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Swissmedic GCP Inspections
Report 2022-2024

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Abbreviations

AE	Adverse Event
ALCOAC	Attributable, Legible, Contemporaneous, Original, Accurate, Complete
CRF	Case Report Form
CTU	Clinical Trial Unit
eCRF	electronic Case Report Form
EMA	European Medicines Agency
FDA	Food and Drug Administration
FIH	First in Human
FOPH	Federal Office of Public Health
FTS	File Transfer Service
GCP	Good Clinical Practice
HRA	Human Research Act
ICF	Informed Consent Form
IDMC	Independent Data Monitoring Committee
IMP	Investigational Medicinal Product
PI	Principal Investigator
PMDA	Pharmaceuticals and Medical Devices Agency
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
USA	United States of America

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Executive Summary

This report provides a comprehensive overview of Good Clinical Practice (GCP) inspections conducted in Switzerland between 2022 and 2024. The inspections focused on clinical trials involving medicinal products, excluding medical devices and advanced therapy medicinal products. The primary objective of these inspections is to ensure the protection of trial participants' rights, safety, and well-being, as well as the reliability of clinical trial data. The report highlights Swissmedic's intensified monitoring efforts following recommendations from the Federal Office of Public Health (FOPH) in 2019 to strengthen surveillance of clinical trials. Over the three-year period, Swissmedic conducted 114 inspections, including routine and for-cause inspections, as well as participation in inspections by foreign authorities of the USA, the European Union and Japan in Switzerland. In total, 139 clinical trials were inspected during these three years.

Between 2022 and 2024, inspections were predominantly routine, with only a few for-cause inspections conducted in 2024. The total number of inspections increased steadily from 34 in 2022 to 42 in 2024. On-site inspections were the most common, while remote inspections dropped in number to a single one in 2024. Inspections of commercially sponsored trials rose significantly over this period, from 19 in 2022 to 30 in 2024, whereas inspections of academic trials remained largely stable at around 12 per year.

In terms of findings, the majority were categorised as major, while critical findings stabilised in 2023 and remained at a similar level in 2024. Academic sponsors recorded a much higher proportion of critical findings in 2024 (58.3%) compared to commercial sponsors (16.7%). Key challenges for academic sponsors were observed in areas such as computer validation and quality management systems. Critical findings related to the safety evaluation were most frequently associated with Phase IV trials, followed by Phase II and First-in-Human studies.

The imposition of administrative measures initially increased in 2023 but decreased again in 2024, with academic sponsors being more frequently affected than commercial sponsors. The most common findings included deficiencies in safeguarding participant safety, monitoring processes, source documentation, and organisational structures and personnel. Specific examples were delayed safety evaluations, insufficient training, and non-compliance with monitoring plans.

The report underscores the importance of robust quality management systems and sponsor oversight to address recurring deficiencies and ensure compliance with GCP standards.

A. Introduction

The Swiss Agency for Therapeutic Products (Swissmedic) is responsible for the authorisation and oversight of clinical trials with medicinal products and medical devices in Switzerland. To enforce the legislation on therapeutic products, Swissmedic can take administrative measures and initiate administrative proceedings. The basis for the activities of Swissmedic is the legislation governing therapeutic products[1]. The objective of Good Clinical Practice (GCP) inspections is to assess whether the rights, safety and well-being of trial participants in Switzerland are protected and whether the clinical trial data are reliable. This report provides an overview of GCP inspections conducted between 2022 and 2024 in clinical trials involving medicinal products[2].

As of 2022, Swissmedic continuously intensified the surveillance of clinical trials with medicinal products. This was a consequence of the publication of the report on the evaluation of the effectiveness of the Human Research Act by the Federal Office of Public Health (FOPH) [FOPH report of 6 December 2019 'Human Research Act (HRA): Results of the evaluation and next steps']. The report recommended the strengthening of the monitoring of ongoing studies through appropriate measures. Swissmedic's management decision in 2023 to intensify GCP inspections was a strategic move to enhance patient safety and ensure compliance with legal requirements.

