OSAC (Oral Steroids for Acute Cough) Trial Patient Primary Care Notes Review Form
SECTION A: PATIENT IDENTIFICATION AND TRIAL PARTICIPATION DETAILS

1. Site ID: | | | | | **2. Patient Trial ID:** | | | | | | |

3. Entry Date: ____/____/_____ **4. Date of Birth:** ____/____/_____

5. NHS Number | | | | | | | | | | |

6. Do all of the five pre-completed fields above match information in the notes exactly? Yes ☐ No ☐

If no, please note any difference below and CONTACT THE OSAC TRIAL TEAM before continuing to complete this form.

7. 28-day Follow-up End Date: ____/____/_____

8. 3-month Follow-up End Date: ____/____/_____

9. Earliest Date for Review to be completed: ____/____/_____
(4 months after trial entry)

10. Reviewer's Name: _____
(please print)

11. Review Date: ____/____/_____

OSAC TRIAL TEAM:
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SECTION B: PRIMARY CARE NOTES REVIEW DETAILS

1.a) Are notes available for review? Yes ☐ No ☐

b) **If yes,** which types of notes are you reviewing? Paper ☐ Electronic ☐ Both ☐

c) **If no,** please describe reason notes not available:

2.a) Is the patient still with the practice? Yes ☐ No ☐

b) **If no,** date they left the practice? ____/____/_____

3.a) Has the patient died? Yes ☐ No ☐

b) **If yes,** date of death? ____/____/_____

c) Has the death been reported to the trial team? Yes ☐ No ☐

If the death has **NOT** been reported to the trial team as a Serious Adverse Event and occurred within (28 days of study recruitment, this must be done immediately (see OSAC Trial SAE Reporting Form and Procedure in the trial site file).

d) Cause of death (include ICD10 code **if known**): ICD10 Code

SECTION C: ONGOING HEALTH PROBLEMS IN THE 12 MONTH PERIOD PRIOR TO TRIAL ENTRY

From: ____/____/_____ **to:** ____/____/_____

Please record any ongoing health problems that are noted in the patient's primary care record in the 12 month period prior to trial entry.

☐ **If there were no ongoing health problems during this period, please tick this box and proceed to Section D**

1.a) Are any ongoing (chronic) health problems recorded for this period?

Yes ☐ No ☐

b) If yes, please state main conditions (tick **all** that apply):

Diabetes ☐ 1 High blood pressure ☐ 2 Anxiety / depression ☐ 3

Previous stroke/ CVA/TIA ☐ 4 Other (tick box and enter details): ☐ 5

SECTION D: PRIMARY CARE CONSULTATIONS FOR CHEST INFECTIONS, ACUTE BRONCHITIS, PNEUMONIA AND OTHER RESPIRATORY TRACT INFECTIONS (RTIs) IN THE 12 MONTHS PRIOR TO TRIAL ENTRY

From: ____/____/_____ **to:** ____/____/_____

Please enter the total number of consultations for all RTIs in the 12 month period prior to trial entry. Include GP, Nurse Practitioner and Out of Hours face-to-face consultations (no need to record telephone consultations).

☐ **If there were no relevant consultations during this period, please tick this box and proceed to Section E**

NB: Please look for evidence in consultations for these signs/symptoms/diagnoses being recorded. If **any** evidence of **LRTI terms** used when diagnosed as an **URTI,** record that consultation as an **LRTI** and **NOT** an **URTI**, e.g. if "sputum" is noted with "common cold", record as **LRTI.**

	Specific reasons for RTI consultation (signs/symptoms/diagnoses)	**Number of consultations**
1.	**Upper Respiratory Tract Infection (URTI):** including influenza; viral illness; sinusitis – sinus pain/tenderness/face pain; nasal congestion/runny nose/blocked nose/rhinorrhea/coryza/common cold; tonsillitis/pharyngitis/quinsy/throat abscess/peritonsillar cellulitis; cough unspecified/dry cough; sore throat/difficult or painful swallowing/inflamed pharynx or tonsils; ear ache/pain/otalgia/difficulty hearing/ear discharge/red ear; acute otitis media/ear infection.	
2.	**Lower Respiratory Tract Infection (LRTI):** including chest infection; acute bronchitis; pneumonia; exacerbation of asthma; viral wheeze; tracheitis; productive cough/sputum/phlegm; chesty cough with breathing difficulties, e.g. dyspnoea, short of breath, breathing faster than normal, wheeze, whistling in chest, crackles, crepitations, ronchi, rales, bronchial breathing, pleural rub, intercostal/subcostal recession; low oxygen saturation/low O_2 sats.	

