

OSAC TRIAL DOCUMENTS: FEBRUARY 2014

Key: Rows highlighted in green refer to documents currently undergoing amendments. Updated versions will be provided to all trial centres and GP practices (as applicable) as soon as the new versions are finalised or approved. Rows highlighted in yellow represent drafts in progress.

Document	Current version #	Version date	Approvals required	Date of current approval	Will there be local (centre) versions?	On website	Website version updated
Protocol	1.5	22 Jan 2014	Ethics	24 Jan 2014 (minor amendment, notified to REC)	No	V1.5 (22 Jan 2014)	04 Feb 2014
Patient information							
Consent form	1.3 1.4	13 Dec 2012 04 Feb 2014	Ethics	5 Feb 2013 From 24 Feb 2014	No	No	/
Consent to contact form	1.0	05 Sep 2013	Ethics	07 Nov 2013 (REC) and 19 Dec 2013 (MHRA)	No	No	/
Patient Information Booklet (PIB)	1.4	05 Sep 2013	Ethics	07 Nov 2013 (REC) and 19 Dec 2013 (MHRA)	No	V1.4 (05 Sep 2013)	13 Jan 2014
Summary PIS	1.4	05 Sep 2013	Ethics	07 Nov 2013 (REC) and 19 Dec 2013 (MHRA)	No	V1.4 (05 Sep 2013)	13 Jan 2014
Peak Flow Meter instructions	1.0	13 Dec 2012	Ethics	5 Feb 2013	No	V1.0 (13 Dec 2012)	Not known, but current version is online.
Trial poster	1.1	28 Aug 2013	Ethics	07 Nov 2013 (REC) and 19 Dec 2013 (MHRA)	No	V1.1 (28 Aug 2013)	10 Jan 2013
IMP (see also Drug Handling SOP below)							
Trial prescription	1.8	08 Nov 2013	Sponsor	08 Nov 2013	No	No	/
Medicine pack label	1.4	9 Jul 2012	MHRA	24 Oct 2012	No	No	/

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Trial Participation Card	1.0	31 May 2012	Ethics	25 Oct 2012	No	No	/
GP information							
Letter to GP Practices	1.0	31 May 2012	Ethics	25 Oct 2012	Yes	No	/
GP Information Sheet (for PCRN)	1.0	18 Feb 2013	No	/	Yes – owned by the trial centres	No	/
Eligibility Criteria Laminated Card	1.3	23 Sep 2013	No	/	No	v1.3 (23 Sep 2013)	13 Jan 2014
Receptionist Script	1.0	22 Mar 2013	No	/	Yes	No	/
Telephone follow-up							
Weekly Questions	1.0	16 May 2013	Trial Manager	16 May 2013	No	No	/
EQ-5D 5L	2.0	2009	No	/	No	No	/
Telephone Follow-up SOP	1.0	16 May 2013	Trial Manager	16 May 2013	No	No	/
Data collection forms							
CRF Section 1: Eligibility Assessment	1.2	23 Sep 2013	Ethics	07 Nov 2013 (REC) and 19 Dec 2013 (MHRA)	No	V1.2 (23 Sep 2013)	13 Jan 2014
CRF Section 2: Clinical Examination	1.2	23 Sep 2013	No	/	No	V1.2 (23 Sep 2013)	13 Jan 2014
CRF Section 3: Patient Registration	1.2	23 Sep 2013	No	/	No	V1.2 (23 Sep 2013)	13 Jan 2014
CRF Section 4: Symptoms and Medical History	1.2	23 Sep 2013	No	/	No	V1.2 (23 Sep 2013)	13 Jan 2014
Patient Symptom Diary	1.1	22 Jan 2014	Ethics	24 Jan 2014	No	No ¹	/

¹ Electronic/online symptom diary will be a data entry system not a document.

