

Full report of survey results

Survey on researchers' opinion and experience with the Swiss Federal Act on Research involving Human Beings (HRA)

Explanatory note:

This document complements the report of the project titled "Survey on researchers' opinion about and experience with the Swiss Federal Act on Research involving Human Beings" (Forschung im Geltungsbereich des Schweizer Humanforschungsgesetzes 2016/2017, Report of Project part 2).

It provides the detailed results based on survey responses of researchers who applied for ethical approval to a Swiss cantonal ethics committee in 2017. The presentation follows the structure of the survey questionnaire in Part A and Part B.

For introduction, description of methods, selection of main results and discussion please refer to the main report.

Report prepared by:
Clinical Trial Unit Basel Department
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Freetext answers **(deleted from the published report due to privacy reasons; a clustered analysis of the freetext answers is available in the main report)**

ii	Question A3: What was particularly positive with the submission process? Please, give an example:	88
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List of abbreviations

BASEC	Business Administration System for Ethics Committees
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)
FOPH	Federal Office of Public Health
FUP	Respondents who submitted a 'further use' project (HRO Chapter 3).
SM+	Respondents who submitted a clinical trial (ClinO) involving Swissmedic.
SM-	Respondents who submitted a project (ClinO or HRO Chapter 2) not involving Swissmedic.
NA	Aggregation of both <i>not available</i> (missing data) and <i>not applicable</i> (e.g. by excluding answers like "Don't know", "no experience" for consistency reasons)
Part A	Questions concerning the experience of the application process in the BASEC portal addressed to investigators/project managers/coordinators in charge of application submission
Part B	Questions concerning the opinion about the impact of the HRA and its ordinances on research activities addressed to investigators that take the overall responsibility of research projects

Definition:

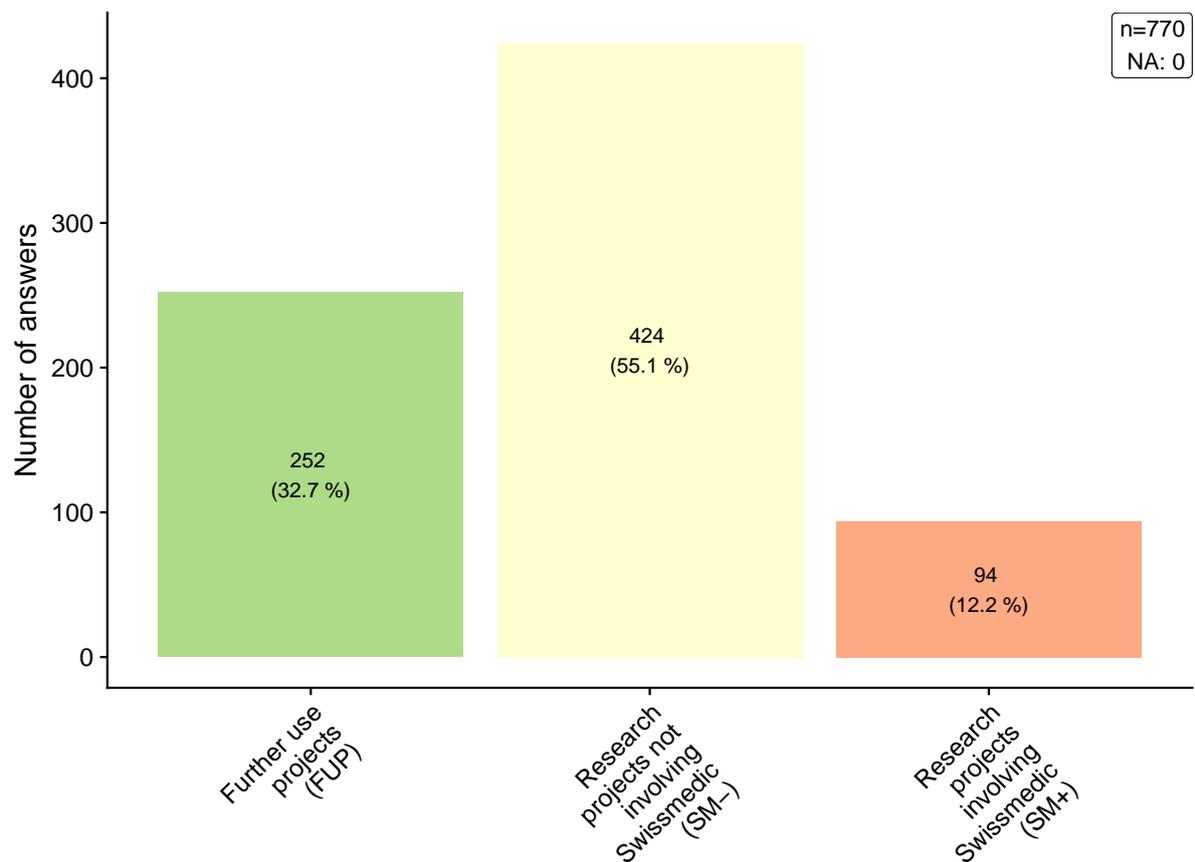
The projects were grouped into 3 types of studies:

