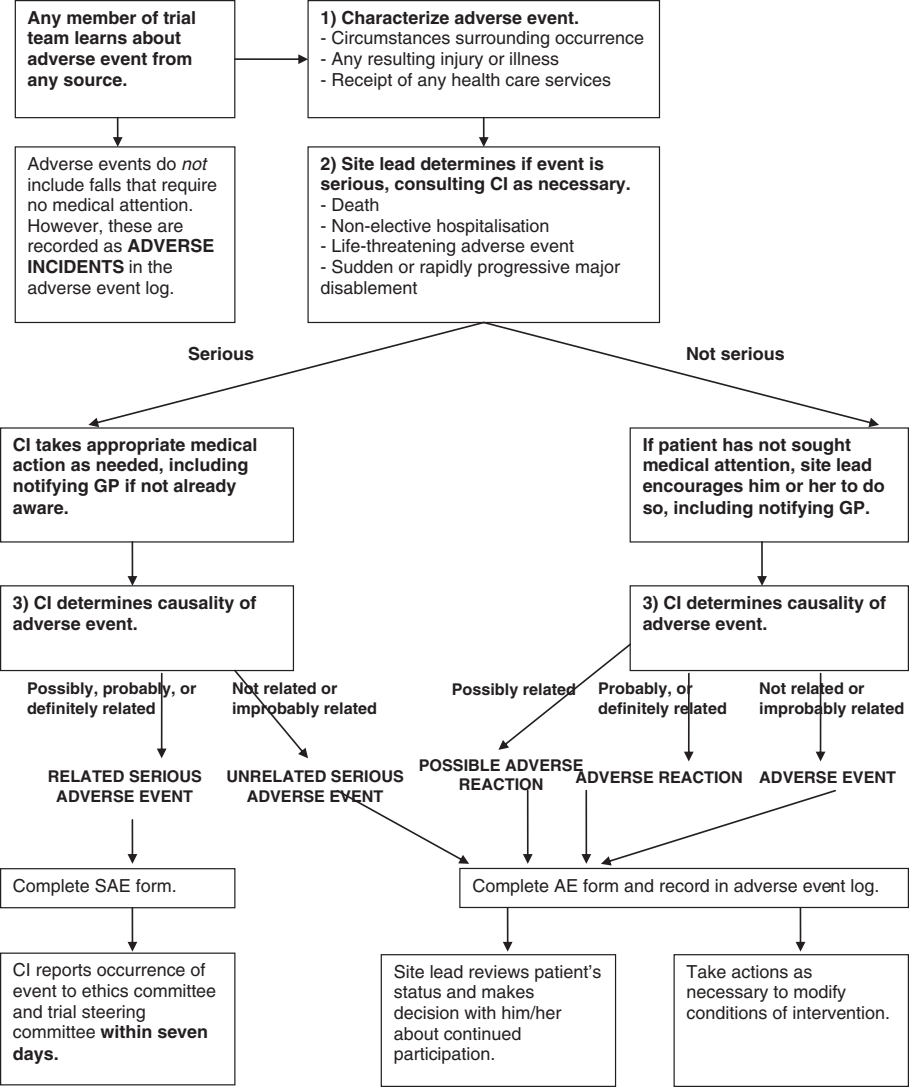
Any member of trial team learns about adverse event from any source.
1) Characterize adverse event.
- Circumstances surrounding occurrence
- Any resulting injury or illness
- Receipt of any health care services
Adverse events do *not* include falls that require no medical attention. However, these are recorded as **ADVERSE INCIDENTS** in the adverse event log.
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.
3) CI determines causality of adverse event.
Possibly, probably, or definitely related
Not related or improbably related
Possibly related
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.
CI reports occurrence of event to ethics committee and trial steering committee **within seven days.**
Site lead reviews patient's status and makes decision with him/her about continued participation.
Take actions as necessary to modify conditions of intervention.