Human Research in Switzerland 2018

Descriptive statistics on research covered by the Human Research Act (HRA) based on the BASEC data

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

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

swissethics
Schweizerische Ethikkommissionen für die Forschung am Menschen
Commissions d'éthique suisses relative à la recherche sur l'être humain
Commissioni etiche svizzere per la ricerca sull'essere umano
Swiss Ethics Committees on research involving humans

Contents

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List of abbreviations

BASEC	Business Administration System for Ethics Committees
SNCTP	Swiss National Clinical Trials Portal
AS1	Analysis set 1: all projects submitted in the year 2018
AS2	Analysis set 2: all projects approved in the year 2018
HRA	Federal Act on Research involving Human Beings (Human Research Act)
HRO	Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance)
ClinO	Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance)
IQR	Inter-quartile range
FOPH	Federal Office of Public Health
EC	Ethics committee
CCER	Commission cantonale d'éthique de la recherche (Genève)
CE-TI	Comitato etico cantonale Ticino
CER-VD	Commission cantonale d'éthique de la recherche sur l'être humain Vaud
EKNZ	Ethikkommission Nordwest- und Zentralschweiz
EKOS	Ethikkommission Ostschweiz
KEK-BE	Kantonale Ethikkommission Bern
KEK-ZH	Kantonale Ethikkommission Zürich

1 Introduction

The aim of this report is to describe research covered by the Swiss Federal Act on Research involving Human Beings (HRA). For this, data collected using the Business Administration System for Ethics Committees (BASEC) web portal maintained by the Swiss Ethics Committees on research involving humans (swissethics) were analysed. The initially provided report shall be updated on a yearly basis for the time period 2018–2020 and be extended by analyses exploring potential time trends. This is the third yearly report. It contains a comparison vs. last year's characteristics of submitted and approved projects falling under the HRA.

The purpose of the BASEC web portal is to optimise the application process by providing a unique entry point for applications in the scope of the HRA irrespective of the involved ethics committees (ECs). Since the beginning of 2016, all applications are submitted via BASEC. The standardised and structured information on all submitted research projects provides a unique opportunity for a comprehensive overview on the Swiss human research landscape.

1.1 Report structure

In the subsequent section, the sources of the analysed data are described and limitations are discussed. This results in the definition of two analysis sets (AS): one based on submissions (AS1) and the other based on approved projects in the reporting year (AS2). The analysis sets are described in detail in section 1.3.

First, an overview on the BASEC data in the true calendar year 2018 is provided by specifying input (submissions in the index years and pending decisions from previous year(s)) and output (decisions, pending decisions and withdrawals) in detail (chapter 2).

Second, chapter 3 describes all submissions (AS1) via the web portal in year 2018. A stratification by EC, project status and type of research gives insights into the workload of the individual ECs and the type of the submitted projects.

Third, chapter 4 provides a more scientific view on the projects with a descriptive analysis of various characteristics of all projects approved in 2018 based on the analysis set AS2.

Fourth, a more detailed view on the application process is provided in chapter 5. This analysis is mainly based on data provided by the individual ECs and gives insights into response times and the review process.

Lastly, a longitudinal analysis is provided in chapters 6 and 7 by comparing the number of research projects (chapter 6: submitted projects (AS1), chapter 7: approved projects (AS2)) per type of research per year.

1.2 Data source and limitations

This report is based on data entered into the BASEC web portal by two different parties:
1. All data concerning the submitted research projects are entered by the applicant.
2. With the exception of the submission date, all data on response times and on the review process are entered by the individual ethics committees under the supervision of swissethics.

A BASEC data export provided by swissethics dated April 2, 2019 has been used for this report.

1.2.1 Data provided by the applicant

The BASEC web portal enables the applicant to submit all information and documents needed by the ECs to assess the projects according to the HRA and its ordinances. The web interface is dynamic by showing/hiding fields depending on the type of research projects (e.g. clinical trial or 'further use' project) or depending on previous answers.

Within BASEC, the classification in different types of research projects is generally in conformity with the HRA and its ordinances. However, some compromises have been made with the aim of facilitating the application process. This includes projects that cover two groups of research projects defined by the law but constitute a single research project (e.g. clinical trial including further use of existing data; see section 1.3.3).

The HRA and its ordinances form the basis of the work of the ECs. Generally, the terminology and categories used in BASEC tend to be in close conformity with the law whenever there are legal restrictions relevant for the application process. Some questions and categories in the web portal are, however, BASEC-specific with the aim to further characterise the research projects.

It has to be kept in mind that the BASEC data have limitations: the data in BASEC are primarily entered and reviewed with the

purpose of submitting/assessing a project application and not in view of a further scientific analysis. The data are entered solely by the applicant and not edited by the ECs directly after the submission. This means that information retrieved from BASEC, especially from submitted but not yet reviewed projects, may contain irregularities. The ECs review the content of an application primarily with respect to legal, regulatory and ethical compliance but not for logical inconsistencies that arise from the application process itself. Still, the ECs actively ask the project applicant to correct the data entered in BASEC if this is found to be obviously incorrect.

1.2.2 Data on response times and on the review process provided by individual ethics committees

For each project, the dates of specific milestones indicated in the ordinances (Art. 26 and 27 ClinO, Art. 16 and 17 HRO) are captured. The milestones are:

Reception date: The date when the applicant submits the project for the first time.
First reaction date: The date when the ethics committee notifies the project applicant of either the acceptance of the application (in this case the first reaction date coincides with the "date the application data declared complete"), or of any formal deficiency in the application documents and the need for resubmission.
Date the application data declared complete: The date at which the application data are considered formally complete and ready for review by ordinary, simplified or presidential procedure.
First decision date: Date of the decision after the first review procedure. The first decision date coincides with the "final decision date" if the project is approved (i.e. without charges) in the first run.
Final decision date: Date of the final decision which can be: approved (and all charges have been fulfilled), declined, non-consideration, withdrawn.

These dates are used to calculate response times which are presented in chapter 5 on pages 35ff. In addition to the dates, the ECs report for each project the outcome of the first and the final decision as well as the review procedure applied (ordinary, simplified, presidential). An overview of the different EC decisions can be found in Table 3 on page 12 with short descriptions as table footnotes.

Only the reception date is recorded automatically by the system. All other dates are entered in BASEC manually by the ECs. The completeness and consistency of these data are checked periodically by swissethics (irrespective of this report) and ECs are reminded when mandatory fields are found empty or when discrepancies are identified.

1.3 Analysis sets

1.3.1 Definition of analysis sets

The analysis set **AS1** consists of all projects **submitted in 2018.** The AS1 includes all applications which have been submitted over the BASEC web portal irrespective of whether the projects were subsequently approved or not.
The analysis set **AS2** consists of all projects **approved** (i.e. projects having obtained a favorable final decision) **in 2018** irrespective of whether the projects were submitted in the reporting year or before.

The BASEC data can be used to quantify and compare the workload of the individual ECs. This analysis is performed on the entirety of all submissions in a given year. We defined this as the first analysis set *AS1*. For each project the most recent version of the submitted data (e.g. type of research, risk category) at the time of the data export is used. For a fraction of the projects, the approval status may be pending and the project characteristics may be subject to changes.

A BASEC data export always presents a snapshot. Some projects have already been assessed and a final decision has been made, and other projects are pending for various reasons: the application data are still incomplete, the decision by the EC is pending or the EC makes the decision on the project dependent on certain charges/conditions. Furthermore, submitted projects may later be declined by the EC, the project may not be covered by the HRA (non-consideration) or may be withdrawn by the applicant (including submissions that are never completed).

During the application process, the BASEC data are subject to change with the quality and completeness of the data increasing as the application process progresses. Even for approved projects the data may change over time due to amendments.

All these restrictions have an effect on the resulting analyses and their interpretation. A scientific analysis of the characteristics of the research projects can therefore only be performed on the subset of approved projects (i.e. projects having obtained a favorable final decision) in a given year for which the data in BASEC tend to be complete and to have – to a certain extent – been adapted or corrected by the ECs. We defined this as the second analysis set *AS2*. The set of approved projects as opposed to declined and withdrawn/non-considered projects represents research that is actually going to be conducted and thereby provides insights on the current medical research landscape.

In addition to the above described limitations with regard to the content of applications, the data are capped on both ends, which further complicates the comparison of the data over years (see Figure 1): only submissions after the beginning of 2016 are captured in BASEC, and, the data are censored at the time of data export.

1.3.2 Influence of time on project status

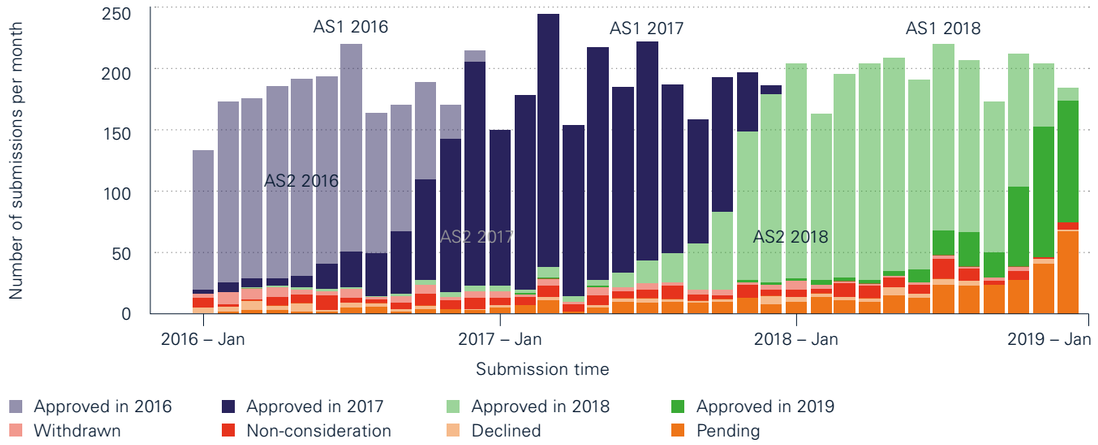
Figure 1 shows all submissions via BASEC in the years 2016 up to 2018. Each bar represents the number of submissions in a given month. The bars are coloured according to the current status of the respective submissions as of the time of the data export.

The proportion of projects not approved (declined, withdrawn, non-consideration) is quite stable over time. These projects are not part of *AS2* and will not be analysed scientifically. The proportion of pending projects is low in early years: projects that have been pending for a long time (after reminding the applicants for multiple times) are periodically reclassified by swissethics to withdrawn or declined, depending whether the project passed the 'application data declared complete' milestone. The proportion of pending projects increases over the course of the year 2018, since a single up-todate export is used for all years (export date: April 2, 2019) and not individual exports for each reporting year.

For approved projects, the year of the final decision is provided. When focusing on projects approved in a given year *(AS2)*, the 2016 data set only includes projects submitted in 2016 (after the introduction of BASEC; in light blue). In contrast to this, the data sets starting from 2017 also include submissions from the previous years. The fact that the 2016 AS2 data set is truncated on the left side makes a longitudinal analysis of the 2016 and 2017 AS2 data meaningless. However, in this report, the AS2 data does not suffer from left-truncation anymore, and therefore will allow a meaningful longitudinal analysis.

The two analysis sets represent compromises and are a trade-off between how exhaustive the data set is and the quality/completeness of the individual data points, i.e. the projects. The analysis set *AS1* focuses on the former aspect and *AS2* on the latter.

Figure 1: Overview of submissions via BASEC in the years 2016–2018 coloured by the current status as of the time of the data export (April 2, 2019).



1.3.3 Definition of the basic unit of analysis

For both analysis sets, individual BASEC submissions form the basis of this report, irrespective of whether a single EC or multiple ECs are involved in the assessment. Projects involving multiple ECs were counted only once and are assigned to the lead EC.[1]

Throughout this report, mono-centric and multi-centric studies are defined based on the number of involved study sites but irrespective of the number of involved ECs (see the definition of the main stratification variables in chapter 4.3.1).

Projects with characteristics that simultaneously fall into two separate legally defined project types represent a special case. In BASEC, such projects are called "combined research projects" and consist of the following two types:
1. Research involving a combination of a clinical trial (ClinO) or a research project involving persons (HRO Chapter 2) and the further-use of existing data or biological material (HRO Chapter 3). BASEC allows these combined projects to be submitted as a single research project.
2. Research involving a combination of a medicinal product and a medical device such as drug-eluting stents or a spray dose with a marked active substance.

Stratification of such projects by project type is not straightforward. In the overarching analyses, we count combined research projects only once like single research projects. However, when looking at subgroups of projects (e.g. 'further use' projects) we count them separately in each category since in this case the specific characteristics of these projects are in focus. For instance, clinical trials or research with persons according to the HRO combined with 'further use' are considered a single research project and are attributed to the category ClinO or research with persons (HRO) in all overview tables (Tables 2, 4 and 7ff). However, in the subgroup analysis of 'further use' projects, these combined projects are included. Explanatory footnotes are added to the relevant tables. Similarly, medical device/medicinal product combinations are counted once in the overview tables and are analysed separately in the subgroup analysis.

1 Exception: In section 3.2 on page 14, the data are summarised from a EC perspective by counting individual evaluations thereby assigning projects involving multiple local committees to all ECs.

2 BASEC data in the calendar year 2018

Table 1: Calendar-year-centric view on the BASEC data.

			n	%[1]
Input		Submission in 2018 (AS1)	2378	78.5
	Projects pending from 2017	Pending first decision in 2017	222	7.3
		Pending final decision in 2017 (first decision before 2018)	429	14.2
		Total Pending from 2017	651	21.5
		Grand Total Input 2018	3029	100.0
Output	Final decision in 2018	Approvals (AS2)	2047	67.7
		Rejections (declined projects)	43	1.4
		Non-considerations	105	3.5
		Total Decisions	2195	72.6
	Withdrawn during 2018	Withdrawal before first decision	8	0.3
		Withdrawal after first decision 'approvals with charges'	3	0.1
		Withdrawal after first decision 'not-yet-approved projects with conditions'	13	0.4
		Total Withdrawn	24	0.8
	Pending at end of 2018	Pending first decision	268	8.9
		Pending final decision (first decision issued)	538	17.8
		Total Pending	806	26.6
		Grand Total Output 2018	3025	100.0

Discrepancies in the number of decisions presented here and in subsequent tables are explained by the different cut-off dates: here only decisions in calendar year are considered whereas in tables based on the AS1 all decisions until the date of data export are taken into account.
Discrepancies between the grand total input and output are due to the input of old (approved) projects from the pre-BASEC area that have been digitalized in 2018 and hence obtained a new BASEC number.

➔ Information on rejected, non-considerated or withdrawn projects per type of research can be found in the Annex in section A.1

3 Overview of all projects submitted to BASEC in 2018 (AS1)

Table 2: Total number of research projects **submitted via BASEC in 2018** (analysis set AS1), including information on type of research and the legal basis.

Type of research	Legal basis	n	$\%_{col}$
Clinical trial	ClinO	540 [1]	22.7
Research involving persons, but not a clinical trial	HRO, Chapter 2	818 [2]	34.4
Further use of health-related personal data and/or biological material	HRO, Chapter 3	994	41.8
Research involving deceased persons	HRO, Chapter 4	26	1.1
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	0	0.0
Total number		2378	100.0

1 46 of these projects also include an application for further use of data/biological material.
2 212 of these projects also include an application for further use of data/biological material.

3.1 Submissions per ethics committee

Table 3: Overview of application details of all projects **submitted** via BASEC in 2018 (analysis set AS1) by ethics committee.

		Total		Ethics committee													
				KEK-ZH		EKNZ		CER-VD		KEK-BE		CCER		EKOS		CE-TI	
		n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$
First decision	Approved [1]	311	13.1	116	17.5	79	16.4	16	3.7	29	7.8	21	7.7	29	31.5	21	30.9
	Approved with charges [2]	622	26.2	20	3.0	292	60.6	185	42.8	11	3.0	66	24.4	35	38.0	13	19.1
	Not approved, conditions [3]	1265	53.2	469	70.7	96	19.9	198	45.8	300	81.1	154	56.8	20	21.7	28	41.2
	Declined	47	2.0	15	2.3	9	1.9	9	2.1			11	4.1	2	2.2	1	1.5
	Non-consideration [4]	83	3.5	25	3.8	5	1.0	9	2.1	21	5.7	13	4.8	6	6.5	4	5.9
	First decision still pending [5]	50	2.1	18	2.7	1	0.2	15	3.5	9	2.4	6	2.2			1	1.5
Final decision	Approved [6]	1940	81.6	541	81.6	443	91.9	322	74.5	278	75.1	219	80.8	77	83.7	60	88.2
	Declined	38	1.6	12	1.8	5	1.0	9	2.1			11	4.1			1	1.5
	Non-consideration	89	3.7	27	4.1	5	1.0	13	3.0	21	5.7	13	4.8	6	6.5	4	5.9
	Withdrawn	30	1.3	10	1.5	7	1.5	1	0.2	2	0.5	7	2.6	3	3.3		
	Final decision still pending [7]	281	11.8	73	11.0	22	4.6	87	20.1	69	18.6	21	7.7	6	6.5	3	4.4
Review procedure	Ordinary [8]	357	15.0	92	13.9	47	9.8	71	16.4	46	12.4	18	6.6	21	22.8	62	91.2 [11]
	Simplified [9]	1662	69.9	401	60.5	381	79.0	302	69.9	309	83.5	222	81.9	46	50.0	1	1.5
	Presidential [10]	310	13.0	152	22.9	54	11.2	44	10.2	6	1.6	25	9.2	25	27.2	4	5.9
	First decision still pending	49	2.1	18	2.7			15	3.5	9	2.4	6	2.2			1	1.5
	Total number in AS1	2378	100.0	663	100.0	482	100.0	432	100.0	370	100.0	271	100.0	92	100.0	68	100.0

1 Projects already approved in the first review process.
2 Charges: The projects are approved but with charges.
3 Conditions: These projects are not approved until the conditions are addressed.
4 Non-consideration: Research not covered by the HRA.
5 Information missing: The status information was missing at the time of the report generation.
6 This includes projects approved in the index year but also in the subsequent year(s) until time of data export explaining the differences to Tables 7.
7 Pending at export date. 48.8% of the pending projects were submitted in the last quarter of the reporting year.
8 Decision taken at full committee meeting by at least seven members of the ethics committee, as per the provisions of Art. 5, OrgO-HRA.
9 Decision taken by three members of the ethics committee, as per the provisions of Art. 6 OrgO-HRA.
10 Decision taken by the president or vice-president of the ethics committee, as per the provisions of Art. 7 OrgO-HRA.
11 CE-TI exclusively uses the ordinary procedure.

Table 4: Number of **submissions in 2018** (analysis set AS1) by type of research project and ethics committee.
Projects involving multiple ECs are assigned to the lead EC.

			Total		Ethics committee											
					KEK-ZH		EKNZ		CER-VD		KEK-BE		CCER		EKOS		CE-TI	
Type of research	Research details	Risk cat.	n	%col	n	%col	n	%col	n	%col	n	%col	n	%col	n	%col	n	%col
Clinical trial	Medicinal products	A	23	11.3	4	6.1	2	5.7	3	12.5	8	29.6	3	20.0	1	5.0	2	12.5
		B	29	14.3	7	10.6	4	11.4	5	20.8	4	14.8	5	33.3	4	20.0		
		C	151	74.4	55	83.3	29	82.9	16	66.7	15	55.6	7	46.7	15	75.0	14	87.5
		All	203	100.0	66	100.0	35	100.0	24	100.0	27	100.0	15	100.0	20	100.0	16	100.0
	Medical devices	A	82	69.5	36	73.5	12	75.0	6	46.2	11	64.7	12	85.7	3	100.0	2	33.3
		C	36	30.5	13	26.5	4	25.0	7	53.8	6	35.3	2	14.3			4	66.7
		All	118	100.0	49	100.0	16	100.0	13	100.0	17	100.0	14	100.0	3	100.0	6	100.0
	Other clinical trials	A	183	88.8	50	87.7	43	95.6	28	82.4	29	85.3	15	83.3	11	100.0	7	100.0
		B	23	11.2	7	12.3	2	4.4	6	17.6	5	14.7	3	16.7				
		All	206	100.0	57	100.0	45	100.0	34	100.0	34	100.0	18	100.0	11	100.0	7	100.0
	Combination drugs/devices	A	2	40.0							2	66.7						
		C	3	60.0			1	100.0	1	100.0	1	33.3						
		All	5	100.0			1	100.0	1	100.0	3	100.0						
	Transplant products	C	5	100.0	1	100.0	1	100.0	2	100.0	1	100.0						
		All	5	100.0	1	100.0	1	100.0	2	100.0	1	100.0						
	Gene therapy	C	1	100.0	1	100.0												
		All	1	100.0	1	100.0												
	Transplantation	A	2	100.0	1	100.0							1	100.0				
		All	2	100.0	1	100.0							1	100.0				
	All	All	540	100.0	175	100.0	98	100.0	74	100.0	82	100.0	48	100.0	34	100.0	29	100.0
Research w/ persons		A	789	96.5	185	95.9	158	97.5	196	96.6	93	94.9	107	98.2	26	89.7	24	100.0
		B	29	3.5	8	4.1	4	2.5	7	3.4	5	5.1	2	1.8	3	10.3		
		All	818	100.0	193	100.0	162	100.0	203	100.0	98	100.0	109	100.0	29	100.0	24	100.0
Further use		n.a.	994	100.0	279	100.0	217	100.0	154	100.0	188	100.0	113	100.0	28	100.0	15	100.0
Deceased, embryos		n.a.	26	100.0	16	100.0	5	100.0	1	100.0	2	100.0	1	100.0	1	100.0		
Total number			2378	100.0	663	100.0	482	100.0	432	100.0	370	100.0	271	100.0	92	100.0	68	100.0

Note that this table includes all BASEC submissions irrespective of whether the project was approved.
The type of project and the risk category at the time of the data export is used.

3.2 Individual evaluations by lead or local ethics committees

Table 5: Perspective of the ethics committee (EC): Number of applications to be evaluated (analysis set AS1).
Note that this table includes only local ECs involved at submission or reported until the date of data export.

	n	%
Single EC involved	2126	73.4
Multiple ECs involved: lead EC	252	8.7
Multiple ECs involved: local EC	518	17.9
Total submissions to be evaluated	2896	100.0

Table 6: Perspective of the ethics committee (EC): Number of submissions to be evaluated per EC.

	Ethics committee													
	KEK-ZH		EKNZ		CER-VD		KEK-BE		CCER		EKOS		CE-TI	
	n	%col	n	%col	n	%col	n	%col	n	%col	n	%col	n	%col
Single EC involved	585	77.6	430	76.6	329	70.8	397	79.1	252	74.3	72	45.3	61	52.6
Multiple: lead EC	78	10.3	52	9.3	41	8.8	35	7.0	19	5.6	20	12.6	7	6.0
Multiple: local EC	91	12.1	79	14.1	95	20.4	70	13.9	68	20.1	67	42.1	48	41.4
Total submissions	754	100.0	561	100.0	465	100.0	502	100.0	339	100.0	159	100.0	116	100.0

4 Scientific characterisation of projects approved in 2018 (AS2)

4.1 Overview

Table 7: Total number of research projects **approved in 2018** (analysis set AS2) per type of research, including information on the legal basis.

