

BASEC Annual Report 2025

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

January 1, 2025 – December 31, 2025



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Eidgenössisches Departement des Innern EDI
Bundesamt für Gesundheit BAG

swissethics

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

Report prepared by:
Department of Clinical Research
University Hospital Basel

BASEC export date: April 04, 2026
September 2, 2026

Contents

1	Introduction	4
1.1	Report structure	4
1.2	Data source and limitations	4
1.2.1	Data provided by the applicant	5
1.2.2	Data on response times and on the review process provided by individual ethics committees	6
1.3	Analysis sets	7
1.3.1	Definition of analysis sets	7
1.3.2	Influence of time on project status	7
1.3.3	Definition of the basic unit of analysis	8
2	BASEC data in the calendar year 2025	10
3	Overview of all projects submitted to BASEC in 2025 (AS1)	11
3.1	Submissions per ethics committee	12
3.2	Individual evaluations by lead or local ethics committees	14
4	Scientific characterisation of projects approved in 2025 (AS2)	15
4.1	Overview	15
4.2	Application process	16
4.3	Stratification by project characteristics	17
4.3.1	Description and derivation of stratification variables	17
4.3.2	Risk category, study design and initiator	19
4.3.3	Lead ethics committee	20
4.3.4	Review procedure	21
4.4	Subgroups of research projects	22
4.4.1	Subgroup “Clinical trials” - research covered by the ClinO	22
4.4.1.1	Therapeutic area	22
4.4.1.2	Primary area of research	25
4.4.2	Subgroups of “Clinical trials”	26
4.4.2.1	Subgroup “Clinical trials with medicinal products” (ClinO Art 19) and “Clinical trials with medical devices” (ClinO-MD Art 6)	27

4.4.3	Subgroup “Research involving persons, but not a clinical trial” - research covered by HRO Chapter 2	29
4.4.4	Subgroup “Further use of data/biological material” - research covered by HRO Chapter 3	31
4.5	Information about the parties involved in human research projects	36
4.5.1	Project initiator and funding	36
5	Response times and review procedure (AS2)	37
5.1	Definitions	37
5.2	Overview of median response times	38
5.3	Stratification of response time by review procedure for projects according to ClinO and HRO but not ClinO-MD	39
5.3.1	Time from status “complete” to first decision	39
5.3.2	Time from reception to final decision	41
5.4	Stratification of response time by type of research	43
5.4.1	Time from status “complete” to first decision	46
5.4.2	Time from reception to final decision	48
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 . .	51
6	Comparison of submitted projects (AS1) since the introduction of BASEC	53
7	Comparison of approved projects of reporting year (AS2) with previous years	54
7.1	Study design: mono-/multi-centric, national/international	55
7.2	Project initiator	57
7.3	Risk category	58
7.4	Subgroups of clinical trials	59
7.4.1	Clinical trials with medicinal products	61
7.4.2	Clinical trials with medical devices	62
7.5	Subgroup Further use of data/biological material	63
7.6	Response time	66
8	Annex	69
8.1	Vulnerable persons	69
8.2	Response time: First decision is final decision	72
8.3	Therapeutic Area - old categorization	73

List of abbreviations

BASEC	Business Administration System for Ethics Committees
HumRes	www.humanresearch-switzerland.ch
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 2025 (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 2025. 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 2025 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 2025. 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 2025 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 ten years (2016 - 2025) and for approved projects (AS2) over nine years (2017 - 2025). 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 04, 2026 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 2025**. 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 2025** 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.

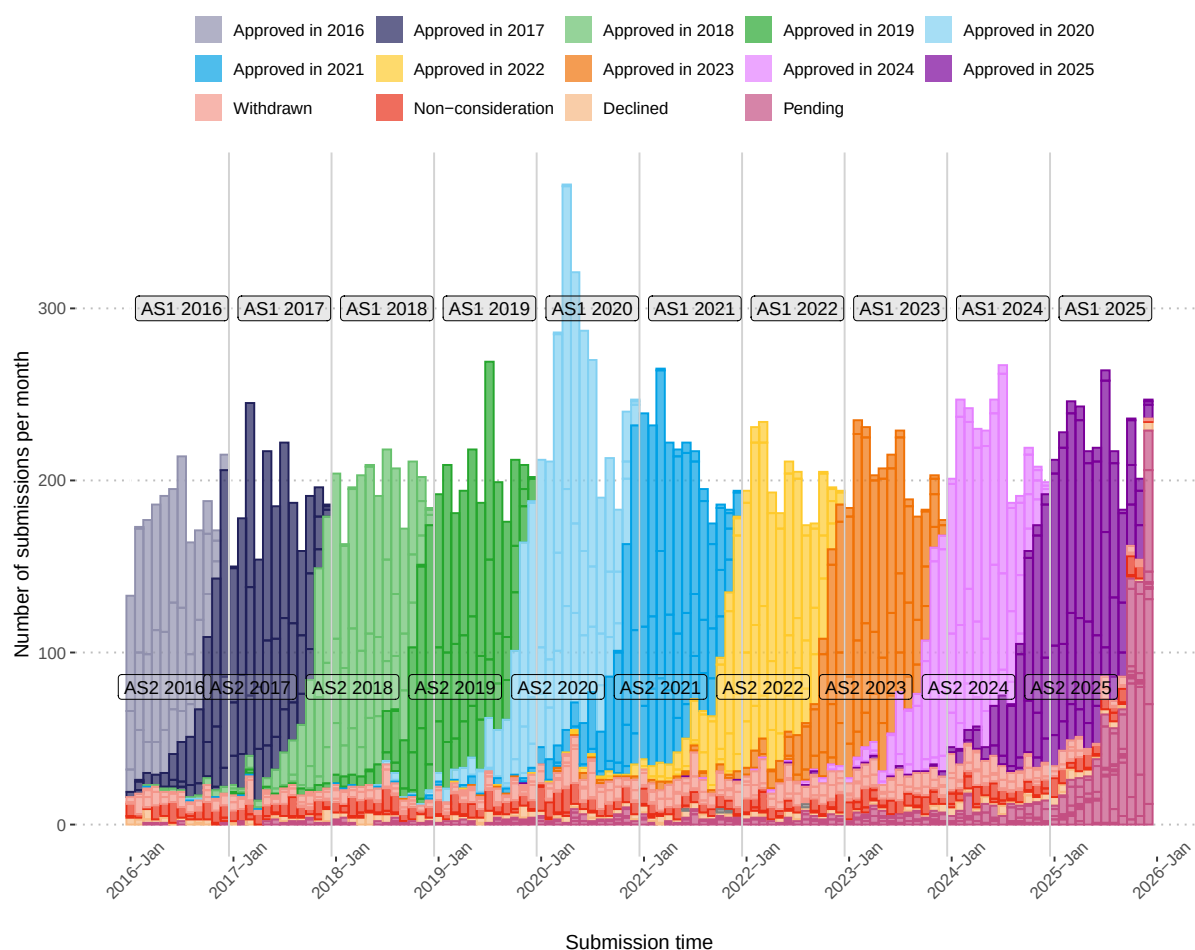


Figure 1: Overview of submissions via BASEC in the years 2016-2025 coloured by the current status as of the time of the data export (April 04, 2026).

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 2025, since a single up-to-date export is used for all years (export date: April 04, 2026) 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.

¹Exception: 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 2025

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

			N	% _{col}
Input	Submission in 2025 (AS1)		2713	70.1
	Projects pending from 2024	Pending first decision in 2024	373	9.6
		Pending final decision in 2024 (first decision before 2025)	785	20.3
		Total Pending from 2024	1158	29.9
	Grand Total Input 2025		3871	100.0
Output	Final decision in 2025	Approvals (AS2)	2313	59.8
		Rejections (declined projects)	50	1.3
		Non-considerations	109	2.8
		Total Decisions	2472	63.9
	Withdrawn during 2025	Withdrawal before first decision	43	1.1
		Withdrawal after first decision 'approvals with charges'	2	0.1
		Withdrawal after first decision 'not-yet-approved projects with conditions'	32	0.8
		Withdrawal after first decision 'non-considerations'	6	0.2
		Total Withdrawn	83	2.1
	Pending at end of 2025	Pending first decision	483	12.5
		Pending final decision (first decision issued)	833	21.5
		Total Pending	1316	34.0
	Grand Total Output 2025		3871	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.

3 Overview of all projects submitted to BASEC in 2025 ([AS1](#))

Table 2: Total number of research projects **submitted via BASEC in 2025** (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	555 ¹	20.5
Research involving persons, but not a clinical trial	HRO, Chapter 2	864 ²	31.8
Further use of health-related personal data and/or biological material	HRO, Chapter 3	1242	45.8
Research involving deceased persons	HRO, Chapter 4	52	1.9
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	0	0.0
Total number		2713	100.0

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

² 235 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 2025 (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	227	8.4	32	4.2	39	6.0	43	10.7	20	5.8	37	10.6	39	38.6	17	14.7
	Approved with charges ³	648	23.9	35	4.6	258	39.9	189	47.1	18	5.2	50	14.4	48	47.5	50	43.1
	Not approved, conditions ⁴	1506	55.5	593	78.8	306	47.3	131	32.7	244	70.3	188	54.0	6	5.9	38	32.8
	Declined	41	1.5	7	0.9	3	0.5	1	0.2	3	0.9	27	7.8				
	Non-consideration ⁵	87	3.2	31	4.1	6	0.9	9	2.2	28	8.1	8	2.3	3	3.0	2	1.7
	First decision still pending ⁶	93	3.4	32	4.2	10	1.5	15	3.7	14	4.0	17	4.9	2	2.0	3	2.6
Final decision	Approved ⁷	2119	78.1	554	73.6	573	88.6	326	81.3	266	76.7	218	62.6	94	93.1	88	75.9
	Declined	47	1.7	11	1.5	4	0.6	1	0.2	3	0.9	28	8.0				
	Non-consideration	92	3.4	30	4.0	6	0.9	11	2.7	31	8.9	9	2.6	3	3.0	2	1.7
	Withdrawn	78	2.9	28	3.7	13	2.0	7	1.7	16	4.6	12	3.4	1	1.0	1	0.9
	Final decision still pending ⁸	377	13.9	130	17.3	51	7.9	56	14.0	31	8.9	81	23.3	3	3.0	25	21.6
Review procedure	Ordinary ⁹	409	15.1	77	10.2	77	11.9	54	13.5	48	13.8	28	8.0	17	16.8	108	93.1 ¹²
	Simplified ¹⁰	1603	59.1	396	52.6	418	64.6	236	58.9	271	78.1	229	65.8	50	49.5	3	2.6
	Presidential ¹¹	593	21.9	246	32.7	139	21.5	96	23.9	10	2.9	73	21.0	29	28.7		
	First decision still pending	108	4.0	34	4.5	13	2.0	15	3.7	18	5.2	18	5.2	5	5.0	5	4.3
Total number in AS1		2713	100.0	753	100.0	647	100.0	401	100.0	347	100.0	348	100.0	101	100.0	116	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. 54.4% 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 2025** (analysis set [AS1](#)) by type of research project and lead ethics committee. Projects involving multiple ECs are assigned to the lead EC.

Type of research	Research details	Risk cat.	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
Clinical trial	Medicinal products	A	19	10.6	4	7.7	5	10.4	4	22.2	4	13.8	1	9.1	0	0.0	1	16.7
		B	27	15.1	10	19.2	7	14.6	3	16.7	3	10.3	1	9.1	3	20.0	0	0.0
		C	133	74.3	38	73.1	36	75.0	11	61.1	22	75.9	9	81.8	12	80.0	5	83.3
		All	179	100.0	52	100.0	48	100.0	18	100.0	29	100.0	11	100.0	15	100.0	6	100.0
	Medical devices ¹	A1	43	39.4	13	59.1	6	24.0	4	30.8	8	42.1	9	42.9	1	33.3	2	33.3
		A2	12	11.0	1	4.5	7	28.0	0	0.0	2	10.5	1	4.8	0	0.0	1	16.7
		C1	7	6.4	1	4.5	1	4.0	1	7.7	1	5.3	3	14.3	0	0.0	0	0.0
		C2	47	43.1	7	31.8	11	44.0	8	61.5	8	42.1	8	38.1	2	66.7	3	50.0
		All	109	100.0	22	100.0	25	100.0	13	100.0	19	100.0	21	100.0	3	100.0	6	100.0
	Other clinical trials	A	223	86.4	63	85.1	64	86.5	20	87.0	38	86.4	21	91.3	7	100.0	10	76.9
		B	35	13.6	11	14.9	10	13.5	3	13.0	6	13.6	2	8.7	0	0.0	3	23.1
		All	258	100.0	74	100.0	74	100.0	23	100.0	44	100.0	23	100.0	7	100.0	13	100.0
	Combination drugs/devices	A1	1	50.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		C2	1	50.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0
		All	2	100.0	1	100.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0
	Transplant products	C	1	100.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
All		1	100.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	
Gene therapy	C	3	100.0	2	100.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	
	All	3	100.0	2	100.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	
Transplantation	A	1	100.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	
	All	1	100.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	
Pathogenic organisms	C	2	100.0	0	0.0	1	100.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	
	All	2	100.0	0	0.0	1	100.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	
All	All	555	100.0	152	100.0	149	100.0	54	100.0	93	100.0	57	100.0	25	100.0	25	100.0	
Research w/ persons (HRO Chapter 2)	A	836	96.8	208	97.2	182	97.3	162	95.9	100	93.5	117	97.5	22	100.0	45	100.0	
	B	28	3.2	6	2.8	5	2.7	7	4.1	7	6.5	3	2.5	0	0.0	0	0.0	
	All	864	100.0	214	100.0	187	100.0	169	100.0	107	100.0	120	100.0	22	100.0	45	100.0	
Further use (HRO Chapter 3)	n.a.	1242	100.0	355	100.0	302	100.0	177	100.0	145	100.0	166	100.0	53	100.0	44	100.0	
Deceased and embryos from stillbirths or abortion (HRO Chapter 4 + 5)	n.a.	52	100.0	32	100.0	9	100.0	1	100.0	2	100.0	5	100.0	1	100.0	2	100.0	
Total number		2713	100.0	753	100.0	647	100.0	401	100.0	347	100.0	348	100.0	101	100.0	116	100.0	

¹Medical devices include 4 in-vitro diagnostic medical devices IVD-MD projects and 8 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	2374	69.4
Multiple ECs involved: lead EC	339	9.9
Multiple ECs involved: local EC	709	20.7
Total submissions to be evaluated	3422	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	657	74.7	565	72.3	367	72.7	294	63.1	315	73.3	80	44.2	96	53.3
Multiple: lead EC	96	10.9	82	10.5	34	6.7	53	11.4	33	7.7	21	11.6	20	11.1
Multiple: local EC	126	14.3	134	17.2	104	20.6	119	25.5	82	19.1	80	44.2	64	35.6
Total submissions	879	100.0	781	100.0	505	100.0	466	100.0	430	100.0	181	100.0	180	100.0

4 Scientific characterisation of projects approved in 2025 ([AS2](#))

4.1 Overview

Table 7: Total number of research projects **approved in 2025** (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	475 ¹	20.5
Research involving persons, but not a clinical trial	HRO, Chapter 2	656 ²	28.4
Further use of health-related personal data and/or biological material	HRO, Chapter 3	1129	48.8
Research involving deceased persons	HRO, Chapter 4	53	2.3
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	0	0.0
Total number		2313	100.0

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

² 193 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 2025 (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	2019	1	0.04	0	0.0	0	0.0	1	0.3	0	0.0	0	0.0	0	0.0	0	0.0
	2021	2	0.09	0	0.0	0	0.0	1	0.3	0	0.0	1	0.4	0	0.0	0	0.0
	2022	4	0.17	1	0.2	0	0.0	1	0.3	0	0.0	2	0.7	0	0.0	0	0.0
	2023	15	0.65	2	0.3	2	0.4	5	1.4	1	0.3	5	1.9	0	0.0	0	0.0
	2024	642	27.76	231	36.2	105	18.6	101	27.7	77	26.6	95	35.3	17	17.2	16	18.6
	2025	1649	71.29	405	63.4	459	81.1	256	70.1	211	73.0	166	61.7	82	82.8	70	81.4
First decision ¹	Approved	231	9.99	28	4.4	41	7.2	47	12.9	19	6.6	36	13.4	41	41.4	19	22.1
	Approved with charges ²	620	26.81	27	4.2	255	45.1	190	52.1	17	5.9	51	19.0	43	43.4	37	43.0
	Not approved, conditions ³	1373	59.36	560	87.6	252	44.5	118	32.3	240	83.0	169	62.8	11	11.1	23	26.7
	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	328	14.18	68	10.6	53	9.4	49	13.4	41	14.2	16	5.9	18	18.2	83	96.5
	Simplified	1397	60.40	331	51.8	379	67.0	214	58.6	240	83.0	179	66.5	51	51.5	3	3.5
	Presidential	588	25.42	240	37.6	134	23.7	102	27.9	8	2.8	74	27.5	30	30.3	0	0.0
Total number in AS2		2313	100.00	639	100.0	566	100.0	365	100.0	289	100.0	269	100.0	99	100.0	86	100.0

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

² Charges: the projects are approved but with charges.

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

⁴ Reconsideration 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 21 on page 36, the above classification is compared to the main financing source indicating that this question indeed seems to be a good proxy to distinguish industry from academic studies.

Research to obtain a degree: The question in BASEC is “Is this research project solely or principally designed to obtain a degree? (Master/PhD/etc)”, with allowed answers “yes” or “no”.

Vulnerable persons: This is a multiple choice field in BASEC and the allowed answers are: “None”, “Embryos / fetuses intrauteri”, “Children (0-13, until one day before 14th birthday)”, “Adolescents (14-17, until one day before 18th birthday)”, “Emergencies (transient incapacity to consent, HRA art 30-31, ClinO art 15-17, HRO art 11)”, “Pregnant women”, “prisoners”, “Persons unable to consent (long-term incapacity to consent, HRA art 21-24)”, “Healthy volunteers”. To save table space, the 3 rarest categories are grouped to “Others”. This question is not asked in BASEC for projects involving “Further use” or “Deceased persons”.

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.

Type of research	Research details	Risk cat.	Study design										Initiator	
			Total		Mono		Multi CH		Multi Int.		Industry		Investigator	
			N	%col	n	%row	n	%row	n	%row	n	%row	n	%row
Clinical trial	Medicinal products (ClinO Art 19)	A	12	7.9	7	58.3	2	16.7	3	25.0	0	0.0	12	100.0
		B	25	16.6	7	28.0	5	20.0	13	52.0	7	28.0	18	72.0
		C	114	75.5	9	7.9	2	1.8	103	90.4	100	87.7	14	12.3
		All	151	100.0	23	15.2	9	6.0	119	78.8	107	70.9	44	29.1
	Medical devices (ClinO-MD Art 6) ¹	A1	38	45.8	23	60.5	3	7.9	12	31.6	14	36.8	24	63.2
		A2	8	9.6	4	50.0	1	12.5	3	37.5	4	50.0	4	50.0
		C1	11	13.3	5	45.5	1	9.1	5	45.5	7	63.6	4	36.4
		C2	26	31.3	14	53.8	1	3.8	11	42.3	13	50.0	13	50.0
		All	83	100.0	46	55.4	6	7.2	31	37.3	38	45.8	45	54.2
	Other clinical trials (ClinO Art 61)	A	203	88.6	138	68.0	36	17.7	29	14.3	4	2.0	199	98.0
		B	26	11.4	13	50.0	4	15.4	9	34.6	2	7.7	24	92.3
		All	229	100.0	151	65.9	40	17.5	38	16.6	6	2.6	223	97.4
	Combination drugs/devices	C	2	50.0	0	0.0	0	0.0	2	100.0	2	100.0	0	0.0
		C2	2	50.0	0	0.0	1	50.0	1	50.0	1	50.0	1	50.0
		All	4	100.0	0	0.0	1	25.0	3	75.0	3	75.0	1	25.0
	Transplant products (ClinO Art 21)	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
	Gene therapy (ClinO Art 22)	C	4	100.0	0	0.0	0	0.0	4	100.0	4	100.0	0	0.0
		All	4	100.0	0	0.0	0	0.0	4	100.0	4	100.0	0	0.0
	Transplantation (ClinO Art 49)	A	1	100.0	0	0.0	0	0.0	1	100.0	0	0.0	1	100.0
		All	1	100.0	0	0.0	0	0.0	1	100.0	0	0.0	1	100.0
	Pathogenic organisms	C	1	100.0	0	0.0	0	0.0	1	100.0	1	100.0	0	0.0
		All	1	100.0	0	0.0	0	0.0	1	100.0	1	100.0	0	0.0
	All	All	475	100.0	221	46.5	56	11.8	198	41.7	160	33.7	315	66.3
Research w/ persons (HRO Chapter 2)		A	634	96.6	497	78.4	58	9.1	79	12.5	30	4.7	604	95.3
		B	22	3.4	13	59.1	5	22.7	4	18.2	2	9.1	20	90.9
		All	656	100.0	510	77.7	63	9.6	83	12.7	32	4.9	624	95.1
Further use (HRO Chapter 3)		n.a.	1129	100.0	896	79.4	78	6.9	155	13.7	48	4.3	1081	95.7
Deceased and embryos from stillbirths or abortion (HRO Chapter 4+5)		n.a.	53	100.0	51	96.2	1	1.9	1	1.9	5	9.4	48	90.6
Total number		Total number	2313	100.0	1678	72.5	198	8.6	437	18.9	245	10.6	2068	89.4

¹Medical devices include 4 in-vitro diagnostic medical devices IVD-MD projects and 8 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.

Type of research	Research details	Risk cat.	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
Clinical trial	Medicinal products	A	12	7.9	1	2.3	3	8.6	3	17.6	4	16.7	1	12.5	0	0.0	0	0.0
		B	25	16.6	9	20.5	8	22.9	3	17.6	3	12.5	1	12.5	1	6.7	0	0.0
		C	114	75.5	34	77.3	24	68.6	11	64.7	17	70.8	6	75.0	14	93.3	8	100.0
		All	151	100.0	44	100.0	35	100.0	17	100.0	24	100.0	8	100.0	15	100.0	8	100.0
	Medical devices	A1	38	45.8	11	57.9	6	33.3	4	40.0	5	41.7	9	69.2	1	25.0	2	28.6
		A2	8	9.6	1	5.3	3	16.7	1	10.0	1	8.3	0	0.0	0	0.0	2	28.6
		C1	11	13.3	3	15.8	2	11.1	3	30.0	1	8.3	2	15.4	0	0.0	0	0.0
		C2	26	31.3	4	21.1	7	38.9	2	20.0	5	41.7	2	15.4	3	75.0	3	42.9
		All	83	100.0	19	100.0	18	100.0	10	100.0	12	100.0	13	100.0	4	100.0	7	100.0
		Other clinical trials	A	203	88.6	60	88.2	62	89.9	19	90.5	30	81.1	17	94.4	7	100.0	8
	B		26	11.4	8	11.8	7	10.1	2	9.5	7	18.9	1	5.6	0	0.0	1	11.1
	All		229	100.0	68	100.0	69	100.0	21	100.0	37	100.0	18	100.0	7	100.0	9	100.0
	Combination drugs/devices	C	2	50.0	0	0.0	0	0.0	0	0.0	1	50.0	0	0.0	1	100.0	0	0.0
		C2	2	50.0	1	100.0	0	0.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0
		All	4	100.0	1	100.0	0	0.0	0	0.0	2	100.0	0	0.0	1	100.0	0	0.0
	Transplant products	C	2	100.0	1	100.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0
		All	2	100.0	1	100.0	0	0.0	0	0.0	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	1	100.0	1	100.0	0	0.0	0	0.0
		All	4	100.0	0	0.0	0	0.0	2	100.0	1	100.0	1	100.0	0	0.0	0	0.0
	Transplantation	A	1	100.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		All	1	100.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Pathogenic organisms	C	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0
		All	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0
	All	All	475	100.0	134	100.0	122	100.0	50	100.0	76	100.0	42	100.0	27	100.0	24	100.0
Research w/ persons (HRO Chapter 2)	A	634	96.6	146	95.4	144	97.3	133	97.1	82	93.2	81	98.8	19	100.0	29	100.0	
	B	22	3.4	7	4.6	4	2.7	4	2.9	6	6.8	1	1.2	0	0.0	0	0.0	
	All	656	100.0	153	100.0	148	100.0	137	100.0	88	100.0	82	100.0	19	100.0	29	100.0	
Further use (HRO Chapter 3)	n.a.	1129	100.0	322	100.0	286	100.0	176	100.0	122	100.0	140	100.0	52	100.0	31	100.0	
Deceased and embryos from stillbirths or abortion (HRO Chapters 4 and 5)	n.a.	53	100.0	30	100.0	10	100.0	2	100.0	3	100.0	5	100.0	1	100.0	2	100.0	
Total number	Total number	2313	100.0	639	100.0	566	100.0	365	100.0	289	100.0	269	100.0	99	100.0	86	100.0	

4.3.4 Review procedure

Table 11: Stratification of all approved projects by characteristics of the review procedure.

