Medicine & Research
Statistical Report

Human Research in Switzerland 2020

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

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

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

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

Contents

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List of abbreviations

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

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 report should distinguish between COVID-19 specific and non-COVID-19 specific applications and authorizations for selected tables and figures.

1.2 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 1.4.

First, an overview on the BASEC data in the true calendar year 2020 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 2020. 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 2020 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 five years (2016, 2017, 2018, 2019 and 2020) and for approved projects (AS2) over four years (2017, 2018, 2019 and 2020). The reason for this difference in the years compared is described in section 1.4.3.

1.3 Data source and limitations

This report is based on data entered into the BASEC web portal by two different parties:

1. All data concerning the submitted research projects are entered by the applicant.
2. With the exception of the submission date, all data on response times and on the review process are entered by the individual ethics committees under the supervision of swissethics.

A BASEC data export provided by swissethics dated April 4, 2021 has been used for this report.

1.3.1 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 1.4.4).

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.

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

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

Reception date: The date when the applicant submits the project for the first time.

First reaction date: The date when the ethics committee notifies the project applicant of either the acceptance of the application (in this case the first reaction date coincides with the "date the application data declared complete"), or of any formal deficiency in the application documents and the need for resubmission.

Date the application data declared complete: The date at which the application data are considered formally complete and ready for review by ordinary, simplified or presidential procedure.

First decision date: Date of the decision after the first review procedure. The first decision date coincides with the "final decision date" if the project is approved (i.e. without charges) in the first run.

Final decision date: Date of the final decision which can be: approved (and all charges have been fulfilled), declined, non-consideration, withdrawn.

These dates are used to calculate response times which are presented in chapter 5 on pages 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", 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.

1.4 Analysis sets

1.4.1 Definition of analysis sets

Definition:
AS1 The analysis set AS1 consists of all projects **submitted in 2020.** 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 2020** irrespective of whether the projects were submitted in the reporting year or before.

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

A BASEC data export always presents a snapshot. Some projects have already been assessed and a final decision has been made, and other projects are pending for various reasons: the application data are still incomplete, the decision by the EC is pending or the EC makes the decision on the project dependent on certain charges/conditions. Furthermore, submitted projects may later be declined by the EC, the project may not be covered

by the HRA (non-consideration) or may be withdrawn by the applicant (including submissions that are never completed).

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

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

In addition to the above described limitations with regard to the content of applications, the data are capped on both ends, which further complicates the comparison of the data over years (see Figure 1.1): only submissions after the beginning of 2016 are captured in BASEC, and, the data are censored at the time of data export.

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

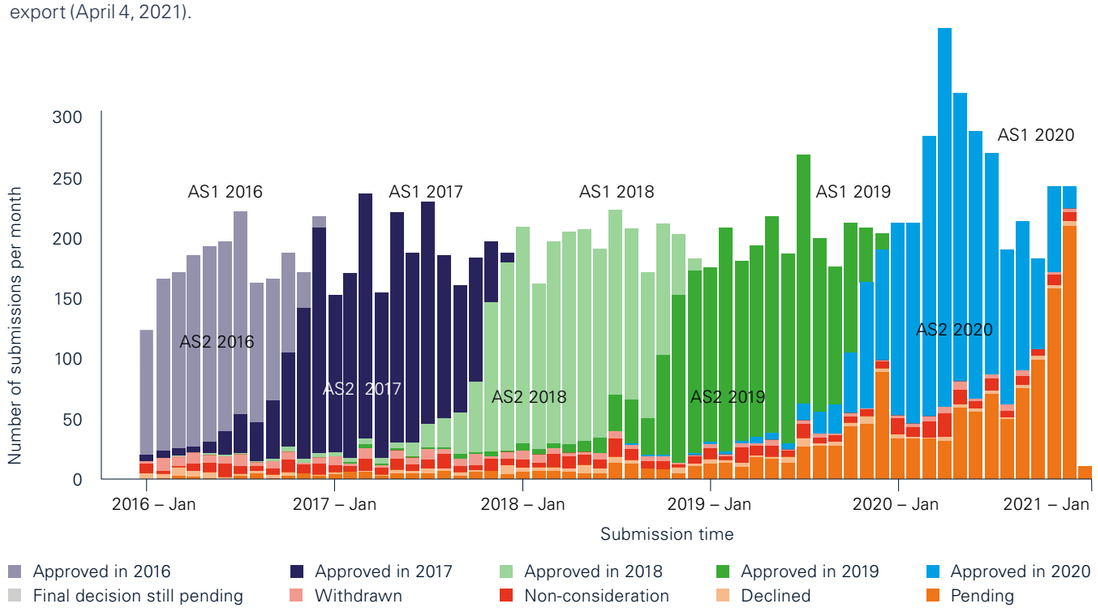
COVID-19 studies have been selected using the following method: Studies with at least one of the following terms – covid, ncov, sars, cov-2, corona – in the protocol title were pre-selected. Each pre-selected study was subsequently checked individually to exclude false positives (e.g., studies on coronary 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.

1.4.3 Influence of time on project status

Figure 1.1 shows all submissions via BASEC in the years 2016 up to 2020. Each bar represents the number of submissions in a given month. The bars are coloured according to the current status of the respective submissions as of the time of the data export.

Figure 1.1: Overview of submissions via BASEC in the years 2016–2020 coloured by the current status as of the time of the data export (April 4, 2021).

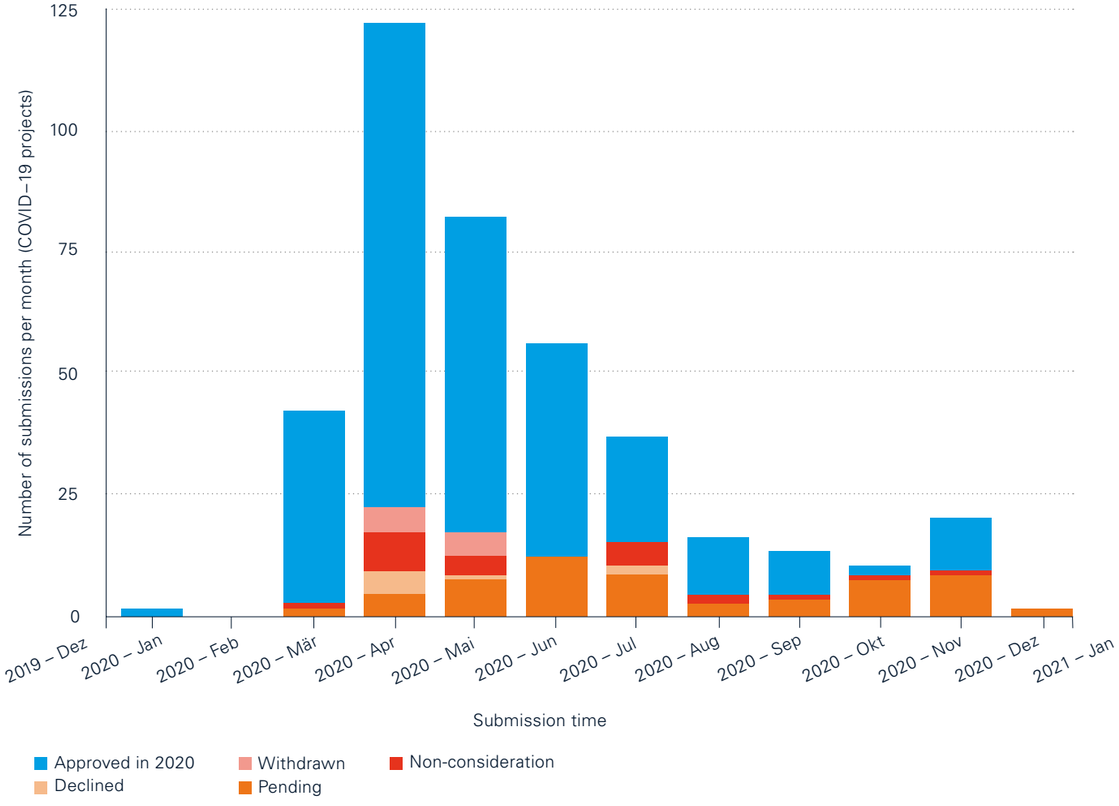


The proportion of projects not approved (declined, withdrawn, non-consideration) is quite stable over time. These projects are not part of AS2 and will not be analysed scientifically. The proportion of pending projects is low in early years: projects that have been pending for a long time (after reminding 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 2020, since a single up-todate export is used for all years (export date: April 4, 2021) and not individual exports for each reporting year.

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

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

Figure 1.2: Overview of submissions via BASEC in the year 2020 for **COVID-19** studies coloured by the current status as of the time of the data export (April 4, 2021)



1.4.4 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 a research project involving persons (HRO Chapter 2) and the further-use of existing data or biological material (HRO Chapter 3). BASEC allows these combined projects to be submitted as a single research project.
2. Research involving a combination of a medicinal product and a medical device such as drug-eluting stents or a nasal spray device.

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

1 Exception: In section 3.2 on page 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 2020

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

					COVID-19	
			n	$\%_{col}$	n	$\%_{row}$
Input	Submission in 2020 (AS1)		3033	78.8	420	13.8
	Projects pending from 2019	Pending first decision in 2019	250	6.5	0	0.0
		Pending final decision in 2019 (first decision before 2020)	559	14.7	0	0.0
		Total Pending from 2019	809	21.2	0	0.0
		Grand Total Input 2020	3842	100.0	420	10.9
Output	Final decision in 2020	Approvals (AS2)	2447	63.7	309	12.6
		Rejections (declined projects)	34	0.9	7	20.6
		Non-considerations	111	2.9	21	18.9
		Total Decisions	2592	67.4	337	13.0
	Withdrawn during 2020	Withdrawal before first decision	19	0.5	2	10.5
		Withdrawal after first decision 'approvals with charges'	3	0.1	0	0.0
		Withdrawal after first decision 'not-yet-approved projects with conditions'	27	0.7	8	29.6
		Total Withdrawn	49	1.3	10	20.4
	Pending at end of 2020	Pending first decision	320	8.3	17	5.3
		Pending final decision (first decision issued)	881	23.0	56	6.4
		Total Pending	1201	31.3	73	6.1
		Grand Total Output 2020	3842	100.0	420	10.9

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 2020 and hence obtained a new BASEC number.

3 Overview of all projects submitted to BASEC in 2020 (AS1)

Table 2: Total number of research projects **submitted via BASEC in 2020** (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	609 [1]	20.1	39	6.4
Research involving persons, but not a clinical trial	HRO, Chapter 2	1025 [2]	33.8	187	18.2
Further use of health-related personal data and/or biological material	HRO, Chapter 3	1357	44.7	187	13.8
Research involving deceased persons	HRO, Chapter 4	41	1.4	7	17.1
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	1	0.0	0	0.0
Total number		3033	100.0	420	13.8

1 48 of these projects also include an application for further use of data/biological material.
2 263 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 2020 (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	Approved [1]	473	15.6	213	28.4	83	13.8	26	4.7	25	5.0	44	11.8	36	30.5	46	30.9
	Approved with charges [2]	564	18.6	7	0.9	310	51.7	59	10.8	24	4.8	58	15.6	54	45.8	52	34.9
	Not approved, conditions [3]	1768	58.3	485	64.7	182	30.3	417	76.1	399	80.4	234	62.9	16	13.6	35	23.5
	Declined	32	1.1	10	1.3	10	1.7	2	0.4	1	0.2	6	1.6	3	2.5		
	Non-consideration [4]	110	3.6	30	4.0	7	1.2	15	2.7	22	4.4	19	5.1	7	5.9	10	6.7
	First decision still pending [5]	86	2.8	5	0.7	8	1.3	29	5.3	25	5.0	11	3.0	2	1.7	6	4.0
Final decision	Approved [6]	2374	78.3	647	86.3	469	78.2	410	74.8	345	69.6	291	78.2	101	85.6	111	74.5
	Declined	32	1.1	10	1.3	10	1.7	2	0.4	1	0.2	6	1.6	3	2.5		
	Non-consideration	112	3.7	30	4.0	9	1.5	14	2.6	22	4.4	20	5.4	7	5.9	10	6.7
	Withdrawn	47	1.5	4	0.5	7	1.2	7	1.3	16	3.2	9	2.4	2	1.7	2	1.3
	Final decision still pending [7]	468	15.4	59	7.9	105	17.5	115	21.0	112	22.6	46	12.4	5	4.2	26	17.4
Review procedure	Ordinary [8]	463	15.3	111	14.8	62	10.3	78	14.2	64	12.9	20	5.4	18	15.3	110	73.8 [11]
	Simplified [9]	2037	67.2	437	58.3	430	71.7	362	66.1	409	82.5	303	81.5	71	60.2	25	16.8
	Presidential [10]	441	14.5	190	25.3	102	17.0	72	13.1	7	1.4	39	10.5	22	18.6	9	6.0
	First decision still pending	92	3.0	12	1.6	6	1.0	36	6.6	16	3.2	10	2.7	7	5.9	5	3.4
	Total number in AS1	3033	100.0	750	100.0	600	100.0	548	100.0	496	100.0	372	100.0	118	100.0	149	100.0
	COVID-19	420	13.8	60	8.0	74	12.3	92	16.8	47	9.5	74	19.9	17	14.4	56	37.6

1 Projects already approved in the first review process.
2 Charges: The projects are approved but with charges.
3 Conditions: These projects are not approved until the conditions are addressed.
4 Non-consideration: Research not covered by the HRA.
5 Information missing: The status information was missing at the time of the report generation.
6 This includes projects approved in the index year but also in the subsequent year(s) until time of data export explaining the differences to Tables 7.
7 Pending at export date. 35.7% of the pending projects were submitted in the last quarter of the reporting year.
8 Decision taken at full committee meeting by at least seven members of the ethics committee, as per the provisions of Art. 5, OrgO-HRA.
9 Decision taken by three members of the ethics committee, as per the provisions of Art. 6 OrgO-HRA.
10 Decision taken by the president or vice-president of the ethics committee, as per the provisions of Art. 7 OrgO-HRA.
11 CE-TI uses the ordinary procedure for most of the research applications.

Table 4.1: Number of **submissions in 2020** (analysis set AS1) by type of research project and lead ethics committee.
Projects involving multiple ECs are assigned to the lead EC.

