Medicine & Research
Statistical Report

Human Research in Switzerland 2021

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

Report prepared by:
Department of Clinical Research
University Hospital Basel

BASEC export date: April 5, 2022

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’ethique de la recherche (Genève)
CE-TI	Comitato etico cantonale Ticino
CER-VD	Commission cantonale d’ethique 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

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 fifth yearly report. Up to date, the reports cover a period of six years (2016–2021).

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 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 application 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.

1.2 Influence of the ClinO-MD

On 26 May 2021, the new ordinance on clinical trials with medical devices (ClinO-MD) came into force and replaced the previous legal provisions for clinical trials with medical devices, which were up to this point in time regulated in the ClinO. The ClinO-MD regulates clinical trials with medical devices. It has to be noted that clinical trials with in-vitro-diagnostic (IVD) devices, a subgroup of medical devices, were still regulated in the ClinO until 26 May 2022. The enactment of the ClinO-MD on 26 May 2021 has had only one significant effect on the present statistics report: since the processing times in the ClinO-MD are regulated differently than in the ClinO, the processing times are displayed separately for the 87 (41) submitted (approved) ClinO-MD projects (see table 25.1 in chapter 5). Apart from this, the presentation of the clinical trials with medical devices in chapters 3, 4, 6 and 7 of this statistics report have remained the same as in the past years. Which means: the 57 (79) clinical trials with medical devices that were submitted (approved) under the ClinO are added to the number of clinical trials that were submitted (approved) under the ClinO-MD, to give a total number of submitted (approved) clinical trials of 144 (120) with medical devices for the year 2021.

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 2021 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 2021. 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 2021 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 six years (2016, 2017, 2018, 2019, 2020, 2021) and for approved projects (AS2) over five years (2017, 2018, 2019, 2020, 2021). The reason for this difference in the years compared is described in section 1.5.3.

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, 2022 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 1.5.4).

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 notes the project applicant of either the acceptance of the application (in this case the rst reaction date coincides with the date the application data declared complete), or of any formal deciency 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. (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 39ff. 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 2021.** 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 2021** 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).

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.

1.5.2 Consideration of COVID-19 within the analysis sets AS1 and AS2

COVID-19 studies have been selected using the following method: Studies with at least one of the following terms – covid, ncov, sars, cov-2, corona – in the protocol title were pre-selected. Each pre-selected study was subsequently checked individually to exclude false positives (e. g., studies on coronary heart diseases not associated to the corona virus).

In accordance with this selection, some of the tables and figures in this report have been subdivided to compare **COVID-19** and **non-COVID-19 studies.** All figures and tables are labeled accordingly.

Figure 1: Overview of submissions via BASEC in the years 2016–2021 coloured by the current status as of the time of the data export (April 5, 2022).

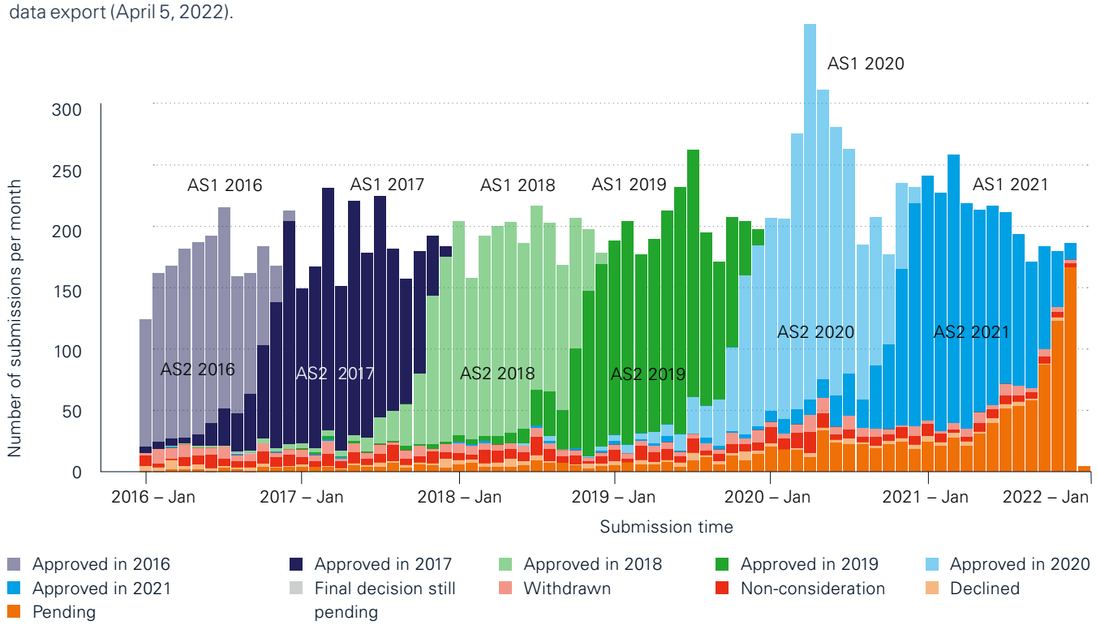
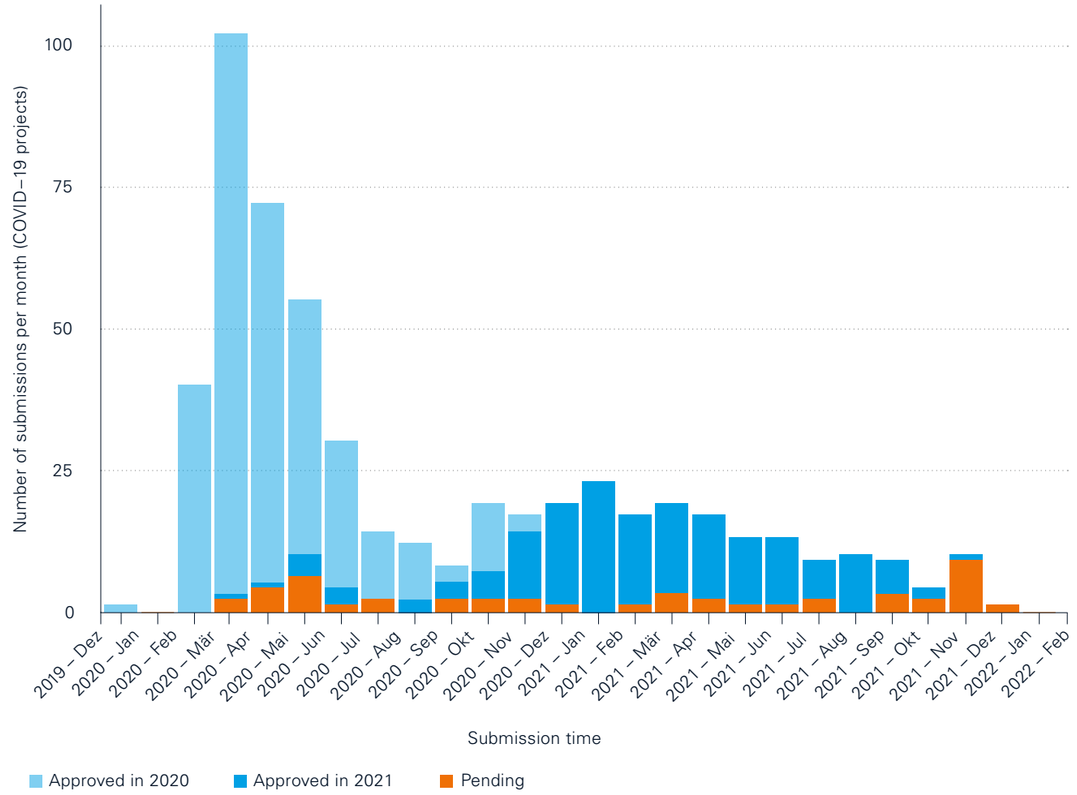


Figure 1.1: Overview of submissions via BASEC in the years 2020 and 2021 for COVID-19 studies coloured by the current status as of the time of the data export (April 5, 2022)



1.5.3 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 2021, since a single up-to-date export is used for all years (export date: April 5, 2022) 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 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.

1.5.4 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.

Stratication 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 / ClinO-MD 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 16, 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 2021

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

					COVID-19	
			n	$\%_{col}$	n	$\%_{row}$
Input	Submission in 2021 (AS1)		2558	69.62	163	6.4
	Projects pending from 2020	Pending first decision in 2020	304	8.27	12	3.9
		Pending final decision in 2020 (first decision before 2021)	812	22.1	41	5
		Total Pending from 2020	1116	30.38	53	4.7
		Grand Total Input 2021	3674	100.0	216	5.9
Output	Final decision in 2021	Approvals (AS2)	2311	62.9	169	7.3
		Rejections (declined projects)	43	1.17	0	0
		Non-considerations	72	1.96	0	0
		Total Decisions	2426	66.03	169	7.0
	Withdrawn during 2021	Withdrawal before first decision	29	0.79	0	0.0
		Withdrawal after first decision 'approvals with charges'	2	0.05	0	0.0
		Withdrawal after first decision 'not-yet-approved projects with conditions'	23	0.63	0	0.0
		Withdrawal after first decision 'non-considerations'	13	0.35	0	0.0
		Total Withdrawn	67	1.82	0	0.0
	Pending at end of 2021	Pending first decision	353	9.61	14	4.0
		Pending final decision (first decision issued)	828	22.54	33	4.0
		Total Pending	1181	32.14	47	4.0
		Grand Total Output 2021	3674	100.0	216	5.9

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 2021 and hence obtained a new BASEC number.

3 Overview of all projects submitted to BASEC in 2021 (AS1)

Table 2: Total number of research projects **submitted via BASEC in 2021** (analysis set AS1), including information on type of research and the legal basis as well as the proportion of COVID-19 projects.

				COVID-19	
Type of research	**Legal basis**	n	$\%_{col}$	n	$\%_{row}$
Clinical trial	ClinO or ClinO-MD	583[1]	22.8	7	1.2
Research involving persons, but not a clinical trial	HRO, Chapter 2	838[2]	32.8	76	9.1
Further use of health-related personal data and/or biological material	HRO, Chapter 3	1118	43.7	78	7.0
Research involving deceased persons	HRO, Chapter 4	19	0.7	2	10.5
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	0	0.0	0	NaN
Total number		2558	100	163	6.4

1 68 of these projects also include an application for further use of data/biological material.
2 198 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 2021 (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]	350	13.7	139	21.4	62	11.3	37	8.3	15	3.7	27	9.6	30	31.6	40	32.8
	Approved with charges[3]	575	22.5	5	0.8	286	52.2	139	31.1	10	2.4	50	17.8	45	47.4	40	32.8
	Not approved, conditions[4]	1328	52	439	67.4	170	31	218	48.8	302	73.7	158	56.2	10	10.5	31	25.4
	Declined	34	1.3	8	1.2	8	1.5	1	0.2	5	1.2	12	4.3				
	Non-consideration[5]	73	2.9	23	3.5	4	0.7	9	2.0	18	4.4	14	5.0	2	2.1	3	2.5
	First decision still pending[6]	111	4.3	12	1.8	10	1.8	34	7.6	34	8.3	12	4.3	5	5.3	4	3.3
Final decision	Approved[7]	1998	78.2	570	87.6	450	82.1	336	75.2	261	63.7	212	75.4	80	84.2	89	73.0
	Declined	39	1.5	8	1.2	11	2.0	2	0.4	6	1.5	12	4.3				
	Non-consideration	66	2.6	14	2.2	5	0.9	9	2.0	18	4.4	15	5.3	3	3.2	2	1.6
	Withdrawn	65	2.5	23	3.5	4	0.7	10	2.2	18	4.4	8	2.8			2	1.6
	Final decision still pending[8]	386	15.1	36	5.5	78	14.2	90	20.1	107	26.1	34	12.1	12	12.6	29	23.8
Review procedure	Ordinary[9]	358	14.0	81	12.4	46	8.4	51	11.4	47	11.5	17	6.0	16	16.8	100	82.0[12]
	Simplified[10]	1666	65.2	361	55.5	405	73.9	283	63.3	319	77.8	229	81.5	51	53.7	18	14.8
	Presidential[11]	408	16.0	191	29.3	87	15.9	74	16.6	11	2.7	24	8.5	21	22.1		
	First decision still pending	122	4.8	18	2.8	10	1.8	39	8.7	33	8.0	11	3.9	7	7.4	4	3.3
	Total number in AS1[13]	2558	100.0	651	100.0	548	100.0	447	100.0	410	100.0	281	100.0	95	100.0	122	100.0
	COVID-19	163	6.4	34	5.2	27	4.9	21	4.7	20	4.9	26	9.3	15	15.8	20	16.4

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. 39.9% 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 4 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 2021** (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 committee											
					KEK-ZH		EKNZ		CER-VD		KEK-BE		CCER		EKOS		CE-TI	
Type of research	Research details	Risk cat.	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$
Clinical trial	Medicinal products	A	21	11.0	4	7.1	5	16.7	1	4.8	4	11.8	1	9.1			6	24.0
		B	33	17.3	6	10.7	5	16.7	6	28.6	9	26.5	2	18.2	3	21.4	2	8.0
		C	137	71.7	46	82.1	20	66.7	14	66.7	21	61.8	8	72.7	11	78.6	17	68.0
		All	191	100.0	56	100.0	30	100.0	21	100.0	34	100.0	11	100.0	14	100.0	25	100.0
	Medical devices	A	114	79.2	40	87.0	17	77.3	9	56.2	32	88.9	10	76.9	3	75.0	3	42.9
		C	30	20.8	6	13.0	5	22.7	7	43.8	4	11.1	3	23.1	1	25.0	4	57.1
		All	144	100.0	46	100.0	22	100.0	16	100.0	36	100.0	13	100.0	4	100.0	7	100.0
	Other clinical trials	A	208	89.3	62	84.9	49	86.0	28	96.6	37	94.9	23	95.8	1	50.0	8	88.9
		B	25	10.7	11	15.1	8	14.0	1	3.4	2	5.1	1	4.2	1	50.0	1	11.1
		All	233	100.0	73	100.0	57	100.0	29	100.0	39	100.0	24	100.0	2	100.0	9	100.0
	Combination drugs/devices	A	2	50.0							2	100.0						
		C	2	50.0	2	100.0												
		All	4	100.0	2	100.0					2	100.0						
	Transplant products	C	4	100.0					1	100.0	1	100.0	2	100.0				
		All	4	100.0					1	100.0	1	100.0	2	100.0				
	Gene therapy	C	2	100.0			2	100.0										
		All	2	100.0			2	100.0										
	Transplantation	A	1	100.0							1	100.0						
		All	1	100.0							1	100.0						
	Pathogenic organisms	C	2	100.0	1	100.0					1	100.0						
		All	2	100.0	1	100.0					1	100.0						
	In-vitro diagnostic	A	1	50.0									1	100.0				
		C	1	50.0	1	100.0												
		All	2	100.0	1	100.0							1	100.0				
	All	All	583	100.0	179	100.0	111	100.0	67	100.0	114	100.0	51	100.0	20	100.0	41	100.0
Research w/persons		A	816	97.4	152	96.2	180	98.4	195	98.5	98	93.3	117	97.5	31	100.0	43	100.0
		B	22	2.6	6	3.8	3	1.6	3	1.5	7	6.7	3	2.5				
		All	838	100.0	158	100.0	183	100.0	198	100.0	105	100.0	120	100.0	31	100.0	43	100.0
Further use		n. a.	1118	100.0	306	100.0	250	100.0	181	100.0	193	100.0	108	100.0	42	100.0	38	100.0
Deceased and embryos from stillbirths or abortion		n. a.	19	100.0	9	100.0	4	100.0	1	100.0	1	100.0	2	100.0	2	100.0		
Total number			2558	100.0	652	100.0	548	100.0	447	100.0	413	100.0	281	100.0	95	100.0	122	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.

Table 4.1: Number of **submissions in 2021** (analysis set AS1) by type of research project and lead ethics committee for **COVID-19 projects.** 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	1	25.0			1	100.0										
		B	1	25.0	1	50.0												
		C	2	50.0	1	50.0			1	100.0								
		All	4	100.0	2	100.0	1	100.0	1	100.0								
	Medical devices	A	1	100.0	1	100.0												
		All	1	100.0	1	100.0												
	Other clinical trials	A	2	100.0			1	100.0			1	100.0						
		All	2	100.0			1	100.0			1	100.0						
Research w/persons	All	All	76	100.0	12	100.0	11	100.0	11	100.0	7	100.0	16	100.0	7	100.0	12	100.0
Further use		n.a.	78	100.0	19	100.0	14	100.0	9	100.0	12	100.0	10	100.0	6	100.0	8	100.0
Deceased and embryos from stillbirths or abortion		n.a.	2	100.0											2	100.0		
Total number			163	100.0	34	100.0	27	100.0	21	100.0	20	100.0	26	100.0	15	100.0	20	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	2250	70.7
Multiple ECs involved: lead EC	308	9.7
Multiple ECs involved: local EC	626	19.7
Total submissions to be evaluated	3184	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	563	75.4	483	74	360	67.5	406	75.7	260	72.4	73	41.7	105	58
Multiple: lead EC	89	11.9	65	10.0	53	9.9	41	7.6	21	5.8	22	12.6	17	9.4
Multiple: local EC	95	12.7	105	16.1	120	22.5	89	16.6	78	21.7	80	45.7	59	32.6
Total submissions	747	100.0	653	100.0	533	100.0	536	100.0	359	100.0	175	100.0	181	100.0

4 Scientific characterisation of projects approved in 2021 (AS2)

4.1 Overview

Table 7: Total number of research projects **approved in 2021** (analysis set AS2) per type of research, including information on the legal basis as well as the proportion of **COVID-19 projects.**

					COVID-19	
Type of research	**Legal basis**	n	$\%_{col}$	n	$\%_{row}$
Clinical trial	ClinO or ClinO-MD	522[1]	22.59	9	1.7
Research involving persons, but not a clinical trial	HRO, Chapter 2	735[2]	31.80	79	10.7
Further use of health-related personal data and/or biological material	HRO, Chapter 3	1034	44.74	79	7.6
Research involving deceased persons	HRO, Chapter 4	19	0.82	2	10.5
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	1	0.04	0	0.0
Total number		2311	100.00	169	7.3

1 56 of these projects also include 'further use' of existing data and/or material.
2 182 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 2021 (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.

