



Medicines & Healthcare products Regulatory Agency

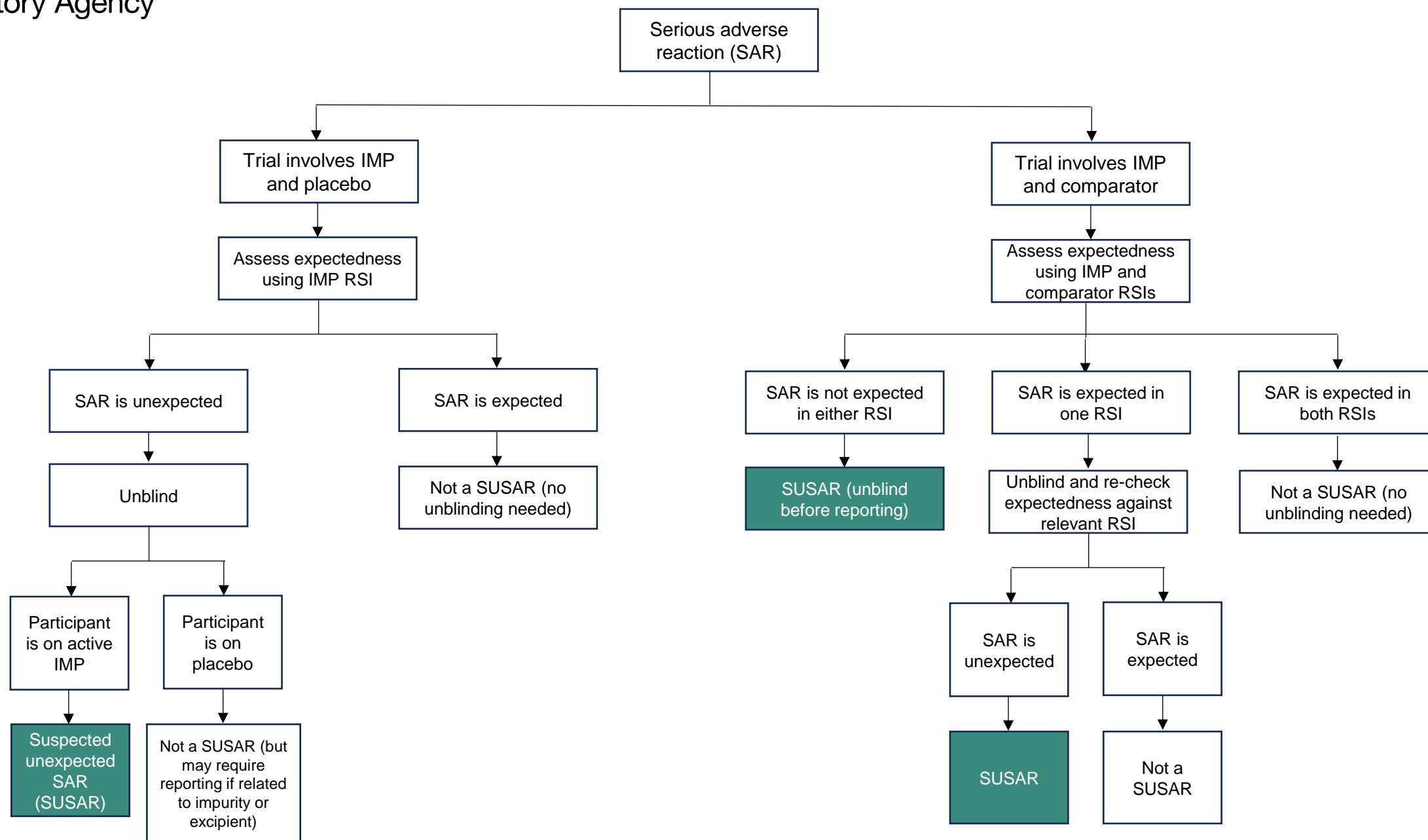


Figure 3. Decision tree to determine when treatment allocation should be unblinded following a serious adverse reaction. Please note that the treatment allocation of the participant should be unblinded before the SUSAR is reported to the licensing authority, even where unblinding was not required to determine that the SAR was unexpected.