

Adverse Event Reporting SOP

A complete technical writing project by Harmeet Kaur

STANDARD OPERATING PROCEDURE (SOP)

Table of Contents

A complete technical writing project by Harmeet Kaur	1
Table of Contents	2
2. Scope	4
3. Definitions and Abbreviations	4
3.1 Definitions	5
3.2 Abbreviations	6
4. Responsibilities	6
5. Minimum Criteria for a Valid Case	7
6. Sources of Adverse Events	8
7. Case Intake Process	8
7.1 Initial Contact	8
7.2 Collecting Required Information	8
A. Patient Information	8
B. Event Information	9
C. Product Information	9
D. Reporter Information	9
7.3 Serious Case Escalation	9
8. Data Entry Into Safety Database	10
9. Causality Assessment	11
10. Quality Control (QC) Process	11
11. Reporting Requirements	12
11.1 Reporting Timelines	12
11.2 Submission Format	12
12. Record Management	12
14. Templates	13
A. Serious Case Escalation Email	13
B. Follow-Up Questionnaire	14
C. Medical Narrative Template	14
15. Example Case (Appendix A)	14
16. Compliance Notes	15
17. Revision History	15

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to establish a consistent, compliant, and standardized process for the identification, documentation, assessment, and reporting of Adverse Drug Events (ADEs).

This SOP ensures adherence to global pharmacovigilance regulations including Health Canada, FDA, EMA, MHRA, CDSCO, and WHO guidelines, and supports overall patient safety by ensuring timely and accurate reporting.

This SOP aims to:

- Ensure accurate case intake and documentation
- Maintain regulatory compliance
- Enable effective safety signal detection
- Ensure audit readiness
- Protect patient safety across all markets

2. Scope

This SOP applies to all employees and contractors who may receive or document adverse events, including but not limited to:

- Pharmacovigilance Associates
- Medical Information Specialists
- Customer Service Representatives
- Field Staff (Sales, Medical Reps)
- Social Media Monitoring Teams
- Product Complaint Teams
- Quality Assurance Personnel

This SOP covers adverse events received from all sources including consumer calls, emails, product complaints, healthcare professionals, literature, and publicly available social media content.

3. Definitions and Abbreviations

3.1 Definitions

Adverse Drug Event (ADE):

Any undesirable medical occurrence associated with the use of a medicinal product, whether or not causally related.

Adverse Drug Reaction (ADR):

An ADE that is suspected to be related to the drug.

Serious Adverse Event (SAE):

Any event that results in:

- Death
- Life-threatening condition
- Hospitalization or prolongation
- Persistent disability
- Congenital anomaly
- Major medical intervention

Causality Assessment:

Clinical judgment determining the relationship between drug and event.

Reporter:

Person providing the information (consumer, HCP, caregiver, etc.)

MedDRA:

Medical Dictionary for Regulatory Activities — dictionary for medical coding.

Case Narrative:

A medical, chronological summary of the case written by PV personnel.

Follow-Up:

Additional information obtained after initial report.

3.2 Abbreviations

Term	Meaning
AE	Adverse Event
ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
SAE	Serious Adverse Event
PV	Pharmacovigilance
MI	Medical Information
HCP	Healthcare Professional
SOC	System Organ Class
PT	Preferred Term
ICSR	Individual Case Safety Report

4. Responsibilities

Role	Responsibilities
Pharmacovigilance Associate Medical Reviewer Customer Service Representative MI Specialist QA Personnel PV Manager/Supervisor	Intake, data entry, verifying validity, MedDRA coding, narrative writing, seriousness classification, follow-ups Performs causality assessment, clinical evaluation, and case approval Identifies potential AEs, collects minimum criteria, escalates serious cases Transfers safety information from inquiries to PV Ensures compliance, performs internal audits Oversight, ensures regulatory timelines, final approval

5. Minimum Criteria for a Valid Case

A valid ICSR must contain the following four essential elements:

1. Identifiable Patient
 - Initials, age, gender, or demographic description
2. Identifiable Reporter
 - Name, contact, or professional information
3. Suspect Product

- Brand name, generic name, dose, lot number (if available)

4. Adverse Event Information

- Symptom description, diagnosis, onset dates

If any of these are missing, the case remains invalid until information is collected.