				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	2016	3	0.13	2	0.3					1	0.3						
	2017	3	0.13	1	0.2					1	0.3	1	0.4				
	2018	8	0.35	5	0.8	1	0.2			1	0.3	1	0.4				
	2019	26	1.13	4	0.6			7	1.7	7	2	7	2.7	1	1.1		
	2020	600	25.96	142	22.4	92	19.0	138	34.1	134	38.2	71	27.3	12	13.6	11	12.6
	2021	1671	72.31	481	75.7	392	80.8	260	64.2	207	59.0	180	69.2	75	85.2	76	87.4
First decision[1]	Approved	351	15.19	141	22.2	62	12.8	40	9.9	17	4.8	29	11.2	29	33.0	33	37.9
	Approved with charges[2]	554	23.97	6	0.9	262	54.0	141	34.8	9	2.6	57	21.9	41	46.6	38	43.7
	Not approved, conditions[3]	1362	58.94	472	74.3	157	32.4	222	54.8	311	88.6	170	65.4	16	18.2	14	16.1
	Declined[4]	1	0.04	1	0.2												
	Non-consideration[5]	2	0.09	1	0.2					1	0.3						
Review procedure	Ordinary[6]	364	15.75	110	17.3	52	10.7	54	13.3	46	13.1	14	5.4	17	19.3	71	81.6
	Simplified	1575	68.15	352	55.4	352	72.6	282	69.6	302	86.0	222	85.4	49	55.7	16	18.4
	Presidential	372	16.10	173	27.2	81	16.7	69	17.0	3	0.9	24	9.2	22	25.0		
	Total number in AS2	2311	100.00	635	100.0	485	100.0	405	100.0	351	100.0	260	100.0	88	100.0	87	100.0
	COVID-19	169	7.31	36	5.7	24	4.9	28	6.9	19	5.4	27	10.4	15	17.0	20	23.0

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 Resubmission and approval of a previously declined project, reusing the electronic submission form with the old BASEC number.
5 Resubmission of a previously non-considered project, reusing the electronic submission form with the old BASEC number.
6 CE-TI uses the ordinary procedure for most of the research applications.

4.3 Stratification by project characteristics

In Tables 9–10 on page 22–29, 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, 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 projects 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 20 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	7.5	9	56.2	1	6.2	6	37.5	3	18.8	13	81.2
		B	33	15.5	18	54.5	5	15.2	10	30.3	7	21.2	26	78.8
		C	164	77.0	18	11.0	1	0.6	145	88.4	138	84.1	26	15.9
		All	213	100.0	45	21.1	7	3.3	161	75.6	148	69.5	65	30.5
	Medical devices (ClinO-MD Art 6)[1]	A	82	68.3	42	51.2	5	6.1	35	42.7	31	37.8	51	62.2
		C	38	31.7	29	76.3	2	5.3	7	18.4	15	39.5	23	60.5
		All	120	100.0	71	59.2	7	5.8	42	35.0	46	38.3	74	61.7
	Other clinical trials (ClinO Art 61)	A	157	86.3	123	78.3	12	7.6	22	14.0	2	1.3	155	98.7
		B	25	13.7	14	56.0	2	8.0	9	36.0			25	100.0
		All	182	100.0	137	75.3	14	7.7	31	17.0	2	1.1	180	98.9
	Combination drugs/devices	C	2	100.0					2	100.0	2	100.0		
		All	2	100.0					2	100.0	2	100.0		
	Transplant products (ClinO Art 21)	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
	Gene therapy (ClinO Art 22)	C	1	100.0					1	100.0	1	100.0		
		All	1	100.0					1	100.0	1	100.0		
	Transplantation (ClinO Art 49)	All	0	0										
	Pathogenic organisms	C	1	100.0					1	100.0	1	100.0		
		All	1	100.0					1	100.0	1	100.0		
	In-vitro diagnostic	C	1	100.0					1	100.0	1	100.0		
		All	1	100.0					1	100.0	1	100.0		
	All	All	522	100.0	254	48.7	29	5.6	239	45.8	201	38.5	321	61.5
Research w/persons (HRO Chapter 2)		A	718	97.7	537	74.8	60	8.4	121	16.9	58	8.1	660	91.9
		B	17	2.3	12	70.6	2	11.8	3	17.6	1	5.9	16	94.1
		All	735	100.0	549	74.7	62	8.4	124	16.9	59	8.0	676	92.0
Further use (HRO Chapter 3)		n. a.	1034	100.0	825	79.8	68	6.6	141	13.6	50	4.8	984	95.2
Deceased and embryos from stillbirths or abortion (HRO Chapter 4+5)		n. a.	20	100.0	20	100.0					1	5.0	19	95.0
Total number			2311	100.0	1648	71.3	159	6.9	504	21.8	311	13.5	2000	86.5

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

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

Table 9.1: Stratification of approved **COVID-19 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	2	33.3			1	50.0	1	50.0			2	100.0
		B	1	16.7					1	100.0			1	100.0
		C	3	50.0	1	33.3			2	66.7	2	66.7	1	33.3
		All	6	100.0	1	16.7	1	16.7	4	66.7	2	33.3	4	66.7
	Medical devices (ClinO-MD Art 6)[1]	A	1	100.0	1	100.0							1	100.0
		All	1	100.0	1	100.0							1	100.0
	Other clinical trials (ClinO Art 61)	A	1	50.0	1	100.0							1	100.0
		B	1	50.0	1	100.0							1	100.0
		All	2	100.0	2	100.0							2	100.0
	Combination drugs/devices	All	0											
	Transplant products (ClinO Art 21)	All	0											
	Gene therapy (ClinO Art 22)	All	0											
	Transplantation (ClinO Art 49)	All	0											
	Pathogenic organisms	All	0											
	In-vitro diagnostic	All	0											
	All	All	9	100.0	4	44.4	1	11.1	4	44.4	2	22.2	7	77.8
Research w/persons (HRO Chapter 2)		A	78	98.7	64	82.1	5	6.4	9	11.5	4	5.1	74	94.9
		B	1	1.3	1	100.0							1	100.0
		All	79	100.0	65	82.3	5	6.3	9	11.4	4	5.1	75	94.9
Further use (HRO Chapter 3)		n.a.	79	100.0	57	72.2	8	10.1	14	17.7			79	100.0
Deceased, embryos (HRO Chapter 4+5)		n.a.	2	100.0	2	100.0							2	100.0
Total number			169	100.0	128	75.7	14	8.3	27	16.0	6	3.6	163	96.4

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

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

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	7.5	4	5.0	4	10.5	3	13.0	3	9.7	1	9.1	0	0.0	1	6.7
		B	33	15.5	10	12.5	7	18.4	5	21.7	7	22.6	0	0.0	3	20.0	1	6.7
		C	164	77.0	66	82.5	27	71.1	15	65.2	21	67.7	10	90.9	12	80.0	13	86.7
		All	213	100.0	80	100.0	38	100.0	23	100.0	31	100.0	11	100.0	15	100.0	15	100.0
	Medical devices	A	82	68.3	24	68.6	14	77.8	8	50.0	22	73.3	9	75.0	2	66.7	3	50.0
		C	38	31.7	11	31.4	4	22.2	8	50.0	8	26.7	3	25.0	1	33.3	3	50.0
		All	120	100.0	35	100.0	18	100.0	16	100.0	30	100.0	12	100.0	3	100.0	6	100.0
	Other clinical trials	A	157	86.3	50	83.3	36	81.8	16	100.0	30	90.9	19	86.4	1	50.0	5	100.0
		B	25	13.7	10	16.7	8	18.2	0	0.0	3	9.1	3	13.6	1	50.0	0	0.0
		All	182	100.0	60	100.0	44	100.0	16	100.0	33	100.0	22	100.0	2	100.0	5	100.0
	Combination drugs/devices	C	2	100.0	2		0		0		0		0		0		0	
		All	2	100.0	2		0		0		0		0		0		0	
	Transplant products	C	2	100.0	0		0		2	100.0	0		0		0		0	
		All	2	100.0	0		0		2	100.0	0		0		0		0	
	Gene therapy	C	1	100.0	1		0		0		0		0		0		0	
		All	1	100.0	1		0		0		0		0		0		0	
	Transplantation	All	0		0		0		0		0		0		0		0	
	Pathogenic organisms	C	1	100.0	1		0		0		0		0		0		0	
		All	1	100.0	1		0		0		0		0		0		0	
	In-vitro diagnostic	C	1	100.0	1		0		0		0		0		0		0	
		All	1	100.0	1		0		0		0		0		0		0	
	All	All	522	100.0	180	100.0	100	100.0	57	100.0	94	100.0	45	100.0	20	100.0	26	100.0
Research w/persons		A	718	97.7	144	96.0	153	97.5	167	99.4	88	95.7	110	98.2	22	100.0	34	100.0
		B	17	2.3	6	4.0	4	2.5	1	0.6	4	4.3	2	1.8	0	0.0	0	0.0
		All	735	100.0	150	100.0	157	100.0	168	100.0	92	100.0	112	100.0	22	100.0	34	100.0
Further use		n. a.	1034	100.0	295	100.0	225	100.0	178	100.0	164	100.0	101	100.0	44	100.0	27	100.0
Deceased and embryos from stillbirths or abortion		n. a.	20	100.0	10	100.0	3	100.0	2	100.0	1	100.0	2	100.0	2	100.0	0	
Total number			2311	100.0	635	100.0	485	100.0	405	100.0	351	100.0	260	100.0	88	100.0	87	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		Non-consid.	
Type of research	Research details	Risk cat.	N	%col	n	%row	n	%row	n	%row	n	%row	n	%row	n	%row	n	%row	n	%row
Clinical trial	Medicinal products	A	16	7.5	3	18.75	13	81.25			1	6.25	1	6.25	14	87.50				
		B	33	15.5	33	100.00							9	27.27	24	72.73				
		C	164	77.0	164	100.00					7	4.27	30	18.29	127	77.44				
		All	213	100.0	200	93.90	13	6.10			8	3.76	40	18.78	165	77.46				
	Medical devices	A	82	68.3	7	8.54	74	90.24	1	1.22	2	2.44	6	7.32	43	52.44				
		C	38	31.7	37	97.37	1	2.63			1	2.63	1	2.63	27	71.05				
		All	120	100.0	44	36.67	75	62.5	1	0.83	3	2.50	7	5.83	70	58.33				
	Other clinical trials	A	157	86.3	16	10.19	140	89.17	1	0.64	3	1.91	25	15.92	129	82.17				
		B	25	13.7	21	84.00	4	16.00					7	28.00	18	72.00				
		All	182	100.0	37	20.33	144	79.12	1	0.55	3	1.65	32	17.58	147	80.77				
	Combination drugs/devices	C	2	100.0	2	100.00									1	50.00				
		All	2	100.0	2	100.00									1	50.00				
	Transplant products	C	2	100.0	2	100.00									2	100.00				
		All	2	100.0	2	100.00									2	100.00				
	Gene therapy	C	1	100.0	1	100.00									1	100.00				
		All	1	100.0	1	100.00									1	100.00				
	Transplantation	All	0	0.0																
	Pathogenic organisms	C	1	100.0	1	100.00									1	100.00				
		All	1	100.0	1	100.00									1	100.00				
	In-vitro diagnostic	C	1	100.0	1	100.00					1	100.00								
		All	1	100.0	1	100.00					1	100.00								
	All	All	522	100.0	288	55.17	232	44.44	2	0.38	15	2.87	79	15.13	387	74.14				
Research w/persons		A	718	97.7	38	5.29	675	94.01	5	0.70	44	6.13	197	27.44	476	66.30	1	0.14		
		B	17	2.3	15	88.24	2	11.76							17	100.00				
		All	735	100.0	53	7.21	677	92.11	5	0.68	44	5.99	197	26.80	493	67.07	1	0.14		
Further use		n.a.	1034	100.0	23	2.22	646	62.48	365	35.30	280	27.08	276	26.69	476	46.03			2	0.19
Deceased and embryos from stillbirths or abortion		n.a.	20	100.0			20	100.00			12	60.00	2	10.00	6	30.00				
Total number			2311	100.0	364	15.75	1575	68.15	372	16.10	351	15.19	554	23.97	1362	58.94	1	0.04	2	0.09

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 11: 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 7 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	124	23.8	11	37	17.4	8	27	22.5	0	59	32.4	3
Nervous System diseases	39	7.5	10	13	6.1	5	8	6.7	1	18	9.9	4
Cancer: Other	34	6.5	12	29	13.6	11	1	0.8	0	3	1.6	1
Surgery	34	6.5	1	9	4.2	1	7	5.8	0	18	9.9	0
Musculoskeletal diseases (non cancer)	33	6.3	6	7	3.3	3	8	6.7	1	18	9.9	2
Mental and Behavioural diseases	29	5.6	1	5	2.3	0	3	2.5	0	21	11.5	1
Cancer: Lung	25	4.8	2	20	9.4	2	1	0.8	0	3	1.6	0
Basic research (Anatomy/Physiology)	23	4.4	1	3	1.4	0	2	1.7	0	18	9.9	1
Respiratory diseases (non cancer)	23	4.4	2	8	3.8	1	5	4.2	0	10	5.5	1
Brain diseases (non cancer)	20	3.8	3	3	1.4	1	6	5.0	0	11	6.0	2
Infections and Infestations	20	3.8	1	15	7.0	1	1	0.8	0	4	2.2	0
Nutritional and Metabolic diseases	17	3.3	1	4	1.9	1	0	0.0	0	13	7.1	0
Digestive Systems diseases (non cancer)	16	3.1	3	12	5.6	3	1	0.8	0	3	1.6	0
Coronary Heart disease	15	2.9	1	5	2.3	1	7	5.8	0	3	1.6	0
Arterial and venous diseases including deep venous thrombosis and lung embolism	14	2.7	3	5	2.3	3	5	4.2	0	4	2.2	0
Cancer: Head and Neck	12	2.3	4	9	4.2	4	3	2.5	0	0	0.0	0
Injury	12	2.3	0	0	0.0	0	2	1.7	0	10	5.5	0
Cancer: Melanoma	10	1.9	1	7	3.3	1	2	1.7	0	0	0.0	0
Eye diseases	10	1.9	0	5	2.3	0	3	2.5	0	1	0.5	0
Skin and Connective Tissues diseases (non cancer)	10	1.9	2	8	3.8	1	0	0.0	0	2	1.1	1
Cancer: Breast	9	1.7	0	6	2.8	0	1	0.8	0	2	1.1	0
Endocrinological diseases (non cancer)	9	1.7	1	1	0.5	1	1	0.8	0	7	3.8	0
Hematologic diseases (non cancer)	9	1.7	5	6	2.8	4	1	0.8	0	1	0.5	0
Urological and Genital diseases (non cancer)	9	1.7	2	4	1.9	1	1	0.8	0	4	2.2	1
Cancer: Leukemia	8	1.5	4	6	2.8	3	0	0.0	0	2	1.1	1
Dementia and Alzheimer disease	8	1.5	0	2	0.9	0	1	0.8	0	5	2.7	0
Cancer: Lymphoma	6	1.1	2	6	2.8	2	0	0.0	0	0	0.0	0
Cancer: Prostate	6	1.1	0	6	2.8	0	0	0.0	0	0	0.0	0
Cancer: Colon and Rectal	5	1.0	0	3	1.4	0	1	0.8	0	1	0.5	0
Ear, Nose, and Throat diseases (non cancer)	5	1.0	1	3	1.4	1	1	0.8	0	1	0.5	0
Genetic disorders	5	1.0	5	2	0.9	2	1	0.8	1	2	1.1	2
Pregnancy and Childbirth	5	1.0	0	1	0.5	0	1	0.8	0	3	1.6	0
Cancer: Bladder	4	0.8	1	4	1.9	1	0	0.0	0	0	0.0	0
Cancer: Non-Hodgkin Lymphoma	4	0.8	1	4	1.9	1	0	0.0	0	0	0.0	0
Cancer: Kidney	3	0.6	2	3	1.4	2	0	0.0	0	0	0.0	0
Cancer: Pancreatic	3	0.6	0	1	0.5	0	0	0.0	0	2	1.1	0
Cancer: Endometrial	2	0.4	0	1	0.5	0	0	0.0	0	1	0.5	0
Occupational diseases	2	0.4	0	0	0.0	0	0	0.0	0	2	1.1	0
Periodontal diseases	2	0.4	0	0	0.0	0	0	0.0	0	2	1.1	0
Cancer: Thyroid	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	0
Neonatal diseases	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	0
Total projects	522	119.5	65	213	100.0	50	120	100.0	3	182	100.0	11

Rare disease: A rare disease or orphan disease is defined as a disease or condition that affects fewer than 5 in 10000 people and is life-threatening or chronically debilitating. Total projets: 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 7 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	295	56.5	156	73.2	57	47.5	75	41.2
Other	78	14.9	9	4.2	14	11.7	55	30.2
PK/PD/safety	43	8.2	35	16.4	5	4.2	3	1.6
Prevention	34	6.5	10	4.7	6	5.0	18	9.9
Diagnosis	31	5.9	3	1.4	15	12.5	13	7.1
Rehabilitation	24	4.6	0	0.0	8	6.7	16	8.8
Palliation	4	0.8	0	0.0	2	1.7	2	1.1
Total projects	522	100.0	213	100.0	120	100.0	182	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.

