

BASEC Annual Report 2017

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

January 1, 2017 – December 31, 2017



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swissethics

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

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List of abbreviations

BASEC	Business Administration System for Ethics Committees
AS1	Analysis set 1: all projects submitted in the year 2017
AS2	Analysis set 2: all projects approved in the year 2017
HRA	Federal Act on Research involving Human Beings (Human Research Act)
HRO	Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance)
ClinO	Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance)
IQR	Inter-quartile range
FOPH	Federal Office of Public Health
EC	Ethics committee
CCER	Commission cantonale d'éthique de la recherche (Genève)
CE-TI	Comitato etico cantonale Ticino
CER-VD	Commission cantonale d'éthique de la recherche sur l'être humain Vaud
EKNZ	Ethikkommission Nordwest- und Zentralschweiz
EKOS	Ethikkommission Ostschweiz
KEK-BE	Kantonale Ethikkommission Bern
KEK-ZH	Kantonale Ethikkommission Zürich

1 Introduction

The aim of this report is to describe research covered by the Swiss Federal Act on Research involving Human Beings (HRA). For this, data collected using the Business Administration System for Ethics Committees (BASEC) web portal maintained by the Swiss Ethics Committees on research involving humans (swissethics) were analysed. The initially provided report shall be updated on a yearly basis for the time period 2018–2020 and be extended by analyses exploring potential time trends.

The purpose of the BASEC web portal is to optimise the application process by providing a unique entry point for applications in the scope of the HRA irrespective of the involved ethics committees (ECs). Since the beginning of 2016, all applications are submitted via BASEC. The standardised and structured information on all submitted research projects provides a unique opportunity for a comprehensive overview on the Swiss human research landscape.

1.1 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 true calendar year 2017 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 2017. 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 2017 based on the analysis set *AS2*.

Fourth, a more detailed view on the application 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 preliminary longitudinal analysis is provided in chapter 6 by comparing the number of submissions per type of research in 2016 and 2017.

Some distinctive features in the implementation of the BASEC web form complicated the analysis of the data. These issues are briefly described in a separate document (“Addendum to the BASEC Report”) together with a comment on the general design of BASEC and the interplay of its data with data on response times reported by the individual ECs.

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 2, 2018 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.

It may be discussed whether the individual responsibilities of applicants and ECs are clear and well defined enough and whether, for example, a catalogue of standard consistency checks may need to be defined. Many rule-based checks are already implemented within the dynamic BASEC interface. The detailed stratification of the data presented in this report may uncover logically impossible combinations of project characteristics which arise, e.g. due to imprecise formulations. These may lead to the implementation of additional rules and thereby improve data quality. Some issues observed during the analysis are described in the addendum of this report.

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. 16 and 17 HRO) are captured. The milestones are:

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

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

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

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

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

These dates are used to calculate response times which are presented in chapter 5 on pages 57ff. 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 14 with short descriptions as table footnotes.

Only the reception date is recorded automatically by the system. All other dates are entered in BASEC manually by the ECs. The completeness and consistency of these data are checked periodically by swissethics (irrespective of this report) and ECs are reminded when mandatory fields are found empty or when discrepancies are identified.

1.2.3 Post-processing of the BASEC data export

BASEC stores data submitted over the web form in key/value stores. A new version of the data for an application is generated whenever the submission button is clicked. The complete key/value data of all versions are available in coded form as a JSON dump via an API and data of the current project versions are available in tabular form. Both data sets have been made available by swissethics.

Generally, BASEC seems to perform data integrity checks essentially at the front-end level (the submission form) and not at the back-end, e.g. by defining and applying a data model. The detailed and machine-readable code books describing all the questions (data type, label, dependency rules hiding fields) and answers (for single and multiple choice fields) are provided by swissethics and are available as separate documents (`Fields.xlsx`, `answers.xlsx`).

swissethics performs some initial post-processing of the BASEC data export e.g. by parsing the JSON-data, checking the character encoding of the data, removing white spaces from numeric fields or by identifying potential damaged project versions.

Before starting the analysis, the data were subjected to additional integrity checks and post-processing. The following basic steps were performed specifically to prepare the data provided by swissethics for the analyses in this report:

- Load and parse the code books.
- Load the parsed JSON data provided by swissethics and extract the most recent version of each project.
- Decode the data by translating codes to the respective question and answer names using the code books.
- Reshape the decoded JSON data into tabular form.
- Check whether variable names agree with specifications in the “questions code book” and rename variable names if the names are ambiguous.
- Check whether the data type of each column is in accordance to the “answers code book” (inconsistencies are already communicated to swissethics and will be integrated in an updated version of the codebook), check if the levels of single and multiple choice answers agree with the specifications in the code book, and split multiple choice answers to multiple fields as needed.
- Apply the code book while loading the data.
- In a last step, a set of core variables used extensively in the report is processed for the purpose of standardising the answers (e.g. capitalising) and optimise them for presentation in tables (order levels, shorten long answers). In addition, some derived variables are built by combining several variables or grouping answers. These variables and other variables used for stratification are defined briefly at the beginning of the respective sections where they are used (see sections [4.3.1](#) and [4.4.1](#)).

All data processing and analyses were done using the statistical software R version 3.5.1.

1.3 Analysis sets

1.3.1 Definition of analysis sets

Definition:

AS1 The analysis set AS1 consists of all projects **submitted in 2017**. 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 in 2017** 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 in a given year** for which the data tend to be complete and reviewed to a certain extent 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

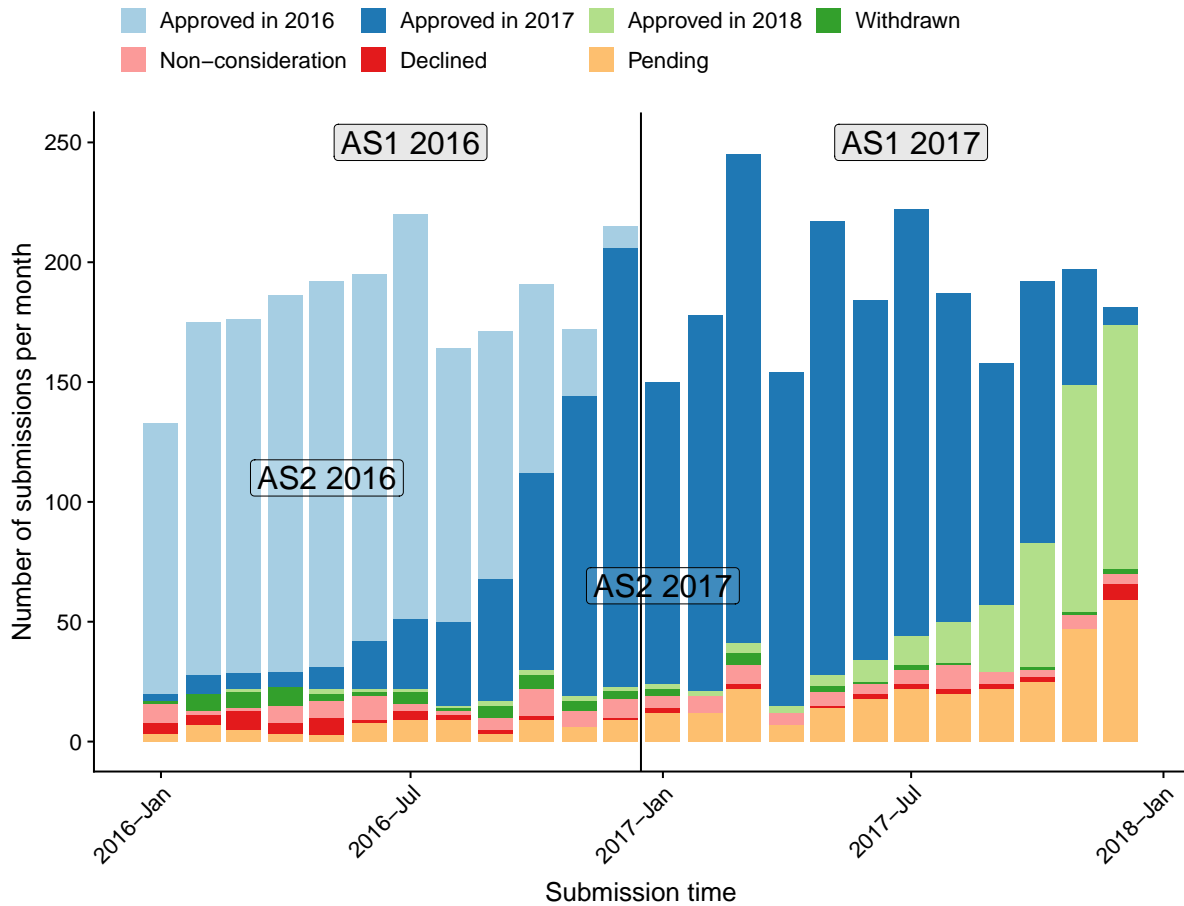


Figure 1: Overview of submissions via BASEC in the years 2016-2017 coloured by the current status as of the time of the data export (April 2, 2018).

Figure 1 shows all submissions via BASEC in the years 2016 and 2017. Each bar represents the number of submissions in a given month. The bars are coloured according to the current status of the respective submissions as of the time of the data export.

The proportion of projects not approved (declined, withdrawn, non-consideration) is quite stable over time. These projects are not part of AS2 and will not be analysed scientifically. The proportion of pending projects is low for 2016: 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 2017, since the data export point is identical for both years (April 2, 2018).

For approved projects, the year of the final decision is provided. When focusing on projects approved in a given year (AS2), the 2016 data set only includes projects submitted in 2016 (after the introduction of BASEC; in light blue). In contrast to this, the 2017 data set also includes submissions from 2016 (dark blue portion on the left side). The fact that the 2016 AS2 data set is truncated on the left side makes a longitudinal analysis of the 2016 and 2017 AS2 data meaningless. However, in the future, when

comparing 2017 to 2018 and subsequent years, the AS2 data will not suffer from left-truncation anymore, and therefore will allow a meaningful longitudinal analysis.

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

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 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.

Stratification of such projects by project type is not straightforward. In the overarching analyses, we count combined research projects only once like single research projects. However, when looking at subgroups of projects (e.g. ‘further use’ projects) we count them separately in each category since in this case the specific characteristics of these projects are in focus. For instance, clinical trials or research with persons according to the HRO combined with ‘further use’ are considered a single research project and are attributed to the category ClinO or research with persons (HRO) in all overview tables (Tables 2, 5 and 8ff). 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 17, 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 2017

Table 1: Calendar-year-centric view on the BASEC data. Note that pending applications of projects submitted before 2016 are not stored in BASEC.

			n	%
Input		Submission in 2017 (AS1)	2275	77.7
	Projects pending from 2016	<i>Pending first decision in 2016</i>	249	8.5
		<i>Pending final decision in 2016 (first decision issued in 2016)</i>	405	13.8
		Total Pending from 2016	654	22.3
Grand Total Input 2017			2929	100.0
Output	Final decision in 2017	Approvals (AS2)	2109	72.0
		Rejections (declined projects)	21	0.7
		Non-considerations	74	2.5
		Total Decisions	2204	75.2
Withdrawn during 2017	Withdrawal before first decision	4	0.1	
	Withdrawal after first decision 'approvals with charges'	1	0.0	
	Withdrawal after first decision 'not-yet-approved projects with conditions'	9	0.3	
	Total Withdrawn	14	0.5	
Pending at end of 2017	<i>Pending first decision</i>	255	8.7	
	<i>Pending final decision (first decision issued)</i>	456	15.6	
	Total Pending	711	24.3	
Grand Total Output 2017			2929	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 2017 (AS1)

Table 2: Total number of research projects **submitted via BASEC in 2017** (analysis set [AS1](#)), including information on type of research and the legal basis.

Type of research	Legal basis	n	%col
Clinical trial	ClinO	541 ¹	23.8
Research involving persons, but not a clinical trial	HRO, Chapter 2	826 ²	36.3
Further use of health-related personal data and/or biological material	HRO, Chapter 3	879	38.6
Research involving deceased persons	HRO, Chapter 4	29	1.3
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	0	0.0
Total number		2275	100.0

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

² 65 of these projects also include an application for further use of data/biological material.

Description of distinctive features of the results:

Only about 12% of the submitted projects are already approved at the first review process (i.e. first decision). For the majority of applications a potential future approval is bound to conditions. Compared to conditions, a study with decision 'approved with charges' is considered approved, and the fulfilment of the charges is a presidential decision in addition (personal communication by swissethics). However, there is also a scope of discretion between conditions and charges. This may explain to some extent the differences found between individual ECs in Table 4 on the next page.

Table 3: Status information of all projects submitted in 2017. This information is manually curated by the individual ethics committees.

		n	%col
First decision	Approved ¹	265	11.6
	Approved with charges ²	622	27.3
	Not approved, conditions ³	1238	54.4
	Declined	23	1.0
	Non-consideration ⁴	71	3.1
	Pending first decision ⁵	56	2.5
Final decision	Approved ⁶	1885	82.9
	Declined	22	1.0
	Non-consideration	69	3.0
	Withdrawn	24	1.1
	Pending final decision ⁷	275	12.1
Review procedure	Ordinary ⁸	400	17.6
	Simplified ⁹	1537	67.6
	Presidential ¹⁰	282	12.4
	Pending first decision	56	2.5
Total number in AS1		2275	100.0

¹ Projects already approved in the first review process.

² Charges: The projects are approved but with charges.

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

⁴ Non-consideration: Research not covered by the HRA.

⁵ Information missing: The status information was missing at the time of the report generation.

⁶ Note that this includes projects approved both in the index year as well as in the subsequent year(s) until the time of the data export which explains the different numbers in Tables 3 and 9.

⁷ Pending at export date. 48.0% of the pending projects were submitted in the last quarter of the reporting year.

⁸ Decision taken at full commission meeting by at least seven members of the ethics committee, as per the provisions of Art. 5, OrgO-HRA.

⁹ Decision taken by three members of the ethics committee, as per the provisions of Art. 6 OrgO-HRA.

¹⁰ Decision taken by the president or vice-president of the ethics committee, as per the provisions of Art. 7 OrgO-HRA.

3.1 Submissions per ethics committee

Table 4: Overview of application details of all projects **submitted** via BASEC in 2017 (analysis set [AS1](#)) by ethics committee (for abbreviations see page [4](#)).

		Ethics committee															
		Total		KEK-ZH		EKNZ		CER-VD		KEK-BE		CCER		EKOS		CE-TI	
		N	%col	n	%col	n	%col	n	%col	n	%col	n	%col	n	%col	n	%col
First decision	Approved	265	11.6	86	14.0	58	12.7	17	4.3	31	8.7	24	8.9	25	25.3	24	28.2
	Approved with charges ¹	622	27.3	17	2.8	294	64.6	182	45.7	26	7.3	46	17.1	47	47.5	10	11.8
	Not approved, conditions ²	1238	54.4	461	75.2	97	21.3	174	43.7	266	74.7	175	65.1	22	22.2	43	50.6
	Declined	23	1.0	8	1.3			3	0.8	4	1.1	7	2.6	1	1.0		
	Non-consideration ³	71	3.1	24	3.9	4	0.9	14	3.5	18	5.1	7	2.6			4	4.7
	Pending first decision	56	2.5	17	2.8	2	0.4	8	2.0	11	3.1	10	3.7	4	4.0	4	4.7
Final decision	Approved	1885	82.9	497	81.1	430	94.5	309	77.6	282	79.2	212	78.8	87	87.9	68	80.0
	Declined	22	1.0	5	0.8	1	0.2	3	0.8	4	1.1	8	3.0	1	1.0		
	Non-consideration	69	3.0	20	3.3	4	0.9	14	3.5	18	5.1	9	3.3			4	4.7
	Withdrawn	24	1.1	12	2.0	2	0.4	3	0.8	4	1.1	1	0.4	1	1.0	1	1.2
	Pending final decision	275	12.1	79	12.9	18	4.0	69	17.3	48	13.5	39	14.5	10	10.1	12	14.1
Review procedure	Ordinary	400	17.6	110	17.9	61	13.4	66	16.6	56	15.7	13	4.8	17	17.2	77 ⁴	90.6
	Simplified	1537	67.6	359	58.6	319	70.1	296	74.4	276	77.5	225	83.6	62	62.6		
	Presidential	282	12.4	127	20.7	73	16.0	28	7.0	13	3.7	21	7.8	16	16.2	4	4.7
	Pending first decision	56	2.5	17	2.8	2	0.4	8	2.0	11	3.1	10	3.7	4	4.0	4	4.7
Total number in AS1		2275	100.0	613	100.0	455	100.0	398	100.0	356	100.0	269	100.0	99	100.0	85	100.0

¹ Charges: The projects are approved but with charges.

² Conditions: These projects are not approved until the conditions are addressed.

³ Non-consideration: Research not covered by the HRA.

⁴ CE-TI reviews all projects in an 'Ordinary procedure'.

Table 5: Number of **submissions in 2017** (analysis set [AS1](#)) by type of research project and ethics committee. Projects involving multiple ECs are assigned to the lead EC.

Type of research	Research details	Risk cat.	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	23	11.3	5	6.8	6	18.2	3	17.6	4	11.8	5	38.5				
		B	37	18.2	8	11.0	6	18.2	3	17.6	9	26.5	3	23.1	3	21.4	5	26.3
		C	143	70.4	60	82.2	21	63.6	11	64.7	21	61.8	5	38.5	11	78.6	14	73.7
		All	203	100.0	73	100.0	33	100.0	17	100.0	34	100.0	13	100.0	14	100.0	19	100.0
	Medical devices	A	101	72.1	31	60.8	18	75.0	15	78.9	16	76.2	10	90.9	6	85.7	5	71.4
		C	39	27.9	20	39.2	6	25.0	4	21.1	5	23.8	1	9.1	1	14.3	2	28.6
		All	140	100.0	51	100.0	24	100.0	19	100.0	21	100.0	11	100.0	7	100.0	7	100.0
	Other clinical trials	A	151	83.4	40	88.9	35	77.8	18	72.0	18	85.7	26	92.9	7	77.8	7	87.5
		B	30	16.6	5	11.1	10	22.2	7	28.0	3	14.3	2	7.1	2	22.2	1	12.5
		All	181	100.0	45	100.0	45	100.0	25	100.0	21	100.0	28	100.0	9	100.0	8	100.0
	Combination drugs/devices	A	2	33.3	1	33.3					1	33.3						
		C	4	66.7	2	66.7					2	66.7						
		All	6	100.0	3	100.0					3	100.0						
	Transplant products	A	1	12.5									1	100.0				
		C	7	87.5	4	100.0	1	100.0	2	100.0								
		All	8	100.0	4	100.0	1	100.0	2	100.0				1	100.0			
	Gene therapy	C	2	100.0					2	100.0								
		All	2	100.0					2	100.0								
	Transplantation	C	1	100.0	1	100.0												
		All	1	100.0	1	100.0												
	All	All	541	100.0	177	100.0	103	100.0	65	100.0	79	100.0	53	100.0	30	100.0	34	100.0
Research w/ persons	A		802	97.1	173	96.1	170	98.3	182	97.8	107	94.7	103	99.0	36	97.3	31	93.9
	B		24	2.9	7	3.9	3	1.7	4	2.2	6	5.3	1	1.0	1	2.7	2	6.1
	All		826	100.0	180	100.0	173	100.0	186	100.0	113	100.0	104	100.0	37	100.0	33	100.0
Further use	n.a.		879	100.0	249	100.0	173	100.0	145	100.0	161	100.0	101	100.0	32	100.0	18	100.0
Deceased, embryos	n.a.		29	100.0	7	100.0	6	100.0	2	100.0	3	100.0	11	100.0				
Total number			2275	100.0	613	100.0	455	100.0	398	100.0	356	100.0	269	100.0	99	100.0	85	100.0

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

3.2 Individual evaluations by lead or local ethics committees

Table 6: 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	2028	72.9
Multiple ECs involved: lead EC	247	8.9
Multiple ECs involved: local EC	505	18.2
Total submissions to be evaluated	2780	100.0

Table 7: Perspective of the ethics committee (EC): Number of submissions to be evaluated per EC.

	Ethics committee													
	KEK-ZH		EKNZ		KEK-BE		CER-VD		CCER		EKOS		CE-TI	
	n	% _{col}	n	% _{col}	n	% _{col}	n	% _{col}	n	% _{col}	n	% _{col}	n	% _{col}
Single EC involved	546	77.4	411	75.4	307	69.9	369	78.8	245	73.4	74	48.1	76	56.3
Multiple: lead EC	67	9.5	44	8.1	49	11.2	29	6.2	24	7.2	25	16.2	9	6.7
Multiple: local EC	92	13.0	90	16.5	83	18.9	70	15.0	65	19.5	55	35.7	50	37.0
Total submissions	705	100.0	545	100.0	439	100.0	468	100.0	334	100.0	154	100.0	135	100.0

4 Scientific characterisation of projects approved in 2017 (AS2)

4.1 Overview

Table 8: Total number of research projects **approved in 2017** (analysis set [AS2](#)) per type of research, including information on the legal basis.

Type of research	Legal basis	n	% _{col}
Clinical trial	ClinO	512 ¹	24.3
Research involving persons, but not a clinical trial	HRO, Chapter 2	720 ²	34.1
Further use of health-related personal data and/or biological material	HRO, Chapter 3	854	40.5
Research involving deceased persons	HRO, Chapter 4	22	1.0
Research involving embryos and fetuses from induced abortions or stillbirths	HRO, Chapter 5	1	0.0
Total number		2109	100.0

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

² 29 of these projects also include 'further use' of existing data and/or material.

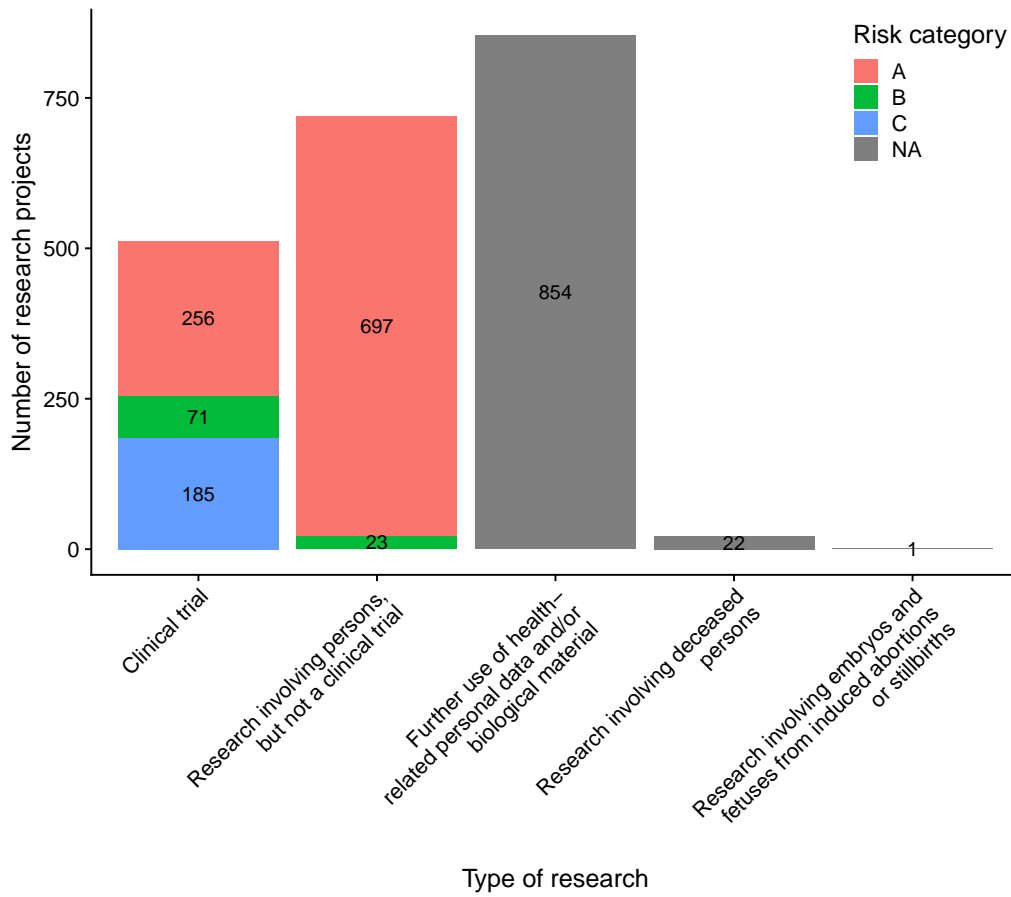


Figure 2: Stratification of all research projects by type of research and risk category.

