ADVERSE EVENT

Serious
(results in death; is life-threatening; requires hospitalisation or prolongation of existing hospitalisation; results in persistent or significant disability or incapacity; is a congenital anomaly or birth defect)

Not Serious

Centre to fax report to CTSU immediately (defined as within 24 hours of knowledge of event). Original to be posted to CTSU.

CTSU to arrange urgent clinical review of SAE by Chief Investigator. Decision to be documented. (Note timelines for review/report below)

Suspected Unexpected Serious Adverse Reaction (SUSAR)

Fatal or life threatening

*CI to report within 7 days of notification of event to MHRA and MREC (+ 8 days for further information) and to send copy to investigator concerned

NOT fatal or life threatening

*CI to report within 15 days of notification of event to MHRA and MREC, and to send copy to investigator concerned

Other Suspected Serious Adverse Reaction (SSAR) or other serious adverse event not related to protocol drugs

Entered in study database

*CI to provide annual progress report to MREC

*CI = Chief Investigator