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-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	16	7.4					3	18.8	6	37.5	7	43.8		
B	33	15.3	2	6.1	8	24.2	10	30.3	9	27.3	4	12.1		
C	166	77.2	31	18.7	44	26.5	87	52.4			3	1.8	9	5.4
Total number	215	100.0	33	15.3	52	24.2	100	46.5	15	7.0	14	6.5	9	4.2

The total number of 215 research projects consist of 213 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	82	67.2	82	100.0					1	1.2
C	40	32.8	2	5.0	8	20.0	30	75.0	19	47.5
Total number	122	100.0	84	68.9	8	6.6	30	24.6	20	16.4

The total number of 122 research projects consist of 120 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	274	37.3	268	97.8	6	2.2	204	74.5	25	9.1	45	16.4	14	5.1	260	94.9
Registry/ Quality control[1]	55	7.5	54	98.2	1	1.8	26	47.3	2	3.6	27	49.1	13	23.6	42	76.4
Case control study	74	10.1	74	100.0			64	86.5	4	5.4	6	8.1			74	100.0
Other or n/a	332	45.2	322	97.0	10	3.0	255	76.8	31	9.3	46	13.9	32	9.6	300	90.4
Total number	735	100.0	718	97.7	17	2.3	549	74.7	62	8.4	124	16.9	59	8.0	676	92.0

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	185	25.2	61	22.3	12	21.8	9	12.2	103	31.0
Basic science	107	14.6	38	13.9	3	5.5	18	24.3	48	14.5
Psychology	86	11.7	28	10.2	0	0.0	16	21.6	42	12.7
Surgery	72	9.8	33	12.0	6	10.9	13	17.6	20	6.0
Qualitative research	54	7.3	16	5.8	5	9.1	1	1.4	32	9.6
Healthcare services research	51	6.9	17	6.2	5	9.1	2	2.7	27	8.1
Epidemiology	51	6.9	34	12.4	9	16.4	3	4.1	5	1.5
Physiology/anatomy	49	6.7	20	7.3	2	3.6	8	10.8	19	5.7
Medical devices	44	6.0	17	6.2	10	18.2	2	2.7	15	4.5
Drugs	20	2.7	7	2.6	1	1.8	1	1.4	11	3.3
Dentistry	16	2.2	3	1.1	2	3.6	1	1.4	10	3.0
Total projects	735	100.0	274	100.0	55	100.0	74	100.0	332	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 singleselect 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.

				COVID-19	
		n	$\%_{col}$	n	$\%_{row}$
Genetic data/biol. material	Yes	261	20.5	16	6.1
	No	1011	79.5	86	8.5
Coding (HRO Art. 25–27)	Coded	1155	90.8	95	8.2
	Open, non-coded	117	9.2	7	6.0
Consent (HRO Art. 28–32)	Consent for all data	677	53.2	60	8.9
	Consent for some but not all data (partially Art. 34 HRA)	371	29.2	27	7.3
	No consent for all data, Art. 34 HRA	224	17.6	15	6.7
Combined vs. stand-alone projects	Stand-alone further use project	1034	81.3	79	7.6
	Further use project as part of a clinical trial	56	4.4	2	3.6
	Further use project as part of a non-clinical research project	182	14.3	21	11.5
Total number		1272	100.0	102	8.0

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

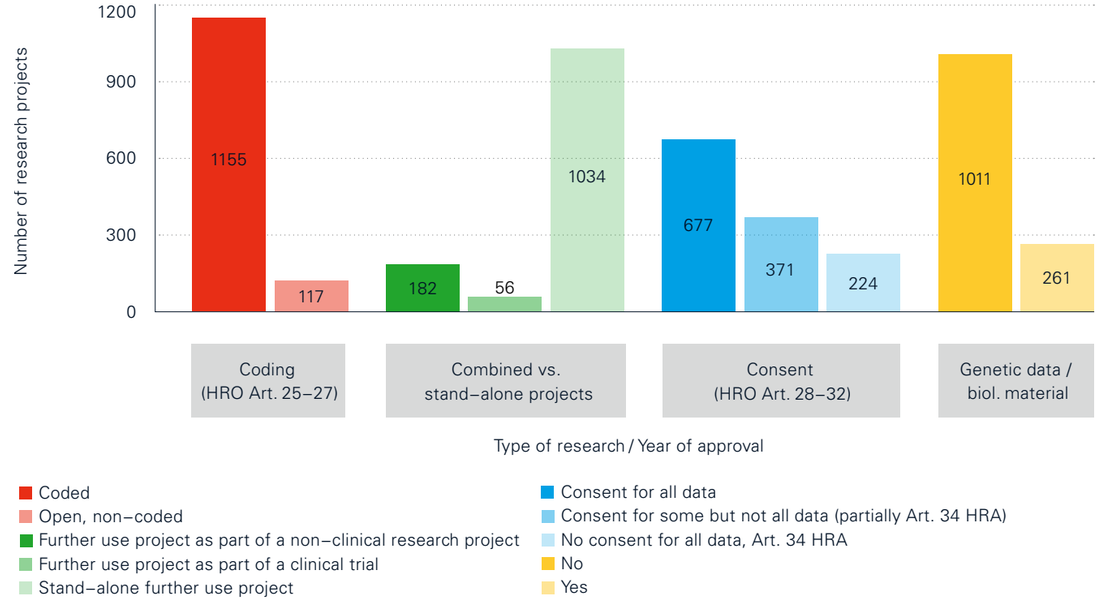


Table 19: Stratification of **projects involving further use of data / biological material** by study design and initiator.
All combinations of the following three factors are shown: 1) Use of genetic data and/or biological material (Genetic D+M), 2) coded vs. uncoded, 3) consent for further use.

			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	178	70.9	109	61.2	10	5.6	59	33.1	46	25.8	132	74.2
		Consent for some but not all data (partially Art. 34 HRA)	50	19.9	36	72.0	1	2.0	13	26.0	1	2.0	49	98.0
		No consent for all data, Art. 34 HRA	23	9.2	17	73.9	4	17.4	2	8.7	1	4.3	22	95.7
		All	251	100.0	162	64.5	15	6.0	74	29.5	48	19.1	203	80.9
	Open, non-coded	Consent for all data	7	70.0	7	100.0					1	14.3	6	85.7
		Consent for some but not all data (partially Art. 34 HRA)	2	20.0	2	100.0							2	100.0
		No consent for all data, Art. 34 HRA	1	10.0	1	100.0							1	100.0
		All	10	100.0	10	100.0					1	10.0	9	90.0
	All		261	100.0	172	65.9	15	5.7	74	28.4	49	18.8	212	81.2
No	Coded	Consent for all data	433	47.9	324	74.8	38	8.8	71	16.4	30	6.9	403	93.1
		Consent for some but not all data (partially Art. 34 HRA)	288	31.9	237	82.3	16	5.6	35	12.2	1	0.3	287	99.7
		No consent for all data, Art. 34 HRA	183	20.2	156	85.2	10	5.5	17	9.3			183	100.0
		All	904	100.0	717	79.3	64	7.1	123	13.6	31	3.4	873	96.6
	Open, non-coded	Consent for all data	59	55.1	53	89.8	3	5.1	3	5.1	2	3.4	57	96.6
		Consent for some but not all data (partially Art. 34 HRA)	31	29.0	25	80.6	3	9.7	3	9.7			31	100.0
		No consent for all data, Art. 34 HRA	17	15.9	13	76.5	3	17.6	1	5.9			17	100.0
		All	107	100.0	91	85.0	9	8.4	7	6.5	2	1.9	105	98.1
	All		1011	100.0	808	79.9	73	7.2	130	12.9	33	3.3	978	96.7
Total number			1272	100.0	980	77.0	88	6.9	204	16.0	82	6.4	1190	93.6

1 Multiple selection possible.
The total number of 1272 research projects consist of 1034 standard 'further use' projects and 238 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	677	53.2	248	66.5	133	47.5	98	47.6	97	49.2	57	43.2	26	50.0	18	56.2
Consent for some but not all data (partially Art. 34 HRA)	371	29.2	94	25.2	106	37.9	65	31.6	72	36.5	11	8.3	11	21.2	12	37.5
No consent for all data, Art. 34 HRA	224	17.6	31	8.3	41	14.6	43	20.9	28	14.2	64	48.5	15	28.8	2	6.2
Total number	1272	100.0	373	100.0	280	100.0	206	100.0	197	100.0	132	100.0	52	100.0	32	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)'.

				COVID-19	
Initiator	**Financing (main source)**	n	$\%_{col}$	n	$\%_{row}$
Investigator	Public, other	1242	66.1	101	8.1
	Industry	77[1]	4.1	3	3.9
	Universities/hospitals	242	12.9	23	9.5
	Private (non-industry)	177	9.4	14	7.9
	Swiss National Science Foundation	140	7.5	8	5.7
	All	1878	100.0	149	7.9
Industry	Public, other	59[2]	19.0	1	1.7
	Industry	249[3]	80.1	5	2.0
	Universities/hospitals	2	0.6	0	0.0
	Private (non-industry)	1	0.3	0	0.0
	Swiss National Science Foundation	0	0.0	0	NaN
	All	311	100.0	6	1.9
Other	Public, other	90	73.8	12	13.3
	Industry	4	3.3	0	0.0
	Universities/hospitals	14	11.5	2	14.3
	Private (non-industry)	9	7.4	0	0.0
	Swiss National Science Foundation	5	4.1	0	0.0
	All	122[4]	100.0	14	11.5

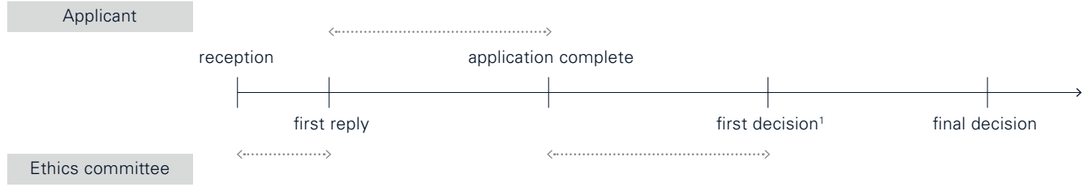
1 Applicants almost exclusively from academic institutions.
2 Inspecting the sponsor information reveals that these are almost exclusively industry projects.
3 248 of the industry-initiated projects are financed exclusively by industry.
4 35 of these projects initiated by others are projects solely or 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 6, 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	107	17.2	7	[7,7]	7	[7,8]	29	[24,36]	105	[77,163]	21	[15,28]	96	[70,155]
	EKNZ	51	10.6	3	[1,6]	3	[1,6]	29	[20,4]	100	[62,134]	26	[15,35]	90	[54,132]
	CER-VD	53	13.2	6	[4,7]	6	[4,8]	27	[22,33]	146	[98,194]	19	[17,22]	134	[77,183]
	KEK-BE	45	13.3	4	[1,5]	7	[4,20]	28	[22,41]	237	[159,328]	20	[18,27]	230	[140,301]
	CCER	12	4.7	5	[4,6]	8	[5,16]	36	[25,61]	108	[83,154]	30	[20,42]	100	[71,116]
	EKOS	17	19.8	3	[1,4]	3	[2,5]	22	[15,28]	101	[85,118]	19	[14,24]	100	[84,118]
	CE-TI	69	81.2	7	[7,8]	7	[7,8]	28	[21,36]	42	[27,84]	20	[14,28]	35	[20,76]
	All	354	15.6	7	[4,7]	7	[5,8]	28	[22,36]	107	[63,171]	20	[15,28]	100	[54,160]
Simplified	KEK-ZH	341	54.9	7	[7,7]	7	[7,8]	32	[26,40]	63	[42,103]	22	[18,29]	54	[34,88]
	EKNZ	349	72.6	4	[2,6]	5	[2,7]	22	[13,30]	52	[30,79]	15	[7,21]	44	[24,70]
	CER-VD	281	69.7	5	[2,6]	6	[3,9]	23	[19,31]	83	[56,136]	16	[15,21]	72	[49,124]
	KEK-BE	291	86.1	2	[1,4]	6	[3,14]	25	[20,38]	96	[56,154]	18	[14,20]	85	[49,140]
	CCER	220	85.9	3	[1,5]	7	[4,11]	29	[23,37]	76	[49,124]	21	[17,26]	63	[42,105]
	EKOS	47	54.7	1	[1,2]	1	[1,4]	7	[3,10]	20	[5,40]	3	[2,7]	16	[3,31]
	CE-TI	16	18.8	7	[7,8]	7	[7,10]	17	[10,28]	44	[17,64]	8	[2,12]	32	[8,44]
	All	1545	68.1	4	[2,7]	7	[3,9]	26	[19,35]	68	[42,118]	19	[14,23]	59	[35,101]
Presidential	KEK-ZH	173	27.9	7	[3,7]	7	[3,8]	21	[14,28]	28	[19,48]	13	[8,20]	21	[13,40]
	EKNZ	81	16.8	4	[1,5]	5	[2,7]	9	[6,16]	16	[8,38]	4	[1,7]	8	[2,25]
	CER-VD	69	17.1	5	[3,6]	5	[4,7]	20	[15,37]	52	[21,108]	14	[10,20]	43	[16,89]
	KEK-BE	2	0.6	0	[0,0]	7	[4,10]	43	[25,61]	54	[41,66]	36	[22,50]	46	[37,56]
	CCER	24	9.4	5	[2,8]	7	[5,13]	12	[9,15]	13	[9,16]	2	[1,5]	2	[1,6]
	EKOS	22	25.6	1	[1,2]	1	[1,3]	4	[2,6]	5	[3,30]	1	[1,5]	3	[1,29]
	CE-TI	0	0												
	All	371	16.3	5	[2,7]	6	[3,7]	16	[9,26]	27	[13,50]	10	[5,15]	19	[7,41]
Overall	KEK-ZH	621	100.0	7	[6,7]	7	[7,8]	29	[22,36]	57	[34,103]	21	[14,28]	49	[26,88]
	EKNZ	481	100.0	4	[2,6]	5	[2,7]	21	[13,30]	50	[27,84]	14	[6,21]	43	[21,72]
	CER-VD	403	100.0	5	[3,6]	6	[4,8]	23	[19,31]	85	[53,146]	16	[14,21]	72	[44,129]
	KEK-BE	338	100.0	2	[1,4]	6	[3,14]	26	[20,39]	112	[60,188]	18	[15,20]	94	[54,172]
	CCER	256	100.0	3	[1,6]	7	[4,12]	29	[21,36]	72	[42,120]	20	[16,26]	60	[35,101]
	EKOS	86	100.0	1	[1,3]	1	[1,3]	7	[3,14]	22	[5,89]	4	[1,10]	19	[2,84]
	CE-TI	85	100.0	7	[7,8]	7	[7,8]	26	[19,35]	42	[25,73]	18	[11,27]	34	[18,66]
	All	2270	100.0	5	[2,7]	7	[3,8]	26	[18,34]	65	[37,118]	18	[13,23]	56	[30,104]

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 4.1: Violin plot of the time between status 'complete' to the first decision by EC for **non-COVID-19 projects.** 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.