[1] Federal Act on Medicinal Products and Medical Devices, TPA [SR 812.21], International Council for Harmonisation (ICH) Harmonised Tripartite Guideline – Guideline for Good Clinical Practice, ICH GCP E6, EU Guidelines to Good Manufacturing Practice, EudraLex Vol. 4, Annex 13 (Investigational Medicinal Products), Federal Act on Research involving Human Beings, HRA [SR 810.30], Ordinance on Clinical Trials with the exception of Clinical Trials of Medical Devices, ClinO [SR 810.305], Ordinance on Organisational Aspects of the Human Research Act, OrgO-HRA [SR 810.308].

[2] Not included are GCP inspections covering trials with medical devices and advanced therapy medicinal products.

B. Inspection metrics

This report covers the period of 1 January 2022 to 31 December 2024.
During this period, Swissmedic conducted a total of 114 GCP inspections. In the framework of this inspection programme, 139 clinical trials with medicinal products were inspected.

The number of GCP inspections comprises inspections carried out by Swissmedic as well as inspections by foreign authorities in Switzerland. Swissmedic GCP inspectors conduct two types of inspections: routine and for-cause. Routine inspections involve the selection of clinical trials based on predetermined risk criteria in the framework of the yearly planning. For-cause inspections are initiated if there is a suspicion of severe non-compliances that may impact the participants' safety or data integrity. Additionally, Swissmedic inspectors participate as observers in inspections conducted by foreign authorities in Switzerland (see Table 1).

Table 1: For-cause (suspicion of severe non-compliances) / Routine inspections (selection of clinical trials based on predetermined risk criteria)

Year	Routine	For-cause	Foreign governmental inspections	Total Swissmedic
2022	34	0	1	34
2023	38	0	6	38
2024	39	3	6	42

In 2022, the US Food and Drug Administration (FDA) was the only foreign authority to conduct an inspection in Switzerland.

In 2023, three inspections were conducted by the European Medicines Agency (EMA), two by the FDA and one by the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) in Switzerland.

In 2024, one inspection by the EMA, four by the FDA and one by the PMDA were performed in Switzerland.

1 Inspections: Settings and types (only Swissmedic inspections)

GCP inspections may be performed on site, remotely or desk-based as follows (see Table 2):

- **On site**: the inspection is performed on the premises of the inspected party (i.e. sponsor, contract research organisation or trial site).
- **Remote**: the inspection is performed remotely by means of video conferencing (interviews are held via tele/video conferencing; documents are shared via desktop sharing or using a secure File Transfer Service (FTS)).
- **Desk-based**: follow-up inspection based on the review of selected documents deemed to determine whether the Corrective and Preventive Action Plan (CAPA) has been implemented as described (only if necessary, an interview session is organised).

Table 2: Types of inspection

Inspections	2022	2023	2024
On site	25	27	35
Remote	5	5	1
Desk-based	4	6	6

GCP inspections may have the following settings:

- **Trial site inspections** focus on the conduct of a trial at a specific location,
- **System inspections** evaluate the sponsor's or clinical research organisation's overall management of the trial.

Depending on the extent and the complexity of the clinical trial, Swissmedic adapts the duration of the inspection, up to 3 days, and the number of inspectors, up to 3.

2 Inspections: Overall summary – 3-year comparison

Table 3 and Table 4 present the number of inspections conducted in 2022, 2023 and 2024. Most of the inspections were conducted at clinical investigator sites followed by system inspections of the sponsor. The academic sponsors had mainly system inspections compared to site inspections.

Table 3: Inspections (academic vs. commercial)

Type of inspection	2022	2023	2024
Site - academic	8	7	3
Site - commercial	11	15	21
System - academic	7	5	9
System - commercial	8	11	9
Total	**34**	**38**	**42**

The number of system inspections in 2024 was the same for academic and commercial (9) sponsors, whereas the commercially sponsored trials had the highest number of site inspections (21).