4.2 Application process

Table 9: Overview of review procedure and first decision for all projects approved in 2017 (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 [14](#).

		n	%col
Submission year	2016	551	26.1
	2017	1558	73.9
Review procedure	Ordinary	392	18.6
	Simplified	1473	69.8
	Presidential	244	11.6
First decision	Approved	258	12.2
	Approved with charges	622	29.5
	Not approved, conditions	1227	58.2
	Declined	2	0.1
	Non-consideration	0	0.0
Total number in AS2		2109	100.0

Table 10: Overview of application details for all projects approved in 2017 - per ethics committee.

		Ethics committee															
		Total		KEK-ZH		EKNZ		CER-VD		KEK-BE		CCER		EKOS		CE-TI	
		N	%col	n	%col	n	%col	n	%col	n	%col	n	%col	n	%col	n	%col
Submission year	2016	551	26.1	174	29.2	99	20.9	87	26.0	81	27.5	78	32.1	15	16.3	17	22.7
	2017	1558	73.9	421	70.8	375	79.1	248	74.0	214	72.5	165	67.9	77	83.7	58	77.3
First decision	Approved	258	12.2	85	14.3	57	12.0	20	6.0	25	8.5	20	8.2	27	29.3	24	32.0
	Approved with charges ¹	622	29.5	20	3.4	321	67.7	163	48.7	22	7.5	44	18.1	43	46.7	9	12.0
	Not approved, conditions ²	1227	58.2	489	82.2	96	20.3	152	45.4	248	84.1	179	73.7	22	23.9	41	54.7
	Declined	2	0.1	1	0.2											1	1.3
	Non-consideration ³	0	0.0														
Review procedure	Ordinary ⁴	392	18.6	103	17.3	67	14.1	45	13.4	64	21.7	21	8.6	17	18.5	75	100.0
	Simplified	1473	69.8	374	62.9	333	70.3	268	80.0	228	77.3	209	86.0	61	66.3		
	Presidential	244	11.6	118	19.8	74	15.6	22	6.6	3	1.0	13	5.3	14	15.2		
Total number in AS2		2109	100.0	595	100.0	474	100.0	335	100.0	295	100.0	243	100.0	92	100.0	75	100.0

¹ Charges: the projects are approved but with charges.

² Conditions: These projects are not approved until the conditions are addressed.

³ Non-consideration: Research not covered by the HRA.

⁴ CE-TI exclusively uses the ordinary procedure.

4.3 Stratification by project characteristics

In Tables [11-16](#) on page [24-31](#), 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 [11](#). In the subgroup analyses starting on page [32](#), 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). 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 [4.5.1](#) on page [55](#), the above classification is compared to the main financing source indicating that this question indeed seems to be a good proxy to distinguish industry from academic studies.

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

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

Ionising radiation: The question in BASEC is “Does your study involve ionising radiation?”. The allowed answers are: “No”, “Yes, the main focus of the project is related to radiopharmaceuticals (medicinal products) or to devices emitting ionising radiation (medical devices)”, “Yes, but the study is only using ionising radiation for imaging/control purposes”. This question is shown only for clinical trials and research involving persons according to HRO chapter 2.

Ethics committee: Column-wise percentages are reported when stratifying by lead EC.

Application 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 11: Stratification of approved projects by study design and initiator. Subgroups in blue refer to chapters with the respective subgroup analyses and the legal basis is denoted in parentheses.

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 (ClinO)	Medicinal products (ClinO Art 19)	A	20	10.2	11	55.0	4	20.0	5	25.0	2	10.0	18	90.0	
		B	41	20.9	14	34.1	7	17.1	20	48.8	11	26.8	30	73.2	
		C	135	68.9	15	11.1	6	4.4	114	84.4	108	80.0	27	20.0	
		All	196	100.0	40	20.4	17	8.7	139	70.9	121	61.7	75	38.3	
	Medical devices (ClinO Art 20)	A	96	70.1	67	69.8	2	2.1	27	28.1	22	22.9	74	77.1	
		C	41	29.9	23	56.1	3	7.3	15	36.6	24	58.5	17	41.5	
		All	137	100.0	90	65.7	5	3.6	42	30.7	46	33.6	91	66.4	
	Other clinical trials (ClinO Art 61)	A	136	81.9	103	75.7	14	10.3	19	14.0	4	2.9	132	97.1	
		B	30	18.1	25	83.3			5	16.7	1	3.3	29	96.7	
		All	166	100.0	128	77.1	14	8.4	24	14.5	5	3.0	161	97.0	
	Combination drugs/devices	A	4	44.4	2	50.0			2	50.0	2	50.0	2	50.0	
		C	5	55.6	1	20.0			4	80.0	4	80.0	1	20.0	
All		9	100.0	3	33.3			6	66.7	6	66.7	3	33.3		
Transplant products (ClinO Art 21)	C	4	100.0	3	75.0			1	25.0	1	25.0	3	75.0		
	All	4	100.0	3	75.0			1	25.0	1	25.0	3	75.0		
Gene therapy (ClinO Art 22)	All	0													
Transplantation (ClinO Art 49)	All	0													
All	All	512	100.0	264	51.6	36	7.0	212	41.4	179	35.0	333	65.0		
Research w/ persons (HRO Chapter 2)	A	697	96.8	529	75.9	55	7.9	113	16.2	57	8.2	640	91.8		
	B	23	3.2	18	78.3	2	8.7	3	13.0			23	100.0		
	All	720	100.0	547	76.0	57	7.9	116	16.1	57	7.9	663	92.1		
Further use (HRO Chapter 3)	n.a.	854	100.0	734	85.9	33	3.9	87	10.2	35	4.1	819	95.9		
Deceased, embryos (HRO Chapter 4+5)	n.a.	23	100.0	21	91.3			2	8.7	1	4.3	22	95.7		
Total number		2109	100.0	1566	74.3	126	6.0	417	19.8	272	12.9	1837	87.1		

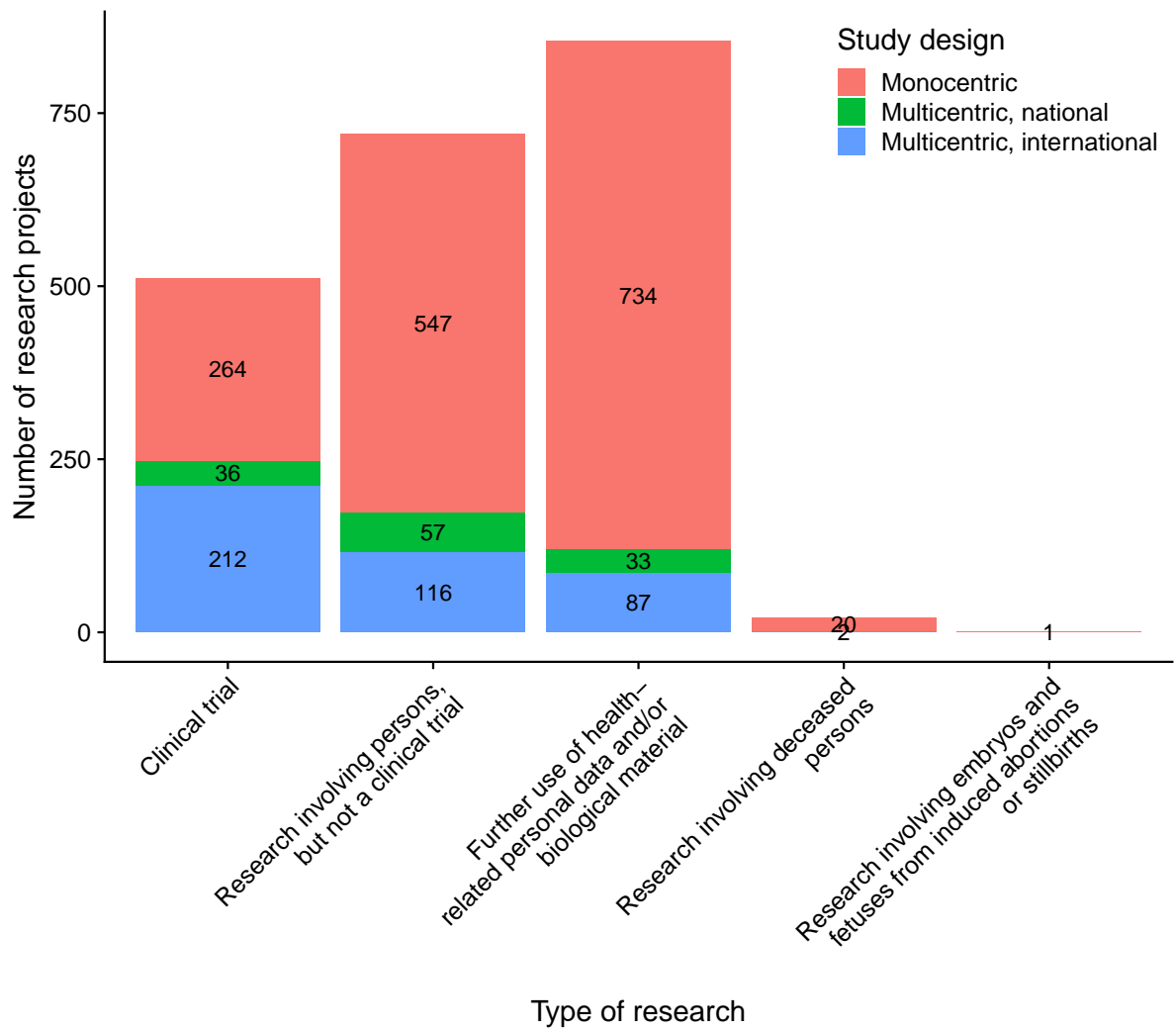


Figure 3: Stratification of all research projects by type of research and study design.

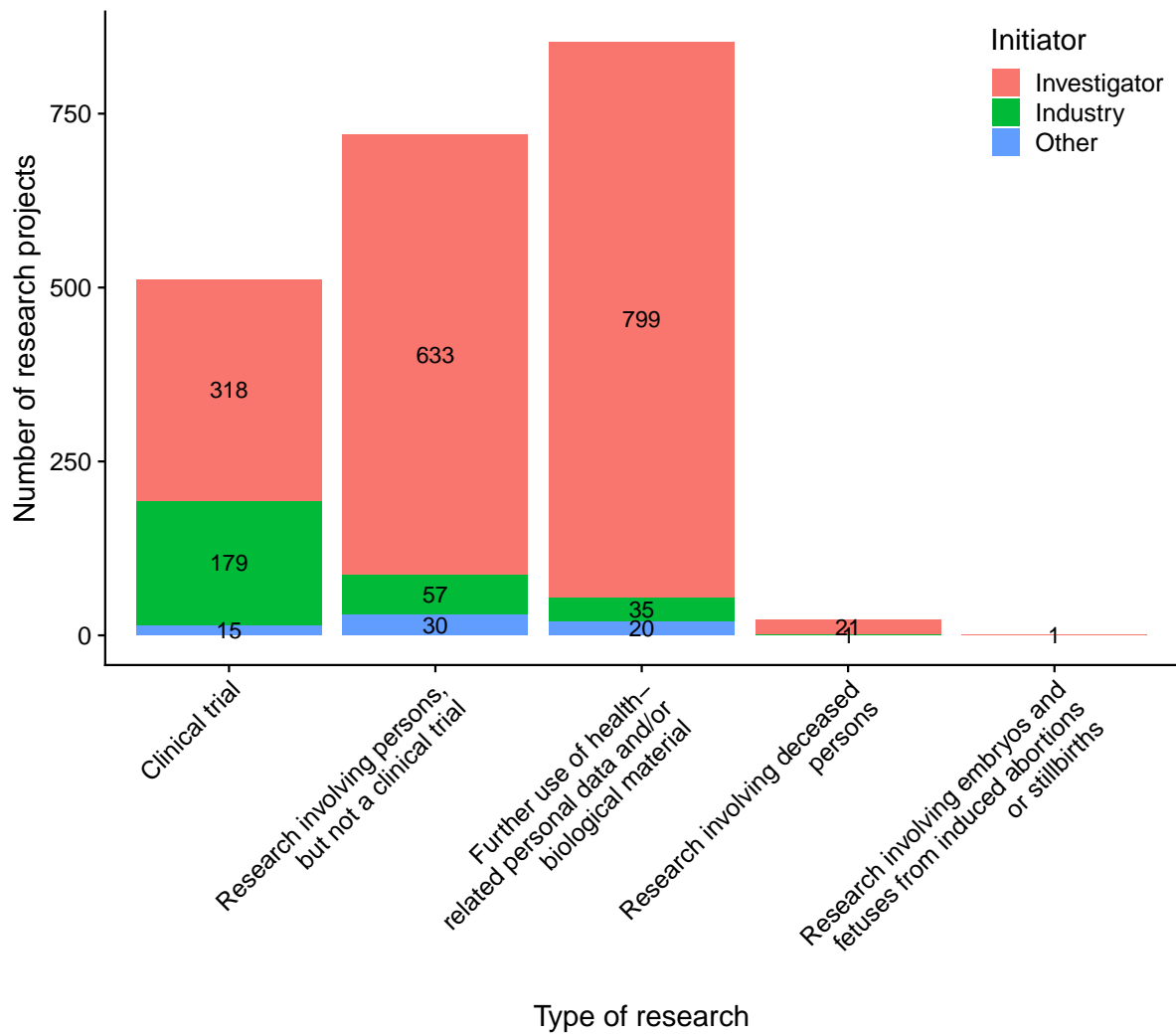


Figure 4: Stratification of all research projects by type of research and initiator.

4.3.3 Research to obtain degree

Table 12: Stratification of all approved projects by whether the research project was solely or principally designed to obtain a degree - and if yes, what degree.

Type of research	Research details	Risk cat.	Total		Primarily for degree		What degree (multiple answers possible)					
			N	%col	n	%row	MD/PhD thesis		Master		Other degree	
							n	%row	n	%row	n	%row
Clinical trial	Medicinal products	A	20	10.2	4	20.0	4	100.0				
		B	41	20.9	1	2.4	1	100.0				
		C	135	68.9								
		All	196	100.0	5	2.6	5	100.0				
	Medical devices	A	96	70.1	21	21.9	7	33.3	14	66.7	1	4.8
		C	41	29.9	1	2.4	1	100.0				
		All	137	100.0	22	16.1	8	36.4	14	63.6	1	4.5
	Other clinical trials	A	136	81.9	38	27.9	15	39.5	23	60.5	1	2.6
		B	30	18.1	4	13.3	4	100.0				
		All	166	100.0	42	25.3	19	45.2	23	54.8	1	2.4
	Combination drugs/devices	A	4	44.4								
		C	5	55.6	1	20.0	1	100.0				
		All	9	100.0	1	11.1	1	100.0				
	Transplant products	C	4	100.0								
		All	4	100.0								
	Gene therapy	All	0									
	Transplantation	All	0									
	All	All	512	100.0	70	13.7	33	47.1	37	52.9	2	2.9
Research w/ persons	A		697	96.8	214	30.7	93	43.5	111	51.9	13	6.1
	B		23	3.2	2	8.7	1	50.0	1	50.0		
	All		720	100.0	216	30.0	94	43.5	112	51.9	13	6.0
Further use	n.a.		854	100.0	341	39.9	146	42.8	188	55.1	21	6.2
Deceased, embryos	n.a.		23	100.0	4	17.4	4	100.0				
Total number			2109	100.0	631	29.9	277	43.9	337	53.4	36	5.7

Since multiple answers are possible, the row-wise percentages may sum up to a total over 100%.

4.3.4 Vulnerable persons

Table 13: 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	What groups (multiple possible)													
				Any vulnerable		Healthy vol.		Children		Adolescents		Unable to cons.		Emergencies		Others	
				n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}
Clinical trial	Medicinal products	A	20	7	35.0	1	14.3	1	14.3			2	28.6	3	42.9	1	14.3
		B	41	10	24.4	5	50.0	2	20.0	2	20.0	2	20.0	3	30.0		
		C	135	21	15.6	5	23.8	14	66.7	16	76.2						
		All	196	38	19.4	11	28.9	17	44.7	18	47.4	4	10.5	6	15.8	1	2.6
	Medical devices	A	96	29	30.2	19	65.5	5	17.2	4	13.8	1	3.4	4	13.8	2	6.9
		C	41	11	26.8	7	63.6	4	36.4	2	18.2			3	27.3		
		All	137	40	29.2	26	65.0	9	22.5	6	15.0	1	2.5	7	17.5	2	5.0
	Other clinical trials	A	136	58	42.6	31	53.4	14	24.1	14	24.1	10	17.2	3	5.2	1	1.7
		B	30	12	40.0	7	58.3	1	8.3	2	16.7			2	16.7		
		All	166	70	42.2	38	54.3	15	21.4	16	22.9	10	14.3	5	7.1	1	1.4
	Combination drugs/devices	A	4														
		C	5	1	20.0			1	100.0								
		All	9	1	11.1			1	100.0								
	Transplant products	C	4	2	50.0	1	50.0			1	50.0						
		All	4	2	50.0	1	50.0			1	50.0						
	Gene therapy	All	0														
	Transplantation	All	0														
	All	All	512	151	29.5	76	50.3	42	27.8	41	27.2	15	9.9	18	11.9	4	2.6
Research w/ persons	A	697	274	39.3	146	53.3	80	29.2	76	27.7	28	10.2	26	9.5	20	7.3	
	B	23	7	30.4	7	100.0	2	28.6	2	28.6							
	All	720	281	39.0	153	54.4	82	29.2	78	27.8	28	10.0	26	9.3	20	7.1	
Further use	n.a.	854															
Deceased, embryos	n.a.	23															
Total number			2109	432	20.5	229	53.0	124	28.7	119	27.5	43	10.0	44	10.2	24	5.6

Since multiple answers are possible, the row-wise percentages may sum up to a total over 100%.

4.3.5 Ionising radiation

Table 14: Stratification of clinical trials and research involving persons but not a clinical trial by involvement of ionising radiation.

Type of research	Research details	Risk cat.	Ionising radiation involved					
			Total		For imaging/control purposes		As primary object of investigation	
			N	% _{col}	n	% _{row}	n	% _{row}
Clinical trial	Medicinal products	A	20	10.2	4	20.0	1	5.0
		B	41	20.9	15	36.6		
		C	135	68.9	69	51.1	2	1.5
		All	196	100.0	88	44.9	3	1.5
	Medical devices	A	96	70.1	18	18.8	3	3.1
		C	41	29.9	9	22.0		
		All	137	100.0	27	19.7	3	2.2
	Other clinical trials	A	136	81.9	8	5.9	3	2.2
		B	30	18.1	5	16.7	1	3.3
		All	166	100.0	13	7.8	4	2.4
	Combination drugs/devices	A	4	44.4	1	25.0		
		C	5	55.6	1	20.0		
All		9	100.0	2	22.2			
Transplant products	C	4	100.0	2	50.0			
	All	4	100.0	2	50.0			
Gene therapy	All	0						
Transplantation	All	0						
All	All	512	100.0	132	25.8	10	2.0	
Research w/ persons	A	697	96.8	51	7.3			
	B	23	3.2	4	17.4			
	n.a.	720	100.0	55	7.6			
Total number		1232	100.0	187	15.2	10	0.8	

4.3.6 Ethics committee

Table 15: Stratification of all approved projects by ethics committee.

Type of research	Research details	Risk cat.	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	20	10.2	4	6.5	2	6.2	3	21.4	4	9.5	6	37.5	1	7.1		
		B	41	20.9	8	12.9	8	25.0			12	28.6	5	31.2	3	21.4	5	31.2
		C	135	68.9	50	80.6	22	68.8	11	78.6	26	61.9	5	31.2	10	71.4	11	68.8
		All	196	100.0	62	100.0	32	100.0	14	100.0	42	100.0	16	100.0	14	100.0	16	100.0
	Medical devices	A	96	70.1	33	62.3	19	73.1	7	70.0	18	75.0	9	75.0	5	71.4	5	100.0
		C	41	29.9	20	37.7	7	26.9	3	30.0	6	25.0	3	25.0	2	28.6		
		All	137	100.0	53	100.0	26	100.0	10	100.0	24	100.0	12	100.0	7	100.0	5	100.0
	Other clinical trials	A	136	81.9	39	81.2	35	79.5	7	53.8	15	93.8	25	89.3	8	88.9	7	87.5
		B	30	18.1	9	18.8	9	20.5	6	46.2	1	6.2	3	10.7	1	11.1	1	12.5
		All	166	100.0	48	100.0	44	100.0	13	100.0	16	100.0	28	100.0	9	100.0	8	100.0
	Combination drugs/devices	A	4	44.4	2	50.0					2	50.0						
		C	5	55.6	2	50.0					2	50.0	1	100.0				
All		9	100.0	4	100.0					4	100.0	1	100.0					
Transplant products	C	4	100.0	1	100.0	1	100.0	1	100.0			1	100.0					
	All	4	100.0	1	100.0	1	100.0	1	100.0			1	100.0					
Gene therapy	All																	
Transplantation	All	0																
All	All	512	100.0	168	100.0	103	100.0	38	100.0	86	100.0	58	100.0	30	100.0	29	100.0	
	A	697	96.8	156	95.1	173	96.6	146	98.0	78	96.3	90	97.8	28	96.6	26	100.0	
	All	720	100.0	164	100.0	179	100.0	149	100.0	81	100.0	92	100.0	29	100.0	26	100.0	
Further use	n.a.	854	100.0	257	100.0	188	100.0	147	100.0	124	100.0	85	100.0	33	100.0	20	100.0	
Deceased, embryos	n.a.	23	100.0	6	100.0	4	100.0	1	100.0	4	100.0	8	100.0					
Total number		2109	100.0	595	100.0	474	100.0	335	100.0	295	100.0	243	100.0	92	100.0	75	100.0	

4.3.7 Application procedure

Table 16: Stratification of all approved projects by characteristics of the application procedure.

Type of research	Research details	Risk cat.	Review procedure							First decision								
			Total		Ordinary		Simplified		Presidential		Approved		Charges		Conditions		Declined	
			N	%col	n	%row	n	%row	n	%row	n	%row	n	%row	n	%row	n	%row
Clinical trial	Medicinal products	A	20	10.2	6	30.0	14	70.0					2	10.0	18	90.0		
		B	41	20.9	40	97.6	1	2.4			2	4.9	9	22.0	30	73.2		
		C	135	68.9	135	100.0					2	1.5	25	18.5	108	80.0		
		All	196	100.0	181	92.3	15	7.7			4	2.0	36	18.4	156	79.6		
	Medical devices	A	96	70.1	18	18.8	78	81.2					21	21.9	75	78.1		
		C	41	29.9	41	100.0							5	12.2	36	87.8		
		All	137	100.0	59	43.1	78	56.9					26	19.0	111	81.0		
	Other clinical trials	A	136	81.9	17	12.5	119	87.5			3	2.2	41	30.1	91	66.9	1	0.7
		B	30	18.1	28	93.3	2	6.7					8	26.7	22	73.3		
		All	166	100.0	45	27.1	121	72.9			3	1.8	49	29.5	113	68.1	1	0.6
	Combination drugs/devices	A	4	44.4			4	100.0							4	100.0		
		C	5	55.6	4	80.0	1	20.0							5	100.0		
		All	9	100.0	4	44.4	5	55.6							9	100.0		
	Transplant products	C	4	100.0	4	100.0							1	25.0	3	75.0		
		All	4	100.0	4	100.0							1	25.0	3	75.0		
	Gene therapy	All	0															
	Transplantation	All	0															
	All	All	512	100.0	293	57.2	219	42.8			7	1.4	112	21.9	392	76.6	1	0.2
Research w/ persons	A	697	96.8	53	7.6	625	89.7	19	2.7	24	3.4	230	33.0	442	63.4	1	0.1	
	B	23	3.2	20	87.0	3	13.0			1	4.3	7	30.4	15	65.2			
	All	720	100.0	73	10.1	628	87.2	19	2.6	25	3.5	237	32.9	457	63.5	1	0.1	
Further use	n.a.	854	100.0	26	3.0	606	71.0	222	26.0	221	25.9	267	31.3	366	42.9			
Deceased, embryos	n.a.	23	100.0			20	87.0	3	13.0	5	21.7	6	26.1	12	52.2			
Total number			2109	100.0	392	18.6	1473	69.8	244	11.6	258	12.2	622	29.5	1227	58.2	2	0.1

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

4.4 Subgroups of research projects

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

4.4.1.1 Project characteristics used as stratification variables 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. Since not all project characteristics are appropriate or meaningful for certain subgroups, the BASEC web portal applies logical filtering.

