Medicine & Research
Statistical Report

Human Research in Switzerland 2023

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

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List of abbreviations

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

1 Introduction

This report describes all human research projects submitted to and approved by the Ethics Committees in Switzerland in the year 2023 (chapters 2 to 5). In addition, chapters 6 and 7 provide a longitudinal comparison over the years 2015 (submitted projects) and 2016 (approved projects), respectively, up to the year 2023. The data used for the present analysis come from the Business Administration System for Ethics Committees, BASEC.
The purpose of the BASEC web portal is to optimise the application process by providing a unique entry point for applications in the scope of the HRA irrespective of the involved ethics committees (ECs). Since the beginning of 2016, all applications are submitted via BASEC. The standardised and structured information on all submitted and approved research projects provides a unique opportunity for a comprehensive overview on the Swiss human research landscape.

1.1 Report structure

In the subsequent section, the sources of the analysed data are described and limitations are discussed. This results in the definition of two analysis sets (AS): one based on submissions *(AS1)* and the other based on approved projects in the reporting year *(AS2)*. The analysis sets are described in detail in section 1.3.
First, an overview on the BASEC data in the calendar year 2023 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 2023. 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 2023 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 eight years (2016 – 2023) and for approved projects *(AS2)* over seven years (2017 – 2023). The reason for this difference in the years compared is described in section 1.3.2.

1.2 Data source and limitations

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

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

A BASEC data export provided by swissethics dated April 5, 2024 has been used for this report.

1.2.1 Data provided by the applicant

The BASEC web portal enables the applicant to submit all information and documents needed by the ECs to assess the projects according to the HRA and its ordinances. The web interface is dynamic by showing/hiding fields depending on the type of research projects (e.g. clinical trial or "further use" project) or depending on previous answers.
Within BASEC, the classification in different types of research projects is generally in conformity with the HRA and its ordinances. However, some compromises have been made with the aim of facilitating the application process. This includes projects that cover two groups of research projects defined by the law but constitute a single research project (e.g. clinical trial including further use of existing data; see section 1.3.3).
The HRA and its ordinances form the basis of the work of the ECs. Generally, the terminology and categories used in BASEC tend to be in close conformity with the law whenever there are legal restrictions relevant for the application process. Some questions and categories in the web portal are, however, BASEC-specific with the aim to further characterise the research projects.
It has to be kept in mind that the BASEC data have limitations: the data in BASEC are primarily entered and reviewed with the purpose of submitting/assessing a project application and not in view of a further scientific analysis. The data are entered solely by the applicant and not edited by the ECs directly after the submission. This means that information retrieved from BASEC, especially from submitted but not yet reviewed projects, may contain irregularities. The ECs review the content of an application primarily with respect to legal, regulatory and ethical compliance but not for logical inconsistencies that arise from the application process itself.
Still, the ECs actively ask the project applicant to correct the data entered in BASEC if this is found to be obviously incorrect.

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

For each project, the dates of specific milestones indicated in the ordinances (Art. 26 and 27 ClinO, Art. 12 and 13 ClinO-MD, Art. 16 and 17 HRO) are captured. The milestones are:
Reception date: The date when the applicant submits the project for the first time.
First reaction date: The date when the ethics committee notifies the project applicant of either the confirmation of the completeness of the application or of any formal deficiency in the application and the need for resubmission.
Date the application data declared complete: The date at which the application data are considered formally complete and ready for review by ordinary, simplified or presidential procedure.
First decision date: Date of the decision after the first review procedure. The first decision date coincides with the "final decision date" if the project is approved (i.e. without charges) in the first run. (Only applicable for clinical trials conducted under ClinO and research projects conducted under HRO.)
Final decision date: Date of the final decision which can be: approved (and all charges have been fulfilled), declined, non-consideration, withdrawn.

These dates are used to calculate response times which are presented in chapter 5 on pages 37ff. In addition to the dates, the ECs report for each project the outcome of the first and the final decision as well as the review procedure applied (ordinary, simplified, presidential). An overview of the different EC decisions can be found in Table 3 on page 12 with short descriptions as table footnotes.
Apart from the "final decision date" of clinical trials under ClinO and research projects under HRO, which is entered manually by the ECs, all other milestones are recorded automatically. The completeness and consistency of these data are checked periodically by swissethics (irrespective of this report) and corrected by the ECs manually, if mandatory fields are found empty or when discrepancies are identified.

1.3 Analysis sets

1.3.1 Definition of analysis sets

Definition:
AS1 The analysis set AS1 consists of all projects **submitted in 2023**. 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 2023** 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/nonconsidered projects represents research that is actually going to be conducted and thereby provides insights on the current medical research landscape.

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

1.3.2 Influence of time on project status

The proportion of projects not approved (declined, withdrawn, non-consideration) is quite stable over time. These projects are not part of *AS2* and will not be analysed scientifically. The proportion of pending projects is low in early years: projects that have been pending for a long time (after reminding the applicants for multiple times) are periodically reclassified by swissethics to withdrawn or declined, depending whether the project passed the 'application data declared complete' milestone. The proportion of pending projects increases over the course of the year 2023, since a single up-to-date export is used for all years (export date: April 5, 2024) and not individual exports for each reporting year.

For approved projects, the year of the final decision is provided. When focusing on projects approved in a given year *(AS2)*, the 2016 data set only includes projects submitted in 2016 (after the introduction of BASEC). In contrast to this, the data sets starting from 2017 also include submissions from the previous years.

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

1.3.3 Definition of the basic unit of analysis

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

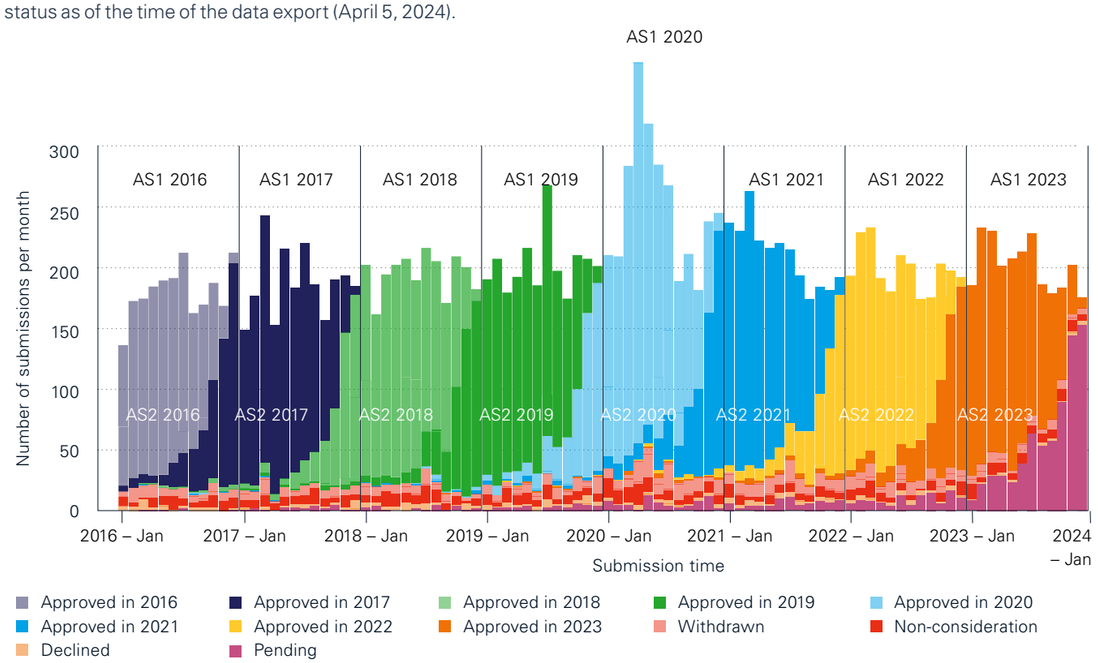
Throughout this report, mono-centric and multi-centric studies are defined based on the number of involved study sites but irrespective of the number of involved ECs (see the definition of the main stratification variables in chapter 4.3.1).

Projects with characteristics that simultaneously fall into two separate legally defined project types represent a special case. In BASEC, such projects are called "combined research projects" and consist of the following two types:

1. Research involving a combination of a clinical trial (ClinO or 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.

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

Figure 1: Overview of submissions via BASEC in the years 2016-2023 coloured by the current status as of the time of the data export (April 5, 2024).



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 2023

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

			n	$\%_{col}$
Input	Submission in 2023 (AS1)		2445	71
	Projects pending from 2022	Pending first decision in 2022	312	9.1
		Pending first decision in 2022 (first decision before 2023)	689	20
		Total Pending from 2022	999	29
		Grand Total Input 2023	3444	100
Output	Final decision in 2023	Approvals (AS2)	2117	61.5
		Rejections (declined projects)	20	0.6
		Non-considerations	93	2.7
		Total Decisions	2230	64.8
	Withdrawn during 2023	Withdrawal before first decision	50	1.5
		Withdrawal after first decision 'approvals with charges'	2	0.1
		Withdrawal after first decision 'not-yet-approved projects with conditions'	30	0.9
		Withdrawal after first decision 'non-considerations'	9	0.3
		Total Withdrawn	91	2.6
	Pending at end of 2023	Pending first decision	404	11.7
		Pending final decision (first decision issued)	719	20.9
		Total Pending	1123	32.6
		Grand Total Output 2023	3444	100

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 2023 (AS1)

Table 2: Total number of research projects **submitted via BASEC in 2023** (analysis set AS1), including information on type of research and the legal basis.

Type of research	Legal basis	n	$\%_{col}$
Clinical trial	ClinO or ClinO-MD	516 [1]	21.1
Research involving persons, but not a clinical trial	HRO, Chapter 2	786 [2]	32.1
Further use of health-related personal data and/or biological material	HRO, Chapter 3	1111	45.4
Research involving deceased persons	HRO, Chapter 4	30	1.2
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	2	0.1
Total number		2445	100

1 49 of these projects also include an application for further use of data/biological material.

2 190 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 2023 (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]	246	10.1	48	7.9	44	8.0	32	7.7	21	5.8	34	11.8	47	42.3	20	17.5
	Approved with charges[3]	566	23.1	8	1.3	269	49.1	159	38.5	13	3.6	30	10.5	43	38.7	44	38.6
	Not approved, conditions[4]	1295	53.0	464	76.2	212	38.7	152	36.8	258	71.1	166	57.8	8	7.2	35	30.7
	Declined	20	0.8	4	0.7					4	1.1	10	3.5			2	1.8
	Non-consideration[5]	87	3.6	31	5.1	1	0.2	4	1.0	23	6.3	17	5.9	9	8.1	2	1.8
	First decision still pending[6]	114	4.7	22	3.6	6	1.1	45	10.9	19	5.2	16	5.6	2	1.8	4	3.5
Final decision	Approved[7]	1914	78.3	477	78.3	495	90.3	305	73.8	276	76.0	179	62.4	94	84.7	88	77.2
	Declined	23	0.9	5	0.8			1	0.2	5	1.4	10	3.5			2	1.8
	Non-consideration	93	3.8	29	4.8	1	0.2	5	1.2	26	7.2	21	7.3	9	8.1	2	1.8
	Withdrawn	84	3.4	22	3.6	3	0.5	13	3.1	31	8.5	8	2.8	2	1.8	5	4.4
	Final decision still pending[8]	331	13.5	76	12.5	49	8.9	89	21.5	25	6.9	69	24.0	6	5.4	17	14.9
Review procedure	Ordinary[9]	359	14.7	70	11.5	53	9.7	53	12.8	40	11.0	23	8.0	16	14.4	104	91.2[12]
	Simplified[10]	1501	61.4	336	55.2	375	68.4	241	58.4	285	78.5	208	72.5	54	48.6	2	1.8
	Presidential[11]	464	19.0	188	30.9	113	20.6	74	17.9	17	4.7	40	13.9	31	27.9	1	0.9
	First decision still pending	121	4.9	15	2.5	7	1.3	45	10.9	21	5.8	16	5.6	10	9.0	7	6.1
	Total number in AS1	2445	100.0	609	100.0	548	100.0	413	100.0	363	100.0	287	100.0	111	100.0	114	100.0

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

2 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. 42.9% 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.

Table 4: Number of **submissions in 2023** (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	15	8.9	4	8.0	5	13.9	2	9.5	3	14.3			1	6.2		
		B	26	15.5	8	16.0	6	16.7	4	19.0	3	14.3	3	30.0	2	12.5		
		C	127	75.6	38	76.0	25	69.4	15	71.4	15	71.4	7	70.0	13	81.2	14	100.0
		All	168	100.0	50	100.0	36	100.0	21	100.0	21	100.0	10	100.0	16	100.0	14	100.0
	Medical devices[1]	A1	57	50.4	16	57.1	8	53.3	11	52.4	8	33.3	6	42.9	4	100.0	4	57.1
		A2	5	4.4							3	12.5	2	14.3				
		C1	7	6.2			2	13.3	1	4.8	2	8.3	1	7.1			1	14.3
		C2	43	38.1	12	42.9	5	33.3	9	42.9	10	41.7	5	35.7			2	28.6
		C3	1	0.9							1	4.2						
		All	113	100.0	28	100.0	15	100.0	21	100.0	24	100.0	14	100.0	4	100.0	7	100.0
	Other clinical trials	A	179	84.8	60	88.2	43	81.1	19	95.0	28	82.4	12	66.7	7	100.0	10	90.9
		B	32	15.2	8	11.8	10	18.9	1	5.0	6	17.6	6	33.3			1	9.1
		All	211	100.0	68	100.0	53	100.0	20	100.0	34	100.0	18	100.0	7	100.0	11	100.0
	Combination drugs/devices	A1	3	18.8	2	25.0					1	50.0						
		C	8	50.0	4	50.0			4	80.0								
		C1	2	12.5			1	100.0			1	50.0						
		C2	3	18.8	2	25.0			1	20.0								
		All	16	100.0	8	100.0	1	100.0	5	100.0	2	100.0						
	Transplant products	A	2	50.0	1	100.0					1	100.0						
		C	2	50.0			1	100.0									1	100.0
		All	4	100.0	1	100.0	1	100.0			1	100.0					1	100.0
	Gene therapy	C	2	100.0					1	100.0	1	100.0						
		All	2	100.0					1	100.0	1	100.0						
	Pathogenic organisms	C	2	100.0			1	100.0					1	100.0				
		All	2	100.0			1	100.0					1	100.0				
	All	All	516	100.0	155	100.0	107	100.0	68	100.0	83	100.0	43	100.0	27	100.0	33	100.0
Research w/ persons		A	773	98.3	154	98.7	155	98.7	182	98.9	106	95.5	111	98.2	23	100.0	42	100.0
		B	13	1.7	2	1.3	2	1.3	2	1.1	5	4.5	2	1.8				
		All	786	100.0	156	100.0	157	100.0	184	100.0	111	100.0	113	100.0	23	100.0	42	100.0
Further use		n.a.	1111	100.0	279	100.0	279	100.0	161	100.0	165	100.0	128	100.0	60	100.0	39	100.0
Deceased and embryos from stillbirths or abortion		n.a.	32	100.0	19	100.0	5	100.0			4	100.0	3	100.0	1	100.0		
Total number			2445	100.0	609	100.0	548	100.0	413	100.0	363	100.0	287	100.0	111	100.0	114	100.0

1 Medical devices include 2 in-vitro diagnostic project submitted under the ClinO regulation before 26.05.2022 and 8 in-vitro diagnostic projects under the revised ClinO-MD regulation, which applies to IVD trials from 26.05.2022.

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

3.2 Individual evaluations by lead or local ethics committees

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

	n	%
Single EC involved	2147	70.5
Multiple ECs involved: lead EC	298	9.8
Multiple ECs involved: local EC	600	19.7
Total submissions to be evaluated	3045	100.0

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

	Ethics committee													
	KEK-ZH		EKNZ		CER-VD		KEK-BE		CCER		EKOS		CE-TI	
	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$
Single EC involved	528	76.2	479	71.7	378	74.9	316	66.4	258	73.3	89	47.6	99	60.4
Multiple: lead EC	81	11.7	69	10.3	35	6.9	47	9.9	29	8.2	22	11.8	15	9.1
Multiple: local EC	84	12.1	120	18.9	92	18.2	113	23.7	65	18.5	76	40.6	50	30.5
Total submissions	693	100.0	668	100.0	505	100.0	476	100.0	352	100.0	187	100.0	164	100.0

4 Scientific characterisation of projects approved in 2023 (AS2)

4.1 Overview

Table 7: Total number of research projects **approved in 2023** (analysis set AS2) per type of research, including information on the legal basis.

