Safety reporting and definitions

Safety

Definitions

Unexpected events that have not been defined as endpoints should be classified as either an SAE or AE depending on their severity. There is no requirement to report AE's. All SAEs must be recorded from the time at which the randomisation of the participant has occurred until the last study visit. The member of the research team should ask about the occurrence of SAEs at every visit during the study. Open-ended and non-leading verbal questioning of the participant should be used to enquire about AE/SAE occurrence. Participants should also be asked if they have been admitted to hospital, had any accidents, used any new medicines or changed concomitant medication regimens. If there is any doubt as to whether a clinical observation is an SAE, the event should be recorded. However, common symptoms in dialysis patients such as headache, nausea, itching etc., as well as infections not requiring hospitalisation, will not be recorded. Each initial SAE will be considered for severity, causality or expectedness and may be reclassified as a serious event or reaction based on prevailing circumstances.

A serious adverse event (SAE) is any AE that:

- 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.

Unexpected Serious Adverse Events

SAEs should be reported to the Clinical Trials Unit within 7 days. The report should include an assessment of causality by the Principal Investigator at each site (see section 5.4). The Chief Investigator will be responsible for the prompt notification of findings that could adversely affect the health of subjects or impact on the conduct of the trial. Notification of confirmed unexpected SAEs will be to the Sponsor, the Research Ethics Committee and the Data and Safety Monitoring Committee (DSMC).

Assessment of intensity

Mild: The subject is aware of the event or symptom, but the event or symptom is easily tolerated.
Moderate: The subject experiences sufficient discomfort to interfere with or reduce his or her usual level of activity.
Severe: Significant impairment of functioning; the subject is unable to carry out usual activities and/or the subject's life is at risk from the event