

Activities of the Research Ethics Committees 2015

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



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

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

Foreword

With this report for 2015, the Coordination Office for Human Research (kofam) of the Federal Office of Public Health (FOPH) is, for the second time, fulfilling its duty to inform the public about the activities of the cantonal research ethics committees.

The Human Research Act (HRA)¹ specifies the conditions under which research projects involving human beings may be carried out, with the prime goal being to protect human dignity, privacy and health. The research ethics committees are assigned the key responsibility of assessing each research project falling within the scope of the Act and determining whether these conditions are met, both before and during the conduct of the project. The ethics committees report annually to kofam on their activities, and in particular on the type and number of research projects assessed and on the processing times. In turn, kofam informs the public by producing a summary of the ethics committees' annual reports and a statistical overview of the research projects approved.

Since the HRA came into effect on 1 January 2014, numerous processes regulated by this Act have been further elaborated, and this report therefore differs in various ways from its predecessor in terms of both presentation and content. In order to further improve the thematic organisation vis-à-vis 2014, efforts were made in collaboration with swissethics² and the ethics committees to further harmonise and standardise the way in which the committees' reports are structured. The original versions of the ethics committees' annual reports can be found on the websites of the committees and of kofam³.

For 2015, the statistical information on the type and number of research projects submitted, and the time required for assessment, has been further standardised. As a result – unlike the previous year – the committees' individual activities can be compared and placed in a national context. This improvement in data availability is largely attributable to the coordination efforts undertaken by swissethics.

OrgO-HRA⁴, Coordination Office Art. 10

- 1 The Federal Office of Public Health (FOPH) shall manage the coordination office as specified in Article 55 HRA.
- 2 In particular, the coordination office has the following duties:
 - a. It ensures regular exchanges between the supervisory authorities concerned.
 - b. It ensures regular exchanges with research representatives and institutions.
 - c. In cooperation with the ethics committees and, where appropriate, other supervisory authorities concerned, it issues recommendations on authorisation and notification procedures and on specific aspects of decision-making practice.
 - d. It participates in the design and implementation of basic and further training for members of ethics committees.
 - e. It provides information for the public, preparing in particular a summary of the annual reports submitted by ethics committees and a statistical overview of the research projects authorised.
- 3 It may, within the framework of the operation of the portal and the supplementary federal database in accordance with Article 67 ClinO, enable the electronic exchange of documents relating to the authorisation and notification procedures between applicants and authorisation authorities.
- 4 It shall issue guidelines on the content of the reports to be submitted by ethics committees in accordance with Article 55 paragraph 2 HRA.

The present report is also available on the kofam website³, together with the supplementary factsheet "The Human Research Act and the Ethics Committees for Research".

Bern, December 2016

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¹ Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA; SR 810.30)

² swissethics – until 24 May 2014 known as the Swiss Association of Ethics Committees (AGEK) – is the umbrella organisation of the cantonal ethics committees, cf. Section 4.

³ www.kofam.ch

⁴ Ordinance of 20 September 2013 on Organisational Aspects of the Human Research Act (HRA Organisation Ordinance, OrgO-HRA; SR 810.308)

1 List of ethics committees

CCER – Cantonal Research Ethics Committee, Geneva

Commission cantonale d'éthique de la recherche (CCER)

Rue Adrien-Lachenal 8

CH-1207 Geneva

ccer@etat.ge.ch

www.ge.ch/ccer

Chair: Professor Bernard Hirschel

Region covered: Canton of Geneva

Relevant cantonal regulations

- Regulations of 4 December 2013 for implementation of the Federal Act on Research involving Human Beings (RaLRH; K 4 06.02)

CCVEM – Cantonal Medical Ethics Committee, Valais

Commission cantonale valaisanne d'éthique médicale (CCVEM)

Institut Central des Hôpitaux

Av. Grand-Champsec 86

CH-1951 Sion

ccvem@hopitalvs.ch

No website

Chair: Professor Patrick Ravussin

Region covered: Canton of Valais

Relevant cantonal regulations

- Cantonal Health Law of 14 February 2008
- Ordinance of 4 March 2009 on Biomedical Research involving Human Beings

CE-TI – Cantonal Ethics Committee, Ticino

Comitato etico cantonale

c/o Ufficio di sanità

Via Orico 5

CH-6501 Bellinzona

dss-ce@ti.ch

www.ti.ch/ce

Chair: Giovan Maria Zanini, Cantonal Pharmacist, Department of Health and Social Affairs, Mendrisio

Region covered: Canton of Ticino

Relevant cantonal regulations

- Law of 18 April 1989 on Health Promotion and Coordination (Health Law) (6.1.1.1)
- Ethics Committee Decree of 25 November 2002 "Recruitment of research subjects by means of advertisements"
- Agreement between the Canton Ticino Ethics Committee and the CRO on the Cantonal Registry of Healthy Volunteers

CER-VD – Commission cantonale (VD) d'éthique de la recherche sur l'être humain

Commission cantonale (VD) d'éthique de la recherche sur l'être humain (CER-VD)

Avenue de Chailly 23

CH-1012 Lausanne

secretariat.cer@vd.ch

www.cer-vd.ch

Chair: Professor Patrick Francioli

Region covered: Cantons of Fribourg, Neuchâtel, Vaud

Relevant cantonal regulations

- Canton of Vaud Public Health Law of 29 May 1985 (800.01)

EKNZ – Ethics Committee of Northwestern and Central Switzerland

Ethikkommission Nordwest- und Zentralschweiz (EKNZ)

Hebelstrasse 53

CH-4056 Basel

eknz@bs.ch

www.eknz.ch

Chair: Professor André P. Perruchoud

Region covered: Cantons of Aargau, Basel-Landschaft, Basel-Stadt, Jura, Lucerne, Nidwalden, Obwalden, Schwyz, Solothurn, Uri, Zug

Relevant cantonal regulations

- Agreement of 6 September 2013 on the appointment of a joint ethics committee for Northwestern and Central Switzerland (EKNZ Agreement)

KEK-BE – Cantonal Ethics Committee, Bern

Kantonale Ethikkommission Bern (KEK-BE)

Postfach 56

CH-3010 Bern

kek@kek.unibe.ch

www.kek-bern.ch

Chair: Professor Christian Seiler, Deputy Chief Physician, Department of Cardiology, University Hospital, Bern

Region covered: Canton of Bern

Relevant cantonal regulations

- Ordinance on the Cantonal Ethics Committee of 20 August 2014 (KEKV; BSG 811.05)

EKSG – Cantonal Ethics Committee, St Gallen

Ethikkommission des Kantons St. Gallen

Kantonsspital

Haus 37

CH-9007 St Gallen

susanne.driessen@kssg.ch

www.sg.ch/home/gesundheit/ethikkommission.html

Chair: Dr Susanne Driessen, Dip. Pharmaceutical Medicine

Region covered: Cantons of Appenzell Ausserrhoden, Appenzell Innerrhoden, St Gallen

Relevant cantonal regulations

- Canton of St Gallen Therapeutic Products Ordinance of 29 October 2009
- EKSG by-laws. The by-laws now available on the website are those of the Ethics Committee of Eastern Switzerland (EKOS), which was established on 1 June 2016.

KEK-TG – Cantonal Ethics Committee, Thurgau

KEK-TG – Kantonale Ethikkommission des Kantons Thurgau

Spitalcampus 1

CH-8596 Münsterlingen

rainer.andenmatten@stgag.ch

No website

Chair: Dr Rainer Andenmatten, Cantonal Pharmacist

Region covered: Canton of Thurgau

Relevant cantonal regulations

- Canton Thurgau, Law of 3 December 2014 on the Health System (Health Law), § 6 Ethics committee.

KEK-ZH – Cantonal Ethics Committee, Zurich

Kantonale Ethikkommission Zürich

Stampfenbachstrasse 121

CH-8090 Zurich

Info.KEK@kek.zh.ch

www.kek.zh.ch

Chair: Professor Peter Meier-Abt

Region covered: Cantons of Glarus, Graubünden, Schaffhausen and Zurich, and the Principality of Liechtenstein

Relevant cantonal regulations

- Therapeutic Products Ordinance of the Canton of Zurich
- By-laws

Comparison of the ethics committees

Various aspects of the committees are compared below, based on the statistical data provided and on information given in the committees' reports. In cases where only certain committees are mentioned, information on the topic in question is not available for the other committees. Additional information may possibly be found on the committees' websites.

