Adverse event case processing (pharmacovigilance)

Process Definition Document (PDD): template and worked example

Example company (fictional): Brennholt Pharma AB, a mid-sized marketing authorisation holder in Uppsala, Sweden (about 260 employees, 14 products on the market in 22 countries).

Document control

Field	Value
Process name	Adverse event case processing (pharmacovigilance)
Process owner	[Name, role]
Prepared by	[Name]
Reviewed by	[Names of the people who do the work]
Approved by	[Name, date]
Version	1.0 (as-is)
Status	Draft

How to use this template

This is a complete process definition document (PDD) for adverse event case processing, also called individual case safety report (ICSR) handling, safety case intake or pharmacovigilance case management. It describes how a marketing authorisation holder turns a raw report of a suspected adverse reaction into a coded, assessed and submitted case: from the first email, call or literature hit to the archived case file. The company is fictional, but the roles, systems and checkpoints are those of a typical pharmacovigilance department.

Use it as a starting point. Replace the company details, keep the sections, and walk through each step with the case processors, safety physicians and the quality contact who run it. Most departments change the intake channels, the triage rules for non-serious cases and the follow-up schedule. Signal detection, aggregate reports, risk management plans and literature search strategy need their own documents. Reporting timelines differ by country and report type, so every deadline in this document must be checked against the regulations that apply to your products. The template describes a process. It does not make an organisation compliant.

- Replace the company, the safety database and the list of recipients with yours. If you outsource case processing to a partner, add the partner as a role and make the handover steps explicit.
- Check every timeline against the regulations that apply to your products and markets, and write the due dates into the reporting matrix. The numbers in this document are placeholders for the review times, not regulatory claims.
- Decide how non-serious cases from literature or solicited programmes are handled. Some departments use a simplified path with lighter review.
- Set your own follow-up schedule, number of attempts and wording by report type. The 7 and 14 day reminders are an example.
- Check the percentages with real data. A month of intake normally shows the true share of duplicates, invalid cases and rejections.
- Keep the as-is version after you redesign the process. It is your baseline for measuring the change.

1. Purpose and scope

This procedure describes how the pharmacovigilance department of Brennholt Pharma AB processes individual adverse event cases, from the moment any employee, partner, healthcare professional, patient or literature search delivers a report, to the moment the case is submitted to the authorities that require it and the case file is archived. It gives the

safety team, the medical reviewers, the affiliates and the quality function one shared description of who does what and by when, so that no report is lost, every case is assessed consistently and submissions leave inside the reporting clock.

In scope

- Case intake from every source: direct reports, affiliates, partners, literature, regulatory authority databases and solicited programmes
- Duplicate check and validity check of the four minimum criteria
- Data entry, coding and narrative writing in the safety database
- Seriousness, causality and expectedness assessment
- Medical review, follow-up requests and case versioning
- Submission of cases to authorities and partners within the applicable reporting clock
- Archiving of the case and its source documents

Out of scope

- Signal detection and signal evaluation
- Periodic safety update reports and other aggregate reports
- Risk management plan maintenance
- Literature search strategy and screening
- Product quality complaints that carry no adverse event

2. Process at a glance

Item	Description
Trigger	Any employee, partner, healthcare professional, patient or literature search delivers information about a suspected adverse reaction linked to one of the company's products.
Starts when	The Case Intake Coordinator registers the source document in the safety inbox tracker and stamps the day of first receipt.
Ends when	The final case version is submitted to the required recipients, the acknowledgement is stored and the case file is archived.
Inputs	Source document (email, form, call note, literature article, partner report), Product and licence information, Safety database dictionaries and coding conventions, Reporting rules by country and report type, Follow-up responses from reporters
Outputs	Registered and triaged intake record, Valid or invalid case decision, Coded case with narrative, Assessment of seriousness, causality and expectedness, Medically reviewed case, Submitted case with authority acknowledgement, Archived case file
Volume	About 9,800 incoming reports a year, of which about 6,400 become valid cases and about 2,100 are serious
Working hours	Monday to Friday 08:00 to 17:00 CET. A duty processor covers the safety inbox at weekends for serious reports, and the clock for any case starts on the day of first receipt by any employee, not the next working day.

