Medicine & Research
Statistical Report

Human Research in Switzerland 2019

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

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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BASEC export date: April 4, 2020

List of abbreviations

BASEC	Business Administration System for Ethics Committees
SNCTP	Swiss National Clinical Trials Portal
AS1	Analysis set 1: all projects submitted in a given year
AS2	Analysis set 2: all projects approved in a given year
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. This is the fourth yearly report.

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 2019 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 2019. 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 2019 based on the analysis set *AS2*.

Fourth, a more detailed view on the review 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 chapter 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. This comparison is made for submitted projects (AS1) over four years (2016, 2017, 2018 and 2019) and for approved projects (AS2) over three years (2017, 2018 and 2019). The reason for this difference in the years compared is described in section 1.3.2.

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 4, 2020 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 36ff. 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 3.1 on page 12 with short descriptions as table footnotes.

Apart from the "final decision date", which is entered manually by the ECs, all other milestones are recorded automatically. The completeness and consistency of these data are checked periodically by swissethics (irrespective of this report) and corrected by the ECs manually, if mandatory fields are found empty or when discrepancies are identified.

1.3 Analysis sets

1.3.1 Definition of analysis sets

AS1 The analysis set AS1 consists of all projects **submitted in 2019.** The AS1 includes all applications which have been submitted over the BASEC web portal irrespective of whether the projects were subsequently approved or not.
AS2 The analysis set AS2 consists of all projects **approved** (i.e. projects having obtained a favorable final decision) **in 2019** 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.

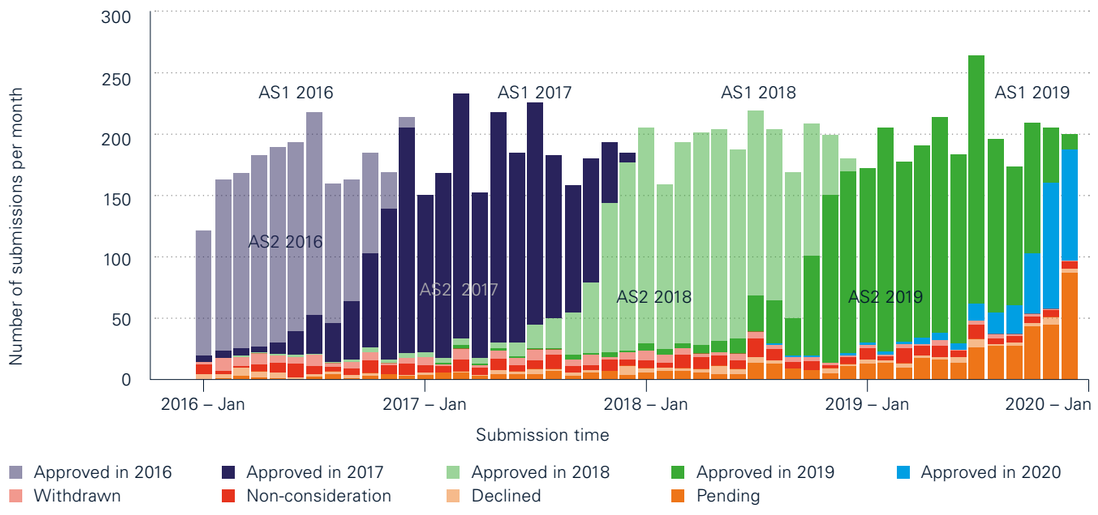
1.3.2 Influence of time on project status

Figure 1 shows all submissions via BASEC in the years 2016 up to 2019. 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 2019, since a single up-to-date export is used for all years (export date: April 4, 2020) 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.

Figure 1: Overview of submissions via BASEC in the years 2016–2019 coloured by the current status as of the time of the data export (April 4, 2020).



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.

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 nasal spray device.

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 2019

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

			n	%
Input	Submission in 2019 (AS1)		2453	76.5
	Projects pending from 2018	Pending first decision in 2018	256	8.0
		Pending final decision in 2018 (first decision before 2019)	497	15.5
		Total Pending from 2019	753	23.5
		Grand Total Input 2019	3206	100.0
Output	Final decision in 2019	Approvals (AS2)	2159	67.3
		Rejections (declined projects)	45	1.4
		Non-considerations	89	2.8
		Total Decisions	2293	71.5
	Withdrawn during 2019	Withdrawal before first decision	13	0.4
		Withdrawal after first decision 'approvals with charges'	2	0.1
		Withdrawal after first decision 'not-yet-approved projects with conditions'	9	0.3
		Total Withdrawn	26	0.8
	Pending at end of 2019	Pending first decision	264	8.2
		Pending final decision (first decision issued)	624	19.5
		Total Pending	887	27.7
		Grand Total Output 2019	3206	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 2019 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 2019 (AS1)

Table 2: Total number of research projects **submitted via BASEC in 2019** (analysis set AS1), including information on type of research and the legal basis.

Type of research	Legal basis	n	$\%_{col}$
Clinical trial	ClinO	532 [1]	21.7
Research involving persons, but not a clinical trial	HRO, Chapter 2	854 [2]	34.8
Further use of health-related personal data and/or biological material	HRO, Chapter 3	1050	42.8
Research involving deceased persons	HRO, Chapter 4	16	0.7
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	1	0.0
Total number		2453	100.0

1 55 of these projects also include an application for further use of data/biological material.
2 205 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 2019 (analysis set AS1) by lead ethics committee.

				Lead ethics commitee													
		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	$\%_{col}$
First decision	Approved [1]	330	13.5	129	20.4	72	14.2	13	2.8	35	8.5	19	7.1	40	39.6	22	31.0
	Approved with charges [2]	521	21.2	6	0.9	301	59.3	90	19.7	15	3.6	44	16.4	42	41.6	23	32.4
	Not approved, conditions [3]	1417	57.8	441	69.7	123	24.2	320	69.9	336	81.2	162	60.4	14	13.9	21	29.6
	Declined	42	1.7	8	1.3	5	1.0	13	2.8	2	0.5	13	4.9			1	1.4
	Non-consideration [4]	80	3.3	34	5.4	3	0.6	7	1.5	14	3.4	17	6.3	3	3.0	2	2.8
	First decision still pending [5]	63	2.6	15	2.4	4	0.8	15	3.3	12	2.9	13	4.9	2	2.0	2	2.8
Final decision	Approved [6]	1947	79.4	530	83.7	464	91.3	318	69.4	315	76.1	173	64.6	91	90.1	56	78.9
	Declined	44	1.8	9	1.4	5	1.0	13	2.8	2	0.5	14	5.2			1	1.4
	Non-consideration	83	3.4	33	5.2	4	0.8	10	2.2	14	3.4	17	6.3	3	3.0	2	2.8
	Withdrawn	31	1.3	5	0.8	4	0.8	5	1.1	8	1.9	8	3.0			1	1.4
	Final decision still pending [7]	348	14.2	56	8.8	31	6.1	112	24.5	75	18.1	56	20.9	7	6.9	11	15.5
Review procedure	Ordinary [8]	347	14.1	72	11.4	49	9.6	71	15.5	60	14.5	16	6.0	15	14.9	64	90.1 [11]
	Simplified [9]	1742	71.0	407	64.3	379	74.6	323	70.5	342	82.6	222	82.8	66	65.3	3	4.2
	Presidential [10]	306	12.5	138	21.8	77	15.2	49	10.7	5	1.2	17	6.3	17	16.8	3	4.2
	First decision still pending	58	2.4	16	2.5	3	0.6	15	3.3	7	1.7	13	4.9	3	3.0	1	1.4
	Total number in AS1	2453	100.0	633	100.0	508	100.0	458	100.0	414	100.0	268	100.0	101	100.0	71	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. 51.4 % 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 uses the ordinary procedure for most of the research applications.

Table 4: Number of **submissions in 2019** (analysis set AS1) by type of research project and lead ethics committee.
Projects involving multiple ECs are assigned to the lead EC.

			Total		Lead ethics commitee											
					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	17	9.6	5	9.6	5	13.5	1	4.8	1	3.3	2	28.6	2	12.5	1	6.7
		B	28	15.7	8	15.4	7	18.9	3	14.3	5	16.7	1	14.3	3	18.8	1	6.7
		C	133	74.7	39	75.0	25	67.6	17	81.0	24	80.0	4	57.1	11	68.8	13	86.7
		All	178	100.0	52	100.0	37	100.0	21	100.0	30	100.0	7	100.0	16	100.0	15	100.0
	Medical devices	A	97	69.8	38	74.5	15	78.9	4	26.7	20	69.0	12	80.0	7	100.0	1	33.3
		C	42	30.2	13	25.5	4	21.1	11	73.3	9	31.0	3	20.0			2	66.7
		All	139	100.0	51	100.0	19	100.0	15	100.0	29	100.0	15	100.0	7	100.0	3	100.0
	Other clinical trials	A	182	90.5	51	91.1	36	87.8	27	87.1	33	97.1	27	90.0	4	100.0	4	80.0
		B	19	9.5	5	8.9	5	12.2	4	12.9	1	2.9	3	10.0			1	20.0
		All	201	100.0	56	100.0	41	100.0	31	100.0	34	100.0	30	100.0	4	100.0	5	100.0
	Combination drugs/devices	A	1	20.0			1	100.0										
		C	4	80.0	2	100.0			1	100.0					1	100.0		
		All	5	100.0	2	100.0	1	100.0	1	100.0					1	100.0		
	Transplant products	C	6	100.0			1	100.0	1	100.0	2	100.0	2	100.0				
		All	6	100.0			1	100.0	1	100.0	2	100.0	2	100.0				
	Gene therapy	C	2	100.0					1	100.0			1	100.0				
		All	2	100.0					1	100.0			1	100.0				
	Transplantation	C	1	100.0									1	100.0				
		All	1	100.0									1	100.0				
	All	All	532	100.0	161	100.0	99	100.0	70	100.0	95	100.0	56	100.0	28	100.0	23	100.0
Research w/ persons		A	830	97.2	190	97.4	168	97.7	182	96.3	125	95.4	109	99.1	34	100.0	22	95.7
		B	24	2.8	5	2.6	4	2.3	7	3.7	6	4.6	1	0.9			1	4.3
		All	854	100.0	195	100.0	172	100.0	189	100.0	131	100.0	110	100.0	34	100.0	23	100.0
Further use		n.a.	1050	100.0	269	100.0	233	100.0	197	100.0	187	100.0	101	100.0	38	100.0	25	100.0
Deceased, embryos		n.a.	17	100.0	8	100.0	4	100.0	2	100.0	1	100.0	1	100.0	1	100.0		
Total number			2453	100.0	633	100.0	508	100.0	458	100.0	414	100.0	268	100.0	101	100.0	71	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	2179	71.8
Multiple ECs involved: lead EC	274	9.0
Multiple ECs involved: local EC	580	19.1
Total submissions to be evaluated	3033	100.0

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

	Ethics committee													
	KEK-ZH		EKNZ		KEK-BE		CER-VD		CCER		EKOS		CE-TI	
	n	%col	n	%col	n	%col	n	%col	n	%col	n	%col	n	%col
Single EC involved	551	75.4	456	72.7	362	70.6	428	77.5	237	68.5	81	50.9	64	61.0
Multiple: lead EC	82	11.2	52	8.3	52	10.1	30	5.4	31	9.0	20	12.6	7	6.7
Multiple: local EC	98	13.4	119	19.0	99	19.3	94	17.0	78	22.5	58	36.5	34	32.4
Total submissions	731	100.0	627	100.0	513	100.0	552	100.0	346	100.0	159	100.0	105	100.0

4 Scientific characterisation of projects approved in 2019 (AS2)

4.1 Overview

Table 7: Total number of research projects **approved in 2019** (analysis set AS2) per type of research, including information on the legal basis.

Type of research	Legal basis	n	$\%_{col}$
Clinical trial	ClinO	483[1]	22.4
Research involving persons, but not a clinical trial	HRO, Chapter 2	730[2]	33.8
Further use of health-related personal data and/or biological material	HRO, Chapter 3	932	43.2
Research involving deceased persons	HRO, Chapter 4	14	0.6
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	0	0.0
Total number		2159	100.0

1 45 of these projects also include 'further use' of existing data and/or material.
2 183 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 2019 (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 12–13 per lead ethics committee.

				Lead 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	2017	20	0.9	3	0.5	1	0.2	5	1.4	7	2.0	4	1.9				
	2018	514	23.8	139	23.4	69	14.2	119	32.8	95	27.3	68	31.8	15	15.5	9	15.5
	2019	1625	75.3	451	76.1	416	85.6	239	65.8	246	70.7	142	66.4	82	84.5	49	84.5
First decision	Approved	328	15.2	134	22.6	71	14.6	15	4.1	31	8.9	17	7.9	39	40.2	21	36.2
	Approved with charges [1]	559	25.9	4	0.7	292	60.1	118	32.5	20	5.7	63	29.4	42	43.3	20	34.5
	Not approved, conditions [2]	1269	58.8	455	76.7	121	24.9	230	63.4	297	85.3	134	62.6	15	15.5	17	29.3
	Declined [3]	3	0.1			2	0.4							1	1.0		
	Non-consideration [4]	0	0.0														
Review procedure	Ordinary [5]	321	14.9	78	13.2	48	9.9	62	17.1	43	12.4	15	7.0	19	19.6	56	96.6
	Simplified	1577	73.0	392	66.1	365	75.1	267	73.6	304	87.4	184	86.0	64	66.0	1	1.7
	Presidential	261	12.1	123	20.7	73	15.0	34	9.4	1	0.3	15	7.0	14	14.4	1	1.7
	Total number in AS2	2159	100.0	593	100.0	486	100.0	363	100.0	348	100.0	214	100.0	97	100.0	58	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 9–11 on page 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 66, 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.

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

Review 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.

			Total		Study design						Initiator			
					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 (ClinO)	Medicinal products (ClinO Art. 19)	A	18	9.6	11	61.1	2	11.1	5	27.8	1	5.6	17	94.4
		B	26	13.9	9	34.6	1	3.8	16	61.5	7	26.9	19	73.1
		C	143	76.5	21	14.7	8	5.6	114	79.7	108	75.5	35	24.5
		All	187	100.0	41	21.9	11	5.9	135	72.2	116	62.0	71	38.0
	Medical devices (ClinO Art. 20)	A	81	73.6	49	60.5	4	4.9	28	34.6	18	22.2	63	77.8
		C	29	26.4	12	41.4	3	10.3	14	48.3	14	48.3	15	51.7
		All	110	100.0	61	55.5	7	6.4	42	38.2	32	29.1	78	70.9
	Other clinical trials (ClinO Art. 61)	A	157	89.2	118	75.2	17	10.8	22	14.0	4	2.5	153	97.5
		B	19	10.8	8	42.1	3	15.8	8	42.1			19	100.0
		All	176	100.0	126	71.6	20	11.4	30	17.0	4	2.3	172	97.7
	Combination drugs/devices	A	1	25.0	1	100.0							1	100
		C	3	75.0			1	33.3	2	66.7	1	33.3	2	67.7
		All	4	100.0	1	25.0	1	25.0	2	50.0	1	25.0	3	75.0
	Transplant products (ClinO Art. 21)	C	4	100.0	2	50.0			2	50.0	2	50.0	2	50.0
		All	4	100.0	2	50.0			2	50.0	2	50.0	2	50.0
	Gene therapy (ClinO Art. 22)	C	2	100.0	1	50.0			1	50.0			2	100.0
		All	2	100.0	1	50.0			1	50.0			2	100.0
	Transplantation (ClinO Art. 49)	All	0											
	All	All	483	100.0	232	48.0	39	8.1	212	43.9	155	32.1	328	67.9
Research w/ persons (HRO Chapter 2)		A	709	97.1	543	76.6	58	8.2	108	15.2	49	6.9	660	93.1
		B	21	2.9	16	76.2	3	14.3	2	9.5	1	4.8	20	95.2
		All	730	100.0	559	76.6	61	8.4	110	15.1	50	6.8	680	93.2
Further use (HRO Chapter 3)		n.a.	932	100.0	776	83.3	44	4.7	112	12.0	43	4.6	889	95.4
Deceased, embryos (HRO Chapter 4+5)		n.a.	14	100.0	13	92.9			1	7.1			14	100.0
Total number			2159	100.0	1580	73.2	144	6.7	435	20.1	248	11.5	1911	88.5

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 Lead ethics committee

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

					Lead ethics committee													
			Total		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	18	9.6	5	8.2	6	15.0			3	13.6			3	15.0	1	7.1
		B	26	13.9	9	14.8	6	15.0	3	14.3	3	13.6			4	20.0	1	7.1
		C	143	76.5	47	77.0	28	70.0	18	85.7	16	72.7	9	100.0	13	65.0	12	85.7
		All	187	100.0	61	100.0	40	100.0	21	100.0	22	100.0	9	100.0	20	100.0	14	100.0
	Medical devices	A	81	73.6	33	78.6	15	88.2	4	28.6	15	71.4	6	100.0	6	100.0	2	50.0
		C	29	26.4	9	21.4	2	11.8	10	71.4	6	28.6					2	50.0
		All	110	100.0	42	100.0	17	100.0	14	100.0	21	100.0	6	100.0	6	100.0	4	100.0
	Other clinical trials	A	157	89.2	51	89.5	31	91.2	23	85.2	28	93.3	16	80.0	5	100.0	3	100.0
		B	19	10.8	6	10.5	3	8.8	4	14.8	2	6.7	4	20.0				
		All	176	100.0	57	100.0	34	100.0	27	100.0	30	100.0	20	100.0	5	100.0	3	100.0
	Combination drugs/devices	A	1	25.0			1	50.0										
		C	3	75.0			1	50.0			1	100.0			1	100.0		
		All	4	100.0			2	100.0			1	100.0			1	100.0		
	Transplant products	C	4	100.0	1	100.0			2	100.0	1	100.0						
		All	4	100.0	1	100.0			2	100.0	1	100.0						
	Gene therapy	C	2	100.0					1	100.0			1	100.0				
		All	2	100.0					1	100.0			1	100.0				
	Transplantation	All	0															
	All	All	483	100.0	161	100.0	93	100.0	65	100.0	75	100.0	36	100.0	32	100.0	21	100.0
Research w/ persons		A	709	97.1	174	96.7	167	98.8	139	97.2	95	94.1	89	97.8	30	100.0	15	93.8
		B	21	2.9	6	3.3	2	1.2	4	2.8	6	5.9	2	2.2			1	6.2
		All	730	100.0	180	100.0	169	100.0	143	100.0	101	100.0	91	100.0	30	100.0	16	100.0
Further use		n.a.	932	100.0	245	100.0	221	100.0	153	100.0	172	100.0	86	100.0	34	100.0	21	100.0
Deceased, embryos		n.a.	14	100.0	7	100.0	3	100.0	2	100.0			1	100.0	1	100.0		
Total number			2159	100.0	593	100.0	486	100.0	363	100.0	348	100.0	214	100.0	97	100.0	58	100.0

