OSAC TRIAL SAE/SUSAR REPORTING INSTRUCTIONS FOR RECRUITING SITES

(SEE ADVERSE EVENT REPORTING STANDARD OPERATING PROCEDURE, v1.0, 13/03/2013)

An event/reaction is serious if it:

- **results in death,**
- **is life threatening,**
- **results in persistent or significant disability/incapacity,**
- **requires hospitalisation,**
- **prolongs a current hospitalisation**
- **results in a congenital anomaly or birth defect**
- **other: an adverse event the nature or severity of which is not consistent with the known information about the drug provided in the SPC (summarised in the trial protocol and in the Patient Information Booklet)**

Adverse Events reported or notified to GPs by patients or via hospital admission/A&E letters

1. The delegated clinician will decide which AEs require reporting to UH Bristol monitor and the Bristol trial centre – refer to trial protocol or PIB for list of trial medication's known side-effects.

2. The delegated clinician must notify UH Bristol monitor **immediately** (by email: **research@uhbristol.nhs.uk** or telephone: **0117 342 0233**) of reported / notified SAEs. This report can be brief – the purpose is simply to notify UH Bristol monitor (acting on behalf of the trial sponsor) that the event happened.

3. If notifying by email, the instructions below must be followed:-
   - SAE reports should be sent only to research@uhbristol.nhs.uk
   - The format of the message should be as follows:

   A. OSAC trial
   B. Advance notice of SAE report to follow by fax
   C. Participant Identification Number: XXXXXX (**DO NOT include the patient's name or any other patient identifiable information)**
   D. Brief details of SAE if known

4. **All of sections 1-8** of the SAE Initial Report Form must be completed and submitted by fax to UH Bristol monitor **within 24 hours of becoming aware of the event (see contact details below).**

5. The recording and submission of the Initial Report Form must be logged on the patient's electronic medical record by the delegated clinician.

SAEs identified at 3-month primary care notes review

1. The primary care notes review may identify an AE, e.g. hospitalisation, serious ill health or death, for which a SAE Initial Report Form may need completing retrospectively. The delegated clinician will decide which events require reporting to UH Bristol monitor.

2. **All of sections 1-8** of the Initial Report Form must be completed and submitted by fax to UH Bristol monitor **within 24 hours of becoming aware of the event (see contact details below).**

3. The Bristol trial centre will log all retrospective SAE reports onto the trial management database.

Reporting and completion of SAE Initial Report Form

1. Responsibility for reporting SAEs and SUSARs at GP practices:
   - Healthcare professionals involved in trial recruitment (Responsible Clinician; Recruiting Clinician)

2. Staff reporting a SAE will, **as soon** as they become aware of the event:-
   - **immediately** contact UH Bristol monitor (by email to **research@uhbristol.nhs.**uk or telephone **0117 342 0233**) to briefly report that the event happened;

   - complete the Initial Report Form sections 1-8, and section 11 if necessary, and fax the form **directly to UH Bristol monitor within 24 hours of becoming aware of the event**;

   - fax a copy of the **unsigned I**nitial Report Form to the Bristol trial centre **at the same time** as sending it to UH Bristol monitor;

   - email the Bristol trial centre, who must reply to confirm the report has been received (see contact details below).

3. **The Chief Investigator** will review the Initial Report Form, complete sections 9 and 12 and sign the form.

4. **The Bristol trial centre** will send the **signed** Initial Report Form by fax direct to UH Bristol monitor **as soon as possible (and within 5 working days) after receiving it from the GP practice**.

5. **The CI will delegate responsibility for completing and signing the Initial Report Form (and Follow-up Report Form) to another academic GP in the event of them being away from the OSAC trial duties.**

6. Contact details for UH Bristol monitor and Bristol trial centre are:-

UH Bristol monitor	fax: 0117 342 0239
	tel: 0117 342 0233
	email**:** research@uhbristol.nhs.uk
Bristol trial centre	fax: 0117 928 7341
	email: osac-trial@bristol.ac.uk

UNDER NO CIRCUMSTANCES SHOULD SAFETY REPORTING PAPERWORK BE FAXED, EMAILED OR POSTED TO ANY OTHER DESTINATIONS

PLEASE USE THE OSAC TRIAL FAX COVER SHEET SUPPLIED

7. File the original Initial Report Form paperwork in the Trial Site File / Trial Master File respectively.

OSAC TRIAL ADVERSE EVENTS SAFETY REPORTING FLOW DIAGRAM FOR GP RECRUITING SITES

Follow-up of SAEs and completion of Follow-up Report Form

1. All SAEs need to be followed up until they are resolved.

2. A follow-up report is NOT necessary if the SAE is resolved at the time of the Initial report.

3. The Bristol trial centre is responsible for ensuring that SAEs are followed-up within the required timescales.

4. If any SAEs remain unresolved beyond the required timescales, UH Bristol monitor will instruct the CI / Trial Manager accordingly.

5. The Trial Manager and Trial Research Nurse will co-ordinate with GP practices in completing the SAE Follow-up Report Form.

6. **Reporting staff in GP practices (**Ideally the same person who completed the Initial Report Form) will:-
   - complete the Follow-up Report form, **as soon as possible**, and **at the latest within 5 working days** of becoming aware of event;
   - for **SUSARS all sections** on the Follow-up Report form must be completed, and for **other SAEs sections 1, 2 and 3** must be completed;
   - fax a copy of the **unsigned** Follow-up Report form to Bristol trial centre;
   - email Bristol trial centre, who must reply to confirm the report has been received.

7. The CI will sign and send the Follow-up Report form by fax direct to UH Bristol monitor **immediately on receiving the report, or within 24 hours (the Follow-up Report must be sent to UH Bristol no later than 5 working days after the Initial Report Form)**.

   The Initial Report and the Follow-up Report Forms may be done together, if within 24 hours of becoming aware of the event.

8. Reporting staff at both GP practices and the Bristol trial centre must file the original document in the Trial Site File / Trial Master File respectively.

9. The Trial Manager will co-ordinate with GP practices for the completion and return (as above) of further Follow-up Report Form(s) for data collected **later than 5 days post-SAE** until the SAE has resolved or a decision for no further follow-up has been taken (UH Bristol monitor will co-ordinate with Trial Manager / CI).

10. A paper copy of the Follow-up Report Form(s) with signatures will be sent to the sponsor.