

**T0 VISIT RESEARCHER AIDE-MEMOIRE**

**BEFORE THE VISIT**

- Ensure that you have seen the signed and countersigned consent form, CRF T-2, and prescription form
- Ensure that you have collected the trial drug in good time from your local pharmacy and that the subject number on the box matches that on the prescription and CRF T0.
- Ensure that you have a copy of the CRF T0 and have **completed sections 1 and 2 in advance.**
- Ensure that you have copies of the diary card and understand its use.
- Ensure that appropriate **language arrangements** are in place if English is not the parents' first language.

**DURING THE VISIT**

Diary Card

- Explain the use of the diary card
- Provide one diary card per course of medication (usually five per box)
- Explain diary card return procedure

Medication

- Check the parents' possession of and knowledge of the use of spacer and MDI (may be brief if already performed e.g. on ward/at T-2 visit)
- Give IMP to parents and explain when and how to use and return it

Communication

- Give advice and information regarding researcher contact (including email and phone contact numbers – in PIS).
- Explain what to do if there are concerns regarding drug reactions or trial participation (contact local healthcare provider if child acutely unwell, contact researcher otherwise).

T0 Trial Entry CRF

- Work systematically through CRF

**AFTER THE VISIT**

- Researcher completing to ensure their sign off is complete (*N.B.* researcher signing form must be delegated on the site delegation log to take consent/complete CRFs)
- Keep one copy of the CRF in the local site file, send one copy to the London Trial coordinator.
- Send a recruited/not recruited letter to the GP and put a copy of this and the consent form in the clinical notes if appropriate.