Medicine & Research
Statistical Report

Human Research in Switzerland 2022

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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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 with the exception of Clinical Trials of Medical Devices (Clinical Trials Ordinance)
ClinO-MD	Ordinance on Clinical Trials of Medical Devices
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
COVID-19	Coronavirus Disease 2019

1 Introduction

This report describes all human research projects submitted to and approved by the Ethics Committees in Switzerland in the year 2022 (chapters 2 to 5). In addition, chapters 6 and 7 provide a longitudinal comparison over the years 2015 (submitted projects) and 2016 (approved projects), respectively, up to the year 2022. The data used for the present analysis come from the Business Administration System for Ethics Committees, BASEC.

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 and approved research projects provides a unique opportunity for a comprehensive overview on the Swiss human research landscape.

1.1 Influence of the COVID-19 pandemic

The COVID-19 pandemic, with its first detected positive case in Switzerland in February 2020, did influence human research projects in Switzerland in a global way. Assuming that the COVID-19 pandemic had a specific effect on the number of applications and the type of research, as well as on procedures and processing times by the Ethics Committees, it was decided that the 2020 as well as the 2021 report should distinguish between COVID-19 specific and non-COVID-19 specific applications and authorizations for selected tables and figures. With the ongoing decline of COVID-19 cases in 2022, and thus the decline in COVID-19-related research applications to the Ethics Committees, it was decided to no longer make the distinction between COVID-19 and non-COVID-19 specific applications for the reports from 2022 onwards. In total, 36 COVID-19 projects were submitted in 2022 (clinical trials: 8, non-clinical trials involving persons: 7, further use personal data/biological material: 21).

1.2 Influence of the ClinO-MD

On 26 May 2022, the legal basis for clinical trials with in-vitro diagnostic (IVD) products changed: Previously regulated by the Ordinance on Clinical Trials with the Exception of Clinical Trials of Medical Devices (ClinO), IVD products have since been regulated in the Ordinance on Clinical Trials with Medical Devices (ClinO-MD). With the change in the legal basis for IVD products as of May 26, 2022, clinical trials involving IVD products are subject to the following changes: First, they undergo a specific categorization into one of the categories A1, A2, C1, C2 or C3 as is already the case for clinical trials with regular medical devices (see Article 6 and 6a of the ClinO-MD). Second, they are subject to maximal response times other than the ones for clinical trials involving drugs and other types of clinical trials (see Articles 12 and Articles 13 of the ClinO-MD). This change is reflected in the current report in table 4, which shows the categorization of all submitted clinical trials with medical devices and IVD products displayed in the new sub-categories A1, A2, C1, C2, C3, and also in table 25.1, where the response times for medical devices, including IVD products, are displayed separately for the 101 approved ClinO-MD projects. Apart from this, the presentation of clinical trials with medical devices in chapters 3, 4, 6 and 7 of this statistics report have remained the same as in previous years.

1.3 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 1.5.

First, an overview on the BASEC data in the true calendar year 2022 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 2022. 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 2022 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 seven years (2016, 2017, 2018, 2019, 2020, 2021, 2022) and for approved projects (AS2) over six years (2017, 2018, 2019, 2020, 2021, 2022). The reason for this difference in the years compared is described in section 1.5.2.

1.4 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 5, 2023 has been used for this report.

1.4.1 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 1.5.3).

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.

1.4.2 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. 12 and 13 ClinO-MD, 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 confirmation of the completeness of the application or of any formal deficiency in the application 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. (Only applicable for clinical trials conducted under ClinO and research projects conducted under HRO.)

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 37ff. In addition to the dates, the ECs report for each project the outcome of the first and the

final decision as well as the review procedure applied (ordinary, simplified, presidential). An overview of the different EC decisions can be found in Table 3 on page 12 with short descriptions as table footnotes.

Apart from the "final decision date" of clinical trials under ClinO and research projects under HRO, 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.

1.5 Analysis sets

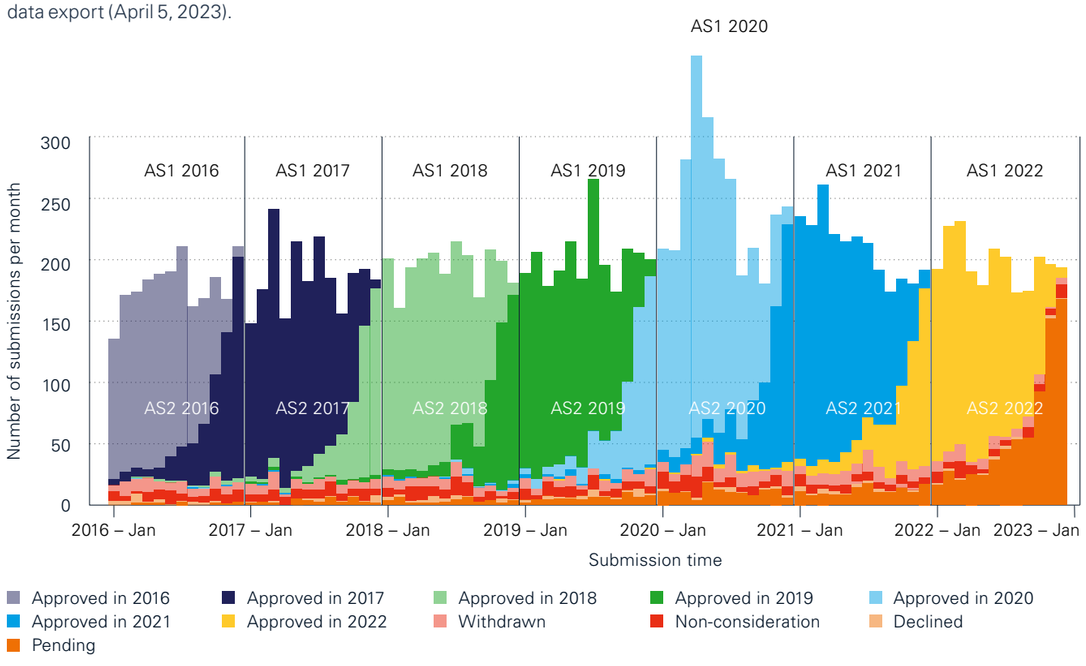
1.5.1 Definition of analysis sets

Definition:
AS1 The analysis set AS1 consists of all projects **submitted in 2022.** 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 2022** 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 (nonconsideration) or may be withdrawn by the applicant (including submissions that are never completed).

Figure 1: Overview of submissions via BASEC in the years 2016-2022 coloured by the current status as of the time of the data export (April 5, 2023).



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/nonconsidered 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.

1.5.2 Influence of time on project status

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 2022, since a single up-to-date export is used for all years (export date: April 5, 2023) 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 contrast to this, the data sets starting from 2017 also include submissions from the previous years.

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.

1.5.3 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 ClinO-MD) 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.

1 Exception: In section 3.2 on page 16, the data are summarised from a EC perspective by counting individual evaluations thereby assigning projects involving multiple local committees to all ECs.

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/ClinOMD 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.

2 BASEC data in the calendar year 2022

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

			n	$\%_{col}$
Input	Submission in 2022 (AS1)		2407	72.1
	Projects pending from 2021	Pending first decision in 2021	271	8.1
		Pending final decision in 2021 (first decision before 2022)	662	19.8
		Total Pending from 2021	933	27.9
		Grand Total Input 2022	3340	100.0
Output	Final decision in 2022	Approvals (AS2)	2014	60.3
		Rejections (declined projects)	35	1
		Non-considerations	79	2.4
		Total Decisions	2128	63.7
	Withdrawn during 2022	Withdrawal before first decision	43	1.3
		Withdrawal after first decision 'approvals with charges'	6	0.2
		Withdrawal after first decision 'not-yet-approved projects with conditions'	26	0.8
		Withdrawal after first decision 'non-considerations'	9	0.3
		Total Withdrawn	84	2.5
	Pending at end of 2022	Pending first decision	401	12
		Pending final decision (first decision issued)	727	21.8
		Total Pending	1128	33.8
		Grand Total Output 2022	3340	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 2020 and hence obtained a new BASEC number.

3 Overview of all projects submitted to BASEC in 2022 (AS1)

Table 2: Total number of research projects **submitted via BASEC in 2022** (analysis set AS1), including information on type of research and the legal basis.

Type of research	Legal basis	n	$\%_{col}$
Clinical trial	ClinO or ClinO-MD	591[1]	24.6
Research involving persons, but not a clinical trial	HRO, Chapter 2	797[2]	33.1
Further use of health-related personal data and/or biological material	HRO, Chapter 3	990	41.1
Research involving deceased persons	HRO, Chapter 4	29	1.2
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	0	0.0
Total number		2407	100.0

1 60 of these projects also include an application for further use of data/biological material.
2 193 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 2022 (analysis set AS1) by 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	$\%_{col}$
First decision[1]	Approved[2]	314	13.1	132	21.3	38	8.1	41	9.3	18	5	34	11.2	24	24.5	27	24.1
	Approved with charges[3]	514	21.4	1	0.2	230	48.8	162	36.9	8	2.2	36	11.8	48	49	29	25.9
	Not approved, conditions[4]	1236	51.4	406	65.6	178	37.8	179	40.8	243	67.1	176	57.9	14	14.3	40	35.7
	Declined	34	1.4	4	0.6	2	0.4	1	0.2	9	2.5	17	5.6			1	0.9
	Non-consideration[5]	77	3.2	26	4.2			5	1.1	28	7.7	10	3.3	6	6.1	2	1.8
	First decision still pending[6]	102	4.2	15	2.4	5	1.1	38	8.7	24	6.6	13	4.3	2	2	5	4.5
Final decision	Approved[7]	1891	78.6	515	83.2	398	84.5	324	73.8	257	71	228	75	83	84.7	86	76.8
	Declined	35	1.5	2	0.3	2	0.4	1	0.2	9	2.5	20	6.6			1	0.9
	Non-consideration	78	3.2	21	3.4			5	1.1	30	8.3	11	3.6	7	7.1	4	3.6
	Withdrawn	76	3.2	23	3.7	10	2.1	11	2.5	23	6.4	8	2.6			1	0.9
	Final decision still pending[8]	325	13.5	58	9.4	61	13	98	22.3	43	11.9	37	12.2	8	8.2	20	17.9
Review procedure	Ordinary[9]	400	16.6	92	14.9	51	10.8	57	13	49	13.5	30	9.9	24	24.5	97	86.6[12]
	Simplified[10]	1487	61.8	340	54.9	336	71.3	275	62.6	263	72.7	224	73.7	44	44.9	5	4.5
	Presidential[11]	404	16.8	168	27.1	79	16.8	66	15	30	8.3	38	12.5	23	23.5		
	First decision still pending	114	4.7	19	3.1	5	1.1	41	9.3	20	5.5	12	3.9	7	7.1	10	8.9
	Total number in AS1[13]	2407	100.0	619	100.0	471	100.0	439	100	362	100	304	100	98	100	112	100

1 Not applicable for clinical investigations with medical devices submitted under the ClinO-MD, as these projects do not receive a first decision.
2 Projects already approved in the first review process.
3 Charges: The projects are approved but with charges.
4 Conditions: These projects are not approved until the conditions are addressed.
5 Non-consideration: Research not covered by the HRA.
6 Information missing: The status information was missing at the time of the report generation.
7 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.
8 Pending at export date. 43.7% of the pending projects were submitted in the last quarter of the reporting year.
9 Decision taken at full committee meeting by at least seven members of the ethics committee, as per the provisions of Art. 5, OrgO-HRA.
10 Decision taken by three members of the ethics committee, as per the provisions of Art. 6 OrgO-HRA.
11 Decision taken by the president or vice-president of the ethics committee, as per the provisions of Art. 7 OrgO-HRA.
12 CE-TI uses the ordinary procedure for most of the research applications.
13 The total number includes 2 clinical investigations with medical devices with the status 'not admitted', as per Art. 12 ClinO-MD. These are not listed separately in the table.

Table 4: Number of submissions in 2022 (analysis set AS1) by type of research project and lead ethics committee.
Projects involving multiple ECs are assigned to the lead EC.

					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	23	10.8	4	6.6	4	11.8	5	21.7	5	12.5	5	22.7				
		B	23	10.8	6	9.8	6	17.6	1	4.3	4	10.0	5	22.7			1	9.1
		C	167	78.4	51	83.6	24	70.6	17	73.9	31	77.5	12	54.5	22	100.0	10	90.9
		All	213	100.0	61	100.0	34	100.0	23	100.0	40	100.0	22	100.0	22	100.0	11	100.0
	Medical devices[1]	A1	64	50.8	26	72.2	10	58.8	7	53.8	10	32.3	8	47.1	2	50.0	1	12.5
		A2	16	12.7	1	2.8	3	17.6	2	15.4	6	19.4	1	5.9			3	37.5
		C1	9	7.1	2	5.6					5	16.1			2	50.0		
		C2	37	29.4	7	19.4	4	23.5	4	30.8	10	32.3	8	47.1			4	50.0
		All	126	100.0	36	100.0	17	100.0	13	100.0	31	100.0	17	100.0	4	100.0	8	100.0
	Other clinical trials	A	206	86.9	53	79.1	47	81.0	33	97.1	27	90.0	23	92.0	14	100.0	9	100.0
		B	31	13.1	14	20.9	11	19.0	1	2.9	3	10.0	2	8.0				
		All	237	100.0	67	100.0	58	100.0	34	100.0	30	100.0	25	100.0	14	100.0	9	100.0
	Combination drugs/devices	A2	1	20.0							1	33.3						
		C1	1	20.0							1	33.3						
		C2	3	60.0			1	100.0			1	33.3	1	100.0				
		All	5	100.0			1	100.0			3	100.0	1	100.0				
	Transplant products	C	9	100.0	2	100.0	1	100.0	1	100.0			1	100.0			4	100.0
		All	9	100.0	2	100.0	1	100.0	1	100.0			1	100.0			4	100.0
	Transplantation	C	1	100.0					1	100.0								
		All	1	100.0					1	100.0								
	All	All	591	100.0	166	100.0	111	100.0	72	100.0	104	100.0	66	100.0	40	100.0	32	100.0
Research w/persons		A	776	97.4	162	94.7	159	100.0	181	96.3	98	97.0	110	98.2	25	100.0	41	100.0
		B	21	2.6	9	5.3			7	3.7	3	3.0	2	1.8				
		All	797	100.0	171	100.0	159	100.0	188	100.0	101	100.0	112	100.0	25	100.0	41	100.0
Further use		n.a.	990	100.0	266	100.0	196	100.0	176	100.0	157	100.0	124	100.0	33	100.0	38	100.0
Deceased and embryos from stillbirths or abortion		n.a.	29	100.0	16	100.0	5	100.0	3	100.0	2	100.0	2	100.0			1	100.0
Total number			2407	100.0	619	100.0	471	100.0	439	100.0	364	100.0	304	100.0	98	100.0	112	100.0

1 Medical devices include 1 in-vitro diagnostic project submitted under the ClinO regulation before 26.05.2022 and 5 in-vitro diagnostic projects under the revised ClinO-MD regulation, which applies to IVD trials from 26.05.2022.

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	2114	69.7
Multiple ECs involved: lead EC	293	9.7
Multiple ECs involved: local EC	627	20.7
Total submissions to be evaluated	3034	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	548	73.8	409	71.3	305	63.8	410	77.4	274	75.3	69	38.3	99	60.0
Multiple: lead EC	71	9.6	62	10.8	59	12.3	29	5.5	30	8.2	29	16.1	13	7.9
Multiple: local EC	124	16.7	103	17.9	114	23.8	91	17.2	60	16.5	82	45.6	53	32.1
Total submissions	743	100.0	574	100.0	478	100.0	530	100.0	364	100.0	180	100.0	165	100.0

4 Scientific characterisation of projects approved in 2022 (AS2)

4.1 Overview

Table 7: Total number of research projects **approved in 2022** (analysis set AS2) per type of research, including information on the legal basis.