Table 4: Inspections (site vs. system)

Type of inspection	2022	2023	2024
Site	19 (55.9%)	22 (57.9%)	24 (57.1%)
System	15 (44.1%)	16 (42.1%)	18 (42.9%)
Total	**34**	**38**	**42**

Over the years, the percentage of site vs. system inspections has remained constant.

Table 5 lists the number of inspections per clinical development phase of the trial.

The clinical trial unit inspections were excluded (therefore the total number of inspections is not the same as in the above table) since these involved the inspection of the processes and did not consider any specific trials (three in the years 2022 and 2024, two in 2023).

Table 5: Types of inspection depending on the phase of the trial per year

Trial Phase	2022	2023	2024
FIH	0	5	6
Phase I	8	6	4
Phase II	9	9	10
Phase III	13	16	14
Phase IV	1	0	5
Total	**31**	**36**	**39**

3 Inspections of academic vs. commercial clinical trials

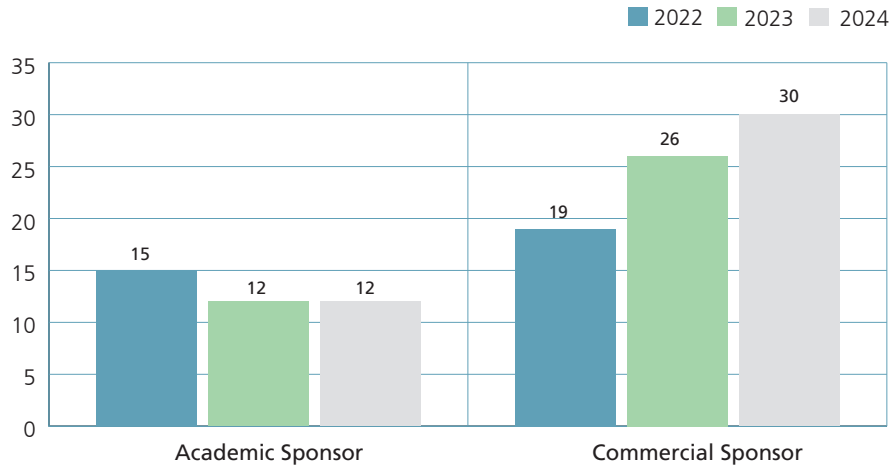

Figure 1: Inspection of academic vs. commercial clinical trials per year

A clinical trial sponsor is a person or institution based or represented in Switzerland that assumes responsibility for initiating a clinical trial, namely for its commencement, management and financing in Switzerland (definition from ClinO).

Sponsors are often pharmaceutical companies, but can also be academic institutions, or other private organisations.

The number of academic trials inspected has remained consistent over the past three years, with a negligible downward trend. On the other hand, there has been a notable increase in the number of inspections of commercially sponsored trials, rising from 19 in 2022 to 30 in 2024.

