BASEC Annual Report 2024

Descriptive statistics on research covered by the
Swiss Federal Act on Research involving Human Beings

January 1, 2024 – December 31, 2024

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Schweizerische Vereinigung der Forschungsethikkommissionen
Association suisse des Commissions d'éthique de la recherche
Associazione svizzera delle Commissioni etiche della ricerca
Swiss Association of Research Ethics Committees

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Contents

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 2024 (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 2024. 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 2024 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 2024. 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 2024 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 nine years (2016 - 2024) and for approved projects (AS2) over eight years (2017 - 2024). 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 05, 2025 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 34ff. 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 2024**. 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 2024** irrespective of whether the projects were submitted in the reporting year or before.

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

A BASEC data export always presents a snapshot. Some projects have already been assessed and a final decision has been made, and other projects are pending for various reasons: the application data are still incomplete, the decision by the EC is pending or the EC makes the decision on the project dependent on certain charges/conditions. Furthermore, submitted projects may later be declined by the EC, the project may not be covered by the HRA (non-consideration) or may be withdrawn by the applicant (including submissions that are never completed).

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

All these restrictions have an effect on the resulting analyses and their interpretation.

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

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

1.3.2 Influence of time on project status

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.

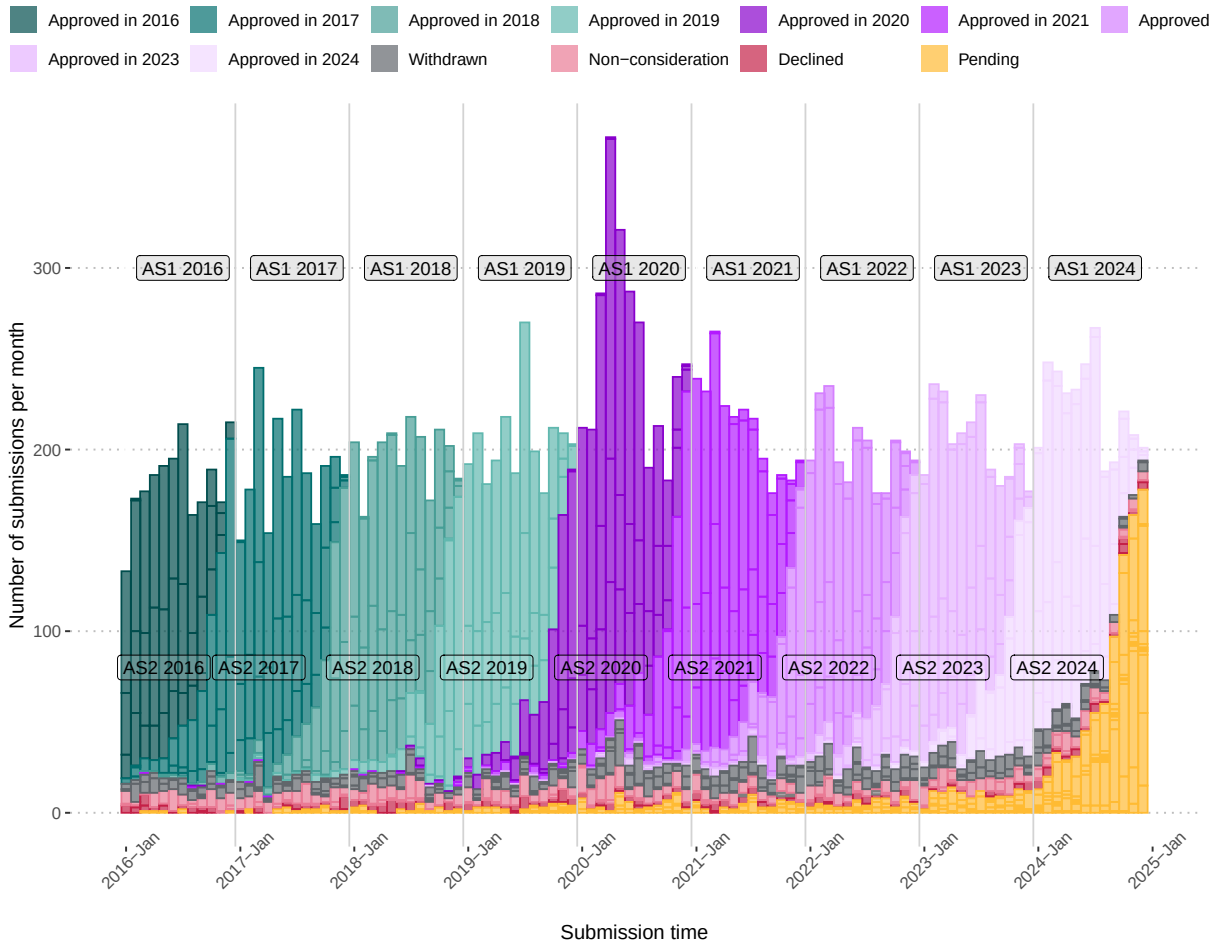

Figure 1: Overview of submissions via BASEC in the years 2016-2024 coloured by the current status as of the time of the data export (April 05, 2025).

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 2024, since a single up-to-date export is used for all years (export date: April 05, 2025) 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/ClinO-MD or research with persons (HRO) in all overview tables (Tables 2, 4 and 7ff). However, in the subgroup analysis of 'further use' projects, these combined projects are included. Explanatory footnotes are added to the relevant tables. Similarly, medical device/medicinal product combinations are counted once in the overview tables and are analysed separately in the subgroup analysis.

[1] Exception: In section 3.2 on page 14, the data are summarised from a EC perspective by counting individual evaluations thereby assigning projects involving multiple local committees to all ECs.

2 BASEC data in the calendar year 2024

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

			N	$\%_{col}$
Input	Submission in 2024 (AS1)		2681	73.1
	Projects pending from 2023	Pending first decision in 2023	298	8.1
		Pending final decision in 2023 (first decision before 2024)	691	18.8
		Total Pending from 2023	985	26.9
		Grand Total Input 2024	3666	100.0
Output	Final decision in 2024	Approvals (AS2)	2101	57.3
		Rejections (declined projects)	52	1.4
		Non-considerations	101	2.8
		Total Decisions	2254	61.5
	Withdrawn during 2024	Withdrawal before first decision	74	2.0
		Withdrawal after first decision 'approvals with charges'	2	0.1
		Withdrawal after first decision 'not-yet-approved projects with conditions'	31	0.8
		Withdrawal after first decision 'non-considerations'	9	0.2
		Total Withdrawn	116	3.2
	Pending at end of 2024	Pending first decision	448	12.2
		Pending final decision (first decision issued)	848	23.1
		Total Pending	1296	35.4
		Grand Total Output 2024	3666	100.0

Discrepancies in the number of decisions presented here and in subsequent tables are explained by the different cut-off dates: here only decisions in calendar year are considered whereas in tables based on the AS1 all decisions until the date of data export are taken into account.
Discrepancies between the grand total input and output are due to the input of old (approved) projects from the pre-BASEC area that have been digitalized in 2020 and hence obtained a new BASEC number.

3 Overview of all projects submitted to BASEC in 2024 (AS1)

Table 2: Total number of research projects **submitted via BASEC in 2024** (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	558 [1]	20.8
Research involving persons, but not a clinical trial	HRO, Chapter 2	794 [2]	29.6
Further use of health-related personal data and/or biological material	HRO, Chapter 3	1290	48.1
Research involving deceased persons	HRO, Chapter 4	36	1.3
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	3	0.1
Total number		2681	100.0

[1] 78 of these projects also include an application for further use of data/biological material.
[2] 191 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 2024 (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]	207	7.7	41	5.3	41	7.4	34	8.0	17	4.3	17	5.3	39	32.8	18	18.4
	Approved with charges [3]	618	23.1	25	3.2	255	46.3	206	48.2	22	5.6	29	9.0	49	41.2	32	32.7
	Not approved, conditions [4]	1467	54.7	579	75.2	228	41.4	132	30.9	262	66.5	217	67.4	17	14.3	32	32.7
	Declined	39	1.5	6	0.8	3	0.5	1	0.2	5	1.3	22	6.8			2	2.0
	Non-consideration [5]	82	3.1	28	3.6	4	0.7	4	0.9	30	7.6	8	2.5	8	6.7		
	First decision still pending [6]	151	5.6	53	6.9	11	2.0	36	8.4	28	7.1	18	5.6	1	0.8	4	4.1
Final decision	Approved [7]	1998	74.5	533	69.2	489	88.7	330	77.3	281	71.3	189	58.7	101	84.9	75	76.5
	Declined	50	1.9	14	1.8	3	0.5	1	0.2	7	1.8	23	7.1			2	2.0
	Non-consideration	90	3.4	26	3.4	5	0.9	6	1.4	32	8.1	11	3.4	9	7.6	1	1.0
	Withdrawn	117	4.4	40	5.2	6	1.1	20	4.7	39	9.9	9	2.8	2	1.7	1	1.0
	Pending [8]	8	0.3	4	0.5	2	0.4	1	0.2					1	0.8		
	Final decision still pending	418	15.6	153	19.9	46	8.3	69	16.2	35	8.9	90	28.0	6	5.0	19	19.4
Review procedure	Ordinary [10]	347	12.9	83	10.8	53	9.6	40	9.4	48	12.2	15	4.7	17	14.3	91	92.9
	Simplified [11]	1581	59.0	387	50.3	360	65.3	237	55.5	299	75.9	239	74.2	56	47.1	3	3.1
	Presidential	613	22.9	267	34.7	128	23.2	112	26.2	18	4.6	51	15.8	37	31.1		
	First decision still pending	140	5.2	33	4.3	10	1.8	38	8.9	29	7.4	17	5.3	9	7.6	4	4.1
	Total number in AS1	2681	100.0	770	100.0	551	100.0	427	100.0	394	100.0	322	100.0	119	100.0	98	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. 51.7% of the pending projects were submitted in the last quarter of the reporting year.
[9] Decision taken at full committee meeting by at least seven members of the ethics committee, as per the provisions of Art. 5, OrgO-HRA.
[10] Decision taken by three members of the ethics committee, as per the provisions of Art. 6 OrgO-HRA.
[11] Decision taken by the president or vice-president of the ethics committee, as per the provisions of Art. 7 OrgO-HRA.
[12] CE-TI uses the ordinary procedure for most of the research applications.

Table 4: Number of **submissions in 2024** (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	12	7.2	5	9.6	2	6.2	1	8.3	4	13.8	0	0.0	0	0.0	0	0.0
		B	22	13.3	6	11.5	8	25.0	0	0.0	5	17.2	3	27.3	0	0.0	0	0.0
		C	132	79.5	41	78.8	22	68.8	11	91.7	20	69.0	8	72.7	16	100.0	14	100.0
		All	166	100.0	52	100.0	32	100.0	12	100.0	29	100.0	11	100.0	16	100.0	14	100.0
	Medical devices[1]	A1	69	57.0	18	54.5	4	44.4	10	62.5	21	61.8	10	83.3	3	50.0	3	27.3
		A2	12	9.9	2	6.1	1	11.1	1	6.2	4	11.8	1	8.3	0	0.0	3	27.3
		C1	9	7.4	2	6.1	1	11.1	2	12.5	2	5.9	0	0.0	1	16.7	1	9.1
		C2	31	25.6	11	33.3	3	33.3	3	18.8	7	20.6	1	8.3	2	33.3	4	36.4
		All	121	100.0	33	100.0	9	100.0	16	100.0	34	100.0	12	100.0	6	100.0	11	100.0
	Other clinical trials	A	212	86.9	66	88.0	54	81.8	19	100.0	33	80.5	27	93.1	5	100.0	8	88.9
		B	32	13.1	9	12.0	12	18.2	0	0.0	8	19.5	2	6.9	0	0.0	1	11.1
		All	244	100.0	75	100.0	66	100.0	19	100.0	41	100.0	29	100.0	5	100.0	9	100.0
	Combination drugs/devices	A	1	8.3	1	14.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		A1	2	16.7	1	14.3	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0
		B	1	8.3	1	14.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		C	4	33.3	0	0.0	0	0.0	0	0.0	3	100.0	0	0.0	1	100.0	0	0.0
		C1	2	16.7	2	28.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		C2	2	16.7	2	28.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		All	12	100.0	7	100.0	0	0.0	0	0.0	3	100.0	1	100.0	1	100.0	0	0.0
	Transplant products	A	2	22.2	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		C	7	77.8	1	33.3	3	100.0	2	100.0	0	0.0	1	100.0	0	0.0	0	0.0
		All	9	100.0	3	100.0	3	100.0	2	100.0	0	0.0	1	100.0	0	0.0	0	0.0
	Gene therapy	C	4	100.0	0	0.0	0	0.0	2	100.0	2	100.0	0	0.0	0	0.0	0	0.0
		All	4	100.0	0	0.0	0	0.0	2	100.0	2	100.0	0	0.0	0	0.0	0	0.0
	Transplantation	A	1	50.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		C	1	50.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		All	2	100.0	1	100.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Research w/ persons		A	776	97.7	181	97.8	158	98.1	169	97.1	96	97.0	119	98.3	22	100.0	31	96.9
		B	18	2.3	4	2.2	3	1.9	5	2.9	3	3.0	2	1.7	0	0.0	1	3.1
		All	794	100.0	185	100.0	161	100.0	174	100.0	99	100.0	121	100.0	22	100.0	32	100.0
Further use		n.a.	1290	100.0	396	100.0	273	100.0	199	100.0	182	100.0	140	100.0	68	100.0	32	100.0
Deceased and embryos from stillbirths or abortion		n.a.	39	100.0	18	100.0	6	100.0	3	100.0	4	100.0	7	100.0	1	100.0	0	0.0
Total number			2681	100.0	770	100.0	551	100.0	427	100.0	394	100.0	322	100.0	119	100.0	98	100.0

[1]Medical devices include 9 in-vitro diagnostic medical devices IVD-MD projects and 0 in-vitro diagnostic medical devices CDx (Companion Diagnostics) projects.
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	2329	67.8
Multiple ECs involved: lead EC	352	10.2
Multiple ECs involved: local EC	756	22.0
Total submissions to be evaluated	3437	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	669	76.1	488	69.9	396	73.5	324	62.3	282	66.2	98	45.0	72	45.9
Multiple: lead EC	101	11.5	63	9.0	31	5.8	70	13.5	40	9.4	21	9.6	26	16.6
Multiple: local EC	109	12.4	147	21.1	112	20.8	126	24.2	104	24.4	99	45.4	59	37.6
Total submissions	879	100.0	698	100.0	539	100.0	520	100.0	426	100.0	218	100.0	157	100.0

4 Scientific characterisation of projects approved in 2024 (AS2)

4.1 Overview

Table 7: Total number of research projects **approved in 2024** (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	452 [1]	21.5
Research involving persons, but not a clinical trial	HRO, Chapter 2	623 [2]	29.6
Further use of health-related personal data and/or biological material	HRO, Chapter 3	1000	47.6
Research involving deceased persons	HRO, Chapter 4	24	1.1
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	2	0.1
Total number		2101	100.0

[1] 56 of these projects also include 'further use' of existing data and/or material.
[2] 152 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 2024 (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	2021	1	0.05	0	0.0	0	0.0	1	0.3	0	0.0	0	0.0	0	0.0	0	0.0
	2022	19	0.90	4	0.7	2	0.4	9	2.4	0	0.0	4	2.0	0	0.0	0	0.0
	2023	524	24.94	173	30.2	88	18.0	102	27.7	72	24.7	67	32.8	10	10.1	12	16.0
	2024	1557	74.11	396	69.1	400	81.6	256	69.6	220	75.3	133	65.2	89	89.9	63	84.0
First decision [1]	Approved	198	9.42	43	7.5	38	7.8	33	9.0	13	4.5	17	8.3	37	37.4	17	22.7
	Approved with charges [2]	558	26.56	18	3.1	242	49.4	185	50.3	21	7.2	25	12.3	44	44.4	23	30.7
	Not approved, conditions [3]	1236	58.83	469	81.8	204	41.6	133	36.1	235	80.5	153	75.0	15	15.2	27	36.0
	Declined [4]	0	0.00	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Non-consideration	0	0.00	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Review procedure	Ordinary [5]	296	14.09	71	12.4	43	8.8	45	12.2	38	13.0	15	7.4	12	12.1	72	96.0
	Simplified	1311	62.40	310	54.1	327	66.7	229	62.2	239	81.8	151	74.0	52	52.5	3	4.0
	Presidential	494	23.51	192	33.5	120	24.5	94	25.5	15	5.1	38	18.6	35	35.4	0	0.0
	Total number in AS2	2101	100.00	573	100.0	490	100.0	368	100.0	292	100.0	204	100.0	99	100.0	75	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 19-21, 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 22, 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 33, 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	15	10.0	10	66.7	3	20.0	2	13.3	1	6.7	14	93.3
		B	14	9.3	7	50.0	4	28.6	3	21.4	2	14.3	12	85.7
		C	121	80.7	10	8.3	8	6.6	103	85.1	101	83.5	20	16.5
		All	150	100.0	27	18.0	15	10.0	108	72.0	104	69.3	46	30.7
	Medical devices (ClinO-MD Art 6)[1]	A1	43	44.8	25	58.1	1	2.3	17	39.5	14	32.6	29	67.4
		A2	6	6.2	2	33.3	1	16.7	3	50.0	5	83.3	1	16.7
		C1	3	3.1	2	66.7	0	0.0	1	33.3	2	66.7	1	33.3
		C2	43	44.8	20	46.5	2	4.7	21	48.8	27	62.8	16	37.2
		C3	1	1.0	0	0.0	1	100.0	0	0.0	1	100.0	0	0.0
		All	96	100.0	49	51.0	5	5.2	42	43.8	49	51.0	47	49.0
	Other clinical trials (ClinO Art 61)	A	157	84.4	123	78.3	16	10.2	18	11.5	2	1.3	155	98.7
		B	29	15.6	19	65.5	3	10.3	7	24.1	1	3.4	28	96.6
		All	186	100.0	142	76.3	19	10.2	25	13.4	3	1.6	183	98.4
	Combination drugs/devices	A1	2	22.2	1	50.0	0	0.0	1	50.0	1	50.0	1	50.0
		B	1	11.1	0	0.0	0	0.0	1	100.0	1	100.0	0	0.0
		C	4	44.4	0	0.0	0	0.0	4	100.0	4	100.0	0	0.0
		C1	1	11.1	0	0.0	0	0.0	1	100.0	1	100.0	0	0.0
		C2	1	11.1	0	0.0	0	0.0	1	100.0	1	100.0	0	0.0
		All	9	100.0	1	11.1	0	0.0	8	88.9	8	88.9	1	11.1
	Transplant products (ClinO Art 21)	A	1	14.3	1	100.0	0	0.0	0	0.0	0	0.0	1	100.0
		C	6	85.7	1	16.7	1	16.7	4	66.7	2	33.3	4	66.7
		All	7	100.0	2	28.6	1	14.3	4	57.1	2	28.6	5	71.4
	Gene therapy (ClinO Art 22)	C	2	100.0	1	50.0	0	0.0	1	50.0	1	50.0	1	50.0
		All	2	100.0	1	50.0	0	0.0	1	50.0	1	50.0	1	50.0
	Transplantation (ClinO Art 49)	C	2	100.0	0	0.0	0	0.0	2	100.0	0	0.0	2	100.0
		All	2	100.0	0	0.0	0	0.0	2	100.0	0	0.0	2	100.0
	All	All	452	100.0	222	49.1	40	8.8	190	42.0	167	36.9	285	63.1
Research w/ persons (HRO Chapter 2)		A	615	98.7	459	74.6	61	9.9	95	15.4	38	6.2	577	93.8
		B	8	1.3	6	75.0	0	0.0	2	25.0	0	0.0	8	100.0
		All	623	100.0	465	74.6	61	9.8	97	15.6	38	6.1	585	93.9
Further use (HRO Chapter 3)		n.a.	1000	100.0	800	80.0	68	6.8	132	13.2	50	5.0	950	95.0
Deceased and embryos from stillbirths or abortion (HRO Chapter 4+5)		n.a.	26	100.0	26	100.0	0	0.0	0	0.0	2	7.7	24	92.3
Total number		Total number	2101	100.0	1513	72.0	169	8.0	419	19.9	257	12.2	1844	87.8