Type of research	Legal basis	n	$\%_{col}$
Clinical trial	ClinO or ClinO-MD	491[1]	24.4
Research involving persons, but not a clinical trial	HRO, Chapter 2	654[2]	32.5
Further use of health-related personal data and/or biological material	HRO, Chapter 3	842	41.8
Research involving deceased persons	HRO, Chapter 4	27	1.3
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	0	0.0
Total number		2014	100.0

1 45 of these projects also include 'further use' of existing data and/or material.
2 171 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 2022 (i. e. the final decision is 'approved'; AS2). A fraction of the projects are already approved at the 'first decision', the remaining at the 'final decision'. For a definition of all terms see Table 3 on page 12 – per lead ethics committee.

		Total		Lead ethics committee											
				KEK-ZH		EKNZ		CER-VD		KEK-BE		CCER		EKOS		CE-TI	
		N	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$
Submission year	2019	4	0.20			1	0.2	3	0.8								
	2020	26	1.29	3	0.6	5	1.2	11	2.8	5	1.7	1	0.4			1	1.2
	2021	489	24.28	106	20.2	82	19.3	120	31	116	39.9	41	18.4	7	9	17	19.8
	2022	1495	74.23	415	79.2	337	79.3	253	65.4	170	58.4	181	81.2	71	91	68	79.1
First decision[1]	Approved	301	14.95	120	22.9	35	8.2	42	10.9	16	5.5	35	15.7	25	32.1	28	32.6
	Approved with charges[2]	465	23.09			213	50.1	152	39.3	9	3.1	34	15.2	41	52.6	16	18.6
	Not approved, conditions[3]	1144	56.80	373	71.2	162	38.1	184	47.5	237	81.4	143	64.1	8	10.3	37	43
	Declined[4]	1	0.05	1	0.2												
	Non-consideration	0	0.00														
Review procedure	Ordinary[5]	325	16.14	74	14.1	44	10.4	48	12.4	39	13.4	22	9.9	18	23.1	80	93
	Simplified	1324	65.74	311	59.4	303	71.3	274	70.8	231	79.4	161	72.2	38	48.7	6	7
	Presidential	365	18.12	139	26.5	78	18.4	65	16.8	21	7.2	40	17.9	22	28.2		
	Total number in AS2	2014	100.00	524	100.0	425	100.0	387	100.0	291	100.0	223	100.0	78	100.0	86	100.0

1 Not applicable for clinical investigations with medical devices submitted under the ClinO-MD, as these projects do not receive a first decision.
2 Charges: the projects are approved but with charges.
3 Conditions: These projects are not approved until the conditions are addressed.
4 Reconsideratoin and approval of a previously declined project, reusing the electronic submission form with the old BASEC number.
5 CE-TI uses the ordinary procedure for most of the research applications.

4.3 Stratification by project characteristics

In Tables 9–11 on page 22–27, 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 28, 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 as well as ClinO-MD Art. 6). 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 21 on page 36, 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.

					Study design						Initiator			
			Total		Mono		Multi CH		Multi Int.		Industry		Investigator	
Type of research	Research details	Risk cat.	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Clinical trial (ClinO)	Medicinal products (ClinO Art 19)	A	16	9.8	12	75.0	1	6.2	3	18.8	1	6.2	15	93.8
		B	25	15.2	11	44.0	2	8.0	12	48.0	5	20.0	20	80.0
		C	123	75.0	14	11.4	2	1.6	107	87.0	96	78.0	27	22.0
		All	164	100.0	37	22.6	5	3.0	122	74.4	102	62.2	62	37.8
	Medical devices (ClinO-MD Art 6)[1]	A	70	69.3	37	52.9	5	7.1	28	40.0	21	30.0	49	70.0
		C	31	30.7	20	64.5	1	3.2	10	32.3	15	48.4	16	51.6
		All	101	100.0	57	56.4	6	5.9	38	37.6	36	35.6	65	64.4
	Other clinical trials (ClinO Art 61)	A	183	86.3	145	79.2	16	8.7	22	12.0	4	2.2	179	97.8
		B	29	13.7	20	69.0	1	3.4	8	27.6	1	3.4	28	96.6
		All	212	100.0	165	77.8	17	8.0	30	14.2	5	2.4	207	97.6
	Combination drugs/devices	A	1	50.0	1	100.0							1	100.0
		C	1	50.0					1	100.0	1	100.0		
		All	2	100.0	1	50.0			1	50.0	1	50.0	1	50.0
	Transplant products (ClinO Art 21)	C	7	100.0	2	28.6	1	14.3	4	57.1	5	71.4	2	28.6
		All	7	100.0	2	28.6	1	14.3	4	57.1	5	71.4	2	28.6
	Gene therapy (ClinO Art 22)	C	2	100.0					2	100.0	2	100.0		
		All	2	100.0					2	100.0	2	100.0		
	Transplantation (ClinO Art 49)	A	1	100.0	1	100.0							1	100.0
		All	1	100.0	1	100.0							1	100.0
	Pathogenic organisms	C	2	100.0			1	50.0	1	50.0	1	50.0	1	50.0
		All	2	100.0			1	50.0	1	50.0	1	50.0	1	50.0
	All	All	491	100.0	263	53.6	30	6.1	198	40.3	152	31.0	339	69.0
Research w/ persons (HRO Chapter 2)		A	634	96.9	483	76.2	62	9.8	89	14.0	55	8.7	579	91.3
		B	20	3.1	15	75.0	3	15.0	2	10.0			20	100.0
		All	654	100.0	498	76.1	65	9.9	91	13.9	55	8.4	599	91.6
Further use (HRO Chapter 3)		n.a.	842	100.0	685	81.4	40	4.8	117	13.9	43	5.1	799	94.9
Deceased and embryos from stillbirths or abortion (HRO Chapter 4+5)		n.a.	27	100.0	26	96.3	1	3.7			3	11.1	24	88.9
Total number			2014	100.0	1472	73.1	136	6.8	406	20.2	253	12.6	1761	87.4

1 Medical devices include 0 in-vitro diagnostic projects approved under the ClinO regulation before 26.05.2022 and 0 in-vitro diagnostic projects under the revised ClinO-MD regulation, which applies to IVD trials from 26.05.2022.

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

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	16	9.8	4	8.5	4	15.4	1	5.6	2	6.7	5	27.8	0	0.0	0	0.0
		B	25	15.2	6	12.8	6	23.1	3	16.7	5	16.7	5	27.8	0	0.0	0	0.0
		C	123	75.0	37	78.7	16	61.5	14	77.8	23	76.7	8	44.4	16	100.0	9	100.0
		All	164	100.0	47	100.0	26	100.0	18	100.0	30	100.0	18	100.0	16	100.0	9	100.0
	Medical devices	A	70	69.3	24	80.0	11	78.6	4	44.4	18	64.3	8	72.7	2	50.0	3	60.0
		C	31	30.7	6	20.0	3	21.4	5	55.6	10	35.7	3	27.3	2	50.0	2	40.0
		All	101	100.0	30	100.0	14	100.0	9	100.0	28	100.0	11	100.0	4	100.0	5	100.0
	Other clinical trials	A	183	86.3	57	83.8	49	83.1	19	86.4	24	92.3	18	90.0	9	100.0	7	87.5
		B	29	13.7	11	16.2	10	16.9	3	13.6	2	7.7	2	10.0	0	0.0	1	12.5
		All	212	100.0	68	100.0	59	100.0	22	100.0	26	100.0	20	100.0	9	100.0	8	100.0
	Combination drugs/devices	A	1	50.0	0		0		0		1	100.0	0		0		0	
		C	1	50.0	0		1	100.0	0		0		0		0		0	
		All	2	100.0	0		1	100.0	0		1	100.0	0		0		0	
	Transplant products	C	7	100.0	1	100.0	0		1	100.0	0		1	100.0	0		4	100.0
		All	7	100.0	1	100.0	0		1	100.0	0		1	100.0	0		4	100.0
	Gene therapy	C	2	100.0	0		2	100.0	0		0		0		0		0	
		All	2	100.0	0		2	100.0	0		0		0		0		0	
	Transplantation	A	1	100.0	0		0		0		1	100.0	0		0		0	
		All	1	100.0	0		0		0		1	100.0	0		0		0	
	Pathogenic organisms	C	2	100.0	1	100.0	0		0		1	100.0	0		0		0	
		All	2	100.0	1	100.0	0		0		1	100.0	0		0		0	
	All	All	491	100.0	147	100.0	102	100.0	50	100.0	87	100.0	50	100.0	29	100.0	26	100.0
Research w/persons		A	634	96.9	123	93.2	139	100.0	169	98.3	75	93.8	77	96.2	19	100.0	32	100.0
		B	20	3.1	9	6.8	0	0.0	3	1.7	5	6.2	3	3.8	0	0.0	0	0.0
		All	654	100.0	132	100.0	139	100.0	172	100.0	80	100.0	80	100.0	19	100.0	32	100.0
Further use		n.a.	842	100.0	230	100.0	177	100.0	163	100.0	123	100.0	91	100.0	30	100.0	28	100.0
Deceased and embryos from stillbirths or abortion		n.a.	27	100.0	15	100.0	7	100.0	2	100.0	1	100.0	2		0		0	
Total number			2014	100.0	524	100.0	425	100.0	387	100.0	291	100.0	223	100.0	78	100	86	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	16	9.8	1	6.25	15	93.75					1	6.25	15	93.75		
		B	25	15.2	24	96.00	1	4.00					4	16.00	21	84.00		
		C	123	75.0	123	100.00					3	2.44	27	21.95	93	75.61		
		All	164	100.0	148	90.24	16	9.76			3	1.83	32	19.51	129	78.66		
	Medical devices	A	70	69.3	11	15.71	47	67.14	12	17.14								
		C	31	30.7	23	74.19			8	25.81								
		All	101	100.0	34	33.66	47	46.53	20	19.80								
	Other clinical trials	A	183	86.3	12	6.56	171	93.44			12	6.56	28	15.30	143	78.14		
		B	29	13.7	29	100.00							3	10.34	26	89.66		
		All	212	100.0	41	19.34	171	80.66			12	5.66	31	14.62	169	79.72		
	Combination drugs/devices	A	1	50.0			1	100.00										
		C	1	50.0	1	100.00												
		All	2	100.0	1	50.00	1	50.00										
	Transplant products	C	7	100.0	7	100.00							1	14.29	6	85.71		
		All	7	100.0	7	100.00							1	14.29	6	85.71		
	Gene therapy	C	2	100.0	2	100.00									2	100.00		
		All	2	100.0	2	100.00									2	100.00		
	Transplantation	A	1	100.0			1	100.00							1	100.00		
		All	1	100.0			1	100.00							1	100.00		
	Pathogenic organisms	C	2	100.0	2	100.00									2	100.00		
		All	2	100.0	2	100.00									2	100.00		
	All	All	491	100.0	235	47.86	236	48.07	20	4.07	15	3.05	64	13.03	309	62.93		
Research w/ persons		A	634	96.9	45	7.10	587	92.59	2	0.32	32	5.05	141	22.24	460	72.56	1	0.16
		B	20	3.1	17	85.00	3	15.00					2	10.00	18	90.00		
		All	654	100.0	62	9.48	590	90.21	2	0.31	32	4.89	143	21.87	478	73.09	1	0.15
Further use		n.a.	842	100.0	27	3.21	472	56.06	343	40.74	244	28.98	248	29.45	350	41.57		
Deceased and embryos from stillbirths or abortion		n.a.	27	100.0	1	3.70	26	96.30			10	37.04	10	37.04	7	25.93		
Total number			2014	100.0	325	16.14	1324	65.74	365	18.12	301	14.95	465	23.09	1144	56.80	1	0.05

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 14 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		
Therapeutic area	N	$\%_{col}$	n_{rare}	n	%	n_{rare}	n	%	n_{rare}	n	%	n_{rare}
Other	128	26.1	9	31	18.9	8	22	21.8	0	74	34.9	1
Nervous System diseases	45	9.2	7	11	6.7	5	11	10.9	0	23	10.8	2
Basic research (Anatomy/Physiology)	37	7.5	0	2	1.2	0	10	9.9	0	25	11.8	0
Cancer: Other	37	7.5	8	18	11.0	4	4	4.0	0	9	4.2	0
Mental and Behavioural diseases	33	6.7	0	3	1.8	0	3	3.0	0	27	12.7	0
Surgery	32	6.5	0	4	2.4	0	10	9.9	0	17	8.0	0
Brain diseases (non cancer)	28	5.7	0	3	1.8	0	10	9.9	0	15	7.1	0
Musculoskeletal diseases (non cancer)	28	5.7	0	2	1.2	0	7	6.9	0	18	8.5	0
Respiratory diseases (non cancer)	27	5.5	6	12	7.3	4	4	4.0	0	11	5.2	2
Arterial and venous diseases including deep venous thrombosis and lung embolism	22	4.5	0	4	2.4	0	12	11.9	0	6	2.8	0
Infections and Infestations	21	4.3	2	16	9.8	1	1	1.0	0	4	1.9	1
Cancer: Breast	20	4.1	0	13	7.9	0	4	4.0	0	3	1.4	0
Coronary Heart disease	19	3.9	0	2	1.2	0	10	9.9	0	7	3.3	0
Cancer: Lung	16	3.3	1	10	6.1	0	2	2.0	0	4	1.9	1
Eye diseases	14	2.9	3	3	1.8	1	5	5.0	0	3	1.4	0
Nutritional and Metabolic diseases	14	2.9	0	1	0.6	0	2	2.0	0	11	5.2	0
Cancer: Head and Neck	13	2.6	3	6	3.7	3	3	3.0	0	4	1.9	0
Cancer: Melanoma	13	2.6	0	8	4.9	0	1	1.0	0	3	1.4	0
Digestive Systems diseases (non cancer)	13	2.6	3	10	6.1	3	2	2.0	0	1	0.5	0
Cancer: Colon and Rectal	11	2.2	1	6	3.7	1	0	0.0	0	5	2.4	0
Cancer: Prostate	11	2.2	0	6	3.7	0	2	2.0	0	3	1.4	0
Skin and Connective Tissues diseases (non cancer)	11	2.2	2	7	4.3	2	1	1.0	0	2	0.9	0
Cancer: Leukemia	10	2.0	4	8	4.9	4	0	0.0	0	1	0.5	0
Endocrinological diseases (non cancer)	10	2.0	4	4	2.4	3	4	4.0	1	2	0.9	0
Cancer: Bladder	9	1.8	0	5	3.0	0	0	0.0	0	3	1.4	0
Cancer: Kidney	8	1.6	0	3	1.8	0	2	2.0	0	3	1.4	0
Cancer: Pancreatic	8	1.6	2	6	3.7	2	0	0.0	0	2	0.9	0
Genetic disorders	8	1.6	8	6	3.7	6	0	0.0	0	0	0.0	0
Dementia and Alzheimer disease	7	1.4	0	1	0.6	0	2	2.0	0	4	1.9	0
Hematologic diseases (non cancer)	7	1.4	4	4	2.4	4	1	1.0	0	2	0.9	0
Injury	7	1.4	0	1	0.6	0	3	3.0	0	3	1.4	0
Cancer: Lymphoma	6	1.2	3	4	2.4	3	0	0.0	0	2	0.9	0
Ear, Nose, and Throat diseases (non cancer)	6	1.2	1	2	1.2	0	1	1.0	0	3	1.4	1
Urological and Genital diseases (non cancer)	6	1.2	0	2	1.2	0	2	2.0	0	1	0.5	0
Cancer: Endometrial	5	1.0	0	4	2.4	0	0	0.0	0	1	0.5	0
Cancer: Non-Hodgkin Lymphoma	4	0.8	0	1	0.6	0	1	1.0	0	2	0.9	0
Cancer: Thyroid	4	0.8	0	2	1.2	0	1	1.0	0	1	0.5	0
Neonatal diseases	4	0.8	0	1	0.6	0	0	0.0	0	3	1.4	0
Periodontal diseases	4	0.8	0	1	0.6	0	2	2.0	0	1	0.5	0
Pregnancy and Childbirth	4	0.8	0	0	0.0	0	2	2.0	0	2	0.9	0
Occupational diseases	1	0.2	0	0	0.0	0	0	0.0	0	1	0.5	0

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.