Type of research	Research details	Risk cat.	Review procedure										First decision			
			Total		Ordinary		Simplified		Presidential		Approved		Charges ¹		Conditions ²	
			N	% _{col}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}
Clinical trial	Medicinal products	A	12	7.9	3	25.0	9	75.0	0	0.0	0	0.0	3	25.0	9	75.0
		B	25	16.6	24	96.0	1	4.0	0	0.0	0	0.0	3	12.0	22	88.0
		C	114	75.5	114	100.0	0	0.0	0	0.0	2	1.8	15	13.2	97	85.1
		All	151	100.0	141	93.4	10	6.6	0	0.0	2	1.3	21	13.9	128	84.8
	Medical devices ³	A1	38	45.8	4	10.5	31	81.6	3	7.9	n/a	n/a	n/a	n/a	n/a	n/a
		A2	8	9.6	7	87.5	0	0.0	1	12.5	n/a	n/a	n/a	n/a	n/a	n/a
		C1	11	13.3	11	100.0	0	0.0	0	0.0	n/a	n/a	n/a	n/a	n/a	n/a
		C2	26	31.3	20	76.9	1	3.8	5	19.2	n/a	n/a	n/a	n/a	n/a	n/a
		All	83	100.0	42	50.6	32	38.6	9	10.8	n/a	n/a	n/a	n/a	n/a	n/a
	Other clinical trials	A	203	88.6	16	7.9	186	91.6	1	0.5	1	0.5	32	15.8	170	83.7
		B	26	11.4	22	84.6	4	15.4	0	0.0	0	0.0	1	3.8	25	96.2
		All	229	100.0	38	16.6	190	83.0	1	0.4	1	0.4	33	14.4	195	85.2
	Combination drugs/devices	C	2	50.0	2	100.0	0	0.0	0	0.0	0	0.0	1	50.0	1	50.0
		C2	2	50.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		All	4	100.0	4	100.0	0	0.0	0	0.0	0	0.0	1	25.0	1	25.0
	Transplant products	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
	Gene therapy	C	4	100.0	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	4	100.0
		All	4	100.0	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	4	100.0
	Transplantation	A	1	100.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	1	100.0
		All	1	100.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	1	100.0
	Pathogenic organisms	C	1	100.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0
		All	1	100.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0
	All	All	475	100.0	232	48.8	233	49.1	10	2.1	3	0.6	55	11.6	332	69.9
Research w/ persons (HRO Chapter 2)		A	634	96.6	38	6.0	593	93.5	3	0.5	16	2.5	154	24.3	464	73.2
		B	22	3.4	21	95.5	1	4.5	0	0.0	0	0.0	0	0.0	22	100.0
		All	656	100.0	59	9.0	594	90.5	3	0.5	16	2.4	154	23.5	486	74.1
Further use (HRO Chapter 3)		n.a.	1129	100.0	34	3.0	520	46.1	575	50.9	203	18.0	396	35.1	526	46.6
Deceased and embryos from stillbirths or abortion (HRO Chapter 4+5)		n.a.	53	100.0	3	5.7	50	94.3	0	0.0	9	17.0	15	28.3	29	54.7
Total number		Total number	2313	100.0	328	14.2	1397	60.4	588	25.4	231	10.0	620	26.8	1373	59.4

¹ Approved with charges

² Not approved with conditions.

³ Not applicable for clinical investigations with medical devices submitted under the ClinO-MD, as these projects do not receive a first decision.

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 of therapeutic areas by initiator for clinical trials. Each project is counted once per therapeutic area category, even if multiple sub-areas within the same category apply. Multiple therapeutic area categories per project are possible. The number of projects investigating a rare disease is provided.

Therapeutic area	Initiator	All clinical trials			Medicinal products			Medical devices			Other clinical trials		
		N	%	n _{rare}	N	%	n _{rare}	N	%	n _{rare}	N	%	n _{rare}
Basic research (anatomy/physiology)	Industry	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	0
	Investigator	21	6.7	0	2	4.5	0	1	2.2	0	18	8.1	0
	All	21	4.4	0	2	1.3	0	1	1.2	0	18	7.9	0
Cardiovascular	Industry	11	6.9	0	3	2.8	0	8	21.1	0	0	0.0	0
	Investigator	25	7.9	0	6	13.6	0	4	8.9	0	15	6.7	0
	All	36	7.6	0	9	6.0	0	12	14.5	0	15	6.6	0
Dermatology	Industry	10	6.2	3	8	7.5	2	0	0.0	0	0	0.0	0
	Investigator	5	1.6	0	1	2.3	0	1	2.2	0	2	0.9	0
	All	15	3.2	3	9	6.0	2	1	1.2	0	2	0.9	0
Endocrinology	Industry	6	3.8	1	5	4.7	1	0	0.0	0	0	0.0	0
	Investigator	21	6.7	3	3	6.8	1	3	6.7	0	15	6.7	2
	All	27	5.7	4	8	5.3	2	3	3.6	0	15	6.6	2
Gastroenterology	Industry	13	8.1	3	12	11.2	3	0	0.0	0	0	0.0	0
	Investigator	4	1.3	1	0	0.0	0	0	0.0	0	4	1.8	1
	All	17	3.6	4	12	7.9	3	0	0.0	0	4	1.7	1
Genetics	Industry	3	1.9	3	3	2.8	3	0	0.0	0	0	0.0	0
	Investigator	3	1.0	1	1	2.3	0	0	0.0	0	2	0.9	1
	All	6	1.3	4	4	2.6	3	0	0.0	0	2	0.9	1
Hematology	Industry	2	1.2	2	2	1.9	2	0	0.0	0	0	0.0	0
	Investigator	1	0.3	0	0	0.0	0	0	0.0	0	1	0.4	0
	All	3	0.6	2	2	1.3	2	0	0.0	0	1	0.4	0
Infectious diseases	Industry	4	2.5	1	4	3.7	1	0	0.0	0	0	0.0	0
	Investigator	5	1.6	0	2	4.5	0	1	2.2	0	2	0.9	0
	All	9	1.9	1	6	4.0	1	1	1.2	0	2	0.9	0
Musculoskeletal	Industry	5	3.1	2	2	1.9	2	1	2.6	0	1	16.7	0
	Investigator	22	7.0	0	1	2.3	0	4	8.9	0	17	7.6	0
	All	27	5.7	2	3	2.0	2	5	6.0	0	18	7.9	0
Neurology	Industry	12	7.5	8	11	10.3	8	1	2.6	0	0	0.0	0
	Investigator	47	14.9	2	5	11.4	0	11	24.4	0	31	13.9	2
	All	59	12.4	10	16	10.6	8	12	14.5	0	31	13.5	2
Obstetrics and gynecology	Industry	1	0.6	0	0	0.0	0	1	2.6	0	0	0.0	0
	Investigator	4	1.3	0	1	2.3	0	2	4.4	0	1	0.4	0
	All	5	1.1	0	1	0.7	0	3	3.6	0	1	0.4	0
Occupational diseases	Industry	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	0
	Investigator	1	0.3	0	0	0.0	0	0	0.0	0	1	0.4	0
	All	1	0.2	0	0	0.0	0	0	0.0	0	1	0.4	0
Oncology	Industry	61	38.1	8	49	45.8	5	10	26.3	2	0	0.0	0
	Investigator	61	19.4	6	15	34.1	3	10	22.2	0	34	15.2	3
	All	122	25.7	14	64	42.4	8	20	24.1	2	34	14.8	3
Ophthalmology	Industry	3	1.9	0	2	1.9	0	0	0.0	0	0	0.0	0
	Investigator	3	1.0	1	1	2.3	1	2	4.4	0	0	0.0	0
	All	6	1.3	1	3	2.0	1	2	2.4	0	0	0.0	0
Otolaryngology	Industry	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	0
	Investigator	4	1.3	0	0	0.0	0	0	0.0	0	4	1.8	0
	All	4	0.8	0	0	0.0	0	0	0.0	0	4	1.7	0
Pediatrics	Industry	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	0
	Investigator	1	0.3	0	0	0.0	0	0	0.0	0	1	0.4	0
	All	1	0.2	0	0	0.0	0	0	0.0	0	1	0.4	0
Psychiatry	Industry	2	1.2	0	2	1.9	0	0	0.0	0	0	0.0	0
	Investigator	30	9.5	0	4	9.1	0	1	2.2	0	25	11.2	0

Table 12: Overview of therapeutic areas by initiator for clinical trials. Each project is counted once per therapeutic area category, even if multiple sub-areas within the same category apply. Multiple therapeutic area categories per project are possible. The number of projects investigating a rare disease is provided. (*continued*)

Therapeutic area	Initiator	All clinical trials			Medicinal products			Medical devices			Other clinical trials		
		N	%	n _{rare}	N	%	n _{rare}	N	%	n _{rare}	N	%	n _{rare}
Respiratory	All	32	6.7	0	6	4.0	0	1	1.2	0	25	10.9	0
	Industry	3	1.9	0	3	2.8	0	0	0.0	0	0	0.0	0
	Investigator	23	7.3	1	0	0.0	0	2	4.4	0	21	9.4	1
	All	26	5.5	1	3	2.0	0	2	2.4	0	21	9.2	1
Surgery	Industry	6	3.8	0	0	0.0	0	6	15.8	0	0	0.0	0
	Investigator	25	7.9	1	1	2.3	0	8	17.8	0	16	7.2	1
	All	31	6.5	1	1	0.7	0	14	16.9	0	16	7.0	1
Trauma and emergency medicine	Industry	1	0.6	0	0	0.0	0	1	2.6	0	0	0.0	0
	Investigator	12	3.8	0	0	0.0	0	3	6.7	0	9	4.0	0
	All	13	2.7	0	0	0.0	0	4	4.8	0	9	3.9	0
Urology	Industry	3	1.9	0	2	1.9	0	1	2.6	0	0	0.0	0
	Investigator	4	1.3	0	0	0.0	0	2	4.4	0	2	0.9	0
	All	7	1.5	0	2	1.3	0	3	3.6	0	2	0.9	0
Other	Industry	28	17.5	3	8	7.5	3	13	34.2	0	5	83.3	0
	Investigator	93	29.5	1	9	20.5	1	11	24.4	0	72	32.3	0
	All	121	25.5	4	17	11.3	4	24	28.9	0	77	33.6	0

% column-wise within initiator group. 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. Data for the 12 clinical trials not falling in the 3 main clinical trial types medicinal product, medical devices, other are not included in the stratification.

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

Area of research	Type of clinical trial							
	All clinical trials		Medicinal products		Medical devices		Other clinical trials	
	N	%	N	% _{col}	N	% _{col}	N	% _{col}
Treatment	252	53.1	114	75.5	42	50.6	88	38.4
Other	82	17.3	4	2.6	13	15.7	65	28.4
Prevention	36	7.6	5	3.3	2	2.4	29	12.7
Rehabilitation	32	6.7	0	0.0	6	7.2	26	11.4
PK / PD / safety	32	6.7	24	15.9	0	0.0	4	1.7
Diagnosis	29	6.1	4	2.6	12	14.5	13	5.7
Safety	7	1.5	0	0.0	7	8.4	0	0.0
Palliation	5	1.1	0	0.0	1	1.2	4	1.7
Total projects	475	100.0	151	100.0	83	100.0	229	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)

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'.

Type of clinical trial	Risk category	Phase													
		Total		1		2		3		4		n/a		first-in-human	
		N	%col	n	%row	n	%row	n	%row	n	%row	n	%row	n	%row
Medicinal products	A	12	5.0	0	0.0	0	0.0	1	8.3	8	66.7	3	25.0	0	0.0
	B	25	10.5	1	4.0	10	40.0	13	52.0	0	0.0	1	4.0	0	0.0
	C	114	47.9	21	18.4	32	28.1	60	52.6	0	0.0	1	0.9	7	6.1
	All	151	63.4	22	14.6	42	27.8	74	49.0	8	5.3	5	3.3	7	4.6
Medical devices	A1	38	16.0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	0	0.0
	A2	8	3.4	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	0	0.0
	C1	11	4.6	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	3	27.3
	C2	26	10.9	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	8	30.8
	All	83	34.9	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	11	13.3
Combination medicinal products/devices	C	2	0.8	0	0.0	1	50.0	1	50.0	0	0.0	0	0.0	0	0.0
	C2	2	0.8	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	2	100.0	0	0.0
	All	4	1.7	0	0.0	1	25.0	1	25.0	0	0.0	2	50.0	0	0.0
Total number		238	100.0	22	9.2	43	18.1	75	31.5	8	3.4	7	2.9	18	7.6

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

Table 15: Stratification of clinical trials with medicinal products by initiator, phase, and first-in-human status.

Type of clinical trial	Initiator	<i>Phase</i>													
		Total		1		2		3		4		n/a		First-in-human	
		n	%col	n	%row	n	%row	n	%row	n	%row	n	%row	n	%row
Medicinal products	Industry	107	70.9	15	14.0	28	26.2	63	58.9	0	0.0	1	0.9	6	5.6
	Investigator	44	29.1	7	15.9	14	31.8	11	25.0	8	18.2	4	9.1	1	2.3
	All	151	100.0	22	14.6	42	27.8	74	49.0	8	5.3	5	3.3	7	4.6

4.4.3 Subgroup “Research involving persons, but not a clinical trial” - research covered by HRO Chapter 2

Table 16: Stratification of **research projects involving persons, but not a clinical trial**, by risk category, study design and initiator. The 'type of research projects' reported in the following tables are self-reported and BASEC-specific without a legal basis in the HRA.

Type of research project	Total		Risk category				Study design						Initiator			
			A		B		Mono		Multi CH		Multi Int.		Industry		Investigator	
	N	% _{col}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}
Cohort study	295	45.0	288	97.6	7	2.4	226	76.6	27	9.2	42	14.2	10	3.4	285	96.6
Registry / Quality control ¹	31	4.7	30	96.8	1	3.2	20	64.5	2	6.5	9	29.0	5	16.1	26	83.9
Case control study	59	9.0	57	96.6	2	3.4	48	81.4	6	10.2	5	8.5	0	0.0	59	100.0
Other or n/a	271	41.3	259	95.6	12	4.4	216	79.7	28	10.3	27	10.0	17	6.3	254	93.7
Total number	656	100.0	634	96.6	22	3.4	510	77.7	63	9.6	83	12.7	32	4.9	624	95.1

¹ Only quality control studies under the HRA.

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

Area of research	Type of research project									
	Overall		Cohort study		Registry / Quality control		Case control study		Other or n/a	
	N	% _{col}	N	% _{col}	N	% _{col}	N	% _{col}	N	% _{col}
Other	155	23.6	63	21.4	10	32.3	11	18.6	71	26.2
Basic science	118	18.0	55	18.6	2	6.5	13	22.0	48	17.7
Psychology	65	9.9	21	7.1	0	0.0	15	25.4	29	10.7
Healthcare services research	62	9.5	21	7.1	5	16.1	2	3.4	34	12.5
Surgery	57	8.7	38	12.9	2	6.5	5	8.5	12	4.4
Physiology/anatomy	56	8.5	34	11.5	1	3.2	8	13.6	13	4.8
Epidemiology	40	6.1	24	8.1	2	6.5	2	3.4	12	4.4
Medical devices	39	5.9	14	4.7	7	22.6	0	0.0	18	6.6
Qualitative research	38	5.8	12	4.1	2	6.5	1	1.7	23	8.5
Dentistry	13	2.0	9	3.1	0	0.0	1	1.7	3	1.1
Drugs	13	2.0	4	1.4	0	0.0	1	1.7	8	3.0
Total projects	656	100.0	295	100.0	31	100.0	59	100.0	271	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 18: Overview of characteristics of all approved 'further use' projects.

		N	% _{col}
Genetic data / biol. material	Yes	322	23.1
	No	1073	76.9
Coding (HRO Art. 25-27)	Coded	1331	95.4
	Open, non-coded	64	4.6
Consent (HRO Art. 28-32)	Consent for all data	944	67.7
	Consent for some but not all data (partially Art. 34 HRA)	372	26.7
	No consent for all data, Art. 34 HRA	79	5.7
Combined vs. stand-alone projects	Stand-alone further use project	1129	80.9
	Further use project as part of a clinical trial	73	5.2
	Further use project as part of a non-clinical research project	193	13.8
Total number		1395	100.0

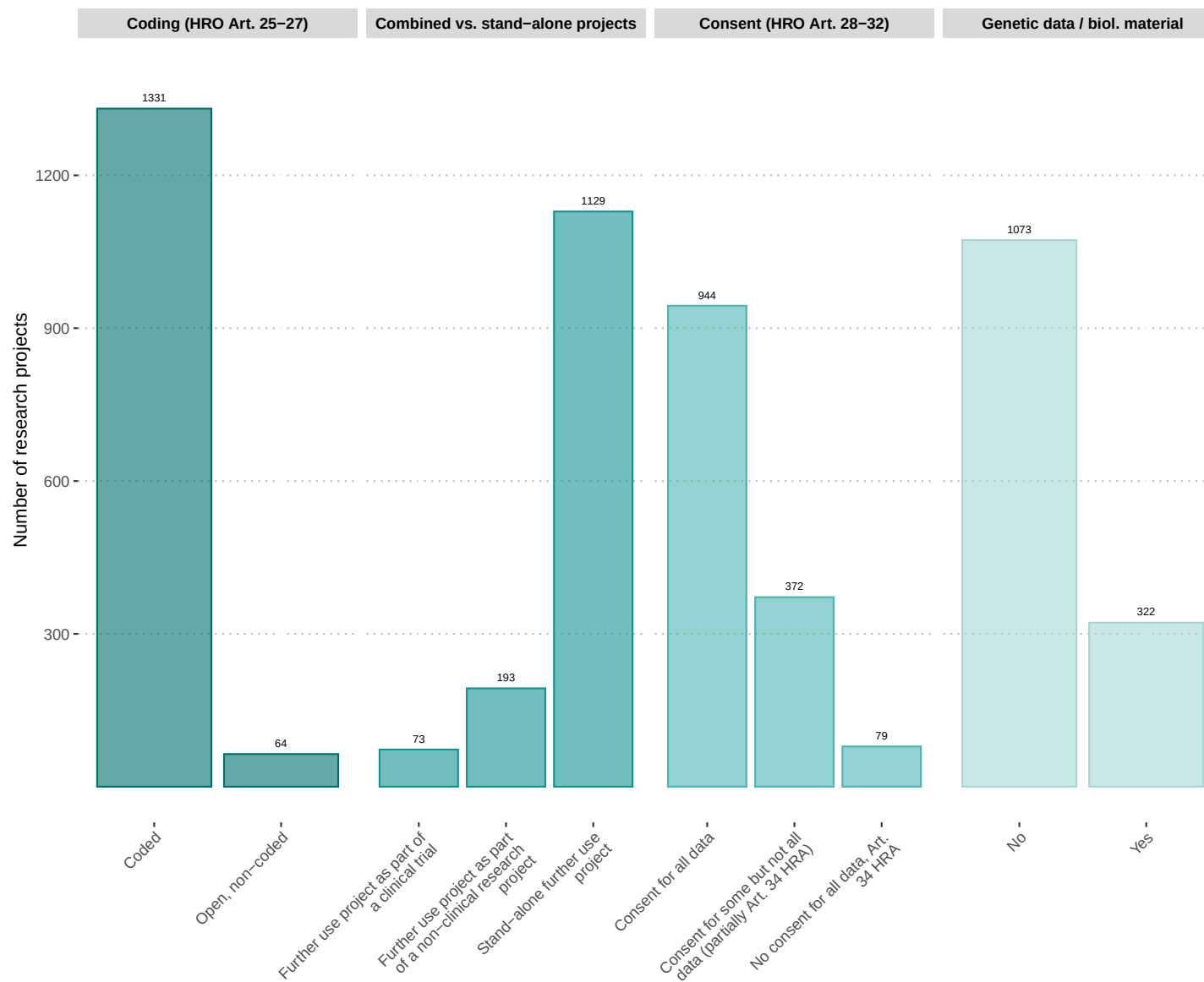


Figure 2: Overview of characteristics of all approved 'further use' projects separately for all research projects.

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

Genetic D+M	Coded	Consent ¹	Study design										Initiator	
			Total		Mono		Multi CH		Multi Int.		Industry		Investigator	
			N	%col	n	%row	n	%row	n	%row	n	%row	n	%row
Yes	Coded	Consent for all data	245	77.3	148	60.4	24	9.8	73	29.8	55	22.4	190	77.6
		Consent for some but not all data (partially Art. 34 HRA)	64	20.2	48	75.0	4	6.2	12	18.8	0	0.0	64	100.0
		No consent for all data, Art. 34 HRA	8	2.5	6	75.0	0	0.0	2	25.0	0	0.0	8	100.0
		All	317	100.0	202	63.7	28	8.8	87	27.4	55	17.4	262	82.6
	Open, non-coded	Consent for all data	4	80.0	1	25.0	0	0.0	3	75.0	1	25.0	3	75.0
		No consent for all data, Art. 34 HRA	1	20.0	1	100.0	0	0.0	0	0.0	0	0.0	1	100.0
		All	5	100.0	2	40.0	0	0.0	3	60.0	1	20.0	4	80.0
	All		322	100.0	204	63.4	28	8.7	90	28.0	56	17.4	266	82.6
No	Coded	Consent for all data	654	64.5	513	78.4	55	8.4	86	13.1	28	4.3	626	95.7
		Consent for some but not all data (partially Art. 34 HRA)	295	29.1	242	82.0	25	8.5	28	9.5	4	1.4	291	98.6
		No consent for all data, Art. 34 HRA	65	6.4	57	87.7	4	6.2	4	6.2	0	0.0	65	100.0
		All	1014	100.0	812	80.1	84	8.3	118	11.6	32	3.2	982	96.8
	Open, non-coded	Consent for all data	41	69.5	37	90.2	1	2.4	3	7.3	0	0.0	41	100.0
		Consent for some but not all data (partially Art. 34 HRA)	13	22.0	10	76.9	1	7.7	2	15.4	0	0.0	13	100.0
		No consent for all data, Art. 34 HRA	5	8.5	4	80.0	0	0.0	1	20.0	1	20.0	4	80.0
		All	59	100.0	51	86.4	2	3.4	6	10.2	1	1.7	58	98.3
	All		1073	100.0	863	80.4	86	8.0	124	11.6	33	3.1	1040	96.9
Total number			1395	100.0	1067	76.5	114	8.2	214	15.3	89	6.4	1306	93.6

¹ Multiple selection possible.