6. Sources of Adverse Events

- Direct consumer reports
 - Phone calls to support or medical information
 - Emails or webforms
 - Social media posts (publicly accessible)
 - Healthcare professional reports
 - Sales or field staff reports
 - Published literature
 - Product complaints involving injury
-

7. Case Intake Process

7.1 Initial Contact

Upon receiving a potential ADE:

1. Greet the reporter calmly and professionally.
2. Thank them for sharing the information.
3. State the purpose: "To ensure safety, I will ask you a few short questions."
4. Ensure confidentiality.
5. Start collecting minimum criteria.

7.2 Collecting Required Information

A. Patient Information

- Age/group
- Gender
- Past medical history
- Allergies
- Pregnancy/lactation status (if applicable)

B. Event Information

- Symptoms experienced
- Start date
- Duration
- Outcome
- Hospitalization details
- Medical treatment received

C. Product Information

- Drug name
- Strength and dosage
- Route of administration
- Lot/batch number (if available)
- Indication (reason for use)

D. Reporter Information

- Name
- Role (consumer/HCP)
- Phone/email
- Relationship to patient

7.3 Serious Case Escalation

An event is considered serious if it results in:

- Hospitalization
- Life-threatening condition
- Disability
- Birth defect
- Death
- Medically significant condition

Actions for serious cases:

- Escalate within 24 hours
- Mark as priority in database
- Notify supervisor immediately

8. Data Entry Into Safety Database

1. Log in to the safety system.
2. Create a new case.
3. Enter:
 - Reporter demographics
 - Patient details
 - Event data in verbatim form
4. Apply MedDRA coding:
 - SOC
 - HLT
 - PT
5. Add seriousness classification.

6. Upload attachments (emails, screenshots, etc.)
7. Write the medical narrative:
 - Chronological
 - Neutral tone
 - No assumptions
8. Route case to medical reviewer.

9. Causality Assessment

Performed only by medical reviewer or trained personnel.

Factors considered:

- Temporal relationship
- Known side-effect profile
- Dechallenge/rechallenge
- Concomitant medications
- Medical plausibility
- Existing medical history

Scale used:

- Certain
- Probable
- Possible
- Unlikely
- Conditional/Unassessable

10. Quality Control (QC) Process

QC specialist checks:

- Correctness of MedDRA coding

- Accuracy of seriousness classification
- Completeness of fields
- Narrative quality
- Missing follow-ups
- Duplicate detection
- Regulatory deadlines

Incomplete cases are returned for correction.

11. Reporting Requirements

11.1 Reporting Timelines

Case Type	Reporting Deadline
Serious Unexpected	15 calendar days
Serious Expected	30 days
Non-Serious	Periodic safety update reports

