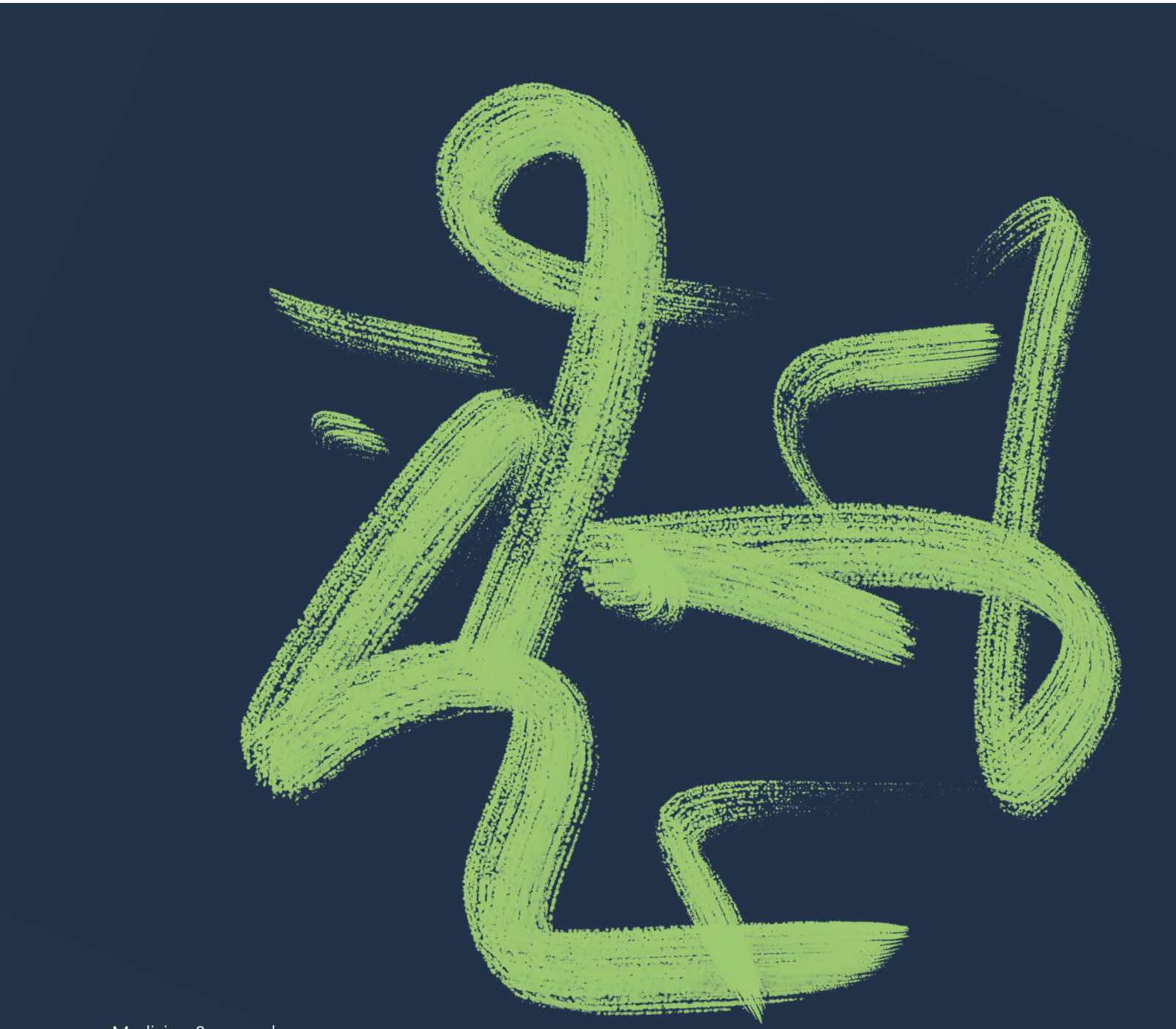
Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH



Medicine & research
Activity report

Activities of the Research Ethics Committees 2022

Summary Report of the Coordination Office for Human Research (Kofam)

Contents

Foreword

Research involving human beings is an important component of medicine, helping to develop new methods of treatment and diagnosis and improving existing therapies. Although research presents abundant opportunities, it also involves risks, including potential impacts on health and infringements of the personal rights of participants. To protect participants, the Human Research Act (HRA) stipulates that all human research projects must be assessed and approved by independent supervisory bodies such as ethics committees.

The Coordination Office for Human Research (kofam) has the task of informing the public about developments in human research in Switzerland. This report for 2022 summarises the activities of the seven, primarily supracantonal, ethics committees and other bodies involved in the assessment and approval process. These ensure that proposed research projects are ethically acceptable and scientifically sound. They also verify that participants have been appropriately informed of the risks and benefits of the research and that they are taking part in it voluntarily.

The original versions of the individual ethics committees' annual reports, on which this summary report was based, can be found on their respective websites (see list on page 3). The reports published by Swissmedic and Swissethics can be found on those organisations' websites.

kofam would like to thank the ethics committees, their umbrella organisation Swissethics and the other supervisory authorities for their work and commitment in safeguarding the rights and safety of project participants.

Summary

Research involving humans has returned to normal in Switzerland after the challenges of the pandemic. The majority of ethics committees report that the number of applications submitted stabilised at pre-pandemic levels during 2022. Only two committees received more applications than in the previous year. Applications for Covid-19 projects declined sharply, the primary focus of interest shifting to the use of personal health data for research purposes. Moreover, projects that make further use of such data without participants' consent are becoming ever rarer. This may be because data used for research purposes are increasingly covered by a declaration of general consent. Overall, the number of projects approved greatly exceeded the number of rejections, which was in the single-digit percent range.

Ethics committees were again successful in keeping the time from receipt of complete application dossiers to initial decision short during 2022, at a median of 18 days. The committees are basically satisfied with the efficiency and professionalism of their activities.

Despite the post-pandemic return to normality, the future will bring challenges at various levels. These include, for example, the process of revising the ordinances associated with the HRA, which is currently in progress, or how to treat medical devices in the context of the other European countries. In addition, the committees continue to address issues connected with the digitalisation of research, particularly with regard to topics such as artificial intelligence or big data, as well as decentralised clinical trials. To address these challenges and safeguard the high quality of their work, the ethics committees are keen to highlight the importance of appropriate training and continuing education provision for their members.