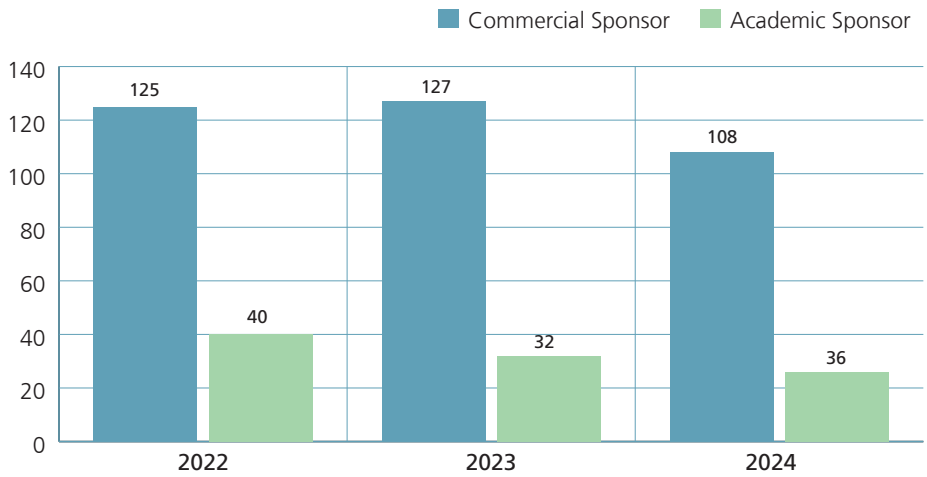

Figure 2: Number of clinical trials approved by Swissmedic (category B and C clinical trials) per year

This is also indicative of the ratio between the number of approved commercially vs. academically sponsored trials as shown in Figure 2.

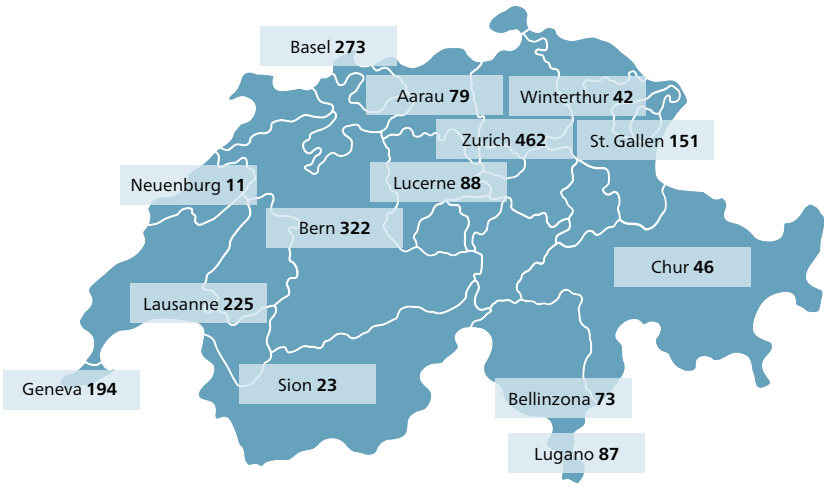

Figure 3: Swiss map representing the number of clinical trials actively recruiting

The numbers shown in Figure 3 on the map represent the number of clinical trials per region (Extract from Humanforschung-Schweiz Studiensuche - Humanforschung Schweiz, representing all active trials as at 25 August 2025).

Most of the clinical trials are carried out in the region of Zurich, followed by Bern, Basel, Lausanne and Geneva.

In 2024, seven inspections were carried out in Bern, four each in Basel, Geneva, St. Gallen and Zurich, followed by three in Lausanne, two in Aarau and one each in Bellinzona, Rotkreuz, Glattbrugg, Zug, Baar, Frauenfeld and Lugano, making a total of 35 on-site inspections.

In 2024, two thirds (30 out of 42) of the inspections concerned trials initiated by a commercial sponsor, while 12 inspections concerned academic sponsors. In the 30 inspections related to commercial sponsors 44 clinical trials were inspected, whereas in the 12 inspections related to academic sponsors 14 clinical trials were inspected. Nine system inspections were performed for academic sponsors and nine for commercial sponsors. During system inspections two or more inspectors stay on site for two or three days.

The ratios between academically and commercially sponsored trials approved and inspected were comparable (108 vs. 36 approved and 44 vs. 14 inspected trials).

4 Inspections and administrative measures

The majority of inspections conducted in the past three years were routine inspections, and only a small number were for-cause inspections (see Table 6). In 2022, in around 3% of all routine inspections, Swissmedic imposed administrative measures on the inspected party to ensure that the lawful state of affairs was restored. A significant increase was observed in 2023 (18.4%), with a subsequent reduction in 2024 (approximately 10%, considering the routine inspections and the for-cause inspections that resulted in the imposition of administrative measures). The rise in inspection activity has also led to an increase in administrative measures (from just 1 in 2022 to 7 in 2023 and 3 in 2024). The administrative measures comprised among other the interruption of subject recruitment.