Organisation

All the cantonal ethics committees, as far as is apparent, are organisationally attached to the cantonal health or social services departments, with some being assigned to the Cantonal Pharmacist's Office (Bern, Geneva, Ticino, Thurgau). In the cantons of Thurgau and Ticino, the Cantonal Pharmacist also serves as chair of the committee. In 2015, the Geneva com-

mittee moved to the premises of the Cantonal Pharmacist's Office, but it continues to meet at the Geneva University Hospitals (HUG). In the canton of Bern, in the interests of Bern's position as a research centre, the Cantonal Education Directorate is involved in the supervision of the ethics committee via a co-reporting procedure. The Northwestern and Central Switzerland committee is overseen by an intercantonal supervisory body which was established following the merger of the individual predecessor committees. The internal organisation of Switzerland's largest committee – the Cantonal Ethics Committee, Zurich – has a managerial structure comprising a chair, vice-chair, director, and heads of the legal and scientific secretariats. The ethics committee itself is subdivided into two sections of equal status (A and B), led by the chair and vice-chair. The Vaud committee also consists of two sections.

OrgO-HRA, Chapter 1: Research Ethics Committee, Art. 1 Composition

- 1 The research ethics committee (ethics committee) shall be composed at least of persons possessing expertise in the following disciplines:
 - a. medicine;
 - b. psychology;
 - c. nursing;
 - d. pharmaceuticals or pharmaceutical medicine;
 - e. biology;
 - f. biostatistics;
 - g. ethics; and
 - h. law, including data protection.
- 2 It shall be of balanced composition as regards gender and professional groups.
- 3 The ethics committee must be able to draw on knowledge of local conditions in the various areas of responsibility.
- 4 If the ethics committee lacks the expertise required for the assessment of a research project, it must call in external specialists.

Table 1: Number of ethics committee members and disciplines represented (as of 31 December 2015)

Details of ethics committee composition: number of members for each discipline represented (more than one discipline possible per member)	Total		KEK-TG		CCVEM		CE-TI		EKSG		CCER		KEK-BE		EKNZ		CER-VD		KEK-ZH	
	Number (N)	Per cent (%)																		
Medicine	98	41.5	3	42.9	5	41.7	9	45.0	6	28.6	12	33.3	11	47.8	12	38.7	15	39.5	25	52.1
Psychology	14	5.9	1	14.3	0	0.0	0	0.0	1	4.8	2	5.6	2	8.7	2	6.5	2	5.3	4	8.3
Biology	13	5.5	0	0.0	1	8.3	1	5.0	2	9.5	2	5.6	2	8.7	1	3.2	2	5.3	2	4.2
Law	21	8.9	1	14.3	1	8.3	2	10.0	3	14.3	2	5.6	3	13.0	4	12.9	3	7.9	2	4.2
Ethics	22	9.3	1	14.3	1	8.3	2	10.0	3	14.3	5	13.9	1	4.3	3	9.7	4	10.5	2	4.2
Pharmaceuticals or pharmaceutical medicine	22	9.3	1	14.3	1	8.3	2	10.0	2	9.5	3	8.3	1	4.3	3	9.7	4	10.5	5	10.4
Epidemiology or biostatistics	15	6.4	0	0.0	1	8.3	2	10.0	1	4.8	4	11.1	1	4.3	3	9.7	1	2.6	2	4.2
Patient advocacy	4	1.7	0	0.0	1	8.3	0	0.0	1	4.8	1	2.8	0	0.0	0	0.0	0	0.0	1	2.1
Nursing	21	8.9	0	0.0	1	8.3	2	10.0	2	9.5	4	11.1	1	4.3	3	9.7	3	7.9	5	10.4
Other	6	2.5	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	1	4.3	0	0.0	4	10.5	0	0.0
Total: disciplines represented	236	100.0	7	100.0	12	100.0	20	100.0	21	100.0	36	100.0	23	100.0	31	100.0	38	100.0	48	100.0
Total: members	211	100.0	8	3.8	12	5.7	19	9.0	15	7.1	36	17.1	22	10.4	31	14.7	29	13.7	39	18.5

Appointment of members

Certain committees report that their members are appointed by the cantonal executive authorities – in the case of the Geneva and Valais committees by the cantonal government, in the case of the Vaud committee by the departmental head for a period of two years, and in the case of the Zurich committee by the Executive Council (at the request of the Health Directorate) for four years. In the canton of St Gallen, ethics committee members are appointed by the Health Department, and in Thurgau by the Department of Finance and Social Affairs, for four years in each case. The Northwestern and Central Switzerland committee reports one personnel change for the year under review, while Bern reports four new members and five departures. One new member – also employed in the scientific secretariat – was appointed to the St Gallen committee.

HRA, Chapter 9: Research Ethics Committees,

Art. 52 Independence

- 1 Ethics committees shall exercise their duties in a professionally independent manner, without being subject to instructions from the supervisory authority in this regard.
- 2 The members of ethics committees shall disclose their interests. Each ethics committee shall maintain a publicly accessible register of interests.
- 3 Members who are interested parties shall not participate in the assessment and decision procedures.

Art. 54 Organisation and financing

- 1 Each canton shall designate the ethics committee responsible for its territory and appoint the members thereof. It shall oversee the activities of the ethics committee.
- 2 Each canton has at most one ethics committee. Several cantons may appoint a joint ethics committee or agree that one canton's ethics committee is also to be responsible for other cantons.
- 3 The Federal Council may issue guidelines concerning the minimum number of research projects to be assessed by an ethics committee per year. It shall first consult the cantons.
- 4 Each ethics committee shall have a scientific secretariat. Details of the organisation and working methods are to be publicly accessible in by-laws.
- 5 The canton shall assure the financing of the ethics committee. It may make provision for the charging of fees.

Secretariats

Under Art. 54 HRA, ethics committees are required to have a scientific secretariat. In some cases, the information provided by the committees on these bodies also covers their administrative secretariats.

The Geneva committee, for example, reports that it has a scientific secretary (70 % position) and three administrative secretaries (210 %). As the committee's office also employs a legal specialist (20 %), as well as the chair (40 %), the total is 340 %. The Vaud committee's secretariat (as of 31 December 2015) consists of four people (280 %, including one with a PhD) plus temporary staff (130 %); the full-time PhD-level position is vacant. Two people completed an internship. In 2015, two academic staff were employed by the Bern committee for implementation of the HRA. St Gallen reports that it has one person in its scientific and two in its administrative secretariat (total: 160 %). The Valais committee operates its secretariat with a 20 % position. The Zurich committee's scientific secretariat (as of 31 December 2015) was staffed by five people (four with a scientific background and one legal professional; total: 400 %). The Ticino committee has two academic staff (total: 150 %) and an administrative secretary (70 %).

Financial data

Seven of the nine ethics committees include financial data in their activity reports (Geneva, Northwestern and Central Switzerland, St Gallen, Thurgau, Vaud, Valais, Zurich), and the Vaud and Valais committees also make reference to detailed annual accounts published online.⁵ The Northwestern and Central Switzerland committee reports a "considerable profit" without giving any further details. The Vaud committee reports a surplus of CHF 242,926 (approx. 20 % of revenues).

The extent to which costs are covered by fees is approx. two thirds on average, although it varies widely for the four ethics committees that include this data in their reports: the figures are 86 % for Geneva, 75 % for Zurich, 67 % for Vaud and 38 % for Valais.

Two committees report an increase in their fee income compared to the previous year (St Gallen and Vaud, with the latter reporting an increase of approx. 20 % since 1 January 2014). The Vaud committee received approx. CHF 55,000 in fees for approving 85 substantial amendments. As regards expenditures, the Geneva committee reports that personnel costs account for 80 % of the total.