Type of research	Legal basis	n	$\%_{col}$
Clinical trial	ClinO	459[1]	22.4
Research involving persons, but not a clinical trial	HRO, Chapter 2	692[2]	33.8
Further use of health-related personal data and/or biological material	HRO, Chapter 3	868	42.4
Research involving deceased persons	HRO, Chapter 4	28	1.4
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	0	0.0
Total number		2047	100.0

1 40 of these projects also include 'further use' of existing data and/or material.
2 170 of these projects also include 'further use' of existing data and/or material.

4.2 Application process

Table 8: Overview of review procedure and first decision for all projects approved in 2018 (i.e. the final decision is 'approved'; AS2). A fraction of the projects are already approved at the 'first decision', the remaining at the 'final decision'. For a definition of all terms see Table 3 on page 12 – per ethics committee.

				Ethics committee													
		Total		KEK-ZH		EKNZ		CER-VD		KEK-BE		CCER		EKOS		CE-TI	
		n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$
Submission year	2016	21	1.0	7	1.3	2	0.4	4	1.1	1	0.3	4	1.8	2	2.5	1	1.4
	2017	450	22.0	110	19.9	64	14.0	96	27.6	88	28.3	62	27.2	14	17.3	16	23.2
	2018	1576	77.0	437	78.9	390	85.5	248	71.3	222	71.4	162	71.1	65	80.2	52	75.4
First decision	Approved	319	15.6	110	19.9	84	18.4	17	4.9	34	10.9	27	11.8	28	34.6	19	27.5
	Approved with charges [1]	603	29.5	22	4.0	282	61.8	182	52.3	11	3.5	53	23.2	39	48.1	14	20.3
	Not approved, conditions [2]	1122	54.8	422	76.2	87	19.1	149	42.8	266	85.5	148	64.9	14	17.3	36	52.2
	Declined [3]	2	0.1			2	0.4										
	Non-consideration [4]	1	0.0			1	0.2										
Review procedure	Ordinary [5]	318	15.5	86	15.5	38	8.3	55	15.8	43	13.8	13	5.7	15	18.5	68	98.6
	Simplified	1479	72.3	347	62.6	361	79.2	267	76.7	268	86.2	189	82.9	46	56.8	1	1.4
	Presidential	250	12.2	121	21.8	57	12.5	26	7.5			26	11.4	20	24.7		
	Total number in AS2	2047	100.0	554	100.0	456	100.0	348	100.0	311	100.0	228	100.0	81	100.0	69	100.0

1 Charges: the projects are approved but with charges.
2 Conditions: These projects are not approved until the conditions are addressed.
3 Resubmission and approval of a previously declined project, reusing the electronic submission form with the old BASEC number.
4 Resubmission of a previously non-considerated project, reusing the electronic submission form with the old BASEC number.
5 CE-TI exclusively uses the ordinary procedure.

4.3 Stratification by project characteristics

In Tables 20–25, the approved projects are grouped row-wise by type of research (the corresponding legal basis is denoted in the first table) and stratified column-wise by generic project characteristics (design, project initiator, etc.).

For the most important types of research projects, subgroup analyses are provided in the following sections. Links to the sub-chapter covering the corresponding subgroup analysis are embedded in Table 9. In the subgroup analyses starting on page 70, a similar table structure is used with more generic characteristics in the columns and subgroup specific characteristics in the rows.

4.3.1 Description and derivation of stratification variables

Risk category: The risk category is used as a stratification variable in all tables. In general, category "A" stands for low risk – however, the exact meaning depends on the type of research project and is defined in the respective ordinances (ClinO Art. 19, 20, 49, 61 and HRO Art. 7). The risk category is derived from the approved project's final risk category ruling stored in BASEC.

Study design: Mono-centric and multi-centric studies are defined based on the number of involved study sites irrespective of whether single or multiple ECs are involved. This is a variable derived from two BASEC questions: "How many research sites in Switzerland are involved in the project?" and "Is the project taking place in countries other than Switzerland?". Mono-centric studies have only one site in Switzerland and no sites in other countries.

Initiator: The initiator of the project is derived from the answer to the BASEC question "Who initiated the project? Indicate here who had the original idea for the research project (do not indicate here who is financing, conducting or leading the project)". Allowed answers are "Investigator", "Industry" and "Other" (very rare). To keep it simple, studies with an initiator defined as "Other" are considered investigator initiated studies in the tables. In Table 4.5.1 on page 34, the above classification is compared to the main financing source indicating that this question indeed seems to be a good proxy to distinguish industry from academic studies.

Research to obtain a degree: The question in BASEC is "Is this research project solely or principally designed to obtain a degree? (Master/PhD/etc)", with allowed answers "yes" or "no".

Vulnerable persons: This is a multiple choice field in BASEC and the allowed answers are: "None", "Embryos/fetuses intrauteri", "Children (0–13, until one day before 14th birthday)", "Adolescents (14–17, until one day before 18th birthday)", "Emergencies (transient incapacity to consent, HRA art 30–31, ClinO art 15–17, HRO art 11)", "Pregnant women", "prisoners", "Persons unable to consent (long-term incapacity to consent, HRA art 21–24)", "Healthy volunteers". To save table space, the 3 rarest categories are grouped to "Others". This question is not asked in BASEC for projects involving "Further use" or "Deceased persons".

Ionising radiation: The question in BASEC is "Does your study involve ionising radiation?". The allowed answers are: "No", "Yes, the main focus of the project is related to radiopharmaceuticals (medicinal products) or to devices emitting ionising radiation (medical devices)", "Yes, but the study is only using ionising radiation for imaging/control purposes". This question is shown only for clinical trials and research involving persons according to HRO chapter 2.

Ethics committee: Column-wise percentages are reported when stratifying by lead EC.

Application procedure: The information on the applied review procedure (ordinary, simplified, presidential) as well as the first decision is reported by the individual ECs.

4.3.2 Risk category, study design and initiator

Table 9: Stratification of approved projects by study design and initiator. Subgroups in blue refer to chapters with the respective subgroup analyses and the legal basis is denoted in parentheses.

					Study design						Initiator			
			Total		Mono		Multi CH		Multi Int.		Industry		Investigator	
Type of research	Research details	Risk cat.	n	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Clinical trial	Medicinal products (ClinO Art 19)	A	19	11.6	11	57.9	2	10.5	6	31.6			19	100.0
		B	27	16.5	10	37.0	6	22.5	11	40.7	4	14.8	23	85.2
		C	118	72.0	19	16.1	6	5.1	93	78.8	89	75.4	29	24.6
		All	164	100.0	40	24.4	14	8.5	110	67.1	93	56.7	71	43.3
	Medical devices (ClinO Art 20)	A	71	67.6	48	67.6	2	2.8	21	29.6	16	22.5	55	77.5
		C	34	32.4	23	67.6	3	8.8	8	23.5	15	44.1	19	55.9
		All	105	100.0	71	67.6	5	4.8	29	27.6	31	29.5	74	70.5
	Other clinical trials (ClinO Art 61)	A	154	88.0	128	83.1	15	9.7	11	7.1	3	1.9	151	98.1
		B	21	12.0	12	57.1	1	4.8	8	38.1			21	100.0
		All	175	100.0	140	80.0	16	9.1	19	10.9	3	1.7	172	98.3
	Combination drugs/devices	A	3	100.0					3	100.0	2	66.7	1	33.3
		All	3	100.0					3	100.0	2	66.7	1	33.3
	Transplant products (ClinO Art 21)	C	8	100.0			1	12.5	7	87.5	5	62.5	3	37.5
		All	8	100.0			1	12.5	7	87.5	5	62.5	3	37.5
	Gene therapy (ClinO Art 22)	C	3	100.0	1	33.3			2	66.7	1	33.3	2	66.7
		All	3	100.0	1	33.3			2	66.7	1	33.3	2	66.7
	Transplantation (ClinO Art 49)	A	1	100.0					1	100.0			1	100.0
		All	1	100.0					1	100.0			1	100.0
	All	All	459	100.0	252	54.9	36	7.8	171	37.3	135	29.4	324	70.6
Research w/ persons (HRO Chapter 2)		A	666	96.2	501	75.2	52	7.8	113	17.0	46	6.9	620	93.1
		B	26	3.8	23	88.5	2	7.7	1	3.8			26	100.0
		All	692	100.0	524	75.7	54	7.8	114	16.5	46	6.6	646	93.4
Further use (HRO Chapter 3)		n.a.	868	100.0	740	85.3	40	4.6	88	10.1	33	3.8	835	96.2
Deceased, embryos (HRO Chapter 4+5)		n.a.	28	100.0	26	92.9	1	3.6	1	3.6			28	100..0
Total number			2047	100.0	1542	75.3	131	6.4	37.4	18.3	214	10.5	1833	89.5

To keep it simple, studies with an initiator defined as 'Other' are considered investigator initiated studies.

Further information can be found in the Annex in section A.2

4.3.3 Ethics committee

Table 10: Stratification of all approved projects by ethics committee.

			Total		Ethics committee													
					KEK-ZH		EKNZ		CER-VD		KEK-BE		CCER		EKOS		CE-TI	
Type of research	Research details	Risk cat.	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$
Clinical trial	Medicinal products	A	19	11.6	3	4.8	3	11.5	3	20.0	5	25.0	4	33.3			1	6.7
		B	27	16.5	8	12.7	4	15.4	3	20.0	4	20.0	4	33.3	3	23.1	1	6.7
		C	118	72.0	52	82.5	19	73.1	9	60.0	11	55.0	4	33.3	10	76.9	13	86.7
		All	164	100.0	63	100.0	26	100.0	15	100.0	20	100.0	12	100.0	13	100.0	15	100.0
	Medical devices	A	71	67.6	33	73.3	10	66.7	5	71.4	9	56.2	10	76.9	3	100.0	1	16.7
		C	34	32.4	12	26.7	5	33.3	2	28.6	7	43.8	3	23.1			5	83.3
		All	105	100.0	45	100.0	15	100.0	7	100.0	16	100.0	13	100..0	3	100.0	6	100.0
	Other clinical trials	A	154	88.0	41	91.1	38	88.4	22	84.6	19	82.6	15	88.2	10	83.3	9	100.0
		B	21	12.0	4	8.9	5	11.6	4	15.4	4	17.4	2	11.8	2	16.7		
		All	175	100.0	45	100.0	43	100.0	26	100.0	23	100.0	17	100.0	12	100.0	9	100.0
	Combination drugs/devices	A	3	100.0							3	100.0						
		All	3	100.0							3	100.0						
	Transplant products	C	8	100.0	3	100.0	1	100.0	3	100.0	1	100.0						
		All	8	100.0	3	100.0	1	100.0	3	100.0	1	100.0						
	Gene therapy	C	3	100.0	1	100.0			2	100.0								
		All	3	100.0	1	100.0			2	100.0								
	Transplantation	A	1	100.0									1	100.0				
		All	1	100.0									1	100.0				
	All	All	459	100.0	157	100.0	85	100.0	53	100.0	63	100.0	43	100.0	28	100.0	30	100.0
Research w/ persons		A	666	96.2	138	95.8	142	97.9	168	95.5	83	94.3	89	98.9	22	95.7	24	92.3
		B	26	3.8	6	4.2	3	2.1	8	4.5	5	5.7	1	1.1	1	4.3	2	7.7
		All	692	100.0	144	100.0	145	100.0	176	100.0	88	100.0	90	100.0	23	100.0	26	100.0
Further use		n.a.	868	100.0	238	100.0	220	100.0	118	100.0	158	100.0	92	100.0	29	100.0	13	100.0
Deceased, embryos		n.a.	28	100.0	15	100.0	6	100.0	1	100.0	2	100.0	3	100.0	1	100.0		
Total number			2047	100.0	554	100.0	456	100.0	348	100.0	311	100.0	228	100.0	81	100.0	69	100.0

4.3.4 Application procedure

Table 11: Stratification of all approved projects by characteristics of the application procedure.

					Review procedure						First decision									
			Total		Ordinary		Simplified		Presidential		Approved		Charges		Conditions		Declined		Non-consid.	
Type of research	Research details	Risk cat.	n	%col	n	%row	n	%row	n	%row	n	%row	n	%row	n	%row	n	%row	n	%row
Clinical trial	Medicinal products	A	19	11.6	5	26.3	14	73.7					2	10.5	17	89.5				
		B	27	16.5	27	100.0					2	7.4	5	18.5	20	74.1				
		C	118	72.0	118	100.0					5	4.2	24	20.3	89	75.4				
		All	164	100.0	150	91.5	14	8.5			7	4.3	31	18.9	126	76.8				
	Medical devices	A	71	67.6	6	8.5	65	91.5			1	1.4	10	14.4	60	84.5				
		C	34	32.4	31	91.2	3	8.8			1	2.9	4	11.8	29	85.3				
		All	105	100.0	37	35.2	68	64.8			2	1.9	14	13.3	89	84.8				
	Other clinical trials	A	154	88.0	18	11.7	134	87.0	2	1.3	3	1.9	44	28.6	107	69.5				
		B	21	12.0	17	81.0	4	19.0					8	38.1	13	61.9				
		All	175	100.0	35	20.2	138	78.9	2	1.1	3	1.7	52	29.7	120	68.6				
	Combination drugs/devices	A	3	100.0			3	100.0							3	100.0				
		All	3	100.0			3	100.0							3	100.0				
	Transplant products	C	8	100.0	8	100.0									8	100.0				
		All	8	100.0	8	100.0									8	100.0				
	Gene therapy	C	3	100.0	3	100.0									3	100.0				
		All	3	100.0	3	100.0									3	100.0				
	Transplantation	A	1	100.0			1	100.0							1	100.0				
		All	1	100.0			1	100.0							1	100.0				
	All	All	459	100.0	233	50.8	224	48.8	2	0.4	12	2.6	97	21.1	350	76.3				
Research w/ persons		A	666	96.2	47	7.1	611	91.7	8	1.2	38	5.7	227	34.1	399	59.9	2	0.3		
		B	26	3.8	23	88.5	2	7.7	1	3.8			5	19.2	21	80.8				
		All	692	100.0	70	10.1	613	88.6	9	1.3	38	5.5	232	33.5	420	60.7	2	0.3		
Further use		n.a.	868	100.0	14	1.6	615	70.9	239	27.5	255	29.4	270	31.1	342	39.4			1	0.1
Deceased, embryos		n.a.	28	100.0	1	3.6	27	96.4			14	50.0	4	14.3	10	35.7				
Total number			2047	100.0	318	15.5	1479	72.3	250	12.2	319	15.6	603	29.5	1122	54.8	2	0.1	1	0.0

Charges = Approved with charges; Conditions = Not approved with conditions.

4.4 Subgroups of research projects

4.4.1 Subgroup "Clinical trials" – research covered by the ClinO

4.4.1.1 Therapeutic area

Table 12: Overview on therapeutic area ('disease under investigation') for clinical trials according to Swiss National Clinical Trials Portal (SNCTP) – (multiple answers possible) – stratification by trial type. The proportion of projects investigating a rare disease is provided. Data for the 15 clinical trials not falling in the 3 main clinical trial types medicinal product, medical devices, other are not included in the stratification, but in the total projects number.

	Type of clinical trial											
	All clinical trials			Medicinal products			Medical devices			Other clinical trials		
Therapeutic area	n	$\%_{col}$	n_{rare}	n	$\%_{col}$	n_{rare}	n	$\%_{col}$	n_{rare}	n	$\%_{col}$	n_{rare}
Other	129	28.1	2	27	16.5	1	34	32.4	1	67	38.3	0
Cancer: Other	38	8.3	9	29	17.7	8	3	2.9	0	6	3.4	1
Nervous System diseases	37	8.1	5	8	4.9	3	13	12.4	0	16	9.1	2
Surgery	34	7.4	1	5	3.0	1	12	11.4	0	16	9.1	0
Musculoskeletal diseases (non cancer)	32	7.0	3	4	2.4	2	10	9.5	0	17	9.7	1
Basic research (Anatomy/Physiology)	28	6.1	1	3	1.8	0	6	5.7	0	19	10.9	1
Mental and Behavioural diseases	23	5.0	0	5	3.0	0	2	1.9	0	16	9.1	0
Brain diseases (non cancer)	18	3.9	1	3	1.8	0	3	2.9	0	12	6.9	1
Coronary Heart disease	17	3.7	0	1	0.6	0	9	8.6	0	4	2.3	0
Nutritional and Metabolic diseases	17	3.7	2	5	3.0	0	1	1.0	0	11	6.3	2
Cancer: Lung	16	3.5	1	12	7.3	1	1	1.0	0	3	1.7	0
Infections and Infestations	16	3.5	0	7	4.3	0	3	2.9	0	4	2.3	0
Cancer: Breast	14	3.1	1	6	3.7	1	3	2.9	0	5	2.9	0
Cancer: Head and Neck	14	3.1	1	10	6.1	1	1	1.0	0	2	1.1	0
Digestive Systems diseases (non cancer)	14	3.1	1	8	4.9	0	3	2.9	0	3	1.7	1
Eye diseases	13	2.8	2	5	3.0	2	5	4.8	0	3	1.7	0
Injury	13	2.8	0	1	0.6	0	6	5.7	0	5	2.9	0
Respiratory diseases (non cancer)	13	2.8	3	8	4.9	2	2	1.9	0	3	1.7	1
Skin and Connective Tissues diseases (non cancer)	12	2.6	2	8	4.9	2	1	1.0	0	1	0.6	0
Cancer: Melanoma	11	2.4	1	8	4.9	1	0	0.0	0	2	1.1	0
Cancer: Prostate	10	2.2	0	4	2.4	0	0	0.0	0	6	3.4	0
Ear, Nose, and Throat diseases (non cancer)	10	2.2	0	0	0.0	0	8	7.6	0	2	1.1	0
Endocrinological diseases (non cancer)	9	2.0	2	3	1.8	1	1	1.0	0	5	2.9	1
Cancer: Bladder	8	1.7	1	5	3.0	1	1	1.0	0	2	1.1	0
Cancer: Endometrial	8	1.7	0	5	3.0	0	0	0.0	0	2	1.1	0
Cancer: Lymphoma	8	1.7	3	5	3.0	2	0	0.0	0	2	1.1	0
Cancer: Non-Hodgkin Lymphoma	8	1.7	1	5	3.0	1	0	0.0	0	2	1.1	0
Cancer: Pancreatic	8	1.7	0	5	3.0	0	1	1.0	0	2	1.1	0
Genetic disorders	8	1.7	7	7	4.3	6	0	0.0	0	1	0.6	1
Urological and Genital diseases (non cancer)	8	1.7	0	4	2.4	0	3	2.6	0	1	0.6	0
Arterial and venous diseases including deep venous thrombosis and lung embolism	7	1.5	1	3	1.8	1	4	3.8	0	0	0.0	0
Cancer: Colon and Rectal	7	1.5	0	3	1.8	0	0	0.0	0	4	2.3	0
Cancer: Leukemia	6	1.3	2	4	2.4	2	0	0.0	0	2	1.1	0
Dementia and Alzheimer disease	6	1.3	0	0	0.0	0	1	1.0	0	5	2.9	0
Hematologic diseases (non cancer)	6	1.3	5	4	2.4	3	0	0.0	0	1	0.6	1
Pregnancy and Childbirth	6	1.3	0	2	1.2	0	1	1.0	0	3	1.7	0
Cancer: Kidney	5	1.1	0	2	1.2	0	1	1.0	0	2	1.1	0
Neonatal diseases	5	1.1	0	1	0.6	0	2	1.9	0	2	1.1	0
Cancer: Thyroid	4	0.9	1	2	1.2	1	0	0.0	0	2	1.1	0
Periodontal diseases	3	0.7	0	0	0.0	0	2	1.9	0	1	0.6	0
Occupational diseases	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	0
Total projects	459	141.1	48	164	100	37	105	100.0	1	175	100.0	8

Rare disease: A rare disease or orphan disease is defined as a disease or condition that affects fewer than 5 in 10'000 people and is life-threatening or chronically debilitating. Total projects: The last line in the table denotes the total number of approved clinical trials (or the respective subgroup). Since multiple answers are possible, this number does not correspond to the sum in the table.

4.4.1.2 Primary area of research

Table 13: Overview on primary area of **research for clinical trials – stratification by trial** type. Data for the 15 clinical trials not falling in the 3 main clinical trial types medicinal product, medical devices, other are not included in the stratification.

			Type of clinical trial					
	All clinical trials		Medicinal products		Medical devices		Other clinical trials	
Area of research	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$
Treatment	259	56.4	121	73.8	59	56.2	66	37.7
Other	50	10.9	4	2.4	6	5.7	40	22.9
PK/PD/safety	36	7.8	32	19.5	1	1.0	2	1.1
Basic science	29	6.3	1	0.6	6	5.7	22	12.6
Diagnosis	29	6.3	1	0.6	16	15.2	12	6.9
Prevention	28	6.1	5	3.0	4	3.8	18	10.3
Rehabilitation	27	5.9	0	0.0	13	12.4	14	8.0
Palliation	1	0.2	0	0.0	0	0.0	1	0.6
Total projects	459	100.0	164	100.0	105	100.0	175	100.0

➔ A further stratification according to project characteristics of clinical trials overall can be found in the Annex in section A.3.1.

4.4.2 Subgroups of "Clinical trials"

The allowed answers of project characteristics according to the entry mask of BASEC are reported below. No further explanations are provided in BASEC. Not all project characteristics are appropriate for certain subgroups: in this case, the respective questions are hidden on the BASEC web portal.

Phase: This question is only asked for drug and drug/device combination trials. Single choice field with allowed answers: "Phase 1", "Phase 1/2", "Phase 2", "Phase 3", "Phase 4", "n/a". During post-processing "Phase 1" and "Phase 1/2" were assigned to "Phase 1".

First in man: Single choice field ("Yes", "No"). This question is only asked for drug, device and drug/device combination trials.

Standard use of medical device: The first question is "Does your project only involve standard use of existing medical devices with conformity marking?". If the answer is "No", the answer can be further specified: "New use of existing device" (i.e. a CE-marked medical device used outside of the intended use), "New medical device" (i.e. a medical device that has no CE-marking).

➔ The definition of project chracteristics used in stratifications presented in the Annex are reported there

4.4.2.1 Subgroup "Clinical trials with medicinal products" (ClinO Art 19)

Table 14: Stratification of **medicinal products trials** by risk category, phase and whether 'first in man'.