In the years 2022 and 2023, no for-cause inspections were conducted, as no circumstances arose that would have justified such an inspection. It should be taken into account that these were the two years post COVID-19, where the health system was returning to normal after a pandemic.

Table 6: Relationship between routine and for-cause inspections with or without administrative measures

Year	Routine without administrative measures	Routine with administrative measures	For-cause without administrative measures	For-cause with administrative measures
2022	33 (97.1%)	1 (2.9%)	-	-
2023	31 (81.6%)	7 (18.4%)	-	-
2024	36 (85.7%)	3 (7.1%)	2 (4.8%)	1 (2.4%)

As shown in Table 7, a trend is apparent towards a higher number of administrative measures imposed in the framework of clinical trials carried out by academic sponsors. In contrast, an inverse trend is identified in inspections of commercial sponsors. In 2023, Swissmedic had to adopt 6 administrative measures and only one in 2024 for commercial sponsors. Whether this is the result of a significant improvement in the processes of commercial sponsors will need to be confirmed in the years to come.

Table 7: Relationship between the sponsor of the trial and the resulting administrative measures. (N= number of inspections considered. Percentages are compared to the total number of inspections performed of academic and commercial sponsors).

	Administrative measures 2022	Administrative measures 2023	Administrative measures 2024
Academic sponsor	1 (N=15) (6.7%)	1 (N=12) (8.3%)	3 (N=12) (25%)
Commercial sponsor	0 (N=19) (0%)	6 (N=26) (23.1%)	1 (N=30) (3.3%)

5 Inspections: Findings and grading

Swissmedic categorises findings from GCP inspections into minor, major and critical based on the severity of non-compliance. These categories are aligned with the EMA grading system for inspection findings (please refer to Appendix I for details).

A critical finding in a clinical trial can be defined by a pattern of major deviations that adversely affect the rights, safety, or well-being of subjects, or the quality/integrity of the data. These patterns are considered totally unacceptable and may lead to rejection of data or legal action, as a single major deviation can sometimes be classified as critical if it has a significant impact on the trial's results or patient safety.

The metrics presented in this report consider only the principal findings and do not enter into the details of the sub-findings.

Table 8: Number of findings and percentages in relation to the grade of the finding per year

Year	Critical	Major	Minor	Total
2022	6 (2.3%)	115 (44.9%)	135 (52.7%)	**256**
2023	24 (8.2%)	137 (46.8%)	132 (45.1%)	**293**
2024	27 (7.7%)	175 (50.0%)	148 (42.3%)	**350**

There has been a stabilisation in the percentage of critical findings in the last two years (2023-2024), with the majority of findings being graded major (see Table 8). Major findings are conditions, practices or processes that might adversely affect the rights, safety or well-being of the subjects and/or the quality and integrity of data. Major observations are serious deficiencies and are direct violations of GCP principles. The proportion of major findings has increased over the 3-year period, possibly due to the fact that many minor findings are summed up in a major finding. The proportion of findings classified as minor has decreased over the 3-year period.

