



Work Instruction

Completing the Notes Review CRF

Thank you for your support for PRINCIPLE and for providing important data. The following information will help to guide you through the completion of the Case Report Form and will help to minimise any queries arising from the data provided.

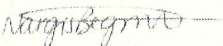
1. Completing CRFs:

- Blank spaces should not be left on the CRF. If data are unavailable 'Unknown', 'Missing' or 'Not Done' should be recorded. Ambiguous phrases such as 'not available' should be avoided.
- All entries should be accurate, legible and verifiable with source data (e.g. medical records) where appropriate.
- Where applicable, CRFs should be signed and dated by an authorised individual to confirm capture of correct data.
- Please ensure that the Participant ID is recorded on the CRF and referenced in all correspondence.

2. Corrections/Amendments:

Entries should never be over-written, nor correction fluid used. Corrections should be made as per the following procedure:

- The incorrect entry should be crossed through with a single line so the original text is still legible.
- Correct data should then be recorded next to the incorrect entry.
- Initials and date of change should be supplied beside the update.
- An explanation of the correction should be provided if it is not obvious why the change was made.

	NAME	TITLE	SIGNATURE	DATE
Author:	Julie Allen	Senior Trial Manager		13-Jan-2021
Reviewed by:	Nargis Begum	Trial Manager		18-Jan-2021


29 JUL 2021

Date originally approved 18-Jan-2021