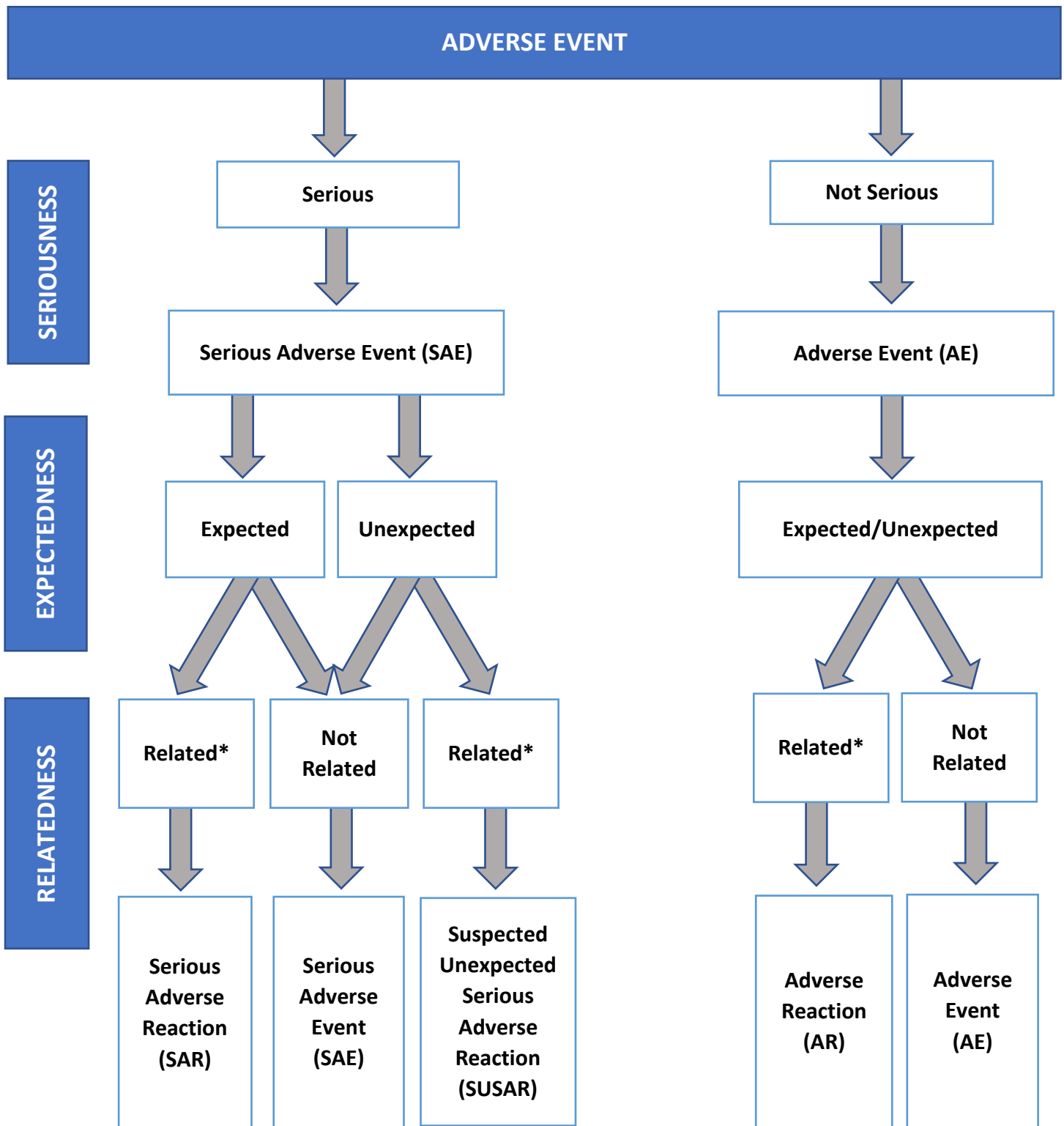


# NIAMS Safety Reporting Assessment Flowchart



NOTE: Depending on the designation of the event, different oversight entities (e.g., FDA, IRB, OHRP, NIAMS, and monitoring body) will need to be notified according to their specified timelines. For example, SAEs should be reported to the NIAMS and the monitoring body within 48 hours of the investigator becoming aware of the event.

\*Related = Definitely Related or Possibly/Probably Related