			Phase											
	Total		1		2		3		4		n/a		First in man	
Risk category	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
A	22	13.2	1	4.5	2	9.1	2	9.1	10	45.5	7	31.8		
B	27	16.2	5	18.5	6	22.2	8	29.6	4	14.8	4	14.8		
C	118	70.7	25	21.2	35	29.7	52	44.1			6	5.1	8	6.8
Total number	167	100.0	31	18.6	43	25.7	62	37.1	14	8.4	17	10.2	8	4.8

The total number of 167 research projects consist of 164 medicinal product trials and 3 trials on a combination medicinal product and medical device.

➔ A further stratification of medicinal products trials according to project characteristics listed on the previous page can be found in the Annex in section A.3.2.1

4.4.2.2 Subgroup "Clinical trials with medical devices" (ClinO Art 20)

Table 15: Stratification of **trials with medical devices** by risk category, device details and whether 'first in man'.

			Phase							
	Total		CE-marked, intended use		CE-marked, not intended use		Not CE-marked		First in man	
Risk category	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
A	74	68.5	71	95.9					7	9.5
C	34	31.5	4	11.8	8	23.5	22	64.7	13	38.2
Total number	108	100.0	75	69.4	8	7.4	22	20.4	20	18.5

The total number of 108 research projects consist of 105 trials with medical devices and 3 trials on a combination medicinal product and medical device. Intended use: used in accordance with the instructions; Non-intended use: not used in accordance with the intended purposes recognised in the conformity assessment and specified in the instructions.

➔ A further stratification of clinical trials with medical devices can be found in the Annex in section A.3.2.2

4.4.2.3 Subgroup "Other clinical trials" (ClinO Art 61)

➔ further stratification of "other clinical trials" can be found in the Annex in section A.3.2.3

4.4.3 Subgroup "Research involving persons, but not a clinical trial" - research covered by HRO Chapter 2

Table 16: Stratification of research projects involving persons, but not a clinical trial, by risk category, study design and initiator. The 'type of research projects' reported in the following tables are self-reported and BASEC-specific without a legal basis in the HRA.

	Total		Risk category				Study design						Initiator			
			A		B		Mono		Multi CH		Multi int.		Industry		Investigator	
Type of research project	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Cohort study	206	29.8	199	96.6	7	3.4	151	73.3	16	7.8	39	18.9	5	2.4	201	97.6
Registry / Quality control [1]	65	9.4	64	98.5	1	1.5	38	58.5	2	3.1	25	38.5	14	21.5	51	78.5
Case control study	77	11.1	66	85.7	11	14.3	68	88.3	5	6.5	4	5.2	1	1.3	76	98.7
Other or n/a	344	49.7	337	98.0	7	2.0	267	77.6	31	9.0	46	13.4	26	7.6	318	92.4
Total number	692	100.0	666	96.2	26	3.8	524	75.7	54	7.8	114	16.5	46	6.6	646	93.4

1 Only quality control studies under the HRA.

Table 17: Overview on primary area of research for research projects involving persons – stratification by project type.

			Type of research project							
	Overall		Cohort study		Registry / Quality control		Case control study		Other or n/a	
Area of research	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Other	216	31.2	51	24.8	12	18.5	26	33.8	127	36.9
Psychology	91	13.2	34	16.5	3	4.6	12	15.6	42	12.2
Physiology/anatomy	74	10.7	25	12.1	2	3.1	13	16.9	34	9.9
Qualitative research	69	10.0	18	8.7	11	16.9	3	3.9	37	10.8
Medical devices	55	7.9	14	6.8	14	21.5	2	2.6	25	7.3
Healthcare services research	51	7.4	16	7.8	7	10.8	2	2.6	26	7.6
Surgery	46	6.6	16	7.8	5	7.7	11	14.3	14	4.1
Epidemiology	44	6.4	24	11.7	8	12.3	5	6.5	7	2.0
Drugs	31	4.5	5	2.4	3	4.6	2	2.6	21	6.1
Dentistry	15	2.2	3	1.5	0	0.0	1	1.3	11	3.2
Total number	692	100.0	206	100.0	65	100.0	77	100.0	344	100.0

➔ Further information can be found in the Annex in section A.3.3

4.4.4 Subgroup "Further use of data/biological material" – research covered by HRO Chapter 3

The projects are stratified based on the following 3 questions:

Genetic data: The BASEC question "Your project involves" can be answered with "Non-genetic data only" or "Genetic-data and/or biological material".

Coding: The BASEC question "Please select how your research data will be kept" can be answered with "Coded" or "Open, non-coded". A reference to HRO Art. 25–27 is provided.

Consent: The BASEC question "Consent for further use of data/material" can be answered with "Prior consent exists", "Consent to be sought" or "No consent for some or all of the samples/data". Applicants are informed that if they "Have an informed consent from before the human research act (2014), check whether it is conformable to law (Articles 28–32 HRO). If not, the consent is not sufficient. If there is pre-existing consent for some samples/records, but not for others, Art 34 HRA may apply".

- If **Prior consent exists** has been selected, the researchers are informed that if they have an informed consent from before the human research act (2014), they must check whether the consent is conformable to the law (Articles 28–32 HRO). If not, the consent is not legally valid.
- If **Consent to be sought** has been selected, researchers will need to obtain the study participants' consent prior using data and/or biological material for the research project.
- If **no consent for some or all data** has been selected, the researchers might apply for exemption of the consent according to Art. 34 HRA. Research projects where the consent is available for some of the data are counted as Art. 34 HRA projects.

Combined project: "Combined project" are those research projects that combine a clinical trial (ClinO) or a research project involving persons according to HRO Chapter 2, with a 'further use' of existing data or biological material (HRO Chapter 3).

Table 18: Overview of characteristics of all approved 'further use' projects.

		n	%
Genetic data/biol. material	Yes	218	20.2
	No	860	79.8
Coding (HRO Art. 25–27)	Coded	901	83.6
	Open, non-coded	177	16.4
Consent (HRO Art. 28–32)	Prior consent exists	309	28.7
	Consent to be sought	234	21.7
	No consent for some/all data	535	49.6
Combined vs. stand-alone projects	Stand-alone further use project	868	80.5
	Further use project as part of a clinical trial	40	3.7
	Further use project as part of a non-clinical research project	170	15.8
Total number		1078	100.0

Table 19: Stratification of **projects involving further use of data/biological material** by study design and initiator.
All combinations of the following three factors are shown: 1) Use of genetic data and/or biological material (Genetic D+M), 2) coded vs. uncoded, 3) consent for further use.

			Total		Study design						Initiator			
					Mono		Multi CH		Multi Int.		Industry		Investigator	
Genetic D+M	Coded	Consent	n	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Yes	Coded	Prior consent exists	79	38.7	47	59.5	7	8.9	25	31.6	21	26.6	58	73.4
		Consent to be sought	63	30.9	33	52.4	13	20.6	17	27.0	5	7.9	58	92.1
		No consent for some/all data	62	30.4	47	75.8	7	11.3	8	12.9	4	6.5	58	93.5
		All	204	100.0	127	62.3	27	13.2	50	24.5	30	14.7	174	85.3
	Open, non-coded	Prior consent exists	5	35.7	4	80.0			1	20.0			5	100.0
		Consent to be sought	4	28.6	4	100.0							4	100.0
		No consent for some/all data	5	35.7	4	80.0			1	20.0			5	100.0
		All	14	100.0	12	85.7			2	14.3			14	100.0
	All		218	100.0	139	63.8	27	12.4	52	23.9	30	13.8	188	86.2
No	Coded	Prior consent exists	179	25.7	157	87.7	2	1.1	20	11.2	5	2.8	174	97.2
		Consent to be sought	145	20.8	103	71.0	10	6.9	32	22.1	12	8.3	133	91.7
		No consent for some/all data	373	53.5	334	89.5	20	5.4	19	5.1	2	0.5	371	99.5
		All	697	100.0	594	85.2	32	4.6	71	10.2	19	2.7	678	97.3
	Open, non-coded	Prior consent exists	46	28.2	43	93.5	1	2.2	2	4.3			46	100.0
		Consent to be sought	22	13.5	20	90.9			2	9.1	2	9.1	20	90.9
		No consent for some/all data	95	58.3	91	95.8	2	2.1	2	2.1	1	1.1	94	98.9
		All	163	100.0	154	94.5	3	1.8	6	3.7	3	1.8	160	98.2
	All		860	100.0	748	87.0	35	4.1	77	9.0	22	2.6	838	97.4
Total number			1078	100.0	887	82.3	62	5.8	129	12.0	52	4.8	1026	95.2

The total number of 1078 research projects consist of 868 standard 'further use' projects and 210 ClinO or research with persons (HRO) projects that include further use of data/biological material.

Table 20: Stratification of **projects involving further use of data/biological material** by ethics committee.

	Total		Ethics committee													
			KEK-ZH		EKNZ		CER-VD		KEK-BE		CCER		EKOS		CE-TI	
Consent	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$
Prior consent exists	309	28.7	121	39.9	59	22.3	30	19.1	52	27.2	32	29.4	10	31.2	5	23.8
Consent to be sought	234	21.7	63	20.8	59	22.3	27	17.2	44	23.0	23	21.1	9	28.1	9	42.9
No consent for some/all data	535	49.6	119	39.3	147	55.5	100	63.7	95	49.7	54	49.5	13	40.6	7	33.3
Total number	1078	100.0	303	100.0	265	100.0	157	100.0	191	100.0	109	100.0	32	100.0	21	100.0

Note that there are regional differences in time point of the introduction of the 'general consent' and some hospitals have not introduced it yet.

➔ Further information can be found in the Annex in section A.3.4

4.5 Information about the parties involved in human research projects

4.5.1 Project initiator and funding

Table 21: Answers to the question "Who initiated the project?" stratified by the main financing source. The researchers are asked to 'indicate here who had the original idea for the research project (do not indicate here who is financing, conducting or leading the project)'.

Initiator	Financing (main source)	n	$\%_{col}$
Investigator	Public, other	1126	64.9
	Industry	89[1]	5.1
	Universities/hospitals	253	14.6
	Private (non-industry)	147	8.5
	Swiss National Science Foundation	121	7.0
	All	1736	100.0
Industry	Public, other	45[2]	21.0
	Industry	167[3]	78.0
	Universities/hospitals	1	0.5
	Private (non-industry)	1	0.5
	Swiss National Science Foundation	0	0.0
	All	214	100.0
Other	Public, other	78	80.4
	Industry	3	3.1
	Universities/hospitals	7	7.2
	Private (non-industry)	7	7.2
	Swiss National Science Foundation	2	2.1
	All	97[4]	100.0

1 Applicants almost exclusively from academic institutions.
2 Inspecting the sponsor information reveals that these are almost xclusively industry projects.
3 163 of the industry-initiated projects are financed exclusively by industry.
4 32 of these projects initiated by others are projects solely or principally designed to obtain a degree (the tutor is the initiator). Apart from that, these projects are quite heterogenous.

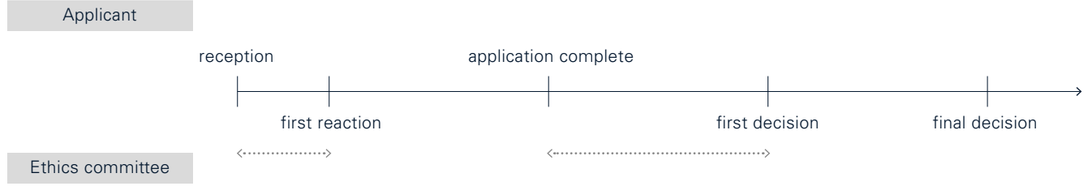
➔ Further information can be found in the Annex in section A.4

5 Response times and review procedure (AS2)

5.1 Definitions

As described in the introduction on page 8, the data analysed in the following are selfreported by the individual ECs. As outlined in the figure below, the ECs manually enter the dates of milestones for all individual applications into BASEC. Thereby the only two periods that solely depend on the EC are: 1) reception (initial submission) to first reaction and 2) application data complete to first decision. The interval between "first reaction" and "application complete" is mainly dependent on the applicant. All other intervals encompass periods in the responsibility of both EC and applicant. During any request of information by the EC directed to the applicant, a clock-stop of the EC deadline may be applied, but clock-stops are not consistently tracked in BASEC.

Figure 2: Overview of dates of milestones reported by the ECs for each application. The only two periods that purely depend on the EC are denoted.



5.2 Overview of median response times

Table 22: Overview of response times in days – median (M) and inter-quartile range (IQR) per review procedure and ethics committee.

				Time interval from …									
				receipt to first reply		receipt to complete		receipt to first decision		receipt to final decision		complete to first d.		complete to final d.	
Procedure	EC	N	$\%_{EC}$	Median	IQR	Median	IQR	Median	IQR	Median	IQR	Median	IQR	Median	IQR
Ordinary	KEK-ZH	86	16	7	[7, 7]	15	[9, 21]	32	[26, 37]	120	[77, 179]	14	[10, 20]	98	[61, 165]
	EKNZ	38	8	3	[1, 6]	4	[1, 6]	33	[22, 40]	78	[62, 96]	26	[18, 33]	73	[56, 91]
	CER-VD	55	16	5	[4, 7]	6	[4, 7]	28	[22, 34]	126	[91, 192]	21	[17, 28]	119	[84, 188]
	KEK-BE	43	14	4	[1, 5]	5	[2, 12]	25	[20, 32]	118	[80, 179]	19	[15, 22]	106	[72, 170]
	CCER	13	6	3	[1, 4]	7	[5, 12]	35	[33, 40]	141	[88, 181]	27	[23, 31]	118	[77, 144]
	EKOS	15	19	3	[1, 5]	3	[1, 5]	23	[20, 32]	75	[54, 108]	21	[17, 28]	74	[52, 104]
	CE-TI	68	99	7	[7, 7]	7	[7, 8]	28	[20, 36]	54	[28, 92]	15	[12, 27]	42	[17, 77]
	All	318	16	7	[4, 7]	7	[5, 13]	29	[21, 36]	97	[63, 151]	19	[14, 26]	84	[55, 135]
Simplified	KEK-ZH	347	63	7	[7, 8]	18	[11, 24]	33	[27, 42]	62	[42, 102]	14	[11, 19]	42	[27, 77]
	EKNZ	361	79	4	[1, 5]	4	[1, 6]	20	[14, 26]	40	[23, 65]	15	[9, 20]	35	[19, 56]
	CER-VD	267	77	5	[3, 6]	5	[3, 7]	24	[21, 29]	69	[51, 110]	20	[16, 22]	63	[48, 104]
	KEK-BE	268	86	2	[1, 4]	5	[1, 13]	21	[17, 32]	75	[49, 108]	15	[13, 19]	65	[42, 92]
	CCER	189	83	2	[1, 4]	5	[2, 11]	28	[23, 37]	95	[61, 145]	22	[19, 27]	83	[55, 127]
	EKOS	46	57	2	[1, 3]	2	[1, 4]	16	[10, 23]	32	[18, 58]	14	[9, 17]	28	[14, 48]
	CE-TI	1	1	10	[10, 10]	10	[10, 10]	26	[26, 26]	27	[27, 27]	16	[16, 16]	17	[17, 17]
	All	1479	72	4	[2, 7]	6	[3, 14]	25	[19, 34]	62	[41, 99]	16	[13, 21]	52	[30, 85]
Presidential	KEK-ZH	121	22	7	[7, 7]	9	[7, 15]	21	[15, 27]	29	[20, 51]	8	[6, 15]	17	[8, 35]
	EKNZ	57	12	4	[2, 6]	5	[3, 8]	12	[7, 17]	18	[13, 48]	6	[3, 8]	12	[6, 35]
	CER-VD	26	7	6	[3, 6]	6	[4, 7]	21	[18, 30]	46	[34, 75]	16	[13, 21]	40	[28, 61]
	KEK-BE	0	0												
	CCER	26	11	2	[1, 4]	6	[2, 16]	14	[8, 27]	14	[8, 27]	5	[4, 10]	6	[4, 12]
	EKOS	20	25	2	[1, 3]	2	[1, 4]	8	[6, 13]	12	[6, 34]	6	[4, 10]	8	[4, 26]
	CE-TI	0	0												
	All	250	12	6	[2, 7]	7	[4, 13]	18	[12, 26]	26	[15, 51]	7	[4, 15]	15	[7, 38]
Overall	KEK-ZH	554	100	7	[7, 7]	15	[9, 22]	31	[23, 39]	61	[38, 105]	14	[9, 19]	42	[22, 83]
	EKNZ	456	100	4	[1, 6]	4	[2, 7]	20	[14, 27]	41	[21, 70]	15	[7, 20]	35	[16, 61]
	CER-VD	348	100	5	[3, 6]	5	[3, 7]	24	[21, 31]	74	[52, 123]	20	[16, 22]	67	[48, 113]
	KEK-BE	311	100	2	[1, 4]	5	[2, 12]	22	[18, 32]	80	[52, 119]	15	[13, 20]	68	[46, 106]
	CCER	228	100	2	[1, 4]	5	[2, 11]	28	[23, 36]	90	[53, 142]	22	[16, 27]	76	[49, 124]
	EKOS	81	100	2	[1, 3]	3	[1, 4]	16	[9, 24]	32	[14, 72]	14	[7, 18]	28	[10, 58]
	CE-TI	69	100	7	[7, 7]	7	[7, 9]	27	[20, 36]	52	[27, 91]	15	[12, 27]	41	[17, 76]
	All	2047	100	5	[2, 7]	7	[3, 14]	25	[19, 34]	63	[36, 104]	16	[12, 21]	52	[28, 90]

CE-TI reviews all projects in an 'Ordinary procedure'.

5.3 Stratification of response time by review procedure

5.3.1 Time from status "complete" to first decision

Definition: In the following, violin plots are used to visualise the distribution of response times. Violin plots are similar to box plots except that they show more details on the distribution of the data by showing the probability density of the data at different values (kernel density plot). In addition, we denote the 1st, 2nd and 3rd quartile of the data by vertical lines in the plot which makes the data comparable to what is provided in the tables (median and inter-quartile range).

Figure 3: Violin plot of the time between status 'complete' to the first decision by EC. 7 projects with t > 60 days are not shown for layout reasons.

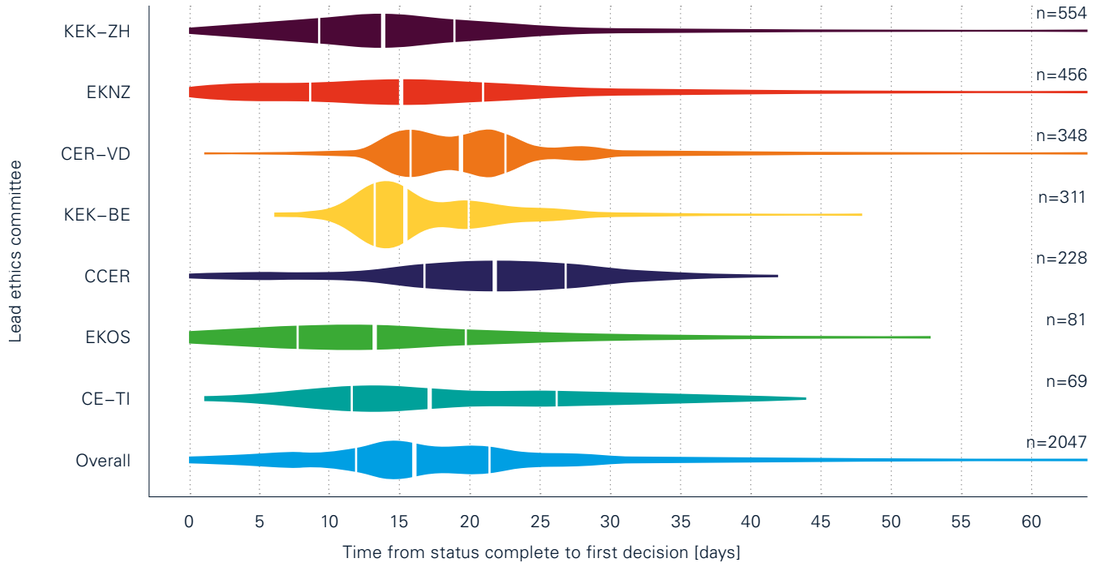
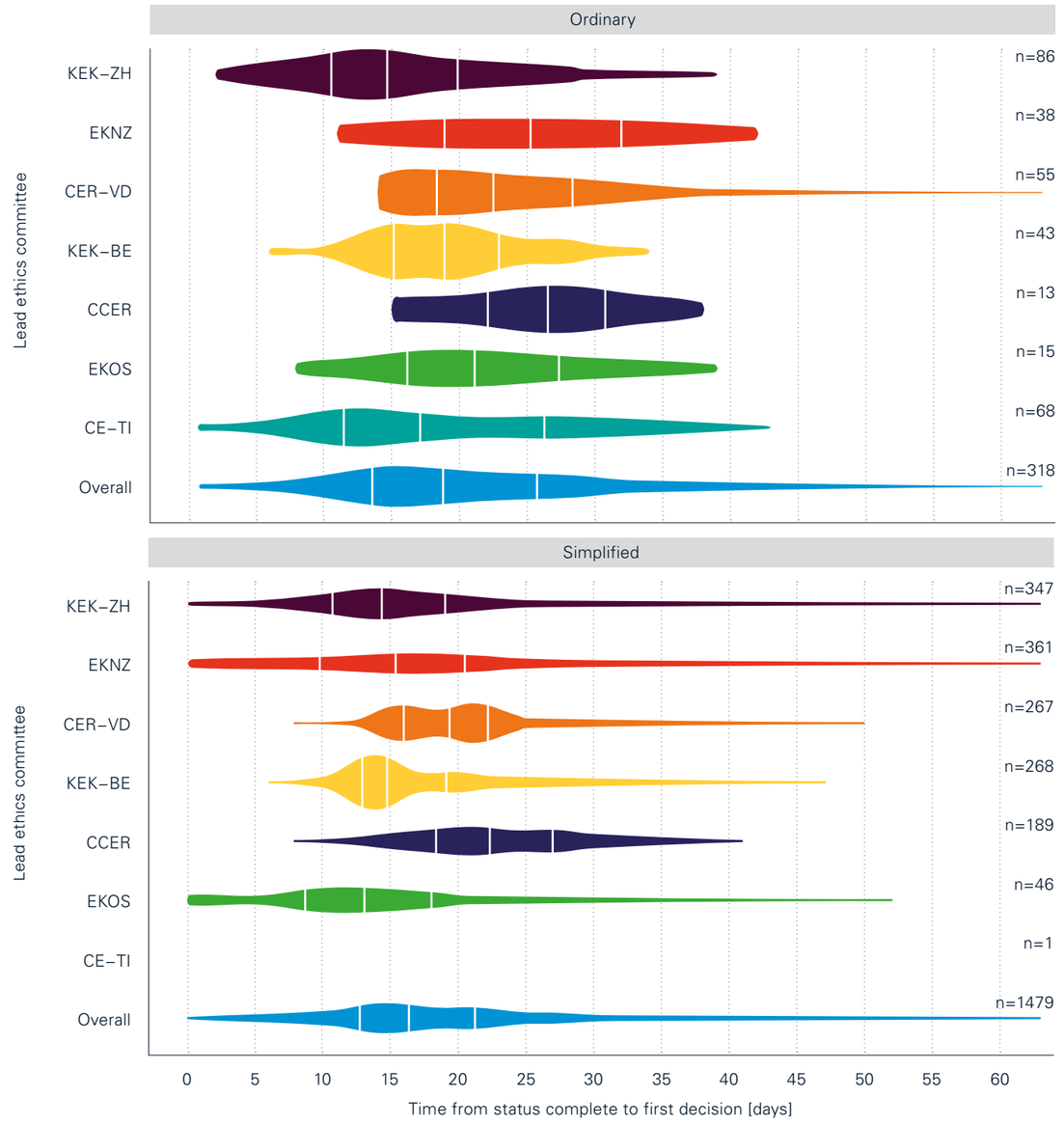
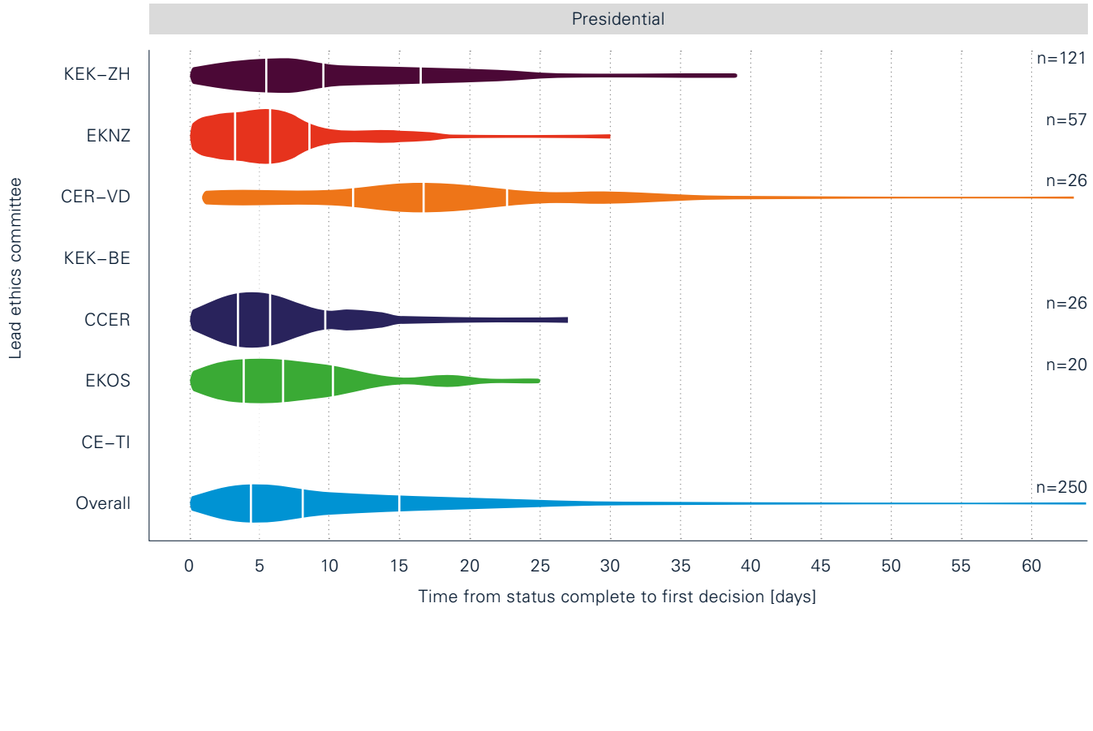


