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Pharmacovigilance and Safety Reporting: Practical Guidance for Category A Clinical Trials with Investigational Medicinal Products

Publication date
This guidance was first released in October 2025

Publisher
Swiss Clinical Trial Organisation (SCTO)
Bern, Switzerland

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Recommended form of citation
Safety Platform of the Swiss Clinical Trial Organisation (SCTO) (2025). Pharmacovigilance and Safety Reporting - Practical Guidance for Category A Clinical Trials with Investigational Medicinal Products. Edited by the SCTO.
doi: 10.54920/SCTO.2025.01

Acknowledgements
The Safety Platform thanks the Regional Pharmacovigilance Centre of Southern Switzerland and the Centre Régional de pharmacovigilance in Geneva for their careful and constructive review of this document.

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Introduction

Category A clinical trials on Investigational Medicinal Products (IMPs) are low-risk studies involving authorised drugs used within their approved indication, dosage, and population. They require authorisation from the Ethics Committee only; Swissmedic authorisation is not needed. Such studies are typically conducted by Sponsor-Investigators, often hospital physicians, who use medicines from hospital stock rather than specially manufactured study drugs. Even though these products are authorised and used as indicated, adverse event management and reporting remain mandatory —just as they are in routine clinical practice when using approved medicines— to ensure patient safety and regulatory compliance. For this reason, Sponsor-Investigators must comply with both the reporting obligations defined under the Clinical Trials Ordinance (ClinO) and those under the Therapeutic Products Act (TPA), which governs post-marketing vigilance.

The purpose of this practical guidance is to clarify the specific regulatory requirements and reporting procedures that apply to Category A Clinical Trials on IMPs.

Definitions

Pharmacovigilance (PV) is defined as the science and set of activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. Its purpose is to ensure that medicines are safe for their intended use.

In clinical trials, PV ensures continuous evaluation of the benefit–risk balance of investigational medicinal products. For this reason, understanding how adverse events (AEs) are managed and reported is essential.

Adverse Event (AE): Any untoward medical occurrence in a clinical trial participant, which does not necessarily have a causal relationship with the study intervention or its comparator.

Serious Adverse Event (SAE): An AE is considered *serious* if it meets at least one of the following criteria:

- Results in death
- Is life-threatening
- Requires hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Is medically important*

*Medically Important Event: An event which, while not immediately life-threatening, may require medical intervention to prevent serious outcomes.

Adverse Drug Reaction (ADR): If a causal relationship between an AE and the investigational product can be established, the AE is classified as an ADR.

Suspected Unexpected Serious Adverse Reaction (SUSAR): An AE that is simultaneously serious, drug-related, and unexpected. “Unexpected” means that the nature or severity of the event is inconsistent with the reference safety information of the Investigator’s Brochure for investigational products or the Summary of Product Characteristics (SmPC)/Fachinformation for authorised medicines.

Documentation, reporting and safety updates

The documentation and reporting of AEs in clinical drug trials are strictly regulated under the Swiss Human Research Act (HRA) and the Clinical Trials Ordinance (ClinO). Requirements vary depending on the type and severity of the event, as well as the trial category.

Documentation in Category A Trials

Documentation in clinical trials refers to recording events in the case report form (CRF). Investigators are not required to document AEs; however, they must record all SAEs in the CRF.

Reporting in Category A Trials

Reporting to Sponsor

The investigator must notify the sponsor of any Serious Adverse Event (SAE) within 24 hours.

Reporting to Swiss Authorities

Depending on the study setup—whether single-centre or multicentre—the reporting to Swiss authorities may be carried out either by the local investigator or by the Sponsor-Investigator.

In all cases, the following events occurring in Switzerland must be reported:

1- to the Ethics Committee (EC), in accordance with Article 41(4) of the Clinical Trials Ordinance (OClin)

- **Serious, Unexpected, and Related Adverse Events (SUSARs) within 7 days if fatal/ life-threatening, all other cases within 15 days.**

2- to the Safety of Medicines Department at Swissmedic, in accordance with the provisions of Art. 59 TPA (Art. 41 para. 4 ClinO)/ Ordinance on Medicinal Products (OMed), Art.63:

- Serious Adverse Drug Reactions (SADRs), whether expected or unexpected, within 15 days
- Unexpected, non-serious Adverse Drug Reactions (ADRs) within 60 days.

Reporting to the Safety of Medicines Department at Swissmedic is done via the **ElVis platform** (https://www.swissmedic.ch/swissmedic/en/home/services/egov-services/elvis.html) or by contacting a regional pharmacovigilance centre, which are located in Basel, Geneva, Lausanne, Lugano and Zürich.

In the free-text field "Other comments," the following must be specified: *Category A study, #Study name#*.