The total number of 1395 research projects consist of 1129 standard 'further use' projects and 266 ClinO/ClinO-MD or research with persons (HRO) projects that include further use of data/biological material.

Table 20: Stratification of **projects involving further use of data/biological material** by lead ethics committee.

Consent ¹	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
Consent for all data	944	67.7	326	79.7	202	57.5	130	66.7	109	68.6	105	62.9	45	66.2	27	58.7
Consent for some but not all data (partially Art. 34 HRA)	372	26.7	72	17.6	132	37.6	62	31.8	46	28.9	32	19.2	11	16.2	17	37.0
No consent for all data, Art. 34 HRA	79	5.7	11	2.7	17	4.8	3	1.5	4	2.5	30	18.0	12	17.6	2	4.3
Total number	1395	100.0	409	100.0	351	100.0	195	100.0	159	100.0	167	100.0	68	100.0	46	100.0

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

4.5 Information about the parties involved in human research projects

4.5.1 Project initiator and funding

Table 21: Answers to the question “Who initiated the project?” stratified by the main financing source. The researchers are asked to 'indicate here who had the original idea for the research project (do not indicate here who is financing, conducting or leading the project)’.

Initiator	Financing (main source)	N	% _{col}
Investigator	Public, other	1630	82.0
	Industry	56 ¹	2.8
	Universities/hospitals	113	5.7
	Private (non-industry)	153	7.7
	Swiss National Science Foundation	37	1.9
	All	1989	100.0
Industry	Public, other	78 ²	31.8
	Industry	164 ³	66.9
	Universities/hospitals	0	0.0
	Private (non-industry)	3	1.2
	Swiss National Science Foundation	0	0.0
	All	245	100.0
Other	Public, other	61	77.2
	Industry	3	3.8
	Universities/hospitals	6	7.6
	Private (non-industry)	7	8.9
	Swiss National Science Foundation	2	2.5
	All	79 ⁴	100.0

¹ Applicants almost exclusively from academic institutions.

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

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

⁴ 23 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.

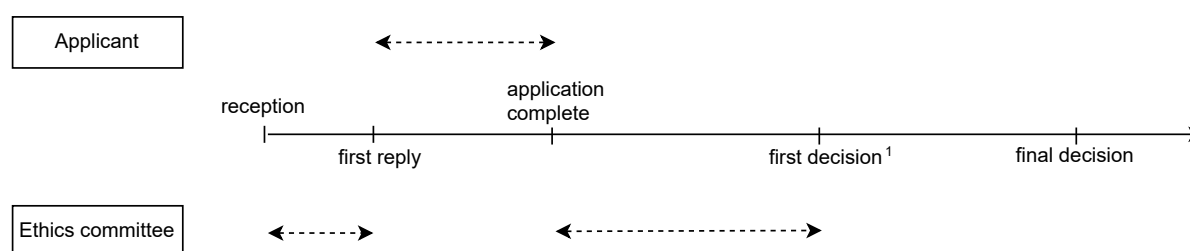


Figure 3: Overview of dates of milestones for each application. The only two periods that solely depend on the EC are denoted as well as the period that is mainly dependent on the applicant.

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

5.2 Overview of median response times

Table 22: Overview of response times in days - median (M) and inter-quartile range (IQR) per review procedure and ethics committee. ClinO-MD projects are not included but separately displayed in table 27.

				Time interval from ...																	
Procedure	EC	N	%EC	receipt to first reply			receipt to complete			receipt to first decision			receipt to final decision			complete to first d.			complete to final d.		
				Median	IQR		Median	IQR		Median	IQR		Median	IQR		Median	IQR		Median	IQR	
Ordinary	KEK-ZH	59	10	6.0	6.0,	6.0]	6.0	6.0,	7.0]	39.0	31.0,	48.0]	122.0	81.0,	174.0]	32.0	24.5,	36.0]	113.0	74.0,	146.0]
	EKNZ	41	7	4.0	1.0,	4.0]	3.0	0.2,	4.8]	27.0	19.0,	40.0]	89.0	62.0,	135.0]	23.0	16.0,	32.0]	77.0	58.0,	134.0]
	CER-VD	41	12	4.5	3.0,	6.0]	6.0	3.0,	17.0]	29.0	24.0,	42.0]	162.0	98.0,	249.0]	20.0	18.0,	25.0]	158.0	89.0,	216.0]
	KEK-BE	39	14	4.0	2.0,	6.0]	6.5	3.2,	15.0]	26.0	17.0,	48.5]	147.0	103.0,	175.0]	19.0	14.5,	27.0]	138.0	94.5,	166.5]
	CCER	12	5	9.0	5.8,	12.0]	12.0	9.0,	13.0]	46.5	31.5,	49.2]	167.5	128.8,	244.0]	32.0	21.8,	36.0]	152.0	117.5,	233.5]
	EKOS	16	17	2.0	0.5,	3.0]	2.0	0.5,	3.0]	23.0	19.8,	34.0]	98.5	81.0,	141.5]	22.5	17.0,	31.0]	97.0	79.5,	138.0]
	CE-TI	76	96	6.0	6.0,	6.0]	6.0	6.0,	6.0]	37.5	29.2,	43.0]	62.0	40.5,	97.0]	31.0	19.5,	36.2]	51.5	31.8,	89.5]
	All	284	13	6.0	3.0,	6.0]	6.0	4.0,	8.0]	34.0	25.0,	44.0]	106.5	73.0,	166.0]	26.0	18.0,	34.0]	98.0	64.8,	152.2]
Simplified	KEK-ZH	321	52	6.0	6.0,	7.0]	7.0	6.0,	9.0]	74.0	65.0,	83.0]	133.0	99.0,	185.0]	64.0	54.0,	73.0]	116.0	86.0,	159.0]
	EKNZ	373	68	2.0	0.0,	4.0]	4.0	1.0,	10.0]	19.0	12.0,	29.0]	49.0	29.0,	89.0]	13.0	7.0,	20.0]	42.0	25.0,	77.0]
	CER-VD	212	60	4.0	2.0,	6.0]	6.0	4.0,	9.0]	27.0	20.0,	34.0]	92.5	60.0,	139.2]	19.0	15.0,	24.0]	81.5	52.0,	126.2]
	KEK-BE	237	86	3.0	1.0,	5.0]	5.0	4.0,	12.0]	24.0	18.0,	39.0]	75.0	51.0,	118.0]	15.0	13.0,	19.0]	66.0	44.0,	98.0]
	CCER	170	66	9.0	6.0,	14.8]	13.0	8.0,	24.0]	47.5	39.0,	61.0]	160.0	104.2,	240.2]	32.5	24.0,	40.8]	138.0	90.0,	226.2]
	EKOS	49	52	1.0	0.0,	3.0]	2.0	0.0,	4.0]	7.0	4.0,	11.0]	23.0	8.0,	55.0]	6.0	3.0,	8.0]	22.0	7.0,	52.0]
	CE-TI	3	4	3.0	1.5,	6.0]	9.0	6.0,	9.0]	38.0	28.0,	40.0]	73.0	48.0,	76.0]	29.0	22.0,	31.0]	64.0	42.0,	67.0]
	All	1365	61	4.0	1.0,	6.0]	6.0	4.0,	12.0]	32.0	19.0,	63.0]	92.0	53.0,	153.0]	20.0	14.0,	43.0]	81.0	46.0,	133.0]
Presidential	KEK-ZH	239	39	6.0	6.0,	7.0]	6.0	6.0,	8.0]	64.0	55.0,	75.0]	110.0	81.0,	161.5]	55.0	45.0,	66.5]	99.0	70.5,	148.5]
	EKNZ	134	24	2.0	0.0,	4.0]	2.0	0.0,	6.0]	6.0	3.2,	13.0]	29.0	11.0,	50.5]	4.0	1.0,	6.0]	21.5	6.2,	48.5]
	CER-VD	102	29	3.0	1.0,	4.0]	5.0	3.0,	11.0]	17.0	12.0,	25.0]	46.0	19.2,	93.8]	11.0	7.0,	14.8]	34.5	13.2,	75.0]
	KEK-BE	0	0	n/a	n/a,	n/a]	n/a	n/a,	n/a]	n/a	n/a,	n/a]	n/a	n/a,	n/a]	n/a	n/a,	n/a]	n/a	n/a,	n/a]
	CCER	74	29	14.0	8.0,	19.0]	20.5	15.0,	37.0]	33.0	25.2,	48.8]	60.5	33.2,	107.8]	10.0	6.0,	15.5]	33.5	9.0,	70.2]
	EKOS	30	32	1.0	0.0,	3.0]	1.0	0.5,	3.0]	6.0	2.0,	8.5]	7.0	4.0,	29.5]	3.0	1.2,	6.0]	6.0	2.0,	11.8]
	CE-TI	0	0	n/a	n/a,	n/a]	n/a	n/a,	n/a]	n/a	n/a,	n/a]	n/a	n/a,	n/a]	n/a	n/a,	n/a]	n/a	n/a,	n/a]
	All	579	26	5.5	1.2,	7.0]	6.0	4.0,	12.0]	35.0	11.0,	64.5]	71.0	28.5,	126.0]	14.0	5.5,	50.5]	60.0	15.0,	106.5]
Overall	KEK-ZH	619	100	6.0	6.0,	7.0]	6.0	6.0,	9.0]	69.0	56.0,	79.0]	123.0	87.0,	175.5]	58.0	44.5,	70.0]	109.0	78.0,	154.0]
	EKNZ	548	100	2.0	0.0,	4.0]	4.0	1.0,	8.0]	18.0	8.0,	27.0]	47.0	26.0,	88.2]	12.0	6.0,	19.0]	41.0	20.0,	77.0]
	CER-VD	355	100	4.0	1.5,	6.0]	6.0	3.0,	11.0]	25.0	18.0,	33.5]	88.0	52.0,	147.0]	18.0	14.0,	21.0]	77.0	44.5,	126.5]
	KEK-BE	276	100	3.0	1.0,	5.0]	6.0	4.0,	13.0]	24.0	18.0,	40.0]	82.0	54.8,	133.2]	15.0	13.0,	21.0]	71.0	50.0,	118.5]
	CCER	256	100	10.0	6.0,	17.0]	17.0	9.0,	25.0]	45.0	32.8,	58.0]	131.0	76.0,	205.8]	27.0	16.0,	36.0]	107.0	62.0,	183.8]
	EKOS	95	100	1.0	0.0,	3.0]	2.0	0.0,	3.2]	8.0	4.0,	19.0]	28.0	7.0,	82.0]	6.0	2.5,	12.0]	22.0	5.5,	79.0]
	CE-TI	79	100	6.0	6.0,	6.0]	6.0	6.0,	6.0]	38.0	28.5,	42.5]	63.0	40.0,	96.0]	31.0	19.0,	36.0]	52.0	31.5,	89.0]
	All	2228	100	5.0	2.0,	6.0]	6.0	4.0,	11.0]	33.0	18.0,	61.0]	89.0	49.0,	148.0]	20.0	13.0,	43.0]	78.0	41.0,	132.0]

CE-TI reviews almost 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).

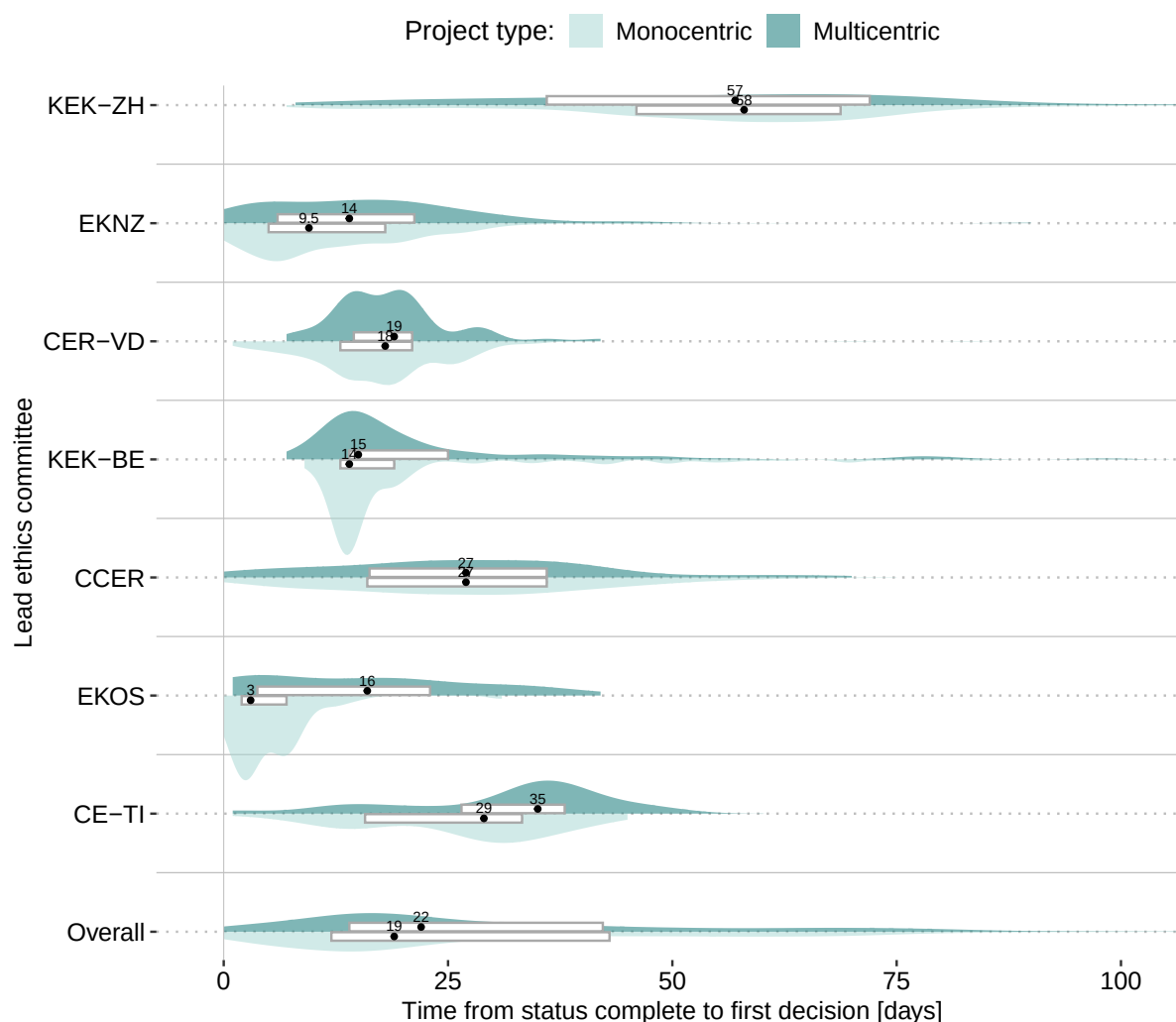


Figure 4: Violin plot of the time between status 'complete' to the first decision by EC. 32 projects with $t > 60$ days are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 27.

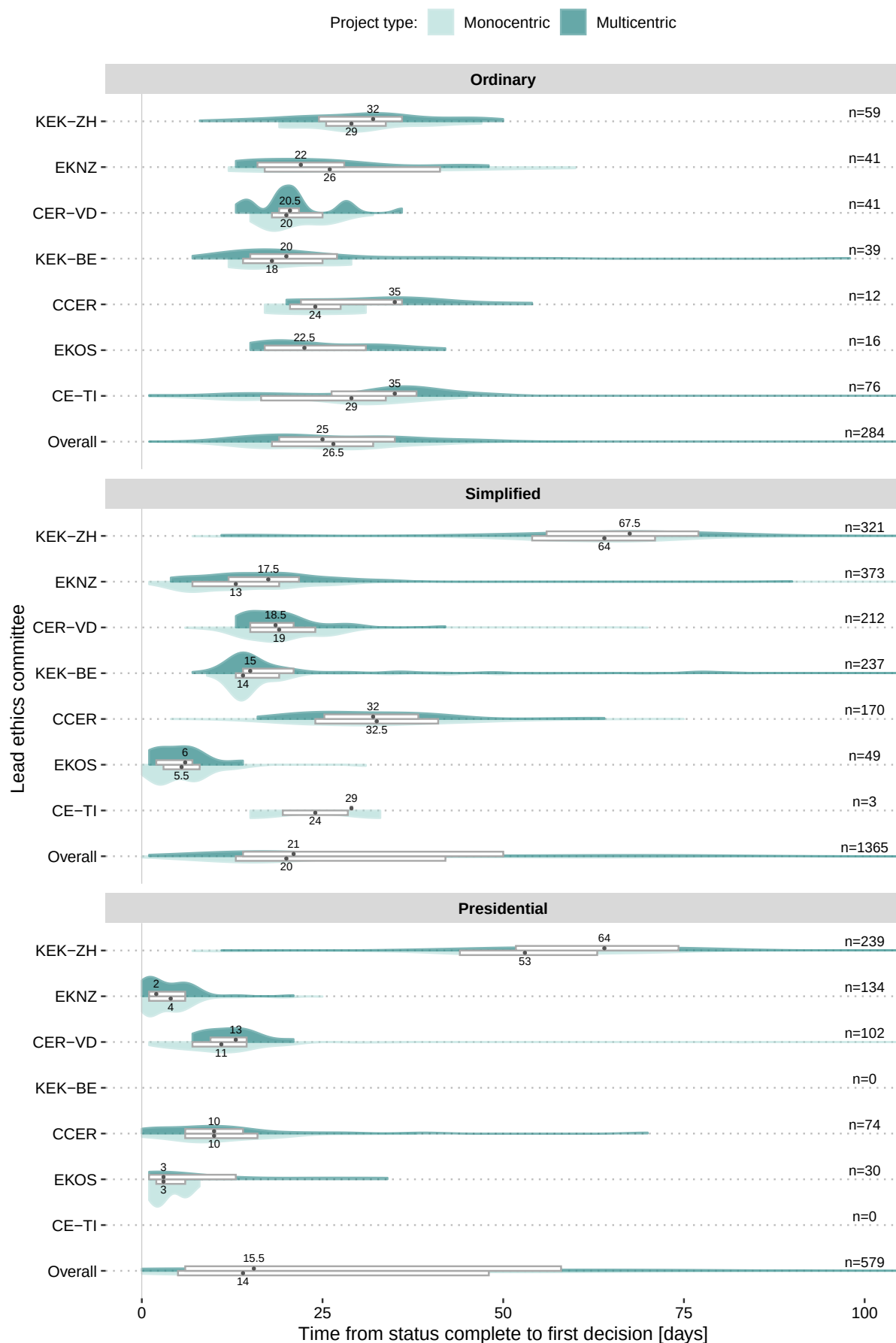


Figure 5: Violin plot of the time between status 'complete' to the first decision by EC and stratified by review procedure. 297 projects with $t > 100$ days are not shown for layout reasons. Note: *CE-TI* typically processes all submissions in a plenary session (ordinary procedure) but with adapted fees. *KEK-BE* did not approve any submissions through presidential procedure in 2025. ClinO-MD projects are not included but separately displayed in table 27.

5.3.2 Time from reception to final decision

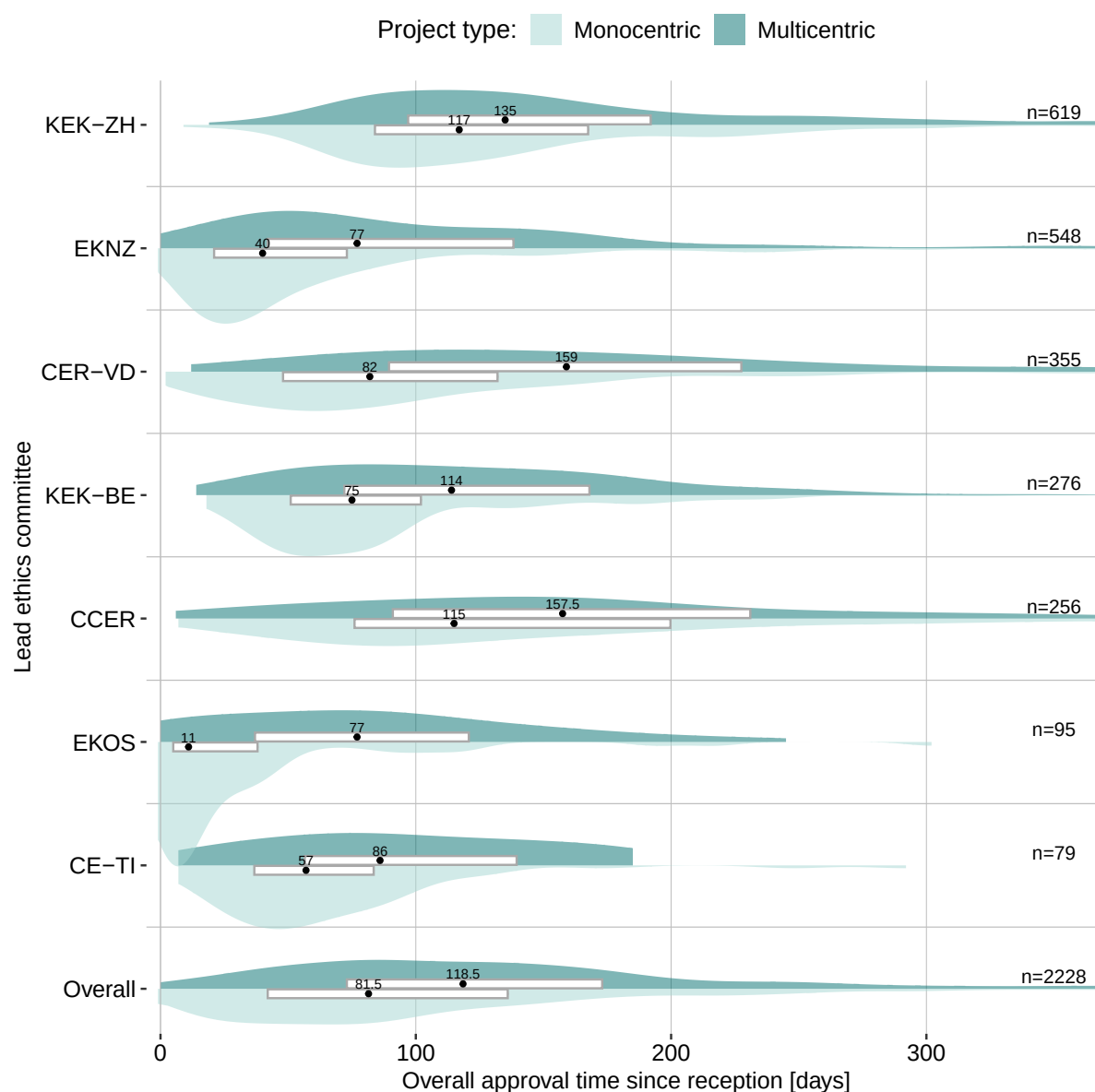


Figure 6: Violin plot of the overall approval time by EC from reception to final decision. 57 projects with approval time > 1 year are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 27.