Allocation: Single choice field with allowed answers: "Randomised controlled trial", "Non-randomised controlled trial" and "Not applicable".

Masking technique: Single choice field with allowed answers: "Open", "Single-blind", "Double-blind".

Type of control: Single choice field with allowed answers: "Placebo", "Active", "Before-after (historic)", "Dosage comparison", "None".

Participant arms/distribution: Single choice field to indicate the trial participant arms / distribution with allowed answers: "Single-armed", "Parallel groups", "Cross-over", "Factorial", "Other or n/a"

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".

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

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

Type of research project in projects covered by HRO Chapter 2 Single choice field with allowed answers: "Cohort study", "Registry / Quality control" (only quality control studies under the HRA), "Case control study" and "Other or n/a". The last group also includes projects declared as "Observational study" before this option was disabled on August 21, 2017.

4.4.1.2 Stratification of 'Clinical trials'

Table 17: Stratification of **all clinical trials** by risk category, study design and initiator of the research project. The classification of clinical trials according to allocation, control and masking technique is BASEC-specific.

Allocation	Control	Masking	Risk category								Study design						Initiator			
			Total		A		B		C		Mono		Multi CH		Multi Int.		Industry		Investigator	
			N	%col	n	%row	n	%row	n	%row	n	%row	n	%row	n	%row	n	%row	n	%row
Randomised controlled	Active	Open	97	32.6	51	52.6	19	19.6	27	27.8	32	33.0	9	9.3	56	57.7	30	30.9	67	69.1
		Double-blind	18	6.0	6	33.3	5	27.8	7	38.9	9	50.0			9	50.0	9	50.0	9	50.0
		Single-blind	32	10.7	27	84.4	1	3.1	4	12.5	22	68.8	4	12.5	6	18.8	3	9.4	29	90.6
	Placebo	Open	8	2.7	5	62.5	2	25.0	1	12.5	6	75.0			2	25.0	1	12.5	7	87.5
		Double-blind	79	26.5	15	19.0	14	17.7	50	63.3	25	31.6	3	3.8	51	64.6	44	55.7	35	44.3
		Single-blind	18	6.0	10	55.6	5	27.8	3	16.7	15	83.3	2	11.1	1	5.6			18	100.0
	Before/after	Open	7	2.3	7	100.0					5	71.4	1	14.3	1	14.3			7	100.0
		Single-blind	4	1.3	3	75.0	1	25.0			3	75.0			1	25.0			4	100.0
		Dosage	5	1.7	2	40.0	2	40.0	1	20.0	1	20.0	3	60.0			2	40.0	1	20.0
	None	Double-blind	1	0.3					1	100.0					1	100.0	1	100.0		
		Single-blind	2	0.7	2	100.0					2	100.0							2	100.0
		Open	13	4.4	10	76.9	1	7.7	2	15.4	6	46.2			7	53.8	5	38.5	8	61.5
		Double-blind	3	1.0	2	66.7	1	33.3			2	66.7	1	33.3					3	100.0
		Single-blind	11	3.7	9	81.8	2	18.2			8	72.7	1	9.1	2	18.2	2	18.2	9	81.8
	All	298	100.0	149	50.0	53	17.8	96	32.2	138	46.3	21	7.0	139	46.6	96	32.2	202	67.8	
	Non-random. controlled	Active	Open	11	20.8	8	72.7			3	27.3	9	81.8			2	18.2	2	18.2	9
Double-blind			3	5.7					3	100.0					3	100.0	3	100.0		
Before/after		Open	9	17.0	8	88.9	1	11.1			7	77.8	2	22.2			1	11.1	8	88.9
		Double-blind	1	1.9					1	100.0	1	100.0					1	100.0		
Dosage		Open	1	1.9	1	100.0									1	100.0			1	100.0
None		Open	28	52.8	14	50.0	1	3.6	13	46.4	15	53.6	2	7.1	11	39.3	12	42.9	16	57.1
		All	53	100.0	31	58.5	2	3.8	20	37.7	32	60.4	4	7.5	17	32.1	19	35.8	34	64.2
Not applicable	Active	Open	13	8.1	5	38.5			8	61.5	8	61.5	1	7.7	4	30.8	4	30.8	9	69.2
		Single-blind	1	0.6					1	100.0	1	100.0					1	100.0		
	Placebo	Open	1	0.6	1	100.0					1	100.0							1	100.0
		Double-blind	1	0.6	1	100.0					1	100.0							1	100.0
	Before/after	Open	19	11.8	13	68.4	3	15.8	3	15.8	15	78.9	2	10.5	2	10.5	3	15.8	16	84.2
	Dosage	Open	2	1.2					2	100.0					2	100.0	2	100.0		
	None	Open	118	73.3	51	43.2	13	11.0	54	45.8	64	54.2	7	5.9	47	39.8	52	44.1	66	55.9
		Double-blind	1	0.6	1	100.0					1	100.0							1	100.0
		Single-blind	5	3.1	4	80.0			1	20.0	3	60.0	1	20.0	1	20.0	2	40.0	3	60.0
		All	161	100.0	76	47.2	16	9.9	69	42.9	94	58.4	11	6.8	56	34.8	64	39.8	97	60.2
	Total number		512	100.0	256	50.0	71	13.9	185	36.1	264	51.6	36	7.0	212	41.4	179	35.0	333	65.0

Note that some categories of 'Control' are not meaningful for certain subtype of clinical trials (e.g. dosage for medical device).

Table 18: Stratification of **all clinical trials** by participant arms/distribution.

Allocation	Control	Masking	Participant arms/distribution											
			Total		Single-arm		Parallel groups		Crossover		Factorial		Other or n/a	
			N	% _{col}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}
Randomised controlled	Active	Open	97	32.6	1	1.0	84	86.6	10	10.3	2	2.1		
		Double-blind	18	6.0			14	77.8	2	11.1			2	11.1
		Single-blind	32	10.7	2	6.2	29	90.6	1	3.1				
	Placebo	Open	8	2.7			6	75.0					2	25.0
		Double-blind	79	26.5			64	81.0	12	15.2			3	3.8
		Single-blind	18	6.0	1	5.6	9	50.0	7	38.9			1	5.6
	Before/after	Open	7	2.3			6	85.7	1	14.3				
		Single-blind	4	1.3	1	25.0	2	50.0					1	25.0
	Dosage	Open	5	1.7			4	80.0	1	20.0				
		Double-blind	1	0.3			1	100.0						
		Single-blind	2	0.7			1	50.0	1	50.0				
	None	Open	13	4.4	2	15.4	9	69.2	2	15.4				
		Double-blind	3	1.0			2	66.7	1	33.3				
		Single-blind	11	3.7	1	9.1	8	72.7	2	18.2				
All		298	100.0	8	2.7	239	80.2	40	13.4	2	0.7	9	3.0	
Non-random. controlled	Active	Open	11	20.8	5	45.5	4	36.4	1	9.1			1	9.1
		Double-blind	3	5.7			2	66.7	1	33.3				
	Before/after	Open	9	17.0	4	44.4	1	11.1	1	11.1			3	33.3
		Double-blind	1	1.9	1	100.0								
	Dosage	Open	1	1.9	1	100.0								
	None	Open	28	52.8	15	53.6	3	10.7	2	7.1			8	28.6
		All	53	100.0	26	49.1	10	18.9	5	9.4			12	22.6
Not applicable	Active	Open	13	8.1	5	38.5	2	15.4	2	15.4			4	30.8
		Single-blind	1	0.6					1	100.0				
	Placebo	Open	1	0.6	1	100.0								
		Double-blind	1	0.6	1	100.0								
	Before/after	Open	19	11.8	10	52.6	2	10.5	2	10.5			5	26.3
		Open	2	1.2			1	50.0					1	50.0
	None	Open	118	73.3	60	50.8	9	7.6	1	0.8			48	40.7
		Double-blind	1	0.6									1	100.0
		Single-blind	5	3.1	3	60.0							2	40.0
	All	161	100.0	80	49.7	14	8.7	6	3.7			61	37.9	
Total number			512	100.0	114	22.3	263	51.4	51	10.0	2	0.4	82	16.0

4.4.2 Subgroups of “Clinical trials”

Table 19: Overview of type of clinical trial.

Type of clinical trial	Legal basis (ClinO)	n	% _{col}
Medicinal products	Art 19	196	38.3
Medical devices	Art 20	137	26.8
Other clinical trials	Art 61	166	32.4
Combination drugs/devices ¹		9	1.8
Transplant products	Art 21	4	0.8
Gene therapy	Art 22	0	0.0
Transplantation	Art 49	0	0.0
Total number		512	100.0

¹ Combination of medical device and medical product: this category is BASEC-specific.

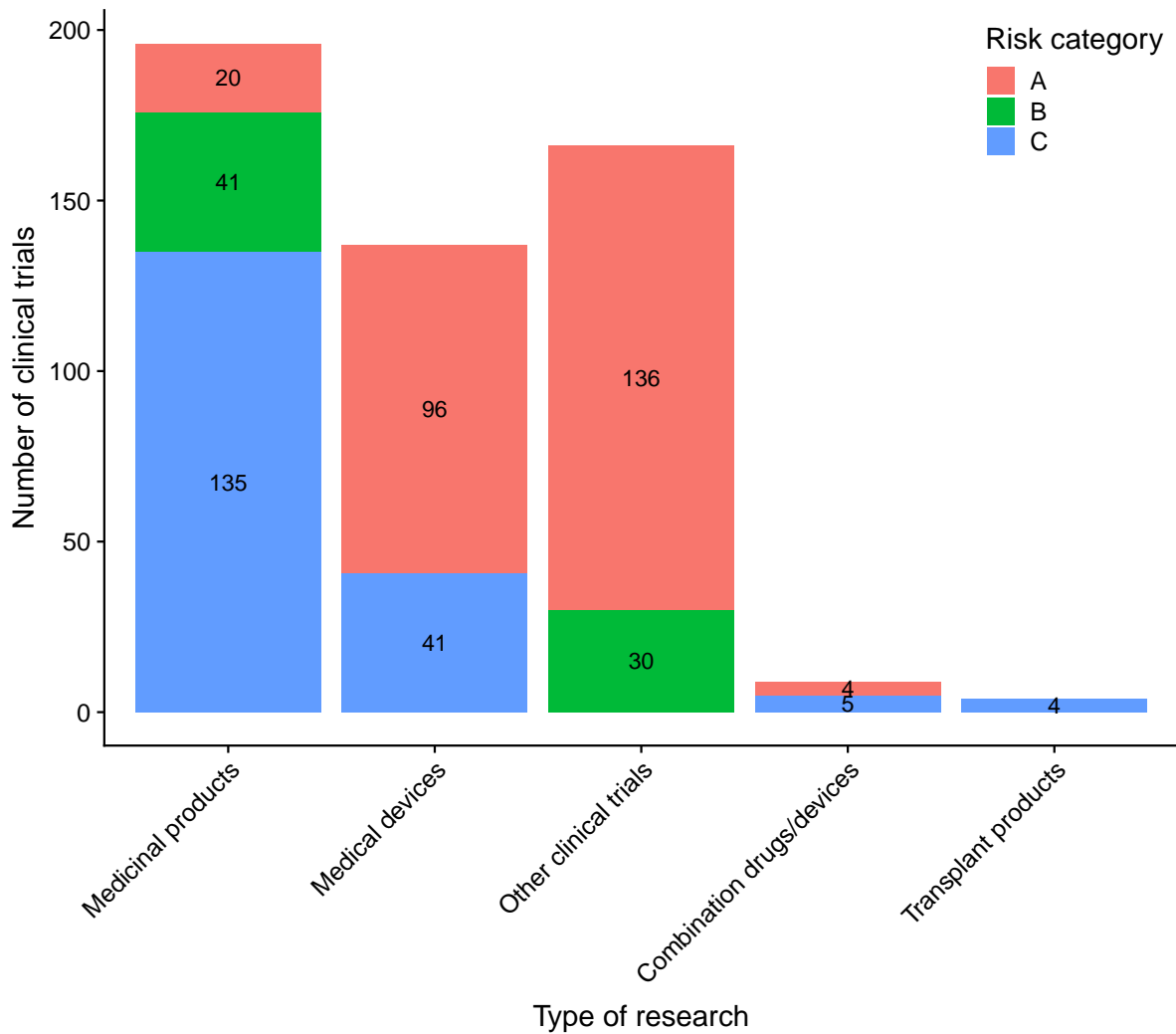


Figure 5: Stratification of all clinical trials by type of trial and risk category.

Description of distinctive features of the results:

As expected, a large fraction of the trials on medicinal products are international multi-center studies from industry. The majority of medical device trials involve standard use of the device (risk category A), are mono-centric and investigator initiated trials.

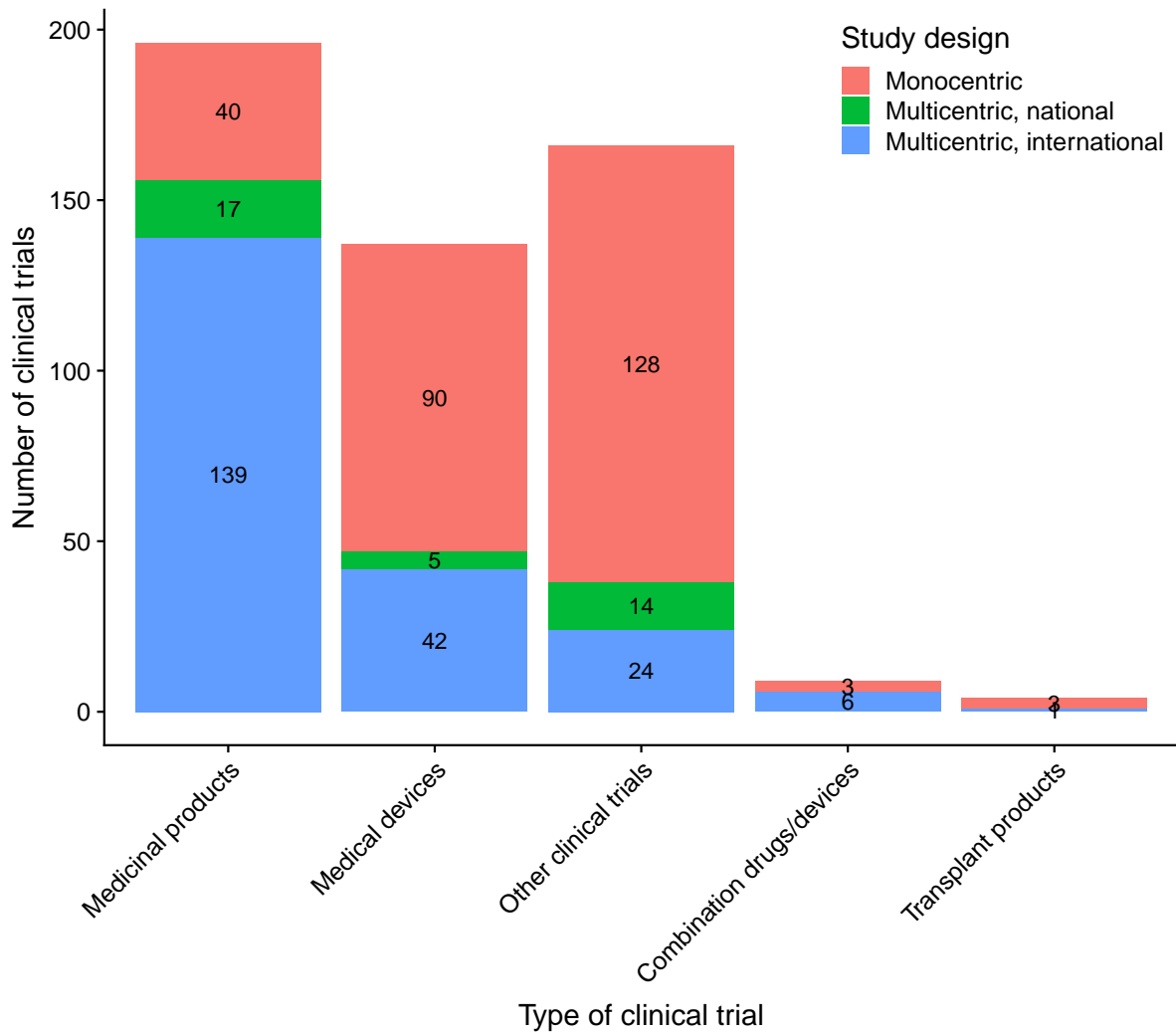


Figure 6: Stratification of all clinical trials by type of trial and study design.

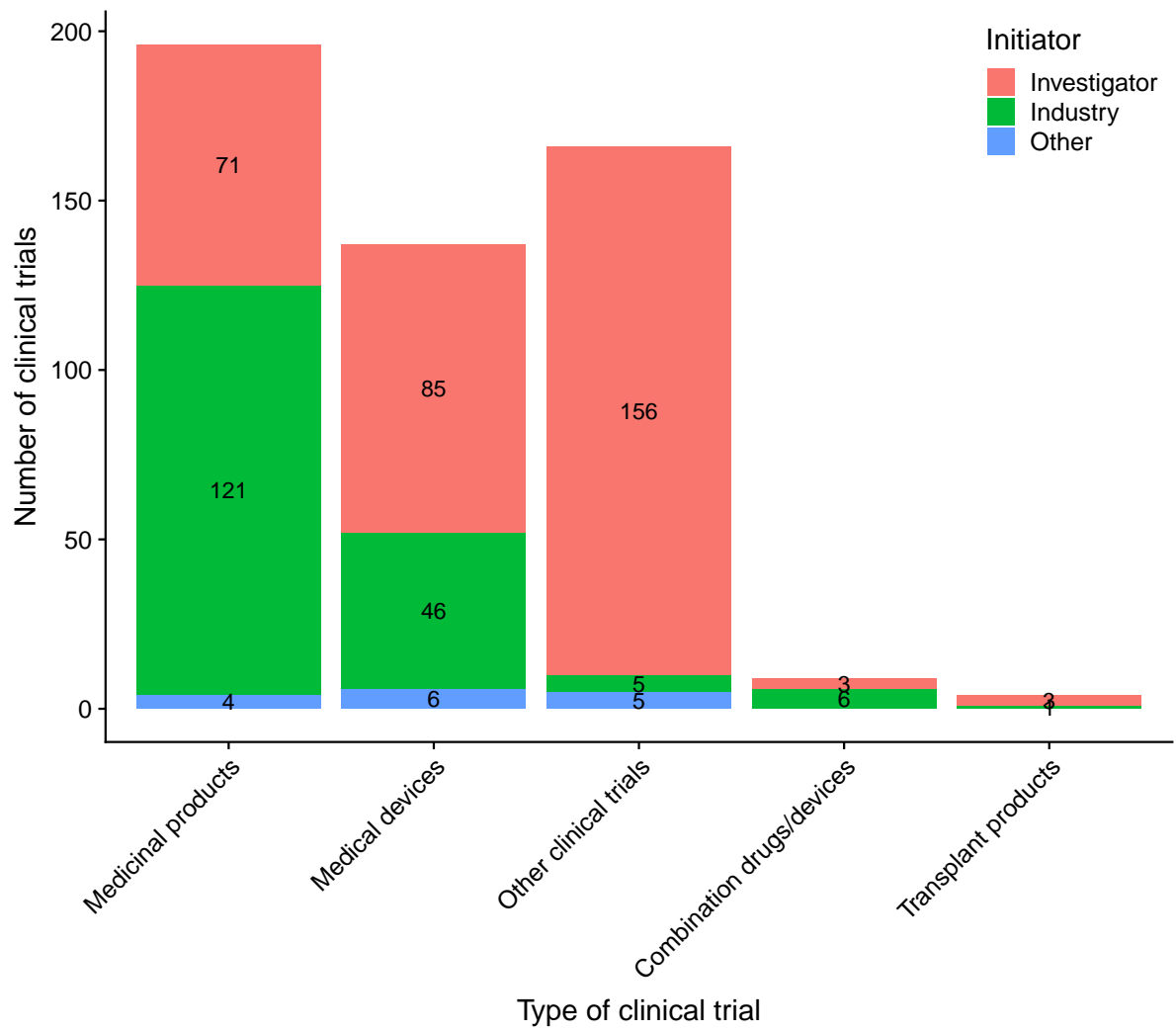


Figure 7: Stratification of all clinical trials by type of trial and initiator.

4.4.2.1 Subgroup “Medicinal products trials” (ClinO Art 19)

Table 20: Stratification of **medicinal products trials** by risk category, study design and initiator of the research project. The classification of clinical trials according to allocation, control and masking technique is BASEC-specific.

Allocation	Control	Masking	Total		Risk category						Study design						Initiator			
			N	%col	A		B		C		Mono		Multi CH		Multi Int.		Industry		Investigator	
					n	%row	n	%row	n	%row	n	%row	n	%row	n	%row	n	%row	n	%row
Randomised controlled	Active	Open	41	31.5	6	14.6	11	26.8	24	58.5	4	9.8	2	4.9	35	85.4	24	58.5	17	41.5
		Double-blind	12	9.2	2	16.7	4	33.3	6	50.0	4	33.3			8	66.7	8	66.7	4	33.3
		Single-blind	4	3.1	1	25.0			3	75.0	1	25.0	1	25.0	2	50.0	3	75.0	1	25.0
	Placebo	Open	2	1.5			1	50.0	1	50.0	1	50.0			1	50.0	1	50.0	1	50.0
		Double-blind	60	46.2	2	3.3	10	16.7	48	80.0	9	15.0	3	5.0	48	80.0	43	71.7	17	28.3
		Single-blind	3	2.3	2	66.7	2	66.7	1	33.3	2	66.7	1	33.3					3	100.0
	Before/after Dosage	Single-blind	1	0.8	1	100.0					1	100.0							1	100.0
		Open	3	2.3	1	33.3	1	33.3	1	33.3	2	66.7			1	33.3	1	33.3	2	66.7
	None	Double-blind	1	0.8					1	100.0					1	100.0	1	100.0		
		Open	1	0.8	1	100.0									1	100.0			1	100.0
		Double-blind	1	0.8			1	100.0					1	100.0					1	100.0
		Single-blind	1	0.8			1	100.0							1	100.0	1	100.0		
		All	130	100.0	14	10.8	31	23.8	85	65.4	24	18.5	8	6.2	98	75.4	82	63.1	48	36.9
Non-random. controlled	Active	Open	3	20.0					3	100.0	1	33.3			2	66.7	2	66.7	1	33.3
		Double-blind	3	20.0					3	100.0					3	100.0	3	100.0		
	Before/after Dosage	Open	2	13.3	1	50.0	1	50.0			1	50.0	1	50.0					2	100.0
		Open	1	6.7	1	100.0									1	100.0			1	100.0
	None	Open	6	40.0					6	100.0	2	33.3			4	66.7	3	50.0	3	50.0
All	15	100.0	2	13.3	1	6.7	12	80.0	4	26.7	1	6.7	10	66.7	8	53.3	7	46.7		
Not applicable	Active	Open	6	10.0					6	100.0	2	33.3			4	66.7	4	66.7	2	33.3
		Open	7	11.7	3	42.9	3	42.9	1	14.3	4	57.1	2	28.6	1	14.3	1	14.3	6	85.7
	Before/after Dosage	Open	2	3.3					2	100.0					2	100.0	2	100.0		
		Open	44	73.3	4	9.1	6	13.6	34	77.3	9	20.5	5	11.4	30	68.2	29	65.9	15	34.1
	None	Single-blind	1	1.7	1	100.0							1	100.0			1	100.0		
All	60	100.0	8	13.3	9	15.0	43	71.7	15	25.0	8	13.3	37	61.7	37	61.7	23	38.3		
Total number			205	100.0	24	11.7	41	20.0	140	68.3	43	21.0	17	8.3	145	70.7	127	62.0	78	38.0

The total number of 205 research projects consist of 196 medicinal product trials and 9 trials on a combination medicinal product and medical device.

Table 21: Stratification of **medicinal products trials** by phase and whether 'first in man'.