[1]Medical devices include 9 in-vitro diagnostic medical devices IVD-MD projects and 0 in-vitro diagnostic medical devices CDx (Companion Diagnostics) projects.
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	15	10.0	5	10.2	5	17.2	0	0.0	5	18.5	0	0.0	0	0.0	0	0.0
		B	14	9.3	6	12.2	2	6.9	0	0.0	1	3.7	3	37.5	2	16.7	0	0.0
		C	121	80.7	38	77.6	22	75.9	14	100.0	21	77.8	5	62.5	10	83.3	11	100.0
		All	150	100.0	49	100.0	29	100.0	14	100.0	27	100.0	8	100.0	12	100.0	11	100.0
	Medical devices	A1	43	44.8	15	46.9	4	66.7	7	43.8	11	47.8	2	25.0	2	66.7	2	25.0
		A2	6	6.2	1	3.1	0	0.0	0	0.0	2	8.7	1	12.5	0	0.0	2	25.0
		C1	3	3.1	0	0.0	0	0.0	0	0.0	1	4.3	1	12.5	0	0.0	1	12.5
		C2	43	44.8	16	50.0	2	33.3	9	56.2	8	34.8	4	50.0	1	33.3	3	37.5
		C3	1	1.0	0	0.0	0	0.0	0	0.0	1	4.3	0	0.0	0	0.0	0	0.0
		All	96	100.0	32	100.0	6	100.0	16	100.0	23	100.0	8	100.0	3	100.0	8	100.0
	Other clinical trials	A	157	84.4	44	86.3	44	77.2	18	100.0	27	87.1	14	77.8	6	100.0	4	80.0
		B	29	15.6	7	13.7	13	22.8	0	0.0	4	12.9	4	22.2	0	0.0	1	20.0
		All	186	100.0	51	100.0	57	100.0	18	100.0	31	100.0	18	100.0	6	100.0	5	100.0
	Combination drugs/devices	A1	2	22.2	1	33.3	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0
		B	1	11.1	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		C	4	44.4	0	0.0	0	0.0	2	66.7	2	100.0	0	0.0	0	0.0	0	0.0
		C1	1	11.1	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		C2	1	11.1	0	0.0	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0
		All	9	100.0	3	100.0	0	0.0	3	100.0	2	100.0	1	100.0	0	0.0	0	0.0
	Transplant products	A	1	14.3	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		C	6	85.7	0	0.0	3	100.0	2	100.0	0	0.0	0	0.0	0	0.0	1	100.0
		All	7	100.0	1	100.0	3	100.0	2	100.0	0	0.0	0	0.0	0	0.0	1	100.0
	Gene therapy	C	2	100.0	0	0.0	0	0.0	1	100.0	1	100.0	0	0.0	0	0.0	0	0.0
		All	2	100.0	0	0.0	0	0.0	1	100.0	1	100.0	0	0.0	0	0.0	0	0.0
	Transplantation	C	2	100.0	1	100.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
		All	2	100.0	1	100.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
	All	All	452	100.0	137	100.0	95	100.0	55	100.0	84	100.0	35	100.0	21	100.0	25	100.0
Research w/ persons		A	615	98.7	130	98.5	145	99.3	144	98.0	78	100.0	77	98.7	20	100.0	21	95.5
		B	8	1.3	2	1.5	1	0.7	3	2.0	0	0.0	1	1.3	0	0.0	1	4.5
		All	623	100.0	132	100.0	146	100.0	147	100.0	78	100.0	78	100.0	20	100.0	22	100.0
Further use		n.a.	1000	100.0	289	100.0	245	100.0	166	100.0	127	100.0	88	100.0	57	100.0	28	100.0
Deceased and embryos from stillbirths or abortion		n.a.	26	100.0	15	100.0	4	100.0	0	0.0	3	100.0	3	100.0	1	100.0	0	0.0
Total number		Total number	2101	100.0	573	100.0	490	100.0	368	100.0	292	100.0	204	100.0	99	100.0	75	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	
Type of research	**Research details**	**Risk cat.**	**N**	**%col**	**n**	**%row**	**n**	**%row**	**n**	**%row**	**n**	**%row**	**n**	**%row**	**n**	**%row**
Clinical trial	Medicinal products	A	15	10.0	0	0.0	15	100.0	0	0.0	0	0.0	2	13.3	13	86.7
		B	14	9.3	13	92.9	1	7.1	0	0.0	0	0.0	2	14.3	12	85.7
		C	121	80.7	120	99.2	0	0.0	1	0.8	4	3.3	11	9.1	106	87.6
		All	150	100.0	133	88.7	16	10.7	1	0.7	4	2.7	15	10.0	131	87.3
	Medical devices	A1	43	44.8	4	9.3	32	74.4	7	16.3	0	0.0	0	0.0	0	0.0
		A2	6	6.2	5	83.3	1	16.7	0	0.0	0	0.0	0	0.0	0	0.0
		C1	3	3.1	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		C2	43	44.8	35	81.4	2	4.7	6	14.0	0	0.0	0	0.0	0	0.0
		C3	1	1.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		All	96	100.0	48	50.0	35	36.5	13	13.5	0	0.0	0	0.0	0	0.0
	Other clinical trials	A	157	84.4	11	7.0	145	92.4	1	0.6	1	0.6	27	17.2	129	82.2
		B	29	15.6	27	93.1	2	6.9	0	0.0	0	0.0	2	6.9	27	93.1
		All	186	100.0	38	20.4	147	79.0	1	0.5	1	0.5	29	15.6	156	83.9
	Combination drugs/devices	A1	2	22.2	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0
		B	1	11.1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0
		C	4	44.4	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	4	100.0
		C1	1	11.1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		C2	1	11.1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		All	9	100.0	7	77.8	2	22.2	0	0.0	0	0.0	0	0.0	5	55.6
	Transplant products	A	1	14.3	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	1	100.0
		C	6	85.7	6	100.0	0	0.0	0	0.0	0	0.0	2	33.3	4	66.7
		All	7	100.0	6	85.7	1	14.3	0	0.0	0	0.0	2	28.6	5	71.4
	Gene therapy	C	2	100.0	2	100.0	0	0.0	0	0.0	0	0.0	1	50.0	1	50.0
		All	2	100.0	2	100.0	0	0.0	0	0.0	0	0.0	1	50.0	1	50.0
	Transplantation	C	2	100.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	2	100.0
		All	2	100.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	2	100.0
	All	All	452	100.0	236	52.2	201	44.5	15	3.3	5	1.1	47	10.4	300	66.4
Research w/ persons		A	615	98.7	27	4.4	580	94.3	8	1.3	10	1.6	164	26.7	440	71.5
		B	8	1.3	6	75.0	2	25.0	0	0.0	0	0.0	1	12.5	7	87.5
		All	623	100.0	33	5.3	582	93.4	8	1.3	10	1.6	165	26.5	447	71.7
Further use		n.a.	1000	100.0	27	2.7	502	50.2	471	47.1	179	17.9	342	34.2	472	47.2
Deceased and embryos from stillbirths or abortion		n.a.	26	100.0	0	0.0	26	100.0	0	0.0	4	15.4	4	15.4	17	65.4
Total number		Total number	2101	100.0	296	14.1	1311	62.4	494	23.5	198	9.4	558	26.6	1236	58.8

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 20 clinical trials not falling in the 3 main clinical trial types medicinal product, medical devices, other are not included in the stratification.

				Type of clinical trial								
	All clinical trials			Medicinal products			Medical devices			Other clinical trials		
Therapeutic area	N	$\%_{col}$	n_{rare}	N	%	n_{rare}	N	%	n_{rare}	N	%	n_{rare}
Other	135	29.9	8	27	18.0	6	32	33.3	1	74	39.8	1
Nervous System diseases	36	8.0	6	8	5.3	0	13	13.5	2	11	5.9	2
Cancer: Other	29	6.4	4	16	10.7	3	5	5.2	0	6	3.2	0
Cancer: Lung	28	6.2	2	16	10.7	2	3	3.1	0	7	3.8	0
Surgery	27	6.0	0	4	2.7	0	9	9.4	0	12	6.5	0
Basic research (Anatomy/Physiology)	25	5.5	2	3	2.0	1	3	3.1	0	19	10.2	1
Musculoskeletal diseases (non cancer)	25	5.5	1	0	0.0	0	7	7.3	0	15	8.1	1
Mental and Behavioural diseases	21	4.6	1	4	2.7	1	2	2.1	0	15	8.1	0
Brain diseases (non cancer)	19	4.2	1	1	0.7	0	3	3.1	0	15	8.1	1
Cancer: Breast	18	4.0	0	9	6.0	0	2	2.1	0	7	3.8	0
Digestive Systems diseases (non cancer)	18	4.0	1	8	5.3	1	6	6.2	0	3	1.6	0
Endocrinological diseases (non cancer)	18	4.0	3	5	3.3	1	4	4.2	0	8	4.3	2
Respiratory diseases (non cancer)	18	4.0	5	7	4.7	4	2	2.1	0	8	4.3	1
Cancer: Colon and Rectal	17	3.8	1	5	3.3	1	6	6.2	0	6	3.2	0
Cancer: Melanoma	17	3.8	2	8	5.3	2	3	3.1	0	4	2.2	0
Nutritional and Metabolic diseases	16	3.5	1	3	2.0	1	3	3.1	0	9	4.8	0
Infections and Infestations	15	3.3	1	10	6.7	0	2	2.1	0	3	1.6	1
Skin and Connective Tissues diseases (non cancer)	15	3.3	2	12	8.0	2	1	1.0	0	1	0.5	0
Coronary Heart disease	13	2.9	0	3	2.0	0	3	3.1	0	7	3.8	0
Arterial and venous diseases including deep venous thrombosis and lung embolism	12	2.7	1	5	3.3	1	4	4.2	0	2	1.1	0
Cancer: Leukemia	11	2.4	2	7	4.7	1	1	1.0	0	3	1.6	1
Cancer: Head and Neck	10	2.2	1	5	3.3	0	0	0.0	0	4	2.2	0
Cancer: Prostate	10	2.2	0	5	3.3	0	1	1.0	0	4	2.2	0
Urological and Genital diseases (non cancer)	10	2.2	1	4	2.7	1	3	3.1	0	3	1.6	0
Injury	9	2.0	3	0	0.0	0	4	4.2	2	4	2.2	1
Cancer: Lymphoma	8	1.8	2	4	2.7	2	2	2.1	0	2	1.1	0
Eye diseases	8	1.8	0	1	0.7	0	3	3.1	0	4	2.2	0
Cancer: Bladder	7	1.5	0	2	1.3	0	1	1.0	0	4	2.2	0
Cancer: Pancreatic	7	1.5	1	3	2.0	1	1	1.0	0	3	1.6	0
Hematologic diseases (non cancer)	7	1.5	2	4	2.7	1	1	1.0	0	2	1.1	1
Cancer: Endometrial	6	1.3	0	3	2.0	0	0	0.0	0	3	1.6	0
Cancer: Kidney	6	1.3	0	2	1.3	0	1	1.0	0	3	1.6	0
Genetic disorders	6	1.3	5	5	3.3	5	0	0.0	0	0	0.0	0
Dementia and Alzheimer disease	5	1.1	0	1	0.7	0	1	1.0	0	3	1.6	0
Periodontal diseases	5	1.1	0	0	0.0	0	4	4.2	0	1	0.5	0
Cancer: Non-Hodgkin Lymphoma	4	0.9	0	2	1.3	0	0	0.0	0	2	1.1	0
Cancer: Thyroid	4	0.9	0	2	1.3	0	0	0.0	0	2	1.1	0
Ear, Nose, and Throat diseases (non cancer)	4	0.9	0	0	0.0	0	3	3.1	0	1	0.5	0
Pregnancy and Childbirth	4	0.9	1	2	1.3	1	0	0.0	0	2	1.1	0
Neonatal diseases	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	0
Occupational diseases	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	0
Total projects	452	144.5	43	150	100.0	29	96	100.0	2	186	100.0	9

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 20 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	227	50.2	99	66.0	41	42.7	72	38.7
Other	79	17.5	6	4.0	15	15.6	56	30.1
PK / PD / safety	40	8.8	36	24.0	0	0.0	2	1.1
Diagnosis	35	7.7	4	2.7	19	19.8	12	6.5
Prevention	31	6.9	5	3.3	3	3.1	23	12.4
Rehabilitation	26	5.8	0	0.0	7	7.3	19	10.2
Safety	12	2.7	0	0.0	11	11.5	0	0.0
Palliation	2	0.4	0	0.0	0	0.0	2	1.1
Total projects	452	100.0	150	100.0	96	100.0	186	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	15	5.9	0	0.0	0	0.0	1	6.7	8	53.3	6	40.0	0	0.0
	B	14	5.5	1	7.1	2	14.3	4	28.6	2	14.3	5	35.7	1	7.1
	C	121	47.5	28	23.1	32	26.4	59	48.8	1	0.8	1	0.8	13	10.7
	All	150	58.8	29	19.3	34	22.7	64	42.7	11	7.3	12	8.0	14	9.3
Medical devices	A1	43	16.9	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	0	0.0
	A2	6	2.4	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	0	0.0
	C1	3	1.2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	0	0.0
	C2	43	16.9	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	16	37.2
	C3	1	0.4	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	0	0.0
	All	96	37.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	16	16.7
Combination medicinal products/devices	A1	2	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	B	1	0.4	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0
	C	4	1.6	0	0.0	0	0.0	4	100.0	0	0.0	0	0.0	0	0.0
	C1	1	0.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0
	C2	1	0.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	All	9	3.5	0	0.0	0	0.0	5	55.6	0	0.0	0	0.0	1	11.1
	Total number	255	100.0	29	11.4	34	13.3	69	27.1	11	4.3	12	4.7	31	12.2

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

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	281	45.1	275	97.9	6	2.1	204	72.6	28	10.0	49	17.4	9	3.2	272	96.8
Registry / Quality control [1]	28	4.5	28	100.0			14	50.0	1	3.6	13	46.4	8	28.6	20	71.4
Case control study	53	8.5	51	96.2	2	3.8	40	75.5	7	13.2	6	11.3			53	100.0
Other or n/a	261	41.9	261	100.0			207	79.3	25	9.6	29	11.1	21	8.0	240	92.0
Total number	623	100.0	615	98.7	8	1.3	465	74.6	61	9.8	97	15.6	38	6.1	585	93.9

[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**	**%col**
Other	165	26.5	82	29.2	4	14.3	8	15.1	71	27.2
Basic science	119	19.1	56	19.9	5	17.9	14	26.4	44	16.9
Psychology	74	11.9	27	9.6	0	0.0	13	24.5	34	13.0
Physiology/anatomy	49	7.9	24	8.5	2	7.1	5	9.4	18	6.9
Qualitative research	48	7.7	10	3.6	5	17.9	1	1.9	32	12.3
Epidemiology	40	6.4	24	8.5	0	0.0	4	7.5	12	4.6
Surgery	37	5.9	22	7.8	3	10.7	3	5.7	9	3.4
Healthcare services research	34	5.5	14	5.0	1	3.6	2	3.8	17	6.5
Medical devices	27	4.3	7	2.5	5	17.9	0	0.0	15	5.7
Drugs	20	3.2	9	3.2	3	10.7	1	1.9	7	2.7
Dentistry	10	1.6	6	2.1	0	0.0	2	3.8	2	0.8
Total projects	623	100.0	281	100.0	28	100.0	53	100.0	261	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 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	246	20.4
	No	962	79.6
Coding (HRO Art. 25-27)	Coded	1148	95.0
	Open, non-coded	60	5.0
Consent (HRO Art. 28-32)	Consent for all data	759	62.8
	Consent for some but not all data (partially Art. 34 HRA)	357	29.6
	No consent for all data, Art. 34 HRA	92	7.6
Combined vs. stand-alone projects	Stand-alone further use project	1000	82.8
	Further use project as part of a clinical trial	56	4.6
	Further use project as part of a non-clinical research project	152	12.6
Total number		1208	100.0

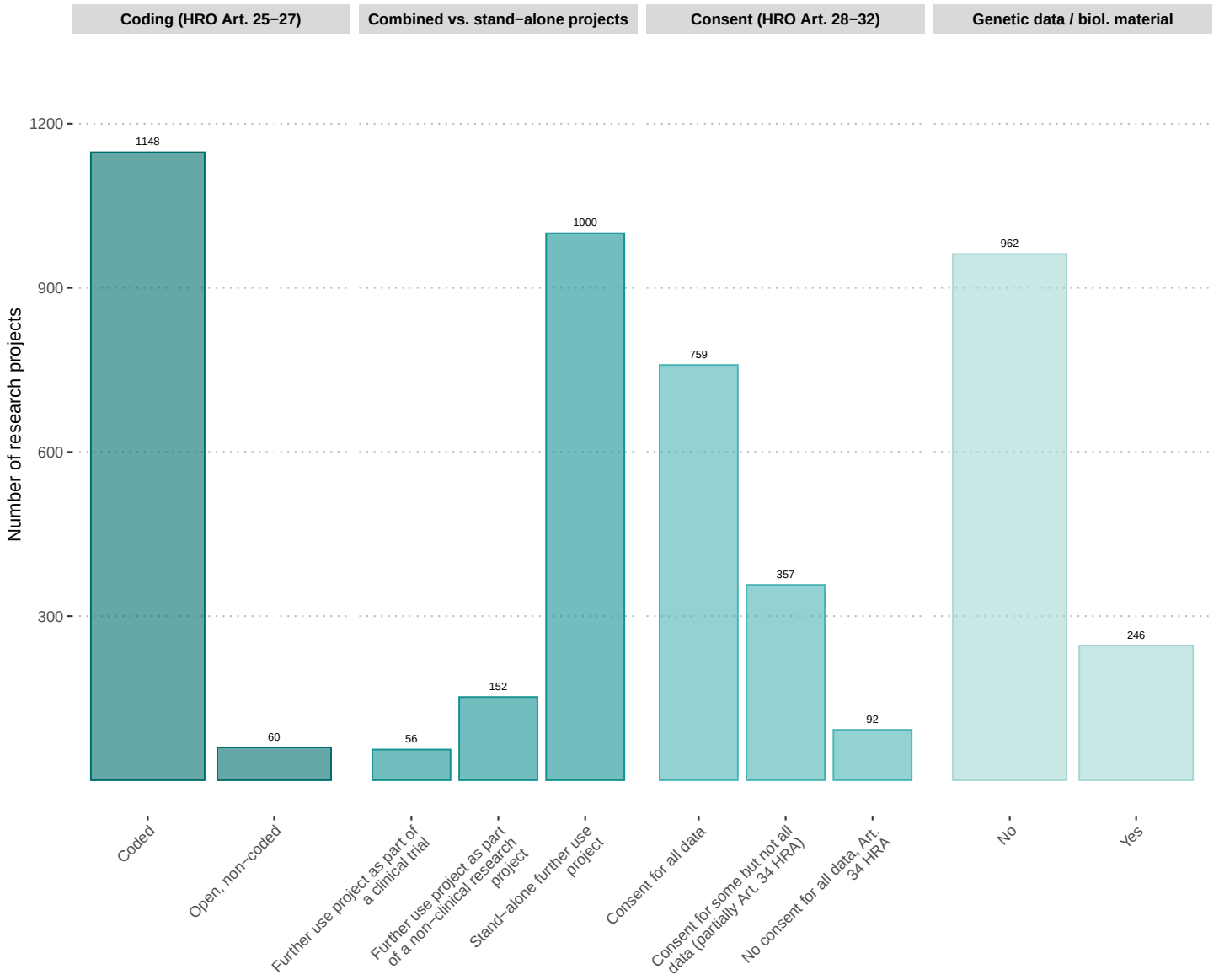

Figure 2: Overview of characteristics of all approved 'further use' projects separately for all research projects.