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				(notified to REC)			
Primary Care Notes Review	1.0	27 Nov 2012	No	/	No	v1.0 (27 Nov 2012)	12 Feb 2014
Trial management SOPs / Forms (NB: after initial sponsor approval, further approval does not need to be sought for updates to these documents)							
GP site file contents list	1.2	09 Sep 2013	Sponsor	19 Apr 2013	No	No	/
Trial centre contacts	1.0	19 Nov 2013	No	/	Yes	No	/
Training Log	1.0	18 Mar 2013	Sponsor	19 Apr 2013	Yes	No	/
Trial Centre Delegation Log	1.0	11 Mar 2013	Sponsor	19 Apr 2013	Yes	No	/
GP Site Delegation Log	1.0	22 Apr 2013	Sponsor	19 Apr 2013	Yes	v1.0 (22 Apr 2013)	Not known, but current version is online.
Screening Log	1.0	22 Apr 2013	Sponsor	19 Apr 2013	Yes	v1.0 (22 Apr 2013)	Not known, but current version is online.
Patient Withdrawal Form	1.0	22 Apr 2013	Sponsor	22 Apr 2013		v1.0 (22 Apr 2013)	Not known, but current version is online.
Adverse Event Reporting SOP	1.1	18 June 2013	Sponsor	19 Apr 2013	No	V1.1 (18 June 2013)	28 June 2013
SAE Initial Reporting Form	1.0	13 March 2013	Sponsor	19 Apr 2013	No	V1.0 (13 Mar 2013)	28 June 2013
SAE Follow-up Reporting Form	1.0	13 March 2013	Sponsor	19 Apr 2013	No	No	/
SAE Weekly Check Log	1.2	03 October 2013	No	/	No	V1.2 (03 Oct 2013)	01 Nov 2013
Drug Handling SOP	1.0	27 Mar 2013	Sponsor	27 Mar 2013	No	v1.0 (27 Mar 2013)	Not known, but current version is online.

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IMP Patient Pack Requisition and Transfer Log	1.2	22 Oct 2013	As per Drug Handling SOP		No	V1.2 (22 Oct 2013)	22 Oct 2013
IMP GP Site Patient Pack Accountability Log	1.0	27 Mar 2013	As per Drug Handling SOP			No	/
IMP Trial Centre Patient Pack Accountability Log	1.0	27 Mar 2013	As per Drug Handling SOP			No	/
IMP Storage Risk Assessment	1.0	27 Mar 2013	As per Drug Handling SOP			No	/
IMP Significant Temperature Variations Log	1.0	27 Mar 2013	As per Drug Handling SOP			No	/
IMP Weekly Temperature Monitoring Log	1.1	19 July 2013	As per Drug Handling SOP			V1.1 (19 July 2013)	19 July 2013
Unblinding SOP	1.0	26 Mar 2013	Sponsor	26 Mar 2013	No	V1.0 (26 Mar 2013)	Not known, but current version is online.
Unblinding Accountability Log	1.0	26 Mar 2013	As per Emergency Unblinding SOP			No	/
Fax Transmission SOP	1.0	13 Mar 2013	Sponsor	/	No	V1.0 (13 Mar 2013)	Not known, but current version is online.
Fax Cover Sheet	1.0	2 May 2013	No	/	Yes	V1.0 (02 May 2013)	Not known, but current version is online.

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Protocol Deviations SOP	1.0	17 Jun 2013	CI	19 June 2013	No	V1.0 (17 June 2013)	28 June 2013
Trial Centre Protocol and GCP Deviations Log	1.0	17 Jun 2013	As per Protocol Deviations SOP		No	No	/
Clinical Database Specification and Data Management Plan	0.5	18 June 2013	Sponsor	Draft in progress	No	No	/
Data Monitoring SOP	1.0 1.1	30 Oct 2013 18 Nov 2013	CI / Sponsor	Revision in progress	No	To be added	
Patient Pack Reallocations SOP	1.0	07 Feb 2014	CI / Sponsor	Approved	No	No	/
Patient Pack Reallocations Log	1.0	07 Feb 2014	CI / Sponsor	Approved	No	No	/
Archiving Plan	0.1	18 June 2013	Sponsor	Awaiting review by sponsor	No	No	/
OSAC Trial Site Agreement 44167	1.2	16 May 2013	Sponsor	Approved	Yes	No	/
OSAC eCRF Access Instructions	1.2	01 Nov 2013	None	/	No	V1.2 (01 Nov 2013)	01 Nov 2013
OSAC trial labelling instructions for GP practices	1.1	01 Nov 2013	None	/	No	V1.1 (01 Nov 2013)	01 Nov 2013
OSAC trial guidance for interpreting output of www.peakflow.com for calculating predicted peak flow (CRF 4, Clinical Observations, Question 4.1.3)	1.0	17 Sep 2013	None	/	No	No	/

FORMS NO LONGER USED

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Confirmation by GP of patient eligibility to participate in the OSAC trial ²	1.0	28 Aug 2013	Sponsor	23 August 2013	No	No	/

Updated by Harriet Downing, OSAC Trial Manager, 12 February 2014

² For use in recruitment where an Advanced Nurse Practitioner acts in the role of Responsible Clinician and authorises the trial prescription.