List of ethics committees

At the end of 2022, Switzerland had a total of seven (supra) cantonal ethics committees. This number has thus remained unchanged since the end of 2016. Below, the committees are listed by number of applications received, in ascending order, with one exception: Although the Cantonal Ethics Committee Ticino (CE-TI) has received more applications than the Ethics Committee of Eastern Switzerland since the pandemic, the original pre-pandemic order has been retained.

Cantonal Ethics Committee Ticino (CE-TI)

Comitato etico cantonale del Cantone Ticino
c/o Ufficio di sanità
Via Orico 5
CH-6501 Bellinzona
dss-ce@ti.ch
www.ti.ch/ce
Chair: Giovan Maria Zanini
Region covered: canton of Ticino

Ethics Committee of Eastern Switzerland (EKOS)

Ethikkommission Ostschweiz
Scheibenackerstrasse 4
CH-9000 St.Gallen
sekretariat@ekos.ch
www.sg.ch/gesundheit-soziales/gesundheit/gremien.html
Chair: Dr Susanne Driessen
Region covered: cantons of St.Gallen, Thurgau, Appenzell Ausserrhoden and Appenzell Innerrhoden

Cantonal Ethics Committee, Bern (KEK-BE)

Kantonale Ethikkommission Bern
Murtenstrasse 31
CH-3010 Bern
info.kek.kapa@gef.be.ch
www.be.ch/kek
Chair: Prof. Christian Seiler
Region covered: canton of Bern and cantons of Fribourg and Valais for German-language submissions

Ethics Committee of Northwestern and Central Switzerland (EKNZ)

Ethikkommission Nordwest- und Zentralschweiz
Hebelstrasse 53
CH-4056 Basel
eknz@bs.ch
www.eknz.ch
Chair: Prof. Christoph Beglinger
Region covered: cantons of Aargau, Basel-Landschaft, Basel-Stadt, Jura, Lucerne, Nidwalden, Obwalden, Solothurn, Schwyz, Uri and Zug

Cantonal Research Ethics Committee, Geneva (CCER)

Commission cantonale d'éthique de la recherche de Genève
Rue Adrien Lachenal 8
CH-1207 Genève
ccer@etat.ge.ch
www.ge.ch/lc/ccer
Chair: Prof. Bernard Hirschel
Region covered: canton of Geneva

Cantonal Research Ethics Committee, Vaud (CER-VD)

Commission cantonale d'éthique de la recherche sur l'être humain
Avenue de Chailly 23
CH-1012 Lausanne
secretariat.cer@vd.ch
www.cer-vd.ch
Chair: Prof. Dominique Sprumont
Region covered: cantons of Vaud and Neuchâtel, and cantons of Fribourg and Valais for French-language submissions

Cantonal Ethics Committee, Zurich (KEK-ZH)

Kantonale Ethikkommission Zürich
Stampfenbachstrasse 121
CH-8090 Zurich
info.kek@kek.zh.ch
www.kek.zh.ch
Chair: Emeritus Prof. David Nadal
Region covered: cantons of Zurich, Glarus, Graubünden, Schaffhausen and the Principality of Liechtenstein

1 Organisation of the ethics committees

Switzerland has seven ethics committees, most of which are attached to cantonal health directorates or social services departments. They are overseen by the responsible cantonal government or health department. All the committees operate independently and are not subject to instructions from the supervisory authority.

Part-time public service

The ethics committees operate on a part-time public service basis and comprise experts from various specialist fields. Some 40% of members have a medical qualification (see Figure 1). Gender distribution across all committees is a balanced 46.5% women and 53.5% men, although the actual percentages vary widely between committees. Members are generally elected by the cantonal executive bodies at the recommendation of the committee Chair. In individual cases, medical facilities also have the right to propose members. In the case of supracantonal committees, appointments are made by an intercantonal supervisory body.

Committee members generally serve for four or five years and reappointment is possible. However, some ethics committees apply an age limit or limit the maximum number of years members may serve. The committees vary greatly in size, with member numbers ranging from 13 to 42.

Figure 1: Disciplines represented (several mentions possible) and gender breakdown by ethics committee