4.3.4 Review procedure

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

					Review procedure				First decision									
			Total		Ordinary		Simplified		Presidential		Approved		Charges		Conditions		Declined	
Type of research	Research details	Risk cat.	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Clinical trial	Medicinal products	A	18	9.6	3	16.7	15	83.3					8	44.4	10	55.6		
		B	26	13.9	26	100.0					1	3.8	7	26.9	18	69.2		
		C	143	76.5	141	98.6	2	1.4			5	3.5	28	19.6	109	76.2	1	0.7
		All	187	100.0	170	90.9	17	9.1			6	3.2	43	23.0	137	73.3	1	0.5
	Medical devices	A	81	73.6	7	8.6	74	91.4			5	6.2	9	11.1	67	82.7		
		C	29	26.4	27	93.1	2	6.9			1	3.4	1	3.4	27	93.1		
		All	110	100.0	34	30.9	76	69.1			6	5.5	10	9.1	94	85.5		
	Other clinical trials	A	157	89.2	15	9.6	142	90.4			4	2.5	28	17.8	125	79.6		
		B	19	10.8	19	100.0							5	26.3	14	73.7		
		All	176	100.0	34	19.3	142	80.7			4	2.3	33	18.8	139	79.0		
	Combination drugs/devices	A	1	25.0			1	100.0					1	100.0				
		C	3	75.0	3	100.0									3	100.0		
		All	4	100.0	3	75.0	1	25.0					1	25.0	3	75.0		
	Transplant products	C	4	100.0	4	100.0									4	100.0		
		All	4	100.0	4	100.0									4	100.0		
	Gene therapy	C	2	100.0	2	100.0									2	100.0		
		All	2	100.0	2	100.0									2	100.0		
	Transplantation	All	0															
	All	All	483	100.0	247	51.1	236	48.9			16	3.3	87	18.0	379	78.5	1	0.2
Research w/ persons		A	709	97.1	33	4.7	669	94.4	7	1.0	43	6.1	213	30.0	451	63.6	2	0.3
		B	21	2.9	19	90.5	2	9.5					1	4.8	20	95.2		
		All	730	100.0	52	7.1	671	91.9	7	1.0	43	5.9	214	29.3	471	64.5	2	0.3
Further use		n.a.	932	100.0	22	2.4	658	70.6	252	27.0	264	28.3	252	27.0	416	44.6		
Deceased, embryos		n.a.	14	100.0			12	85.7	2	14.3	5	35.7	6	42.9	3	21.4		
Total number			2159	100.0	321	14.9	1577	73.0	261	12.1	328	15.2	559	25.9	1269	58.8	3	0.1

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 10 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	%	n_{rare}	n	%	n_{rare}	n	%	n_{rare}
Other	119	24.6	2	35	18.7	1	28	25.5	0	56	31.8	1
Cancer: Other	34	7.0	8	23	12.3	7	3	2.7	0	6	3.4	1
Mental and Behavioural diseases	33	6.8	0	4	2.1	0	4	3.6	0	25	14.2	0
Nervous System diseases	32	6.6	7	15	8.0	6	9	8.2	1	8	4.5	0
Surgery	31	6.4	0	3	1.6	0	15	13.6	0	12	6.8	0
Musculoskeletal diseases (non cancer)	30	6.2	2	3	1.6	1	15	13.6	1	12	6.8	0
Basic research (Anatomy/Physiology)	26	5.4	0	2	1.1	0	6	5.5	0	18	10.2	0
Coronary Heart disease	26	5.4	0	6	3.2	0	12	10.9	0	6	3.4	0
Brain diseases (non cancer)	24	5.0	1	6	3.2	1	7	6.4	0	11	6.2	0
Nutritional and Metabolic diseases	21	4.3	2	4	2.1	1	3	2.7	0	14	8.0	1
Arterial and venous diseases including deep venous thrombosis and lung embolism	20	4.1	1	8	4.3	1	8	7.3	0	3	1.7	0
Cancer: Lung	20	4.1	0	16	8.6	0	1	0.9	0	2	1.1	0
Eye diseases	20	4.1	2	7	3.7	1	10	9.1	1	2	1.1	0
Cancer: Breast	18	3.7	1	10	5.3	1	1	0.9	0	6	3.4	0
Digestive Systems diseases (non cancer)	17	3.5	1	12	6.4	1	2	1.8	0	3	1.7	0
Endocrinological diseases (non cancer)	16	3.3	3	9	4.8	3	3	2.7	0	4	2.3	0
Respiratory diseases (non cancer)	15	3.1	0	2	1.1	0	4	3.6	0	9	5.1	0
Skin and Connective Tissues diseases (non cancer)	15	3.1	4	9	4.8	4	2	1.8	0	4	2.3	0
Cancer: Head and Neck	14	2.9	0	8	4.3	0	4	3.6	0	2	1.1	0
Infections and Infestations	14	2.9	2	8	4.3	2	2	1.8	0	3	1.7	0
Cancer: Colon and Rectal	13	2.7	0	8	4.3	0	1	0.9	0	3	1.7	0
Cancer: Leukemia	11	2.3	6	9	4.8	6	1	0.9	0	1	0.6	0
Cancer: Non-Hodgkin Lymphoma	11	2.3	5	7	3.7	4	1	0.9	0	1	0.6	0
Cancer: Melanoma	10	2.1	0	7	3.7	0	1	0.9	0	1	0.6	0
Pregnancy and Childbirth	9	1.9	0	1	0.5	0	0	0.0	0	8	4.5	0
Urological and Genital diseases (non cancer)	9	1.9	1	5	2.7	1	4	3.6	0	0	0.0	0
Cancer: Pancreatic	8	1.7	0	4	2.1	0	1	0.9	0	2	1.1	0
Dementia and Alzheimer disease	8	1.7	0	1	0.5	0	2	1.8	0	5	2.8	0
Cancer: Bladder	7	1.4	0	5	2.7	0	1	0.9	0	1	0.6	0
Cancer: Prostate	7	1.4	0	3	1.6	0	1	0.9	0	3	1.7	0
Hematologic diseases (non cancer)	7	1.4	3	4	2.1	3	1	0.9	0	2	1.1	0
Injury	7	1.4	0	1	0.5	0	4	3.6	0	2	1.1	0
Periodontal diseases	6	1.2	0	0	0.0	0	4	3.6	0	2	1.1	0
Cancer: Kidney	5	1.0	0	3	1.6	0	1	0.9	0	1	0.6	0
Cancer: Lymphoma	5	1.0	2	3	1.6	2	1	0.9	0	1	0.6	0
Ear, Nose, and Throat diseases (non cancer)	5	1.0	0	0	0.0	0	4	3.6	0	1	0.6	0
Neonatal diseases	5	1.0	2	1	0.5	1	0	0.0	0	4	2.3	1
Cancer: Endometrial	4	0.8	0	1	0.5	0	1	0.9	0	2	1.1	0
Genetic disorders	4	0.8	2	2	1.1	2	1	0.9	0	1	0.6	0
Cancer: Thyroid	2	0.4	0	0	0.0	0	1	0.9	0	1	0.6	0
Occupational diseases	1	0.2	0	0	0.0	0	0	0.0	0	1	0.6	0
Total projects	483	142.7	47	187	100.0	41	110	100.0	1	176	100.0	4

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 10 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	%	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$
Treatment	257	53.2	134	71.7	58	52.7	57	32.4
Other	92	19.0	9	4.8	19	17.3	64	36.4
PK/PD/safety	37	7.7	31	16.6	2	1.8	2	1.1
Diagnosis	36	7.5	6	3.2	20	18.2	10	5.7
Prevention	30	6.2	6	3.2	1	0.9	23	13.1
Rehabilitation	24	5.0	0	0.0	8	7.3	16	9.1
Palliation	7	1.4	1	0.5	2	1.8	4	2.3
Total projects	483	100.0	187	100.0	110	100.0	176	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". n/a: Clinical trials for which the applicants have not indicated any phases or which do not fit in phase 1–4.

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 **clinical trials with medicinal products** 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	19	9.9	1	5.3	1	5.3	1	5.3	7	36.8	9	47.4		
B	26	13.6	3	11.5	6	23.1	11	42.3	5	19.2	1	3.8		
C	146	76.4	26	17.8	43	29.5	67	45.9	5	3.4	5	3.4	5	3.4
Total number	191	100.0	30	15.7	50	26.2	79	41.4	17	8.9	15	7.9	5	2.6

The total number of 191 research projects consist of 187 medicinal product trials and 4 trials on a combination medicinal product and medical device. n/a: Clinical trials for which the applicants have not indicated any phases or which do not fit in phase 1–4.

➔ 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 **clinical trials with medical devices** by risk category, device details and whether 'first in man'.

	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	82	71.9	81	98.8					2	2.4
C	32	28.1	3	9.4	6	18.8	20	62.5	11	34.4
Total number	114	100.0	84	73.7	6	5.3	20	17.5	13	11.4

The total number of 114 research projects consist of 110 trials with medical devices and 4 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)

➔ A 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	251	34.4	242	96.4	9	3.6	194	77.3	23	9.2	34	13.5	10	4.0	241	96.0
Registry / Quality control [1]	63	8.6	60	95.2	3	4.8	27	42.9	4	6.3	32	50.8	13	20.6	50	79.4
Case control study	64	8.8	63	98.4	1	1.6	54	84.4	3	4.7	7	10.9	3	4.7	61	95.3
Other or n/a	352	48.2	344	97.7	8	2.3	284	80.7	31	8.8	37	10.5	24	6.8	328	93.2
Total number	730	100.0	709	97.1	21	2.9	559	76.6	61	8.4	110	15.1	50	6.8	680	93.2

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.

	Overall		Type of research project: Cohort study		Registry / Quality control		Case control study		Other or n/a	
Area of research	N	%	n	%	n	%	n	%	n	%
Other	251	34.4	90	35.9	16	25.4	13	20.3	132	37.5
Psychology	87	11.9	20	8.0	0	0.0	18	28.1	49	13.9
Physiology/anatomy	68	9.3	25	10.0	1	1.6	13	20.3	29	8.2
Surgery	63	8.6	32	12.7	11	17.5	7	10.9	13	3.7
Healthcare services research	57	7.8	13	5.2	7	11.1	0	0.0	37	10.5
Qualitative research	56	7.7	12	4.8	8	12.7	5	7.8	31	8.8
Epidemiology	54	7.4	26	10.4	5	7.9	2	3.1	21	6.0
Medical devices	50	6.8	18	7.2	12	19.0	4	6.2	16	4.5
Drugs	34	4.7	12	4.8	3	4.8	2	3.1	17	4.8
Dentistry	10	1.4	3	1.2	0	0.0	0	0.0	7	2.0
Total projects	730	100.0	251	100.0	63	100.0	64	100.0	352	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	247	21.3
	No	913	78.7
Coding (HRO Art. 25–27)	Coded	1004	86.6
	Open, non-coded	156	13.4
Consent (HRO Art. 28–32)	Prior consent exists	323	27.8
	Consent to be sought	257	22.2
	No consent Art. 34 HRA	580	50.0
Combined vs. stand-alone projects	Stand-alone further use project	932	80.3
	Further use project as part of a clinical trial	45	3.9
	Further use project as part of a non-clinical research project	183	15.8
Total number		1160	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	92	39.5	62	67.4	4	4.3	26	28.3	23	25.0	69	75.0
		Consent to be sought	79	33.9	48	60.8	10	12.7	21	26.6	10	12.7	69	87.3
		No consent Art. 34 HRA	62	26.6	49	79.0	3	4.8	10	16.1	1	1.6	61	98.4
		All	233	100.0	159	68.2	17	7.3	57	24.5	34	14.6	199	85.4
	Open, non-coded	Prior consent exists	5	35.7	5	100.0							5	100.0
		Consent to be sought	4	28.6	3	75.0	1	25.0					4	100.0
		No consent Art. 34 HRA	5	35.7	3	60.0	1	20.0	1	20.0			5	100.0
		All	14	100.0	11	78.6	2	14.3	1	7.1			14	100.0
	All		247	100.0	170	68.8	19	7.7	58	23.5	34	13.8	213	86.2
No	Coded	Prior consent exists	186	24.1	148	79.6	10	5.4	28	15.1	6	3.2	180	96.8
		Consent to be sought	150	19.5	111	74.0	11	7.3	28	18.7	18	12.0	132	88.0
		No consent Art. 34 HRA	435	56.4	387	89.0	21	4.8	27	6.2	4	0.9	431	99.1
		All	771	100.0	646	83.8	42	5.4	83	10.8	28	3.6	743	96.4
	Open, non-coded	Prior consent exists	40	28.2	36	90.0	1	2.5	3	7.5	1	2.5	39	97.5
		Consent to be sought	24	16.9	21	87.5	2	8.3	1	4.2			24	100.0
		No consent Art. 34 HRA	78	54.9	72	92.3	4	5.1	2	2.6			78	100.0
		All	142	100.0	129	90.8	7	4.9	6	4.2	1	0.7	141	99.3
	All		913	100.0	775	84.9	49	5.4	89	9.7	29	3.2	884	96.8
Total number			1160	100.0	945	81.5	68	5.9	147	12.7	63	5.4	1097	94.6

The total number of 1160 research projects consist of 932 standard 'further use' projects and 228 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 lead ethics committee.

			Lead ethics committee													
	Total		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	323	27.8	119	35.1	78	29.7	33	18.1	63	30.9	13	12.3	13	31.7	4	16.0
Consent to be sought	257	22.2	96	28.3	47	17.9	28	15.4	43	21.1	27	25.5	7	17.1	9	36.0
No consent Art. 34 HRA	580	50.0	124	36.6	138	52.5	121	66.5	98	48.0	66	62.3	21	51.2	12	48.0
Total number	1160	100.0	339	100.0	263	100.0	182	100.0	204	100.0	106	100.0	41	100.0	25	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	1188	66.1
	Industry	84 [1]	4.7
	Universities/hospitals	226	12.6
	Private (non-industry)	162	9.0
	Swiss National Science Foundation	137	7.6
	All	1797	100.0
Industry	Public, other	41 [2]	16.5
	Industry	207 [3]	83.5
	Universities/hospitals	0	0.0
	Private (non-industry)	0	0.0
	Swiss National Science Foundation	0	0.0
	All	248	100.0
Other	Public, other	82	71.9
	Industry	4	3.5
	Universities/hospitals	7	6.1
	Private (non-industry)	16	14.0
	Swiss National Science Foundation	5	4.4
	All	114 [4]	100.0

1 Applicants almost exclusively from academic institutions.
2 Inspecting the sponsor information reveals that these are almost exclusively industry projects.
3 205 of the industry-initiated projects are financed exclusively by industry.
4 41 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.

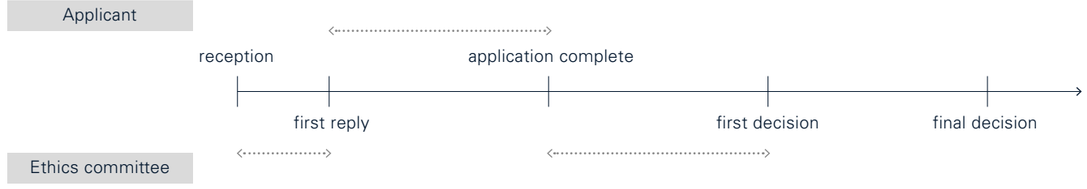
➔ Further information can be found in the Annex in section A.4

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 automatically recorded, apart from the "final decision date" which is manually entered by the ECs. Thereby the only two periods that solely depend on the EC are: 1) reception (initial submission) to first reply and 2) application data complete to first decision. The interval between "first reply" 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 for each application. The only two periods that solely depend on the EC are denoted as well as the period that is mainly dependent on the applicant.



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	78	13.2	7	[7, 7]	7	[7, 12]	28	[24, 33]	107	[69, 176]	17	[14, 22]	100	[60, 155]
	EKNZ	48	9.9	3	[1, 5]	4	[1, 6]	27	[19, 38]	79	[57, 120]	21	[15, 29]	74	[52, 115]
	CER-VD	62	71.1	5	[4, 6]	6	[4, 7]	32	[27, 40]	143	[91, 197]	26	[21, 31]	136	[82, 184]
	KEK-BE	43	12.4	3	[1, 4]	5	[2, 14]	29	[20, 34]	179	[131, 239]	20	[15, 22]	169	[122, 208]
	CCER	15	7.0	4	[3, 6]	9	[6, 14]	35	[31, 39]	140	[94, 162]	24	[20, 34]	126	[78, 154]
	EKOS	19	19.6	3	[1, 4]	3	[1, 4]	24	[21, 31]	108	[70, 140]	21	[18, 26]	105	[68, 136]
	CE-TI	56	96.6	7	[7, 7]	7	[7, 7]	24	[20, 30]	44	[24, 81]	17	[13, 22]	37	[14, 74]
	All	321	14.9	6	[3, 7]	7	[5, 8]	29	[22, 35]	108	[62, 171]	21	[15, 26]	99	[56, 159]
Simplified	KEK-ZH	392	66.1	7	[7, 8]	7	[7, 12]	35	[28, 42]	62	[45, 105]	22	[15, 31]	50	[34, 90]
	EKNZ	365	75.1	3	[1, 5]	4	[1, 7]	20	[13, 27]	46	[27, 76]	14	[7, 20]	40	[22, 67]
	CER-VD	267	73.6	5	[3, 7]	6	[3, 8]	28	[22, 36]	93	[67, 133]	22	[17, 27]	82	[60, 118]
	KEK-BE	304	87.4	3	[1, 4]	4	[2, 7]	21	[19, 31]	88	[55, 132]	17	[14, 20]	82	[49, 114]
	CCER	184	86.0	2	[1, 6]	7	[3, 13]	30	[23, 40]	76	[50, 112]	21	[17, 27]	64	[42, 95]
	EKOS	64	66.0	2	[1, 3]	3	[1, 4]	12	[8, 18]	21	[10, 43]	9	[6, 14]	18	[7, 42]
	CE-TI	1	1.7	6	[6, 6]	6	[6, 6]	25	[25, 25]	25	[25, 25]	19	[19, 19]	19	[19, 19]
	All	1577	73.0	4	[2, 7]	6	[3, 9]	26	[20, 36]	68	[43, 110]	19	[14, 25]	58	[35, 98]
Presidential	KEK-ZH	123	20.7	5	[2, 7]	6	[2, 8]	17	[13, 26]	24	[14, 40]	11	[7, 17]	16	[8, 30]
	EKNZ	73	15.0	4	[2, 5]	4	[2, 7]	8	[5, 15]	15	[7, 37]	3	[1, 7]	8	[2, 28]
	CER-VD	34	9.4	4	[3, 5]	5	[4, 7]	28	[22, 35]	85	[61, 120]	20	[16, 28]	78	[46, 110]
	KEK-BE	1	0.3	7	[7, 7]	217	[217, 217]	235	[235, 235]	284	[284, 284]	18	[18, 18]	67	[67, 67]
	CCER	15	7.0	4	[2, 7]	7	[6, 42]	15	[8, 44]	15	[10, 47]	4	[2, 8]	4	[2, 8]
	EKOS	14	14.4	2	[1, 3]	3	[2, 4]	6	[5, 7]	6	[5, 8]	3	[1, 4]	3	[1, 4]
	CE-TI	1	1.7	4	[4, 4]	4	[4, 4]	4	[4, 4]	4	[4, 4]	0	[0, 0]	0	[0, 0]
	All	261	12.1	4	[2, 6]	5	[2, 8]	15	[8, 26]	24	[12, 54]	8	[4, 17]	14	[6, 35]
Overall	KEK-ZH	593	100.0	7	[6, 8]	7	[7, 10]	31	[22, 39]	61	[38, 106]	20	[13, 28]	48	[28, 90]
	EKNZ	486	100.0	3	[1, 5]	4	[1, 7]	19	[11, 27]	46	[25, 76]	13	[7, 20]	38	[19, 67]
	CER-VD	363	100.0	5	[3, 7]	6	[4, 7]	29	[22, 36]	98	[69, 145]	22	[18, 28]	87	[62, 132]
	KEK-BE	348	100.0	3	[1, 4]	4	[2, 8]	22	[19, 33]	96	[59, 155]	18	[14, 21]	88	[51, 137]
	CCER	214	100.0	3	[1, 6]	7	[4, 14]	31	[23, 40]	76	[49, 121]	21	[16, 27]	64	[42, 97]
	EKOS	97	100.0	2	[1, 3]	3	[1, 4]	13	[7, 21]	24	[9, 70]	9	[4, 17]	18	[6, 66]
	CE-TI	58	100.0	7	[7, 7]	7	[7, 7]	24	[20, 30]	44	[22, 80]	17	[12, 22]	35	[14, 74]
	All	2159	100.0	4	[2, 7]	6	[3, 9]	26	[19, 35]	68	[39, 116]	18	[13, 24]	57	[31, 102]

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. 18 projects with t > 60 days are not shown for layout reasons.

