

Safety Expert Finder

Participant safety is of utmost importance and must be considered throughout the conduct of a clinical study.

Need support with safety management?

The Safety Expert Finder provides an overview of the key safety processes and helps you quickly identify the right experts and resources to address your safety questions. We are happy to provide advice free of charge. Any collaboration beyond this may be considered a chargeable service of the Clinical Research Center (CRC) contacted or the Swiss Cancer Institute, and you will be informed in advance.

Bringing safety experts on board can lead to safer clinical research studies.

Contact us for advice or to initiate cooperation: safety@scto.ch

1. Preparation and review of safety-specific study documents

We can help you with the preparation, review, or study-specific adaptation of the following important safety management documents.

1.1. Protocol

We can advise you on how to complete the safety section of your study protocol, for example:

- which adverse events (AEs) to collect and for which period of time
- which grading system for severity and causality to use and how to assess AEs
- which safety reporting procedures to follow.

Get in touch with a safety expert

All of the safety experts in our Network can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

1.2. Information and consent form

We can advise you on how to complete the risks and discomfort section of your information and consent form, for example which adverse events (AEs) you should list when informing your participants.

Get in touch with a safety expert

All of the safety experts in our Network can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

1.3. (Serious) adverse event forms

We can advise you on how to prepare your study-specific adverse event (AE) and serious adverse event (SAE) forms both for case report forms (CRFs) and source documents. For SAE reporting, we can also provide templates.

Get in touch with a safety expert

All of the safety experts in our Network can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

1.4. Safety management plan (SMP) (for extensive trials)

A safety management plan (SMP) defines all the safety-related activities of a study (e.g. serious adverse event (SAE) and suspected unexpected serious adverse reaction (SUSAR) processing, responsible persons, communication lines, documentation requirements, timelines, and unblinding).

We can advise you on how safety reporting and safety management can be organised in your study with respect to allocated responsibilities as well as legal and contractual obligations (e.g. reporting timelines, contacts, allocation of responsibilities, who reports to whom, communication flow, query management, monitoring, oversight of reports, and reporting). We can also help you write a comprehensive safety management plan.

Get in touch with a safety expert

The safety experts from the CTU HOCH St. Gallen, CTU-EOC Lugano, CRC Lausanne, CRC Geneva and the Swiss Cancer Institute can support you on this topic. Contact us for advice or to initiate co-operation (safety@scto.ch).

1.5. Agreements

We can help you set up and/or review any agreement required to define responsibilities and obligations with respect to the procedures for collecting, processing, evaluating, reporting, and exchanging safety information (e.g. a safety data exchange agreement).

Get in touch with a safety expert

The safety experts from the CRC Geneva, CTU-EOC Lugano, CTU HOCH St. Gallen and the Swiss Cancer Institute can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

1.6. Data safety monitoring board (DSMB)

We can help you set up a data safety monitoring board (DSMB), which is an independent group of experts that regularly reviews your study's safety and, when appropriate, efficacy data. Further, we can provide support on writing a DSMB charter in which duties of the DSMB and timelines are defined.

Get in touch with a safety expert

The safety experts from the DKF Basel, CRC Geneva, CRC Lausanne and the CTU-EOC Lugano can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

1.7. Investigator's brochure (IB)

We can help you prepare the safety-related parts of your investigator's brochure (IB): Adverse event (AE) listing, a summary of data, and guidance for the investigator part, which includes a reference safety information (RSI) section.

We can write the IB on your behalf.

Get in touch with a safety expert

The safety experts from the CRC Lausanne can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

2. Case handling

We can help you from start to finish with the handling of safety events that occur in your study.

2.1. Triage

We can advise you on how to ensure that cases requiring expedited reporting are submitted to the ethics committee and regulatory authorities within applicable timelines. You can request services for the registration and assessment of each incoming event.

Get in touch with a safety expert

The safety experts from the DKF Basel, CRC Geneva, CRC Lausanne, CTU-EOC Lugano, CTU HOCH St. Gallen, CTC Zürich, and the Swiss Cancer Institute can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

2.2. Medical assessment

On behalf of the sponsor, we can provide a medical assessment and review each incoming event with regard to causality, severity, seriousness, and expectedness.