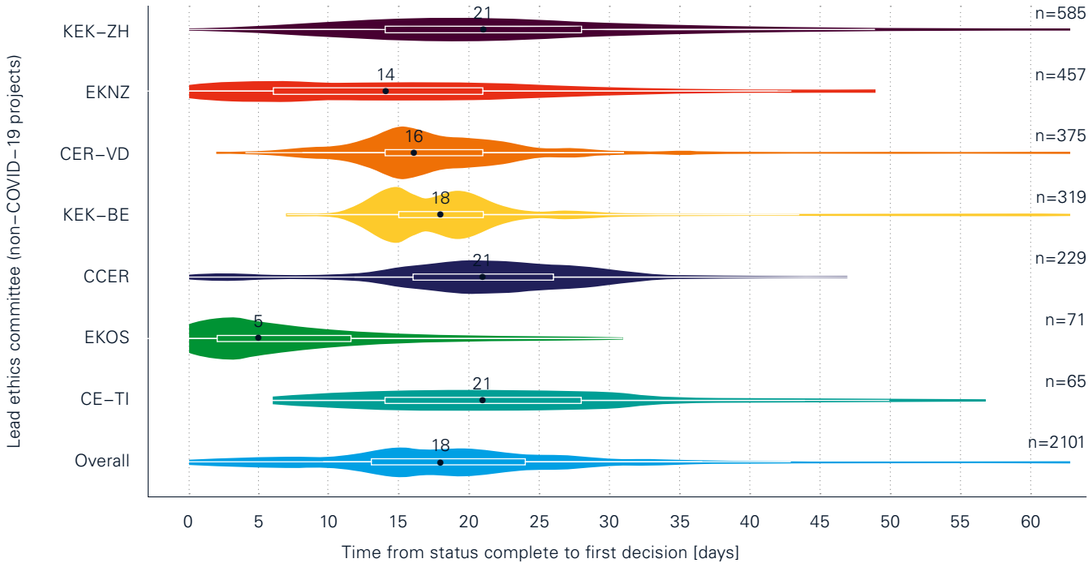


Figure 4.2: Violin plot of the time between status 'complete' to the first decision by EC for **COVID-19 projects.** 32 projects with t > 60 days are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 25.1.

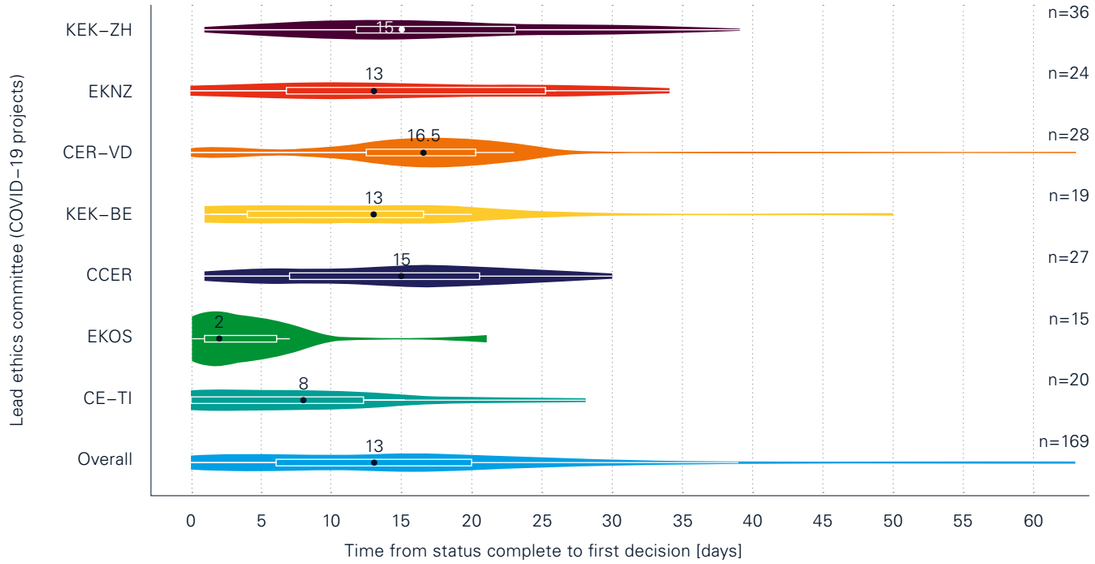
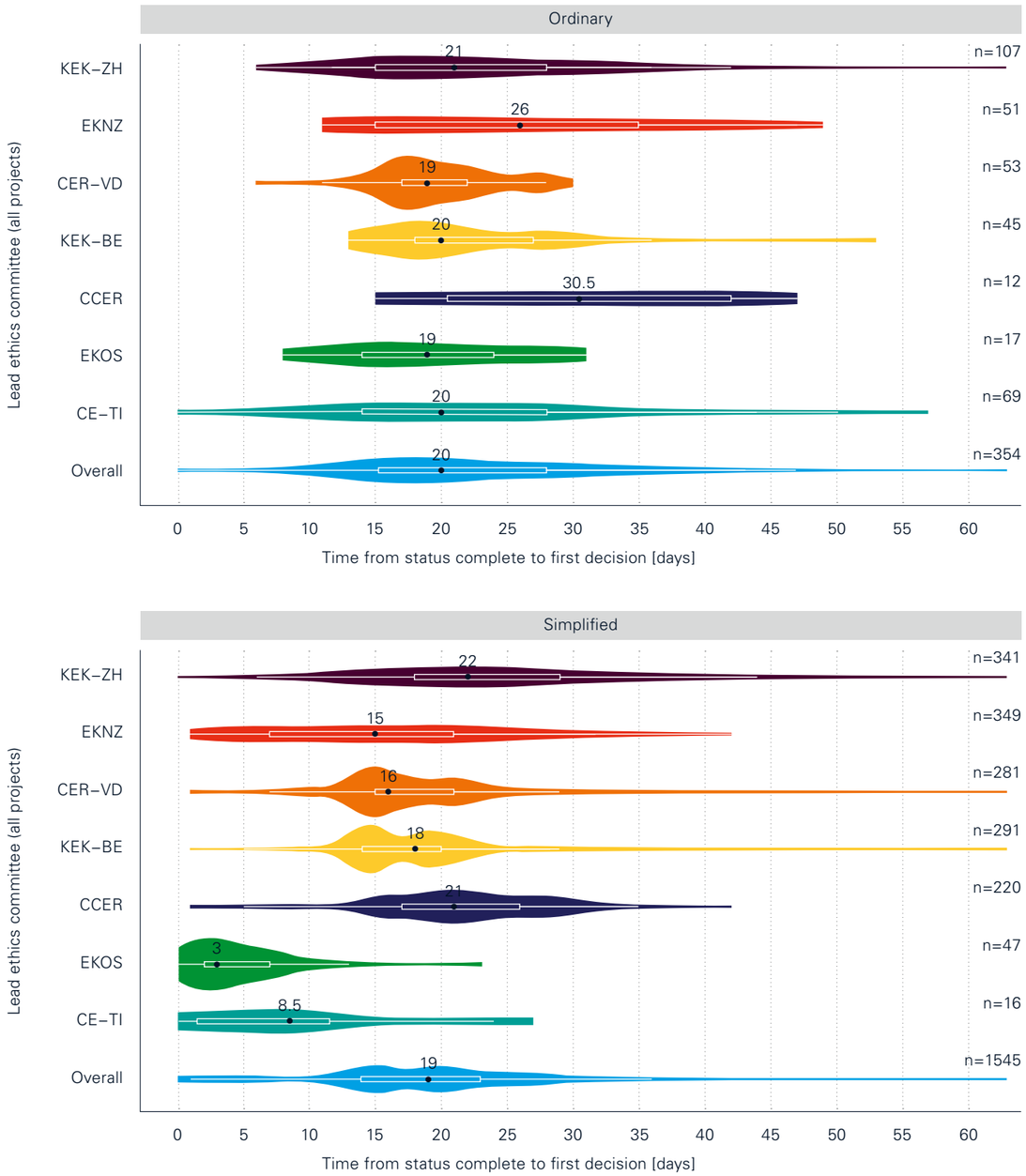
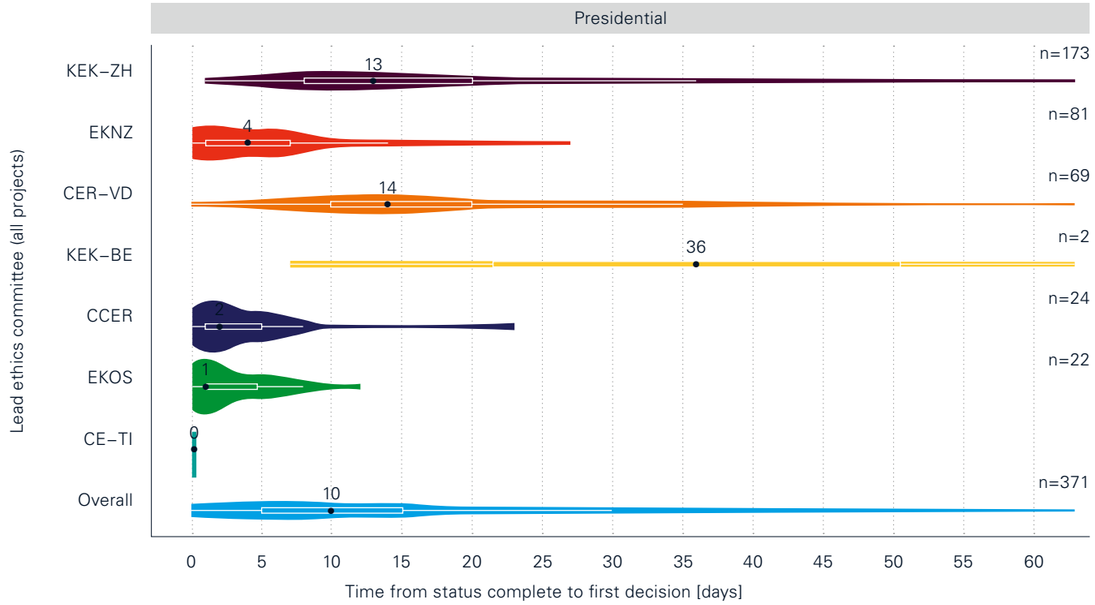


Figure 5: Violin plot of the time between status 'complete' to the first decision by EC and stratified by review procedure. 33 projects with t > 60 days are not shown for layout reasons. Note: *CE-TI* typically processes all submissions in a plenary session (ordinary procedure) but with adapted fees. ClinO-MD projects are not included but separately displayed in table 25.1.





5.3.2 Time from reception to final decision

Figure 6.1: Violin plot of the overall approval time by EC from reception to final decision for **non-COVID-19 projects.** 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.

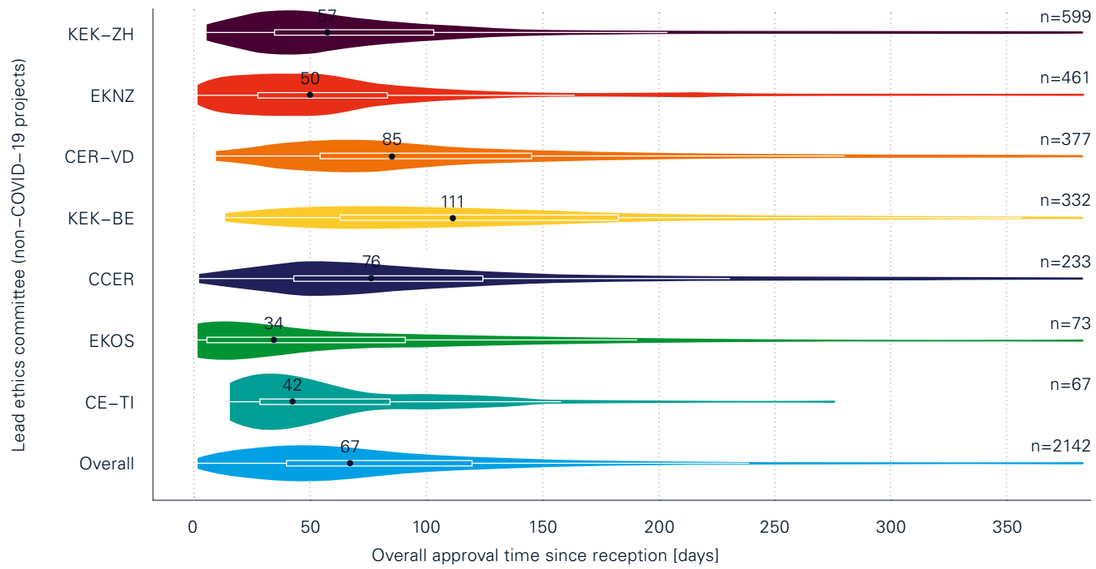


Figure 6.2: Violin plot of the overall approval time by EC from reception to final decision for **COVID-19 projects.** ClinO-MD projects are not included but separately displayed in table 25.1.

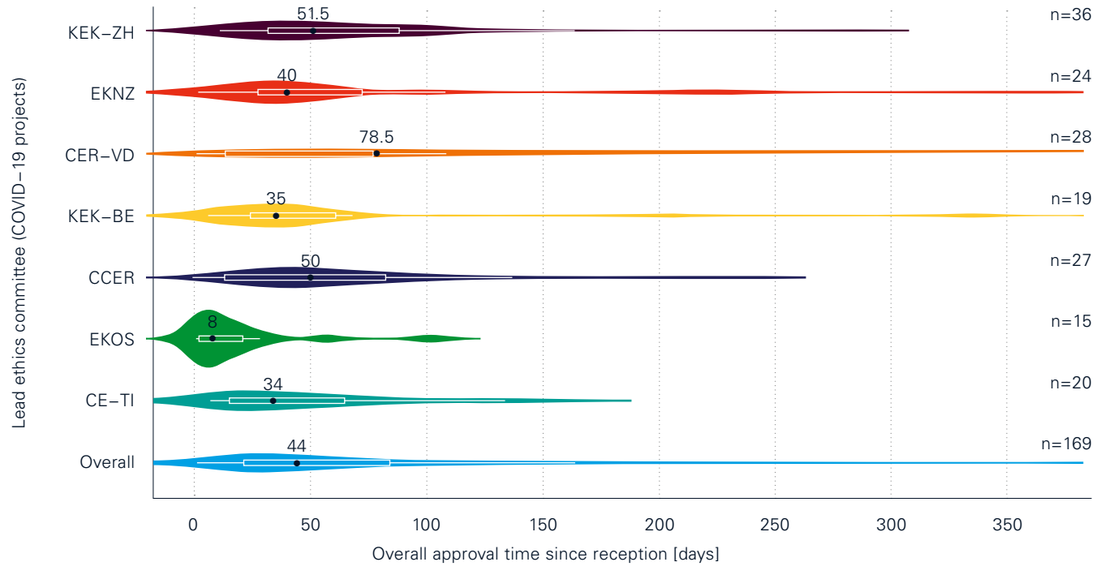
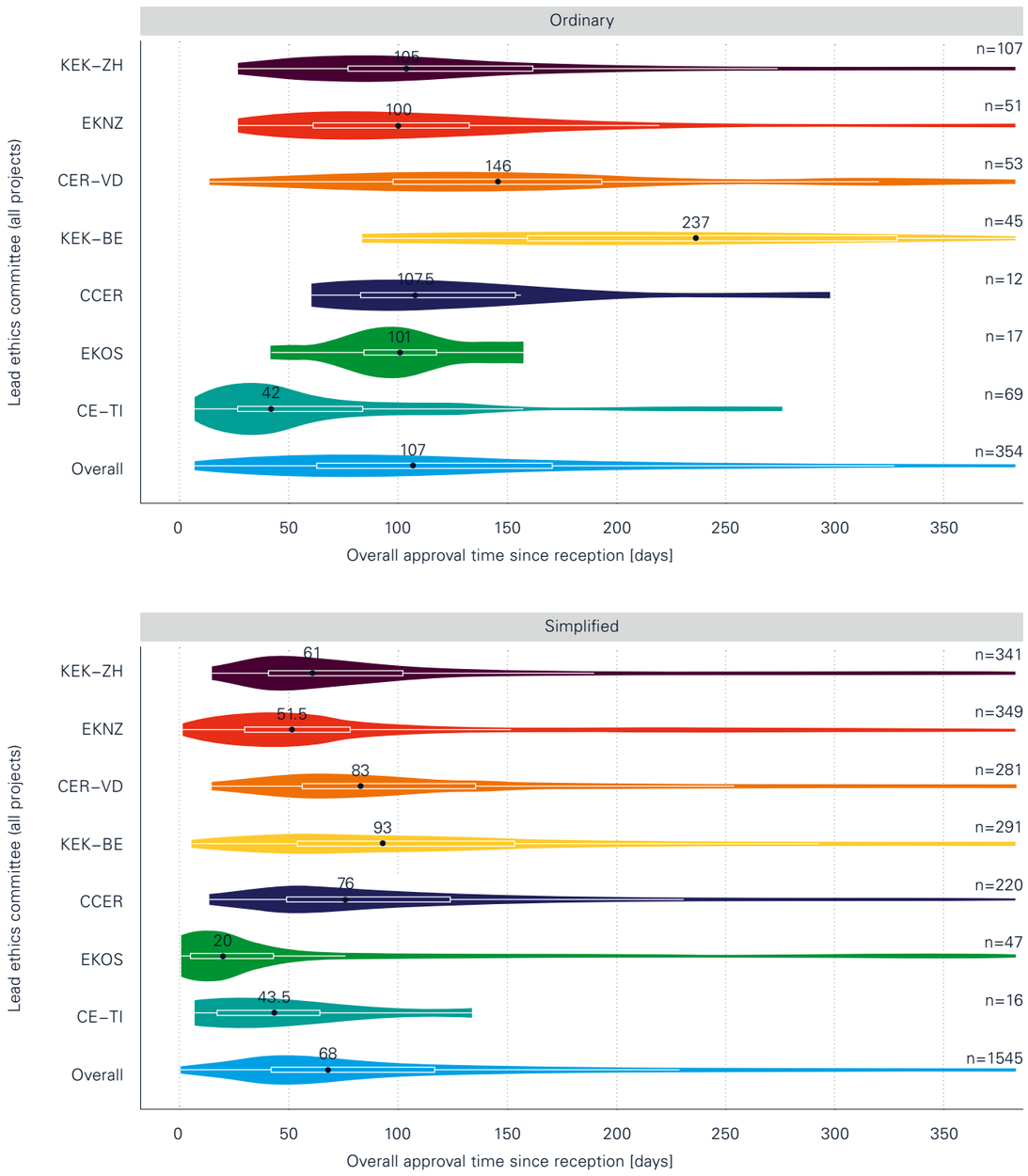
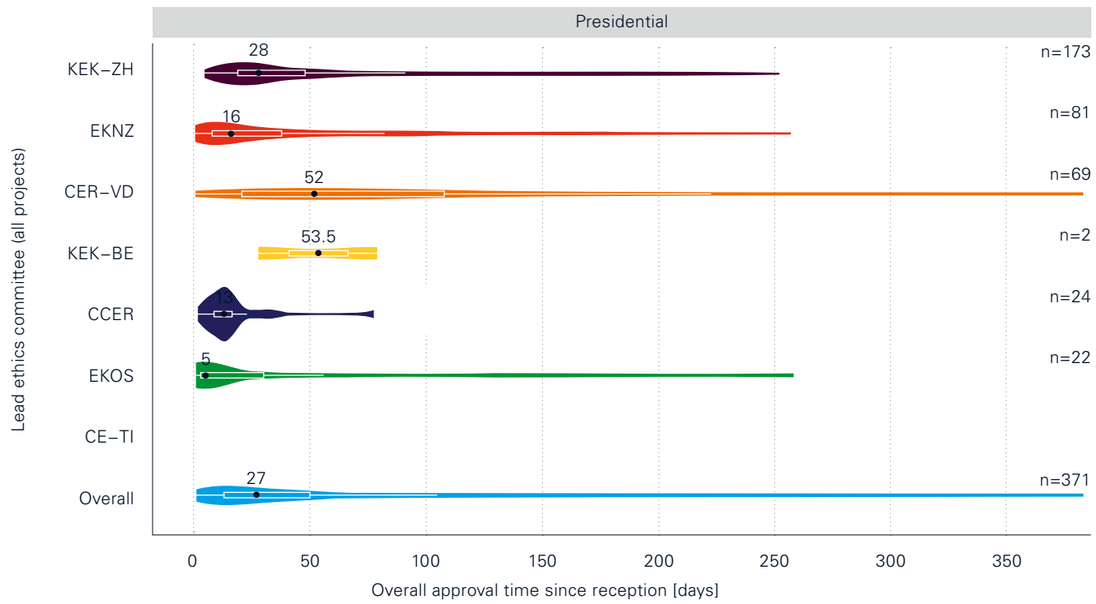


