OSAC (Oral Steroids for Acute Cough) Trial CASE REPORT FORM	**Section 1 (YELLOW CRF):** Face-to-Face Patient Eligibility Check **To be completed for:** all patients willing to be screened for eligibility to participate in the OSAC trial **(NB: all questions to be completed)** **To be completed by:** Responsible Clinician **(NB: on paper or online)**

Today's Date:

D	D	M	M	Y	Y	Y	Y

Patient ID Number:

[affix PID label]

OSAC Site ID:

OSAC Screening ID:

[affix SID label]

OSAC Clinician ID:

PLEASE TICK (√) THE APPROPRIATE BOXES AND COMPLETE SECTION 1 IN FULL

Is the patient willing to be screened for eligibility to participate in the OSAC trial, and for data to be stored anonymously if they are not eligible? □ Yes □ No

1.1 INCLUSION CRITERIA

Please exclude the patient if the answer is 'NO' to any of the following (apart from question 3, for which only one screening symptom is necessary for eligibility):

1. Aged 18 years or over □ Yes □ No
2. Consulting for an acute (≤ 28 days) cough as the main presenting symptom □ Yes □ No
3. In the past 24 hours, the patient has had **at least one** of the symptoms listed below (a-d), localizing to the lower respiratory tract and suggestive of an acute respiratory tract infection (RTI):
   - **a.** Phlegm (sputum) □ Yes □ No
   - **b.** Chest pain □ Yes □ No
   - **c.** Shortness of breath □ Yes □ No
   - **d.** Wheeze □ Yes □ No
4. Patient and practice have sufficient time for consent and randomisation into the trial by the end of today? □ Yes □ No
5. Patient able and willing to give informed consent? □ Yes □ No
6. Patient able and willing to complete the daily symptom diary? □ Yes □ No
7. Patient able, willing **and available,** to receive weekly follow-up telephone calls from the trial team? □ Yes □ No

1.2 EXCLUSION CRITERIA

Please exclude the patient if the answer is 'YES' to any of the following:

1. Known lung cancer or chronic lung disease (e.g. COPD, bronchiectasis or cystic fibrosis)? □ Yes □ No
2. Has an 'active' diagnosis of asthma ('active' meaning has received any asthma medication in the past 5 years) □ Yes □ No
3. Does the patient's RTI warrant same day hospital admission or immediate antibiotics? **(NB: use of delayed prescription does not preclude OSAC trial participation)** □ Yes □ No
   If yes, please choose the appropriate options (A-C) below and tick all relevant boxes:

   According to NICE guidelines, the patient warrants immediate antibiotic treatment by virtue of ONE OR MORE of the following:

   A. Is clinically very unwell or has symptoms and signs suggestive of pneumonia, *e.g. tachypnoea (>20bpm), unilateral chest signs or consolidation, or hypoxia (oxygen saturation <94%);* or other systemic infection, *e.g. suspected bacteraemia* □

   B. Is at high risk of complications, including patients with chronic heart, chronic lung (e.g. COPD, bronchiectasis or CF), chronic renal, chronic liver or neuromuscular disease or immunosuppression; or with complications from previous episodes of lower respiratory tract infection e.g. hospital admission for pneumonia □

   C. AGED OVER 65 years with at least **TWO** of the following criteria, or AGED OVER 80 years with at least **ONE** of the following criteria: □
      i. Unplanned hospitalisation within the previous year;
      ii. Type 1 or Type 2 diabetes;
      iii. History of cardiac failure
4. Requires an antibiotic today to treat another infection unrelated to their acute cough, e.g. a co-existing cellulitis □ Yes □ No
5. Recently (≤1 month) used inhaled corticosteroids □ Yes □ No
6. Recently (≤1 month) used short (≤2 weeks) course systemic corticosteroids □ Yes □ No