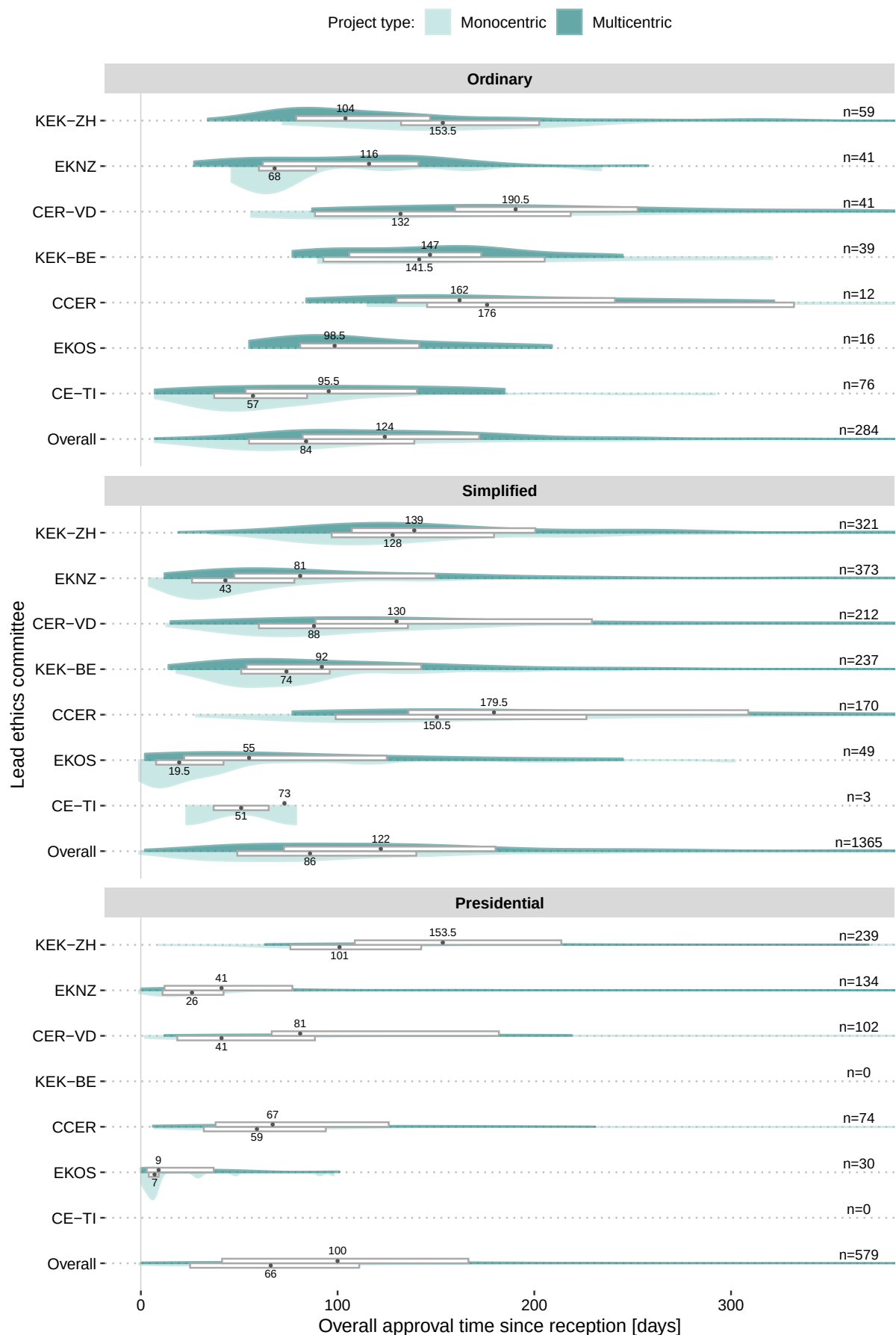


Figure 7: Violin plot of the overall approval time by EC from reception to final decision and stratified by review procedure. 67 projects with approval time > 1 year are not shown for layout reasons. Note: *CE-TI* typically processes all submissions in a plenary session (ordinary procedure) but with adapted fees. *KEK-BE* did not approve any submissions through presidential procedure in 2025. ClinO-MD projects are not included but separately displayed in Table 27.

5.4 Stratification of response time by type of research

Table 23: Overview of response time in days - Median (M) and inter-quartile range (IQR) per type of research and ethics committee. ClinO-MD projects are not included but separately displayed in table 27.

Type of research	EC	N	%EC	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.		
				Median	IQR		Median	IQR		Median	IQR		Median	IQR		Median	IQR		Median	IQR	
Clinical trial	KEK-ZH	114	29.2	6.0	6.0, 7.0	6.0	6.0, 7.0	60.0	40.0, 78.0	133.0	90.5, 185.0	46.0	30.5, 68.8	121.5	80.2, 173.5						
	EKNZ	104	26.7	3.0	1.0, 5.0	4.0	1.0, 8.0	24.5	19.0, 34.0	78.0	49.5, 140.0	19.0	14.0, 25.0	68.5	45.0, 129.2						
	CER-VD	40	10.3	3.5	2.0, 5.8	6.0	3.0, 7.0	26.5	20.0, 34.0	160.5	110.5, 242.2	20.0	17.0, 24.2	157.5	103.2, 219.2						
	KEK-BE	63	16.1	4.0	1.0, 5.5	5.0	2.2, 13.8	24.0	16.5, 35.0	106.0	75.0, 153.0	15.0	13.5, 20.5	92.0	69.5, 148.5						
	CCER	29	7.4	9.0	6.0, 12.0	12.0	7.0, 16.0	44.0	33.0, 49.0	173.0	115.0, 241.0	33.0	22.0, 36.0	155.0	106.0, 229.0						
	EKOS	23	5.9	2.0	0.0, 3.0	2.0	0.0, 3.0	20.0	15.5, 29.5	92.0	48.5, 131.0	17.0	13.5, 27.0	90.0	41.5, 128.0						
	CE-TI	17	4.4	6.0	6.0, 6.0	6.0	6.0, 6.0	37.0	30.0, 43.0	86.0	61.0, 125.0	31.0	24.0, 38.0	80.0	48.0, 119.0						
	All	390	100.0	5.0	2.0, 6.0	6.0	3.0, 9.0	33.0	20.0, 49.8	116.5	76.0, 168.0	23.0	17.0, 36.0	105.0	69.0, 155.0						
Research w/ persons (HRO Chapter 2)	KEK-ZH	153	23.3	6.0	6.0, 7.0	7.0	6.0, 9.0	75.0	66.0, 83.0	134.0	108.0, 173.0	64.0	52.0, 72.0	120.0	93.0, 152.0						
	EKNZ	148	22.6	2.0	0.0, 4.0	3.0	1.0, 6.5	22.0	16.0, 30.0	54.5	33.8, 93.8	18.0	12.0, 22.2	49.0	30.0, 82.2						
	CER-VD	137	20.9	4.5	2.0, 6.0	6.0	5.0, 12.8	27.0	21.0, 35.0	95.0	60.0, 150.0	19.0	15.0, 24.0	82.0	53.0, 133.0						
	KEK-BE	88	13.4	3.0	1.0, 5.0	6.0	4.0, 11.0	22.0	18.0, 39.2	89.5	63.5, 154.2	15.0	13.0, 19.2	83.5	56.8, 144.5						
	CCER	82	12.5	8.0	4.8, 13.0	11.0	6.0, 22.0	46.5	35.2, 56.8	161.5	105.0, 263.5	31.5	26.2, 40.0	139.5	92.8, 229.2						
	EKOS	19	2.9	2.5	0.0, 3.8	2.0	0.0, 3.5	8.0	4.5, 11.5	42.0	14.0, 87.0	6.0	3.0, 7.5	38.0	10.5, 84.5						
	CE-TI	29	4.4	6.0	5.0, 6.0	6.0	6.0, 6.0	35.0	21.0, 39.0	57.0	42.0, 78.0	29.0	15.0, 34.0	50.0	36.0, 72.0						
	All	656	100.0	5.0	2.0, 6.0	6.0	4.0, 10.0	33.5	20.0, 62.0	99.5	59.0, 158.0	21.0	15.0, 41.0	90.0	53.0, 141.5						
Further use (HRO Chapter 3)	KEK-ZH	322	28.5	6.0	6.0, 7.0	7.0	6.0, 9.0	66.0	56.0, 77.0	116.0	84.0, 175.5	57.0	45.2, 67.0	103.0	74.0, 154.8						
	EKNZ	286	25.3	2.0	0.0, 4.0	4.0	1.0, 10.0	10.0	6.0, 18.0	33.0	17.0, 64.0	6.0	3.0, 8.8	27.0	13.0, 52.2						
	CER-VD	176	15.6	3.0	1.0, 5.0	5.0	2.5, 10.5	20.0	14.8, 28.0	62.0	28.8, 117.2	14.0	10.0, 20.0	53.5	20.8, 89.2						
	KEK-BE	122	10.8	3.0	1.0, 5.0	6.0	5.0, 12.2	24.5	19.0, 41.8	66.5	45.2, 100.8	15.0	13.2, 21.0	56.5	36.2, 88.2						
	CCER	140	12.4	11.0	7.0, 18.0	19.5	12.0, 29.2	42.5	29.0, 59.0	102.5	54.5, 168.0	20.0	9.0, 33.0	78.5	23.0, 139.2						
	EKOS	52	4.6	1.0	0.0, 3.0	1.0	0.0, 3.5	7.0	2.8, 9.0	7.5	4.0, 34.8	3.0	1.8, 7.0	6.0	2.0, 29.5						
	CE-TI	31	2.8	6.0	6.0, 6.0	6.0	6.0, 8.0	40.0	32.5, 46.0	69.0	35.5, 96.0	33.0	17.0, 36.5	49.0	20.5, 84.0						
	All	1129	100.0	5.0	1.0, 6.0	6.0	4.0, 13.0	31.0	14.0, 62.0	76.0	34.0, 131.0	15.0	7.0, 44.0	63.0	26.0, 111.0						
Deceased and embryos from stillbirths or abortion (HRO Chapter 4+5)	KEK-ZH	30	56.6	6.0	6.0, 6.0	6.0	6.0, 6.0	66.5	62.0, 74.8	88.0	70.8, 123.2	61.0	56.0, 68.8	84.0	64.0, 118.0						
	EKNZ	10	18.9	1.0	0.0, 3.0	1.0	0.0, 5.0	24.0	19.0, 30.0	50.0	40.2, 95.0	19.5	18.2, 25.8	45.0	36.5, 95.2						
	CER-VD	2	3.8	3.0	1.5, 4.5	38.0	22.0, 54.0	57.5	41.8, 73.2	187.0	169.5, 204.5	19.5	19.2, 19.8	149.0	115.5, 182.5						
	KEK-BE	3	5.7	4.0	3.0, 4.5	5.0	4.0, 21.5	20.0	18.5, 37.0	82.0	68.0, 116.0	15.0	14.5, 15.5	77.0	46.5, 112.0						
	CCER	5	9.4	17.0	15.0, 18.0	17.0	15.0, 18.0	53.0	43.0, 71.0	132.0	117.0, 161.0	35.0	23.0, 56.0	109.0	101.0, 144.0						
	EKOS	1	1.9	0.0	0.0, 0.0	0.0	0.0, 0.0	8.0	8.0, 8.0	8.0	8.0, 8.0	8.0	8.0, 8.0	8.0	8.0, 8.0						
	CE-TI	2	3.8	6.0	6.0, 6.0	7.5	6.8, 8.2	39.5	37.8, 41.2	62.5	49.2, 75.8	32.0	29.5, 34.5	55.0	41.0, 69.0						
	All	53	100.0	6.0	4.0, 6.0	6.0	5.0, 7.0	61.0	34.0, 71.0	86.0	64.0, 133.0	54.0	23.0, 64.0	83.0	58.0, 120.0						
Overall	KEK-ZH	619	100.0	6.0	6.0, 7.0	6.0	6.0, 9.0	69.0	56.0, 79.0	123.0	87.0, 175.5	58.0	44.5, 70.0	109.0	78.0, 154.0						
	EKNZ	548	100.0	2.0	0.0, 4.0	4.0	1.0, 8.0	18.0	8.0, 27.0	47.0	26.0, 88.2	12.0	6.0, 19.0	41.0	20.0, 77.0						
	CER-VD	355	100.0	4.0	1.5, 6.0	6.0	3.0, 11.0	25.0	18.0, 33.5	88.0	52.0, 147.0	18.0	14.0, 21.0	77.0	44.5, 126.5						
	KEK-BE	276	100.0	3.0	1.0, 5.0	6.0	4.0, 13.0	24.0	18.0, 40.0	82.0	54.8, 133.2	15.0	13.0, 21.0	71.0	50.0, 118.5						
	CCER	256	100.0	10.0	6.0, 17.0	17.0	9.0, 25.0	45.0	32.8, 58.0	131.0	76.0, 205.8	27.0	16.0, 36.0	107.0	62.0, 183.8						
	EKOS	95	100.0	1.0	0.0, 3.0	2.0	0.0, 3.2	8.0	4.0, 19.0	28.0	7.0, 82.0	6.0	2.5, 12.0	22.0	5.5, 79.0						
	CE-TI	79	100.0	6.0	6.0, 6.0	6.0	6.0, 6.0	38.0	28.5, 42.5	63.0	40.0, 96.0	31.0	19.0, 36.0	52.0	31.5, 89.0						
	All	2228	100.0	5.0	2.0, 6.0	6.0	4.0, 11.0	33.0	18.0, 61.0	89.0	49.0, 148.0	20.0	13.0, 43.0	78.0	41.0, 132.0						

Table 24: Overview of response time in days - Median and inter-quartile range (IQR) per type of research and depending on whether a single or multiple ECs are involved. ClinO-MD projects are not included but separately displayed in table 27.

Type of research	Time interval	Application involves					
		Multiple ECs			Single EC		
		N	Median	IQR	N	Median	IQR
Clinical trial	from receipt to first reply	138	5	[2, 6]	252	5	[1, 6]
	from receipt to status 'complete'	138	6	[3, 8]	252	6	[4, 9]
	from receipt to first decision	138	33	[22, 47]	252	32	[20, 56]
	from receipt to final decision	138	124	[82, 169]	252	110	[70, 166]
	from 'complete' to first decision	138	23	[19, 36]	252	22	[15, 39]
	from 'complete' to final decision	138	118	[76, 158]	252	96	[62, 154]
Research w/ persons (HRO Chapter 2)	from receipt to first reply	69	4	[2, 6]	587	5	[2, 6]
	from receipt to status 'complete'	69	6	[4, 16]	587	6	[4, 9]
	from receipt to first decision	69	38	[22, 66]	587	33	[20, 62]
	from receipt to final decision	69	128	[68, 176]	587	97	[58, 154]
	from 'complete' to first decision	69	21	[15, 36]	587	21	[14, 42]
	from 'complete' to final decision	69	116	[59, 155]	587	87	[52, 139]
Further use (HRO Chapter 3)	from receipt to first reply	85	6	[3, 7]	1044	5	[1, 6]
	from receipt to status 'complete'	85	6	[5, 10]	1044	6	[4, 13]
	from receipt to first decision	85	52	[26, 73]	1044	28	[13, 60]
	from receipt to final decision	85	133	[80, 199]	1044	71	[32, 124]
	from 'complete' to first decision	85	34	[15, 60]	1044	15	[7, 43]
	from 'complete' to final decision	85	125	[74, 182]	1044	60	[22, 101]
Deceased and embryos from stillbirths or abortion (HRO Chapter 4+5)	from receipt to first reply	0		[,]	53	6	[4, 6]
	from receipt to status 'complete'	0		[,]	53	6	[5, 7]
	from receipt to first decision	0		[,]	53	61	[34, 71]
	from receipt to final decision	0		[,]	53	86	[64, 133]
	from 'complete' to first decision	0		[,]	53	54	[23, 64]
	from 'complete' to final decision	0		[,]	53	83	[58, 120]
Overall	from receipt to first reply	292	5	[2, 6]	1936	5	[1, 6]
	from receipt to status 'complete'	292	6	[4, 10]	1936	6	[4, 12]
	from receipt to first decision	292	38	[23, 55]	1936	32	[18, 62]
	from receipt to final decision	292	128	[80, 175]	1936	84	[45, 140]
	from 'complete' to first decision	292	25	[16, 42]	1936	19	[12, 43]
	from 'complete' to final decision	292	119	[74, 162]	1936	72	[37, 124]

Table 25: Overview of response time in days - Median and inter-quartile range (IQR) stratified by lead ethics committee and depending on whether a single or multiple ECs are involved. ClinO-MD projects are not included but separately displayed in table 27.

Lead EC	Time interval	Application involves					
		Multiple ECs			Single EC		
		N	Median	IQR	N	Median	IQR
KEK-ZH	from receipt to first reply	89	6.0	[6.0, 7.0]	530	6.0	[6.0, 7.0]
	from receipt to status 'complete'	89	6.0	[6.0, 8.0]	530	7.0	[6.0, 9.0]
	from receipt to first decision	89	65.0	[47.0, 78.0]	530	69.0	[58.0, 79.0]
	from receipt to final decision	89	134.0	[99.0, 188.0]	530	121.5	[86.2, 172.0]
	from 'complete' to first decision	89	50.0	[33.0, 67.0]	530	58.0	[46.0, 70.0]
	from 'complete' to final decision	89	126.0	[91.0, 165.0]	530	107.0	[77.0, 152.0]
EKNZ	from receipt to first reply	61	3.0	[1.0, 5.0]	487	2.0	[0.0, 4.0]
	from receipt to status 'complete'	61	4.0	[1.0, 7.0]	487	4.0	[1.0, 8.2]
	from receipt to first decision	61	26.0	[19.0, 33.0]	487	16.0	[7.0, 26.0]
	from receipt to final decision	61	91.0	[55.0, 148.0]	487	41.0	[22.5, 79.5]
	from 'complete' to first decision	61	20.0	[14.0, 26.0]	487	9.0	[5.0, 18.0]
	from 'complete' to final decision	61	85.0	[49.0, 147.0]	487	36.0	[19.0, 67.0]
CER-VD	from receipt to first reply	27	3.0	[1.0, 5.0]	328	4.0	[2.0, 6.0]
	from receipt to status 'complete'	27	6.0	[2.0, 36.5]	328	6.0	[3.0, 10.0]
	from receipt to first decision	27	27.0	[18.5, 50.5]	328	25.0	[18.0, 33.0]
	from receipt to final decision	27	168.0	[110.0, 246.5]	328	84.0	[49.0, 136.0]
	from 'complete' to first decision	27	19.0	[15.0, 21.0]	328	18.0	[13.0, 21.0]
	from 'complete' to final decision	27	135.0	[98.5, 210.5]	328	72.0	[42.0, 120.2]
KEK-BE	from receipt to first reply	53	4.0	[1.0, 6.0]	223	3.0	[1.0, 5.0]
	from receipt to status 'complete'	53	6.0	[5.0, 15.0]	223	5.0	[4.0, 12.0]
	from receipt to first decision	53	28.0	[20.0, 42.0]	223	23.0	[18.0, 39.0]
	from receipt to final decision	53	117.0	[74.0, 168.0]	223	78.0	[53.5, 126.0]
	from 'complete' to first decision	53	17.0	[14.0, 27.0]	223	15.0	[13.0, 20.0]
	from 'complete' to final decision	53	99.0	[56.0, 155.0]	223	70.0	[49.0, 103.0]
CCER	from receipt to first reply	26	10.0	[5.0, 13.0]	230	10.0	[7.0, 17.0]
	from receipt to status 'complete'	26	12.5	[6.8, 15.0]	230	18.0	[9.0, 27.0]
	from receipt to first decision	26	42.5	[33.5, 47.8]	230	46.0	[33.0, 60.0]
	from receipt to final decision	26	164.5	[111.8, 250.0]	230	123.0	[74.2, 201.8]
	from 'complete' to first decision	26	29.0	[22.0, 35.8]	230	27.0	[14.0, 36.0]
	from 'complete' to final decision	26	146.5	[95.5, 242.5]	230	98.0	[56.2, 172.0]
EKOS	from receipt to first reply	23	3.0	[0.8, 3.0]	72	1.0	[0.0, 3.0]
	from receipt to status 'complete'	23	3.0	[0.8, 3.0]	72	1.0	[0.0, 4.0]
	from receipt to first decision	23	23.0	[15.5, 34.0]	72	7.0	[2.8, 9.0]
	from receipt to final decision	23	93.0	[57.0, 145.0]	72	10.5	[5.0, 41.2]
	from 'complete' to first decision	23	20.0	[14.5, 31.0]	72	3.0	[2.0, 7.0]
	from 'complete' to final decision	23	91.0	[55.0, 142.0]	72	8.0	[3.0, 35.0]
CE-TI	from receipt to first reply	13	6.0	[6.0, 6.0]	66	6.0	[5.0, 6.0]
	from receipt to status 'complete'	13	6.0	[6.0, 6.0]	66	6.0	[6.0, 6.0]
	from receipt to first decision	13	44.0	[43.0, 48.0]	66	36.0	[26.2, 40.0]
	from receipt to final decision	13	138.0	[105.0, 161.0]	66	57.0	[37.2, 82.0]
	from 'complete' to first decision	13	38.0	[37.0, 42.0]	66	29.0	[16.0, 33.8]
	from 'complete' to final decision	13	132.0	[99.0, 155.0]	66	48.5	[28.0, 69.8]
Overall	from receipt to first reply	292	5.0	[2.0, 6.0]	1936	5.0	[1.0, 6.0]
	from receipt to status 'complete'	292	6.0	[4.0, 10.0]	1936	6.0	[4.0, 12.0]
	from receipt to first decision	292	38.0	[23.0, 55.2]	1936	32.0	[18.0, 62.0]
	from receipt to final decision	292	128.5	[80.0, 175.2]	1936	84.0	[45.0, 140.0]
	from 'complete' to first decision	292	25.0	[16.0, 42.0]	1936	19.0	[12.0, 43.0]
	from 'complete' to final decision	292	119.0	[74.0, 162.0]	1936	72.5	[36.8, 124.0]

5.4.1 Time from status “complete” to first decision

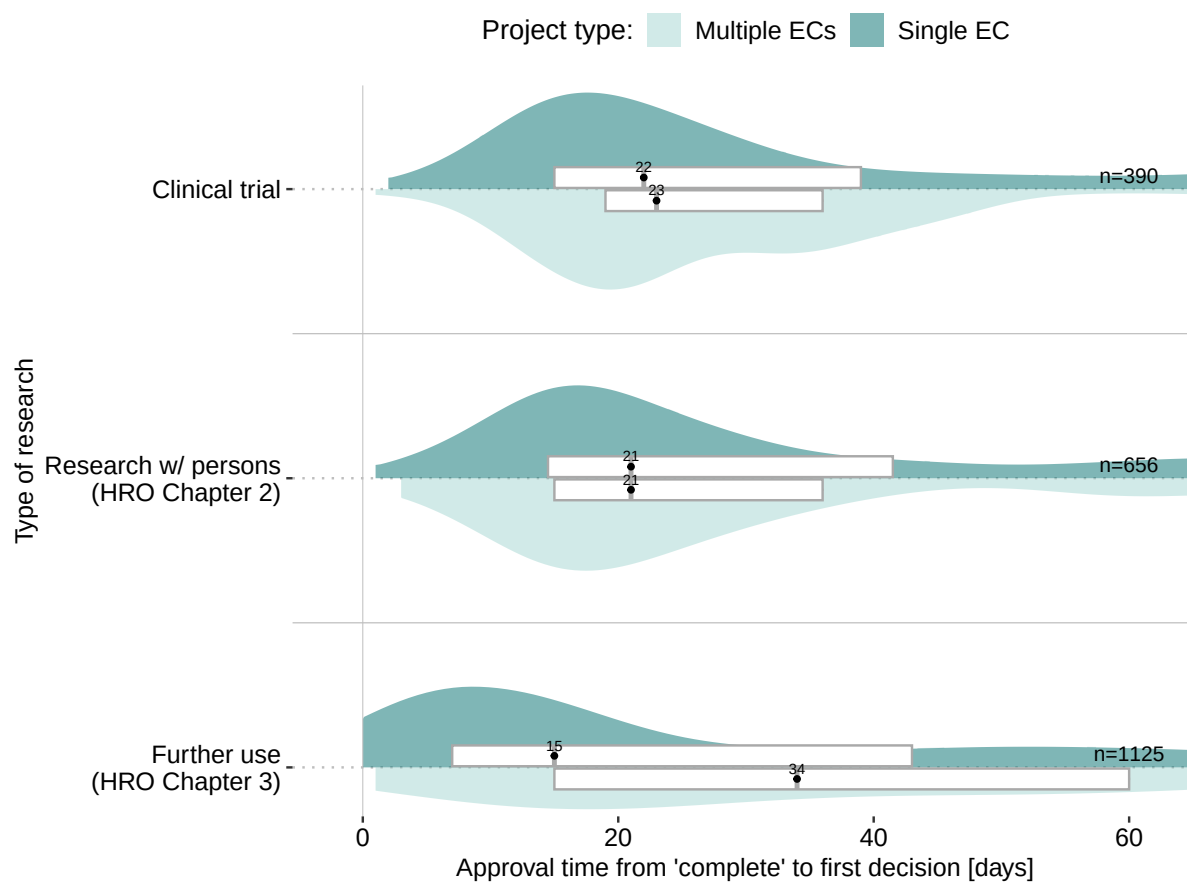


Figure 8: Violin plot of the **approval time starting from status 'complete' to the first decision** per type of research (only the 3 major groups are shown). 32 projects with approval time > 60 days are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 27.