SECTION E: UNPLANNED HOSPITAL ADMISSIONS RELEVANT TO RTI IN THE 12 MONTHS PRIOR TO TRIAL ENTRY

From: **____/____/_____ to: ____/____/_____**

Please enter any unplanned hospital admissions for RTI in the 12 month period prior to trial entry.

☐ **If there were no unplanned hospital admissions during this period, please tick this box and proceed to Section F**

1. a) Admission date: ___/___/_____ b) Discharge date: ___/___/_____

   c) Discharge diagnosis: d) ICD10 code **(if known):** | | | | |

2. a) Admission date: ___/___/_____ b) Discharge date: ___/___/_____

   c) Discharge diagnosis: d) ICD10 code **(if known):** | | | | |

3. a) Admission date: ___/___/_____ b) Discharge date: ___/___/_____

   c) Discharge diagnosis: d) ICD10 code **(if known):**

4. a) Admission date: ___/___/_____ b) Discharge date: ___/___/_____

   c) Discharge diagnosis: d) ICD10 code **(if known):** | | | | |

SECTION F: PRESCRIPTIONS ISSUED FOR ANTIBIOTICS IN THE 28 DAYS PRIOR TO TRIAL ENTRY

From: **____/____/_____ to: ____/____/_____**

Please give details of **all** prescriptions for antibiotics* issued to this patient by a primary care clinician, **both in- and out-of-hours**, in the 28 days prior to trial entry. *NB: **see Appendix 1 for list of antibiotics.**

☐ **If no antibiotic prescriptions were issued during this period, please tick box and proceed to Section G**

1. a) Date issued: ___/___/_____

   b) Antibiotic:

   c) Duration of course (days): ☐☐

2. a) Date issued: ___/___/_____

   b) Antibiotic:

   c) Duration of course (days): ☐☐

3. a) Date issued: ___/___/_____

   b) Antibiotic:

   c) Duration of course (days): ☐☐

4. a) Date issued: ___/___/_____

   b) Antibiotic:

   c) Duration of course (days): ☐☐

5. a) Date issued: ___/___/_____

   b) Antibiotic:

   c) Duration of course (days): ☐☐

SECTION G: PRIMARY CARE CONSULTATIONS AND MANAGEMENT DETAILS, RELATING TO RTI, IN THE 28 DAYS FOLLOWING TRIAL ENTRY

From: **____/____/_____ to: ____/____/_____**

Please give details of every face-to-face appointment with a doctor or nurse in the 28 days following trial entry, using the list of symptoms and diagnoses below to identify the relevant consultations, i.e. related to, or possibly related to RTI.

1. Please use this list to identify the relevant consultations entered for Question 2 (see next page).

Signs, Symptoms and Diagnoses
Upper respiratory tract infection (URTI)
Viral illness
Chest infection / bronchitis / lower respiratory tract infection (LRTI
Pneumonia
Exacerbation of asthma
Viral wheeze
Otitis media / ear infection
Sinusitis
Tonsillitis / pharyngitis / quinsy / throat abscess / peritonsillar cellulitis
Tracheitis
Cough (unspecified as to dry or productive)
Dry cough
Productive cough / sputum
Runny nose / blocked nose / rhinorrhoea / coryza / nasal congestion/common cold
Sinus pain / tenderness / face pain
Dyspnoea / short of breath / breathing faster than normal
Intercostal recession / subcostal recession
Wheeze / whistling in chest
Crackles / crepitations / ronchi / rales / bronchial breathing / pleural rub
Sore throat / difficult or painful swallowing / inflamed pharynx or tonsils
Ear ache / ear pain / otalgia / difficulty hearing / ear discharge / red ear
Low oxygen saturation / low O_2 sats

SECTION G: PRIMARY CARE CONSULTATIONS AND MANAGEMENT DETAILS, RELATING TO RTI, IN THE 28 DAYS FOLLOWING TRIAL ENTRY

2.**a)** Using the list of symptoms, signs and diagnoses on the previous page, have there been any primary care consultations in the 28 days following OSAC trial entry? (tick **one** box)