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 14 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	239	48.7	111	67.7	44	43.6	70	33.0
Other	99	20.2	7	4.3	20	19.8	72	34.0
PK / PD / safety	39	7.9	37	22.6	0	0.0	2	0.9
Prevention	39	7.9	7	4.3	5	5.0	27	12.7
Rehabilitation	34	6.9	0	0.0	8	7.9	26	12.3
Diagnosis	30	6.1	2	1.2	16	15.8	12	5.7
Safety	8	1.6	0	0.0	8	7.9	0	0.0
Palliation	3	0.6	0	0.0	0	0.0	3	1.4
Total projects	491	100.0	164	100.0	101	100.0	212	100.0

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

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-human'.

			Phase											
	Total		1		2		3		4		n/a		first-in-human	
Risk category	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
A	17	10.2			2	11.8	2	11.8	8	47.1	4	23.5		
B	25	15.1	1	4.0	8	32.0	8	32.0	5	20.0	3	12.0		
C	124	74.7	28	22.6	30	24.2	60	48.4	1	0.8	4	3.2	11	8.9
Total number	166	100.0	29	17.5	40	24.1	70	42.2	14	8.4	11	6.6	11	6.6

The total number of 166 research projects consist of 164 medicinal product trials and 2 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.

4.4.2.2 Subgroup "Clinical trials with medical devices" (ClinO-MD Art 6)[1]

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

	Total		CE-marked, intended use		CE-marked, not intended use		Not CE-marked		first-in-human	
Risk category	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
A	71	68.9	71	100.0						
C	32	31.1			8	25.0	24	75.0	10	31.2
Total number	103	100.0	71	68.9	8	7.8	24	23.3	10	9.7

The total number of 103 research projects consist of 101 trials with medical devices and 2 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.

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.

			Risk category				Study design						Initiator			
	Total		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	271	41.4	260	95.9	11	4.1	198	73.1	33	12.2	40	14.8	14	5.2	257	94.8
Registry / Quality control[1]	45	6.9	43	95.6	2	4.4	25	55.6	4	8.9	16	35.6	10	22.2	35	77.8
Case control study	60	9.2	58	96.7	2	3.3	51	85.0	6	10.0	3	5.0	3	5.0	57	95.0
Other or n/a	278	42.5	273	98.2	5	1.8	224	80.6	22	7.9	32	11.5	28	10.1	250	89.9
Total number	654	100.0	634	96.9	20	3.1	498	76.1	65	9.9	91	13.9	55	8.4	599	91.6

1 Only quality control studies under the HRA.

1 Please note that until and including 25.5.2021, clinical trials with medical devices were regulated under ClinO Art. 20

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

			Type of research project							
	Overall		Cohort study		Registry / Quality control		Case control study		Other or n/a	
Area of research	N	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	%
Other	158	24.2	58	21.4	8	17.8	12	20.0	80	28.8
Basic science	114	17.4	41	15.1	2	4.4	19	31.7	52	18.7
Surgery	56	8.6	37	13.7	6	13.3	4	6.7	9	3.2
Qualitative research	56	8.6	12	4.4	7	15.6	3	5.0	34	12.2
Epidemiology	55	8.4	31	11.4	5	11.1	3	5.0	16	5.8
Healthcare services research	54	8.3	23	8.5	3	6.7	3	5.0	25	9.0
Physiology/anatomy	50	7.6	25	9.2	1	2.2	7	11.7	17	6.1
Psychology	48	7.3	17	6.3	2	4.4	8	13.3	21	7.6
Drugs	35	5.4	18	6.6	3	6.7	0	0.0	14	5.0
Medical devices	25	3.8	8	3.0	8	17.8	1	1.7	8	2.9
Dentistry	3	0.5	1	0.4	0	0.0	0	0.0	2	0.7
Total projects	654	100.0	271	100.0	45	100.0	60	100.0	278	100.0

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 "Nongenetic 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: In the reporting years to date (2016, 2017, 2018 and 2019), the researcher could choose in BASEC under "Consent for further uses of data/material" between three single-select options: 1. Prior consent exists, 2. Consent to be sought, or 3. no consent for some or all data. Since 1st of January 2020 researchers have been given in BASEC a multi-select option with the following options: 1. Consent to be sought, 2. No Consent – Art. 34 HRA, 3. Prior consent/general Consent exists. This was done in order to better understand which kind of consent is used by researchers for further use projects (i.e. individual or general consent), and to which extent a single project is making use of a mixed consent approach (e.g. one part of the datasets comes with a general consent, the other part comes with no consent at all). In the present report, the combination of these three options are summarized into the following three categories:

- The category **"Consent for all data"** comprises further use projects for which either a prior consent (e.g. a general consent) for all the used datasets exists, or for which a consent will be or has been obtained before using the data and/or biological material.
- The category **"Consent for some but not all data (partially Art. 34 HRA)"** comprises projects for which the researchers apply for exemption of the consent according to Art. 34 HRA for some, but not for all the used datasets.
- The category **"No consent for all data, Art. 34 HRA"** comprises projects for which the researchers apply for exemption of the consent (according to Art. 34 HRA) for all the used datasets.

Applicants are informed that if they have an informed consent from before the human research act (2014), they have to check whether it is conformable to law (Articles 28–32 HRO). If not, the consent is not considered sufficient.

Combined project: "Combined project" are those research projects that combine a clinical trial (ClinO or ClinO-MD) 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	$\%_{col}$
Genetic data/biol. material	Yes	226	21.4
	No	832	78.6
Coding (HRO Art. 25–27)	Coded	959	90.6
	Open, non-coded	99	9.4
Consent (HRO Art. 28–32)	Consent for all data	632	59.7
	Consent for some but not all data (partially Art. 34 HRA)	326	30.8
	No consent for all data, Art. 34 HRA	100	9.5
Combined vs. stand-alone projects	Stand-alone further use project	842	79.6
	Further use project as part of a clinical trial	45	4.3
	Further use project as part of a non-clinical research project	171	16.2
Total number		1058	100.0

Figure 2: Overview of characteristics of all approved 'further use' projects separately for all research projects.

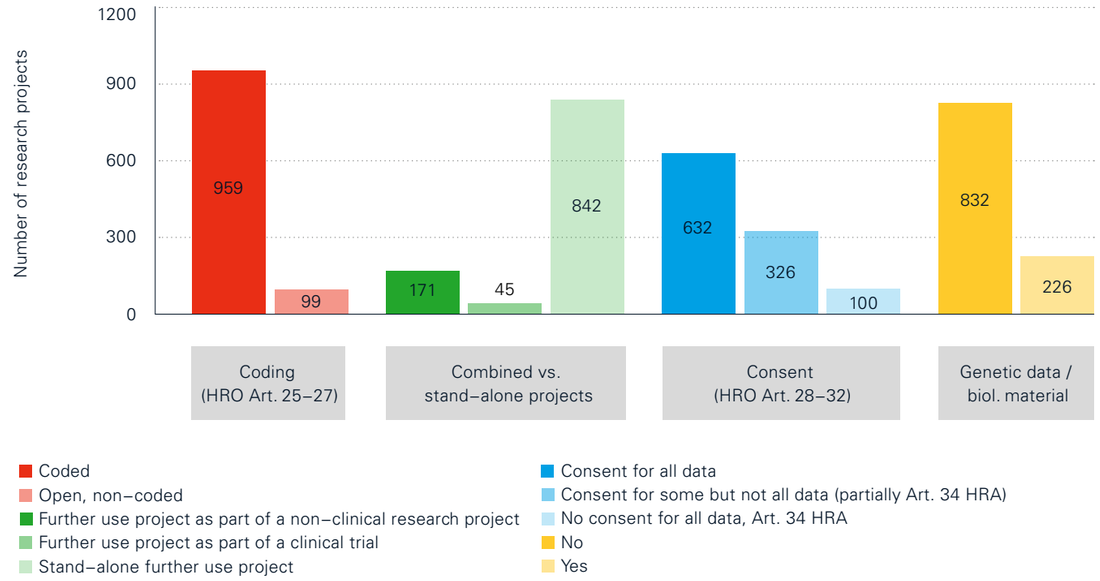


Table 19: Stratification of **projects involving further use of data/biological material** by study design and initiator.
All combinations of the following three factors are shown: 1) Use of genetic data and/or biological material (Genetic D+M), 2) coded vs. uncoded, 3) consent for further use.

			Total		Study design						Initiator			
					Mono		Multi CH		Multi Int.		Industry		Investigator	
Genetic D+M	Coded	Consent[1]	N	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Yes	Coded	Consent for all data	161	74.9	93	57.8	11	6.8	57	35.4	43	26.7	118	73.3
		Consent for some but not all data (partially Art. 34 HRA)	48	22.3	35	72.9	2	4.2	11	22.9	1	2.1	47	97.9
		No consent for all data, Art. 34 HRA	6	2.8	3	50.0	2	33.3	1	16.7			6	100.0
		All	215	100.0	131	60.9	15	7.0	69	32.1	44	20.5	171	79.5
	Open, non-coded	Consent for all data	6	54.5	5	83.3	1	16.7			1	16.7	5	83.3
		Consent for some but not all data (partially Art. 34 HRA)	5	45.5	4	80.0	1	20.0					5	100.0
		All	11	100.0	9	81.8	2	18.2			1	9.1	10	90.9
	All		226	100.0	140	61.9	17	7.5	69	30.5	45	19.9	181	80.1
No	Coded	Consent for all data	408	54.8	335	82.1	19	4.7	54	13.2	20	4.9	388	95.1
		Consent for some but not all data (partially Art. 34 HRA)	247	33.2	208	84.2	15	6.1	24	9.7	3	1.2	244	98.8
		No consent for all data, Art. 34 HRA	89	12.0	78	87.6	7	7.9	4	4.5			89	100.0
		All	744	100.0	621	83.5	41	5.5	82	11.0	23	3.1	721	96.9
	Open, non-coded	Consent for all data	57	64.8	51	89.5			6	10.5	2	3.5	55	96.5
		Consent for some but not all data (partially Art. 34 HRA)	26	29.5	24	92.3			2	7.7			26	100.0
		No consent for all data, Art. 34 HRA	5	5.7	3	60.0	2	40.0					5	100.0
		All	88	100.0	78	88.6	2	2.3	8	9.1	2	2.3	86	97.7
	All		832	100.0	699	84.0	43	5.2	90	10.8	25	3.0	807	97.0
Total number			1058	100.0	839	79.3	60	5.7	159	15.0	70	6.6	988	93.4

1 Multiple selection possible.
The total number of 1058 research projects consist of 842 standard 'further use' projects and 216 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[1]	N	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$
Consent for all data	632	59.7	212	69.3	109	51.9	94	49.2	94	60.6	77	63.1	30	75.0	16	47.1
Consent for some but not all data (partially Art. 34 HRA)	326	30.8	78	25.5	82	39.0	74	38.7	52	33.5	17	13.9	9	22.5	14	41.2
No consent for all data, Art. 34 HRA	100	9.5	16	5.2	19	9.0	23	12.0	9	5.8	28	23.0	1	2.5	4	11.8
Total number	1058	100.0	306	100.0	210	100.0	191	100.0	155	100.0	122	100.0	40	100.0	34	100.0

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

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	1173	71.0
	Industry	75[1]	4.5
	Universities/hospitals	206	12.5
	Private (non-industry)	169	10.2
	Swiss National Science Foundation	30	1.8
	All	1653	100.0
Industry	Public, other	57[2]	22.5
	Industry	195[3]	77.1
	Universities/hospitals	0	0.0
	Private (non-industry)	1	0.4
	Swiss National Science Foundation	0	0.0
	All	253	100
Other	Public, other	82	75.9
	Industry	3	2.8
	Universities/hospitals	10	9.3
	Private (non-industry)	11	10.2
	Swiss National Science Foundation	2	1.9
	All	108[4]	100.0

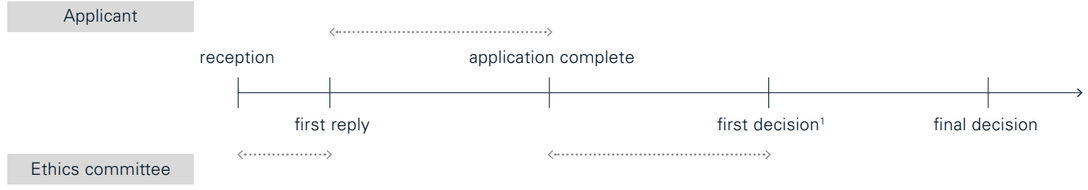
1 Applicants almost exclusively from academic institutions.
2 Inspecting the sponsor information reveals that these are almost exclusively industry projects.
3 192 of the industry-initiated projects are financed exclusively by industry.
4 30 of these projects initiated by others are projects solely or principally designed to obtain a degree (the tutor is the initiator). Apart from that, these projects are quite heterogenous.

5 Response times and review procedure (AS2)

5.1 Definitions

As described in the introduction on page 7, 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 3: 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.



1 Not applicable for clinical investigations with medical devices submitted under the ClinO-MD, as these projects do not receive a first decision.

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	67	13.6	7	[7,7]	7	[7,8]	29	[22,36]	96	[69,121]	21	[16,28]	88	[62,112]
	EKNZ	37	9.0	4	[2, 6]	5	[2,7]	33	[22,38]	82	[61,117]	28	[15,34]	77	[54,112]
	CER-VD	41	10.8	4	[2,5]	4	[3,7]	24	[17,29]	158	[81,293]	17	[14,21]	146	[77,288]
	KEK-BE	36	13.7	4	[2,6]	10	[6,28]	35	[25,55]	208	[156,284]	20	[15,26]	192	[136,257]
	CCER	18	8.5	3	[1,6]	7	[4,12]	42	[35,47]	108	[78,172]	32	[23,38]	94	[75,169]
	EKOS	16	21.6	4	[2,5]	4	[2,5]	29	[22,42]	93	[71,128]	27	[20,34]	88	[68,123]
	CE-TI	75	92.6	7	[7,7]	7	[7,7]	28	[21,34]	58	[28,84]	21	[14,26]	50	[20,76]
	All	290	15.2	7	[3,7]	7	[5,8]	29	[21,37]	96	[64,155]	21	[15,28]	86	[56,146]
Simplified	KEK-ZH	288	58.3	7	[7,8]	7	[7,8]	34	[29,38]	68	[47,108]	25	[20,29]	58	[35,90]
	EKNZ	295	72.0	4	[2,6]	5	[2,7]	23	[16,30]	55	[35,100]	18	[12,22]	49	[31,92]
	CER-VD	272	72.0	3	[2,5]	5	[3,11]	20	[17,29]	84	[51,155]	14	[13,19]	70	[44,124]
	KEK-BE	225	85.9	2	[1,5]	7	[3,19]	26	[19,46]	106	[68,203]	15	[14,19]	91	[53,164]
	CCER	154	72.6	3	[1,4]	6	[3,12]	32	[27,40]	79	[54,124]	24	[21,29]	66	[48,113]
	EKOS	36	48.6	2	[1,3]	3	[1,6]	13	[8,22]	30	[14,72]	8	[4,10]	22	[9,46]
	CE-TI	6	7.4	7	[7,9]	7	[7,9]	24	[22,25]	28	[26,163]	15	[13,18]	21	[18,152]
	All	1276	66.8	4	[2,7]	7	[3,9]	27	[19,35]	74	[46,130]	19	[14,25]	63	[39,112]
Presidential	KEK-ZH	139	28.1	7	[7,8]	7	[7,8]	29	[22,34]	33	[27,52]	21	[14,26]	25	[18,41]
	EKNZ	78	19.0	3	[1,6]	3	[2,6]	9	[6,14]	26	[13,54]	6	[1,8]	21	[8,45]
	CER-VD	65	17.2	4	[2,6]	6	[4,7]	19	[14,35]	51	[15,105]	11	[7,16]	40	[11,77]
	KEK-BE	1	0.4	5	[5,5]	5	[5,5]	46	[46,46]	76	[76,76]	41	[41,41]	71	[71,71]
	CCER	40	18.9	3	[1,5]	4	[3,11]	14	[8,23]	15	[8,24]	7	[3,14]	7	[3,16]
	EKOS	22	29.7	1	[1,3]	1	[1,3]	7	[4,10]	13	[7,39]	4	[2,7]	8	[3,33]
	CE-TI	0	0.0												
	All	345	18.1	5	[2,7]	7	[3,8]	20	[11,30]	32	[16,58]	12	[6,21]	23	[11,50]
Overall	KEK-ZH	494	100.0	7	[7, 8]	7	[7,8]	32	[26,37]	61	[35,98]	23	[17,28]	50	[28,88]
	EKNZ	410	100.0	4	[2,6]	5	[2,7]	21	[13,29]	54	[33,98]	15	[8,21]	48	[28,89]
	CER-VD	378	100.0	4	[2,5]	5	[3,9]	21	[16,29]	82	[49,166]	14	[12,19]	70	[43,134]
	KEK-BE	262	100.0	2	[1,5]	7	[4,20]	28	[20,46]	122	[75,219]	15	[14,20]	104	[57,189]
	CCER	212	100.0	3	[1,4]	6	[3,12]	30	[22,39]	71	[43,117]	23	[16,28]	57	[36,106]
	EKOS	74	100.0	2	[1,3]	2	[1,5]	13	[7,26]	42	[13,93]	8	[3,15]	34	[7,80]
	CE-TI	81	100.0	7	[7,7]	7	[7,7]	28	[21,33]	57	[28,85]	20	[14,24]	45	[20,77]
	All	1911	100.0	5	[2,7]	7	[3,8]	27	[19,35]	69	[38,123]	18	[13,25]	59	[31,110]

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

5.3 Stratification of response time by review procedure for projects according to ClinO and HRO but not ClinO-MD

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 a small box plot inside the plot which makes the data comparable to what is provided in the tables (median and inter-quartile range).