⁵ Valais: http://www.hopitalduvalais.ch/fileadmin/files/hopital/Rapports/Rapport-de-gestion-HVS-2015_FR.pdf
Vaud: http://www.cer-vd.ch/fileadmin/user_upload/documents/Rapport_Activite___20160429_Final_2.pdf

2 Activities of the ethics committees

Under Article 51 HRA, supervisory authorities are responsible for assessing, in advance, research projects that fall within the scope of the HRA, on the basis of the project documentation submitted. They are subsequently required to assess whether the conduct of approved projects complies with the relevant requirements. In both cases, the assessment must primarily determine whether the researchers ensure that human dignity, privacy and health are duly protected. The main supervisory authorities, involved in every project, are the cantonal research ethics committees; in addition, certain projects require the involvement of Swissmedic and the FOPH (Radiological Protection and Transplantation).

Assessment of research projects (authorisation procedures)

For 2015, as for the previous year, details are given of the number of applications *submitted*. From next year (for the 2016 report), thanks to the electronic application submission and management system BASEC (Business Administration System for Ethical Committees), the number of research projects *assessed* – i. e. actually approved or rejected by the supervisory authorities – should be available.

Statistical overviews

Under the HRA, if a research project is to be conducted at a number of sites, for which various ethics committees are responsible (i. e. a multicentre research project), the opinion of all the committees concerned must be sought. However, the ethics committee which is responsible at the site of activity of the investigator coordinating the project serves as the lead committee and provides a final assessment of the research project for all sites. To assess whether the professional and operational requirements are met at the sites outside the territory for which it is responsible, the lead committee seeks the opinion of the other (local or participating) committees. A multicentre research project thus gives rise to assessment procedures within a number of committees – the preparation of opinions by local committees for the lead committee, and the actual authorisation procedure carried out by the lead committee.

HRA, Art. 1 Purpose

- 1 The purpose of this Act is to protect the dignity, privacy and health of human beings involved in research.
- 2 It is also designed to:
 - a. create favourable conditions for research involving human beings;
 - b. help to ensure the quality of research involving human beings;
 - c. ensure the transparency of research involving human beings.

To calculate the total number of research projects submitted for assessment in Switzerland, the applications submitted for monocentre studies are first added to those submitted to the lead committee in the case of multicentre projects. Thus, in 2015, a total of 2002 research projects were submitted for assessment, of which 246 (9.2 %) were multicentre projects. On average, 3.7 cantonal ethics committees were involved in the assessment of multicentre projects.

If the number of opinions prepared by local ethics committees is then added to the number of research projects submitted, a total of 2674 project assessment procedures were triggered in 2015. Of these, 663 (24.8 %) were opinions prepared by local ethics committees for the lead committee as part of a multicentre authorisation procedure. Of the 2674 assessment procedures, 1765 (66 %) concerned applications for monocentre research projects – i. e., in accordance with the HRA, projects to be conducted within the territory of a single ethics committee.⁶ The remaining 909 (34 %) were assessment procedures for multicentre projects.

Table 2: Total number of applications submitted to all ethics committees, broken down by type of research and mono-/multicentre research projects.

	Number (N)	Per cent (%)
No. of applications for approval of a research project	2674	100.0
No. of applications received for approval of a monocentre research project	1765 ¹⁰	66.0
No. of applications for approval of a multicentre research project received as the lead ethics committee	246	9.2
No. of applications for approval of a multicentre research project received as a local ethics committee	663	24.8
No. of applications received for approval of a mono- or multicentre research project (multicentre only as the lead ethics committee)	2002 ¹⁰	100.0
No. of applications received for approval of a mono- or multicentre clinical trial (multicentre only as the lead ethics committee)	585	29.2
No. of applications received, as the lead ethics committee, for approval of a mono- or multicentre research project involving measures for sampling of biological material or collection of health-related personal data from persons (HRO, Chapter 2)	696	34.8
No. of applications received, as the lead ethics committee, for approval of a mono- or multicentre research project involving biological material and/or health-related data (HRO, Chapter 4, incl. research projects approved in accordance with Art. 34 HRA)	720	36.0

Of the 2002 research projects submitted, 585 (29.2 %) were clinical trials⁷, 696 (34.8 %) were non-clinical trial research projects⁸, and 720 (36 %) were research projects involving further use of biological material and health-related personal data.⁹ The Zurich committee additionally reported the submission of 9 projects involving deceased persons¹⁰.

⁶ Projects carried out at several sites within the region for which a single committee is responsible also count as monocentre (e.g. a project conducted in Basel, Aarau and Lucerne, because it takes place within the territory of the Northwestern and Central Switzerland committee).

⁷ Cf. Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, ClinO; SR 810.305), Chapters 2–4

⁸ Cf. Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO; SR 810.301), Chapter 2

⁹ Cf. Chapter 3 HRO

¹⁰ Nine applications for projects with deceased subjects are included in the number of applications for authorization of a single-centre research project (1765), but not in the number of applications received for authorization of a single-centre and multicentre research project (2002).

Table 3: Research projects, by type and category

	Number (N)	Per cent (%)						
No. of applications received for approval of a mono- or multicentre clinical trial (multicentre only as lead ethics committee)	585	100.0						
			Category A		Category B		Category C	
No. of applications received, as the lead ethics committee, for approval of a mono- or multicentre clinical trial of medicinal products	262	44.8	31	11.8	67	25.6	164	62.6
No. of applications received, as the lead ethics committee, for approval of a mono- or multicentre clinical trial of medical devices	148	25.3	108	73.0	–	–	40	27.0
No. of applications received, as the lead ethics committee, for approval of a mono- or multicentre clinical trial of transplant products	7	1.2	4	57.1	0	0.0	3	42.9
No. of applications received, as the lead ethics committee, for approval of a mono- or multicentre clinical trial of gene therapy, or of genetically modified or pathogenic organisms	5	0.9	2	40.0	0	0.0	3	60.0
No. of applications received, as the lead ethics committee, for approval of a mono- or multicentre clinical trial of another kind, in accordance with Chapter 4 ClinO	163	27.9	142	87.1	21	12.9	–	–
No. of applications received, as the lead ethics committee, for approval of a mono- or multicentre research project involving measures for sampling of biological material or collection of health-related personal data from persons (HRO, Chapter 2)	696	100.0	665	95.5	31	4.5	–	–

In Table 3, the various types of research project are further broken down by risk category. For example, of the 262 applications submitted to ethics committees for clinical trials of medicinal products, 11.8 % were assigned to Category A¹¹, 25.6 % to Category B and 62.6 % to Category C. In the clinical trials of medical devices, 108 (73 %) of the 148 applications were Category A and 40 (27 %) Category C.

In Table 4, the total number of applications received by each committee is broken down by the type of research project. The committees are sorted in ascending order by the total number of applications received – starting with the Thurgau committee, which received the lowest number of applications (26), and ending with the Zurich committee (675 applications). Details of the number of applications by type of project for each individual ethics committee can be found on the kofam website.

Depending on the type of research project submitted, ethics committees use different assessment procedures – the regular (plenary), simplified (three member subcommittee), or presidential procedure (decision made by the chair alone). The type of procedure thus depends on the type of project and the risk category. Table 5 provides a comparative overview of the number of decisions made by each ethics committee, broken down by type of procedure. The total number of assessment procedures triggered within local or lead committees in 2015

(2674) differs from the number of decisions made¹² in that year (2505) since the period from submission of an application to decision may extend over two calendar years (submission in 2014, decision in 2015/submission in 2015, decision in 2016).

Table 6 shows the median time taken by each ethics committee to process an application and communicate a decision.¹³

¹¹ For categorisation, cf. Art. 19 ClinO

¹² These include, firstly, the approval decisions communicated to researchers by lead committees and, secondly, the (purely) internal decisions taken by local ethics committees regarding the opinion to be communicated to the lead committee as part of the authorisation procedure for multicentre projects.