Figure 4: Violin plot of the time between status 'complete' to the first decision by EC and stratified by review procedure. 7 projects with t > 60 days are not shown for layout reasons. Note: CE-TI typically processes all submissions in a plenary session (ordinary procedure) but with adapted fees.





5.3.2 Time from reception to final decision

Figure 5: Violin plot of the overall approval time by EC from reception to final decision. 42 projects with approval time > 1 year are not shown for layout reasons.

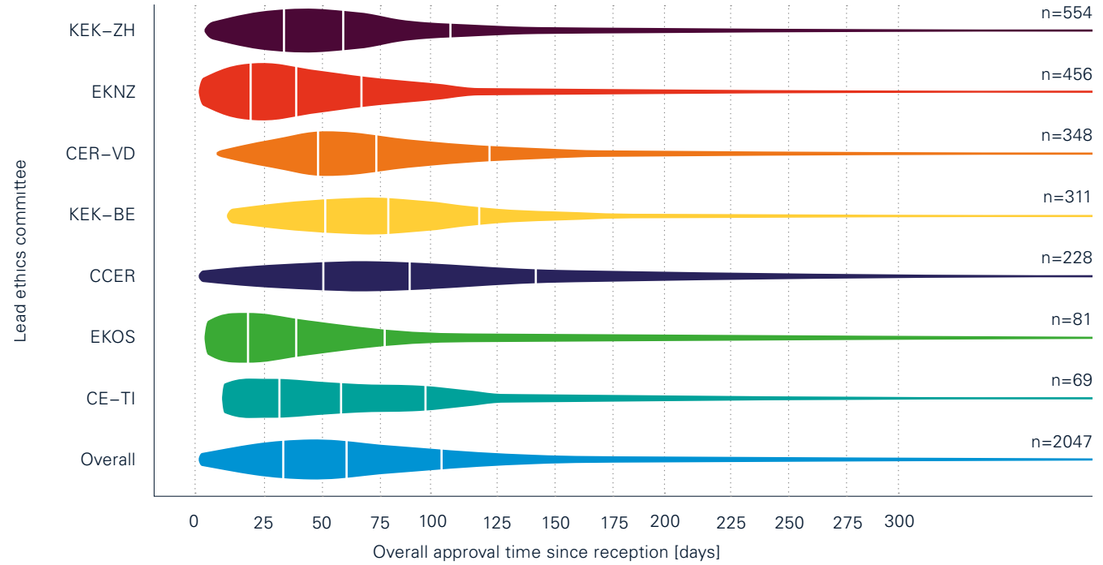
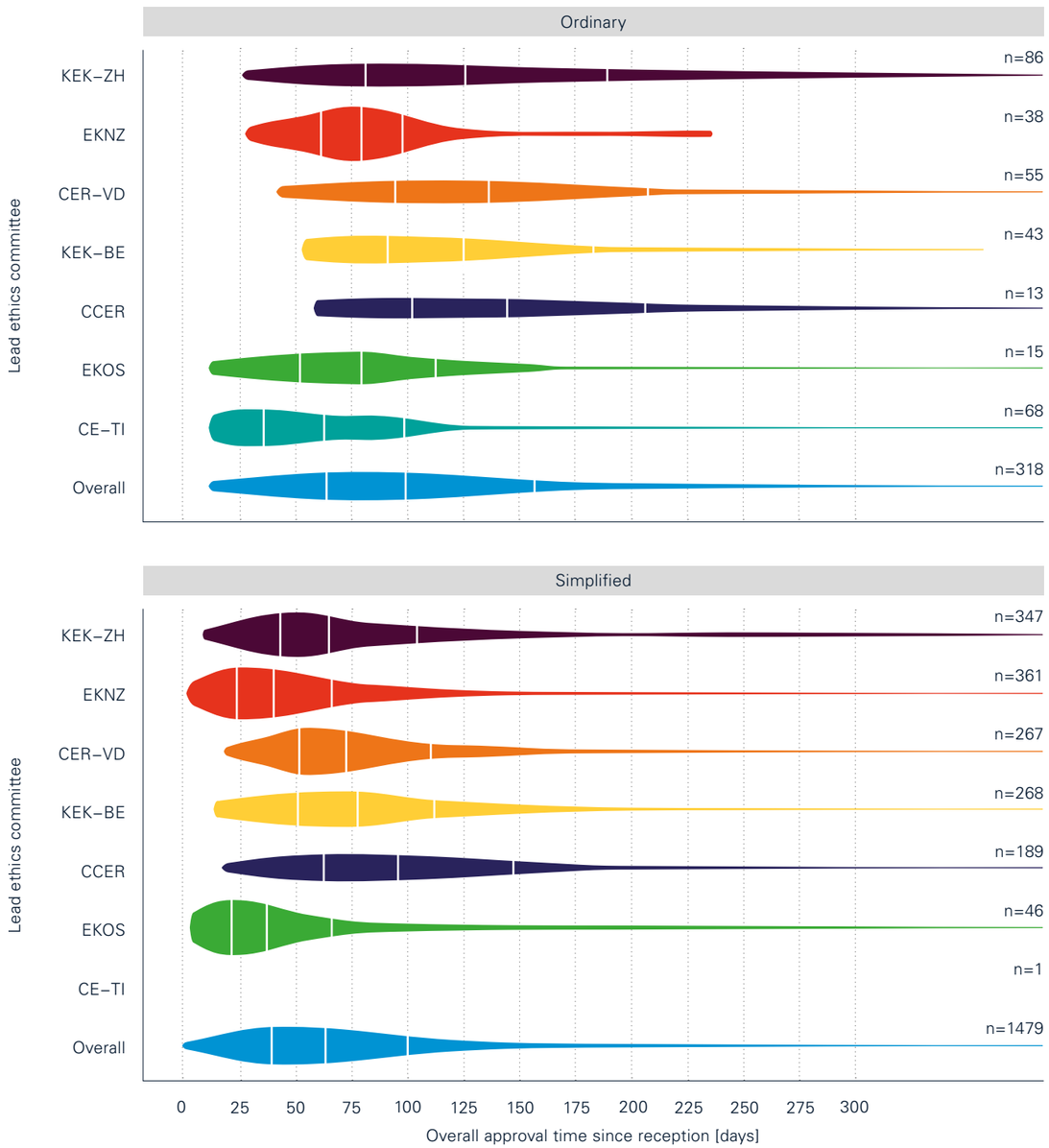
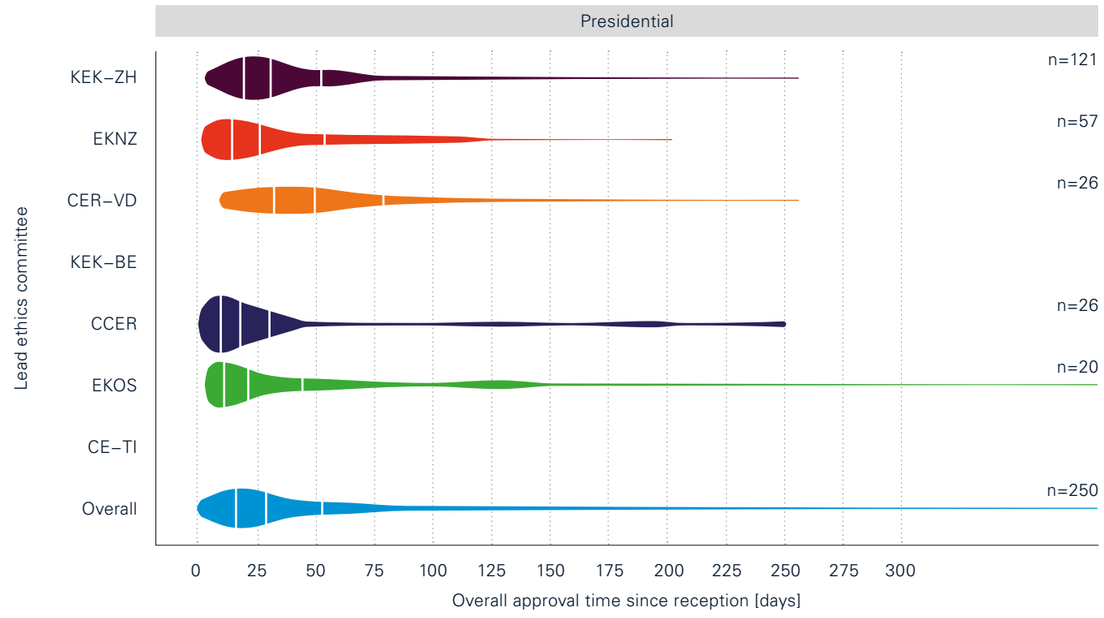


Figure 6: Violin plot of the overall approval time by EC from reception to final decision and stratified by review procedure. 42 projects with approval time > 1 year are not shown for layout reasons.





5.4 Stratification of response time by type of research

Table 23: Overview of response time in days – Median (M) and inter-quartile range (IQR) per type of research and ethics committee.

				Time interval from …									
				receipt to first reply		receipt to complete		receipt to first decision		receipt to final decision		complete to first decision		complete to final decision	
Type of research	EC	N	$\%_{EC}$	Median	IQR	Median	IQR	Median	IQR	Median	IQR	Median	IQR	Median	IQR
Clinical trial	KEK-ZH	157	28.34	7	[7, 7]	20	[13, 28]	35	[28, 42]	102	[68, 166]	14	[11, 19]	78	[47, 146]
	EKNZ	85	18.64	4	[1, 6]	4	[1, 7]	27	[20, 34]	69	[43, 89]	20	[16, 26]	62	[37, 81]
	CER-VD	53	15.23	5	[4, 6]	6	[4, 7]	27	[21, 32]	123	[74, 161]	20	[16, 23]	106	[58, 154]
	KEK-BE	63	20.26	3	[1, 5]	5	[2, 9]	23	[19, 30]	118	[81, 184]	18	[14, 21]	106	[74, 170]
	CCER	43	18.86	3	[2, 5]	8	[6, 18]	34	[26, 45]	123	[90, 185]	22	[20, 27]	100	[79, 158]
	EKOS	28	34.57	4	[1, 5]	4	[1, 5]	22	[16, 29]	59	[32, 84]	18	[13, 26]	54	[28, 78]
	CE-TI	30	43.48	7	[7, 7]	7	[7, 9]	26	[20, 42]	68	[26, 94]	15	[13, 28]	50	[19, 74]
	All	459	22.42	6	[3, 7]	7	[4, 18]	29	[21, 39]	92	[62, 142]	18	[14, 23]	78	[49, 132]
Research w/ persons	KEK-ZH	144	25.99	7	[7, 8]	21	[15, 27]	37	[29, 43]	65	[50, 105]	14	[11, 19]	46	[29, 80]
	EKNZ	145	31.80	4	[2, 5]	4	[2, 6]	22	[19, 29]	53	[36, 76]	17	[14, 22]	47	[31, 63]
	CER-VD	176	50.57	5	[3, 6]	5	[3, 7]	24	[21, 31]	78	[57, 120]	20	[16, 22]	71	[51, 113]
	KEK-BE	88	28.30	2	[1, 5]	6	[2, 18]	23	[19, 34]	72	[53, 119]	15	[14, 19]	64	[46, 90]
	CCER	90	39.47	1	[0, 3]	4	[1, 8]	28	[23, 34]	95	[60, 159]	23	[19, 27]	83	[56, 148]
	EKOS	23	28.40	2	[1, 3]	2	[1, 3]	16	[10, 23]	32	[18, 65]	12	[9, 18]	27	[16, 40]
	CE-TI	26	37.68	7	[6, 7]	7	[7, 8]	24	[18, 34]	56	[36, 104]	15	[10, 27]	50	[28, 96]
	All	692	33.81	5	[2, 7]	6	[3, 16]	27	[21, 35]	68	[48, 108]	18	[14, 22]	56	[39, 95]
Further use	KEK-ZH	238	42.96	7	[7, 7]	10	[7, 15]	25	[20, 31]	40	[26, 63]	13	[7, 18]	27	[14, 48]
	EKNZ	220	48.25	3	[1, 6]	4	[1, 7]	14	[8, 20]	24	[14, 41]	8	[4, 16]	19	[8, 35]
	CER-VD	118	33.91	4	[3, 6]	5	[3, 7]	23	[20, 29]	62	[45, 82]	20	[16, 22]	56	[39, 76]
	KEK-BE	158	50.80	2	[1, 4]	4	[1, 12]	21	[16, 31]	72	[46, 104]	14	[13, 19]	61	[36, 92]
	CCER	92	40.35	2	[1, 4]	6	[2, 11]	27	[20, 35]	63	[27, 106]	20	[12, 25]	54	[19, 91]
	EKOS	29	35.80	1	[1, 3]	2	[1, 4]	12	[6, 17]	17	[7, 33]	9	[4, 14]	12	[4, 31]
	CE-TI	13	18.84	7	[7, 7]	7	[7, 10]	28	[20, 34]	34	[27, 40]	16	[12, 24]	22	[13, 30]
	All	868	42.40	4	[2, 7]	6	[3, 11]	21	[15, 29]	43	[22, 76]	14	[8, 20]	34	[15, 67]
Deceased persons	KEK-ZH	15	2.71	7	[7, 8]	8	[8, 14]	27	[18, 33]	29	[18, 62]	16	[9, 20]	18	[9, 46]
	EKNZ	6	1.32	3	[2, 7]	6	[2, 8]	18	[15, 22]	24	[23, 54]	13	[12, 14]	15	[14, 50]
	CER-VD	1	0.29	5	[5, 5]	76	[76, 76]	96	[96, 96]	160	[160, 160]	20	[20, 20]	84	[84, 84]
	KEK-BE	2	0.64	3	[3, 3]	10	[6, 14]	28	[26, 30]	68	[61, 75]	18	[16, 20]	58	[48, 68]
	CCER	3	1.32	7	[4, 8]	7	[4, 11]	24	[23, 32]	99	[96, 154]	20	[18, 23]	97	[92, 146]
	EKOS	1	1.23	3	[3, 3]	3	[3, 3]	3	[3, 3]	3	[3, 3]	0	[0, 0]	0	[0, 0]
	CE-TI	0	0.00												
	All	28	1.37	7	[3, 7]	8	[7, 14]	24	[17, 31]	33	[22, 86]	15	[11, 20]	23	[12, 73]
Overall	KEK-ZH	554	100.00	7	[7, 7]	15	[9, 22]	31	[23, 39]	61	[38, 105]	14	[9, 19]	42	[22, 83]
	EKNZ	456	100.00	4	[1, 6]	4	[2, 7]	20	[14, 27]	41	[21, 70]	15	[7, 20]	35	[16, 61]
	CER-VD	348	100.00	5	[3, 6]	5	[3, 7]	24	[21, 31]	74	[52, 123]	20	[16, 22]	67	[48, 113]
	KEK-BE	311	100.00	2	[1, 4]	5	[2, 12]	22	[18, 32]	80	[52, 119]	15	[13, 20]	68	[46, 106]
	CCER	228	100.00	2	[1, 4]	5	[2, 11]	28	[23, 36]	90	[53, 142]	22	[16, 27]	76	[49, 124]
	EKOS	81	100.00	2	[1, 3]	3	[1, 4]	16	[9, 24]	32	[14, 72]	14	[7, 18]	28	[10, 58]
	CE-TI	69	100.00	7	[7, 7]	7	[7, 9]	27	[20, 36]	52	[27, 91]	15	[12, 27]	41	[17, 76]
	All	2047	100.00	5	[2, 7]	7	[3, 14]	25	[19, 34]	63	[36, 104]	16	[12, 21]	52	[28, 90]

Table 24: Overview of response time in days – Median and inter-quartile range (IQR) per type of research and depending on whether a single or multiple ECs are involed.

		Application involves					
		Multiple ECs			Single EC		
Type of research	Time interval	n	Median	IQR	n	Median	IQR
Clinical trial	from receipt to first reply	117	6	[3, 7]	342	6	[3, 7]
	from receipt to status 'complete'	117	7	[4, 17]	342	7	[4, 19]
	from receipt to first decision	117	32	[23, 40]	342	29	[21, 38]
	from receipt to final decision	117	114	[80, 163]	342	84	[56, 131]
	from 'complete' to first decision	117	20	[14, 27]	342	17	[14, 22]
	from 'complete' to final decision	117	100	[75, 153]	342	70	[44, 120]
Research w/ persons	from receipt to first reply	65	4	[1, 7]	627	5	[2, 7]
	from receipt to status 'complete'	65	7	[2, 18]	627	6	[3, 16]
	from receipt to first decision	65	28	[21, 42]	627	27	[21, 35]
	from receipt to final decision	65	93	[62, 140]	627	66	[48, 104]
	from 'complete' to first decision	65	18	[14, 24]	627	17	[14, 22]
	from 'complete' to final decision	65	76	[50, 128]	627	55	[37, 92]
Further use	from receipt to first reply	42	4	[1, 6]	826	4	[2, 7]
	from receipt to status 'complete'	42	6	[2, 10]	826	6	[3, 11]
	from receipt to first decision	42	25	[19, 33]	826	21	[15, 28]
	from receipt to final decision	42	76	[45, 102]	826	42	[22, 75]
	from 'complete' to first decision	42	18	[13, 23]	826	14	[7, 20]
	from 'complete' to final decision	42	68	[38, 84]	826	32	[14, 65]
Deceased persons	from receipt to first reply	0			28	7	[3, 7]
	from receipt to status 'complete'	0			28	8	[7, 14]
	from receipt to first decision	0			28	24	[17, 31]
	from receipt to final decision	0			28	33	[22, 86]
	from 'complete' to first decision	0			28	15	[11, 20]
	from 'complete' to final decision	0			28	23	[12, 73]
Overall	from receipt to first reply	224	5	[2, 7]	1823	5	[2, 7]
	from receipt to status 'complete'	224	7	[3, 17]	1823	7	[3, 13]
	from receipt to first decision	224	29	[22, 39]	1823	25	[18, 33]
	from receipt to final decision	224	98	[69, 148]	1823	59	[34, 96]
	from 'complete' to first decision	224	19	[14, 25]	1823	16	[12, 21]
	from 'complete' to final decision	224	84	[60, 139]	1823	49	[25, 83]

Table 25: Overview of response time in days – Median and inter-quartile range (IQR) stratified by lead ethics committee and depending on whether a single or multiple ECs are involed.

