQ-5D-5L index values
 - EQ VAS

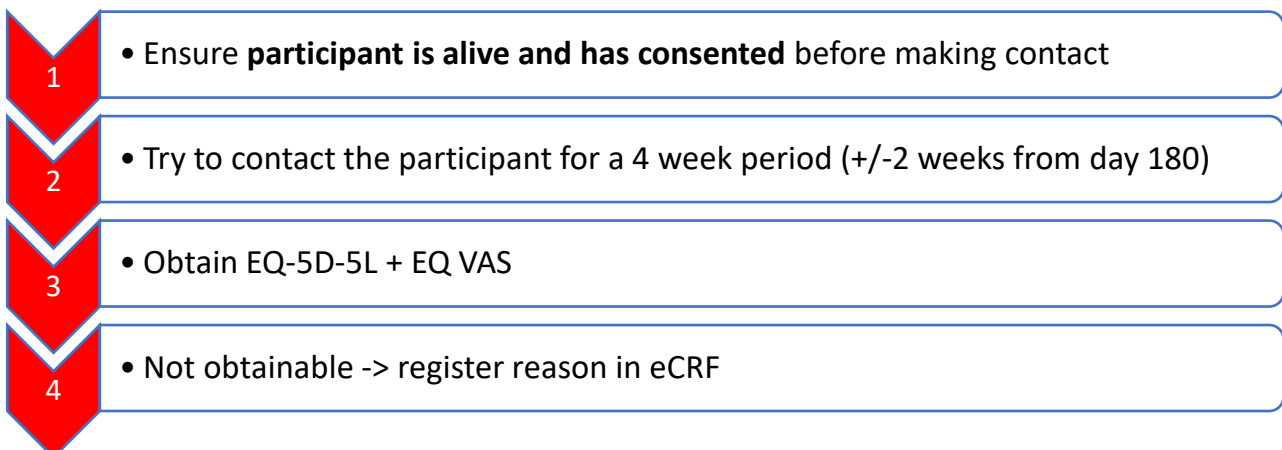
Retention strategies

- Follow-up data for **HRQoL should be collected as close to day 180 as possible** but may be collected within a 14-day period (in both directions). However, mortality is registered according to the status on exactly day 180 after randomisation.
- When obtaining participant consent, please assure that the participants are informed about the 180-day follow up and that we will ***contact them by telephone.***
- Similarly, inform the relatives about the half-year follow-up when obtaining their consent.
- If the participants cannot be reached at 180-day follow-up, aim to contact the participant daily for 2 weeks. It is also okay to use days beyond the 2 weeks, if it is realistic obtaining the follow-up – the most important thing is to get the answers.
- If the participant is assumed to be at work, then try to make contact during late afternoon.
- If the participant chooses to respond electronically, it should be via secure electronic post.
- If the participant chooses physical mail, the time for obtaining answers is extended by another 4 weeks, with a reminder 2 weeks after the letter has been posted. The date to be entered in the EasyRF is the date the questionnaire is fully completed.

We cannot contact any participants who rejected to be contacted or who withdrew with a demand of no further data registration.

Procedure at follow-up:

- The trial follow-up will be conducted by the site's trial staff using a procedure aiming at reducing risk of bias. This means that trial staff should not review the allocations before doing the follow-up.
- Staff should **not access participants' electronic health records** at 180-day follow-up, except to assess whether the patient is alive or not.
- Access EasyRF at 180 days follow-up using either of these log-in options:
 - If the **participant is dead** – use your standard access for EasyRF and register death as an event including the date of death. Then the follow-up forms will disappear and cannot be completed.
 - If the **participant is alive** – use your 180 days follow-up log-in for EasyRF
- Allocation should not be discussed with the participant (or their proxy) before the EQ-5D-5L + EQ VAS has been completed.
- **Please read the instructions** for the questionnaire beforehand, to obtain as objective answers as possible.
- It is important to register whether HRQoL is obtained by proxy.
- If by proxy it is important that the answer is given on behalf of what proxy believes the patient would have answered.



Follow-up data are entered directly into the EasyRF, which is the source data.

HRQoL is assessed with the EQ-5D-5L. It is a 5-item questionnaire together with 5 response levels for each item and a visual analogue scale (VAS) score (0-100); it takes 5 minutes to complete. We recommend conducting the interview by phone, but it is also possible to answer the questionnaire by physical mail. If the participant is too frail or cognitively impaired to consistently complete EQ-5D-5L, try to obtain the participant's HRQoL by proxy (a relative) *asking the proxy to respond from the participant's point of view*. There is specific questionnaire for proxies assessing the HRQoL from the participant's point of view.

Resources for each 180-day follow-up you conduct. The payment for conducting follow-up is outlined in the document 'Case money for participating in EMPRESS placed in the Site File #16.1.1.

Contact details: empress@cric.nu or phone +45 3545 0606.