Type of research	Legal basis	n	$\%_{col}$
Clinical trial	ClinO or ClinO-MD	478[1]	22.6
Research involving persons, but not a clinical trial	HRO, Chapter 2	650[2]	30.7
Further use of health-related personal data and/or biological material	HRO, Chapter 3	961	45.4
Research involving deceased persons	HRO, Chapter 4	27	1.3
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	1	0.0
Total number		2117	100.0

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

2 151 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 2023 (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	2018	1	0.05							1	0.3						
	2019	5	0.24					1	0.3	4	1.1						
	2020	17	0.8			1	0.2	3	0.9	12	3.2	1	0.5				
	2021	36	1.7	2	0.4	6	1.2	5	1.4	13	3.5	7	3.2	3	2.9		
	2022	529	24.99	127	26.5	78	16.0	103	29.5	118	31.8	64	29.0	14	13.5	25	24.0
	2023	1529	72.22	351	73.1	403	82.6	237	67.9	223	60.1	149	67.4	87	83.7	79	76.0
First decision[1]	Approved	259	12.23	58	12.1	46	9.4	30	8.6	24	6.5	32	14.5	47	45.2	22	21.2
	Approved with charges[2]	541	25.56	7	1.5	228	46.7	172	49.3	16	4.3	26	11.8	49	47.1	43	41.3
	Not approved, conditions[3]	1229	58.05	394	82.1	197	40.4	135	38.7	313	84.4	150	67.9	5	4.8	35	33.7
	Declined[4]	1	0.05									1	0.5				
	Non-consideration	2	0.09	1	0.2									1	1.0		
Review procedure	Ordinary[5]	356	16.82	60	12.5	57	11.7	41	11.7	56	15.1	24	10.9	17	16.3	101	97.1
	Simplified	1371	64.76	277	57.7	334	68.4	231	66.2	300	80.9	167	75.6	59	56.7	3	2.9
	Presidential	390	18.42	143	29.8	97	19.9	77	22.1	15	4.0	30	13.6	28	26.9		
	Total number in AS2	2117	100.00	480	100.0	488	100.0	349	100.0	371	100.0	221	100.0	104	100.0	104	100.0

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

2 Charges: the projects are approved but with charges.

3 Conditions: These projects are not approved until the conditions are addressed.

4 Reconsideratoin and approval of a previously declined project, reusing the electronic submission form with the old BASEC number.

5 CE-TI uses the ordinary procedure for most of the research applications.

4.3 Stratification by project characteristics

In Tables 9–11 on page 22–26, the approved projects are grouped row-wise by type of research (the corresponding legal basis is denoted in the first table) and stratified column-wise by generic project characteristics (design, project initiator, etc.).
For the most important types of research projects, subgroup analyses are provided in the following sections. Links to the sub-chapter covering the corresponding subgroup analysis are embedded in Table 9.
In the subgroup analyses starting on page 28, a similar table structure is used with more generic characteristics in the columns and subgroup specific characteristics in the rows.

4.3.1 Description and derivation of stratification variables

Risk category: The risk category is used as a stratification variable in all tables. In general, category "A" stands for low risk - however, the exact meaning depends on the type of research project and is defined in the respective ordinances (ClinO Art. 19, 20, 49, 61 and HRO Art. 7 as well as ClinO-MD Art. 6). The risk category is derived from the approved project's final risk category ruling stored in BASEC.

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

Initiator: The initiator of the project is derived from the answer to the BASEC question "Who initiated the project? Indicate here who had the original idea for the research project (do not indicate here who is financing, conducting or leading the project)". Allowed answers are "Investigator", "Industry" and "Other" (very rare). To keep it simple, studies with an initiator defined as "Other" are considered investigator initiated studies in the tables. In Table 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".

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.

					Study design						Initiator			
			Total		Mono		Multi CH		Multi Int.		Industry		Investigator	
Type of research	Research details	Risk cat.	n	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Clinical trial	Medicinal products (ClinO Art 19)	A	17	9.0	9	52.9	1	5.9	7	41.2	1	5.9	16	94.1
		B	26	13.8	13	50.0			13	50.0	6	23.1	20	76.9
		C	145	77.1	10	6.9	2	1.4	133	91.7	130	89.7	15	10.3
		All	188	100.0	32	17.0	3	1.6	153	81.4	137	72.9	51	27.1
	Medical devices (ClinO-MD Art 6)[1]	A1	47	58.0	24	51.1	5	10.6	18	38.3	18	38.3	29	61.7
		A2	3	3.7	1	33.3			2	66.7	2	66.7	1	33.3
		C1	8	9.9	3	37.5	1	12.5	4	50.0	4	50.0	4	50.0
		C2	23	28.4	11	47.8	2	8.7	10	43.5	17	73.9	6	26.1
		All	81	100.0	39	48.1	8	9.9	34	42.0	41	50.6	40	49.4
	Other clinical trials (ClinO Art 61)	A	161	84.7	125	77.6	14	8.7	22	13.7	3	1.9	158	98.1
		B	29	15.3	19	65.5	4	13.8	6	20.7	1	3.4	28	96.6
		All	190	100.0	144	75.8	18	9.5	28	14.7	4	2.1	186	97.9
	Combination drugs/devices	A1	1	10.0	1	100.0							1	100.0
		A2	1	10.0					1	100.0			1	100.0
		C	4	40.0					4	100.0	4	100.0		
		C1	1	10.0					1	100.0	1	100.0		
		C2	3	30.0					3	100.0	3	100.0		
		All	10	100.0	1	10.0			9	90.0	8	80.0	2	20.0
	Transplant products (ClinO Art 21)	A	2	33.3	1	50.0			1	50.0			2	100.0
		C	4	66.7	2	50.0			2	50.0	2	50.0	2	50.0
		All	6	100.0	3	50.0			3	50.0	2	33.3	4	66.7
	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		
	Pathogenic organisms	C	2	100.0					2	100.0	2	100.0		
		All	2	100.0					2	100.0	2	100.0		
	All	All	478	100.0	219	45.8	29	6.1	230	48.1	195	40.8	283	59.2
Research w/ persons (HRO Chapter 2)		A	634	97.5	488	77.0	65	10.3	81	12.8	32	5.0	602	95.0
		B	16	2.5	16	100.0							16	100.0
		All	650	100.0	504	77.5	65	10.0	81	12.5	32	4.9	618	95.1
Further use (HRO Chapter 3)		n.a.	961	100.0	779	81.1	58	6.0	124	12.9	48	5.0	913	95.0
Deceased and embryos from stillbirths or abortion (HRO Chapter 4 + 5)		n.a.	28	100.0	27	96.4			1	3.6	3	10.7	25	89.3
Total number		Total number	2117	100.0	1529	72.2	152	7.2	436	20.6	278	13.1	1839	86.9

1 Medical devices include 0 in-vitro diagnostic projects approved under the ClinO regulation before 26.05.2022 and 6 in-vitro diagnostic projects under the revised ClinO-MD regulation, which applies to IVD trials from 26.05.2022.

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

4.3.3 Lead ethics committee

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

					Lead ethics committee													
			Total		KEK-ZH		EKNZ		CER-VD		KEK-BE		CCER		EKOS		CE-TI	
Type of research	Research details	Risk cat.	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$	n	$\%_{col}$
Clinical trial	Medicinal products	A	17	9.0	5	9.8	1	3.2	5	23.8	4	10.5	1	6.7	1	5.9		
		B	26	13.8	5	9.8	6	19.4	5	23.8	5	13.2	4	26.7			1	6.7
		C	145	77.1	41	80.4	24	77.4	11	52.4	29	76.3	10	66.7	16	94.1	14	93.3
		All	188	100.0	51	100.0	31	100.0	21	100.0	38	100.0	15	100.0	17	100.0	15	100.0
	Medical devices	A1	47	58.0	14	77.8	8	50.0	10	83.3	6	37.5	5	45.5	4	100.0		
		A2	3	3.7							1	6.2	2	18.2				
		C1	8	9.9	1	5.6	2	12.5			4	25.0					1	25.0
		C2	23	28.4	3	16.7	6	37.5	2	16.7	5	31.2	4	36.4			3	75.0
		All	81	100.0	18	100.0	16	100.0	12	100.0	16	100.0	11	100.0	4	100.0	4	100.0
	Other clinical trials	A	161	84.7	43	87.8	38	74.5	19	95.0	32	82.1	11	91.7	6	100.0	12	92.3
		B	29	15.3	6	12.2	13	25.5	1	5.0	7	17.9	1	8.3			1	7.7
		All	190	100.0	49	100.0	51	100.0	20	100.0	39	100.0	12	100.0	6	100.0	13	100.0
	Combination drugs/devices	A1	1	10.0	1	20.0												
		A2	1	10.0							1	50.0						
		C	4	40.0	3	60.0			1	100.0								
		C1	1	10.0			1	100.0										
		C2	3	30.0	1	20.0					1	50.0	1	100.0				
		All	10	100.0	5	100.0	1	100.0	1	100.0	2	100.0	1	100.0				
	Transplant products	A	2	33.3	1	50.0					1	100.0						
		C	4	66.7	1	50.0	2	100.0					1	100.0				
		All	6	100.0	2	100.0	2	100.0			1	100.0	1	100.0				
	Gene therapy	C	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				
	All	All	478	100.0	125	100.0	102	100.0	54	100.0	97	100.0	41	100.0	27	100.0	32	100.0
Research w/ persons		A	634	97.5	118	99.2	140	98.6	145	98.0	96	92.3	80	97.6	22	100.0	33	100.0
		B	16	2.5	1	0.8	2	1.4	3	2.0	8	7.7	2	2.4				
		All	650	100.0	119	100.0	142	100.0	148	100.0	104	100.0	82	100.0	22	100.0	33	100.0
Further use		n.a.	961	100.0	220	100.0	240	100.0	147	100.0	165	100.0	96	100.0	54	100.0	39	100.0
Deceased and embryos from stillbirths or abortion		n.a.	28	100.0	16	100.0	4	100.0			5	100.0	2	100.0	1	100.0		
Total number		Total number	2117	100.0	480	100.0	488	100.0	349	100.0	371	100.0	221	100.0	104	100.0	104	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	17	9.0	2	11.76	15	88.24					3	17.65	14	82.35				
		B	26	13.8	26	100.00							5	19.23	21	80.77				
		C	145	77.1	144	99.31	1	0.69			3	2.07	22	15.17	120	82.76				
		All	188	100.0	172	91.49	16	8.51			3	1.60	30	15.96	155	82.45				
	Medical devices	A1	47	58.0	9	19.15	33	70.21	5	10.64			2	4.26						
		A2	3	3.7			2	66.67	1	33.33										
		C1	8	9.9	4	50.00			4	50.00										
		C2	23	28.4	17	73.91	1	4.35	5	21.74										
		All	81	100.0	30	37.04	36	44.44	15	18.52			2	2.47						
	Other clinical trials	A	161	84.7	22	13.66	138	85.71	1	0.62	6	3.73	30	18.63	124	77.02			1	0.62
		B	29	15.3	26	89.66	3	10.34					4	13.79	25	86.21				
		All	190	100.0	48	25.26	141	74.21	1	0.53	6	3.16	34	17.89	149	78.42			1	0.53
	Combination drugs/devices	A1	1	10.0			1	100.00												
		A2	1	10.0					1	100.00										
		C	4	40.0	4	100.00									4	100.00				
		C1	1	10.0	1	100.00														
		C2	3	30.0	2	66.67			1	33.33										
		All	10	100.0	7	70.00	1	10.00	2	20.00					4	40.00				
	Transplant products	A	2	33.3			2	100.00							2	100.00				
		C	4	66.7	4	100.00							1	25.00	3	75.00				
		All	6	100.0	4	66.67	2	33.33					1	16.67	5	83.33				
	Gene therapy	C	1	100.0	1	100.00									1	100.00				
		All	1	100.0	1	100.00									1	100.00				
	Pathogenic organisms	C	2	100.0	2	100.00									2	100.00				
		All	2	100.0	2	100.00									2	100.00				
	All	All	478	100.0	264	55.23	196	41.00	18	3.77	9	1.88	67	14.02	316	66.11			1	0.21
Research w/ persons		A	634	97.5	41	6.47	590	93.06	3	0.47	20	3.15	165	26.03	448	70.66	1	0.16		
		B	16	2.5	12	75.00	3	18.75	1	6.25			2	12.50	14	87.5				
		All	650	100.0	53	8.15	593	91.23	4	0.62	20	3.08	167	25.69	462	71.08	1	0.15		
Further use		n.a.	961	100.0	38	3.95	555	57.75	368	38.29	221	23.00	302	31.43	437	45.47			1	0.10
Deceased and embryos from stillbirths or abortion		n.a.	28	100.0	1	3.57	27	96.43			9	32.14	5	17.86	14	50.00				
Total number	Total number		2117	100.0	356	16.82	1371	64.76	390	18.42	259	12.23	541	25.56	1229	58.05	1	0.05	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 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 19 clinical trials not falling in the 3 main clinical trial types medicinal product, medical devices, other are not included in the stratification.

	Type of clinical trial											
	All clinical trials			Medicinal products			Medical devices			Other clinical trials		
Therapeutic area	N	$\%_{col}$	n_{rare}	N	$\%_{col}$	n_{rare}	N	$\%_{col}$	n_{rare}	N	$\%_{col}$	n_{rare}
Other	121	25.3	9	25	13.3	5	25	30.9	2	67	35.3	1
Cancer: Other	45	9.4	8	27	14.4	7	8	9.9	0	9	4.7	1
Nervous System diseases	36	7.5	12	15	8.0	10	7	8.6	1	13	6.8	1
Surgery	35	7.3	1	6	3.2	0	9	11.1	1	19	10.0	0
Musculoskeletal diseases (non cancer)	34	7.1	5	9	4.8	5	5	6.2	0	20	10.5	0
Cancer: Lung	26	5.4	1	17	9.0	1	4	4.9	0	4	2.1	0
Mental and Behavioural diseases	24	5.0	2	5	2.7	1	4	4.9	0	15	7.9	1
Respiratory diseases (non cancer)	24	5.0	1	15	8.0	1	3	3.7	0	6	3.2	0
Basic research (Anatomy/Physiology)	23	4.8	1	2	1.1	0	1	1.2	0	20	10.5	1
Skin and Connective Tissues diseases (non cancer)	22	4.6	9	16	8.5	8	2	2.5	0	2	1.1	1
Brain diseases (non cancer)	20	4.2	2	4	2.1	1	5	6.2	0	10	5.3	1
Coronary Heart disease	20	4.2	0	6	3.2	0	10	12.3	0	4	2.1	0
Arterial and venous diseases including deep venous thrombosis and lung embolism	19	4.0	0	5	2.7	0	9	11.1	0	4	2.1	0
Endocrinological diseases (non cancer)	18	3.8	4	8	4.3	3	2	2.5	0	6	3.2	1
Infections and Infestations	17	3.6	1	12	6.4	1	0	0	0	4	2.1	0
Nutritional and Metabolic diseases	17	3.6	2	5	2.7	2	2	2.5	0	10	5.3	0
Cancer: Head and Neck	14	2.9	0	9	4.8	0	1	1.2	0	3	1.6	0
Digestive Systems diseases (non cancer)	14	2.9	1	11	5.9	1	0	0	0	2	1.1	0
Injury	14	2.9	2	1	0.5	0	5	6.2	2	7	3.7	0
Cancer: Melanoma	13	2.7	0	10	5.3	0	0	0	0	2	1.1	0
Cancer: Prostate	12	2.5	0	5	2.7	0	1	1.2	0	6	3.2	0
Genetic disorders	11	2.3	8	9	4.8	6	1	1.2	1	1	0.5	1
Cancer: Breast	10	2.1	0	7	3.7	0	2	2.5	0	1	0.5	0
Cancer: Lymphoma	10	2.1	1	6	3.2	1	1	1.2	0	2	1.1	0
Eye diseases	10	2.1	1	3	1.6	0	4	4.9	0	2	1.1	1
Cancer: Leukemia	9	1.9	3	6	3.2	2	0	0	0	3	1.6	1
Cancer: Pancreatic	9	1.9	3	3	1.6	1	1	1.2	0	3	1.6	0
Periodontal diseases	8	1.7	0	0	0	0	4	4.9	0	3	1.6	0
Cancer: Colon and Rectal	7	1.5	0	5	2.7	0	1	1.2	0	1	0.5	0
Dementia and Alzheimer disease	7	1.5	0	2	1.1	0	2	2.5	0	3	1.6	0
Hematologic diseases (non cancer)	7	1.5	4	6	3.2	4	1	1.2	0	0	0	0
Urological and Genital diseases (non cancer)	7	1.5	1	3	1.6	1	2	2.5	0	2	1.1	0
Cancer: Bladder	6	1.3	0	4	2.1	0	0	0	0	2	1.1	0
Cancer: Kidney	6	1.3	0	3	1.6	0	1	1.2	0	2	1.1	0
Pregnancy and Childbirth	6	1.3	1	0	0	0	3	3.7	1	3	1.6	0
Cancer: Endometrial	5	1.0	0	4	2.1	0	0	0	0	1	0.5	0
Cancer: Non-Hodgkin Lymphoma	5	1.0	0	3	1.6	0	0	0	0	2	1.1	0
Neonatal diseases	3	0.6	1	1	0.5	1	0	0	0	2	1.1	0
Cancer: Thyroid	2	0.4	0	1	0.5	0	0	0	0	1	0.5	0
Ear, Nose, and Throat diseases (non cancer)	2	0.4	0	0	0	0	2	2.5	0	0	0	0
Occupational diseases	0	0	0	0	0	0	0	0	0	0	0	0
Total projects	478	146.0	62	188	100.0	48	81	100.0	4	190	100.0	7

Rare disease: A rare disease or orphan disease is defined as a disease or condition that affects fewer than 5 in 10'000 people and is life-threatening or chronically debilitating.