Yes ☐ 1 Unsure ☐ 2 No ☐ 3 → **If no, please go to Section H**

If unsure, enter reason(s) for consultation

b) **If yes or unsure**, please enter details below:

Consultation 1

i) Date: ___/___/_____

ii) Provider (tick **one**): GP practice ☐ 1 Out-of hours ☐ 2 Walk-in centre ☐ 3

iii) Type (tick **one**): Face to face ☐ 1 Telephone ☐ 2 Home visit ☐ 3
DNA ☐ 4 Unclear in notes ☐ 5

iv) Seen by (tick **all** that apply): GP ☐ 1 Nurse practitioner ☐ 2 Practice nurse ☐ 3
District nurse ☐ 4 Other (tick box and specify): ☐ 5

v) Is this consultation for the same illness for which the patient was recruited to the OSAC Trial? (tick **one** box)

Yes, there is recorded evidence of same symptoms/illness as the recruitment consultation, e.g. "cough" ☐ 1

No, there is recorded evidence of a different illness, e.g. "new illness or "recovered from cough…" ☐ 2

Not clear, there is no statement of whether same or different illness ☐ 3

vi) Are any symptoms or the health state of the patient mentioned? (tick **one** box)

Yes, and documentation that symptoms are getting worse ☐ 1

Yes, and documentation that the symptoms are the same/no better ☐ 2

Yes, and documentation that the symptoms are getting better ☐ 3

No symptoms or health state mentioned ☐ 4

(vii) Comments (e.g. anything unclear):

SECTION G: PRIMARY CARE CONSULTATIONS AND MANAGEMENT DETAILS, RELATING TO RTI, IN THE 28 DAYS FOLLOWING TRIAL ENTRY

Consultation 2

i) Date: ___/___/_____

ii) Provider (tick **one**): GP practice ☐ 1 Out-of hours ☐ 2 Walk-in centre ☐ 3

iii) Type (tick **one**): Face to face ☐ 1 Telephone ☐ 2 Home visit ☐ 3
DNA ☐ 4 Unclear in notes ☐ 5

iv) Seen by (tick **all** that apply): GP ☐ 1 Nurse practitioner ☐ 2 Practice nurse ☐
District nurse ☐ 4 Other (tick box and specify): ☐ 5 ☐

v) Is this consultation for the same illness for which the patient was recruited to the OSAC Trial? (tick **one** box)

Yes, there is recorded evidence of same symptoms/illness as the recruitment consultation, e.g. "cough" ☐ 1

No, there is recorded evidence of a different illness, e.g. "new illness or "recovered from cough…" ☐ 2

Not clear, there is no statement of whether same or different illness ☐ 3

vi) Are any symptoms or the health state of the patient mentioned? (tick **one** box)

Yes, and documentation that symptoms are getting worse ☐ 1

Yes, and documentation that the symptoms are the same/no better ☐ 2

Yes, and documentation that the symptoms are getting better ☐ 3

No symptoms or health state mentioned ☐ 4

vii) Comments (e.g. anything unclear):

☐

PLEASE USE CONTINUATION SHEET/S IF >2 RTI RELATED CONSULTATIONS

SECTION H: VISITS TO ACCIDENT AND EMERGENCY, RELATING TO RTI, IN THE 28 DAYS FOLLOWING TRIAL ENTRY

From: ____/____/_____ **to:** ____/____/_____

Please enter any visits to A&E, relating to RTI, in the 28 days after trial entry. **NB: any overnight visits to A&E must be reported as an SAE**

☐ **If there were no relevant A&E visits during this period, please tick this box and proceed to Section I**

a) **Visit 1 Date**: ___/___/_____

b) **Main** reason for visit? (enter details in box):

ICD10 code **(if known)**:

c) Was the patient admitted? (tick **one** box)

Yes ☐ 1 No ☐ 2 Don't know ☐ 3

d) Name of hospital in which A&E department located (include Trust):

a**) Visit 2 Date**: ___/___/_____

b) **Main** reason for visit? (enter details in box):

ICD10 code **(if known)**:

c) Was the patient admitted? (tick **one** box)

