Suspected Unexpected Serious Adverse Reactions (SUSARS)
What to do?

1. PURPOSE
This document describes the process for identifying, recording and reporting Suspected Unexpected Serious Adverse Reactions (SUSARs) to the IMP in the IST-3 trial. This should be used as a supporting document to the guidance given in section 12 ‘Data and Safety Monitoring’ of the IST-3 trial protocol, located in Section 8 of your IST-3 trial manual.

2. DEFINITION OF SERIOUS UNEXPECTED SERIOUS ADVERSE REACTION (SUSAR)
An unexpected adverse reaction (UAR) is an adverse reaction that is not consistent with the product information in the SPC.

A suspected unexpected serious adverse reaction (SUSAR) is any UAR that at any dose:
- results in death;
- is life threatening (i.e. the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe);
- requires hospitalisation or prolongation of existing hospitalisation;
- results in persistent or significant disability or incapacity;
- is a congenital anomaly or birth defect.

3. WHAT TO REPORT
All SUSARs, as defined in Section 2 of this document should be reported to the IST-3 trial Sponsor Pharmacovigilance Team in ACCORD within 24 hours of becoming aware of the event.

4. HOW TO REPORT SUSARS TO ACCORD
- Once a SUSAR has been identified, this must be reported to the ACCORD office by the Principal Investigator or person delegated this task within 24 hours.
- To report a SUSAR the CIOMS report form must be completed. This can be found in Section 7 of your trial manual and on the IST-3 website (www.ist3.com).
- Reports should be as complete as possible and contain all the information available at the time of reporting. If the Investigator does not have all the information regarding the SUSAR at the time of reporting, they should not wait for this before completing the form.
- To report the SUSAR the Investigator must complete the CIOMS form and fax the report with the IST-3 SUSAR report cover sheet to the ACCORD office on 0131 242 9447. The fax cover sheet can be found in Section 7 of your trial manual or on the IST-3 website (www.ist3.com)
- The ACCORD office will confirm receipt of a report by sending a fax receipt form. If this receipt fax is not received within 24 hours of sending the fax, the Investigator should phone the ACCORD office on 0131 242 9443 to confirm that the report was received.
- In the absence of a functioning fax machine, a verbal report may be given to a member of the ACCORD office by telephoning +44 (0)131 242 9446. All verbal reports must be followed up as soon as possible with a completed CIOMS form from the PI.