Total projects: The last line in the table denotes the total number of approved clinical trials (or the respective subgroup). Since multiple answers are possible, this number does not correspond to the sum in the table.

4.4.1.2 Primary area of research

Table 13: Overview on primary area of research for clinical trials - stratification by trial type. Data for the 19 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	254	53.1	129	68.6	37	45.7	73	38.4
Other	69	14.4	3	1.6	13	16.0	52	27.4
PK / PD / safety	56	11.7	50	26.6	0	0.0	5	2.6
Prevention	32	6.7	5	2.7	5	6.2	22	11.6
Rehabilitation	30	6.3	0	0.0	13	16.0	16	8.4
Diagnosis	25	5.2	0	0.0	5	6.2	20	10.5
Safety	8	1.7	0	0.0	7	8.6	0	0.0
Palliation	4	0.8	1	0.5	1	1.2	2	1.1
Total projects	478	100.0	188	100.0	81	100.0	190	100.0

4.4.2 Subgroups of "Clinical trials"

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

Phase: This question is only asked for drug and drug/device combination trials. Single choice field with allowed answers: "Phase 1", "Phase 1/2", "Phase 2", "Phase 3", "Phase 4", "n/a". During post-processing "Phase 1" and "Phase 1/2" were assigned to "Phase 1". n/a: Clinical trials for which the applicants have not indicated any phases or which do not fit in phase 1–4.

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

4.4.2.1 Subgroup "Clinical trials with medicinal products" (ClinO Art 19) and "Clinical trials with medical devices" (ClinO-MD Art 6)[1]

Table 14: Stratification of clinical trials with medicinal products, medical devices, or combination medicinal products/device by risk category, phase and whether 'first-in-human'.

				Phase											
		Total		1		2		3		4		n/a		first-in-human	
Type of clinical trial	Risk category	n	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Medicinal products	A	17	6.1			2	11.8	2	11.8	6	35.3	7	41.2		
	B	26	9.3	3	11.5	6	23.1	13	50.0	2	7.7	2	7.7	1	3.8
	C	145	52.0	29	20.0	41	28.3	72	49.7	2	1.4	1	0.7	14	9.7
	All	188	67.4	32	17.0	49	26.1	87	46.3	10	5.3	10	5.3	15	8.0
Medical devices	A1	47	16.8	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a		
	A2	3	1.1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a		
	C1	8	2.9	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	1	12.5
	C2	23	8.2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	8	34.8
	All	81	29.0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	9	11.1
Combination medicinal products/devices	A1	1	0.4												
	A2	1	0.4												
	C	4	1.4	1	25.0	2	50.0	1	25.0						
	C1	1	0.4												
	C2	3	1.1											1	33.3
	All	10	3.6	1	10.0	2	20.0	1	10.0					1	10.0
	Total number	279	100.0	33	11.8	51	18.3	88	31.5	10	3.6	10	3.6	25	9.0

n/a: 'Phase' is not applicable to clinical trials involving medical devices.

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

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

Table 15: 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	275	42.3	267	97.1	8	2.9	209	76	27	9.8	39	14.2	10	3.6	265	96.4
Registry / Quality control[1]	37	5.7	35	94.6	2	5.4	21	56.8	4	10.8	12	32.4	3	8.1	34	91.9
Case control study	59	9.1	58	98.3	1	1.7	45	76.3	9	15.3	5	8.5	1	1.7	58	98.3
Other or n/a	279	42.9	274	98.2	5	1.8	229	82.1	25	9.0	25	9.0	18	6.5	261	93.5
Total number	650	100.0	634	97.5	16	2.5	504	77.5	65	10.0	81	12.5	32	4.9	618	95.1

1 Only quality control studies under the HRA.

Table 16: 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	158	24.3	71	25.8	10	27	15	25.4	62	22.2
Basic science	136	20.9	59	21.5	3	8.1	14	23.7	60	21.5
Psychology	57	8.8	13	4.7	0	0.0	12	20.3	32	11.5
Qualitative research	56	8.6	11	4.0	5	13.5	1	1.7	39	14.0
Healthcare services research	47	7.2	21	7.6	4	10.8	2	3.4	20	7.2
Physiology/anatomy	45	6.9	25	9.1	1	2.7	3	5.1	16	5.7
Surgery	44	6.8	22	8.0	6	16.2	5	8.5	11	3.9
Medical devices	34	5.2	17	6.2	6	16.2	0	0.0	11	3.9
Drugs	33	5.1	15	5.5	0	0.0	3	5.1	15	5.4
Epidemiology	31	4.8	19	6.9	2	5.4	2	3.4	8	2.9
Dentistry	9	1.4	2	0.7	0	0.0	2	3.4	5	1.8
Total projects	650	100.0	275	100.0	37	100.0	59	100.0	279	100.0

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

The projects are stratified based on the following 3 questions:

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

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

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

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

Applicants are informed that if they have an informed consent from before enactment of the HRA (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 17: Overview of characteristics of all approved 'further use' projects.

		n	$\%_{col}$
Genetic data/biol. material	Yes	252	21.9
	No	900	78.1
Coding (HRO Art. 25–27)	Coded	1063	92.3
	Open, non-coded	89	7.7
Consent (HRO Art. 28–32)	Consent for all data	673	58.4
	Consent for some but not all data (partially Art. 34 HRA)	370	32.1
	No consent for all data, Art. 34 HRA	109	9.5
Combined vs. stand-alone projects	Stand-alone further use project	961	83.4
	Further use project as part of a clinical trial	40	3.5
	Further use project as part of a non-clinical research project	151	13.1
Total number		1152	100.0

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

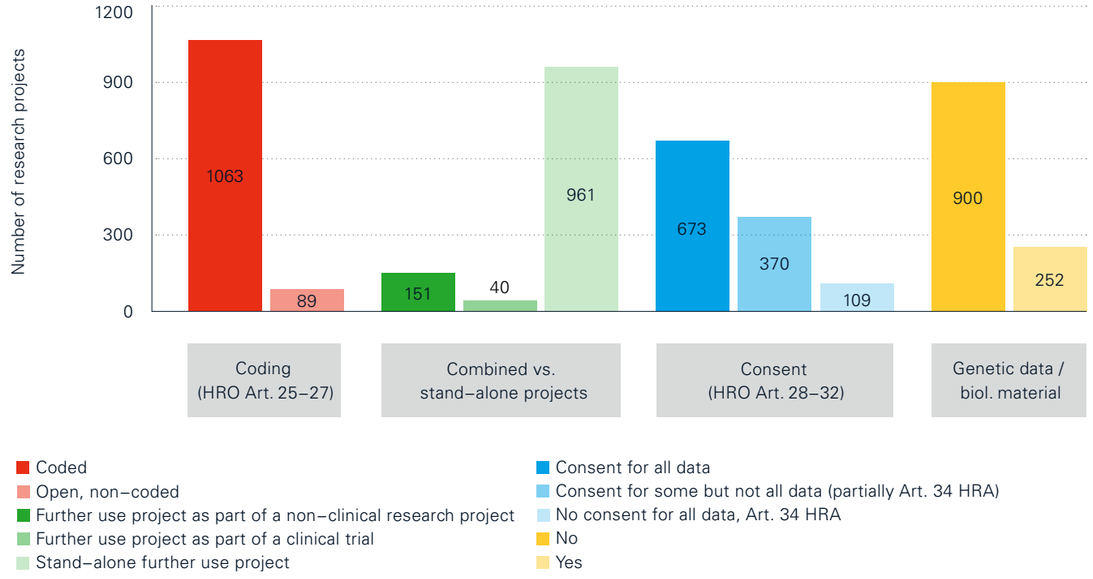


Table 18: Stratification of **projects involving further use of data/biological material** by study design and initiator.
All combinations of the following three factors are shown: 1) Use of genetic data and/or biological material (Genetic D+M), 2) coded vs. uncoded, 3) consent for further use.

					Study design						Initiator			
			Total		Mono		Multi CH		Multi Int.		Industry		Investigator	
Genetic D+M	Coded	Consent	n	$\%_{col}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$	n	$\%_{row}$
Yes	Coded	Consent for all data	180	74.1	130	72.2	11	6.1	39	21.7	44	24.4	136	75.6
		Consent for some but not all data (partially Art. 34 HRA)	58	23.9	44	75.9	6	10.3	8	13.8	3	5.2	55	94.8
		No consent for all data, Art. 34 HRA	5	2.1	4	80.0	1	20.0					5	100.0
		All	243	100.0	178	73.3	18	7.4	47	19.3	47	19.3	196	80.7
	Open, non-coded	Consent for all data	6	66.7	4	66.7	1	16.7	1	16.7	1	16.7	5	83.3
		Consent for some but not all data (partially Art. 34 HRA)	1	11.1	1	100.0							1	100.0
		No consent for all data, Art. 34 HRA	2	22.2	2	100.0							2	100.0
		All	9	100.0	7	77.8	1	11.1	1	11.1	1	11.1	8	88.9
	All		252	100.0	185	73.4	19	7.5	48	19.0	48	19.0	204	81.0
No	Coded	Consent for all data	429	52.3	331	77.2	29	6.8	69	16.1	20	4.7	409	95.3
		Consent for some but not all data (partially Art. 34 HRA)	299	36.5	235	78.6	27	9.0	37	12.4	1	0.3	298	99.7
		No consent for all data, Art. 34 HRA	92	11.2	78	84.8	7	7.6	7	7.6	1	1.1	91	98.9
		All	820	100.0	644	78.5	63	7.7	113	13.8	22	2.7	798	97.3
	Open, non-coded	Consent for all data	58	72.5	52	89.7	2	3.4	4	6.9	1	1.7	57	98.3
		Consent for some but not all data (partially Art. 34 HRA)	12	15.0	11	91.7	1	8.3					12	100.0
		No consent for all data, Art. 34 HRA	10	12.5	9	90.0			1	10.0			10	100.0
		All	80	100.0	72	90.0	3	3.8	5	6.2	1	1.2	79	98.8
	All		900	100.0	716	79.6	66	7.3	118	13.1	23	2.6	877	97.4
Total number			1152	100.0	901	78.2	85	7.4	166	14.4	71	6.2	1081	93.8

1 Multiple selection possible.
The total number of 1152 research projects consist of 961 standard 'further use' projects and 191 ClinO or research with persons (HRO) projects that include further use of data/biological material.

Table 19: 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	673	58.4	199	71.3	141	50.2	88	53.3	134	66.0	50	44.2	36	58.1	25	51.0
Consent for some but not all data (partially Art. 34 HRA)	370	32.1	64	22.9	117	41.6	68	41.2	59	29.1	27	23.9	18	29.0	17	34.7
No consent for all data, Art. 34 HRA	109	9.5	16	5.7	23	8.2	9	5.5	10	4.9	36	31.9	8	12.9	7	14.3
Total number	1152	100.0	279	100.0	281	100.0	165	100.0	203	100.0	113	100.0	62	100.0	49	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 20: Answers to the question "Who initiated the project?" stratified by the main financing source. The researchers are asked to 'indicate here who had the original idea for the research project (do not indicate here who is financing, conducting or leading the project)'.

Initiator	Financing (main source)	n	$\%_{col}$
Investigator	Public, other	1435	82.1
	Industry	69[1]	3.9
	Universities/hospitals	95	5.4
	Private (non-industry)	118	6.8
	Swiss National Science Foundation	31	1.8
	All	1748	100.0
Industry	Public, other	67[2]	24.1
	Industry	209[3]	75.2
	Universities/hospitals	0	0.0
	Private (non-industry)	2	0.7
	Swiss National Science Foundation	0	0.0
	All	278	100.0
Other	Public, other	72	79.1
	Industry	4	4.4
	Universities/hospitals	6	6.6
	Private (non-industry)	9	9.9
	Swiss National Science Foundation	0	0.0
	All	91[4]	100.0

1 Applicants almost exclusively from academic institutions.

2 Inspecting the sponsor information reveals that these are almost exclusively industry projects.

3 206 of the industry-initiated projects are financed exclusively by industry.

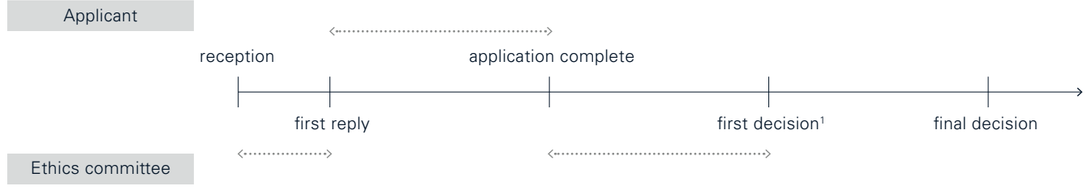
4 24 of these projects initiated by others are projects solely or principally designed to obtain a degree (the tutor is the initiator). Apart from that, these projects are quite heterogenous.

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 21: 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	54	12	7	[7,8]	7	[7,8]	34	[30,41]	94	[83,128]	26	[22,34]	87	[76,122]
	EKNZ	49	10	3	[1,5]	4	[1,6]	33	[23,40]	79	[60,131]	27	[20,35]	76	[56,127]
	CER-VD	31	9	4	[2,6]	5	[3,7]	27	[25,32]	153	[113,196]	20	[16,23]	147	[109,189]
	KEK-BE	56	16	6	[3,6]	7	[6,21]	31	[27,51]	168	[113,263]	20	[19,23]	161	[103,209]
	CCER	19	9	5	[2,7]	7	[4,12]	34	[25,42]	97	[82,126]	21	[20,34]	95	[74,113]
	EKOS	17	17	3	[2,5]	3	[2,6]	25	[21,38]	93	[78,102]	24	[17,32]	90	[72,99]
	CE-TI	97	97	7	[7,7]	7	[7,7]	33	[24,39]	63	[41,95]	24	[16,28]	53	[28,84]
	All	323	16	6	[4,7]	7	[5,8]	32	[25,41]	96	[64,155]	23	[18,29]	88	[57,140]
Simplified	KEK-ZH	264	57	7	[7,8]	7	[7,8]	42	[36,48]	80	[60,114]	34	[28,39]	72	[51,106]
	EKNZ	325	69	2	[1,5]	4	[1,7]	21	[14,27]	50	[33,79]	15	[9,20]	43	[27,74]
	CER-VD	229	68	4	[2,6]	6	[4,11]	24	[20,30]	84	[55,139]	16	[14,19]	69	[45,112]
	KEK-BE	297	84	4	[1,6]	7	[5,15]	27	[21,40]	79	[49,134]	16	[14,21]	66	[41,118]
	CCER	160	77	3	[2,5]	6	[3,11]	28	[24,34]	86	[56,140]	21	[19,26]	77	[47,133]
	EKOS	57	56	2	[1,4]	4	[2,10]	12	[7,23]	22	[9,58]	6	[3,12]	13	[5,35]
	CE-TI	3	3	2	[2,3]	2	[2,4]	28	[15,32]	28	[15,199]	21	[10,28]	21	[10,195]
	All	1335	66	4	[2,7]	7	[3,9]	27	[20,40]	70	[45,119]	19	[14,27]	62	[38,104]
Presidential	KEK-ZH	142	31	7	[7,8]	7	[7,8]	39	[35,43]	64	[44,91]	31	[27,35]	55	[36,81]
	EKNZ	97	21	2	[1,5]	3	[1,7]	7	[5,11]	21	[9,42]	3	[1,6]	18	[6,35]
	CER-VD	77	23	4	[2,6]	5	[3,7]	14	[10,26]	41	[20,70]	9	[6,13]	29	[11,56]
	KEK-BE	0	0												
	CCER	30	14	4	[2,8]	10	[5,16]	14	[11,32]	14	[11,32]	4	[3,12]	4	[3,14]
	EKOS	28	27	2	[1,3]	2	[1,3]	6	[4,9]	8	[4,29]	3	[2,7]	4	[3,14]
	CE-TI	0	0												
	All	374	18	5	[2,7]	7	[3,8]	22	[8,39]	40	[15,76]	11	[4,29]	32	[9,63]
Overall	KEK-ZH	460	100	7	[7,8]	7	[7,8]	40	[35,45]	78	[56,111]	32	[27,37]	70	[46,102]
	EKNZ	471	100	2	[1,5]	4	[1,7]	20	[11,28]	48	[28,82]	14	[6,20]	41	[22,76]
	CER-VD	337	100	4	[2,6]	6	[3,10]	23	[17,29]	77	[46,139]	15	[12,19]	63	[38,112]
	KEK-BE	353	100	4	[2,6]	7	[6,15]	28	[21,41]	93	[54,166]	18	[14,21]	80	[43,141]
	CCER	209	100	3	[2,6]	6	[3,12]	28	[22,35]	77	[48,133]	21	[16,26]	70	[39,118]
	EKOS	102	100	2	[1,4]	3	[2,6]	12	[6,25]	28	[8,74]	6	[3,14]	14	[3,63]
	CE-TI	100	100	7	[7,7]	7	[7,7]	32	[24,39]	62	[40,96]	24	[16,28]	52	[27,84]
	All	2032	100	5	[2,7]	7	[4,8]	28	[19,40]	69	[41,116]	19	[13,28]	60	[34,102]

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).
The violin plots distinguish between mono- and multicentric studies.