		Application involves					
		Multiple ECs			Single EC		
Lead EC	Time interval	n	Median	IQR	n	Median	IQR
KEK-ZH	from receipt to first reply	70	7	[7, 7]	484	7	[7, 7]
	from receipt to status 'complete'	70	18	[12, 26]	484	15	[9, 22]
	from receipt to first decision	70	34	[27, 43]	484	30	[23, 39]
	from receipt to final decision	70	128	[92, 199]	484	56	[34, 91]
	from 'complete' to first decision	70	14	[11, 21]	484	14	[9, 19]
	from 'complete' to final decision	70	102	[64, 183]	484	36	[21, 69]
EKNZ	from receipt to first reply	50	3	[1, 5]	406	4	[2, 6]
	from receipt to status 'complete'	50	4	[1, 6]	406	4	[2, 7]
	from receipt to first decision	50	24	[21, 35]	406	19	[13, 26]
	from receipt to final decision	50	72	[57, 88]	406	36	[20, 62]
	from 'complete' to first decision	50	19	[16, 25]	406	14	[7, 20]
	from 'complete' to final decision	50	68	[49, 80]	406	30	[14, 55]
CER-VD	from receipt to first reply	32	4	[2, 6]	316	5	[3, 6]
	from receipt to status 'complete'	32	5	[2, 7]	316	5	[3, 7]
	from receipt to first decision	32	24	[21, 35]	316	24	[21, 30]
	from receipt to final decision	32	136	[78, 167]	316	70	[50, 112]
	from 'complete' to first decision	32	20	[16, 25]	316	20	[16, 22]
	from 'complete' to final decision	32	130	[75, 163]	316	63	[48, 106]
KEK-BE	from receipt to first reply	35	3	[2, 5]	276	2	[1, 4]
	from receipt to status 'complete'	35	5	[2, 10]	276	5	[2, 12]
	from receipt to first decision	35	25	[18, 33]	276	21	[18, 31]
	from receipt to final decision	35	105	[84, 140]	276	76	[52, 112]
	from 'complete' to first decision	35	20	[14, 25]	276	15	[13, 19]
	from 'complete' to final decision	35	97	[70, 119]	276	66	[43, 98]
CCER	from receipt to first reply	12	3	[0, 4]	216	2	[1, 4]
	from receipt to status 'complete'	12	7	[1, 10]	216	5	[2, 11]
	from receipt to first decision	12	33	[26, 36]	216	28	[23, 36]
	from receipt to final decision	12	100	[82, 130]	216	86	[51, 142]
	from 'complete' to first decision	12	22	[18, 27]	216	22	[16, 27]
	from 'complete' to final decision	12	85	[71, 126]	216	76	[48, 124]
EKOS	from receipt to first reply	16	2	[1, 4]	65	2	[1, 3]
	from receipt to status 'complete'	16	4	[1, 5]	65	3	[1, 4]
	from receipt to first decision	16	24	[21, 31]	65	14	[8, 20]
	from receipt to final decision	16	75	[55, 106]	65	29	[12, 53]
	from 'complete' to first decision	16	22	[15, 29]	65	10	[6, 17]
	from 'complete' to final decision	16	74	[54, 104]	65	27	[8, 42]
CE-TI	from receipt to first reply	9	7	[3, 7]	60	7	[7, 7]
	from receipt to status 'complete'	9	8	[7, 9]	60	7	[7, 8]
	from receipt to first decision	9	41	[38, 44]	60	25	[20, 34]
	from receipt to final decision	9	99	[80, 142]	60	45	[26, 86]
	from 'complete' to first decision	9	32	[25, 35]	60	15	[12, 24]
	from 'complete' to final decision	9	92	[71, 135]	60	36	[17, 73]
Overall	from receipt to first reply	224	5	[2, 7]	1823	5	[2, 7]
	from receipt to status 'complete'	224	7	[3, 17]	1823	7	[3, 13]
	from receipt to first decision	224	29	[22, 39]	1823	25	[18, 33]
	from receipt to final decision	224	98	[69, 148]	1823	59	[34, 96]
	from 'complete' to first decision	224	19	[14, 25]	1823	16	[12, 21]
	from 'complete' to final decision	224	84	[60, 139]	1823	49	[25, 83]

5.4.1 Time from status "complete" to first decision

Definition: In the following, violin plots are used to visualise the distribution of response times. Violin plots are similar to box plots except that they show more details on the distribution of the data by showing the probability density of the data at different values (kernel density plot). In addition, we denote the 1st, 2nd and 3rd quartile of the data by vertical lines in the plot which makes the data comparable to what is provided in the tables (median and inter-quartile range).

Figure 7: Violin plot of the **approval time starting from status 'complete' to the first decision** per type of research (only the 3 major groups are shown). 7 projects with approval time > 60 days are not shown for layout reasons.

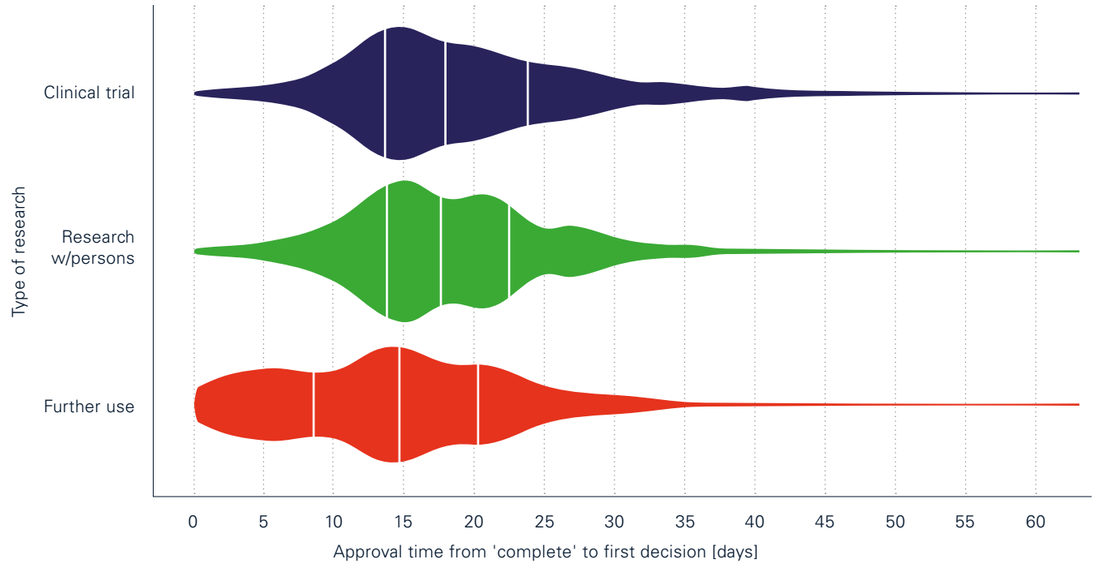
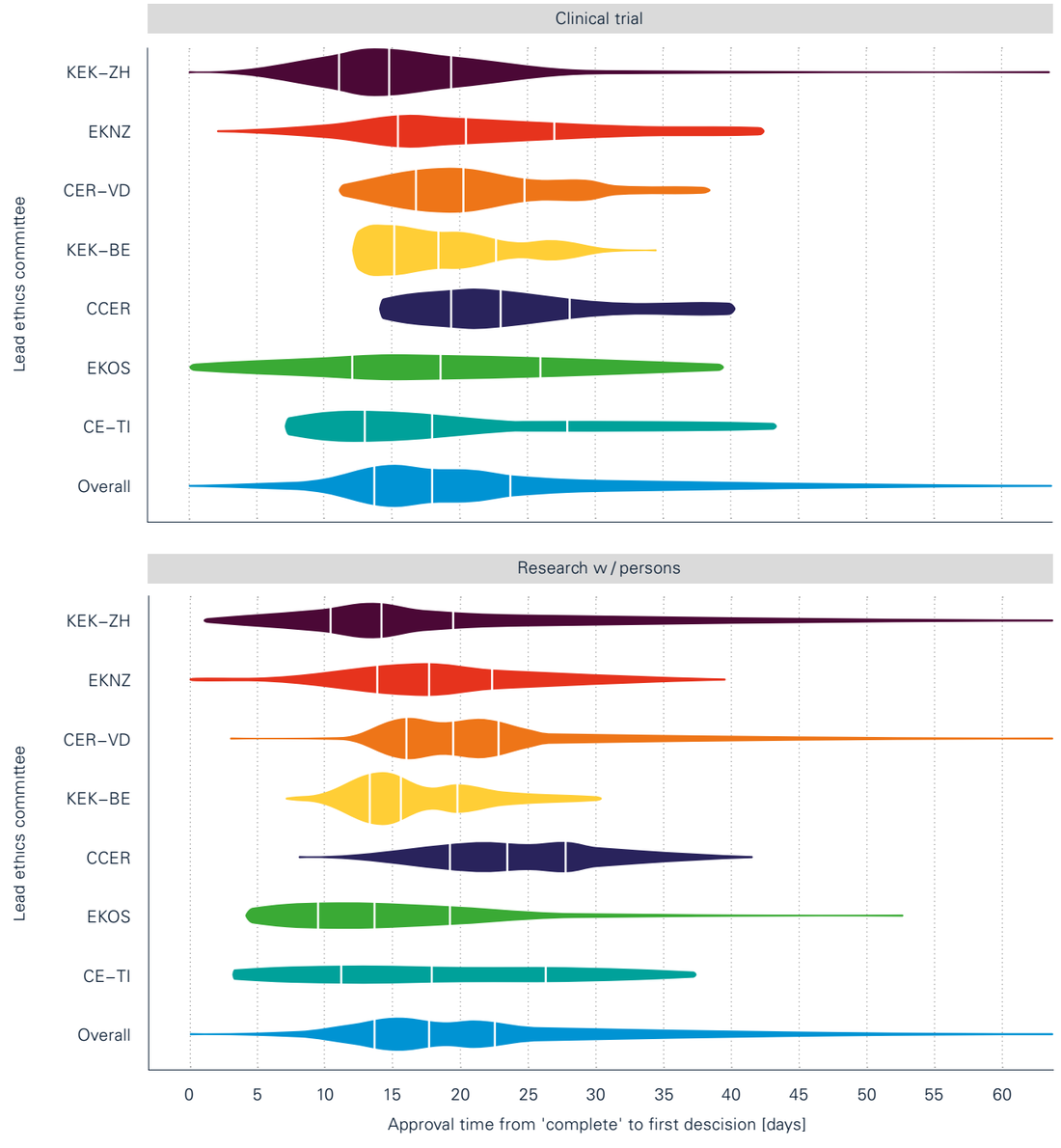


Figure 8: Violin plot of the **approval time starting from status 'complete' to the first decision** per type of research (only the 3 major groups are shown) stratified by EC. 7 projects with approval time > 60 days are not shown for layout reasons.



5.4.2 Time from reception to final decision

Figure 9: Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown). 42 projects with an overall approval time > 1 year are not shown for layout reasons.

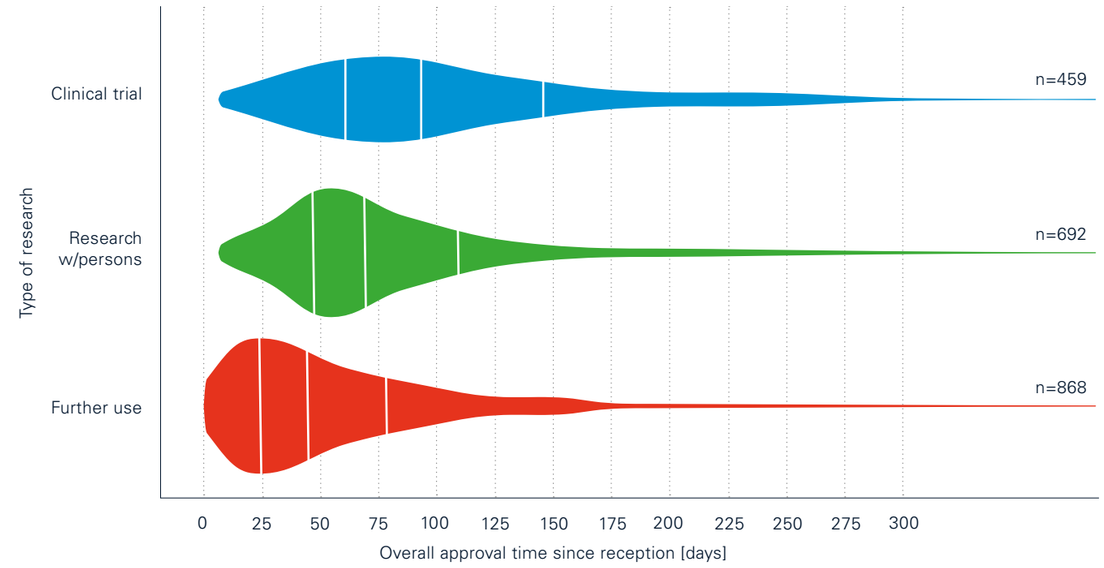
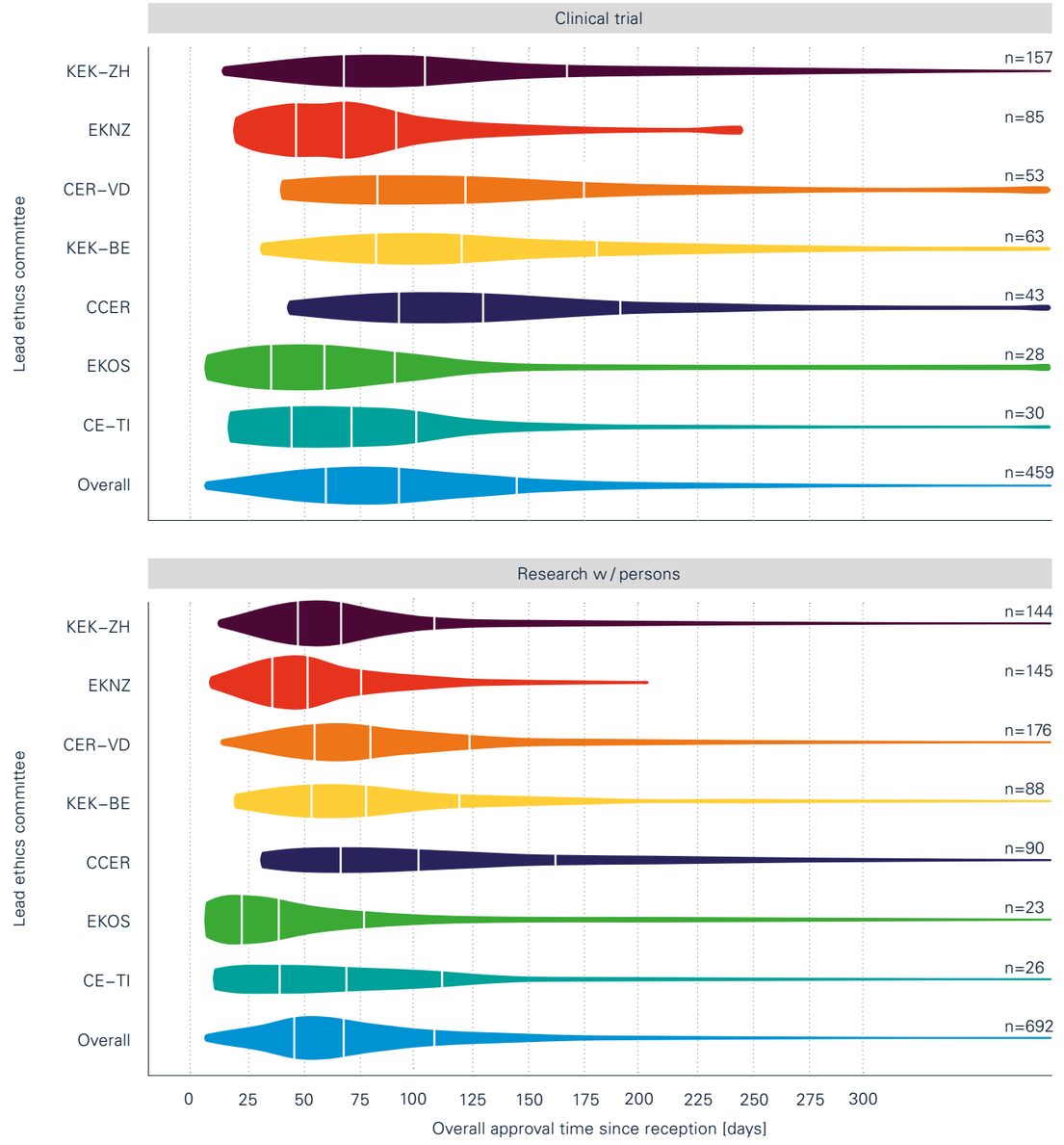
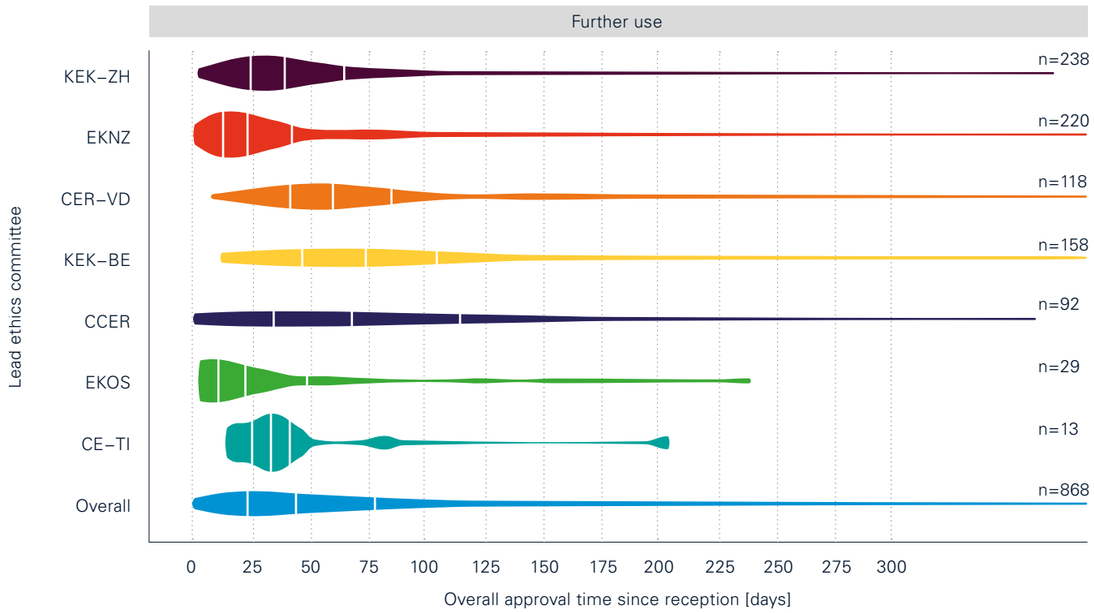


Figure 10: Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown) stratified by EC. 42 projects with an overall approval time > 1 year are not shown for layout reasons.





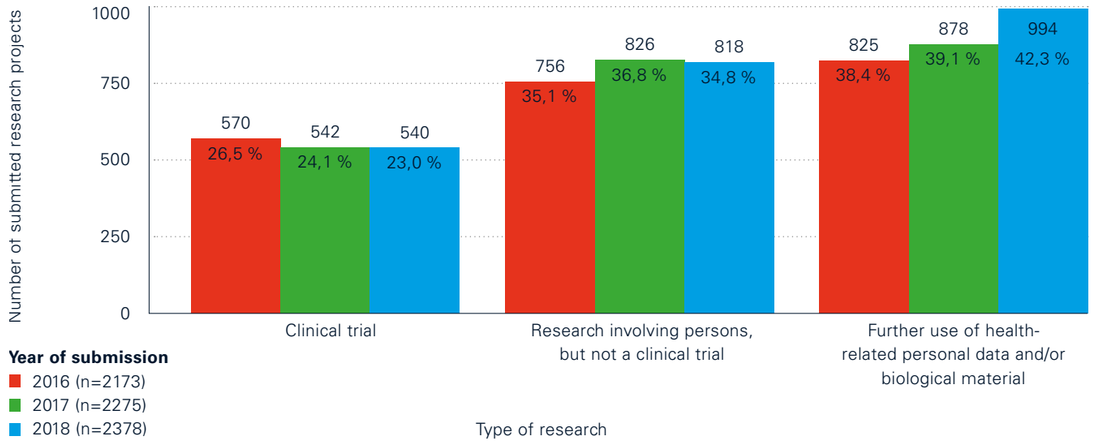
5.5 Stratification of response time by involvement of single or multiple ECs

➔ Information can be found in the Annex in Figure 26

6 Comparison of submitted projects (AS1) since the introduction of BASEC

Note: In this chapter, specific parameters of the research projects are compared between the years of submission. BASEC is regularly monitored for data integrity and data quality, and for this reason the Ethics Committee or the researchers can adjust and correct the data in BASEC, whenever necessary. Consequently, the data in this report might slightly differ from the data published in last year report.

Figure 11: Total number of submitted projects per year and type of research.

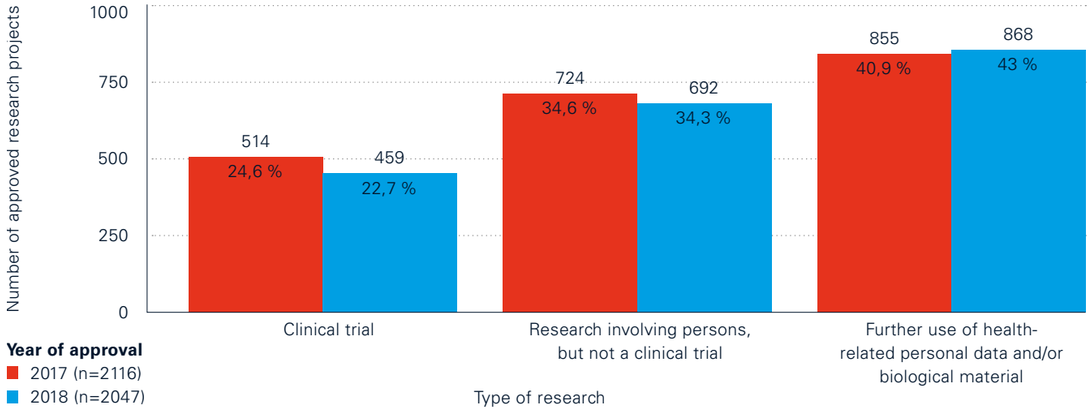


Data not shown in the above figure: Research involving deceased persons (2016: 20, 2017: 29, 2018: 26) and Research involving embryos and fetuses from induced abortions or stillbirths (2016: 2, 2017: 0, 2018: 0)

7 Comparison of approved projects of reporting year (AS2) with previous year

Note: In this chapter, specific parameters of the research projects approved in the reporting year and the last year are compared. BASEC is regularly monitored for data integrity and data quality, and for this reason the Ethics Committee or the researchers can adjust and correct the data in BASEC, whenever necessary. Consequently, the data in this report might slightly differ from the data published in last year report.

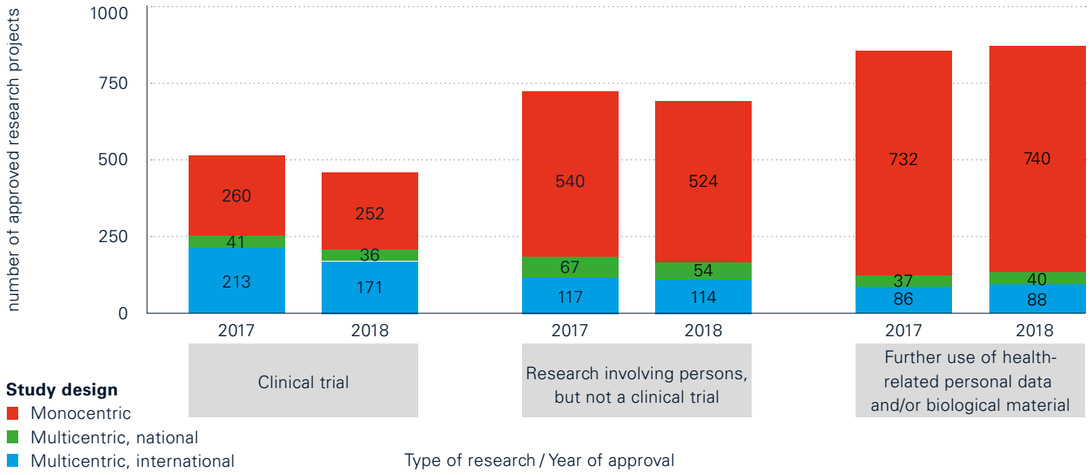
Figure 12: Total number of approved projects per year and type of research.



