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Unexpected Adverse Drug Reaction

National Cancer Institute

Source

National Cancer Institute. *Unexpected Adverse Drug Reaction*. NCI Thesaurus. Code C142744.

An adverse drug reaction, whose nature, severity, specificity, or outcome is not consistent with the term or description used in the applicable product information (e.g., IB for an unapproved investigational product or PI/summary of product characteristics for an approved product, and/or scientific literature). (ICH)