Allocation	Control	Masking	Phase ¹														
			Total		1		2		3		4		n/a		First in man ²		
			N	% _{col}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}	
Randomised controlled	Active	Open	41	31.5	4	9.8	4	9.8	26	63.4	6	14.6	1	2.4	1	2.4	
		Double-blind	12	9.2	1	8.3			8	66.7	2	16.7	1	8.3			
		Single-blind	4	3.1			1	25.0	1	25.0	1	25.0	1	25.0			
	Placebo	Open	2	1.5					2	100.0							
		Double-blind	60	46.2	1	1.7	16	26.7	38	63.3	3	5.0	2	3.3			
		Single-blind	3	2.3			2	66.7			1	33.3					
	Before/after	Single-blind	1	0.8									1	100.0			
		Dosage	Open	3	2.3	2	66.7					1	33.3				
	None	Double-blind	1	0.8					1	100.0							
		Single-blind	1	0.8					1	100.0			1	100.0			
	All		130	100.0	8	6.2	23	17.7	77	59.2	15	11.5	7	5.4	1	0.8	
	Non-random. controlled	Active	Open	3	20.0			1	33.3	1	33.3			1	33.3		
			Double-blind	3	20.0					3	100.0						
Before/after		Open	2	13.3			1	50.0			1	50.0					
		Dosage	Open	1	6.7								1	100.0			
None		Open	6	40.0			4	66.7	2	33.3							
		All	15	100.0			6	40.0	6	40.0	1	6.7	2	13.3			
Not applicable	Active	Open	6	10.0	2	33.3	1	16.7	1	16.7	2	33.3					
		Before/after	Open	7	11.7	1	14.3	3	42.9			1	14.3	2	28.6	2	28.6
	None	Dosage	Open	2	3.3	1	50.0	1	50.0								
		Open	44	73.3	19	43.2	12	27.3	7	15.9	1	2.3	5	11.4	6	13.6	
	All	Single-blind	1	1.7							1	100.0					
Total number			205	100.0	31	15.1	46	22.4	91	44.4	21	10.2	16	7.8	9	4.4	

¹ In this table the two categories 'phase 1' and 'phase 1/2' are grouped to 'phase 1'.

² 'First in man' can be selected for phase 1 and 1/2 studies as well as studies without a defined phase ('n/a').

Table 22: Stratification of **medicinal products trials** by participant arms/distribution.

Allocation	Control	Masking	Participant arms/distribution											
			Total		Single-arm		Parallel groups		Crossover		Factorial		Other or n/a	
			N	% _{col}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}
Randomised controlled	Active	Open	41	31.5			34	82.9	5	12.2	2	4.9		
		Double-blind	12	9.2			10	83.3	1	8.3			1	8.3
		Single-blind	4	3.1			4	100.0						
	Placebo	Open	2	1.5			1	50.0					1	50.0
		Double-blind	60	46.2			54	90.0	3	5.0			3	5.0
		Single-blind	3	2.3			1	33.3	2	66.7				
	Before/after Dosage	Single-blind	1	0.8			1	100.0						
		Open	3	2.3			3	100.0						
	None	Double-blind	1	0.8			1	100.0						
		Open	1	0.8			1	100.0						
		Double-blind	1	0.8			1	100.0						
			Single-blind	1	0.8			1	100.0					
		All	130	100.0			112	86.2	11	8.5	2	1.5	5	3.8
Non-random. controlled	Active	Open	3	20.0	2	66.7	1	33.3						
		Double-blind	3	20.0			2	66.7	1	33.3				
	Before/after Dosage	Open	2	13.3	2	100.0								
		Open	1	6.7	1	100.0								
	None	Open	6	40.0	6	100.0								
		All	15	100.0	11	73.3	3	20.0	1	6.7				
Not applicable	Active	Open	6	10.0	3	50.0			1	16.7			2	33.3
		Open	7	11.7	5	71.4							2	28.6
	None	Open	2	3.3			1	50.0					1	50.0
		Open	44	73.3	31	70.5	8	18.2					5	11.4
		Single-blind	1	1.7									1	100.0
	All	60	100.0	39	65.0	9	15.0	1	1.7			11	18.3	
Total number			205	100.0	50	24.4	124	60.5	13	6.3	2	1.0	16	7.8

4.4.2.2 Subgroup “Medical device trials” (ClinO Art 20)

Table 23: Stratification of **medical device trials** by risk category, study design and initiator of the research project. The classification of clinical trials according to allocation, control and masking technique is BASEC-specific.

Allocation	Control	Masking	Total		Risk category				Study design						Initiator			
			N	%col	A		C		Mono		Multi CH		Multi Int.		Industry		Investigator	
					n	%row	n	%row	n	%row	n	%row	n	%row	n	%row	n	%row
Randomised controlled	Active	Open	24	35.8	19	79.2	5	20.8	11	45.8			13	54.2	8	33.3	16	66.7
		Double-blind	1	1.5	1	100.0							1	100.0	1	100.0		
		Single-blind	14	20.9	11	78.6	3	21.4	10	71.4	1	7.1	3	21.4	2	14.3	12	85.7
	Placebo	Double-blind	10	14.9	8	80.0	2	20.0	7	70.0			3	30.0	1	10.0	9	90.0
		Single-blind	5	7.5	3	60.0	2	40.0	5	100.0							5	100.0
	Before/after	Open	1	1.5	1	100.0			1	100.0							1	100.0
		Single-blind	1	1.5	1	100.0			1	100.0							1	100.0
	None	Open	7	10.4	5	71.4	2	28.6	2	28.6			5	71.4	5	71.4	2	28.6
		Single-blind	4	6.0	4	100.0			2	50.0	1	25.0	1	25.0	1	25.0	3	75.0
		All	67	100.0	53	79.1	14	20.9	39	58.2	2	3.0	26	38.8	18	26.9	49	73.1
Non-random. controlled	Active	Open	4	17.4	4	100.0			4	100.0							4	100.0
		Before/after	2	8.7	2	100.0			2	100.0					1	50.0	1	50.0
	None	Double-blind	1	4.3			1	100.0	1	100.0					1	100.0		
		Open	16	69.6	9	56.2	7	43.8	9	56.2	1	6.2	6	37.5	9	56.2	7	43.8
		All	23	100.0	15	65.2	8	34.8	16	69.6	1	4.3	6	26.1	11	47.8	12	52.2
Not applicable	Active	Open	6	10.7	3	50.0	3	50.0	4	66.7	1	16.7	1	16.7	1	16.7	5	83.3
		Single-blind	1	1.8			1	100.0	1	100.0					1	100.0		
	Placebo	Open	1	1.8	1	100.0			1	100.0							1	100.0
		Before/after	6	10.7	4	66.7	2	33.3	5	83.3			1	16.7	2	33.3	4	66.7
	None	Open	40	71.4	23	57.5	17	42.5	26	65.0	1	2.5	13	32.5	18	45.0	22	55.0
		Single-blind	2	3.6	1	50.0	1	50.0	1	50.0			1	50.0	1	50.0	1	50.0
		All	56	100.0	32	57.1	24	42.9	38	67.9	2	3.6	16	28.6	23	41.1	33	58.9
Total number			146	100.0	100	68.5	46	31.5	93	63.7	5	3.4	48	32.9	52	35.6	94	64.4

The total number of 146 research projects consist of 137 medical device trials and 9 trials on a combination medicinal product and medical device.

Table 24: Stratification of **medical device trials** by participant arms/distribution.

Allocation	Control	Masking	Participant arms/distribution									
			Total		Single-arm		Parallel groups		Crossover		Other or n/a	
			N	% _{col}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}
Randomised controlled	Active	Open	24	35.8			22	91.7	2	8.3		
		Double-blind	1	1.5			1	100.0				
		Single-blind	14	20.9			14	100.0				
	Placebo	Double-blind	10	14.9			6	60.0	4	40.0		
		Single-blind	5	7.5	1	20.0			3	60.0	1	20.0
	Before/after	Open	1	1.5			1	100.0				
		Single-blind	1	1.5			1	100.0				
	None	Open	7	10.4	2	28.6	5	71.4				
		Single-blind	4	6.0	1	25.0	3	75.0				
All		67	100.0	4	6.0	53	79.1	9	13.4	1	1.5	
Non-random. controlled	Active	Open	4	17.4	2	50.0			1	25.0	1	25.0
		Before/after	2	8.7	2	100.0						
	None	Double-blind	1	4.3	1	100.0						
		Open	16	69.6	8	50.0	3	18.8	1	6.2	4	25.0
		All	23	100.0	13	56.5	3	13.0	2	8.7	5	21.7
Not applicable	Active	Open	6	10.7	3	50.0	1	16.7			2	33.3
		Single-blind	1	1.8					1	100.0		
	Placebo	Open	1	1.8	1	100.0						
		Before/after	6	10.7	4	66.7	1	16.7	1	16.7		
	None	Open	40	71.4	18	45.0					22	55.0
		Single-blind	2	3.6	2	100.0						
All	56	100.0	28	50.0	2	3.6	2	3.6	24	42.9		
Total number			146	100.0	45	30.8	58	39.7	13	8.9	30	20.5

Table 25: Stratification of **medical device trials** by information on standard use of medical devices with conformity marking and details for non-standard use as well as whether first in man.

Allocation	Control	Masking	CE-marked + standard use						Details of medical device					
			Total		Yes		No		Not CE-marked		CE but non-intended use		First in man	
			N	%col	n	%row	n	%row	n	%row	n	%row	n	%row
Randomised controlled	Active	Open	24	35.8	18	75.0	3	12.5	1	33.3	2	66.7	3	12.5
		Double-blind	1	1.5	1	100.0								
		Single-blind	14	20.9	10	71.4	1	7.1	1	100.0				
	Placebo	Double-blind	10	14.9	8	80.0	2	20.0	1	50.0	1	50.0	2	20.0
		Single-blind	5	7.5	3	60.0	2	40.0	2	100.0			2	40.0
	Before/after	Open	1	1.5	1	100.0								
		Single-blind	1	1.5										
	None	Open	7	10.4	6	85.7	1	14.3	1	100.0				
		Single-blind	4	6.0	4	100.0								
		All	67	100.0	51	76.1	9	13.4	6	66.7	3	33.3	7	10.4
Non-random. controlled	Active	Open	4	17.4	4	100.0								
		Before/after	2	8.7	2	100.0								
	None	Double-blind	1	4.3			1	100.0	1	100.0				
		Open	16	69.6	10	62.5	6	37.5	5	83.3	1	16.7	5	31.2
		All	23	100.0	16	69.6	7	30.4	6	85.7	1	14.3	5	21.7
Not applicable	Active	Open	6	10.7	4	66.7	1	16.7	1	100.0			1	16.7
		Single-blind	1	1.8			1	100.0	1	100.0				
	Placebo	Open	1	1.8	1	100.0								
		Before/after	6	10.7	4	66.7	2	33.3	2	100.0			4	66.7
	None	Open	40	71.4	22	55.0	17	42.5	13	76.5	4	23.5	14	35.0
		Single-blind	2	3.6	1	50.0	1	50.0	1	100.0			1	50.0
		All	56	100.0	32	57.1	22	39.3	18	81.8	4	18.2	20	35.7
Total number			146	100.0	99	67.8	38	26.0	30	78.9	8	21.1	32	21.9

Note: 3 of 99 medical device trials with 'standard use' are risk category 'C' the rest is 'A', explaining potential discrepancies to Table 11.

4.4.2.3 Subgroup “Other clinical trials” (ClinO Art 61)

Table 26: Stratification of **other clinical trials** by risk category, study design and initiator of the research project. The classification of clinical trials according to allocation, control and masking technique is BASEC-specific.

Allocation	Control	Masking	Risk category						Study design						Initiator			
			Total		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}
Randomised controlled	Active	Open	35	32.7	27	77.1	8	22.9	17	48.6	7	20.0	11	31.4	1	2.9	34	97.1
		Double-blind	4	3.7	3	75.0	1	25.0	4	100.0							4	100.0
		Single-blind	17	15.9	16	94.1	1	5.9	12	70.6	2	11.8	3	17.6			17	100.0
	Placebo	Open	6	5.6	5	83.3	1	16.7	5	83.3			1	16.7			6	100.0
		Double-blind	9	8.4	5	55.6	4	44.4	9	100.0							9	100.0
		Single-blind	10	9.3	7	70.0	3	30.0	8	80.0	1	10.0	1	10.0			10	100.0
	Before/after	Open	6	5.6	6	100.0			4	66.7	1	16.7	1	16.7			6	100.0
		Single-blind	3	2.8	2	66.7	1	33.3	2	66.7			1	33.3			3	100.0
	Dosage	Open	2	1.9	1	50.0	1	50.0	1	50.0			1	50.0			2	100.0
		Single-blind	2	1.9	2	100.0			2	100.0							2	100.0
	None	Open	5	4.7	4	80.0	1	20.0	4	80.0			1	20.0			5	100.0
		Double-blind	2	1.9	2	100.0			2	100.0							2	100.0
		Single-blind	6	5.6	5	83.3	1	16.7	6	100.0							6	100.0
		All	107	100.0	85	79.4	22	20.6	76	71.0	11	10.3	20	18.7	1	0.9	106	99.1
Non-random. controlled	Active	Open	4	26.7	4	100.0			4	100.0							4	100.0
		Before/after	5	33.3	5	100.0			4	80.0	1	20.0					5	100.0
	None	Open	6	40.0	5	83.3	1	16.7	4	66.7	1	16.7	1	16.7			6	100.0
		All	15	100.0	14	93.3	1	6.7	12	80.0	2	13.3	1	6.7			15	100.0
Not applicable	Active	Open	2	4.5	2	100.0			2	100.0							2	100.0
		Double-blind	1	2.3	1	100.0			1	100.0							1	100.0
	Before/after	Open	6	13.6	6	100.0			6	100.0							6	100.0
		None	32	72.7	25	78.1	7	21.9	28	87.5	1	3.1	3	9.4	4	12.5	28	87.5
	None	Double-blind	1	2.3	1	100.0			1	100.0							1	100.0
		Single-blind	2	4.5	2	100.0			2	100.0							2	100.0
All	44	100.0	37	84.1	7	15.9	40	90.9	1	2.3	3	6.8	4	9.1	40	90.9		
Total number			166	100.0	136	81.9	30	18.1	128	77.1	14	8.4	24	14.5	5	3.0	161	97.0

Table 27: Stratification of **other clinical trials** by participant arms/distribution.

Allocation	Control	Masking	Participant arms/distribution									
			Total		Single-arm		Parallel groups		Crossover		Other or n/a	
			N	% _{col}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}
Randomised controlled	Active	Open	35	32.7	1	2.9	31	88.6	3	8.6		
		Double-blind	4	3.7			3	75.0			1	25.0
		Single-blind	17	15.9	2	11.8	14	82.4	1	5.9		
	Placebo	Open	6	5.6			5	83.3			1	16.7
		Double-blind	9	8.4			4	44.4	5	55.6		
		Single-blind	10	9.3			8	80.0	2	20.0		
	Before/after	Open	6	5.6			5	83.3	1	16.7		
		Single-blind	3	2.8	1	33.3	1	33.3			1	33.3
	Dosage	Open	2	1.9			1	50.0	1	50.0		
		Single-blind	2	1.9			1	50.0	1	50.0		
	None	Open	5	4.7			3	60.0	2	40.0		
		Double-blind	2	1.9			1	50.0	1	50.0		
		Single-blind	6	5.6			4	66.7	2	33.3		
		All	107	100.0	4	3.7	81	75.7	19	17.8	3	2.8
	Non-random. controlled	Active	Open	4	26.7	1	25.0	3	75.0			
Before/after		Open	5	33.3			1	20.0	1	20.0	3	60.0
None		Open	6	40.0	1	16.7			1	16.7	4	66.7
All			15	100.0	2	13.3	4	26.7	2	13.3	7	46.7
Not applicable	Active	Open	2	4.5			1	50.0	1	50.0		
	Placebo	Double-blind	1	2.3	1	100.0						
	Before/after	Open	6	13.6	1	16.7	1	16.7	1	16.7	3	50.0
	None	Open	32	72.7	11	34.4	1	3.1	1	3.1	19	59.4
		Double-blind	1	2.3							1	100.0
		Single-blind	2	4.5	1	50.0					1	50.0
All		44	100.0	14	31.8	3	6.8	3	6.8	24	54.5	
Total number			166	100.0	20	12.0	88	53.0	24	14.5	34	20.5

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

Table 28: 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	106	14.7	103	97.2	3	2.8	80	75.5	10	9.4	16	15.1	1	0.9	105	99.1
Registry / Quality control ¹	56	7.8	55	98.2	1	1.8	33	58.9	3	5.4	20	35.7	10	17.9	46	82.1
Case control study	47	6.5	43	91.5	4	8.5	41	87.2	3	6.4	3	6.4	1	2.1	46	97.9
Other or n/a ²	511	71.0	496	97.1	15	2.9	393	76.9	41	8.0	77	15.1	45	8.8	466	91.2
	720	100.0	697	96.8	23	3.2	547	76.0	57	7.9	116	16.1	57	7.9	663	92.1

¹ Only quality control studies under the HRA.

² This group also includes projects declared as ‘observational study’ before this option was disabled on August 21, 2017.

Table 29: Stratification of **research projects involving persons, but not a clinical trial**, by whether the research project was solely or principally designed to obtain a degree - and if yes, what degree.

Type of research project	Total		Primarily for degree		What degree (multiple answers possible)					
	N	%col	n	%row	MD/PhD thesis		Master		Other degree	
					n	%row	n	%row	n	%row
Cohort study	106	14.7	25	23.6	14	56.0	10	40.0	1	4.0
Registry / Quality control	56	7.8	15	26.8	6	40.0	8	53.3	1	6.7
Case control study	47	6.5	10	21.3	5	50.0	5	50.0		
Other or n/a	511	71.0	166	32.5	69	41.6	89	53.6	11	6.6
	720	100.0	216	30.0	94	43.5	112	51.9	13	6.0

Table 30: Stratification of **research projects involving persons, but not a clinical trial**, by ethics committee.

Type of research project	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
Cohort study	106	14.7	25	15.2	29	16.2	15	10.1	10	12.3	17	18.5	6	20.7	4	15.4
Registry / Quality control	56	7.8	19	11.6	18	10.1	3	2.0	6	7.4	3	3.3	2	6.9	5	19.2
Case control study	47	6.5	14	8.5	7	3.9	14	9.4	5	6.2	7	7.6				
Other or n/a	511	71.0	106	64.6	125	69.8	117	78.5	60	74.1	65	70.7	21	72.4	17	65.4
	720	100.0	164	100.0	179	100.0	149	100.0	81	100.0	92	100.0	29	100.0	26	100.0

Table 31: Stratification of **research projects involving persons, but not a clinical trial**, by review procedure and first decision.

Type of research project	Review procedure									First decision						
	Total		Ordinary		Simplified		Presidential		Approved		Charges		Conditions		Declined	
	N	% _{col}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}	n	% _{row}
Cohort study	106	14.7	12	11.3	89	84.0	5	4.7	4	3.8	29	27.4	73	68.9		
Registry / Quality control	56	7.8	7	12.5	44	78.6	5	8.9	1	1.8	20	35.7	35	62.5		
Case control study	47	6.5	4	8.5	41	87.2	2	4.3			12	25.5	35	74.5		
Other or n/a	511	71.0	50	9.8	454	88.8	7	1.4	20	3.9	176	34.4	314	61.4	1	0.2
	720	100.0	73	10.1	628	87.2	19	2.6	25	3.5	237	32.9	457	63.5	1	0.1

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

4.4.4 Subgroup “Further use of data/biological material” - research covered by HRO Chapter 3

Table 32: Overview of characteristics of all approved ‘further use’ projects.

		n	%
Genetic data / biol. material	Yes	173	19.2
	No	726	80.8
Coding (HRO Art. 25-27)	Coded	412	45.8
	Open, non-coded	487	54.2
Consent (HRO Art. 28-32)	Prior consent exists	213	23.7
	Consent to be sought ¹	130	14.5
	No consent for some/all data (HRA Art 34)	556	61.8
Combined projects ²	Further use project	854	95.0
	Part of clinical trial	16	1.8
	Part of non-clinical research project	29	3.2
Total number		899	100.0

¹ Consent to be sought means that the ECs do not apply HRA Art 34 and request the researchers to obtain the consent

² 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).

4.4.4.1 Description and derivation of stratification variables applied to “further use” projects

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: The BASEC question “Consent for further use of data/material” can be answered with “Prior consent exists”, “Consent to be sought” or “No consent for some or all of the samples/data”. Applicants are informed that if they “Have an informed consent from before the human research act (2014), check whether it is conformable to law (Articles 28-32 HRO). If not, the consent is not sufficient. If there is pre-existing consent for some samples/records, but not for others, Art 34 HRA may apply”.

A “Further use” project nested into a clinical trial or a HRO research project involving persons requires an additional justification statement to be provided: “Justification and information for the use of Art. 34 HRA”, “Confirmation that no data/samples will be used, if a document refusal exists” and “Justification of interest of research”.

Table 33: 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. Approved applications for which Art. 34 HRA has been requested are listed separately at the bottom (total of all projects with 'No consent for some/all data').

Genetic D+M	Coded	Consent	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	Prior consent exists	59	48.8	43	72.9			16	27.1	24	40.7	35	59.3
		Consent to be sought	26	21.5	17	65.4	1	3.8	8	30.8	7	26.9	19	73.1
		No consent for some/all data (HRA Art 34)	36	29.8	27	75.0	1	2.8	8	22.2	2	5.6	34	94.4
		All	121	100.0	87	71.9	2	1.7	32	26.4	33	27.3	88	72.7
	Open, non-coded	Prior consent exists	7	13.5	5	71.4			2	28.6			7	100.0
		Consent to be sought	8	15.4	7	87.5			1	12.5	1	12.5	7	87.5
		No consent for some/all data (HRA Art 34)	37	71.2	35	94.6	1	2.7	1	2.7			37	100.0
		All	52	100.0	47	90.4	1	1.9	4	7.7	1	1.9	51	98.1
	All		173	100.0	134	77.5	3	1.7	36	20.8	34	19.7	139	80.3
No	Coded	Prior consent exists	54	18.6	41	75.9	3	5.6	10	18.5	2	3.7	52	96.3
		Consent to be sought	42	14.4	33	78.6	4	9.5	5	11.9	2	4.8	40	95.2
		No consent for some/all data (HRA Art 34)	195	67.0	164	84.1	12	6.2	19	9.7	1	0.5	194	99.5
		All	291	100.0	238	81.8	19	6.5	34	11.7	5	1.7	286	98.3
	Open, non-coded	Prior consent exists	93	21.4	86	92.5	1	1.1	6	6.5			93	100.0
		Consent to be sought	54	12.4	47	87.0	2	3.7	5	9.3	1	1.9	53	98.1
		No consent for some/all data (HRA Art 34)	288	66.2	262	91.0	11	3.8	15	5.2	2	0.7	286	99.3
		All	435	100.0	395	90.8	14	3.2	26	6.0	3	0.7	432	99.3
	All		726	100.0	633	87.2	33	4.5	60	8.3	8	1.1	718	98.9
		Total HRA Art 34	556	100.0	488	87.8	25	4.5	43	7.7	5	0.9	551	99.1
Total number			899	100.0	767	85.3	36	4.0	96	10.7	42	4.7	857	95.3

The total number of 899 research projects consist of 854 standard 'further use' projects and 45 ClinO or research with persons (HRO) projects that include further use of data/biological material.

Table 34: Stratification of projects involving further use of data/biological material. 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. Approved applications for which Art. 34 HRA has been requested are listed separately at the bottom (total of all projects with 'No consent for some/all data') by whether the research project was solely or principally designed to obtain a degree - and if yes, what degree.

Genetic D+M	Coded	Consent	Total		Primarily for degree		What degree (multiple answers possible)						
			N	%col	n	%row	MD/PhD thesis		Master		Other degree		
							n	%row	n	%row	n	%row	
Yes	Coded	Prior consent exists	59	48.8	6	10.2	6	100.0					
		Consent to be sought	26	21.5	3	11.5	3	100.0	1	33.3			
		No consent for some/all data (HRA Art 34)	36	29.8	7	19.4	4	57.1	2	28.6	1	14.3	
		All	121	100.0	16	13.2	13	81.2	3	18.8	1	6.2	
	Open, non-coded	Prior consent exists	7	13.5									
		Consent to be sought	8	15.4									
		No consent for some/all data (HRA Art 34)	37	71.2	14	37.8	8	57.1	6	42.9	2	14.3	
		All	52	100.0	14	26.9	8	57.1	6	42.9	2	14.3	
		All	173	100.0	30	17.3	21	70.0	9	30.0	3	10.0	
	No	Coded	Prior consent exists	54	18.6	21	38.9	9	42.9	10	47.6	2	9.5
			Consent to be sought	42	14.4	13	31.0	8	61.5	6	46.2		
			No consent for some/all data (HRA Art 34)	195	67.0	84	43.1	35	41.7	44	52.4	7	8.3
All			291	100.0	118	40.5	52	44.1	60	50.8	9	7.6	
Open, non-coded		Prior consent exists	93	21.4	35	37.6	10	28.6	24	68.6	3	8.6	
		Consent to be sought	54	12.4	19	35.2	6	31.6	12	63.2	2	10.5	
		No consent for some/all data (HRA Art 34)	288	66.2	149	51.7	63	42.3	87	58.4	4	2.7	
		All	435	100.0	203	46.7	79	38.9	123	60.6	9	4.4	
		All	726	100.0	321	44.2	131	40.8	183	57.0	18	5.6	
		Total HRA Art 34	556	100.0	254	45.7	110	43.3	139	54.7	14	5.5	
		Total number	899	100.0	351	39.0	152	43.3	192	54.7	21	6.0	

Table 35: Stratification of **projects involving further use of data/biological material** by ethics committee.