Data not shown in the above figure: Research involving deceased persons (2017: 22, 2018: 28) and Research involving embryos and fetuses from induced abortions or stillbirths (2017: 1, 2018: 0)

7.1 Study design: mono-/multi-centric, national/international

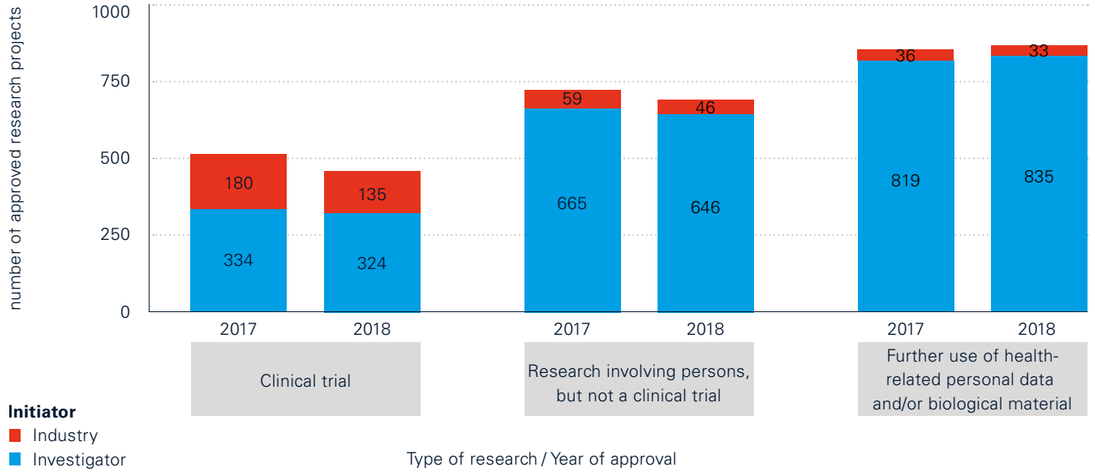
Figure 13: Approved projects per year stratified by type of research project and by study design.



Data not shown in the above figure: Research involving deceased persons (2017: 22, 2018: 28) and Research involving embryos and fetuses from induced abortions or stillbirths (2017: 1, 2018: 0)

7.2 Project initiator

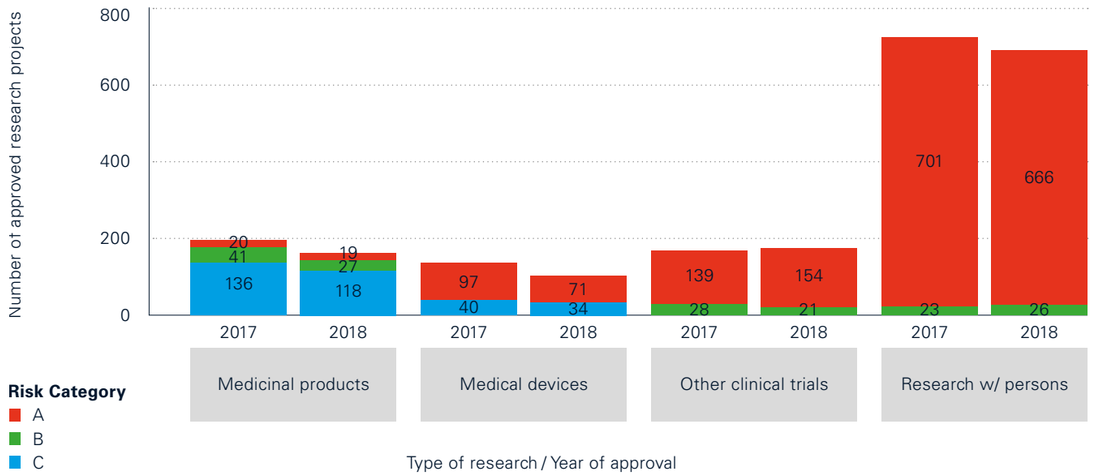
Figure 14: Approved projects per year stratified by type of research project and by project initiator.



Data not shown in the above figure: Research involving deceased persons (2017: 22, 2018: 28) and Research involving embryos and fetuses from induced abortions or stillbirths (2017: 1, 2018: 0)

7.3 Risk category

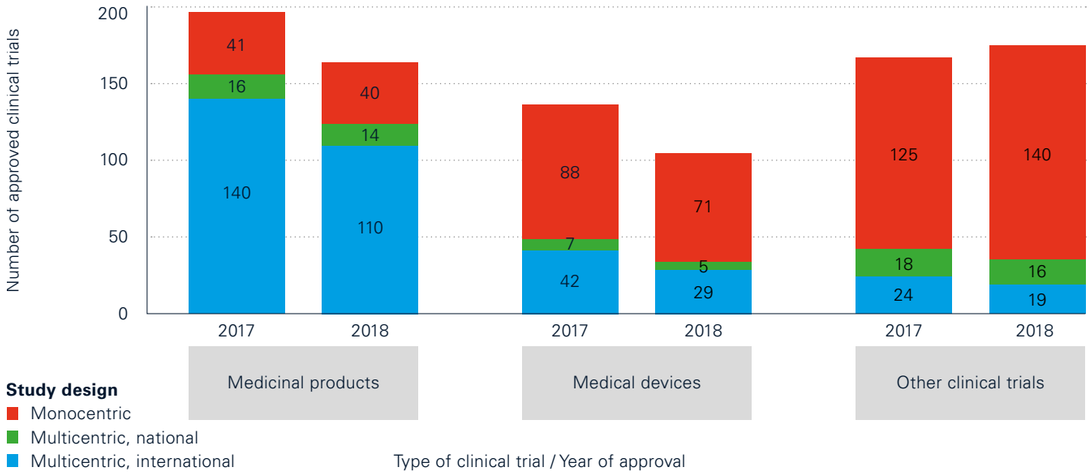
Figure 15: Clinical trials and research projects involving persons approved per year stratified by type of research project and risk category.



Data not shown in the above figure: Research involving transplant products (2017: 4, 2018: 8), combination drugs/devices (2017: 9, 2018: 3), gene therapy (2017: 0, 2018: 3) and transplantation (2017: 0, 2018: 1)

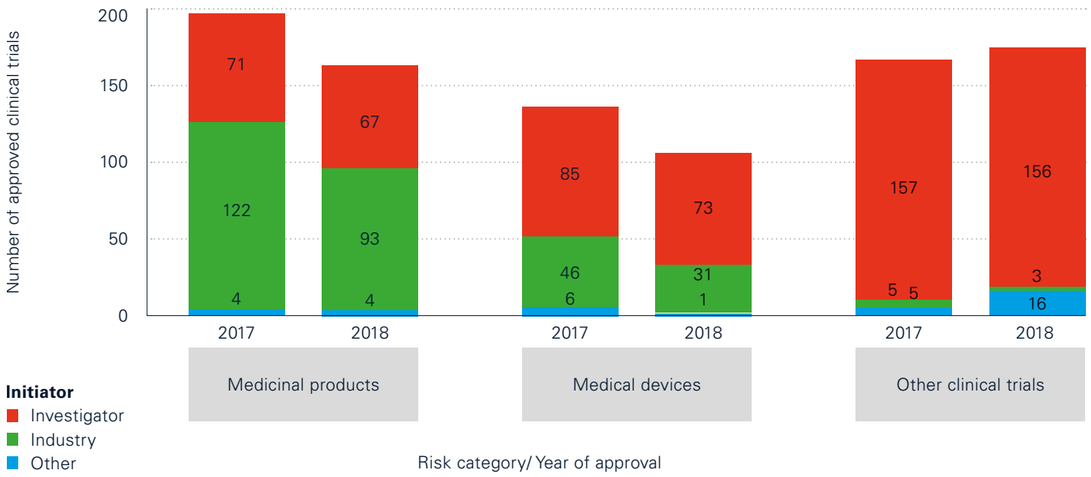
7.4 Subgroups of clinical trials

Figure 16: Clinical trials approved per year stratified by trial type and trial design.



Data not shown in the above figure: Research involving transplant products (2017: 4, 2018: 8), combination drugs/devices (2017: 9, 2018: 3), gene therapy (2017: 0, 2018: 3) and transplantation (2017: 0, 2018: 1)

Figure 17: Clinical trials approved per year stratified by trial type and initiator.



Data not shown in the above figure: Research involving transplant products (2017: 4, 2018: 8), combination drugs/devices (2017: 9, 2018: 3), gene therapy (2017: 0, 2018: 3) and transplantation (2017: 0, 2018: 1)

7.4.1 Clinical trials with medicinal products

Figure 18: Clinical trials with medicinal products approved per year stratified by study phase.

Proportion of trials 'first in man': 2017: 6, 2018: 8.

7.4.2 Clinical trials with medical devices

Figure 19: Clinical trials with medical devices approved per year stratified by risk category and by CE certification / intended use.

Intended use: used in accordance with the instructions; Non-intended use: not used in accordance with the intended purposes recognised in the conformity assessment and specified in the instructions. Proportion of trials 'first in man': 2017: 30, 2018: 20

7.5 Subgroup Further use of data/biological material

Table 26: Overview of characteristics of all approved 'further use' projects.

		Approval year			
		2017		2018	
		n	%	n	%
Genetic data/biol. material	Yes	176	19.4	218	20.2
	No	729	80.6	860	79.8
Coding (HRO Art. 25–27)	Coded	417	46.1	901	83.6
	Open, non-coded	488	53.9	177	16.4
Consent (HRO Art. 28–32)	Prior consent exists	213	23.5	309	28.7
	Consent to be sought	134	14.8	234	21.7
	No consent for some/all data	558	61.7	535	49.6
Combined vs. stand-alone projects[1]	Stand-alone further use project	855	94.5	868	80.5
	Further use project as part of a clinical trial	18	2.0	40	3.7
	Further use project as part of a non-clinical research project	32	3.5	170	15.8
	Total number	905	100.0	1078	100.0

1 Combined projects: Research projects concerning a clinical trial (ClinO) or research involving persons according to HRO Chapter 2 that additionally include the 'further use' of existing data or biological material (HRO Chapter 3).

Figure 20: Number of approved 'further use' projects per year and fraction without informed consent.

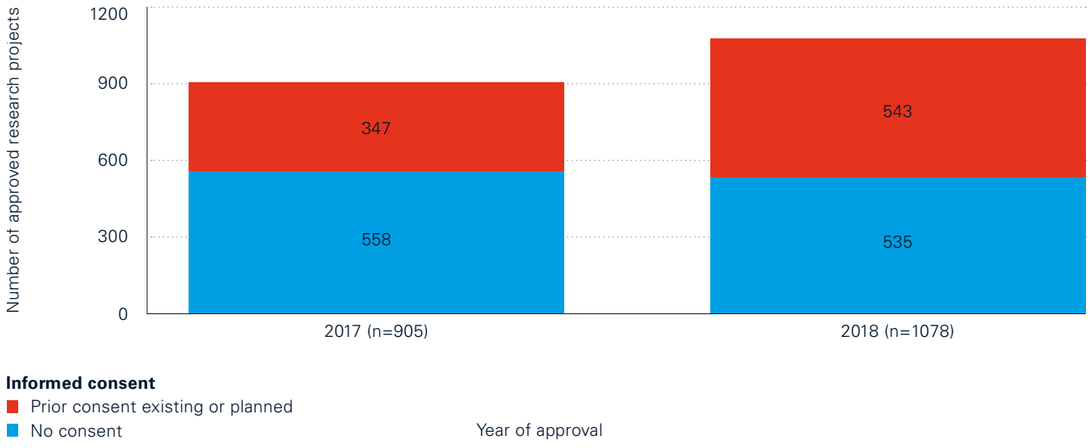
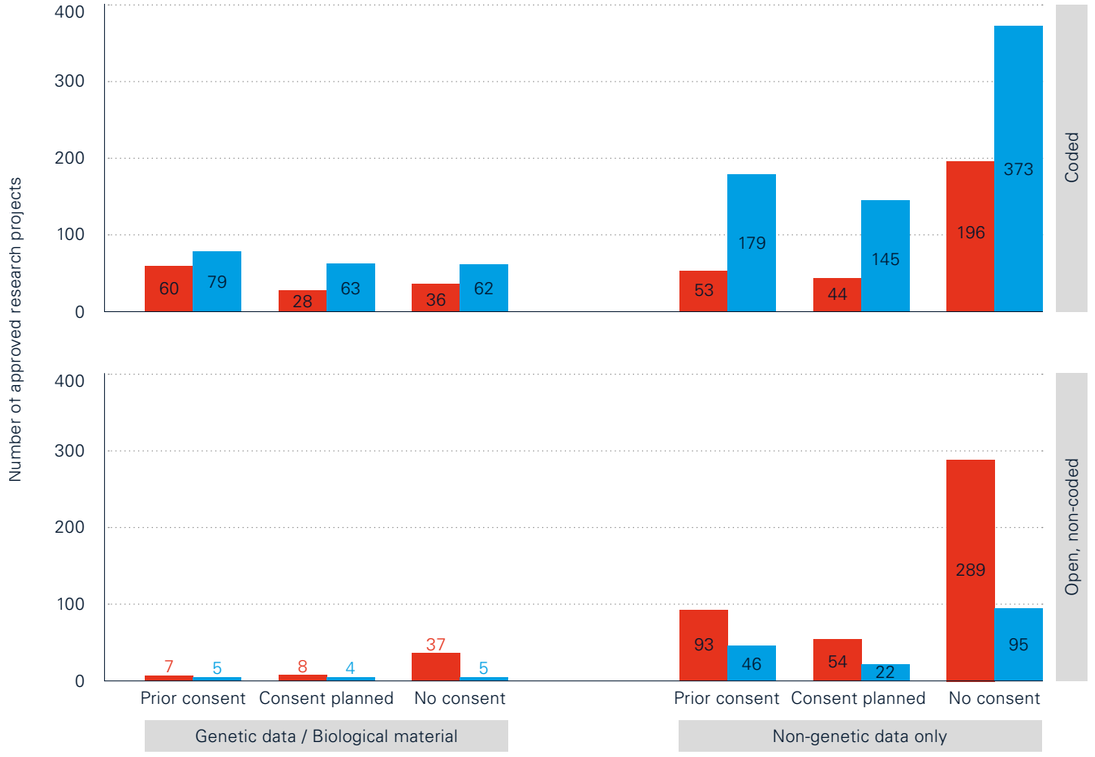
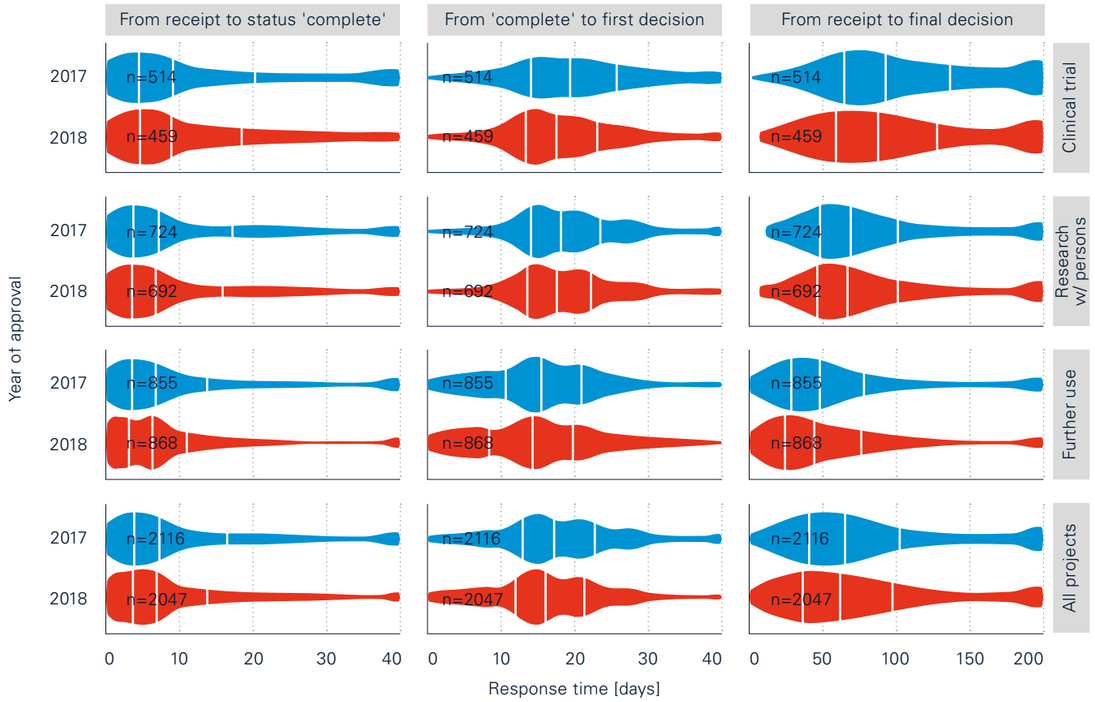


Figure 21: Number of approved 'further use' projects per year stratified by 1) Use of genetic data and/or biological material, 2) coded vs. uncoded, 3) consent for further use.



7.6 Response time

Figure 22: Violin plot of response times by approval year for the three major type of research projects and overall. For visualisation purposes, response times are capped at 40 days on the left and middle panel and to 200 days at the right panel.



A Annex

A.1 Projects rejected, non-considerated or withdrawn per type of research

Table 27: Total number of research projects **rejected, non-considerated or withdrawn in 2018** per type of research.

	Reason					
	Rejections		Non-considerations		Withdrawals	
Type of research	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$
Clinical trial	14	32.6	8	7.6	8	50.0
Research involving persons, but not a clinical trial	15	34.9	56	53.3	5	31.2
Further use of health-related personal data and/or biological material	14	32.6	41	39.0	3	18.8
Research involving deceased persons	0	0.0	0	0.0	0	0.0
Research involving embryos and fetuses from induced abortions or stillbirths	0	0.0	0	0.0	0	0.0
Total number	43	100.0	105	100.0	16	100.0

A.2 All projects stratified by project characteristics

A.2.1 Research to obtain degree

Table 28: Stratification of all approved projects by whether the research project was solely or principally designed to obtain a degree – and if yes, what degree.

							What degree (multiple answers possible)					
			Total		Primarily for degree		MD/PhD thesis		Master		Other degree	
Type of research	Research details	Risk cat.	n	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Clinical trial	Medicinal products	A	19	11.6	3	15.8	3	100.0				
		B	27	16.5								
		C	118	72.0								
		All	164	100.0	3	1.8	3	100.0				
	Medical devices	A	71	67.6	14	19.7	8	57.1	6	42.9		
		C	34	32.4	2	5.9	2	100.0				
		All	105	100.0	16	15.2	10	62.5	6	37.5		
	Other clinical trials	A	154	88.0	51	33.1	29	56.9	17	33.3	5	9.8
		B	21	12.0	3	14.3	2	66.7	1	33.3		
		All	175	100.0	54	30.9	31	57.4	18	33.3	5	9.3
	Combination drugs/devices	A	3	100.0								
		All	3	100.0								
	Transplant products	C	8	100.0								
		All	8	100.0								
	Gene therapy	C	3	100.0								
		All	3	100.0								
	Transplantation	A	1	100.0								
		All	1	100.0								
	All	All	459	100.0	73	15.9	44	60.3	24	32.9	5	6.8
Research w/ persons		A	666	96.2	197	29.6	84	42.6	105	53.3	11	5.6
		B	26	3.8	5	19.2	2	40.0	3	60.0		
		All	692	100.0	202	29.2	86	42.6	108	53.5	11	5.4
Further use		n.a.	868	100.0	327	37.7	153	46.8	164	50.2	19	5.8
Deceased, embryos		n.a.	28	100.0	5	17.9	4	80.0			1	20.0
Total number			2047	100.0	607	29.7	287	47.3	296	48.8	36	5.9

Since multiple answers are possible, the row-wise percentages may sum up to a total over 100 %

A.2.2 Special populations

Table 29: Stratification of all approved projects by whether the research project was solely or principally designed to obtain a degree – and if yes, what degree.

				What groups (multiple possible)													
				Any vulnerable		Healthy vol.		Children		Adolescents		Unable to cons.		Emergencies		Others	
Type of research	Research details	Risk cat.	N	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Clinical trial	Medicinal products	A	19	6	31.6	3	50.0	2	33.3	1	16.7			1	16.7	1	16.7
		B	27	10	37.0	4	40.0	5	50.0	5	50.0			1	10.0		
		C	118	25	21.2	6	24.0	15	60.0	11	44.0	1	4.0	2	8.0	1	4.0
		All	164	41	25.0	13	31.7	22	53.7	17	41.5	1	2.4	4	9.8	2	4.9
	Medical devices	A	71	15	21.1	8	53.3	5	33.3	3	20.0			3	20.0		
		C	34	14	41.2	8	57.1	4	28.6	1	7.1	1	7.1			1	7.1
		All	105	29	27.6	16	55.2	9	31.0	4	13.8	1	3.4	3	10.3	1	3.4
	Other clinical trials	A	154	57	37.0	33	57.9	13	22.8	10	17.5	8	14.0	4	7.0		
		B	21	9	42.9	6	66.7	1	11.1			1	11.1	2	22.2		
		All	175	66	37.7	39	59.1	14	21.2	10	15.2	9	13.6	6	9.1		
	Combination drugs/devices	A	3	1	33.3									1	100.0		
		All	3	1	33.3									1	100.0		
	Transplant products	C	8	2	25.0			1	50.0	1	50.0			1	50.0		
		All	8	2	25.0			1	50.0	1	50.0			1	50.0		
	Gene therapy	C	3	1	33.3	1	100.0										
		All	3	1	33.3	1	100.0										
	Transplantation	A	1	1	100.0			1	100.0	1	100.0						
		All	1	1	100.0			1	100.0	1	100.0						
	All	All	459	141	30.7	69	48.9	47	33.3	33	23.4	11	7.8	15	10.6	3	2.1
Research w/ persons		A	666	260	39.0	129	49.6	98	37.7	86	33.1	24	9.2	16	6.2	27	10.4
		B	26	14	53.8	10	71.4	3	21.4	3	21.4	1	7.1	1	7.1		
		All	692	274	39.6	139	50.7	101	36.9	89	32.5	25	9.1	17	6.2	27	9.9
Further use		n.a.	868														
Deceased, embryos		n.a.	28														
Total number			2047	415	20.3	208	50.1	148	35.7	122	29.4	36	8.7	32	7.7	30	7.2

Special populations (vulnerable persons include: "Embryos/fetuses intrauteri", "Children (0–13, until one day before 14th birthday)", "Adolescents (14–17, until one day before 18th birthday)", "Emergencies (transient incapacity to consent, HRA art 30–31, ClinO art 15–17, HRO art 11)", "Pregnant women", "prisoners", "Persons unable to consent (long-term incapacity to consent, HRA art 21–24)", "Healthy volunteers". Since multiple answers are possible, the row-wise percentages may sum up to a total over 100%.