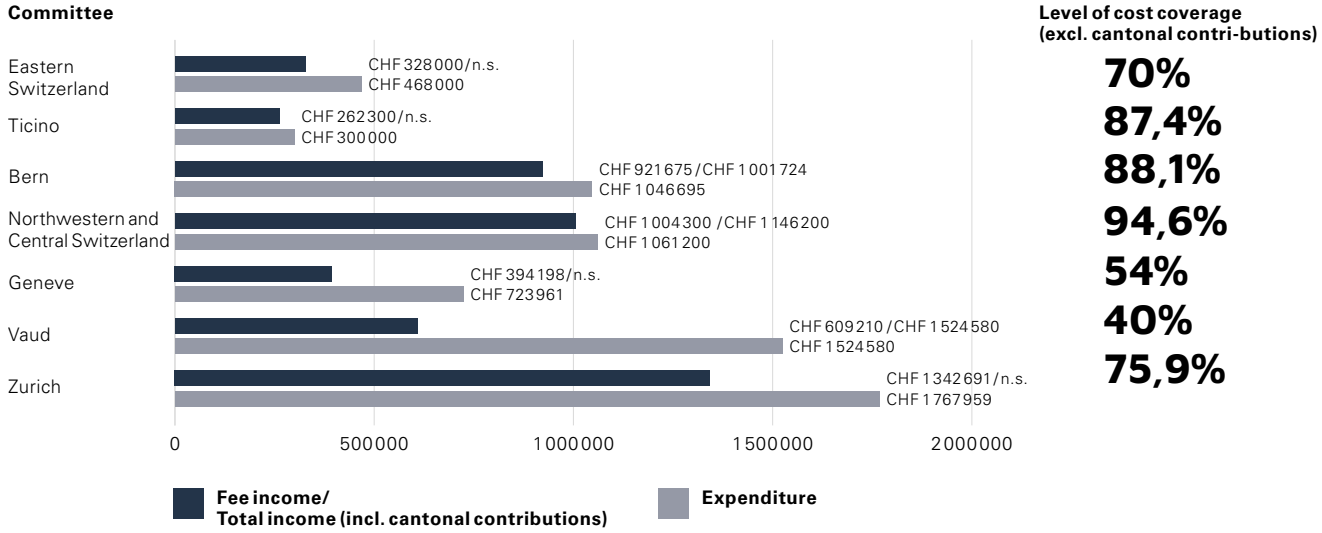
	Ethics committees															
	CE-TI		EKOS		KEK-BE		EKNZ		CCER		CER-VD		KEK-ZH		Total	
	Number	Per Cent	Number	Per Cent	Number	Per Cent	Number	Per Cent	Number	Per Cent	Number	Per Cent	Number	Per Cent	Number	Per Cent
Number of members **Medicine**	8	44,4	5	29,4	11	44,0	10	37,0	17	37,0	16	34,0	27	57,4	94	41,4
Number of members **Psychology**	1	5,6	1	5,9	2	8,0	2	7,4	3	6,5	4	8,5	2	4,3	15	6,6
Number of members **Biology**	0	0,0	2	11,8	2	8,0	2	7,4	5	10,9	1	2,1	2	4,3	14	6,2
Number of members **Law**	2	11,1	2	11,8	4	16,0	3	11,1	4	8,7	3	6,4	3	6,4	21	9,3
Number of members **Ethics**	2	11,1	1	5,9	1	4,0	2	7,4	2	4,3	4	8,5	2	4,3	14	6,2
Number of members **Pharmacy/Pharmacology**	2	11,1	2	11,8	1	4,0	1	3,7	4	8,7	5	10,6	2	4,3	17	7,5
Number of members **Statistics/Epidemiology**	1	5,6	1	5,9	1	4,0	3	11,1	4	8,7	5	10,6	2	4,3	17	7,5
Number of members **Patient representation**	1	5,6	1	5,9	1	4,0	1	3,7	3	6,5	2	4,3	2	4,3	11	4,8
Number of members **Care/Nursing**	1	5,6	2	11,8	1	4,0	3	11,1	3	6,5	3	6,4	5	10,6	18	7,9
Number of members **Other fields**	0	0,0	0	0,0	1	4,0	0	0,0	1	2,2	4	8,5	0	0,0	6	2,6
Total **per discipline represented**	18	7,9	17	7,5	25	11,0	27	11,9	46	20,3	47	20,7	47	20,7	227	100
Total members (without multiple entries)	17	8,7	13	6,6	23	11,7	26	13,0	39	19,5	40	20,0	42	21,0	200	100
Number **of women**	**5** 29,4%		**6** 46,2%		**6** 26,1%		**11** 42,3%		**27** 69,2%		**22** 55,0%		**16** 38,1%		**93 Women** 46,5%	
Number **of men**	**12** 70,6%		**7** 53,8%		**17** 73,9%		**15** 57,7%		**12** 30,8%		**18** 45,0%		**26** 61,9%		**107 Men** 53,5%	

Figure 2: Staffing levels in the scientific and administrative secretariats

	Total no./percentage	Scientific secretariat	Administrative secretariat
Ticino (CE-TI)	3 persons **220%**	2 persons /150%	1 person/70%
Eastern Switzerland (EKOS)	3 persons **190%**	1 person/80%	2 persons /110% [1]
Bern (KEK-BE)	5 persons [3] **370%**	4 persons /340%	1 person/30% [2]
Northwestern and Central Swit-zerland (EKNZ) (plus 3 students paid on an hourly basis)	6 persons **400%**	4 persons /250%	2 persons /150%
Geneva (CCER) (of which 50% for the Chair)	6 persons **420%**	2 persons /140%	3 persons /210% Legal secretariat: 1 person/20%
Vaud (CER-VD) (one person works in both secretariats)	8 persons [4] **610%**	5 persons /340%	4 persons /270%
Zurich (KEK-ZH)	10 persons **805%**	5 persons /405% [5]	4 persons /350% Legal secretariat: 1 person/50%

[1] One person (work-time percentage: 70%) has been unable to work owing to illness since the start of 2022. A staff member has been deputising for this individual on a 40% basis since May. Although this results in salary costs for a staffing level of 110%, the actual work-time percentage was 40%.
[2] As at year end; 1–3 persons (30–130%) in the course of the year.
[3] As at year end; 5–7 persons (370–470%) in the course of the year.
[4] One person works in both secretariats.
[5] One position is vacant (60%, filled as of January 2023), one person (70%) was unable to work for a protracted period.

Figure 3: Financing of ethics committees



There were no significant changes in committee membership during 2022, although the Zurich, Geneva and Vaud committees replaced individual departing members. Furthermore, the Zurich and Vaud committees each added two members.

Focusing on expertise

Newly appointed committee members generally take part in the annual basic training course run by Swissethics. One such course, on the "Cornerstones of scientific, ethical and legal assessment", was held in German in Zurich on 29 November 2022. Five new members attended. On 27 September 2022, committee members had the opportunity to bring their knowledge of the "Basics of assessment practice" and "Equity considerations" up to date at a continuing education event. A continuing education event for French-speaking members, organised by the Geneva and Vaud committees, was held in Geneva on 24 November. Participants were able to attend the event, which was about "Artificial intelligence and research", either in person or online. Some committees also report that local continuing education events were held for their members.

Swissethics has developed an online tool for logging members' training and continuing education status, in which committee members are required to enter the events they have attended. In addition to attending events, members have access to self-study training material in the electronic Swissethics Library.

Organisation of the secretariat

All ethics committees have a scientific secretariat. This is required by law and led by a natural scientist, generally a biologist. Each committee also has an administrative secretariat. There are considerable variations between committees in the staff resources available in the secretariats (see Figure 2).

Financing

The ethics committees are mainly funded via fees and cantonal contributions. The latter take the form of a fixed annual sum or a deficit guarantee. The overview of income and expenditure for 2022 given in Figure 3 includes the relevant contribution and level of cost coverage (income from fees divided by expenditure).

