Recording 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.
- 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 SDV.

All other visits

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

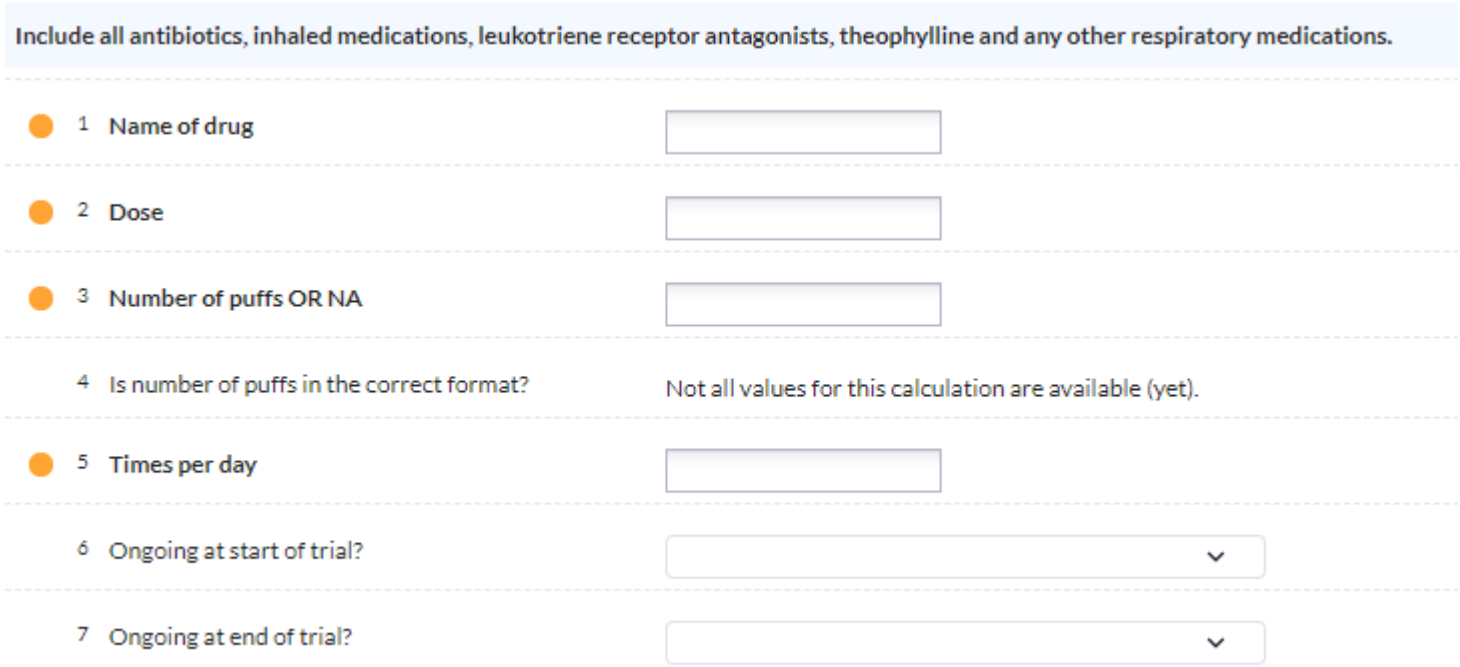
Excluded Medications

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

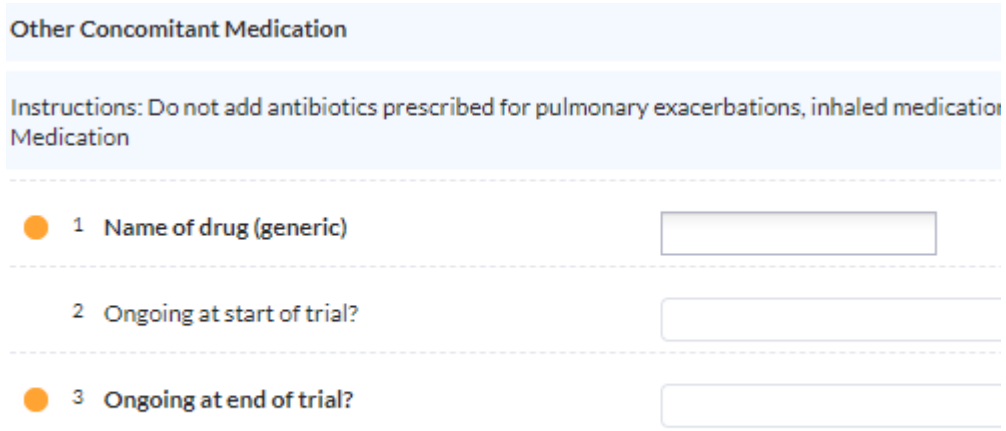
eCRF

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 Codydramol list separately as codeine, paracetamol.



eCRF

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

- Any medications stopped should have an end date
- At last visit all medications should have either an end date or ticked as ongoing at end of trial