Consent	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}
Prior consent exists	213	23.7	87	32.5	50	24.8	23	15.1	35	27.1	13	14.8	5	14.3	0	0.0
Consent to be sought	130	14.5	40	14.9	39	19.3	14	9.2	15	11.6	8	9.1	5	14.3	9	36.0
No consent for some/all data (HRA Art 34)	556	61.8	141	52.6	113	55.9	115	75.7	79	61.2	67	76.1	25	71.4	16	64.0
	899	100.0	268	100.0	202	100.0	152	100.0	129	100.0	88	100.0	35	100.0	25	100.0

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

Table 36: Stratification of projects involving further use of data/biological material. 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. Approved applications for which Art. 34 HRA has been requested are listed separately at the bottom (total of all projects with 'No consent for some/all data') by review procedure and first decision.

Genetic D+M	Coded	Consent	Review procedure									First decision					
			Total		Ordinary		Simplified		Presidential		Approved		Charges		Conditions		
			N	%col	n	%row	n	%row	n	%row	n	%row	n	%row	n	%row	
Yes	Coded	Prior consent exists	59	48.8	3	5.1	15	25.4	41	69.5	31	52.5	19	32.2	9	15.3	
		Consent to be sought	26	21.5	11	42.3	9	34.6	6	23.1	4	15.4	8	30.8	14	53.8	
		No consent for some/all data (HRA Art 34)	36	29.8	5	13.9	27	75.0	4	11.1	8	22.2	16	44.4	12	33.3	
		All	121	100.0	19	15.7	51	42.1	51	42.1	43	35.5	43	35.5	35	28.9	
	Open, non-coded	Prior consent exists	7	13.5	1	14.3	1	14.3	5	71.4	3	42.9	1	14.3	3	42.9	
		Consent to be sought	8	15.4	1	12.5			7	87.5	1	12.5	1	12.5	6	75.0	
		No consent for some/all data (HRA Art 34)	37	71.2	1	2.7	36	97.3			3	8.1	12	32.4	22	59.5	
		All	52	100.0	3	5.8	37	71.2	12	23.1	7	13.5	14	26.9	31	59.6	
	No	Coded	Prior consent exists	54	18.6			27	50.0	27	50.0	17	31.5	18	33.3	19	35.2
			Consent to be sought	42	14.4	5	11.9	26	61.9	11	26.2	3	7.1	14	33.3	25	59.5
			No consent for some/all data (HRA Art 34)	195	67.0	12	6.2	177	90.8	6	3.1	51	26.2	62	31.8	82	42.1
			All	291	100.0	17	5.8	230	79.0	44	15.1	71	24.4	94	32.3	126	43.3
Open, non-coded		Prior consent exists	93	21.4			15	16.1	78	83.9	39	41.9	20	21.5	34	36.6	
		Consent to be sought	54	12.4	2	3.7	19	35.2	33	61.1	16	29.6	12	22.2	26	48.1	
		No consent for some/all data (HRA Art 34)	288	66.2	2	0.7	281	97.6	5	1.7	48	16.7	100	34.7	140	48.6	
		All	435	100.0	4	0.9	315	72.4	116	26.7	103	23.7	132	30.3	200	46.0	
Total HRA Art 34		All		726	100.0	21	2.9	545	75.1	160	22.0	174	24.0	226	31.1	326	44.9
				556	100.0	20	3.6	521	93.7	15	2.7	110	19.8	190	34.2	256	46.0
				899	100.0	43	4.8	633	70.4	223	24.8	224	24.9	283	31.5	392	43.6

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

4.5 Information about the parties involved in human research projects

4.5.1 Project initiator and funding

Description of distinctive features of the results:

Table 37 shows that investigator-initiated studies are mostly publicly funded and even when the funding comes from industry, a PI from academia is the initiator. Conversely, industry-initiated studies tend to be (purely) industry-funded and if not, mostly an industry sponsor is involved. This table indicates that the question “Who initiated the project?” is a good proxy for distinguishing between industry-driven projects and investigator-initiated studies.

Table 37: Answers to the question “Who initiated the project?” stratified by the main financing source.

Initiator	Financing (main source)	n	% _{col}
Investigator	Public, other	1146	64.7
	Industry	85 ¹	4.8
	Universities/hospitals	278	15.7
	Private (non-industry)	144	8.1
	SNF	119	6.7
	All	1772	100.0
Industry	Public, other	53 ²	19.5
	Industry	219 ³	80.5
	Universities/hospitals	0	0.0
	Private (non-industry)	0	0.0
	SNF	0	0.0
	All	272	100.0
Other	Public, other	46	70.8
	Industry	3	4.6
	Universities/hospitals	5	7.7
	Private (non-industry)	11	16.9
	SNF	0	0.0
	All	65 ⁴	100.0

¹ Applicants almost exclusively from academic institutions.

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

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

⁴ 27 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.

4.5.2 Applicant of the project

Table 38: Overview of the applicants of the project.

Applicant	Type of research	n	%_{col}
Project leader / PI ¹	Clinical trial	293	16.8
	Research w/ persons	629	36.1
	Further use	797	45.8
	Deceased, embryos	22	1.3
	Total	1741	100.0
Sponsor	Clinical trial	106	56.4
	Research w/ persons	58	30.9
	Further use	24	12.8
	Deceased, embryos	0	0.0
	Total	188	100.0
CRO	Clinical trial	61	67.8
	Research w/ persons	20	22.2
	Further use	8	8.9
	Deceased, embryos	1	1.1
	Total	90	100.0
Sponsor's representative in CH	Clinical trial	52	57.8
	Research w/ persons	13	14.4
	Further use	25	27.8
	Deceased, embryos	0	0.0
	Total	90	100.0
Overall	Clinical trial	512	24.3
	Research w/ persons	720	34.1
	Further use	854	40.5
	Deceased, embryos	23	1.1
	Total	2109	100.0

¹ 'Project leader' includes sponsor responsibility

5 Response times and review procedure (AS2)

5.1 Definitions

As described in the introduction on page 7, the data analysed in the following are self-reported by the individual ECs. As outlined in Figure 8, the ECs manually enter the dates of milestones for all individual applications into BASEC. Thereby the only two periods that solely depend on the EC are: 1) reception (initial submission) to first reaction and 2) application data complete to first decision. The interval between “first reaction” 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.

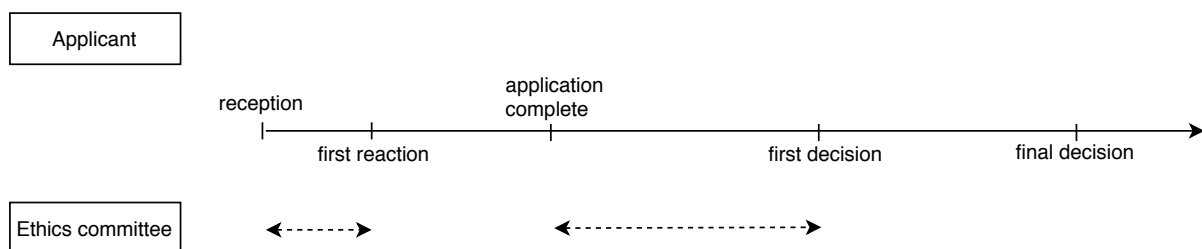


Figure 8: Overview of dates of milestones reported by the ECs for each application. The only two periods that purely depend on the EC are denoted.

5.2 Overview of median response times

Description of distinctive features of the results:

By inspecting Table 39 next page, differences in response times and type of procedures between EK become apparent. These are primarily explained by their different modes of operation and by how response times and status changes are reported but potentially also by regional differences in the type of submitted research projects.

Table 39: Overview of response times in days - median (M) and inter-quartile range (IQR) per review procedure and ethics committee.

Procedure	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
Ordinary	KEK-ZH	103	17	7	[7, 8]	20	[14, 28]	38	[31, 50]	118	[80, 170]	18	[14, 22]	92	[62, 131]
	EKNZ	67	14	5	[2, 7]	5	[2, 7]	28	[23, 36]	85	[70, 118]	23	[16, 30]	78	[68, 112]
	CER-VD	45	13	5	[3, 6]	5	[4, 7]	29	[24, 37]	125	[78, 158]	23	[17, 28]	112	[70, 153]
	KEK-BE	64	22	3	[1, 5]	5	[2, 10]	30	[22, 46]	128	[87, 204]	22	[16, 28]	110	[77, 166]
	CCER	21	9	3	[1, 8]	8	[3, 13]	43	[33, 45]	164	[112, 230]	34	[26, 34]	164	[99, 222]
	EKOS	17	18	2	[1, 4]	2	[1, 4]	27	[21, 31]	78	[53, 130]	25	[20, 28]	77	[52, 129]
	CE-TI	75	100	7	[6, 7]	7	[7, 8]	31	[22, 41]	53	[28, 104]	21	[13, 30]	46	[18, 94]
	All	392	19	6	[3, 7]	7	[4, 17]	33	[25, 43]	100	[70, 154]	22	[16, 28]	88	[63, 139]
Simplified	KEK-ZH	374	63	7	[7, 8]	21	[14, 29]	37	[29, 49]	70	[47, 102]	14	[10, 21]	42	[27, 76]
	EKNZ	333	70	4	[2, 6]	4	[2, 7]	24	[18, 30]	51	[36, 76]	18	[14, 23]	45	[29, 66]
	CER-VD	268	80	4	[3, 6]	5	[3, 7]	25	[20, 30]	70	[50, 119]	18	[16, 22]	62	[44, 106]
	KEK-BE	228	77	2	[1, 4]	5	[1, 13]	21	[18, 32]	63	[45, 98]	15	[14, 18]	55	[39, 77]
	CCER	209	86	3	[1, 6]	5	[2, 11]	30	[25, 41]	85	[58, 131]	23	[20, 29]	77	[53, 116]
	EKOS	61	66	2	[1, 3]	2	[1, 4]	16	[13, 22]	38	[21, 58]	14	[10, 20]	35	[16, 56]
	CE-TI	0	0		[,]		[,]		[,]		[,]		[,]		[,]
	All	1473	70	5	[2, 7]	6	[3, 18]	27	[20, 38]	64	[44, 100]	17	[14, 22]	54	[35, 85]
Presidential	KEK-ZH	118	20	7	[6, 8]	14	[8, 21]	27	[20, 34]	36	[27, 51]	11	[6, 17]	20	[11, 32]
	EKNZ	74	16	4	[2, 6]	5	[3, 7]	13	[8, 25]	35	[12, 70]	7	[4, 17]	29	[7, 56]
	CER-VD	22	7	5	[2, 6]	6	[5, 12]	28	[18, 36]	53	[28, 59]	12	[10, 23]	37	[20, 54]
	KEK-BE	3	1	2	[2, 2]	2	[2, 12]	37	[25, 38]	37	[25, 56]	14	[12, 25]	14	[12, 43]
	CCER	13	5	3	[2, 4]	4	[2, 9]	13	[9, 15]	13	[9, 15]	5	[4, 11]	5	[4, 11]
	EKOS	14	15	2	[1, 5]	3	[1, 5]	7	[4, 8]	7	[5, 9]	4	[2, 6]	5	[2, 7]
	CE-TI	0	0		[,]		[,]		[,]		[,]		[,]		[,]
	All	244	12	6	[3, 7]	7	[4, 16]	22	[12, 30]	34	[19, 54]	9	[5, 17]	20	[8, 38]
Overall	KEK-ZH	595	100	7	[7, 8]	20	[12, 28]	35	[27, 46]	67	[42, 113]	14	[10, 20]	42	[23, 83]
	EKNZ	474	100	4	[2, 6]	4	[2, 7]	24	[17, 30]	55	[35, 83]	18	[13, 24]	48	[29, 75]
	CER-VD	335	100	5	[3, 6]	5	[4, 7]	26	[20, 33]	72	[52, 126]	19	[15, 23]	65	[46, 112]
	KEK-BE	295	100	3	[1, 5]	5	[2, 12]	22	[19, 36]	75	[51, 127]	15	[14, 21]	63	[43, 98]
	CCER	243	100	3	[1, 6]	5	[2, 11]	30	[24, 42]	88	[57, 136]	23	[20, 30]	78	[52, 118]
	EKOS	92	100	2	[1, 4]	2	[1, 4]	17	[10, 22]	38	[15, 67]	14	[8, 21]	36	[14, 65]
	CE-TI	75	100	7	[6, 7]	7	[7, 8]	31	[22, 41]	53	[28, 104]	21	[13, 30]	46	[18, 94]
	All	2109	100	5	[2, 7]	7	[3, 18]	28	[20, 38]	66	[42, 109]	17	[13, 23]	56	[32, 91]

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

5.3 Stratification of response time by review procedure

5.3.1 Time from status “complete” to first decision

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

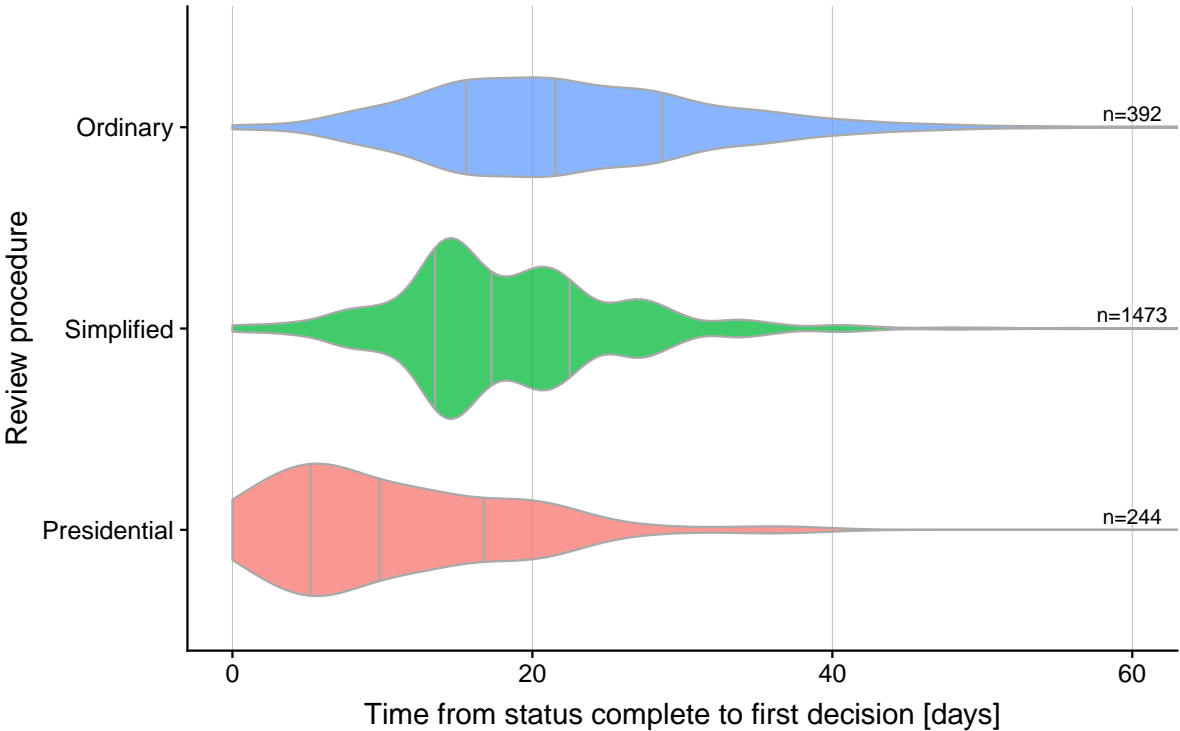


Figure 9: Violin plot (kernel density plot) of the time between status ‘complete’ to the first decision (i.e. the time between submission is considered ‘complete’ to final decision) by review procedure. 19 projects with $t > 60$ days are not shown for layout reasons.

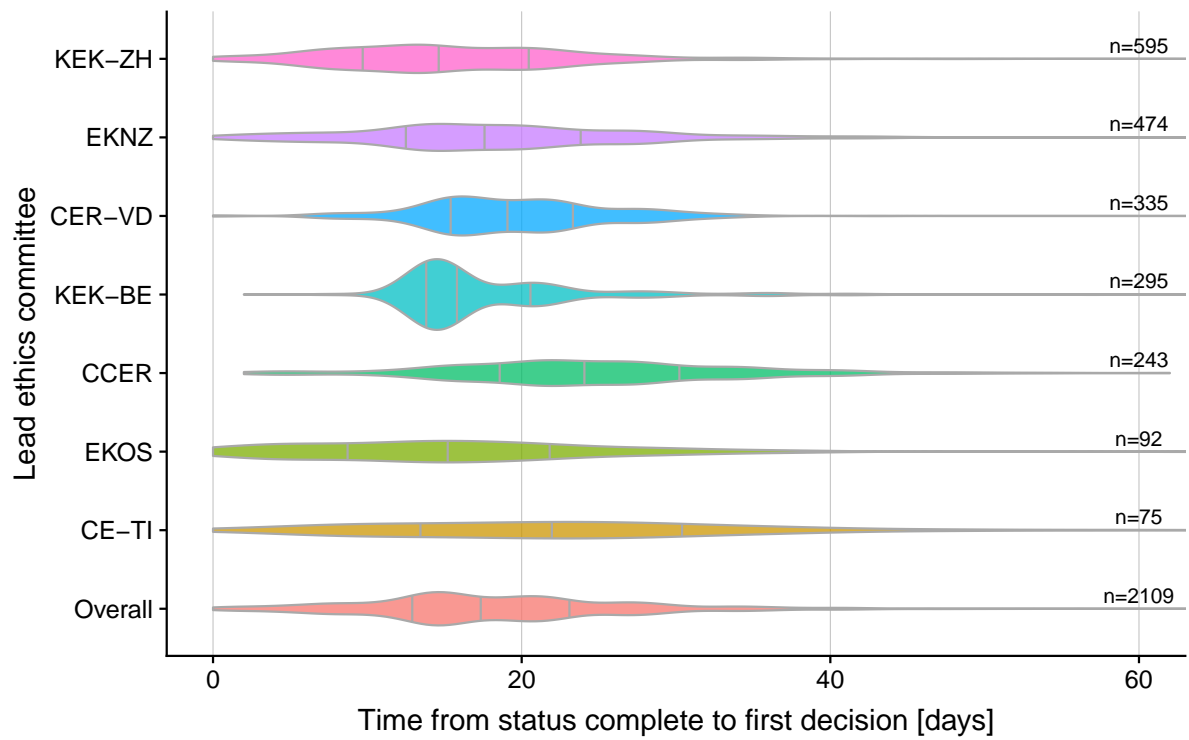


Figure 10: Violin plot of the time between status 'complete' to the first decision by EC. 19 projects with $t > 60$ days are not shown for layout reasons for layout reasons.

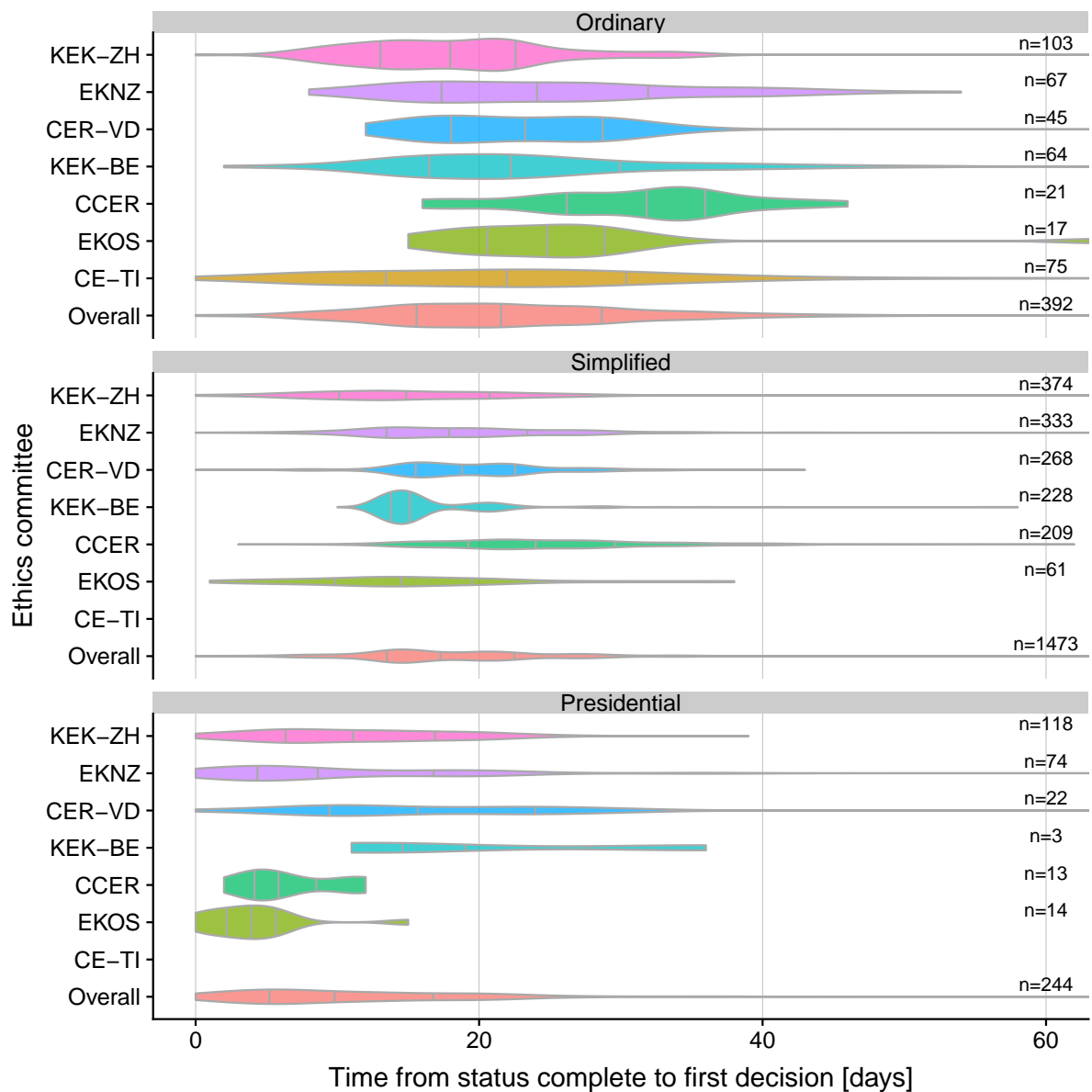


Figure 11: Violin plot of the time between status 'complete' to the first decision by EC and stratified by review procedure. 19 projects with $t > 60$ days are not shown for layout reasons. Note: *CE-TI* typically processes all submissions in a plenary session (ordinary procedure) but with adapted fees.