Safeguarding independence

It is important for ethics committees to retain their independence – both while providing advice to researchers and when making decisions. Specific rules have therefore been put in place to safeguard independence. If a committee member faces a potential conflict of interest, they must either recuse themselves or be excluded from the assessment and discussion of the application. All committees are committed to transparency and publish their members' vested interests on their websites. Some also publish their current recusal rules online.

2 Activities of the ethics committees

The core task of the ethics committees is to assess and approve research projects. Depending on their design, research projects may be conducted in several medical facilities spread across several cantons, and thus fall under areas of responsibility of various ethics committees A distinction is therefore made between monocentre and multicentre projects. Monocentre research projects involve one ethics committee, whereas multicentre projects involve several. In the latter case, one committee acts as lead ethics committee.

Assessment and approval of research projects

In addition to this summary report, kofam/the FOPH publishes an annual statistical report on the nature and number of research projects submitted to and approved by the ethics committees (Human Research in Switzerland). This statistical report is always published at the same time as the ethics committees' summary annual report and can be found in the "Downloads" section of the kofam website. The sections below contain the main key figures from the statistical report. Additional tables and charts can be found in the report itself.

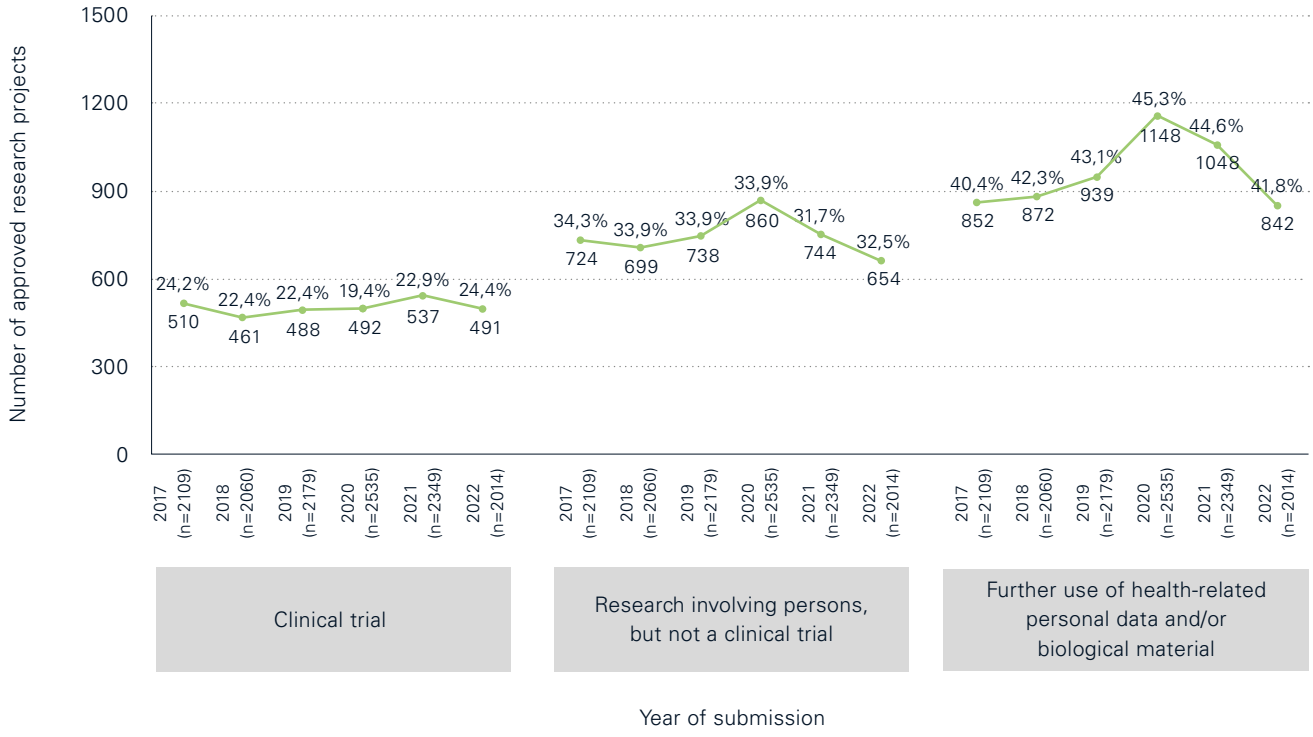
Year-on-year decline in number of research projects

2,407 research projects were submitted to the ethics committees in 2022, while the committees approved 2,014 projects in the same period. This reveals a fall in the number of projects compared to 2021 – specifically 151 (6%) fewer projects submitted and 297 (13%) fewer projects approved. This decline could be attributable to the decrease in projects specifically related to Covid-19.

Number of research projects approved falls to pre-pandemic levels

Looking at the trend in the number of research projects approved since 2017 by research type (see Figure 4), it is noticeable that:

Figure 4: Total number of approved projects per year and type of research. Percentages on the top of the lines refer to the proportion of studies of a given type compared to all studies approved in a given year.



- The number of clinical trials approved since 2017 is relatively stable;
- The number of trials involving persons but not clinical trials is stable from 2017 to 2019, then increases sharply during 2020, the first year of the pandemic, before dipping to just under pre-pandemic levels in 2022.
- The number of research projects involving further use of data or samples increased consistently in the pre-pandemic period between 2017 and 2019, peaked during the pandemic in 2020 and 2021, then dropped to slightly below 2017–2019 levels.

Overall, the total number of research projects approved in 2022 is slightly below the corresponding figures for the years prior to the pandemic.

Processing times stable throughout the years

The assessment procedure most frequently used by the ethics committees during 2022 was the simplified procedure (around 60% of decisions), in which decisions are made by three committee members. The regular (at least seven-member) procedure and presidential procedure were each used in just under 17% of decisions. Procedures that had yet to be conducted at the time the data were exported account for the remaining 4.7% (Figure 5). There are significant differences in the individual committees' usage of procedures.

The median time between confirmation of receipt of formally correct applications and the initial decision by the ethics committees is 18 days. Figure 6 provides a breakdown by ethics committee.