					Lead ethics committee											
			Total		KEK-ZH		EKNZ		CER-VD		KEK-BE		CCER		EKOS		CE-TI	
Type of research	Research details	Risk cat.	n	%col	n	%col	n	%col	n	%col	n	%col	n	%col	n	%col	n	%col
Clinical trial	Medicinal products	A	23	9.8	2	2.7	4	9.5	4	13.8	6	15.4	3	20.0			4	19.0
		B	37	15.7	11	14.9	13	31.0	3	10.3	6	15.4	1	6.7	1	6.7	2	9.5
		C	175	74.5	61	82.4	25	59.5	22	75.9	27	69.2	11	73.3	14	93.3	15	71.4
		All	235	100.0	74	100.0	42	100.0	29	100.0	39	100.0	15	100.0	15	100.0	21	100.0
	Medical devices	A	94	67.1	28	65.1	14	70.0	12	60.0	19	70.4	11	73.3	2	66.7	8	66.7
		C	46	32.9	15	34.9	6	30.0	8	40.0	8	29.6	4	26.7	1	33.3	4	33.3
		All	140	100.0	43	100.0	20	100.0	20	100.0	27	100.0	15	100.0	3	100.0	12	100.0
	Other clinical trials	A	187	84.6	63	87.5	37	72.5	21	91.3	34	91.9	18	85.7	7	77.8	7	87.5
		B	34	15.4	9	12.5	14	27.5	2	8.7	3	8.1	3	14.3	2	22.2	1	12.5
		All	221	100.0	72	100.0	51	100.0	23	100.0	37	100.0	21	100.0	9	100.0	8	100.0
	Combination drugs/devices	B	1	100.0					1	100.0								
		All	1	100.0					1	100.0								
	Transplant products	C	6	100.0			1	100.0	4	100.0	1	100.0						
		All	6	100.0			1	100.0	4	100.0	1	100.0						
	Gene therapy	C	2	100.0	2	100.0												
		All	2	100.0	2	100.0												
	Transplantation	C	1	100.0	1	100.0												
		All	1	100.0	1	100.0												
	All	All	609	100.0	193	100.0	114	100.0	78	100.0	104	100.0	52	100.0	27	100.0	41	100.0
Research w/persons		A	1001	97.7	197	96.6	185	98.4	229	99.6	143	93.5	148	98.0	43	100.0	56	100.0
		B	24	2.3	7	3.4	3	1.6	1	0.4	10	6.5	3	2.0				
		All	1025	100.0	204	100.0	188	100.0	230	100.0	153	100.0	151	100.0	43	100.0	56	100.0
Further use		n.a.	1357	100.0	333	100.0	289	100.0	235	100.0	239	100.0	161	100.0	48	100.0	52	100.0
Deceased, embryos		n.a.	42	100.0	20	100.0	9	100.0	5	100.0			8	100.0				
Total number			3033	100.0	750	100.0	600	100.0	548	100.0	496	100.0	372	100.0	118	100.0	149	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 4.2: Number of **submissions in 2020** (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	4	16.7			1	16.7			1	33.3	2	66.7				
		B	9	37.5	3	60.0	2	33.3	2	66.7	1	33.3					1	25.0
		C	11	45.8	2	40.0	3	50.0	1	33.3	1	33.3	1	33.3			3	75.0
		All	24	100.0	5	100.0	6	100.0	3	100.0	3	100.0	3	100.0			4	100.0
	Medical devices	A	3	60.0	1	100.0			1	50.0	1	100.0						
		C	2	40.0					1	50.0			1	100.0				
		All	5	100.0	1	100.0			2	100.0	1	100.0	1	100.0				
	Other clinical trials	A	7	70.0	1	50.0	4	80.0					2	100.0				
		B	3	30.0	1	50.0	1	20.0									1	100.0
		All	10	100.0	2	100.0	5	100.0					2	100.0			1	100.0
	All	All	39	100.0	8	100.0	11	100.0	5	100.0	4	100.0	6	100.0			5	100.0
Research w/persons		A	186	99.5	21	100.0	26	96.3	52	100.0	24	100.0	30	100.0	11	100.0	22	100.0
		B	1	0.5			1	3.7										
		All	187	100.0	21	100.0	27	100.0	52	100.0	24	100.0	30	100.0	11	100.0	22	100.0
Further use		n.a.	187	100.0	29	100.0	31	100.0	35	100.0	19	100.0	38	100.0	6	100.0	29	100.0
Deceased, embryos		n.a.	7	100.0	2	100.0	5	100.0										
Total number			420	100.0	60	100.0	74	100.0	92	100.0	47	100.0	74	100.0	17	100.0	56	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	2705	71.9
Multiple ECs involved: lead EC	328	8.7
Multiple ECs involved: local EC	729	19.4
Total submissions to be evaluated	3762	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	651	75.8	537	73.7	438	70.3	506	76.6	343	73.8	97	46.4	133	61.6
Multiple: lead EC	99	11.5	63	8.6	58	9.3	42	6.4	29	6.2	21	10.0	16	7.4
Multiple: local EC	109	12.7	129	17.7	127	20.4	113	17.1	93	20.0	91	43.5	67	31.0
Total submissions	859	100.0	729	100.0	623	100.0	661	100.0	465	100.0	209	100.0	216	100.0

4 Scientific characterisation of projects approved in 2020 (AS2)

4.1 Overview

Table 7: Total number of research projects **approved in 2020** (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	476[1]	19.5	25	5.3
Research involving persons, but not a clinical trial	HRO, Chapter 2	829[2]	33.9	139	16.8
Further use of health-related personal data and/or biological material	HRO, Chapter 3	1110	45.4	139	12.5
Research involving deceased persons	HRO, Chapter 4	32	1.3	6	18.8
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	0	0.0	0	NaN
Total number		2447	100.0	309	12.6

1 37 of these projects also include 'further use' of existing data and/or material.
2 212 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 2020 (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	2	0.1							1	0.3	1	0.3				
	2018	14	0.6	3	0.5			7	1.6	3	0.8	1	0.3				
	2019	499	20.4	112	17.4	62	13.4	131	29.4	108	29.2	63	20.5	13	12.4	10	8.9
	2020	1932	79.0	530	82.2	400	86.6	308	69.1	258	69.7	242	78.8	92	87.6	102	91.1
First decision	Approved	447	18.3	198	30.7	74	16.0	22	4.9	28	7.6	42	13.7	38	36.2	45	40.2
	Approved with charges [1]	482	19.7	6	0.9	279	60.4	36	8.1	18	4.9	49	16.0	53	50.5	41	36.6
	Not approved, conditions [2]	1514	61.9	438	67.9	108	23.4	388	87.0	324	87.6	216	70.4	14	13.3	26	23.2
	Declined [3]	3	0.1	2	0.3	1	0.2										
	Non-consideration [4]	1	0.0	1	0.2												
Review procedure	Ordinary [5]	361	14.8	88	13.6	53	11.5	61	13.7	41	11.1	15	4.9	16	15.2	87	77.7
	Simplified	1709	69.8	394	61.1	320	69.3	322	72.2	329	88.9	255	83.1	69	65.7	20	17.9
	Presidential	377	15.4	163	25.3	89	19.3	63	14.1			37	12.1	20	19.0	5	4.5
	Total number in AS2	2447	100.0	645	100.0	462	100.0	446	100.0	370	100.0	307	100.0	105	100.0	112	100.0
	COVID-19	309	12.6	46	7.1	55	11.9	64	14.3	32	8.6	55	17.9	15	14.3	42	37.5

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

4.3 Stratification by project characteristics

In Tables 9.1–11 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 9.1.

4.3.1 Description and derivation of stratification variables

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

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

Initiator: The initiator of the project is derived from the answer to the BASEC question "Who initiated the project? Indicate here who had the original idea for the research project (do not indicate here who is financing, conducting or leading the project)". Allowed answers are "Investigator", "Industry" and "Other" (very rare). To keep it simple, studies with an initiator defined as "Other" are considered investigator initiated studies in the tables. In Table 21 on page 38, 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 9.1: 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	14	8.1	8	57.1	2	14.3	4	28.6			14	100.0
		B	32	18.5	13	40.6	8	25.0	11	34.4	7	21.9	25	78.1
		C	127	73.4	21	16.5	5	3.9	101	79.5	99	78.0	28	22.0
		All	173	100.0	42	24.3	15	8.7	116	67.1	106	61.3	67	38.7
	Medical devices (ClinO Art 20)	A	75	68.2	44	58.7	5	6.7	26	34.7	20	26.7	55	73.3
		C	35	31.8	24	68.6	3	8.6	8	22.9	15	42.9	20	57.1
		All	110	100.0	68	61.8	8	7.3	34	30.9	35	31.8	75	68.2
	Other clinical trials (ClinO Art 61)	A	150	83.3	122	81.3	12	8.0	16	10.7	4	2.7	146	97.3
		B	30	16.7	21	70.0	1	3.3	8	26.7	2	6.7	28	93.3
		All	180	100.0	143	79.4	13	7.2	24	13.3	6	3.3	174	96.7
	Combination drugs/devices	B	1	25.0	1	100.0							1	100.0
		C	3	75.0	1	33.3			2	66.7	1	33.3	2	66.7
		All	4	100.0	2	50.0			2	50.0	1	25.0	3	75.0
	Transplant products (ClinO Art 21)	C	6	100.0	4	66.7	1	16.7	1	16.7	1	16.7	5	83.3
		All	6	100.0	4	66.7	1	16.7	1	16.7	1	16.7	5	83.3
	Gene therapy (ClinO Art 22)	C	2	100.0					2	100.0	2	100.0		
		All	2	100.0					2	100.0	2	100.0		
	Transplantation (ClinO Art 49)	C	1	100.0	1	100.0							1	100.0
		All	1	100.0	1	100.0							1	100.0
	All	All	476	100.0	260	54.6	37	7.8	179	37.6	151	31.7	325	68.3
Research w/persons (HRO Chapter 2)		A	811	97.8	634	78.2	56	6.9	121	14.9	64	7.9	747	92.1
		B	18	2.2	15	83.3	1	5.6	2	11.1	1	5.6	17	94.4
		All	829	100.0	649	78.3	57	6.9	123	14.8	65	7.8	764	92.2
Further use (HRO Chapter 3)		n.a.	1110	100.0	919	82.8	70	6.3	121	10.9	39	3.5	1071	96.5
Deceased, embryos (HRO Chapter 4+5)		n.a.	32	100.0	25	78.1	4	12.5	3	9.4	1	3.1	31	96.9
Total number			2447	100.0	1853	75.7	168	6.9	426	17.4	256	10.5	2191	89.5

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

Table 9.2: 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.

					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	2	11.8			1	50.0	1	50.0			2	100.0
		B	6	35.3	1	16.7	5	83.3					6	100.0
		C	9	52.9	2	22.2	2	22.2	5	55.6	3	33.3	6	66.7
		All	17	100.0	3	17.6	8	47.1	6	35.3	3	17.6	14	82.4
	Medical devices (ClinO Art 20)	A	2	66.7	1	50.0			1	50.0			2	100.0
		C	1	33.3			1	100.0					1	100.0
		All	3	100.0	1	33.3	1	33.3	1	33.3			3	100.0
	Other clinical trials (ClinO Art 61)	A	3	60.0	3	100.0							3	100.0
		B	2	40.0	2	100.0							2	100.0
		All	5	100.0	5	100.0							5	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											
	All	All	25	100.0	9	36.0	9	36.0	7	28.0	3	12.0	22	88.0
Research w/persons (HRO Chapter 2)		A	138	99.3	103	74.6	14	10.1	21	15.2	2	1.4	136	98.6
		B	1	0.7	1	100.0							1	100.0
		All	139	100.0	104	74.8	14	10.1	21	15.1	2	1.4	137	98.6
Further use (HRO Chapter 3)		n.a.	139	100.0	108	77.7	10	7.2	21	15.1	1	0.7	138	99.3
Deceased, embryos (HRO Chapter 4+5)		n.a.	6	100.0	3	50.0	2	33.3	1	16.7			6	100.0
Total number			309	100.0	224	72.5	35	11.3	50	16.2	6	1.9	303	98.1

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

4.3.3 Lead ethics committee

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

					Lead ethics committee													
			Total		KEK-ZH		EKNZ		CER-VD		KEK-BE		CCER		EKOS		CE-TI	
Type of research	Research details	Risk cat.	N	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$
Clinical trial	Medicinal products	A	14	8.1	3	5.4	2	6.5			2	8.3	4	40.0			3	18.8
		B	32	18.5	7	12.5	11	35.5	5	21.7	5	20.8	1	10.0	1	7.7	2	12.5
		C	127	73.4	46	82.1	18	58.1	18	78.3	17	70.8	5	50.0	12	92.3	11	68.8
		All	173	100.0	56	100.0	31	100.0	23	100.0	24	100.0	10	100.0	13	100.0	16	100.0
	Medical devices	A	75	68.2	29	67.4	10	66.7	5	45.5	14	77.8	8	66.7	3	75.0	6	85.7
		C	35	31.8	14	32.6	5	33.3	6	54.5	4	22.2	4	33.3	1	25.0	1	14.3
		All	110	100.0	43	100.0	15	100.0	11	100.0	18	100.0	12	100.0	4	100.0	7	100.0
	Other clinical trials	A	150	83.3	51	86.4	24	63.2	22	95.7	23	95.8	19	90.5	5	71.4	6	75.0
		B	30	16.7	8	13.6	14	36.8	1	4.3	1	4.2	2	9.5	2	28.6	2	25.0
		All	180	100.0	59	100.0	38	100.0	23	100.0	24	100.0	21	100.0	7	100.0	8	100.0
	Combination drugs/devices	B	1	25.0					1	50.0								
		C	3	75.0	2	100.0			1	50.0								
		All	4	100.0	2	100.0			2	100.0								
	Transplant products	C	6	100.0			2	100.0	2	100.0	1	100.0	1	100.0				
		All	6	100.0			2	100.0	2	100.0	1	100.0	1	100.0				
	Gene therapy	C	2	100.0	2	100.0												
		All	2	100.0	2	100.0												
	Transplantation	C	1	100.0									1	100.0				
		All	1	100.0									1	100.0				
	All	All	476	100.0	162	100.0	86	100.0	61	100.0	67	100.0	45	100.0	24	100.0	31	100.0
Research w/persons		A	811	97.8	172	96.6	134	97.8	186	99.5	113	95.0	123	98.4	40	100.0	43	100.0
		B	18	2.2	6	3.4	3	2.2	1	0.5	6	5.0	2	1.6				
		All	829	100.0	178	100.0	137	100.0	187	100.0	119	100.0	125	100.0	40	100.0	43	100.0
Further use		n.a.	1110	100.0	291	100.0	230	100.0	196	100.0	183	100.0	131	100.0	41	100.0	38	100.0
Deceased, embryos		n.a.	32	100.0	14	100.0	9	100.0	2	100.0	1	100.0	6	100.0				
Total number			2447	100.0	645	100.0	462	100.0	446	100.0	370	100.0	307	100.0	105	100.0	112	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	14	8.1	3	21.4	11	78.6			1	7.1	4	28.6	9	64.3				
		B	32	18.5	31	96.9	1	3.1			2	6.2	7	21.9	23	71.9				
		C	127	73.4	127	100.0					9	7.1	23	18.1	95	74.8				
		All	173	100.0	161	93.1	12	6.9			12	6.9	34	19.7	127	73.4				
	Medical devices	A	75	68.2	13	17.3	62	82.7			6	8.0	9	12.0	60	80.0				
		C	35	31.8	35	100.0					2	5.7	5	14.3	28	80.0				
		All	110	100.0	48	43.6	62	56.4			8	7.3	14	12.7	88	80.0				
	Other clinical trials	A	150	83.3	19	12.7	130	86.7	1	0.7	2	1.3	21	14.0	125	83.3	1	0.7	1	0.7
		B	30	16.7	29	96.7	1	3.3					10	33.3	20	66.7				
		All	180	100.0	48	26.7	131	72.8	1	0.6	2	1.1	31	17.2	145	80.6	1	0.6	1	0.6
	Combination drugs/devices	B	1	25.0	1	100.0									1	100.0				
		C	3	75.0	3	100.0									3	100.0				
		All	4	100.0	4	100.0									4	100.0				
	Transplant products	C	6	100.0	6	100.0							2	33.3	4	66.7				
		All	6	100.0	6	100.0							2	33.3	4	66.7				
	Gene therapy	C	2	100.0	2	100.0									2	100.0				
		All	2	100.0	2	100.0									2	100.0				
	Transplantation	C	1	100.0	1	100.0									1	100.0				
		All	1	100.0	1	100.0									1	100.0				
	All	All	476	100.0	270	56.7	205	43.1	1	0.2	22	4.6	81	17.0	371	77.9	1	0.2	1	0.2
Research w/persons		A	811	97.8	48	5.9	759	93.6	4	0.5	70	8.6	144	17.8	596	73.5	1	0.1		
		B	18	2.2	16	88.9	2	11.1					2	11.1	16	88.9				
		All	829	100.0	64	7.7	761	91.8	4	0.5	70	8.4	146	17.6	612	73.8	1	0.1		
Further use		n.a.	1110	100.0	26	2.3	712	64.1	372	33.5	346	31.2	242	21.8	521	46.9	1	0.1		
Deceased, embryos		n.a.	32	100.0	1	3.1	31	96.9			9	28.1	13	40.6	10	31.2				
Total number			2447	100.0	361	14.8	1709	69.8	377	15.4	447	18.3	482	19.7	1514	61.9	3	0.1	1	0.0