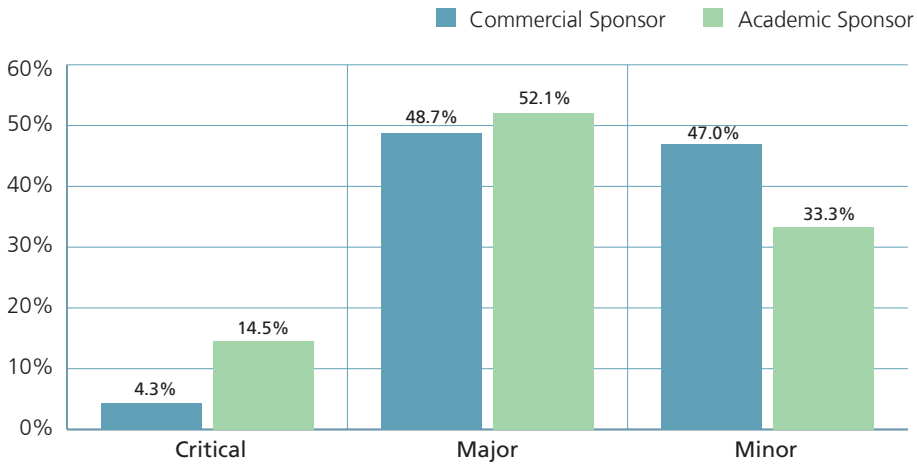

Figure 4: Percentage of finding types depending on the type of sponsor (academic vs. commercial) in 2024

An analysis of the findings reveals that fewer critical and more minor findings are identified in the framework of inspections of clinical trials conducted by commercial sponsors compared to academic sponsors. Academically sponsored trials have been shown to produce a significant number of critical findings (see Figure 4).

In the framework of some site inspections, critical and major findings were noted that fall under the sponsor's responsibility and do not originate from the activities conducted by the site personnel. As more data become available this observation will need to be redefined.

Table 9: Percentage of inspections with at least one critical finding, academic vs. commercial sponsor

Inspections with at least one critical finding	2022	2023	2024
Academic sponsor	5 (33.3%) (N=15)	4 (33.3%) (N=12)	7 (58.3%) (N=12)
Commercial sponsor	1 (5.3%) (N=19)	8 (30.8%) (N=26)	5 (16.7%) (N=30)

According to the metrics shown in Table 9, commercial sponsors are subject to fewer critical findings per inspection performed, whereas in the case of academic sponsors this trend is not confirmed.

The critical findings noted in 2024 in the framework of inspections of academic sponsors were related to the computer system validation (n=3), quality management system (n=2), the safeguard of the safety and well-being of the subjects treated in the clinical trials (n=6), and others (n=5).

On the other hand, the critical findings noted in the framework of inspections of commercial sponsors in 2024 were related to the source documentation (n=4), informed consent form (n=4), and the safeguard of the safety and well-being of the subjects treated in the clinical trials (n=7).

It is interesting to note that the number of critical findings related to deficiencies in ensuring the safeguard of the safety and well-being of the subjects treated in the clinical trials is nearly the same for academically and commercially sponsored trials (e.g. deficient ongoing safety evaluation, non-compliances with legal reporting requirements). Academically sponsored trials have shown comparatively more findings in computer system validation and in the quality management system than commercially sponsored trials. The informed consent form was an issue in one commercially sponsored trial, where 4 different non-compliances were observed (delayed provision of the approved ICF to the investigator site, delayed reconsenting of the patient, the failure to inform a patient about urgent safety measures, patient informed with outdated ICF).

Please refer to Table 10, which summarises the number of critical findings identified depending on the clinical development phase of the trial: First in Human (FIH), Phase I, Phase II, Phase III or Phase IV. The Clinical Trial Unit (CTU) inspections are included in this table, even though their processes are inspected and not specifically a trial.

The CTUs inspected yielded no critical findings. This demonstrates that the CTUs can significantly help academic researchers to perform legally compliant clinical trials. But due to their cost, in some cases the sponsors' investigators can request their support only for certain tasks of the clinical trials.

On the contrary, the highest percentage of critical findings is observed in Phase IV trials, followed by Phase II and then FIH trials. This result suggests that critical findings are more likely to be identified in the later phases than in the early ones. This fact demonstrates

that significant attention is devoted to the planning and execution of the early development phases. An exhaustive examination of these relationships should be incorporated into next year's report, since the number of inspections currently analysed is rather low. Further investigation and more data are required to fully understand the root cause of this finding.