3. Roles and responsibilities

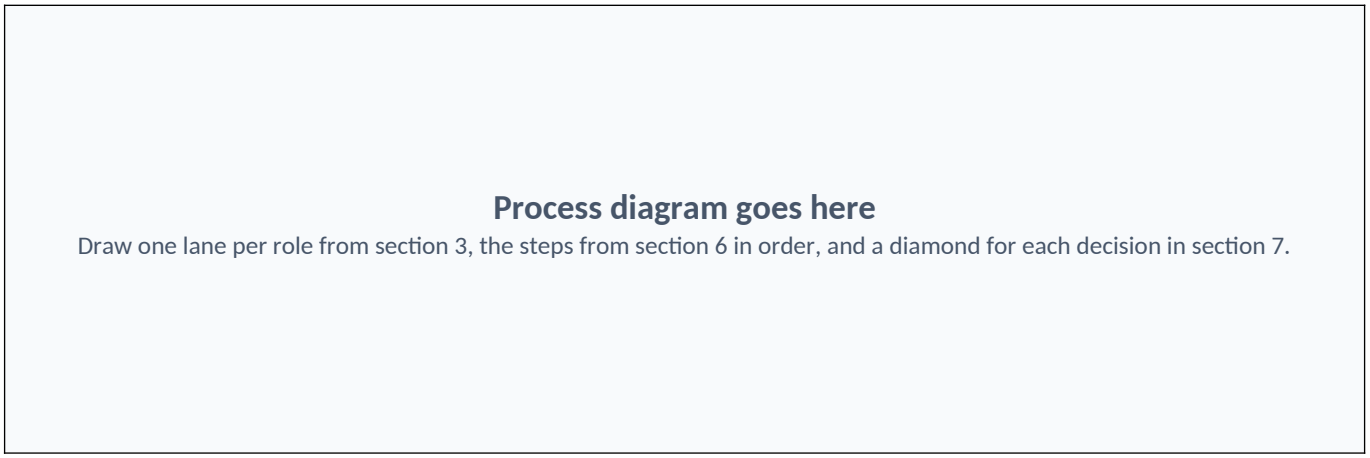
Role	Responsibilities
Case Intake Coordinator	Monitors the safety inbox and hotline, registers every source document, stamps the receipt date, triages by seriousness and sends obvious non-cases back to the sender.
Case Processor	Searches for duplicates, checks the four minimum criteria, enters and codes the case, writes the narrative, requests follow-up and prepares the case for review.
Safety Physician	Confirms seriousness, reviews causality and expectedness against the reference safety information, edits the company comment and approves the case for submission.
Regulatory Submissions Specialist	Applies the reporting rules, schedules and sends submissions to authorities and partners, monitors acknowledgements and handles rejected transmissions.

Role	Responsibilities
Quality Contact	Samples cases for quality review, tracks compliance with the reporting clock, logs deviations and supports audits and inspections.
Affiliate Safety Representative (external)	Receives reports in the local language, forwards them to the central team within the agreed time and answers follow-up questions in the country.
Reporter (external)	A healthcare professional, patient or partner who supplied the report and who may be asked for more information.

4. Systems

- Argus Safety: safety database for cases, coding, assessment and submissions
- MedDRA and WHODrug dictionaries, loaded in the safety database
- Shared safety mailbox and 24-hour hotline
- Veeva Vault QMS: deviations and quality review records
- EudraVigilance gateway and national authority portals
- SharePoint: intake tracker, reference safety information and archive index

5. Process map



6. Procedure, step by step

#	Step	Who	What happens	System	Output
1	Register the source document	Case Intake Coordinator	Logs each report that arrives by email, form, call or partner exchange, records the sender, product and channel, and stamps the date the company first received it. Reports that reach other departments are forwarded the same day, and the date of first receipt by any employee is kept.	SharePoint intake tracker, safety mailbox	Intake record with day zero
2	Triage by seriousness and urgency	Case Intake Coordinator	Reads the report and flags anything that may be serious, involves death, a pregnancy or a product of special interest. Flagged reports go to the front of the queue and to the duty processor the same day. This takes 5 to 10 minutes.	SharePoint intake tracker	Priority flag, queue position
3	Screen out non-cases	Case Intake Coordinator	If the report carries no product of the company, no suspected reaction or only a	SharePoint intake tracker	Closed non-case, or case for