¹³ See the outline of the legally prescribed processing periods on p. 10 of the Factsheet “The Human Research Act and the Ethics Committees for Research”, available at: www.kofam.ch

Table 4: Number and type of applications for approval of a research project received by each ethics committee

No. and type of applications received in 2015	Total		KEK-TG		CCVEM		CE-TI		EKSG		CCER		KEK-BE		EKNZ		CER-VD		KEK-ZH	
	Number (N)	Per cent (%)																		
Applications for approval of a multicentre research project received as the lead ethics committee	246	100.0	4	1.6	3	1.2	11	4.5	25	10.2	21	8.5	45	18.3	49	19.9	27	11.0	61	24.8
Applications for approval of a multicentre research project received as a local ethics committee	663	100.0	15	2.3	20	3.0	61	9.2	68	10.3	82	12.4	101	15.2	110	16.6	93	14.0	113	17.0
Applications received for approval of a monocentre research project	1765	100.0	7	0.4	24	1.4	56	3.2	78	4.4	203	11.5	250	14.2	288	16.3	358	20.3	501	28.4
Applications received for approval of a mono- or multicentre* research project	2002	100.0	11	0.5	27	1.3	67	3.3	103	5.1	224	11.2	295	14.7	337	16.8	385	19.2	553	27.6
Applications received for approval of a mono- or multicentre* clinical trial	585	100.0	9	1.5	18	3.1	36	6.2	36	6.2	61	10.4	79	13.5	103	17.6	77	13.2	166	28.4
Applications received for approval of a mono- or multicentre* clinical trial of medicinal products	262	100.0	1	0.4	1	0.4	23	8.8	21	8.0	28	10.7	41	15.6	54	20.6	34	13.0	59	22.5
Category A	31	100.0	1	3.2	1	3.2	1	3.2	2	6.5	6	19.4	6	19.4	6	19.4	5	16.1	3	9.7
Category B	67	100.0	0	0.0	0	0.0	5	7.5	6	9.0	11	16.4	11	16.4	13	19.4	8	11.9	13	19.4
Category C	164	100.0	0	0.0	0	0.0	17	10.4	13	7.9	11	6.7	24	14.6	35	21.3	21	12.8	43	26.2
Applications received for approval of a mono- or multicentre* clinical trial of medical devices	148	100.0	3	2.0	5	3.4	5	3.4	7	4.7	21	14.2	17	11.5	23	15.5	18	12.2	49	33.1
Category A	108	100.0	2	1.9	5	4.6	3	2.8	7	6.5	14	13.0	13	12.0	16	14.8	13	12.0	35	32.4
Category C	40	100.0	1	2.5	0	0.0	2	5.0	0	0.0	7	17.5	4	10.0	7	17.5	5	12.5	14	35.0
Applications received for approval of a mono- or multicentre* clinical trial of transplant products	7	100.0	0	0.0	0	0.0	0	0.0	0	0.0	2	28.6	3	42.9	2	28.6	0	0.0	0	0.0
Category A	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	1	25.0	3	75.0	0	0.0	0	0.0	0	0.0
Category B	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
Category C	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0
Applications received for approval of a mono- or multicentre* clinical trial of gene therapy, or of genetically modified or pathogenic organisms	5	100.0	0	0.0	0	0.0	0	0.0	0	0.0	1	20.0	0	0.0	0	0.0	2	40.0	2	40.0
Category A	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	1	50.0
Category B	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
Category C	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	66.7	1	33.3
Applications received for approval of a mono- or multicentre* clinical trial of another kind, in accordance with Chapter 4 ClinO	163	100.0	5	3.1	12	7.4	8	4.9	8	4.9	9	5.5	18	11.0	24	14.7	23	14.1	56	34.4
Category A	142	100.0	5	3.5	12	8.5	8	5.6	6	4.2	7	4.9	15	10.6	21	14.8	21	14.8	47	33.1
Category B	21	100.0	0	0.0	0	0.0	0	0.0	2	9.5	2	9.5	3	14.3	3	14.3	2	9.5	9	42.9
Applications received for approval of a mono- or multicentre* research project involving measures for sampling of biological material or collection of health-related personal data from persons (HRO, Chapter 2)	696	100.0	2	0.3	9	1.3	21	3.0	34	4.9	96	13.8	90	12.9	122	17.5	180	25.9	142	20.4
Category A	665	100.0	2	0.3	9	1.4	20	3.0	33	5.0	95	14.3	85	12.8	118	17.7	165	24.8	138	20.8
Category B	31	100.0	0	0.0	0	0.0	1	3.2	1	3.2	1	3.2	5	16.1	4	12.9	15	48.4	4	12.9
Applications received for approval of a mono- or multicentre* research project involving further use of biological material and/or health-related data (HRO, Chapter 3), incl. cases where informed consent is absent, in accordance with Art. 34 HRA	720	100.0	0	0.0	0	0.0	10	1.4	33	4.6	67	9.3	126	17.5	111	15.4	128	17.8	245	34.0

* for multicentre studies, only those where the ethics committee acts as the lead EC

Table 5: Number of decisions, by type of procedure and ethics committee

Details of procedures	Total		KEK-TG		CCVEM		CE-TI		EKSG		CCER		KEK-BE		EKNZ		CER-VD		KEK-ZH	
	Number (N)	Per cent (%)																		
No. of decisions made under the regular procedure (Art. 5 OrgO-HRA)	425	17.0	8	30.8	13	27.7	93	69.9	21	12.3	34	11.1	51	17.7	67	19.9	54	10.3	84	12.4
No. of decisions made under the simplified procedure (Art. 6 OrgO-HRA)	1322	52.8	4	15.4	14	29.8	29	21.8	60	35.1	182	59.5	219	76.0	235	69.7	178	34.1	401	59.4
No. of decisions made by the chair (Art. 7 OrgO-HRA)	758	30.3	14	53.8	20	42.6	11	8.3	90	52.6	90	29.4	18	6.3	35	10.4	290	55.6	190	28.1
Total no. of initial decisions made	2505	100.0	26	100.0	47	100.0	133	100.0	171	100.0	306	100.0	288	100.0	337	100.0	522	100.0	675	100.0
Number of plenary committee meetings	117	100.0	4	3.4	7	6.0	11	9.4	8	6.8	12	10.3	22	18.8	12	10.3	21	17.9	20	17.1

Table 6: Median processing times, by type of project and ethics committee (excluding the time required by applicants to supply any additional documents requested)

	KEK-TG	CCVEM	CE-TI	EKSG	CCER	KEK-BE	EKNZ	CER-VD	KEK-ZH
Processing times for applications in 2015 (median no. of days)	Median								
Time from receipt of application to confirmation of completeness	5	0	7	4	0	6	19	5	30
Time from confirmation of completeness to initial decision (approval, approval subject to conditions/requirements or rejection) for monocentre studies	15	8	21.5	14	28	14	14	21	12
Time from confirmation of completeness to initial decision (approval, approval subject to conditions/requirements or rejection) for multicentre studies (only as lead EC)	15	9	45	26.5	32	14	27	27	26

Assessment of the conduct of research projects

The assessment of the conduct of research projects is regulated in particular with regard to researchers' obligations to notify and inform the ethics committees and other supervisory authorities. However, the legislation also provides for measures that may be taken to protect persons participating in research projects. Certain amendments to existing research projects must be submitted to the ethics committee for approval before being implemented. In addition, the committees are entitled to report suspected violations of the HRA to the competent criminal investigation authorities.

The information reproduced below is that which is included in the reports of the ethics committees indicated. To date, this data is not systematically collected in a standard manner.

Official measures (Art. 48 HRA)

The Geneva ethics committee reports that the trial of an anti-Ebola virus vaccine was suspended because of joint pain and skin lesions. The committee met in an extraordinary session at the beginning of 2015; it was decided that the trial should be resumed with lower doses. However, this had no influence on the adverse effects, which were, fortunately, transient. In view of its excellent efficacy, the vaccine is nonetheless promising; the adverse effects are acceptable given the serious nature of the disease. The Zurich committee reports that it suspended a clinical trial on account of safety concerns. The Thurgau committee explicitly notes that no measures had to be taken under Article 48 paragraph 1 HRA.

HRA, Art. 46 Notification and information requirements

- 1 The Federal Council may specify notification or information requirements, in particular with regard to:
 - a. the completion or discontinuation of a research project;
 - b. adverse events observed in connection with a research project;
 - c. the occurrence of circumstances during the conduct of a research project which could affect the safety or health of the participants.
- 2 In doing so, it shall have regard to recognised international regulations.

Art. 48 Official measures

- 1 If the safety or health of the persons concerned is at risk, the ethics committee may revoke or suspend its authorisation or make the continuation of the research project subject to additional conditions.
- 2 The ethics committee may request information or documentation from the holder of the authorisation. This must be provided or made available free of charge.
- 3 The competent federal and cantonal authorities retain the right to take measures.
- 4 The authorities and ethics committees shall keep each other informed and coordinate their measures.