Table 10: Percentage of inspections with at least one critical finding depending on the clinical development phase (N = number of inspections performed)

Trial Phase	2022	2023	2024
Academic CTU	0 (N=3)	0 (N=2)	0 (N=3)
FIH	0 (N=0)	3 (60.0%) (N=5)	2 (33.3%) (N=6)
I	1 (16.7%) (N=6)	0 (N=6)	0 (N=5)
II	2 (18.2%) (N=11)	4 (44.4%) (N=9)	5 (50%) (N=10)
III	2 (16.7%) (N=12)	5 (31.3%) (N=16)	1 (7.7%) (N=13)
IV	1 (50.0%) (N=2)	NA (N=0)	4 (80.0%) (N=5)
Total	**6 (17.6%) (N=34)**	**12 (31.6%) (N=38)**	**12 (28.6%) (N=42)**

Table 11 presents an extract of the most frequently observed findings in the critical and major categories during the period from 2022 to 2024. Qualification/training and standard operating procedure (SOP) findings remain constant over the 3 years, with a downward trend.

Findings related to the safeguard of the safety and well-being of subjects, monitoring, reporting in Case Report Form (CRF)/Diary of the patient, organisation and personnel, source documentation and others show significant increases over the 3 years. These increases can be explained only in part by the increased surveillance activity by Swissmedic. On the other hand, sites with only little clinical trial activity were also inspected in 2024.

Protocol/CRF/Diary of the patient/Questionnaire design and protocol compliance findings increased slightly, whereas non-compliances with essential documents decreased over the years.

Table 11: Most observed findings (critical and major) observed during the years 2022-2024

Finding category	2022	2023	2024
Safeguard of the Safety and well-being of Subject	2	9	17
Protocol/CRF/Diary/Questionnaire design	10	11	12
Monitoring	13	13	24
Document Control	4	10	9
Protocol Compliance (Others)	8	8	11
Reporting in CRF/Diary of the patient	14	11	17
Organisation and Personnel	16	15	23
Qualification/Training	16	15	15
SOPs	18	13	15
Source Documentation	17	18	26
Essential Documents	19	18	15
Others	10	8	16

Table 12 presents some examples of the findings related to the category Safeguard of the Safety and well-being of Subject:

Table 12: Typical examples of observed findings (critical and major) during the years 2022-2024 for the category Safeguard of the Safety and well-being of Subject

Safeguard of the Safety and well-being of Subject
Deficiencies related to the documentation of the conduct of the ongoing safety evaluation
Deficiencies with SAE reporting
Delayed acknowledgment of Dear Investigator Letters by investigators at various sites
Delayed review and acknowledgment of safety letters/reports
Failure of the sponsor to implement a correct serious adverse event evaluation process
Inadequate facilities and equipment for first-in-human trials
Insufficient sponsor oversight in the framework of IDMC activities
No reconciliations of the clinical/safety databases performed and examples of discrepancies between the clinical and safety databases
Ongoing safety evaluation not performed by the sponsor and failure to define relevant aspects related to the ongoing safety evaluation process prior to trial start (i.e. frequency of analysis of aggregated safety data, responsibility)
SUSAR not reported to Swissmedic

Table 13 presents some examples of the findings related to the category Monitoring:

Table 13: Typical examples of observed findings (critical and major) during the years 2022-2024 for the category Monitoring

Monitoring
Deficiencies in the process of trial site initiation and activation
Deficiencies related to monitoring/monitoring processes
Delayed review of protocol deviations
Failure to document trial specific trainings and handovers of the monitors
Failure to perform Source Data Verification on the basis of original source documents
Incomplete site initiation visit and no evidence of risk assessment to determine the monitoring frequency
Insufficient quality control applied in relation to monitoring activities
Non-compliance with the monitoring plan

The number of findings related to the monitoring category nearly doubled during the period from 2023 to 2024. Considering the fact that most commercial sponsors outsource monitoring activities to contract research organisations, this observation points towards a lack of sponsor oversight.