Figure 7: Violin plot of the overall approval time by EC from reception to final decision and stratified by review procedure. 91 projects with approval time > 1 year are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 25.1.





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	166	26.73	7.0	[7.0,7.0]	7.0	[7.0, 8.0]	31.0	[25.0,39.0]	99.0	[67.2,180.0]	22.0	[16.0,30.0]	84.0	[55.0,164.0]
	EKNZ	96	19.96	4.0	[1.0,5.0]	4.0	[1.0,6.2]	25.5	[20.0,36.2]	66.5	[51.8,114.8]	20.0	[15.0,28.0]	61.0	[48.0,103.8]
	CER-VD	55	13.65	6.0	[3.0,6.0]	6.0	[3.5,11.0]	27.0	[21.0,31.5]	139.0	[83.0,187.5]	19.0	[17.0,22.0]	113.0	[71.0,174.0]
	KEK-BE	81	23.96	6.0	[1.0,4.0]	6.0	[2.0,13.0]	26.0	[20.0,35.0]	191.0	[124.0,294.0]	19.0	[15.0,22.0]	171.0	[115.0,286.0]
	CCER	41	16.02	7.0	[2.0,6.0]	7.0	[4.0,11.0]	29.0	[26.0,40.0]	112.0	[63.0,154.0]	22.0	[19.0,26.0]	101.0	[58.0,135.0]
	EKOS	18	20.93	3.0	[1.2,4.0]	3.0	[2.0,4.8]	22.0	[15.0,28.0]	96.0	[82.0,116.0]	18.0	[14.0,24.0]	93.5	[79.5,115.2]
	CE-TI	24	28.24	7.0	[7.0,8.0]	7.0	[7.0,8.0]	30.5	[24.0,37.0]	51.0	[38.2,105.0]	22.0	[17.8,28.5]	44.0	[28.0,98.0]
	All	481	21.19	7.0	[2.0,7.0]	7.0	[4.0,8.0]	28.0	[22.0,37.0]	106.0	[63.0,179.0]	20.0	[16.0,27.0]	96.0	[56.0,167.0]
Research w/persons	KEK-ZH	150	24.15	7.0	[7.0,7.0]	7.0	[7.0,8.0]	34.0	[28.0,41.0]	67.0	[47.2,103.8]	25.0	[19.2,32.0]	59.0	[39.0,92.0]
	EKNZ	157	32.64	5.0	[2.0,6.0]	5.0	[3.0,7.0]	27.0	[21.0,34.0]	66.0	[47.0,98.0]	20.0	[15.0,27.0]	57.0	[41.0,92.0]
	CER-VD	168	41.69	5.0	[3.0,6.0]	6.0	[4.0,7.2]	23.0	[19.0,29.0]	84.5	[62.0,135.0]	16.0	[14.8,21.0]	78.0	[52.8,121.2]
	KEK-BE	92	27.22	3.0	[1.0,5.0]	6.0	[3.0,16.2]	26.0	[19.8,40.0]	97.0	[58.2,148.8]	16.5	[15.0,21.0]	87.0	[48.0,145.5]
	CCER	112	43.75	3.0	[1.0,5.0]	7.0	[3.0,11.0]	29.0	[22.0,36.0]	70.0	[50.8,113.2]	21.5	[16.0,26.0]	59.5	[43.8,97.2]
	EKOS	22	25.58	1.0	[1.0,2.8]	1.0	[1.0,4.0]	7.5	[6.2,11.5]	26.0	[17.0,45.2]	6.0	[3.0,7.8]	20.5	[16.0,38.0]
	CE-TI	34	40.00	7.0	[7.0,8.0]	7.0	[7.0,8.0]	24.0	[17.0,34.0]	34.5	[21.0,58.8]	15.5	[8.5,26.5]	27.0	[13.2,45.5]
	All	735	32.38	5.0	[2.0,7.0]	7.0	[4.0,8.0]	27.0	[20.0,35.0]	71.0	[48.0,117.0]	20.0	[15.0,26.0]	62.0	[41.0,105.0]
Further use	KEK-ZH	295	47.50	7.0	[3.0,7.0]	7.0	[4.0,8.0]	25.0	[16.5,32.0]	39.0	[23.0,63.5]	16.0	[11.0,22.0]	32.0	[15.0,53.5]
	EKNZ	225	46.78	4.0	[1.0,6.0]	5.0	[2.0,7.0]	12.0	[7.0,20.0]	26.0	[12.0,49.0]	6.0	[2.0,9.0]	20.0	[7.0,38.0]
	CER-VD	178	44.17	5.0	[3.0,6.0]	5.0	[3.0,8.0]	22.0	[17.0,35.0]	72.5	[42.0,140.5]	15.0	[13.0,20.0]	59.0	[35.0,117.2]
	KEK-BE	164	48.52	2.0	[1.0,4.0]	6.0	[3.0,14.0]	26.0	[20.0,37.5]	88.0	[52.0,145.2]	18.0	[14.0,20.0]	66.0	[41.0,125.0]
	CCER	101	39.45	3.0	[2.0,6.0]	7.0	[4.0,14.0]	27.0	[17.0,37.0]	62.0	[31.0,99.0]	19.0	[15.0,24.0]	50.0	[25.0,78.0]
	EKOS	44	51.16	1.0	[1.0,2.0]	1.0	[1.0,3.0]	4.0	[2.0,7.0]	5.0	[2.0,25.8]	2.0	[1.0,4.2]	3.0	[1.0,20.0]
	CE-TI	27	31.76	7.0	[7.0,7.5]	7.0	[7.0,8.0]	25.0	[19.0,30.0]	42.0	[23.5,67.5]	14.0	[9.0,21.5]	32.0	[14.5,60.5]
	All	1034	45.55	4.0	[2.0,7.0]	6.0	[3.0,9.0]	21.0	[13.0,32.0]	46.0	[22.0,91.8]	15.0	[7.0,20.0]	37.0	[16.0,74.0]
Deceased and embryos from stillbirths or abortion	KEK-ZH	10	1.61	5.0	[2.2,6.8]	6.0	[3.2,7.8]	21.5	[17.8,28.5]	27.0	[20.8,32.8]	14.5	[14.0,17.8]	17.5	[14.2,24.8]
	EKNZ	3	0.62	6.0	[3.0,6.5]	6.0	[3.5,6.5]	21.0	[17.5,27.0]	59.0	[54.0,66.5]	15.0	[14.0,20.5]	53.0	[50.5,60.0]
	CER-VD	2	0.50	6.0	[6.0,6.0]	27.5	[16.8,38.2]	42.5	[31.8,53.2]	42.5	[31.8,53.2]	15.0	[15.0,15.0]	15.0	[15.0,15.0]
	KEK-BE	1	0.30	1.0	[1.0,1.0]	6.0	[6.0,6.0]	21.0	[21.0,21.0]	70.0	[70.0,70.0]	15.0	[15.0,15.0]	64.0	[64.0,64.0]
	CCER	2	0.78	2.5	[2.2,2.8]	7.0	[6.0,8.0]	39.0	[35.0,43.0]	261.0	[146.0,376.0]	32.0	[27.0,37.0]	254.0	[138.0,370.0]
	EKOS	2	2.33	0.5	[0.2,0.8]	0.5	[0.2,0.8]	2.5	[2.2,2.8]	9.0	[5.5,12.5]	2.0	[2.0,2.0]	8.5	[5.2,11.8]
	CE-TI	0	0.00												
	All	20	0.88	3.5	[1.8,6.0]	6.0	[2.8,7.2]	21.0	[17.0,31.2]	31.5	[20.8,60.2]	15.0	[13.8,19.0]	20.0	[15.0,49.2]
Overall	KEK-ZH	621	100.00	7.0	[6.0,7.0]	7.0	[7.0,8.0]	29.0	[22.0,36.0]	57.0	[34.0,103.0]	21.0	[14.0,28.0]	49.0	[26.0,88.0]
	EKNZ	481	100.00	4.0	[2.0,6.0]	5.0	[2.0,7.0]	21.0	[13.0,30.0]	50.0	[27.0,84.0]	14.0	[6.0,21.0]	43.0	[21.0,72.0]
	CER-VD	403	100.00	5.0	[3.0,6.0]	6.0	[4.0,8.0]	23.0	[19.0,31.0]	85.0	[53.0,145.5]	16.0	[14.0,21.0]	72.0	[44.0,129.0]
	KEK-BE	338	100.00	2.0	[1.0,4.0]	6.0	[3.0,14.0]	26.0	[20.0,39.0]	111.5	[60.5,188.5]	18.0	[15.0,20.0]	94.0	[54.5,171.8]
	CCER	256	100.00	3.0	[1.0,6.0]	7.0	[4.0,12.0]	29.0	[21.0,36.0]	72.0	[42.0,119.5]	20.5	[16.0,26.0]	60.5	[35.0,101.0]
	EKOS	86	100.00	1.0	[1.0,3.0]	1.0	[1.0,3.0]	7.0	[3.0,14.5]	21.5	[5.0,88.8]	4.0	[1.2,9.8]	19.0	[2.0,84.0]
	CE-TI	85	100.00	7.0	[7.0,8.0]	7.0	[7.0,8.0]	26.0	[19.0,35.0]	42.0	[25.0,73.0]	18.0	[11.0,27.0]	34.0	[18.0,66.0]
	All	2270	100.00	5.0	[2.0,7.0]	7.0	[3.0,8.0]	26.0	[18.0,34.0]	65.0	[37.0,118.0]	18.0	[13.0,23.0]	56.0	[30.0,104.0]

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	141	5	[2,7]	340	6	[2,7]
	from receipt to status 'complete'	141	7	[3,8]	340	7	[4,8]
	from receipt to first decision	141	29	[24,40]	340	27	[21,36]
	from receipt to final decision	141	126	[85,209]	340	96	[59,163]
	from 'complete' to first decision	141	22	[17,31]	340	20	[16,25]
	from 'complete' to final decision	141	119	[83,205]	340	84	[50,154]
Research w/persons	from receipt to first reply	83	6	[3,7]	652	5	[2,7]
	from receipt to status 'complete'	83	7	[5,8]	652	7	[4,8]
	from receipt to first decision	83	31	[24,41]	652	27	[20,35]
	from receipt to final decision	83	97	[68,164]	652	68	[46,111]
	from 'complete' to first decision	83	21	[15,28]	652	19	[15,25]
	from 'complete' to final decision	83	92	[58,152]	652	60	[41,100]
Further use	from receipt to first reply	78	5	[1,7]	956	4	[2,7]
	from receipt to status 'complete'	78	7	[5,14]	956	6	[3,8]
	from receipt to first decision	78	28	[17,40]	956	21	[13,31]
	from receipt to final decision	78	67	[42,119]	956	43	[22,88]
	from 'complete' to first decision	78	16	[11,22]	956	14	[7,20]
	from 'complete' to final decision	78	55	[34,100]	956	35	[15,71]
Deceased and embryos from stillbirths or abortion	from receipt to first reply	0		[,]	20	4	[2,6]
	from receipt to status 'complete'	0		[,]	20	6	[3,7]
	from receipt to first decision	0		[,]	20	21	[17,31]
	from receipt to final decision	0		[,]	20	32	[21,60]
	from 'complete' to first decision	0		[,]	20	15	[14,19]
	from 'complete' to final decision	0		[,]	20	20	[15,49]
Overall	from receipt to first reply	302	5	[2,7]	1968	5	[2,7]
	from receipt to status 'complete'	302	7	[4,9]	1968	7	[3,8]
	from receipt to first decision	302	29	[22,40]	1968	25	[17,34]
	from receipt to final decision	302	106	[68,170]	1968	60	[34,110]
	from 'complete' to first decision	302	21	[15,28]	1968	17	[12,22]
	from 'complete' to final decision	302	95	[56,163]	1968	52	[28,95]

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	105	7	[7,7]	516	7	[6,7]
	from receipt to status 'complete'	105	7	[7,8]	516	7	[7,8]
	from receipt to first decision	105	35	[26,43]	516	28	[21,35]
	from receipt to final decision	105	104	[69,160]	516	53	[32,91]
	from 'complete' to first decision	105	22	[15,34]	516	20	[14,27]
	from 'complete' to final decision	105	92	[60,153]	516	44	[24,77]
EKNZ	from receipt to first reply	66	4	[1,6]	415	4	[2,6]
	from receipt to status 'complete'	66	5	[1,7]	415	5	[2,7]
	from receipt to first decision	66	28	[20,36]	415	20	[12,29]
	from receipt to final decision	66	85	[60,121]	415	47	[24,74]
	from 'complete' to first decision	66	21	[16,28]	415	13	[6,20]
	from 'complete' to final decision	66	81	[50,116]	415	39	[17,62]
CER-VD	from receipt to first reply	33	7	[4,8]	370	5	[3,6]
	from receipt to status 'complete'	33	7	[4,9]	370	5	[3,8]
	from receipt to first decision	33	28	[21,34]	370	23	[19,31]
	from receipt to final decision	33	143	[82,179]	370	83	[52,139]
	from 'complete' to first decision	33	20	[16,24]	370	16	[14,21]
	from 'complete' to final decision	33	114	[69,172]	370	70	[43,124]
KEK-BE	from receipt to first reply	49	2	[1,4]	289	3	[1,5]
	from receipt to status 'complete'	49	7	[3,17]	289	6	[3,14]
	from receipt to first decision	49	27	[21,49]	289	25	[20,38]
	from receipt to final decision	49	174	[114,280]	289	99	[56,158]
	from 'complete' to first decision	49	19	[15,22]	289	18	[15,20]
	from 'complete' to final decision	49	166	[94,258]	289	87	[51,147]

		Application involves					
		Multiple ECs			Single EC		
Lead EC	Time interval	n	Median	IQR	n	Median	IQR
CCER	from receipt to first reply	18	2	[1,4]	238	3	[1,6]
	from receipt to status 'complete'	18	6	[4,12]	238	7	[4,12]
	from receipt to first decision	18	30	[22,39]	238	28	[21,36]
	from receipt to final decision	18	93	[46,136]	238	70	[42,118]
	from 'complete' to first decision	18	22	[16,26]	238	20	[16,26]
	from 'complete' to final decision	18	82	[36,120]	238	60	[35,100]
EKOS	from receipt to first reply	19	1	[1,3]	67	1	[1,2]
	from receipt to status 'complete'	19	3	[1,4]	67	1	[1,3]
	from receipt to first decision	19	20	[12,29]	67	5	[3,10]
	from receipt to final decision	19	104	[66,139]	67	16	[3,40]
	from 'complete' to first decision	19	17	[10,24]	67	3	[1,7]
	from 'complete' to final decision	19	101	[66,135]	67	13	[2,35]
CE-TI	from receipt to first reply	12	7	[7,7]	73	7	[7,8]
	from receipt to status 'complete'	12	7	[7,8]	73	7	[7,8]
	from receipt to first decision	12	34	[23,37]	73	25	[19,34]
	from receipt to final decision	12	73	[52,116]	73	39	[24,63]
	from 'complete' to first decision	12	20	[12,28]	73	18	[11,25]
	from 'complete' to final decision	12	66	[41,109]	73	28	[16,54]
Overall	from receipt to first reply	302	5	[2,7]	1968	5	[2,7]
	from receipt to status 'complete'	302	7	[4,9]	1968	7	[3,8]
	from receipt to first decision	302	29	[22,40]	1968	25	[17,34]
	from receipt to final decision	302	106	[68,170]	1968	60	[34,110]
	from 'complete' to first decision	302	21	[15,28]	1968	17	[12,22]
	from 'complete' to final decision	302	95	[56,163]	1968	52	[28,95]

5.4.1 Time from status "complete" to first decision

Figure 8.1: 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) for **non-COVID-19 projects.** 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.