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** [1]	**N**	**%col**	**n**	**%row**	**n**	**%row**	**n**	**%row**	**n**	**%row**	**n**	**%row**
Yes	Coded	Consent for all data	191	80.3	136	71.2	12	6.3	43	22.5	55	28.8	136	71.2
		Consent for some but not all data (partially Art. 34 HRA)	41	17.2	31	75.6	3	7.3	7	17.1	0	0	41	100.0
		No consent for all data, Art. 34 HRA	6	2.5	4	66.7	0	0	2	33.3	0	0	6	100.0
		All	238	100.0	171	71.8	15	6.3	52	21.8	55	23.1	183	76.9
	Open, non-coded	Consent for all data	3	37.5	2	66.7	0	0	1	33.3	1	33.3	2	66.7
		Consent for some but not all data (partially Art. 34 HRA)	3	37.5	3	100.0	0	0	0	0	0	0	3	100.0
		No consent for all data, Art. 34 HRA	2	25.0	2	100.0	0	0	0	0	0	0	2	100.0
		All	8	100.0	7	87.5	0	0	1	12.5	1	12.5	7	87.5
	All		246	100.0	178	72.4	15	6.1	53	21.5	56	22.8	190	77.2
No	Coded	Consent for all data	535	58.8	401	75.0	46	8.6	88	16.4	34	6.4	501	93.6
		Consent for some but not all data (partially Art. 34 HRA)	295	32.4	226	76.6	27	9.2	42	14.2	2	0.7	293	99.3
		No consent for all data, Art. 34 HRA	80	8.8	73	91.2	3	3.8	4	5.0	0	0	80	100.0
		All	910	100.0	700	76.9	76	8.4	134	14.7	36	4.0	874	96.0
	Open, non-coded	Consent for all data	30	57.7	24	80.0	1	3.3	5	16.7	0	0	30	100.0
		Consent for some but not all data (partially Art. 34 HRA)	18	34.6	18	100.0	0	0	0	0	0	0	18	100.0
		No consent for all data, Art. 34 HRA	4	7.7	4	100.0	0	0	0	0	0	0	4	100.0
		All	52	100.0	46	88.5	1	1.9	5	9.6	0	0	52	100.0
	All		962	100.0	746	77.5	77	8.0	139	14.4	36	3.7	926	96.3
Total number			1208	100.0	924	76.5	92	7.6	192	15.9	92	7.6	1116	92.4

[1] Multiple selection possible.
The total number of 1208 research projects consist of 1000 standard 'further use' projects and 208 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	759	62.8	258	70.9	164	56.9	112	61.2	101	63.5	66	59.5	37	59.7	21	51.2
Consent for some but not all data (partially Art. 34 HRA)	357	29.6	87	23.9	112	38.9	67	36.6	51	32.1	14	12.6	11	17.7	15	36.6
No consent for all data, Art. 34 HRA	92	7.6	19	5.2	12	4.2	4	2.2	7	4.4	31	27.9	14	22.6	5	12.2
Total number	1208	100.0	364	100.0	288	100.0	183	100.0	159	100.0	111	100.0	62	100.0	41	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	1459	82.7
	Industry	57 [1]	3.2
	Universities/hospitals	109	6.2
	Private (non-industry)	112	6.3
	Swiss National Science Foundation	27	1.5
	All	1764	100.0
Industry	Public, other	67 [2]	26.1
	Industry	188 [3]	73.2
	Universities/hospitals	0	0.0
	Private (non-industry)	2	0.8
	Swiss National Science Foundation	0	0.0
	All	257	100.0
Other	Public, other	68	85.0
	Industry	0	0.0
	Universities/hospitals	4	5.0
	Private (non-industry)	7	8.8
	Swiss National Science Foundation	1	1.2
	All	80 [4]	100.0

[1] Applicants almost exclusively from academic institutions.
[2] Inspecting the sponsor information reveals that these are almost exclusively industry projects.
[3] 185 of the industry-initiated projects are financed exclusively by industry.
[4] 26 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.

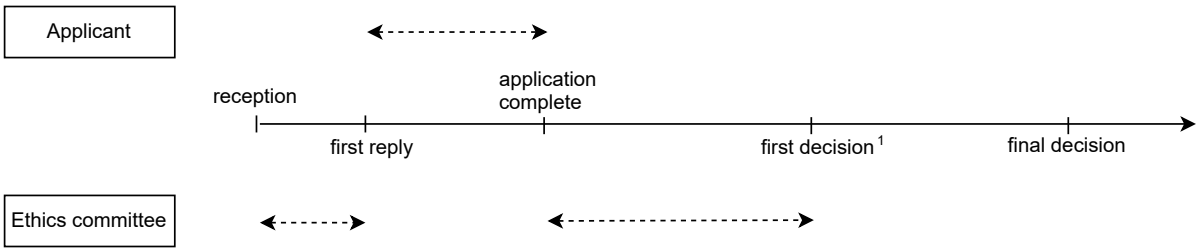

Figure 3: Overview of dates of milestones for each application. The only two periods that solely depend on the EC are denoted as well as the period that is mainly dependent on the applicant.

[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	10	6	[6, 7]	6	[6, 7]	40	[34, 49]	114	[89, 166]	33	[27, 42]	104	[81, 160]
	EKNZ	41	8	2	[0, 4]	4	[0, 5]	28	[19, 39]	81	[52, 132]	23	[18, 34]	77	[50, 125]
	CER-VD	33	9	3	[2, 5]	4	[2, 6]	25	[19, 34]	187	[122, 285]	20	[18, 25]	186	[113, 281]
	KEK-BE	31	12	4	[3, 6]	6	[4, 6]	25	[20, 28]	131	[100, 171]	19	[14, 22]	129	[95, 162]
	CCER	11	6	7	[6, 10]	7	[7, 15]	34	[32, 48]	138	[108, 205]	27	[20, 32]	131	[102, 184]
	EKOS	12	12	0	[0, 2]	2	[0, 4]	28	[18, 39]	80	[58, 135]	26	[16, 36]	78	[57, 109]
	CE-TI	64	96	6	[6, 6]	6	[6, 9]	35	[29, 42]	68	[42, 106]	26	[21, 32]	58	[32, 92]
	All	246	12	6	[3, 6]	6	[4, 7]	33	[24, 42]	105	[68, 169]	25	[19, 33]	97	[61, 156]
Simplified	KEK-ZH	294	55	6	[6, 7]	6	[6, 8]	60	[48, 69]	108	[83, 157]	50	[38, 61]	98	[73, 148]
	EKNZ	324	67	2	[1, 4]	4	[1, 6]	20	[12, 28]	50	[31, 84]	14	[8, 21]	45	[29, 76]
	CER-VD	224	64	3	[1, 5]	5	[2, 10]	24	[20, 32]	88	[57, 144]	18	[15, 21]	78	[50, 113]
	KEK-BE	234	87	4	[1, 5]	6	[5, 15]	25	[20, 44]	76	[54, 110]	15	[13, 20]	64	[47, 95]
	CCER	146	75	8	[4, 13]	14	[8, 24]	50	[37, 64]	152	[109, 202]	30	[23, 41]	127	[94, 176]
	EKOS	49	51	2	[0, 3]	2	[1, 4]	8	[5, 13]	29	[12, 53]	6	[2, 10]	28	[10, 49]
	CE-TI	3	4	6	[6, 6]	6	[6, 6]	32	[24, 33]	46	[39, 126]	26	[18, 27]	41	[34, 120]
	All	1274	64	4	[2, 6]	6	[4, 12]	31	[19, 55]	87	[53, 139]	20	[14, 36]	76	[46, 121]
Presidential	KEK-ZH	191	35	6	[6, 7]	6	[6, 7]	53	[42, 60]	79	[57, 125]	45	[34, 51]	70	[48, 116]
	EKNZ	119	25	2	[0, 4]	4	[1, 7]	8	[5, 14]	36	[11, 63]	5	[2, 7]	28	[7, 54]
	CER-VD	94	27	3	[1, 4]	4	[2, 10]	13	[8, 21]	39	[14, 86]	8	[6, 11]	29	[9, 43]
	KEK-BE	4	1	3	[2, 4]	8	[4, 17]	40	[29, 64]	90	[30, 152]	20	[10, 52]	68	[26, 120]
	CCER	38	19	10	[7, 17]	20	[14, 39]	32	[20, 46]	55	[35, 101]	11	[1, 16]	28	[11, 52]
	EKOS	35	36	2	[0, 2]	2	[0, 3]	7	[5, 10]	13	[6, 48]	3	[2, 8]	9	[3, 34]
	CE-TI	0	0		[,]		[,]		[,]		[,]		[,]		[,]
	All	481	24	5	[2, 6]	6	[3, 8]	31	[10, 52]	57	[28, 97]	11	[5, 41]	43	[15, 80]
Overall	KEK-ZH	539	100	6	[6, 7]	6	[6, 7]	55	[44, 65]	101	[74, 146]	46	[35, 56]	89	[64, 136]
	EKNZ	484	100	2	[0, 4]	4	[1, 6]	18	[10, 27]	49	[28, 82]	13	[6, 21]	43	[25, 75]
	CER-VD	351	100	3	[1, 5]	5	[2, 10]	22	[17, 31]	83	[46, 144]	16	[12, 20]	67	[40, 113]
	KEK-BE	269	100	4	[1, 5]	6	[4, 13]	25	[20, 40]	81	[57, 124]	15	[13, 21]	73	[49, 106]
	CCER	195	100	8	[5, 13]	16	[8, 25]	47	[33, 60]	133	[94, 196]	28	[20, 38]	113	[77, 167]
	EKOS	96	100	1	[0, 3]	2	[0, 4]	8	[5, 15]	28	[8, 61]	6	[2, 13]	25	[7, 56]
	CE-TI	67	100	6	[6, 6]	6	[6, 9]	35	[29, 42]	68	[42, 108]	26	[21, 32]	57	[32, 94]
	All	2001	100	5	[2, 6]	6	[4, 9]	32	[18, 52]	81	[48, 133]	20	[12, 36]	70	[40, 117]

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

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

5.3.1 Time from status "complete" to first decision

Definition:

In the following, **violin plots** are used to visualise the distribution of response times. Violin plots are similar to box plots except that they show more details on the distribution of the data by showing the probability density of the data at different values (kernel density plot). In addition, we denote the 1st, 2nd and 3rd quartile of the data by a small box plot inside the plot which makes the data comparable to what is provided in the tables (median and inter-quartile range).

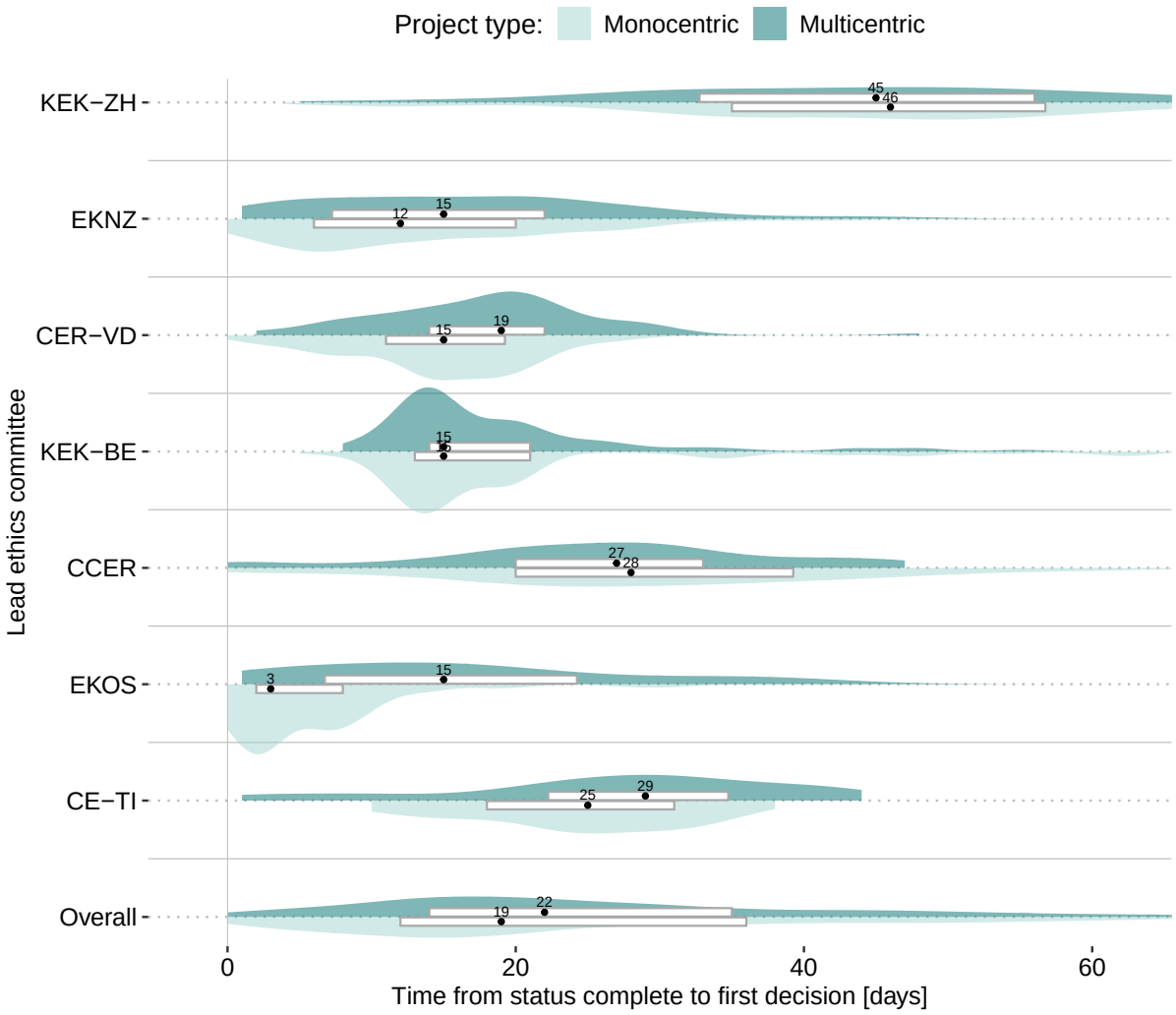

Figure 4: Violin plot of the time between status 'complete' to the first decision by EC. 32 projects with t $>$ 60 days are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 24.1.

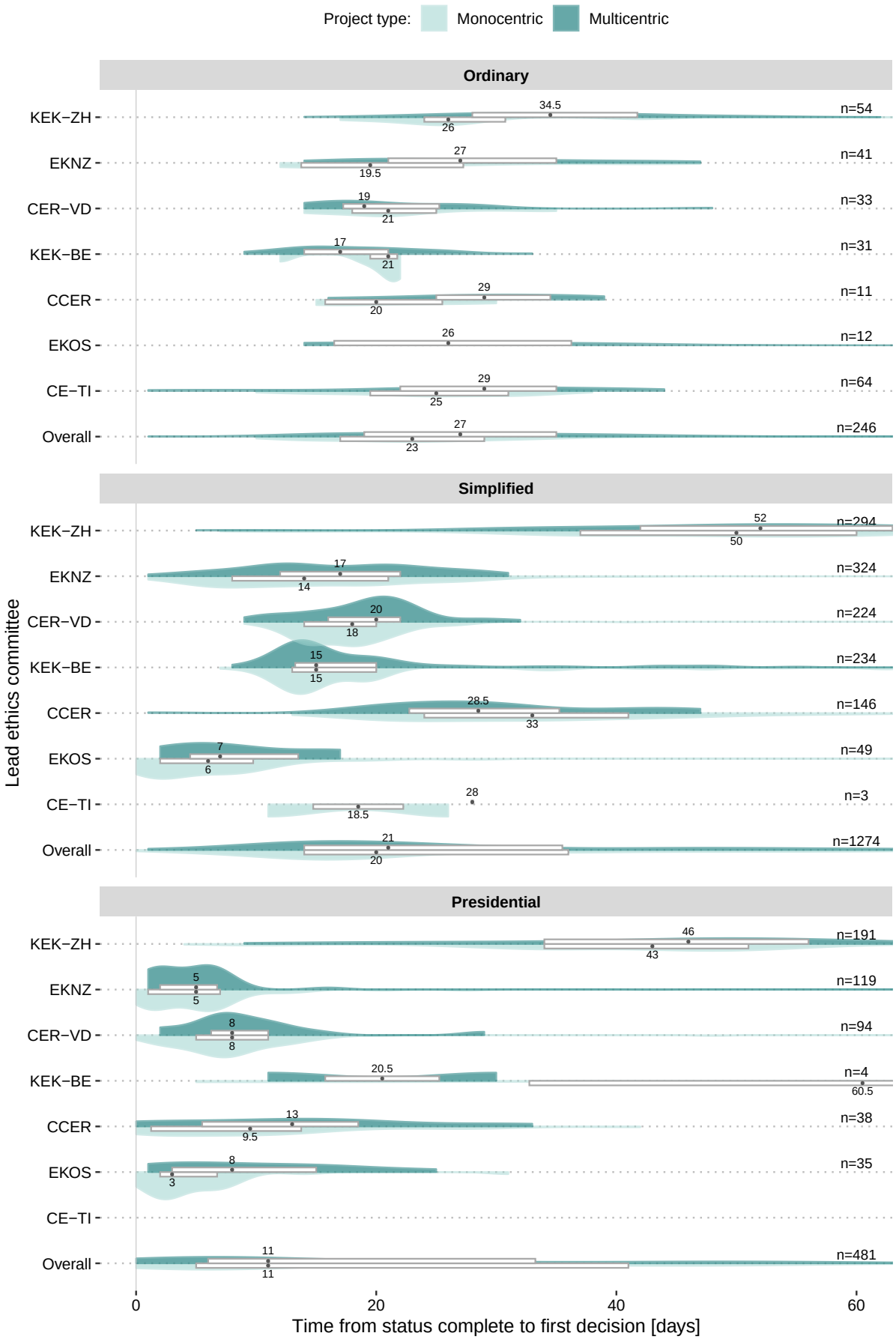

Figure 5: Violin plot of the time between status 'complete' to the first decision by EC and stratified by review procedure. 118 projects with t > 60 days are not shown for layout reasons. Note: *CE-TI* typically processes all submissions in a plenary session (ordinary procedure) but with adapted fees. ClinO-MD projects are not included but separately displayed in table 24.1.