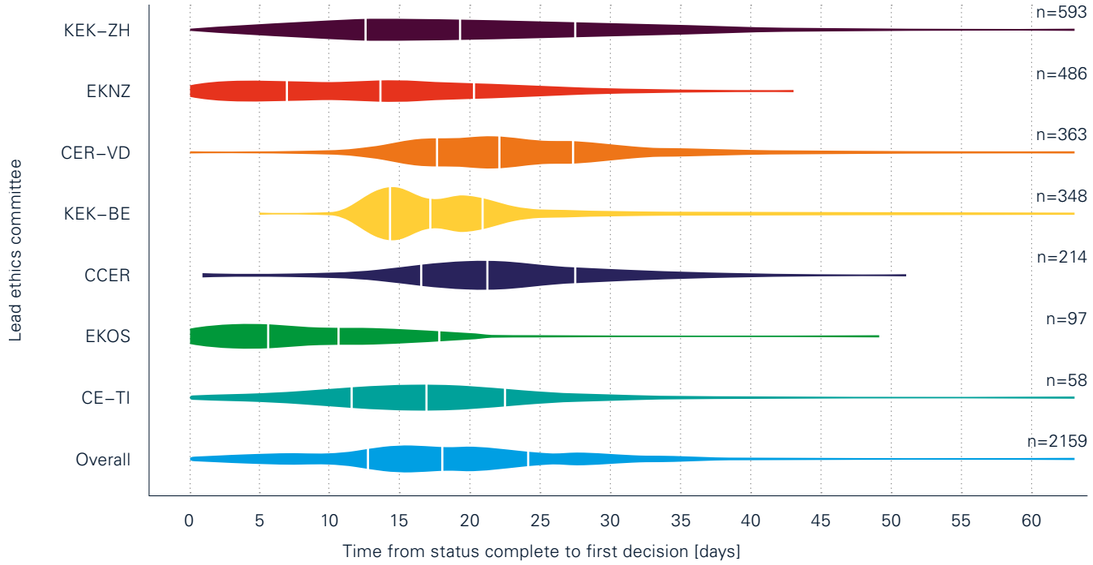
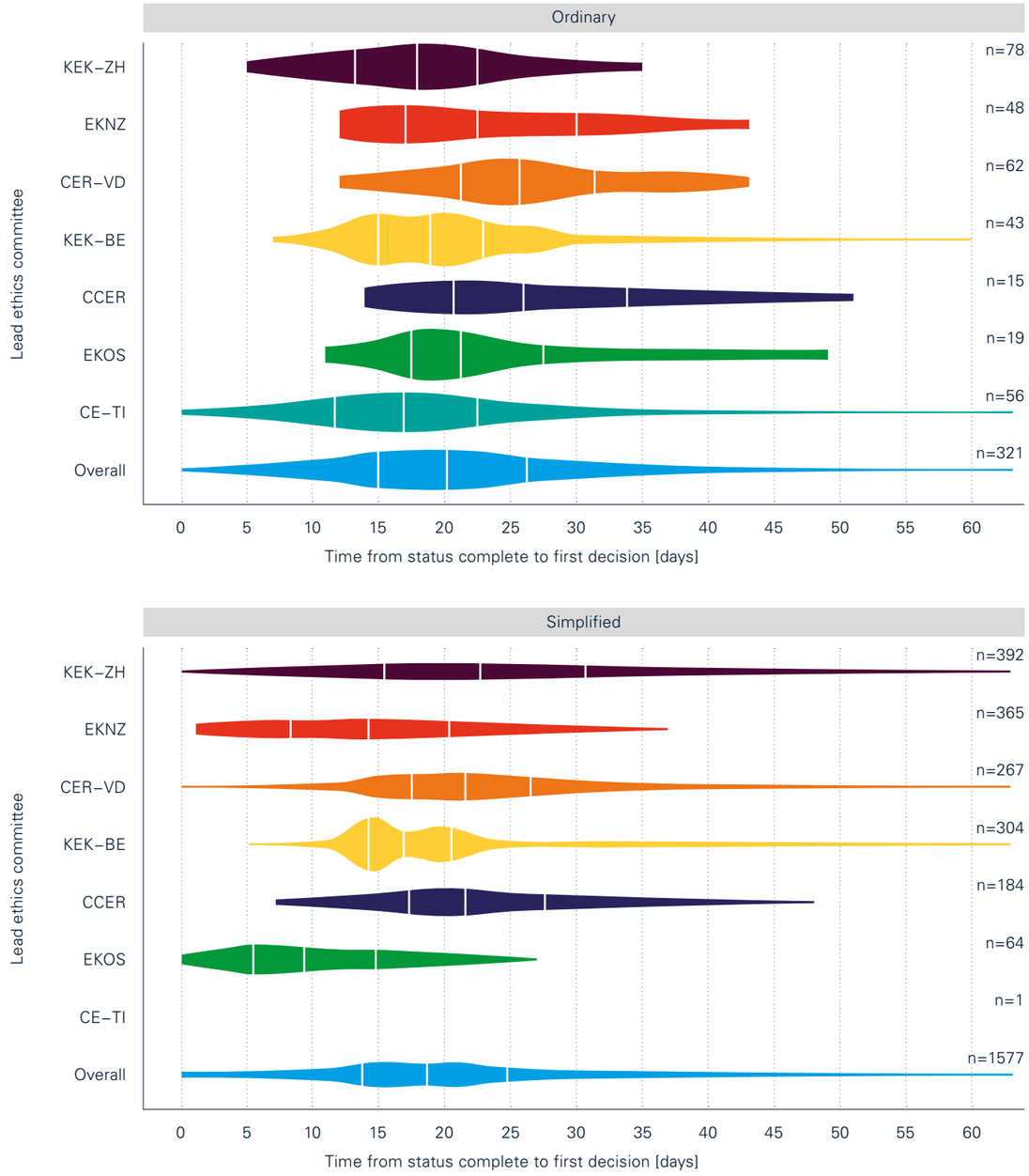
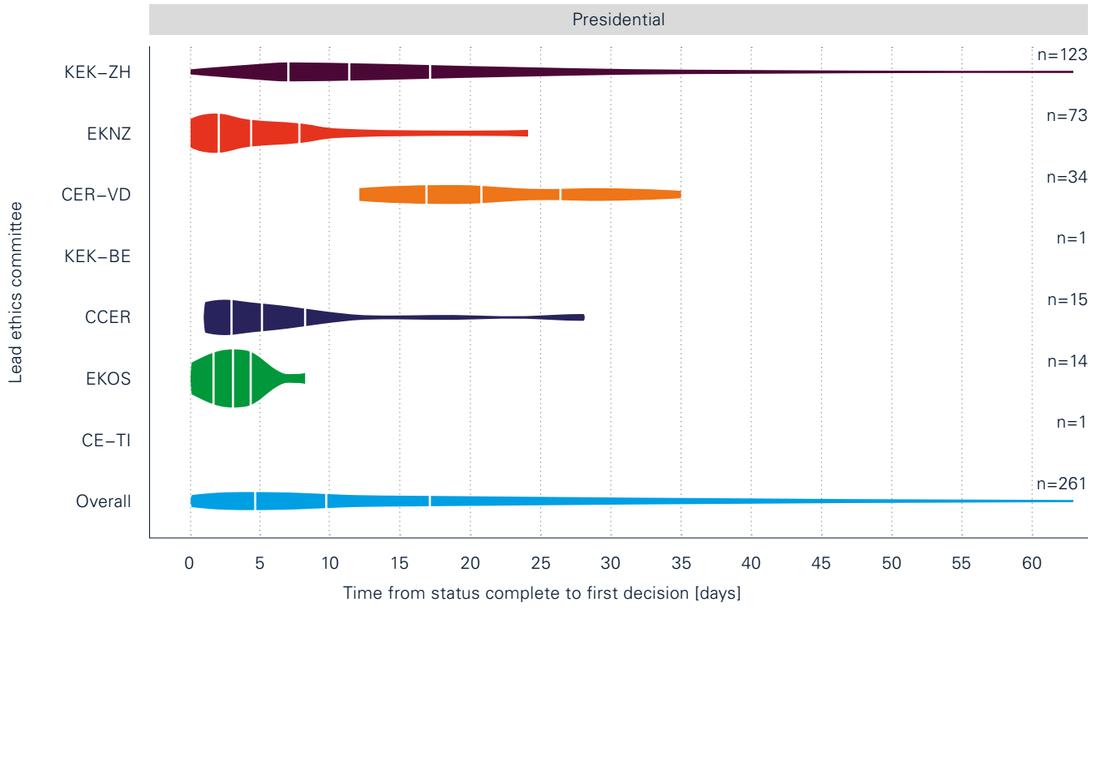


Figure 4: Violin plot of the time between status 'complete' to the first decision by EC and stratified by review procedure. 18 projects with t > 60 days are not shown for layout reasons. Note: *CE-TI* typically processes all submissions in a plenary session (ordinary procedure) but with adapted fees.





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. 45 projects with approval time > 1 year are not shown for layout reasons.

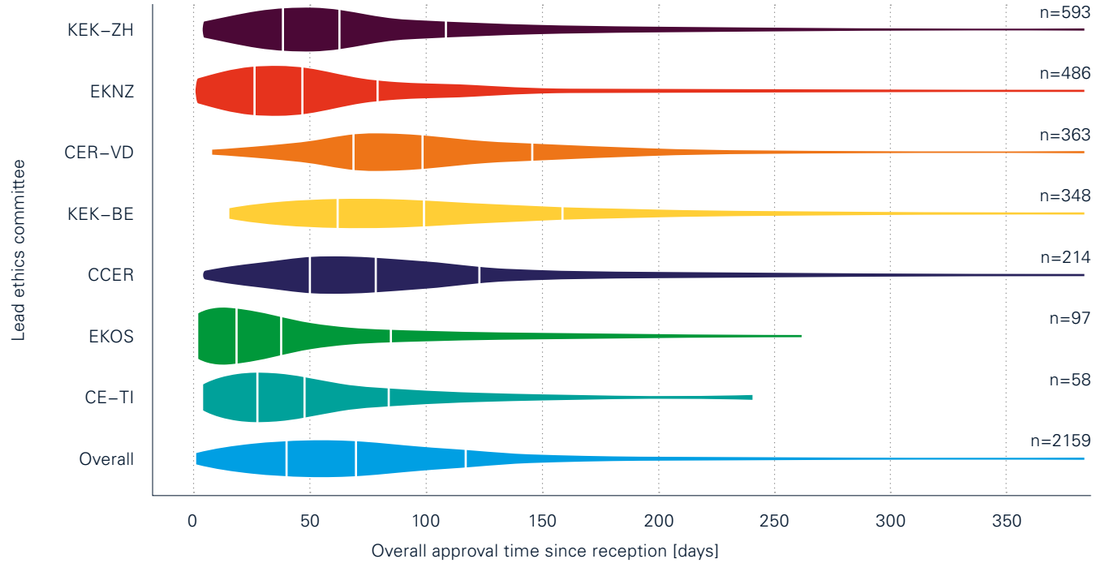
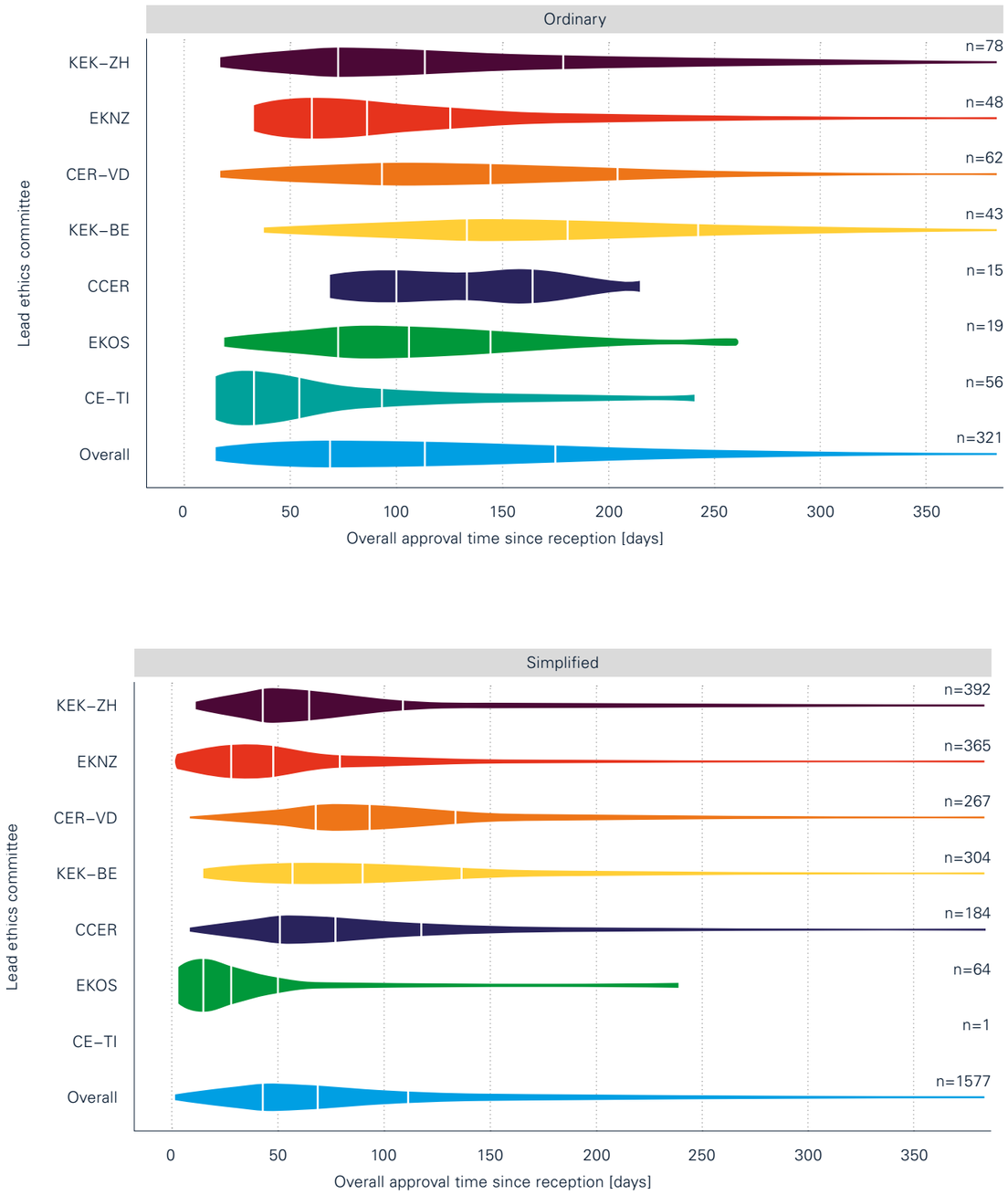
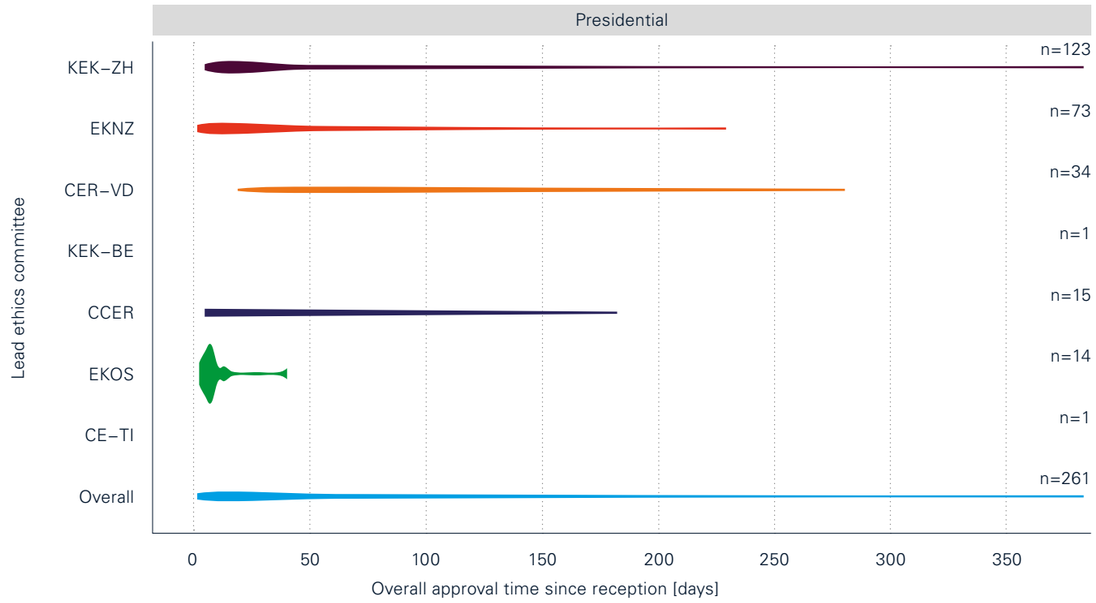


Figure 6: Violin plot of the overall approval time by EC from reception to final decision and stratified by review procedure. 45 projects with approval time > 1 year are not shown for layout reasons.