A.2.3 Ionising radiation

Table 30: Stratification of clinical trials and research involving persons but not a clinical trial by involvement of ionising radiation.

					Ionising radiation involved			
			Total		For imaging/control purposes		As primary object of investigation	
Type of research	Research details	Risk cat.	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$
Clinical trial	Medicinal products	A	19	11.6	3	15.8		
		B	27	16.5	9	33.3	1	3.7
		C	118	72.0	54	45.8	2	1.7
		All	164	100.0	66	40.2	3	1.8
	Medical devices	A	71	67.6	21	29.6		
		C	34	32.4	3	8.8		
		All	105	100.0	24	22.9		
	Other clinical trials	A	154	88.0	7	4.5		
		B	21	12.0	2	9.5	4	19.0
		All	175	100.0	9	5.1	4	2.3
	Combination drugs/devices	A	3	100.0	1	33.3		
		All	3	100.0	1	33.3		
	Transplant products	C	8	100.0	5	62.5		
		All	8	100.0	5	62.5		
	Gene therapy	C	3	100.0	2	66.7		
		All	3	100.0	2	66.7		
	Transplantation	A	1	100.0			1	100.0
		All	1	100.0			1	100.0
	All	All	459	100.0	107	23.3	8	1.7
Research w/ persons		A	666	96.2	43	6.5		
		B	26	3.8	8	30.8		
		All	692	100.0	51	7.4		
Total number			1151	100.0	158	13.7	8	0.7

A.3 Subgroups of research projects

4.3.1 Subgroup "Clinical trials" – research covered by the ClinO

Table 31: Stratification of **all clinical trials** by risk category, study design and initiator of the research project. The classification of clinical trials according to allocation, control and masking technique is BASEC-specific.

					Risk category						Study design						Initiator			
			Total		A		B		C		Mono		Multi CH		Multi Int.		Industry		Investigator	
Allocation	Control	Masking	n	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Randomised controlled	Active	Open	97	32.7	58	59.8	13	13.4	26	26.8	47	48.5	9	9.3	41	42.3	26	26.8	71	73.2
		Double-blind	18	6.1	10	55.6	1	5.6	7	38.9	10	55.6	1	5.6	7	38.9	7	38.9	11	61.1
		Single-blind	35	11.8	31	88.6			4	11.4	28	80.0			7	20.0	6	17.1	29	82.9
	Placebo	Open	6	2.0	5	83.3			1	16.7	4	66.7			2	33.3			6	100.0
		Double-blind	71	23.9	11	15.5	14	19.7	46	64.8	24	33.8	4	5.6	43	60.6	39	54.9	32	45.1
		Single-blind	13	4.4	13	100.0					11	84.6	2	15.4			1	7.7	12	92.3
	Before/after	Open	6	2.0	5	83.3			1	16.7	6	100.0							6	100.0
		Single-blind	4	1.3	2	50.0	1	25.0	1	25.0	3	75.0			1	25.0			4	100.0
	Dosage	Open	7	2.4	4	57.1	1	14.3	2	28.6	3	42.9			4	57.1	1	14.3	6	85.7
		Double-blind	2	0.7	1	50.1			1	50.0					2	100.0	1	50.0	1	50.0
		Single-blind	1	0.3	1	100.0					1	100.0							1	100.0
	None	Open	22	7.4	13	59.1	4	18.2	5	22.7	9	40.9	2	9.1	11	50.0	2	9.1	20	90.9
		Double-blind	4	1.3	3	75.0	1	25.0			3	75.0			1	25.0			4	100.0
		Single-blind	11	3.7	10	90.9			1	9.1	10	90.9	1	9.1			1	9.1	10	90.9
		All	297	100.0	167	56.2	35	11.8	95	32.0	159	53.5	19	6.4	119	40.1	84	28.3	213	71.7
Non-random. controlled	Active	Open	3	8.6	2	66.7			1	33.3	2	66.7			1	33.3	1	33.3	2	66.7
	Before/after	Open	8	22.9	8	100.0					7	87.5			1	12.5	1	12.5	7	87.5
		Single-blind	1	2.9	1	100.0					1	100.0							1	100.0
	None	Open	23	65.7	9	39.1	3	13.0	11	47.8	12	52.2	3	13.0	8	34.8	9	39.1	14	60.9
		All	35	100.0	20	57.1	3	8.6	12	34.3	22	62.9	3	8.6	10	28.6	11	31.4	24	68.6
Not applicable	Active	Open	3	2.4	3	100.0					3	100.0							3	100.0
		Single-blind	2	1.6	1	50.0			1	50.0	2	100.0							2	100.0
	Placebo	Single-blind	1	0.8	1	100.0					1	100.0							1	100.0
	Before/after	Open	7	5.5	4	57.1	2	28.6	1	14.3	5	71.4	1	14.3	1	14.3			7	100.0
	Dosage	Open	2	1.6	1	50.0			1	50.0	2	100.0							2	100.0
	None	Open	105	82.7	46	43.8	8	7.6	51	48.6	51	48.6	13	12.4	41	39.0	39	37.1	66	62.9
		Single-blind	7	5.5	5	71.4			2	28.6	7	100.0					1	14.3	6	85.7
		All	127	100.0	61	48.0	10	7.9	56	44.1	71	55.9	14	11.0	42	33.1	40	31.5	87	68.5
Total number			459	100.0	248	54.0	48	10.5	163	35.5	252	54.9	36	7.8	171	37.3	135	29.4	324	70.6

Note that some categories of 'Control' are not meaningful for certain subtype of clinical trials (e.g. dosage for medical device).

Table 32: Stratification of **all clinical trials** by participant arms/distribution.

					Participant arms/distribution									
			Total		Single-arm		Parallel groups		Crossover		Factorial		Other or n/a	
Allocation	Control	Masking	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Randomised controlled	Active	Open	97	32.7	1	1.0	81	83.5	13	13.4			2	2.1
		Double-blind	18	6.1			14	77.8	4	22.2				
		Single-blind	35	11.8	3	8.6	27	77.1	3	8.6			2	5.7
	Placebo	Open	6	2.0			3	50.0	2	33.3			1	16.7
		Double-blind	71	23.9	1	1.4	59	83.1	8	11.3	1	1.4	2	2.8
		Single-blind	13	4.4	1	7.7	6	46.2	4	30.8	1	7.7	1	7.7
	Before/after	Open	6	2.0			5	83.3	1	16.7				
		Single-blind	4	1.3					3	75.0			1	25.0
	Dosage	Open	7	2.4	1	14.3	5	71.4	1	14.3				
		Double-blind	2	0.7			2	100.0						
		Single-blind	1	0.3			1	100.0						
	None	Open	22	7.4			17	77.3	2	9.1			3	13.6
		Double-blind	4	1.3	1	25.0	2	50.0	1	25.0				
		Single-blind	11	3.7	1	9.1	9	81.8					1	9.1
		All	297	100.0	9	3.0	231	77.8	42	14.1	2	0.7	13	4.4
Non-random. controlled	Active	Open	3	8.6	2	66.7							1	33.3
	Before/after	Open	8	22.9	5	62.5	1	12.5					2	25.0
		Single-blind	1	2.9	1	100.0								
	None	Open	23	65.7	16	69.6	2	8.7					5	21.7
		All	35	100.0	24	68.6	3	8.6					8	22.9
Not applicable	Active	Open	3	2.4									3	100.0
		Single-blind	2	1.6	1	50.0			1	50.0				
	Placebo	Single-blind	1	0.8									1	100.0
	Before/after	Open	7	5.5	4	57.1	1	14.3					2	28.6
	Dosage	Open	2	1.6	1	50.0	1	50.0						
	None	Open	105	82.7	60	57.1	6	5.7	2	1.9			37	35.2
		Single-blind	7	5.5	4	57.1					1	14.3	2	28.6
		All	127	100.0	70	55.1	8	6.3	3	2.4	1	0.8	45	35.4
Total number			459	100.0	103	22.4	242	52.7	45	9.8	3	0.7	66	14.4

A.3.2 Subgroups of "Clinical trials"

The following projects characteristics are additionally used for stratification in the subsequent subchapters:

Allocation: Single choice field with allowed answers: "Randomised controlled trial", "Non-randomised controlled trial" and "Not applicable".
Masking technique: Single choice field with allowed answers: "Open", "Single-blind", "Double-blind".
Type of control: Single choice field with allowed answers: "Placebo", "Active", "Beforeafter (historic)", "Dosage comparison", "None".

Participant arms/distribution: Single choice field to indicate the trial participant arms/distribution with allowed answers: "Single-armed", "Parallel groups", "Crossover", "Factorial", "Other or n/a"
Type of research project in projects covered by HRO Chapter 2 Single choice field with allowed answers: "Cohort study", "Registry/Quality control" (only quality control studies under the HRA), "Case control study" and "Other or n/a". The last group also includes projects declared as "Observational study" before this option was disabled on August 21, 2017.

Table 33: Overview of type of clinical trial.

Type of clinical trial	Legal basis (ClinO)	n	$\%_{col}$
Medicinal products	Art 19	164	35.7
Medical devices	Art 20	105	22.9
Other clinical trials	Art 61	175	38.1
Combination drugs/devices [1]		3	0.7
Transplant products	Art 21	8	1.7
Gene therapy	Art 22	3	0.7
Transplantation	Art 49	1	0.2
Total number		459	100.0

1 Combination of medical device and medical product: this category is BASEC-specific.

Figure 23: Stratification of all clinical trials by type of trial and risk category.

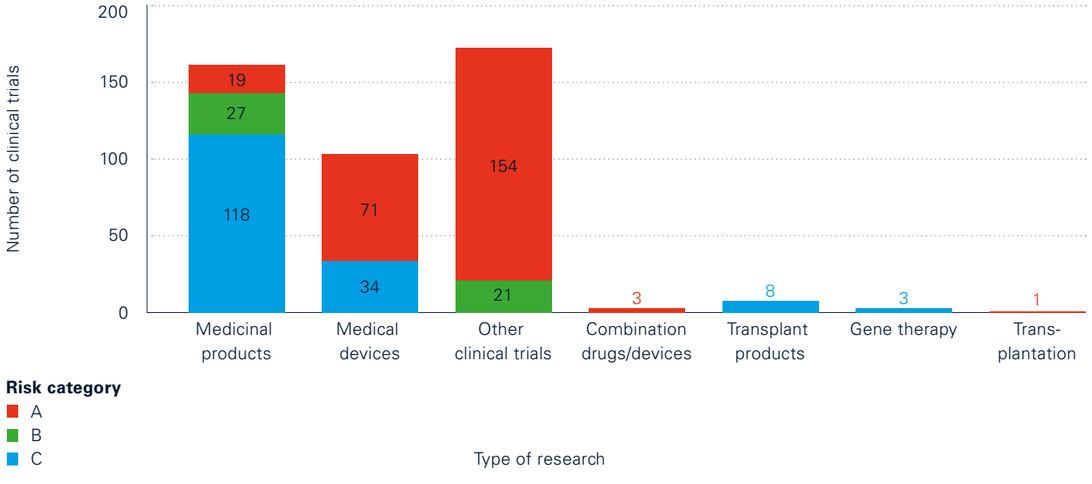


Figure 24: Stratification of all clinical trials by type of trial and study design.

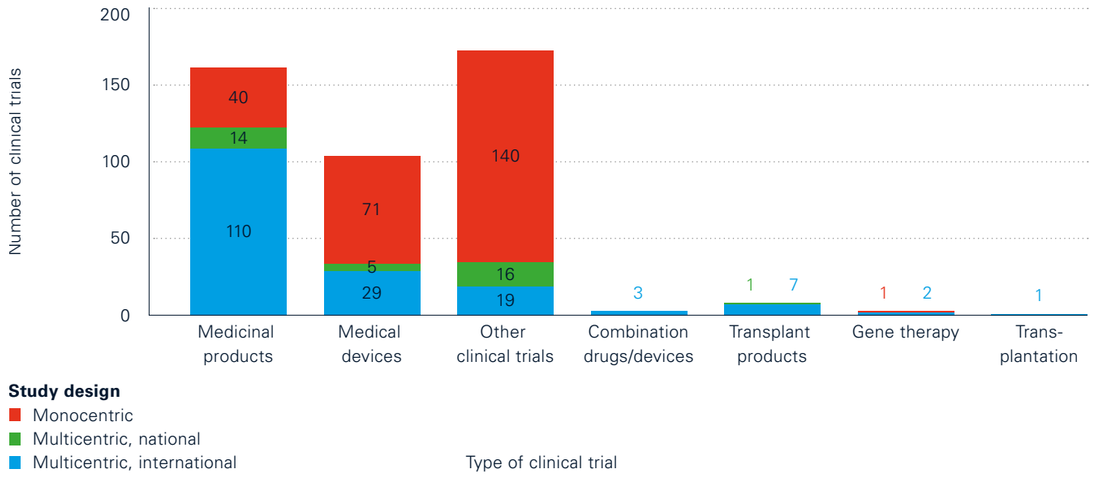
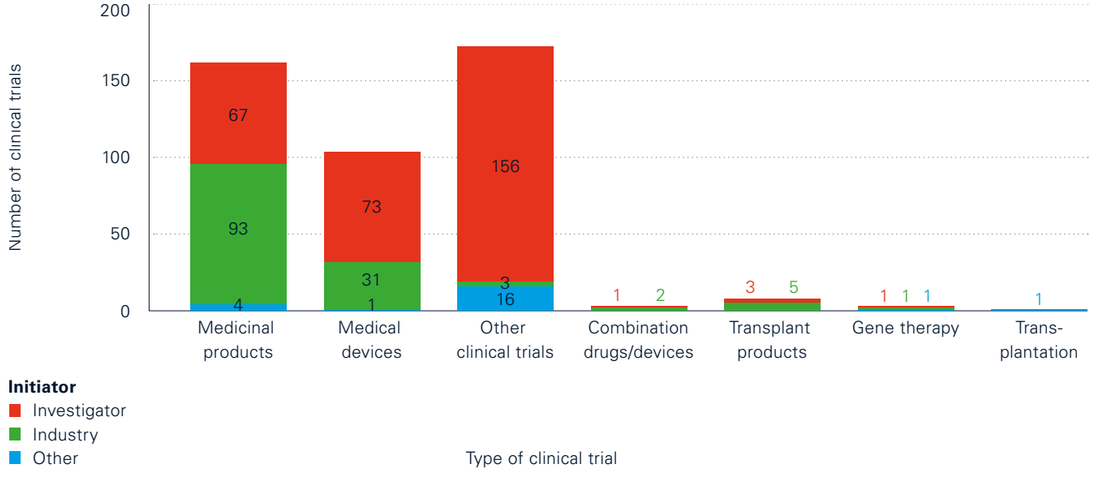


Figure 25: Stratification of all clinical trials by type of trial and initiator.



A.3.2.1 Subgroup "Medicinal products trials" (ClinO Art 19)

Table 34: Stratification of **clinical trials with medicinal products** by risk category, study design and initiator of the research project. The classification of clinical trials according to allocation, control and masking technique is BASEC-specific.

					Risk category						Study design						Initiator			
			Total		A		B		C		Mono		Multi CH		Multi Int.		Industry		Investigator	
Allocation	Control	Masking	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Randomised controlled	Active	Open	32	28.6	6	18.8	7	21.9	19	59.4	11	34.4	2	6.2	19	59.4	16	50.0	16	50.0
		Double-blind	7	6.2					7	100.0			1	14.3	6	85.7	6	85.7	1	14.3
		Single-blind	5	4.5	4	80.0			1	20.0	2	40.0			3	60.0	2	40.0	3	60.0
	Placebo	Double-blind	53	47.3	1	1.9	9	17.0	43	81.1	10	18.9	2	3.8	41	77.4	37	69.8	16	30.2
	Before/after	Open	1	0.9	1	100.0					1	100.0							1	100.0
	Dosage	Open	2	1.8	1	50.0			1	50.0					2	100.0	1	50.0	1	50.0
		Double-blind	2	1.8	1	50.0			1	50.0					2	100.0	1	50.0	1	50.0
	None	Open	8	7.1	2	25.0	2	25.0	4	50.0	1	12.5	1	12.5	6	75.0	1	12.5	7	87.5
		Double-blind	1	0.9	1	100.0									1	100.0			1	100.0
		Single-blind	1	0.9					1	100.0	1	100.0					1	100.0		
		All	112	100.0	17	15.2	18	16.1	77	68.8	26	23.2	6	5.4	80	71.4	65	58.0	47	42.0
Non-random. controlled	Active	Open	1	10.0					1	100.0					1	100.0	1	100.0		
	Before/after	Open	1	10.0	1	100.0					1	100.0							1	100.0
	None	Open	8	80.0			3	37.5	5	62.5	2	25.0	2	25.0	4	50.0	3	37.5	5	62.5
		All	10	100.0	1	10.0	3	30.0	6	60.0	3	30.0	2	20.0	5	50.0	4	40.0	6	60.0
Not applicable	Before/after	Open	1	2.2					1	100.0	1	100.0							1	100.0
	Dosage	Open	1	2.2					1	100.0	1	100.0							1	100.0
	None	Open	43	95.6	4	9.3	6	14.0	33	76.7	9	20.9	6	14.0	28	65.1	26	60.5	17	39.5
		All	45	100.0	4	8.9	6	13.3	35	77.8	11	24.4	6	13.3	28	62.2	26	57.8	19	42.2
Total number			167	100.0	22	13.2	27	16.2	118	70.7	40	24.0	14	8.4	113	67.7	95	56.9	72	43.1

The total number of 167 research projects consist of 164 medicinal product trials and 3 trials on a combination medicinal product and medical device.

Table 35: Stratification of **medicinal products trials** by phase and whether 'first in man'.

					Phase[1]											
			Total		1		2		3		4		n/a		First in man [2]	
Allocation	Control	Masking	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Randomised controlled	Active	Open	32	28.6	5	15.6	13	40.6	8	25.0	4	12.5	2	6.2		
		Double-blind	7	6.2			1	14.3	6	85.7						
		Single-blind	5	4.5					1	20.0	1	20.0	3	60.0		
	Placebo	Double-blind	53	47.3	3	5.7	9	17.0	34	64.2	3	5.7	4	7.5	1	1.9
	Before/after	Open	1	0.9							1	100.0				
	Dosage	Open	2	1.8			1	50.0			1	50.0				
		Double-blind	2	1.8					1	50.0	1	50.0				
	None	Open	8	7.1			4	50.0	2	25.0	1	12.5	1	12.5		
		Double-blind	1	0.9							1	100.0				
		Single-blind	1	0.9									1	100.0		
		All	112	100.0	8	7.1	28	25.0	52	46.4	13	11.6	11	9.8	1	0.9
Non-random. controlled	Active	Open	1	10.0					1	100.0						
	Before/after	Open	1	10.0	1	100.0										
	None	Open	8	80.0	3	37.5	3	37.5	2	25.0						
		All	10	100.0	4	40.0	3	30.0	3	30.0						
Not applicable	Before/after	Open	1	2.2	1	100.0									1	100.0
	Dosage	Open	1	2.2	1	100.0										
	None	Open	43	95.6	17	39.5	12	27.9	7	16.3	1	2.3	6	14.0	6	14.0
		All	45	100.0	19	42.2	12	26.7	7	15.6	1	2.2	6	13.3	7	15.6
Total number			167	100.0	31	18.6	43	25.7	62	37.1	14	8.4	17	10.2	8	4.8

1 In this table the two categories 'phase 1' and 'phase 1/2' are grouped to 'phase 1'.
2 'First in man' can be selected for phase 1 and 1/2 studies as well as studies without a defined phase ('n/a').

Table 36: Stratification of **clinical trials with medicinal products** by participant arms/distribution.

					Participant arms/distribution							
			Total		Single-arm		Parallel groups		Crossover		Other or n/a	
Allocation	Control	Masking	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Randomised controlled	Active	Open	32	28.6			26	81.2	6	18.8		
		Double-blind	7	6.2			7	100.0				
		Single-blind	5	4.5			5	100.0				
	Placebo	Double-blind	53	47.3			51	96.2	1	1.9	1	1.9
	Before/after	Open	1	0.9			1	100.0				
	Dosage	Open	2	1.8			2	100.0				
		Double-blind	2	1.8			2	100.0				
	None	Open	8	7.1			7	87.5			1	12.5
		Double-blind	1	0.9			1	100.0				
		Single-blind	1	0.9			1	100.0				
		All	112	100.0			103	92.0	7	6.2	2	1.8
Non-random. controlled	Active	Open	1	10.0	1	100.0						
	Before/after	Open	1	10.0	1	100.0						
	None	Open	8	80.0	5	62.5	1	12.5			2	25.0
		All	10	100.0	7	70.0	1	10.0			2	20.0
Not applicable	Before/after	Open	1	2.2							1	100.0
	Dosage	Open	1	2.2			1	100.0				
	None	Open	43	95.6	24	55.8	4	9.3	2	4.7	13	30.2
		All	45	100.0	24	53.3	5	11.1	2	4.4	14	31.1
Total number			167	100.0	31	18.6	109	65.3	9	5.4	18	10.8

A.3.2.2 Subgroup "Medical devices" (ClinO Art 20)

Table 37: Stratification of **clinical trials with medical device** by risk category, study design and initiator of the research project.
The classification of clinical trials according to allocation, control and masking technique is BASEC-specific.

