



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

Include all antibiotics, inhaled medications, leukotriene receptor antagonists, theophylline and any other respiratory medications.

1 Name of drug	<input type="text"/>
2 Dose	<input type="text"/>
3 Number of puffs OR NA	<input type="text"/>
4 Is number of puffs in the correct format?	Not all values for this calculation are available (yet).
5 Times per day	<input type="text"/>
6 Ongoing at start of trial?	<input type="text"/>
7 Ongoing at end of trial?	<input type="text"/>

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

1 Name of drug (generic)	<input type="text"/>
2 Ongoing at start of trial?	<input type="text"/>
3 Ongoing at end of trial?	<input type="text"/>



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”.

