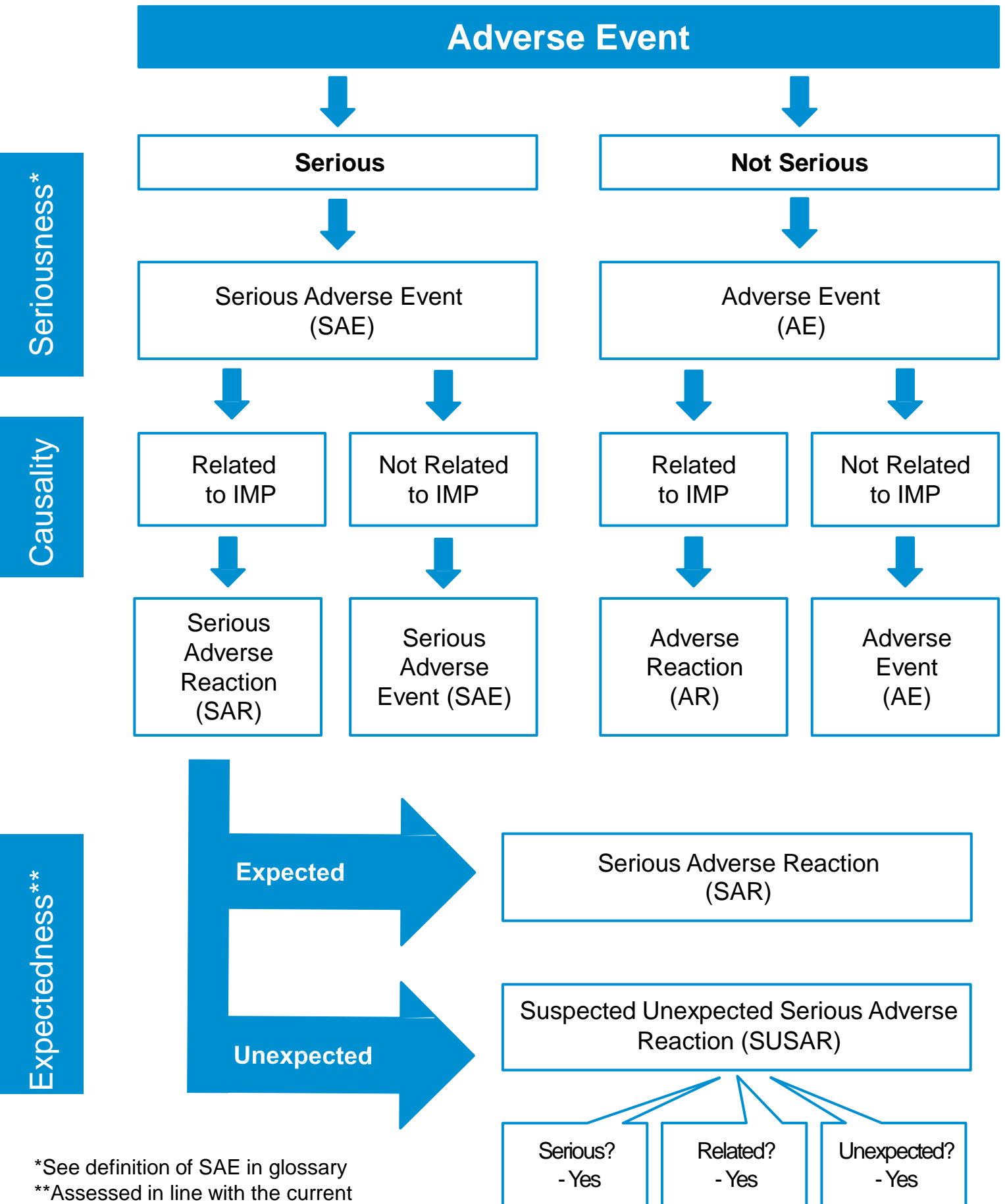


Safety reporting assessment flowchart



*See definition of SAE in glossary
 **Assessed in line with the current approved IB (or SmPC)

Glossary

Adverse Event (AE)	Any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment.
Adverse Reaction (AR)	<p>Any untoward and unintended response to an investigational medicinal product related to any dose administered.</p> <p>Comment: All adverse events judged by either the reporting investigator or the sponsor as having a reasonable causal relationship to a medicinal product would qualify as adverse reactions. The expression 'reasonable causal relationship' means to convey, in general, that there is evidence or argument to suggest a causal relationship.</p>
Investigator's Brochure (IB)	A document containing a summary of the clinical and non-clinical data relating to an investigational medicinal product which are relevant to the study of the product in human subjects.
Investigational Medicinal Product (IMP)	A pharmaceutical form of an active substance or placebo being tested, or to be tested, or used, or to be used, as a reference in a Clinical Trial, and includes a medicinal product which has a marketing authorisation but is, for the purposes of the trial—(a) used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation,(b) used for an indication not included in the summary of product characteristics under the authorisation for that product, or (c) used to gain further information about the form of that product as authorised under the authorisation.
Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR)	<p>Any adverse event or adverse reaction that results in death, is life-threatening*, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.</p> <p>Comment: Medical judgement should be exercised in deciding whether an adverse event/reaction should be classified as serious in other situations. Important adverse events/reactions that are not immediately life-threatening or do not result in death or hospitalisation, but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.</p> <p>*Life-threatening in the definition of a serious adverse event or serious adverse reaction refers to an event in which the subject was at risk of death at the time of the event. It does not refer to an event which hypothetically might have caused death if it were more severe.</p>
Summary of Product Characteristics (SmPC)	<p>The SmPC is the basis of information for health professionals on how to use the medicinal product safely and effectively. SmPCs are written and updated by pharmaceutical companies and are based on their research and product knowledge. The SmPC is then checked and approved by the UK or European medicines licensing agency.</p> <p>The leaflet that is included in the pack with a medicine is a patient-friendly version of the SmPC.</p>
Suspected Unexpected Serious Adverse Reactions (SUSAR)	An adverse reaction that is both unexpected (not consistent with the applicable product information) and also meets the definition of a Serious Adverse Reaction.