Any member of trial team learns about adverse event from any source.

Adverse events do not include falls that require no medical attention. However, these are recorded as ADVERSE INCIDENTS in the adverse event log.

1) Characterize adverse event.
- Circumstances surrounding occurrence
- Any resulting injury or illness
- Receipt of any health care services

2) Site lead determines if event is serious, consulting CI as necessary.
- Death
- Non-elective hospitalisation
- Life-threatening adverse event
- Sudden or rapidly progressive major disablement

Serious

Not serious

CI takes appropriate medical action as needed, including notifying GP if not already aware.

If patient has not sought medical attention, site lead encourages him or her to do so, including notifying GP.

3) CI determines causality of adverse event.
Possibly, probably, or definitely related
Not related or improbably related

RELATED SERIOUS ADVERSE EVENT
UNRELATED SERIOUS ADVERSE EVENT
POSSIBLE ADVERSE REACTION
ADVERSE REACTION
ADVERSE EVENT

Complete SAE form.

Complete AE form and record in adverse event log.

Site lead reviews patient’s status and makes decision with him/her about continued participation.

Take actions as necessary to modify conditions of intervention.

CI reports occurrence of event to ethics committee and trial steering committee within seven days.