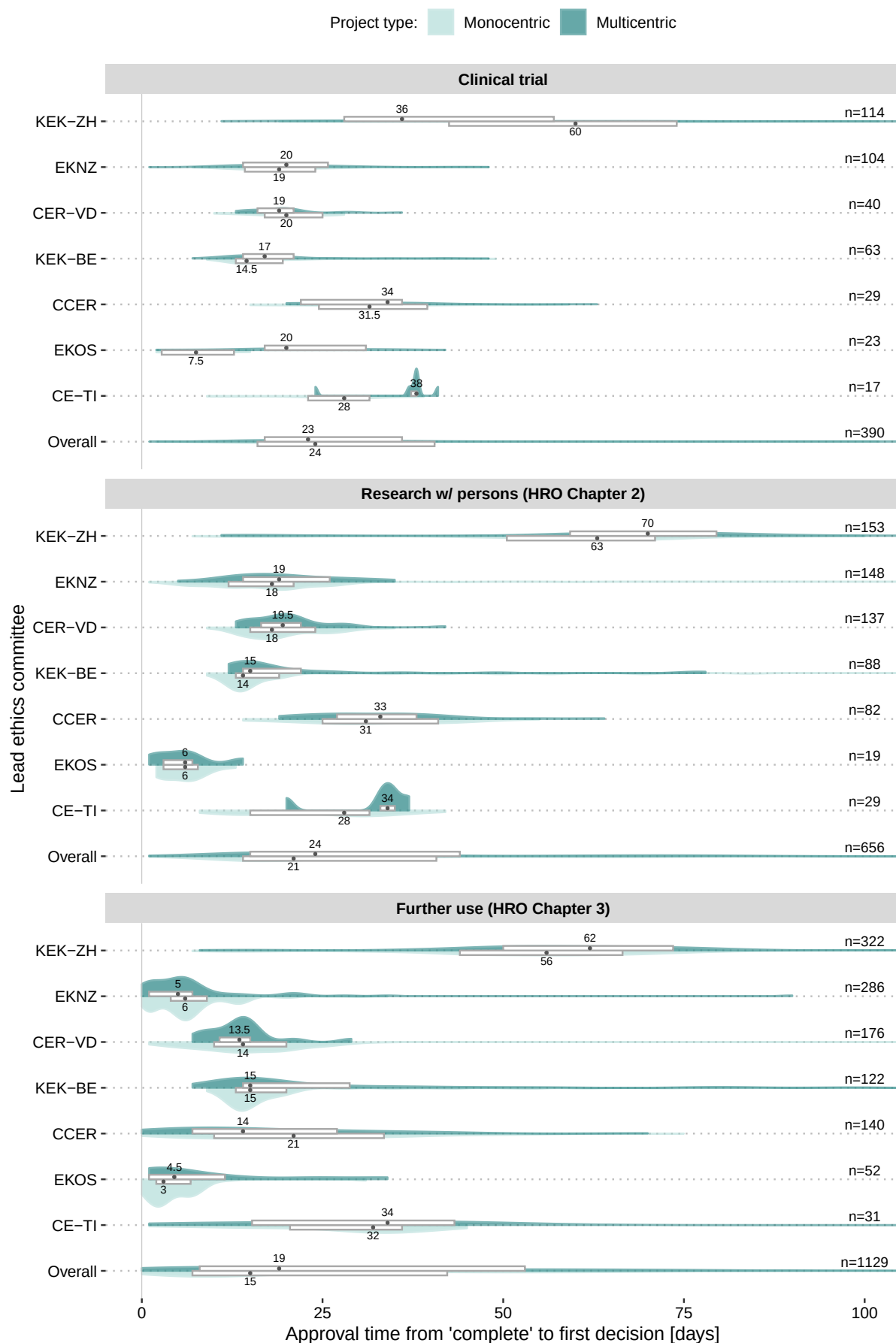


Figure 9: Violin plot of the **approval time starting from status 'complete' to the first decision** per type of research (only the 3 major groups are shown) stratified by EC. 297 projects with approval time > 100 days are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 27.

5.4.2 Time from reception to final decision

Table 26: Overview of **response time from reception to final decision in days**: median and interquartile range (IQR) by type of research and initiator. Clinical trials with medical devices are reported separately.

Type of research	Initiator					
	Industry			Investigator		
	N	Median	IQR	N	Median	IQR
Clinical trials (excluding clinical trials with medical devices) ¹	122	117	[80, 152]	270	116	[71, 178]
Clinical trials with medicinal products	107	115	[80, 146]	44	124	[86, 175]
Other clinical trials	6	88	[77, 118]	223	113	[68, 180]
Further categories ²	9	166	[125, 172]	3	169	[122, 328]
Clinical trials with medical devices ³	38	55	[38, 101]	45	67	[48, 90]
Research w/ persons (HRO Chapter 2)	32	96	[62, 145]	624	100	[58, 158]
Further use (HRO Chapter 3)	48	54	[21, 112]	1081	76	[35, 132]
All⁴	240	92	[60, 140]	2020	87	[48, 147]

¹ The category 'Clinical trials excluding clinical trials with medical devices' comprises clinical trials with medicinal products, other clinical trials, and further categories.

² 'Further categories' include gene therapy, pathogenic organisms/GMO, transplant products, transplantation, and combination drug-device studies.

³ Clinical trials with medical devices are reported separately because no first-decision date is available for these projects, thereby ensuring comparability across response-time analyses.

⁴ Projects with 'Deceased persons' and 'Embryos / fetuses' are not shown.

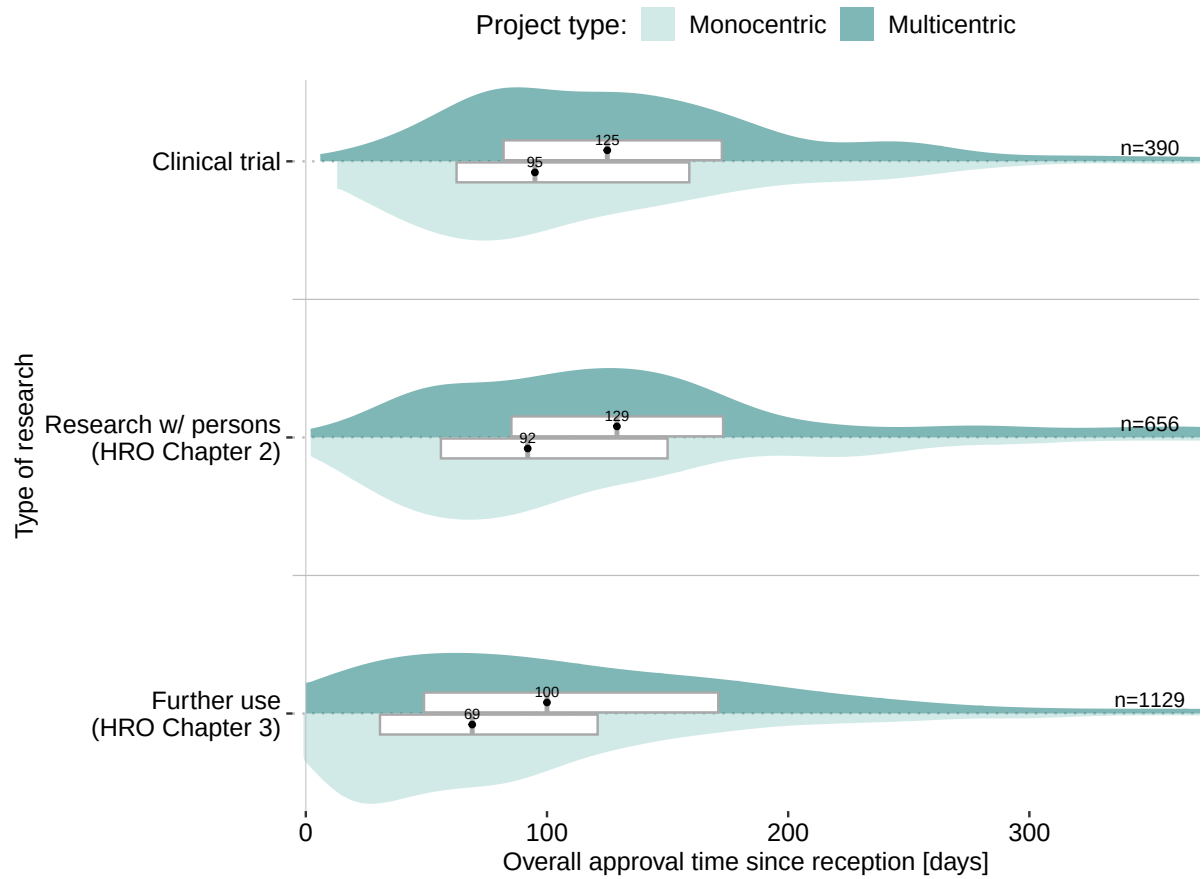


Figure 10: Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown). 57 projects with an overall approval time > 1 year are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 27.

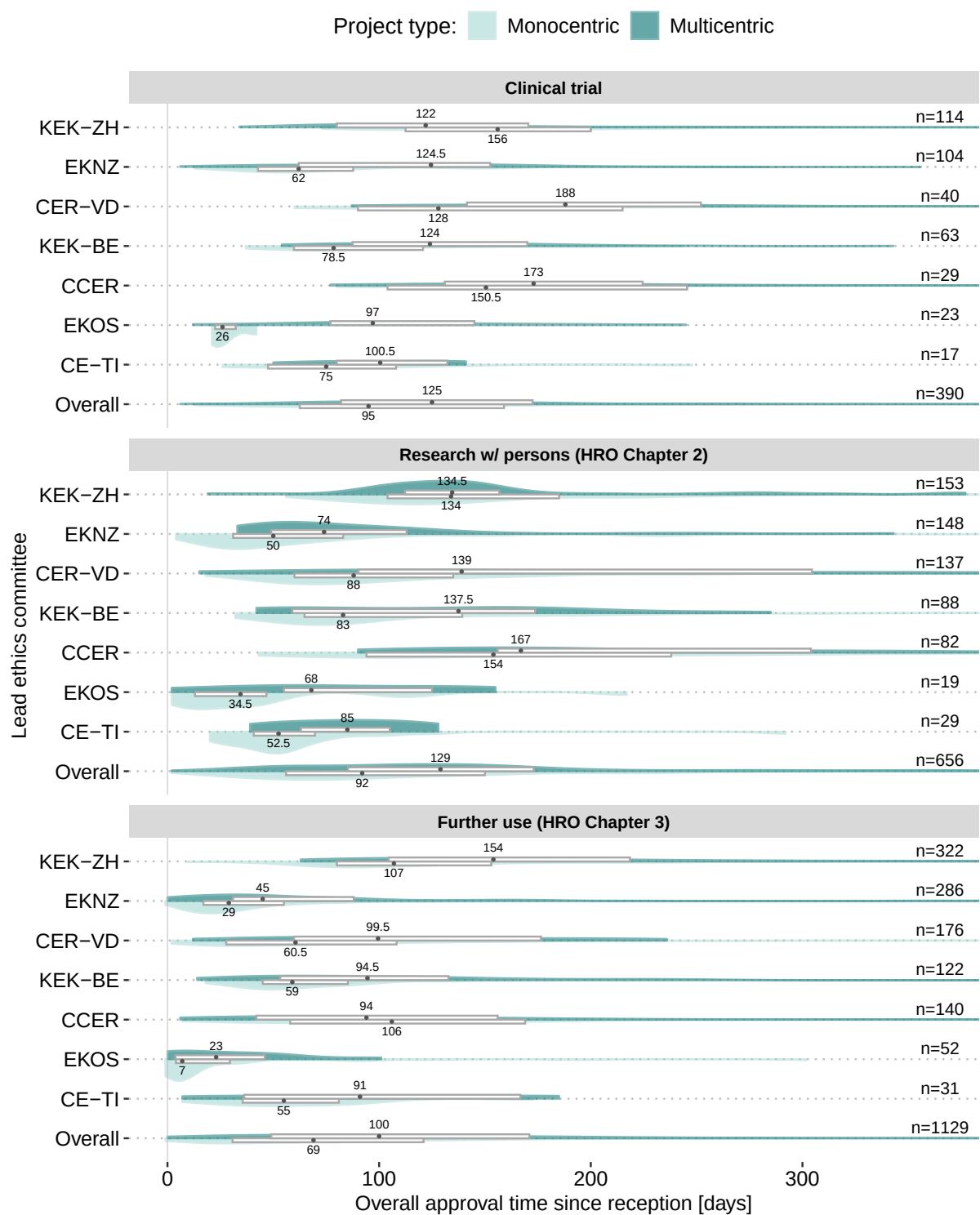


Figure 11: Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown) stratified by EC. 67 projects with an overall approval time > 1 year are not shown for layout reasons. ClinO-MD projects are not included but separately displayed in table 27.

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 27: 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 - **only for ClinO-MD projects**.

Lead EC		Application involves					
		Multiple ECs			Single EC		
		N	Median	IQR	N	Median	IQR
KEK-ZH	from receipt to status 'complete'	2	6	[6 , 7]	18	9	[7, 12]
	from receipt to final decision	2	106	[75 , 138]	18	76	[70, 111]
	from 'complete' to final decision	2	100	[68 , 132]	18	68	[60, 91]
EKNZ	from receipt to status 'complete'	7	5	[2 , 5]	11	3	[2, 5]
	from receipt to final decision	7	41	[34 , 44]	11	26	[22, 34]
	from 'complete' to final decision	7	34	[30 , 40]	11	23	[20, 29]
CER-VD	from receipt to status 'complete'	4	8	[6 , 10]	6	6	[6, 7]
	from receipt to final decision	4	84	[72 , 114]	6	66	[60, 68]
	from 'complete' to final decision	4	75	[61 , 108]	6	60	[52, 62]
KEK-BE	from receipt to status 'complete'	5	9	[6 , 11]	8	6	[4, 8]
	from receipt to final decision	5	60	[54 , 108]	8	41	[38, 53]
	from 'complete' to final decision	5	49	[45 , 102]	8	36	[35, 46]
CCER	from receipt to status 'complete'	2	11	[10 , 12]	11	11	[10, 16]
	from receipt to final decision	2	166	[137 , 194]	11	122	[98, 146]
	from 'complete' to final decision	2	154	[127 , 182]	11	101	[86, 122]
EKOS	from receipt to status 'complete'	2	3	[2 , 4]	2	2	[2, 2]
	from receipt to final decision	2	22	[21 , 24]	2	46	[25, 66]
	from 'complete' to final decision	2	20	[18 , 21]	2	44	[23, 64]
CE-TI	from receipt to status 'complete'	0	n/a	[n/a, n/a]	7	9	[9, 9]
	from receipt to final decision	0	n/a	[n/a, n/a]	7	54	[42, 62]
	from 'complete' to final decision	0	n/a	[n/a, n/a]	7	45	[37, 54]
Overall	from receipt to status 'complete'	22	6	[4 , 9]	63	8	[5, 10]
	from receipt to final decision	22	53	[41 , 104]	63	67	[41, 94]
	from 'complete' to final decision	22	46	[35 , 95]	63	60	[36, 86]

The total number of 85 research projects consist of 83 trials with medical devices and 2 trials on a combination medicinal product and medical device.

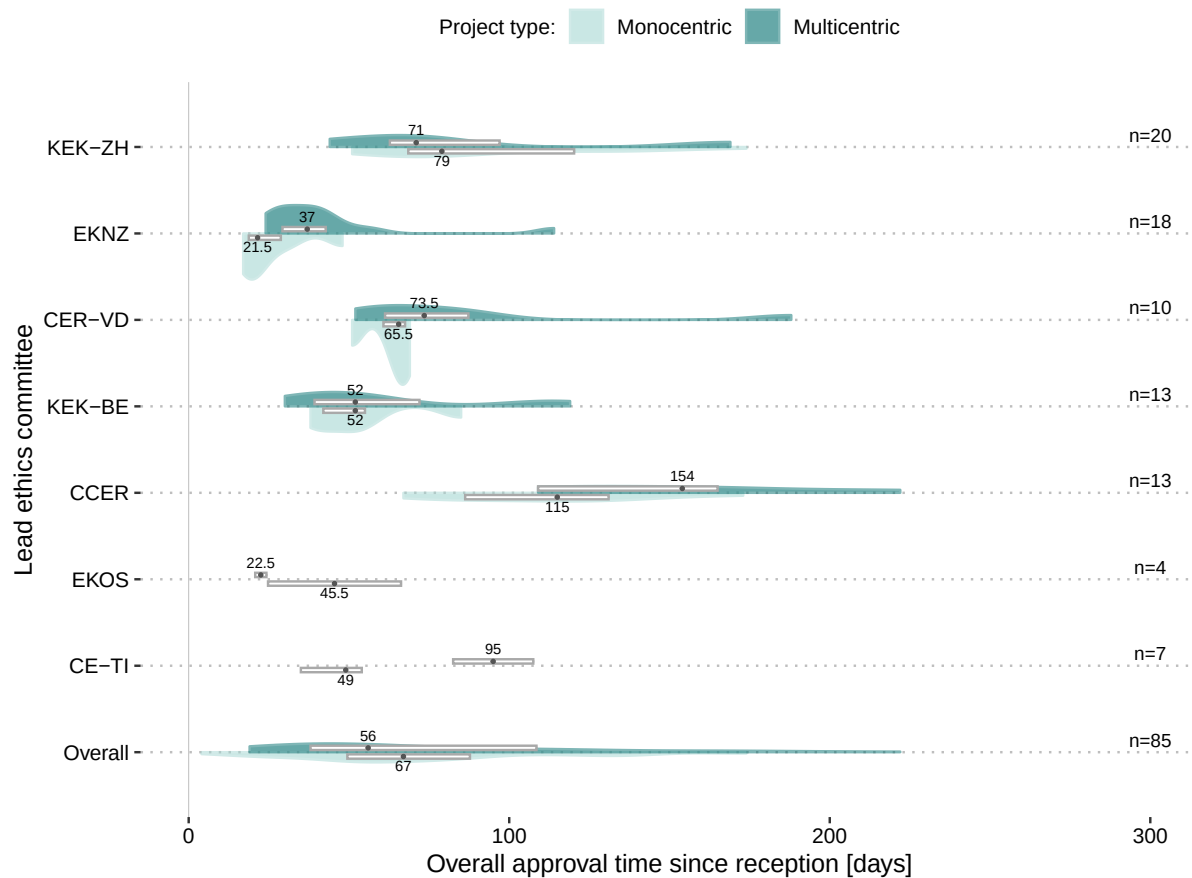


Figure 12: Violin plot of the overall approval time by EC from reception to final decision - **only for ClinO-MD projects**. Note: No density can be calculated and displayed for groups with less than 2 observations.

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.

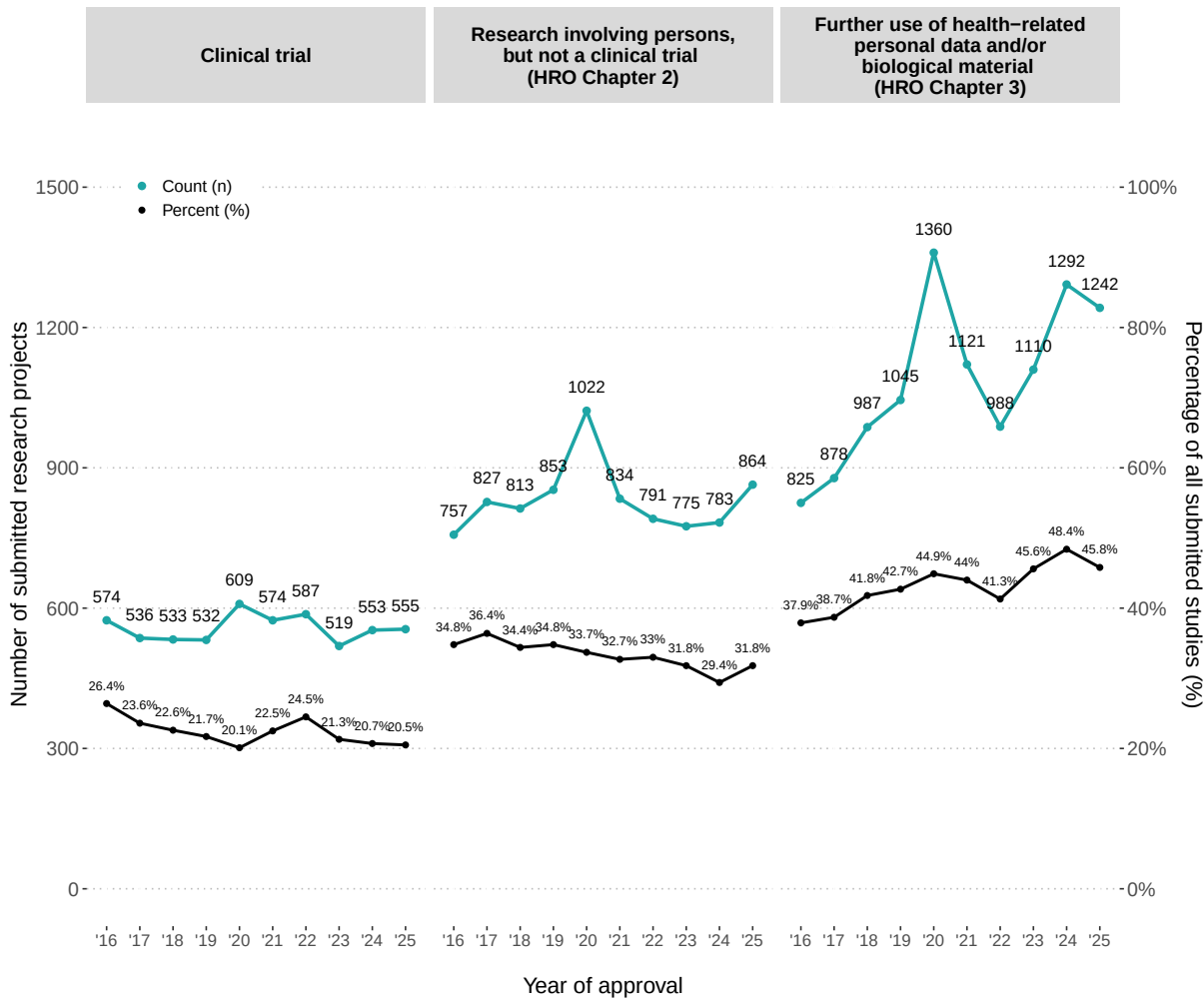


Figure 13: Total number of submitted projects per year and type of research. Percentages refer to the proportion of studies of a given type compared to all studies submitted in a given year.