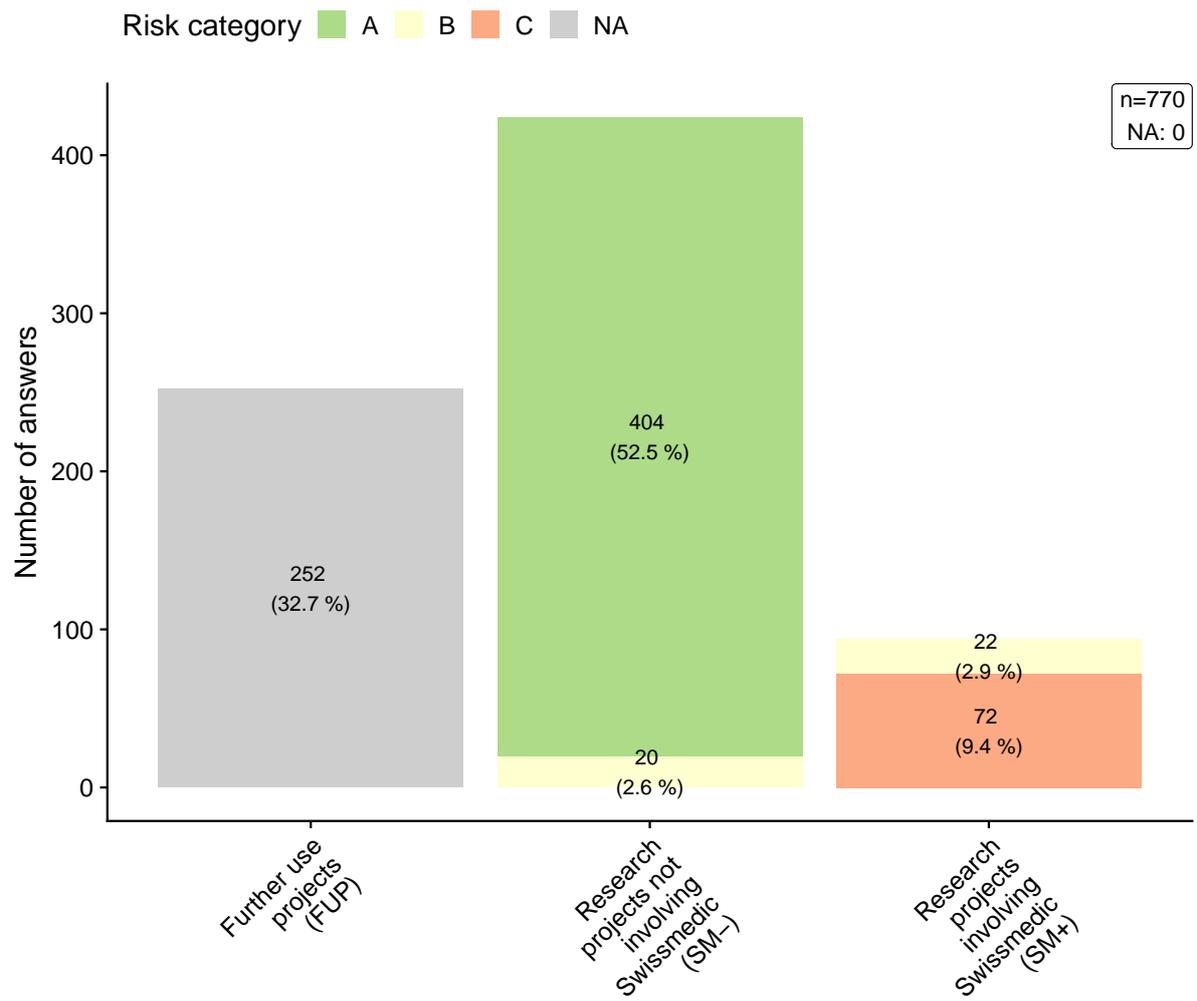
1. **FUP Further use projects:** Projects with use of available personal data/biological material according to Human Research Ordinance (HRO) Chapter 3 (coded as "survey type = 1" in the codebook)
2. **SM- Research projects not involving Swissmedic:** Other research involving persons (HRO Chapter 2) OR clinical trial in risk category A OR "Other clinical trial" (ClinO Chapter 4) in risk category B (coded as "survey type = 2" in the codebook)
3. **SM+ Research projects involving Swissmedic:** Clinical trial in risk category B or C (coded as "survey type = 3" in the codebook)

In the to right corner of each figure, the number of responents answering the given question is provided ("n") which is used as denominator when calculating percentages. In addition, "NA" aggregates both the number *not available* (i.e. missing) and *not applicable* answers. If a question was addressed to only a certain type of study, this is indicated by the 3-letter code defined above.

A Questions concerning the experience of the application process in the BASEC portal addressed to investigators/project managers/coordinators in charge of application submission (Part A)

