TICH-3 – Working Practice Document

Entry of Missing Data
No. 009

Some questions on TICH-3 CRFs may provide "Not applicable", "Not done" and/or "Not known" options, which have been given the following definitions by the trial sponsor.

- **Not applicable** - should be used if a measure was not required for that participant
- **Not done** - should be used if data are unavailable, either because a measure was not taken or a test was not performed
- **Not known** - should be used if the data are unknown, and every effort has been made to find the data

For each question on a CRF, you should either enter a value in the central column(s) or use the drop-down lists in the right-hand column to indicate why the value is missing - but not both. A response must be given in this way for every numbered question on the CRF.

The "Not done" and "Not known" options relate to missing data. Some of these options may be hidden when a TICH-3 online CRF is first accessed, i.e. before any data have been submitted. This is because the options provided reflect the data we need to collect for proper analysis of the trial.

However, some required data may still be missing for legitimate reasons. For example, it may not be possible to measure a participant's weight in the emergency department.

In such cases, to access the hidden "Not done" and "Not known" options, please go to the bottom of the page and set the missing data control to "Yes". Enter a full explanation and submit the form.

After this, you can complete the CRF as usual and submit. Check through your answers and re-submit to store the data that you have entered.

Note that once the hidden options have been revealed, they will continue to be displayed even if you have no missing data (i.e. when none of the questions have "Not done" / "Not known" selected). If no data are missing, please set the control at the bottom of the page to "No" and re-submit. In this case no explanation is required so may be left blank, however relevant comments may always be entered.