Figure 4: Violin plot of the time between status 'complete' to the first decision by EC. 32 projects with t > 60 days are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 24.1.

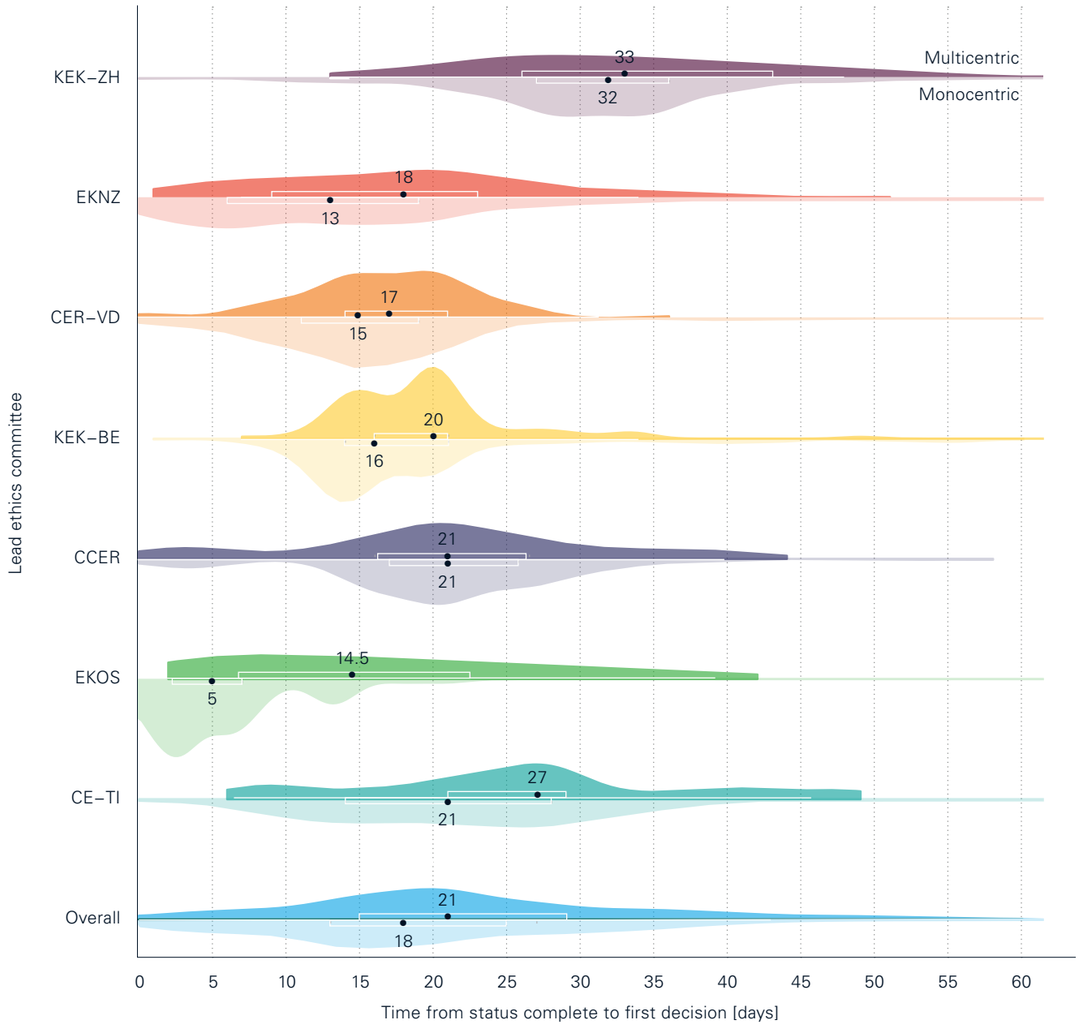
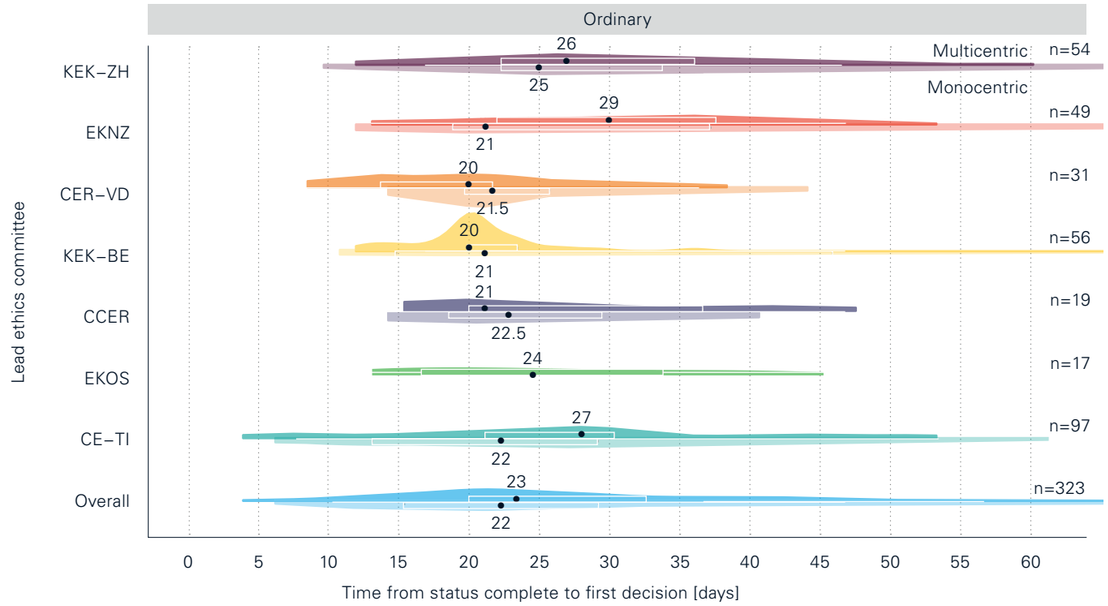
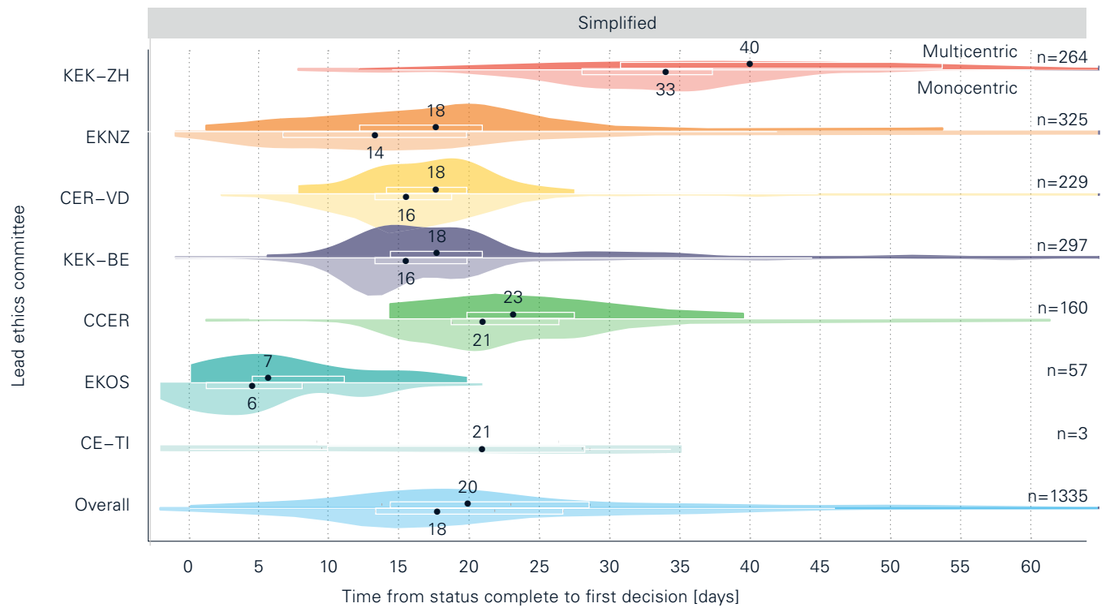
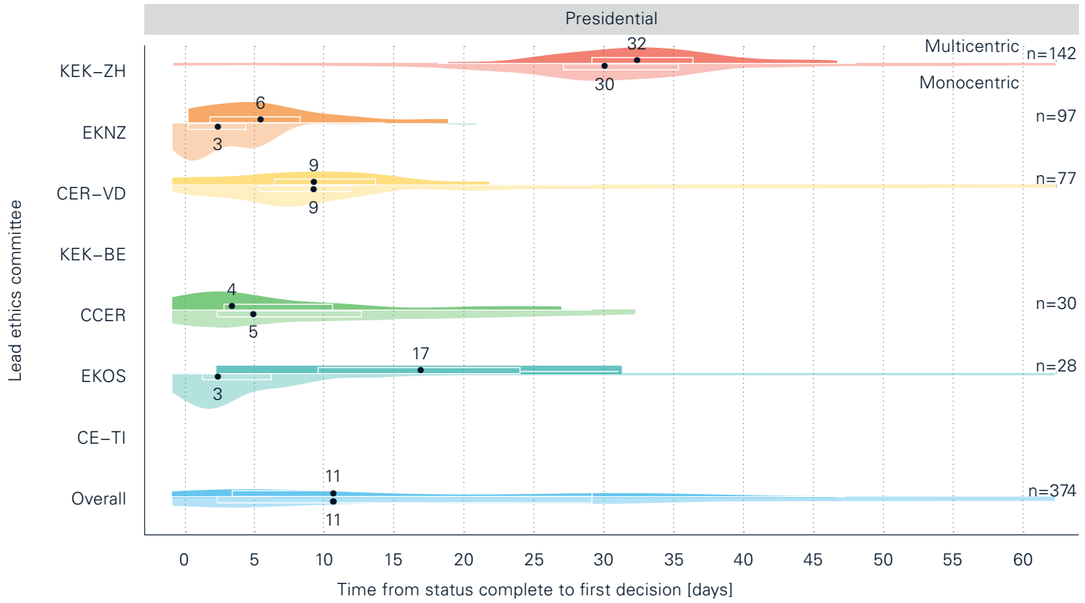


Figure 5: Violin plot of the time between status 'complete' to the first decision by EC and stratified by review procedure. 55 projects with t > 60 days are not shown for layout reasons.
Note: *CE-TI* typically processes all submissions in a plenary session (ordinary procedure) but with adapted fees. ClinO-MD projects are not included but separately displayed in table 24.1.







5.3.2 Time from reception to final decision

Figure 6: Violin plot of the overall approval time by EC from reception to final decision. 57 projects with approval time > 1 year are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 24.1.

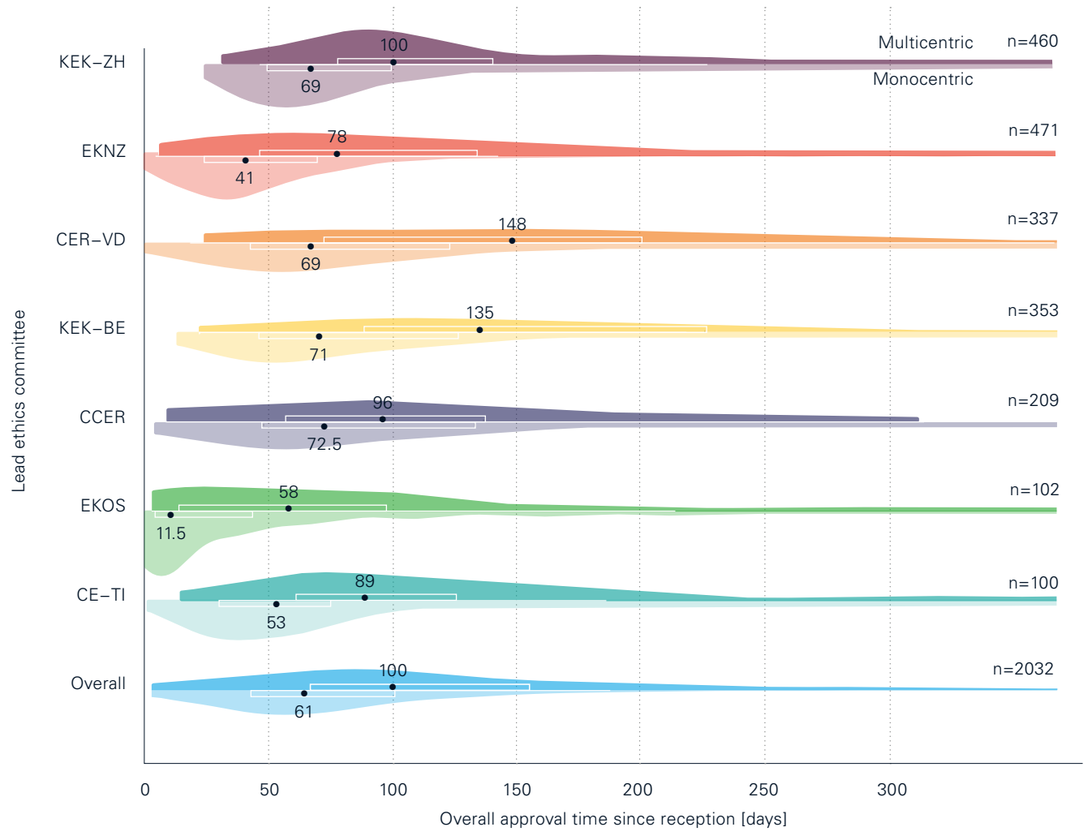
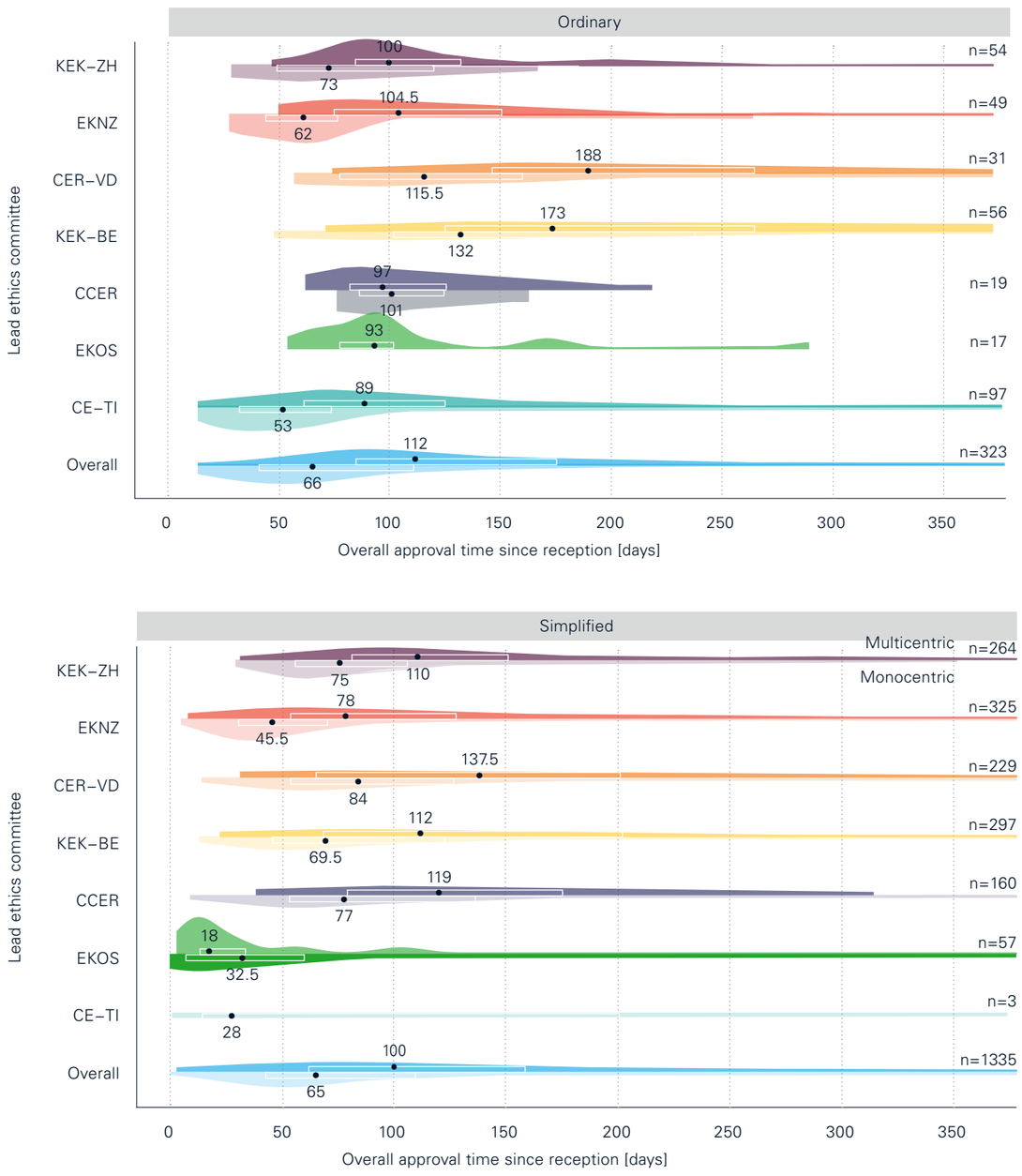
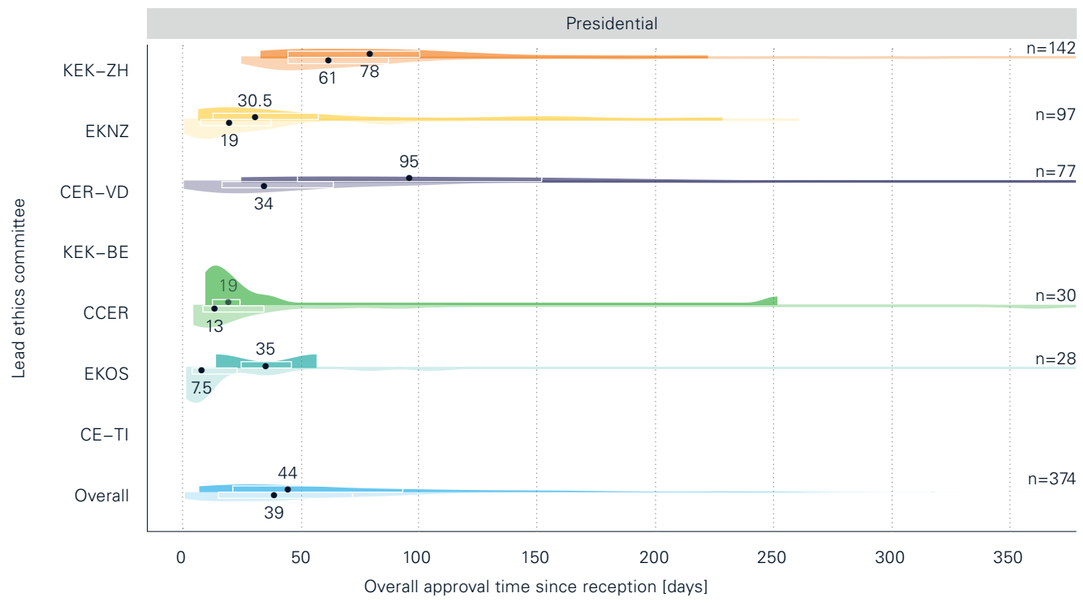