Figure 5: Number of submitted projects divided according to review procedures and ethics committees

		Lead ethics committee															
		KEK-ZH		EKNZ		CER-VD		KEK-BE		CCER		EKOS		CE-TI		Total	
		n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	N	$\%_{col}$
Review procedure	Ordinary[1]	92	14,9	51	10,8	57	13,0	49	13,5	30	9,9	24	24,5	97	86,6[4]	400	16,6
	Simplified[2]	340	54,9	336	71,3	275	62,6	263	72,7	224	73,7	44	44,9	5	4,5	1487	61,8
	Presidential[3]	168	27,1	79	16,8	66	15	30	8,3	38	12,5	23	23,5			404	16,8
	First decision still pending	19	3,1	5	1,1	41	9,3	20	5,5	12	3,9	7	7,1	10	8,9	114	4,7
	Total number in AS1[5]	619	100,0	471	100,0	439	100,0	362	100,0	304	100,0	98	100,0	112	100,0	2407	100,0

1 Decision taken at full committee meeting by at least seven members of the ethics committee, as per the provisions of Art. 5, OrgO-HRA.
2 Decision taken by three members of the ethics committee, as per the provisions of Art. 6 OrgO-HRA.
3 Decision taken by the president or vice-president of the ethics committee, as per the provisions of Art. 7 OrgO-HRA.
4 CE-TI uses the ordinary procedure for most of the research applications.
5 IThe total number includes 2 clinical investigations with medical devices with the status 'not admitted', as per Art. 12 ClinO-MD. These are not listed separately in the table.

Figure 6: Time taken (median) from complete application to initial decision broken down by lead committee.

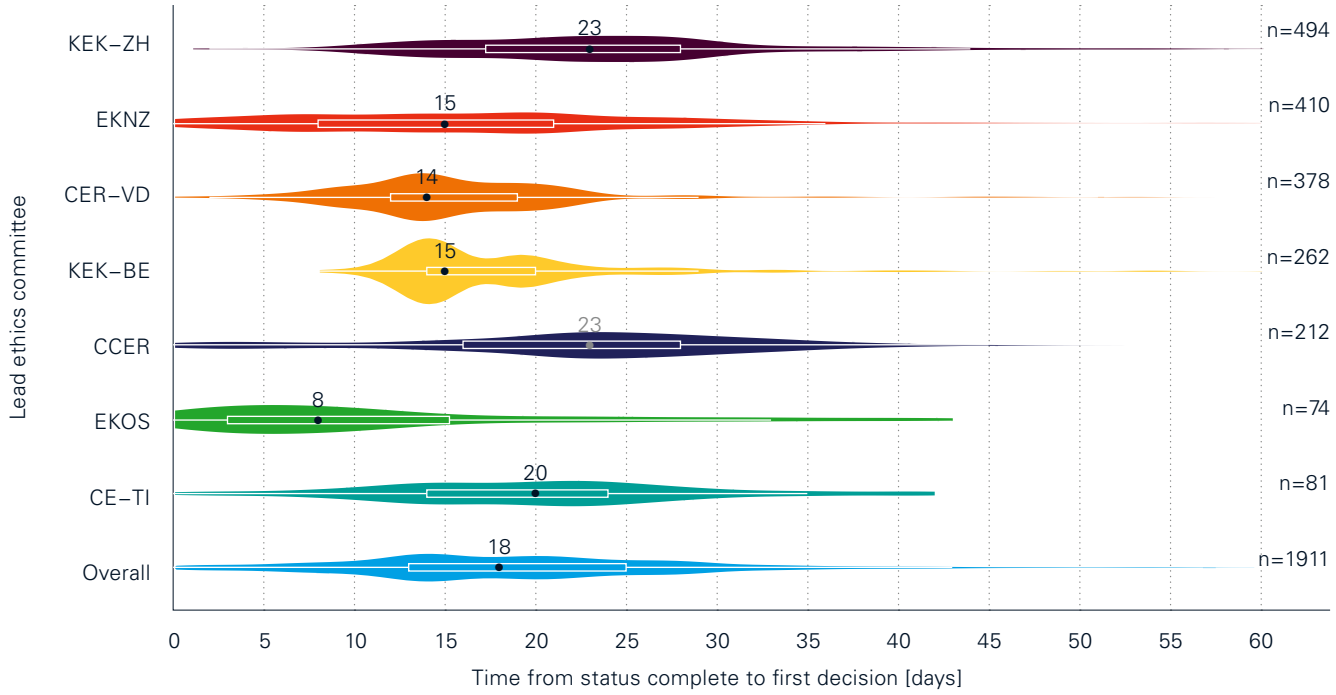
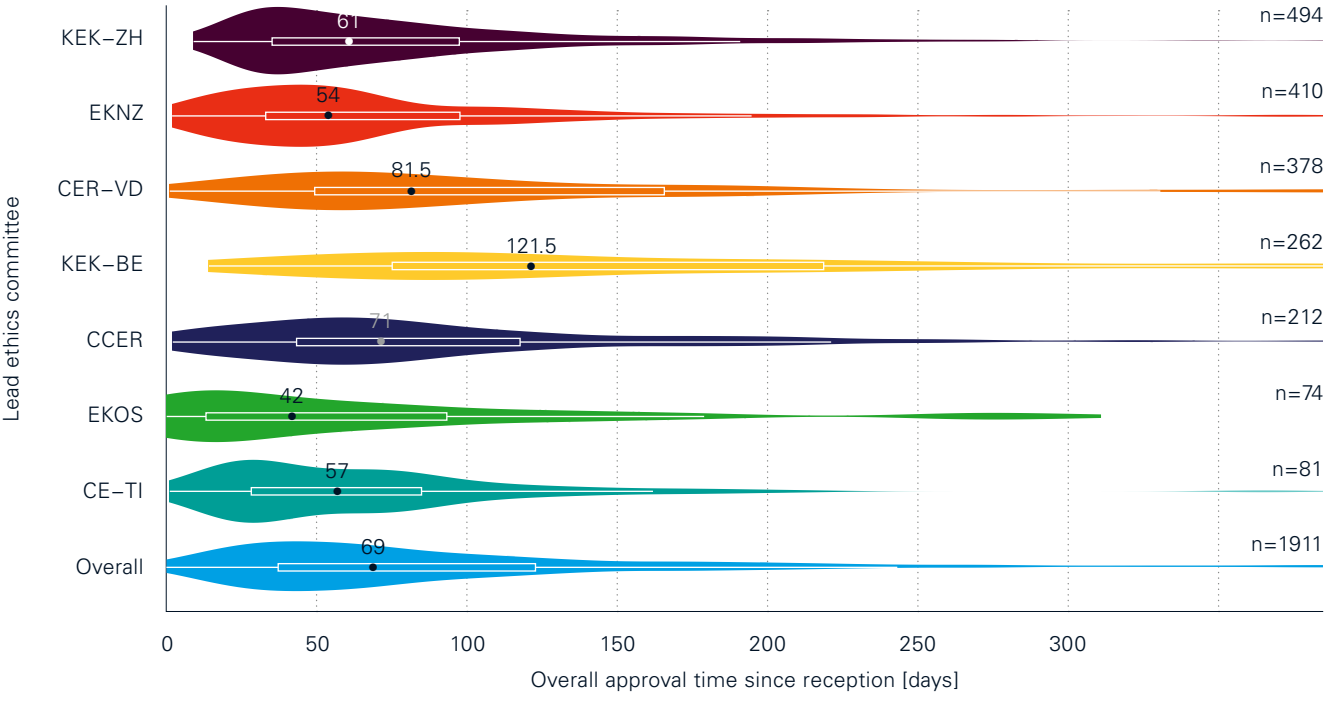