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	161	27.15	7	[7, 8]	7	[7, 13]	34	[27, 40]	85	[62, 144]	22	[15, 29]	77	[50, 128]
	EKNZ	93	19.14	4	[1, 6]	5	[2, 7]	26	[19, 34]	71	[53, 113]	19	[14, 26]	64	[47, 100]
	CER-VD	65	17.91	5	[3, 6]	6	[4, 7]	30	[25, 36]	146	[92, 195]	24	[18, 28]	137	[86, 183]
	KEK-BE	75	21.55	3	[1, 4]	5	[2, 7]	22	[19, 29]	151	[110, 202]	18	[14, 21]	135	[106, 196]
	CCER	36	16.82	4	[3, 7]	8	[6, 13]	34	[29, 42]	103	[74, 160]	24	[20, 30]	95	[64, 136]
	EKOS	32	32.99	3	[1, 4]	3	[1, 4]	22	[15, 27]	81	[41, 136]	18	[11, 22]	72	[39, 133]
	CE-TI	21	36.21	7	[7, 7]	7	[7, 7]	24	[20, 29]	53	[29, 101]	17	[13, 22]	46	[21, 94]
	All	483	22.37	6	[3, 7]	7	[4, 10]	29	[22, 37]	101	[63, 160]	21	[15, 27]	92	[55, 148]
Research w/ persons	KEK-ZH	180	30.35	7	[7, 8]	7	[7, 10]	35	[30, 42]	60	[46, 102]	24	[18, 32]	50	[38, 90]
	EKNZ	169	34.77	4	[2, 6]	4	[2, 8]	22	[18, 28]	54	[38, 87]	17	[13, 21]	49	[34, 76]
	CER-VD	143	39.39	5	[3, 7]	6	[4, 7]	29	[22, 37]	96	[72, 126]	22	[18, 28]	83	[64, 118]
	KEK-BE	101	29.02	3	[1, 4]	5	[1, 12]	22	[19, 34]	82	[55, 118]	17	[14, 20]	70	[47, 102]
	CCER	91	42.52	3	[1, 6]	7	[3, 12]	33	[26, 38]	83	[56, 118]	22	[18, 29]	74	[47, 104]
	EKOS	30	30.93	2	[1, 3]	2	[1, 4]	14	[9, 18]	32	[16, 49]	11	[7, 16]	30	[15, 47]
	CE-TI	16	27.59	7	[7, 7]	7	[7, 12]	28	[24, 31]	48	[29, 70]	17	[9, 23]	40	[14, 58]
	All	730	33.81	5	[2, 7]	7	[3, 9]	28	[21, 37]	69	[46, 109]	20	[15, 26]	60	[40, 97]
Further use	KEK-ZH	245	41.32	7	[3, 7]	7	[4, 10]	24	[16, 34]	38	[21, 81]	14	[10, 21]	28	[14, 56]
	EKNZ	221	45.47	3	[1, 5]	4	[1, 6]	10	[7, 18]	25	[11, 46]	6	[2, 9]	18	[6, 35]
	CER-VD	153	42.15	5	[3, 7]	6	[4, 7]	28	[22, 36]	88	[64, 132]	21	[17, 27]	77	[55, 108]
	KEK-BE	172	49.43	2	[1, 4]	4	[2, 7]	22	[19, 33]	84	[51, 137]	17	[14, 21]	72	[49, 119]
	CCER	86	40.19	2	[1, 6]	7	[2, 16]	27	[20, 37]	56	[38, 88]	19	[11, 22]	42	[25, 70]
	EKOS	34	35.05	2	[1, 3]	2	[1, 4]	7	[5, 11]	8	[6, 12]	4	[2, 7]	4	[3, 8]
	CE-TI	21	36.21	7	[6, 7]	7	[7, 7]	22	[16, 28]	25	[18, 45]	15	[9, 21]	19	[10, 38]
	All	932	43.17	4	[1, 6]	5	[2, 8]	21	[14, 31]	49	[22, 94]	15	[7, 21]	38	[15, 78]
Deceased persons	KEK-ZH	7	1.18	7	[7, 8]	9	[7, 12]	35	[25, 40]	49	[32, 60]	21	[18, 33]	36	[25, 49]
	EKNZ	3	0.62	3	[2, 4]	6	[4, 12]	24	[24, 30]	56	[46, 82]	17	[16, 20]	50	[42, 70]
	CER-VD	2	0.55	4	[3, 6]	106	[54, 158]	124	[71, 178]	204	[128, 281]	18	[17, 20]	98	[74, 123]
	KEK-BE	0	0.0												
	CCER	1	0.47	1	[1, 1]	178	[178, 178]	182	[182, 182]	182	[182, 182]	4	[4, 4]	4	[4, 4]
	EKOS	1	1.03	1	[1, 1]	1	[1, 1]	10	[10, 10]	10	[10, 10]	9	[9, 9]	9	[9, 9]
	CE-TI	0	0.00												
	All	14	0.65	6	[2, 7]	8	[5, 14]	32	[21, 41]	54	[39, 98]	19	[15, 22]	39	[20, 54]
Overall	KEK-ZH	593	100.00	7	[6, 8]	7	[7, 10]	31	[22, 39]	61	[38, 106]	20	[13, 28]	48	[28, 90]
	EKNZ	486	100.00	3	[1, 5]	4	[1, 7]	19	[11, 27]	46	[25, 76]	13	[7, 20]	38	[19, 67]
	CER-VD	363	100.00	5	[3, 7]	6	[4, 7]	29	[22, 36]	98	[69, 145]	22	[18, 28]	87	[62, 132]
	KEK-BE	348	100.00	3	[1, 4]	4	[2, 8]	22	[19, 33]	96	[59, 155]	18	[14, 21]	88	[51, 137]
	CCER	214	100.00	3	[1, 6]	7	[4, 14]	31	[23, 40]	76	[49, 121]	21	[16, 27]	64	[42, 97]
	EKOS	97	100.00	2	[1, 3]	3	[1, 4]	13	[7, 21]	24	[9, 70]	9	[4, 17]	18	[6, 66]
	CE-TI	58	100.00	7	[7, 7]	7	[7, 7]	24	[20, 30]	44	[22, 80]	17	[12, 22]	35	[14, 74]
	All	2159	100.00	4	[2, 7]	6	[3, 9]	26	[19, 35]	68	[39, 116]	18	[13, 24]	57	[31, 102]

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	138	6	[3, 7]	345	6	[3, 7]
	from receipt to status 'complete'	138	7	[4, 10]	345	7	[4, 9]
	from receipt to first decision	138	29	[22, 36]	345	29	[22, 37]
	from receipt to final decision	138	124	[80, 178]	345	93	[60, 147]
	from 'complete' to first decision	138	21	[15, 27]	345	20	[15, 27]
	from 'complete' to final decision	138	120	[72, 168]	345	85	[50, 132]
Research w/ persons	from receipt to first reply	75	3	[1, 7]	655	5	[2, 7]
	from receipt to status 'complete'	75	6	[2, 8]	655	7	[3, 9]
	from receipt to first decision	75	27	[21, 34]	655	28	[21, 37]
	from receipt to final decision	75	84	[53, 134]	655	68	[46, 106]
	from 'complete' to first decision	75	21	[16, 27]	655	20	[15, 26]
	from 'complete' to final decision	75	78	[44, 114]	655	59	[40, 94]
Further use	from receipt to first reply	56	3	[2, 7]	876	4	[1, 6]
	from receipt to status 'complete'	56	7	[3, 12]	876	5	[2, 8]
	from receipt to first decision	56	28	[18, 35]	876	21	[14, 31]
	from receipt to final decision	56	70	[34, 114]	876	48	[22, 92]
	from 'complete' to first decision	56	17	[12, 23]	876	15	[7, 21]
	from 'complete' to final decision	56	58	[29, 102]	876	37	[15, 77]
Deceased persons	from receipt to first reply	0			14	6	[2, 7]
	from receipt to status 'complete'	0			14	8	[5, 14]
	from receipt to first decision	0			14	32	[21, 41]
	from receipt to final decision	0			14	54	[39, 98]
	from 'complete' to first decision	0			14	19	[15, 22]
	from 'complete' to final decision	0			14	39	[20, 54]
Overall	from receipt to first reply	269	5	[2, 7]	1890	4	[2, 7]
	from receipt to status 'complete'	269	7	[3, 10]	1890	6	[3, 9]
	from receipt to first decision	269	28	[21, 35]	1890	25	[18, 35]
	from receipt to final decision	269	101	[64, 160]	1890	64	[37, 108]
	from 'complete' to first decision	269	20	[15, 27]	1890	18	[13, 24]
	from 'complete' to final decision	269	90	[56, 147]	1890	55	[29, 96]

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	88	7	[7, 8]	505	7	[6, 7]
	from receipt to status 'complete'	88	8	[7, 13]	505	7	[7, 10]
	from receipt to first decision	88	30	[24, 40]	505	31	[22, 39]
	from receipt to final decision	88	106	[68, 178]	505	55	[35, 93]
	from 'complete' to first decision	88	18	[13, 28]	505	20	[13, 28]
	from 'complete' to final decision	88	90	[59, 155]	505	42	[25, 76]
EKNZ	from receipt to first reply	49	2	[1, 5]	437	3	[1, 5]
	from receipt to status 'complete'	49	2	[1, 6]	437	4	[2, 7]
	from receipt to first decision	49	23	[16, 29]	437	19	[10, 27]
	from receipt to final decision	49	65	[44, 103]	437	42	[23, 72]
	from 'complete' to first decision	49	19	[14, 27]	437	13	[6, 19]
	from 'complete' to final decision	49	64	[43, 92]	437	35	[17, 63]
CER-VD	from receipt to first reply	31	5	[3, 6]	332	5	[3, 7]
	from receipt to status 'complete'	31	5	[3, 7]	332	6	[4, 7]
	from receipt to first decision	31	30	[26, 36]	332	29	[22, 36]
	from receipt to final decision	31	127	[92, 183]	332	96	[67, 140]
	from 'complete' to first decision	31	23	[20, 28]	332	22	[18, 27]
	from 'complete' to final decision	31	123	[86, 176]	332	82	[60, 130]
KEK-BE	from receipt to first reply	47	3	[1, 4]	301	3	[1, 4]
	from receipt to status 'complete'	47	5	[3, 14]	301	4	[1, 7]
	from receipt to first decision	47	27	[21, 35]	301	21	[19, 32]
	from receipt to final decision	47	135	[98, 178]	301	90	[56, 146]
	from 'complete' to first decision	47	20	[15, 22]	301	17	[14, 20]
	from 'complete' to final decision	47	119	[84, 172]	301	83	[49, 127]
CCER	from receipt to first reply	25	3	[1, 7]	189	3	[1, 6]
	from receipt to status 'complete'	25	9	[6, 13]	189	7	[3, 14]
	from receipt to first decision	25	31	[28, 41]	189	30	[23, 40]
	from receipt to final decision	25	96	[66, 159]	189	75	[47, 112]
	from 'complete' to first decision	25	22	[19, 30]	189	21	[16, 27]
	from 'complete' to final decision	25	78	[42, 154]	189	63	[41, 95]
EKOS	from receipt to first reply	23	2	[1, 3]	74	2	[1, 3]
	from receipt to status 'complete'	23	3	[1, 4]	74	3	[1, 4]
	from receipt to first decision	23	20	[16, 24]	74	10	[7, 18]
	from receipt to final decision	23	67	[34, 141]	74	17	[7, 44]
	from 'complete' to first decision	23	17	[12, 21]	74	7	[4, 14]
	from 'complete' to final decision	23	64	[33, 138]	74	12	[5, 42]
CE-TI	from receipt to first reply	6	7	[7, 7]	52	7	[7, 7]
	from receipt to status 'complete'	6	7	[7, 7]	52	7	[7, 7]
	from receipt to first decision	6	34	[24, 42]	52	24	[20, 29]
	from receipt to final decision	6	69	[58, 80]	52	38	[21, 78]
	from 'complete' to first decision	6	26	[18, 36]	52	17	[11, 21]
	from 'complete' to final decision	6	62	[50, 74]	52	26	[13, 71]
Overall	from receipt to first reply	269	5	[2, 7]	1890	4	[2, 7]
	from receipt to status 'complete'	269	7	[3, 10]	1890	6	[3, 9]
	from receipt to first decision	269	28	[21, 35]	1890	25	[18, 35]
	from receipt to final decision	269	101	[64, 160]	1890	64	[37, 108]
	from 'complete' to first decision	269	20	[15, 27]	1890	18	[13, 24]
	from 'complete' to final decision	269	90	[56, 147]	1890	55	[29, 96]

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). 18 projects with approval time > 60 days are not shown for layout reasons.

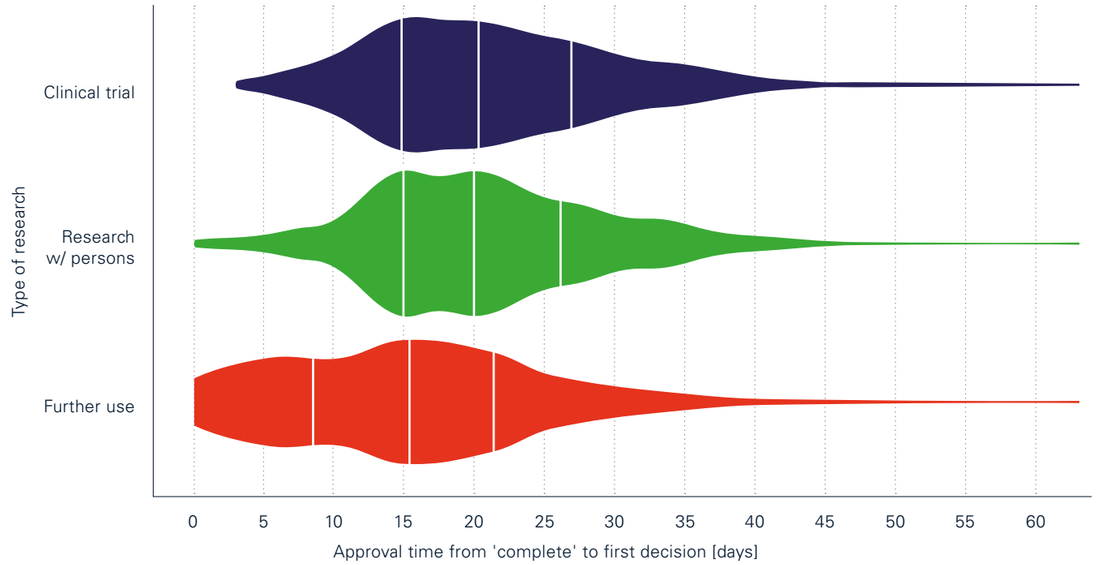
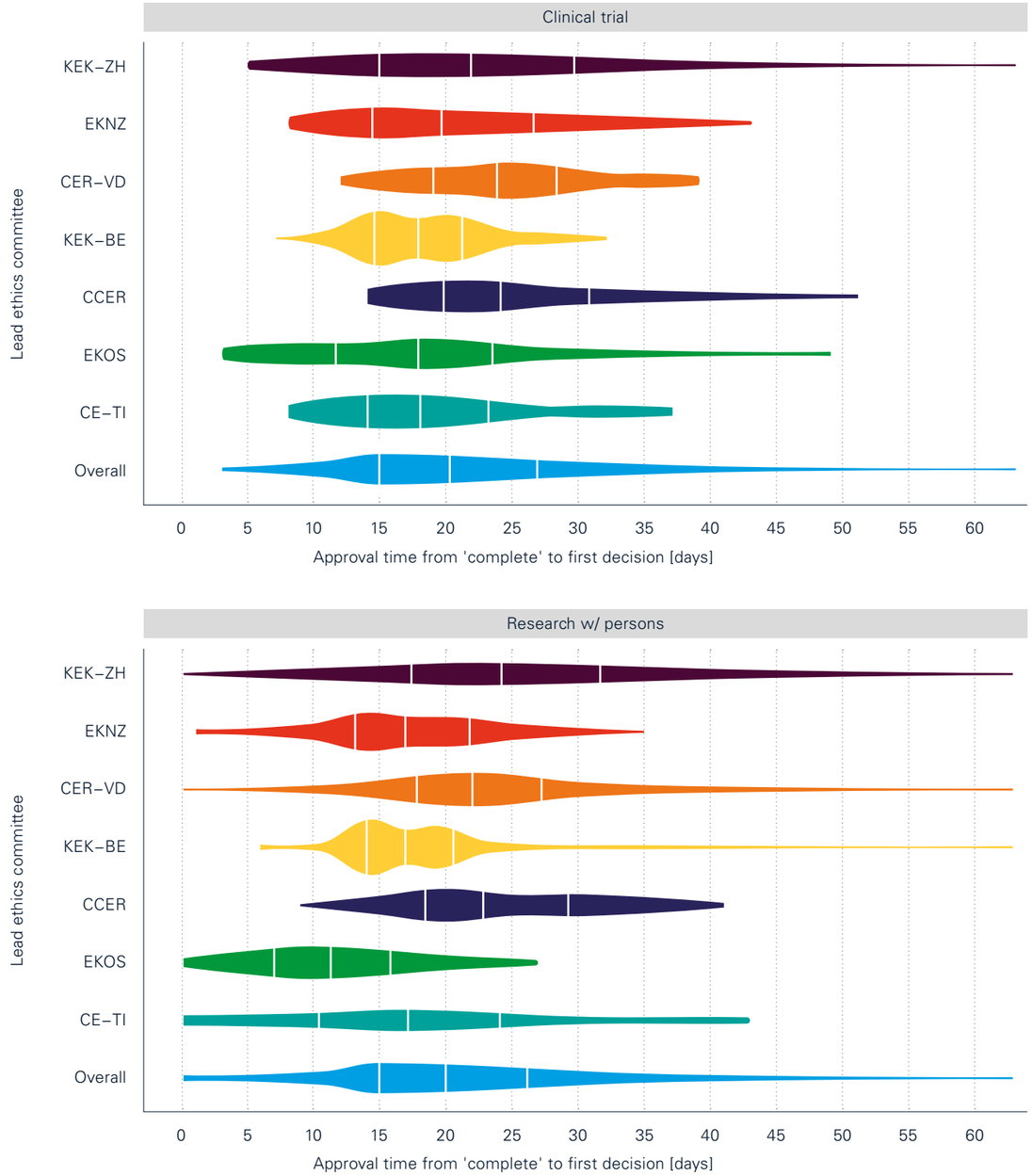


Figure 8: Violin plot of the **approval time starting from status 'complete' to the first decision** per type of research (only the 3 major groups are shown) stratified by EC. 18 projects with approval time > 60 days are not shown for layout reasons.



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). 45 projects with an overall approval time > 1 year are not shown for layout reasons.