Yes ☐ 1 No ☐ 2 Don't know ☐ 3

d) Name of hospital in which A&E department located (include Trust):

a) **Visit 3 Date**: ___/___/_____

b) **Main** reason for visit? (enter details in box):

ICD10 code **(if known):**

c) Was the patient admitted? (tick **one** box)

Yes ☐ 1 No ☐ 2 Don't know ☐ 3

d) Name of hospital in which A&E department located (include Trust):

PLEASE USE CONTINUATION SHEET/S IF >3 RTI RELATED A&E VISITS

SECTION I: EMERGENCY HOSPITAL ADMISSIONS RELATING TO RTI IN THE 28 DAYS FOLLOWING TRIAL ENTRY

From: ____/____/_____ **to:** ____/____/_____

Please enter details of any RTI related hospital admissions. **NB: any overnight admissions (not day cases) to hospital must be reported as an SAE**

☐ **If there were no relevant admissions during this period, please tick this box and proceed to Section J**

Admission 1

a) Admission date: ___/___/_____ b) Discharge date: ___/___/_____

c) Hospital (include Trust):

d) Discharge diagnosis:

e) ICD10 code **(if known)**:

Admission 2

a) Admission date: ___/___/_____ b) Discharge date: ___/___/_____

c) Hospital (include Trust):

d) Discharge diagnosis:

e) ICD10 code **(if known)**:

Admission 3

a) Admission date: ___/___/_____ b) Discharge date: ___/___/_____

c) Hospital (include Trust):

d) Discharge diagnosis:

e) ICD10 code **(if known)**:

PLEASE USE CONTINUATION SHEET/S IF >3 RTI RELATED HOSPITAL ADMISSIONS

SECTION J: INVESTIGATIONS RELATING TO RTI IN THE 28 DAYS FOLLOWING TRIAL ENTRY

From: **____/____/_____ to: ____/____/_____**

Please enter details of any chest x-rays or CT scan investigations, relating to RTI, in the 28 days after trial entry.

☐ **If there were no relevant investigations, please tick this box and proceed to Section K**

1. a) Date of investigation: ___/___/_____

   b) What was the investigation? (tick **all** that apply)

   CXR ☐ → **Go to c) below**

   CT scan chest ☐ → **Go to e) below**

   c) **If CXR**, on what date? **____/____/_____**

   d) CXR result (enter **exact** wording):

   e) **If CT scan chest**, on what date? **____/____/_____**

   f) CT scan result (enter **exact** wording):

2. a) Date of investigation: ___/___/_____

   b) What was the investigation? (tick **all** that apply)

   CXR ☐ → **Go to c) below**

   CT scan chest ☐ → **Go to e) below**

   c) **If CXR**, on what date? **____/____/_____**

   d) CXR result (enter **exact** wording):

   e) **If CT scan chest**, on what date? **____/____/_____**

   f) CT scan result (enter **exact** wording):

PLEASE USE CONTINUATION SHEET/S IF >2 RTI RELATED INVESTIGATIONS

SECTION K: OTHER OUTPATIENT ATTENDANCES RELATING TO RTI IN THE 28 DAYS FOLLOWING TRIAL ENTRY

From: **____/____/_____ to: ____/____/_____**

Please enter details of any outpatient attendances, relating to RTI, in the 28 days after trial entry.

☐ **If there were no relevant outpatient attendances, please tick this box and proceed to Section L**

1. a) Date of consultation: ___/___/_____

   b) Was the patient referred for Outpatient attendance? (tick **one** box))

   Yes ☐ 1 No ☐ 2 Don't know ☐ 3

   c) **If yes**, which speciality?

   d) Hospital:

2. a) Date of consultation: ___/___/_____

   b) Was the patient referred for Outpatient attendance? (tick **one** box))

   Yes ☐ 1 No ☐ 2 Don't know ☐ 3

   c) **If yes**, which speciality?

   d) Hospital:

3. a) Date of consultation: ___/___/_____

   b) Was the patient referred for Outpatient attendance? (tick **one** box))

   Yes ☐ 1 No ☐ 2 Don't know ☐ 3

   c) **If yes**, which speciality?

   d) Hospital:

PLEASE USE CONTINUATION SHEET/S IF >3 RTI RELATED OUTPATIENT ATTENDANCES

SECTION L: ALL PRESCRIPTIONS ISSUED IN THE 28 DAYS FOLLOWING TRIAL ENTRY

From: **____/____/_____ to: ____/____/_____**

Please give details of all prescriptions that were issued to this patient by a primary care clinician, both within hours and out-of-hours, within the 28 day period. Please include **all acute (one-off)** and **only repeat respiratory medication (see Appendices 2, 3 and 4, page 17)** prescriptions.