Inspections and other measures to assess the conduct of research projects

The Northwestern and Central Switzerland committee, as in the previous year, carried out six audits of ongoing, randomly selected research projects. According to the committee, this type of collaboration with investigators¹⁴ (only investigator-driven studies, as monitoring of other studies is delegated to professional agencies) was found to be mutually beneficial, irrespective of the outcome of the assessment. The directors of the hospitals concerned were informed of the audit results. The Thurgau committee did not perform any audits, nor did committee members participate in Swissmedic inspections.

Estimation of effort involved in assessing the conduct of research projects

The Bern ethics committee reports, as in the previous year, that whereas, up until 2014, 200–300 applications were submitted per year, under the HRA (since the beginning of 2014) the annual total has increased to more than 400. As most studies run for several years, the committee, at the end of 2015, had to manage a total of more than 4000 ongoing studies; this involves the processing of protocol amendments subject to approval, reports of adverse events, annual safety reports, final reports, etc.

The Geneva ethics committee notes that it is focusing on its primary duties, i.e. timely assessment of projects submitted. However, assessing the compliance of "research projects and the conduct thereof" implies that cantonal ethics committees should not only examine and, if appropriate, approve projects, but also monitor the implementation of the projects authorised. For lack of resources, the committee only requests feedback on ongoing projects by sending a brief questionnaire to all project leaders once a year; monitoring the conduct of projects would be costly and would require resources which the committee does not have. Around 600 projects are underway in Geneva. If every project had to be inspected every three years, then 200 project inspections would be required per year. The experience of Swissmedic shows that an inspection involves two to three days' work, or roughly 500 working days for 200 projects, corresponding to at least 2.5 full-time equivalent positions (compared to the committee's current total of 3.4 FTEs).

¹⁴ Note inserted by kofam: this term is defined in Art. 2 let. d ClinO.

Ethics committees' comments on their assessment activities

The standardised data submitted to kofam by the ethics committees was used to generate the statistical overviews in this report. In addition, the annual reports of certain ethics committees include comments on their assessment procedures. These comments are summarised by kofam below.

Number of applications compared to the previous year

Increases:

- Geneva reports an increase of 11 %.
- The Northwestern and Central Switzerland committee reports around 23 % more applications (449 compared to 363 in the previous year).
- St Gallen reports over 20 % more applications (211 vs 164 in the previous year). However, the ethics committee points out that this only partly reflects a genuine increase, and partly a catch-up effect after 2014, since the number of applications submitted shortly after the introduction of the HRA was much lower than previously. This may have been due to temporary uncertainty following the introduction of the Act.
- The Ticino ethics committee reports a slight increase (not quantified).
- The Vaud committee reports a slight increase (6 %), but stable figures overall.

Decrease in applications received:

- The Zurich committee received 675 applications, 100 fewer than in 2014 (around 13 % decrease). In addition, Zurich reports a 20 % drop in clinical trials of medicinal products compared to 2014, but a marked increase in clinical trials of medical devices.

Financing of research projects

As regards the financing of research projects, the Ticino committee reports that the relative proportions of industry-sponsored and research group- or investigator-driven projects remained unchanged from the previous year. Of 133 projects, industry accounted for 58, research groups 32 and individual investigators 43. The Vaud ethics committee reports that 22 % of studies were financed by industry, while 76 % were initiated by investigators.

Research projects involving vulnerable persons

Under the heading of "vulnerable persons", the Vaud committee reports that, of the applications approved, 29 (vs 41 the previous year) involved healthy volunteers, 42 involved children, 4 were emergency research projects, 10 involved persons lacking capacity and 7 involved other vulnerable persons. For the Bern committee, particularly vulnerable subjects include children, minors/incapacitated persons, healthy volunteers and persons lacking capacity.

Information on assessment decisions

A number of ethics committees provide more or less detailed information on decisions made concerning applications (approval, rejection, determination of responsibility, etc.).

The Geneva committee, for example, reports that of a total of 306 study protocols, 107 (35 %) were accepted as submitted on initial examination, while 185 (61 %) were returned to the investigator for amendments. The vast majority of these projects have been (or will be) approved on a second reading. Thus, of the 306 submissions reviewed in 2015 (1st and 2nd half), 274 have received a positive final decision, 21 are still pending as of the beginning of May 2016, and 12 (4 %) have been rejected or dismissed (i.e. not further considered).

The Vaud committee reports that 4 studies were not accepted, 2 were withdrawn and 14 were found to fall outside the scope of the HRA. 62 % of the studies were approved on initial examination, with or without requests for amendments (the same as in 2014). In addition, the committee organised 7 hearings with principal investigators in order to support its assessment.

According to the Northwestern and Central Switzerland committee, no applications were rejected; however, outstanding responses to requests for the fulfilment of conditions or requirements, and withdrawals of studies, can in most cases be considered equivalent to a rejection. If clarifications are required or objections are raised to submissions, correspondence is generally conducted electronically, although increasingly discussions with the committee are being chosen as a way of resolving issues. It is also mentioned that 127 declarations of acceptability were issued.

The St Gallen committee reports that, in addition to the assessment decisions, 15 declarations of acceptability were issued and 14 investigations of responsibility were carried out.

A number of submissions were withdrawn, and in other cases missing documentation was not supplied; no applications were rejected. One study assessed by the committee was not approved by Swissmedic and had previously also twice been rated as "non-approvable" by the St Gallen committee.

The Bern ethics committee points out that study protocols are often incomplete and can only be assessed after corrections have been made. The Zurich committee additionally issued 105 declarations of non-responsibility or acceptability. It also suspended one clinical trial on account of safety concerns. The Geneva, St Gallen and Thurgau committees report that no appeals were lodged against their decisions.

Comments on types of procedure

According to the Geneva committee, the frequency of the three types of procedure is more or less unchanged. Vaud notes a substantial increase in protocols necessitating a regular or (especially) simplified procedure. The St Gallen committee describes the effort required for simplified procedures, which are handled by the core team, as moderate, while decisions made by the chair can generally be dealt with rapidly. On two occasions, the Zurich committee made decisions under the regular procedure by circular resolution. About 60 % of all applications were assessed under the simplified procedure, involving not inconsiderable organisational effort.

Interests, non-participation, independence in fulfilment of duties

Members' interests are disclosed on the ethics committees' websites. In the case of the Thurgau committee, which does not have a website, this information is included in an annex to its annual report. How precisely interests are defined and disclosed is a matter to be assessed by the individual committee.

Some committees comment on the questions of non-participation and independence in the fulfilment of their duties:

- Three members of the Geneva committee withdrew from the assessment of research projects. On two occasions, the members concerned were professionally close to the applicant; they participated in the discussion of the project, but not in the decision. On one occasion, the chair was confronted with a project from a start-up of which he was one of the founders. In this case, the submission was handled by one of the vice-chairs; the chair did not participate in the meeting.
- The Thurgau committee mentions that the provisions on non-participation specified in Art. 52 para. 3 HRA did not have to be invoked in 2015. Independence in the fulfilment of duties (Art. 52 para. 1 HRA) was maintained at all times.
- The Vaud committee notes that members withdraw from participation in the event of a conflict of interest, as specified in Art. 4 OrgO-HRA.

Comments on processing periods

The Geneva committee notes that the deadlines are sometimes difficult to meet, especially because the projects that have to be assessed under the regular procedure can only be dealt with once a month. Compared to the previous year, the proportion of submissions dealt with within the prescribed period decreased; however, the average time by which the deadline was exceeded also fell (one application with a delay of more than 30 days). The Vaud committee reports that the two-month deadline (Art. 45, para. 2 HRA) was exceeded for three studies on account of the methodological complexity and/or the need to obtain further information at a hearing. The Northwestern and Central Switzerland committee reports that while, for the second year, deadlines were not successfully met in all cases, a clear improvement was observable. Particularly gratifying was the very short time required to communicate decisions, which compensated for delays in confirming the completeness of submissions, thus making it possible to meet the overall deadline. The Zurich committee also notes that, in 2015, decisions on completeness were only made after the application had been classified and the risk category determined; the reported 30-day processing time thus reflected an assessment of both formal aspects and content. At the beginning of 2016, the two processes were to be separated, so that the 7-day deadline for the preliminary formal assessment could be met.