Data not shown in the above figure: Research involving deceased persons (2021: 18, 2022: 28, 2023: 29, 2024: 36, 2025: 52) and Research involving embryos and fetuses from induced abortions or stillbirths (2021: 0, 2022: 0, 2023: 2, 2024: 3, 2025: 0)

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

Note: In this chapter, specific parameters of the research projects approved in the reporting year 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.

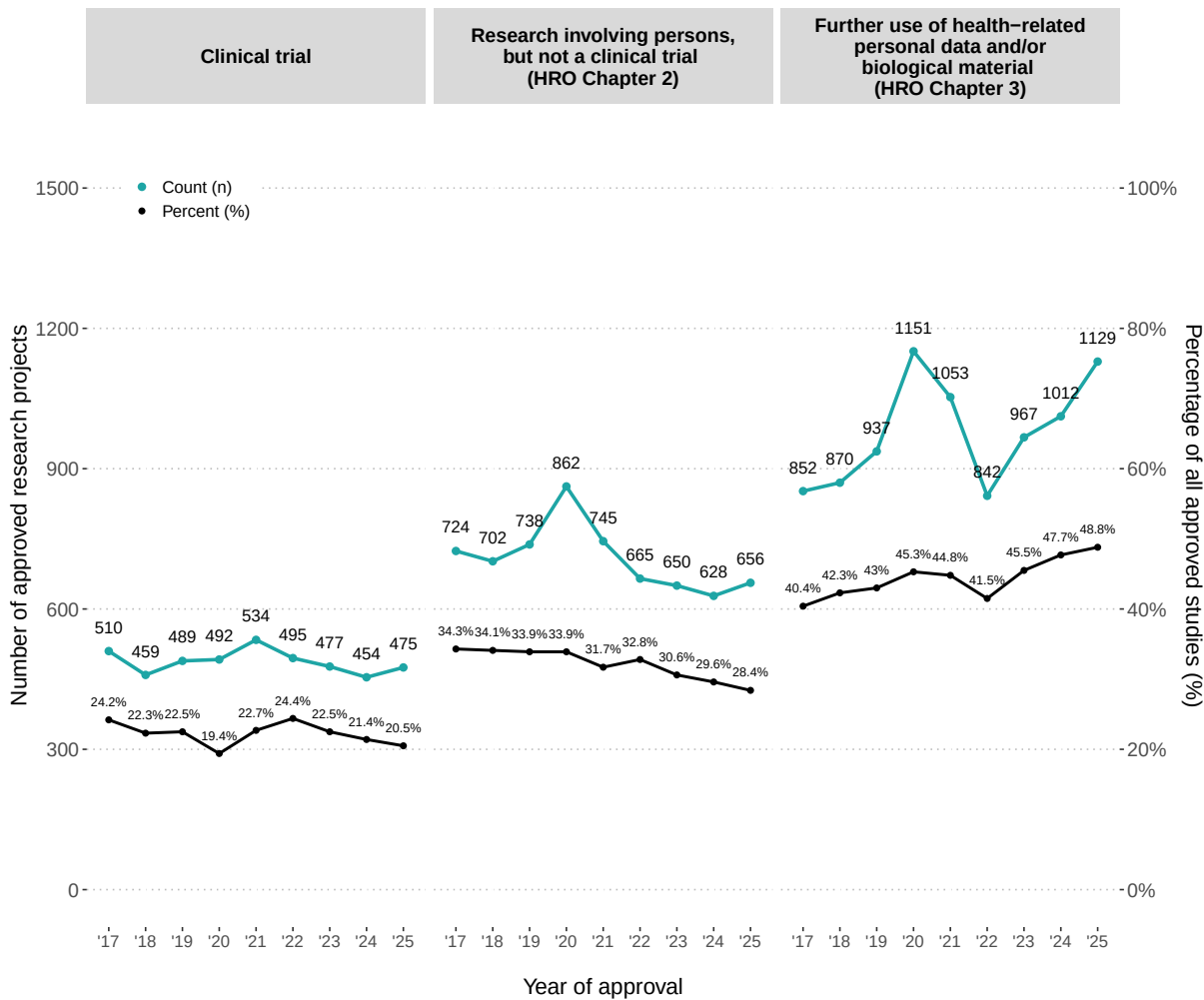


Figure 14: Total number of approved projects per year and type of research. Percentages refer to the proportion of studies of a given type compared to all studies approved in a given year.

Data not shown in the above figure: Research involving deceased persons (2019: 17, 2020: 36, 2021: 18, 2022: 27, 2023: 28, 2024: 24, 2025: 53) and Research involving embryos and fetuses from induced abortions or stillbirths (2019: 1, 2020: 0, 2021: 0, 2022: 0, 2023: 1, 2024: 2 2025: 0)

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

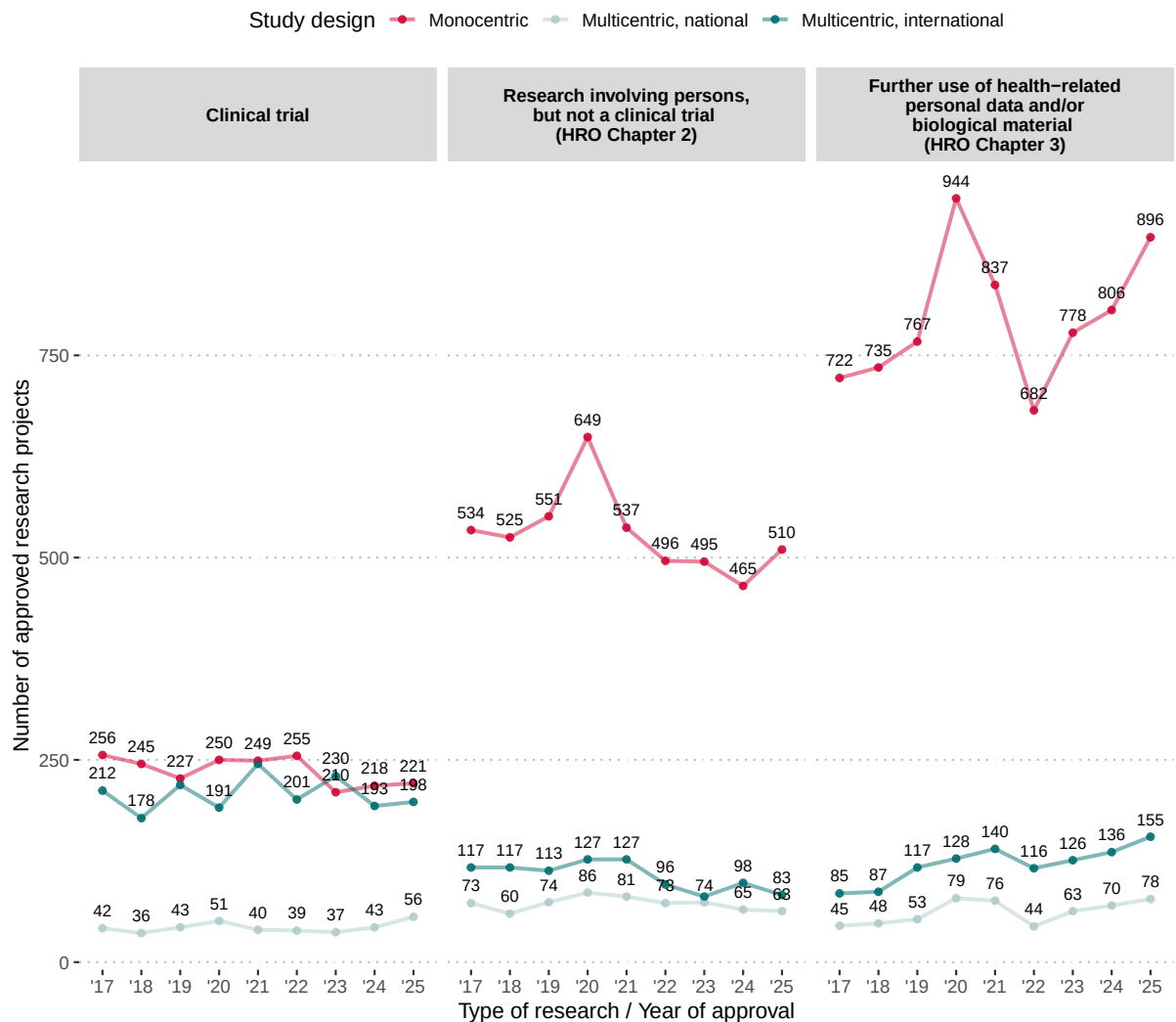


Figure 15: Approved projects per year stratified by type of research project and by study design.

Data not shown in the above figure: Research involving deceased persons (2019: 14, 2020: 36, 2021: 19, 2022: 27, 2023: 28, 2024: 24, 2025: 53) and Research involving embryos and fetuses from induced abortions or stillbirths (2019: 0, 2020: 0, 2021: 1, 2022: 0, 2023: 1, 2024: 2 2025: 0)

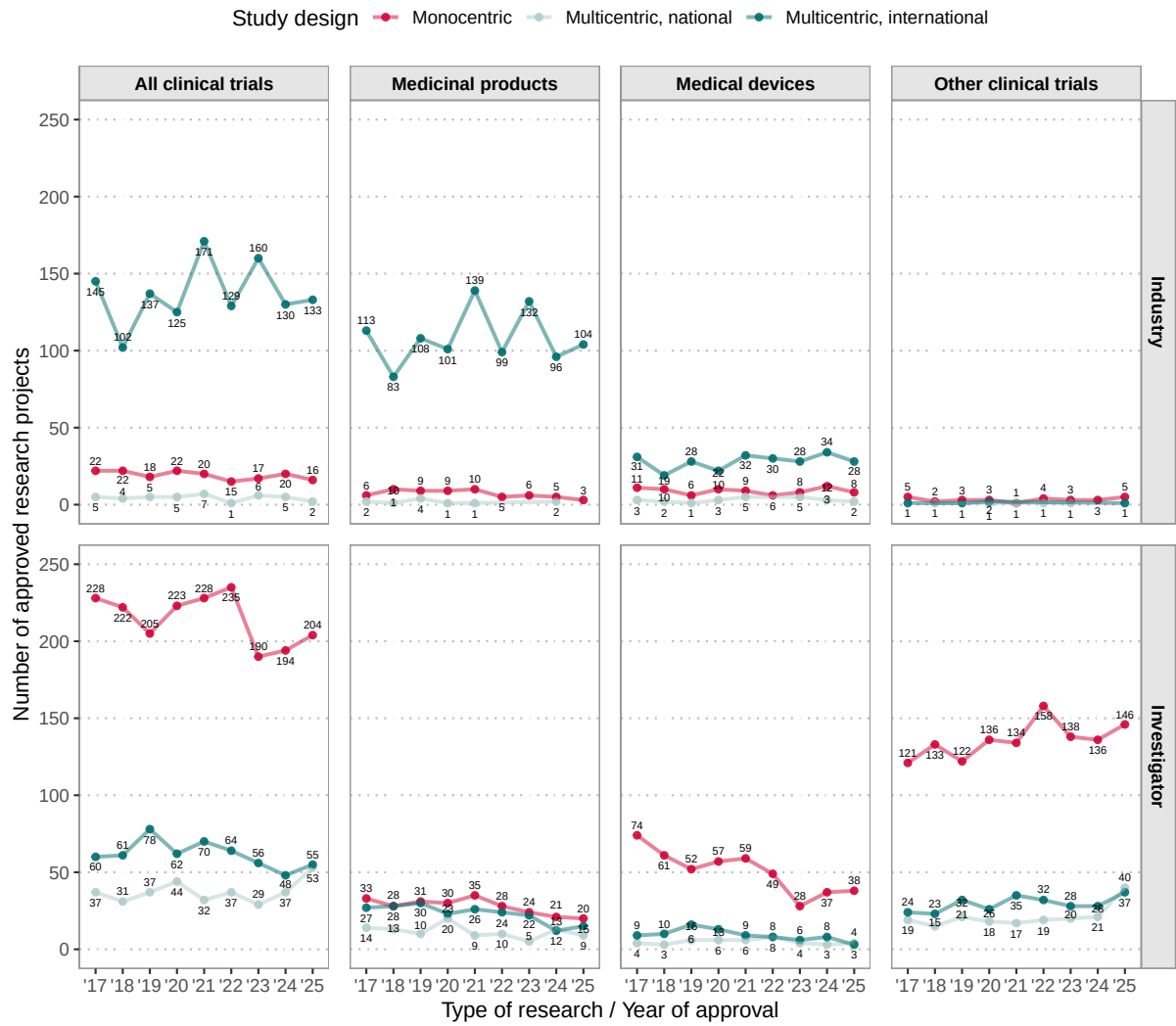


Figure 16: Approved clinical trials per year stratified by initiator and by study design.

7.2 Project initiator

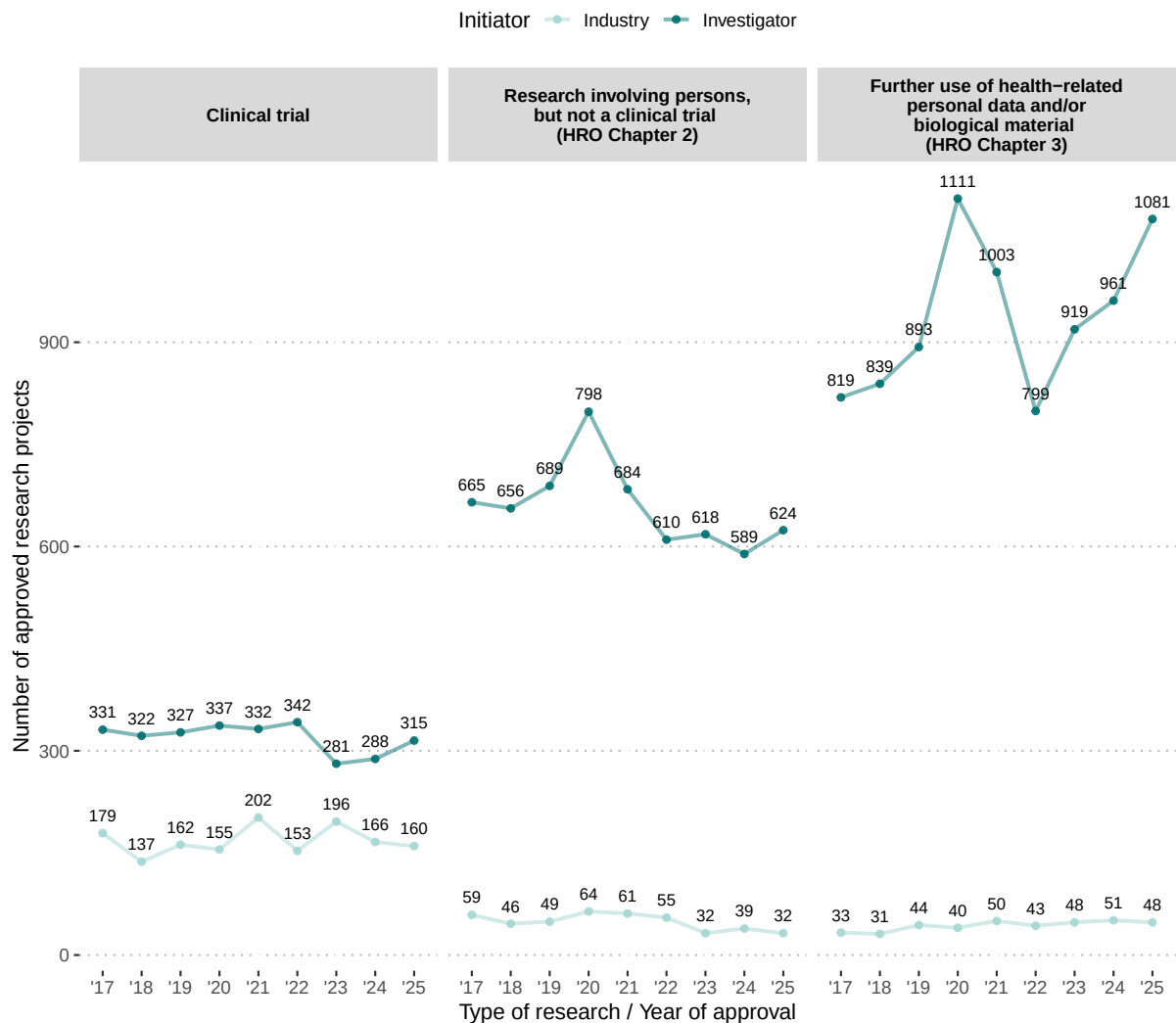


Figure 17: Approved projects per year stratified by type of research project and by project initiator.

Data not shown in the above figure: Research involving deceased persons (2019: 14, 2020: 36, 2021: 19, 2022: 27, 2023: 28, 2024: 24, 2025: 53) and Research involving embryos and fetuses from induced abortions or stillbirths (2019: 0, 2020: 0, 2021: 1, 2022: 0, 2023: 1, 2024: 2 2025: 0)

7.3 Risk category

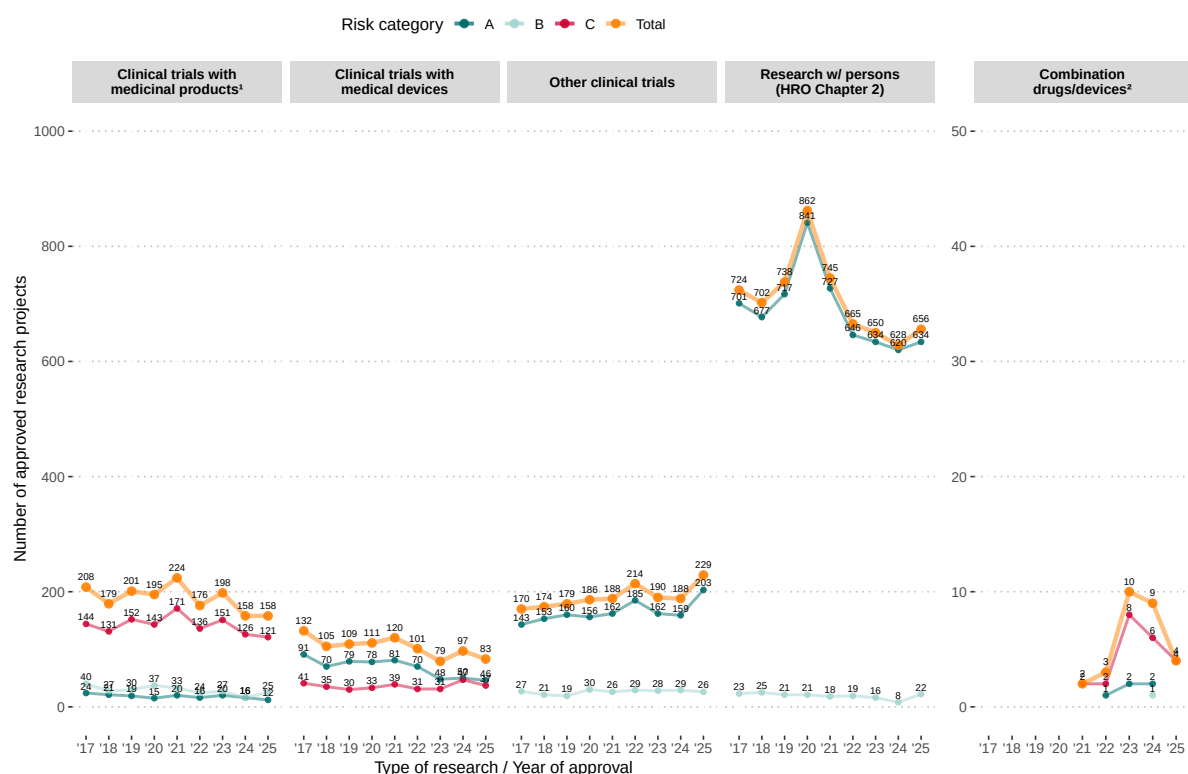


Figure 18: Clinical trials and research projects involving persons approved per year stratified by type of research project and risk category. ¹Clinical trials involving transplant products, gene therapy and pathogenic organisms were added to clinical trials with medicinal products. ²Clinical trials with combination drugs/devices before 2021 were added to clinical trials with medical devices.

Data not shown in the above figure: Research involving transplantation (2019: 0, 2020: 0, 2021: 0, 2022: 1, 2023: 0, 2024: 2, 2025: 1) .

7.4 Subgroups of clinical trials

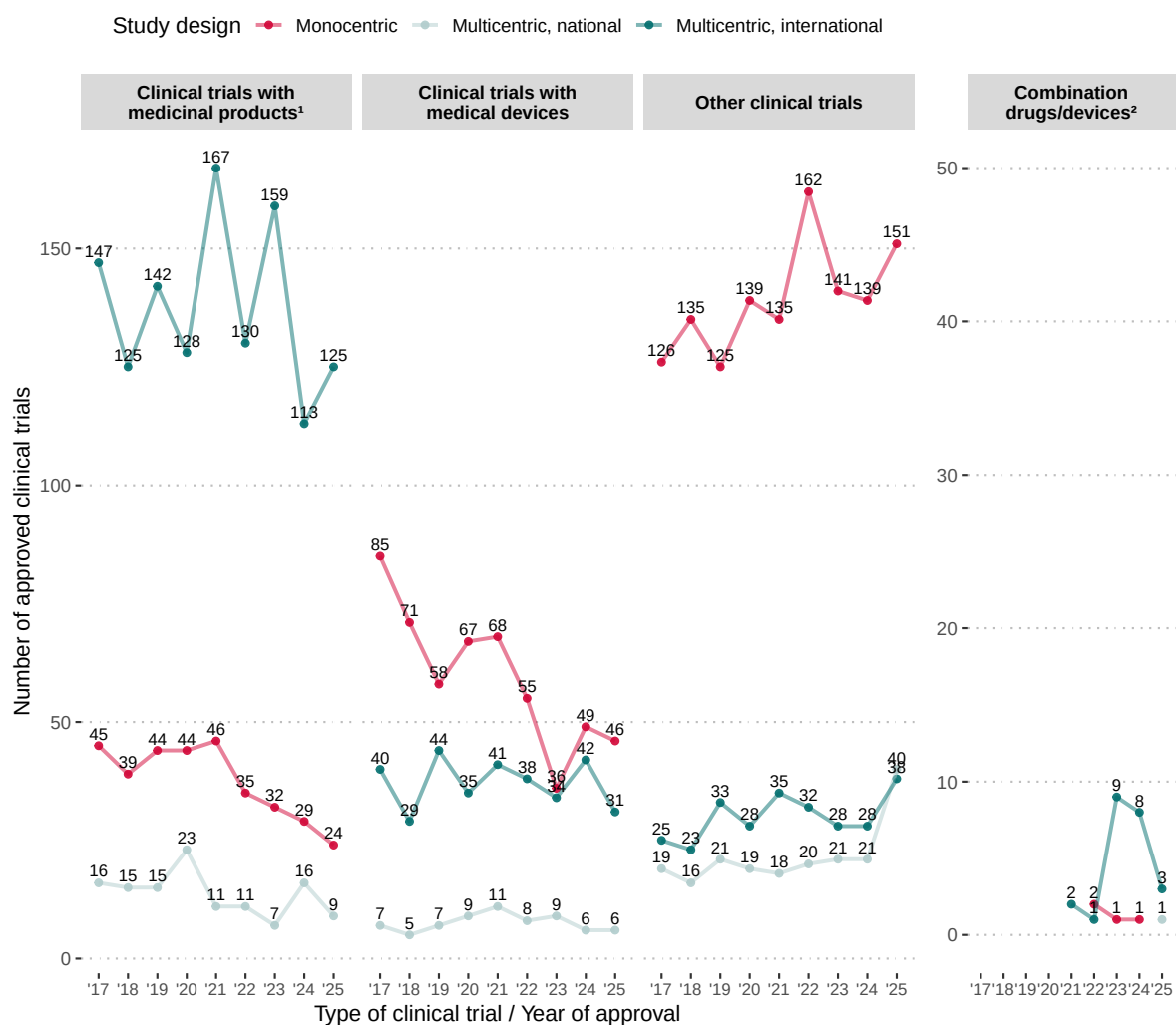


Figure 19: Clinical trials approved per year stratified by trial type and trial design. ¹Clinical trials involving transplant products, gene therapy and pathogenic organisms were added to clinical trials with medicinal products. ²Clinical trials with combination drugs/devices before 2021 were added to clinical trials with medical devices.