Figure 7: Overall approval time (median) by ethics committees from reception to final decision



The median time from receipt to the ethics committee's final decision (approval) is 69 days. Figure 7 provides a breakdown by ethics committee. Median processing times for all ethics committees are largely in line with those for previous years.

Assessment of ongoing research projects

The ethics committees' work is not complete once they have approved projects. They also have a duty to assess ongoing projects, an area where their approaches vary. Clinical trials are inspected by Swissmedic, the Swiss Agency for Therapeutic Products (see "Other supervisory authorities / Swissmedic" section). The competent committees generally attend the final discussion. The Northwestern and Central Switzerland, Vaud and Geneva committees also report on their own inspection activities, which take the form of audits.

The Northwestern and Central Switzerland committee conducted six audits to verify quality and gain a better understanding of the problems facing researchers. The Geneva committee made ten follow-up visits to various departments at Geneva University Hospital. In the course of these, 59 minor and nine serious deficiencies were found; these point to infringement of the rights, safety or wellbeing of the project participants or misuse of their data. The Bern committee reported one case of suspension, revocation or interruption for an ongoing project in response to notifications.

Complaint's procedure and assessment of applications for stem cell research projects

Several committees rejected a small number of applications during 2022 because ethical, formal/legal or scientific shortcomings had been identified. The majority of applicants accepted the rejections. Only one appeal – to the Bern committee – was submitted. In addition, one appeal from 2019 concerning an application rejected by the Zurich committee is still pending.

With the exception of the Eastern Switzerland and Bern committees, all ethics committees reported assessing one application subject to Art. 11 of the Stem Cell Research Act (StRA).

Advice for researchers and determination of responsibility

The ethics committees begin to advise researchers before they submit their research applications. Project design issues and potential conflicts of interest are discussed during the advice process. The informed consent process for participants is also discussed and explained. Although this advisory work reduces the workload involved in subsequent assessment, it also ties up resources and accounts for a substantial part of the committees' work and the work done by their scientific secretariats.

In addition, the number of "determinations of responsibility" has increased sharply. These are written preliminary investigations, in which researchers can resolve uncertainties with the ethics committee before they draw up and submit their research application. Assessing and responding to such requests also ties up considerable resources.

Networking and public relations work

The committees report on their regular dealings with supervisory authorities such as Swissmedic and the FOPH. They also maintain dialogues with the Swiss Academy of Medical Sciences (SAMS), Swiss Clinical Trial Organisation (SCTO), Swiss Biobanking Platform (SBP), Swiss Personalized Health Network (SPHN) and Swiss Society for Biomedical Ethics (SGBE).

In terms of the public relations work undertaken by the ethics committees in 2022, the "lunch LRH" series of events run by the Vaud committee and the publication of the Geneva committee's quarterly bulletin merit particular mention. Although there were virtually no events for people outside the ethics committees, the committees themselves made use of external continuing education platforms, such as those at universities, for presentations.

3 Ethics committees' comments on the research projects submitted

The comments below summarise the ethics committees' assessments of their activities during 2022.

Ethics Committee of Ticino

Advice as well as assessment

There was a significant year-on-year increase in the number of applications submitted in Ticino, particularly in the "Research involving persons, but not a clinical trial" and "Further use of personal data and biological material" categories. However, there was a slight decline in the percentage of clinical trials. The most popular field was oncology, followed by neurology, surgery and cardiology.

In addition to its assessment services, researchers frequently used the Ticino committee as a source of advice on applying the Human Research Act and to resolve procedural and methodological issues.

Ethics Committee of Eastern Switzerland

General consent proving effective

After the two years of the pandemic, assessment activities by the Ethics Committee of Eastern Switzerland (EKOS) returned to normal in 2022. The number of applications submitted is back to pre-pandemic levels, and compliance with processing times was good.

The slight rise in the number of clinical trials was offset by a decline in non-clinical research projects. It is particularly noteworthy that projects involving further use of personal data without participants' consent are becoming ever rarer, something the committee attributes to the increased use of general consent.

Moreover, the committee acted as lead committee and took decisions on projects assessed under the ordinary procedure almost twice as often as in 2021. The ordinary procedure is used for more complex, multicentre research projects. The committee regards this as a sign that sponsors have conducted an increased number of clinical trials after the pandemic.

Ethics Committee of Geneva

Slightly more applications than in 2021

The Ethics Committee of Geneva had slightly more applications to process in 2022, particularly trials involving the further use of biological material and personal data, as well as, to a lesser extent, clinical trials of medicinal products.