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

4.4 Subgroups of research projects

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

4.4.1.1 Therapeutic area

Table 12: Overview on therapeutic area ('disease under investigation') for clinical trials according to Swiss National Clinical Trials Portal (SNCTP) – (multiple answers possible) – stratification by trial type. The proportion of projects investigating a rare disease is provided. Data for the 13 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	134	28.2	6	33	19.1	4	33	30.0	0	64	35.6	1
Surgery	38	8.0	0	6	3.5	0	11	10.0	0	20	11.1	0
Infections and Infestations	35	7.4	1	23	13.3	1	3	2.7	0	9	5.0	0
Nervous System diseases	35	7.4	4	8	4.6	3	12	10.9	1	15	8.3	0
Cancer: Other	29	6.1	6	18	10.4	5	3	2.7	0	6	3.3	1
Respiratory diseases (non cancer)	28	5.9	2	11	6.4	2	7	6.4	0	10	5.6	0
Mental and Behavioural diseases	26	5.5	0	2	1.2	0	4	3.6	0	20	11.1	0
Cancer: Lung	22	4.6	2	17	9.8	2	0	0.0	0	4	2.2	0
Musculoskeletal diseases (non cancer)	22	4.6	3	2	1.2	2	11	10.0	0	7	3.9	0
Arterial and venous diseases including deep venous thrombosis and lung embolism	21	4.4	1	7	4.0	1	8	7.3	0	6	3.3	0
Nutritional and Metabolic diseases	18	3.8	0	1	0.6	0	3	2.7	0	14	7.8	0
Brain diseases (non cancer)	17	3.6	0	3	1.7	0	6	5.5	0	8	4.4	0
Coronary Heart disease	17	3.6	0	2	1.2	0	9	8.2	0	6	3.3	0
Basic research (Anatomy / Physiology)	16	3.4	0	2	1.2	0	2	1.8	0	12	6.7	0
Cancer: Melanoma	16	3.4	0	10	5.8	0	1	0.9	0	2	1.1	0
Cancer: Breast	15	3.2	0	6	3.5	0	2	1.8	0	6	3.3	0
Endocrinological diseases (non cancer)	15	3.2	2	6	3.5	1	2	1.8	0	6	3.3	1
Digestive Systems diseases (non cancer)	14	2.9	0	4	2.3	0	3	2.7	0	7	3.9	0
Cancer: Leukemia	12	2.5	7	10	5.8	6	0	0.0	0	1	0.6	0
Cancer: Head and Neck	11	2.3	1	8	4.6	1	0	0.0	0	1	0.6	0
Cancer: Prostate	11	2.3	0	6	3.5	0	1	0.9	0	3	1.7	0
Ear, Nose, and Throat diseases (non cancer)	11	2.3	0	0	0.0	0	5	4.5	0	5	2.8	0
Eye diseases	11	2.3	2	3	1.7	1	6	5.5	1	2	1.1	0
Injury	11	2.3	1	1	0.6	0	5	4.5	1	3	1.7	0
Cancer: Colon and Rectal	10	2.1	0	5	2.9	0	1	0.9	0	3	1.7	0
Dementia and Alzheimer disease	9	1.9	1	2	1.2	1	0	0.0	0	6	3.3	0
Hematologic diseases (non cancer)	9	1.9	4	7	4.0	4	2	1.8	0	0	0.0	0
Urological and Genital diseases (non cancer)	8	1.7	2	3	1.7	1	5	4.5	1	0	0.0	0
Cancer: Pancreatic	7	1.5	0	3	1.7	0	1	0.9	0	2	1.1	0
Genetic disorders	6	1.3	3	2	1.2	2	0	0.0	0	2	1.1	0
Skin and Connective Tissues diseases (non cancer)	6	1.3	0	2	1.2	0	2	1.8	0	2	1.1	0
Cancer: Bladder	5	1.1	0	2	1.2	0	1	0.9	0	1	0.6	0
Cancer: Kidney	5	1.1	0	2	1.2	0	0	0.0	0	2	1.1	0
Neonatal diseases	5	1.1	0	2	1.2	0	1	0.9	0	2	1.1	0
Periodontal diseases	5	1.1	0	1	0.6	0	1	0.9	0	3	1.7	0
Cancer: Lymphoma	4	0.8	2	2	1.2	1	0	0.0	0	1	0.6	0
Pregnancy and Childbirth	4	0.8	0	1	0.6	0	2	1.8	0	1	0.6	0
Cancer: Endometrial	3	0.6	0	1	0.6	0	0	0.0	0	1	0.6	0
Cancer: Non-Hodgkin Lymphoma	3	0.6	2	1	0.6	1	0	0.0	0	1	0.6	0
Cancer: Thyroid	3	0.6	0	1	0.6	0	0	0.0	0	1	0.6	0
Occupational diseases	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	0
Total projects	476	142.2	42	173	100.0	35	110	100.0	3	180	100.0	2

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 13 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	253	53.2	122	70.5	57	51.8	63	35.0
Other	87	18.3	9	5.2	18	16.4	60	33.3
Diagnosis	42	8.8	4	2.3	22	20.0	15	8.3
Prevention	36	7.6	8	4.6	7	6.4	21	11.7
PK/PD/safety	34	7.1	30	17.3	1	0.9	2	1.1
Rehabilitation	21	4.4	0	0.0	4	3.6	17	9.4
Palliation	3	0.6	0	0.0	1	0.9	2	1.1
Total projects	476	100.0	173	100.0	110	100.0	180	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", "Phase2", "Phase3", "Phase4", "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.

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

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	14	7.9			3	21.4	2	14.3	8	57.1	1	7.1		
B	33	18.6	2	6.1	10	30.3	14	42.4	3	9.1	4	12.1		
C	130	73.4	34	26.2	35	26.9	49	37.7	8	6.2	4	3.1	10	7.7
Total number	177	100.0	36	20.3	48	27.1	65	36.7	19	10.7	9	5.1	10	5.6

The total number of 177 research projects consist of 173 medicinal product trials and4 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 Art 20)

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	75	65.8	74	98.7			1	1.3	5	6.7
B	1	0.9								
C	38	33.3	3	7.9	6	15.8	26	68.4	13	34.2
Total number	114	100.0	77	67.5	6	5.3	27	23.7	18	15.8

The total number of 114 research projects consist of 110 trials with medical devices and 4 trials on a combination medicinal product and medical device. Intended use: used in accordance with the instructions; Non-intended use: not used in accordance with the intended purposes recognised in the conformity assessment and specified in the instructions.

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	310	37.4	306	98.7	4	1.3	243	78.4	33	10.6	34	11.0	12	3.9	298	96.1
Registry/ Quality control [1]	85	10.3	83	97.6	2	2.4	48	56.5	5	5.9	32	37.6	15	17.6	70	82.4
Case control study	67	8.1	66	98.5	1	1.5	58	86.6	2	3.0	7	10.4	1	1.5	66	98.5
Other or n/a	367	44.3	356	97.0	11	3.0	300	81.7	17	4.6	50	13.6	37	10.1	330	89.9
Total number	829	100.0	811	97.8	18	2.2	649	78.3	57	6.9	123	14.8	65	7.8	764	92.2

1 Only quality control studies under the HRA.

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

	Overall		Type of research project: Cohort study		Registry/ Quality control		Case control study		Other or n/a	
Area of research	N	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	%
Other	227	27.4	78	25.2	24	28.2	12	17.9	113	30.8
Epidemiology	97	11.7	55	17.7	14	16.5	8	11.9	20	5.4
Basic science	95	11.5	45	14.5	2	2.4	12	17.9	36	9.8
Psychology	83	10.0	18	5.8	0	0.0	12	17.9	53	14.4
Surgery	67	8.1	36	11.6	9	10.6	10	14.9	12	3.3
Healthcare services research	67	8.1	23	7.4	6	7.1	1	1.5	37	10.1
Qualitative research	56	6.8	11	3.5	7	8.2	1	1.5	37	10.1
Physiology/anatomy	53	6.4	22	7.1	4	4.7	6	9.0	21	5.7
Medical devices	47	5.7	12	3.9	13	15.3	2	3.0	20	5.4
Drugs	27	3.3	6	1.9	5	5.9	2	3.0	14	3.8
Dentistry	10	1.2	4	1.3	1	1.2	1	1.5	4	1.1
Total projects	829	100.0	310	100.0	85	100.0	67	100.0	367	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 "Non-genetic data only" or "Genetic-data and/or biological material".
Coding: The BASEC question "Please select how your research data will be kept" can be answered with "Coded" or "Open, non-coded". A reference to HRO Art. 25–27 is provided.
Consent: In the reporting years to date (2016, 2017, 2018 and 2019), the researcher could choose in BASEC under "Consent for further uses of data/material" between three single-select options: 1. Prior consent exists, 2. Consent to be sought, or 3. no consent for some or all data. Since 1st of January 2020 researchers have been given in BASEC a multi-select option with the following options: 1. Consent to be sought, 2. No Consent – Art. 34 HRA, 3. Prior consent/general Consent exists. This was done in order to better understand which kind of consent is used by researchers for further use projects (i.e. individual or general consent), and to which extent a single project is making use of a mixed consent approach (e.g. one part of the datasets comes with a general consent, the other part comes with no consent at all). In the present report, the combination of these three options are summarized into the following three categories:

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

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

Combined project: "Combined project" are those research projects that combine a clinical trial (ClinO) or 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	264	19.4	48	18.2
	No	1095	80.6	143	13.1
Coding (HRO Art. 25–27)	Coded	1175	86.5	163	13.9
	Open, non-coded	184	13.5	28	15.2
Consent (HRO Art. 28–32)[1]	Consent for all data	704	51.8	92	13.1
	Consent for some but not all data (partially Art. 34 HRA)	287	21.1	53	18.5
	No consent for all data, Art. 34 HRA	368	27.1	46	12.5
Combined vs. stand-alone projects	Stand-alone further use project	1110	81.7	139	12.5
	Further use project as part of a clinical trial	37	2.7	2	5.4
	Further use project as part of a non-clinical research project	212	15.6	50	23.6
Total number		1359	100.0	191	14.1

1 Multiple selection possible.

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

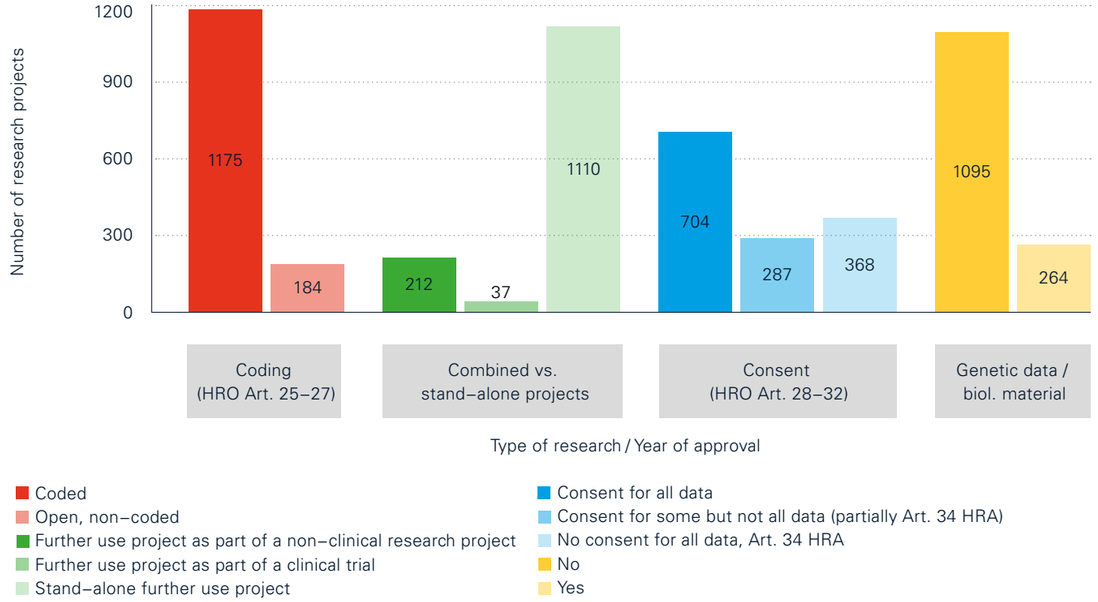


Table 19: Stratification of **projects involving further use of data / biological material** by study design and initiator. All combinations of the following three factors are shown: 1) Use of genetic data and/or biological material (Genetic D+M), 2) coded vs. uncoded, 3) consent for further use.

			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	71.5	111	62.4	14	7.9	53	29.8	34	19.1	144	80.9
		Consent for some but not all data (partially Art. 34 HRA)	44	17.7	32	72.7	10	22.7	2	4.5			44	100.0
		No consent for all data, Art. 34 HRA	27	10.8	20	74.1	6	22.2	1	3.7	2	7.4	25	92.6
		All	249	100.0	163	65.5	30	12.0	56	22.5	36	14.5	213	85.5
	Open, non-coded	Consent for all data	8	53.3	7	87.5	1	12.5					8	100.0
		Consent for some but not all data (partially Art. 34 HRA)	3	20.0	2	66.7	1	33.3					3	100.0
		No consent for all data, Art. 34 HRA	4	26.7	4	100.0							4	100.0
		All	15	100.0	13	86.7	2	13.3					15	100.0
	All		264	100.0	176	66.7	32	12.1	56	21.2	36	13.6	228	86.4
No	Coded	Consent for all data	427	46.1	345	80.8	23	5.4	59	13.8	15	3.5	412	96.5
		Consent for some but not all data (partially Art. 34 HRA)	201	21.7	172	85.6	14	7.0	15	7.5	2	1.0	199	99.0
		No consent for all data, Art. 34 HRA	298	32.2	259	86.9	16	5.4	23	7.7	3	1.0	295	99.0
		All	926	100.0	776	83.8	53	5.7	97	10.5	20	2.2	906	97.8
	Open, non-coded	Consent for all data	91	53.8	87	95.6	2	2.2	2	2.2	1	1.1	90	98.9
		Consent for some but not all data (partially Art. 34 HRA)	39	23.1	32	82.1	1	2.6	6	15.4	1	2.6	38	97.4
		No consent for all data, Art. 34 HRA	39	23.1	35	89.7	1	2.6	3	7.7			39	100.0
		All	169	100.0	154	91.1	4	2.4	11	6.5	2	1.2	167	98.8
All			1095	100.0	930	84.9	57	5.2	108	9.9	22	2.0	1073	98.0
Total number			1359	100.0	1106	81.4	89	6.5	164	12.1	58	4.3	1301	95.7

1 Multiple selection possible.
The total number of 1359 research projects consist of 1110 standard 'further use' projects and 249 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	704	51.8	236	64.3	131	48.0	104	44.3	107	47.3	75	47.8	30	54.5	21	45.7
Consent for some but not all data (partially Art. 34 HRA)	287	21.1	107	29.2	55	20.1	56	23.8	33	14.6	9	5.7	10	18.2	17	37.0
No consent for all data, Art. 34 HRA	368	27.1	24	6.5	87	31.9	75	31.9	86	38.1	73	46.5	15	27.3	8	17.4
Total number	1359	100.0	367	100.0	273	100.0	235	100.0	226	100.0	157	100.0	55	100.0	46	100.0

1 Multiple selection possible.
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	1382	66.8	202	14.6
	Industry	80[1]	3.9	7	8.8
	Universities/hospitals	291	14.1	41	14.1
	Private (non-industry)	179	8.7	24	13.4
	Swiss National Science Foundation	136	6.6	15	11.0
	All	2068	100.0	289	14.0
Industry	Public, other	51[2]	19.9	1	2.0
	Industry	204[3]	79.7	5	2.5
	Universities/hospitals	0	0.0	0	NaN
	Private (non-industry)	0	0.0	0	NaN
	Swiss National Science Foundation	1	0.4	0	0.0
	All	256	100.0	6	2.3
Other	Public, other	97	78.9	11	11.3
	Industry	3	2.4	0	0.0
	Universities/hospitals	7	5.7	1	14.3
	Private (non-industry)	13	10.6	1	7.7
	Swiss National Science Foundation	3	2.4	1	33.3
	All	123[4]	100.0	14	11.4

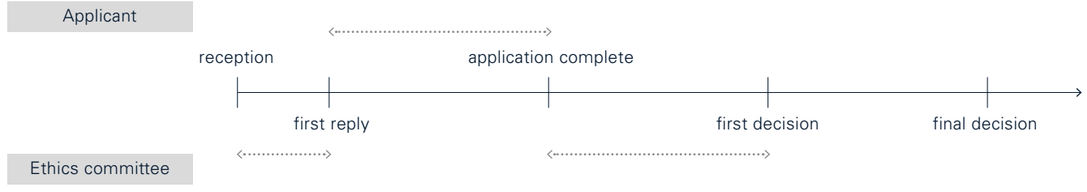
1 Applicants almost exclusively from academic institutions.
2 Inspecting the sponsor information reveals that these are almost exclusively industry projects.
3 202 of the industry-initiated projects are financed exclusively by industry.
4 43 of these projects initiated by others are projects solely or 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

AAs described in the introduction on page 7, the data analysed in the following are automatically recorded, apart from the "final decision date" which is manually entered by the ECs. Thereby the only two periods that solely depend on the EC are: 1) reception (initial submission) to first reply and 2) application data complete to first decision. The interval between "first reply" and "application complete" is mainly dependent on the applicant. All other intervals encompass periods in the responsibility of both EC and applicant. During any request of information by the EC directed to the applicant, a clock-stop of the EC deadline may be applied, but clock-stops are not consistently tracked in BASEC.

Figure 3: Overview of dates of milestones for each application. The only two periods that solely depend on the EC are denoted as well as the period that is mainly dependent on the applicant.