Figure 4: Violin plot of the time between status 'complete' to the first decision by EC. 32 projects with t > 60 days are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 25.1.

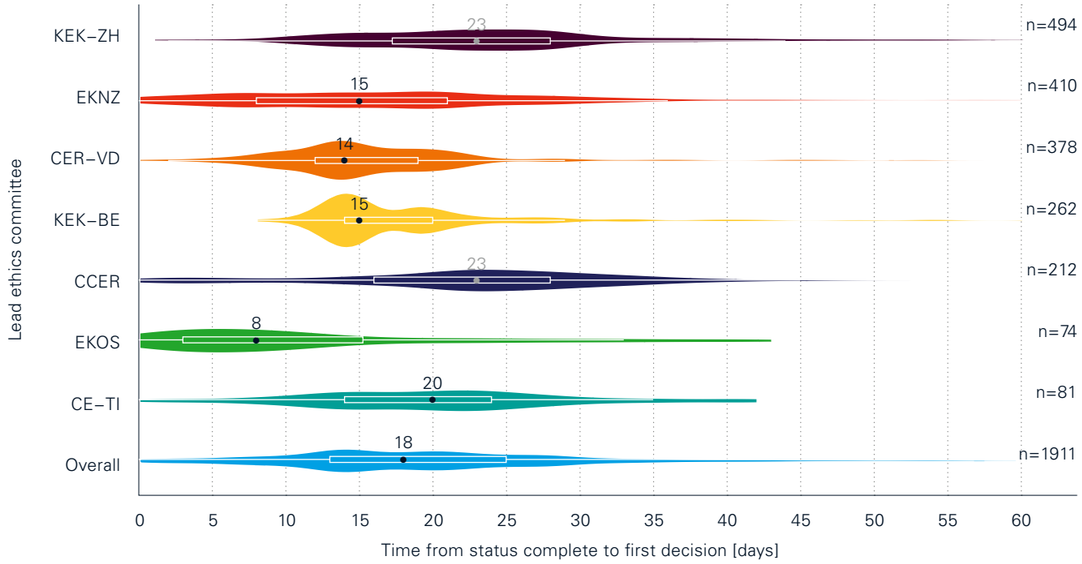
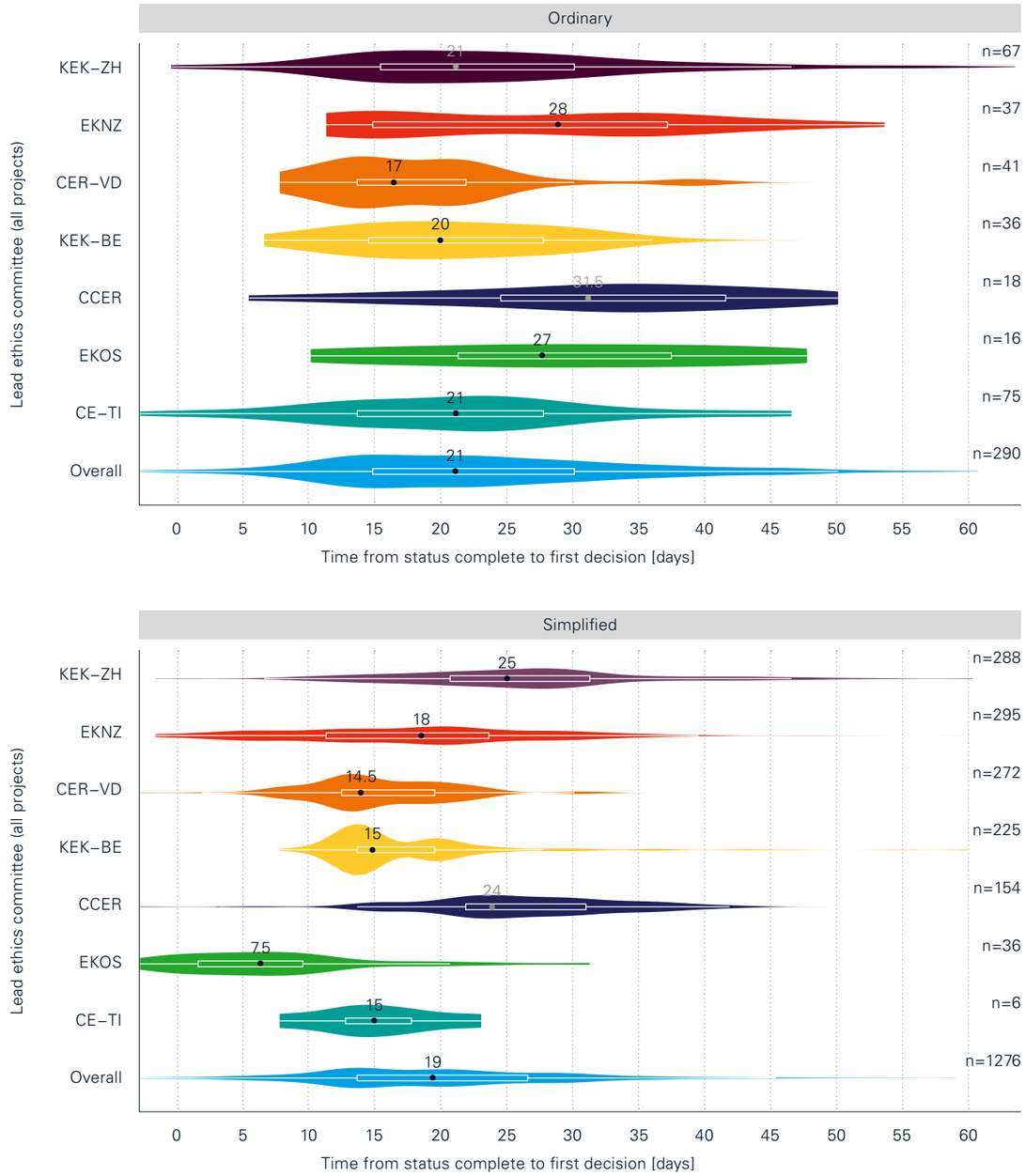
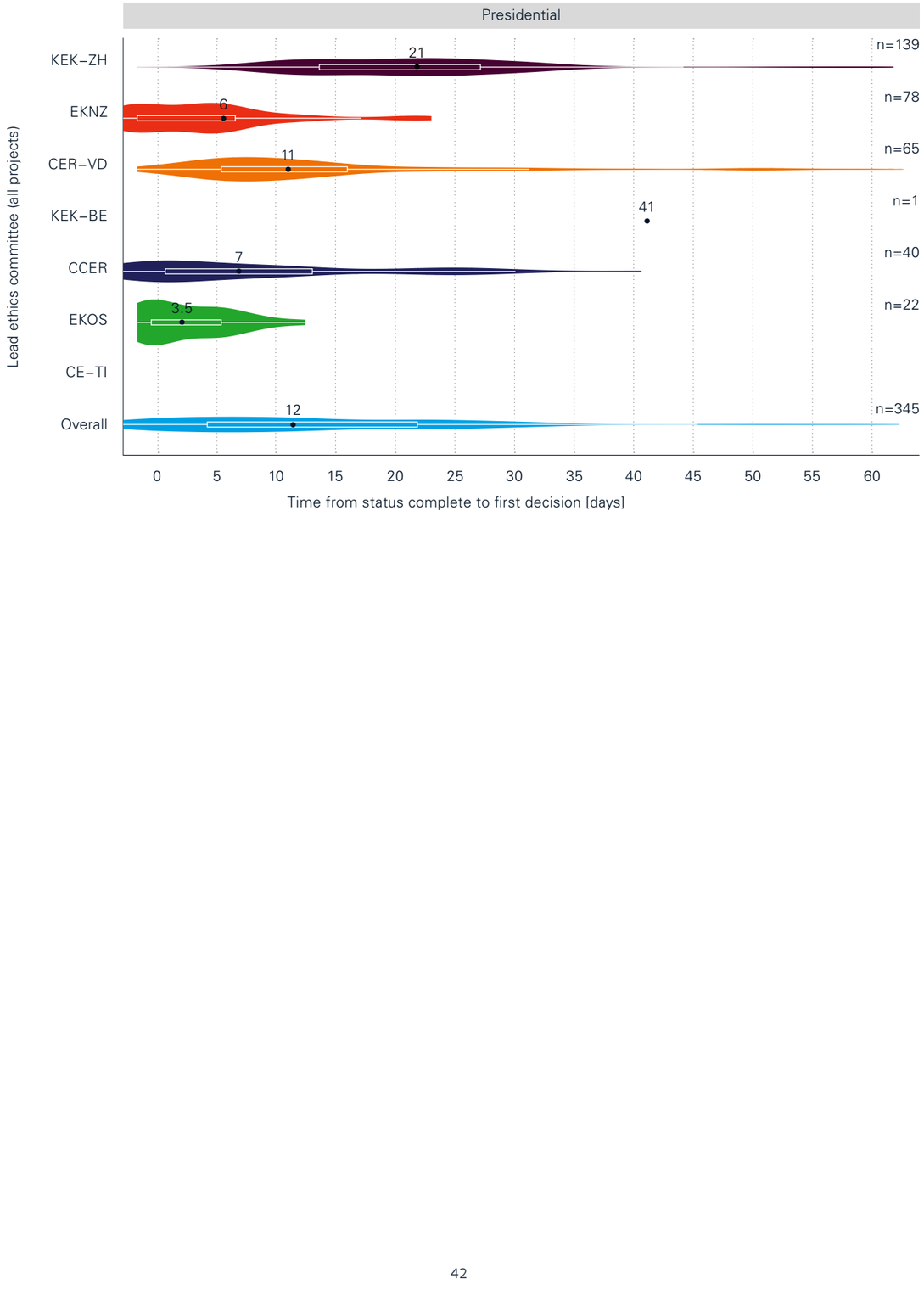


Figure 5: Violin plot of the time between status 'complete' to the first decision by EC and stratified by review procedure. 29 projects with t > 60 days are not shown for layout reasons. Note: *CE-TI* typically processes all submissions in a plenary session (ordinary procedure) but with adapted fees. ClinO-MD projects are not included but separately displayed in table 25.1.





5.3.2 Time from reception to final decision

Figure 6: Violin plot of the overall approval time by EC from reception to final decision. 57 projects with approval time > 1 year are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 25.1.

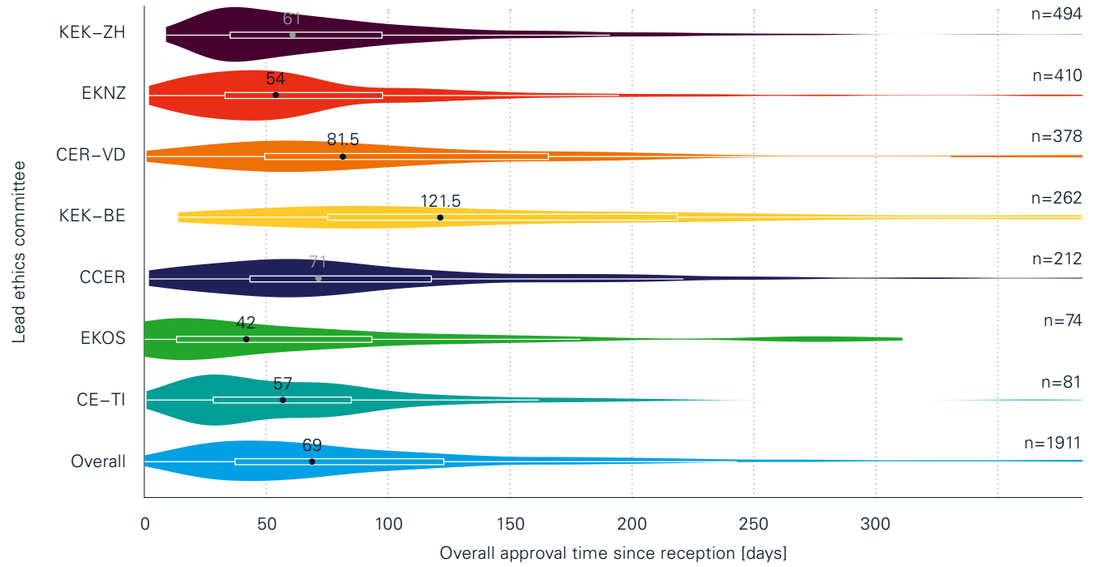
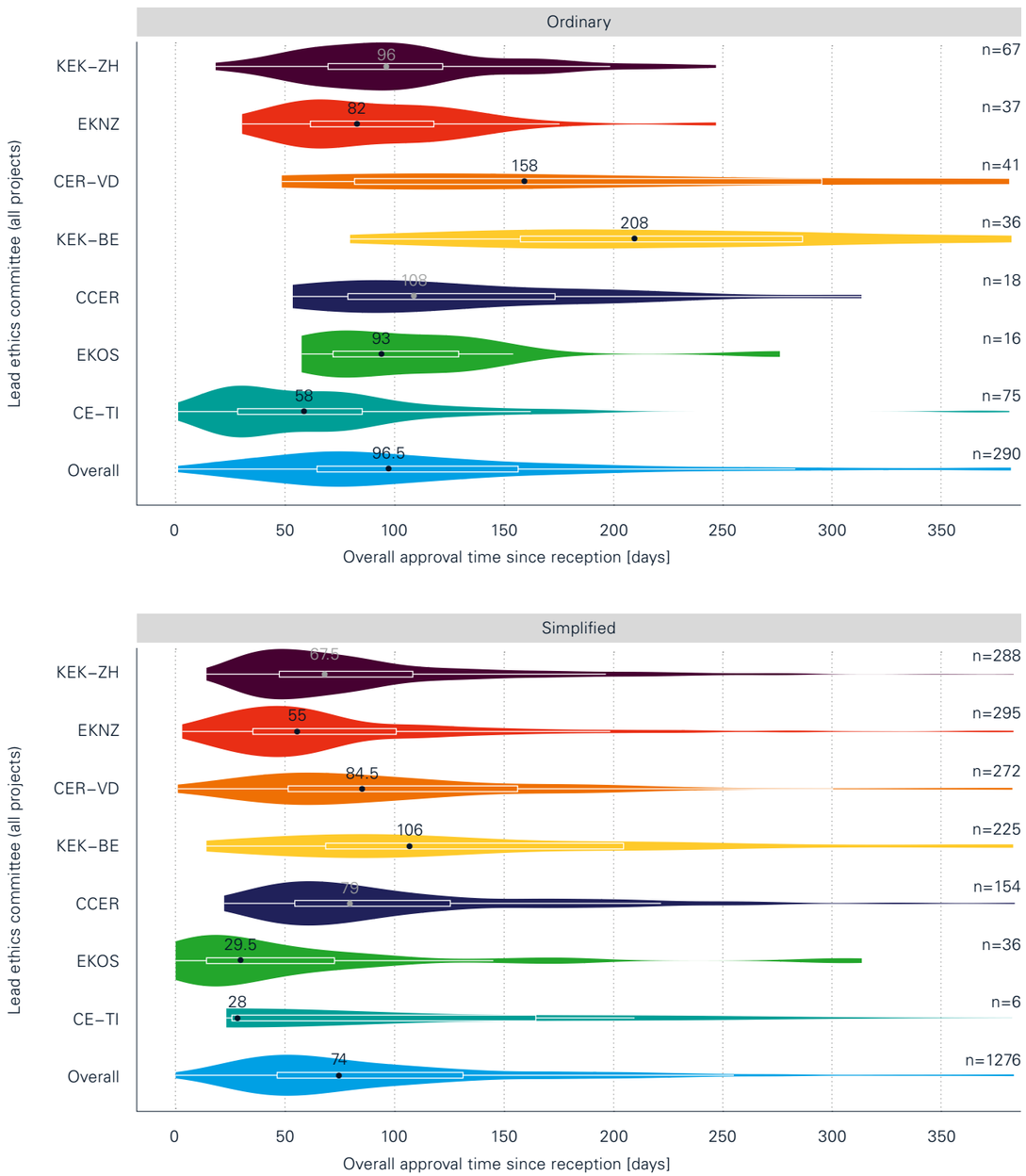
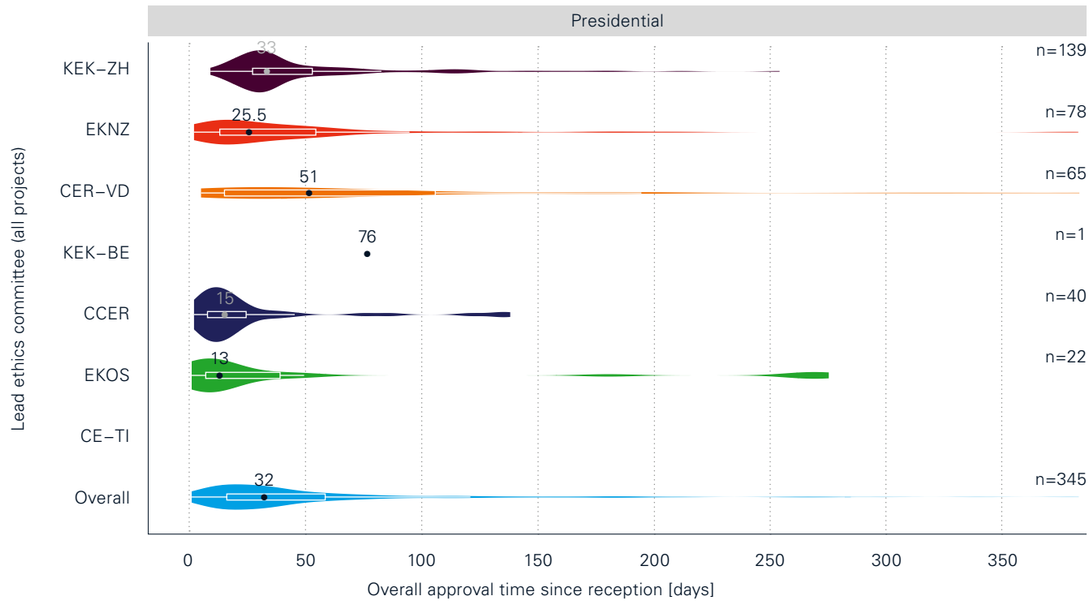