Data not shown in the above figure: Research involving transplantation (2019: 0, 2020: 0, 2021: 0, 2022: 1, 2023: 0, 2024: 2, 2025: 1) .

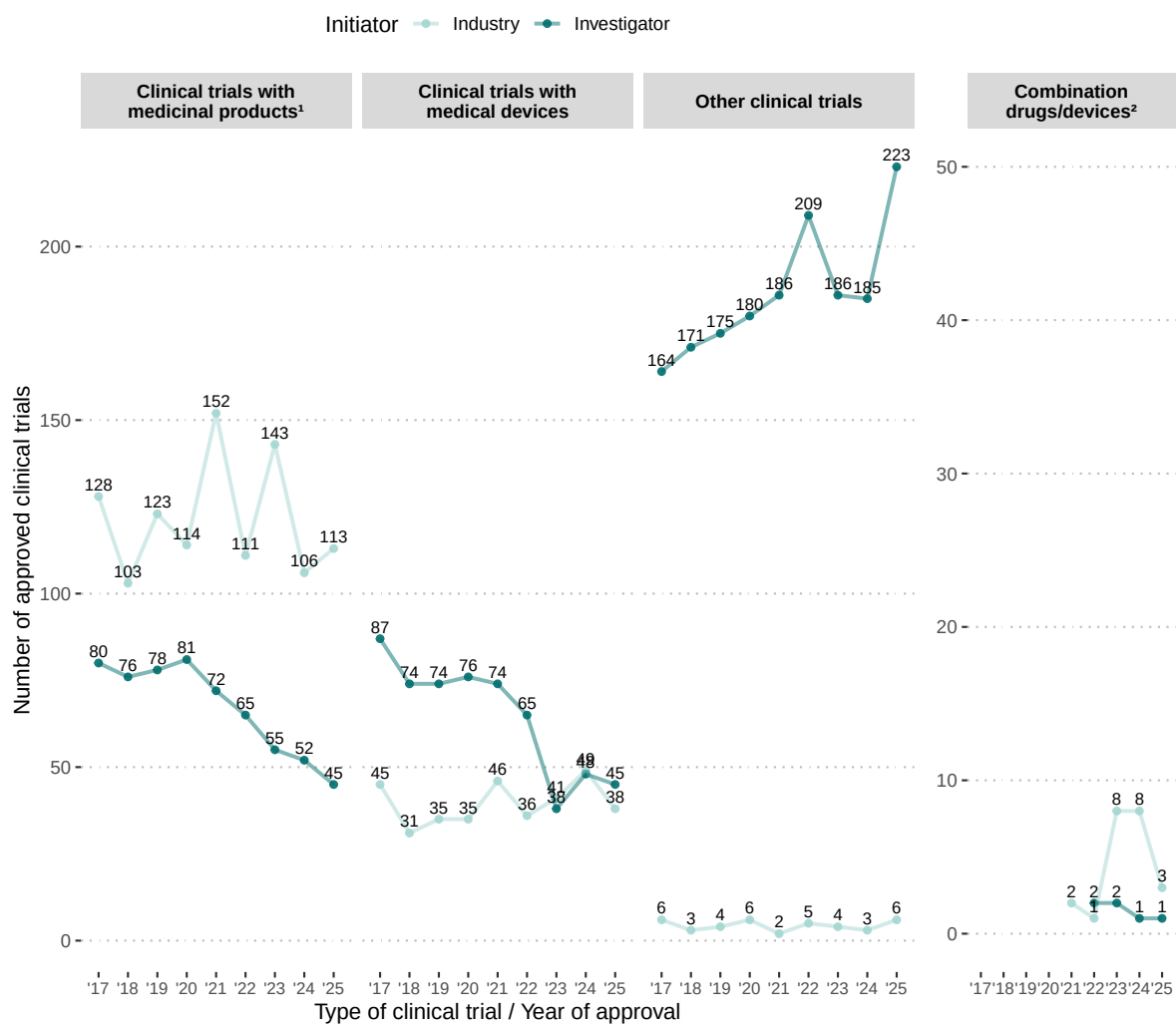


Figure 20: Clinical trials approved per year stratified by trial type and initiator. ¹Clinical trials involving transplant products, gene therapy and pathogenic organisms were added to clinical trials with medicinal products. ²Clinical trials with combination drugs/devices before 2021 were added to clinical trials with medical devices.

Data not shown in the above figure: Research involving transplantation (2019: 0, 2020: 0, 2021: 0, 2022: 1, 2023: 0, 2024: 2, 2025: 1) .

7.4.1 Clinical trials with medicinal products

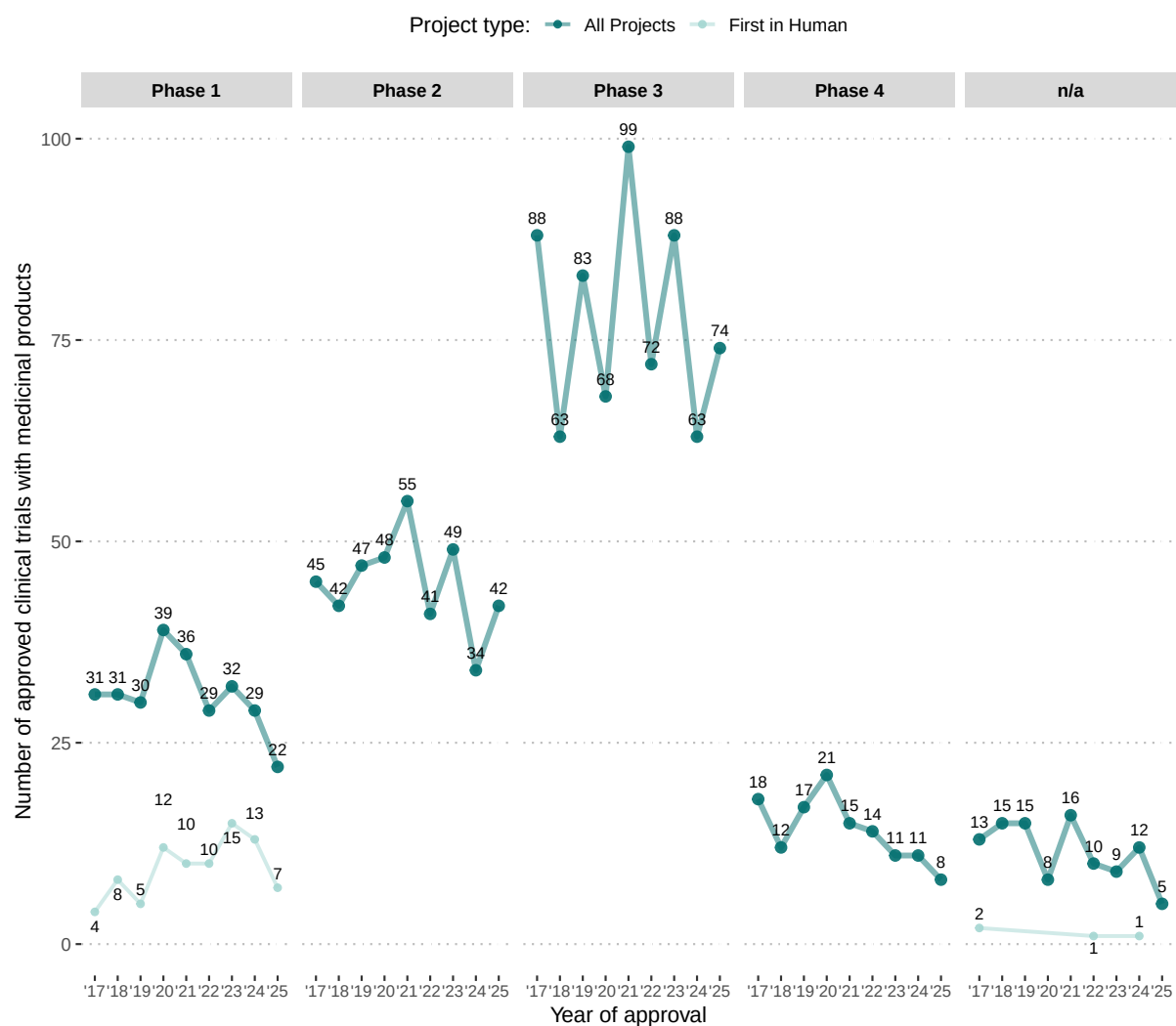


Figure 21: Clinical trials with medicinal products approved per year stratified by study phase.

7.4.2 Clinical trials with medical devices

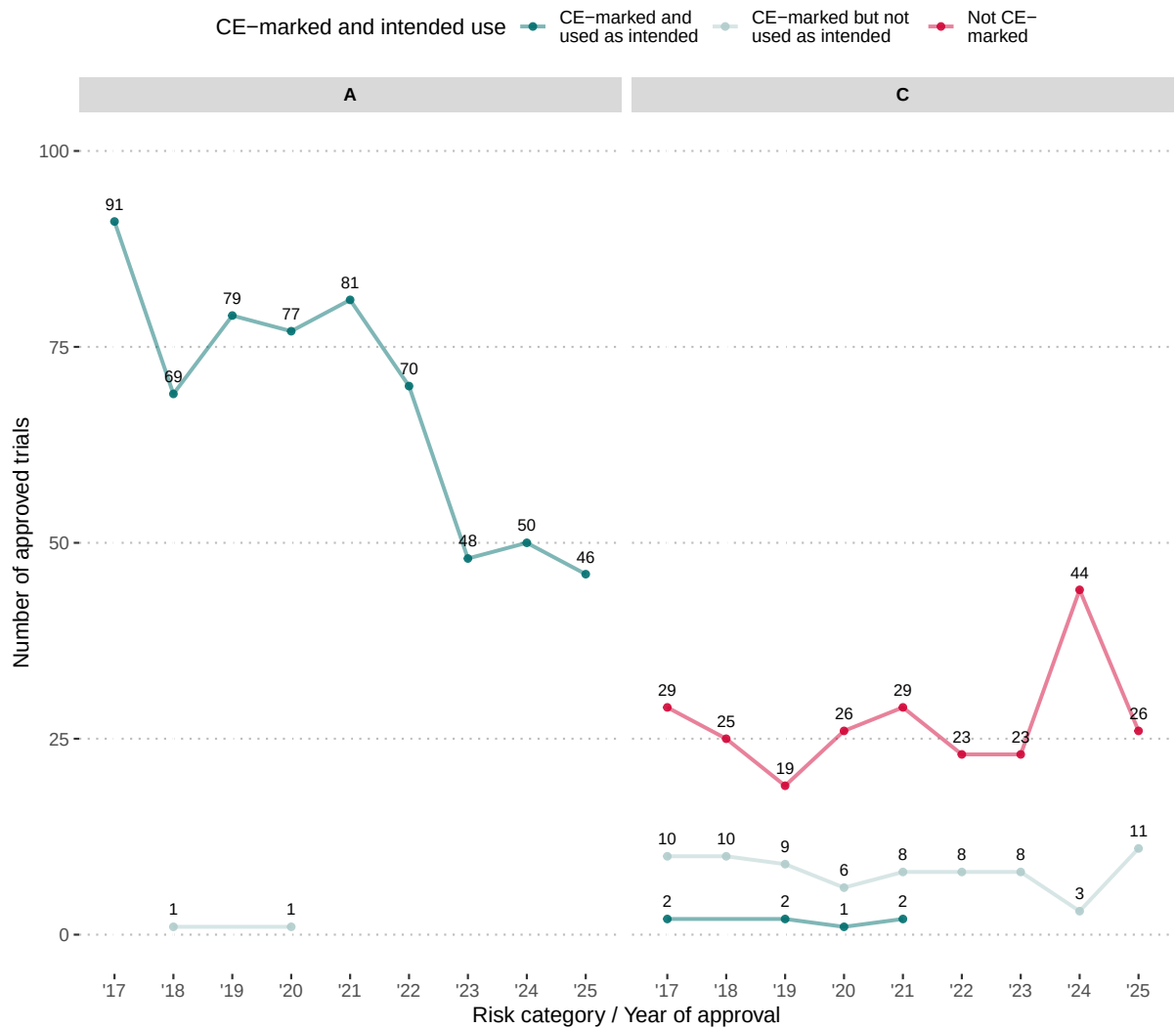


Figure 22: Clinical trials with medical devices approved per year stratified by risk category and by CE certification / intended use.

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': 2019: 5, 2020: 12, 2021: 19, 2022: 10, 2023: 9, 2024: 16, 2025: 11

7.5 Subgroup Further use of data/biological material

Table 28: Overview of characteristics of all approved 'further use' projects.

		Approval year																	
		2017		2018		2019		2020		2021		2022		2023		2024		2025	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Genetic data / biol. material	Yes	176	19.3	215	19.8	251	21.4	276	19.5	267	20.6	231	21.5	255	21.9	250	20.5	322	23.1
	No	735	80.7	872	80.2	923	78.6	1143	80.5	1032	79.4	843	78.5	911	78.1	972	79.5	1073	76.9
Coding (HRO Art. 25-27)	Coded	426	46.8	906	83.3	1017	86.6	1232	86.8	1180	90.8	977	91.0	1074	92.1	1160	94.9	1331	95.4
	Open, non-coded	485	53.2	181	16.7	157	13.4	187	13.2	119	9.2	97	9.0	92	7.9	62	5.1	64	4.6
Consent (HRO Art. 28-32)	Consent for all data	353	38.7	546	50.2	585	49.8	729	51.4	692	53.3	644	60.0	678	58.1	767	62.8	944	67.7
	Consent for some but not all data (partially Art. 34 HRA) ¹	-	--	-	--	-	--	307	21.6	379	29.2	331	30.8	374	32.1	363	29.7	372	26.7
	No consent for all data, Art. 34 HRA ²	558	61.3	541	49.8	589	50.2	383	27.0	228	17.6	99	9.2	114	9.8	92	7.5	79	5.7
Combined vs. stand-alone projects ³	Stand-alone further use project	852	93.5	870	80.0	937	79.8	1151	81.1	1053	81.1	842	78.4	967	82.9	1012	82.8	1129	80.9
	Further use project as part of a clinical trial	20	2.2	43	4.0	45	3.8	44	3.1	59	4.5	55	5.1	43	3.7	58	4.7	73	5.2
	Further use project as part of a non-clinical research project	39	4.3	174	16.0	192	16.4	224	15.8	187	14.4	177	16.5	156	13.4	152	12.4	193	13.8
	Total number	911	100.0	1087	100.0	1174	100.0	1419	100.0	1299	100.0	1074	100.0	1166	100.0	1222	100.0	1395	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).

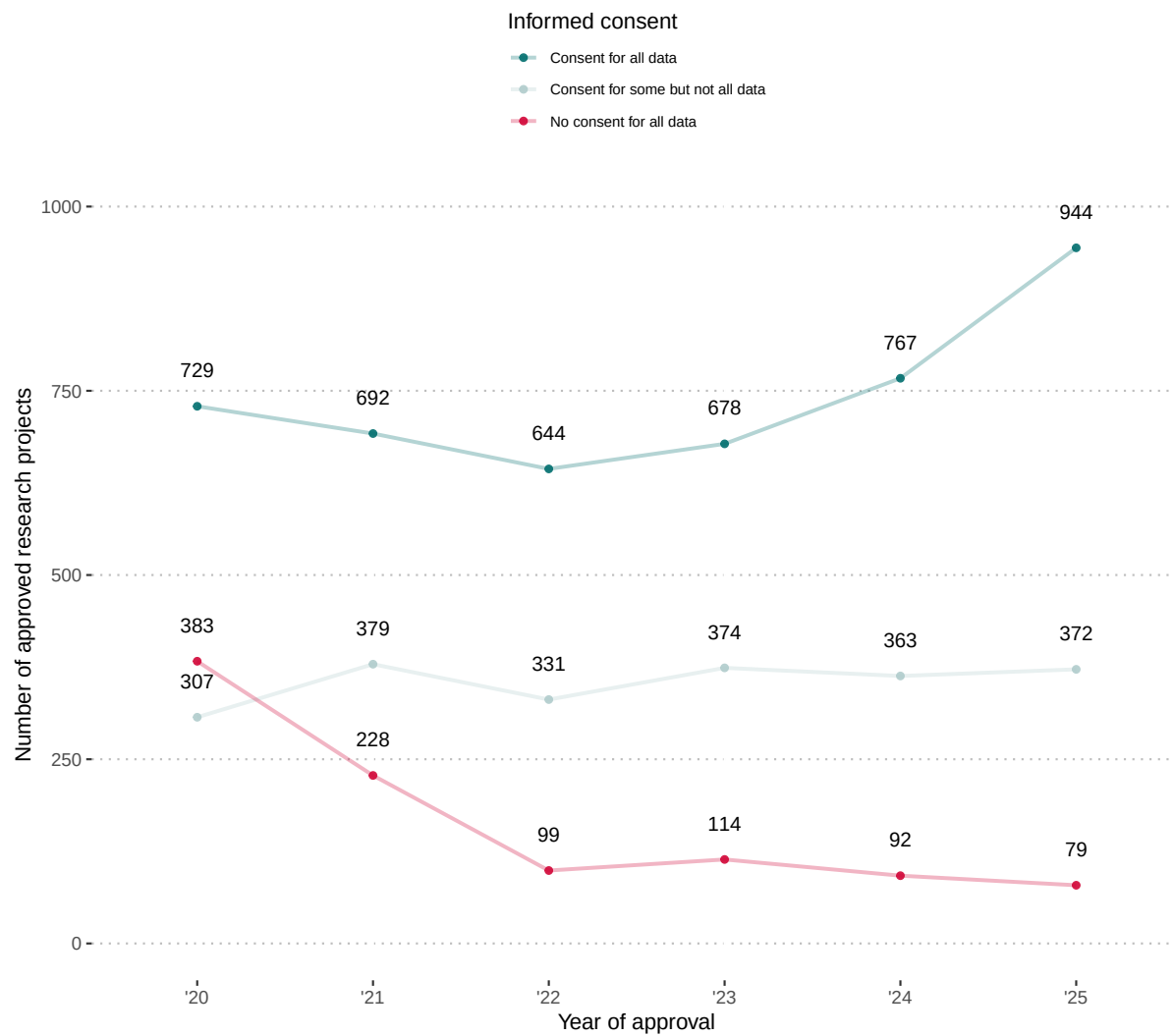


Figure 23: Number of approved 'further use' projects per year and fraction without informed consent.

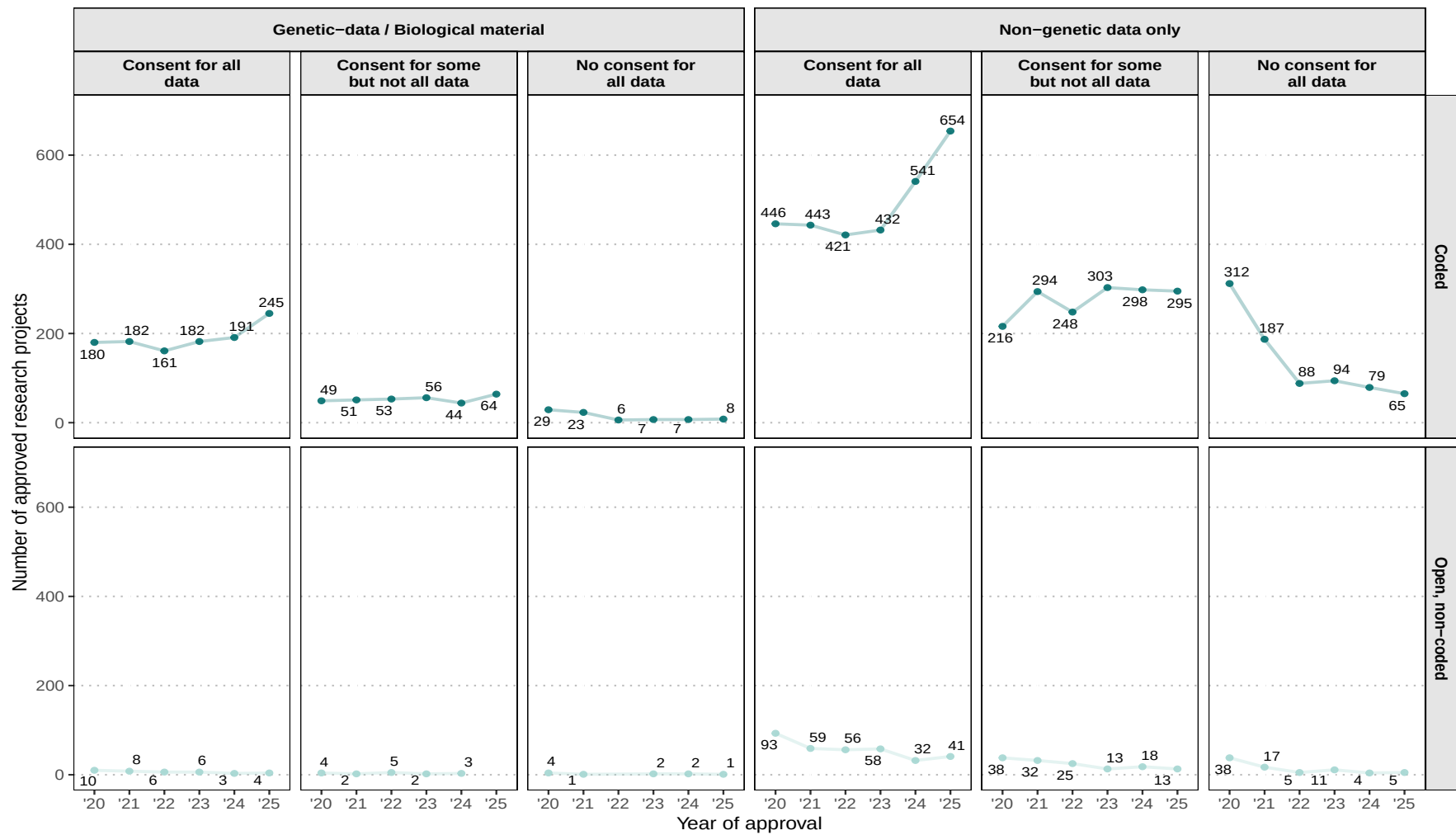


Figure 24: Number of approved 'further use' projects per year stratified by 1) Use of genetic data and/or biological material, 2) coded vs. uncoded, 3) consent for further use.