#	Step	Who	What happens	System	Output
			general enquiry (about 18% of intake), sends it to the right department and closes the record with a reason. Everything else moves on to case processing.		processing
4	Search for duplicates	Case Processor	Searches the database on patient initials or reference, age, sex, product, event and reporter. If a match is found (about 11% of reports), the new information is added to the existing case as a follow-up version rather than opened as a new case. This takes 5 to 15 minutes.	Argus Safety	New case, or follow-up to an existing case
5	Check the four minimum criteria	Case Processor	Confirms that the report names an identifiable reporter, an identifiable patient, a suspect product and a suspected reaction. If a criterion is missing (about 9% of reports), the case is kept open as invalid, the reporter is asked for the missing item and the clock starts when the fourth criterion is met.	Argus Safety	Valid case, or invalid case awaiting information
6	Enter the case data	Case Processor	Enters reporter, patient, product, dosing, event dates, outcome, medical history and concomitant medicines in the structured fields. Data are copied from the source and are not interpreted. This takes 25 to 45 minutes for a standard case.	Argus Safety	Entered case
7	Code events, products and history	Case Processor	Codes the reported terms to the current MedDRA version and the products to the drug dictionary, using the department's coding conventions. Terms that cannot be coded unambiguously are marked for the medical reviewer.	Argus Safety, MedDRA, WHODrug	Coded case
8	Write the narrative	Case Processor	Writes a chronological narrative in plain language that matches the structured data: what happened, when, what treatment was given and what the outcome was. A second processor reads complex narratives. This takes 10 to 20 minutes.	Argus Safety	Case narrative
9	Assess seriousness and expectedness	Case Processor	Proposes seriousness criteria and compares each event with the reference safety information in force, marking it as listed or unlisted. The proposal is not final until the safety physician confirms it.	Argus Safety, reference safety information	Proposed seriousness and expectedness
10	Perform the medical review	Safety Physician	Confirms or changes the seriousness, adds the causality assessment, checks coding and narrative against the source and writes the company comment. Serious cases are reviewed within 1 working day, non-serious cases within 3. If the case needs more information, it returns to the processor.	Argus Safety	Medically reviewed case, or request for information
11	Request follow-up information	Case Processor	For cases that are serious or of special interest, sends a targeted follow-up request through the affiliate or directly to the reporter, usually with a first reminder after 7 days and a second after 14 days. Each attempt is logged in the case. Non-serious cases get one request, if any.	Email, Argus Safety	Follow-up request sent, attempts logged
12	Answer the follow-up	Reporter	Supplies outcome, dates, test results or product details. About 45% of requests are	Email, phone	Follow-up information, or no

#	Step	Who	What happens	System	Output
	request		answered, and many arrive after the first submission. New information is processed as a new version of the case.		response
13	Determine reporting rules	Regulatory Submissions Specialist	Applies the reporting matrix to the case: which authorities and partners receive it, which timeline applies and what the due date is. The matrix lists the rules by country, report type and product and is checked against the applicable regulations at least every year and after every legislative change.	Argus Safety, SharePoint reporting matrix	Reporting schedule with due dates
14	Approve the case for submission	Safety Physician	Locks the final version after confirming that all open questions are answered or documented. No case leaves the database without this approval.	Argus Safety	Approved and locked case version
15	Submit to authorities and partners	Regulatory Submissions Specialist	Generates the electronic report and transmits it before the due date. Cases that cannot be sent electronically are sent by the route the authority accepts and the route is recorded.	Argus Safety, EudraVigilance gateway, national portals	Transmitted report
16	Check acknowledgements and rejections	Regulatory Submissions Specialist	Checks that each transmission was acknowledged. Rejected reports (about 3%) are corrected the same day and resent, and the new date is recorded with the reason. Otherwise the acknowledgement is attached to the case.	Argus Safety, EudraVigilance gateway	Acknowledgement stored, or corrected resubmission
17	Sample cases for quality review	Quality Contact	Reviews a sample of cases each month, with every case that was submitted late reviewed in full. Errors in coding, dates or narrative are logged and sent to the case processor as a correction. A late submission opens a deviation with a cause.	Argus Safety, Veeva Vault QMS	Quality review result, deviation if needed
18	Archive the case file	Case Processor	Stores the source documents, the correspondence with the reporter, the acknowledgements and the audit trail with the case and links them in the archive index. The case file stays retrievable for the period required for the product.	Argus Safety, SharePoint archive	Archived case file