Figure 7: Violin plot of the overall approval time by EC from reception to final decision and stratified by review procedure. 85 projects with approval time > 1 year are not shown for layout reasons. ClinOMD projects are not included but separately displayed in table 25.1.





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	117	30.1	7.0	[7.0,8.0]	7.0	[7.0,8.0]	32.0	[28.0,38.0]	88.0	[63.0,126.0]	25.0	[21.0,30.0]	79.0	[56.0,116.0]
	EKNZ	87	22.4	4.0	[2.0,5.5]	5.0	[2.0,7.0]	27.0	[21.0,35.0]	71.0	[55.5,117.0]	20.0	[15.0,28.0]	68.0	[49.0,112.0]
	CER-VD	41	10.6	4.0	[3.0,6.0]	5.0	[4.0,8.0]	24.0	[18.0,29.0]	143.0	[78.0,320.0]	17.0	[14.0,21.0]	136.0	[70.0,315.0]
	KEK-BE	58	14.9	2.5	[1.0,6.0]	7.0	[4.0,25.8]	27.5	[19.2,46.0]	193.5	[137.0,279.0]	18.0	[14.0,20.0]	172.5	[121.8,255.5]
	CCER	39	10.1	4.0	[1.0,5.5]	6.0	[3.0,13.0]	36.0	[29.0,42.5]	98.0	[63.5,181.5]	28.0	[22.0,32.5]	86.0	[52.5,176.5]
	EKOS	25	6.4	3.0	[2.0,5.0]	4.0	[2.0,5.0]	24.0	[13.0,35.0]	80.0	[60.0,121.0]	20.0	[10.0,32.0]	77.0	[53.0,119.0]
	CE-TI	21	5.4	7.0	[7.0,7.0]	7.0	[7.0,7.0]	36.0	[28.0,42.0]	74.0	[28.0,121.0]	24.0	[21.0,35.0]	69.0	[21.0,100.0]
	All	388	100.0	5.0	[3.0,7.0]	7.0	[4.0,8.0]	30.0	[22.0,38.0]	98.0	[64.0,165.2]	21.0	[15.0,28.0]	90.0	[57.0,153.0]
Research w/persons	KEK-ZH	132	20.2	7.0	[7.0,8.0]	7.0	[7.0,8.0]	34.0	[29.0,38.2]	71.5	[49.0,109.2]	26.0	[20.0,29.2]	63.0	[41.0,98.2]
	EKNZ	139	21.2	4.0	[2.0,6.0]	5.0	[2.0,7.0]	26.0	[20.5,31.5]	63.0	[44.5,109.0]	20.0	[16.0,26.0]	55.0	[40.5,102.0]
	CER-VD	172	26.3	3.0	[1.0,5.0]	5.0	[2.0,8.0]	20.0	[16.0,28.0]	90.0	[57.8,151.2]	14.0	[13.0,19.0]	76.0	[51.0,131.0]
	KEK-BE	80	12.2	2.0	[1.0,5.0]	8.0	[4.0,20.0]	28.0	[20.8,42.2]	107.5	[77.0,187.8]	15.0	[14.0,19.0]	88.5	[57.5,145.2]
	CCER	80	12.2	3.0	[1.0,4.0]	6.0	[4.0,13.0]	32.0	[27.0,41.0]	82.5	[61.0,124.5]	23.0	[21.0,28.0]	75.5	[50.0,113.8]
	EKOS	19	2.9	2.0	[1.0,2.5]	2.0	[1.0,9.5]	14.0	[7.0,28.0]	26.0	[12.5,63.0]	9.0	[4.5,12.5]	21.0	[10.5,41.0]
	CE-TI	32	4.9	7.0	[7.0,7.0]	7.0	[7.0,7.0]	25.5	[20.8,30.0]	53.5	[24.5,76.2]	17.0	[13.0,23.0]	46.5	[17.5,69.0]
	All	654	100.0	4.0	[2.0,7.0]	7.0	[4.0,8.0]	27.0	[20.0,30.0]	77.5	[49.0,126.8]	19.0	[14.0,25.0]	69.0	[43.0,112.0]
Further use	KEK-ZH	230	27.3	7.0	[7.0,8.0]	7.0	[7.0,8.0]	29.0	[23.0,35.0]	39.0	[29.0,72.8]	21.0	[15.0,26.0]	29.0	[21.2,60.5]
	EKNZ	177	21.0	3.0	[1.0,6.0]	4.0	[2.0,7.0]	12.0	[7.0,20.0]	32.0	[17.0,59.0]	7.0	[4.0,13.0]	26.0	[12.0,53.0]
	CER-VD	163	19.4	4.0	[2.0,5.5]	5.0	[3.0,12.0]	21.0	[15.0,34.5]	64.0	[33.5,157.0]	14.0	[10.0,19.0]	53.0	[23.0,98.5]
	KEK-BE	123	14.6	2.0	[1.0,4.0]	7.0	[3.0,19.0]	27.0	[19.0,49.0]	97.0	[56.0,209.0]	15.0	[14.0,21.0]	87.0	[43.5,177.0]
	CCER	91	10.8	3.0	[1.0,4.0]	5.0	[3.0,11.0]	26.0	[16.0,35.0]	47.0	[16.5,87.5]	21.0	[8.0,27.0]	41.0	[9.0,77.5]
	EKOS	30	3.6	1.0	[1.0,2.0]	1.5	[1.0,4.5]	8.0	[5.0,12.5]	13.5	[7.0,47.2]	5.0	[2.0,7.0]	7.5	[3.0,33.2]
	CE-TI	28	3.3	7.0	[7.0,7.0]	7.0	[7.0,7.2]	26.5	[20.8,30.2]	44.5	[28.0,76.2]	19.5	[13.8,23.2]	37.5	[20.8,70.2]
	All	842	100.0	4.0	[2.0,7.0]	7.0	[3.0,8.0]	23.0	[15.0,33.0]	48.0	[25.0,96.8]	15.0	[9.0,22.0]	40.0	[20.0,80.0]
Deceased and embryos from stillbirths or abortion	KEK-ZH	15	55.6	7.0	[7.0,8.0]	7.0	[7.0,8.0]	31.0	[29.0,33.5]	32.0	[30.0,93.0]	23.0	[20.5,25.0]	25.0	[23.0,64.5]
	EKNZ	7	25.9	2.0	[1.5,2.5]	3.0	[2.0,4.5]	35.0	[22.0,36.0]	55.0	[42.5,163.5]	21.0	[18.5,32.0]	52.0	[39.0,120.5]
	CER-VD	2	7.4	6.5	[5.8,7.2]	6.5	[5.8,7.2]	22.0	[20.5,23.5]	74.0	[58.0,90.0]	15.5	[14.8,16.2]	67.5	[52.2,82.8]
	KEK-BE	1	3.7	7.0	[7.0,7.0]	7.0	[7.0,7.0]	27.0	[27.0,27.0]	132.0	[132.0,132.0]	20.0	[20.0,20.0]	125.0	[125.0,125]
	CCER	2	7.4	5.0	[4.0,6.0]	5.0	[4.0,6.0]	28.0	[25.0,31.0]	42.0	[32.0,52.0]	23.0	[21.0,25.0]	37.0	[28.0,46.0]
	EKOS	0	0.0												
	CE-TI	0	0.0												
	All	27	100.0	7.0	[3.0,7.5]	7.0	[5.0,8.0]	30.0	[25.0,35.0]	43.0	[31.5,118.0]	22.0	[18.5,26.0]	37.0	[23.5,98.5]
Overall	KEK-ZH	494	100.0	7.0	[7.0,8.0]	7.0	[7.0,8.0]	32.0	[26.0,37.0]	61.0	[35.0,98.0]	23.0	[17.2,28.0]	50.0	[28.0,87.5]
	EKNZ	410	100.0	4.0	[2.0,6.0]	5.0	[2.0,7.0]	21.0	[13.0,29.0]	54.0	[33.0,98.0]	15.0	[8.0,21.0]	48.0	[28.0,89.2]
	CER-VD	378	100.0	4.0	[2.0,5.0]	5.0	[3.0,9.0]	21.0	[16.0,29.0]	81.5	[49.0,165.8]	14.0	[12.0,19.0]	70.0	[43.0,134.0]
	KEK-BE	262	100.0	2.0	[1.0,5.0]	7.0	[4.0,20.0]	27.5	[20.0,46.0]	121.5	[75.2,218.8]	15.0	[14.0,20.0]	103.5	[57.2,189.0]
	CCER	212	100.0	3.0	[1.0,4.0]	6.0	[3.0,12.0]	30.5	[22.0,39.2]	71.0	[43.0,117.2]	23.0	[16.0,28.0]	57.0	[35.8,106.0]
	EKOS	74	100.0	2.0	[1.0,3.0]	2.5	[1.0,5.0]	13.0	[7.0,26.0]	42.0	[13.0,92.8]	8.0	[3.0,15.2]	34.5	[7.2,79.8]
	CE-TI	81	100.0	7.0	[7.0,7.0]	7.0	[7.0,7.0]	28.0	[21.0,33.0]	57.0	[28.0,85.0]	20.0	[14.0,24.0]	45.0	[20.0,77.0]
	All	1911	100.0	5.0	[2.0,7.0]	7.0	[3.0,8.0]	27.0	[19.0,35.0]	69.0	[38.0,123.0]	18.0	[13.0,25.0]	59.0	[31.0,110.0]

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	119	6	[3,7]	269	5	[3,7]
	from receipt to status 'complete'	119	7	[4,8]	269	7	[4,8]
	from receipt to first decision	119	32	[22,42]	269	30	[22,36]
	from receipt to final decision	119	117	[87,176]	269	84	[57,152]
	from 'complete' to first decision	119	23	[16,33]	269	21	[15,27]
	from 'complete' to final decision	119	111	[79,160]	269	77	[50,136]
Research w/persons	from receipt to first reply	77	3	[1,6]	577	4	[2,7]
	from receipt to status 'complete'	77	6	[3,12]	577	7	[4,8]
	from receipt to first decision	77	27	[21,35]	577	27	[20,35]
	from receipt to final decision	77	111	[68,162]	577	74	[49,118]
	from 'complete' to first decision	77	20	[14,26]	577	19	[14,25]
	from 'complete' to final decision	77	109	[58,148]	577	64	[42,105]
Further use	from receipt to first reply	45	4	[1,7]	797	4	[2,7]
	from receipt to status 'complete'	45	7	[5,23]	797	7	[3,8]
	from receipt to first decision	45	27	[18,50]	797	22	[14,33]
	from receipt to final decision	45	78	[36,181]	797	47	[25,94]
	from 'complete' to first decision	45	18	[13,22]	797	15	[9,22]
	from 'complete' to final decision	45	63	[23,113]	797	39	[19,77]
Deceased persons	from receipt to first reply	0			27	7	[3,8]
	from receipt to status 'complete'	0			27	7	[5,8]
	from receipt to first decision	0			27	30	[25,35]
	from receipt to final decision	0			27	43	[32,118]
	from 'complete' to first decision	0			27	22	[18,26]
	from 'complete' to final decision	0			27	37	[24,98]
Overall	from receipt to first reply	241	5	[2,7]	1670	5	[2,7]
	from receipt to status 'complete'	241	7	[4,8]	1670	7	[3,8]
	from receipt to first decision	241	30	[21,41]	1670	26	[18,35]
	from receipt to final decision	241	108	[71,176]	1670	63	[36,114]
	from 'complete' to first decision	241	21	[15,28]	1670	18	[13,24]
	from 'complete' to final decision	241	98	[63,156]	1670	54	[29,101]

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	56	7	[7,7]	438	7	[7,8]
	from receipt to status 'complete'	56	7	[7,8]	438	7	[7,8]
	from receipt to first decision	56	35	[28,43]	438	32	[26,36]
	from receipt to final decision	56	90	[65,118]	438	56	[34,93]
	from 'complete' to first decision	56	24	[17,35]	438	23	[18,28]
	from 'complete' to final decision	56	81	[56,111]	438	48	[26,84]
EKNZ	from receipt to first reply	49	4	[1,6]	361	4	[2,6]
	from receipt to status 'complete'	49	5	[2,8]	361	5	[2,7]
	from receipt to first decision	49	27	[21,36]	361	20	[13,28]
	from receipt to final decision	49	100	[68,141]	361	51	[30,79]
	from 'complete' to first decision	49	21	[16,28]	361	14	[7,21]
	from 'complete' to final decision	49	92	[63,133]	361	43	[25,76]
CER-VD	from receipt to first reply	32	4	[2,6]	346	3	[2,5]
	from receipt to status 'complete'	32	5	[3,7]	346	5	[3,10]
	from receipt to first decision	32	23	[18,30]	346	20	[16,29]
	from receipt to final decision	32	158	[126,302]	346	77	[47,155]
	from 'complete' to first decision	32	16	[14,21]	346	14	[12,19]
	from 'complete' to final decision	32	154	[122,220]	346	64	[41,114]
KEK-BE	from receipt to first reply	46	3	[1,5]	216	2	[1,5]
	from receipt to status 'complete'	46	8	[4,24]	216	7	[4,18]
	from receipt to first decision	46	32	[21,49]	216	27	[19,46]
	from receipt to final decision	46	180	[100,265]	216	112	[70,206]
	from 'complete' to first decision	46	18	[14,22]	216	15	[14,20]
	from 'complete' to final decision	46	154	[83,226]	216	94	[55,172]