					Risk category				Study design						Initiator			
			Total		A		C		Mono		Multi CH		Multi Int.		Industry		Investigator	
Allocation	Control	Masking	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Randomised controlled	Active	Open	26	45.6	21	80.8	5	19.2	14	53.8	2	7.7	10	38.5	9	34.6	17	65.4
		Double-blind	2	3.5	2	100.0			2	100.0					1	50.0	1	50.0
		Single-blind	17	29.8	14	82.4	3	17.6	11	64.7			6	35.3	5	29.4	12	70.6
	Placebo	Open	1	1.8			1	100.0					1	100.0			1	100.0
		Double-blind	4	7.0	3	75.0	1	25.0	3	75.0			1	25.0	2	50.0	2	50.0
		Single-blind	2	3.5	2	100.0			2	100.0					1	50.0	1	50.0
	Before/after	Open	1	1.8			1	100.0	1	100.0							1	100.0
		Single-blind	1	1.8			1	100.0	1	100.0							1	100.0
	Dosage	Open	1	1.8	1	100.0			1	100.0							1	100.0
	None	Open	2	3.5	1	50.0	1	50.0					2	100.0	1	50.0	1	50.0
		All	57	100.0	44	77.2	13	22.8	35	61.4	2	3.5	20	35.1	19	33.3	38	66.7
Non-random. controlled	Active	Open	1	8.3	1	100.0			1	100.0							1	100.0
	Before/after	Open	4	33.3	4	100.0			3	75.0			1	25.0	1	25.0	3	75.0
	None	Open	7	58.3	2	28.6	5	71.4	4	57.1			3	42.9	3	42.9	4	57.1
		All	12	100.0	7	58.3	5	41.7	8	66.7			4	33.3	4	33.3	8	66.7
Not applicable	Active	Open	3	7.7	3	100.0			3	100.0							3	100.0
		Single-blind	1	2.6			1	100.0	1	100.0							1	100.0
	None	Open	33	84.6	20	60.6	13	39.4	22	66.7	3	9.1	8	24.2	9	27.3	24	72.7
		Single-blind	2	5.1			2	100.	2	100.0					1	50.0	1	50.0
		All	39	100.0	23	59.0	16	41.0	28	71.8	3	7.7	8	20.5	10	25.6	29	74.4
Total number			108	100.0	74	68.5	34	31.5	71	65.7	5	4.6	32	29.6	33	30.6	75	69.4

The total number of 108 research projects consist of 105 trials with medical devices and 3 trials on a combination medicinal product and medical device.

Table 38: Stratification of **clinical trials with medical device** by participant arms/distribution.

					Participant arms/distribution									
			Total		Single-arm		Parallel groups		Crossover		Factorial		Other or n/a	
Allocation	Control	Masking	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Randomised controlled	Active	Open	26	45.6			20	76.9	4	15.4			2	7.7
		Double-blind	2	3.5			1	50.0	1	50.0				
		Single-blind	17	29.8	3	17.6	11	64.7	2	11.8			1	5.9
	Placebo	Open	1	1.8					1	100.0				
		Double-blind	4	7.0			3	75.0					1	25.0
		Single-blind	2	3.5					1	50.0			1	50.0
	Before/after	Open	1	1.8					1	100.0				
		Single-blind	1	1.8					1	100.0				
	Dosage	Open	1	1.8			1	100.0						
	None	Open	2	3.5			1	50.0	1	50.0				
		All	57	100.0	3	5.3	37	64.9	12	21.1			5	8.8
Non-random. controlled	Active	Open	1	8.3	1	100.0								
	Before/after	Open	4	33.3	4	100.0								
	None	Open	7	58.3	5	71.4							2	28.6
		All	12	100.0	10	83.3							2	16.7
Not applicable	Active	Open	3	7.7									3	100.0
		Single-blind	1	2.6	1	100.0								
	None	Open	33	84.6	22	66.7	1	3.0					10	30.3
		Single-blind	2	5.1							1	50.0	1	50.0
		All	39	100.0	23	59.0	1	2.6			1	2.6	14	35.9
Total number			108	100.0	36	33.3	38	35.2	12	11.1	1	0.9	21	19.4

Table 39: Stratification of **trials with medical devices** by information on standard use of medical devices with conformity marking and details for non-standard use as well as whether first in man.

			Total		CE-marked, intended use		CE-marked, not intended use		Not CE-marked		First in man	
Allocation	**Control**	**Masking**	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Randomised controlled	Active	Open	26	45.6	22	84.6	1	3.8	3	11.5	5	19.2
		Double-blind	2	3.5	2	100.0						
		Single-blind	17	29.8	12	70.6			3	17.6	1	5.9
	Placebo	Open	1	1.8			1	100.0				
		Double-blind	4	7.0	3	75.0	1	25.0				
		Single-blind	2	3.5	2	100.0						
	Before/after	Open	1	1.8					1	100.0		
		Single-blind	1	1.8			1	100.0				
	Dosage	Open	1	1.8	1	100.0						
	None	Open	2	3.5	1	50.0	1	50.0				
		All	57	100.0	43	75.4	5	8.8	7	12.3	6	10.5
Non-random. controlled	Active	Open	1	8.3	1	100.0						
	Before/after	Open	4	33.3	4	100.0					1	25.0
	None	Open	7	58.3	3	42.9			4	57.1	3	42.9
		All	12	100.0	8	66.7			4	33.3	4	33.3
Not applicable	Active	Open	3	7.7	3	100.0						
		Single-blind	1	2.6			1	100.0				
	None	Open	33	84.6	21	63.6	1	3.0	10	30.3	10	30.3
		Single-blind	2	5.1			1	50.0	1	50.0		
		All	39	100.0	24	61.5	3	7.7	11	28.2	10	25.6
Total number			108	100.0	75	69.4	8	7.4	22	20.4	20	18.5

Note: 4 of 75 trials with medical devices with 'standard use' are risk category 'C' the rest is 'A', explaining potential discrepancies to Table 9.

A.3.2.3 Subgroup "Other clinical trials" (ClinO Art 61)

Table 40: Stratification of other clinical trials by risk category, study design and initiator of the research project.
The classification of clinical trials according to allocation, control and masking technique is BASEC-specific.

					Risk category				Study design						Initiator			
			Total		A		B		Mono		Multi CH		Multi Int.		Industry		Investigator	
Allocation	Control	Masking	N	%col	n	%row	n	%row	n	%row	n	%col	n	%row	n	%row	n	%row
Randomised controlled	Active	Open	37	29.6	31	83.8	6	16.2	22	59.5	5	13.5	10	27.0			37	100.0
		Double-blind	9	7.2	8	88.9	1	11.1	8	88.9			1	11.1			9	100.0
		Single-blind	15	12.0	15	100.0			15	100.0							15	100.0
	Placebo	Open	5	4.0	5	100.0			4	80.0			1	20.0			5	100.0
		Double-blind	12	9.6	7	58.3	5	41.7	10	83.3	2	16.7					12	100.0
		Single-blind	11	8.8	11	100.0			9	81.8	2	18.2					11	100.0
	Before/after	Open	4	3.2	4	100.0			4	100.0							4	100.0
		Single-blind	3	2.4	2	66.7	1	33.3	2	66.7			1	33.3			3	100.0
	Dosage	Open	3	2.4	2	66.7	1	33.3	2	66.7			1	33.3			3	100.0
		Single-blind	1	0.8	1	100.0			1	100.0							1	100.0
	None	Open	12	9.6	10	83.3	5	16.7	8	66.7	1	8.3	3	25.0			12	100.0
		Double-blind	3	2.4	2	66.7	1	33.3	3	100.0							3	100.0
		Single-blind	10	8.0	10	100.0			9	90.0	1	10.0					10	100.0
		All	125	100.0	108	86.4	17	13.6	97	77.6	11	8.8	17	13.6			125	100.0
Non-random. controlled	Active	Open	1	8.3	1	100.0			1	100.0							1	100.0
	Before/after	Open	3	25.0	3	100.0			3	100.0							3	100.0
		Single-blind	1	8.3	1	100.0			1	100.0							1	100.0
	None	Open	7	58.3	7	100.0			6	85.7	1	14.3			2	28.6	5	71.4
		All	12	100.0	12	100.0			11	91.7	1	8.3			2	16.7	10	83.3
Not applicable	Active	Single-blind	1	2.6	1	100.0			1	100.0							1	100.0
	Placebo	Single-blind	1	2.6	1	100.0			1	100.0							1	100.0
	Before/after	Open	6	15.8	4	66.7	2	33.3	4	66.7	1	16.7	1	16.7			6	100.0
	Dosage	Open	1	2.6	1	100.0			1	100.0							1	100.0
	None	Open	24	63.2	20	91.7	2	8.3	20	83.3	3	12.5	1	4.2	1	4.2	23	95.8
		Single-blind	5	13.2	5	100.0			5	100.0							5	100.0
		All	38	100.0	34	89.5	4	10.5	32	84.2	4	10.5	2	5.3	1	2.6	37	97.4
Total number			175	100.0	154	88.0	21	12.0	140	80.0	16	9.1	19	10.9	3	1.7	172	98.3

Table 41: Stratification of **other clinical trials** by participant arms/distribution.

					Participant arms/distribution									
			Total		Single-arm		Parallel groups		Crossover		Factorial		Other or n/a	
Allocation	Control	Masking	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Randomised controlled	Active	Open	37	29.6			34	91.6	3	8.1				
		Double-blind	9	7.2			6	66.7	3	33.3				
		Single-blind	15	12.0			13	86.7	1	6.7			1	6.7
	Placebo	Open	5	4.0			3	60.0	1	20.0			1	20.0
		Double-blind	12	9.6	1	8.3	3	25.0	7	58.3	1	8.3		
		Single-blind	11	8.8	1	9.1	6	54.5	3	27.3	1	9.1		
	Before/after	Open	4	3.2			4	100.0						
		Single-blind	3	2.4					2	66.7			1	33.3
	Dosage	Open	3	2.4			2	66.7	1	33.3				
		Single-blind	1	0.8			1	100.0						
	None	Open	12	9.6			9	75.0	1	8.3			2	16.7
		Double-blind	3	2.4	1	33.3	1	33.3	1	33.3				
		Single-blind	10	8.0	1	10.0	8	80.0					1	10.0
		All	125	100.0	4	3.2	90	72.0	23	18.4	2	1.6	6	4.8
Non-random. controlled	Active	Open	1	8.3									1	100.0
	Before/after	Open	3	25.0			1	33.3					2	66.7
		Single-blind	1	8.3	1	100.0								
	None	Open	7	58.3	5	71.4	1	14.3					1	14.3
		All	12	100.0	6	50.0	2	16.7					4	33.3
Not applicable	Active	Single-blind	1	2.6					1	100.0				
	Placebo	Single-blind	1	2.6									1	100.0
	Before/after	Open	6	15.8	4	66.7	1	16.7					1	16.7
	Dosage	Open	1	2.6	1	100.0								
	None	Open	24	63.2	10	41.7	1	4.2					13	54.2
		Single-blind	5	13.2	4	80.0							1	20.0
		All	38	100.0	19	50.0	2	5.3	1	2.6			16	42.1
Total number			175	100.0	29	16.6	94	53.7	24	13.7	2	1.1	26	14.9

A.3.3 Subgroup "Research involving persons, but not a clinical trial" – research covered by HRO Chapter 2

Table 42: Stratification of **research projects involving persons, but not a clinical trial,** by whether the research project was solely or principally designed to obtain a degree – and if yes, what degree.

					What degree (multiple answers possible)					
	Total		Primarily for degree		MD/PhD thesis		Master		Other degree	
Type of research project	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Cohort study	206	29.8	42	20.4	21	50.0	19	45.2	2	4.8
Registry / Quality control	65	9.4	16	24.6	5	31.2	12	75.0		
Case control study	77	11.1	21	27.3	6	28.6	14	66.7	1	4.8
Other or n/a	344	49.7	123	35.8	54	43.9	63	51.2	8	6.5
Total number	692	100.0	202	29.2	86	42.6	108	53.5	11	5.4

Table 43: Stratification of **research projects involving persons, but not a clinical trial,** by ethics committee.

			Ethics committee													
	Total		KEK-ZH		EKNZ		CER-VD		KEK-BE		CCER		EKOS		CE-TI	
Type of research project	N	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$
Cohort study	206	29.8	41	28.5	43	29.7	45	25.6	34	38.6	29	32.2	8	34.8	6	23.1
Registry / Quality control	65	9.4	15	10.4	21	14.5	16	9.1	6	6.8	4	4.4	1	4.3	2	7.7
Case control study	77	11.1	16	11.1	18	12.4	14	8.0	11	12.5	11	12.2	2	8.7	5	19.2
Other or n/a	344	49.7	72	50.0	63	43.4	101	57.4	37	42.0	46	51.1	12	52.2	13	50.0
Total number	692	100.0	144	100.0	145	100.0	176	100.0	88	100.0	90	100.0	23	100.0	26	100.0

Table 44: Stratification of **research projects involving persons, but not a clinical trial,** by review procedure and first decision.

			Review procedure						First decision							
	Total		Ordinary		Simplified		Presidential		Approved		Charges		Conditions		Declined	
Type of research	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Cohort study	206	29.8	19	9.2	182	88.3	5	2.4	9	4.4	68	33.0	129	62.6		
Registry / Quality control	65	9.4	5	7.7	60	92.3			1	1.5	24	36.9	40	61.5		
Case control study	77	11.1	15	19.5	62	80.5			3	3.9	24	31.2	50	64.9		
Other or n/a	344	49.7	31	9.0	309	89.8	4	1.2	25	7.3	116	33.7	201	58.4	2	0.6
Total number	692	100.0	70	10.1	613	88.6	9	1.3	38	5.5	232	33.5	420	60.7	2	0.3

Charges = Approved with charges; Conditions = Not approved with conditions.

A.3.4 Subgroup "Further use of data/biological material" – research covered by HRO Chapter 3.

Table 45: Stratification of **projects involving further use of data/biological material. All combinations of the following three factors are shown: 1) Use of genetic data and/or biological material (Genetic D+M), 2) coded vs. uncoded, 3) consent for further use** by whether the research project was solely or principally designed to obtain a degree – and if yes, what degree.

							What degree (multiple answers possible)					
			Total		Primarily for degree		MD/PhD thesis		Master		Other degree	
Genetic D+M	Coded	Consent	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Yes	Coded	Prior consent exists	79	38.7	12	15.2	9	75.0	3	25.0		
		Consent to be sought	63	30.9	7	11.1	6	85.7	1	14.3		
		No consent for some/all data	62	30.4	22	35.5	14	63.6	6	27.3	2	9.1
		All	204	100.0	41	20.1	29	70.7	10	24.4	2	4.9
	Open, non-coded	Prior consent exists	5	35.7	2	40.0	2	100.0	1	50.0		
		Consent to be sought	4	28.6								
		No consent for some/all data	5	35.7	1	20.0			1	100.0		
		All	14	100.0	3	21.4	2	66.7	2	66.7		
	All		218	100.0	44	20.2	31	70.5	12	27.3	2	4.5
No	Coded	Prior consent exists	179	25.7	55	30.7	26	47.3	31	56.4		
		Consent to be sought	145	20.8	38	26.2	13	34.2	22	57.9	3	7.9
		No consent for some/all data	373	53.5	179	48.0	79	44.1	90	50.3	16	8.9
		All	697	100.0	272	39.0	118	43.4	143	52.6	19	7.0
	Open, non-coded	Prior consent exists	46	28.2	8	17.4	3	37.5	5	62.5		
		Consent to be sought	22	13.5	8	36.4	4	50.0	4	50.0		
		No consent for some/all data	95	58.3	43	45.3	17	39.5	25	58.1	1	2.3
		All	163	100.0	59	36.2	24	40.7	34	57.6	1	1.7
	All		860	100.0	331	38.5	142	42.9	177	53.5	20	6.0
Total number			1078	100.0	375	34.8	173	46.1	189	50.4	22	5.9

Table 46: Stratification of **projects involving further use of data/biological material. All combinations of the following three factors are shown: 1) Use of genetic data and/or biological material (Genetic D+M), 2) coded vs. uncoded, 3) consent for further use** by review procedure and first decision.

					Review procedure								First decision							
			Total		Ordinary		Simplified		Presidential		Approved		Charges		Conditions		Non-consid.			
Genetic D+M	Coded	Consent	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$		
Yes	Coded	Prior consent exists	79	38.7	9	11.4	21	26.6	49	62.0	36	45.6	12	15.2	31	39.2				
		Consent to be sought	63	30.9	20	31.7	32	49.2	12	19.0	6	9.5	16	25.4	41	65.1				
		No consent for some/all data	62	30.4	4	6.5	57	91.9	1	1.6	9	14.5	27	43.5	26	41.9				
		All	204	100.0	33	16.2	109	53.4	62	30.4	51	25.0	55	27.0	98	48.0				
	Open, non-coded	Prior consent exists	5	35.7			1	20.0	4	80.0	1	20.0	1	20.0	3	60.0				
		Consent to be sought	4	28.6			3	75.0	1	25.0			1	25.0	3	75.0				
		No consent for some/all data	5	35.7			5	100.0					2	40.0	3	60.0				
		All	14	100.0			9	64.3	5	35.7	1	7.1	4	28.6	9	64.3				
	All		218	100.0	33	15.1	118	54.1	67	30.7	52	23.9	59	27.1	107	49.1				
No	Coded	Prior consent exists	179	25.7	5	2.8	79	44.1	95	53.1	69	38.5	38	21.2	72	40.2				
		Consent to be sought	145	20.8	14	9.7	99	68.3	32	22.1	18	12.4	52	35.9	75	51.7				
		No consent for some/all data	373	53.5	4	1.1	366	98.1	3	0.8	83	22.3	135	36.2	154	41.3	1	0.3		
		All	697	100.0	23	3.3	544	78.0	130	18.7	170	24.4	225	32.3	301	43.2	1	0.1		
	Open, non-coded	Prior consent exists	46	28.2	1	2.2	9	19.6	36	78.3	25	54.3	6	13.0	15	32.6				
		Consent to be sought	22	13.5			15	68.2	7	31.8	3	13.6	6	27.3	13	59.1				
		No consent for some/all data	95	58.3	1	1.1	93	97.9	1	1.1	16	16.8	33	34.7	46	48.4				
		All	163	100.0	2	1.2	117	71.8	44	27.0	44	27.0	45	27.6	74	45.4				
All			860	100.0	25	2.9	661	76.9	174	20.2	214	24.9	270	31.4	375	43.6	1	0.1		
Total number			1078	100.0	58	5.4	779	72.3	241	22.4	266	24.7	329	30.5	482	44.7	1	0.1		

Charges = Approved with charges; Conditions = Not approved with conditions.

A.4 Information about the parties involved in human research projects

A.4.1 Applicant of the project

Table 47: Overview of the applicants of the project.

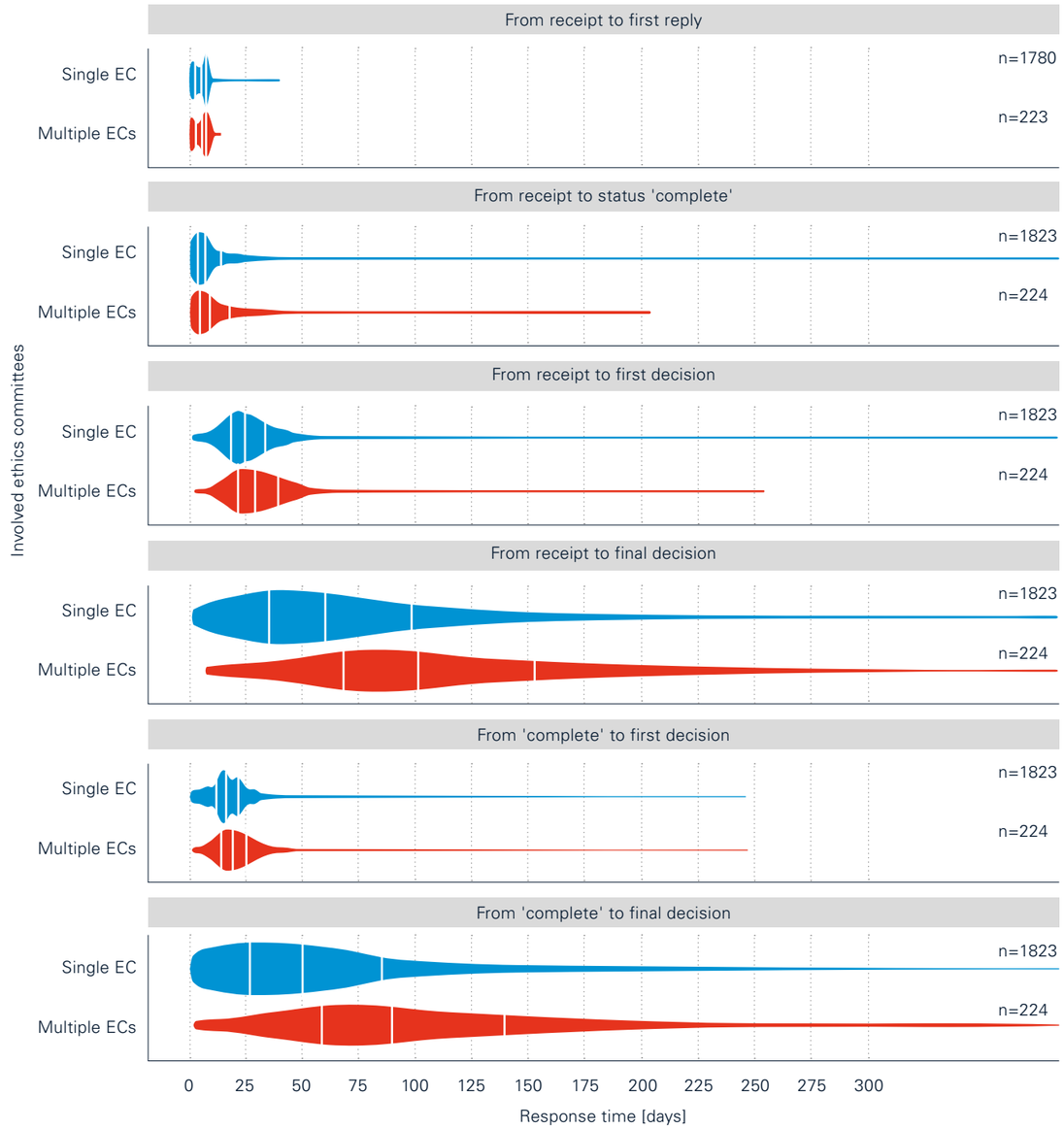
Applicant	Type of research	n	$\%_{col}$
Project leader / PI [1]	Clinical trial	280	16.2
	Research w/ persons	615	35.6
	Further use	803	46.5
	Deceased, embryos	28	1.6
	Total	1726	100.0
Sponsor	Clinical trial	79	54.9
	Research w/ persons	33	22.9
	Further use	32	22.2
	Deceased, embryos	0	0.0
	Total	144	100.0
Sponsor's representative in CH	Clinical trial	48	48.0
	Research w/ persons	29	29.0
	Further use	23	23.0
	Deceased, embryos	0	0.0
	Total	100	100.0
CRO	Clinical trial	52	67.5
	Research w/ persons	15	19.5
	Further use	10	13.0
	Deceased, embryos	0	0.0
	Total	77	100.0
Overall	Clinical trial	459	22.4
	Research w/ persons	692	33.8
	Further use	868	42.4
	Deceased, embryos	28	1.4
	Total	2047	100.0

1 'Project leader' includes sponsor responsibility

A.5 Response times and review procedure (AS2)

A.5.1 Stratification of response time by involvement of single or multiple ECs

Figure 26: Violin plot of all response times depending on whether a single or multiple ECs were involved.



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