Ethics Committee of Vaud

Dialogue with researchers pays off

Application numbers remained largely stable in Vaud in 2022. Clinical trials increased slightly, while the number of non-clinical trials declined slightly. The former represented only about one sixth of all applications.

The Ethics Committee of Vaud was once again able to slightly decrease the average time needed to respond to applications in 2022. This was due firstly to the introduction in 2020 of organisational measures such as greater use of virtual meetings. Secondly, research institutions can help reduce processing times themselves if they have their own support and assistance structures for researchers. The Vaud committee is therefore motivated to further strengthen interaction with research institutions.

Ethics Committee of Bern

Eye on shorter processing times

The Bern ethics committee processed slightly fewer research applications than in the previous year. Despite illness- and maternity-related absences and a change of staff in the secretariat, the committee was able to keep processing times leading to the initial decision within the statutory thresholds. However, staffing shortages meant that the time between the initial and final decisions was too long from the committee's perspective. As a result, measures were adopted to shorten it. For example, there were modifications to the simplified procedure, so that applications no longer undergo a preliminary formal review by the scientific secretariat. In addition, compliance with conditions is now the sole responsibility of the sponsor.

Ethics Committee of Northwestern and Central Switzerland:

Short decision times

Applications were slightly up in northwestern and central Switzerland in 2022 compared with the previous year. However, numbers are now within annual fluctuation thresholds and back to pre-Covid pandemic levels.

As in previous years, the committee was able to ensure short decision times for application processing. The same was true of decisions on trials involving medical devices, an area where the committee recorded processing time data for the first time in 2022.

Ethics Committee of Zurich

Back to pre-pandemic levels

The number of applications submitted in Zurich in 2022 returned to pre-pandemic levels. The clinical trials that account for about a quarter of all applications have been relatively consistently split between the various trial categories, such as clinical trials of medicinal products or medical devices, for several years. The number of applications in the "Other clinical trials" category remained high in 2022.

There were very few notable events. The Zurich committee received isolated reports of safety and protective measures that had to be implemented in connection with clinical studies. Although one trial had to be terminated, there were no cases in which it was necessary to withdraw approval, suspend research projects or instigate criminal proceedings in 2022.

4 Conclusions and outlook

The ethics committees have successfully put the challenging years of the coronavirus pandemic behind them. Their annual reports indicate that working methods returned to normal in 2022 and assessment and approval activities continued to stabilise. The committees were able to fulfil their duties in accordance with requirements. The organisational measures introduced during the pandemic, such as working from home or virtual meetings, were retained where it made sense to do so, and are now an integral part of the way many committees operate.

In their reports, many ethics committees discuss the Medical Device regulation (Ordinance on Clinical Trials with Medical Devices, ClinO-MD), which was revised in 2021 and 2022, particularly in the context of research projects involving in vitro diagnostic medical devices. The challenges they cite include the complexity of the assessment procedure and timeline compliance, as well as coordination with other ethics committees and other supervisory authorities such as Swissmedic.

A further key challenge for the committees is the digitalisation of research, particularly as regards issues such as artificial intelligence, big data and decentralised clinical trials. To deal professionally with these challenges, the ethics committees emphasise the relevance of appropriate training and continuing education provision by Swissethics and external providers.

From a political perspective, the upcoming revision of the HRA ordinances is an important topic.

Ethics Committee of Ticino

Supporting researchers

In 2022, the Ticino committee focused on the entry into force of the Medical Devices Ordinance, which now covers in vitro diagnostic medical devices. The committee emphasises the importance of sensitising researchers in this field to the new rules and assisting them with implementation. The committee views the consultation on the revision of the ordinances associated with the Human Research Act as an opportunity to propose a number of amendments.

Ethics Committee of Eastern Switzerland

Strengthening digital skills

According to the Eastern Switzerland committee, working life returned to normal during 2022 and cooperation was effective, thanks in large part to the committee's stable membership over a period of many years. Despite staffing challenges in the secretariat, the committee is looking ahead to the future. Dealing competently with future research ethics issues will require indepth knowledge of software solutions, data protection and data systems. The committee is therefore planning to keep investing in members' continuing education so that it can safeguard the high quality of its work in the long term.

One political issue that concerns the committee is cost approvals. The question here is how the research and innovation that the ethics committees approve can subsequently be made available to patients. Key decisions on the way forward will be made when the Health Insurance Ordinance (KVV) is revised in 2023.

Ethics Committee of Geneva

Keeping an eye on workload

The Geneva committee reported a further increase in work volume for 2022. This is attributable to the constantly growing number of dossiers submitted and to the greater complexity of procedures. Although it has been possible to deal with the extra workload without additional staffing resources, the committee believes that change is needed.

A new Vice Chair was trained during 2022 and took up her role in January 2023. Due to the end of the term of office in 2023, the membership of the committee will be renewed at the start of 2024. In addition, replacements for the Chair and one position in the administrative secretariat will be organised in 2024.

On top of its regular duties, the committee is planning to complete coordination with Swissmedic for clinical trials conducted under the ClinO-MD in 2023. Moreover, it intends to continue its follow-up visits as a way of identifying problems with the implementation of research protocols. Verification of compliance with the legally prescribed reporting obligations will also be stepped up.

Ethics Committee of Bern

The challenge of recruitment

The Bern committee is satisfied with its established work processes. However, it points out that lack of resources is resulting in long timelines for final decisions on applications in some cases. The committee took action to shorten decision times in December 2022. For example, it is now the sponsor's responsibility to ensure that conditions associated with applications are fulfilled. Moreover, finding female members is proving a challenge for the committee.

The committee feels that cooperation with Swissmedic is established. To accommodate increasingly technologydriven key areas of research, such as artificial intelligence, the committee intends to recruit members with a strong track record in digital transformation in the healthcare sector.

Ethics Committee of Vaud

Intensifying cooperation

The Vaud committee summarises 2022 as a successful year, emphasises the benefits of regular, trust-driven dialogue with research institutions and advocates intensified dialogue. Meetings with managers will therefore be used by both sides to develop skills to take account of the limited resources and give priority to shared use of specialist knowledge.