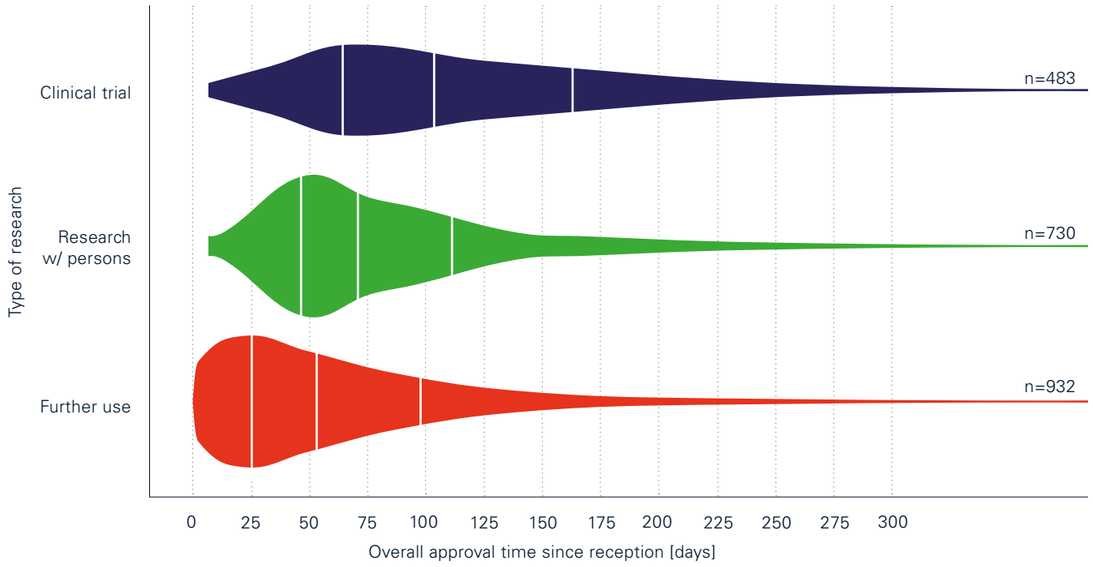
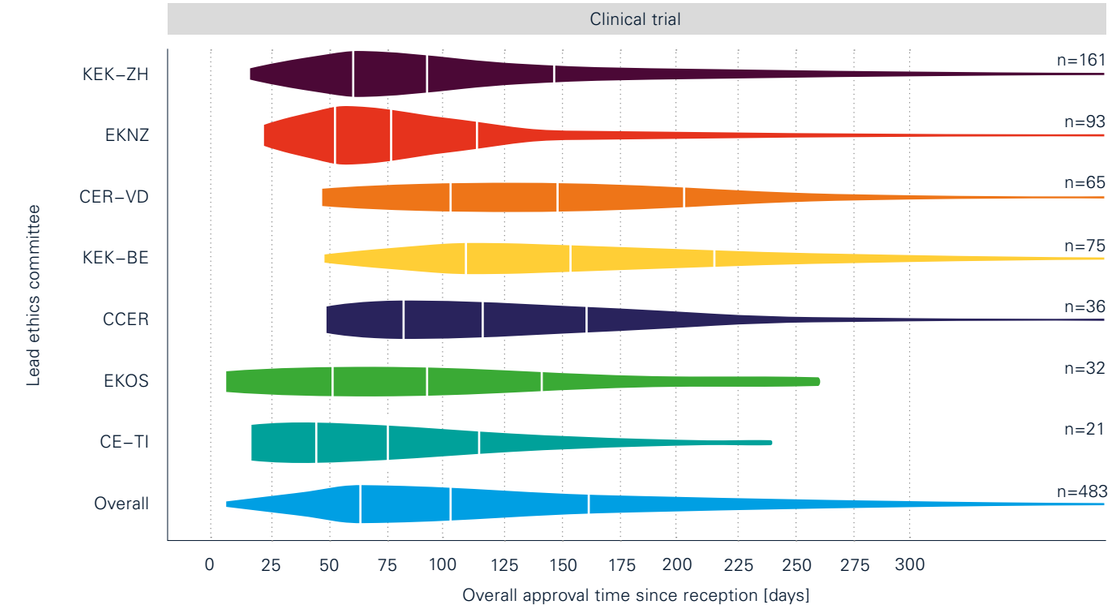
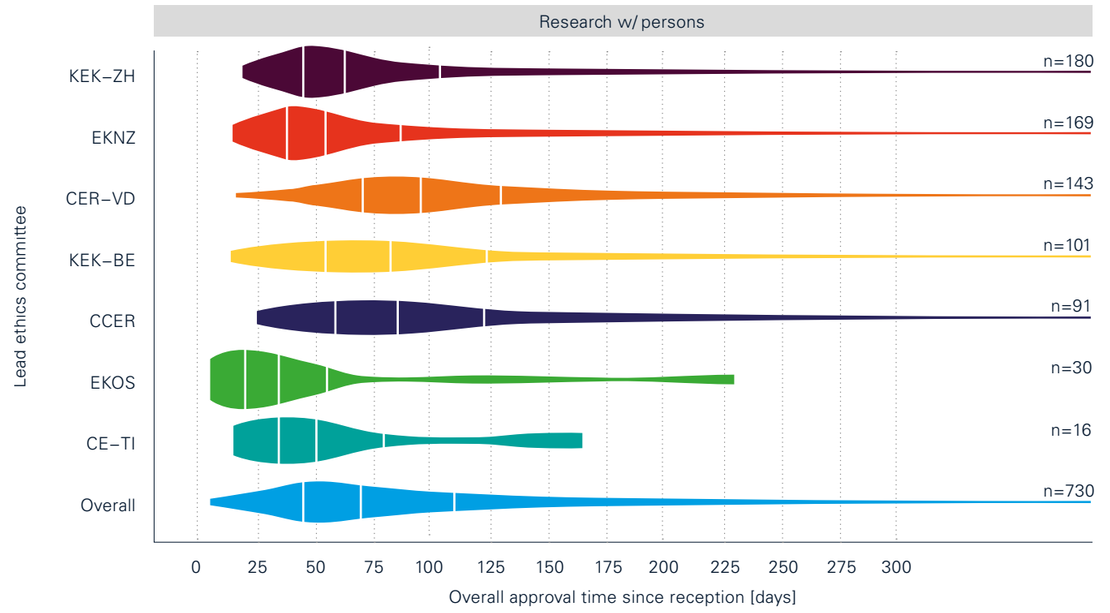
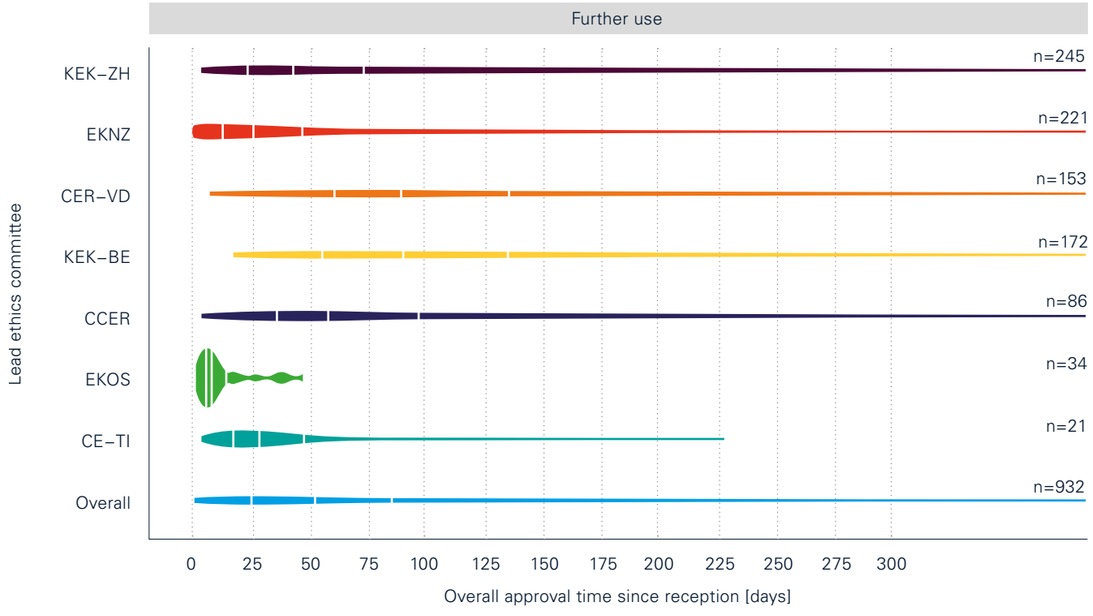


Figure 10: Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown) stratified by EC. 45 projects with an overall approval time > 1 year are not shown for layout reasons.







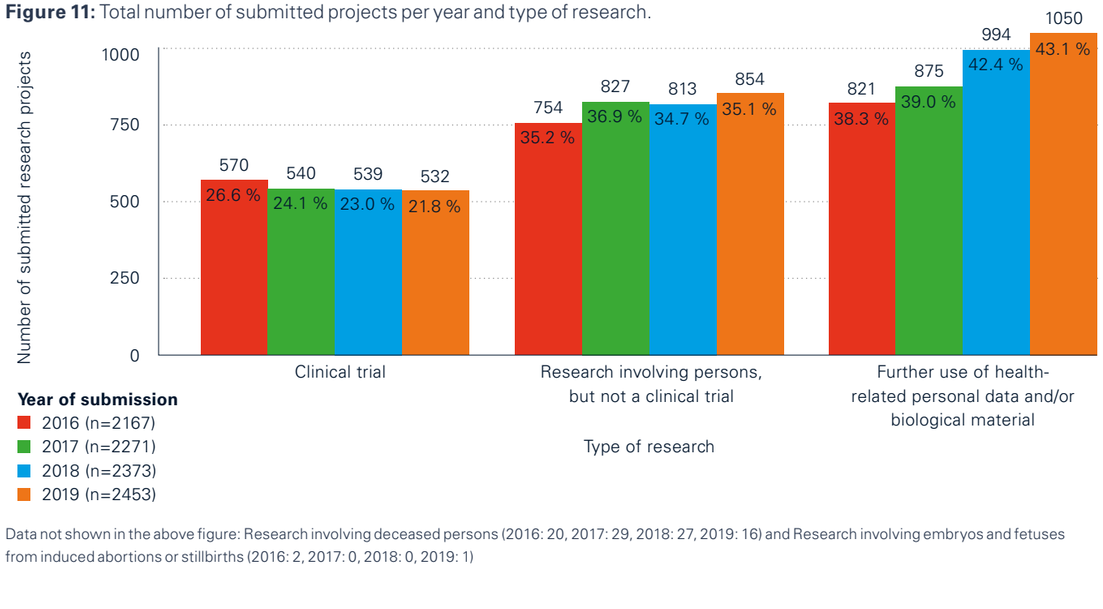
5.5 Stratification of response time by involvement of single or multiple ECs

➔ Information can be found in the Annex in section A.5

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 eommittee 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.

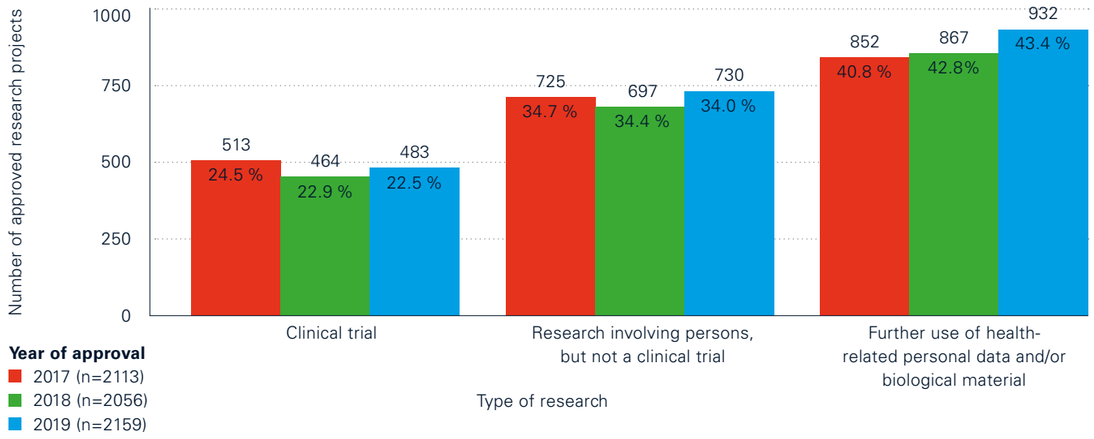


Data not shown in the above figure: Research involving deceased persons (2016: 20, 2017: 29, 2018: 27, 2019: 16) and Research involving embryos and fetuses from induced abortions or stillbirths (2016: 2, 2017: 0, 2018: 0, 2019: 1)

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

Note: In this chapter, specific parameters of the research projects approved in the reporting year and to compared previous back to 2017. 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.

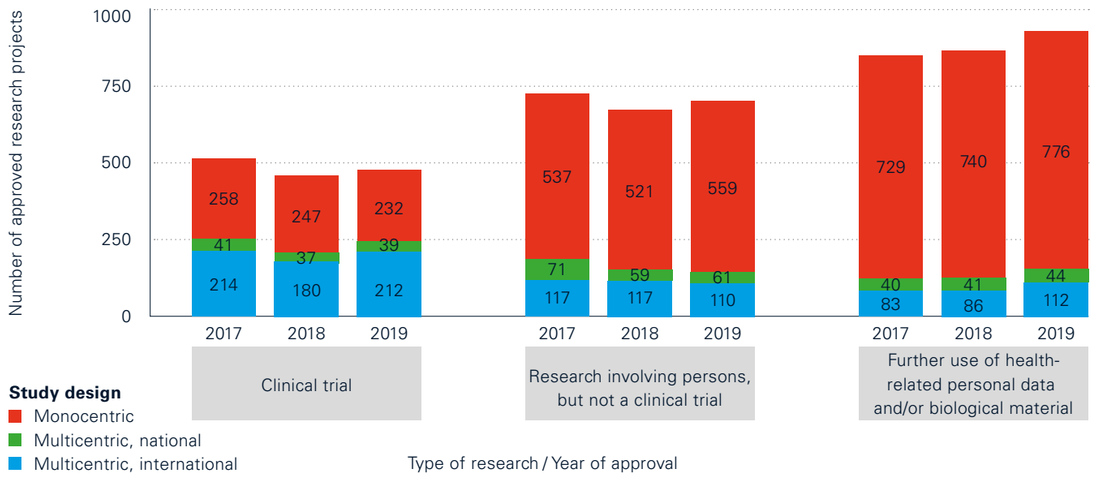
Figure 12: Total number of approved projects per year and type of research.



Data not shown in the above figure: Research involving deceased persons (2017: 22, 2018: 28, 2019: 14) and Research involving embryos and fetuses from induced abortions or stillbirths (2017: 1, 2018: 0, 2019: 0)

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

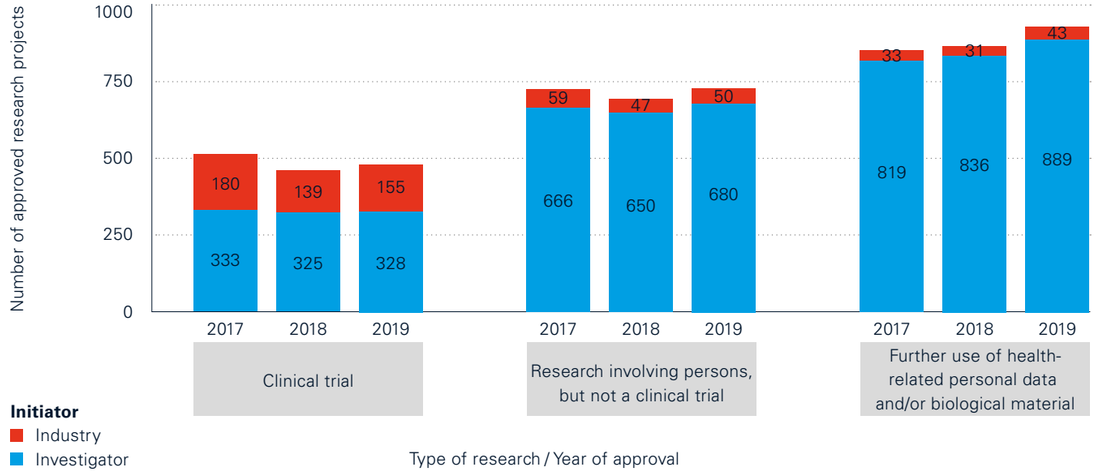
Figure 13: Approved projects per year stratified by type of research project and by study design.



Data not shown in the above figure: Research involving deceased persons (2017: 22, 2018: 28, 2019: 14) and Research involving embryos and fetuses from induced abortions or stillbirths (2017: 1, 2018: 0, 2019: 0)

7.2 Project initiator

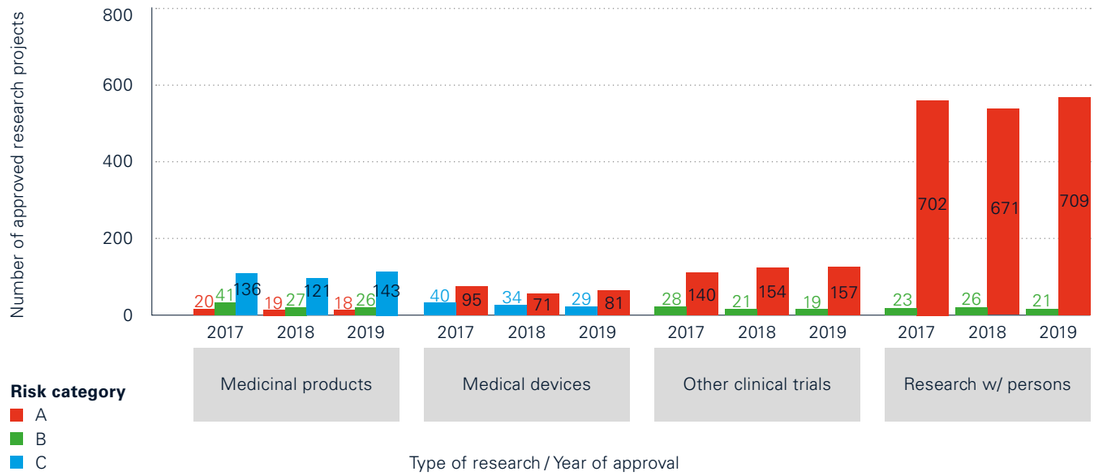
Figure 14: Approved projects per year stratified by type of research project and by project initiator.



Data not shown in the above figure: Research involving deceased persons (2017: 22, 2018: 28, 2019: 14) and Research involving embryos and fetuses from induced abortions or stillbirths (2017: 1, 2018: 0, 2019: 0)

7.3 Risk category

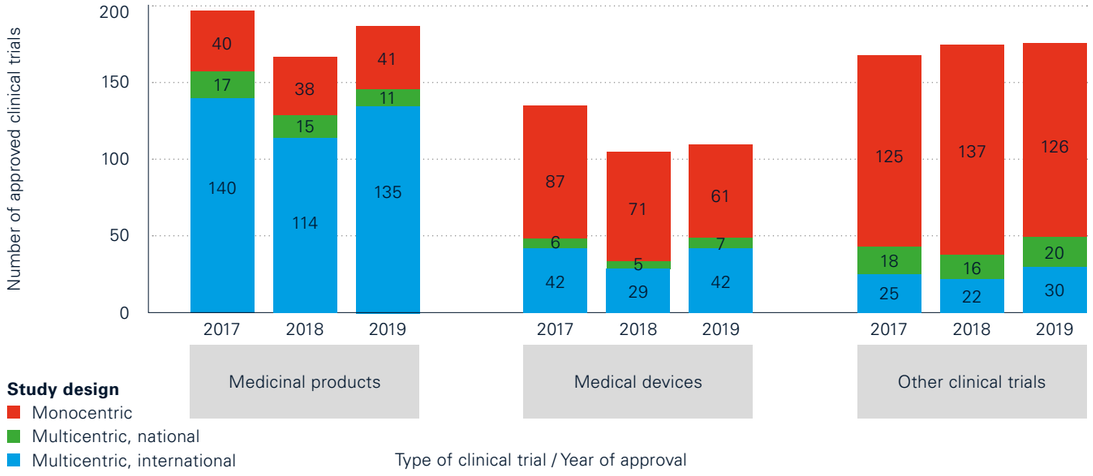
Figure 15: Clinical trials and research projects involving persons approved per year stratified by type of research project and risk category.