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	88	14	7	[7,7]	7	[7,7]	28	[23,34]	89	[63,139]	20	[16,26]	82	[56,132]
	EKNZ	53	11	3	[1,5]	3	[1,6]	32	[21,42]	76	[57,123]	27	[19,36]	70	[53,113]
	CER-VD	61	14	5	[4,6]	6	[4,6]	25	[20,33]	167	[109,220]	19	[15,26]	161	[102,213]
	KEK-BE	41	11	1	[1,4]	2	[1,6]	23	[20,29]	161	[133,199]	20	[18,22]	149	[132,196]
	CCER	15	5	4	[2,6]	6	[4,8]	34	[24,50]	123	[89,251]	28	[16,42]	112	[80,220]
	EKOS	16	15	2	[1,4]	2	[1,4]	25	[17,35]	88	[66,127]	22	[15,32]	84	[61,123]
	CE-TI	87	78	7	[7,10]	8	[7,14]	34	[25,43]	56	[34,91]	21	[8,28]	42	[20,70]
	All	361	15	6	[3,7]	7	[4,7]	28	[21,37]	96	[60,159]	21	[15,28]	85	[51,147]
Simplified	KEK-ZH	393	61	7	[7,8]	7	[7,8]	30	[22,38]	57	[36,86]	21	[14,29]	46	[28,77]
	EKNZ	320	69	4	[2,6]	5	[2,8]	20	[12,28]	46	[26,78]	14	[7,20]	37	[21,64]
	CER-VD	322	72	5	[3,7]	6	[3,7]	24	[18,33]	90	[60,139]	18	[14,22]	79	[54,129]
	KEK-BE	329	89	2	[1,4]	5	[2,11]	25	[19,35]	96	[60,158]	18	[14,21]	87	[52,141]
	CCER	255	83	3	[1,6]	7	[3,11]	33	[23,41]	65	[43,108]	22	[16,29]	54	[36,96]
	EKOS	69	66	1	[1,2]	1	[1,3]	6	[4,11]	18	[7,38]	4	[3,9]	15	[4,37]
	CE-TI	20	18	6	[1,8]	6	[2,10]	6	[4,14]	10	[5,41]	0	[0,2]	8	[1,28]
	All	1708	70	4	[1,7]	6	[3,8]	26	[16,35]	67	[37,117]	18	[12,24]	57	[29,101]
Presidential	KEK-ZH	163	25	6	[1,7]	7	[2,7]	16	[11,23]	20	[12,34]	9	[7,15]	12	[7,22]
	EKNZ	89	19	4	[1,7]	6	[2,8]	10	[6,15]	15	[8,28]	4	[1,7]	7	[2,21]
	CER-VD	63	14	6	[4,7]	7	[5,11]	27	[21,41]	70	[47,114]	20	[14,27]	62	[36,100]
	KEK-BE	0	0												
	CCER	37	12	5	[3,7]	7	[4,10]	12	[8,14]	12	[8,19]	4	[2,5]	4	[2,6]
	EKOS	20	19	1	[1,3]	1	[1,3]	4	[2,5]	4	[2,25]	2	[0,4]	2	[1,7]
	CE-TI	5	4	8	[2,20]	8	[2,20]	8	[2,20]	8	[2,20]	0	[0, 0]	0	[0, 0]
	All	377	15	5	[2,7]	6	[3,8]	15	[8,23]	21	[11,43]	7	[4,15]	12	[5,34]
Overall	KEK-ZH	645	100	7	[5,7]	7	[7,8]	27	[18,36]	50	[24,85]	17	[10,27]	42	[16,76]
	EKNZ	462	100	4	[1,6]	5	[2,7]	19	[11,28]	42	[22,76]	13	[6,20]	35	[15,64]
	CER-VD	446	100	5	[3,7]	6	[3,7]	24	[19,34]	94	[60,154]	18	[14,23]	84	[54,142]
	KEK-BE	370	100	2	[1,4]	5	[1,10]	25	[19,34]	104	[63,168]	19	[14,21]	91	[55,148]
	CCER	307	100	4	[2,6]	7	[3,11]	31	[16,40]	61	[36,107]	21	[6,29]	50	[28,95]
	EKOS	105	100	1	[1,3]	1	[1,3]	7	[4,17]	21	[6,71]	5	[2,14]	17	[4,69]
	CE-TI	112	100	7	[6,10]	7	[7,14]	30	[14,40]	50	[19,83]	16	[0,27]	33	[9,68]
	All	2447	100	5	[2,7]	6	[3,8]	24	[15,35]	62	[31,114]	17	[9,24]	54	[23,100]

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

5.3 Stratification of response time by review procedure

5.3.1 Time from status "complete" to first decision

Definition: In the following, **violin plots** are used to visualise the distribution of response times. Violin plots are similar to box plots except that they show more details on the distribution of the data by showing the probability density of the data at different values (kernel density plot). In addition, we denote the 1st, 2nd and 3rd quartile of the data by 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.

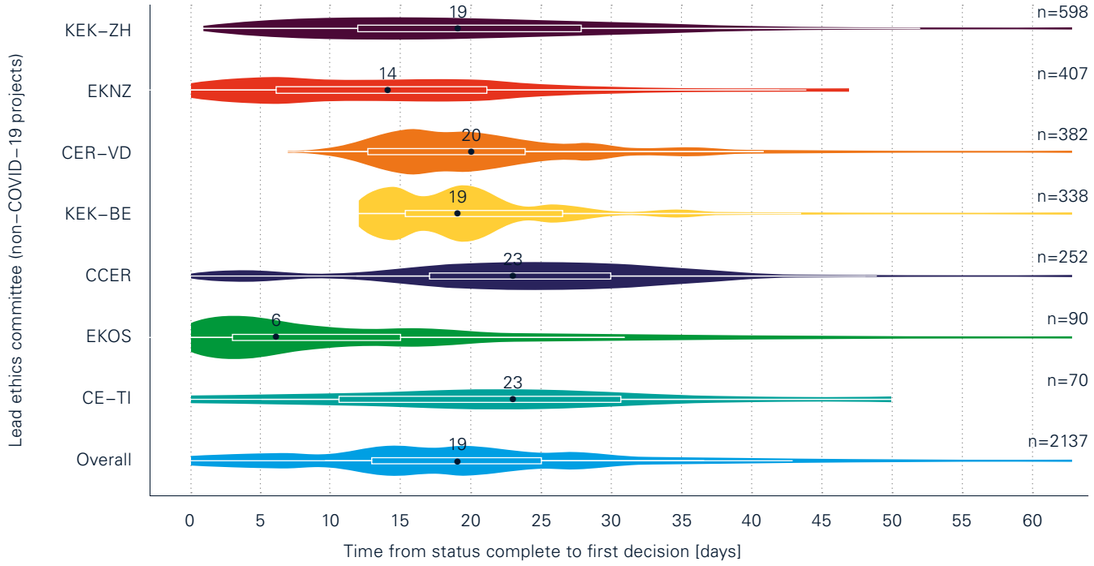


Figure 4.2: Violin plot of the time between status 'complete' to the first decision by EC for **COVID-19** projects. 32 projects with t > 60 days are not shown for layout reasons.

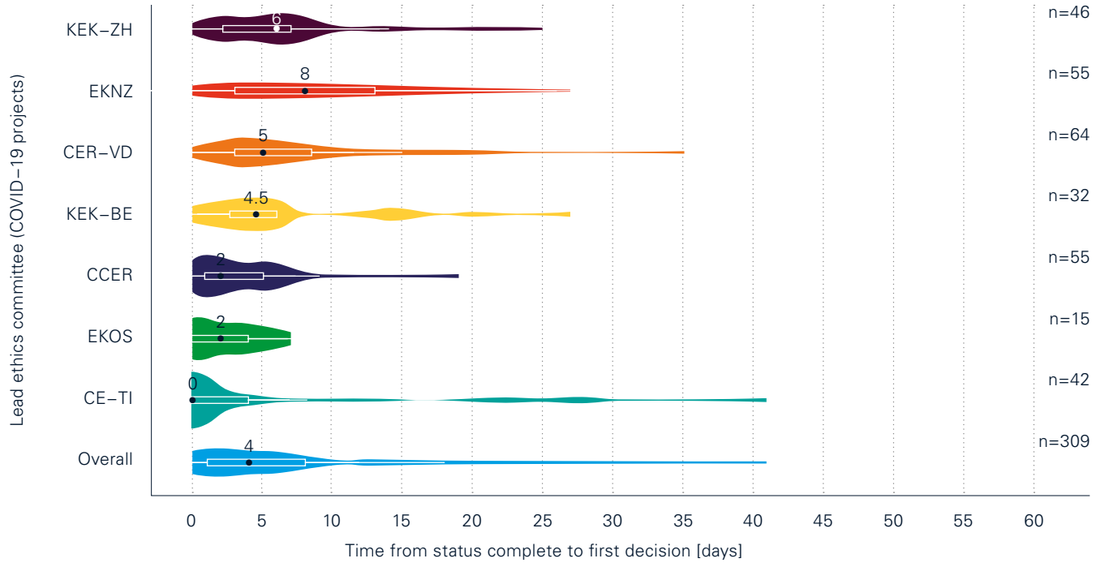
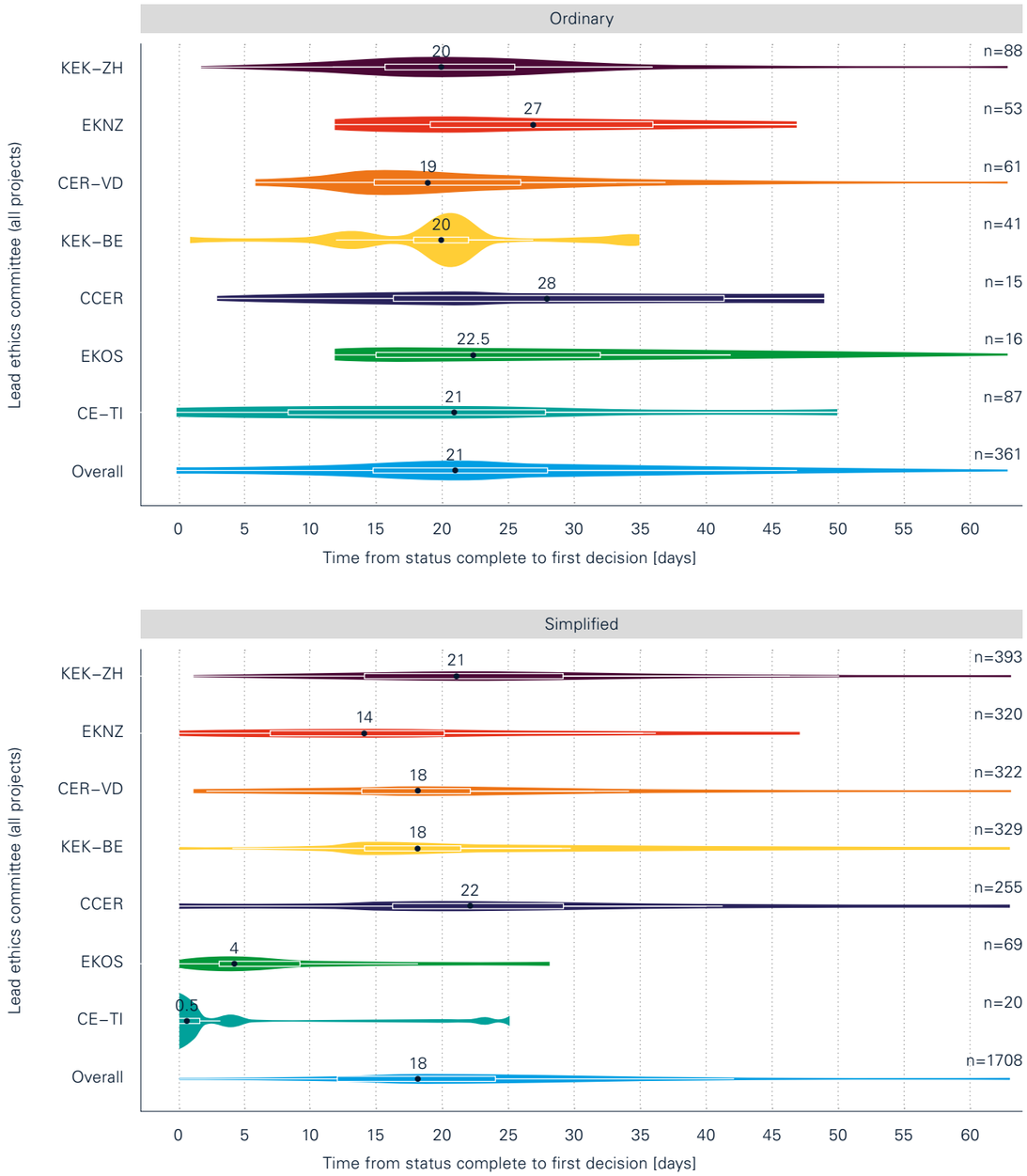


Figure 5: Violin plot of the time between status 'complete' to the first decision by EC and stratified by review procedure. 32 projects with t > 60 days are not shown for layout reasons. Note: *CE-TI* typically processes all submissions in a plenary session (ordinary procedure) but with adapted fees.



5.3.2 Time from reception to final decision

Figure 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.

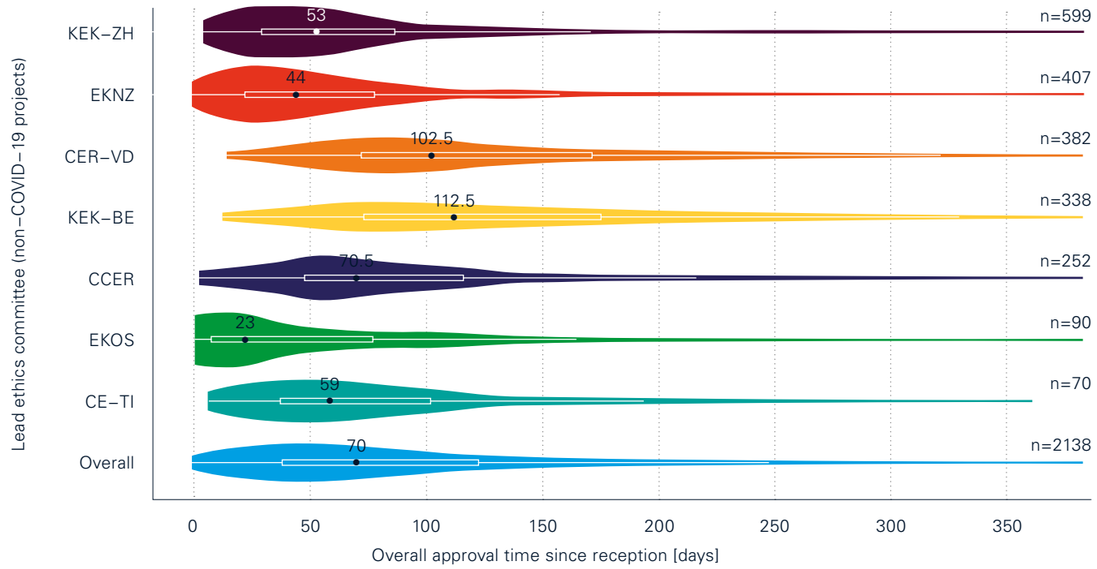


Figure 6.2: Violin plot of the overall approval time by EC from reception to final decision for **COVID-19** projects.

