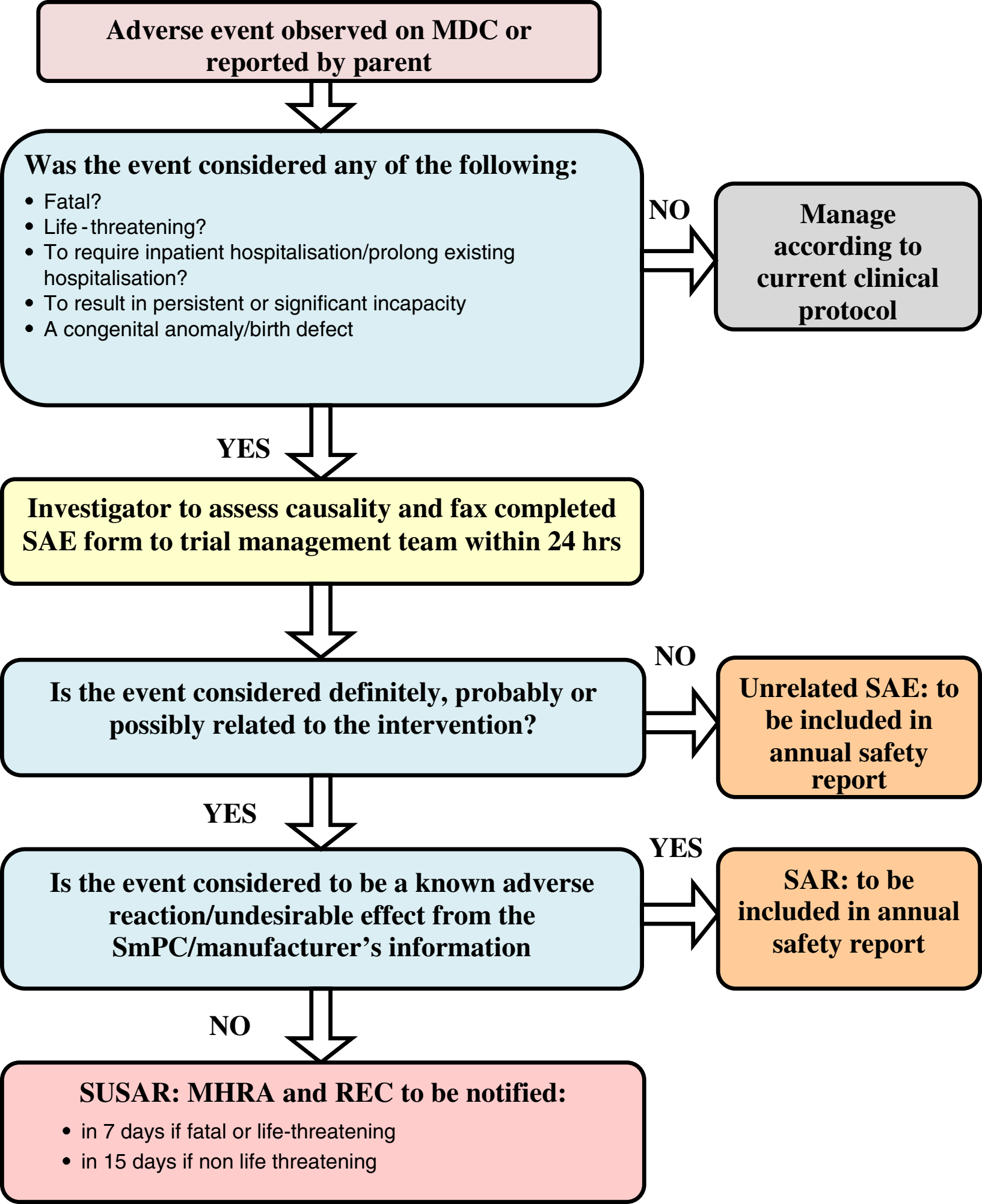
Adverse event observed on MDC or reported by parent
Was the event considered any of the following:
• Fatal?
• Life-threatening?
• To require inpatient hospitalisation/prolong existing hospitalisation?
• To result in persistent or significant incapacity
• A congenital anomaly/birth defect
NO
Manage according to current clinical protocol
YES
Investigator to assess causality and fax completed SAE form to trial management team within 24 hrs
Is the event considered definitely, probably or possibly related to the intervention?
NO
Unrelated SAE: to be included in annual safety report
YES
Is the event considered to be a known adverse reaction/undesirable effect from the SmPC/manufacturer's information
YES
SAR: to be included in annual safety report
NO
SUSAR: MHRA and REC to be notified:
• in 7 days if fatal or life-threatening
• in 15 days if non life threatening