Data not shown in the above figure: Research involving transplant products (2017: 4, 2018: 9, 2019: 4), combination drugs/devices (2018: 4, 2019: 4) , gene therapy (2017: 0, 2018: 3, 2019: 2) and transplantation (2017: 0, 2018: 1, 2019: 0)

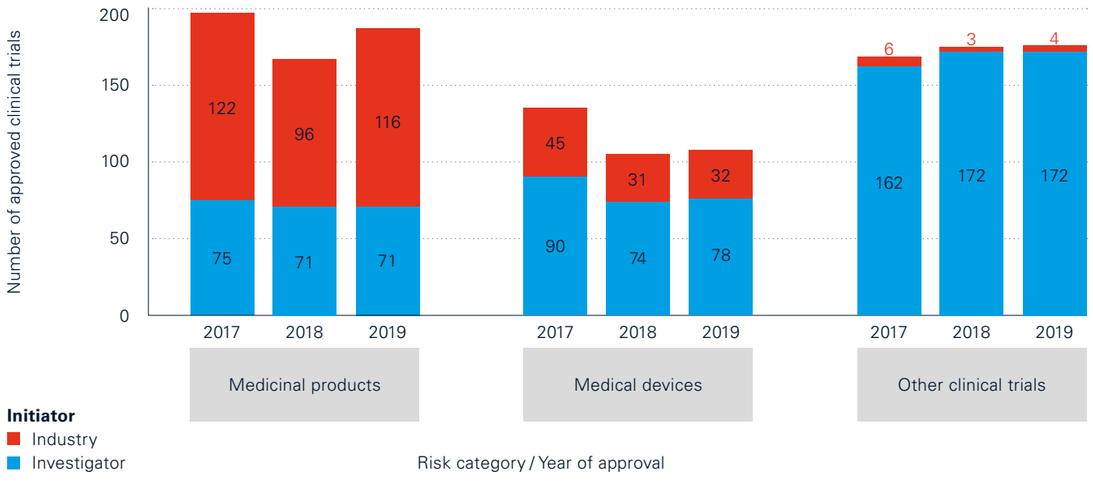
7.4 Subgroups of clinical trials

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: 9, 2019: 4), combination drugs/devices (2017: 9, 2018: 4, 2019: 4) , gene therapy (2017: 0, 2018: 3, 2019: 2) and transplantation (2017: 0, 2018: 1, 2019: 0)

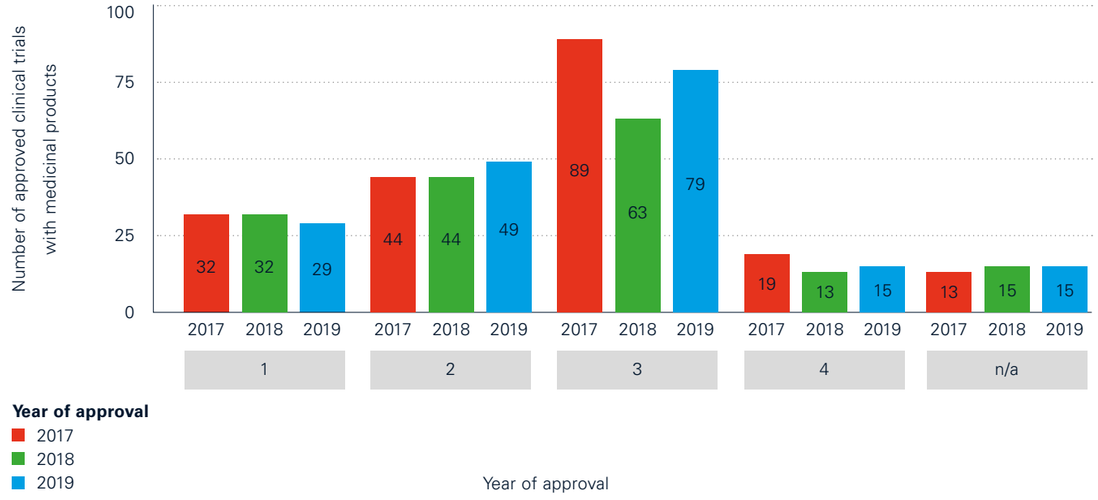
Figure 17: Clinical trials approved per year stratified by trial type and initiator.



Data not shown in the above figure: Research involving transplant products (2017: 4, 2018: 9, 2019: 4), combination drugs/devices (2017: 9, 2018: 4, 2019: 4) , gene therapy (2017: 0, 2018: 3, 2019: 2) and transplantation (2017: 0, 2018: 1, 2019: 0)

7.4.1 Clinical trials with medicinal products

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



Number of trials 'first in man': 2017: 6, 2018: 8, 2019: 5.

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. Number of trials 'first in man': 2017: 30, 2018: 20, 2019: 13

7.5 Subgroup Further use of data / biological material

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

		Approval year					
		2017		2018		2019	
		n	%	n	%	n	%
Genetic data / biol. material	Yes	173	19.1	217	20.1	247	21.3
	No	731	80.9	864	79.9	913	78.7
Coding (HRO Art. 25–27)	Coded	415	45.9	904	83.6	1004	86.6
	Open, non-coded	489	54.1	177	16.4	156	13.4
Consent (HRO Art. 28–32)	Prior consent exists	212	23.5	313	29.0	323	27.8
	Consent to be sought	134	14.8	234	21.6	257	22.2
	No consent Art. 34 HRA	558	61.7	534	49.4	580	50.0
Combined vs. stand-alone projects [1]	Stand-alone further use project	852	94.2	867	80.2	932	80.3
	Further use project as part of a clinical trial	19	2.1	41	3.8	45	3.9
	Further use project as part of a non-clinical research project	33	3.7	173	16.0	183	15.8
	Total number	904	100.0	1081	100.0	1160	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.

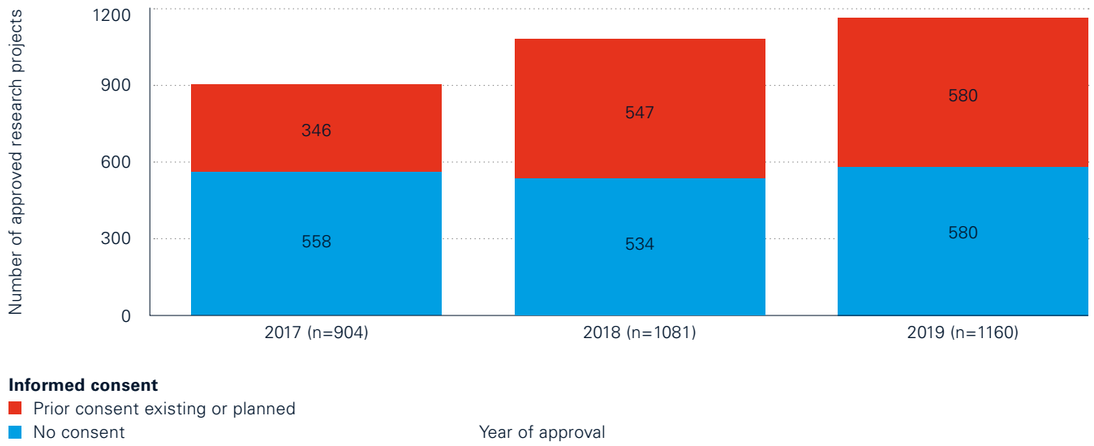
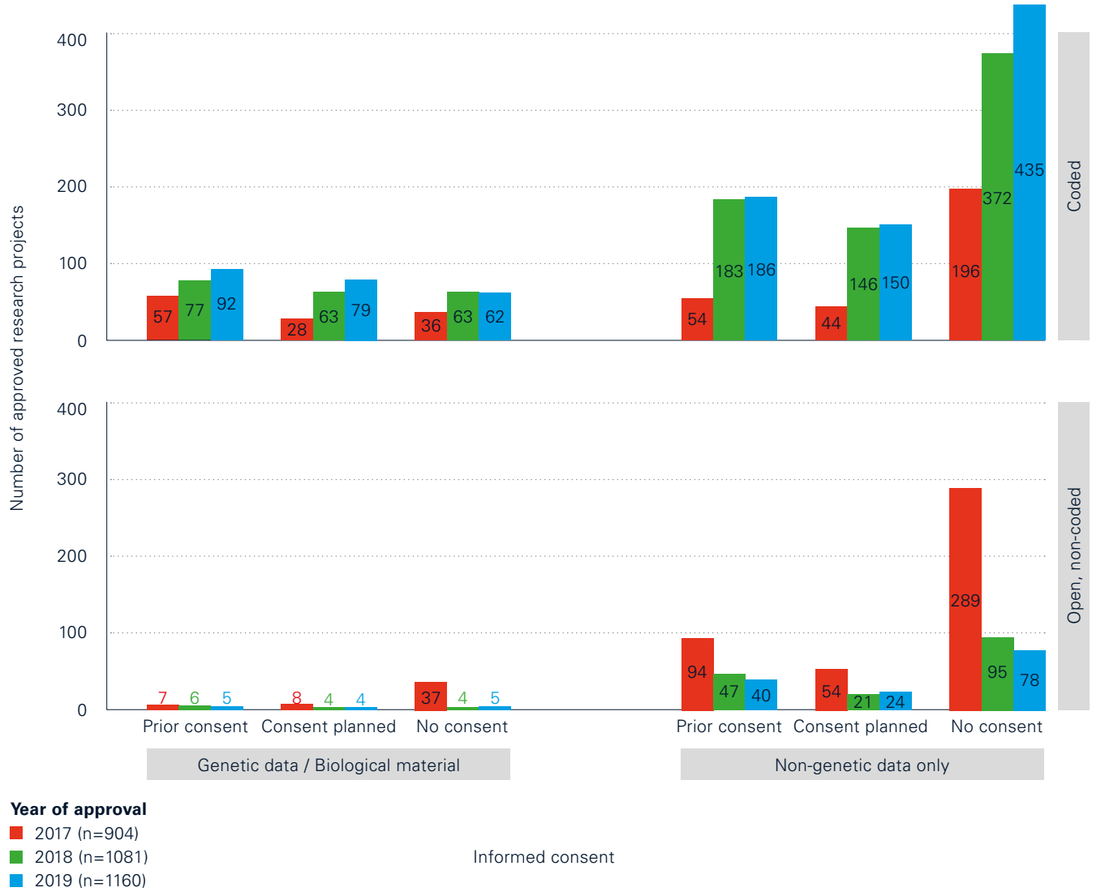
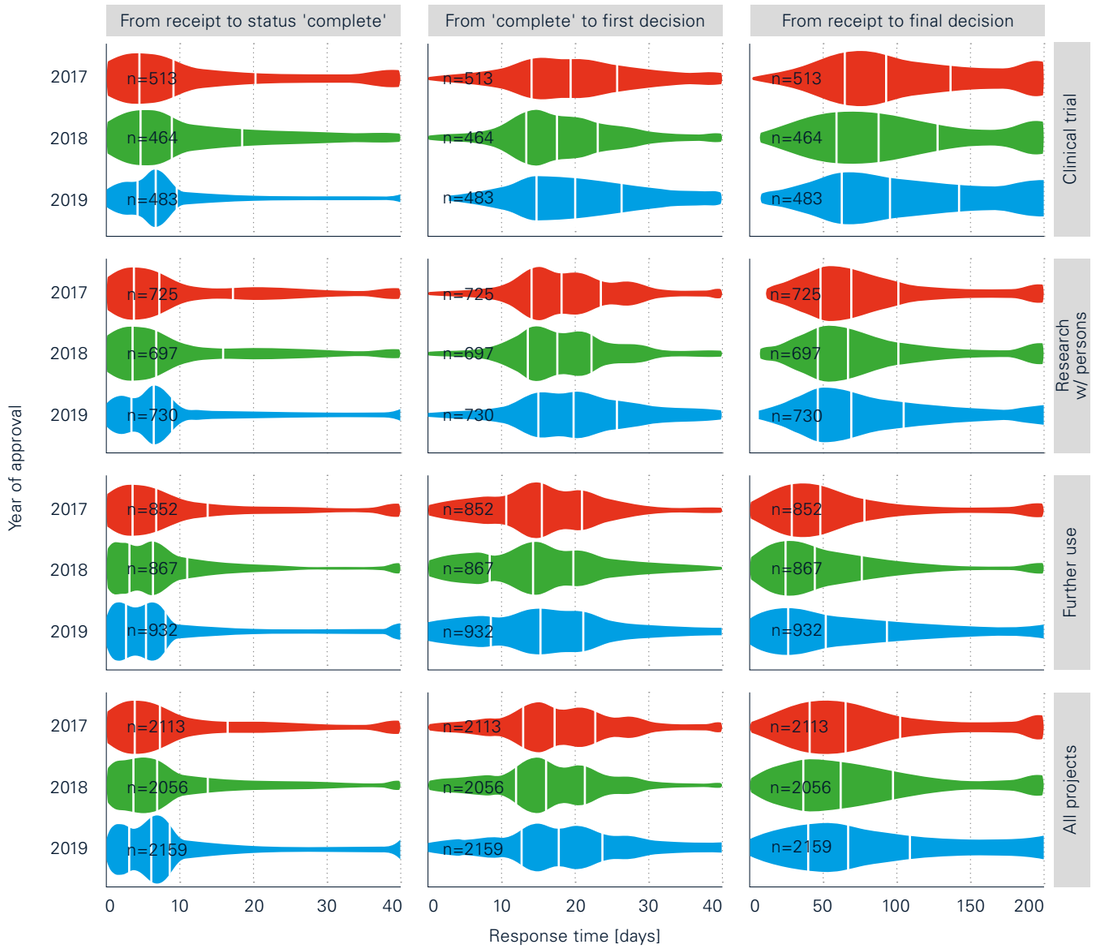


Figure 21: Number of approved 'further use' projects per year stratified by 1) Use of genetic data and/or biological material, 2) coded vs. uncoded, 3) consent for further use.



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 in the left and middle panel and to 200 days in 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 2019** per type of research.

	Reason					
	Rejections		Non-considerations		Withdrawals	
Type of research	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$
Clinical trial	14	31.1	6	6.7	1	5.9
Research involving persons, but not a clinical trial	19	42.2	43	48.3	11	64.7
Further use of health-related personal data and/or biological material	11	24.4	40	44.9	5	29.4
Research involving deceased persons	1	2.2	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	45	100.0	89	100.0	17	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.

			Total		Primarily for degree		What degree (multiple answers possible)					
							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	18	9.6								
		B	26	13.9	1	3.8	1	100.0				
		C	143	76.5	1	0.7	1	100.0				
		All	187	100.0	2	1.1	2	100.0				
	Medical devices	A	81	73.6	17	21.0	11	64.7	5	29.4	1	5.9
		C	29	26.4	1	3.4	1	100.0				
		All	110	100.0	18	16.4	12	66.7	5	27.8	1	5.6
	Other clinical trials	A	157	89.2	43	27.4	31	72.1	15	34.9	1	2.3
		B	19	10.8	2	10.5			2	100.0		
		All	176	100.0	45	25.6	31	68.9	17	37.8	1	2.2
	Combination drugs/devices	A	1	25.0								
		C	3	75.0								
		All	4	100.0								
	Transplant products	C	4	100.0								
		All	4	100.0								
	Gene therapy	C	2	100.0								
		All	2	100.0								
	Transplantation	All	0									
	All	All	483	100.0	65	13.5	45	69.2	22	33.8	2	3.1
Research w/ persons		A	709	97.1	218	30.7	111	50.9	98	45.0	13	6.0
		B	21	2.9	3	14.3	2	66.7	1	33.3		
		All	730	100.0	221	30.3	113	51.1	99	44.8	13	5.9
Further use		n.a.	932	100.0	372	39.9	220	59.1	155	41.7	8	2.2
Deceased, embryos		n.a.	14	100.0	4	28.6	4	100.0				
Total number			2159	100.0	662	30.7	382	57.7	276	41.7	23	3.5

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 involves any vulnerable persons – and if yes, what groups.

				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	18	4	22.2	2	50.0					1	25.0			1	25.0
		B	26	11	42.3	3	27.3	6	54.5	4	36.4	1	9.1	1	9.1		
		C	143	25	17.5	9	36.0	12	48.0	12	48.0	2	8.0	2	8.0	1	4.0
		All	187	40	21.4	14	35.0	18	45.0	16	40.0	4	10.0	3	7.5	2	5.0
	Medical devices	A	81	20	24.7	7	35.0	5	25.0	3	15.0	3	15.0	5	25.0	1	5.0
		C	29	5	17.2	3	60.0	1	20.0			1	20.0	1	20.0		
		All	110	25	22.7	10	40.0	6	24.0	3	12.0	4	16.0	6	24.0	1	4.0
	Other clinical trials	A	157	57	36.3	34	59.6	9	15.8	7	12.3	7	12.3	5	8.8	5	8.8
		B	19	11	57.9	5	45.5					1	9.1	2	18.2	3	27.3
		All	176	68	38.6	39	57.4	9	13.2	7	10.3	8	11.8	7	10.3	8	11.8
	Combination drugs/devices	A	1														
		C	3	1	33.3									1	100.0		
		All	4	1	25.0									1	100.0		
	Transplant products	C	4														
		All	4														
	Gene therapy	C	2														
		All	2														
	Transplantation	All	0														
	All	All	483	134	27.7	63	47.0	33	24.6	26	19.4	16	11.9	17	12.7	11	8.2
Research w/ persons		A	709	270	38.1	127	47.0	90	33.3	90	33.3	26	9.6	15	5.6	26	9.6
		B	21	5	23.8	4	80.0	1	20.0	1	20.0						
		All	730	275	37.7	131	47.6	91	33.1	91	33.1	26	9.5	15	5.5	26	9.5
Further use		n.a.	932														
Deceased, embryos		n.a.	14														
Total number			2159	409	18.9	194	47.4	124	30.3	117	28.6	42	10.3	32	7.8	37	9.0

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.