Get in touch with a safety expert

The safety experts from the DKF Basel, CRC Geneva, CTU-EOC Lugano, CTC Zürich and the Swiss Cancer Institute can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

2.3. Data entry

We can advise you on how to enter incoming reportable events into a case report form (CRF) and how to record serious adverse events (SAEs) on a specific line listing.

We can manage data entry on your behalf. We can also maintain all SAEs, other reportable events, and any follow-up communication with any information to or from the sponsor or authorities in the trial master file (TMF).

Get in touch with a safety expert

The safety experts from the DKF Basel, CRC Geneva, CRC Lausanne, CTU HOCH St. Gallen, CTC Zürich, and the Swiss Cancer Institute can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

2.4. Narrative writing

We can advise you on how to write a short description (“narrative”) of all serious adverse events (SAEs), all adverse events (AEs) leading to discontinuation, and AEs of special interest that occur during your trial. These narratives are included in your final clinical study report (CSR).

Get in touch with a safety expert

The safety experts from the DKF Basel, CRC Geneva, CRC Lausanne, CTU-EOC Lugano, CTU HOCH St. Gallen, CTC Zürich, and the Swiss Cancer Institute can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

2.5. Query management

We can advise you on how to ensure the completeness and accuracy of all cases. We can also manage queries on your behalf. In the event of missing information or discrepancies, we issue queries and send them to the reporter. Once the reply is received, we update or amend data accordingly.

Get in touch with a safety expert

The safety experts from the DKF Basel, CTC Geneva, CRC Lausanne, CTU-EOC Lugano, CTU HOCH St. Gallen, CTC Zürich, and the Swiss Cancer Institute can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

3. Medical coding

We can advise you on how to record events in an internationally standardised manner.

We can register cases and inform authorities, investigators, and others on your behalf about events that occur during a clinical trial using internationally standardised medical terminology (e.g. CTCAE or MedDRA, see below) in order to facilitate information sharing and enable meaningful analysis.

3.1. Common Terminology Criteria for Adverse Events (CTCAE)

The Common Terminology Criteria for Adverse Events (CTCAE) is a descriptive terminology resource that can be used for adverse event (AE) reporting. It is published by the US National Cancer Institute (NCI) and describes the severity of organ toxicity for patients receiving cancer therapy, but it can be used for other indications as well (e.g. in the areas of internal medicine and infectious diseases). A grading scale (severity) is provided for each AE term. It incorporates certain elements of MedDRA terminology.

Get in touch with a safety expert

The safety experts from the DKF Basel, CRC Geneva, CRC Lausanne, CTU-EOC Lugano, CTU HOCH St. Gallen, CTC Zürich, and the Swiss Cancer Institute can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

3.2. Medical Dictionary for Regulatory Activities (MedDRA)

The Medical Dictionary for Regulatory Activities (MedDRA) is a standard, international medical terminology resource developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The MedDRA can be used to code different medical concepts such as symptoms, diseases, diagnoses, and therapeutic indications as well as health effects and device malfunction.

Get in touch with a safety expert

The safety experts from the DKF Basel, CRC Geneva, CRC Lausanne, CTU-EOC Lugano, CTC Zürich, and the Swiss Cancer Institute can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

3.3. Electronic case report forms (eCRFs) with integrated adverse event (AE) catalogues

We can provide electronic case report forms (eCRFs) with integrated catalogues for adverse event (AE) assessment so that you can directly select a term.

Get in touch with a safety expert

The safety experts from the DKF Basel, DCR Bern, CRC Geneva, CRC Lausanne, CTU HOCH St. Gallen, CTC Zürich, and the Swiss Cancer Institute can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

4. Expedited reporting

Certain events (SAEs, SADEs, SUSARs, etc.) require prompt reporting to the sponsor/sponsor-investigator and expedited reporting to the authorities (e.g. Swissmedic, the ethics committee, and other authorities as needed) in order to meet the legally required timelines. We can advise you on the correct procedure.

We can also report these events on your behalf using specific forms and channels.

4.1. To sponsor-investigator/sponsor

We have developed a set of comprehensive forms for serious adverse event (SAE) collection and reporting from the investigator to the sponsor-investigator as well as for sponsor-investigator case assessment. You can download the safety reporting forms for free from the SCTO Tool Finder.