7. Decision points and business rules

- Is the report about a product of the company with a suspected reaction? No (about 18% of intake): route it to the right department and close the record (step 3).
- Is there already a case for this patient and event? Yes (about 11% of reports): add the information as a follow-up version (step 4).
- Are all four minimum criteria met? No (about 9% of reports): keep the case invalid and ask the reporter for the missing item (step 5).
- Is the event serious or of special interest? Yes (about 32% of valid cases): the case moves to the front of the queue and is reviewed within 1 working day (steps 2 and 10).
- Is the event listed in the reference safety information? No: it is unexpected, and the reporting rules for unexpected serious cases apply (steps 9 and 13).
- Does the case need more information before it can be assessed? Yes: a follow-up request goes to the reporter (steps 10 and 11).

- Was the transmission acknowledged? No (about 3%): correct and resend the same day (step 16).

8. Exceptions

- A report arrives on a Friday evening through a partner (a few per month): the duty processor registers it over the weekend so that the clock is not lost.
- A report reaches a sales representative or another employee instead of the safety inbox: the employee forwards it the same day, and day zero is the day that employee received it.
- A literature article describes several patients: one case is opened per identifiable patient, all sharing the same source.
- The reporter cannot be reached after the planned attempts: the case is closed with the attempts documented and is submitted with the information available.
- The safety database is unavailable: the intake coordinator keeps the paper log and the cases are entered with the original receipt date once the system returns.

9. Controls

- Every report is registered with its date of first receipt, and the date is never changed after the fact.
- The processor who enters a case cannot approve it for submission. The safety physician approves every final version.
- The reporting matrix is checked against the applicable regulations at least once a year, and every change is recorded.
- Late submissions are reviewed individually and each opens a deviation with a cause and an action.
- The safety database keeps an audit trail of every change. Coding versions are updated on a fixed schedule and the update is documented.
- Contracts with partners and affiliates state how fast they forward reports, and the forwarding time is measured.
- Case files are archived with source documents and acknowledgements so that any case can be retrieved during an inspection.

10. Known issues today

- Reports sit in individual inboxes of sales and medical staff before they reach the safety team, which shortens the time left in the clock.
- Duplicates are found late because partners send the same report with different references.
- Processors retype data from PDFs and call notes, and typing mistakes surface only at medical review.
- Follow-up responses arrive after submission and are processed in the wrong order, which creates version confusion.
- The reporting matrix lives in a spreadsheet that few people can interpret, so due dates are sometimes set manually.

11. RACI matrix

R = responsible (does the work), A = accountable (owns the outcome), C = consulted, I = informed.

Activity	Intake Coordinator	Case Processor	Safety Physician	Submissions	Quality Contact
Register and triage incoming reports	A/R	C	I		
Check duplicates and validity	I	A/R	C		

Activity	Intake Coordinator	Case Processor	Safety Physician	Submissions	Quality Contact
Enter, code and write the narrative		A/R	C		I
Assess seriousness and expectedness		R	A		
Medical review		C	A/R		
Follow-up requests	I	A/R	C		
Submit and check acknowledgements		I	C	A/R	I
Quality review and deviations		C	C	C	A/R
Archive the case file		A/R		I	I

12. KPIs

KPI	Definition	Target
Timely submission rate	Share of cases submitted on or before the due date set by the applicable reporting rules. The target is 100% for serious cases and at least 98% overall.	[set]
Intake to registration time	Working hours from a report reaching the company to the intake coordinator registering it. The target is under 4 working hours.	[set]
Medical review turnaround	Average working days from a case being ready for review to the safety physician approving it, split by serious and non-serious cases.	[set]
Follow-up response rate	Share of follow-up requests that receive an answer, measured per source type. It shows which channels are worth chasing.	[set]
Case quality error rate	Share of sampled cases with a coding, date or narrative error found in quality review. The target is under 3%.	[set]
Rejected transmissions	Share of submitted reports that the authority gateway rejected on first attempt.	[set]

13. Revision history

Version	Date	Author	Change
1.0	[date]	[name]	First as-is version

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