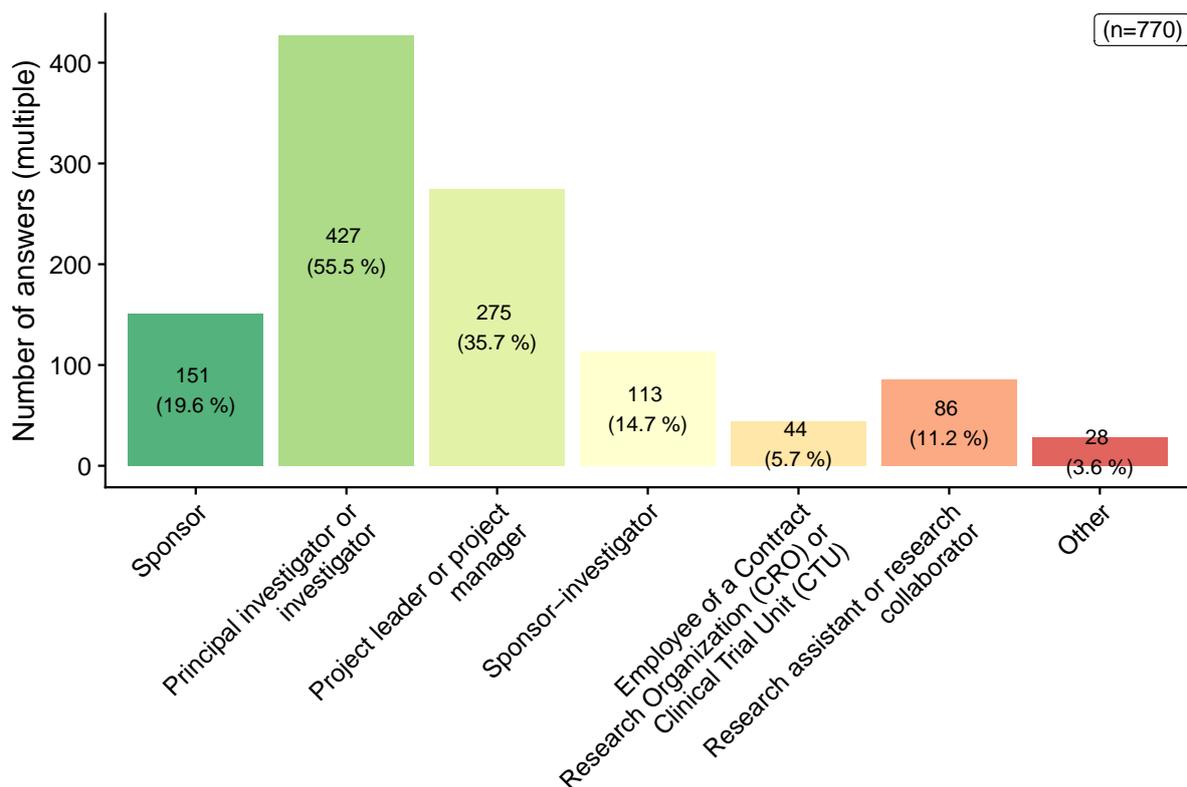
Distribution of projects of survey respondents by type of study





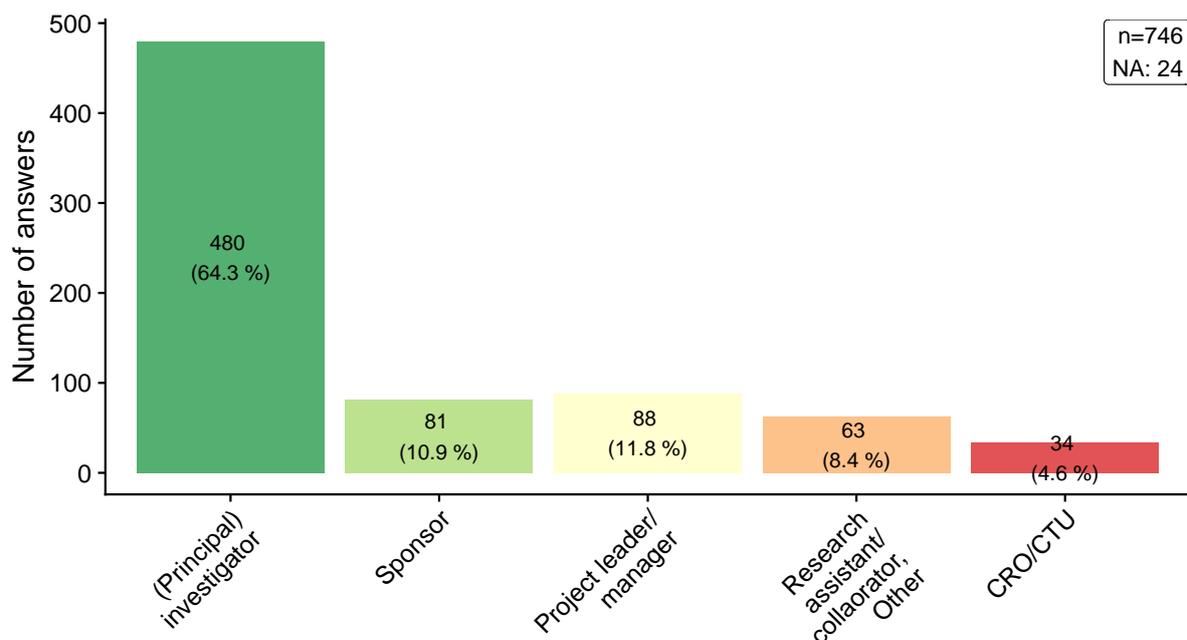
From the 424 **SM-** projects, 313 are observational studies and 111 are clinical trials.

A1 Please indicate your role in the project (multiple answers possible)



Definition:

Since multiple choice questions cannot be used for stratification, the applicants were assigned to a specific and unique role in the following order: (principal) investigator > Sponsor > Project leader > Research assistant > CRO.



A2 Each line below contains a pair of adjectives that may qualify the way you perceive the overall application process of project. For each pair, place a cursor close to the adjective that you think *describes the application process best*. The more appropriate the adjective seems, the closer you should put the cursor.

Definition:

We constructed a total score as a measure of satisfaction with BASEC as the sum of the scores in response to four questions concerning pairs of adjectives. The answers to the individual questions are scored from positive to negative using a gradient from 5 to 1. The total score may be used to sort respondents according to their satisfaction (higher score corresponding to higher satisfaction) with BASEC and to identify and assess the relevance of their respective freetext answers. In the Appendix the freetext answers are sorted by this score (see especially the negative feedback starting from page 115 in the Appendix).