Get in touch with a safety expert

All of the safety experts in our Network can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

4.2. To ethics committee (via BASEC)

We use the dedicated safety reporting portal (safety form) BASEC (Business Administration System for Ethics Committees) for the notification of any safety reports and immediate safety and protective measures to the concerned ethics committee(s) (EC(s)).

Get in touch with a safety expert

All of the safety experts in our Network can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

4.3. To Swissmedic

We report and can report on your behalf the following to Swissmedic:

1. Suspected unexpected serious adverse reactions (SUSARs) and safety measures occurring in category B and C clinical trials of investigational medicinal products (IMPs) via electronic submission and eDok folder structure
2. Serious adverse device effects (SADEs) and device deficiencies with SAE potential and safety measures occurring in category C clinical trials of medical devices via Swissmedic's eMessage portal and clinicaltrials.devices@swissmedic.ch
3. Serious adverse drug reactions (SADRs), unexpected ADRs, and SUSARs occurring in category A clinical trials of IMPs via the online ELViS (Electronic Vigilance System) portal; for this type of trial, pharmacovigilance rules apply
4. Serious incidents occurring in category A clinical trials of investigational medical devices (IMDs), and of in vitro device (IVD) performance studies via materiovigilance@swissmedic.ch; for this type of trial, materiovigilance rules apply
5. Safety events occurring in clinical trials with transplant products (TrP), gene therapy (GT) medicinal products, or products containing genetically modified organisms (GMOs) via biovigilance@swissmedic.ch

Get in touch with a safety expert

All of the safety experts in our Network can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

5. Annual reports

We can advise you on how to write the required annual safety report, a concise summary of your ongoing study status, including all relevant safety information.

We can write it on your behalf.

5.1. Annual Safety and General Progress Trial Report

Annual reporting is mandatory for all trials conducted under ClinO and ClinO-MD regulations, namely all types of interventional studies. The report must include both an evaluation of participant safety and a general overview of the clinical trial's progress; it must be submitted once per year to the Ethics Committee (EC) and, where applicable, to Swissmedic (i.e., for studies classified as risk category B or C).

Swissethics, the Swiss Association of Research Ethics Committees, has developed templates for writing the Annual Safety and General Progress Trial Report for clinical trials according to Swiss regulations. These templates can be used for Investigator initiated trials (IITs) and can be downloaded from <https://swissethics.ch/en/templates/meldungen>

We can write it on your behalf.

Get in touch with a safety expert

All of the safety experts in our Network can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

5.2. Development safety update report (DSUR) for EU trials on investigational medicinal products (IMPs)

A development safety update report (DSUR) is the mandatory format for clinical trials with investigational medicinal products (IMPs) in European Union member states. DSUR is also accepted by Swiss Ethics Committees and Swissmedic but it only covers the safety reporting obligation. It means that if you have a DSUR for your trial, you still need to submit the progress report (see above, **Annual Safety and General Progress Trial Report**).

We can write it on your behalf.

Get in touch with a safety expert

The safety experts from the DKF Basel, CRC Geneva, CTU-EOC Lugano, CTU HOCH St. Gallen, and the Swiss Cancer Institute can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

6. International studies

Some local experts have international safety experience and can also report on your behalf to the following:

- Austrian ethics committees (ECs) and competent authorities (CTU HOCH St. Gallen only)
- German ethics committees (ECs) and competent authorities (CTU HOCH St. Gallen only)
- EudraVigilance (Swiss Cancer Institute only)

Get in touch with a safety expert

Contact us for advice or to initiate cooperation (safety@scto.ch).

7. Clinical study report (CSR)

We can advise you on how to write the safety part of the clinical study report (CSR) for your clinical trial, in which you have to:

1. describe the overall adverse event experience, including the frequency, rate, and occurrence of all adverse events, as well as each death, all serious adverse events (SAEs), and other significant adverse events
2. provide tabular categorisation and line listings of SAEs

We can review this information or write it on your behalf.

Get in touch with a safety expert

All of the safety experts in our Network can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).

8. Publications

We can advise you on how to prepare the safety part of individual papers.
We can also review the safety part or write it on your behalf.

Get in touch with a safety expert

All of the safety experts in our Network can support you on this topic. Contact us for advice or to initiate cooperation (safety@scto.ch).