		Application involves					
		Multiple ECs			Single EC		
Lead EC	Time interval	n	Median	IQR	n	Median	IQR
CCER	from receipt to first reply	27	3	[1,5]	185	3	[1,4]
	from receipt to status 'complete'	27	7	[1,16]	185	6	[3,11]
	from receipt to first decision	27	37	[26,46]	185	29	[22,38]
	from receipt to final decision	27	98	[59,166]	185	68	[43,114]
	from 'complete' to first decision	27	23	[16,32]	185	23	[16,28]
	from 'complete' to final decision	27	81	[46,144]	185	57	[35,96]
EKOS	from receipt to first reply	23	3	[1,5]	51	1	[1,3]
	from receipt to status 'complete'	23	3	[2,5]	51	2	[1,5]
	from receipt to first decision	23	26	[16,38]	51	9	[6,14]
	from receipt to final decision	23	80	[56,128]	51	21	[8,62]
	from 'complete' to first decision	23	22	[11,30]	51	6	[2,10]
	from 'complete' to final decision	23	79	[52,124]	51	14	[6,41]
CE-TI	from receipt to first reply	8	7	[7,7]	73	7	[7,7]
	from receipt to status 'complete'	8	7	[7,7]	73	7	[7,7]
	from receipt to first decision	8	34	[30,44]	73	27	[21,32]
	from receipt to final decision	8	106	[88,125]	73	48	[27,76]
	from 'complete' to first decision	8	27	[23,36]	73	20	[14,24]
	from 'complete' to final decision	8	98	[81,118]	73	40	[20,72]
Overall	from receipt to first reply	241	5	[2,7]	1670	5	[2,7]
	from receipt to status 'complete'	241	7	[4,8]	1670	7	[3,8]
	from receipt to first decision	241	30	[21,41]	1670	26	[18,35]
	from receipt to final decision	241	108	[71,176]	1670	63	[36,114]
	from 'complete' to first decision	241	21	[15,28]	1670	18	[13,24]
	from 'complete' to final decision	241	98	[63,156]	1670	54	[29,101]

5.4.1 Time from status "complete" to first decision

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). 32 projects with approval time > 60 days are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 25.1.

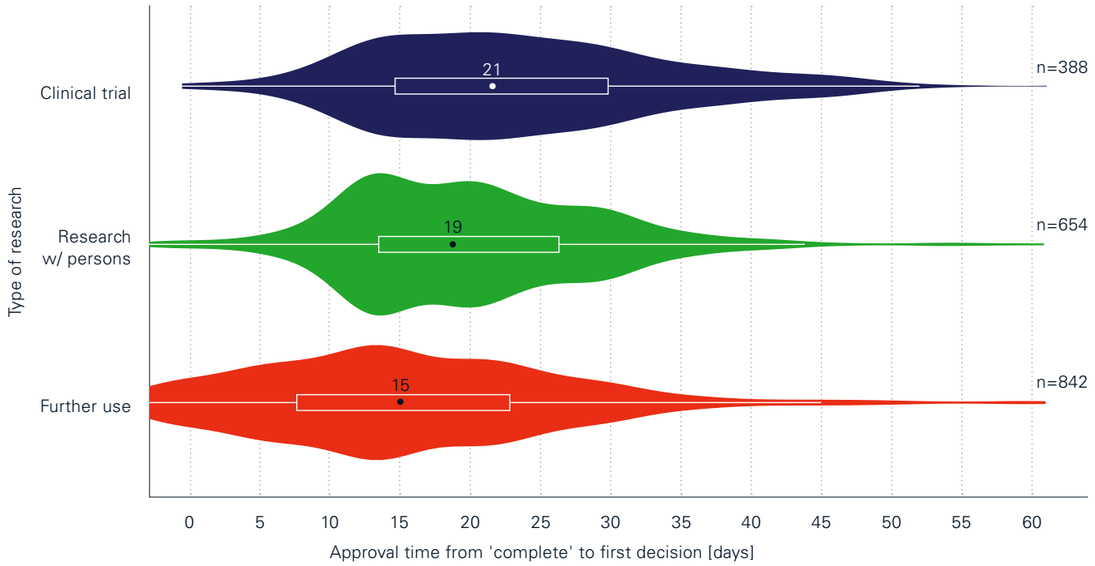
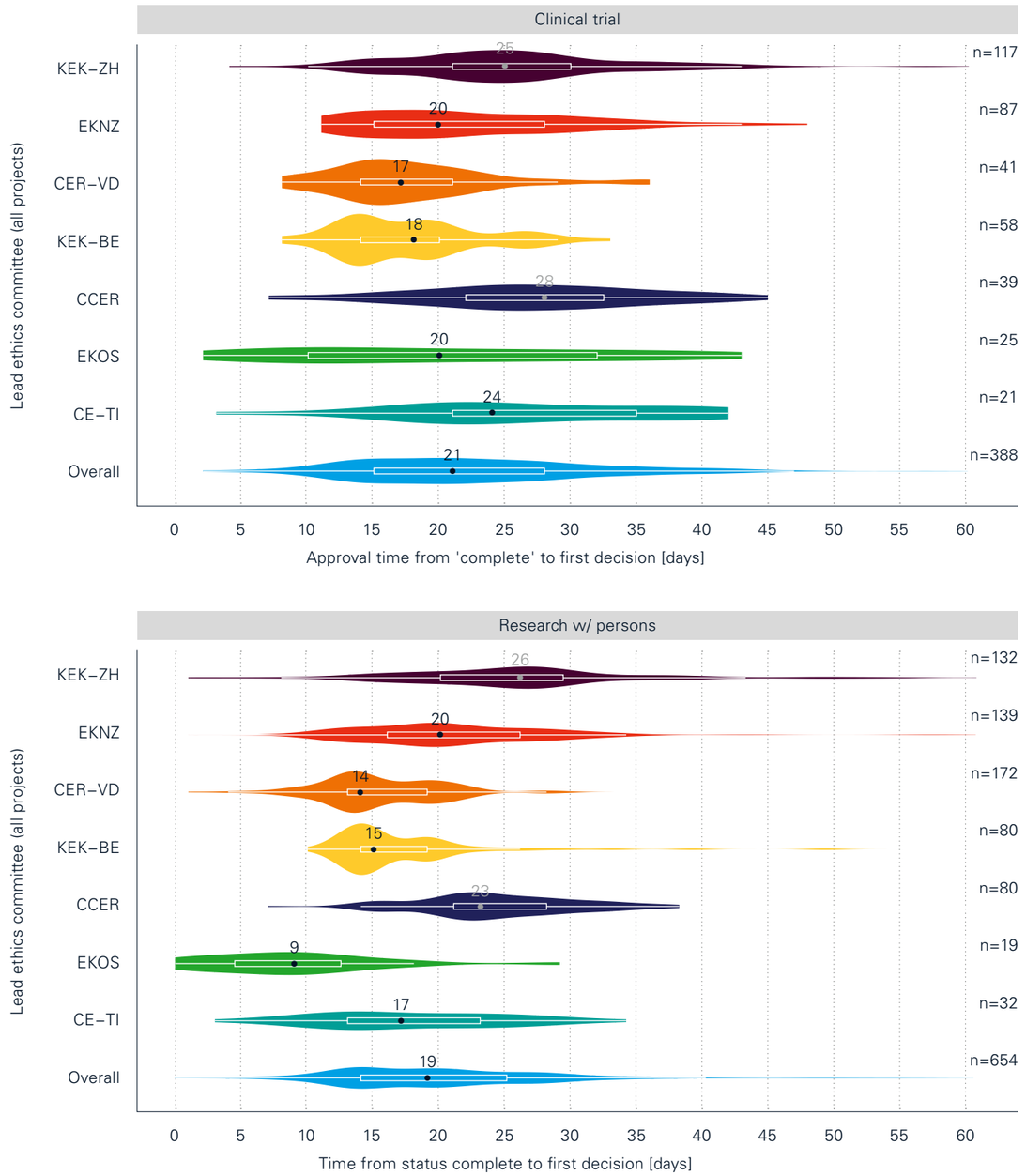
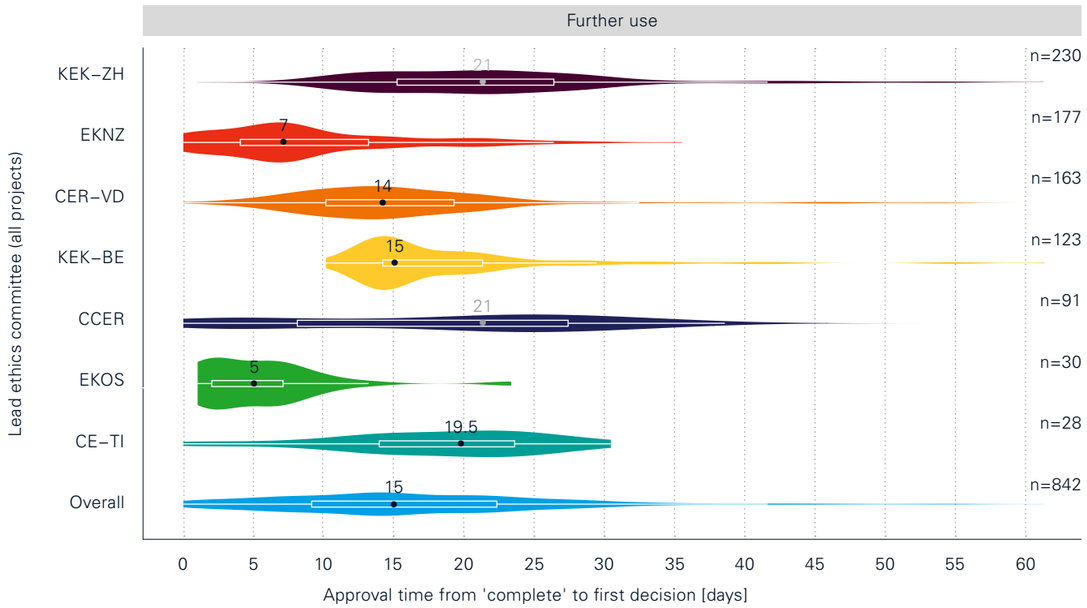


Figure 9: Violin plot of the **approval time starting from status 'complete' to the first decision** per type of research (only the 3 major groups are shown) stratified by EC. 29 projects with approval time > 60 days are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 25.1.





5.4.2 Time from reception to final decision

Figure 10: Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown). 57 projects with an overall approval time > 1 year are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 25.1.

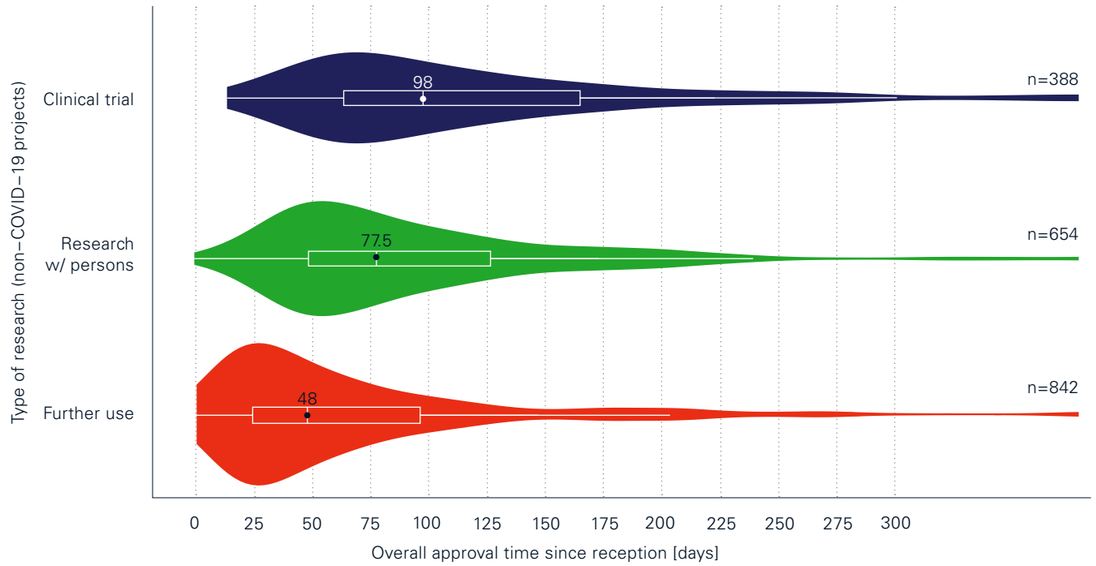
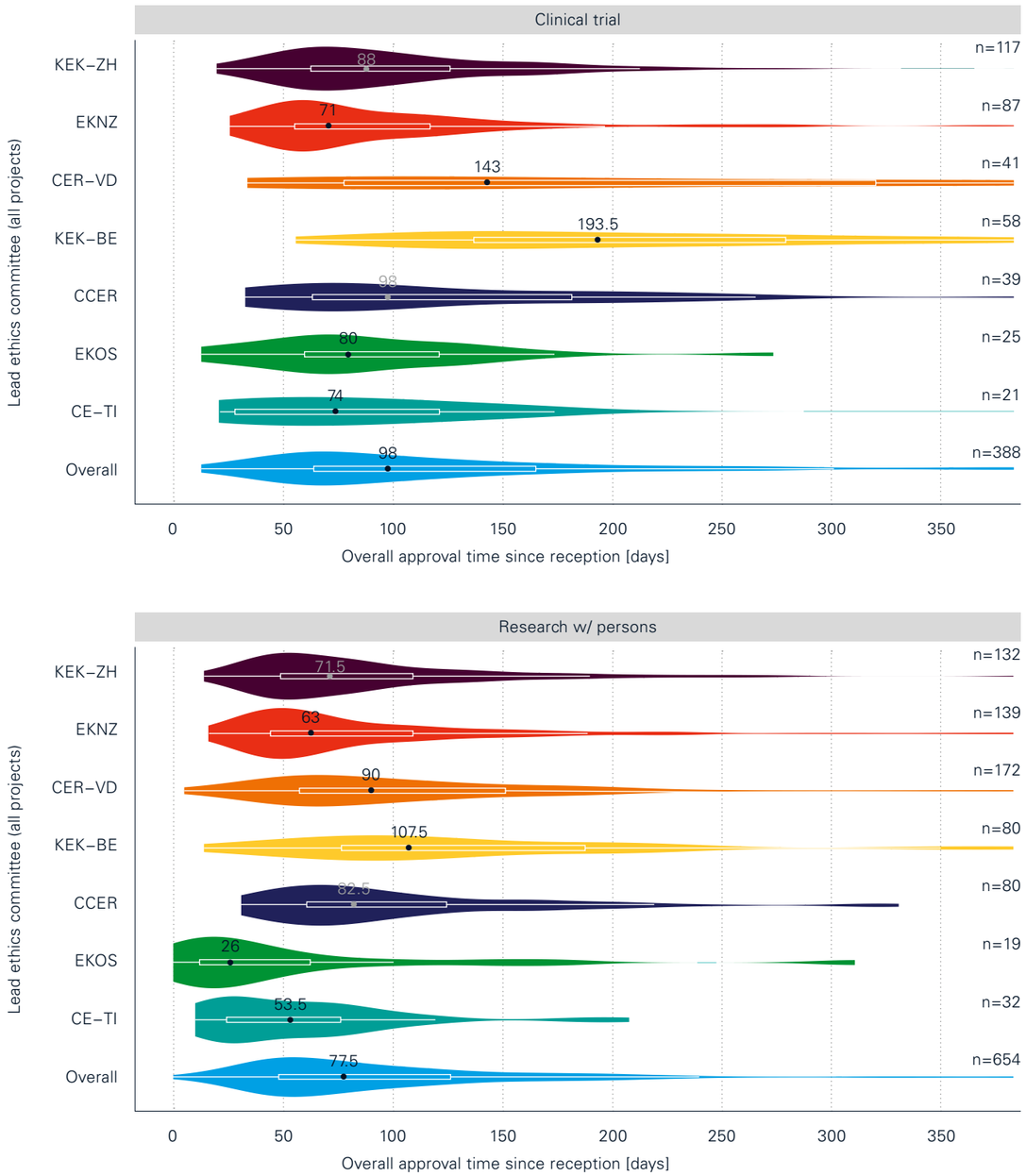
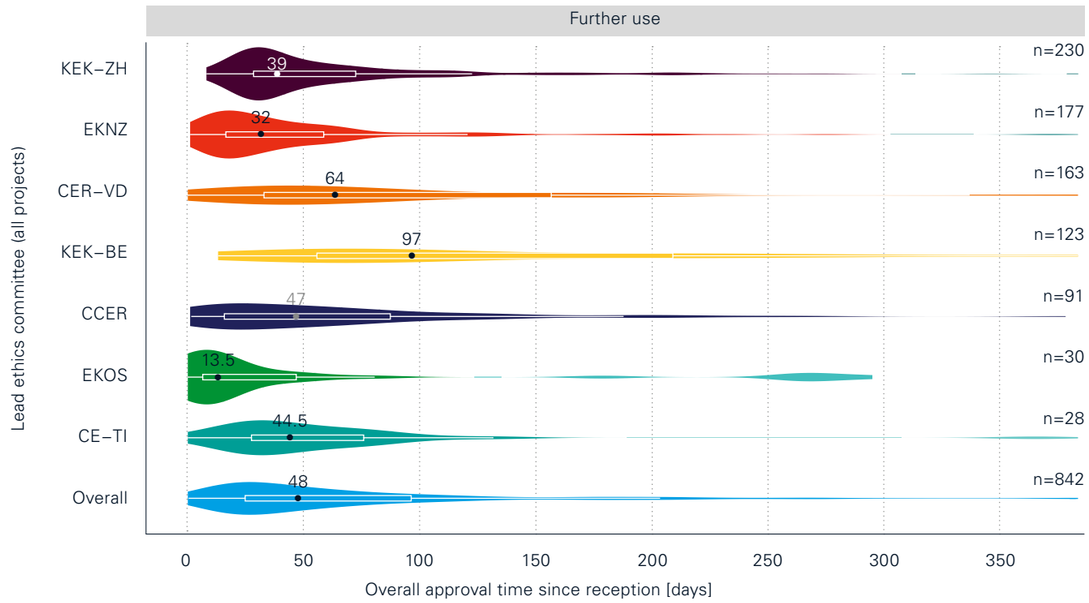