On-site audits will not only be used to verify compliance with requirements, but also to observe the relevance of internal support services and to identify areas where support is still lacking. This will make it possible to include research teams, sponsors and the facility in which the research is being conducted. The committee regards the appointment of two additional members to deal with big data or artificial intelligence projects as a positive development.

Ethics Committee of Northwestern and Central Switzerland

Promoting continuing education for members

The Northwestern and Central Switzerland committee regards 2022 as a successful year and reports that average processing time is comparable to 2021 despite the new requirements of the ClinO-MD. In addition to balancing its budget, the committee also mentions technical aspects of the BASEC portal, which it regards as very helpful overall but too slow in certain functions. In the outlook section of its report, the committee cites moving to new office premises and promoting continuing education as goals for 2023.

Ethics Committee of Zurich

Driving forward standardisation

The Zurich committee did not report any increase in the number of applications submitted in 2022 and continued to work with virtually no change to its membership. However, the process of handing over to the new head of the committee and new head of the scientific secretariat was commenced or has already been completed. In 2023, the cantonal government plans to appoint committee members for the period from June 2023 to May 2027. All current members are offering themselves for reappointment. In addition, standards for rapporteur reports will be introduced and office processes will be consolidated. Although staff shortages make it a challenging task, the committee is confident of being able to maintain timeline management. Like the other ethics committees, the Zurich committee continues to work within Swissethics to harmonise the processes and assessment standards of the cantonal ethics committees nationwide and to optimise them in the interests of the people who take part in research.

5 Other supervisory authorities

Swissmedic
Complexity continues to grow

Clinical trials with medical devices.

Swissmedic approves clinical trials of medical devices if the devices or intended applications are not yet CE-certified (Category C clinical trials). While the trials are in progress, Swissmedic monitors incidents subject to a mandatory reporting requirement, such as serious events or reports on participant safety.

In 2022, Swissmedic approved 37 first-time applications for clinical trials with medical devices and 100 variations to ongoing clinical trials. A total of 143 variations to clinical trials were monitored, as were 106 annual safety reports and 41 safety reports from ongoing trials.

Clinical trials with medicinal products

Swissmedic verifies whether the quality and safety of the test product used in clinical trials of medicinal products in Category B and C is guaranteed.

Swissmedic received 186 applications for clinical trials of medicinal products during 2022. 165 clinical trials were approved. The complexity of the application dossiers continued to rise in line with the growth in medicinal product complexity.

In addition, Swissmedic processed 2,698 (previous year: 2,612) other requests or notifications relating to clinical trials as well as 118 (previous year: 98) reports of suspected unexpected serious adverse reactions (SUSAR).

Federal Office of Public Health
Expertise in radiation protection and transplantation

Transplantation

Category C clinical trials involving the transplantation of human organs, tissues or cells require authorisation from the Transplantation Section of the FOPH. No new applications were submitted to the FOPH in 2022.

Radiation protection

The FOPH Radiation Protection Division prepares an opinion for the ethics committee if, in the case of planned investigations involving radiation sources, the effective dose per person is more than 5 millisieverts (mSv) per year and the interventions in question are not routine examinations using authorised radiopharmaceuticals. This applies both for clinical trials and for all other human research projects. The Radiation Protection Division prepared one opinion for concomitant investigations involving radiation sources.

For Category C clinical trials with therapeutic products capable of emitting ionising radiation in humans, the Radiation Protection Division prepares an opinion for Swissmedic. It did so for nine trials in 2022. Four of these opinions concerned medical devices, while the remainder concerned radiopharmaceuticals. Four of the latter involved first use in humans. In addition, opinions were prepared on requested amendments for ongoing clinical trials. Furthermore, the Radiation Protection Division provided specialist advice to an ethics committee and the management of a research project involving a Category C medical device.

All opinions were delivered within the specified time limit.

6 Swissethics and Kofam

Swissethics
2022 – a multifaceted year

The Swissethics association brings together all seven Swiss research ethics committees. As a national umbrella organisation, Swissethics is a central body handling enquiries from researchers, sponsors, CROs and patients, as well as national institutions. Swissethics coordinates the ethics committees in such a way as to ensure that provisions on research involving humans are applied uniformly.

During 2022, Swissethics' coordination activities included pilot projects with cannabis. Following the revision of the Narcotics Act, controlled dispensing of cannabis for non-medical purposes is permitted in Switzerland subject to scientific supervision. The pilot trials are also being assessed by the ethics committees. By the end of 2022, a total of nine projects had been submitted to the ethics committees.

Regulatory topics also occupied Swissethics: On 26 May 2021, the Medical Device Regulation (MDR) came into force in the EU and the ClinO-MD in Switzerland. One year later, the In Vitro Diagnostic Regulation (IVDR) came into force. swissethics prepared the implementation of these two regulatory changes in the long term with Swissmedic and then applied them in a synchronised manner, so that a largely smooth transition was possible.

Finally, activities in 2022 also focused on amending the guidance document on decentralised clinical trials. A trilateral discussion between industry representatives, Swissmedic and Swissethics was held on the subject in August 2022. Nevertheless, some questions are still unresolved, such as telemedical care for trial participants, data privacy or third-party electronic access to documents.

Coordination Office for Human Research (kofam)
Rapid advance of digitalisation

The Coordination Office for Human Research (kofam) is operated by the Federal Office of Public Health (FOPH). It acts as coordinator between the supervisory authorities on matters related to research involving humans in Switzerland and provides information to both the public and researchers.

kofam held four exchange meetings in 2022, in which representatives of the scientific secretariats of the cantonal ethics committees, their umbrella organisation Swissethics, Swissmedic and the enforcement divisions of the FOPH took part. The topics discussed included coordination between the FOPH and the ethics committees on the approval of pilot trials with cannabis. Furthermore, information sheets on subjects such as the use of software as medical devices were prepared. These are intended to assist researchers and supervisory authorities alike in their work.

The key topic of the main exchange meeting was the electronic consent (e-consent), especially for decentralised clinical trials, where the challenges include the authenticity of electronic signatures, revocation and integration in electronic patient records.

A further focal area of activity in 2022 was the resumption of work on ordinance revision. The federal offices circulated the draft for consultation at the end of 2022. The ethics committees and swissmedic were in-formed of the planned amendments at an event in November.

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