5.3.2 Time from status “complete” to final decision

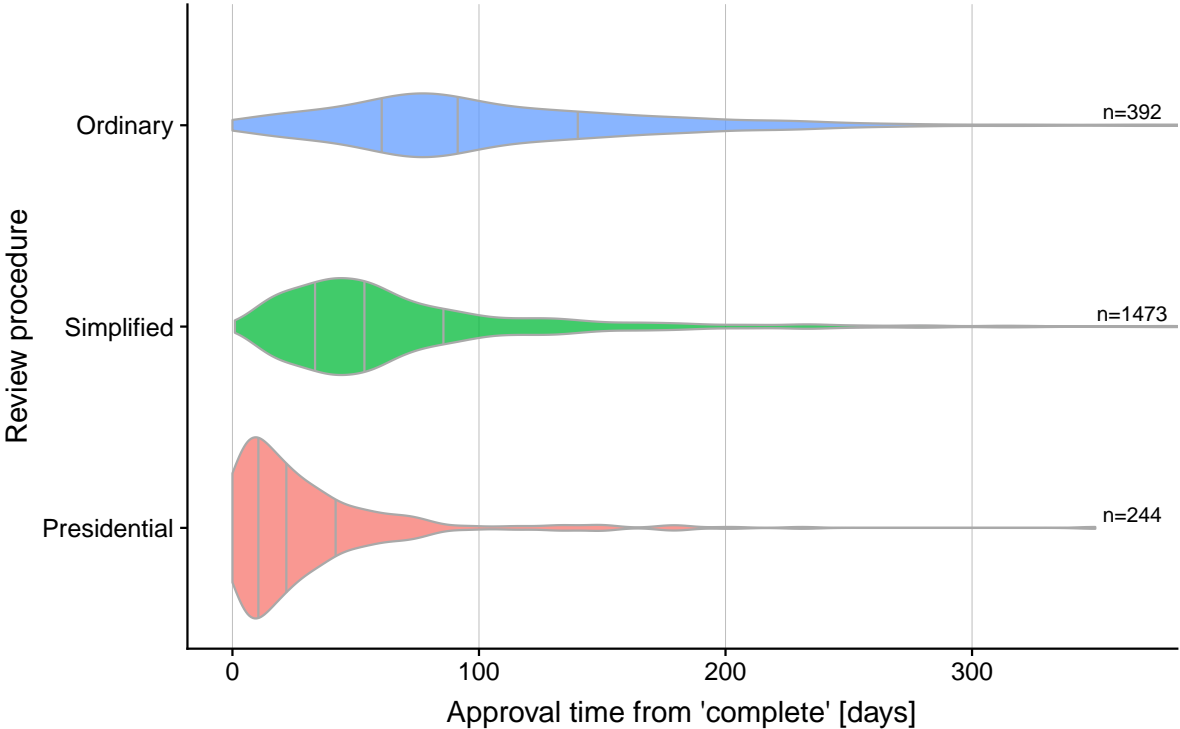


Figure 12: Violin plot of the approval time (i.e. the time between submission is considered 'complete' to final decision) by review procedure. 14 projects with approval time > 1 year are not shown for layout reasons.

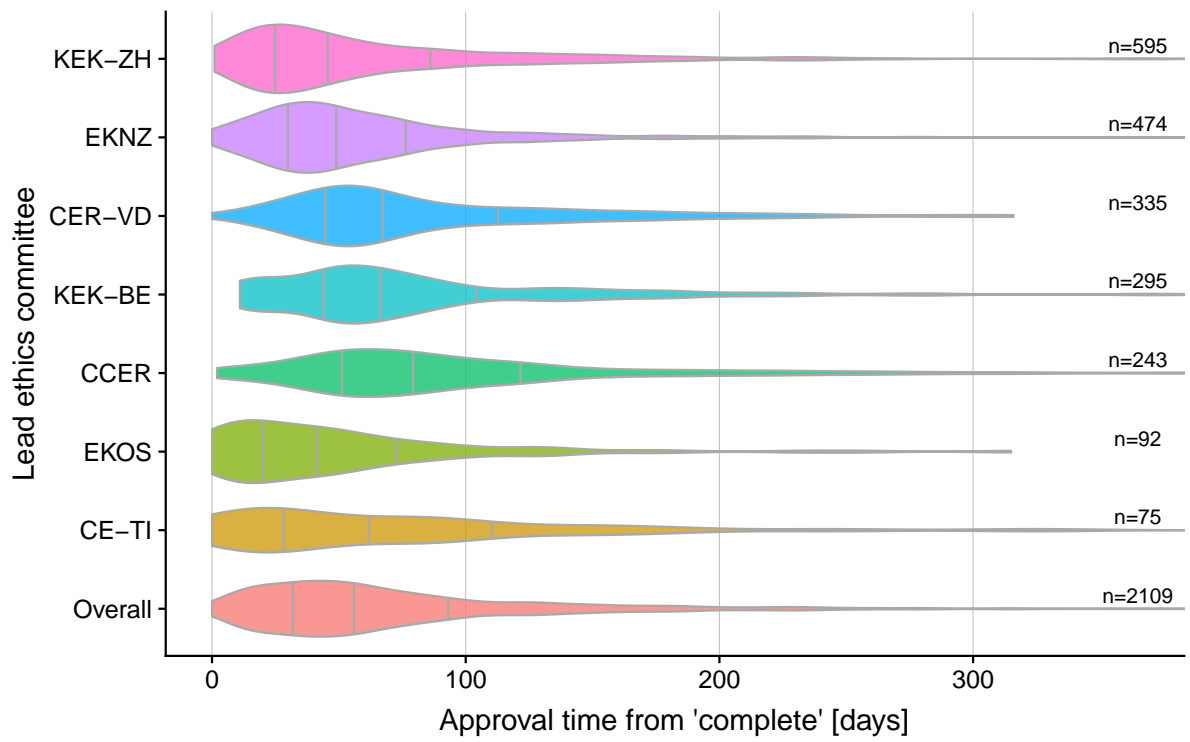


Figure 13: Violin plot of the approval time by EC. 14 projects with approval time > 1 year are not shown for layout reasons.

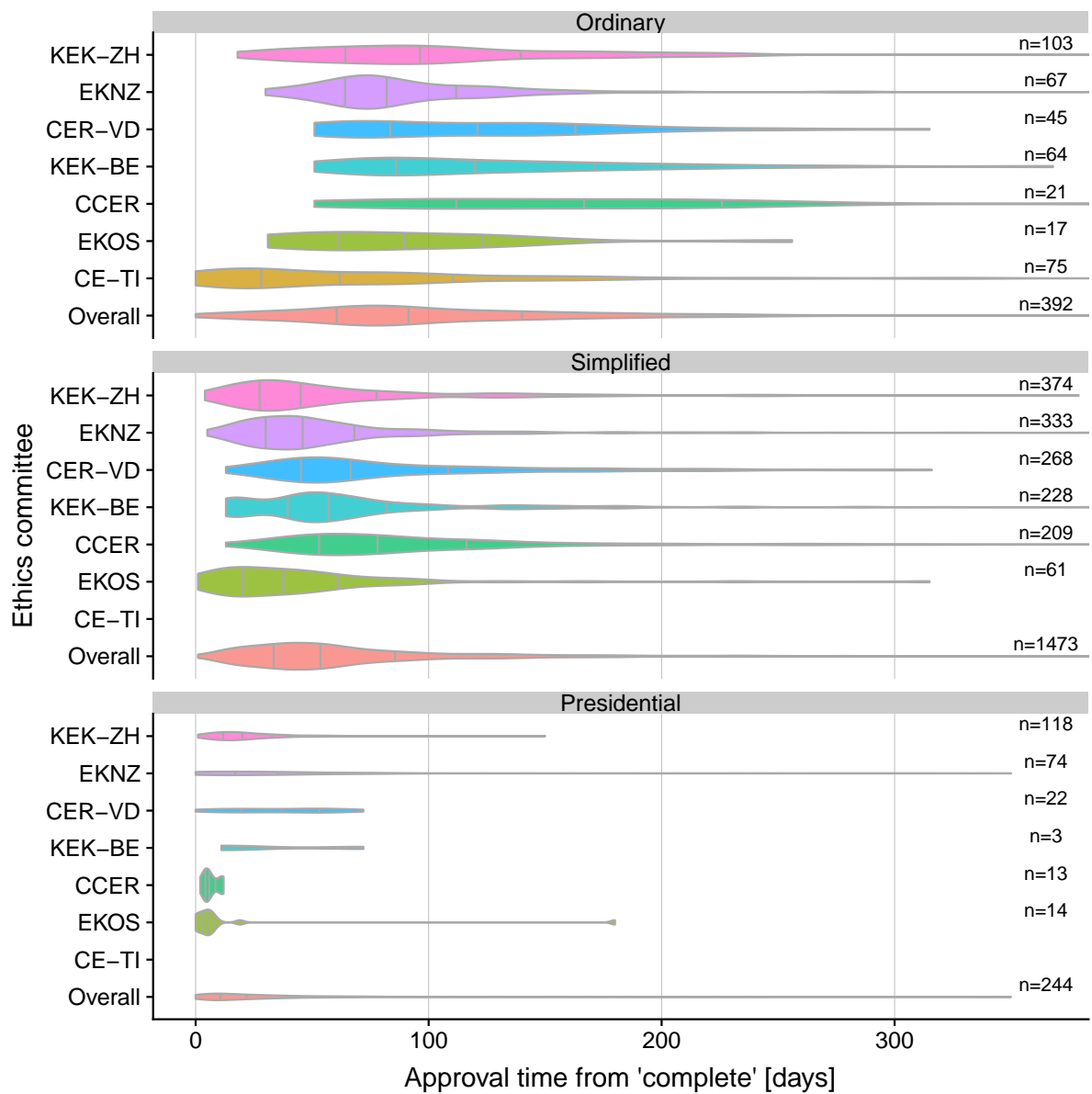


Figure 14: Violin plot of the approval time by EC and stratified by review procedure. 14 projects with approval time > 1 year are not shown for layout reasons.

5.3.3 Time from reception to final decision

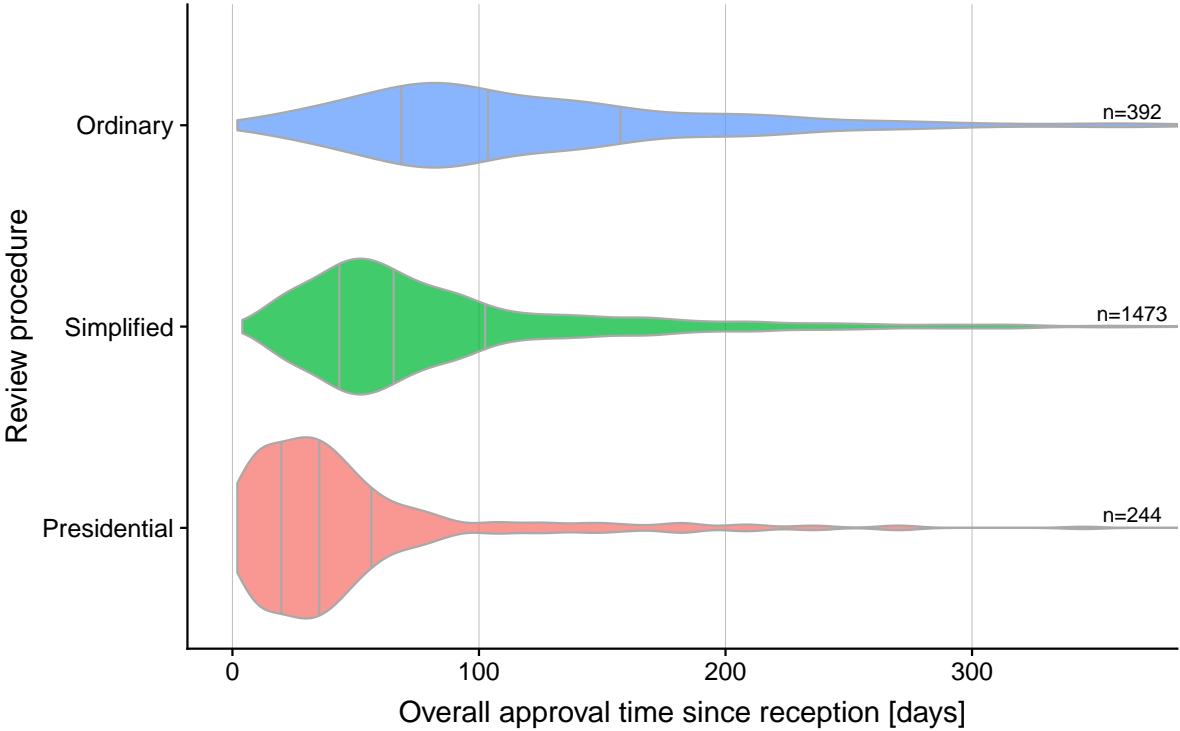


Figure 15: Violin plot of the overall approval time (i.e. the time between reception to final decision) by review procedure. 24 projects with approval time > 1 year are not shown for layout reasons.

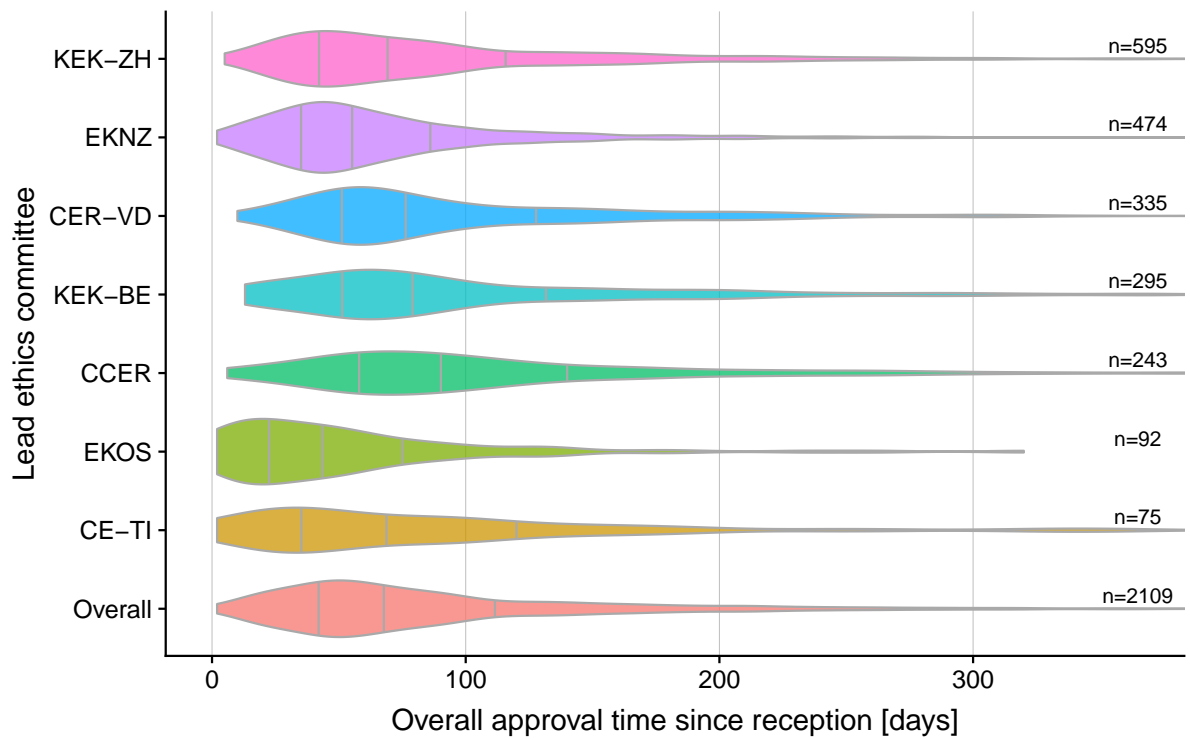


Figure 16: Violin plot of the overall approval time by EC. 24 projects with approval time > 1 year are not shown for layout reasons.

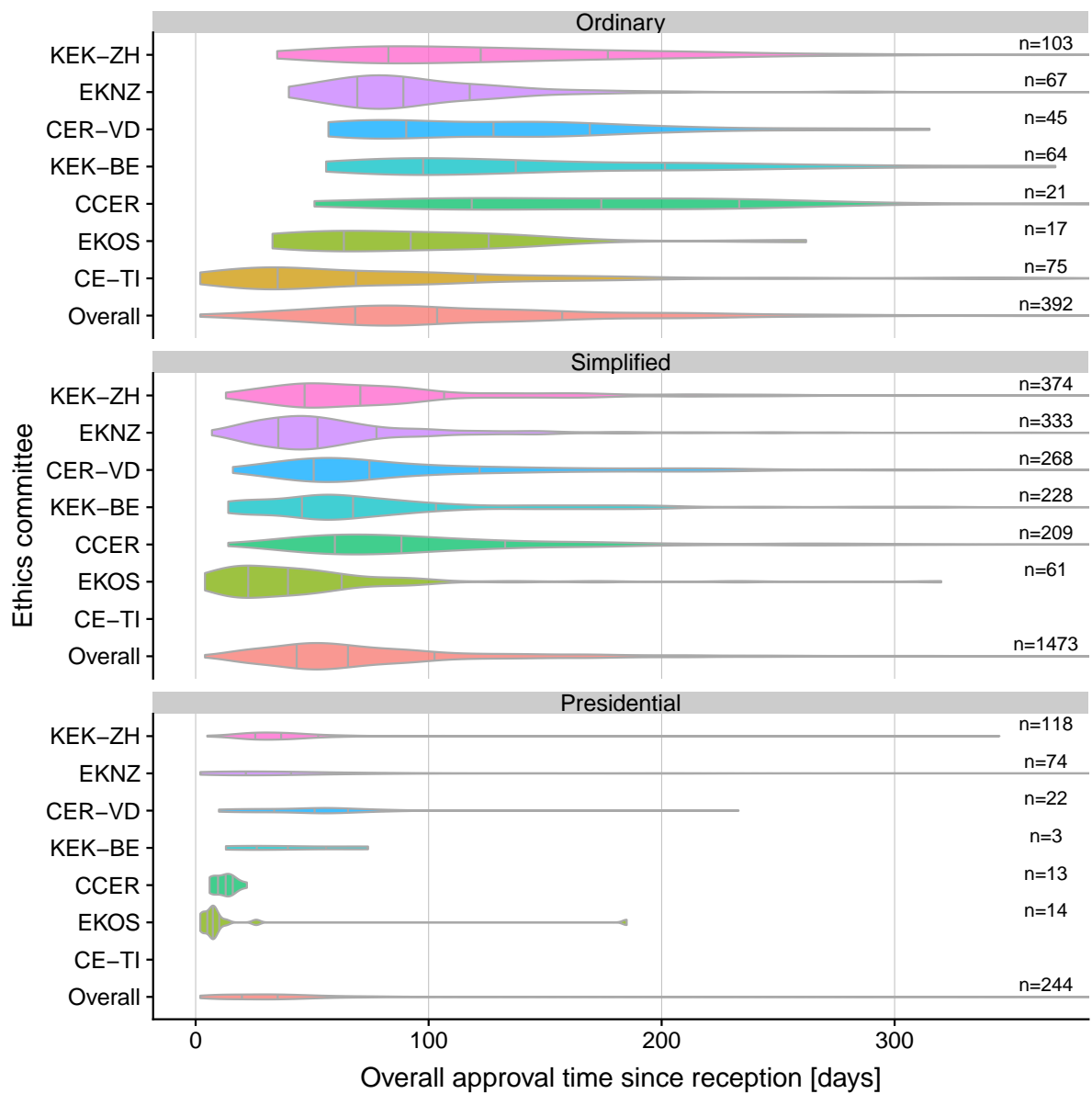


Figure 17: Violin plot of the overall approval time by EC and stratified by review procedure. 24 projects with approval time > 1 year are not shown for layout reasons.

5.4 Stratification of response time by type of research

Table 40: Overview of response time in days - Median (M) and inter-quartile range (IQR) per type of research (3 major groups only) and ethics committee.

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	168	29	7	[7, 8]	22	[16, 36]	40	[32, 55]	99	[71, 160]	16	[11, 22]	81	[43, 122]
	EKNZ	103	22	4	[2, 6]	5	[2, 7]	28	[20, 36]	75	[56, 98]	22	[15, 29]	70	[52, 93]
	CER-VD	38	11	5	[3, 6]	5	[3, 6]	28	[22, 36]	140	[93, 166]	22	[17, 28]	133	[80, 160]
	KEK-BE	86	30	3	[1, 5]	5	[2, 18]	28	[21, 43]	118	[83, 172]	20	[15, 24]	92	[73, 147]
	CCER	58	25	4	[2, 7]	7	[3, 14]	36	[27, 45]	118	[78, 174]	26	[22, 34]	110	[69, 162]
	EKOS	30	33	3	[1, 4]	3	[1, 4]	22	[18, 29]	72	[50, 125]	20	[15, 27]	70	[48, 123]
	CE-TI	29	39	7	[7, 7]	7	[7, 7]	29	[23, 41]	90	[46, 156]	23	[16, 34]	83	[38, 146]
	All	512	25	6	[3, 7]	7	[4, 21]	33	[24, 43]	96	[69, 149]	20	[15, 27]	84	[56, 130]
Research w/ persons	KEK-ZH	164	28	7	[7, 8]	23	[18, 29]	42	[34, 52]	76	[53, 103]	16	[12, 21]	48	[33, 74]
	EKNZ	179	38	4	[2, 6]	4	[2, 7]	25	[19, 30]	60	[42, 92]	19	[14, 25]	54	[36, 78]
	CER-VD	149	45	4	[3, 6]	5	[4, 7]	27	[20, 33]	76	[58, 121]	18	[15, 23]	68	[52, 108]
	KEK-BE	81	28	3	[1, 5]	4	[2, 7]	20	[18, 30]	63	[52, 95]	15	[14, 20]	57	[44, 84]
	CCER	92	39	3	[1, 5]	6	[3, 12]	31	[25, 41]	90	[67, 133]	24	[20, 29]	80	[59, 116]
	EKOS	29	32	2	[1, 3]	2	[1, 4]	15	[13, 21]	40	[25, 57]	14	[10, 20]	37	[22, 56]
	CE-TI	26	35	7	[6, 7]	7	[7, 7]	28	[20, 36]	47	[28, 122]	22	[14, 28]	40	[22, 102]
	All	720	35	5	[2, 7]	6	[3, 18]	28	[21, 40]	70	[49, 105]	19	[14, 23]	58	[39, 91]
Further use	KEK-ZH	257	44	7	[7, 8]	14	[8, 21]	28	[21, 38]	43	[29, 70]	13	[8, 19]	26	[14, 47]
	EKNZ	188	40	4	[2, 6]	4	[2, 7]	20	[13, 27]	40	[23, 60]	14	[8, 20]	32	[19, 52]
	CER-VD	147	44	4	[3, 6]	5	[4, 7]	25	[20, 32]	60	[44, 96]	19	[15, 22]	55	[38, 86]
	KEK-BE	124	43	2	[1, 4]	5	[1, 14]	21	[19, 33]	61	[32, 91]	15	[14, 18]	50	[21, 72]
	CCER	85	36	3	[1, 5]	5	[2, 10]	28	[22, 37]	61	[41, 99]	22	[16, 28]	55	[35, 90]
	EKOS	33	36	2	[1, 4]	2	[1, 4]	10	[7, 18]	13	[7, 22]	6	[4, 14]	8	[4, 19]
	CE-TI	20	27	7	[6, 8]	10	[7, 23]	35	[21, 44]	42	[21, 78]	18	[8, 26]	18	[10, 70]
	All	854	41	5	[2, 7]	7	[3, 14]	24	[18, 33]	47	[28, 81]	15	[11, 21]	37	[18, 65]
Overall	KEK-ZH	589	100	7	[7, 8]	20	[12, 28]	36	[27, 47]	68	[43, 113]	14	[10, 20]	42	[24, 83]
	EKNZ	470	100	4	[2, 6]	4	[2, 7]	24	[17, 30]	55	[35, 84]	18	[13, 24]	48	[29, 75]
	CER-VD	334	100	5	[3, 6]	5	[4, 7]	26	[20, 33]	72	[52, 127]	19	[15, 23]	65	[46, 113]
	KEK-BE	291	100	3	[1, 5]	5	[2, 12]	22	[19, 36]	76	[51, 127]	15	[14, 21]	63	[43, 98]
	CCER	235	100	3	[1, 6]	5	[2, 11]	30	[24, 42]	88	[57, 139]	23	[20, 30]	79	[52, 118]
	EKOS	92	100	2	[1, 4]	2	[1, 4]	17	[10, 22]	38	[15, 67]	14	[8, 21]	36	[14, 65]
	CE-TI	75	100	7	[6, 7]	7	[7, 8]	31	[22, 41]	53	[28, 104]	21	[13, 30]	46	[18, 94]
	All	2086	100	5	[2, 7]	7	[3, 18]	28	[20, 38]	66	[43, 110]	17	[13, 23]	56	[32, 91]

5.4.1 Time from status “complete” to final decision

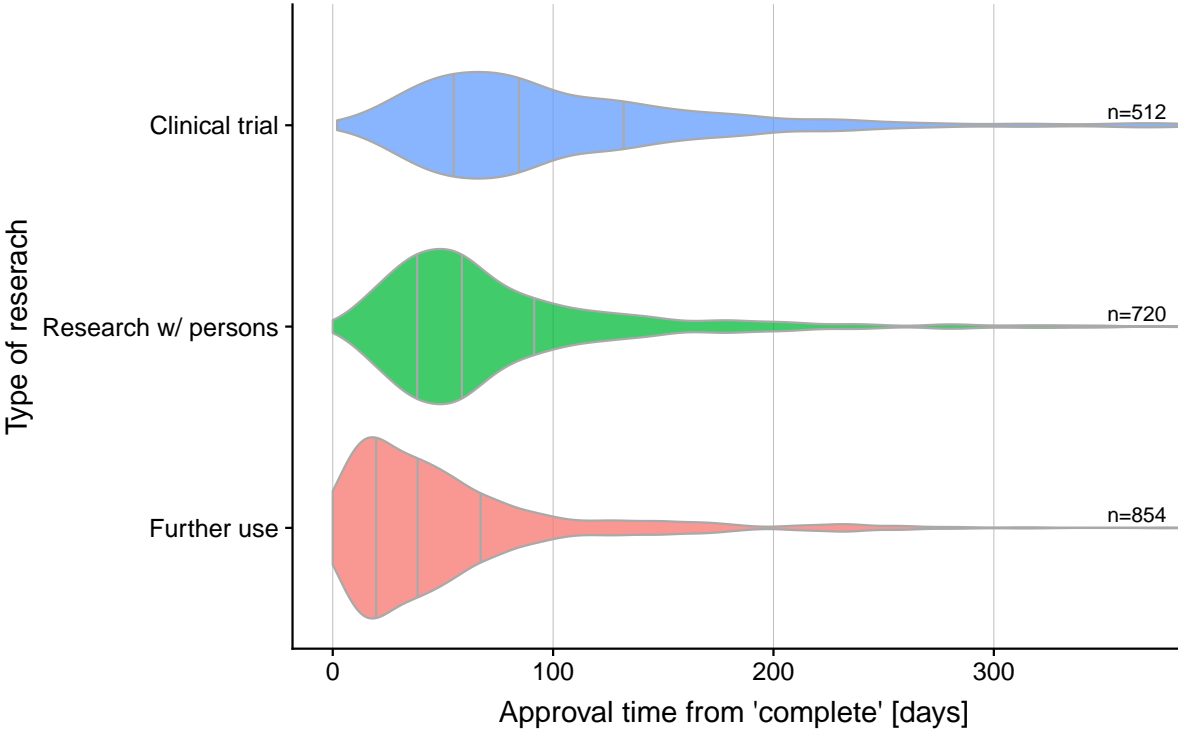


Figure 18: Violin plot of the **approval time starting from status 'complete'** per type of research (only the 3 major groups are shown). 14 projects with approval time > 1 year are not shown for layout reasons.