Figure 11: Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown) stratified by EC. 85 projects with an overall approval time > 1 year are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 25.1.





5.5 Stratification of response time by lead ethics committee and depending on whether a single or multiple ECs are involved – only for ClinO-MD projects

Table 25.1: 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 – **only for ClinO-MD projects.**

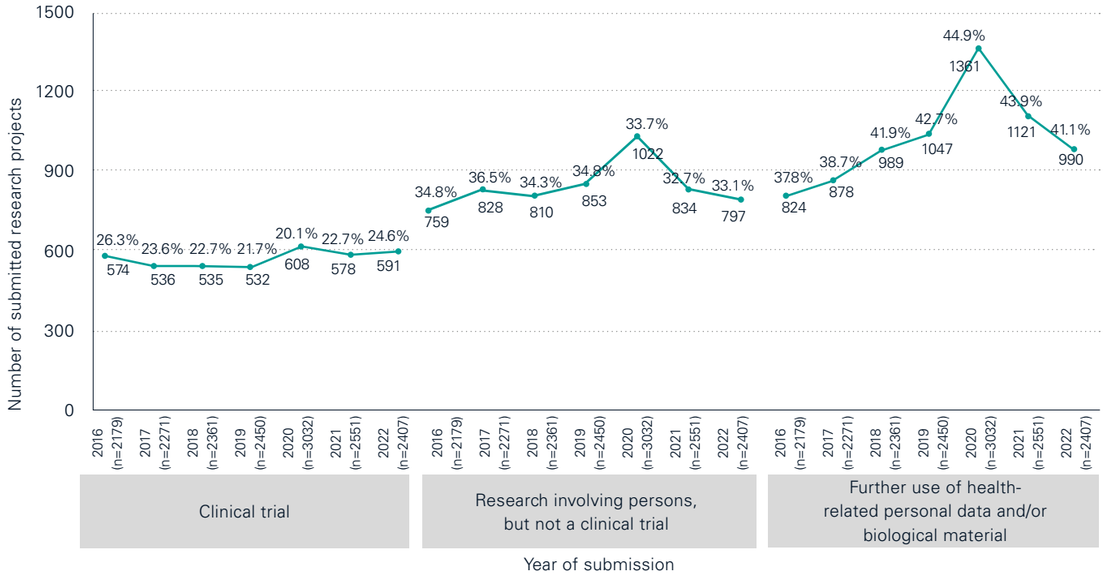
		Application involves					
		Multiple ECs			Single EC		
Lead EC	Time interval	n	Median	IQR	n	Median	IQR
KEK-ZH	from receipt to status 'complete'	4	8	[8,9]	26	8	[6,10]
	from receipt to final decision	4	63	[44,112]	26	38	[26,41]
	from 'complete' to final decision	4	56	[37,104]	26	27	[19,34]
EKNZ	from receipt to status 'complete'	6	6	[3,10]	9	5	[4,6]
	from receipt to final decision	6	47	[44,51]	9	37	[29,38]
	from 'complete' to final decision	6	41	[37,43]	9	27	[24,31]
CER-VD	from receipt to status 'complete'	0			9	5	[4,7]
	from receipt to final decision	0			9	49	[31,91]
	from 'complete' to final decision	0			9	44	[27,84]
KEK-BE	from receipt to status 'complete'	7	7	[3,8]	22	8	[7,10]
	from receipt to final decision	7	45	[44,48]	22	67	[49,77]
	from 'complete' to final decision	7	41	[36,42]	22	60	[41,72]
CCER	from receipt to status 'complete'	0			11	8	[6,12]
	from receipt to final decision	0			11	75	[52,90]
	from 'complete' to final decision	0			11	67	[38,82]
EKOS	from receipt to status 'complete'	0			4	4	[3,5]
	from receipt to final decision	0			4	32	[20,57]
	from 'complete' to final decision	0			4	27	[16,51]
CE-TI	from receipt to status 'complete'	2	15	[12,18]	3	10	[10,10]
	from receipt to final decision	2	42	[36,48]	3	30	[28,32]
	from 'complete' to final decision	2	27	[23,31]	3	20	[18,22]
Overall	from receipt to status 'complete'	19	8	[4,9]	84	7	[5,10]
	from receipt to final decision	19	46	[44,51]	84	43	[30,68]
	from 'complete' to final decision	19	40	[36,43]	84	36	[25,60]

The total number of 103 research projects consist of 101 trials with medical devices and 2 trials on a combination medicinal product and medical device.

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

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

Figure 12: Total number of submitted projects per year and type of research. Percentages on the top of the lines refer to the proportion of studies of a given type compared to all studies submitted in a given year.

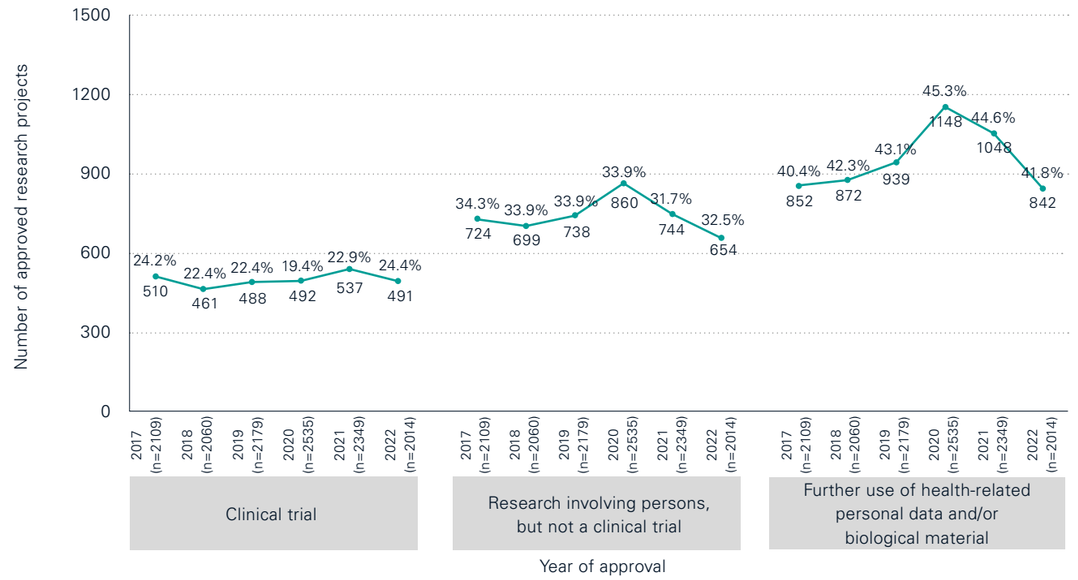


Data not shown in the above figure: Research involving deceased persons (2018: 27, 2019: 17, 2020: 40, 2021: 18, 2022: 29) and Research involving embryos and fetuses from induced abortions or stillbirths (2018: 0, 2019: 1, 2020: 1, 2021: 0 2022: 0)

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.

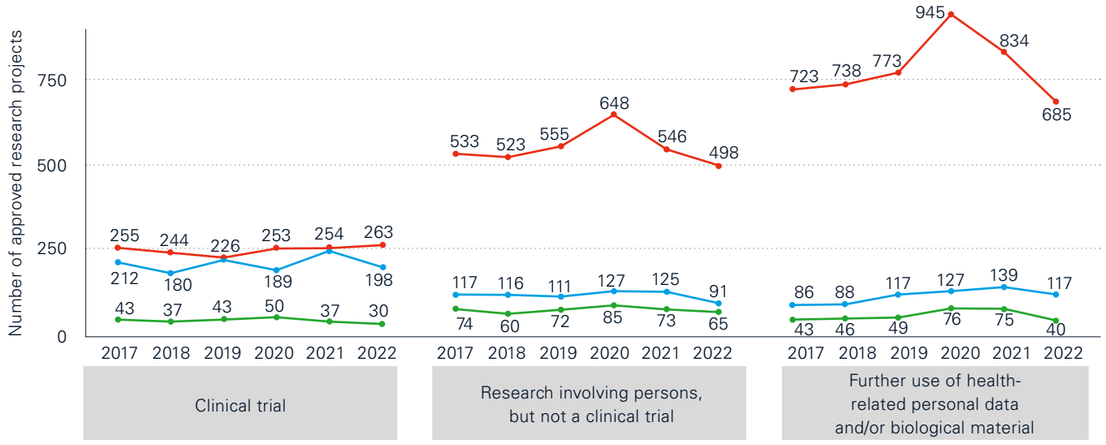
Figure 13: Total number of approved projects per year and type of research. Percentages on the top of the lines refer to the proportion of studies of a given type compared to all studies approved in a given year.



Data not shown in the above figure: Research involving deceased persons (2018: 28, 2019: 14, 2020: 35, 2021: 19, 2022: 27) and Research involving embryos and fetuses from induced abortions or stillbirths (2018: 0, 2019: 0, 2020: 0, 2021: 1 2022: 0)

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

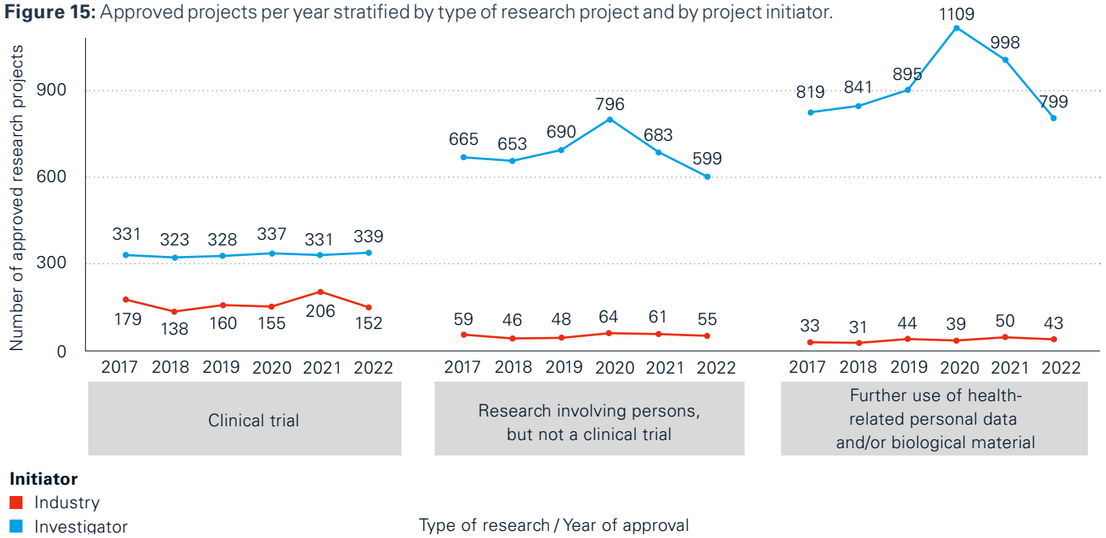
Figure 14: Approved projects per year stratified by type of research project and by study design.



Data not shown in the above figure: Research involving deceased persons (2018: 28, 2019: 14, 2020: 35, 2021: 19, 2022: 27) and Research involving embryos and fetuses from induced abortions or stillbirths (2018: 0, 2019: 0, 2020: 0, 2021: 1 2022: 0)

7.2 Project initiator

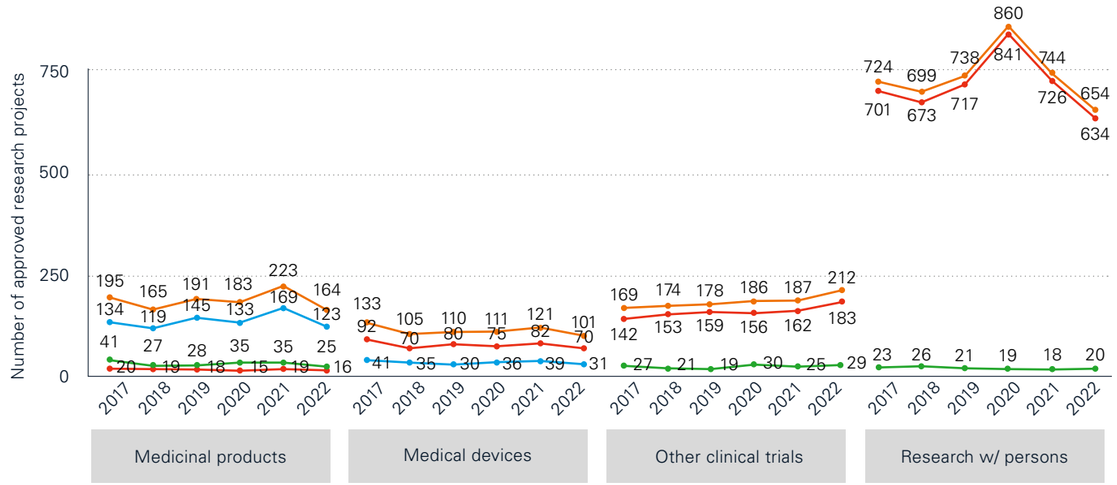
Figure 15: Approved projects per year stratified by type of research project and by project initiator.



