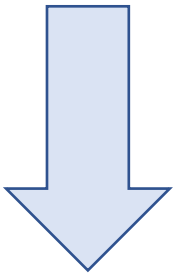
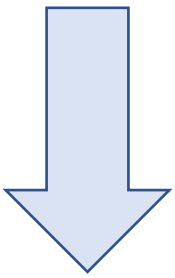
SAE (serious adverse event)	A serious adverse event (SAE) means any untoward medical occurrence that at any dose requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, results in a congenital anomaly or birth defect, is life-threatening, or results in death.
	Causality assessment – is the serious adverse event related to the IMP? In determining whether an adverse event is an adverse reaction, consideration shall be given to whether there is a reasonable possibility of establishing a causal relationship between the event and the investigational medicinal product (IMP) based on an analysis of available evidence. See the reference provided in Appendix 2 for guidance on the causality assessment
SAR (serious adverse reaction)	A serious adverse reaction (SAR) is an SAE that is assessed to be related to the IMP, i.e. the treatment provided in the clinical trial.
	Is the serious adverse reaction expected or unexpected? The determination of whether an event is expected or unexpected is assessed based on the reference safety information (RSI). Example: In the case of authorised medicinal products, the RSI is often section 4.8 of the summary of product characteristics (SmPC). Therefore, an adverse reaction appearing in the SmPC section 4.8 is expected, and an adverse reaction not appearing in the product information is unexpected. Question and Answers Document – Regulation (EU) 536/2014 (section 7) describes the demands for the RSI document.
SUSAR (suspected unexpected serious adverse reaction)	A suspected **unexpected** serious adverse reaction means a serious adverse reaction, the nature, severity or outcome of which is not consistent with the RSI.