5.3.2 Time from reception to final decision

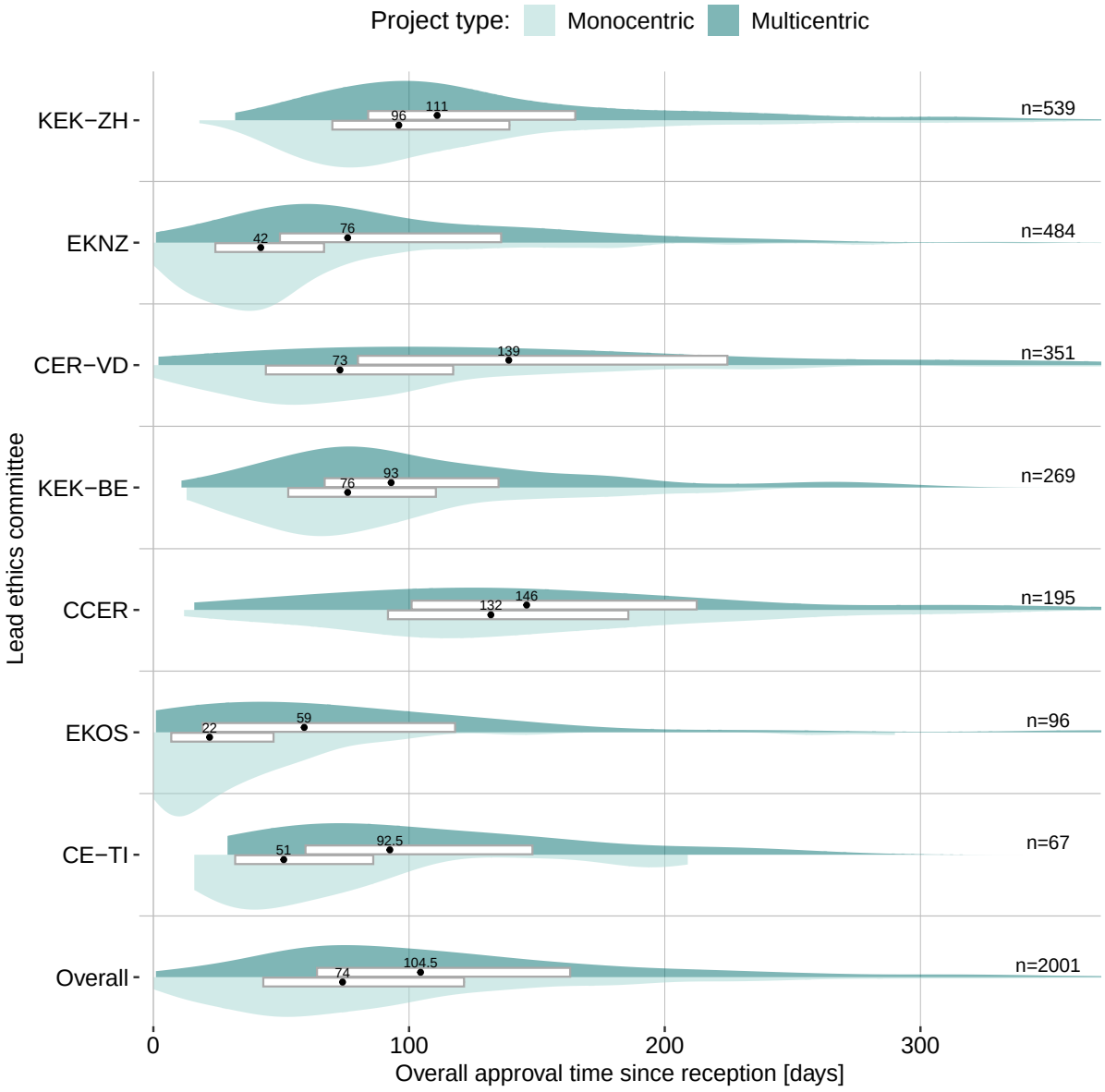

Figure 6: Violin plot of the overall approval time by EC from reception to final decision. 57 projects with approval time $>$ 1 year are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 24.1.

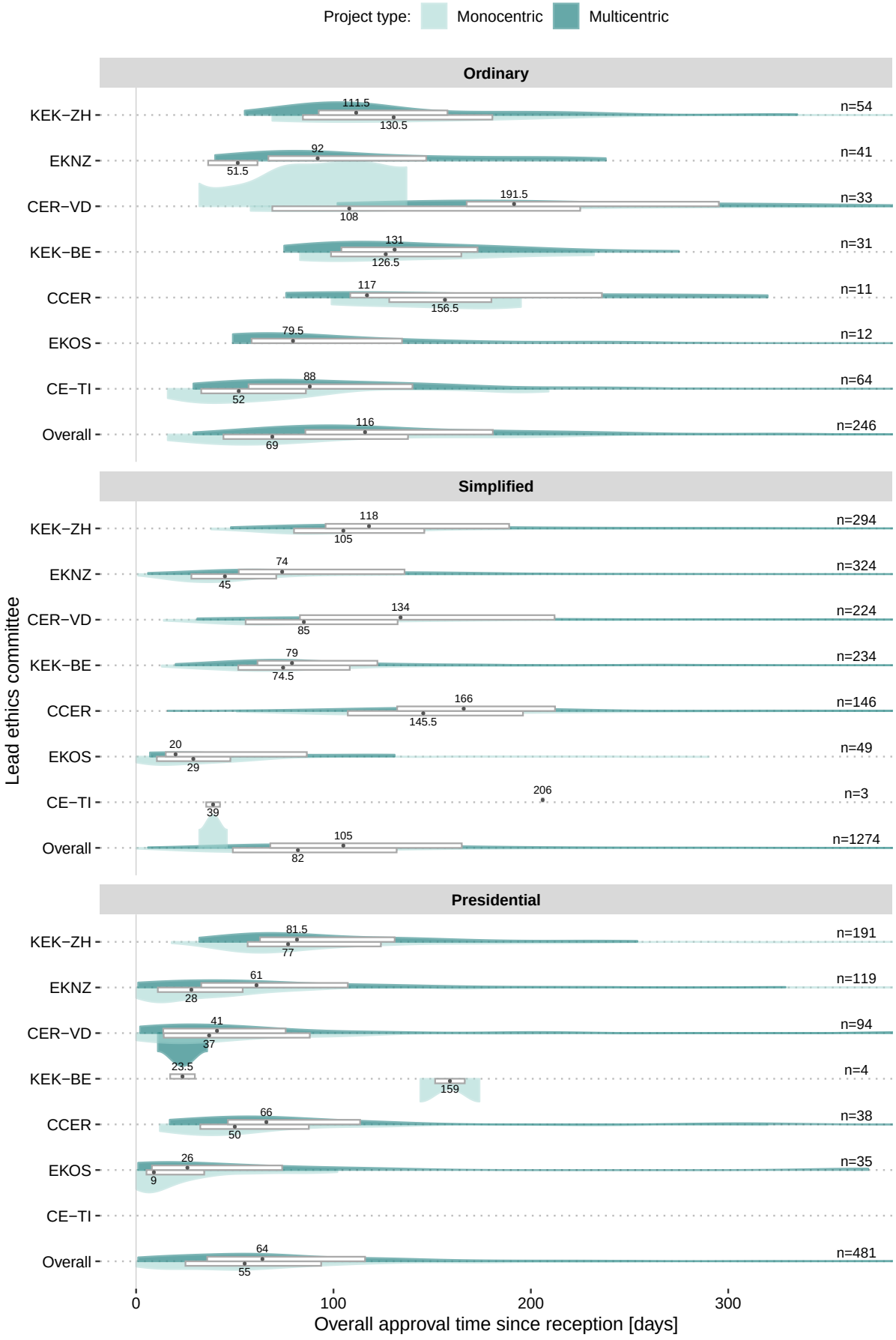

Figure 7: Violin plot of the overall approval time by EC from reception to final decision and stratified by review procedure. 55 projects with approval time $>$ 1 year are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 24.1.

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 d.		complete to final d.	
Type of research	EC	N	$\%_{EC}$	Median	IQR	Median	IQR	Median	IQR	Median	IQR	Median	IQR	Median	IQR
Clinical trial	KEK-ZH	103	29.3	6.0	[6.0, 7.0]	6.0	[6.0, 8.5]	49.0	[38.5, 64.0]	115.0	[92.0, 156.5]	41.0	[28.0, 54.5]	100.0	[81.5, 149.0]
	EKNZ	89	25.3	2.0	[0.0, 5.0]	4.0	[1.0, 6.0]	26.0	[19.0, 34.0]	63.0	[38.0, 124.0]	21.0	[15.0, 27.0]	57.0	[34.0, 111.0]
	CER-VD	38	10.8	3.0	[2.0, 5.0]	5.0	[2.0, 9.0]	25.5	[19.0, 35.5]	180.0	[122.0, 251.8]	19.0	[15.5, 24.2]	167.0	[105.5, 241.5]
	KEK-BE	61	17.3	4.0	[3.0, 6.0]	6.0	[4.8, 11.2]	25.0	[20.0, 34.0]	111.0	[76.0, 170.0]	17.0	[13.0, 21.0]	101.0	[69.0, 153.0]
	CCER	26	7.4	8.0	[5.0, 10.8]	12.5	[7.0, 21.0]	47.5	[35.5, 56.0]	156.5	[118.0, 210.0]	29.5	[23.2, 35.5]	136.0	[105.2, 196.5]
	EKOS	18	5.1	2.0	[0.0, 4.0]	2.0	[0.0, 6.0]	24.0	[15.0, 41.0]	69.5	[50.2, 124.0]	18.5	[13.2, 36.0]	61.0	[50.2, 101.2]
	CE-TI	17	4.8	6.0	[6.0, 6.0]	6.0	[6.0, 7.0]	33.0	[28.0, 39.0]	87.0	[57.0, 132.0]	24.0	[21.0, 33.0]	81.0	[50.0, 126.0]
	All	352	100.0	5.0	[2.0, 6.0]	6.0	[4.0, 9.0]	34.0	[23.0, 50.0]	108.5	[70.0, 169.0]	23.5	[16.0, 36.0]	98.0	[63.0, 152.2]
Research w/ persons	KEK-ZH	132	21.2	6.0	[6.0, 7.0]	6.0	[6.0, 8.0]	62.0	[48.0, 71.0]	110.0	[87.8, 148.8]	53.0	[37.5, 63.0]	99.0	[79.5, 139.0]
	EKNZ	146	23.4	2.0	[1.0, 4.0]	4.0	[1.0, 6.0]	20.0	[17.0, 28.0]	52.5	[38.2, 75.0]	18.0	[13.0, 22.0]	46.5	[34.0, 65.0]
	CER-VD	147	23.6	3.0	[2.0, 5.0]	5.0	[3.0, 9.0]	24.0	[20.0, 31.0]	91.0	[62.0, 140.5]	18.0	[15.0, 21.0]	84.0	[55.0, 125.5]
	KEK-BE	78	12.5	4.0	[1.0, 5.0]	6.0	[4.0, 13.0]	26.0	[18.0, 44.5]	89.5	[72.5, 125.5]	16.5	[14.0, 20.8]	84.0	[61.2, 110.8]
	CCER	78	12.5	8.0	[3.0, 12.2]	12.5	[7.2, 21.0]	47.0	[35.2, 63.5]	153.5	[116.5, 212.2]	30.5	[24.0, 41.0]	134.0	[98.0, 189.8]
	EKOS	20	3.2	2.0	[1.0, 3.0]	3.0	[1.0, 4.0]	8.5	[5.8, 13.0]	32.5	[19.2, 58.0]	5.0	[2.0, 8.5]	29.0	[16.2, 57.8]
	CE-TI	22	3.5	6.0	[6.0, 6.0]	6.0	[6.0, 16.5]	35.0	[34.2, 46.2]	85.0	[49.8, 146.8]	29.0	[25.5, 31.8]	74.5	[41.5, 122.8]
	All	623	100.0	5.0	[2.0, 6.0]	6.0	[4.0, 10.0]	31.0	[20.0, 53.8]	93.0	[58.0, 141.5]	21.0	[15.0, 35.0]	83.0	[50.0, 128.0]
Further use	KEK-ZH	289	28.9	6.0	[6.0, 7.0]	6.0	[6.0, 7.0]	54.0	[44.2, 62.0]	87.0	[64.0, 143.0]	46.0	[35.0, 53.0]	76.0	[53.0, 130.0]
	EKNZ	245	24.5	2.0	[0.0, 4.0]	4.0	[1.0, 6.0]	11.0	[6.0, 19.0]	41.0	[18.0, 78.0]	6.0	[4.0, 9.0]	34.0	[13.0, 67.0]
	CER-VD	166	16.6	2.0	[0.5, 4.0]	4.0	[2.0, 12.8]	19.0	[12.0, 29.8]	53.0	[28.2, 105.2]	12.0	[7.0, 18.0]	42.0	[21.0, 71.0]
	KEK-BE	127	12.7	4.0	[1.0, 5.0]	6.0	[5.0, 15.5]	25.0	[20.0, 44.0]	66.0	[47.5, 96.0]	15.0	[13.0, 20.0]	56.0	[37.0, 81.0]
	CCER	88	8.8	9.0	[5.8, 14.0]	18.5	[11.0, 30.8]	44.0	[31.0, 60.8]	106.0	[61.5, 179.0]	22.0	[11.8, 34.2]	84.0	[31.5, 139.0]
	EKOS	57	5.7	1.0	[0.0, 2.0]	1.5	[0.0, 3.0]	7.0	[4.0, 10.0]	12.0	[6.0, 37.0]	6.0	[2.0, 8.0]	9.0	[3.0, 32.0]
	CE-TI	28	2.8	6.0	[6.0, 6.0]	6.0	[6.0, 8.0]	31.0	[22.8, 38.8]	49.5	[29.0, 69.0]	23.0	[16.5, 29.5]	38.0	[23.0, 58.5]
	All	1000	100.0	5.0	[1.0, 6.0]	6.0	[3.0, 9.2]	29.0	[13.0, 52.0]	66.0	[36.0, 113.2]	15.0	[7.0, 36.0]	54.5	[27.0, 94.0]
Deceased and embryos from stillbirths or abortion	KEK-ZH	15	57.7	6.0	[6.0, 7.0]	6.0	[6.0, 7.0]	46.0	[42.0, 58.2]	71.0	[64.5, 88.0]	40.0	[36.8, 49.8]	65.0	[54.0, 82.0]
	EKNZ	4	15.4	0.0	[0.0, 0.5]	8.0	[5.2, 10.0]	24.0	[21.0, 26.0]	54.5	[49.8, 56.2]	14.0	[10.5, 19.2]	43.5	[38.2, 49.5]
	CER-VD	0	0.0		[,]		[,]		[,]		[,]		[,]		[,]
	KEK-BE	3	11.5	5.0	[2.5, 6.0]	6.0	[5.5, 15.0]	19.0	[16.0, 29.0]	69.0	[65.5, 75.0]	14.0	[10.5, 14.5]	57.0	[56.5, 60.5]
	CCER	3	11.5	10.0	[9.0, 16.0]	22.0	[17.5, 24.0]	41.0	[40.0, 45.5]	145.0	[123.5, 172.5]	24.0	[21.5, 25.0]	119.0	[104.0, 148.5]
	EKOS	1	3.8	3.0	[3.0, 3.0]	3.0	[3.0, 3.0]	13.0	[13.0, 13.0]	13.0	[13.0, 13.0]	10.0	[10.0, 10.0]	10.0	[10.0, 10.0]
	CE-TI	0	0.0		[,]		[,]		[,]		[,]		[,]		[,]
	All	26	100.0	6.0	[4.5, 7.2]	6.0	[6.0, 9.0]	42.0	[26.0, 50.0]	69.5	[57.5, 89.5]	30.0	[15.0, 40.0]	64.0	[49.2, 83.5]
Overall	KEK-ZH	539	100.0	6.0	[6.0, 7.0]	6.0	[6.0, 7.0]	55.0	[44.0, 65.0]	101.0	[74.0, 146.5]	46.0	[35.0, 56.0]	89.0	[64.0, 136.0]
	EKNZ	484	100.0	2.0	[0.0, 4.0]	4.0	[1.0, 6.0]	18.0	[10.0, 27.0]	49.0	[28.0, 82.2]	13.0	[6.0, 21.0]	43.0	[24.8, 75.2]
	CER-VD	351	100.0	3.0	[1.0, 5.0]	5.0	[2.0, 10.0]	22.0	[17.0, 31.0]	83.0	[46.5, 144.0]	16.0	[11.5, 20.0]	67.0	[39.5, 113.0]
	KEK-BE	269	100.0	4.0	[1.0, 5.2]	6.0	[4.0, 13.0]	25.0	[20.0, 40.0]	81.0	[57.0, 124.0]	15.0	[13.0, 21.0]	73.0	[49.0, 106.0]
	CCER	195	100.0	8.0	[5.0, 13.0]	16.0	[8.0, 25.0]	47.0	[33.0, 60.0]	133.0	[94.5, 195.5]	28.0	[20.0, 38.0]	113.0	[77.0, 167.0]
	EKOS	96	100.0	1.0	[0.0, 3.0]	2.0	[0.0, 4.0]	8.0	[5.0, 15.0]	28.5	[8.0, 61.2]	6.5	[2.0, 13.2]	25.0	[7.0, 56.5]
	CE-TI	67	100.0	6.0	[6.0, 6.0]	6.0	[6.0, 9.0]	35.0	[29.0, 41.5]	68.0	[42.0, 108.0]	26.0	[21.0, 32.0]	57.0	[32.0, 94.0]
	All	2001	100.0	5.0	[2.0, 6.0]	6.0	[4.0, 9.0]	32.0	[18.0, 52.0]	81.0	[48.0, 133.0]	20.0	[12.0, 36.0]	70.0	[40.0, 117.0]

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	123	5	[2, 6]	229	5	[2, 6]
	from receipt to status 'complete'	123	6	[4, 7]	229	6	[5, 10]
	from receipt to first decision	123	34	[24, 46]	229	34	[21, 54]
	from receipt to final decision	123	117	[88, 162]	229	99	[58, 169]
	from 'complete' to first decision	123	27	[20, 36]	229	22	[14, 35]
	from 'complete' to final decision	123	107	[84, 152]	229	84	[53, 152]
Research w/ persons	from receipt to first reply	57	5	[1, 6]	566	5	[2, 6]
	from receipt to status 'complete'	57	6	[5, 18]	566	6	[4, 9]
	from receipt to first decision	57	35	[23, 53]	566	31	[20, 54]
	from receipt to final decision	57	128	[79, 158]	566	90	[56, 138]
	from 'complete' to first decision	57	22	[17, 30]	566	21	[15, 35]
	from 'complete' to final decision	57	106	[70, 151]	566	82	[49, 124]
Further use	from receipt to first reply	75	6	[2, 6]	925	4	[1, 6]
	from receipt to status 'complete'	75	10	[6, 24]	925	6	[3, 9]
	from receipt to first decision	75	45	[27, 70]	925	27	[12, 51]
	from receipt to final decision	75	112	[67, 187]	925	62	[34, 107]
	from 'complete' to first decision	75	21	[15, 39]	925	15	[7, 36]
	from 'complete' to final decision	75	91	[56, 160]	925	51	[25, 89]
Deceased persons	from receipt to first reply	0		[,]	26	6	[4, 7]
	from receipt to status 'complete'	0		[,]	26	6	[6, 9]
	from receipt to first decision	0		[,]	26	42	[26, 50]
	from receipt to final decision	0		[,]	26	70	[58, 90]
	from 'complete' to first decision	0		[,]	26	30	[15, 40]
	from 'complete' to final decision	0		[,]	26	64	[49, 84]
Overall	from receipt to first reply	255	5	[2, 6]	1746	5	[2, 6]
	from receipt to status 'complete'	255	6	[4, 14]	1746	6	[4, 9]
	from receipt to first decision	255	35	[25, 53]	1746	31	[17, 52]
	from receipt to final decision	255	117	[80, 173]	1746	76	[44, 126]
	from 'complete' to first decision	255	25	[17, 36]	1746	19	[12, 36]
	from 'complete' to final decision	255	105	[73, 155]	1746	64	[36, 108]

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 involved.