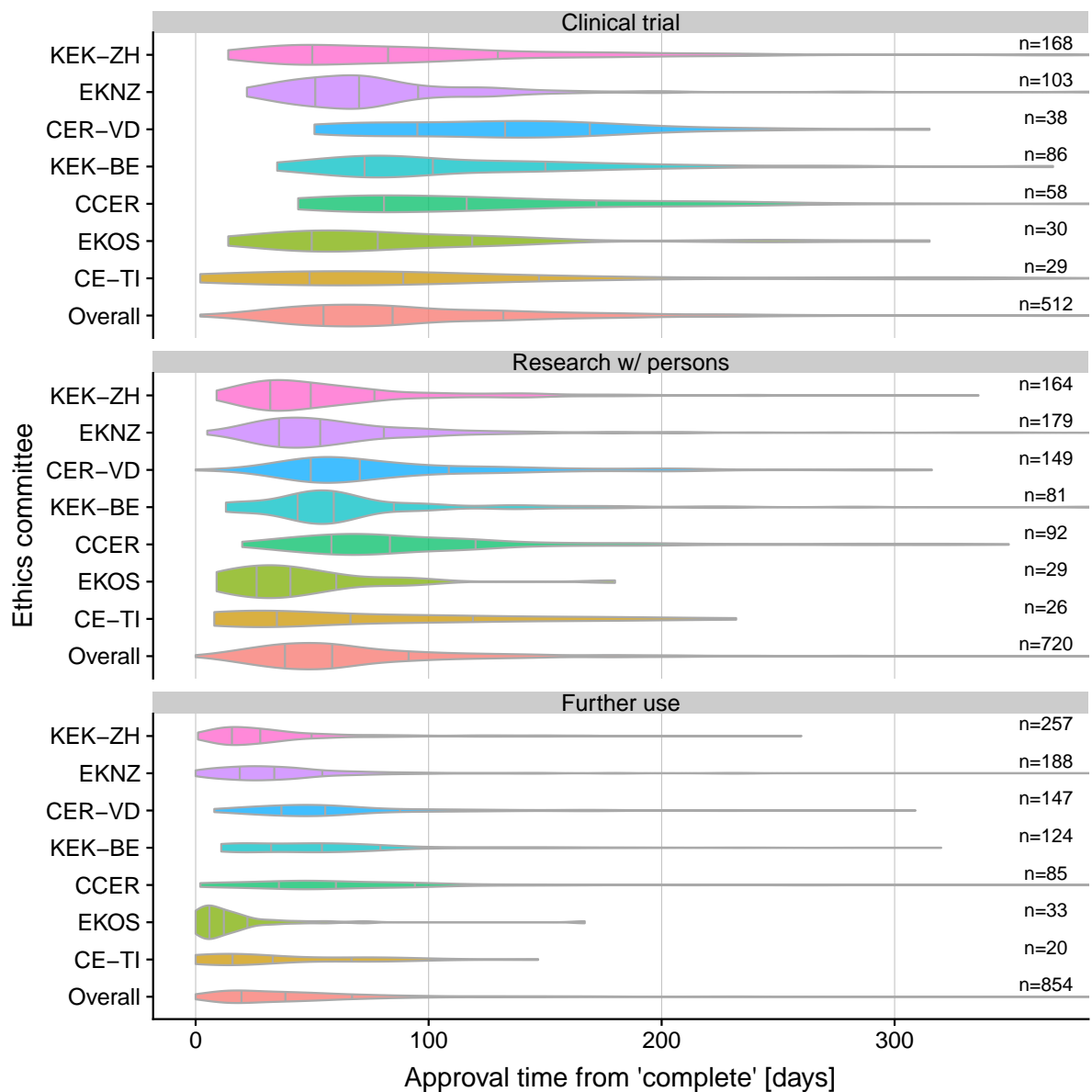


Figure 19: Violin plot of the **approval time starting from status 'complete'** per type of research (only the 3 major groups are shown) stratified by EC. 14 projects with approval time > 1 year are not shown for layout reasons.

5.4.2 Time from reception to final decision

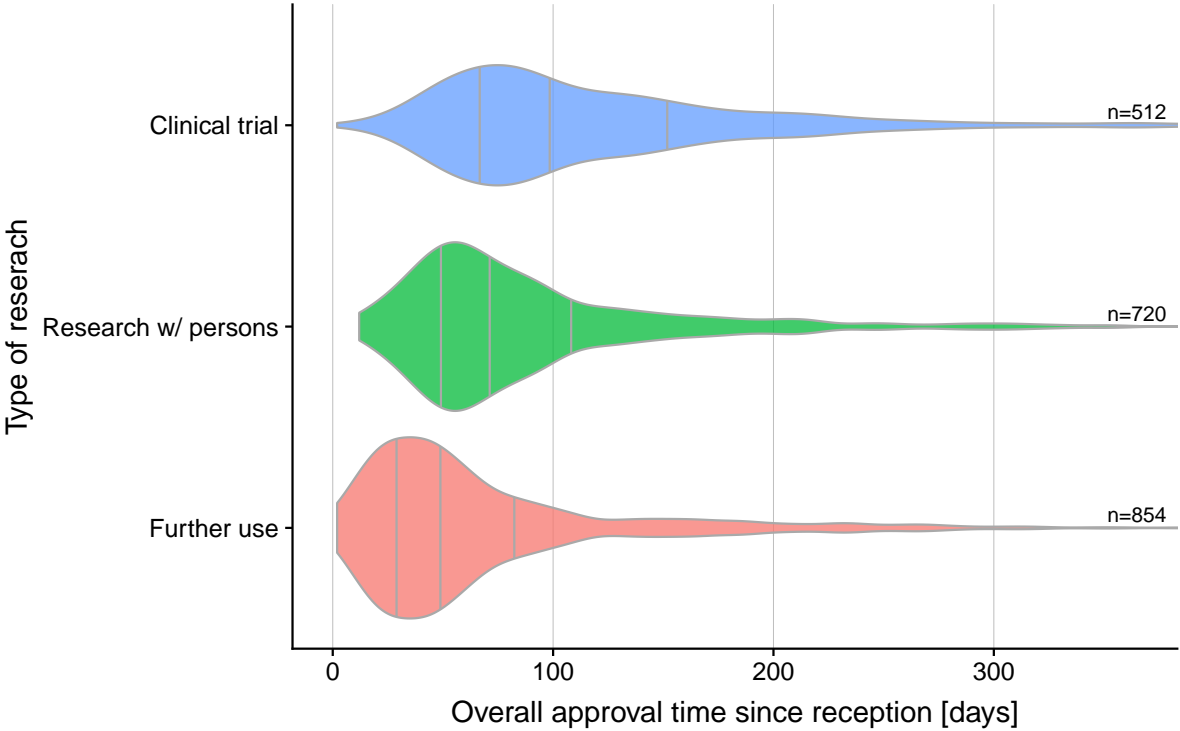


Figure 20: Violin plot of the **overall approval time since reception** per type of re-search (only the 3 major groups are shown). 24 projects with an overall approval time > 1 year are not shown for layout reasons.

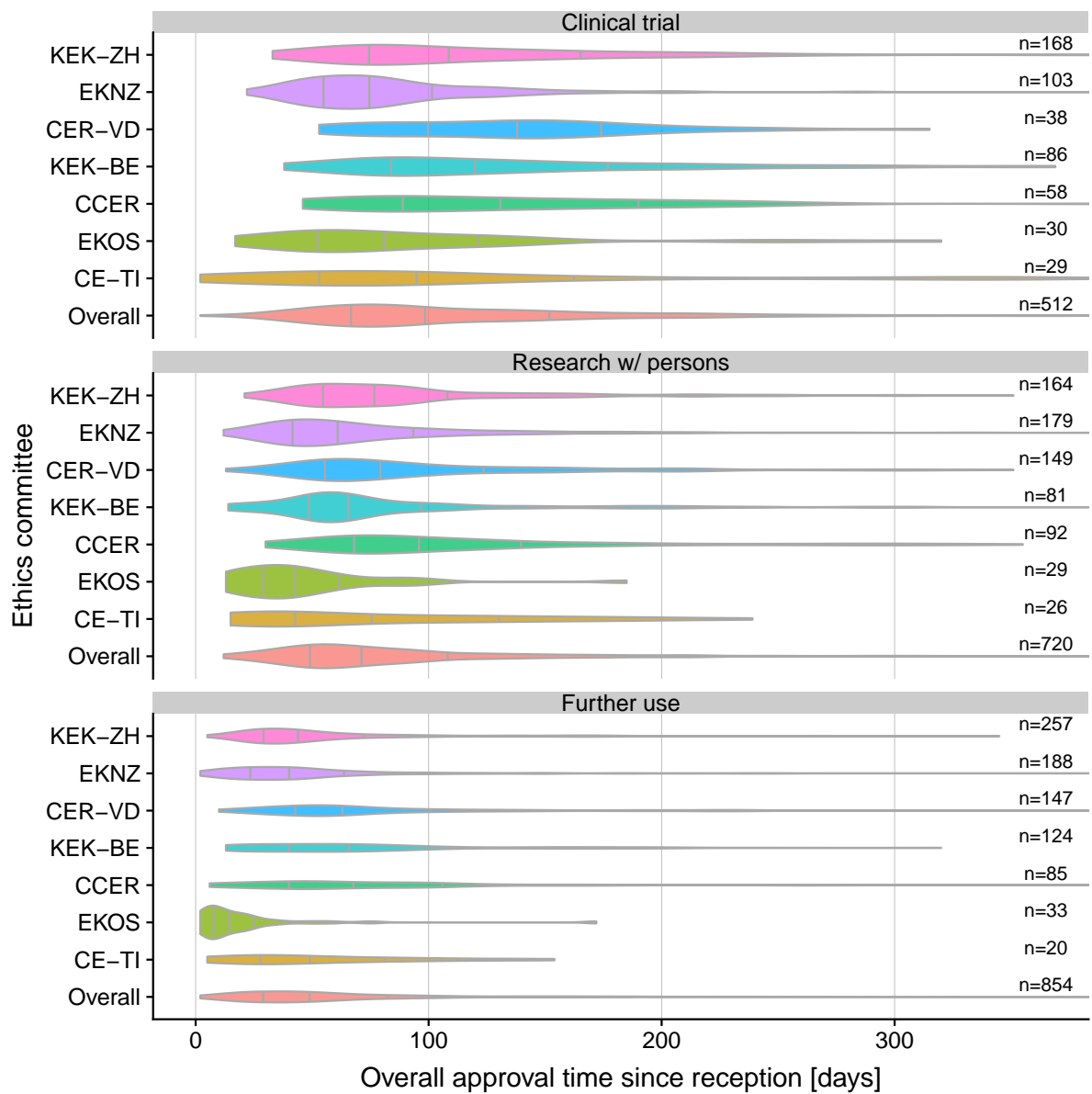


Figure 21: Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown) stratified by EC. 24 projects with an overall approval time > 1 year are not shown for layout reasons.

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

Description of distinctive features of the results:
 As expected, approval times for applications involving multiple ECs tend to be longer compared to applications involving a single EC. The additional time is spent between first and final decision.

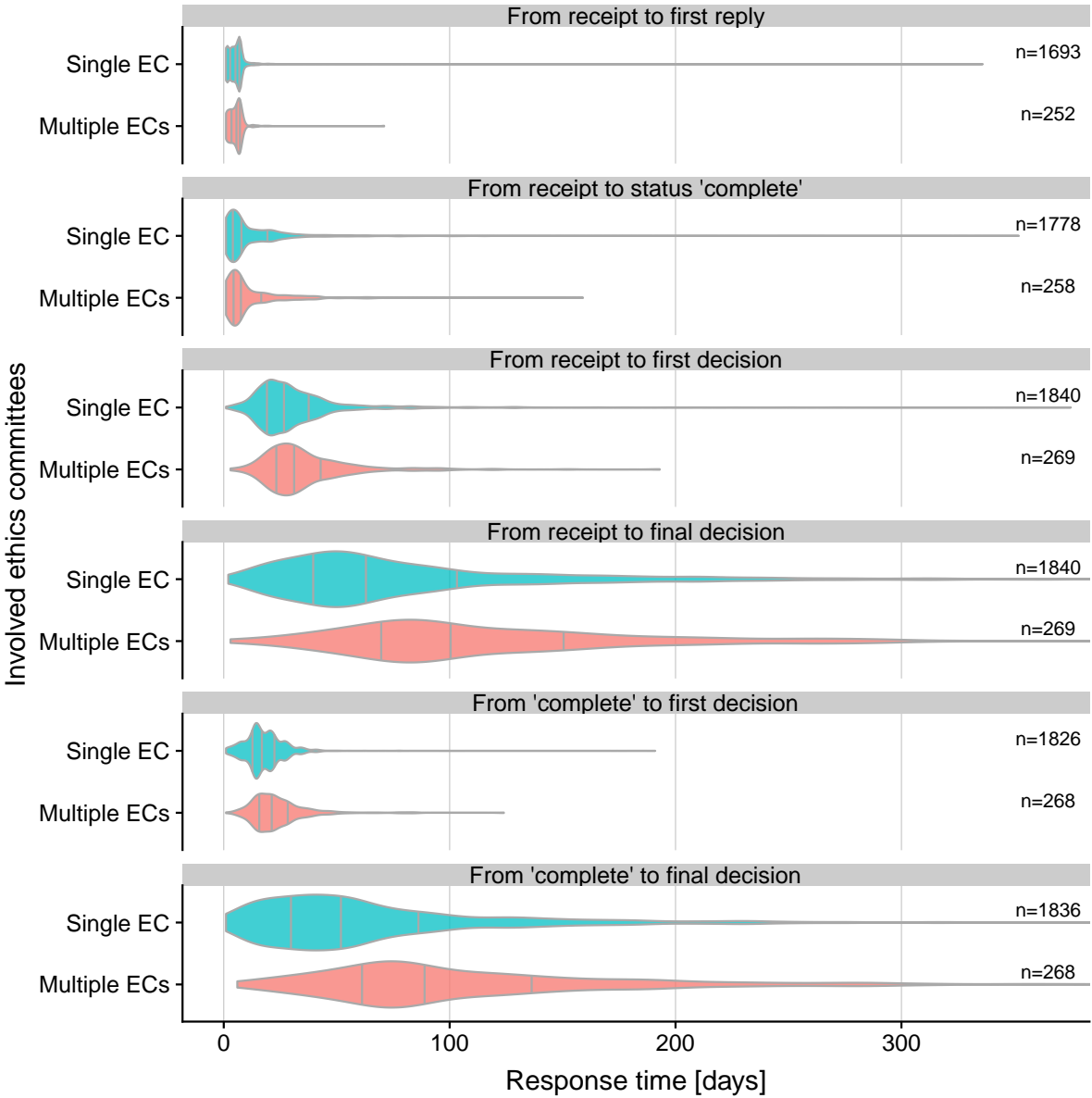


Figure 22: Violin plot of all response times depending on whether a single or multiple ECs were involved.

Table 41: Overview of response time in days - Median and inter-quartile range (IQR) per type of research (3 major groups only) and depending on whether a single or multiple ECs are involved.

Type of research	Time interval	Application involves					
		Multiple ECs			Single EC		
		n	Median	IQR	n	Median	IQR
Clinical trial	from receipt to first reply	143	6	[3, 7]	369	6	[3, 7]
	from receipt to status 'complete'	143	7	[4, 17]	369	7	[4, 22]
	from receipt to first decision	143	35	[28, 48]	369	32	[22, 42]
	from receipt to final decision	143	122	[86, 164]	369	88	[60, 145]
	from 'complete' to first decision	143	23	[17, 30]	369	19	[14, 25]
	from 'complete' to final decision	143	105	[77, 149]	369	75	[49, 124]
Research w/ persons	from receipt to first reply	83	4	[2, 7]	637	5	[3, 7]
	from receipt to status 'complete'	83	5	[2, 8]	637	6	[3, 19]
	from receipt to first decision	83	28	[22, 35]	637	28	[20, 40]
	from receipt to final decision	83	87	[62, 132]	637	68	[49, 104]
	from 'complete' to first decision	83	20	[15, 27]	637	18	[14, 23]
	from 'complete' to final decision	83	77	[54, 118]	637	56	[38, 88]
Further use	from receipt to first reply	43	5	[2, 7]	811	5	[2, 7]
	from receipt to status 'complete'	43	5	[2, 16]	811	7	[3, 14]
	from receipt to first decision	43	26	[20, 36]	811	24	[18, 33]
	from receipt to final decision	43	64	[42, 92]	811	47	[28, 78]
	from 'complete' to first decision	43	17	[14, 23]	811	15	[11, 21]
	from 'complete' to final decision	43	53	[26, 76]	811	36	[18, 63]
Overall	from receipt to first reply	269	5	[3, 7]	1817	5	[2, 7]
	from receipt to status 'complete'	269	7	[3, 15]	1817	7	[3, 18]
	from receipt to first decision	269	30	[23, 43]	1817	27	[20, 38]
	from receipt to final decision	269	96	[73, 149]	1817	62	[41, 102]
	from 'complete' to first decision	269	21	[16, 28]	1817	17	[13, 22]
	from 'complete' to final decision	269	85	[65, 132]	1817	51	[29, 85]

6 Preliminary longitudinal analysis performed on AS1

Like all other analyses in this report, longitudinal analyses comparing frequencies and characteristics of the projects over years should be performed on reviewed data, i.e. on the set of approved projects (AS2). However, AS2 can only be considered representative starting from 2017 when submissions in the previous years were also done via BASEC (see Figure 1 on page 10).

Comparing submissions (AS1) between two years may be considered unfair since projects submitted earlier (2016) are likely to be more complete and data more correct than projects submitted later (2017), because the data cut-off timepoint for both the 2016 and 2017 AS1 sets was April 2, 2018. For instance, projects submitted recently may be subject to change in categories during the approval process. Furthermore, swissethics performs a post-processing of the BASEC data after export, thereby removing invalid/dormant projects - a process which affects more likely older projects compared to newer projects, some of which have not finished the approval procedure.

For these reasons, the following analyses are considered preliminary and should be treated with caution. A thorough longitudinal analysis on the approved projects data sets (AS2) will be conducted starting from 2018.

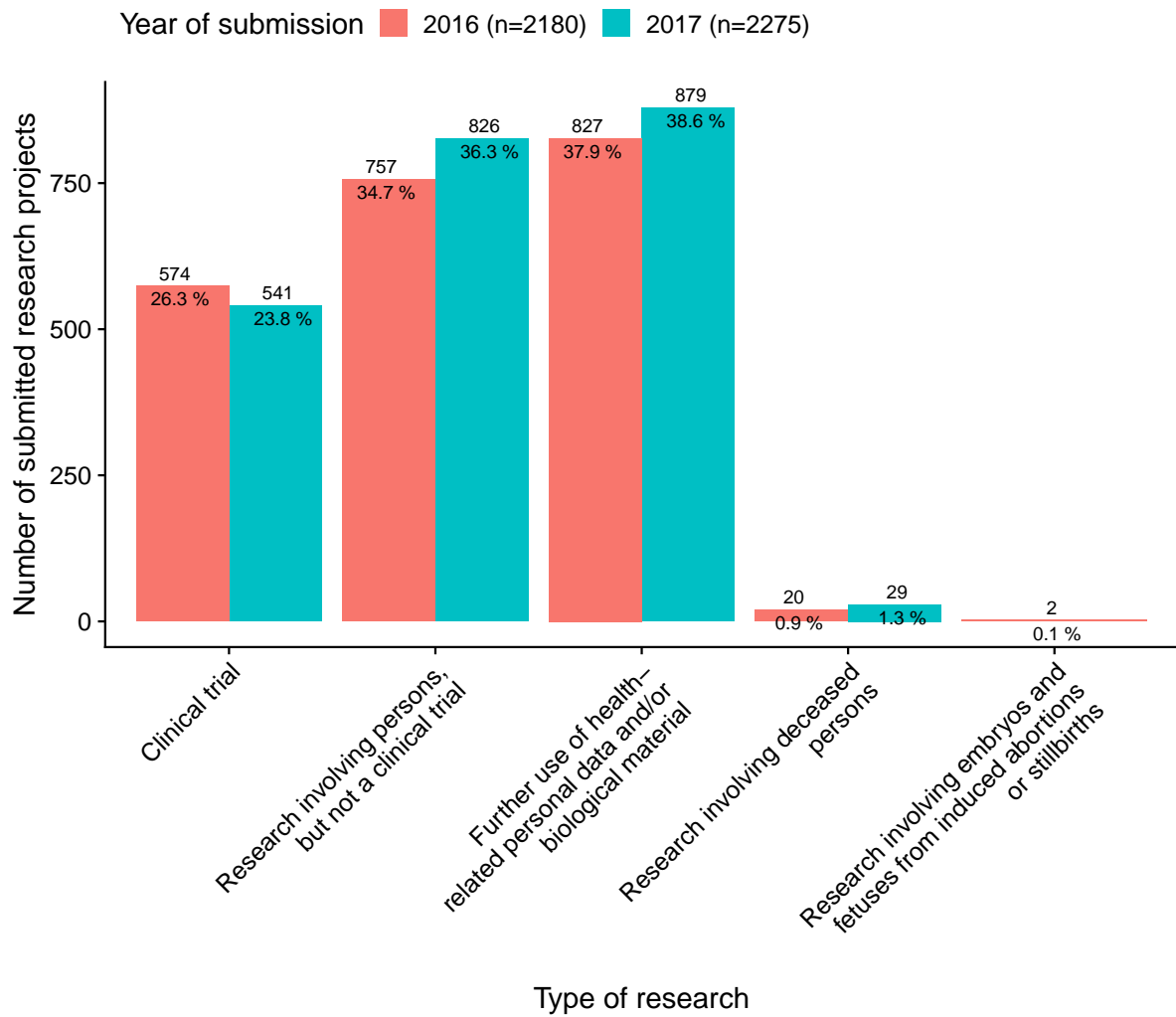


Figure 23: Total number of submissions per year and type of research.

