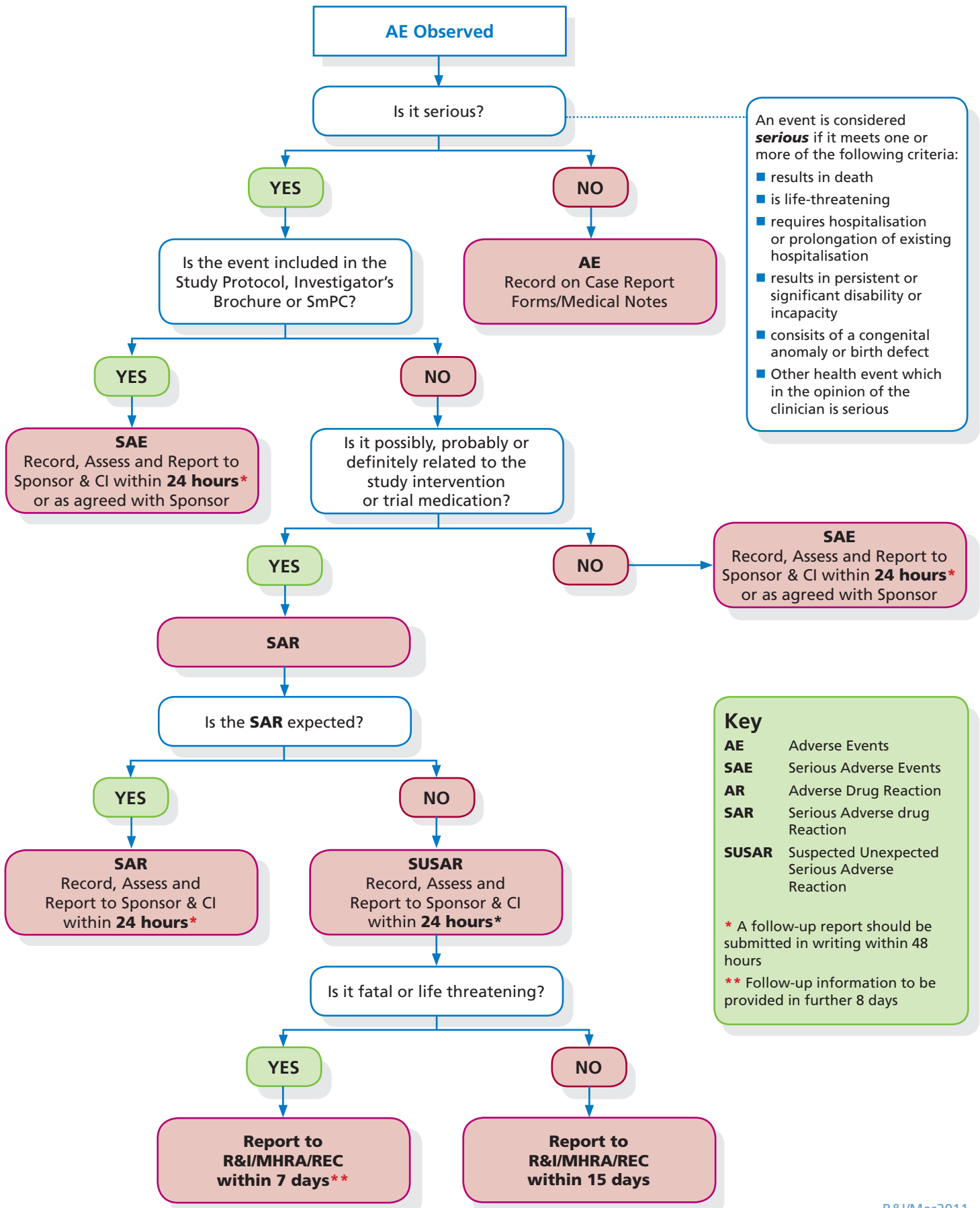


# Safety reporting flowchart



An event is considered **serious** if it meets one or more of the following criteria:

- results in death
- is life-threatening
- requires hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability or incapacity
- consists of a congenital anomaly or birth defect
- Other health event which in the opinion of the clinician is serious

**Key**

- AE** Adverse Events
- SAE** Serious Adverse Events
- AR** Adverse Drug Reaction
- SAR** Serious Adverse drug Reaction
- SUSAR** Suspected Unexpected Serious Adverse Reaction

\* A follow-up report should be submitted in writing within 48 hours  
\*\* Follow-up information to be provided in further 8 days