		Application involves					
		Multiple ECs			Single EC		
Lead EC	Time interval	N	Median	IQR	N	Median	IQR
KEK-ZH	from receipt to first reply	67	6	[6, 7]	472	6	[6, 7]
	from receipt to status 'complete'	67	6	[6, 7]	472	6	[6, 7]
	from receipt to first decision	67	51	[38, 63]	472	56	[45, 65]
	from receipt to final decision	67	118	[94, 165]	472	98	[72, 142]
	from 'complete' to first decision	67	43	[32, 56]	472	46	[35, 56]
	from 'complete' to final decision	67	107	[86, 154]	472	85	[63, 130]
EKNZ	from receipt to first reply	51	2	[0, 4]	433	2	[0, 4]
	from receipt to status 'complete'	51	4	[2, 17]	433	4	[1, 6]
	from receipt to first decision	51	28	[22, 37]	433	17	[10, 26]
	from receipt to final decision	51	99	[64, 146]	433	44	[26, 72]
	from 'complete' to first decision	51	21	[16, 28]	433	12	[6, 20]
	from 'complete' to final decision	51	91	[63, 142]	433	40	[22, 64]
CER-VD	from receipt to first reply	28	3	[2, 5]	323	3	[1, 5]
	from receipt to status 'complete'	28	5	[3, 19]	323	5	[2, 9]
	from receipt to first decision	28	31	[22, 40]	323	21	[16, 30]
	from receipt to final decision	28	168	[122, 266]	323	77	[44, 132]
	from 'complete' to first decision	28	20	[18, 24]	323	15	[11, 20]
	from 'complete' to final decision	28	158	[100, 222]	323	63	[37, 104]
KEK-BE	from receipt to first reply	51	4	[1, 5]	218	4	[1, 6]
	from receipt to status 'complete'	51	6	[5, 15]	218	6	[4, 13]
	from receipt to first decision	51	25	[20, 34]	218	25	[19, 41]
	from receipt to final decision	51	105	[78, 141]	218	76	[52, 111]
	from 'complete' to first decision	51	17	[14, 20]	218	15	[13, 21]
	from 'complete' to final decision	51	98	[65, 136]	218	68	[45, 100]
CCER	from receipt to first reply	26	8	[3, 13]	169	9	[5, 13]
	from receipt to status 'complete'	26	18	[11, 24]	169	15	[8, 25]
	from receipt to first decision	26	47	[36, 58]	169	47	[33, 60]
	from receipt to final decision	26	138	[113, 305]	169	132	[89, 188]
	from 'complete' to first decision	26	30	[20, 34]	169	28	[20, 38]
	from 'complete' to final decision	26	110	[97, 298]	169	118	[73, 160]
EKOS	from receipt to first reply	17	1	[0, 2]	79	2	[0, 3]
	from receipt to status 'complete'	17	2	[0, 4]	79	2	[0, 4]
	from receipt to first decision	17	26	[19, 38]	79	7	[4, 12]
	from receipt to final decision	17	76	[57, 131]	79	21	[7, 48]
	from 'complete' to first decision	17	20	[17, 36]	79	3	[2, 8]
	from 'complete' to final decision	17	76	[50, 122]	79	16	[6, 47]
CE-TI	from receipt to first reply	15	6	[6, 8]	52	6	[6, 6]
	from receipt to status 'complete'	15	7	[6, 12]	52	6	[6, 6]
	from receipt to first decision	15	40	[35, 52]	52	34	[26, 38]
	from receipt to final decision	15	88	[74, 136]	52	52	[36, 96]
	from 'complete' to first decision	15	32	[28, 35]	52	24	[17, 30]
	from 'complete' to final decision	15	80	[56, 127]	52	46	[27, 83]
Overall	from receipt to first reply	255	5	[2, 6]	1746	5	[2, 6]
	from receipt to status 'complete'	255	6	[4, 14]	1746	6	[4, 9]
	from receipt to first decision	255	35	[25, 53]	1746	31	[17, 52]
	from receipt to final decision	255	117	[80, 173]	1746	76	[44, 126]
	from 'complete' to first decision	255	25	[17, 36]	1746	19	[12, 36]
	from 'complete' to final decision	255	105	[73, 155]	1746	64	[36, 108]

5.4.1 Time from status “complete” to first decision

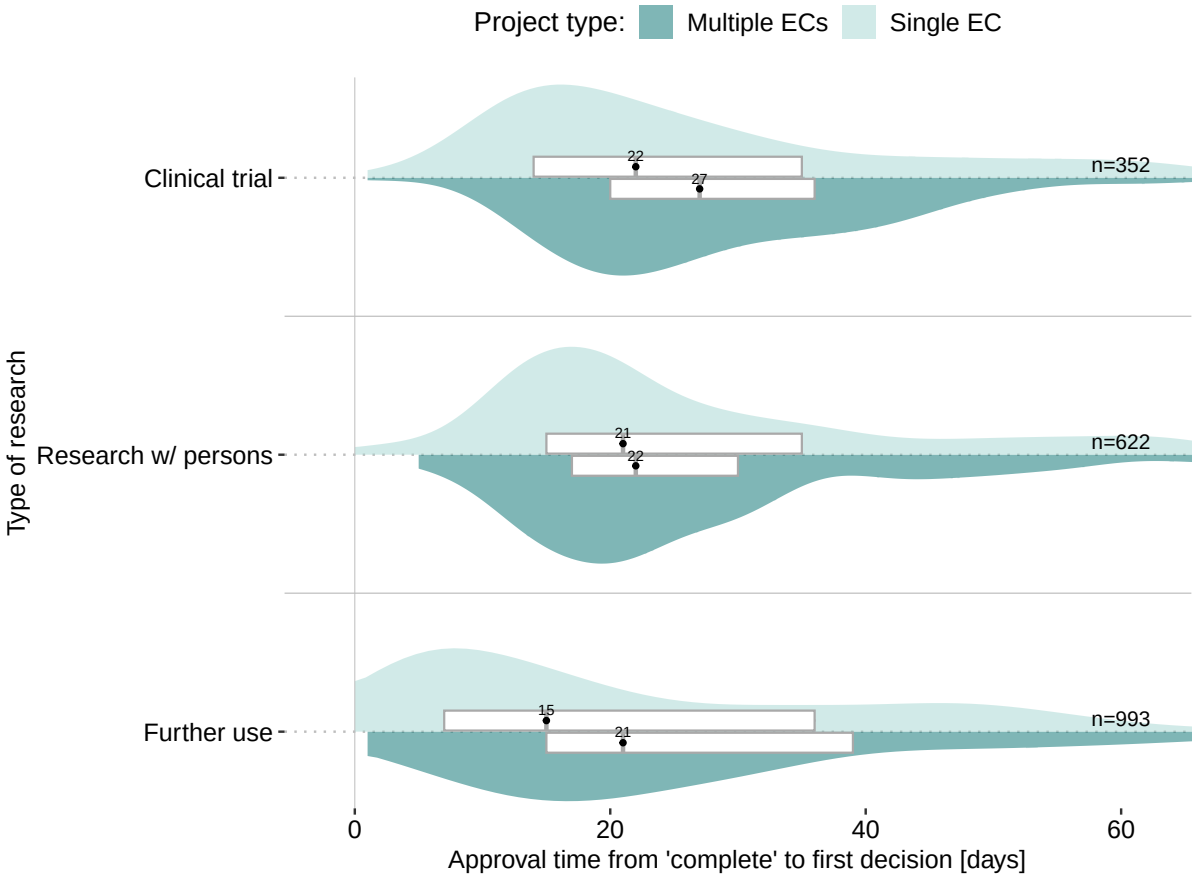

Figure 8: Violin plot of the **approval time starting from status 'complete' to the first decision** per type of research (only the 3 major groups are shown). 32 projects with approval time $>$ 60 days are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table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

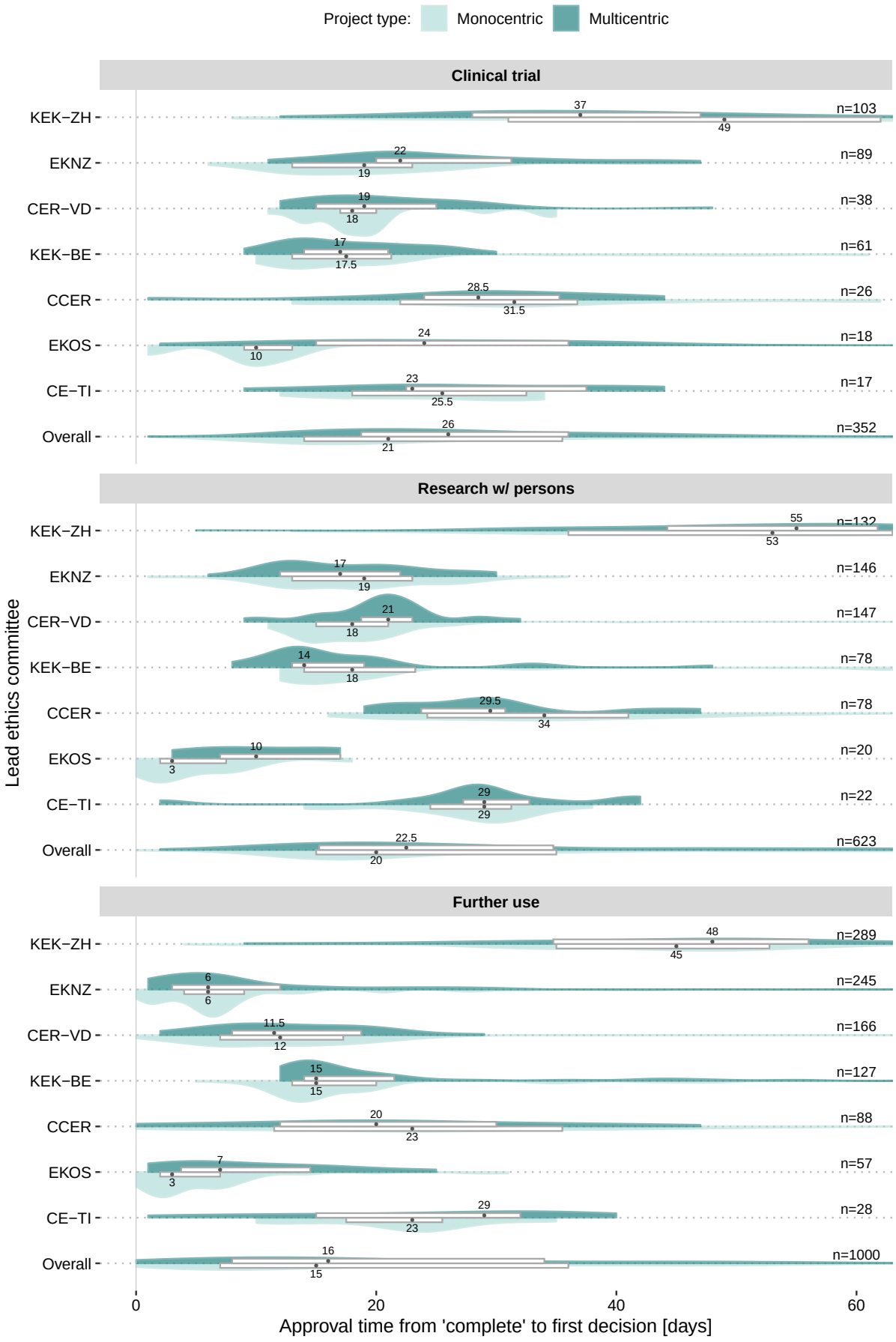

Figure 9: Violin plot of the **approval time starting from status 'complete' to the first decision** per type of research (only the 3 major groups are shown) stratified by EC. 118 projects with approval time > 60 days are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 24.1.

5.4.2 Time from reception to final decision

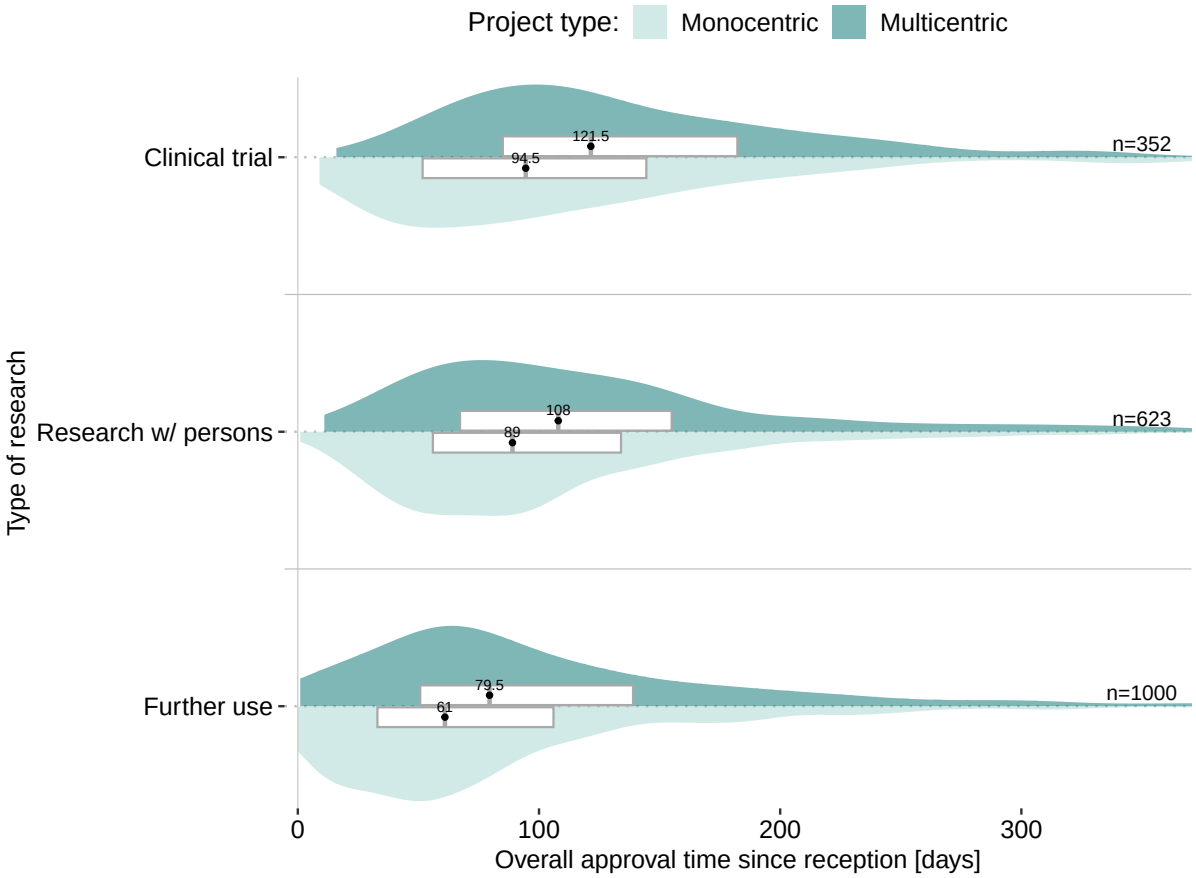

Figure 10: Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown). 57 projects with an overall approval time $>$ 1 year are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 24.1.

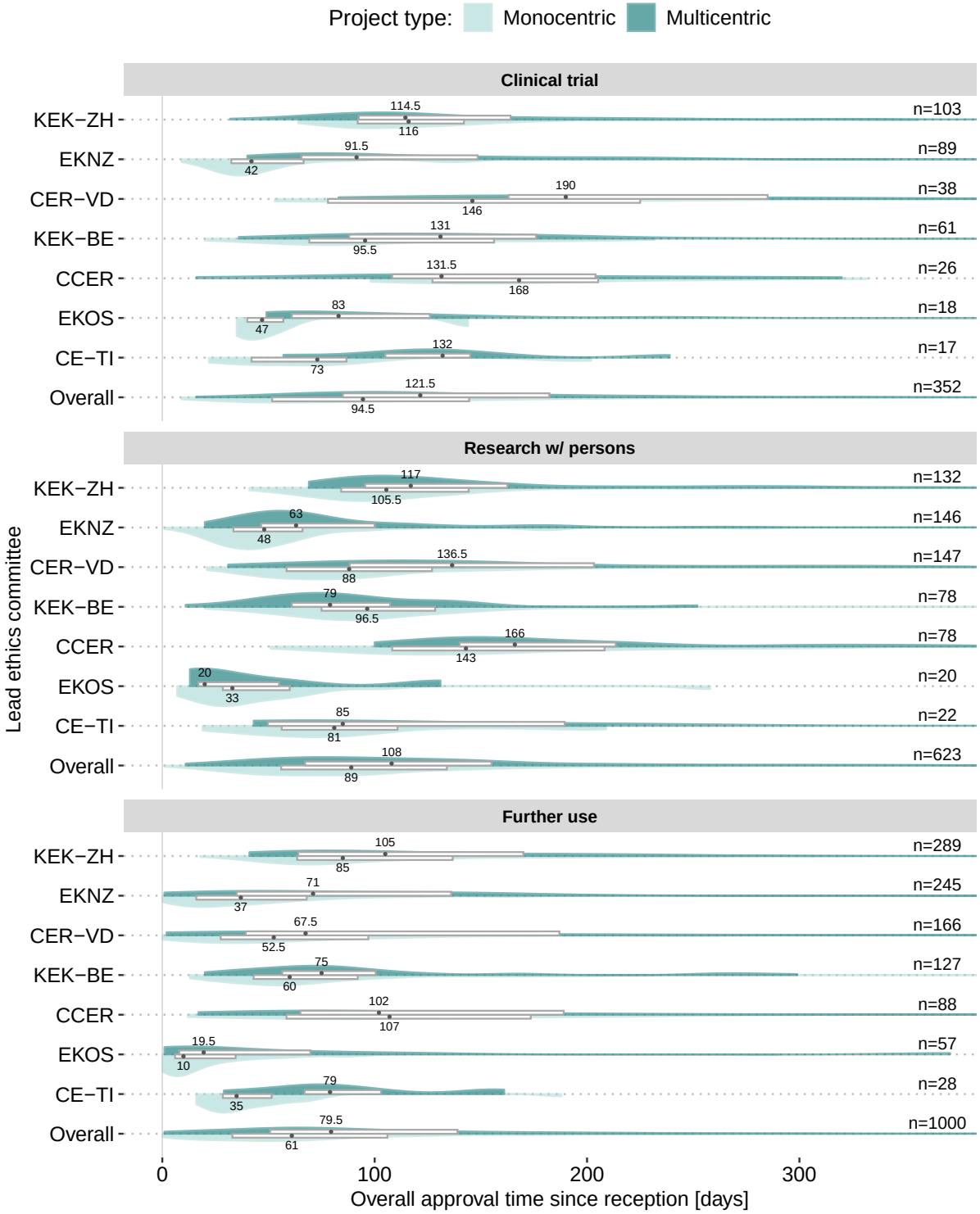

Figure 11: Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown) stratified by EC. 55 projects with an overall approval time $>$ 1 year are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 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		N	Median	IQR	N	Median	IQR
KEK-ZH	from receipt to status 'complete'	9	9	[8, 11]	25	8	[7, 9]
	from receipt to final decision	9	58	[54, 76]	25	57	[39, 80]
	from 'complete' to final decision	9	54	[44, 65]	25	50	[32, 73]
EKNZ	from receipt to status 'complete'	1	5	[5, 5]	5	1	[0, 5]
	from receipt to final decision	1	25	[25, 25]	5	23	[20, 36]
	from 'complete' to final decision	1	20	[20, 20]	5	23	[19, 23]
CER-VD	from receipt to status 'complete'	2	6	[5, 6]	15	6	[4, 9]
	from receipt to final decision	2	62	[52, 71]	15	41	[33, 60]
	from 'complete' to final decision	2	56	[48, 64]	15	35	[27, 48]
KEK-BE	from receipt to status 'complete'	4	7	[5, 8]	19	7	[4, 9]
	from receipt to final decision	4	46	[41, 48]	19	45	[38, 66]
	from 'complete' to final decision	4	40	[32, 44]	19	39	[30, 51]
CCER	from receipt to status 'complete'	2	11	[10, 12]	7	12	[4, 21]
	from receipt to final decision	2	108	[91, 125]	7	105	[82, 142]
	from 'complete' to final decision	2	97	[79, 115]	7	83	[69, 132]
EKOS	from receipt to status 'complete'	0		[,]	3	4	[4, 4]
	from receipt to final decision	0		[,]	3	14	[13, 38]
	from 'complete' to final decision	0		[,]	3	10	[8, 34]
CE-TI	from receipt to status 'complete'	5	9	[9, 10]	3	9	[9, 9]
	from receipt to final decision	5	118	[70, 163]	3	43	[34, 48]
	from 'complete' to final decision	5	109	[59, 154]	3	34	[24, 40]
Overall	from receipt to status 'complete'	23	9	[6, 10]	77	7	[5, 9]
	from receipt to final decision	23	58	[47, 92]	77	49	[36, 72]
	from 'complete' to final decision	23	54	[38, 84]	77	40	[29, 62]

The total number of 100 research projects consist of 96 trials with medical devices and 4 trials on a combination medicinal product and medical device.

