

RECAST-3 – Working Practice Document

Title: Protocol Deviations and Violations, No. 008

Protocol Violation

A protocol violation is a major deviation from the trial protocol where a participant is enrolled in spite of not fulfilling all the inclusion and exclusion criteria, or where major deviations from the protocol could affect the trial delivery or interpretation significantly.

The following practice during the trial constitutes a protocol violation:

1. A participant is enrolled in spite of not fulfilling all the inclusion and exclusion criteria
2. Subsequent randomisation into another drug or devices trial unless this has prior agreement from both CIs and Sponsors
3. Patient does not receive randomised treatment
4. Failure to complete SAEs where appropriate
5. Failure to complete outcomes where appropriate
6. Follow-up assessments are performed (as opposed to submitted online) outside the specified time as shown below:
 - a. 2-day follow-up: >2 days past the due date
 - b. 4-day follow-up: >7 days past the due date
 - c. Discharge or death form: >30 days past the due date
 - d. 90-day follow up: >30 days past the due date

Protocol Deviation

A protocol deviation is a minor deviation from the protocol that affects the conduct of the trial in a minor way. This includes any deviation from the trial protocol that is not listed as a protocol violation. Examples of deviations are given below but this is not exhaustive.

1. Follow-up assessments are performed (as opposed to submitted online) outside the specified time as shown below:
 - a. 2-day follow-up: >1day past the due date
 - b. 4-day follow-up: >2days past the due date
 - c. Discharge or death form: >7days past the due date
 - d. 90-day follow-up: >7 days past the due date

Review of Protocol Violations and Deviations

Protocol violations and deviations should be reported by the participating site via the RECAST-3 database by completing the protocol violation CRF. They will be reviewed on a monthly basis by the Trial Management Committee.

Training

1. Protocol violation and deviation training will be incorporated into site investigator training
2. A triggered monitoring visit may occur to sites with a frequent number of violations or deviations