



Value of inhaled treatment with
aztreonam lysine in bronchiectasis

Recording Concomitant Medications



Concomitant Medications

Visit 1

- Ask participants to bring their current prescription.
- Go through this with them and ensure it is accurate for what the participant is taking at the time of the visit, scoring off medications that the participant is not actively taking on a copy of the prescription.
- File a copy of the prescription in the medical notes for Source Data Verification (SDV)

All other visits

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

Excluded Medications (See exclusion criteria)

- Long-term inhaled or oral anti-pseudomonal antibiotics should not be newly initiated during the study.

Reported concomitant medications must be recorded in medical records for source data verification



eCRF

There are 2 ConMed forms

- Respiratory & antibiotic ConMeds: include 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" value="v"/>
7	Ongoing at end of trial?	<input type="text" value="v"/>

- Other ConMeds: less information required, **generic name** - ingredients of combined medications should be listed separately e.g. for Codydramol 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"/>

Review of Concomitant Medications cont. eCRF

- At visit 1 all medications should be ticked as ongoing at start of trial
- Any new medications added during the course of the trial should have a start date
- Any medications stopped 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