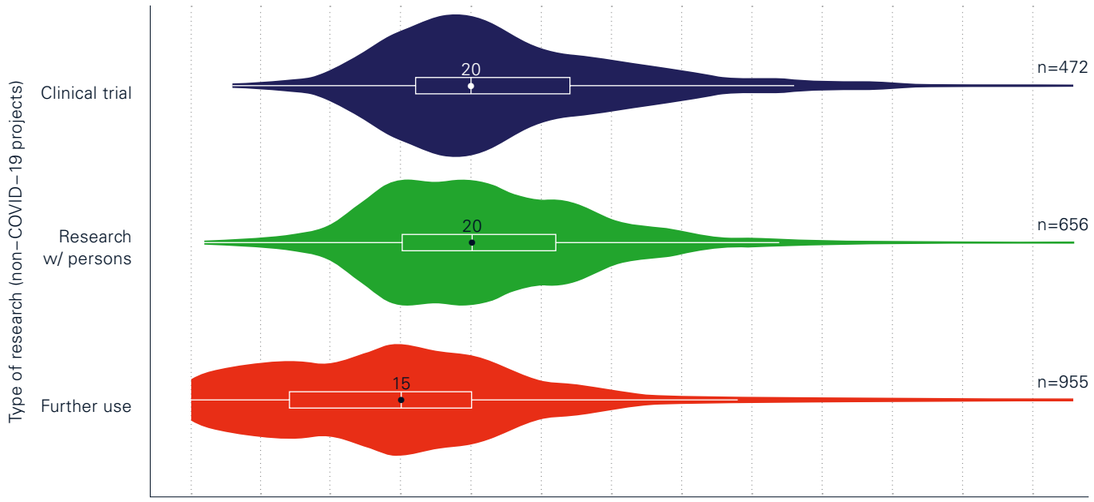


Figure 8.2: Violin plot of the **approval time starting from status 'complete' to the first decision** per type of research (only the 3 major groups are shown) for **COVID-19 projects.** 32 projects with approval time > 60 days are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 25.1.

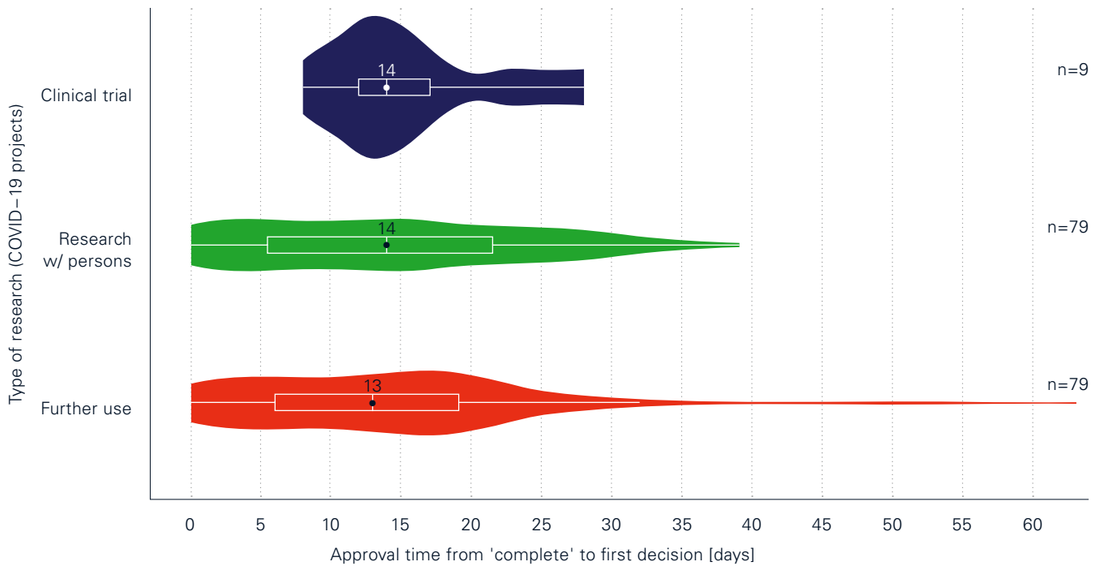
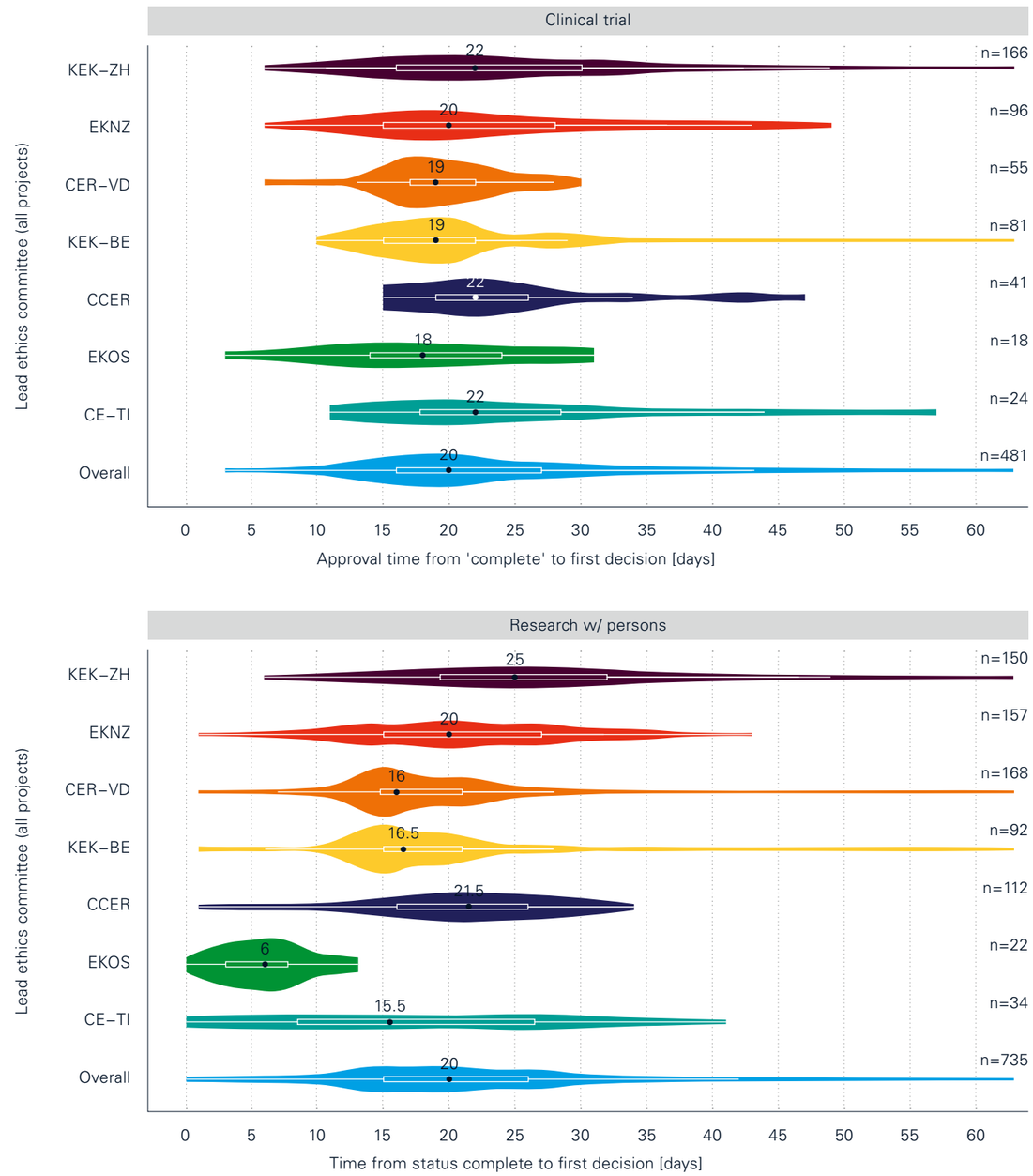


Figure 9: Violin plot of the **approval time starting from status 'complete' to the first decision** per type of research (only the 3 major groups are shown) stratified by EC. 33 projects with approval time > 60 days are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 25.1.



5.4.2 Time from reception to final decision

Figure 10.1: Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown) for **non-COVID-19 projects.** 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.

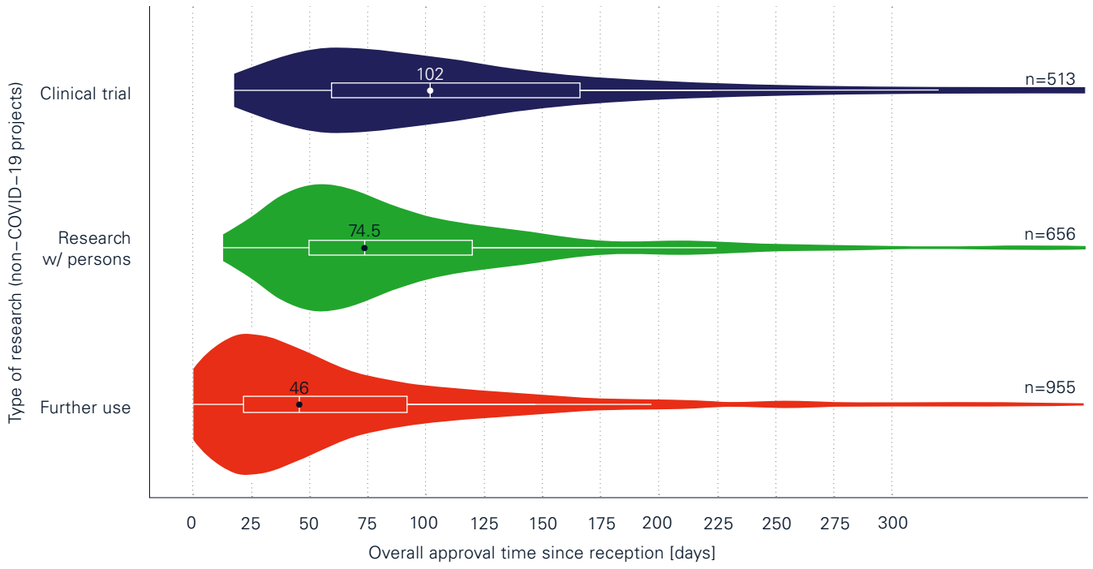


Figure 10.2: Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown) for **COVID-19 projects.** 57 projects with an overall approval time > 1 year are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 25.1.

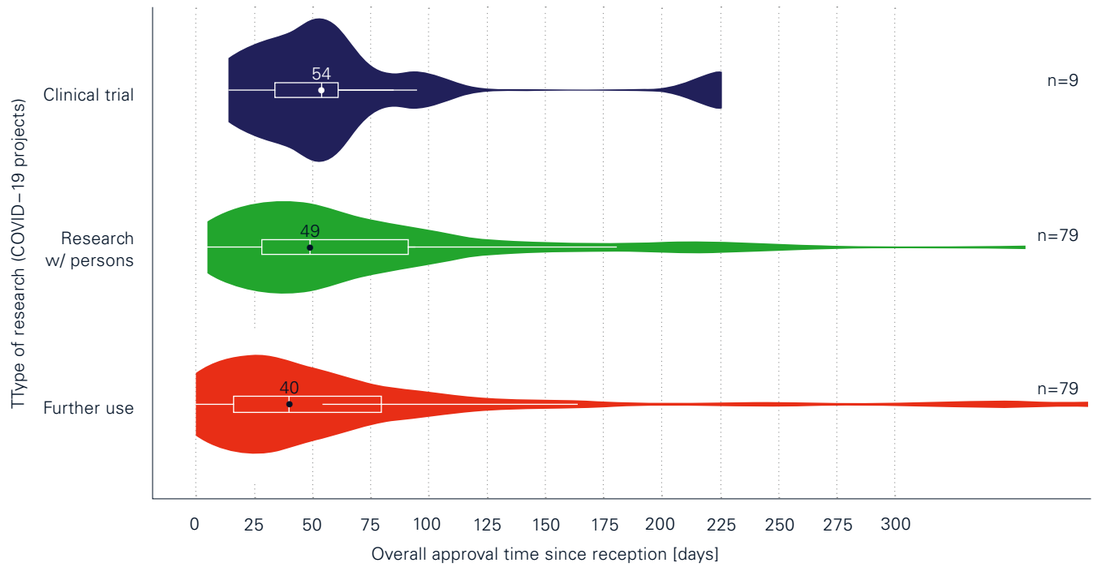
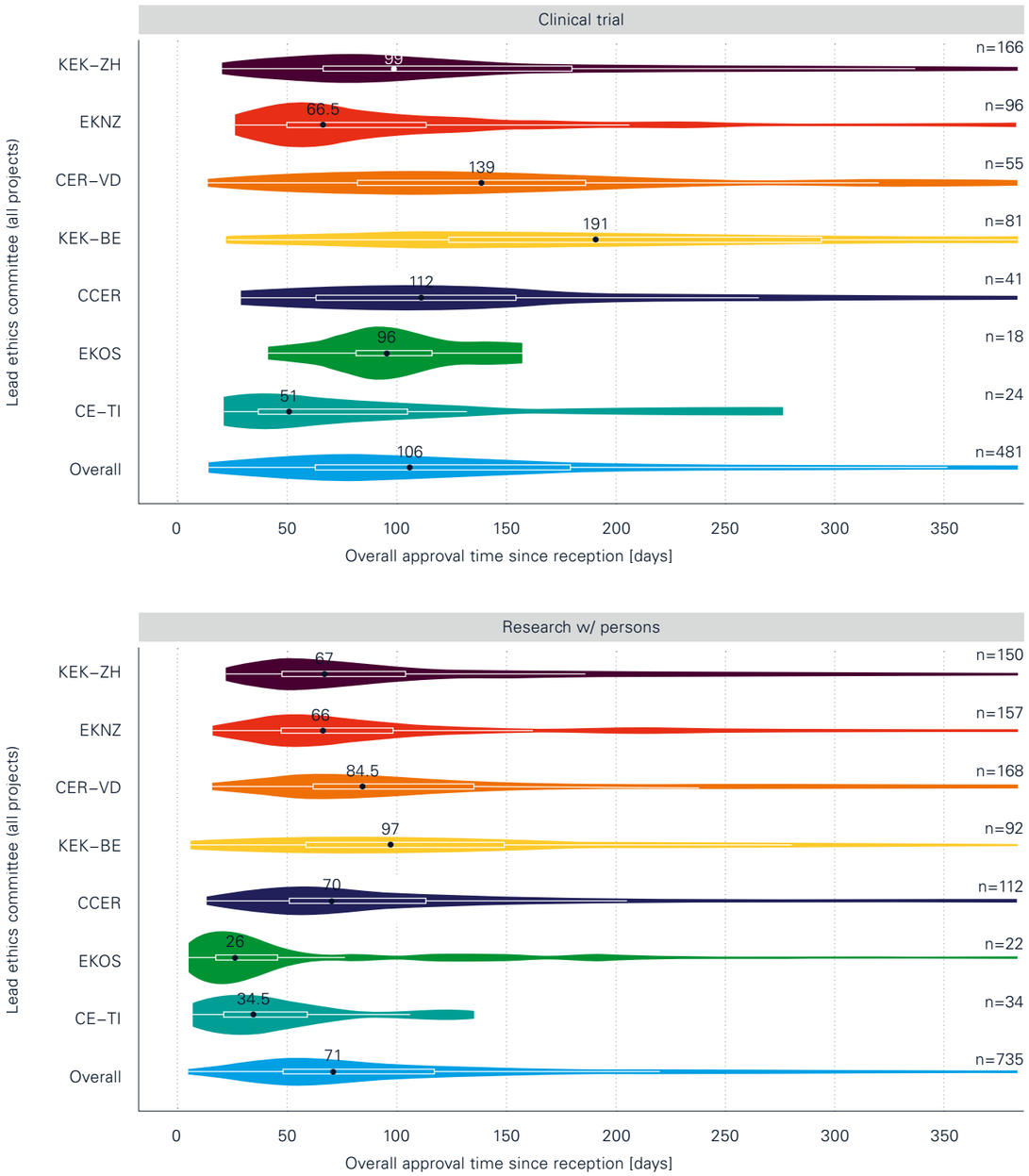
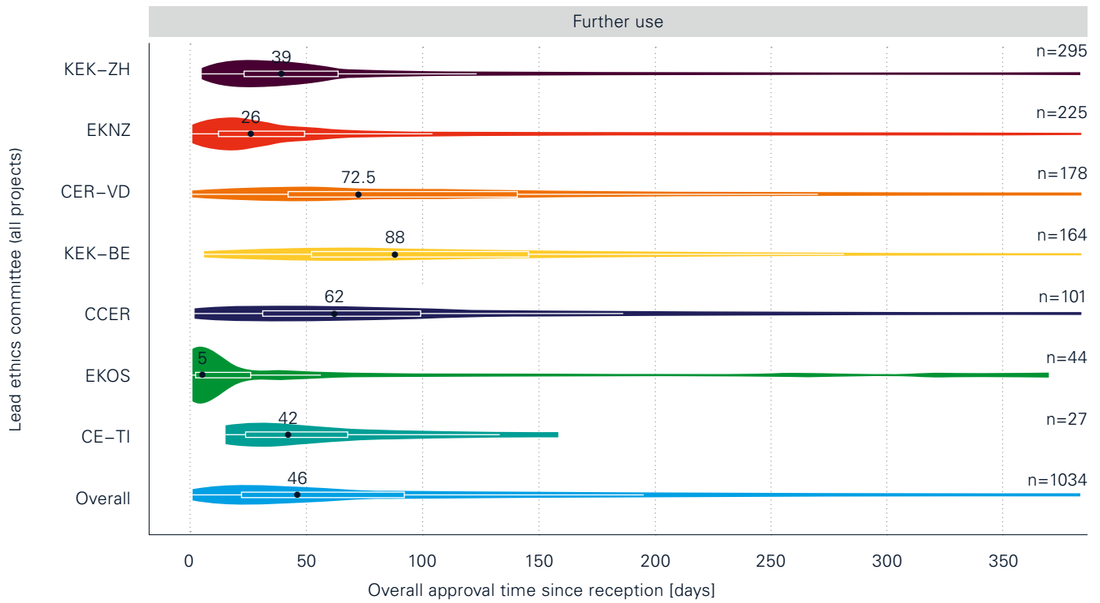