Data not shown in the above figure: Research involving deceased persons (2018: 28, 2019: 14, 2020: 35, 2021: 19, 2022: 27) and Research involving embryos and fetuses from induced abortions or stillbirths (2018: 0, 2019: 0, 2020: 0, 2021: 1 2022: 0)

7.3 Risk category

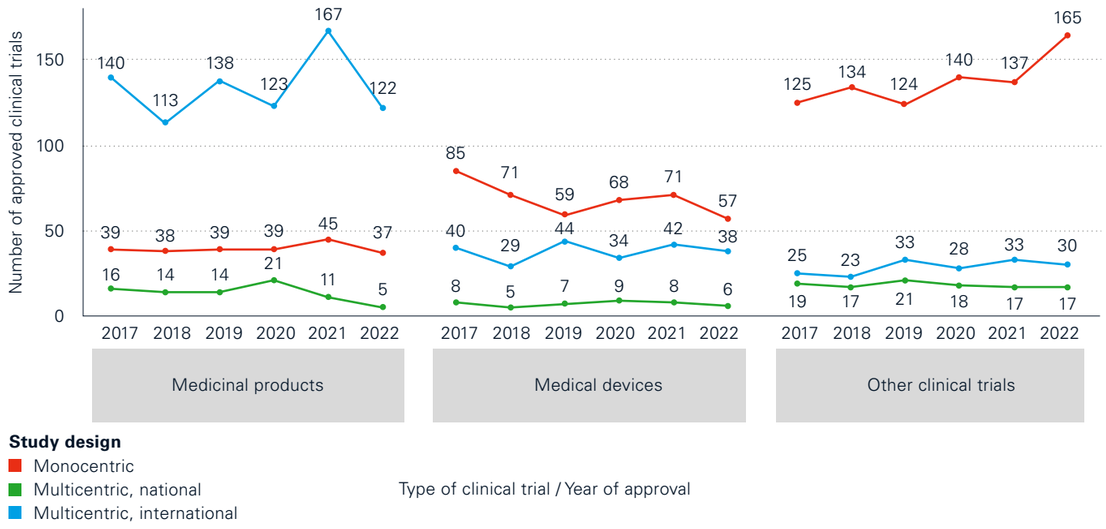
Figure 16: Clinical trials and research projects involving persons approved per year stratified by type of research project and risk category.



Data not shown in the above figure: Research involving transplant products (2018: 9, 2019: 4, 2020: 6, 2021: 2 , 2022: 7), combination drugs/devices (2019: 3, 2020: 4, 2021: 2 , 2022: 2) , gene therapy (2018: 3, 2019: 2, 2020: 1 , 2021: 1 , 2022: 2) , transplantation (2018: 1, 2019: 0, 2020: 1 , 2021: 0 , 2022: 1) and pathogenic organisms (2020: 0 , 2021: 1 , 2022: 2)

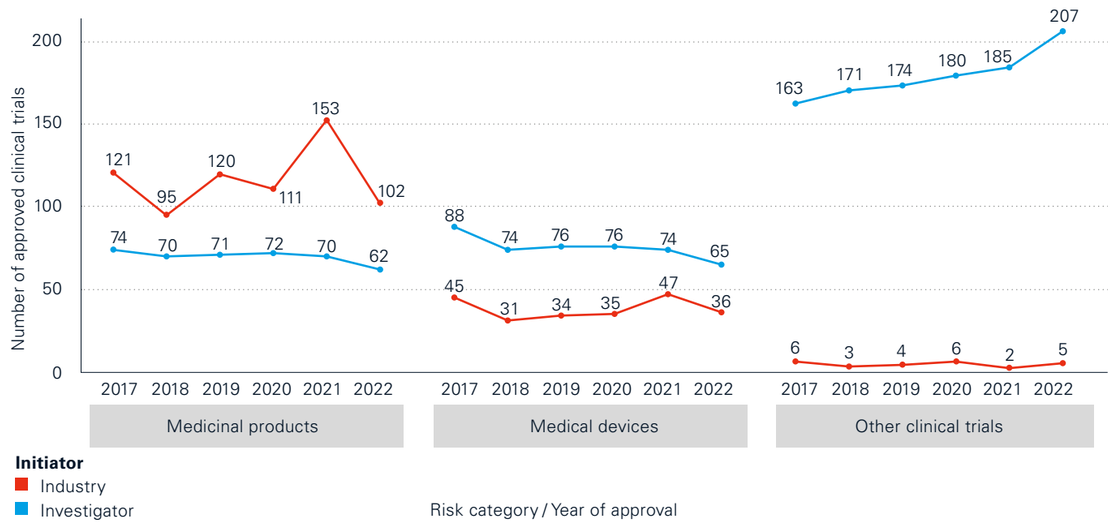
7.4 Subgroups of clinical trials

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



Data not shown in the above figure: Research involving transplant products (2018: 9, 2019: 4, 2020: 6, 2021: 2 , 2022: 7), combination drugs/devices (2019: 3, 2020: 4, 2021: 2 , 2022: 2) , gene therapy (2018: 3, 2019: 2, 2020: 1 , 2021: 1 , 2022: 2) , transplantation (2018: 1, 2019: 0, 2020: 1 , 2021: 0 , 2022: 1) and pathogenic organisms (2020: 0 , 2021: 1 , 2022: 2)

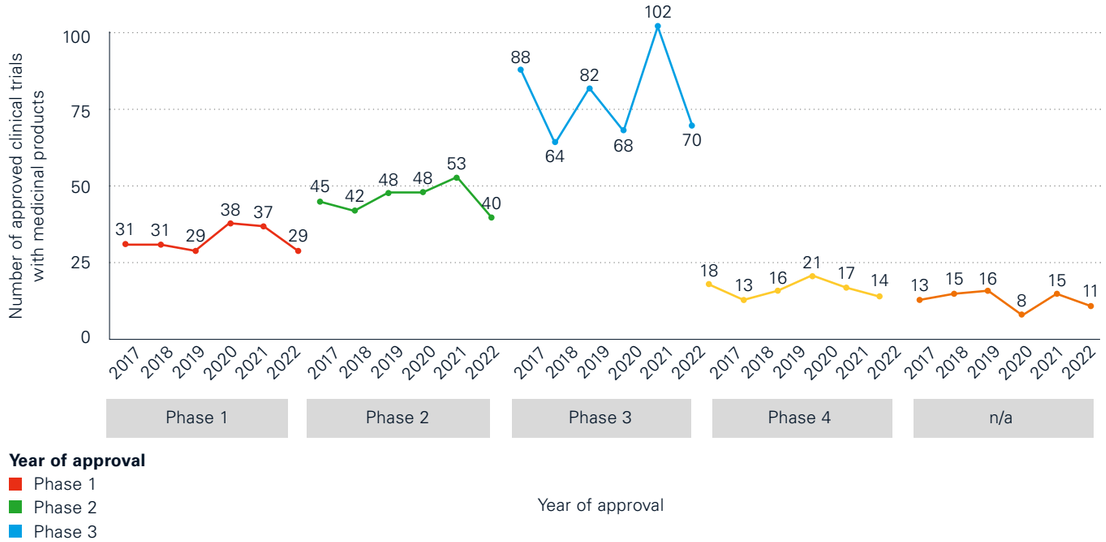
Figure 18: Clinical trials approved per year stratified by trial type and initiator.



Data not shown in the above figure: Research involving transplant products (2018: 9, 2019: 4, 2020: 6, 2021: 2 , 2022: 7), combination drugs/devices (2019: 3, 2020: 4, 2021: 2 , 2022: 2) , gene therapy (2018: 3, 2019: 2, 2020: 1 , 2021: 1 , 2022: 2) , transplantation (2018: 1, 2019: 0, 2020: 1 , 2021: 0 , 2022: 1) and pathogenic organisms (2020: 0 , 2021: 1 , 2022: 2)

7.4.1 Clinical trials with medicinal products

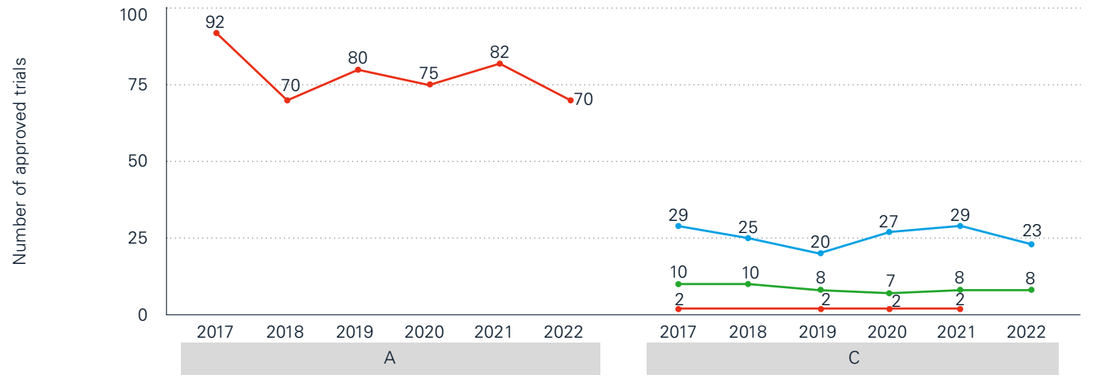
Figure 19: Clinical trials with medicinal products approved per year stratified by study phase.



Number of trials 'first-in-human': 2018: 8, 2019: 5, 2020: 11 , 2021: 10 , 2022: 11

7.4.2 Clinical trials with medical devices

Figure 20: 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-human': 2018: 20, 2019: 14, 2020: 19 , 2021: 20 , 2022: 11

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		2020		2021		2022	
		n	%	n	%	n	%	n	%	n	%	n	%
Genetic data / biol. material	Yes	175	19.3	216	19.9	250	21.3	273	19.4	264	20.5	226	21.4
	No	733	80.7	868	80.1	925	78.7	1137	80.6	1025	79.5	832	78.6
Coding (HRO Art. 25–27)	Coded	422	46.5	904	83.4	1016	86.5	1223	86.7	1171	90.8	959	90.6
	Open, non-coded	486	53.5	180	16.6	159	13.5	187	13.3	118	9.2	99	9.4
Consent (HRO Art. 28–32)	Consent for all data	350	38.5	545	50.3	583	49.6	724	51.3	683	53	632	59.7
	Consent for some but not all data (partially Art. 34 HRA)[1]	–	–	–	–	–	–	306	21.7	378	29.3	326	30.8
	No consent for all data, Art. 34 HRA[2]	558	61.5	539	49.7	592	50.4	380	27	228	17.7	100	9.5
Combined vs. stand-alone projects[3]	Stand-alone further use project	852	93.8	872	80.4	939	79.9	1148	81.4	1048	81.3	842	79.6
	Further use project as part of a clinical trial	19	2.1	41	3.8	46	3.9	42	3	58	4.5	45	4.3
	Further use project as part of a non-clinical research project	37	4.1	171	15.8	190	16.2	220	15.6	183	14.2	171	16.2
	Total number	908	100.0	1084	100.0	1175	100.0	1410	100.0	1289	100.0	1058	100.0

1 In the years 2017, 2018 and 2019, it was not possible to determine this category.
2 For the years 2017, 2018 and 2019, research projects for which consent was available for some but not all data (partially Art. 34 HRA) have been included in this category.
3 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 21: Number of approved 'further use' projects per year and fraction without informed consent.

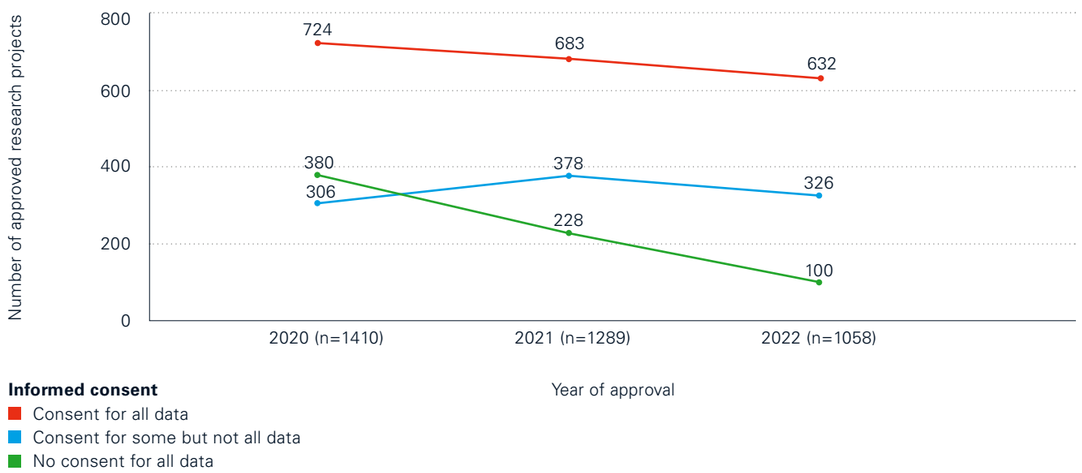
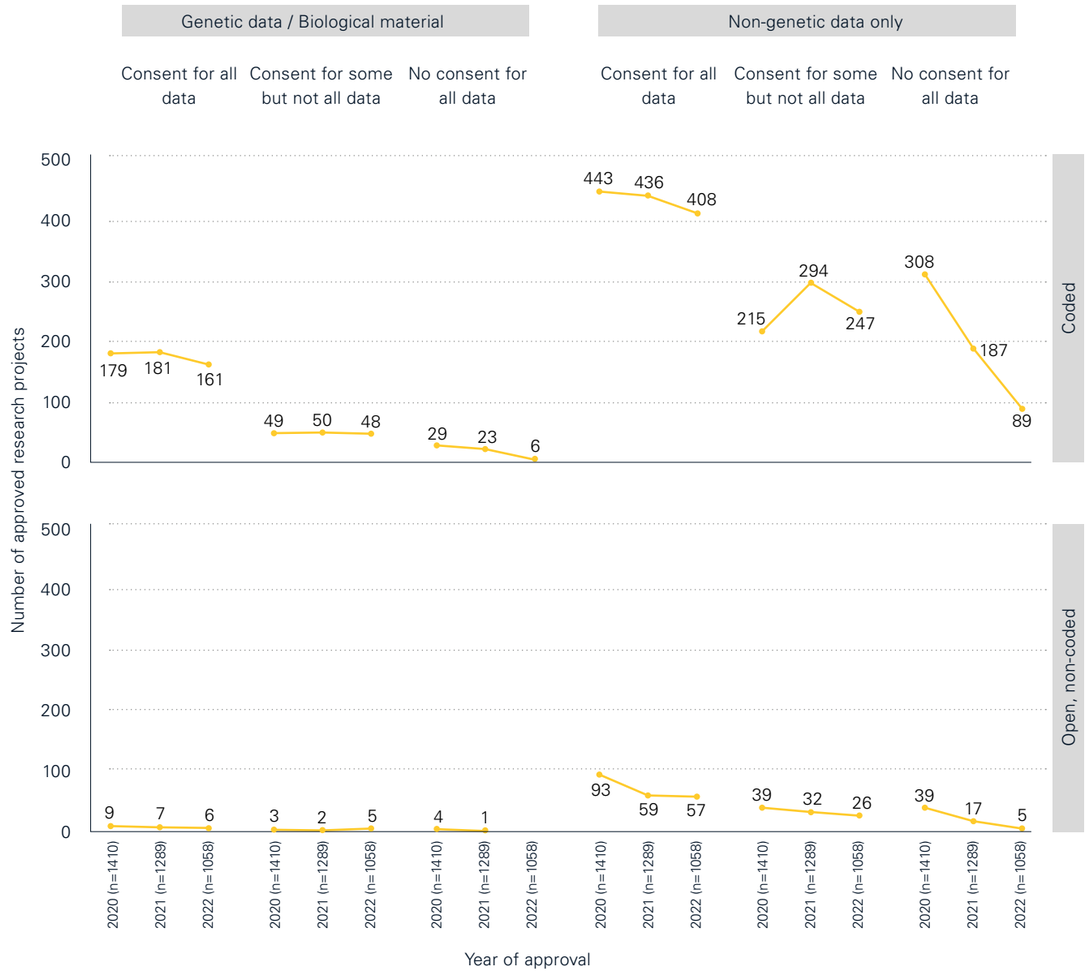


Figure 22: Number of approved 'further use' projects per year stratified by 1) Use of genetic data and/or biological material, 2) coded vs. uncoded, 3) consent for further use.



7.6 Response time

Figure 23: 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.

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