Figure 7: Violin plot of the overall approval time by EC from reception to final decision and stratified by review procedure. 92 projects with approval time > 1 year are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 24.1.





5.4 Stratification of response time by type of research

Table 22: 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	105	26.7	7.0	[7,8]	7.0	[7,8]	38.0	[33,44]	88.0	[71,117]	30.0	[25,36]	81.0	[62,109]
	EKNZ	85	21.6	3.0	[1,5]	4.0	[1,6]	28.0	[21,35]	68.0	[42,112]	21.0	[18,31]	64.0	[40,111]
	CER-VD	42	10.7	4.0	[2.2,6]	6.0	[4,7]	25.0	[21,30.8]	152.5	[109,203.5]	18.0	[15,21]	135.5	[103.5,189]
	KEK-BE	79	20.1	5.0	[3,6]	7.0	[6,17.5]	28.0	[23.5,40]	137.0	[92,212]	20.0	[14.5,22]	130.0	[85,185]
	CCER	29	7.4	4.0	[3,7]	6.0	[4,12]	32.0	[24,41]	95.0	[73,144]	21.0	[17,27]	90.0	[67,139]
	EKOS	25	6.4	3.0	[2,6]	4.0	[2,6]	25.0	[18,37]	86.0	[58,100]	21.0	[13,30]	80.0	[52,97]
	CE-TI	28	7.1	7.0	[7,7]	7.0	[7,8]	34.5	[28.5,44]	75.0	[64,106.5]	27.0	[19.5,30.2]	68.5	[56.8,91.2]
	All	393	100.0	6.0	[3,7]	7.0	[5,8]	32.0	[25,41]	95.0	[66,154]	22.0	[18,31]	88.0	[58,140]
Research w/persons	KEK-ZH	119	18.3	7.0	[7,8]	7.0	[7,8]	41.0	[36,47]	92.0	[64,120]	34.0	[28,39]	85.0	[57,111]
	EKNZ	142	21.9	2.0	[1,5]	3.5	[1,6]	23.0	[19,29]	60.5	[40.2,100.8]	19.0	[14,21.8]	54.5	[36.2,91.5]
	CER-VD	148	22.8	4.0	[2,6]	7.0	[4,12]	24.5	[20,32.5]	88.5	[62.8,147]	16.5	[14,19]	76.5	[51.8,116.5]
	KEK-BE	104	16.0	4.0	[1.8,6]	7.0	[4,16.2]	27.5	[20,42.2]	91.0	[58.8,162.2]	18.0	[14,21]	77.0	[48.8,124.8]
	CCER	82	12.6	3.0	[2,5]	6.0	[4,11]	28.5	[23.2,33]	77.5	[53.2,129]	21.0	[19,25]	68.5	[44.5,115.5]
	EKOS	22	3.4	2.0	[1,4]	4.0	[2,10.8]	15.5	[10,24.2]	36.5	[18.8,65.2]	8.0	[6,13.8]	29.0	[15.5,60.2]
	CE-TI	33	5.1	7.0	[7,7]	7.0	[7,7]	32.0	[23,39]	53.0	[38,98]	24.0	[16,28]	43.0	[28,84]
	All	650	100.0	5.0	[2,7]	7.0	[4,10]	28.0	[21,40]	79.0	[52,123]	20.0	[15,27]	68.5	[43.2,109]
Further use	KEK-ZH	220	22.9	7.0	[7,8]	7.0	[7,8]	40.0	[35,44.2]	68.5	[48,96.2]	32.0	[27,36]	60.0	[39,85]
	EKNZ	240	25.0	2.0	[1,5]	4.0	[1,7]	12.0	[7,20]	33.0	[15.8,61]	7.0	[3,12]	26.0	[12,52.5]
	CER-VD	147	15.3	3.0	[1,5]	5.0	[3,8]	20.0	[13,28]	52.0	[29,90.5]	13.0	[8.5,18]	41.0	[22,70]
	KEK-BE	165	17.2	4.0	[1,6]	7.0	[6,14]	27.0	[21,40]	68.0	[43,132]	16.0	[14,21]	56.0	[35,118]
	CCER	96	10.0	3.5	[2,6]	7.0	[3,14]	27.5	[19,35]	71.5	[26.5,138]	20.5	[13.8,26.2]	58.5	[14,115.8]
	EKOS	54	5.6	2.0	[1,3]	3.0	[1,4.8]	8.0	[4.2,13.8]	9.0	[5,29.2]	3.0	[2,6.8]	5.0	[3,11]
	CE-TI	39	4.1	7.0	[6,7]	7.0	[6.5,7]	31.0	[23,35.5]	55.0	[34.5,80.5]	22.0	[14.5,27]	44.0	[20.5,69.5]
	All	961	100.0	5.0	[2,7]	7.0	[3,8]	25.0	[14,38]	54.0	[30,93]	16.0	[8,27]	43.0	[21,80]
Deceased and embryos from stillbirths or abortion	KEK-ZH	16	57.1	7.0	[7,8]	7.0	[7,8]	37.5	[33.8,40]	47.0	[37.5,60]	30.5	[26,32.5]	40.0	[30.8,53]
	EKNZ	4	14.3	3.0	[2.2,3.5]	3.0	[2.2,3.5]	21.0	[19.5,22.2]	28.5	[25,34.5]	18.5	[17.2,19.2]	26.0	[24.2,30]
	CER-VD	0	0.0												
	KEK-BE	5	17.9	6.0	[3,6]	6.0	[6,11]	25.0	[25,61]	42.0	[36,94]	14.0	[10,55]	31.0	[21,88]
	CCER	2	7.1	2.5	[1.8,3.2]	7.5	[5.8,9.2]	25.5	[24.8,26.2]	42.5	[33.2,51.8]	18.0	[17,19]	35.0	[27.5,42.5]
	EKOS	1	3.6	1.0	[1,1]	1.0	[1,1]	7.0	[7,7]	7.0	[7,7]	6.0	[6,6]	6.0	[6,6]
	CE-TI	0	0.0												
	All	28	100.0	7.0	[3.8,7]	7.0	[5.8,8]	33.5	[23,40.5]	42.0	[32.5,59.5]	26.0	[16,32]	33.0	[26,50.5]
Overall	KEK-ZH	460	100.0	7.0	[7,8]	7.0	[7,8]	40.0	[35,45]	78.0	[56,111.2]	32.0	[27,37]	70.0	[46,102.2]
	EKNZ	471	100.0	2.0	[1,5]	4.0	[1,7]	20.0	[11,27.5]	48.0	[28,82]	14.0	[6,20]	41.0	[22,76]
	CER-VD	337	100.0	4.0	[2,6]	6.0	[3,10]	23.0	[17,29]	77.0	[46,139]	15.0	[12,19]	63.0	[38,112]
	KEK-BE	353	100.0	4.0	[2,6]	7.0	[6,15]	28.0	[21,41]	93.0	[54,166]	18.0	[14,21]	80.0	[43,141]
	CCER	209	100.0	3.0	[2,6]	6.0	[3,12]	28.0	[22,35]	77.0	[48,133]	21.0	[16,26]	70.0	[39,118]
	EKOS	102	100.0	2.0	[1,3.8]	3.0	[2,6]	11.5	[6,25]	27.5	[8,74.5]	6.5	[3,14]	14.0	[3.2,63]
	CE-TI	100	100.0	7.0	[7,7]	7.0	[7,7]	32.5	[23.8,39]	62.5	[40.5,95.8]	24.0	[15.8,28]	52.5	[27,84]
	All	2032	100.0	5.0	[2,7]	7.0	[4,8]	28.0	[19,40]	69.0	[41,116]	19.0	[13,28]	60.0	[34,102]

Table 23: 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	127	6	[3,7]	266	5	[3,7]
	from receipt to status 'complete'	127	7	[5,8]	266	7	[4,8]
	from receipt to first decision	127	33	[27,43]	266	31	[23,40]
	from receipt to final decision	127	112	[87,174]	266	83	[58,140]
	from 'complete' to first decision	127	25	[20,34]	266	21	[16,29]
	from 'complete' to final decision	127	105	[81,164]	266	76	[52,128]
Research w/persons	from receipt to first reply	75	5	[2,7]	575	5	[2,7]
	from receipt to status 'complete'	75	7	[4,12]	575	7	[4,9]
	from receipt to first decision	75	32	[22,54]	575	28	[21,40]
	from receipt to final decision	75	112	[75,164]	575	76	[49,118]
	from 'complete' to first decision	75	21	[16,28]	575	19	[15,26]
	from 'complete' to final decision	75	98	[64,154]	575	64	[43,101]
Further use	from receipt to first reply	66	4	[2,7]	895	5	[2,7]
	from receipt to status 'complete'	66	7	[4,11]	895	7	[3,8]
	from receipt to first decision	66	28	[18,47]	895	25	[13,38]
	from receipt to final decision	66	94	[48,158]	895	52	[28,90]
	from 'complete' to first decision	66	19	[12,32]	895	15	[7,27]
	from 'complete' to final decision	66	78	[36,127]	895	42	[21,76]
Deceased persons	from receipt to first reply				28	7	[4,7]
	from receipt to status 'complete'				28	7	[6,8]
	from receipt to first decision				28	34	[23,40]
	from receipt to final decision				28	42	[32,60]
	from 'complete' to first decision				28	26	[16,32]
	from 'complete' to final decision				28	33	[26,50]
Overall	from receipt to first reply	268	5	[2,7]	1764	5	[2,7]
	from receipt to status 'complete'	268	7	[4,8]	1764	7	[3,8]
	from receipt to first decision	268	33	[23,48]	1764	27	[19,39]
	from receipt to final decision	268	110	[77,168]	1764	64	[39,109]
	from 'complete' to first decision	268	22	[17,34]	1764	19	[13,27]
	from 'complete' to final decision	268	98	[69,151]	1764	56	[31,92]

Table 24: 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.