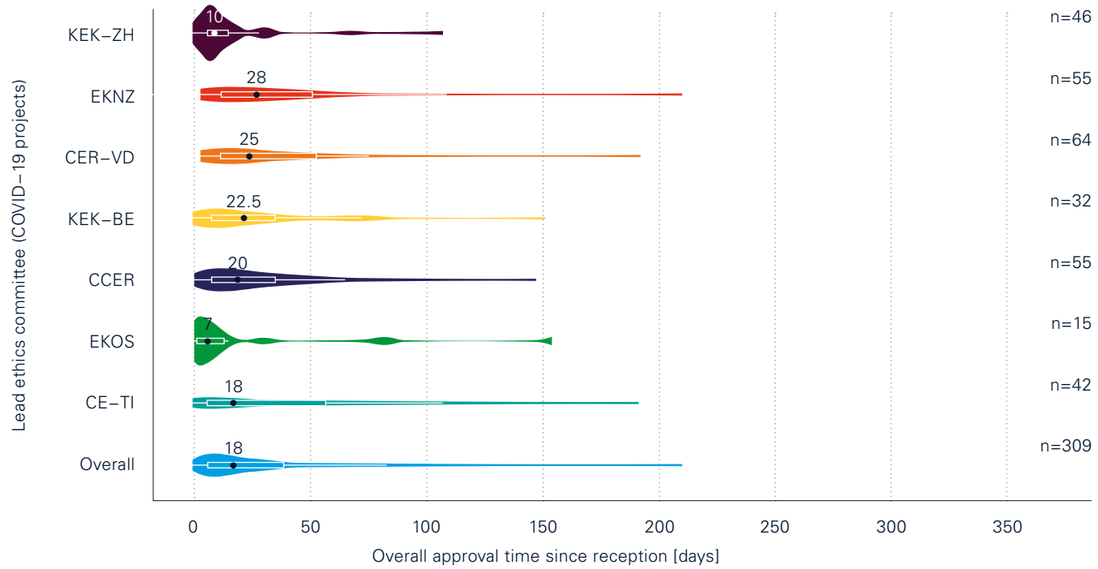
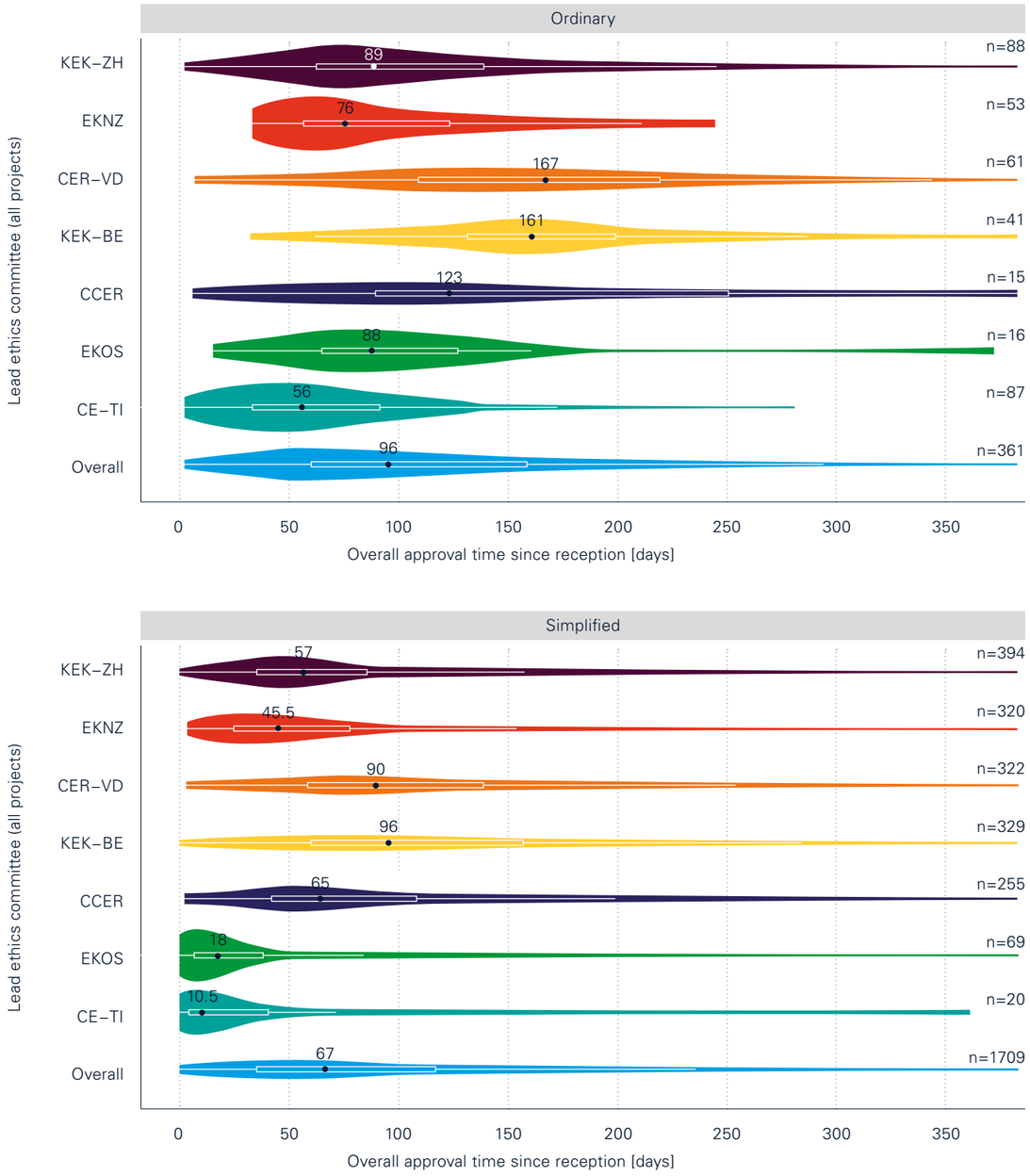


Figure 7: Violin plot of the overall approval time by EC from reception to final decision and stratified by review procedure.
57 projects with approval time > 1 year are not shown for layout reasons.



5.4 Stratification of response time by type of research

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

				Time interval from …									
				receipt to first reply		receipt to complete		receipt to first decision		receipt to final decision		complete to first decision		complete to final decision	
Type of research	EC	N	$\%_{EC}$	Median	IQR	Median	IQR	Median	IQR	Median	IQR	Median	IQR	Median	IQR
Clinical trial	KEK-ZH	162	25.12	7	[7,8]	7	[7,8]	31	[24,37]	83	[59,136]	22	[16,29]	74	[49,127]
	EKNZ	86	18.61	3	[1,5]	4	[1,7]	27	[20,40]	70	[54,106]	20	[15,28]	63	[50,97]
	CER-VD	61	13.68	6	[4,7]	6	[4,7]	24	[20,34]	146	[98,201]	18	[15,28]	140	[91,198]
	KEK-BE	67	18.11	2	[1,4]	3	[1,6]	21	[19,29]	147	[118,198]	19	[14,21]	142	[114,196]
	CCER	45	14.66	5	[2,7]	8	[5,15]	37	[27,48]	109	[74,198]	25	[20,31]	95	[50,154]
	EKOS	24	22.86	2	[1,3]	2	[1,3]	19	[16,31]	70	[37,110]	16	[14,28]	66	[36,106]
	CE-TI	31	27.68	7	[7,8]	7	[7,8]	29	[23,38]	56	[27,98]	22	[14,30]	49	[18,90]
	All	476	19.45	6	[2,7]	7	[3,8]	28	[21,37]	97	[60,151]	20	[15,28]	87	[52,145]
Research w/persons	KEK-ZH	178	27.60	7	[7,8]	7	[7,8]	32	[21,37]	56	[38,84]	22	[13,29]	46	[28,76]
	EKNZ	137	29.65	3	[1,6]	5	[2,8]	25	[19,31]	55	[41,91]	19	[14,22]	49	[34,75]
	CER-VD	187	41.93	5	[3,7]	6	[3,7]	25	[18,32]	92	[60,137]	18	[14,23]	83	[57,127]
	KEK-BE	119	32.16	3	[1,5]	4	[2,8]	24	[18,33]	88	[60,146]	19	[14,22]	83	[54,133]
	CCER	125	40.72	3	[1,6]	7	[3,10]	33	[22,37]	65	[44,106]	22	[16,29]	57	[36,99]
	EKOS	40	38.10	1	[0,2]	1	[1,3]	6	[4,10]	22	[10,78]	6	[2,8]	22	[9,76]
	CE-TI	43	38.39	7	[4,11]	7	[7,14]	30	[14,42]	39	[16,76]	10	[1,26]	27	[8,65]
	All	829	33.88	5	[2,7]	6	[3,8]	27	[18,35]	69	[41,114]	19	[13,25]	61	[34,101]
Further use	KEK-ZH	291	45.12	7	[2,7]	7	[4,8]	21	[14,31]	30	[16,52]	14	[8,21]	21	[9,40]
	EKNZ	230	49.78	4	[2,6]	5	[2,8]	11	[7,19]	23	[12,40]	6	[2,8]	15	[7,31]
	CER-VD	196	43.95	5	[3,7]	6	[3,8]	24	[19,35]	84	[55,139]	18	[14,22]	73	[47,129]
	KEK-BE	183	49.46	2	[1,4]	6	[2,13]	26	[20,40]	96	[57,166]	18	[14,21]	84	[50,142]
	CCER	131	42.67	4	[2,7]	7	[4,13]	27	[9,37]	49	[16,73]	16	[4,27]	40	[6,62]
	EKOS	41	39.05	1	[1,2]	1	[1,3]	4	[3,8]	5	[3,22]	3	[1,4]	3	[1,7]
	CE-TI	38	33.93	8	[7,19]	10	[7,32]	34	[11,40]	48	[15,76]	2	[0,25]	30	[6,54]
	All	1110	45.36	4	[1,7]	6	[3,9]	21	[12,33]	44	[19,90]	14	[6,21]	34	[12,77]
Deceased persons	KEK-ZH	14	2.17	4	[1,6]	6	[4,7]	36	[17,47]	54	[38,67]	14	[9,30]	38	[12,55]
	EKNZ	9	1.95	2	[2,3]	3	[2,3]	28	[14,31]	42	[23,91]	19	[12,26]	39	[22,81]
	CER-VD	2	0.45	7	[7,7]	43	[25,61]	60	[46,74]	150	[149,150]	17	[13,21]	106	[89,124]
	KEK-BE	1	0.27	2	[2,2]	2	[2,2]	23	[23,23]	275	[275,275]	21	[21,21]	273	[273,273]
	CCER	6	1.95	2	[1,4]	3	[2,6]	32	[30,35]	52	[36,85]	30	[26,33]	50	[31,82]
	EKOS	0	0.00												
	CE-TI	0	0.00												
	All	32	1.31	3	[1,4]	4	[3,7]	30	[21,43]	56	[36,99]	22	[10,29]	44	[20,74]
Overall	KEK-ZH	645	100.00	7	[5,7]	7	[7,8]	27	[18,36]	50	[24,85]	17	[10,27]	42	[16,76]
	EKNZ	462	100.00	4	[1,6]	5	[2,7]	19	[11,28]	42	[22,76]	13	[6,20]	35	[15,64
	CER-VD	446	100.00	5	[3,7]	6	[3,7]	24	[19,34]	94	[60,154]	18	[14,23]	84	[54,142]
	KEK-BE	370	100.00	2	[1,4]	5	[1,10]	25	[19,34]	104	[63,168]	19	[14,21]	91	[55,148]
	CCER	307	100.00	4	[2,6]	7	[3,11]	31	[16,40]	61	[36,107]	21	[6,29]	50	[28,95]
	EKOS	105	100.00	1	[1,3]	1	[1,3]	7	[4,17]	21	[6,71]	5	[2,14]	17	[4,69]
	CE-TI	112	100.00	7	[6,10]	7	[7,14]	30	[14,40]	50	[19,83]	16	[0,27]	33	[9,68]
	All	2447	100.00	5	[2,7]	6	[3,8]	24	[15,35]	62	[31,114]	17	[9,24]	54	[23,100]

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 involved.

		Application involves					
		Multiple ECs			Single EC		
Type of research	Time interval	n	Median	IQR	n	Median	IQR
Clinical trial	from receipt to first reply	118	5	[2,7]	358	6	[3,7]
	from receipt to status 'complete'	118	6	[2,7]	358	7	[4,8]
	from receipt to first decision	118	29	[21,38]	358	27	[21,36]
	from receipt to final decision	118	113	[67,168]	358	91	[59,147]
	from 'complete' to first decision	118	22	[16,30]	358	20	[15,28]
	from 'complete' to final decision	118	107	[62,156]	358	83	[50,140]
Research w/persons	from receipt to first reply	84	4	[1,7]	745	5	[2,7]
	from receipt to status 'complete'	84	5	[1,7]	745	6	[3,8]
	from receipt to first decision	84	26	[15,38]	745	27	[18,35]
	from receipt to final decision	84	82	[46,149]	745	66	[41,112]
	from 'complete' to first decision	84	20	[12,27]	745	19	[13,25]
	from 'complete' to final decision	84	76	[42,136]	745	59	[34,99]
Further use	from receipt to first reply	67	4	[2,7]	1043	4	[1,7]
	from receipt to status 'complete'	67	7	[4,15]	1043	6	[3,9]
	from receipt to first decision	67	24	[16,38]	1043	21	[12,33]
	from receipt to final decision	67	55	[22,106]	1043	43	[19,90]
	from 'complete' to first decision	67	16	[8,22]	1043	14	[6,20]
	from 'complete' to final decision	67	42	[16,91]	1043	34	[12,76]
Deceased persons	from receipt to first reply	2	2	[2,2]	30	3	[1,4]
	from receipt to status 'complete'	2	6	[4,7]	30	4	[2,7]
	from receipt to first decision	2	42	[35,48]	30	30	[20,42]
	from receipt to final decision	2	88	[86,89]	30	54	[35,112]
	from 'complete' to first decision	2	36	[30,42]	30	20	[10,29]
	from 'complete' to final decision	2	82	[82,82]	30	41	[17,68]
Overall	from receipt to first reply	271	4	[1,7]	2176	5	[2,7]
	from receipt to status 'complete'	271	7	[2,8]	2176	6	[3,8]
	from receipt to first decision	271	27	[19,38]	2176	24	[15,34]
	from receipt to final decision	271	84	[48,154]	2176	60	[29,109]
	from 'complete' to first decision	271	20	[13,28]	2176	16	[9,23]
	from 'complete' to final decision	271	79	[40,146]	2176	51	[22,97]

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

		Application involves					
		Multiple ECs			Single EC		
Lead EC	Time interval	n	Median	IQR	n	Median	IQR
KEK-ZH	from receipt to first reply	88	7.0	[7.0, 7.0]	557	7.0	[4.0, 7.0]
	from receipt to status 'complete'	88	7.0	[7.0, 8.0]	557	7.0	[7.0, 8.0]
	from receipt to first decision	88	29.0	[22.8, 37.2]	557	27.0	[17.0, 35.0]
	from receipt to final decision	88	72.0	[45.5, 112.5]	557	48.0	[23.0, 79.0]
	from 'complete' to first decision	88	21.0	[14.0, 29.0]	557	17.0	[10.0, 27.0]
	from 'complete' to final decision	88	67.0	[38.5, 98.8]	557	37.0	[15.0, 70.0]
EKNZ	from receipt to first reply	52	3.0	[1.0, 5.0]	410	4.0	[1.0, 6.0]
	from receipt to status 'complete'	52	4.0	[1.8, 7.0]	410	5.0	[2.0, 7.8]
	from receipt to first decision	52	25.0	[20.8, 37.0]	410	18.0	[10.0, 27.0]
	from receipt to final decision	52	77.5	[48.8, 122.0]	410	39.0	[20.0, 64.0]
	from 'complete' to first decision	52	21.0	[14.8, 28.0]	410	12.0	[5.2, 19.0]
	from 'complete' to final decision	52	75.0	[47.8, 112.2]	410	33.0	[14.0, 56.0]
CER-VD	from receipt to first reply	29	4.0	[1.0, 7.0]	417	5.0	[3.0, 7.0]
	from receipt to status 'complete'	29	4.0	[2.0, 8.0]	417	6.0	[3.0, 7.0]
	from receipt to first decision	29	21.0	[17.0, 31.0]	417	25.0	[19.0, 34.0]
	from receipt to final decision	29	152.0	[70.0, 222.0]	417	92.0	[59.0, 148.0]
	from 'complete' to first decision	29	15.0	[12.0, 21.0]	417	18.0	[14.0, 23.0]
	from 'complete' to final decision	29	146.0	[69.0, 196.0]	417	82.0	[53.0, 133.0]
KEK-BE	from receipt to first reply	43	1.0	[0.0, 3.0]	327	2.0	[1.0, 5.0]
	from receipt to status 'complete'	43	3.0	[1.0, 10.5]	327	5.0	[2.0, 10.0]
	from receipt to first decision	43	25.0	[15.0, 41.0]	327	25.0	[19.0, 34.0]
	from receipt to final decision	43	140.0	[58.5, 208.5]	327	100.0	[65.5, 162.5]
	from 'complete' to first decision	43	21.0	[14.5, 24.5]	327	18.0	[14.0, 21.0]
	from 'complete' to final decision	43	108.0	[44.0, 196.0]	327	91.0	[56.0, 144.5]
CCER	from receipt to first reply	31	4.0	[1.5, 5.0]	276	4.0	[1.8, 7.0]
	from receipt to status 'complete'	31	8.0	[3.5, 16.5]	276	7.0	[3.0, 11.0]
	from receipt to first decision	31	30.0	[21.5, 44.5]	276	31.5	[16.0, 39.0]
	from receipt to final decision	31	119.0	[41.5, 206.0]	276	59.0	[35.0, 101.2]
	from 'complete' to first decision	31	23.0	[7.0, 31.0]	276	21.0	[6.0, 29.0]
	from 'complete' to final decision	31	110.0	[36.5, 170.5]	276	49.0	[26.0, 86.8]
EKOS	from receipt to first reply	18	1.0	[1.0, 3.0]	87	1.0	[1.0, 3.0]
	from receipt to status 'complete'	18	1.0	[1.0, 3.0]	87	1.0	[1.0, 3.0]
	from receipt to first decision	18	20.5	[11.5, 35.0]	87	6.0	[3.5, 12.5]
	from receipt to final decision	18	81.0	[59.2, 119.8]	87	16.0	[5.0, 39.0]
	from 'complete' to first decision	18	19.0	[10.2, 30.5]	87	4.0	[2.0, 9.0]
	from 'complete' to final decision	18	80.0	[57.0, 117.5]	87	11.0	[3.0, 36.0]
CE-TI	from receipt to first reply	10	5.5	[3.0, 7.0]	102	7.0	[7.0, 11.0]
	from receipt to status 'complete'	10	7.0	[3.0, 7.8]	102	8.0	[7.0, 14.0]
	from receipt to first decision	10	12.5	[3.0, 37.5]	102	30.5	[16.0, 40.8]
	from receipt to final decision	10	13.0	[5.8, 78.8]	102	52.0	[20.0, 82.0]
	from 'complete' to first decision	10	5.5	[0.0, 27.5]	102	16.0	[0.2, 26.8]
	from 'complete' to final decision	10	9.5	[0.8, 70.5]	102	33.5	[9.2, 66.8]
Overall	from receipt to first reply	271	4.0	[1.0, 7.0]	2176	5.0	[2.0, 7.0]
	from receipt to status 'complete'	271	7.0	[2.0, 8.0]	2176	6.0	[3.0, 8.0]
	from receipt to first decision	271	27.0	[19.0, 38.5]	2176	24.0	[15.0, 34.0]
	from receipt to final decision	271	84.0	[48.0, 153.5]	2176	60.0	[29.0, 109.0]
	from 'complete' to first decision	271	20.0	[13.0, 27.5]	2176	16.0	[9.0, 23.0]
	from 'complete' to final decision	271	79.0	[40.5, 146.0]	2176	51.0	[22.0, 97.0]

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.