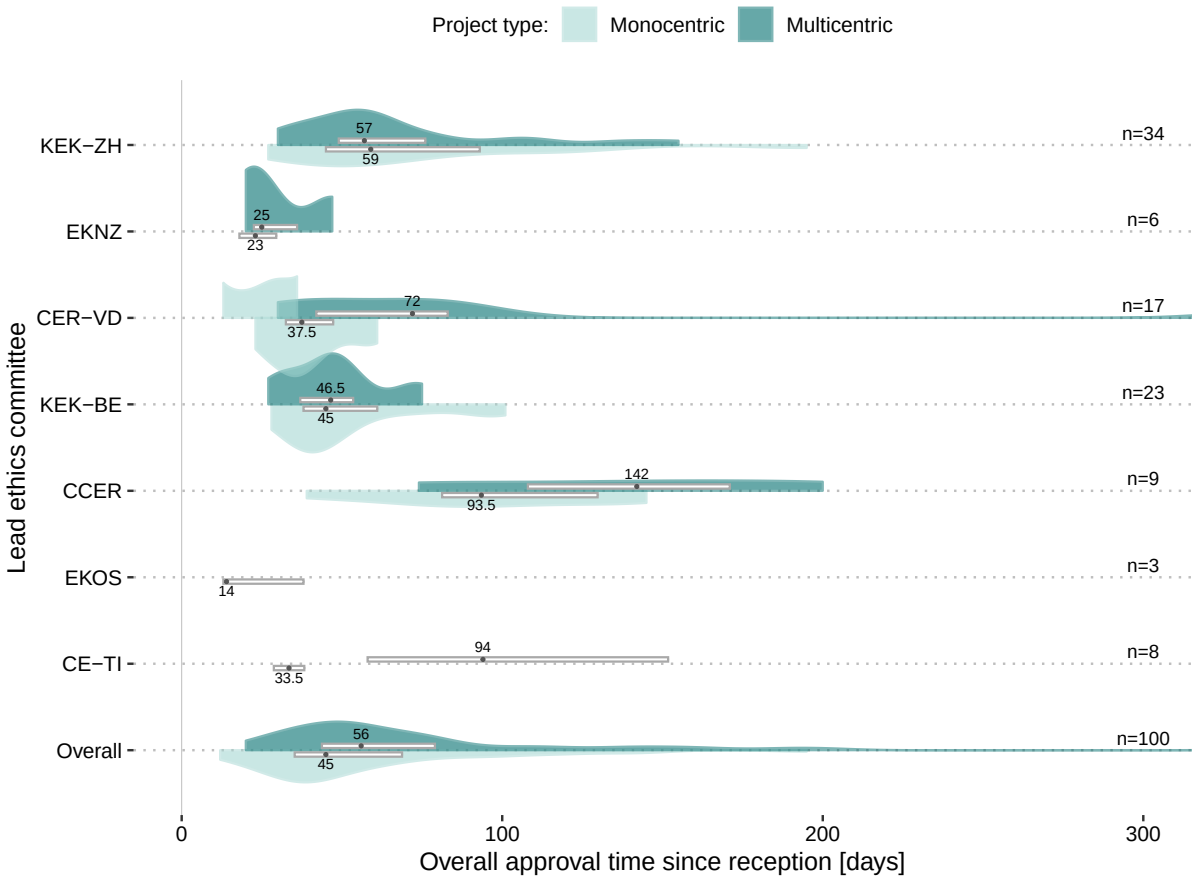

Figure 12: Violin plot of the overall approval time by EC from reception to final decision - **only for ClinO-MD projects**. Note: No density can be calculated and displayed for groups with less than 2 observations.

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.

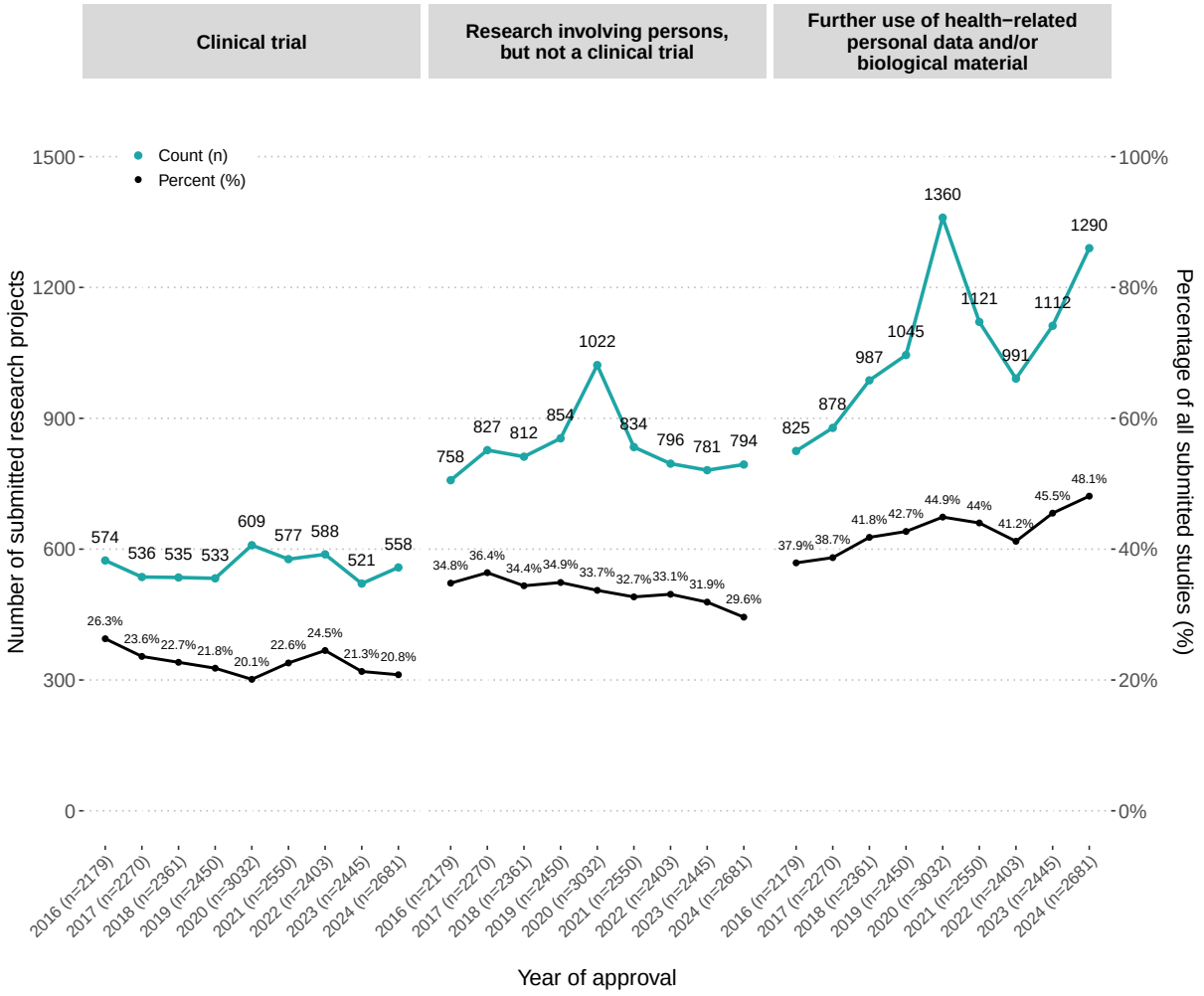

Figure 13: Total number of submitted projects per year and type of research. Percentages refer to the proportion of studies of a given type compared to all studies submitted in a given year.

Data not shown in the above figure: Research involving deceased persons (2020: 40, 2021: 18, 2022: 28, 2023: 29, 2024: 36) and Research involving embryos and fetuses from induced abortions or stillbirths (2020: 1, 2021: 0, 2022: 0, 2023: 2, 2024: 3)

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 are compared with data from previous years, starting in 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.

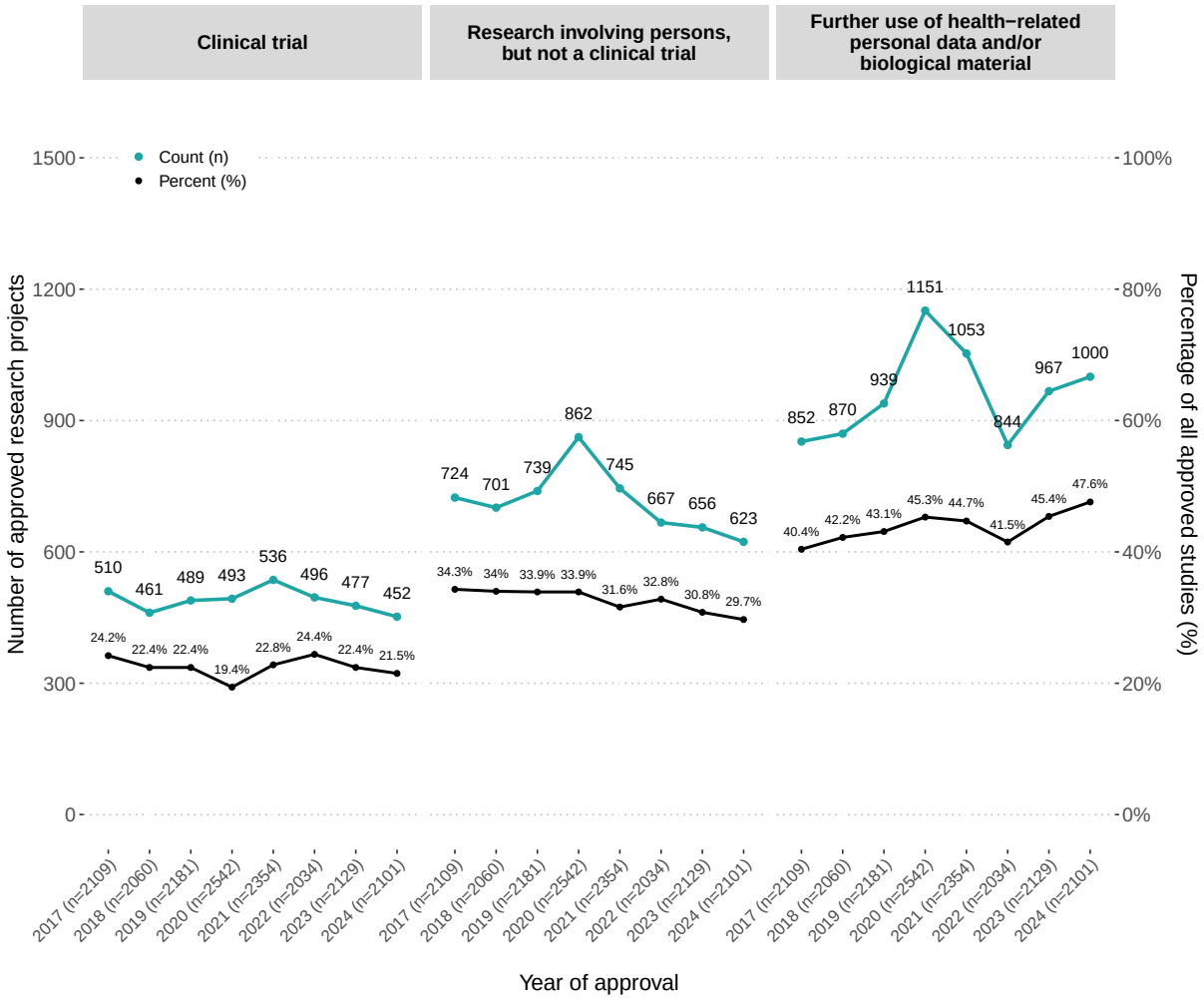

Figure 14: Total number of approved projects per year and type of research. Percentages refer to the proportion of studies of a given type compared to all studies approved in a given year.

Data not shown in the above figure: Research involving deceased persons (2018: 27, 2019: 14, 2020: 40, 2021: 19, 2022: 27, 2023: 28, 2024: 24) and Research involving embryos and fetuses from induced abortions or stillbirths (2018: 0, 2019: 0, 2020: 1, 2021: 1, 2022: 0, 2023: 1 2024: 2)

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

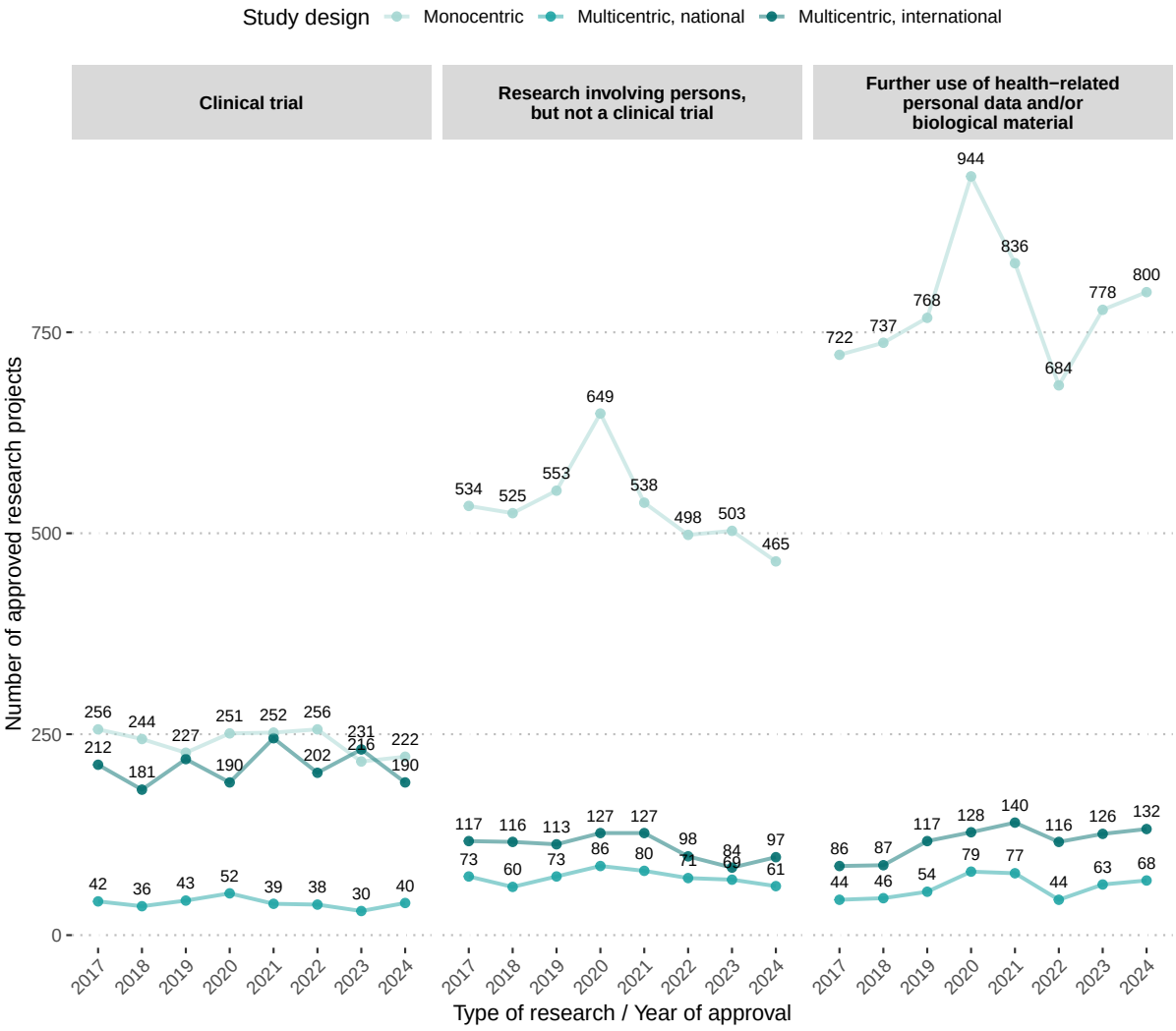

Figure 15: Approved projects per year stratified by type of research project and by study design.