Figure 11: Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown) stratified by EC. 91 projects with an overall approval time > 1 year are not shown for layout reasons.
ClinO-MD projects are not included but separately displayed in table 25.1.





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

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

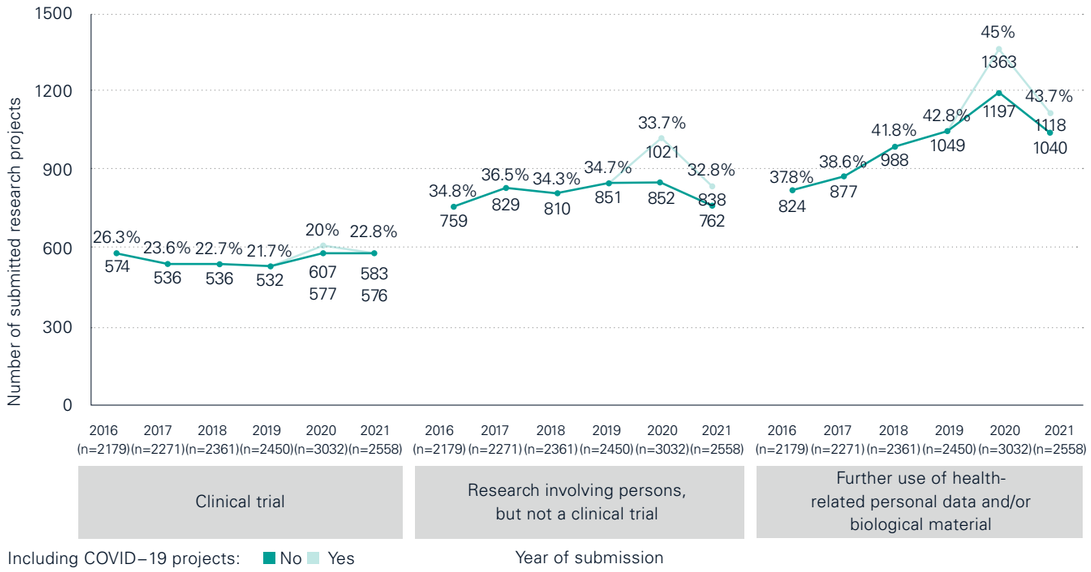
Table 25.1: Overview of response time in days – Median and inter-quartile range (IQR) stratified by lead ethics committee and depending on whether a single or multiple ECs are involed – **only for ClinO-MD projects.**

		Application involves					
		Multiple ECs			Single EC		
Lead EC	Time interval	n	Median	IQR	n	Median	IQR
KEK-ZH	from receipt to status 'complete'	2	15	[14,16]	12	7	[5,10]
	from receipt to final decision	2	43	[42,44]	12	41	[26,45]
	from 'complete' to final decision	2	28	[28,28]	12	32	[19,36]
EKNZ	from receipt to status 'complete'	0		[,]	4	4	[3,6]
	from receipt to final decision	0		[,]	4	30	[22,36]
	from 'complete' to final decision	0		[,]	4	24	[18,30]
CER-VD	from receipt to status 'complete'	0		[,]	2	6	[6,6]
	from receipt to final decision	0		[,]	2	68	[63,72]
	from 'complete' to final decision	0		[,]	2	62	[57,66]
KEK-BE	from receipt to status 'complete'	1	1	[1,1]	12	8	[5,10]
	from receipt to final decision	1	109	[109,109]	12	38	[36,49]
	from 'complete' to final decision	1	108	[108,108]	12	32	[28,41]
CCER	from receipt to status 'complete'	1	9	[9,9]	3	8	[8,9]
	from receipt to final decision	1	77	[77,77]	3	59	[50,89]
	from 'complete' to final decision	1	68	[68,68]	3	51	[42,80]
EKOS	from receipt to status 'complete'	0		[,]	2	6	[4,7]
	from receipt to final decision	0		[,]	2	32	[26,38]
	from 'complete' to final decision	0		[,]	2	26	[22,31]
CE-TI	from receipt to status 'complete'	1	8	[8,8]	1	1	[1,1]
	from receipt to final decision	1	45	[45,45]	1	21	[21,21]
	from 'complete' to final decision	1	37	[37,37]	1	20	[20,20]
Overall	from receipt to status 'complete'	5	9	[8,14]	36	7	[5,9]
	from receipt to final decision	5	45	[44,77]	36	39	[30,49]
	from 'complete' to final decision	5	37	[28,68]	36	32	[21,40]

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.

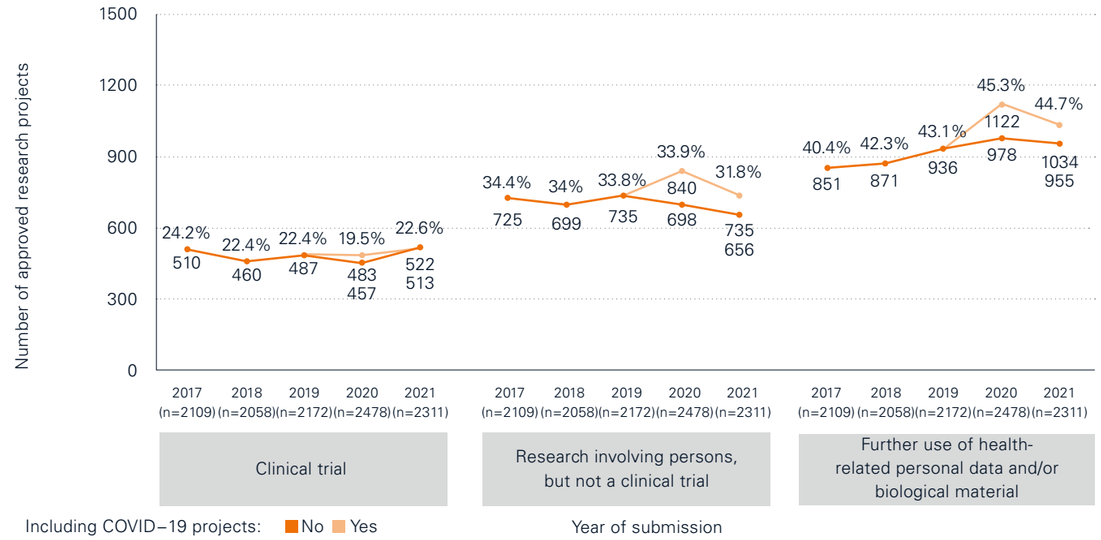


Data not shown in the above figure: Research involving deceased persons (2017: 29, 2018: 27, 2019: 17, 2020: 40, 2021: 19) and Research involving embryos and fetuses from induced abortions or stillbirths (2017: 0, 2018: 0, 2019: 1, 2020: 1 2021: 0)

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.

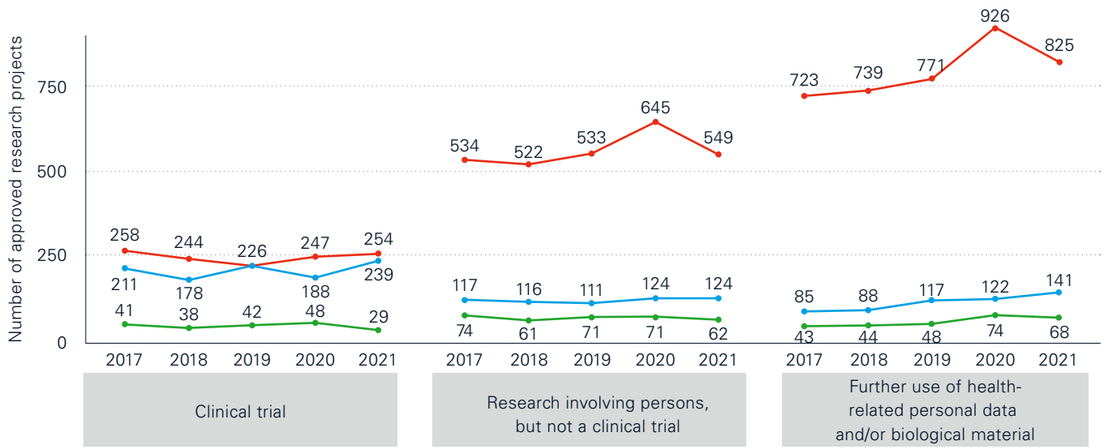
Figure 13: Total number of approved projects per year and type of research. Percentages on the top of the lines refer to the proportion of studies of a given type compared to all studies approved in a given year.



Data not shown in the above figure: Research involving deceased persons (2017: 22, 2018: 28, 2019: 14, 2020: 33, 2021: 19) and Research involving embryos and fetuses from induced abortions or stillbirths (2017: 1, 2018: 0, 2019: 0, 2020: 0 2021: 1)

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

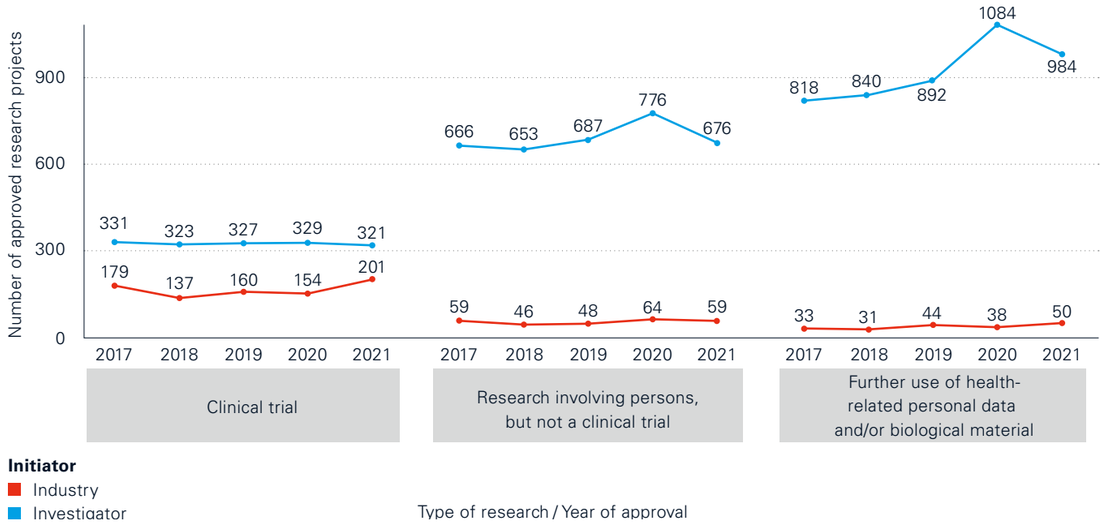
Figure 14: Approved projects per year stratified by type of research project and by study design.



Data not shown in the above figure: Research involving deceased persons (2017: 22, 2018: 28, 2019: 14, 2020: 33, 2021: 19) and Research involving embryos and fetuses from induced abortions or stillbirths (2017: 1, 2018: 0, 2019: 0, 2020: 0 2021: 1)

7.2 Project initiator

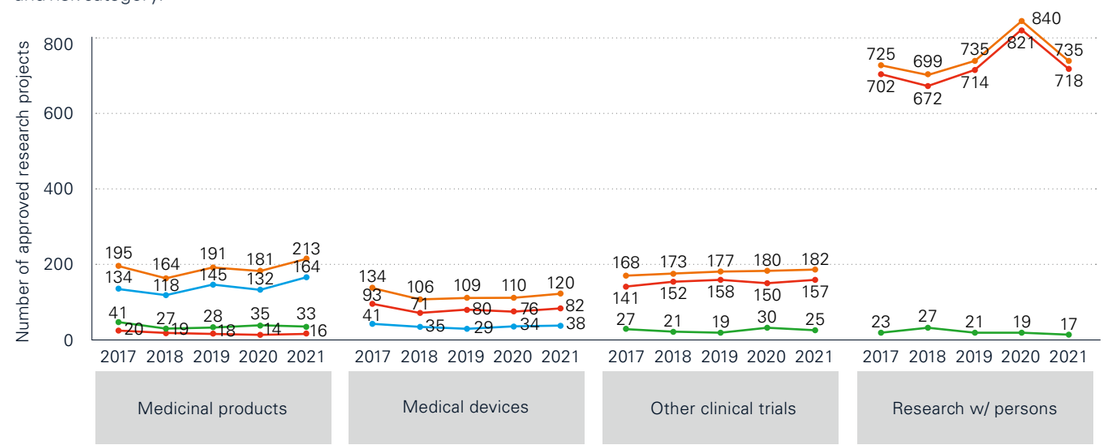
Figure 15: Approved projects per year stratified by type of research project and by project initiator.



Data not shown in the above figure: Research involving deceased persons (2017: 22, 2018: 28, 2019: 14, 2020: 33, 2021: 19) and Research involving embryos and fetuses from induced abortions or stillbirths (2017: 1, 2018: 0, 2019: 0, 2020: 0 2021: 1)

7.3 Risk category

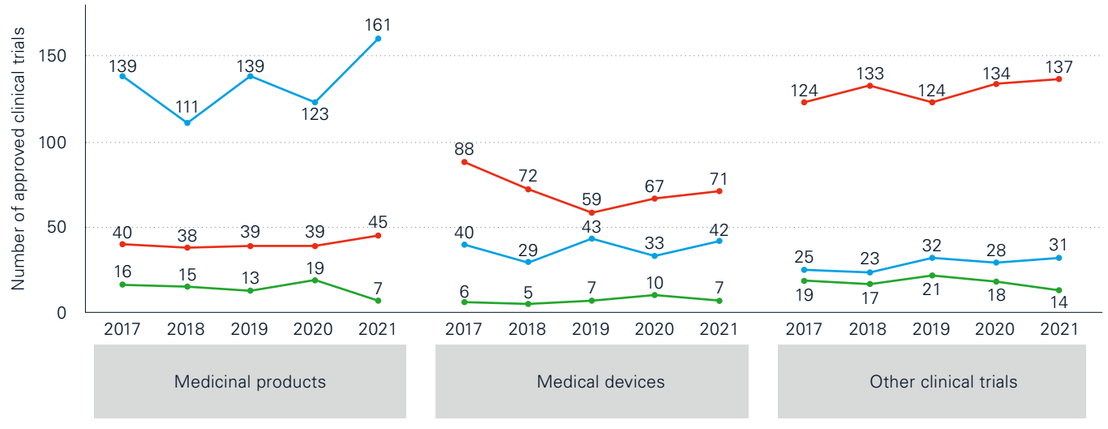
Figure 16: Clinical trials and research projects involving persons approved per year stratified by type of research project and risk category.