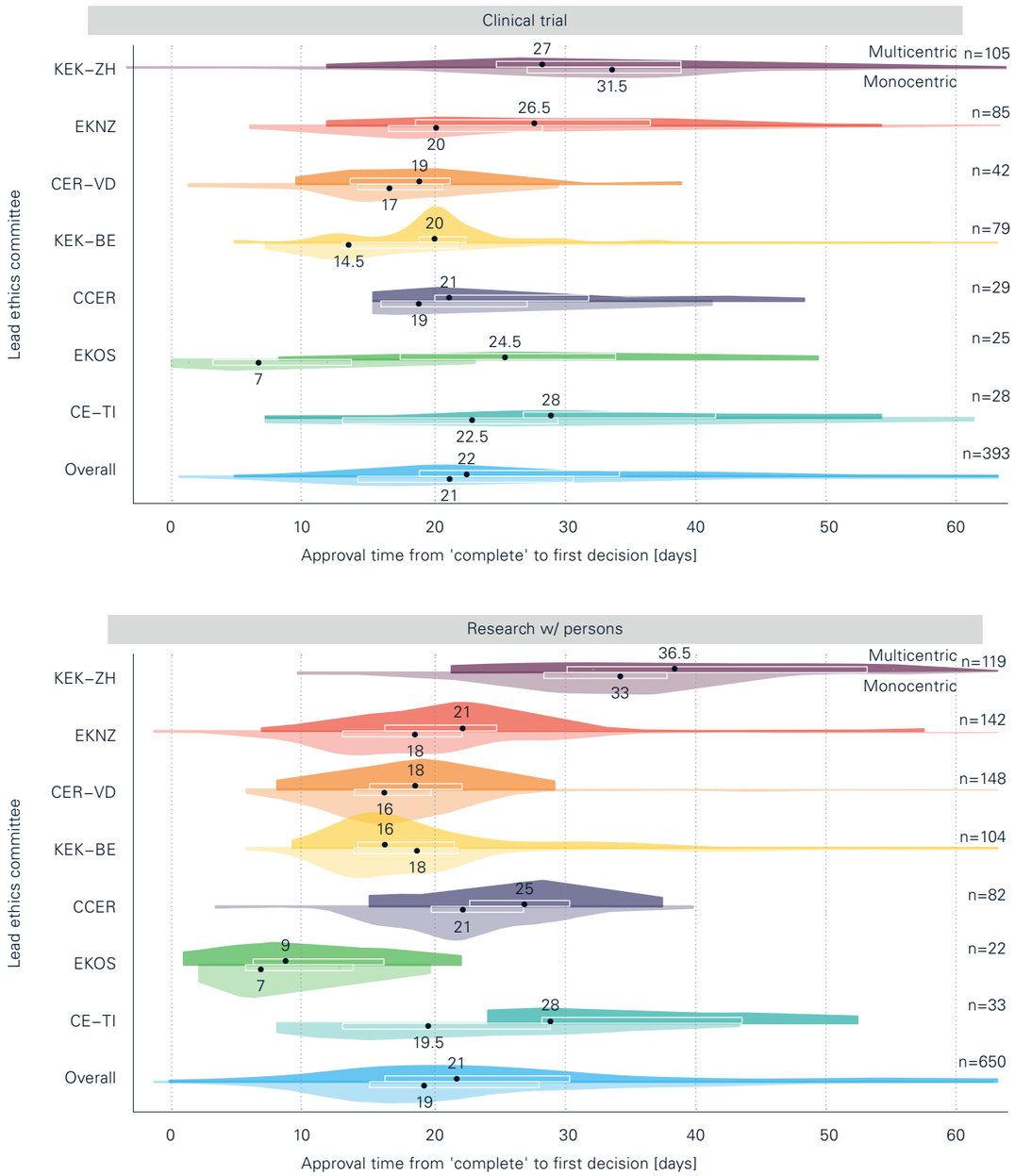
		Application involves					
		Multiple ECs			Single EC		
Lead EC	Time interval	n	Median	IQR	n	Median	IQR
KEK-ZH	from receipt to first reply	69	7	[7,8]	391	7	[7,8]
	from receipt to status 'complete'	69	7	[7,8]	391	7	[7,8]
	from receipt to first decision	69	43	[34,54]	391	39	[35,44]
	from receipt to final decision	69	103	[88,141]	391	73	[52,106]
	from 'complete' to first decision	69	36	[27,47]	391	31	[27,36]
	from 'complete' to final decision	69	95	[81,134]	391	64	[44,98]
EKNZ	from receipt to first reply	59	2	[1,5]	412	2	[1,5]
	from receipt to status 'complete'	59	4	[1,6]	412	3	[1,7]
	from receipt to first decision	59	26	[20,34]	412	19	[10,27]
	from receipt to final decision	59	100	[68,149]	412	42	[26,72]
	from 'complete' to first decision	59	21	[14,26]	412	13	[6,19]
	from 'complete' to final decision	59	93	[60,135]	412	36	[21,64]
CER-VD	from receipt to first reply	27	3	[1,6]	310	4	[2,6]
	from receipt to status 'complete'	27	7	[3,29]	310	6	[3,10]
	from receipt to first decision	27	28	[22,46]	310	23	[17,29]
	from receipt to final decision	27	152	[93,216]	310	75	[45,124]
	from 'complete' to first decision	27	18	[15,21]	310	15	[11,19]
	from 'complete' to final decision	27	139	[64,195]	310	62	[37,102]
KEK-BE	from receipt to first reply	55	5	[3,6]	298	4	[2,6]
	from receipt to status 'complete'	55	7	[6,18]	298	7	[6,15]
	from receipt to first decision	55	29	[24,45]	298	27	[21,41]
	from receipt to final decision	55	136	[98,222]	298	83	[49,150]
	from 'complete' to first decision	55	20	[17,24]	298	16	[14,21]
	from 'complete' to final decision	55	129	[89,206]	298	69	[42,127]
CCER	from receipt to first reply	19	5	[1,6]	190	3	[2,6]
	from receipt to status 'complete'	19	5	[5,10]	190	6	[3,12]
	from receipt to first decision	19	33	[25,44]	190	28	[22,34]
	from receipt to final decision	19	111	[78,177]	190	74	[46,133]
	from 'complete' to first decision	19	23	[20,28]	190	21	[16,25]
	from 'complete' to final decision	19	90	[74,136]	190	64	[36,116]
EKOS	from receipt to first reply	26	3	[2,5]	76	2	[1,3]
	from receipt to status 'complete'	26	4	[2,7]	76	3	[1,5]
	from receipt to first decision	26	24	[16,38]	76	8	[6,16]
	from receipt to final decision	26	88	[24,101]	76	14	[7,53]
	from 'complete' to first decision	26	18	[12,27]	76	6	[3,8]
	from 'complete' to final decision	26	76	[22,92]	76	8	[3,35]
CE-TI	from receipt to first reply	13	7	[7,7]	87	7	[7,7]
	from receipt to status 'complete'	13	7	[7,10]	87	7	[7,7]
	from receipt to first decision	13	43	[29,55]	87	32	[24,36]
	from receipt to final decision	13	123	[64,168]	87	57	[36,88]

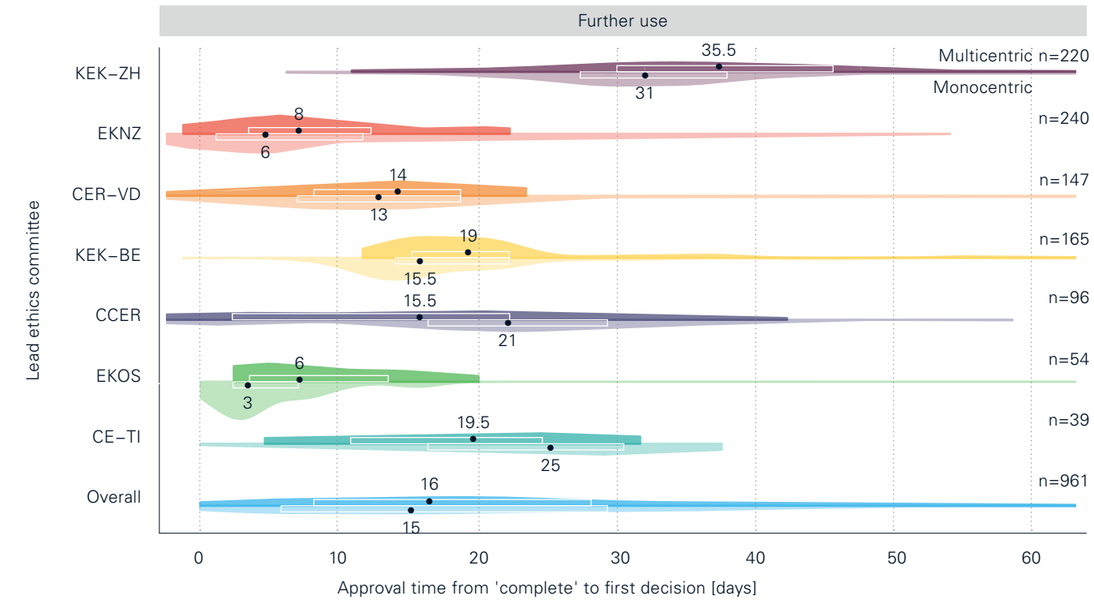
	from 'complete' to first decision	13	24	[16,42]	87	24	[15,28]
	from 'complete' to final decision	13	91	[52,116]	87	49	[26,80]
Overall	from receipt to first reply	268	5	[2,7]	1764	5	[2,7]
	from receipt to status 'complete'	268	7	[4,8]	1764	7	[3,8]
	from receipt to first decision	268	33	[23,48]	1764	27	[19,39]
	from receipt to final decision	268	110	[77,168]	1764	64	[39,109]
	from 'complete' to first decision	268	22	[17,34]	1764	19	[13,27]
	from 'complete' to final decision	268	98	[69,151]	1764	56	[31,92]

5.4.1 Time from status "complete" to first decision

Figure 8: Violin plot of the **approval time starting from status 'complete' to the first decision** per type of research (only the 3 major groups are shown). 32 projects with approval time > 60 days are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 24.1.

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. 55 projects with approval time > 60 days are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 24.1.





5.4.2 Time from reception to final decision

Figure 10: Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown). 57 projects with an overall approval time > 1 year are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 24.1.

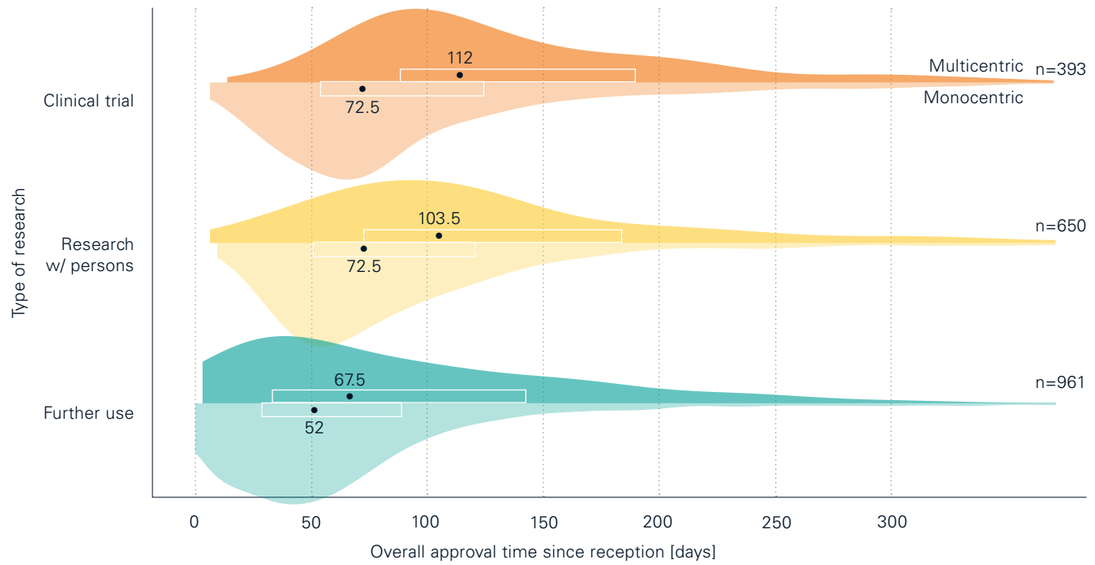
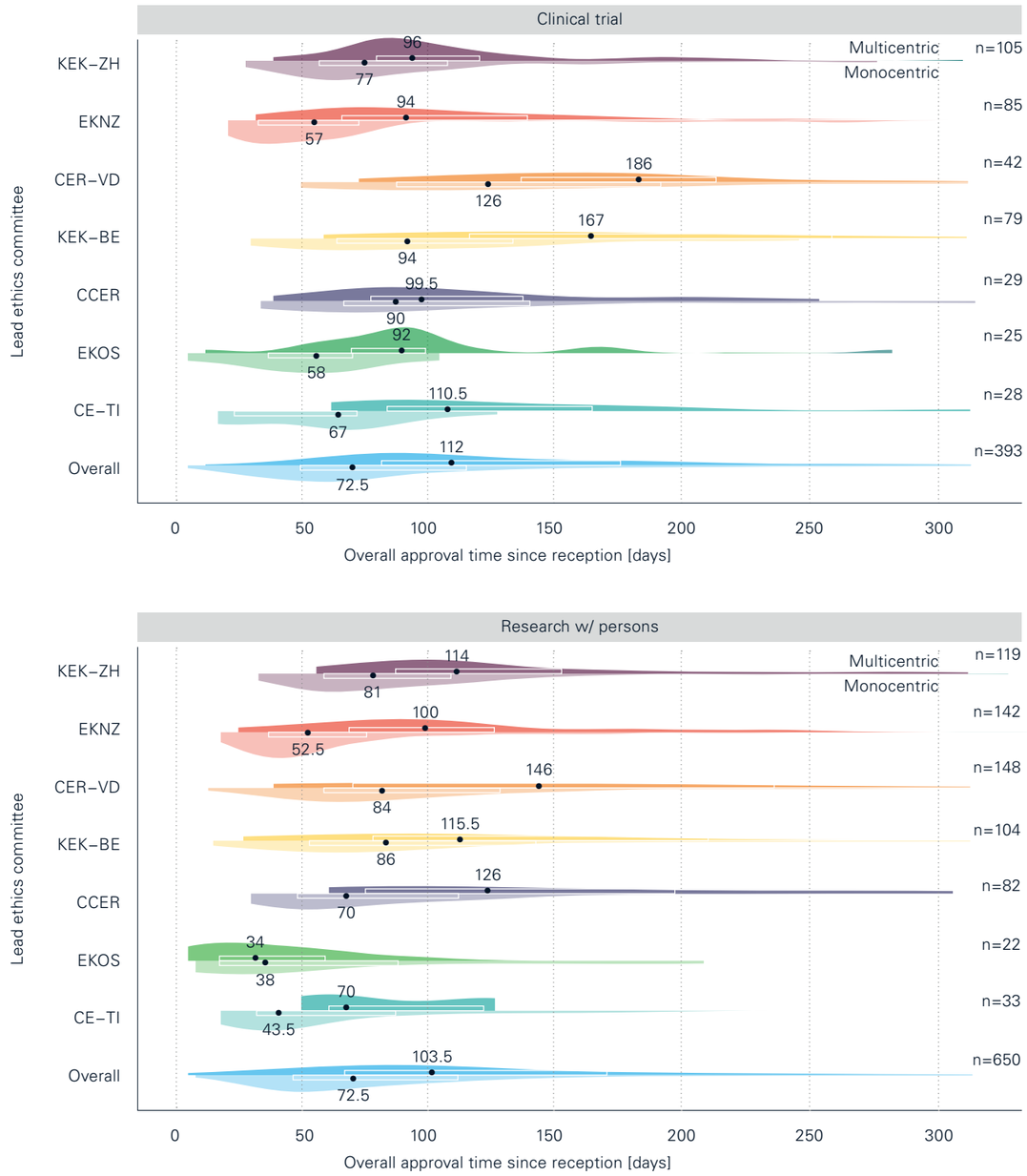
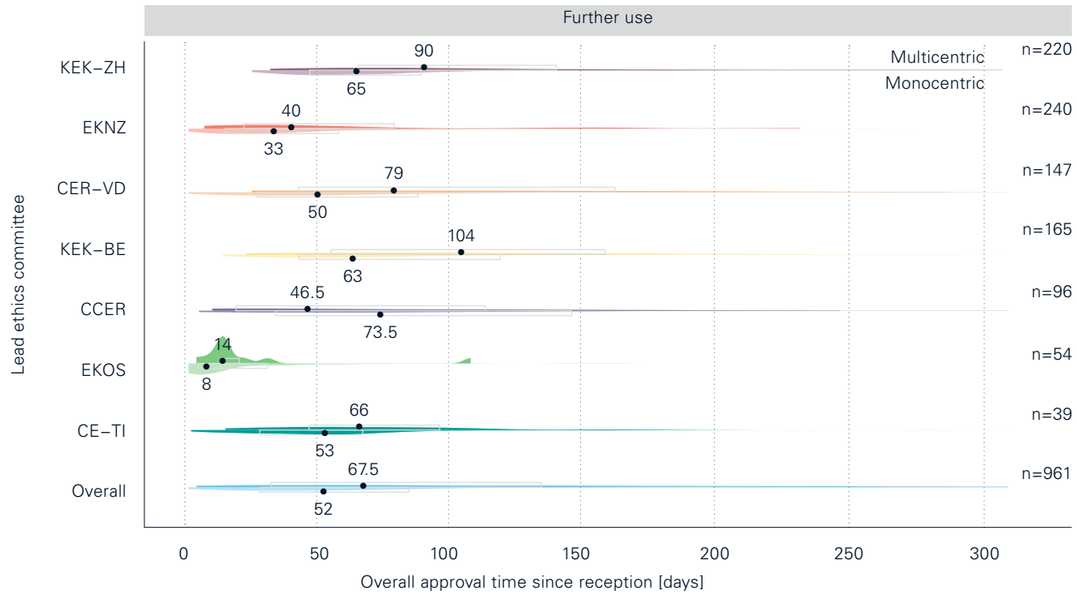


Figure 11: Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown) stratified by EC. 92 projects with an overall approval time > 1 year are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 24.1.





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

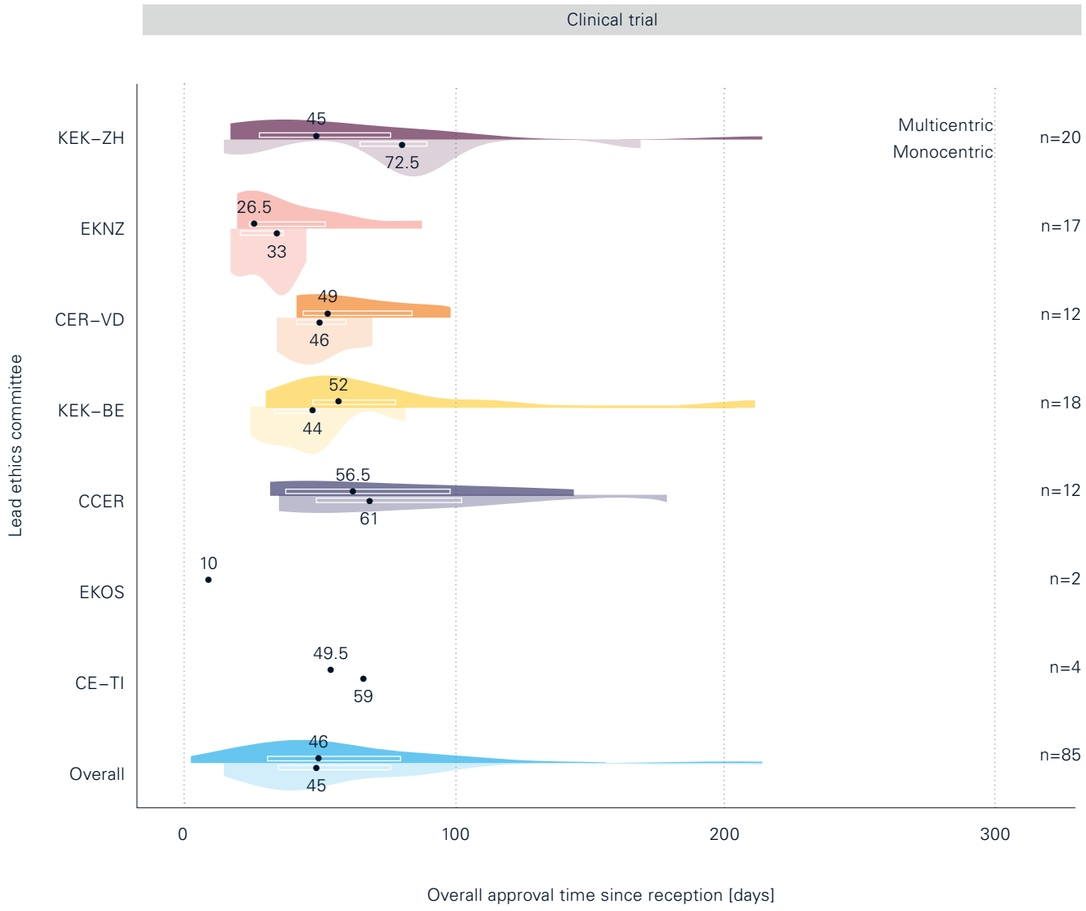
Table 24.1: Overview of response time in days - Median and inter-quartile range (IQR) stratified by lead ethics committee and depending on whether a single or multiple ECs are involed – **only for ClinO-MD projects**.

