Safety reporting flowchart

Adverse Event Reporting: UK Open Label Trial

PI assesses causality

- Related
  - Adverse Reaction (AR)
  - Adverse Event (AE)

- Not related
  - PI assesses seriousness

PI assesses seriousness

Serious SAE/R

PI checks protocol to confirm whether SAE/R requires expedited reporting

- NO
  - PI records and notifies sponsor as per protocol

- YES
  - PI notifies sponsor of SAE/R within 24 hours

Sponsor’s assessment of causality

- Related to IMP
  - Serious Adverse Reaction (SAR)

Sponsor’s assessment of expectedness using the RSI

- Unexpected
  - Suspected Unexpected Serious Adverse Reaction (SUSAR)
    - Sponsor to report to MHRA and Ethics Committee:
      - Fatal or life threatening SUSARs within 7 days
      - All other SUSARs within 15 days
    - SUSARs reported to PIs as per protocol

- Expected
  - Expected Serious Adverse Reaction (SAR)
    - Sponsor keeps records and follows up until resolution

Adverse Event (AE):
Any untoward medical occurrence in a clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment.

Adverse Reaction (AR):
Any untoward and unintended response to an IMP which is related (a reasonable causal relationship) to any dose administered.

Serious Adverse Event/Reaction (SAE/R):
- 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,
- any other safety issues considered medically important.

PI should actively seek follow-up information on reported SAE/Rs.

Footnotes
1 PI or delegate.
2 Notable or safety critical events must be reported as per protocol.
3 Sponsor cannot downgrade the PI’s causality assessment, but can upgrade it.
4 Reference Safety Information (RSI) in IB or SmPC.