☐ **If no prescriptions were issued during this period, please tick box and proceed to Section M**

Medication 1

a) Date issued: ___/___/_____

b) Name of medication:

c) Drug type (tick **one** box):

Tablet ☐ Capsule ☐ Inhaler ☐ Liquid ☐

Other, ☐
please specify:

d) Unit dose (enter amount and tick **one** box): mg ☐ ug/mcg ☐ g ☐ ml ☐

e) Quantity dispensed:

Medication 2

a) Date issued: ___/___/_____

b) Name of medication:

c) Drug type (tick **one** box):

Tablet ☐ Capsule ☐ Inhaler ☐ Liquid ☐

Other, ☐
please specify:

d) Unit dose (enter amount and tick **one** box): mg ☐ ug/mcg ☐ g ☐ ml ☐

e) Quantity dispensed:

SECTION L: ALL PRESCRIPTIONS ISSUED IN THE 28 DAYS FOLLOWING TRIAL ENTRY

Medication 3

a) Date issued: ___/___/_____

b) Name of medication:

c) Drug type (tick **one** box):

Tablet ☐ Capsule ☐ Inhaler ☐ Liquid ☐

Other, ☐
please specify:

d) Unit dose (enter amount and tick **one** box): mg ☐ ug/mcg ☐ g ☐ ml ☐

e) Quantity dispensed:

Medication 4

a) Date issued: ___/___/_____

b) Name of medication:

c) Drug type (tick **one** box):

Tablet ☐ Capsule ☐ Inhaler ☐ Liquid ☐

Other, ☐
please specify:

d) Unit dose (enter amount and tick **one** box): mg ☐ ug/mcg ☐ g ☐ ml ☐

e) Quantity dispensed:

PLEASE USE CONTINUATION SHEET/S IF >4 MEDICATION PRESCRIPTIONS ISSUED

SECTION M: CLINICAL DIAGNOSES OF ASTHMA, COPD, WHOOPING COUGH OR LUNG CANCER IN THE 3 MONTHS FOLLOWING TRIAL ENTRY

From: **____/____/_____ to: ____/____/_____**

Please enter any new clinical diagnoses of asthma, COPD, whooping cough (pertussis) or lung cancer in the 3 months following trial entry. **Enter each separate diagnosis, even if different diagnoses were made on the same date.**

☐ **If there were no relevant diagnoses during this period, please tick this box**

1. a) Was asthma diagnosed? (tick **one** box)

   Yes ☐ 1 No ☐ 2

   b) **If yes,** date of diagnosis: ___/___/_____

   c) Did the patient have spirometry? (tick **one** box)

   Yes ☐ 1 No ☐ 2 Don't know ☐ 3

2. a) Was COPD diagnosed? (please tick **one** box)

   Yes ☐ 1 No ☐ 2

   b) **If yes,** date of diagnosis: ___/___/_____

   c) Did the patient have spirometry? (tick **one** box)

   Yes ☐ 1 No ☐ 2 Don't know ☐ 3

3. a) Was whooping cough (pertussis) diagnosed? (tick **one** box)

   Yes ☐ 1 No ☐ 2

   b) **If yes,** date of diagnosis: ___/___/_____

   c) How was the diagnosis made? (tick **one** box)

   Clinical grounds ☐ 1 Serology ☐ 2 Peri-nasal swab ☐ 3 Unclear ☐ 4

4. a) Was lung cancer diagnosed? (tick **one** box)