Data not shown in the above figure: Research involving deceased persons (2018: 28, 2019: 14, 2020: 36, 2021: 19, 2022: 27, 2023: 28, 2024: 24) and Research involving embryos and fetuses from induced abortions or stillbirths (2018: 0, 2019: 0, 2020: 0, 2021: 1, 2022: 0, 2023: 1 2024: 2)

7.2 Project initiator

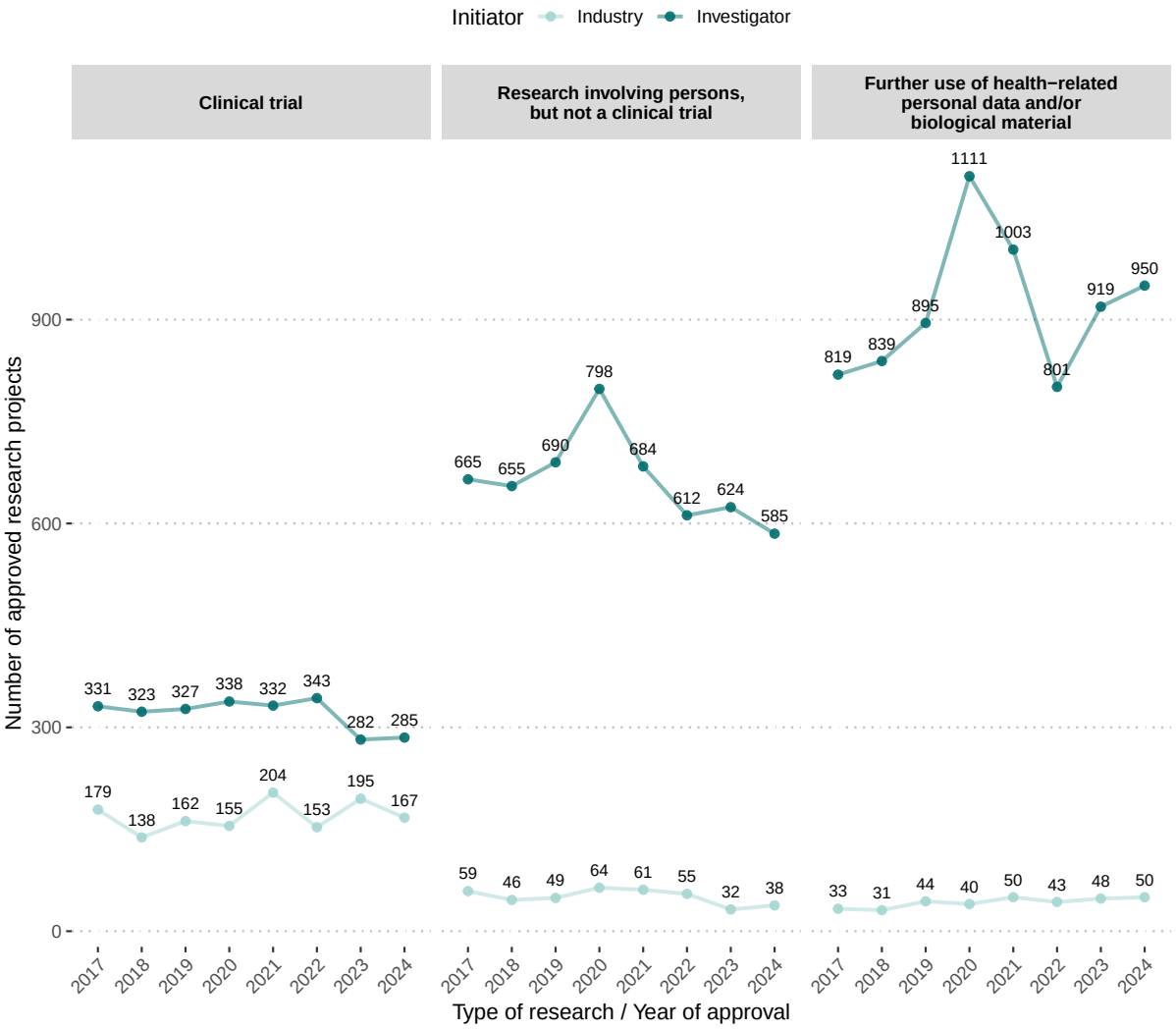

Figure 16: Approved projects per year stratified by type of research project and by project initiator.

Data not shown in the above figure: Research involving deceased persons (2018: 28, 2019: 14, 2020: 36, 2021: 19, 2022: 27, 2023: 28, 2024: 24) and Research involving embryos and fetuses from induced abortions or stillbirths (2018: 0, 2019: 0, 2020: 0, 2021: 1, 2022: 0, 2023: 1 2024: 2)

7.3 Risk category

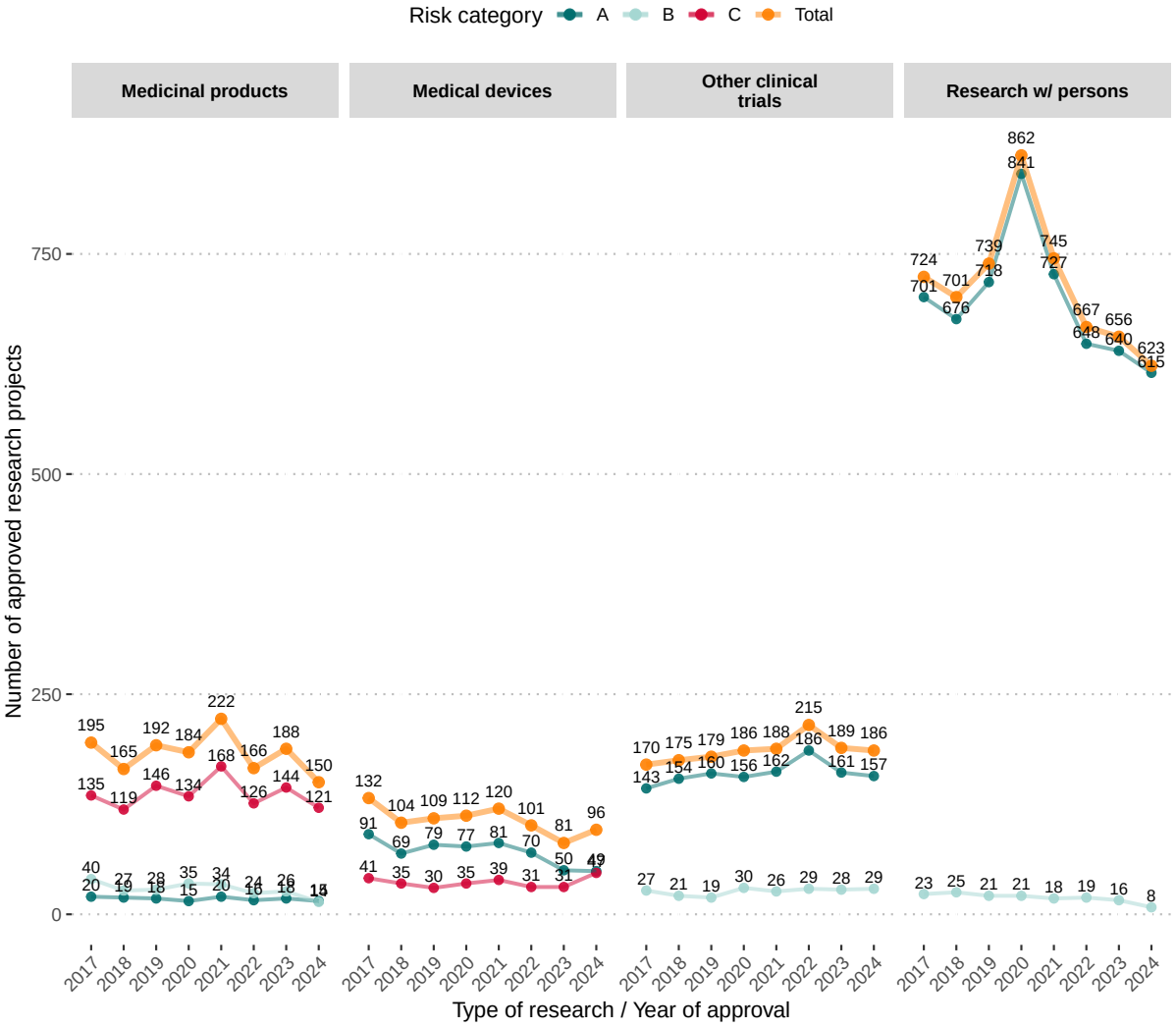

Figure 17: Clinical trials and research projects involving persons approved per year stratified by type of research project and risk category.

Data not shown in the above figure: Research involving transplant products (2018: 9, 2019: 4, 2020: 6, 2021: 2, 2022: 6, 2023: 6 , 2024: 7), combination drugs/devices (2018: 4, 2019: 3, 2021: 2, 2022: 3, 2023: 10, 2024: 9) , gene therapy (2018: 3 2019: 2 2020: 1, 2021: 1, 2022: 2, 2023: 1, 2024: 2) , transplantation (2018: 1, 2019: 0, 2020: 0, 2021: 0, 2022: 1, 2023: 0, 2024: 2) and pathogenic organisms (2022: 2, 2023: 2, 2024: 0)

7.4 Subgroups of clinical trials

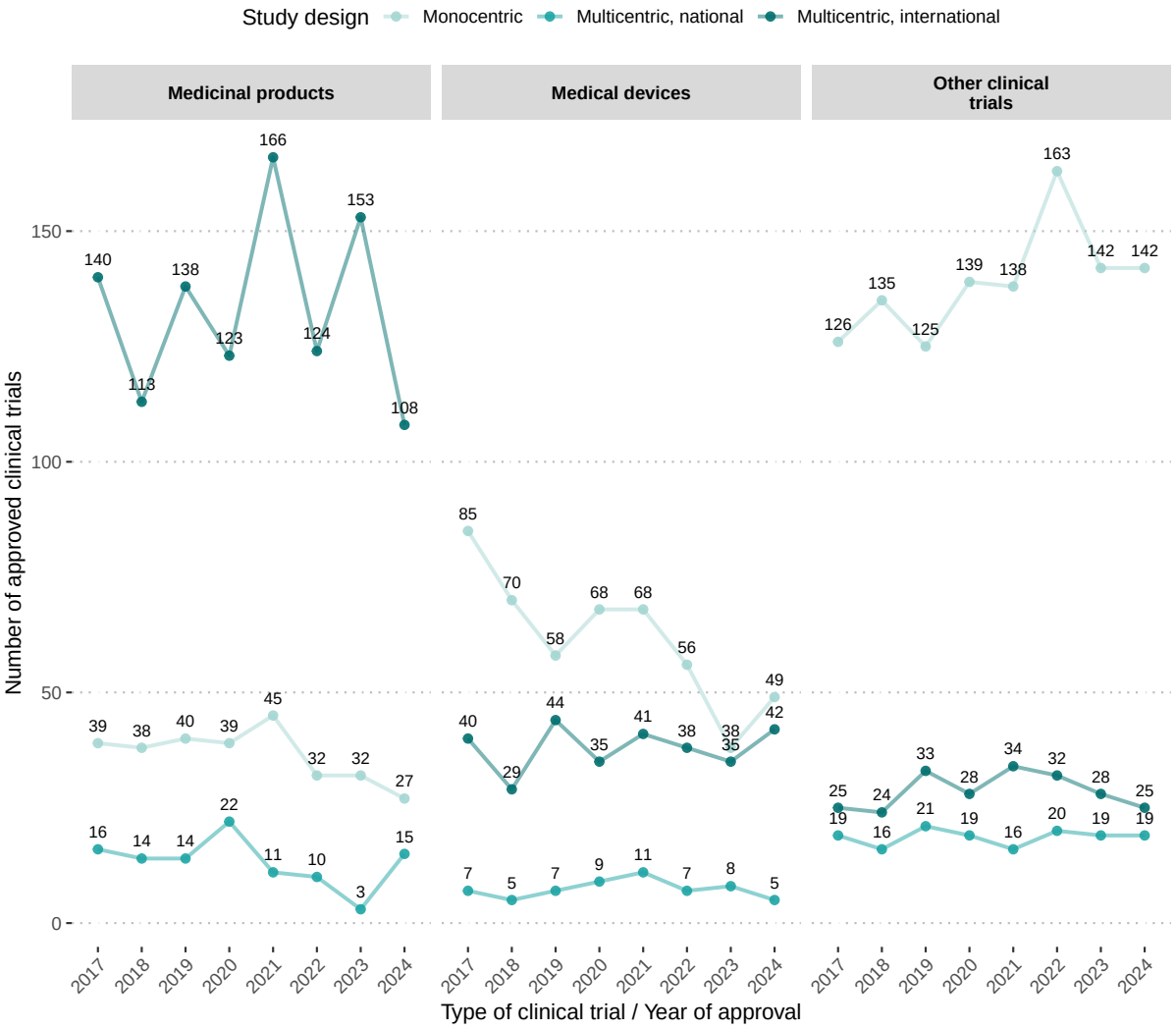

Figure 18: Clinical trials approved per year stratified by trial type and trial design.

Data not shown in the above figure: Research involving transplant products (2018: 9, 2019: 4, 2020: 6, 2021: 2, 2022: 6, 2023: 6 , 2024: 7), combination drugs/devices (2018: 4, 2019: 3, 2021: 2, 2022: 3, 2023: 10, 2024: 9) , gene therapy (2018: 3 2019: 2 2020: 1, 2021: 1, 2022: 2, 2023: 1, 2024: 2) , transplantation (2018: 1, 2019: 0, 2020: 0, 2021: 0, 2022: 1, 2023: 0, 2024: 2) and pathogenic organisms (2022: 2, 2023: 2, 2024: 0)

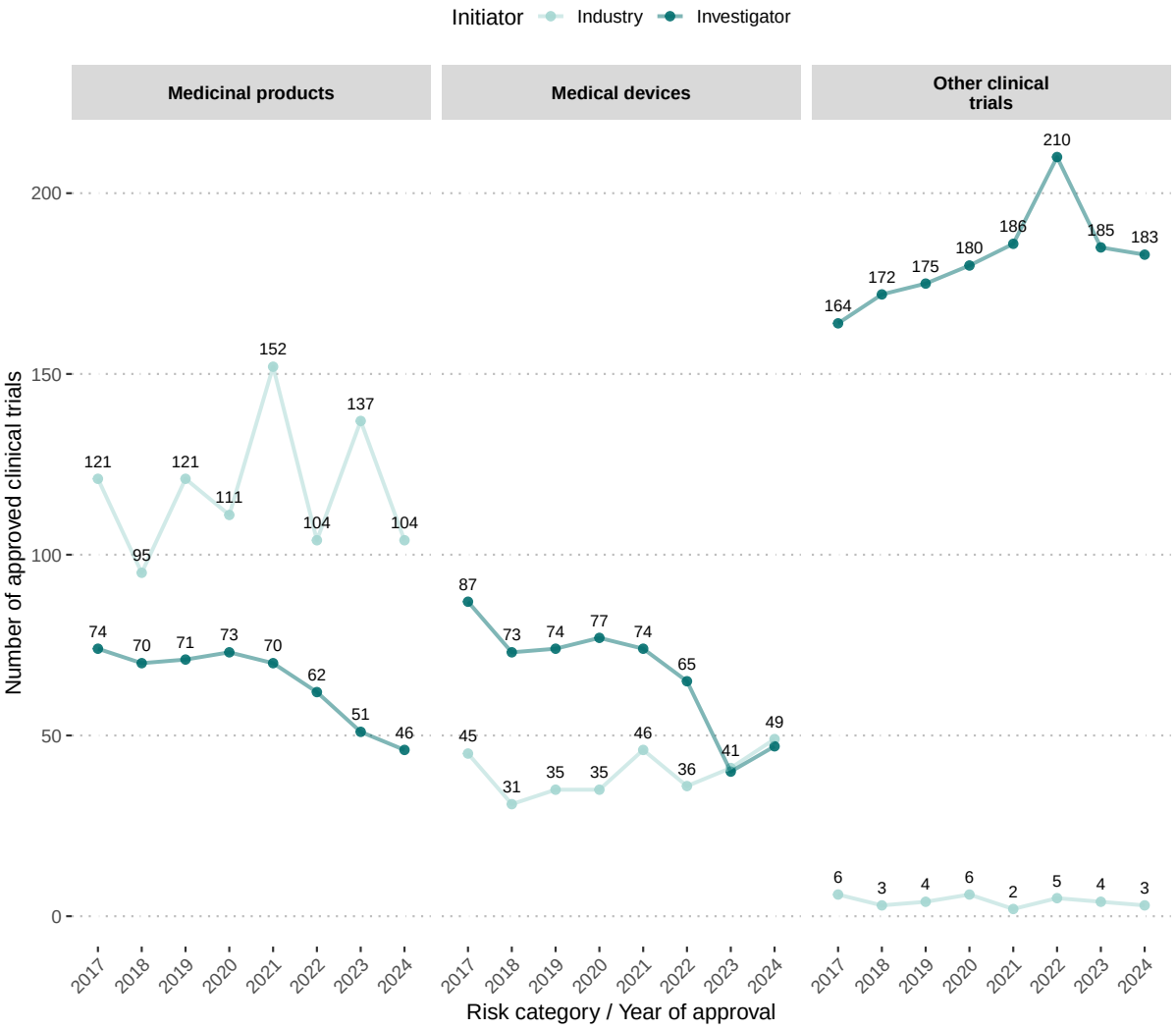

Figure 19: Clinical trials approved per year stratified by trial type and initiator.

Data not shown in the above figure: Research involving transplant products (2018: 9, 2019: 4, 2020: 6, 2021: 2, 2022: 6, 2023: 6 , 2024: 7), combination drugs/devices (2018: 4, 2019: 3, 2021: 2, 2022: 3, 2023: 10, 2024: 9) , gene therapy (2018: 3 2019: 2 2020: 1, 2021: 1, 2022: 2, 2023: 1, 2024: 2) , transplantation (2018: 1, 2019: 0, 2020: 0, 2021: 0, 2022: 1, 2023: 0, 2024: 2) and pathogenic organisms (2022: 2, 2023: 2, 2024: 0)

7.4.1 Clinical trials with medicinal products

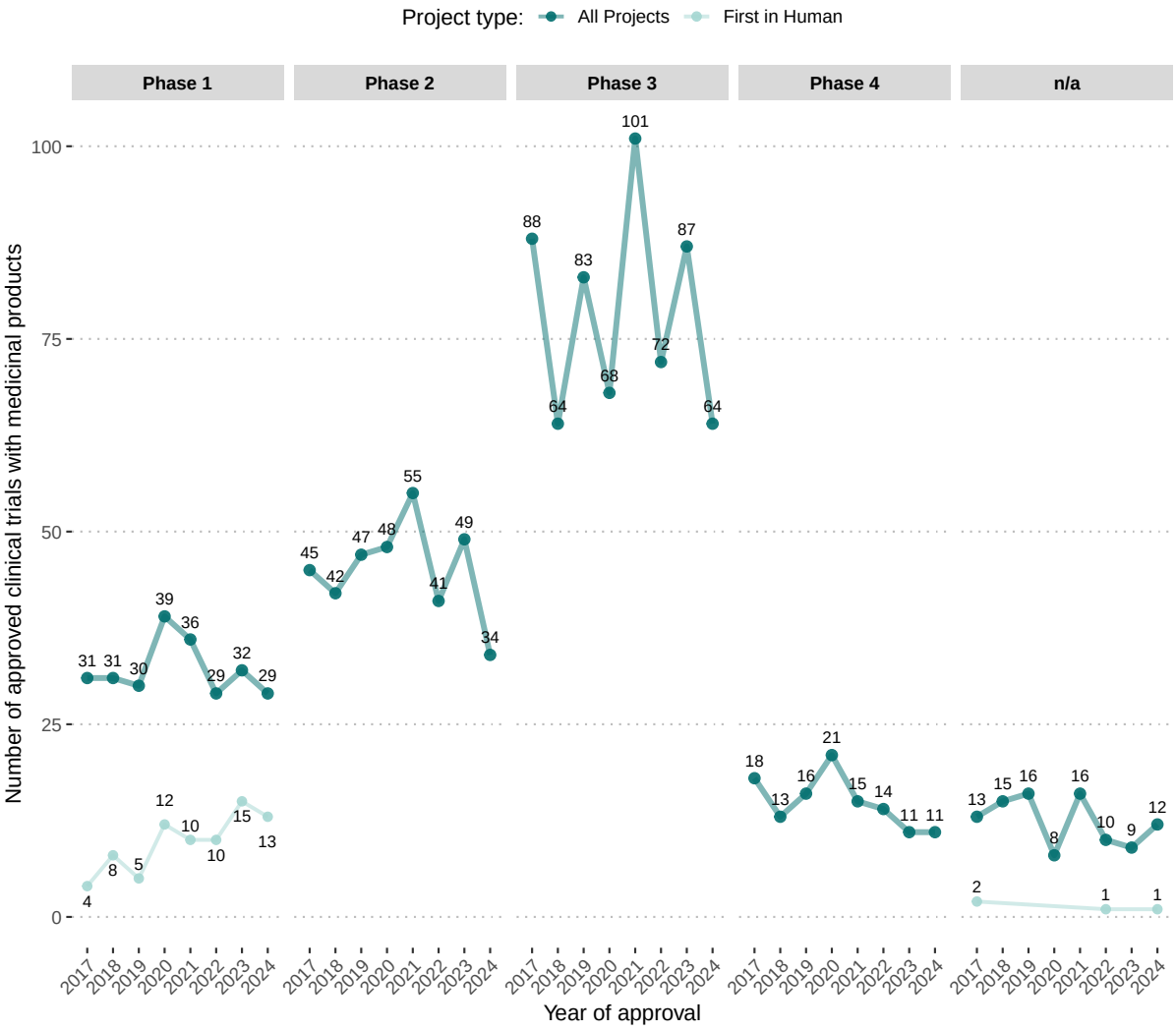

Figure 20: Clinical trials with medicinal products approved per year stratified by study phase.

