

Pharmacovigilance / AE Narrative

Healthcare

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This guide explains what the tool produces, how to use the output, and what to watch for. The actual output (draft/report) is generated on the tool page.

Background

Drafts a pharmacovigilance adverse-event case narrative — chronological, factual and causality-relevant — in regulatory style. De-identify the patient; a qualified PV professional must review, and ensure PvPI/CDSCO reporting compliance.

Purpose of this tool & output

Write an adverse-event case narrative

How the output is used

Use the drafted adverse-event case narrative as a structured starting point for pharmacovigilance reporting.

Important cautions

AI-generated draft; a qualified PV professional must review; ensure de-identification and reporting compliance (PvPI/CDSCO).

Companion documents

- Pharma Regulatory Writing
- Study Protocol Synopsis
- Patient Information Leaflet
- CDSCO Submission Guide
- Product Monograph Draft

This is AI-assisted guidance. Verify with a qualified professional before any binding decision. Fees, authorities and processes vary by state and change over time — confirm with your state authority.