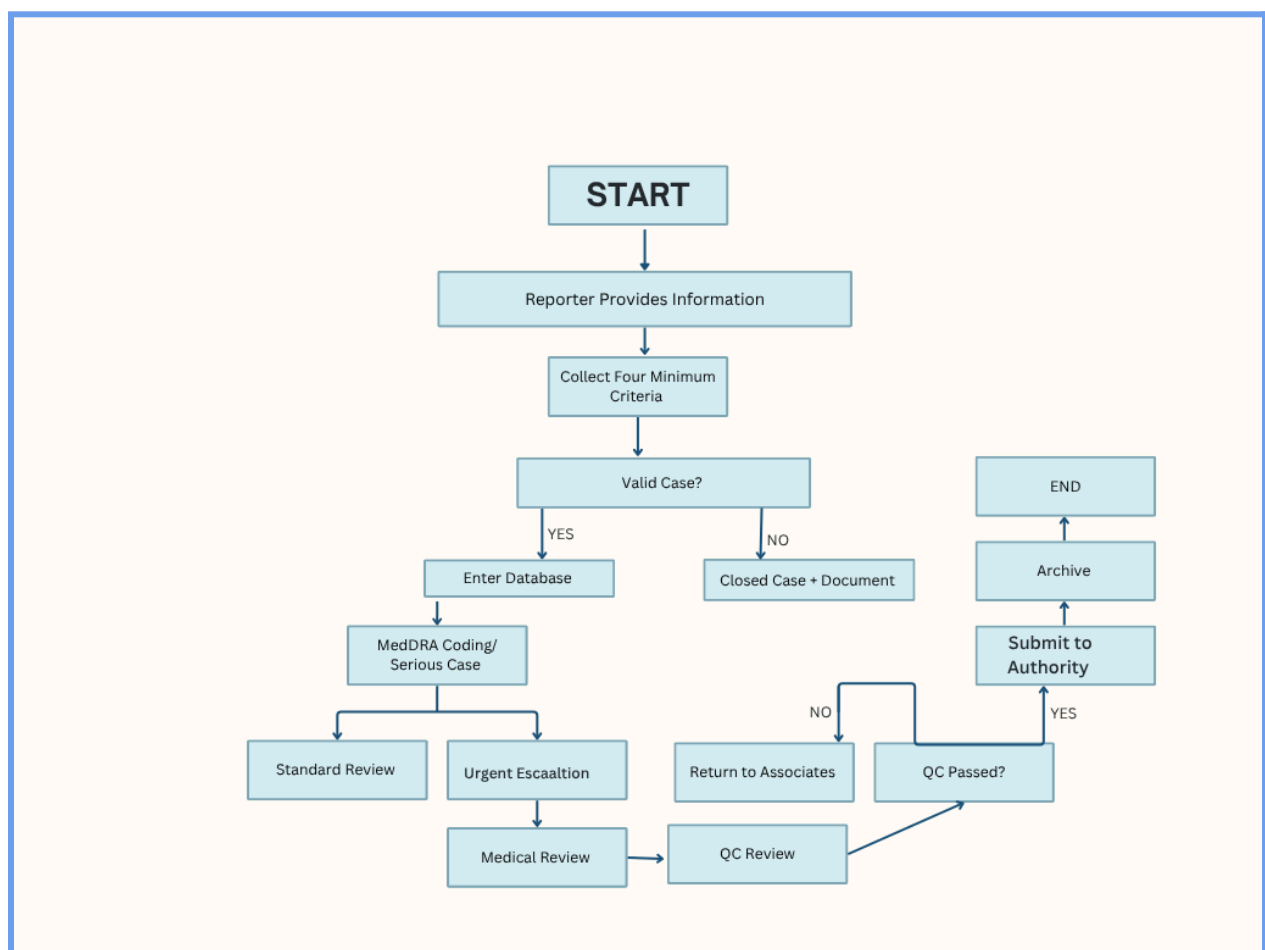
11.2 Submission Format

- E2B(R3) XML format
- CIOMS forms
- National safety reporting portals (where required)

12. Record Management

- All ICSRs retained for minimum 10 years
- Records stored securely within validated systems
- Only authorized personnel may access
- All audit logs maintained automatically

13. Project Flow Chart



14. Templates

A. Serious Case Escalation Email

Subject: URGENT – Serious Adverse Event (SAE) Requires Immediate Review

Hello Team,

A serious adverse event has been identified and requires immediate processing.

Case ID: _____

Patient Outcome: _____

Date Received: _____

Please prioritize according to SAE processing guidelines.

Regards,

Harmeet Kaur

Pharmacovigilance Associate

B. Follow-Up Questionnaire

- Can you describe the symptoms again?
- When did the symptoms begin?
- Did you stop the medication?
- Did the symptoms improve or worsen?
- Did you seek medical attention?
- Are other medications being taken?

C. Medical Narrative Template

A [age]-year-old [gender] reported experiencing [event description] after taking [drug name, dose, route] for [indication]. The event began on [date]. No hospitalization was required. The

patient discontinued the medication on [date], with symptoms improving/worsening. Concomitant medications included [list]. The case is ongoing/resolved.

15. Example Case (Appendix A)

Patient: 32-year-old female

Product: Amoxicillin 500 mg

Event: Rash, itching, mild fever

Severity: Non-serious

Outcome: Recovered

Causality Assessment: Possible

Reporter: Consumer

MedDRA PT: Rash, Pruritus, Pyrexia

16. Compliance Notes

- Follow ICH E2A and E2B guidelines
- Maintain confidentiality at all times
- Ensure regulatory timelines are met
- Maintain audit readiness
- Complete annual PV training

17. Revision History

Version	Date	Description	Author
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