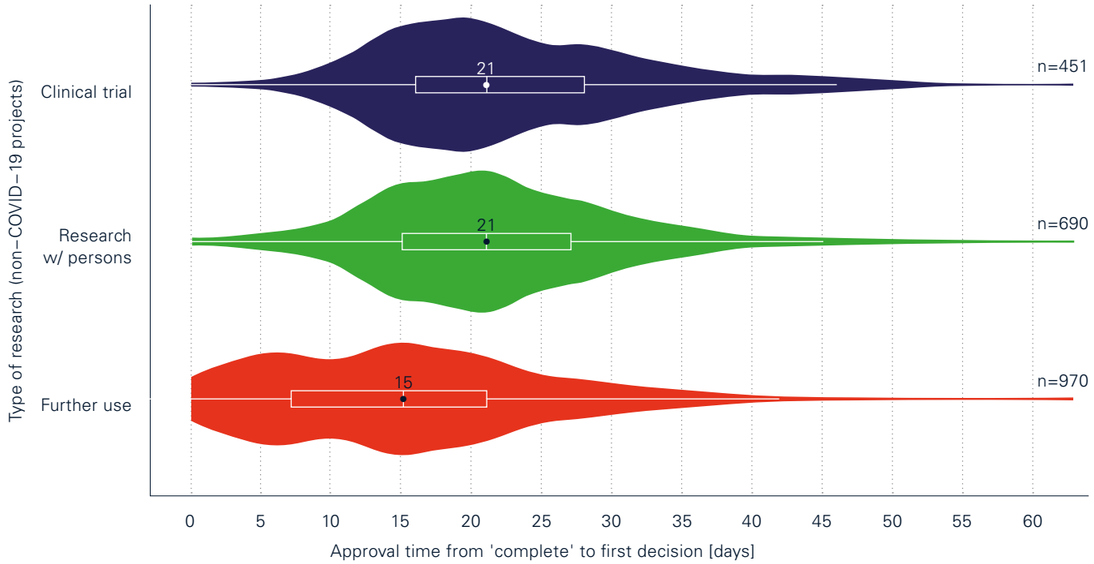


Figure 8.2: Violin plot of the **approval time starting from status 'complete' to the first decision** per type of research (only the 3 major groups are shown) for **COVID-19** projects. 32 projects with approval time > 60 days are not shown for layout reasons.

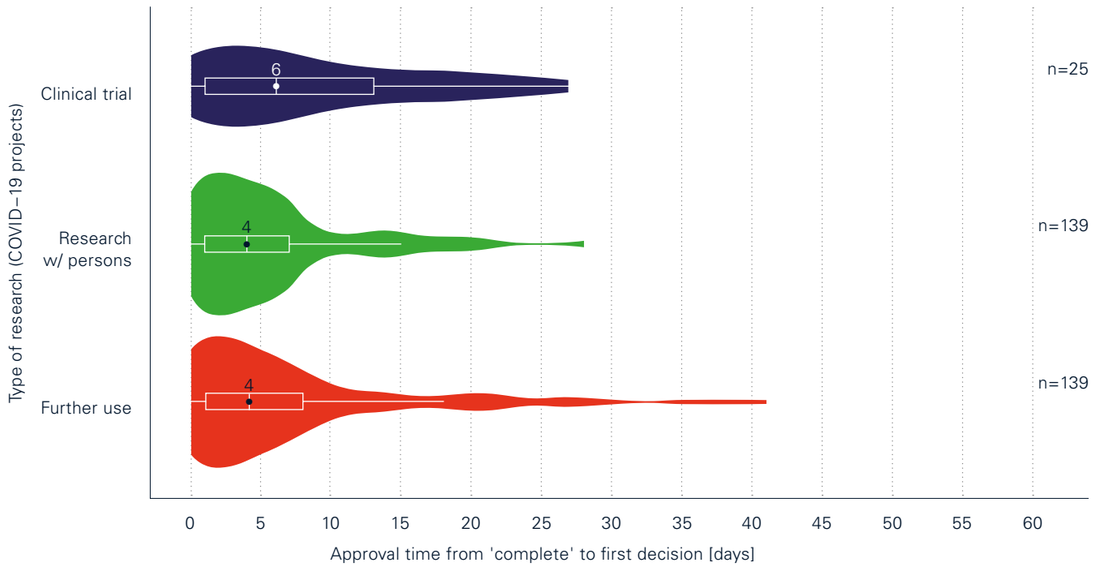
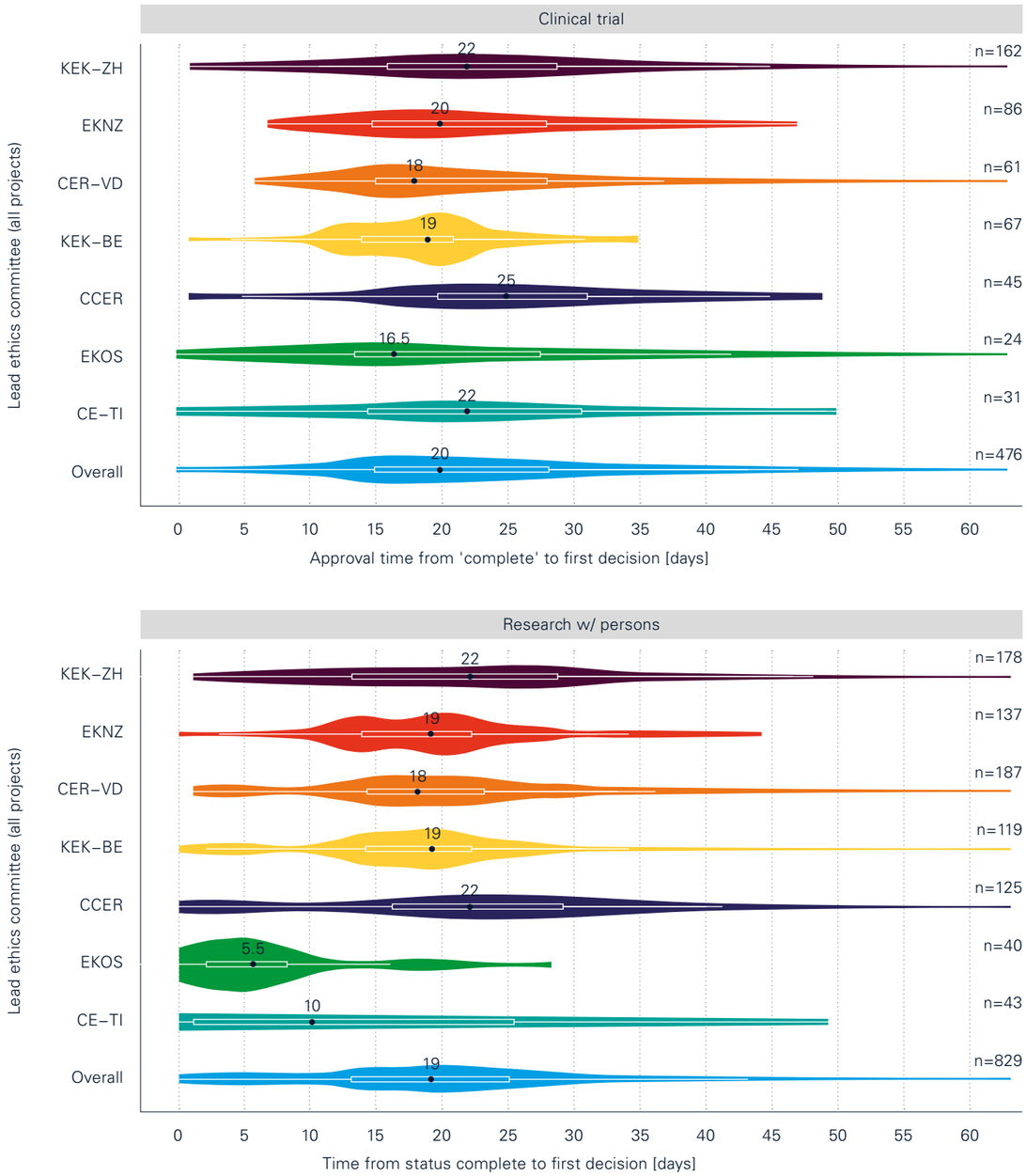


Figure 9: Violin plot of the **approval time starting from status 'complete' to the first decision** per type of research (only the 3 major groups are shown) stratified by EC. 32 projects with approval time > 60 days are not shown for layout reasons.



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.

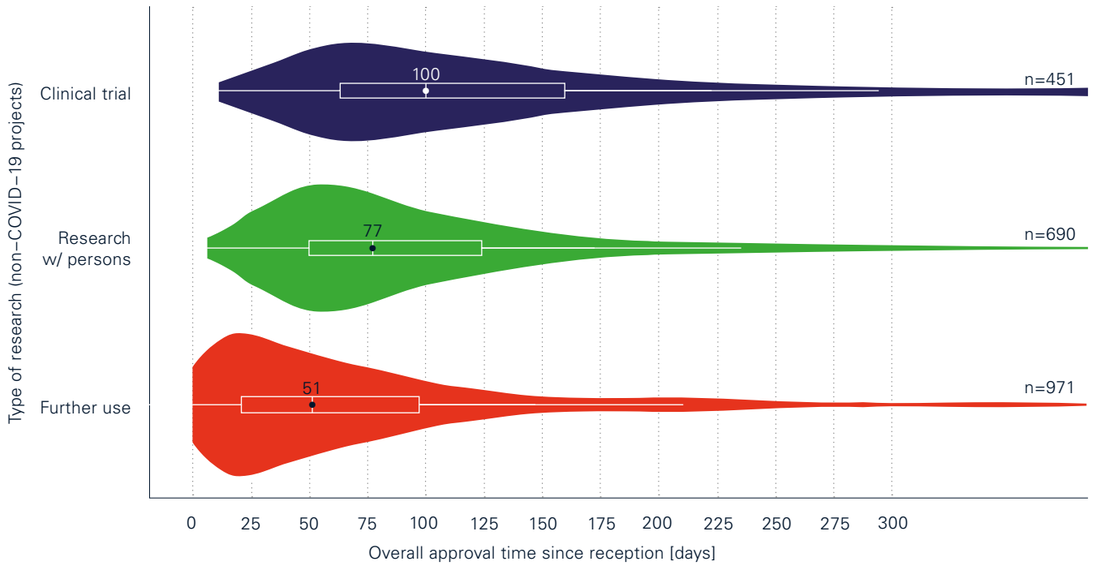


Figure 10.2: Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown) for **COVID-19** projects. 57 projects with an overall approval time > 1 year are not shown for layout reasons.

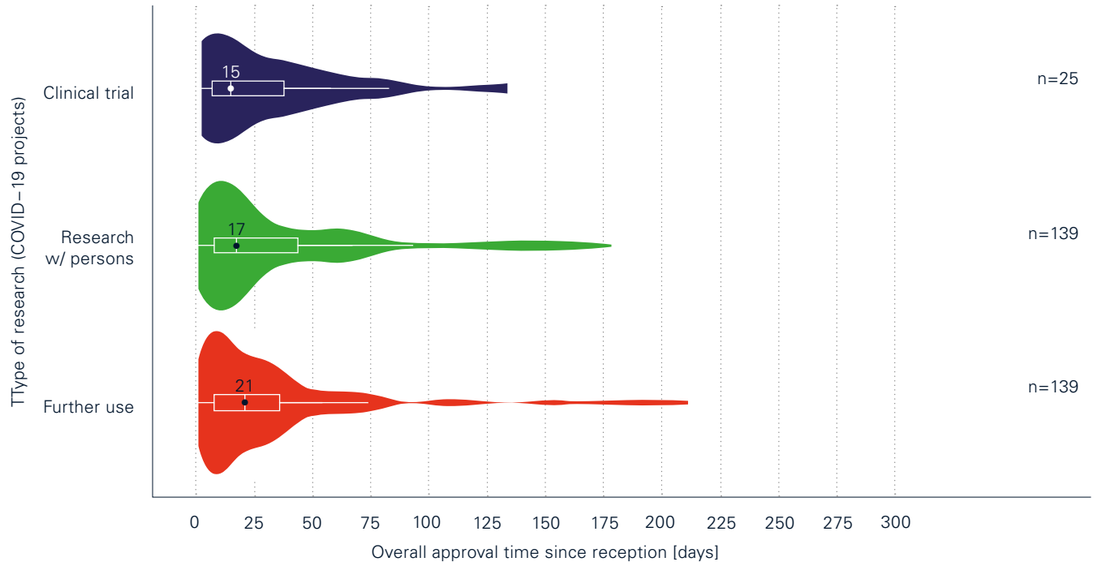
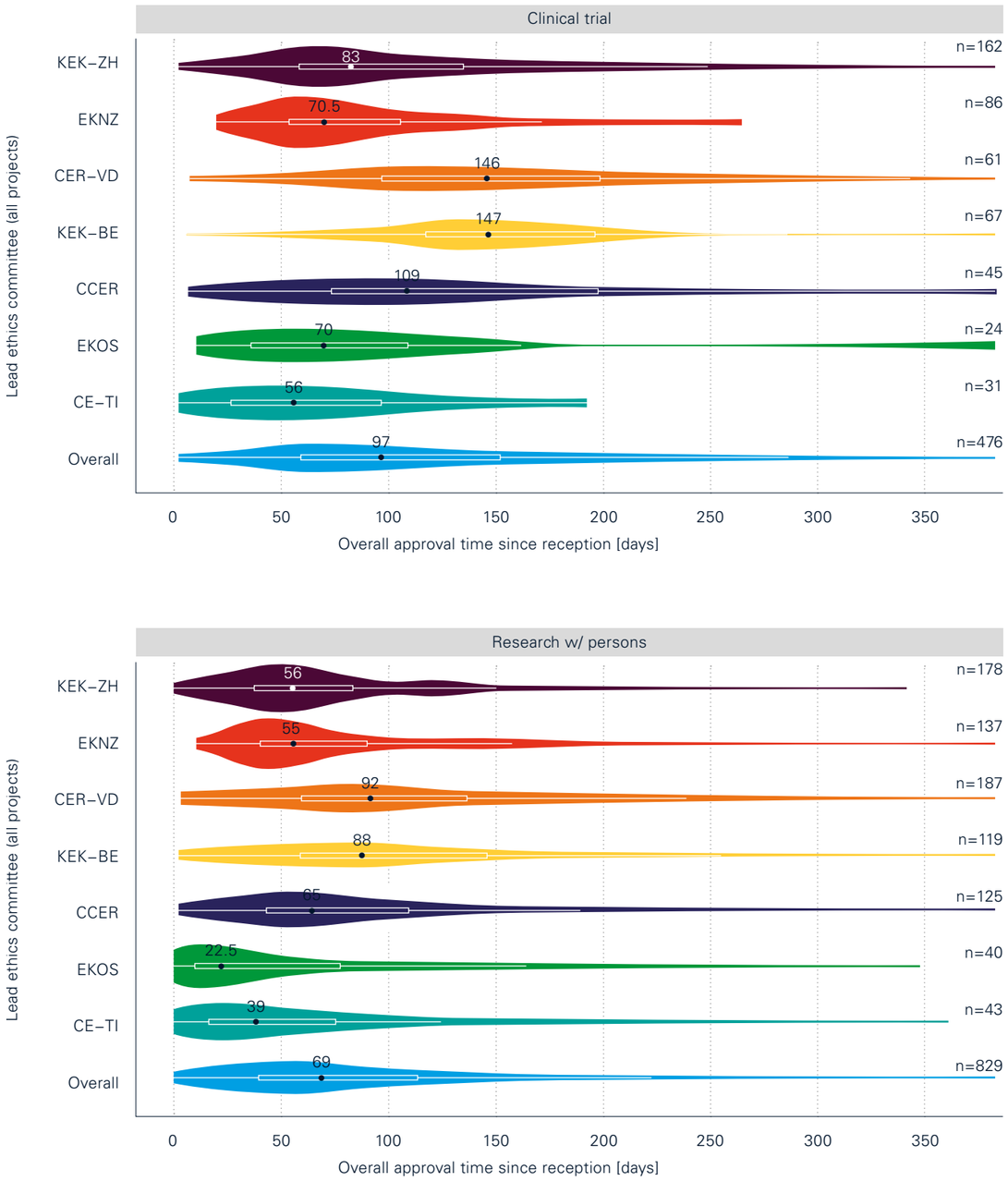
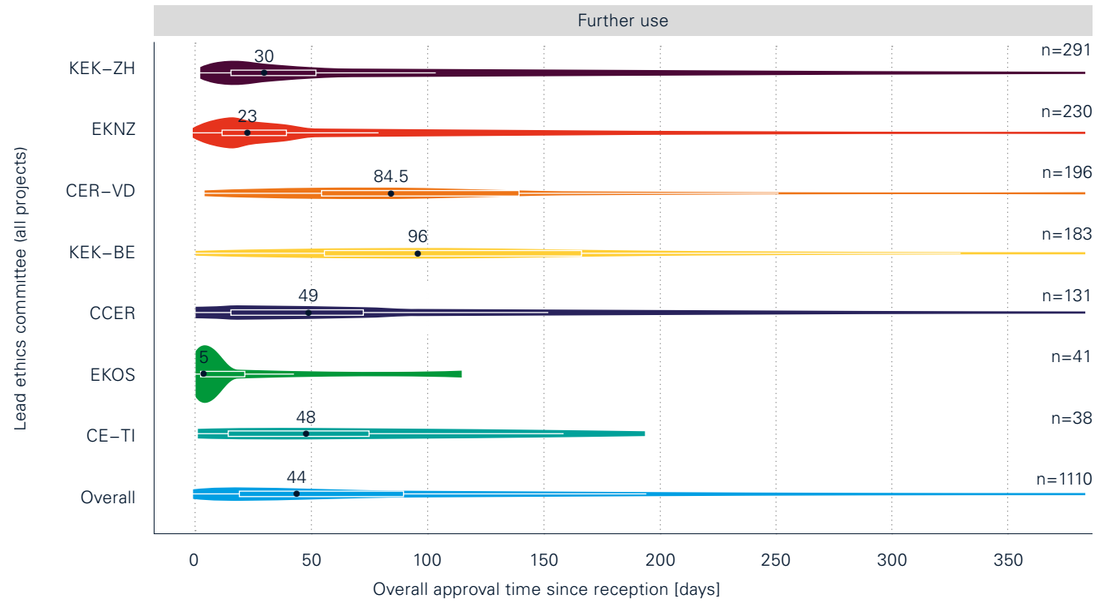