		Application involves					
		Multiple ECs			Single EC		
Lead EC	Time interval	n	Median	IQR	n	Median	IQR
KEK-ZH	from receipt to status 'complete'	3	8	[5,10]	17	8	[7,9]
	from receipt to final decision	3	45	[38,63]	17	63	[26,77]
	from 'complete' to final decision	3	43	[31,58]	17	56	[15,71]
EKNZ	from receipt to status 'complete'	4	4	[3,7]	13	6	[1,6]
	from receipt to final decision	4	48	[41,57]	13	27	[22,35]
	from 'complete' to final decision	4	41	[32,53]	13	21	[20,24]
CER-VD	from receipt to status 'complete'	4	7	[6,10]	8	9	[7,10]
	from receipt to final decision	4	62	[46,80]	8	44	[40,50]
	from 'complete' to final decision	4	50	[40,66]	8	34	[30,44]
KEK-BE	from receipt to status 'complete'	5	8	[6,11]	13	8	[6,10]
	from receipt to final decision	5	45	[43,59]	13	47	[40,72]
	from 'complete' to final decision	5	39	[35,39]	13	39	[29,50]
CCER	from receipt to status 'complete'	2	4	[2,5]	10	7	[4,8]
	from receipt to final decision	2	38	[36,39]	10	74	[45,92]
	from 'complete' to final decision	2	34	[34,34]	10	55	[38,87]

		Application involves					
		Multiple ECs			Single EC		
Lead EC	Time interval	n	Median	IQR	n	Median	IQR
EKOS	from receipt to status 'complete'	0			2	4	[4,4]
	from receipt to final decision	0			2	10	[8,12]
	from 'complete' to final decision	0			2	6	[4,8]
CE-TI	from receipt to status 'complete'	0			4	10	[9,12]
	from receipt to final decision	0			4	52	[51,56]
	from 'complete' to final decision	0			4	40	[40,45]
Overall	from receipt to status 'complete'	18	6	[4,10]	67	7	[6,10]
	from receipt to final decision	18	46	[40,64]	67	45	[30,70]
	from 'complete' to final decision	18	39	[34,53]	67	38	[22,56]

The total number of 85 research projects consist of 79 trials with medical devices and 6 trials on a combination medicinal product and medical device.

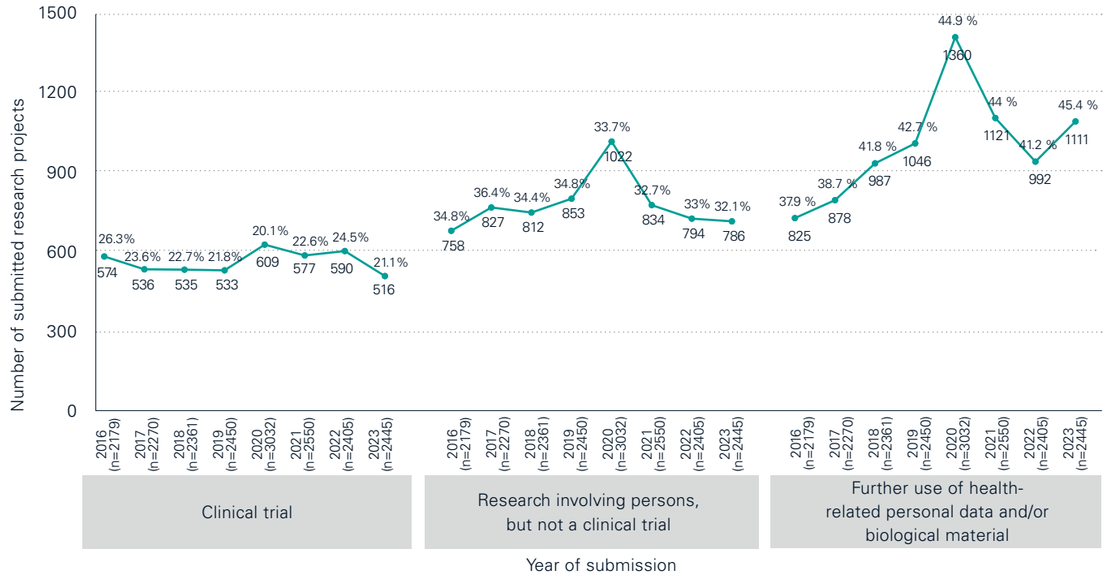
Figure 12: Violin plot of the overall approval time by EC from reception to final decision – **only for ClinO-MD projects**. Note: No density can be calculated and displayed for groups with less than 2 observations.



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 13: 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.

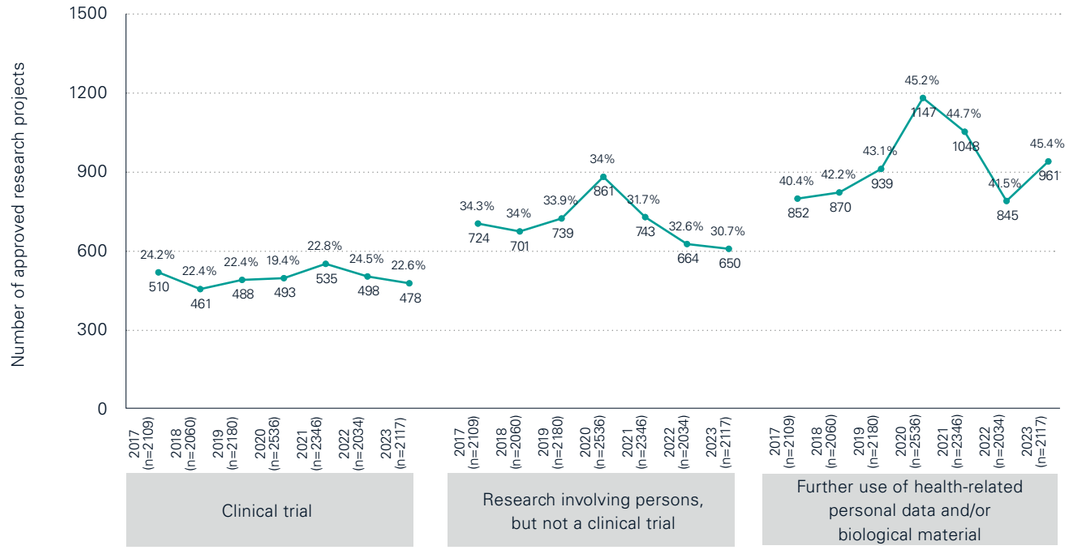


Data not shown in the above figure: Research involving deceased persons (2019: 17, 2020: 40, 2021: 18, 2022: 29, 2023: 30) and Research involving embryos and fetuses from induced abortions or stillbirths (2019: 1, 2020: 1, 2021: 0, 2022: 0, 2023: 2)

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.

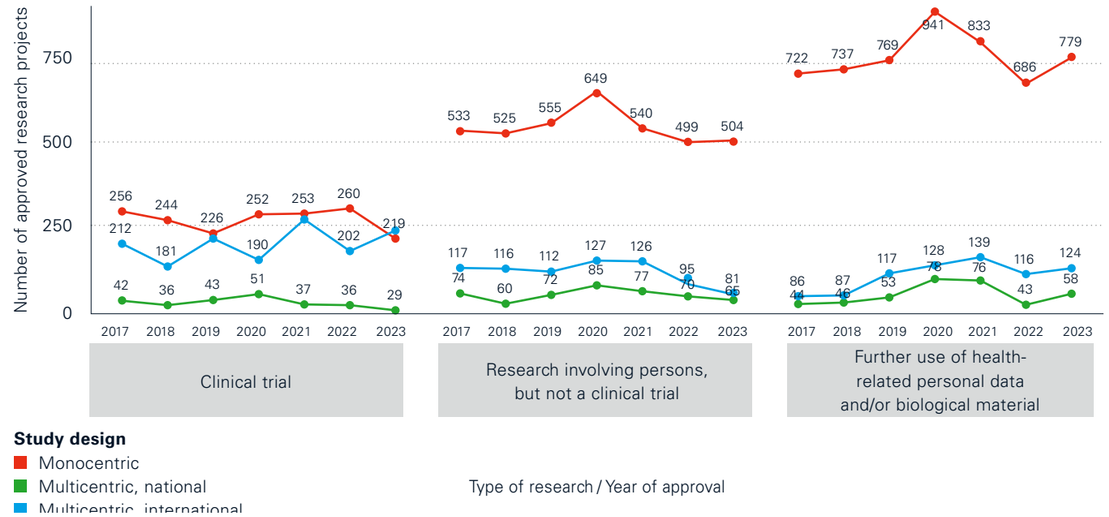
Figure 14: Total number of approved projects per year and type of research. Percentages on the top of the lines refer to the proportion of studies of a given type compared to all studies approved in a given year.



Data not shown in the above figure: Research involving deceased persons (2017: 29, 2018: 28, 2019: 17, 2020: 35, 2021: 19, 2022: 27, 2023: 27) and Research involving embryos and fetuses from induced abortions or stillbirths (2017: 0, 2018: 0, 2019: 1, 2020: 0, 2021: 1, 2022: 0 2023: 1)

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

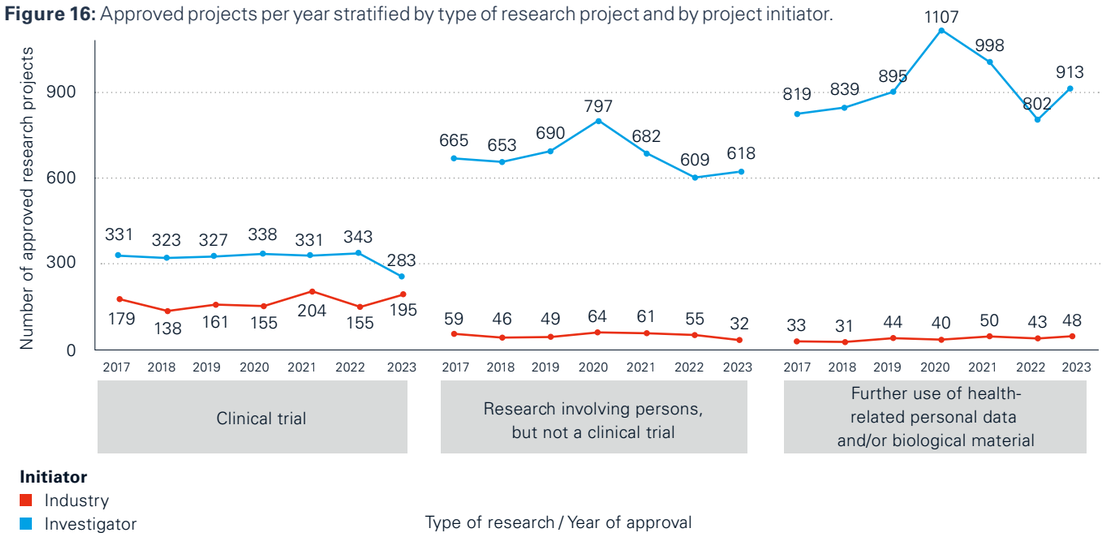
Figure 15: Approved projects per year stratified by type of research project and by study design.



Data not shown in the above figure: Research involving deceased persons (2017: 22, 2018: 28, 2019: 14, 2020: 35, 2021: 19, 2022: 27, 2023: 27) and Research involving embryos and fetuses from induced abortions or stillbirths (2017: 1, 2018: 0, 2019: 0, 2020: 0, 2021: 1, 2022: 0 2023: 1)

7.2 Project initiator

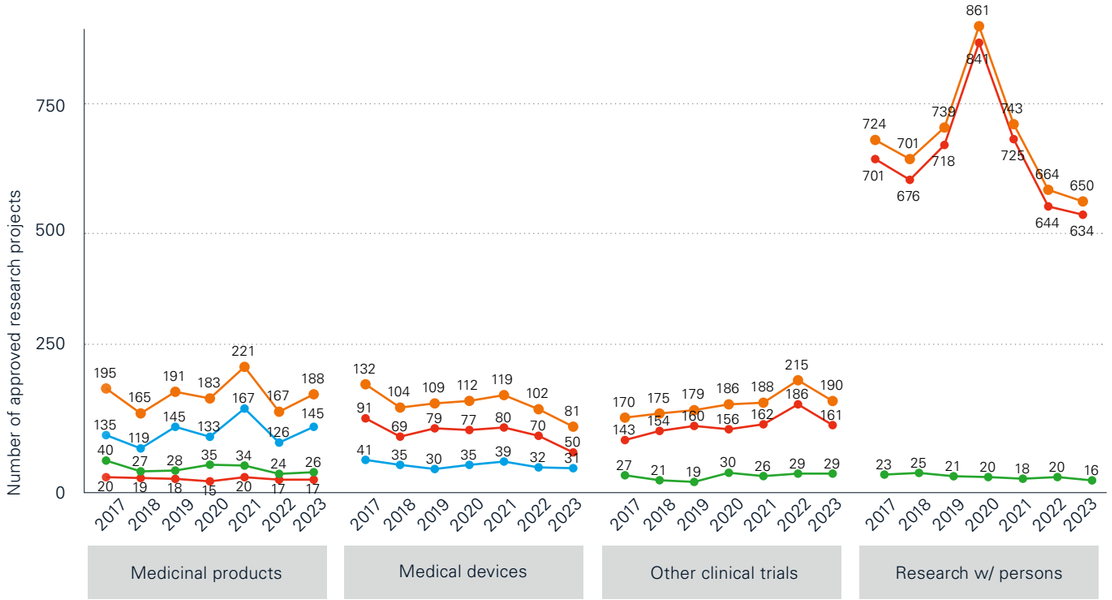
Figure 16: Approved projects per year stratified by type of research project and by project initiator.



Data not shown in the above figure: Research involving deceased persons (2017: 22, 2018: 28, 2019: 14, 2020: 35, 2021: 19, 2022: 27, 2023: 27) and Research involving embryos and fetuses from induced abortions or stillbirths (2017: 1, 2018: 0, 2019: 0, 2020: 0, 2021: 1, 2022: 0 2023: 1)

7.3 Risk category

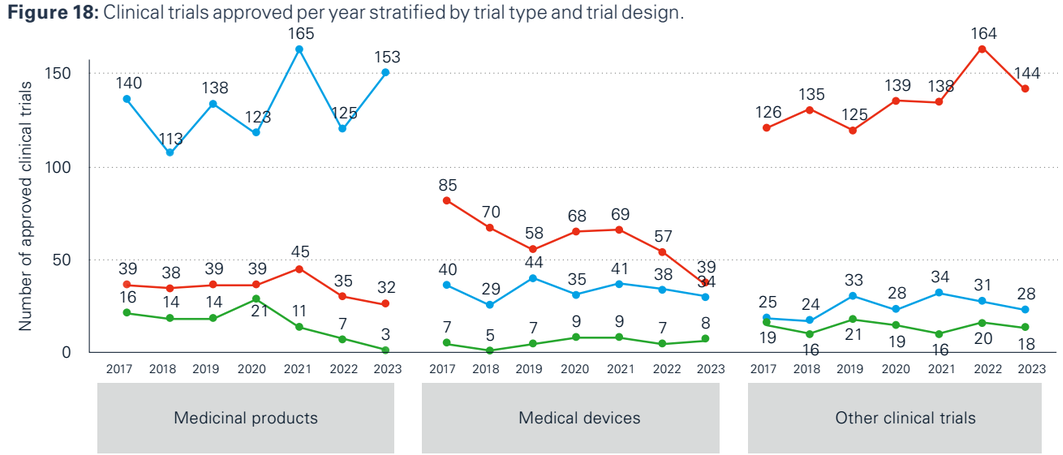
Figure 17: Clinical trials and research projects involving persons approved per year stratified by type of research project and risk category.



