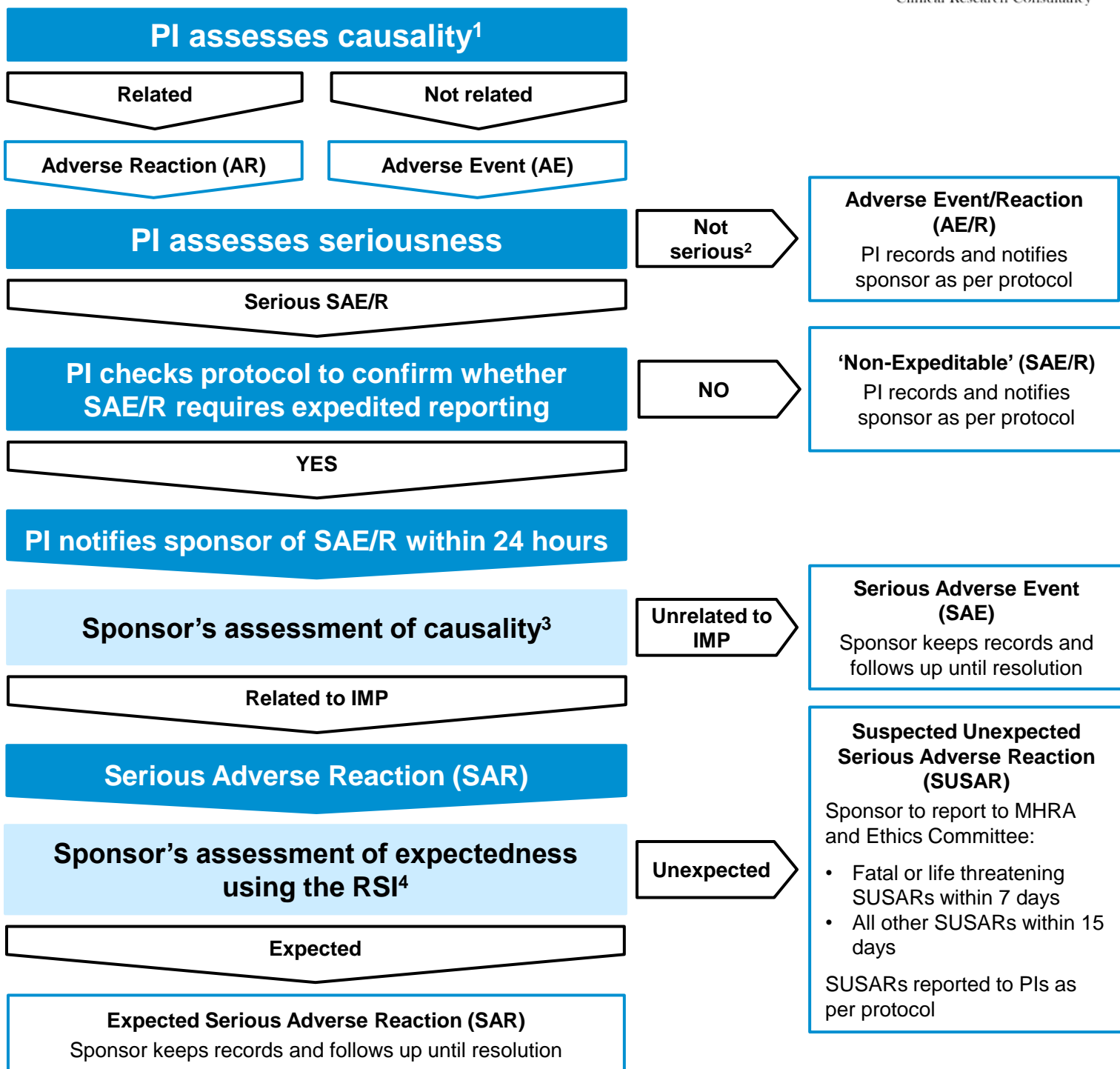


Safety reporting flowchart

Adverse Event Reporting: UK Open Label Trial



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.