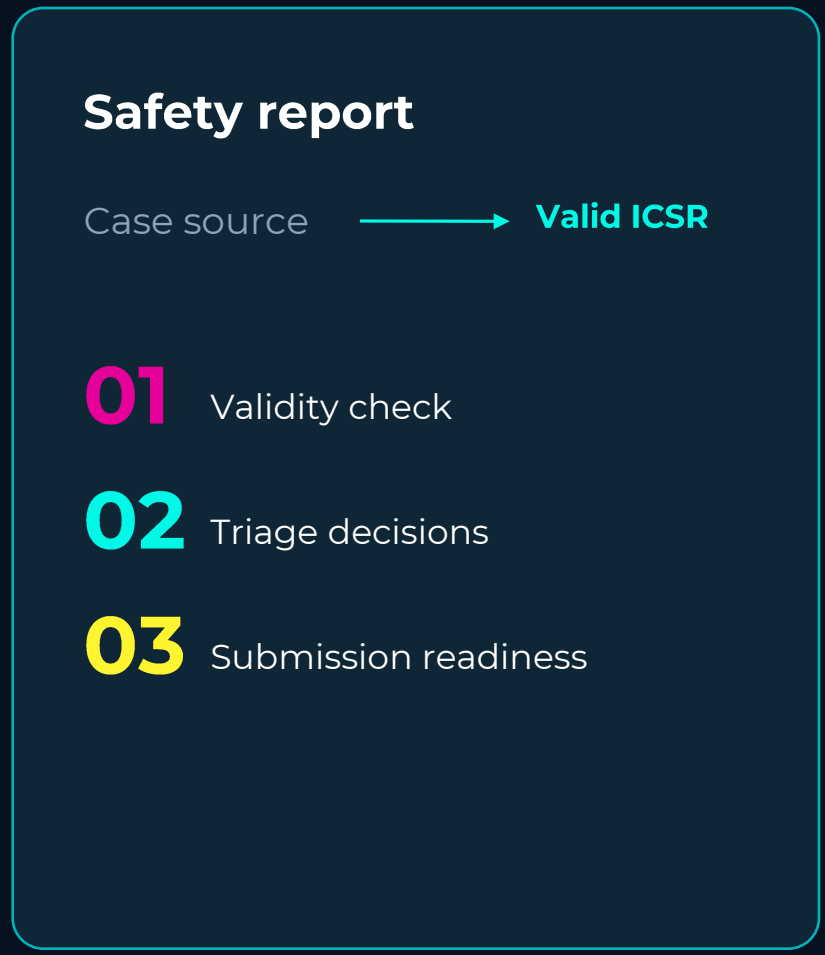
ICSR CASE PROCESSING WORKFLOW

Validity, triage and submission checklist for pharmacovigilance teams

DOWNLOADABLE GUIDE

PHARMACOVIGILANCE

Use this deck to train new PV team members or prepare for case-processing interviews.



Start with the four validity criteria

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A report becomes a valid ICSR only when all minimum information elements are present.

1

Identifiable patient

A patient can be distinguished by age, sex, initials, date of birth or another marker.

2

Identifiable reporter

The source exists and can be reasonably identified by the organisation.

3

Suspected product

A medicine, vaccine or relevant therapeutic product is suspected.

4

Adverse event

A medical occurrence, reaction or safety concern is described.

Missing one element? Document it, follow up, but do not treat it as a valid ICSR yet.

Where do ICSRs come from?

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Replace generic definitions with concrete report sources learners actually meet.

Unsolicited reports

- Healthcare professional reports
- Consumer or patient reports
- Medical information contacts
- Product complaints with AE data

Organised sources

- Clinical trials
- Post-authorisation studies
- Patient-support programmes
- Market research activities

External feeds

- Literature screening
- Regulatory authorities
- Business partners
- Digital media monitoring

Tip: source type affects follow-up, documentation and reporting procedure.

ICSR processing from intake to closure

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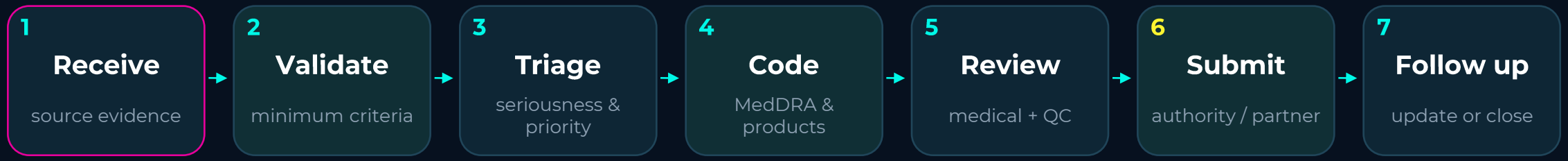
Show the workflow as controlled decisions, not a single data-entry task.



Process rule **Every handover must preserve source documents, decision rationale and audit trail.**

Separate the key ICSR decisions

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A valid ICSR is not automatically serious, unexpected, causally related or reportable.

Decision	Main question	Why it matters
Validity	Are the four minimum criteria present?	Creates a case record
Seriousness	Does it meet seriousness criteria?	Changes priority and timeline
Expectedness	Is the reaction listed or expected?	Supports expedited reporting
Causality	Is there a suspected relationship?	Supports medical assessment
Reportability	Must this case be submitted?	Depends on region and case type

Day zero and initial triage

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Early triage protects timelines and ensures the right review path.

Day zero

The reporting clock generally starts when the organisation first has a valid ICSR.

- Document the receipt date and source.
- Confirm whether the case is valid.
- Escalate serious cases quickly.
- Apply the local SOP and market rules.

Initial triage asks:

1. Is the case serious?
2. Is it expected?
3. Is the product marketed or investigational?
4. Is expedited submission required?
5. What follow-up is missing?

Coding and narrative writing make the case usable

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Good ICSR quality depends on structured coding and a clear medical story.

MedDRA coding

- Select terms that reflect the reported event.
- Code procedures, tests and outcomes consistently.
- Avoid changing the reporter's meaning.
- Keep coding decisions traceable.

Case narrative

- Write a chronological safety story.
- Separate facts from assumptions.
- Include product, event, dates and outcome.
- Highlight important missing information.

Quality target: another reviewer should understand the case without searching across scattered records.

Medical review and QC before submission

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Submission-ready cases need both clinical judgement and technical quality checks.

Medical review

- Causality rationale
- Seriousness logic
- Listedness context
- Clinical coherence

Quality control

- Required fields
- Date consistency
- Coding checks
- Narrative match

Ready to submit

No unexplained gaps

Follow-up, duplicates and nullification

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End-of-case actions must be controlled and fully traceable.

Follow-up

Request missing data. Update the case when new information changes the assessment.

Duplicate management

Compare patient, reporter, product, event, dates and source before consolidation.

Amendment

Update submitted information when new details become available. Keep audit trail.

Nullification

Use only when a submitted case should no longer exist as a valid case.

Never close uncertainty without a documented reason.

One-page submission-readiness checklist

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Use this as the closing downloadable item for the article.

- ✓ Minimum criteria confirmed
- ✓ Source documents saved
- ✓ Day zero recorded
- ✓ Duplicate search completed
- ✓ Seriousness assessed
- ✓ Expectedness checked
- ✓ Causality rationale documented
- ✓ MedDRA coding reviewed
- ✓ Narrative matches case data
- ✓ Follow-up needs recorded
- ✓ QC completed
- ✓ Submission route confirmed

Use it to review case validity, triage decisions and submission readiness before final QC.

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