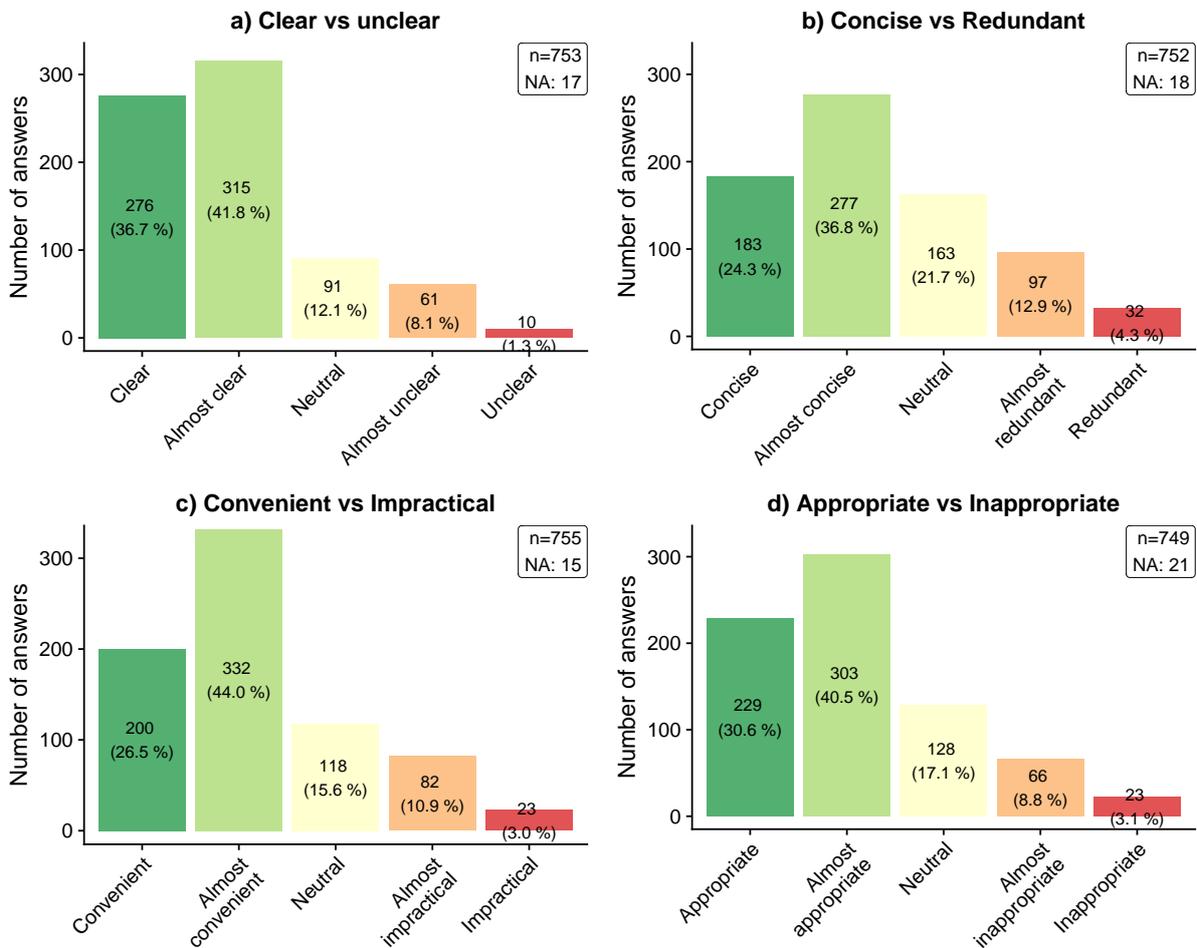


Table A2: The 'total score' is calculated from based on the answers to the questions concerning the adjectives)

Adjectives		Score	n	%
a) Clear vs unclear	Clear	5	276	35.8
	Almost clear	4	315	40.9
	Neutral	3	91	11.8
	Almost unclear	2	61	7.9
	Unclear	1	10	1.3
	NA		17	2.2
b) Concise vs Redundant	Concise	5	183	23.8
	Almost concise	4	277	36.0
	Neutral	3	163	21.2
	Almost redundant	2	97	12.6
	Redundant	1	32	4.2
	NA		18	2.3
c) Convenient vs Impractical	Convenient	5	200	26.0
	Almost convenient	4	332	43.1
	Neutral	3	118	15.3
	Almost impractical	2	82	10.6
	Impractical	1	23	3.0
	NA		15	1.9
d) Appropriate vs Inappropriate	Appropriate	5	229	29.7
	Almost appropriate	4	303	39.4
	Neutral	3	128	16.6
	Almost inappropriate	2	66	8.6
	Inappropriate	1	23	3.0
	NA		21	2.7
Total score	16-20		422	54.8
	11-15		233	30.3
	1-10		84	10.9
	NA (any of a)-d))		31	4.0
All			770	100.0