Number of trials 'first-in-human': 2018: 8, 2019: 5, 2020: 12, 2021: 10, 2022: 11, 2023: 15, 2024: 14

7.4.2 Clinical trials with medical devices

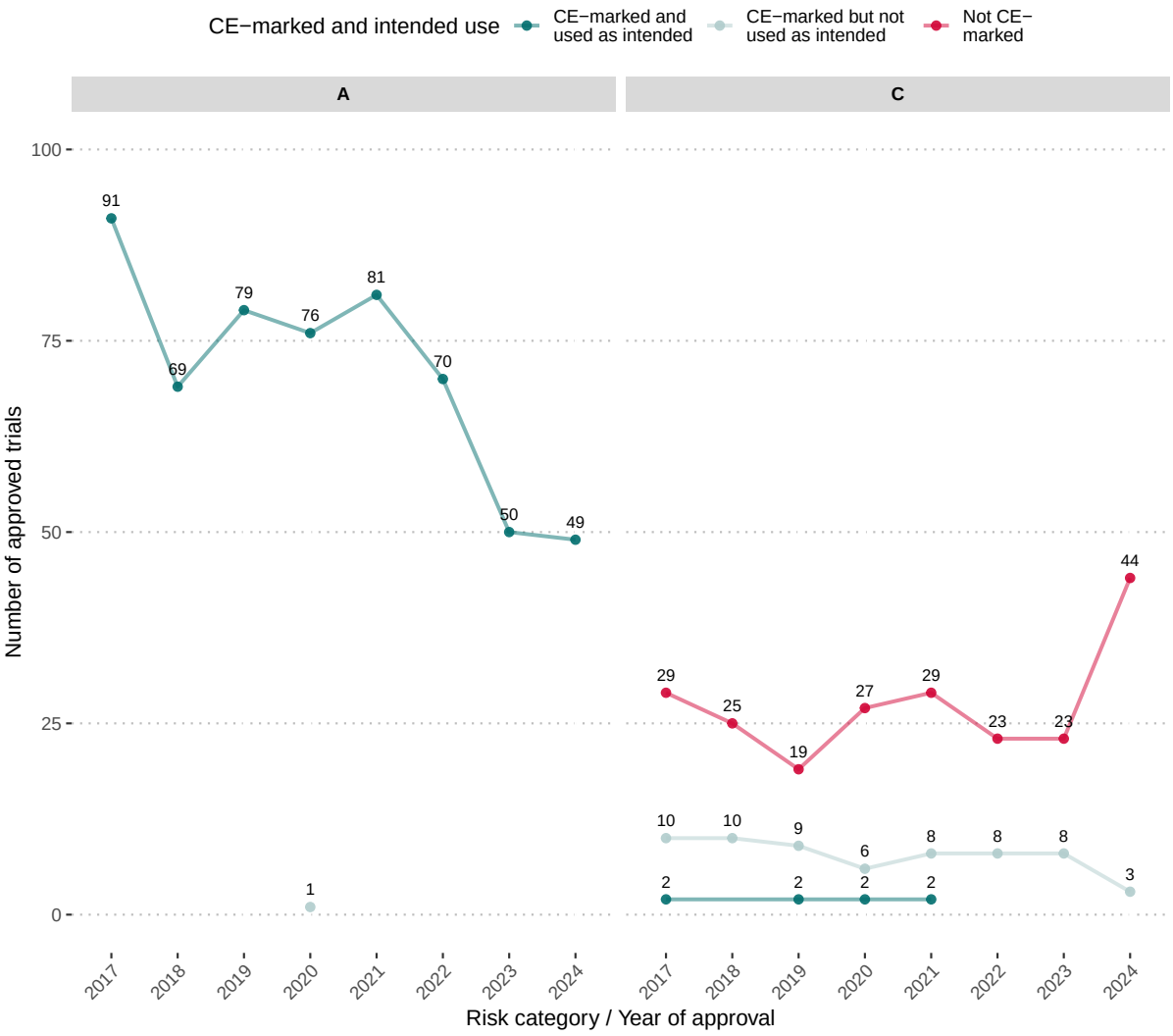

Figure 21: Clinical trials with medical devices approved per year stratified by risk category and by CE certification / intended use.

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': 2018: 8, 2019: 5, 2020: 19, 2021: 19, 2022: 10, 2023: 9, 2024: 16

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		2023		2024	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Genetic data / biol. material	Yes	176	19.3	215	19.8	252	21.4	275	19.4	267	20.6	231	21.5	253	21.7	246	20.4
	No	735	80.7	871	80.2	923	78.6	1143	80.6	1028	79.4	841	78.5	913	78.3	962	79.6
Coding (HRO Art. 25-27)	Coded	424	46.5	905	83.3	1016	86.5	1230	86.7	1176	90.8	974	90.9	1074	92.1	1148	95.0
	Open, non-coded	487	53.5	181	16.7	159	13.5	188	13.3	119	9.2	98	9.1	92	7.9	60	5.0
Consent (HRO Art. 28-32)	Consent for all data	353	38.7	547	50.4	583	49.6	727	51.3	688	53.1	642	59.9	679	58.2	759	62.8
	Consent for some but not all data (partially Art. 34 HRA) [1]	-	— —	-	— —	-	— —	308	21.7	379	29.3	331	30.9	373	32.0	357	29.6
	No consent for all data, Art. 34 HRA [2]	558	61.3	539	49.6	592	50.4	383	27.0	228	17.6	99	9.2	114	9.8	92	7.6
Combined vs. stand-alone projects [3]	Stand-alone further use project	852	93.5	870	80.1	939	79.9	1151	81.2	1053	81.3	844	78.7	967	82.9	1000	82.8
	Further use project as part of a clinical trial	20	2.2	43	4.0	45	3.8	44	3.1	58	4.5	52	4.9	42	3.6	56	4.6
	Further use project as part of a non-clinical research project	39	4.3	173	15.9	191	16.3	223	15.7	184	14.2	176	16.4	157	13.5	152	12.6
	Total number	911	100.0	1086	100.0	1175	100.0	1418	100.0	1295	100.0	1072	100.0	1166	100.0	1208	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).

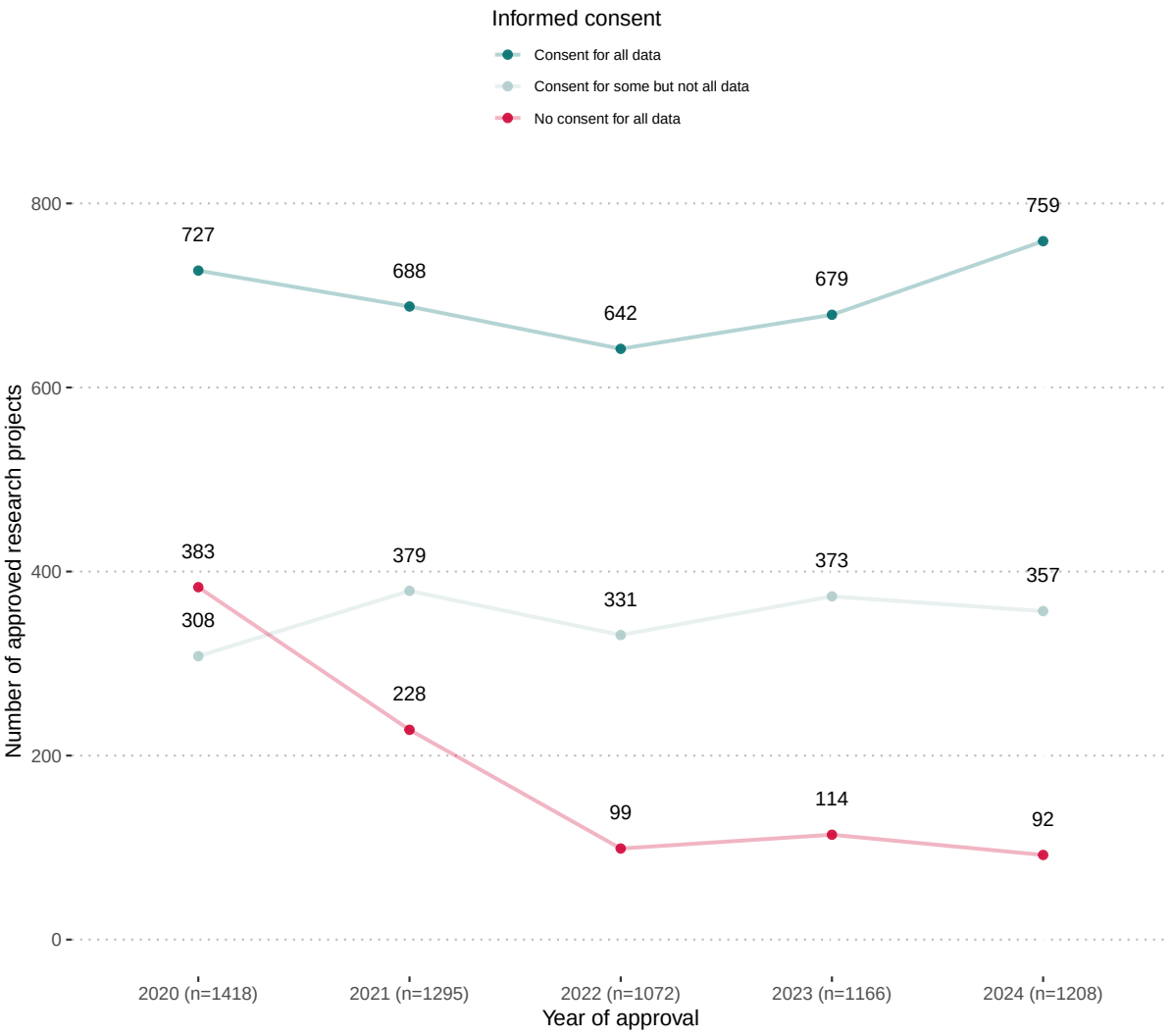

Figure 22: Number of approved 'further use' projects per year and fraction without informed consent.

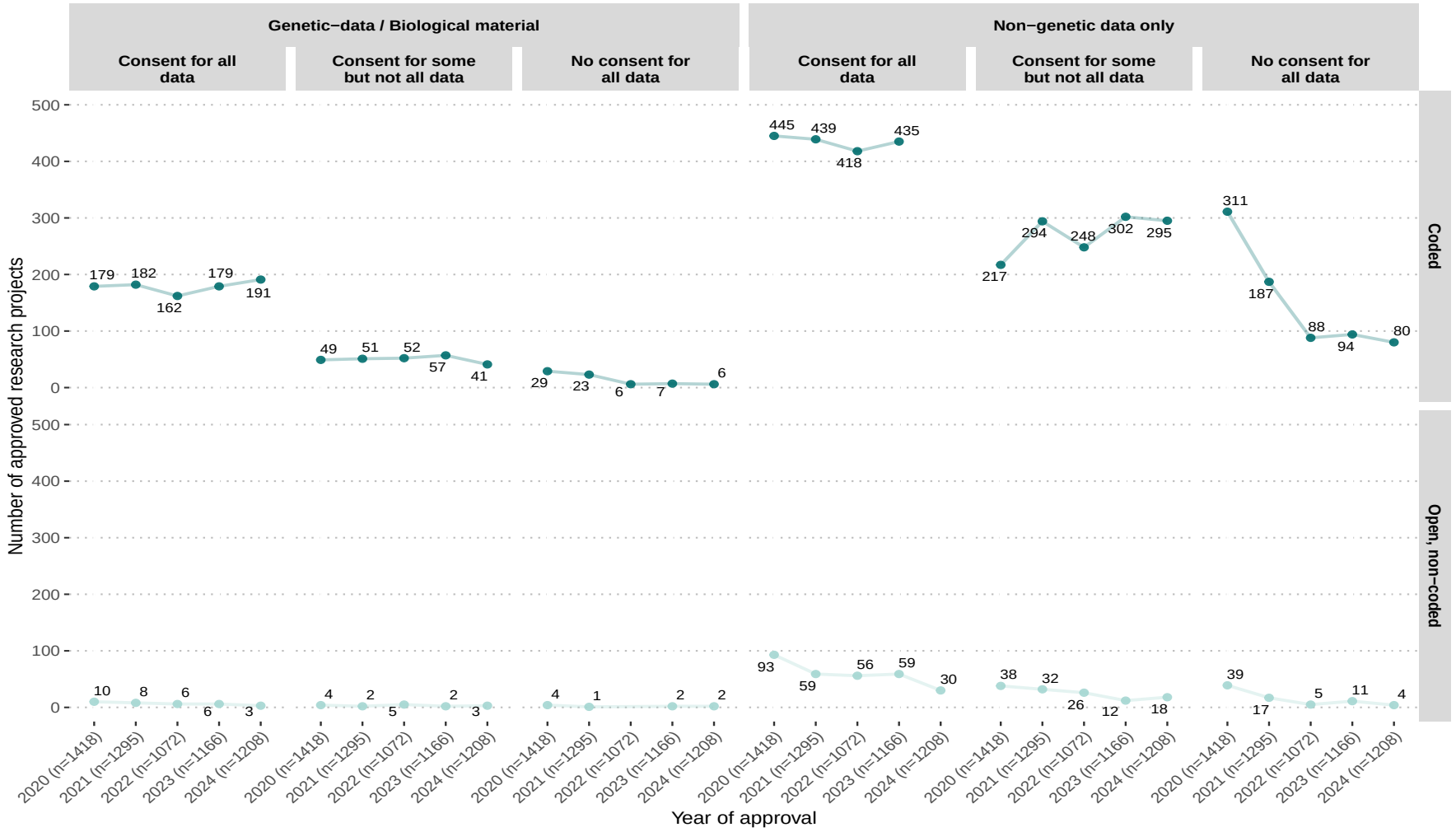

Figure 23: Number of approved 'further use' projects per year stratified by 1) Use of genetic data and/or biological material, 2) coded vs. uncoded, 3) consent for further use.

7.6 Response time

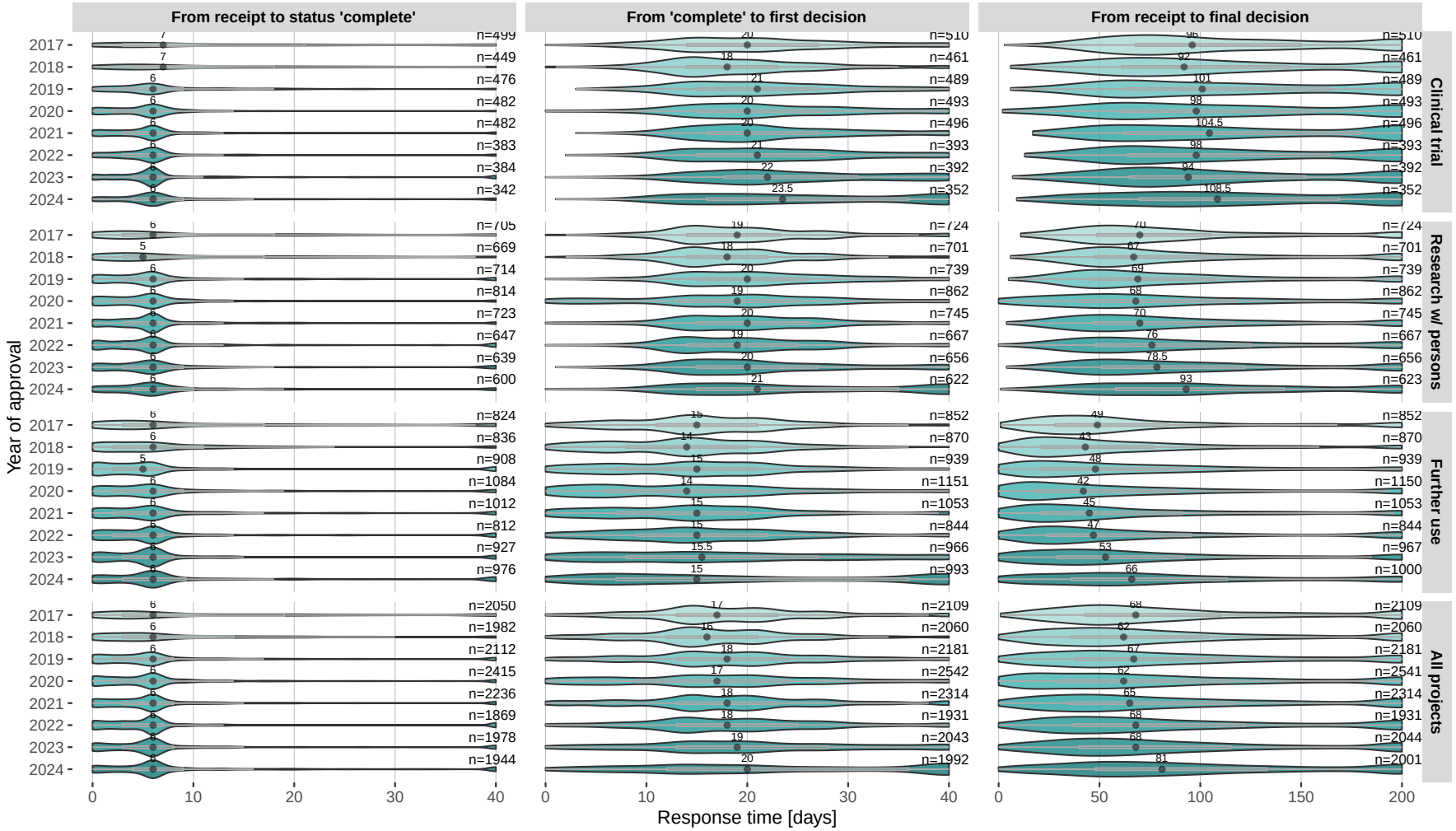

Figure 24: Violin plot of response times by approval year for the three major type of research projects and overall. For visualisation purposes, response times are capped at 40 days in the left and middle panel and to 200 days in the right panel.