Figure 11: Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown) stratified by EC. 57 projects with an overall approval time > 1 year are not shown for layout reasons.

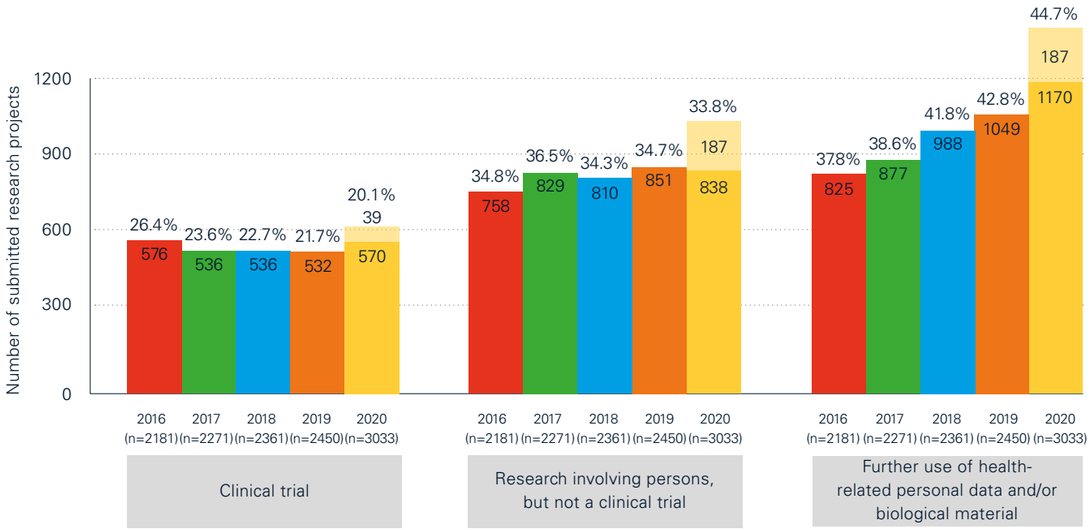




6 Comparison of submitted projects (AS1) since the introduction of BASEC

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 bars refer to the proportion of studies of a given type compared to all studies submitted in a given year.

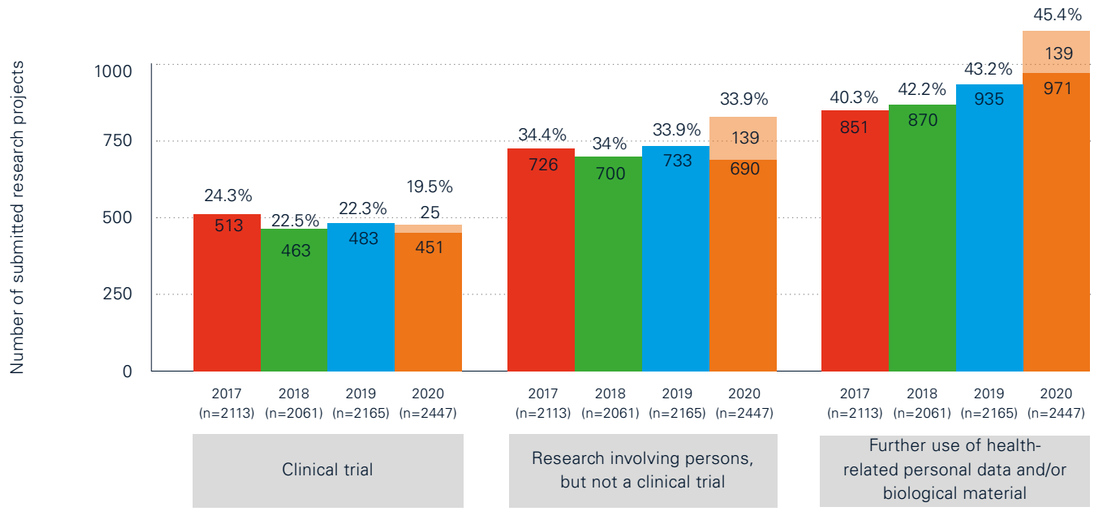


Data not shown in the above figure: Research involving deceased persons (2017: 29, 2018: 27, 2019: 17, 2020: 41) and Research involving embryos and fetuses from induced abortions or stillbirths (2017: 0, 2018: 0, 2019: 1, 2020: 1)

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

Note: In this chapter, specific parameters of the research projects approved in the reporting year and to compared previous back to 2017. BASEC is regularly monitored for data integrity and data quality, and for this reason the ethics committee or the researchers can adjust and correct the data in BASEC, whenever necessary. Consequently, the data in this report might slightly differ from the data published in last year report.

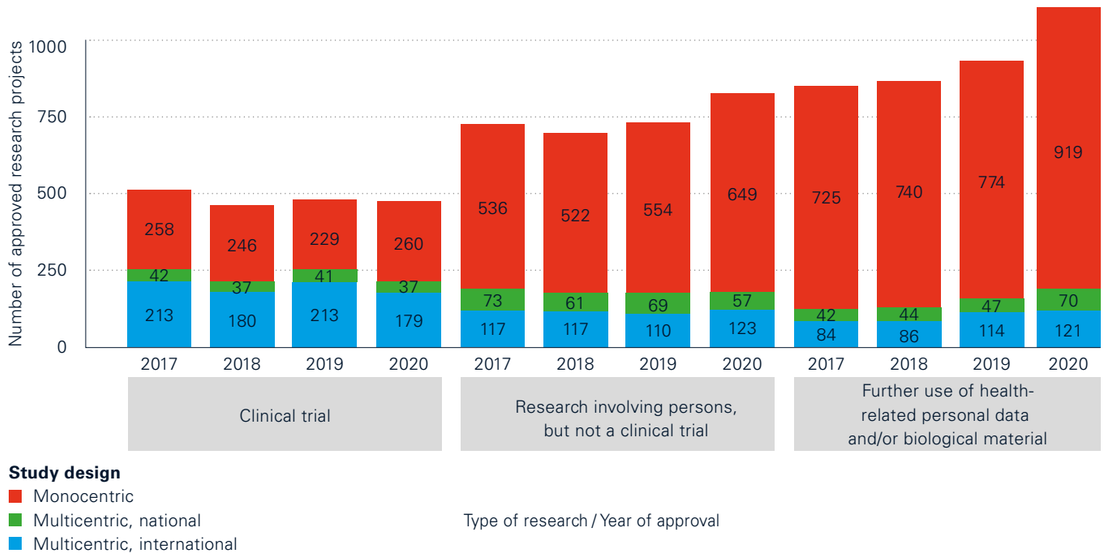
Figure 13: Total number of approved projects per year and type of research. Percentages on the top of the bars refer to the proportion of studies of a given type compared to all studies approved in a given year.



Data not shown in the above figure: Research involving deceased persons (2018: 28, 2019: 14, 2020: 32) and Research involving embryos and fetuses from induced abortions or stillbirths (2018: 0, 2019: 0, 2020: 0)

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

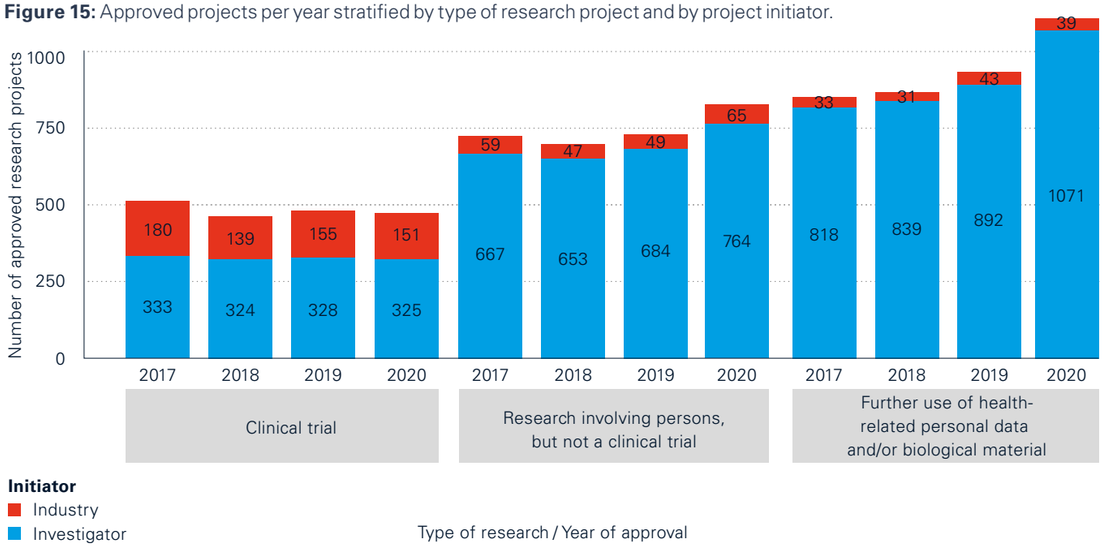
Figure 14: Approved projects per year stratified by type of research project and by study design.



Data not shown in the above figure: Research involving deceased persons (2018: 28, 2019: 14, 2020: 32) and Research involving embryos and fetuses from induced abortions or stillbirths (2018: 0, 2019: 0, 2020: 0)

7.2 Project initiator

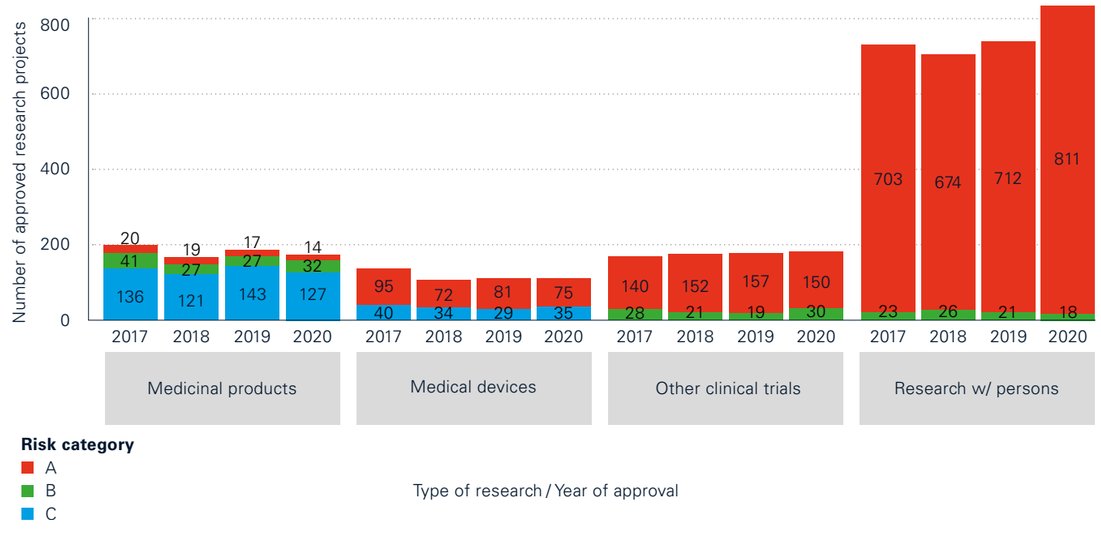
Figure 15: Approved projects per year stratified by type of research project and by project initiator.



Data not shown in the above figure: Research involving deceased persons (2018: 28, 2019: 14, 2020: 32) and Research involving embryos and fetuses from induced abortions or stillbirths (2018: 0, 2019: 0, 2020: 0)

7.3 Risk category

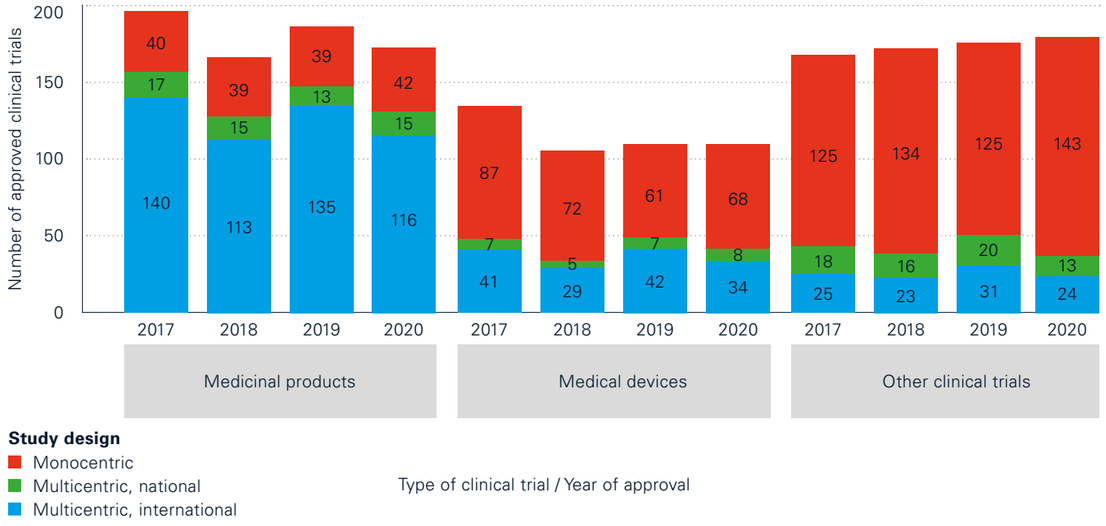
Figure 16: Clinical trials and research projects involving persons approved per year stratified by type of research project and risk category.



