

Concomitant Medications







Review of concomitant medications

- Taken from medical records and participant reporting
- Reported concomitant medications must be recorded in medical records for source data verification

Visit 1

- Ask participants to bring their current prescription.
- Take a copy, clarify if participant is actively taking all their prescription drugs, and score through any on the list which they are not currently taking.
- File a copy of the prescription in the participant's medical notes for SDV.

All other visits

- Ask if there are any changes to medication since previous visit
- Record changes in medical notes and eCRF

Excluded Medications

Please ensure at all visits that the participant is not taking any excluded medicines.





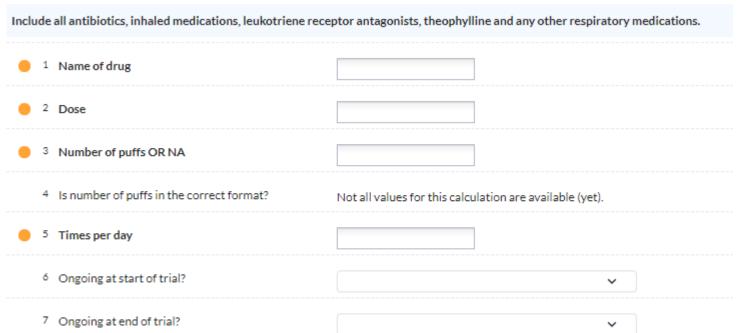


eCRF

There are 2 con med forms:

Respiratory & antibiotic con meds:

- all antibiotics, inhaled medications, leukotriene receptor antagonists, theophylline and any other respiratory medications
- **Brand name** no need to list combined medications separately



Other con meds: less information required, generic name - ingredients of combined medications should be listed separately e.g. for Co-codamol list separately as codeine, paracetamol.

Other (Concomitant Medication	
Instructions: Do not add antibiotics prescribed for pulmonary exacerbations, inhaled medication Medication		
1	Name of drug (generic)	
2	Ongoing at start of trial?	
3	Ongoing at end of trial?	







eCRF

- At Visit 1 all medications should be ticked as ongoing at start of trial.
- Any new medications started during the course of the trial should have a start date.
- Any medications stopped during the participation in the trial should have an end date.
- At the last visit all medications should have either an end date or ticked as "ongoing at end of trial".





