Adverse Drug Reaction [ADR]

A response to a medicinal product which is harmful and unintended. Response in this context means that a causal relationship between the medicinal product and an adverse event is at least a reasonable possibility.

Adapted from the Guideline on good pharmacovigilance practices (GVP) Annex I – Definitions (Rev 4) 2017. https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-annex-i-definitions-rev-4_en.pdf