Table 14 presents some examples of the findings related to the category Organisation and Personnel:

Table 14: Typical examples of observed findings (critical and major) during the years 2022-2024 for the category Organisation and Personnel

Organisation and Personnel
Deficiencies in the study task delegation and signature log
Deficiencies regarding the allocation of responsibilities between sponsor representative and principal investigator
Deficiencies regarding the Staff Signature and Delegation Log
Deficiencies related to the back-up function of the PI
Deficiencies with the training of the site personnel and the documentation of the training
Insufficient evidence of medical oversight by the investigator(s)
Nursing staff took over trial-specific tasks under surveillance of the study coordinator without being authorised
Review of safety letters delegated to non-qualified study team member
Various sponsor responsibilities not defined in writing

Table 15 presents some examples of the findings related to the category Source documentation:

Table 15: Typical examples of observed findings (critical and major) during the years 2022-2024 for the category Source Documentation

Source Documentation
Deficiencies with source document use and definition
Deficient generation of certified copies
Examples of non-adherence to the ALCOAC principles
Inadequate source documentation for Investigational Medicinal Product (IMP) handling and administration
Insufficient documentation of the protocol deviation on the note to file
Insufficient documentation of the consent process
Missing documentation of safety assessment by the investigator
Missing source data for SAEs
Several observations and discrepancies in the source data or between the source data and electronic Case Report Form (eCRF)
Transport of source documents not documented and not defined in guidance documents; access to all source documents for the principal investigator not ensured

6 Conclusions

The Swissmedic GCP Annual Report 2022-2024 highlights significant progress in the oversight of clinical trials in Switzerland, with an increase in the number and scope of inspections over the three-year period. The findings reveal a clear distinction between academic and commercial sponsors, with academic trials facing more critical findings and administrative measures. This underscores the need for academic sponsors to strengthen their quality management systems and processes, particularly in areas such as computer validation, safety evaluations, and training.

The report also identifies a concerning trend of critical findings being more prevalent in Phase IV and Phase II, suggesting that quality control efforts may diminish as trials progress. This calls for sustained attention to quality assurance and quality control throughout all phases of clinical development.

Swissmedic's intensified inspection efforts during the last three years reflect a strategic commitment to enhancing patient safety and promoting high-quality clinical research by increasing data integrity. However, the findings also highlight areas for improvement, particularly in safeguarding participant safety, monitoring and source documentation. Moving forward, Swissmedic's continued fostering compliance with GCP standards will be critical to ensuring the ethical and scientific integrity of clinical trials in Switzerland. Moreover, Swissmedic plans to analyse the relationship between findings and trial phases in greater detail in future reports.

Appendix 1: Criteria for grading of inspection findings[3]

Critical	
Definition	Conditions, practices or processes that adversely affect the rights, safety or well-being of the subjects and/or the quality and integrity of data. Critical observations are considered totally unacceptable.
Possible consequences	Rejection of data and/or legal action required.
Remark	Observations classified as critical may include a pattern of deviations classified as major, bad quality of the data and/or absence of source documents. Manipulation and intentional misrepresentation of data belong to this group.
Major	
Definition	Conditions, practices or processes that might adversely affect the rights, safety or well-being of the subjects and/or the quality and integrity of data. Major observations are serious deficiencies and are direct violations of GCP principles.
Possible consequences	Data may be rejected and/or legal action required.
Remark	Observations classified as major, may include a pattern of deviations and/or numerous minor observations.
Minor	
Definition	Conditions, practices or processes that would not be expected to adversely affect the rights, safety or well-being of the subjects and/or the quality and integrity of data.
Possible consequences	Observations classified as minor, indicate the need for improvement of conditions, practices and processes.
Remark	Many minor observations might indicate a bad quality and the sum might be equal to a major finding with its consequences.
Comment	
Definition	The observations might lead to suggestions on how to improve quality or reduce the potential for a deviation to occur in the future.

[3] Procedure for reporting of GCP inspections requested by the Committee for Medicinal Products for Human Use (CHMP)

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Swissmedic, Swiss Agency for Therapeutic Products
Medicinal product licences and surveillance Sector
Clinical Trials Division
Hallerstrasse 7
3012 Bern
Switzerland
www.swissmedic.ch