Reports from healthcare professionals are evaluated in the Swissmedic National Pharmacovigilance Centre and, if reports involve an important safety signal, in the regional pharmacovigilance centres. The primary reporter receives a confirmation of receipt of the report and a written medical expert evaluation if the report was forwarded to a regional centre for processing.

Based on the evaluation, Swissmedic decides whether the report reveals new safety information and if any risk minimisation measures are required. Each report is also forwarded to the manufacturer and to the international centre for drug safety at the World Health Organization (WHO). Swissmedic is an active member of the Programme for International Drug Monitoring. All submitted reports help increase understanding of potential risks and contribute to improving patient safety.

More information on pharmacovigilance and the ElViS reporting portal is available at swissmedic.ch. Swissmedic clarifies that the term **SUSAR** should only be used for Category B and C trials, and not for adverse events observed in the post-marketing setting. In the case of an unexpected, fatal, or life-threatening **Serious Adverse Drug Reaction (SADR)** in a Category A trial, reporting to Swissmedic within **15 days** is acceptable (in accordance with Art. 41(4) OClin, Art. 59(1–3) TPA, and Art. 62(1)(a) Ordinance on Medicinal Products, OMed) (Swissmedic FAQ). (See Table 1: Summary Table).

Annual Safety and General Progress Trial Report (ASGPR/ DSUR)

Annual reporting to the authorities is mandatory for all interventional trials conducted under ClinO and ClinO-MD. Therefore, once a year, starting from the date of study approval and throughout the duration of the trial, the Sponsor-Investigator of a Category A study must submit a report to the competent Ethics Committee. This report must include a safety evaluation—which comprises a list of all SAEs that occurred during the study—as well as a general overview of the trial's progress.

The final ASGPR or DSUR must cover the last patient's last visit (LPLV) in Switzerland for the trial. No further reporting is required after the LPLV, as the safety information will be included in the clinical study report.

Conclusions

New safety findings from category A studies may directly impact the benefit–risk profile of medicinal products already in routine clinical use. The additional safety knowledge gained is not only a regulatory requirement, but also a valuable contribution to improving patient care—and a central reason for conducting these studies.

The following table summarises key safety documentation and reporting requirements in Category A trials.

Event	Who	To whom	When
SAE	Investigator	Sponsor	24 h
SUSAR	Sponsor-Investigator	Ethics Committee	7 days (fatal/life-threatening) 15 days
SADR	Sponsor-Investigator	Swissmedic PV	15 days
ADR	Sponsor-Investigator	Swissmedic PV	60 days
ASGPR	Sponsor-Investigator	Ethics Committee	Every year

Need support? We are here to help

If you have questions or require assistance with safety reporting, the **Safety Platform of the Swiss Clinical Trial Organisation (SCTO)** offers expert guidance and operational support.

For additional assistance, don't hesitate to reach out to your **Regional Pharmacovigilance Centre**—they are available to help with practical questions and submissions.

References

- Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA)
- Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance, ClinO)
- Ordinance on Licensing in the Medicinal Products Sector (Medicinal Products Licensing Ordinance, MPLO / OAMéd)
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). E6(R3) Guideline for Good Clinical Practice – Principles and Annex 1

Appendix: Overview for Categories B and C (for reference only)

Documentation of AE according to ClinO (Art. 39)

- **Category C trials:**

Investigators must document all AEs in both the patient file and the case report form (CRF). The sponsor may exempt certain non-critical events (e.g., frequent disease-related AEs) if justified in the protocol.

- **Category B trials:**

Investigators must document AEs in the CRF if:

a) They are considered critical for safety evaluation in the protocol, or

b) Required by the regulatory authorities.

Reporting of SAEs and SUSARs in Category B & C Trials

During a clinical trial, the investigator must notify the sponsor within 24 hours of any Serious Adverse Event (SAE). If an SAE is classified as a SUSAR, it must be reported to the competent authorities. The investigator must inform the Ethics Committee, and the sponsor is responsible for notifying Swissmedic.

SUSARs that result in death or are life-threatening must be reported within 7 days. All other SUSARs must be reported within 15 days.

It should be noted that reporting a SUSAR remains mandatory even if the investigator or sponsor becomes aware of it after the trial has ended, provided that the event occurred during or after the clinical trial (see Table 1: Summary).

Annual Safety and General Progress Trial Report

For Category B and C trials, this document must also be submitted by the sponsor to Swissmedic.

Event	Who	To whom	When
AE	Investigator	CRF	*Timely manner*
SAE	Investigator	Sponsor	24h
SAE (line listing)	Sponsor	EC & Swissmedic	1x/years in the ASGPR
SUSAR	Investigator Sponsor	Ethic Committee Swissmedic	15 days 7 days (fatal/life-threatening)
ASGPR	Investigator Sponsor	Ethic Committee Swissmedic	Every year