   Yes ☐ 1 No ☐ 2

   b) **If yes,** date of diagnosis: ___/___/_____

APPENDICES

Appendix 1: Antibiotics

Amikacin	Erymax	Orelox
Amikin	Erythrocin	Oxytetracycline
Amoxicillin	Erythromycin	Penbritin
Amoxil	Erythromycin	Penicillin V
Ampicillin	ethylsuccinate	Phenoxy
Augmentin	Erythromycin	methylpenicillin
Avelox	lactobionate	Piperacillin with
Azactam	Erythroped	Tazobactam
Azithromycin	Erythroped A	Primaxin
Bramitob	Ethambutol	Pyrazinamide
Capreomycin	Fasigyn	Rifater
Cefaclor	Flagyl	Rifampicin
Cefadroxil	Flagyl S	Rifinah
Cefalexin	Floxapen	Rimactane
Cefotaxime	Fortum	Rocephin
Cefradine	Fucidin	Selexid
Ceftazidime	Furadantin	Septrin
Ceftriaxone	Fusidic Acid	Sodium fusidate
Cefuroxime	Gentamicin	Streptomycin
Ceporex	Genticin	sulphate
Chloramphenicol	Hiprex	Sulfadiazine
Cidomycin	Invanz	Suprax
Ciprofloxacin	Isoniazid	Targocid
Ciproxin	Kefadim	Tarivid
Clarithromycin	Keflex	Tavanic
Clindamycin	Kemicetine	Tazocin
Clofazimine	Ketex	Tetracycline
Co-amoxiclav	Klaricid	Tetralysal-300
Co-fluampicil	Klaricid XL	Timentin
Colistin	Macrobid	Tobi
Co-trimoxazole	Macrodantin	Tobramycin
Crystapen	Magnapen	Trimethoprim
Cubicin	Meronem	Tygacil
Cycloserine	Metrolyl	Utinor
Dalacin	Metronidiazole	Vancocin
Dapsone	Minocycline	Vancomycin
Distaclor	Mycobutin	Vibramycin-D
Distaclor MR	Neomycin	Zinacef
Doribax	Nitrofurantoin	Zinnat
Doxycycline	Norfloxacin	Zithromax
Efracea	Ofloxacin	Zyvox

Appendix 2: Inhaled bronchodilators and steroids

Inhaled bronchodilators	**Inhaled bronchodilators and steroids (COMBINED)**	**Inhaled steroids**
Airomir	Fostair	Alvesco
Albuterol	Seretide	Asmabec Clickhaler
Asmasal Clickhaler	Seretide Accuhaler	Asmanex Twisthaler
Atimos Modulite	Seretide Evohaler	Avamys
Atrovent	Symbicort Turbohaler	Beclometasone
Bricanyl Respules		Beclometasone
Bricanyl Turbohaler		dipropionate
Combivent		Becodisks
Easyhaler Salbutamol		Beconase
Eformoterol fumarate		Budelin Novolizer
Foradil		Ciclesonide
Formoterol		Clenil Modulite
Formoterol Easyhaler		Easyhaler Beclometasone
Formoterol fumarate		Easyhaler Budesonide
Ipratropium bromide		Flixonase
Ipratropium Steri-Neb		Flixonase Nasule
Oxis Turbohaler		Flixotide
Pulvinal Salbutamol		Flixotide Accuhaler
Respontin		Filxotide Evohaler
Salamol		Flixotide Nebules
Salamol Easi-Breathe		Fluticasone furoate
Salamol Steri-Neb		Fluticasone propionate
Salbulin Novolizer		Mometasone furoate
Salbutamol		Nasobec Aqueous
Salmeterol		Nasofan
Serevent		Nasonex
Serevent Accuhaler		Pulmicort
Serevent Diskhaler		Pulmicort Respules
Serevent Evohaler		Pulmicort Turbohaler
Spiriva		Pulvinal Beclometasone
Spiriva Handihaler		dipropionate
Spiriva Respimat		Qvar
Terbutaline sulphate		Qvar Autohaler
Tiotropium		Qvar Easi-Breathe
Ventolin Accuhaler		Rhinocort Aqua
Ventolin Evohaler		

Appendix 3: Oral corticosteroids

Betamethasone	Deflazacort
Betnelan	Dexamethasone
Betnesol	Hydrocortisone
Calcort	Lodotra
Cortisone	Medrone
Cortisone acetate	Methylprednisolone
	Prednisone

Appendix 4: Other respiratory medicines

Accolate		
Intal Inhaler		
Montelukast		
Nedocromil sodium		
Singulair		
Tilade Inhaler		
Zafirlukast		
Sodium cromoglicate		