Other activities

According to Article 51 paragraph 2 HRA, ethics committees may – in addition to their statutory authorisation and supervision activities – provide advisory services for researchers, e.g. with regard to research projects outside the scope of the HRA, particularly projects abroad. In addition, other tasks within the cantonal administration are assigned to certain committees by the cantonal authorities, and committees maintain contacts with various interest groups.

IT infrastructure (BASEC)

Reflecting the experience of the committees cited below (similar remarks are also made by the Northwestern and Central Switzerland and the Ticino committee), the St Gallen committee reports that 2015 was notable in particular for the development and launching of the electronic submissions portal BASEC (Business Administration System for Ethical Committees). Over the course of numerous meetings, a steering board – including representatives of all the committees as well as an IT specialist, and led by the chair of the Geneva committee – elaborated a nationwide consensus for the representation of nationally harmonised processes and operations on this portal and in the new eDossier. This involved, firstly, optimising the so-called front end for researchers (primarily, presentation of the Act and Ordinances: which documents are required for which applications?), but also ensuring the functioning of the so-called back end, i.e. the communication and processing of submissions within and between the various ethics committees (eDossier). The transitional period for submission of applications via the new portal began on 2 November 2015. According to the St Gallen committee, both the front end and the back end have proved effective to date, and the processing of applications has run smoothly. The December session was thus the St Gallen committee's first paperless meeting. The overall budget for BASEC across Switzerland amounts to CHF 250,000, with the costs being borne exclusively by the cantons. The Geneva committee declares itself "pleasantly surprised" by the introduction of BASEC; there have been no major technical problems. It has led to the standardisation, simplification and acceleration of procedures, as well as greater transparency, which will permit the generation of statistics that are more reliable and more comparable between the various Swiss committees. On 1 January 2016, all the Swiss committees

joined BASEC. The Vaud committee reports that the launch has also necessitated a series of internal adjustments: while BASEC has contributed significantly to harmonisation, quite a lot of work remains to be done.

Contacts and collaborations

The Ticino and Vaud committees report that in 2015, once again, harmonisation at the national level required major efforts, including numerous meetings and seminars with the other committees, Swissmedic and the FOPH. For 2015, the Bern committee had set itself the goal of optimising cooperation with researchers (e.g. CEC Sounding Board at the University Hospital) and also with Swissmedic, the FOPH and the other committees/swissethics. In addition, through scientific collaboration with the European Network of Research Ethics Committees (EUREC) and, for example, the German Reference Centre for Ethics in the Life Sciences (DRZE) in Bonn, the Bern committee has ensured coordination and evaluation of the latest pan-European findings. The Northwestern and Central Switzerland committee notes that collaboration with the intercantonal supervisory body has proceeded smoothly and continued to prove very valuable. Close collaboration with the Clinical Trial Unit (CTU) of Basel University Hospital has also been fruitful, especially in the form of courses on Good Clinical Practice (GCP). This task is highly labour-intensive, but makes a vital contribution to the correct or improved submission of research projects to the ethics committee. In addition, there have been monthly meetings to promote exchanges between the CTU, the ethics committee and the legal department of Basel University Hospital. The Thurgau committee rates its collaboration with the other ethics committees in connection with multicentre research projects as consistently constructive and appropriate, likewise with regard to Swissmedic and the FOPH; there was no collaboration with regulatory authorities abroad. Within its area of responsibility and intra-institutionally, the Thurgau committee mentions regular meetings with the Cantonal Department of Finance and Social Affairs.

Education and training, events

The Valais committee reports that several members attended the introductory course and/or the further training course run by swissethics and the postgraduate training meeting held by the Vaud committee. The Geneva committee held its traditional one-day event at the Brocher Foundation on 15 October (introduction to BASEC and several presentations on topical issues); the event was attended by 30 of the committee's 36 members. The Vaud committee reports that in 2015, as in the previous year, two further training events were organised for members of the committee, one of which was dedicated to introducing the new IT system for managing all the activities of the committee and the other Swiss ethics committees. Under the heading of "Further training (quality management)", the Northwestern and Central Switzerland committee reports that members attended courses or seminars of their choice, with financial support being provided by the committee. Two plenary meetings were also held in 2015 which, as well as dealing with administrative and organisational matters, included presentations and discussions on current medical topics. These meetings of the ethics committee were each attended by four fifths of the members. The Bern committee mentions the continuing education course for committee members held on 5 November 2015 in Bern. The St Gallen committee adds that this event was organised for the first time by swissethics and was well received overall; it was attended by seven members of the St Gallen committee. In the last year of their independence, the members of the Thurgau committee did not attend any more education or training events. The Zurich committee reports that new members received an introduction and training in June 2015. Committee retreats – with presentations on various human research topics given by internal and external speakers – were held in February and November 2015. Two committees report that they did not organise any events (Thurgau), or any events for external participants (Zurich).

OrgO-HRA, Art. 2 Requirements for members

- 1 Members of the ethics committee must, on commencing their service, attend a course on the duties of the ethics committee and the fundamentals of the assessment of research projects, and must regularly undergo further training in this area.

Advisory services

In the committees' activity reports, advisory services, including education and training events for researchers and other groups or institutions, are sometimes discussed together with education and training activities for committee members.

Numerous committees – e.g. Bern, Geneva, Northwestern and Central Switzerland, Zurich, Vaud, Valais and Ticino – report that they provided extensive advisory services for researchers and third parties. The chairs of the Geneva and the Northwestern and Central Switzerland committee are regularly involved in clinical ethics consultations. The Ticino committee reports that 2015 saw a further increase in advisory activities and, especially, support for researchers and industry. The Valais committee also, in particular, provided expert opinions for the Valais cantonal government. The Northwestern and Central Switzerland committee receives a large number of enquiries from researchers concerning the documentation to be submitted and the requirements to be met by the various documents. In 2015, the committee was also requested by attending hospital physicians to consider ethical questions in individual cases, which is described by the committee as very demanding and rewarding. The Zurich committee was invited by institutions engaged in research to give various presentations on the provisions of the Human Research Act. No advisory services are reported by the Thurgau committee.

3 Ethics committees' conclusions and outlook

Extracts from the committees' reports are reproduced below.

Geneva Ethics Committee

The procedure for multicentre studies, introduced in 2011, is now running smoothly thanks to the excellent cooperation between the ethics committees in Switzerland. With the BASEC system, further improvements will be possible. The committee is focusing on its primary duties, i.e. timely assessment of projects submitted. There is no shortage of volunteers, even though most of the members are not paid for their work.

Northwestern and Central Switzerland Ethics Committee

In its second year, the EKNZ has coped well with its responsibilities and is on track. Internal procedures have been defined, cooperation with researchers is going well, and no hitches occurred in the year under review. Collaboration between members of the three former ethics committees continues to prove valuable and helpful. Knowledge of local conditions is especially important in dealing with research projects. Thanks to continued harmonious cooperation within the committee, the substantial workload was successfully managed. This success is also attributable to the good contacts maintained with researchers and sponsors. The planned reduction in the number of members has not yet been implemented. It is, however, essential so as to ensure that expertise is maintained, which presupposes a certain minimal frequency of meetings for each member. Looking ahead to 2016, finances are to be consolidated, Standard Operating Procedures (SOPs) are to be defined in writing, and a survey of researchers is to be conducted. The overall deadline for the processing of submissions is again to be met, and the time taken for confirmation of submissions is to be reduced from 17 to 12 days.

St Gallen Ethics Committee

Two years after the entry into force of the HRA, the St Gallen Ethics Committee has turned the processes and requirements specified by the Act into routine procedures in everyday practice. The committee's review processes in the Scientific Secretariat, operations and activities within the core team are well established and largely running smoothly. While the committee's role as a decision-making body is less important than before the introduction of HRA, there has been a marked expansion of the workload within the core team, i.e. in the Scientific Secretariat and for the chair, as a result of the mandatory GCP review (full regulatory review of the project, for which Swissmedic was responsible under the previous legislation) and the increase in simplified and presidential procedures.

