

T0 TRIAL ENTRY CRF – PART A

(Copy 1 – Trial Manager, Copy 2 – Local Site File)

Serial number: |_|_|_|_| Site: |_|_| (e.g. AB, LE, LO etc.) Subject Number (IMP): |_|_|_|_|

Patient Initials: |_|_| Researcher Initials: |_|_| Date of THIS Visit: |_|/|_|/|_|

1) CRF Documentation

Tick if you have seen the signed and countersigned:

- i) Consent Form
- ii) CRF T-2
- iii) Prescription Form

2) Samples

Tick if you have:

- i) Collected DNA sample
- ii) Collected urine sample
- iii) Explained the need for additional urine samples on attendance at ED

3) Diary Card

Tick if you have:

- i) Provided and labelled diary cards (x5)
- ii) Explained their usage
- iii) Explained procedure for return

4) Medication

Tick if you or soemone else have (on this or a prior visit)

- i) Checked salbutamol MDI and spacer availability
- ii) Checked MDI/spacer technique
- iii) Checked understanding of appropriate salbutamol usage
- iv) Checked IMP number matches number written by pharmacy on prescription
- v) Provided and explained use of IMP
- vi) Explained procedure for return of IMP
- vii) Explained procedure for replacement of IMP

5) Communication

Tick if you have:

- i) Provided local contact number and email
- ii) Explained indications for contact (solely trial-related and **including suspected drug reactions**, contact local NHS for acute health advice).
- iii) Provided pre-addressed jiffy bag for return of IMP/empty salbutamol canisters/diary cards

Researcher Signature: _____ Print Name: _____ Date: |_|_|/|_|/|_|

I have reviewed all data in this CRF and verify that the contents are consistent with observations and source records.

PI Signature: _____ Print Name: _____ Date: |_|_|/|_|/|_|