Data not shown in the above figure: Research involving transplant products (2017: 4, 2018: 9, 2019: 4, 2020: 6, 2021: 2, 2022: 7 , 2023: 6), combination drugs/ devices (2017: 9, 2018: 4, 2020: 4, 2021: 3, 2022: 2, 2023: 10) , gene therapy (2017: 0 2018: 3 2019: 2, 2020: 1, 2021: 1, 2022: 2, 2023: 1) , transplantation (2017: 0, 2018: 1, 2019: 0, 2020: 1, 2021: 0, 2022: 1, 2023: 0) and pathogenic organisms (2021: 1, 2022: 2, 2023: 2)

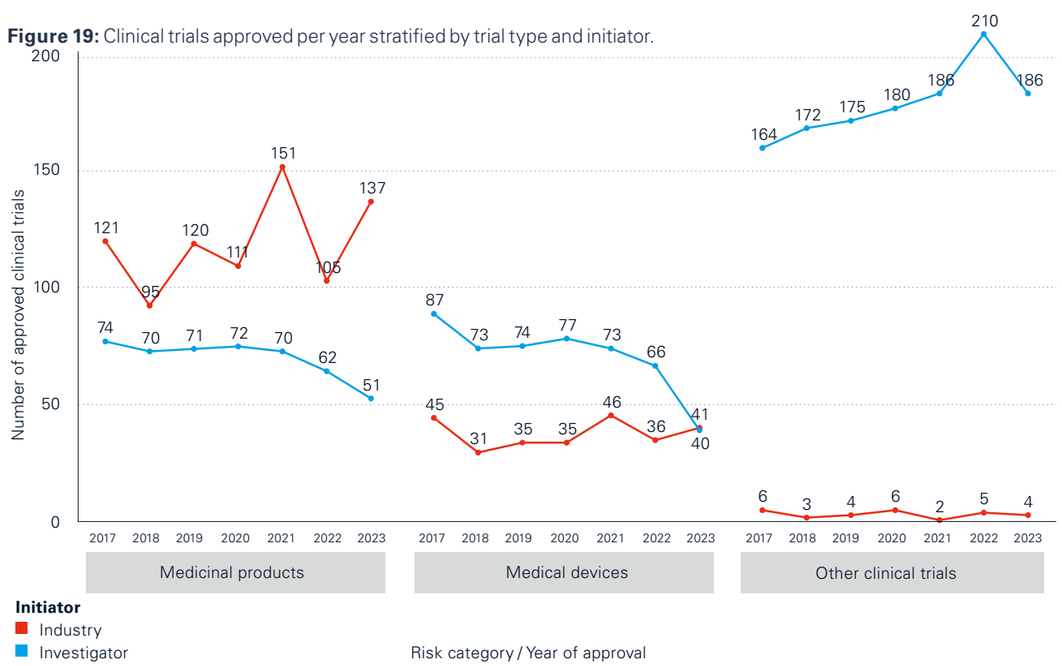
7.4 Subgroups of clinical trials

Figure 18: 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, 2022: 7 , 2023: 6), combination drugs/ devices (2017: 9, 2018: 4, 2020: 4, 2021: 3, 2022: 2, 2023: 10) , gene therapy (2017: 0 2018: 3 2019: 2, 2020: 1, 2021: 1, 2022: 2, 2023: 1) , transplantation (2017: 0, 2018: 1, 2019: 0, 2020: 1, 2021: 0, 2022: 1, 2023: 0) and pathogenic organisms (2021: 1, 2022: 2, 2023: 2)

Figure 19: 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, 2022: 7 , 2023: 6), combination drugs/ devices (2017: 9, 2018: 4, 2020: 4, 2021: 3, 2022: 2, 2023: 10) , gene therapy (2017: 0 2018: 3 2019: 2, 2020: 1, 2021: 1, 2022: 2, 2023: 1) , transplantation (2017: 0, 2018: 1, 2019: 0, 2020: 1, 2021: 0, 2022: 1, 2023: 0) and pathogenic organisms (2021: 1, 2022: 2, 2023: 2)

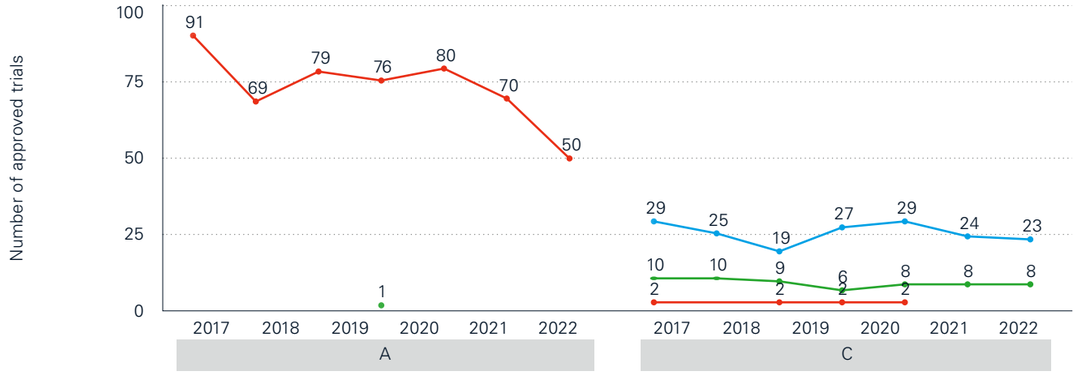
7.4.1 Clinical trials with medicinal products

Figure 20: 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: 10, 2022: 11, 2023: 15

7.4.2 Clinical trials with medical devices

Figure 21: 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: 6, 2018: 8, 2019: 14, 2020: 19, 2021: 19, 2022: 10, 2023: 9

7.5 Subgroup Further use of data/biological material

Table 25: Overview of characteristics of all approved 'further use' projects.

		Approval year											
		2017		2018		2019		2020		2021		2022	
		n	%	n	%	n	%	n	%	n	%	n	%
Genetic data / biol. material	Yes	175	19.2	215	19.9	252	21.4	275	19.5	264	20.5	230	21.5	252	21.9
	No	735	80.8	868	80.1	924	78.6	1136	80.5	1024	79.5	838	78.5	900	78.1
Coding (HRO Art. 25-27)	Coded	424	46.6	903	83.4	1017	86.5	1223	86.7	1170	90.8	970	90.8	1063	92.3
	Open, non-coded	486	53.4	180	16.6	159	13.5	188	13.3	118	9.2	98	9.2	89	7.7
Consent (HRO Art. 28-32)	Consent for all data	352	38.7	545	50.3	584	49.7	725	51.4	683	53.0	638	59.7	673	58.4
	Consent for some but not all data (partially Art. 34 HRA)[1]	–	–	–	–	–	–	306	21.7	378	29.3	330	30.9	370	32.1
	No consent for all data, Art. 34 HRA[2]	558	61.3	538	49.7	592	50.3	380	26.9	227	17.6	100	9.4	109	9.5
Combined vs. stand-alone projects[3]	Stand-alone further use project	852	93.6	870	80.3	939	79.8	1147	81.3	1048	81.4	845	79.1	961	83.4
	Further use project as part of a clinical trial	20	2.2	41	3.8	46	3.9	43	3.0	58	4.5	51	4.8	40	3.5
	Further use project as part of a non-clinical research project	38	4.2	172	15.9	191	16.2	221	15.7	182	14.1	172	16.1	151	13.1
Total number		910	100.0	1083	100.0	1176	100.0	1411	100.0	1288	100.0	1068	100.0	1152	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 22: Number of approved 'further use' projects per year and fraction without informed consent.

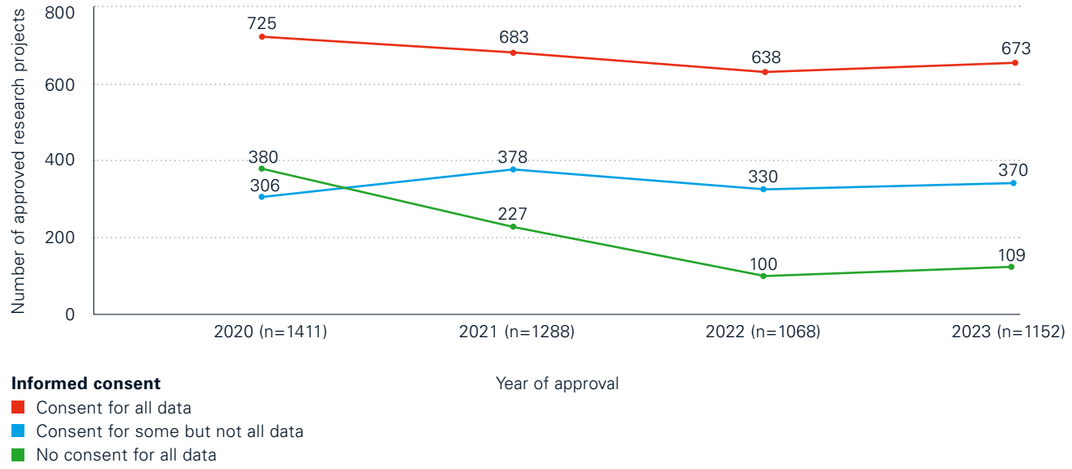
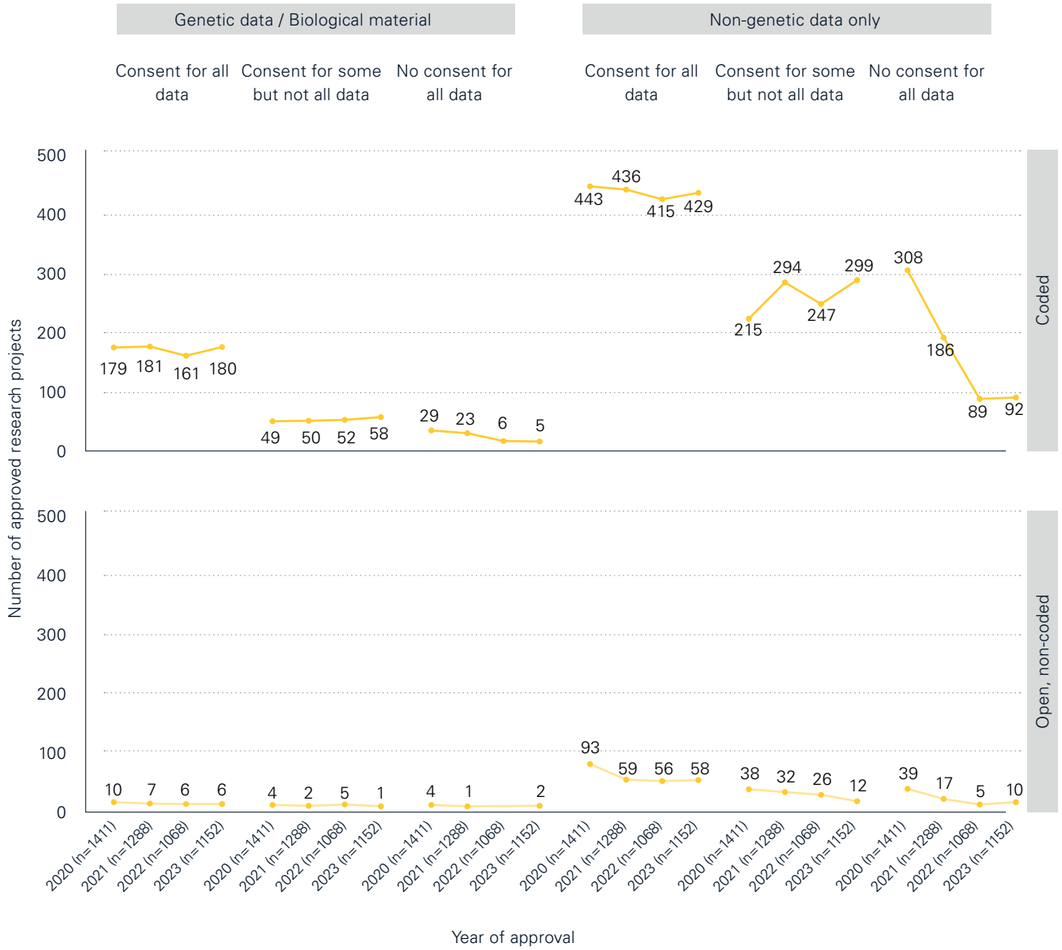
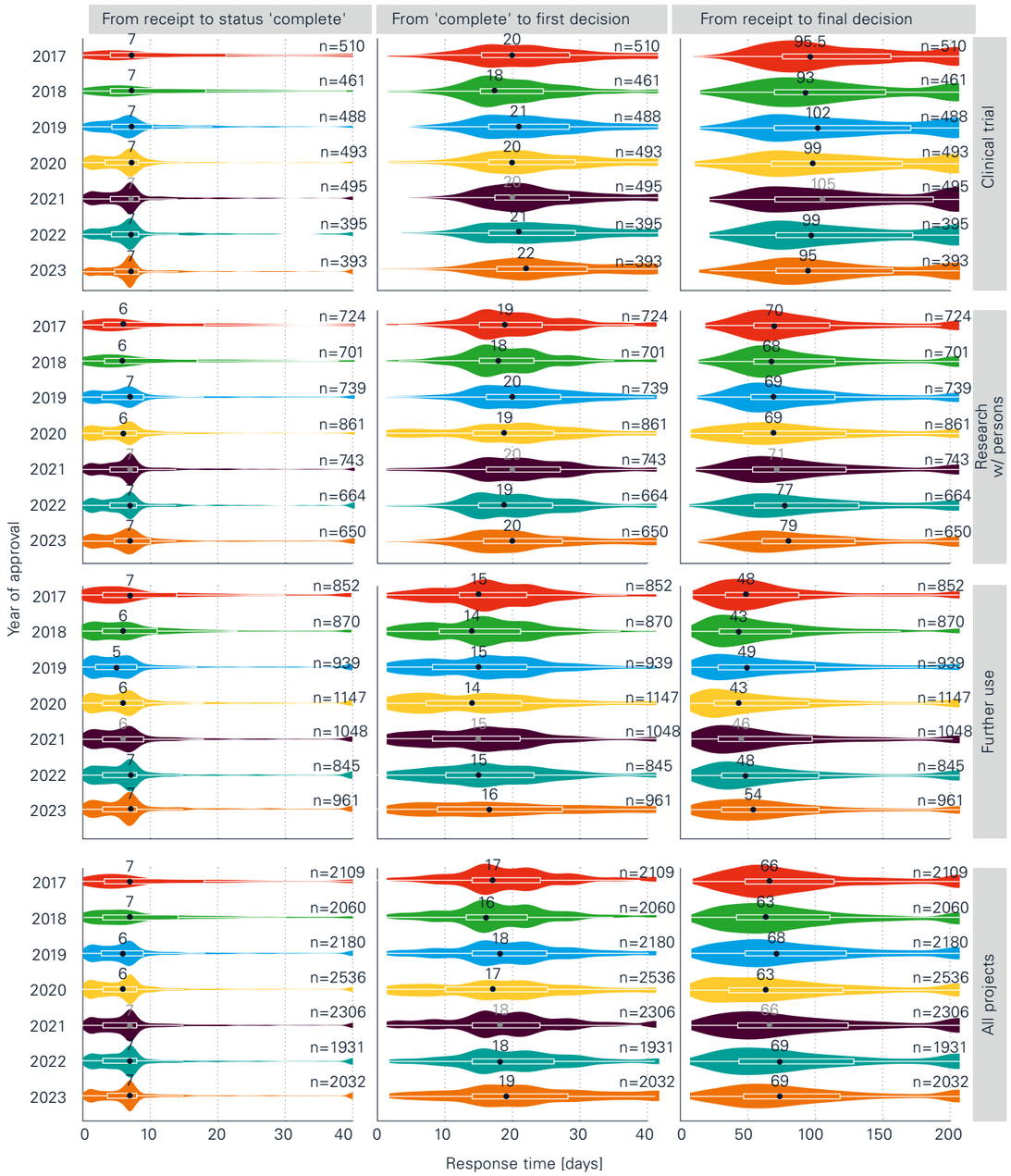


Figure 23: Number of approved 'further use' projects per year stratified by 1) Use of genetic data and/or biological material, 2) coded vs. uncoded, 3) consent for further use.



7.6 Response time

Figure 24: 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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