			Total		Ionising radiation involved			
					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	18	9.6	2	11.1		
		B	26	13.9	8	30.8	1	3.8
		C	143	76.5	49	34.3	7	4.9
		All	187	100.0	59	31.6	8	4.3
	Medical devices	A	81	73.6	12	14.8	1	1.2
		C	29	26.4	8	27.6		
		All	110	100.0	20	18.2	1	0.9
	Other clinical trials	A	157	89.2	11	7.0		
		B	19	10.8	5	26.3	1	5.3
		All	176	100.0	16	9.1	1	0.6
	Combination drugs/devices	A	1	25.0				
		C	3	75.0	1	33.3		
		All	4	100.0	1	25.0		
	Transplant products	C	4	100.0	4	100.0		
		All	4	100.0	4	100.0		
	Gene therapy	C	2	100.0				
		All	2	100.0				
	Transplantation	All	0					
	All	All	483	100.0	100	20.7	10	2.1
Research w/ persons		A	709	97.1	35	4.9		
		B	21	2.9	8	38.1		
		n.a.	730	100.0	43	5.9		
Total number			1213	100.0	143	11.8	10	0.8

A.3 Subgroups of research projects

A.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	91	28.9	57	62.6	12	13.2	22	24.2	36	39.6	7	7.7	48	52.7	21	23.1	70	76.9
		Double-blind	19	6.0	11	57.9			8	42.1	11	57.9	1	5.3	7	36.8	6	31.6	13	68.4
		Single-blind	27	8.6	25	92.6	1	3.7	1	3.7	18	66.7	3	11.1	6	22.2	3	11.1	24	88.9
	Placebo	Open	5	1.6	3	60.0	2	40.0			3	60.0	2	40.0					5	100.0
		Double-blind	93	29.5	18	19.4	9	9.7	66	71.0	28	30.1	4	4.3	61	65.6	51	54.8	42	45.2
		Single-blind	17	5.4	16	94.1	1	5.9			12	70.6	3	17.6	2	11.8	1	5.9	16	94.1
	Before/after	Open	6	1.9	5	83.3			1	16.7	4	66.7			2	33.3			6	100.0
		Single-blind	4	1.3	4	100.0					2	50.0			2	50.0			4	100.0
	Dosage	Open	6	1.9	2	33.3	1	16.7	3	50.0	3	50.0			3	50.0	2	33.3	4	66.7
		Double-blind	4	1.3	1	25.0	1	25.0	2	50.0	1	25.0			3	75.0	2	50.0	2	50.0
		Single-blind	1	0.3	1	100.0					1	100.0							1	100.0
	None	Open	29	9.2	18	62.1	3	10.3	8	27.6	13	44.8	3	10.3	13	44.8	7	24.1	22	75.9
		Double-blind	4	1.3	4	100.0					2	50.0	1	25.0	1	25.0			4	100.0
		Single-blind	9	2.9	9	100.0					9	100.0							9	100.0
		All	315	100.0	174	55.2	30	9.5	111	35.2	143	45.4	24	7.6	148	47.0	93	29.5	222	70.5
Non-random. controlled	Active	Open	9	18.8	3	33.3			6	66.7	6	66.7	1	11.1	2	22.2	2	22.2	7	77.8
	Before/after	Open	13	27.1	10	76.9	2	15.4	1	7.7	11	84.6			2	15.4			13	100.0
	Dosage	Open	2	4.2	1	50.0			1	50.0			1	50.0	1	50.0	1	50.0	1	50.0
	None	Open	24	50.0	9	37.5	2	8.3	13	54.2	11	45.8			13	54.2	15	62.5	9	37.5
		All	48	100.0	23	47.9	4	8.3	21	43.8	28	58.3	2	4.2	18	37.5	18	37.5	30	62.5
Not applicable	Active	Open	7	5.8	4	57.1	1	14.3	2	28.6	4	57.1			3	42.9	3	42.9	4	57.1
		Single-blind	1	0.8	1	100.0					1	100.0							1	100.0
	Before/after	Open	3	2.5	2	66.7	1	33.3			2	66.7	1	33.3					3	100.0
	Dosage	Open	1	0.8			1	100.0					1	100.0			1	100.0		
		Single-blind	1	0.8	1	100.0					1	100.0							1	100.0
	None	Open	104	86.7	49	47.1	8	7.7	47	45.2	50	48.1	11	10.6	43	41.3	40	38.5	64	61.5
		Single-blind	3	2.5	3	100.0					3	100.0							3	100.0
		All	120	100.0	60	50.0	11	9.2	49	40.8	61	50.8	13	10.8	46	38.3	44	36.7	76	63.3
Total number			483	100.0	257	53.2	45	9.3	181	37.5	232	48.0	39	8.1	212	43.9	155	32.1	328	67.9

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	91	28.9	1	1.1	74	81.3	11	12.1			5	5.5
		Double-blind	19	6.0			16	84.2	3	15.8				
		Single-blind	27	8.6	2	7.4	21	77.8	3	11.1			1	3.7
	Placebo	Open	5	1.6	1	20.0	2	40.0	2	40.0				
		Double-blind	93	29.5			75	80.6	13	14.0	2	2.2	3	3.2
		Single-blind	17	5.4			12	70.6	3	17.6			2	11.8
	Before/after	Open	6	1.9	1	16.7	1	16.7	1	16.7			3	50.0
		Single-blind	4	1.3	1	25.0	2	50.0	1	25.0				
	Dosage	Open	6	1.9			5	83.3	1	16.7				
		Double-blind	4	1.3			3	75.0	1	25.0				
		Single-blind	1	0.3			1	100.0						
	None	Open	29	9.2	1	3.4	21	72.4	5	17.2			2	6.9
		Double-blind	4	1.3			3	75.0	1	25.0				
		Single-blind	9	2.9			6	66.7	2	22.2	1	11.1		
		All	315	100.0	7	2.2	242	76.8	47	14.9	3	1.0	16	5.1
Non-random. controlled	Active	Open	9	18.8	1	11.1	4	44.4	2	22.2			2	22.2
	Before/after	Open	13	27.1	10	76.9	2	15.4					1	7.7
	Dosage	Open	2	4.2			1	50.0					1	50.0
	None	Open	24	50.0	23	95.8			1	4.2				
		All	48	100.0	34	70.8	7	14.6	3	6.2			4	8.3
Not applicable	Active	Open	7	5.8	3	42.9	1	14.3	1	14.3			2	28.6
		Single-blind	1	0.8	1	100.0								
	Before/after	Open	3	2.5	2	66.7							1	33.3
	Dosage	Open	1	0.8	1	100.0								
		Single-blind	1	0.8	1	100.0								
	None	Open	104	86.7	64	61.5	5	4.8	4	3.8			31	29.8
		Single-blind	3	2.5	2	66.7							1	33.3
		All	120	100.0	74	61.7	6	5.0	5	4.2			35	29.2
Total number			483	100.0	115	23.8	255	52.8	55	11.4	3	0.6	55	11.4

A.3.2 Subgroups of "Clinical trials with medicinal products"

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	187	38.7
Medical devices	Art 20	110	22.8
Other clinical trials	Art 61	176	36.4
Combination drugs/devices [1]		4	0.8
Transplant products	Art 21	4	0.8
Gene therapy	Art 22	2	0.4
Transplantation	Art 49	0	0.0
Total number		483	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.

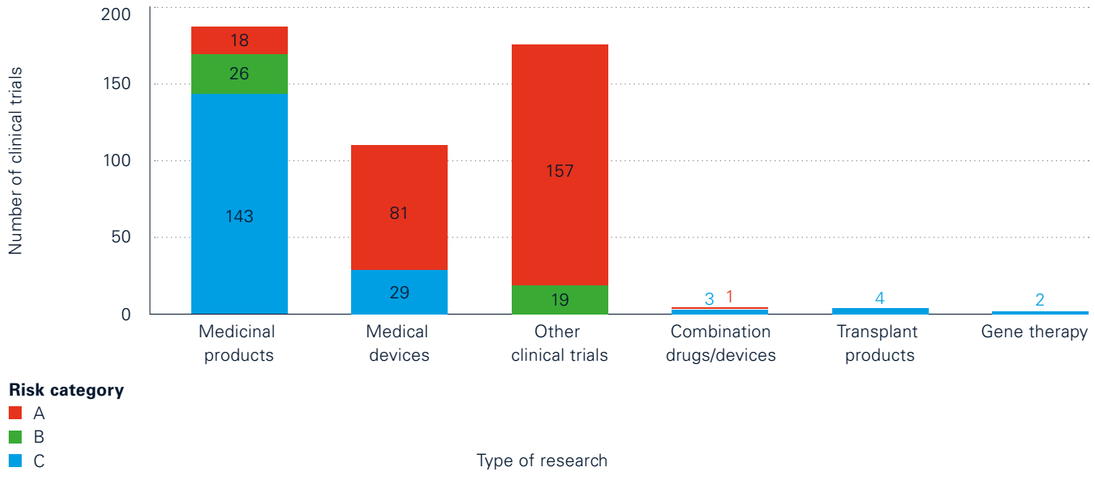


Figure 24: Stratification of all clinical trials by type of trial and study design.

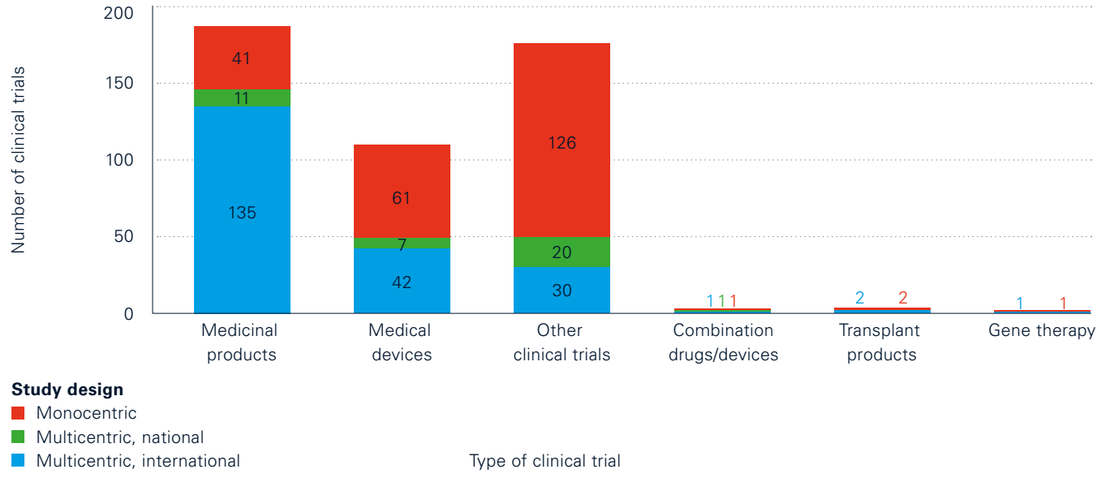
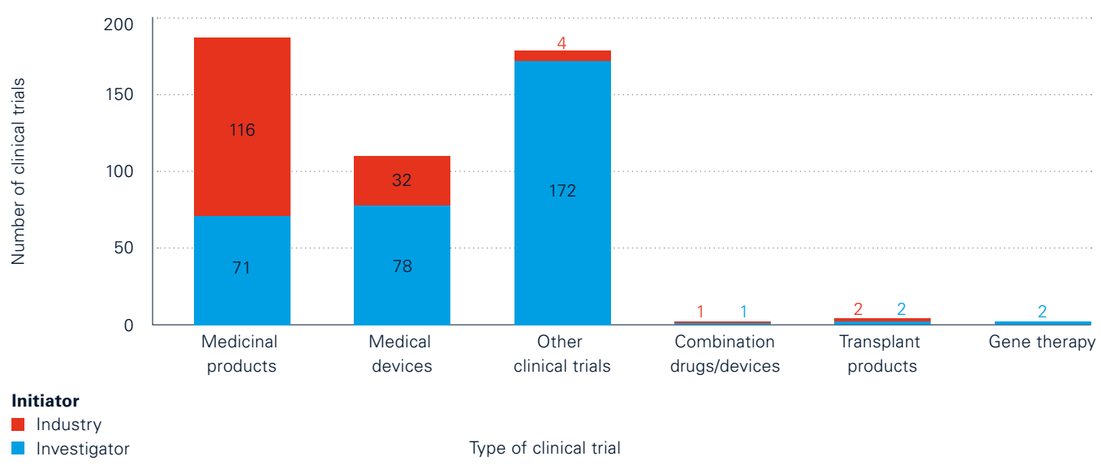


Figure 25: Stratification of all clinical trials by type of trial and initiator.



A.3.2.1 Subgroup "Clinical trials with medicinal products" (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	24.6	5	15.6	10	31.2	17	53.1	5	15.6			27	84.4	16	50.0	16	50.0
		Double-blind	9	6.9	2	22.2			7	77.8	3	33.3			6	66.7	6	66.7	3	33.3
		Single-blind	1	0.8	1	100.0					1	100.0							1	100.0
	Placebo	Open	2	1.5	1	50.0	1	50.0			2	100.0							2	100.0
		Double-blind	72	55.4	4	5.6	5	6.9	63	87.5	12	16.7	2	2.8	58	80.6	50	69.4	22	30.6
	Before/after	Open	1	0.8					1	100.0					1	100.0			1	100.0
	Dosage	Open	4	3.1	1	25.0			3	75.0	2	50.0			2	50.0	2	50.0	2	50.0
		Double-blind	3	2.3			1	33.3	2	66.7					3	100.0	2	66.7	1	33.3
	None	Open	6	4.6					6	100.0					6	100.0	5	83.3	1	16.7
		All	130	100.0	14	10.8	17	13.1	99	76.2	25	19.2	2	1.5	103	79.2	81	62.3	49	37.7
Non-random. controlled	Active	Open	3	15.8					3	100.0	2	66.7			1	33.3	1	33.3	2	66.7
	Before/after	Open	3	15.8	1	33.3	1	33.3	1	33.3	3	100.0							3	100.0
	Dosage	Open	1	5.3					1	100.0					1	100.0	1	100.0		
	None	Open	12	63.2	1	8.3	1	8.3	10	83.3	4	33.3			8	66.7	9	75.0	3	25.0
		All	19	100.0	2	10.5	2	10.5	15	78.9	9	47.4			10	52.6	11	57.9	8	42.1
Not applicable	Active	Open	3	7.1			1	33.3	2	66.7	1	33.3			2	66.7	3	100.0		
	Dosage	Open	1	2.4			1	100.0					1	100.0			1	100.0		
	None	Open	38	90.5	3	7.9	5	13.2	30	78.9	7	18.4	9	23.7	22	57.9	21	55.3	17	44.7
		All	42	100.0	3	7.1	7	16.7	32	76.2	8	19.0	10	23.8	24	57.1	25	59.5	17	40.5
Total number			191	100.0	19	9.9	26	13.6	146	76.4	42	22.0	12	6.3	137	71.7	117	61.3	74	38.7

The total number of 191 research projects consist of 187 medicinal product trials and 4 trials on a combination medicinal product and medical device.
n/a: Clinical trials for which the applicants have not indicated any phases or which do not fit in phase 1–4.

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

			Total		Phase[1]									
					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	24.6	3	9.4	6	18.8	18	56.2	3	9.4	2	6.2		
		Double-blind	9	6.9			2	22.2	4	44.4	1	11.1	2	22.2		
		Single-blind	1	0.8							1	100.0				
	Placebo	Open	2	1.5					1	50.0	1	50.0				
		Double-blind	72	55.4	4	5.6	16	22.2	42	58.3	6	8.3	4	5.6		
	Before/after	Open	1	0.8					1	100.0						
	Dosage	Open	4	3.1			2	50.0	1	25.0			1	25.0		
		Double-blind	3	2.3			1	33.3	2	66.7						
	None	Open	6	4.6	3	50.0	1	16.7	2	33.3					1	16.7
		All	130	100.0	10	7.7	28	21.5	71	54.6	12	9.2	9	6.9	1	0.8
Non-random. controlled	Active	Open	3	15.8			2	66.7					1	33.3		
	Before/after	Open	3	15.8			2	66.7			1	33.3				
	Dosage	Open	1	5.3					1	100.0						
	None	Open	12	63.2	6	50.0	2	16.7	3	25.0			1	8.3	1	8.3
		All	19	100.0	6	31.6	6	31.6	4	21.1	1	5.3	2	10.5	1	5.3
Not applicable	Active	Open	3	7.1					1	33.3	2	66.7				
	Dosage	Open	1	2.4	1	100.0										
	None	Open	38	90.5	13	34.2	16	42.1	3	7.9	2	5.3	4	10.5	3	7.9
		All	42	100.0	14	33.3	16	38.1	4	9.5	4	9.5	4	9.5	3	7.1
Total number			191	100.0	30	15.7	50	26.2	79	41.4	17	8.9	15	7.9	5	2.6

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		Factorial		Other or n/a	
Allocation	Control	Masking	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Randomised controlled	Active	Open	32	24.6			26	81.2	4	12.5			2	6.2
		Double-blind	9	6.9			9	100.0						
		Single-blind	1	0.8			1	100.0						
	Placebo	Open	2	1.5			1	50.0	1	50.0				
		Double-blind	72	55.4			64	88.9	5	6.9	1	1.4	2	2.8
	Before/after	Open	1	0.8			1	100.0						
	Dosage	Open	4	3.1			4	100.0						
		Double-blind	3	2.3			3	100.0						
	None	Open	6	4.6			4	66.7	1	16.7			1	16.7
		All	130	100.0			113	86.9	11	8.5	1	0.8	5	3.8
Non-random. controlled	Active	Open	3	15.8			1	33.3	1	33.3			1	33.3
	Before/after	Open	3	15.8	3	100.0								
	Dosage	Open	1	5.3									1	100.0
	None	Open	12	63.2	12	100.0								
		All	19	100.0	15	78.9	1	5.3	1	5.3			2	10.5
Not applicable	Active	Open	3	7.1	3	100.0								
	Dosage	Open	1	2.4	1	100.0								
	None	Open	38	90.5	31	81.6	1	2.6	1	2.6			5	13.2
		All	42	100.0	35	83.3	1	2.4	1	2.4			5	11.9
Total number			191	100.0	50	26.2	115	60.2	13	6.8	1	0.5	12	6.3

A.3.2.2 Subgroup "Clinical trials with medical devices" (ClinO Art. 20)

Table 37: Stratification of **clinical trials with medical devices** 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	19	33.3	16	84.2	3	15.8	6	31.6	2	10.5	11	57.9	3	15.8	16	84.2
		Double-blind	2	3.5	1	50.0	1	50.0	1	50.0			1	50.0			2	100.0
		Single-blind	10	17.5	9	90.0	1	10.0	7	70.0	1	10.0	2	20.0	2	20.0	8	80.0
	Placebo	Double-blind	8	14.0	5	62.5	3	37.5	5	62.5	1	12.5	2	25.0	1	12.5	7	87.5
		Single-blind	7	12.3	7	100.0			6	85.7			1	14.3	1	14.3	6	85.7
	Before/after	Single-blind	1	1.8	1	100.0			1	100.0							1	100.0
	Dosage	Single-blind	1	1.8	1	100.0			1	100.0							1	100.0
	None	Open	6	10.5	4	66.7	2	33.3	3	50.0	1	16.7	2	33.3	2	33.3	4	66.7
		Double-blind	1	1.8	1	100.0							1	100.0			1	100.0
		Single-blind	2	3.5	2	100.0			2	100.0							2	100.0
		All	57	100.0	47	82.5	10	17.5	32	56.1	5	8.8	20	35.1	9	15.8	48	84.2
Non-random. controlled	Active	Open	4	25.0	1	25.0	3	75.0	2	50.0	1	25.0	1	25.0	1	25.0	3	75.0
	Before/after	Open	3	18.8	3	100.0			3	100.0							3	100.0
	None	Open	9	56.2	6	66.7	3	33.3	4	44.4			5	55.6	6	66.7	3	33.3
		All	16	100.0	10	62.5	6	37.5	9	56.2	1	6.2	6	37.5	7	43.8	9	56.2
Not applicable	Active	Open	1	2.4	1	100.0							1	100.0			1	100.0
		Single-blind	1	2.4	1	100.0			1	100.0							1	100.0
	Dosage	Single-blind	1	2.4	1	100.0			1	100.0							1	100.0
	None	Open	37	90.2	21	56.8	16	43.2	18	48.6	2	5.4	17	45.9	17	45.9	20	54.1
		Single-blind	1	2.4	1	100.0			1	100.0							1	100.0
		All	41	100.0	25	61.0	16	39.0	21	51.2	2	4.9	18	43.9	17	41.5	24	58.5
Total number			114	100.0	82	71.9	32	28.1	62	54.4	8	7.0	44	38.6	33	28.9	81	71.1

The total number of 114 research projects consist of 110 trials with medical devices and 4 trials on a combination medicinal product and medical device.

