AIR-NET

Trial Discontinuation, Withdrawal & Completion

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