PROFILE – SAE reporting requirements

An SAE is any untoward medical occurrence that:

- Results in death.
- Is life-threatening.
- Requires hospitalisation or prolongation of existing inpatients´ hospitalisation.
- Results in persistent or significant disability or incapacity.
- Results in a congenital anomaly or birth defect.
- Is an important medical event - Some medical events may jeopardise the subject or may require an intervention to prevent one of the above characteristics/ consequences. Such events should also be considered as 'serious'.

SAE Reporting Requirements:

Initial Reporting: For all initial reporting of any SAEs this form must be **completed fully or with as much information as possible** and sent to the Cambridge Clinical Trials Unit or Chief Investigator if sending from a participating site within **24 hours** of the incident occurring or being reported to the trial team.

Follow-up Information: New SAE information after an initial submission should be indicated on an SAE follow up report and forwarded to the PROFILE Trial Coordinator as soon as possible. All SAEs must be followed up until resolution. There are two options for subsequent follow-up reporting of an SAE:

1. If only **minimal** follow-up data is being submitted (e.g. 2 or 3 fields): The site may submit the initial SAE form updated as a follow-up. In this case a reporter should add all new or missing information to the initial SAE form.

2. If **significant or many changes** are being submitted: A new SAE Reporting form should be completed with the following information provided as a minimum: trial and participant details (SAE form header), SAE term, SAE onset date and all new or missing information.