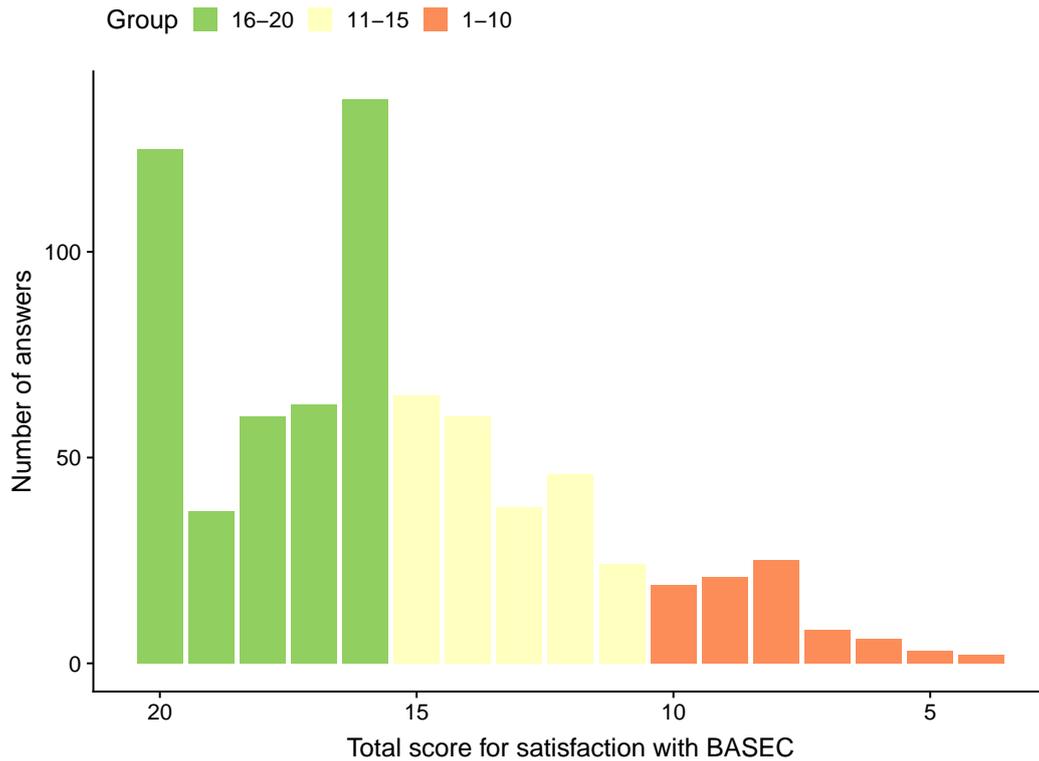


Figure A2.1: Distribution of the total score reflecting the “satisfaction” with BASEC (higher score corresponding to higher satisfaction). See stratifications of the total score by role, type of project and experience in the Appendix

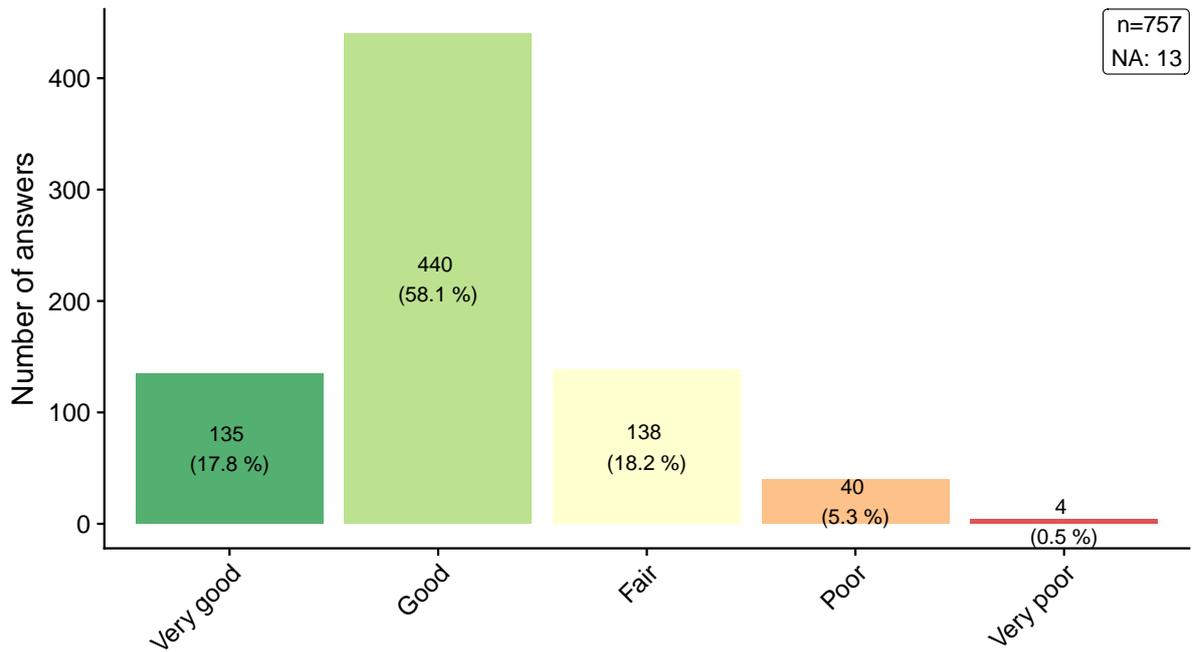
A3 What was particularly positive with the submission process?

→ See answers to freetext fields in the Appendix.