Data not shown in the above figure: Research involving transplant products (2017: 4, 2018: 9, 2019: 4, 2020: 6 , 2021: 2), combination drugs/devices (2018: 4, 2019: 4, 2020: 4 , 2021: 2) , gene therapy (2017: 0, 2018: 3, 2019: 2 , 2020: 1 , 2021: 1) , transplantation (2017: 0, 2018: 1, 2019: 0 , 2020: 1 , 2021: 0) pathogenic organisms (2019: 0 , 2020: 0 , 2021: 1) and in-vitro diagnostic (2021: 1)

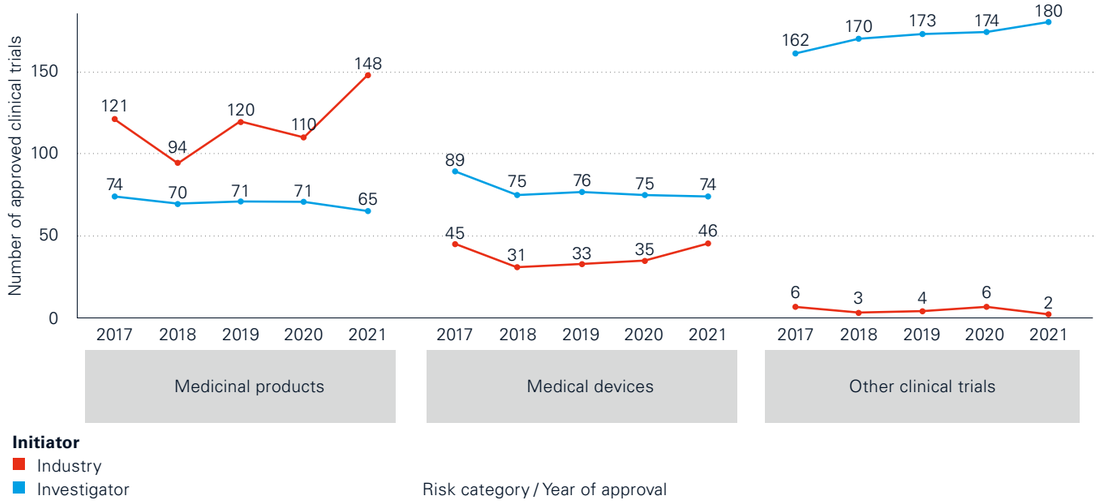
7.4 Subgroups of clinical trials

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 (2017: 4, 2018: 9, 2019: 4, 2020: 6 , 2021: 2), combination drugs/devices (2018: 4, 2019: 4, 2020: 4 , 2021: 2) , gene therapy (2017: 0, 2018: 3, 2019: 2 , 2020: 1 , 2021: 1) , transplantation (2017: 0, 2018: 1, 2019: 0, 2020: 1, 2021: 0) pathogenic organisms (2019: 0, 2020: 0, 2021: 1) and in-vitro diagnostic (2021: 1)

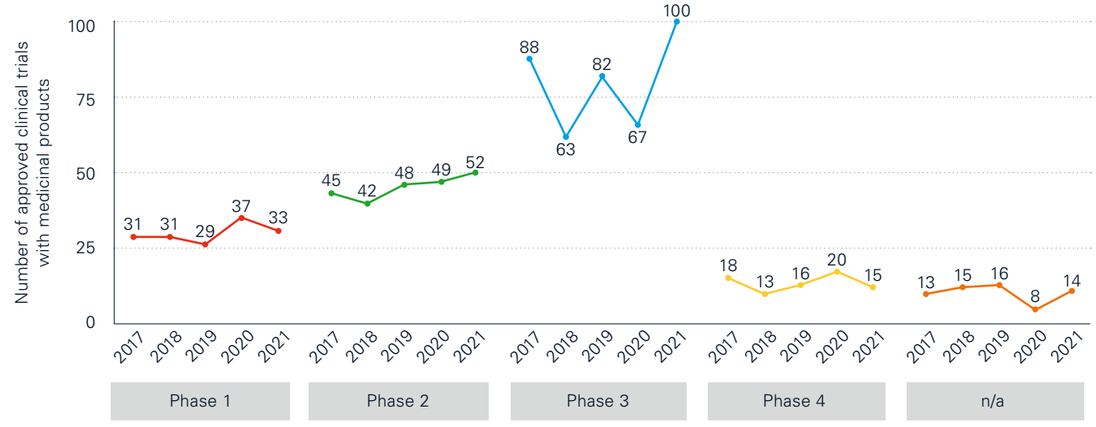
Figure 18: Clinical trials approved per year stratified by trial type and initiator.



Data not shown in the above figure: Research involving transplant products (2017: 4, 2018: 9, 2019: 4, 2020: 6 , 2021: 2), combination drugs/devices (2018: 4, 2019: 4, 2020: 4 , 2021: 2) , gene therapy (2017: 0, 2018: 3, 2019: 2 , 2020: 1 , 2021: 1) , transplantation (2017: 0, 2018: 1, 2019: 0, 2020: 1, 2021: 0) pathogenic organisms (2019: 0, 2020: 0 , 2021: 1) and in-vitro diagnostic (2021: 1)

7.4.1 Clinical trials with medicinal products

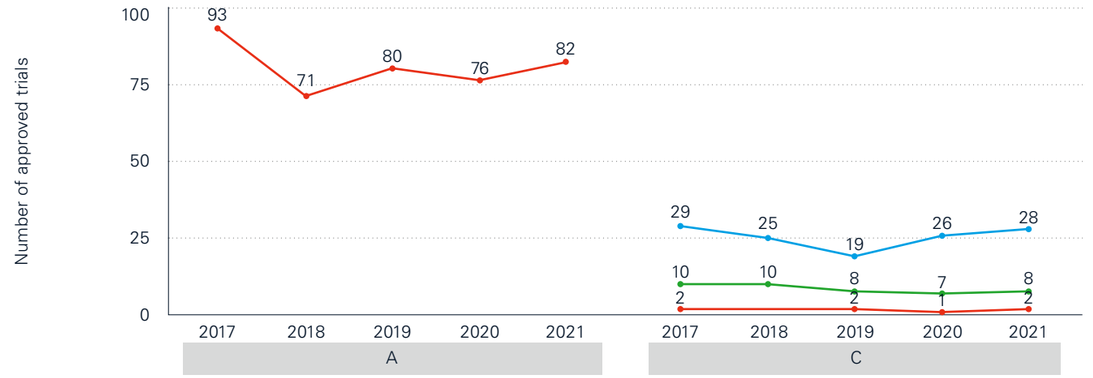
Figure 19: Clinical trials with medicinal products approved per year stratified by study phase.



Number of trials 'first-in-human': 2017: 6, 2018: 8, 2019: 5, 2020: 11, 2021: 9

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': 2017: 30, 2018: 20, 2019: 13 , 2020: 18, 2021: 20

7.5 Subgroup Further use of data / biological material

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

		Approval year									
		2017		2018		2019		2020		2021	
		n	%	n	%	n	%	n	%	n	%
Genetic data/biol. material	Yes	175	19.3	215	19.8	250	21.4	270	19.6	261	20.5
	No	732	80.7	869	80.2	919	78.6	1110	80.4	1011	79.5
Coding (HRO Art. 25–27)	Coded	419	46.2	904	83.4	1013	86.7	1196	86.7	1155	90.8
	Open, non-coded	488	53.8	180	16.6	156	13.3	184	13.3	117	9.2
Consent (HRO Art. 28–32)	Consent for all data	350	38.6	545	50.3	580	49.6	710	51.4	677	53.2
	Consent for some but not all data (partially Art. 34 HRA)[1]	–	–	–	–	–	–	296	21.4	371	29.2
	No consent for all data, Art. 34 HRA[2]	557	61.4	539	49.7	589	50.4	374	27.1	224	17.6
Combined vs. stand-alone projects[3]	Stand-alone further use project	851	93.8	871	80.4	936	80.1	1122	81.3	1034	81.3
	Further use project as part of a clinical trial	19	2.1	41	3.8	46	3.9	40	2.9	56	4.4
	Further use project as part of a non-clinical research project	37	4.1	172	15.9	187	16	218	15.8	182	14.3
	Total number	907	100	1084	100	1169	100	1380	100	1272	100

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.

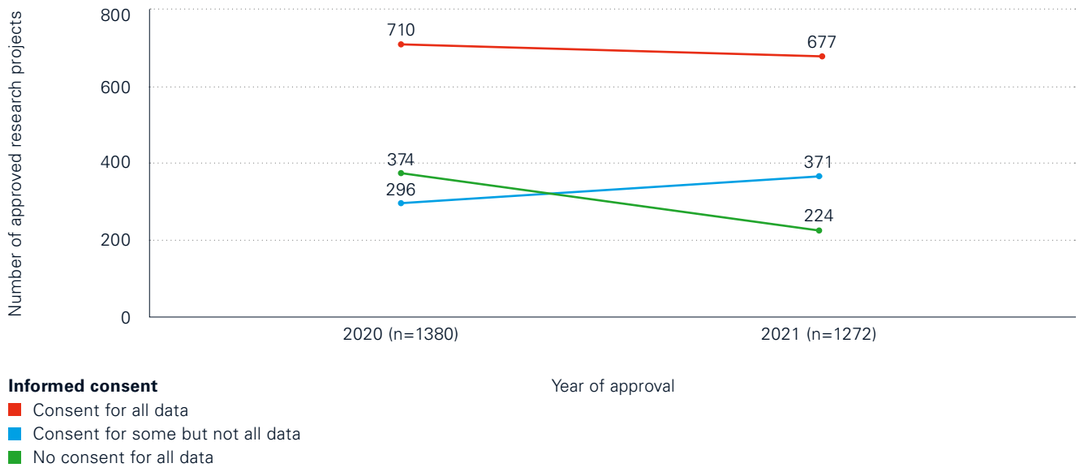
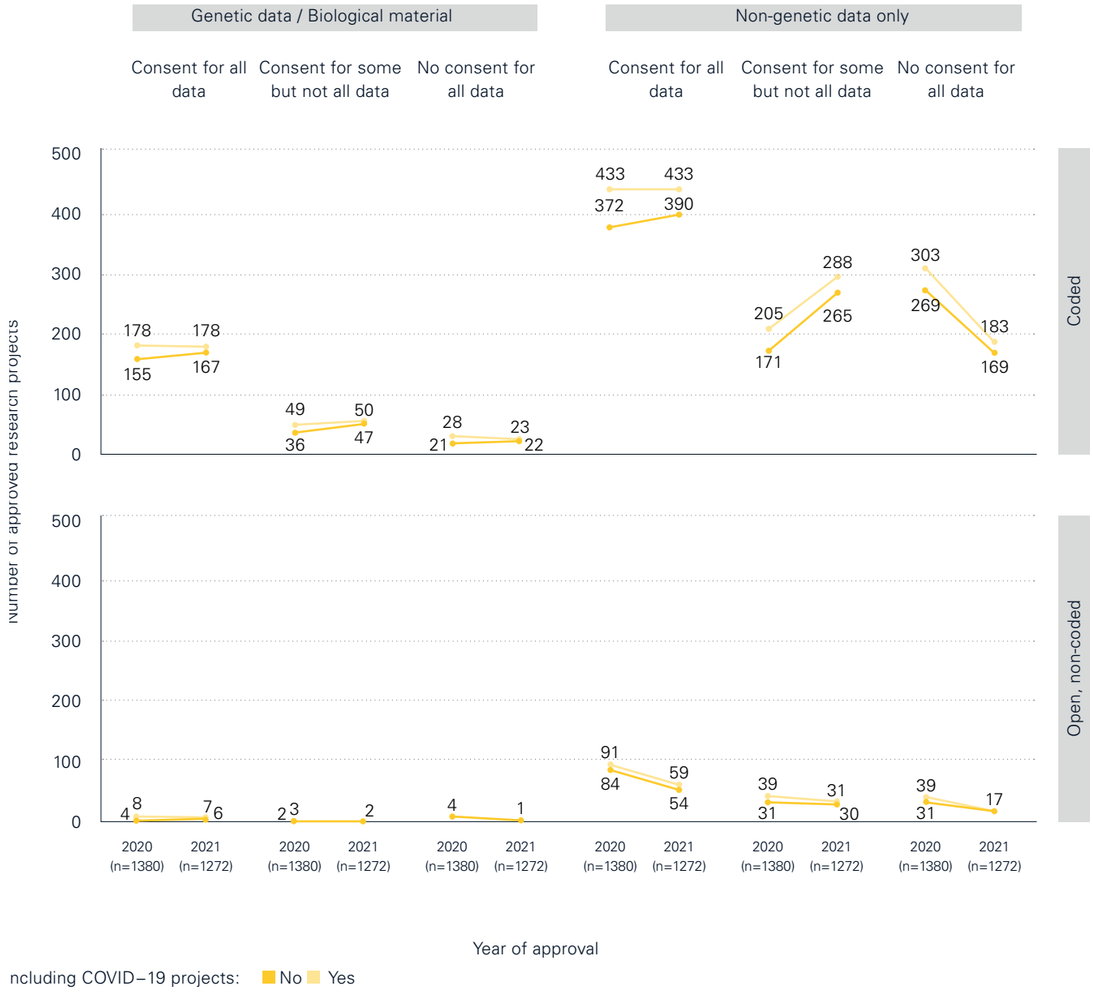
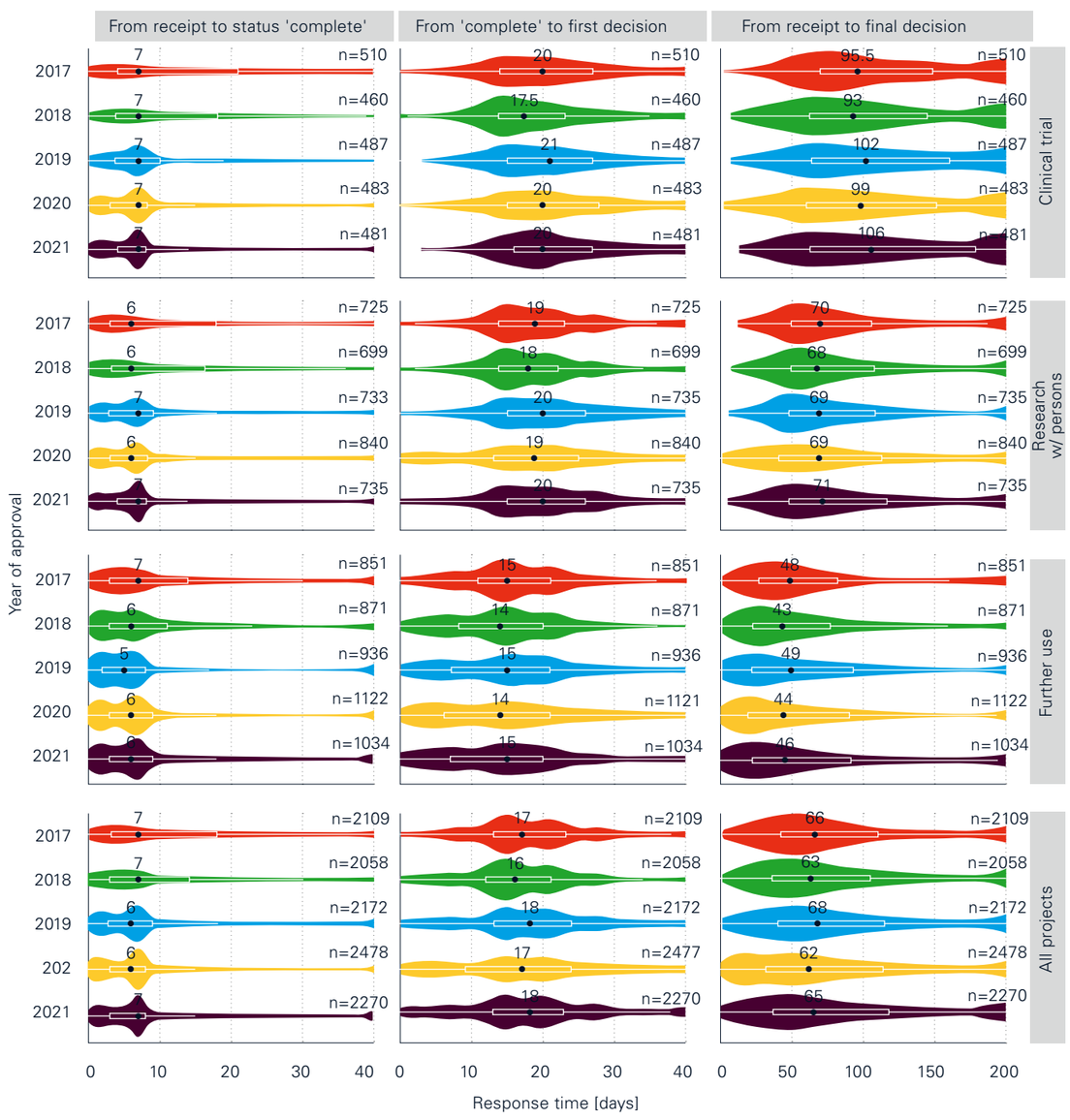


Figure 22: Number of approved 'further use' projects per year stratified by 1) Use of genetic data and/or biological material, 2) coded vs. uncoded, 3) consent for further use.



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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Contact:
Coordination Office for Human Research (kofam)
P.O.Box
CH-3003 Bern
kofam@bag.admin.ch
www.kofam.ch
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