Ticino Ethics Committee

The number of studies submitted to the cantonal ethics committee increased slightly compared to the previous year; however, the relative proportions of studies sponsored by the pharmaceutical industry or initiated by research groups or individual investigators remained unchanged: of the 133 projects submitted, industry accounted for 58, research groups 32 and individual investigators 43. Of these projects, 68 are multicentre studies involving several sites in Switzerland. There was a further increase in advisory services, compared to the previous year, for researchers and industry, mainly due to the demand for support.

Thurgau Ethics Committee

The workload was roughly comparable to that in the previous year. The year 2015 was successfully and routinely concluded with a stagnating and low number of applications for clinical trials to be conducted in the Canton of Thurgau. The canton's ethics committee, established in 1988, is terminating its independent activities with effect from 31 May 2016. Over the past 28 years, it has processed more than 1000 applications for clinical trials. On 1 June 2016, after the dissolution of the Thurgau Ethics Committee, the new Eastern Switzerland Ethics Committee is to be established in conjunction with the St Gallen Ethics Committee. In this committee, the Canton of Thurgau will be actively represented by a vice chair and another member.

Vaud Ethics Committee

Activities in 2015 were relatively stable compared to 2014, with a little more than 500 protocols assessed. The introduction of the new Act has not yet been fully absorbed, with numerous questions still pending, for which the committee remains in close contact with swissethics and the other Swiss ethics committees. The website launched in September 2014 has been very well received and was consulted by more than 19,500 visitors in 2015. Although it is hosted by an external provider, it is accessible via the website of the Canton of Vaud and has a similar layout. It is regularly updated.

Outlook for 2016: The launch of BASEC, together with two years' experience with the new legal framework, will facilitate the "stabilisation" of the committee's operations, as well as the absorption of the additional activities from the Canton of Valais. The introduction of BASEC also brings significant changes in the duties of committee members, and from 2016 the Vaud committee will be making adjustments in line with the new distribution of tasks and demands. Thus, temporary staff will be gradually replaced by permanent staff with new responsibilities, including fewer administrative tasks. It will be important to continue to have close contacts with researchers and research centres (CHUV in particular) in an effort to further improve the quality of research, particularly on the basis of the findings and proposals discussed at the Public Health Department (SSP) on 12 June 2015.

Valais Ethics Committee

The committee, having got into its stride with a well-established structure, a secretariat whose activity (20%) and skills are recognised, and clearly defined objectives, had to address its future together with the Public Health Department (SSP). This was because the introduction of the new Federal Act – calling for harmonisation and rationalisation of the assessment of study protocols in Switzerland, and requiring ethics committees to establish a complex scientific secretariat – has led the various committees to regroup. Several formal and informal preparatory meetings therefore took place, involving the chair of the Valais Ethics Committee, the Cantonal Physician, the Head of the SSP and the State Councillor. In conclusion, from 1 January 2016, the Valais Ethics Committee will hand over the assessment of submissions received in French and in English to the Vaud Ethics Committee, and those in German to the Bern Ethics Committee. The chair of the Valais committee has been appointed as a member of the Vaud committee, representing both the Valais committee and the CHUV. The transfer of protocols outside Valais is certainly felt as a loss. However, it is now up to the Valais committee and the SSP to rebound and breathe new life into the committee's future activities.

4 swissethics

Zurich Ethics Committee

The increased pressure on the committee experienced in 2014 after the entry into force of the HRA was observable again in 2015. The substantial workload generated by the large number of submissions could only be coped with by establishing additional, limited-term positions in the Scientific Secretariat. At the end of December 2015, the processing backlog comprised 40 submissions. Nonetheless, it was possible for processing times to be markedly reduced and brought close to the legally prescribed periods. In the year under review, the committee's structure and processes were subjected to an external evaluation. The consequence of this evaluation was a reduction from four to two committee sections (A and B) and the concentration of all activities at one site. The changes to the structure of the committee were reflected by the revised Cantonal Ethics Committee By-Laws issued in August 2015. In May 2015, an interface attached to the Zurich University Centre for Clinical Research was created. Here, application documents for investigator-initiated studies at Zurich University Hospitals are assessed for formal completeness before being submitted to the Cantonal Ethics Committee. This formal assessment represents an institutionally based quality assurance measure which is to be clearly distinguished from the activities of the ethics committee. In the assessment of submissions, it repeatedly became apparent that there are certain imprecisions and inadequacies in the legal regulations, which need to be addressed in the near future.

Goals of the Zurich Ethics Committee:

- Improved deadline management
- Introduction of a risk-adapted approach for assessment of submissions
- Achievement of greater consistency in the assessment of submissions in accordance with Art. 34 HRA
- Development of ethically oriented assessment guidelines
- Development of standards both for researchers and for ethics committees
- Successful introduction and implementation of BASEC
- Further digitisation of internal procedures
- Improvement of continuing education provision for committee members
- Development of intranet-based communication and information platform for committee members
- Organisation of two joint meetings of the two sections of the committee

- Revision of the system for the disclosure and management of conflicts of interest
- Coordination with other institutionally based ethics committees in the canton (demarcation of activities)
- Supporting swissethics in relation to harmonisation of the procedures of all cantonal ethics committees.

The activity reports of the Vaud, Northwestern and Central Switzerland, and St Gallen ethics committees mention their participation in swissethics (the ethics committees' umbrella organisation) in 2015. The Vaud committee notes that the overall budget of swissethics is around CHF 200,000. Financing is currently provided exclusively by the cantons, on a pro rata basis, according to the number of protocols processed by the individual committees. swissethics is planning to make it possible for performance-related funding also to be obtained from the federal authorities.

In 2015, with the establishment of an office in Bern, swissethics created more favourable conditions for further enhancing the harmonisation and coordination of the ethics committees' activities across Switzerland. To this end, an office was established with a management (40 % position) and, from December 2015, a managing director (70 %). Thanks to this professionalisation, swissethics was able to define new thematic priorities. The flow of information between the committees was continuously improved; numerous meetings took place to promote exchanges between the chairs, committee members, scientific secretariats and the BASEC steering board.

swissethics revised existing and made available new standard HRA-compliant templates for researchers. Further position papers were prepared on ethical issues (experimental therapy versus research projects subject to EC review, remuneration of patients participating in studies). swissethics represented the cantonal ethics committees at the federal level and was represented on the Advisory Board of the SCTO. In addition to the FOPH and the SCTO, primary partners of swissethics include the SAMS, the Swiss Biobanking Platform (SBP) and other national institutions. Many concerns of researchers and stakeholders relating to the ethics committees were addressed primarily to swissethics.

A decisive contribution to further harmonisation across Switzerland has also been made, as mentioned above, by the BASEC portal, which was developed under the direction and project management of the chair of the Geneva ethics committee, and which went live on 1 November 2015. Since then all research applications have been submitted electronically via this portal, which will in future substantially improve the collection of key statistical data and the documentation of the ethics committees' activities.

In 2015, swissethics organised a national continuing education event, which was held in German in Bern. swissethics is also responsible for the recognition of GCP course providers.

Further, more detailed information (in German) can be found in the swissethics 2015 Annual Report.¹⁵

¹⁵ http://swissethics.ch/doc/swissethics/Berichte/Jahresbericht2015_d.pdf

5 Activities of other supervisory authorities

The FOPH has a duty to report on the activities of the cantonal research ethics committees. In the interests of the transparency of the entire authorisation system, the FOPH also invited the other supervisory authorities to submit reports or to make available existing report texts for this public information document.

Swissmedic

The Swiss Agency for Therapeutic Products (Swissmedic) reports annually on its activities. Below, information on clinical trials with medicinal products, transplant products and medical devices is reproduced from the 2015 Annual Report¹⁶.

Clinical trials with medicinal products and transplant products

Clinical trials are used to systematically gather information on medicinal products when used in humans. Swissmedic verifies whether the quality and safety of the test product is guaranteed. Clinical trials may only be carried out in Switzerland if they have been approved by an Ethics Committee and by Swissmedic.

