



Trial Discontinuation, Withdrawal & Completion



University
of Dundee



Discontinuation of trial medication

- If a participant has been randomised and given one or more dose of IMP, they will be asked to complete trial visits as per the protocol, to allow for an intention to treat analysis.
- Participants are free to refuse to do so.
- The Investigator may discontinue a participant's trial medication at any time, if it is in the best interest of the participant and continuing treatment would be detrimental to the participant's wellbeing.
- The Investigator will make a clinical judgment as to whether or not an adverse event (AE) is of sufficient severity to require discontinuation of trial medication.
- A participant may also voluntarily discontinue trial medication due to what they perceive as an intolerable AE.
- Participants will be asked to return their medication box/bottle at visit 5, to record trial medication accountability

Withdrawal from trial – stops all trial activity

- Participants are free to withdraw at any time and are not obliged to give reason(s).
- Make a reasonable effort to ascertain the reason(s), both for those who express their right to withdraw and for those lost to follow up, while fully respecting the individual's rights.
- If a participant withdraws and does not remain on the study, the Completion of Trial/Early Withdrawal form should be completed on the eCRF.

Completion of Trial

AIR-NET TEST ◦ Not Live (v.143.71)

In Progress

Visit 1 - Screening

In Progress

Visit 2 - Baseline and randomisation

Not Started

Visit 3

Not Started

Visit 4

Not Started

Visit 5

Not Started

Visit 6

Not Started

Completion of Trial/Early Withdrawal

Not Started

Completion of Trial/Early Withdrawal

Completion of Trial/Early Withdrawal
73. Completion of Trial/Early Withdrawal

73.1 Did the participant complete the trial?

73.2 Date of Completion/Withdrawal

(DD-MM-YYYY)

To be electronically verified by the PI once participant has completed the trial and all data entered

When the participant has Completed/Withdrawn, please check and follow up any unresolved AEs/SAEs. Also review Concomitant and Respiratory medications and enter End dates or mark as Ongoing (if applicable).