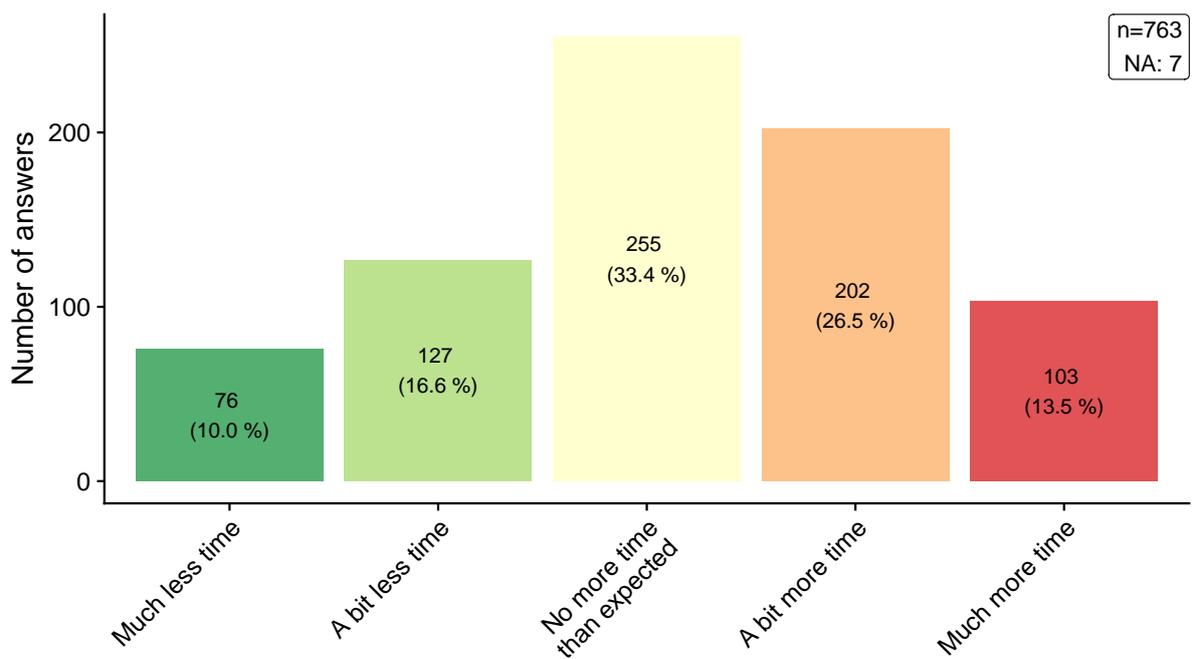
A4 What was particularly negative with the submission process?

→ See answers to freetext fields in the Appendix.

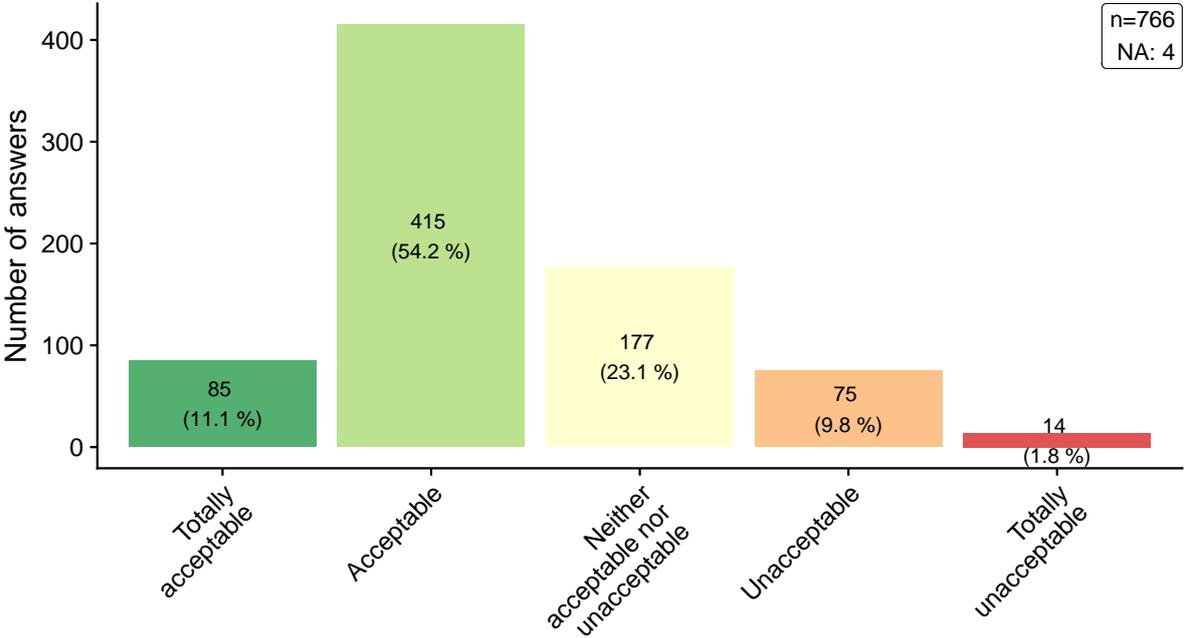
A5 The overall application process was ...



A6 Compared to what you expected, submitting study information and documents using BASEC took ...