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

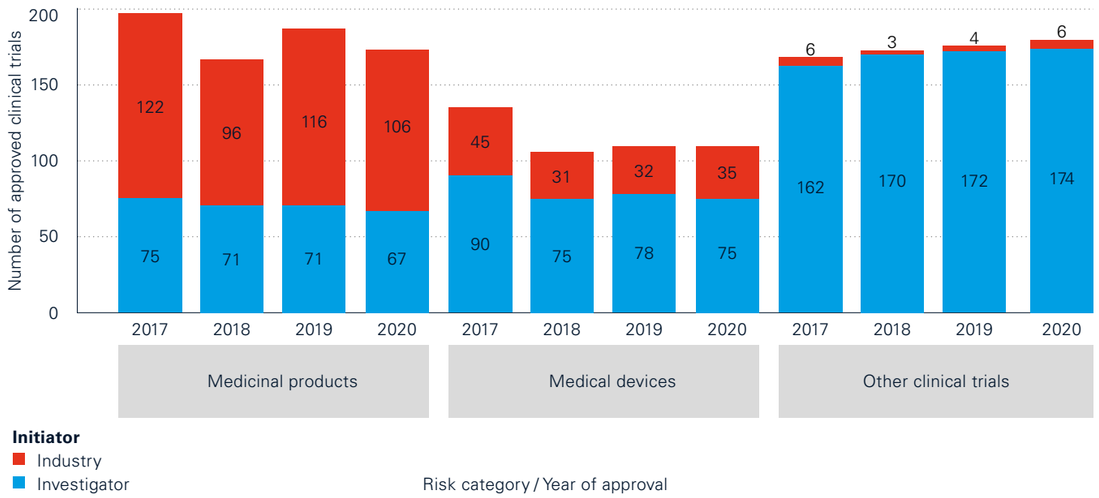
7.4 Subgroups of clinical trials

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 (2018: 9, 2019: 4, 2020: 6), combination drugs/devices (2018: 4, 2019: 4, 2020: 4), gene therapy (2018: 3, 2019: 2, 2020: 2) and transplantation (2018: 1, 2019: 0, 2020: 1)

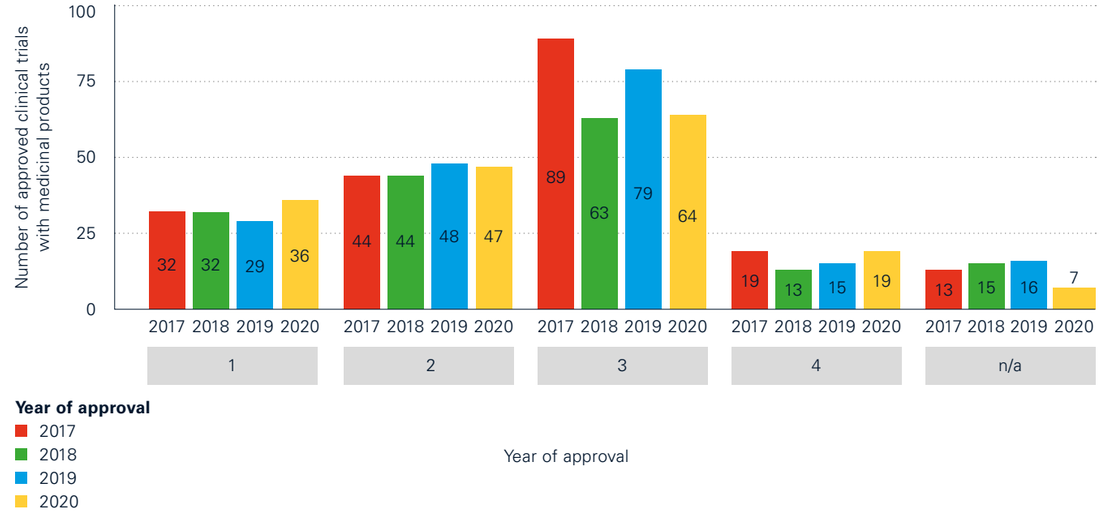
Figure 18: Clinical trials approved per year stratified by trial type and initiator.



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

7.4.1 Clinical trials with medicinal products

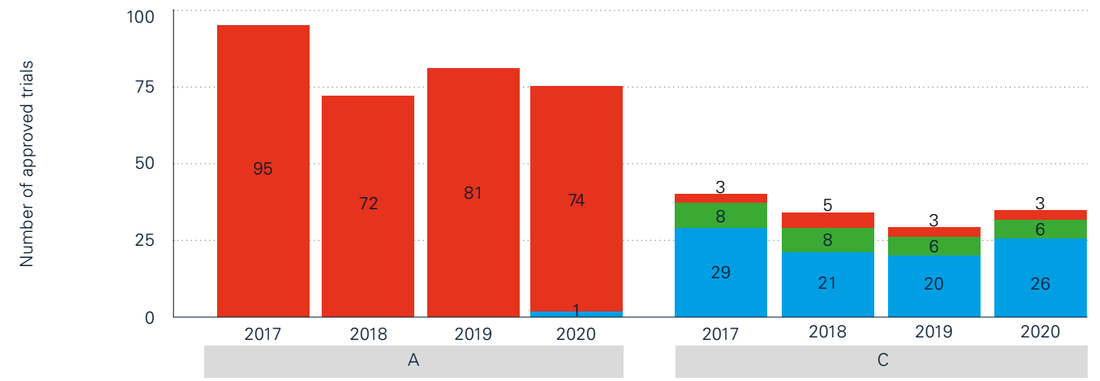
Figure 19: Clinical trials with medicinal products approved per year stratified by study phase.



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

7.4.2 Clinical trials with medical devices

Figure 20: Clinical trials with medical devices approved per year stratified by risk category and by CE certification/intended use.



Intended use: used in accordance with the instructions; Non-intended use: not used in accordance with the intended purposes recognised in the conformity assessment and specified in the instructions. Number of trials 'first-in-human': 2018: 20, 2019: 13, 2020: 18

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	
		n	%	n	%	n	%	n	%
Genetic data/biol. material	Yes	174	19.2	217	20.0	250	21.4	264	19.4
	No	731	80.8	870	80.0	917	78.6	1095	80.6
Coding (HRO Art. 25–27)	Coded	416	46.0	908	83.5	1011	86.6	1175	86.5
	Open, non-coded	489	54.0	179	16.5	156	13.4	184	13.5
Consent (HRO Art. 28–32)	Consent for all data	347	38.3	548	50.4	578	49.5	704	51.8
	Consent for some but not all data (partially Art. 34 HRA) [1]	–	–	–	–	–	–	287	21.1
	No consent for all data, Art. 34 HRA [2]	558	61.7	539	49.6	589	50.5	368	27.1
Combined vs. stand-alone projects [3]	Stand-alone further use project	851	94.0	870	80.0	935	80.1	1110	81.7
	Further use project as part of a clinical trial	19	2.1	43	4.0	45	3.9	37	2.7
	Further use project as part of a non-clinical research project	35	3.9	174	16.0	187	16.0	212	15.6
	Total number	905	100.0	1087	100.0	1167	100.0	1359	100.0

1 In the years 2017, 2018 and 2019, it was not possible to determine this category.
2 For the years 2017, 2018 and 2019, research projects for which consent was available for some but not all data (partially Art. 34 HRA) have been included in this category.
3 Combined projects: Research projects concerning a clinical trial (ClinO) or research involving persons according to HRO Chapter 2 that additionally include the 'further use' of existing data or biological material (HRO Chapter 3).

Figure 21: Number of approved 'further use' projects per year and fraction without informed consent. *Footnote:* [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.

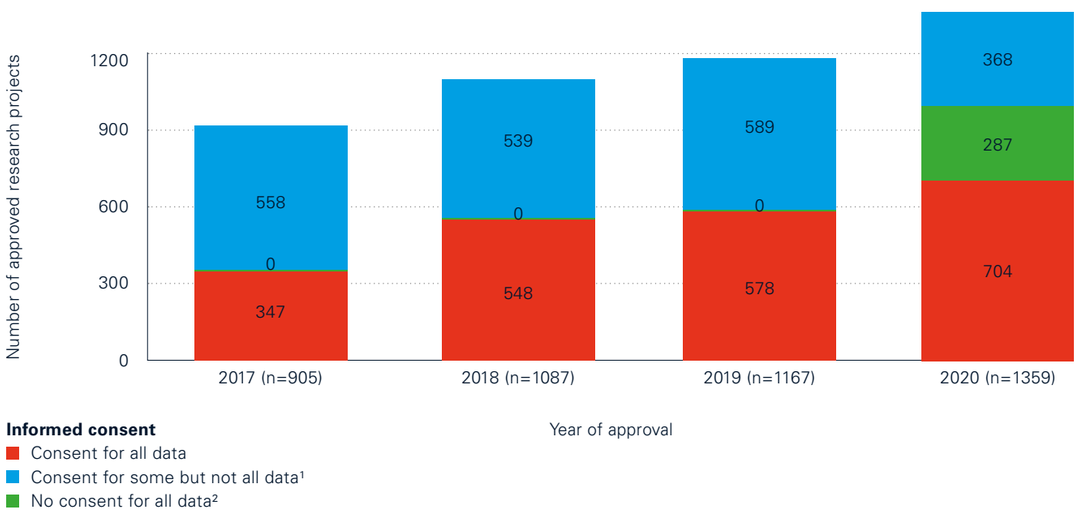
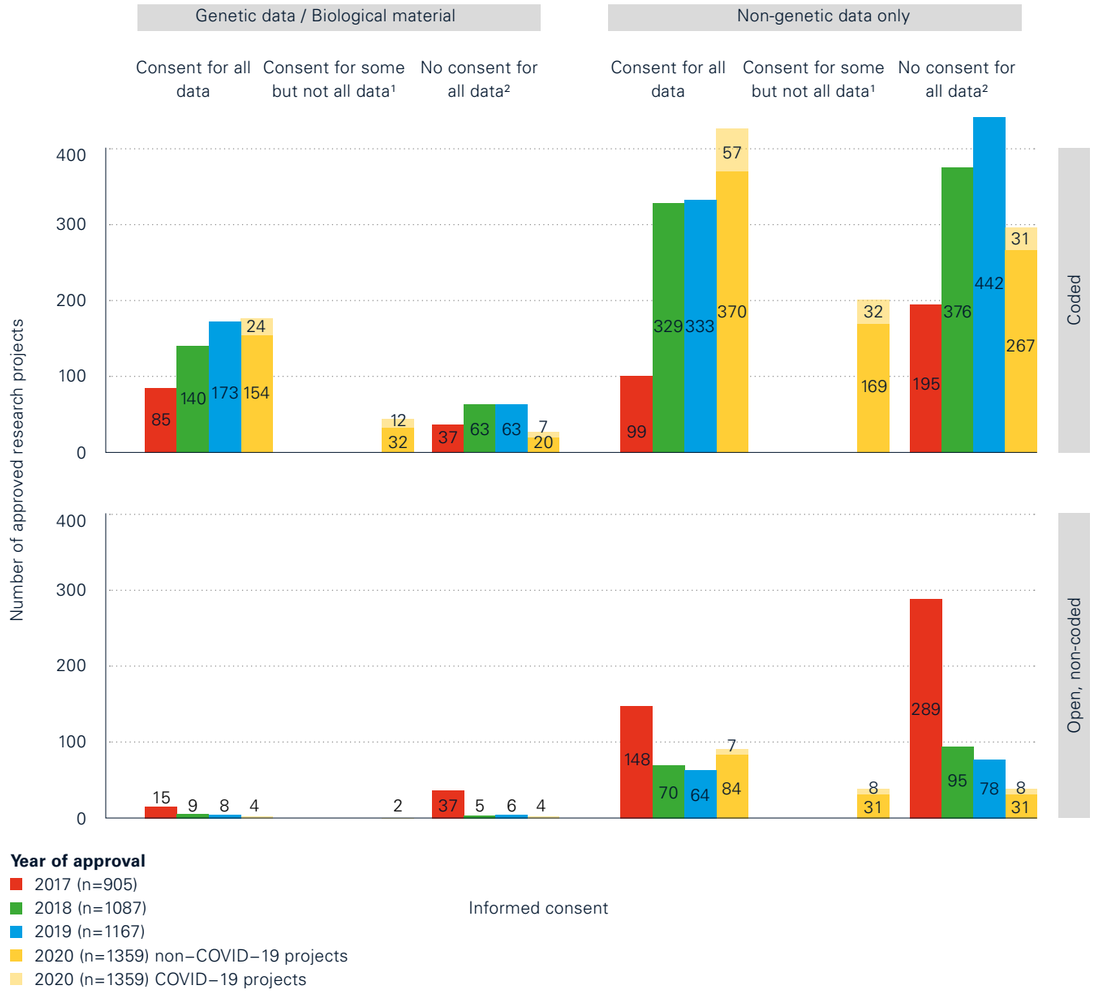
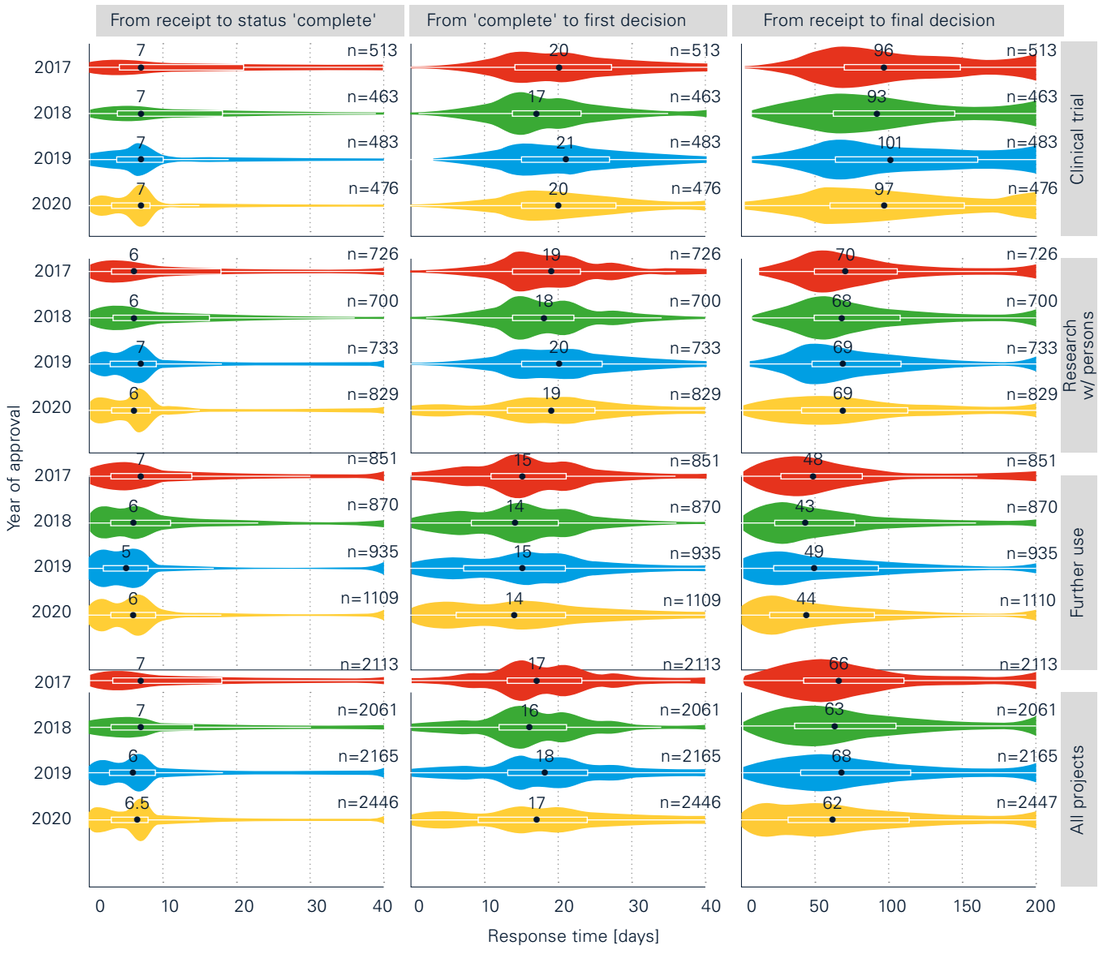


Figure 22: Number of approved 'further use' projects per year stratified by 1) Use of genetic data and/or biological material, 2) coded vs. uncoded, 3) consent for further use. Footnote:[1] In the years 2017, 2018 and 2019, it was not possible to determine this category.[2] For the years 2017, 2018 and 2019, research projects for which consent was available for some but not all data (partially Art. 34 HRA) have been included in this category.



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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