6.1 Risk category

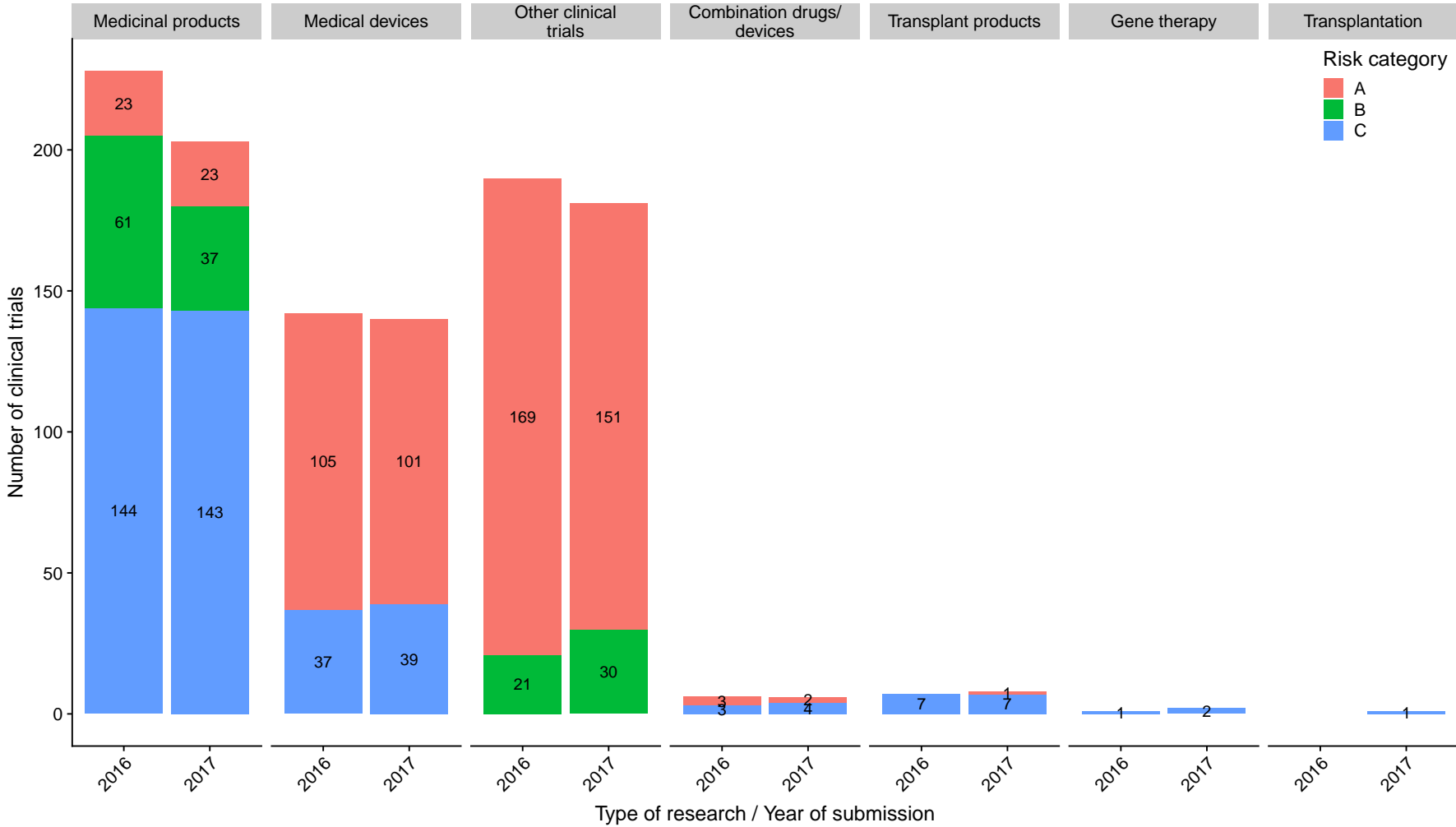


Figure 24: Clinical trials submitted per year stratified by type of clinical trial and risk category.

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

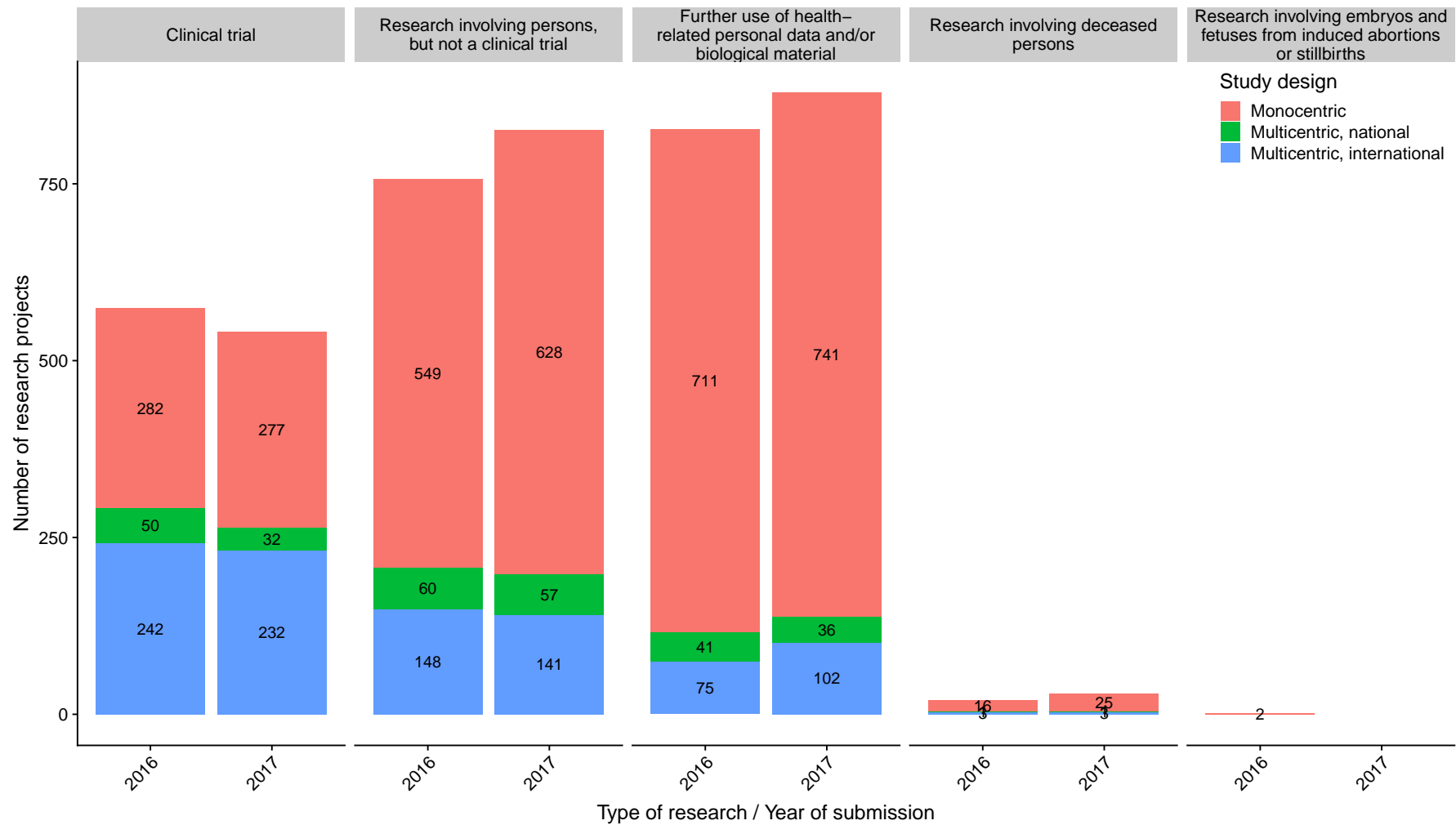


Figure 25: Submissions per year stratified by type of research project and by study design.

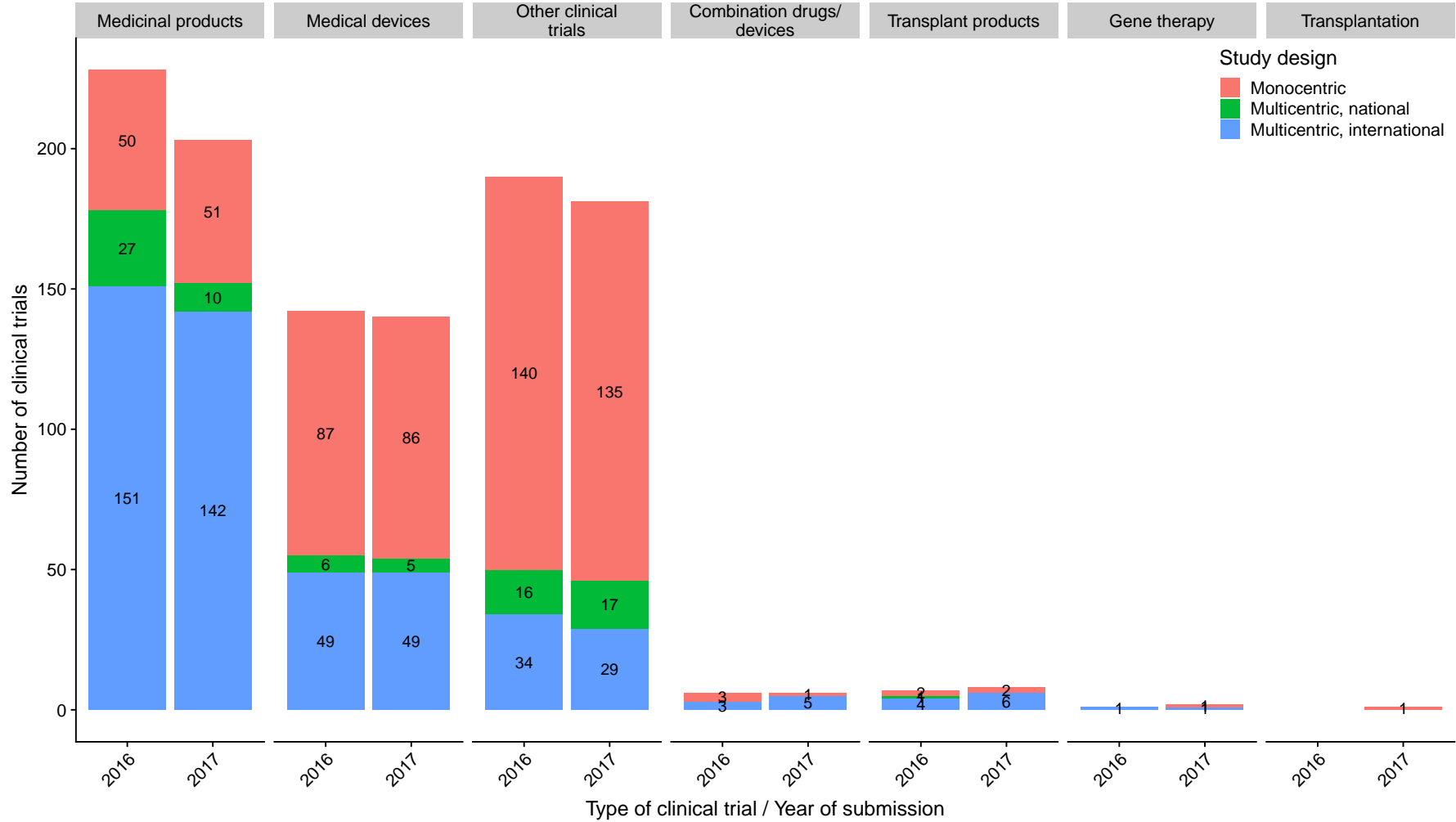


Figure 26: Clinical trials submitted per year stratified by trial type and trial design.

6.3 Subgroup “Further use of data/biological material”

Description of distinctive features of the results:

Overall, the number of “further use” projects has increased between 2016 and 2017. Furthermore, the proportion of projects in which the data are planned to be analysed in a coded form has increased. Interestingly the fraction of projects for which the application of HRA Art. 34 has been requested dropped.

Table 42: Overview of characteristics of all submitted ‘further use’ projects.

		Submission year			
		2016		2017	
		n	%	n	%
Genetic data / biol. material	Yes	124	14.9	195	20.0
	No	708	85.1	781	80.0
Coding (HRO Art. 25-27)	Coded	332	39.9	548	56.1
	Open, non-coded	500	60.1	428	43.9
Consent (HRO Art. 28-32)	Prior consent exists	172	20.7	241	24.7
	Consent to be sought	88	10.6	172	17.6
	No consent for some/all data (HRA Art 34)	572	68.8	563	57.7
Combined projects ¹	Further use project	825	99.2	879	90.1
	Part of clinical trial	5	0.6	32	3.3
	Part of non-clinical research project	2	0.2	65	6.7
Total number		832	100.0	976	100.0

¹ 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).

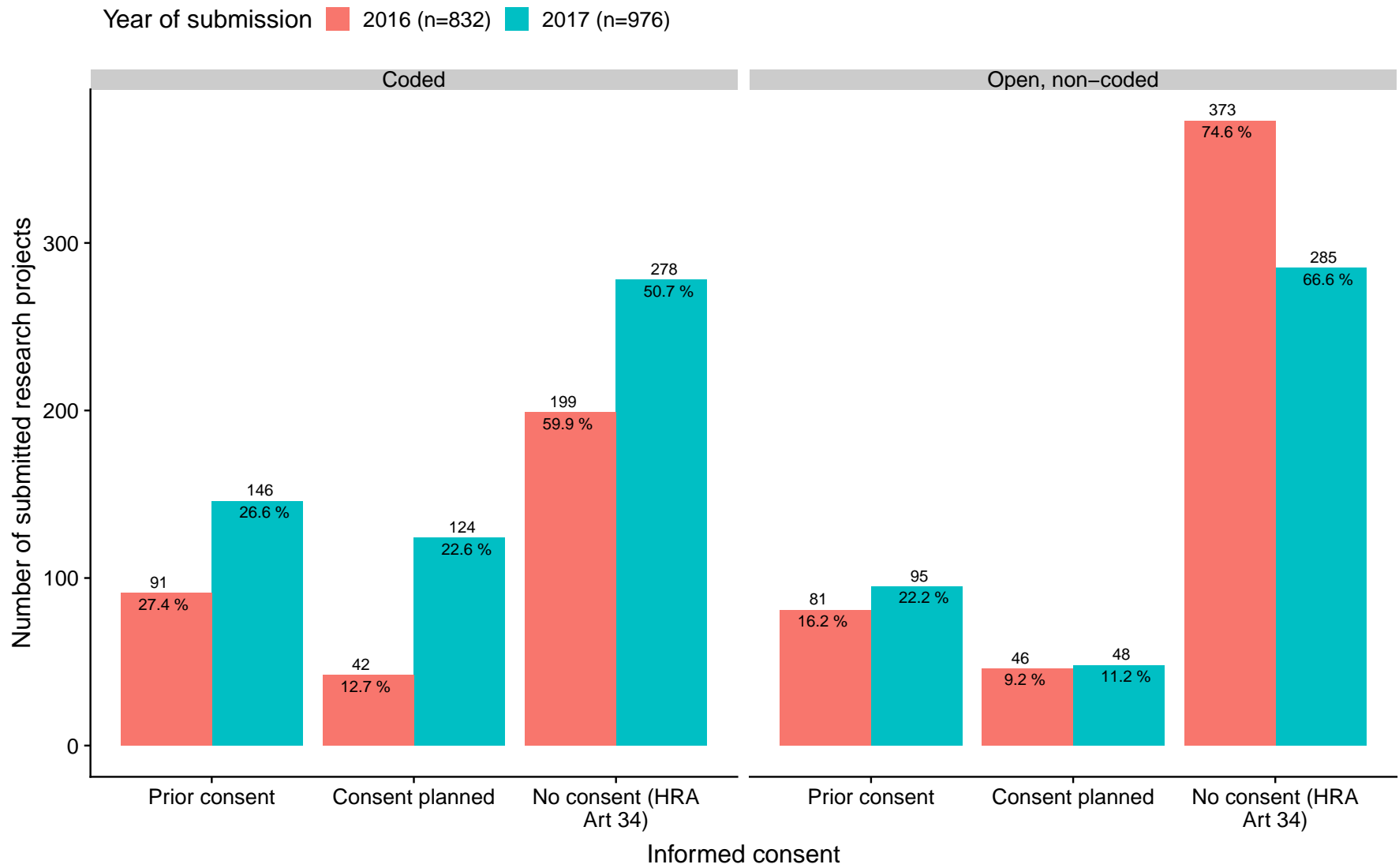


Figure 27: Further use projects submitted per year stratified by coding and consent.

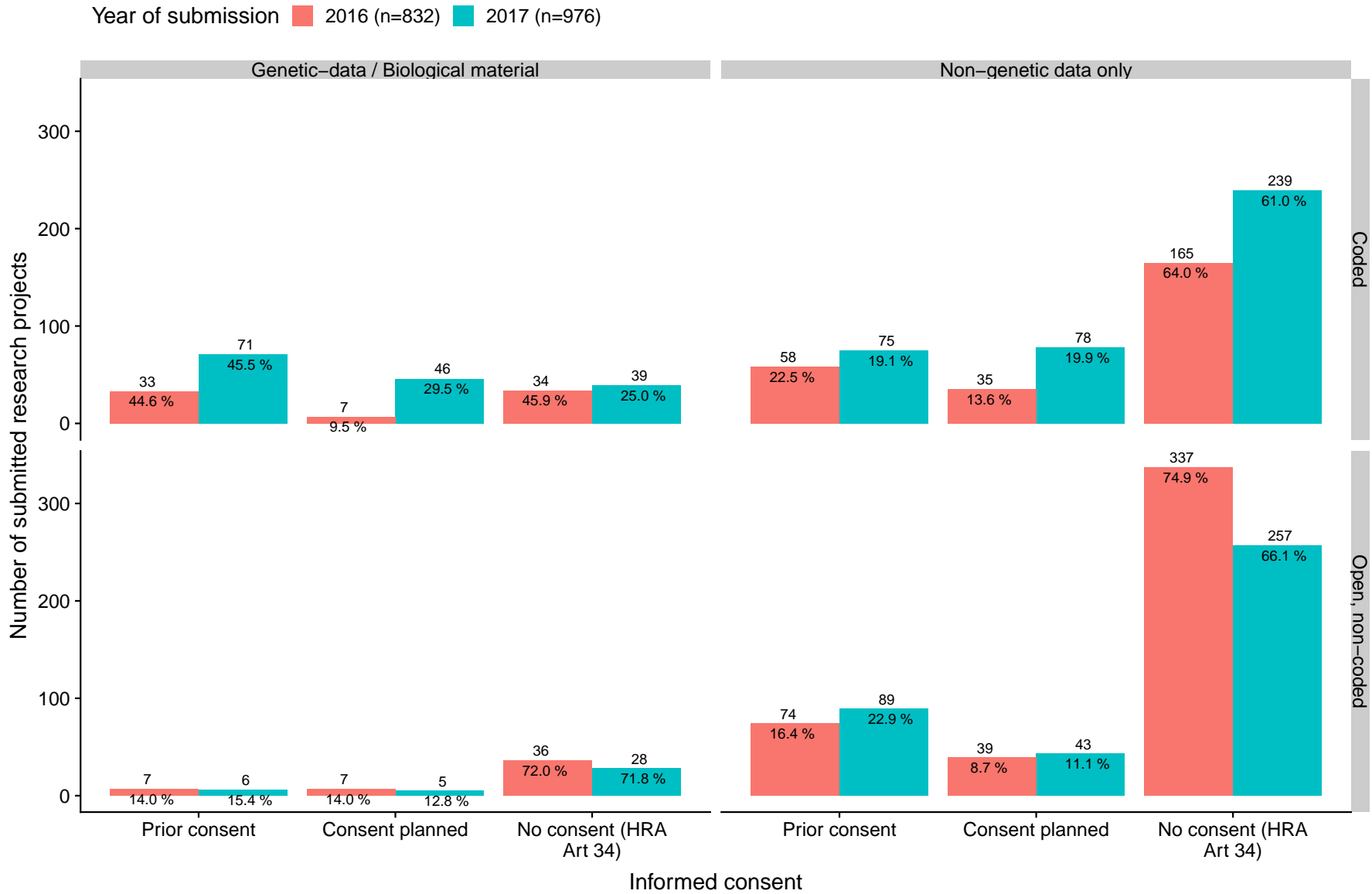


Figure 28: Further use projects submitted per year stratified by 1) Use of genetic data and/or biological material, 2) coded vs. uncoded, 3) consent for further use.

6.4 Response time

Description of distinctive features of the results:
 The median time to first and to final decision seems to have slightly dropped. It needs to be taken into account that some projects submitted in 2017 and still pending at time of data export will have long response times. However, the median is quite resistant towards outliers.

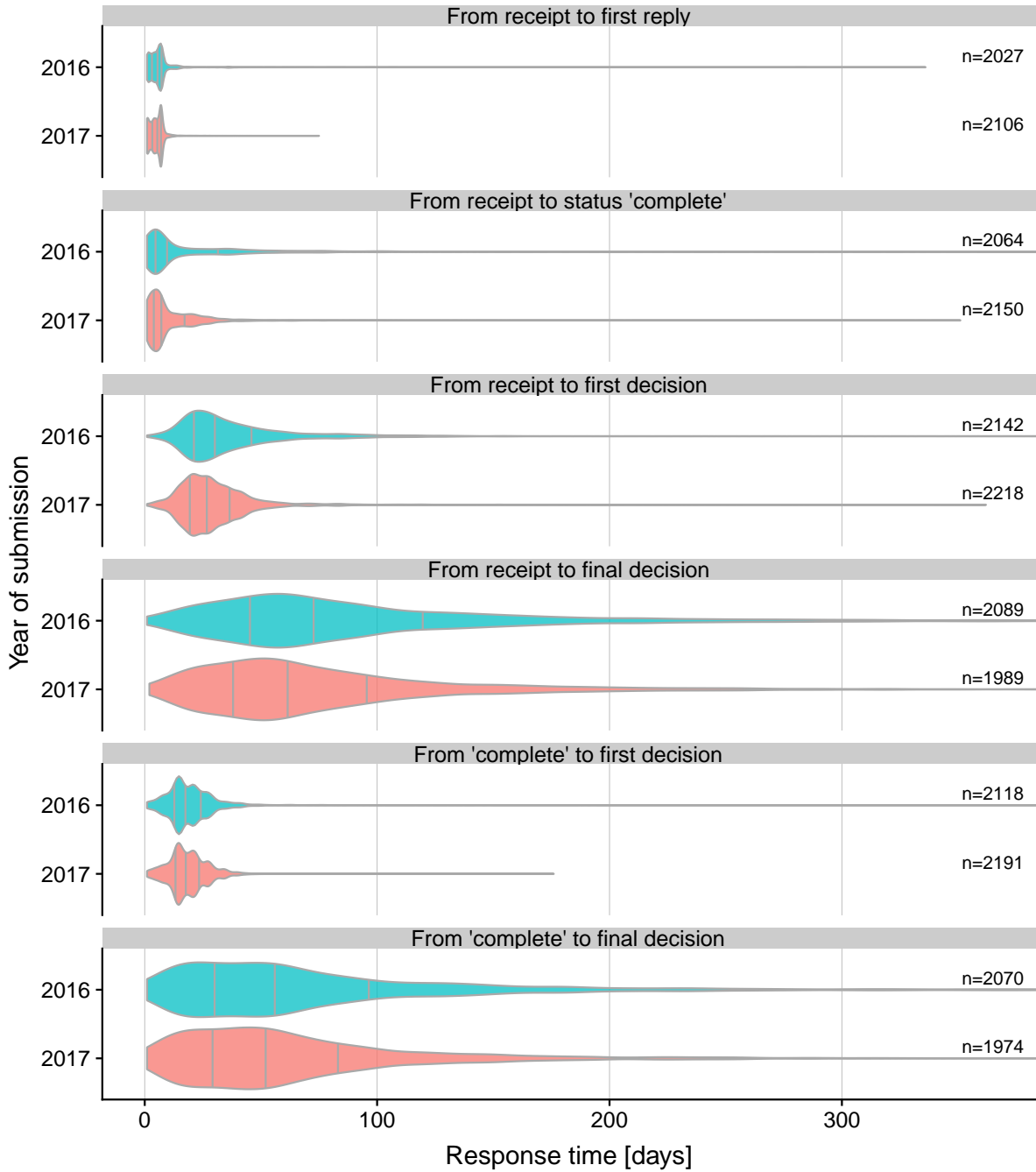


Figure 29: Violin plot combined with boxplot of all response times by submission year.