7.6 Response time

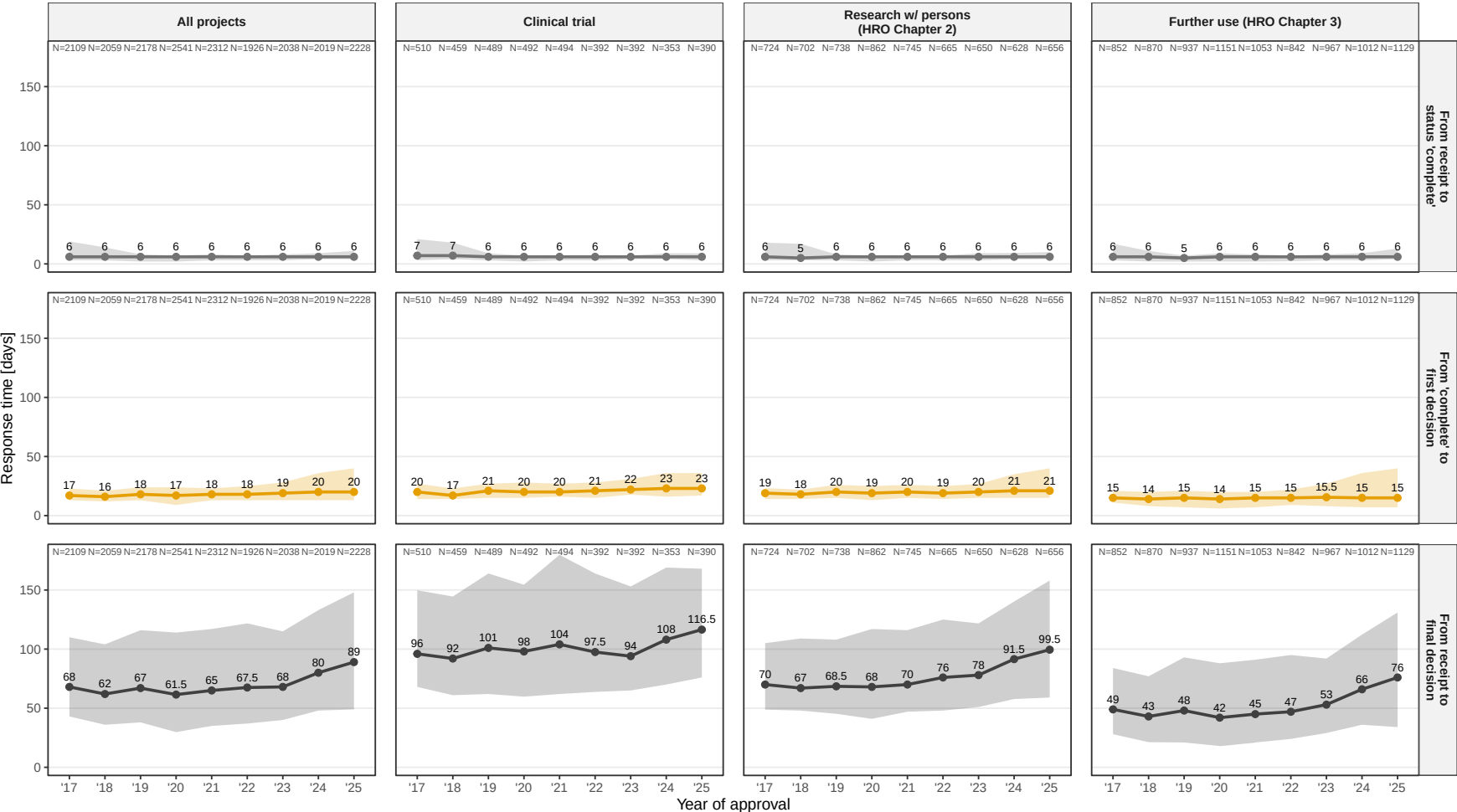


Figure 25: Response times by approval year for the three major types of research projects and overall. The line represents the median, and the shaded ribbon indicates the interquartile range (Q1–Q3). N denotes the number of projects per year. Medical device (ClinO-MD) projects are not included.

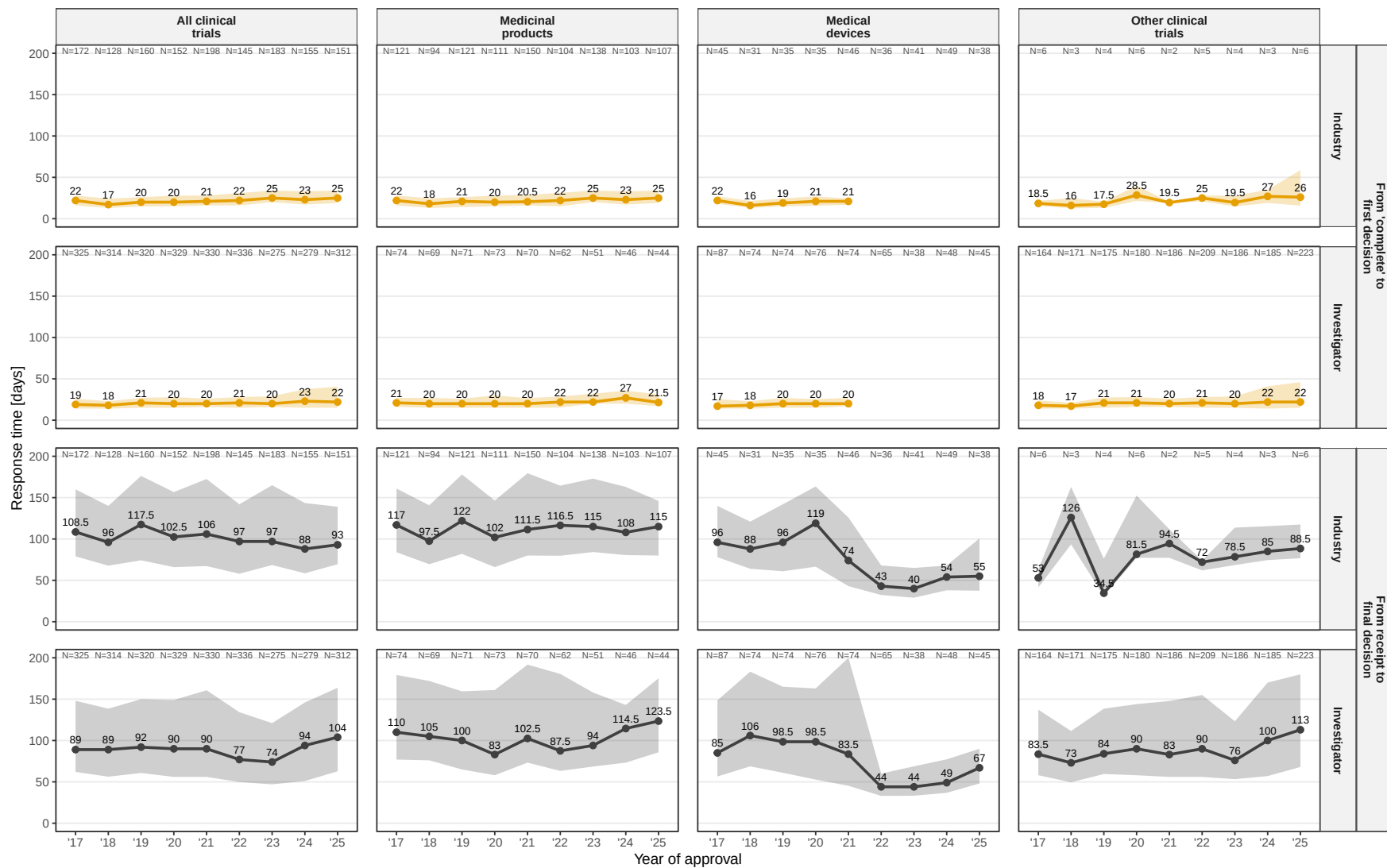


Figure 26: Response times by approval year for clinical trials, shown separately by type of clinical trial, time interval, and initiator. The solid line represents the median; the shaded ribbon indicates the interquartile range (Q1–Q3). N denotes the number of projects per year. Note: From 'complete' to first decision timeline not applicable for medical devices (ClinO-MD), no first decision issued from 2022 onwards (see Figure 3). Further clinical trials including gene therapy, pathogenic organisms, transplant products, transplantation, and combination drug–device studies are not included.

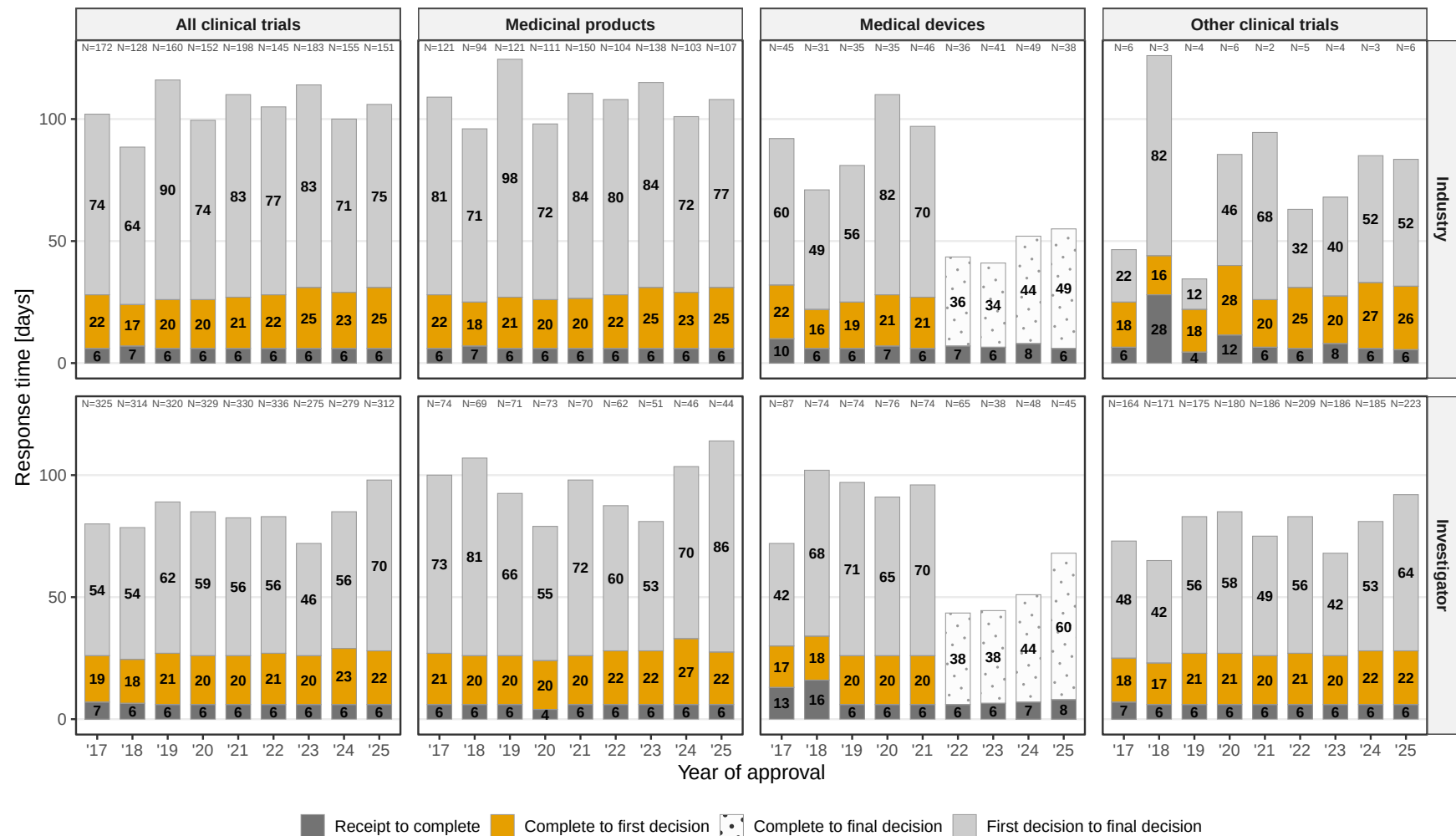


Figure 27: Median response times per phase. The stacked height represents the sum of the three phase medians and is not equal to the median of the total response time. N denotes the number of projects per year. Note: From 'complete' to first decision timeline not applicable for medical devices (ClinO-MD), no first decision issued from 2022 onwards. Response times not shown from 2022 onwards due to lack of comparability (see Figure 3). Further clinical trials including gene therapy, pathogenic organisms, transplant products, transplantation, and combination drug-device studies are not included.

8 Annex

8.1 Vulnerable persons

Table 29: Stratification of all approved projects by whether the research project involves any vulnerable persons and if yes, what groups.

Type of research	Research details	Risk cat.	N	Vulnerabilities (multiple possible)											
				Any vulnerable		Children		Adolescents		Unable to cons.		Emergencies		Others	
				n	%	n	%	n	%	n	%	n	%	n	%
Clinical trial	Medicinal products	A	12	4	33.3	1	8.3	1	8.3	0	0.0	0	0.0	1	8.3
		B	25	5	20.0	3	12.0	3	12.0	0	0.0	1	4.0	1	4.0
		C	114	18	15.8	13	11.4	13	11.4	2	1.8	1	0.9	0	0.0
		All	151	27	17.9	17	11.3	17	11.3	2	1.3	2	1.3	2	1.3
	Medical devices	A	46	12	26.1	1	2.2	1	2.2	0	0.0	4	8.7	2	4.3
		C	37	6	16.2	2	5.4	1	2.7	0	0.0	2	5.4	2	5.4
		All	83	18	21.7	3	3.6	2	2.4	0	0.0	6	7.2	4	4.8
	Other clinical trials	A	203	64	31.5	21	10.3	20	9.9	7	3.4	5	2.5	8	3.9
		B	26	9	34.6	0	0.0	1	3.8	2	7.7	4	15.4	0	0.0
		All	229	73	31.9	21	9.2	21	9.2	9	3.9	9	3.9	8	3.5
	Combination drugs/devices	C	4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		All	4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Transplant products	C	2	1	50.0	1	50.0	1	50.0	1	50.0	1	50.0	0	0.0
		All	2	1	50.0	1	50.0	1	50.0	1	50.0	1	50.0	0	0.0
	Gene therapy	C	4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		All	4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Pathogenic organisms	C	1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		All	1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Transplantation	All	1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	All	All	475	119	25.1	42	8.8	41	8.6	12	2.5	18	3.8	14	2.9
Research w/ persons (HRO Chapter 2)	A	634	253	39.9	90	14.2	86	13.6	22	3.5	10	1.6	29	4.6	
	B	22	8	36.4	1	4.5	1	4.5	1	4.5	1	4.5	0	0.0	
	All	656	261	39.8	91	13.9	87	13.3	23	3.5	11	1.7	29	4.4	
Further use of data/biological material (HRO Chapter 3)	n.a.	1129	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	
Deceased and embryos from stillbirths or abortion (HRO Chapter 4 + 5)	n.a.	53	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	
Total number		2313	380	16.4	133	5.8	128	5.5	35	1.5	29	1.3	43	1.9	

Special populations (vulnerable persons include: 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 (not shown). Since multiple answers are possible, the row-wise percentages may sum up to a total over 100

Table 30: Stratification of all approved projects by type of research and initiator, showing whether the research project involves any vulnerable persons - and if yes, what groups.

Type of research	Initiator	N	Vulnerabilities (multiple possible)											
			Any vulnerable		Children		Adolescents		Unable to cons.		Emergencies		Others	
			n	%	n	%	n	%	n	%	n	%	n	%
Clinical trial	Industry	160	25	15.6	14	8.8	13	8.1	2	1.2	4	2.5	2	1.2
	Investigator	315	94	29.8	28	8.9	28	8.9	10	3.2	14	4.4	12	3.8
	All	475	119	25.1	42	8.8	41	8.6	12	2.5	18	3.8	14	2.9
Research w/ persons (HRO Chapter 2)	Industry	32	6	18.8	4	12.5	3	9.4	0	0.0	0	0.0	2	6.2
	Investigator	624	255	40.9	87	13.9	84	13.5	23	3.7	11	1.8	27	4.3
	All	656	261	39.8	91	13.9	87	13.3	23	3.5	11	1.7	29	4.4
Further use of data/biological material (HRO Chapter 3)	Industry	48	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Investigator	1081	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	All	1129	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Deceased and embryos from stillbirths or abortion (HRO Chapter 4 + 5)	Industry	5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Investigator	48	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	All	53	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Total number	Industry	245	31	12.7	18	7.3	16	6.5	2	0.8	4	1.6	4	1.6
	Investigator	2068	349	16.9	115	5.6	112	5.4	33	1.6	25	1.2	39	1.9
	All	2313	380	16.4	133	5.8	128	5.5	35	1.5	29	1.3	43	1.9

Special populations (vulnerable persons include: 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 (not shown). Since multiple answers are possible, the row-wise percentages may sum up to a total over 100

8.2 Response time: First decision is final decision

Table 31: Response times by type of research and whether the first decision was the final decision. Medical devices (ClinO-MD) excluded.

Type of research	1st decision is final decision	n	%	Median [IQR]		
				From receipt to complete	From complete to first decision	From receipt to final decision
Clinical trials with medicinal products	Yes	2	1.3	5 [4, 6]	25 [24, 26]	30 [28, 32]
	No	149	98.7	6 [3, 7]	25 [18, 34]	117 [82, 151]
Other clinical trials	Yes	1	0.4	5 [5, 5]	1 [1, 1]	6 [6, 6]
	No	228	99.6	6 [3, 10]	22 [15, 46]	112 [70, 174]
Research w/ persons (HRO Chapter 2)	Yes	16	2.4	5 [2, 6]	12 [7, 16]	18 [8, 34]
	No	640	97.6	6 [4, 10]	22 [15, 42]	103 [61, 159]
Further use of data/biological material (HRO Chapter 3)	Yes	207	18.3	6 [2, 13]	10 [4, 16]	19 [7, 39]
	No	922	81.7	6 [4, 13]	19 [8, 48]	89 [49, 146]

8.3 Therapeutic Area - old categorization

Table 32: Overview on therapeutic area ('disease under investigation') for clinical trials according to the categories published on HumRes - (multiple answers possible) - stratification by trial type. The number of projects investigating a rare disease is provided. Data for the 12 clinical trials not falling in the 3 main clinical trial types (medicinal product, medical devices, other) are not included in the stratification.

Therapeutic area	Type of clinical trial											
	All clinical trials			Medicinal products			Medical devices			Other clinical trials		
	N	%col	n _{rare}	N	%	n _{rare}	N	%	n _{rare}	N	%	n _{rare}
Other	121	25.5	4	17	11.3	4	24	28.9	0	77	33.6	0
Nervous System diseases	41	8.6	10	13	8.6	8	7	8.4	0	21	9.2	2
Cancer: Other	38	8.0	7	18	11.9	3	2	2.4	1	14	6.1	2
Cancer: Lung	35	7.4	2	20	13.2	2	7	8.4	0	7	3.1	0
Mental and Behavioural diseases	32	6.7	0	6	4.0	0	1	1.2	0	25	10.9	0
Surgery	31	6.5	1	1	0.7	0	14	16.9	0	16	7.0	1
Brain diseases (non cancer)	28	5.9	0	4	2.6	0	7	8.4	0	17	7.4	0
Respiratory diseases (non cancer)	26	5.5	1	3	2.0	0	2	2.4	0	21	9.2	1
Musculoskeletal diseases (non cancer)	22	4.6	2	2	1.3	2	4	4.8	0	15	6.6	0
Basic research (Anatomy/Physiology)	21	4.4	0	2	1.3	0	1	1.2	0	18	7.9	0
Cancer: Breast	20	4.2	0	7	4.6	0	5	6.0	0	7	3.1	0
Coronary Heart disease	19	4.0	0	5	3.3	0	7	8.4	0	7	3.1	0
Arterial and venous diseases including deep venous thrombosis and lung embolism	18	3.8	0	5	3.3	0	5	6.0	0	8	3.5	0
Cancer: Prostate	17	3.6	0	9	6.0	0	1	1.2	0	6	2.6	0
Digestive Systems diseases (non cancer)	17	3.6	4	12	7.9	3	0	0.0	0	4	1.7	1
Endocrinological diseases (non cancer)	16	3.4	3	5	3.3	2	3	3.6	0	8	3.5	1
Cancer: Head and Neck	15	3.2	2	5	3.3	1	2	2.4	0	7	3.1	1
Nutritional and Metabolic diseases	15	3.2	2	5	3.3	1	2	2.4	0	7	3.1	1
Skin and Connective Tissues diseases (non cancer)	15	3.2	3	9	6.0	2	1	1.2	0	2	0.9	0
Cancer: Colon and Rectal	13	2.7	0	5	3.3	0	0	0.0	0	7	3.1	0
Injury	13	2.7	0	0	0.0	0	4	4.8	0	9	3.9	0
Cancer: Lymphoma	10	2.1	2	4	2.6	0	2	2.4	0	4	1.7	2
Cancer: Leukemia	9	1.9	4	5	3.3	2	1	1.2	1	3	1.3	1
Infections and Infestations	9	1.9	1	6	4.0	1	1	1.2	0	2	0.9	0
Cancer: Melanoma	8	1.7	0	2	1.3	0	1	1.2	0	4	1.7	0
Cancer: Pancreatic	8	1.7	0	3	2.0	0	1	1.2	0	3	1.3	0
Cancer: Bladder	7	1.5	1	3	2.0	0	0	0.0	0	3	1.3	1
Cancer: Endometrial	7	1.5	0	2	1.3	0	1	1.2	0	3	1.3	0
Cancer: Non-Hodgkin Lymphoma	7	1.5	2	3	2.0	0	0	0.0	0	4	1.7	2
Cancer: Thyroid	7	1.5	1	1	0.7	0	2	2.4	0	3	1.3	1
Urological and Genital diseases (non cancer)	7	1.5	0	2	1.3	0	3	3.6	0	2	0.9	0
Cancer: Kidney	6	1.3	1	1	0.7	0	0	0.0	0	4	1.7	1
Eye diseases	6	1.3	1	3	2.0	1	2	2.4	0	0	0.0	0
Genetic disorders	6	1.3	4	4	2.6	3	0	0.0	0	2	0.9	1
Periodontal diseases	5	1.1	0	1	0.7	0	1	1.2	0	3	1.3	0
Pregnancy and Childbirth	5	1.1	0	1	0.7	0	3	3.6	0	1	0.4	0
Ear, Nose, and Throat diseases (non cancer)	4	0.8	0	0	0.0	0	0	0.0	0	4	1.7	0
Hematologic diseases (non cancer)	3	0.6	2	2	1.3	2	0	0.0	0	1	0.4	0
Dementia and Alzheimer disease	2	0.4	0	0	0.0	0	1	1.2	0	1	0.4	0
Neonatal diseases	1	0.2	0	0	0.0	0	0	0.0	0	1	0.4	0
Occupational diseases	1	0.2	0	0	0.0	0	0	0.0	0	1	0.4	0
Total projects	475	145.5	44	151	100.0	32	83	100.0	2	229	100.0	8

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.