7. Currently using, or has previously (≤12 months) used, systemic steroids for a cumulative period >2 weeks, i.e. "long-term" use ☐ Yes ☐ No
8. Known to be pregnant, is trying to conceive or is at risk of pregnancy (e.g. unwilling to take a reliable form of contraception) in the next month? ☐ Yes ☐ No
9. Currently breast-feeding? ☐ Yes ☐ No
10. This is not the patient's usual practice, i.e. patient is visiting or is not intending to stay with the practice for the 3 month trial follow up period ☐ Yes ☐ No
11. Previously entered in the OSAC trial ☐ Yes ☐ No
12. Has been involved in another medicinal trial within the **last 90** days or any other clinical research study within the **last 30** days? ☐ Yes ☐ No
13. Is unable to give informed consent or complete the trial paperwork (including the symptom diary) through mental incapacity, e.g. major current psychiatric illness, learning difficulties and dementia ☐ Yes ☐ No
14. Known immune-deficiency (e.g. chemotherapy causing immunosuppression, asplenia or splenic dysfunction, advanced cancer or HIV infection) ☐ Yes ☐ No
15. **(For winter 2014/2015 only)** patient is aged **78 or 79** and due to receive the shingles vaccine in conjunction with the influenza vaccine ☐ Yes ☐ No
16. Has **any** of the following (A – P) known contra-indications or cautions to oral steroids ☐ Yes ☐ No

Current OR previous history of:

A. Peptic ulcer disease	E. Osteoporosis
B. Previous TB	F. Glaucoma
C. NO previous chickenpox AND known recent (≤28 days) history of close personal contact with chickenpox OR herpes zoster	G. Suspected ocular herpes simplex
	H. Cushing's disease
	I. Epilepsy
D. Known allergy to prednisolone or other OSAC trial tablet ingredients (potato starch, lactose monohydrate, colloidal silicon dioxide, sodium starch glycolate, magnesium stearate), galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption	J. Severe affective disorders, e.g. manic depression, previous steroid psychosis
	K. Previous steroid myopathy
	L. Intention to use a live vaccine in the next 8 weeks OR has received a live vaccine in the previous 2 weeks (NB: assess live vaccine status by checking with BNF)

Current history only:

M. Uncontrolled diabetes (HbA1C > 8%)	O. Taking other interacting medication, e.g. phenytoin and anti-coagulants (NB: check patient's medications for interactions as specified below "FOR ALL PATIENTS")
N. Uncontrolled hypertension (NB: as per Responsible Clinician's routine clinical judgement)	P. ANY OTHER BNF listed contra-indication or caution (NB: as per Responsible Clinician's routine clinical judgement)

FOR ALL PATIENTS: please check the British National Formulary (BNF) and use the patient's electronic medical record to check for medicine interactions, by prescribing prednisolone (quantity = "*0* as per OSAC trial")

17. Were any significant interactions with the patient's existing medication identified? ☐ Yes ☐ No
18. Is unable to swallow tablets ☐ Yes ☐ No

Paperwork Management

- **If the patient <u>is eligible</u> for OSAC trial entry, return the completed Section 1 form to recruitment folder Part 3 and continue to Section 2. Enter Section 1 on the OSAC clinical database WITHIN 24 HOURS.**
- **If the patient <u>is not</u> <u>eligible</u> for trial entry, please <u>do not</u> proceed with recruitment, update the clinical database WITHIN 24 HOURS and file Section 1 in the OSAC Site File.**
- **If the patient DOES NOT WISH TO CONTINUE with trial participation AND CONSENTS TO USE OF DATA COLLECTED THUS FAR, update the OSAC clinical database WITHIN 24 HOURS and place Section 1 in the OSAC Site File.**
- **If the patient WITHDRAWS VERBAL CONSENT TO USE DATA COLLECTED THUS FAR, please note on the Screening Log and shred Section 1 at Recruitment Site.**
- **Please complete the Screening Log for ALL patients approached for trial participation.**