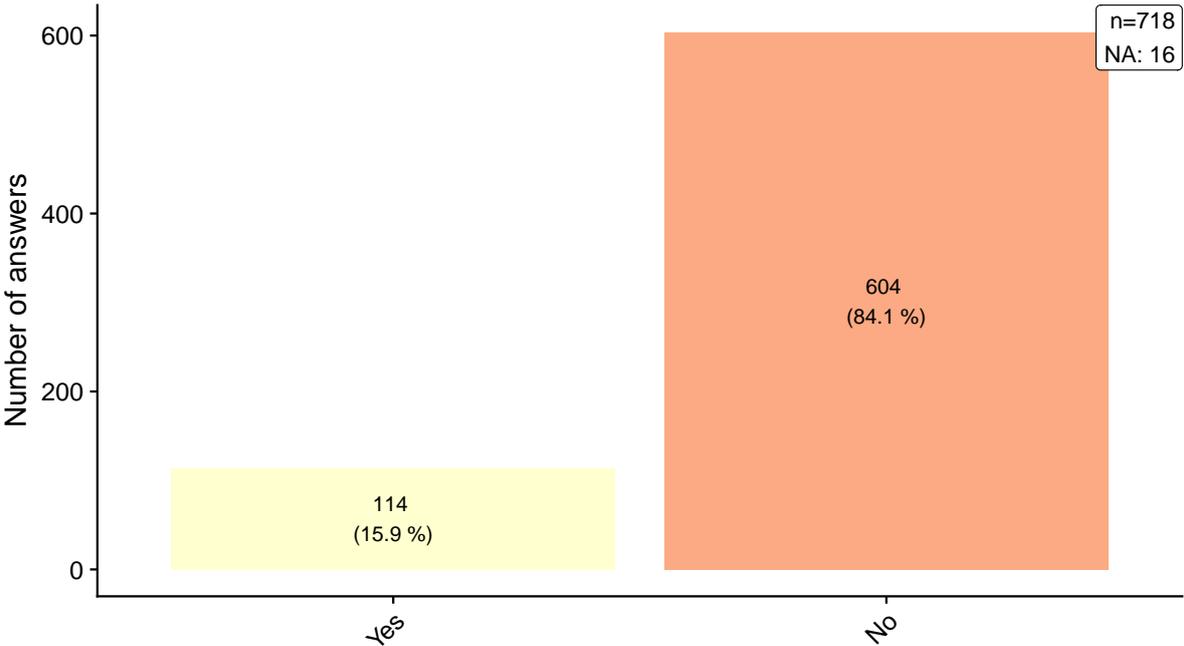


A7 In your opinion, the number of documents that you needed to upload was ...

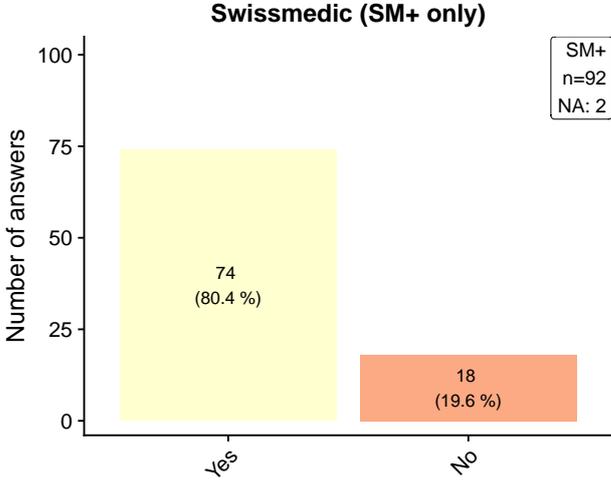
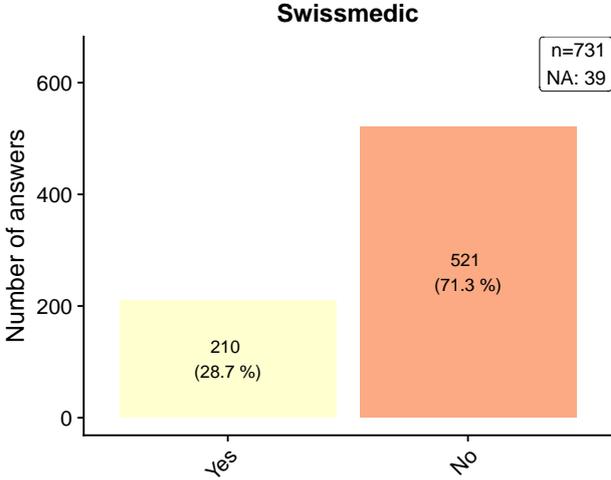
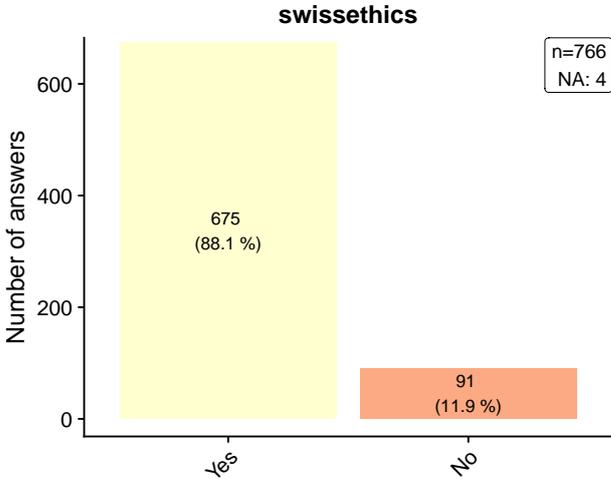
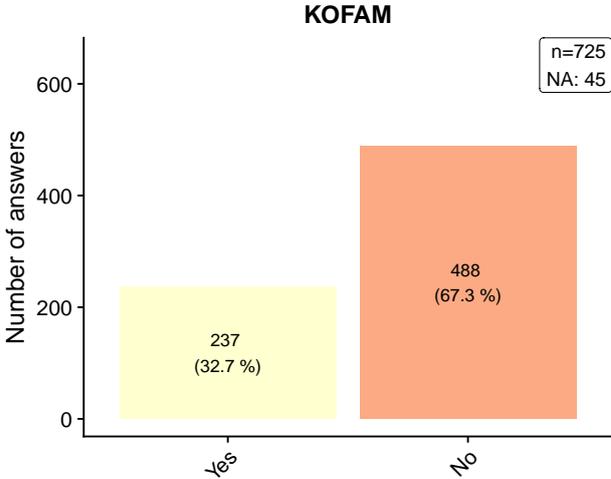


A8 Did you receive any support from a Clinical Trial Unit (CTU) or a Contract Research Organization (CRO)?