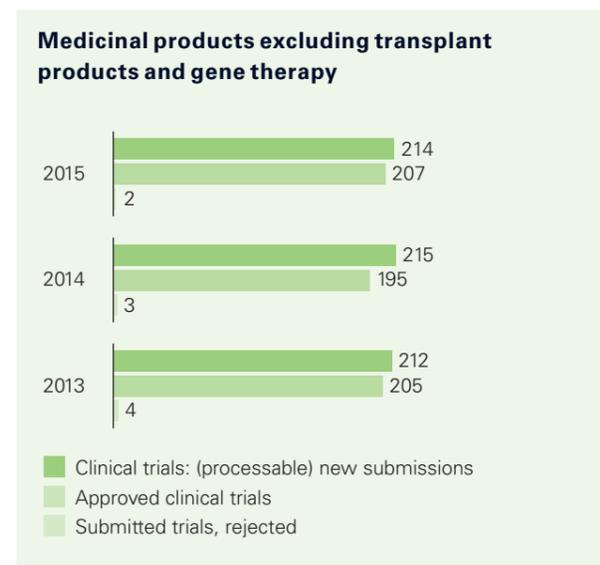
Activities

- Swissmedic received 227 applications for clinical trials with medicinal products in category B or C (excluding transplant products and gene therapies) in 2015. Only 214 of these applications could be processed, as the rest were either incomplete or fell outside the remit of the Clinical Trials division. In total, 207 clinical trials were approved, including 54 in category B and 153 in category C. Two of the applications in the latter category concerned a first-in-human trial. Two clinical trials were rejected and three were withdrawn by the sponsor during evaluation. The other applications are currently being processed.
- Swissmedic processed 2,410 other requests or notifications relating to clinical trials of medicinal products (amendments during the course of clinical trials, end-of-trial notifications, Annual Safety Reports, End-of-trial Reports, as well as 75 reports of suspected unexpected serious adverse reactions (SUSAR)).

- To be able to approve clinical trials involving gene therapy (GT/GMO), Swissmedic needs position statements from the Federal Office of Public Health, the Swiss Expert Committee for Biosafety and the Federal Office for the Environment. In 2015, Swissmedic received ten applications for clinical trials, including six involving GT/GMO products and four involving transplant products (TpP). A total of eight trials were approved, as were 45 amendments, including 34 with GT/GMO products. All of these were category C trials, i.e. they involved products administered to humans for the first time.
- Swissmedic also continued to work with the FOPH and swissethics, the Association of Swiss Ethics Committees on research involving humans, with the aim of coordinating and harmonising the three bodies' interpretation of certain grey areas of the new law. In connection with these efforts, Swissmedic took part in three meetings organised by the FOPH agency responsible for coordinating research involving humans.

Performance indicator

First submissions of clinical trials; proportion of notifications assessed within 30 days: Target 95 % Result 98 %



GCP and GVP inspections

All clinical trials carried out in Switzerland by sponsors and research institutes, as well as trial locations, facilities and laboratories, are inspected by Swissmedic on a random basis with regard to compliance with the rules of Good Clinical Practice (GCP). In doing so, Swissmedic also verifies whether the safety and personal rights of the study participants are guaranteed. Checks are also carried out to establish whether the results of the trials satisfy the scientific criteria for quality and integrity. Pharmacovigilance inspections (Good Vigilance Practice, GVP) are above all designed to examine compliance with the legally prescribed mandatory reporting of adverse drug reactions in clinical trials as well as spontaneous reports.

Activities

- In 2015, Swissmedic carried out 18 GCP inspections of clinical trials involving medicinal products submitted for authorisation in Switzerland.
- The Agency also carried out six GVP inspections in Switzerland and accompanied one GVP inspection in Germany.
- Swissmedic took part in two GCP inspection programmes and one GVP inspection programme under the PIC/S Convention. Within this framework, Swissmedic accompanied two GCP inspections carried out by foreign authorities in Canada and Austria. Two of the six GVP inspections carried out in Switzerland were also part of the PIC/S programme.
- Furthermore, Swissmedic provided expert support for two GCP inspections carried out in Switzerland by the FDA and the EMA.
- In 2015, the GCP/GVP inspectors again participated in the EMA's GCP inspectors working group.
- They performed four GCP inspections in the field of clinical trials with standardised transplants and gene therapy.

Performance indicator

GCP/GVP inspections; degree to which the annual plan was fulfilled: Target 100 % Result 100 %.

Clinical investigations of medical devices

Swissmedic approves and monitors clinical investigations of medical devices for human use if the products or the intended uses are not yet CE certified. Planned investigations of this type have required mandatory approval since 1 January 2014. During the investigations, Swissmedic monitors incidents for which reporting is mandatory, such as serious events and reports on the safety of the participants. Swissmedic may inspect investigators, sponsors and research institutions throughout Switzerland, and records notifications and measures from Switzerland in EUDAMED. Swissmedic moreover takes part in the drafting of international guidelines and training events with a view to enhancing their implementation.

Activities

- The number of applications for investigations with medical devices that are not yet authorised for the market rose by some 5 % to 38 in 2015.
- Three ongoing clinical investigations were inspected during the year under review.

Performance indicator

Approval of clinical investigations; proportion assessed within 30 to 60 days: Target 95 % Result 92 %.

FOPH, Transplantation

Under Article 36 paragraph 1 of the Transplantation Act¹⁷ and Chapter 3 of ClinO, the FOPH is involved in the authorisation procedure for Category C clinical trials of transplantation. In 2015 (as in the previous year), two applications were approved. The first of these was a pilot study on the feasibility and safety of allogeneic islet transplantation to the anterior chamber of the eye. The second pilot study concerned the feasibility, safety and efficacy of an established protocol whereby renal transplant tolerance is to be induced by combined kidney and hematopoietic stem cell transplantation. With regard to notifications concerning ongoing research projects, the FOPH received an annual safety report and a clinical study report.

¹⁶ <https://www.swissmedic.ch/ueber/00134/00441/00445/00568/index.html?lang=en>

¹⁷ Federal Act of 8 October 2004 on the Transplantation of Organs, Tissues and Cells (Transplantation Act; SR 810.21)

FOPH, Radiological Protection

Under Article 36 ClinO, the Radiological Protection Division of the FOPH is involved in the authorisation procedure for Category C clinical trials of therapeutic products capable of emitting ionising radiation. In addition, under Article 28 ClinO, and Article 19 HRO, the Division prepares an opinion for the ethics committee if, in the case of planned concomitant investigations involving radiation sources, the effective dose per person is more than 5 mSv per year and the interventions in question are not routine nuclear medical examinations using authorised radiopharmaceuticals.

In 2015, the Radiological Protection Division delivered opinions to Swissmedic in the case of four Category C clinical trials (three involving radiopharmaceuticals and one medical devices) and one Category B clinical trial of radiopharmaceuticals. In one other Category C clinical trial, the release of a radioactive substance in the body of study participants was to be used, with the aid of an imaging procedure, for a concomitant investigation. As the study product was modified for this purpose, complex questions arose – e.g. concerning responsibility for the testing of pharmaceutical quality, as well as radiological protection aspects. Here, the Radiological Protection Division supported the responsible ethics committee and Swissmedic with scientific investigations and recommendations, even though this would not have been required on the basis of the declared effective dose of less than 5 mSv.

From other enquiries relating to planned projects submitted by researchers or companies, it became clear that often additional investigations are required on the part of the applicant in the case of non-routine interventions. Most of these enquiries (not detailed here) concerned projects where radiological protection is only to be assessed by the ethics committees.

For 11 ongoing clinical trials of radiopharmaceuticals, opinions on requested amendments were delivered to Swissmedic. One other opinion related to a clinical trial involving a radioactive medical device.

In the case of one non-clinical trial using a radioactive substance for a physiological examination, the Radiological Protection Division supported the responsible ethics committee with extensive investigations and recommendations.

All opinions were delivered within the specified deadline.

6 Acknowledgements

kofam would like to thank the cantonal ethics committees for the preparation and submission of the activity reports and also for their constructive input to the present summary. Thanks are also due to the other supervisory authorities for their voluntary contributions or permission to quote from their own reports. Not least, particular thanks are due to swissethics, whose coordination efforts and collaboration considerably facilitated the preparation of this information.

Bern, December 2016

Coordination Office for Human Research (kofam)
Federal Office of Public Health
3003 Bern

www.kofam.ch

www.foph.admin.ch