Table 38: Stratification of **clinical trials with medical devices** 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	19	33.3			16	84.2	2	10.5			1	5.3
		Double-blind	2	3.5			1	50.0	1	50.0				
		Single-blind	10	17.5	1	10.0	9	90.0						
	Placebo	Double-blind	8	14.0			6	75.0			1	12.5	1	12.5
		Single-blind	7	12.3			6	85.7	1	14.3				
	Before/after	Single-blind	1	1.8	1	100.0								
	Dosage	Single-blind	1	1.8			1	100.0						
	None	Open	6	10.5	1	16.7	4	66.7	1	16.7				
		Double-blind	1	1.8			1	100.0						
		Single-blind	2	3.5			1	50.0			1	50.0		
		All	57	100.0	3	5.3	45	78.9	5	8.8	2	3.5	2	3.5
Non-random. controlled	Active	Open	4	25.0			2	50.0	1	25.0			1	25.0
	Before/after	Open	3	18.8	3	100.0								
	None	Open	9	56.2	9	100.0								
		All	16	100.0	12	75.0	2	12.5	1	6.2			1	6.2
Not applicable	Active	Open	1	2.4									1	100.0
		Single-blind	1	2.4	1	100.0								
	Dosage	Single-blind	1	2.4	1	100.0								
	None	Open	37	90.2	22	59.5	3	8.1	2	5.4			10	27.0
		Single-blind	1	2.4	1	100.0								
		All	41	100.0	25	61.0	3	7.3	2	4.9			11	26.8
Total number			114	100.0	40	35.1	50	43.9	8	7.0	2	1.8	14	12.3

Table 39: Stratification of **clinical trials with medical devices** by CE-marking status of the medical device, whether the medical device was used as intended or not 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	19	33.3	17	89.5			2	10.5	1	5.3
		Double-blind	2	3.5	1	50.0			1	50.0		
		Single-blind	10	17.5	8	80.0			1	10.0	2	20.0
	Placebo	Double-blind	8	14.0	6	75.0			1	12.5	1	12.5
		Single-blind	7	12.3	7	100.0						
	Before/after	Single-blind	1	1.8	1	100.0						
	Dosage	Single-blind	1	1.8	1	100.0						
	None	Open	6	10.5	4	66.7	2	33.3			1	16.7
		Double-blind	1	1.8	1	100.0						
		Single-blind	2	3.5	2	100.0						
		All	57	100.0	48	84.2	2	3.5	5	8.8	5	8.8
Non-random. controlled	Active	Open	4	25.0	1	25.0	1	25.0	2	50.0	1	25.0
	Before/after	Open	3	18.8	3	100.0						
	None	Open	9	56.2	6	66.7			3	33.3	1	11.1
		All	16	100.0	10	62.5	1	6.2	5	31.2	2	12.5
Not applicable	Active	Open	1	2.4	1	100.0						
		Single-blind	1	2.4	1	100.0						
	Dosage	Single-blind	1	2.4	1	100.0						
	None	Open	37	90.2	22	59.5	3	8.1	10	27.0	6	16.2
		Single-blind	1	2.4	1	100.0						
		All	41	100.0	26	63.4	3	7.3	10	24.4	6	14.6
Total number			114	100.0	84	73.7	6	5.3	20	17.5	13	11.4

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. Note: 3 of 84 clinical trials with medical devices with 'used as intended' 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	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Randomised controlled	Active	Open	38	29.9	36	94.7	2	5.3	25	65.8	5	13.2	8	21.1			38	100.0
		Double-blind	8	6.3	8	100.0			7	87.5	1	12.5					8	100.0
		Single-blind	17	13.4	16	94.1	1	5.9	11	64.7	2	11.8	4	23.5	1	5.9	16	94.1
	Placebo	Open	3	2.4	2	66.7	1	33.3	1	33.3	2	66.7					3	100.0
		Double-blind	13	10.2	9	69.2	4	30.8	11	84.6	1	7.7	1	7.7			13	100.0
		Single-blind	10	7.9	9	90.0	1	10.0	6	60.0	3	30.0	1	10.0			10	100.0
	Before/after	Open	5	3.9	5	100.0			4	80.0			1	20.0			5	100.0
		Single-blind	3	2.4	3	100.0			1	33.3			2	66.7			3	100.0
	Dosage	Open	2	1.6	1	50.0	1	50.0	1	50.0			1	50.0			2	100.0
		Double-blind	1	0.8	1	100.0			1	100.0							1	100.0
	None	Open	17	13.4	14	82.4	3	17.6	10	58.8	2	11.8	5	29.4			17	100.0
		Double-blind	3	2.4	3	100.0			2	66.7	1	33.3					3	100.0
		Single-blind	7	5.5	7	100.0			7	100.0							7	100.0
		All	127	100.0	114	89.8	13	10.2	87	68.5	17	13.4	23	18.1	1	0.8	126	99.2
Non-random. controlled	Active	Open	2	15.4	2	100.0			2	100.0							2	100.0
	Before/after	Open	7	53.8	6	85.7	1	14.3	5	71.4			2	28.6			7	100.0
	Dosage	Open	1	7.7	1	100.0					1	100.0					1	100.0
	None	Open	3	23.1	2	66.7	1	33.3	3	100.0							3	100.0
		All	13	100.0	11	84.6	2	15.4	10	76.9	1	7.7	2	15.4			13	100.0
Not applicable	Active	Open	3	8.3	3	100.0			3	100.0							3	100.0
	Before/after	Open	3	8.3	2	66.7	1	33.3	2	66.7	1	33.3					3	100.0
	None	Open	28	77.8	25	89.3	3	10.7	22	78.6	1	3.6	5	17.9	3	10.7	25	89.3
		Single-blind	2	5.6	2	100.0			2	100.0							2	100.0
		All	36	100.0	32	88.9	4	11.1	29	80.6	2	5.6	5	13.9	3	8.3	33	91.7
Total number			176	100.0	157	89.2	19	10.8	126	71.6	20	11.4	30	17.0	4	2.3	172	97.7

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	38	29.9	1	2.6	30	78.9	5	13.2			2	5.3
		Double-blind	8	6.3			6	75.0	2	25.0				
		Single-blind	17	13.4	1	5.9	12	70.6	3	17.6			1	5.9
	Placebo	Open	3	2.4	1	33.3	1	33.3	1	33.3				
		Double-blind	13	10.2			4	30.8	8	61.5	1	7.7		
		Single-blind	10	7.9			6	60.0	2	20.0			2	20.0
	Before/after	Open	5	3.9	1	20.0			1	20.0			3	60.0
		Single-blind	3	2.4			2	66.7	1	33.3				
	Dosage	Open	2	1.6			1	50.0	1	50.0				
		Double-blind	1	0.8					1	100.0				
	None	Open	17	13.4			13	76.5	3	17.6			1	5.9
		Double-blind	3	2.4			2	66.7	1	33.3				
		Single-blind	7	5.5			5	71.4	2	28.6				
		All	127	100.0	4	3.1	82	64.6	31	24.4	1	0.8	9	7.1
Non-random. controlled	Active	Open	2	15.4	1	50.0	1	50.0						
	Before/after	Open	7	53.8	4	57.1	2	28.6					1	14.3
	Dosage	Open	1	7.7			1	100.0						
	None	Open	3	23.1	2	66.7			1	33.3				
		All	13	100.0	7	53.8	4	30.8	1	7.7			1	7.7
Not applicable	Active	Open	3	8.3			1	33.3	1	33.3			1	33.3
	Before/after	Open	3	8.3	2	66.7							1	33.3
	None	Open	28	77.8	10	35.7	1	3.6	1	3.6			16	57.1
		Single-blind	2	5.6	1	50.0							1	50.0
		All	36	100.0	13	36.1	2	5.6	2	5.6			19	52.8
Total number			176	100.0	24	13.6	88	50.0	34	19.3	1	0.6	29	16.5

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	251	34.4	55	21.9	34	61.8	22	40.0	1	1.8
Registry / Quality control	63	8.6	10	15.9	3	30.0	6	60.0	1	10.0
Case control study	64	8.8	18	28.1	10	55.6	7	38.9	1	5.6
Other or n/a	352	48.2	138	39.2	66	47.8	64	46.4	10	7.2
Total number	730	100.0	221	30.3	113	51.1	99	44.8	13	5.9

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

			Lead 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	251	34.4	62	34.4	64	37.9	39	27.3	39	38.6	29	31.9	11	36.7	7	43.8
Registry / Quality control	63	8.6	20	11.1	19	11.2	7	4.9	6	5.9	9	9.9	1	3.3	1	6.2
Case control study	64	8.8	25	13.9	16	9.5	7	4.9	8	7.9	6	6.6	1	3.3	1	6.2
Other or n/a	352	48.2	73	40.6	70	41.4	90	62.9	48	47.5	47	51.6	17	56.7	7	43.8
Total number	730	100.0	180	100.0	169	100.0	143	100.0	101	100.0	91	100.0	30	100.0	16	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	251	34.4	21	8.4	230	91.6			20	8.0	77	30.7	153	61.0	1	0.4
Registry / Quality control	63	8.6	4	6.3	58	92.1	1	1.6	2	3.2	19	30.2	42	66.7		
Case control study	64	8.8	4	6.2	59	92.2	1	1.6	5	7.8	12	18.8	47	73.4		
Other or n/a	352	48.2	23	6.5	324	92.0	5	1.4	16	4.5	106	30.1	229	65.1	1	0.3
Total number	730	100.0	52	7.1	671	91.9	7	1.0	43	5.9	214	29.3	471	64.5	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	92	39.5	8	8.7	5	62.5	3	37.5		
		Consent to be sought	79	33.9	5	6.3	2	40.0	1	20.0	2	40.0
		No consent Art. 34 HRA	62	26.6	24	38.7	16	66.7	8	33.3		
		All	233	100.0	37	15.9	23	62.2	12	32.4	2	5.4
	Open, non-coded	Prior consent exists	5	35.7	2	40.0	2	100.0				
		Consent to be sought	4	28.6	2	50.0	2	100.0				
		No consent Art. 34 HRA	5	35.7	2	40.0	1	50.0	1	50.0		
		All	14	100.0	6	42.9	5	83.3	1	16.7		
	All		247	100.0	43	17.4	28	65.1	13	30.2	2	4.7
No	Coded	Prior consent exists	186	24.1	74	39.8	41	55.4	32	43.2	2	2.7
		Consent to be sought	150	19.5	44	29.3	20	45.5	24	54.5		
		No consent Art. 34 HRA	435	56.4	211	48.5	127	60.2	86	40.8	4	1.9
		All	771	100.0	329	42.7	188	57.1	142	43.2	6	1.8
	Open, non-coded	Prior consent exists	40	28.2	12	30.0	7	58.3	6	50.0		
		Consent to be sought	24	16.9	7	29.2	6	85.7	2	28.6		
		No consent Art. 34 HRA	78	54.9	35	44.9	24	68.6	13	37.1	1	2.9
		All	142	100.0	54	38.0	37	68.5	21	38.9	1	1.9
	All		913	100.0	383	41.9	225	58.7	163	42.6	7	1.8
Total number			1160	100.0	426	36.7	253	59.4	176	41.3	9	2.1

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		Declined	
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	92	39.5	4	4.3	32	34.8	56	60.9	44	47.8	13	14.1	35	38.0		
		Consent to be sought	79	33.9	15	19.0	50	63.3	14	17.7	9	11.4	22	27.8	48	60.8		
		No consent Art. 34 HRA	62	26.6	1	1.6	61	98.4			7	11.3	24	38.7	31	50.0		
		All	233	100.0	20	8.6	143	61.4	70	30.0	60	25.8	59	25.3	114	48.9		
	Open, non-coded	Prior consent exists	5	35.7			1	20.0	4	80.0	3	60.0			2	40.0		
		Consent to be sought	4	28.6			3	75.0	1	25.0	1	25.0			3	75.0		
		No consent Art. 34 HRA	5	35.7			5	100.0			2	40.0	2	40.0	1	20.0		
		All	14	100.0			9	64.3	5	35.7	6	42.9	2	14.3	6	42.9		
	All		247	100.0	20	8.1	152	61.5	75	30.4	66	26.7	61	24.7	120	48.6		
No	Coded	Prior consent exists	186	24.1	5	2.7	72	38.7	109	58.6	77	41.4	34	18.3	75	40.3		
		Consent to be sought	150	19.5	7	4.7	113	75.3	30	20.0	24	16.0	21	14.0	104	69.3	1	0.7
		No consent Art. 34 HRA	435	56.4	11	2.5	420	96.6	4	0.9	75	17.2	161	37.0	199	45.7		
		All	771	100.0	23	3.0	605	78.5	143	18.5	176	22.8	216	28.0	378	49.0	1	0.1
	Open, non-coded	Prior consent exists	40	28.2			13	32.5	27	67.5	22	55.0	3	7.5	15	37.5		
		Consent to be sought	24	16.9	2	8.3	13	54.2	9	37.5	7	29.2	5	20.8	12	50.0		
		No consent Art. 34 HRA	78	54.9			76	97.4	2	2.6	12	15.4	12	15.4	54	69.2		
		All	142	100.0	2	1.4	102	71.8	38	26.8	41	28.9	20	14.1	81	57.0		
All			913	100.0	25	2.7	707	77.4	181	19.8	217	23.8	236	25.8	459	50.3	1	0.1
Total number			1160	100.0	45	3.9	859	74.1	256	22.1	283	24.4	297	25.6	579	49.9	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.

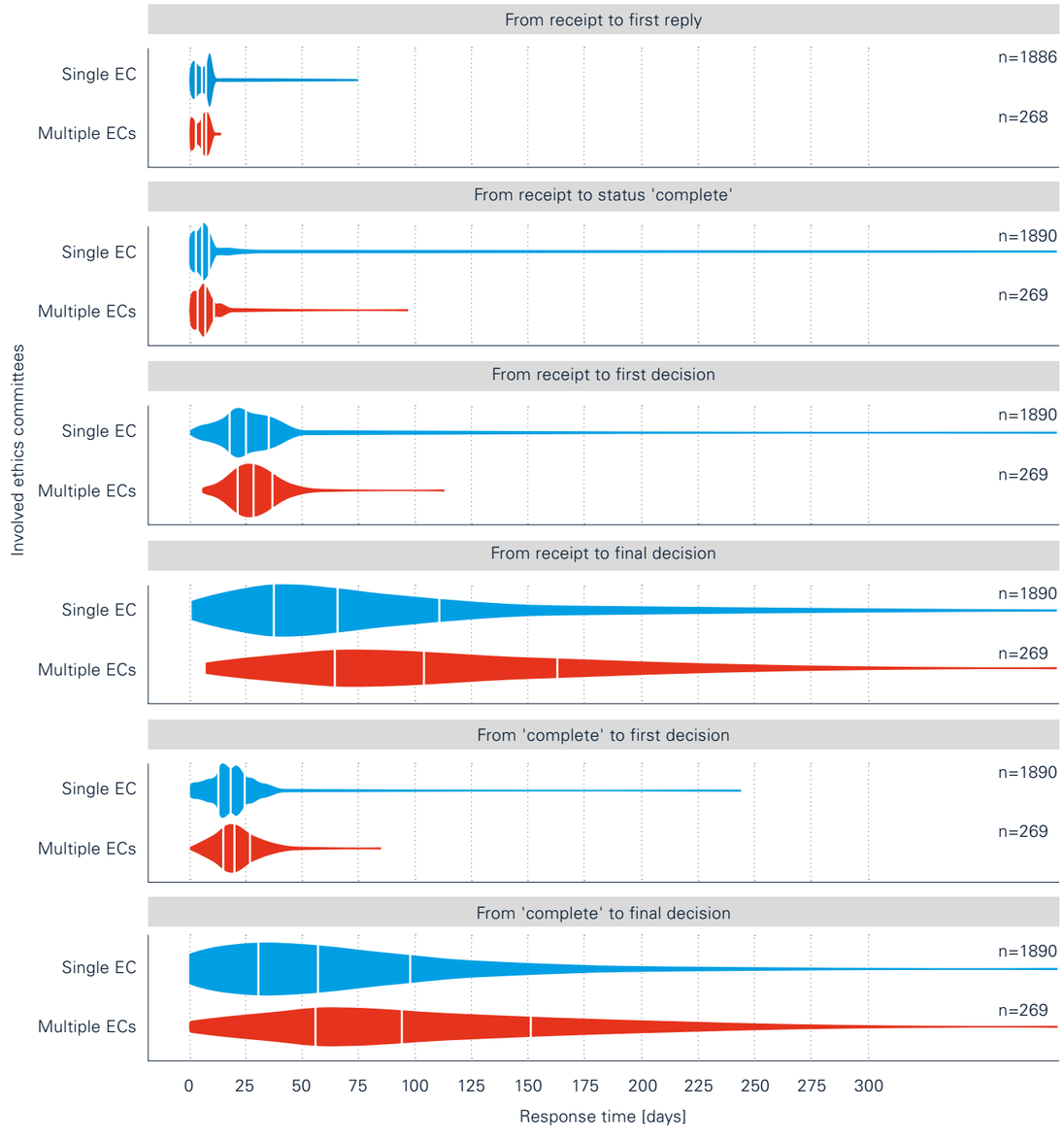
Applicant	Type of research	n	$\%_{col}$
Project leader / PI [1]	Clinical trial	256	14.4
	Research w/ persons	652	36.7
	Further use	854	48.1
	Deceased, embryos	14	0.8
	Total	1776	100.0
Sponsor	Clinical trial	97	54.5
	Research w/ persons	46	25.8
	Further use	35	19.7
	Deceased, embryos	0	0.0
	Total	178	100.0
Sponsor's representative in CH	Clinical trial	66	54.5
	Research w/ persons	21	17.4
	Further use	34	28.1
	Deceased, embryos	0	0.0
	Total	121	100.0
CRO	Clinical trial	64	76.2
	Research w/ persons	11	13.1
	Further use	9	10.7
	Deceased, embryos	0	0.0
	Total	84	100.0
Overall	Clinical trial	483	22.4
	Research w/ persons	730	33.8
	Further use	932	43.2
	Deceased, embryos	14	0.6
	Total	2159	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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