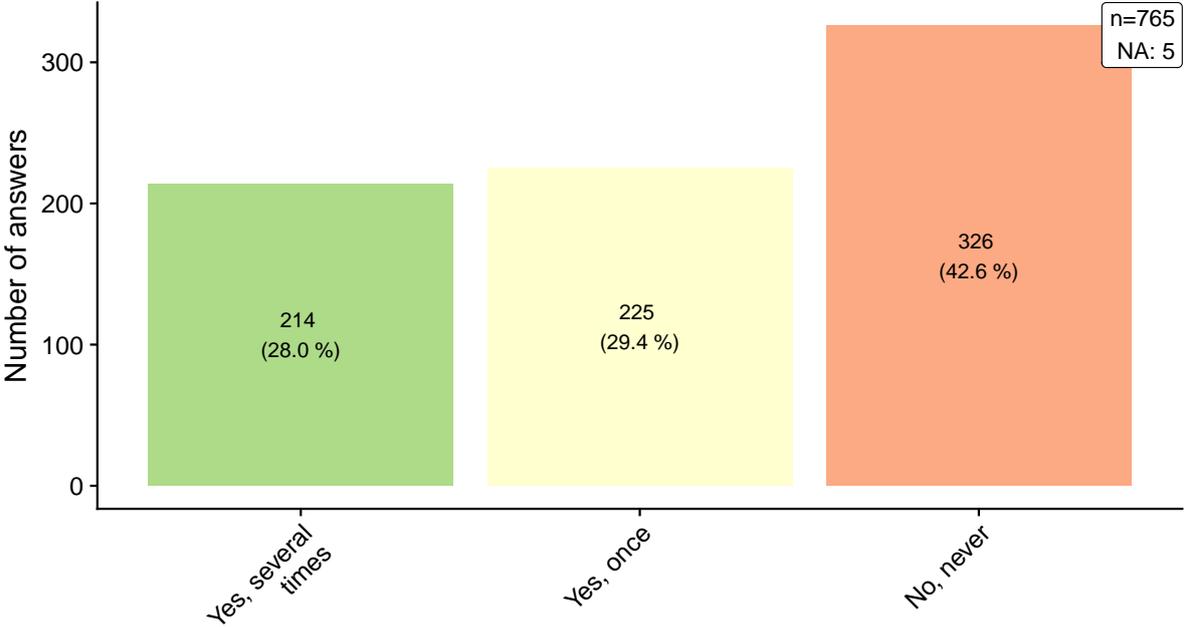
Note: Question was only asked if respondent was not from CTU/CRO (question A1) (n=734)



A9 Before and during the application process, did you visit the websites of the following organisations?

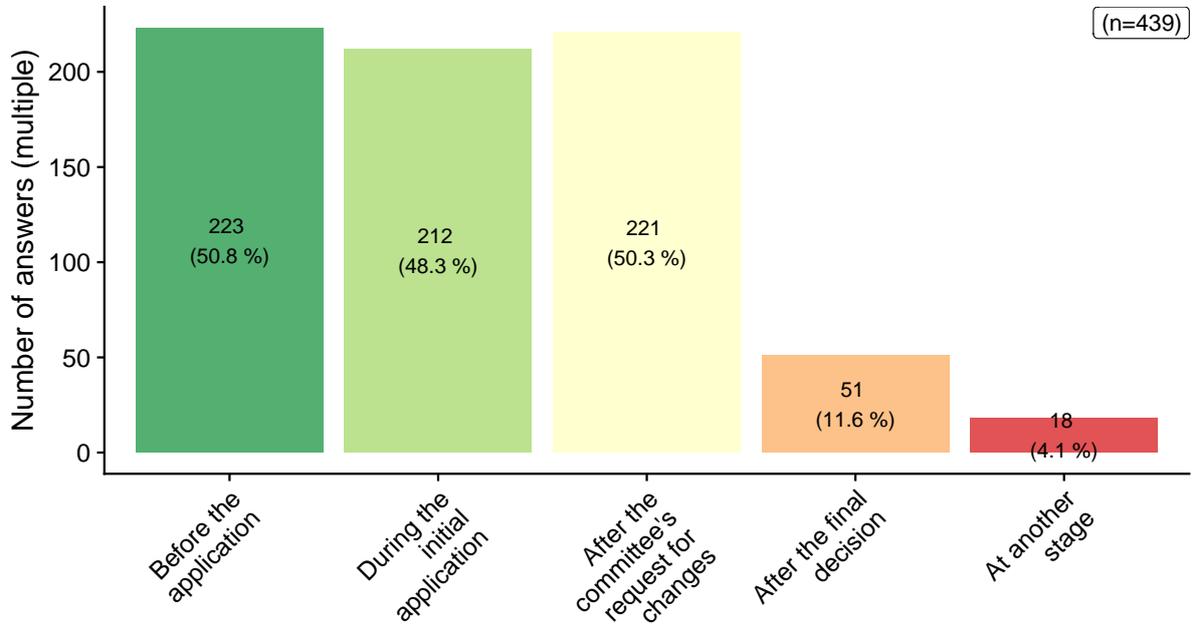


A10 When you submitted your project, did you contact your Ethics Committee or swissethics for questions or advice?

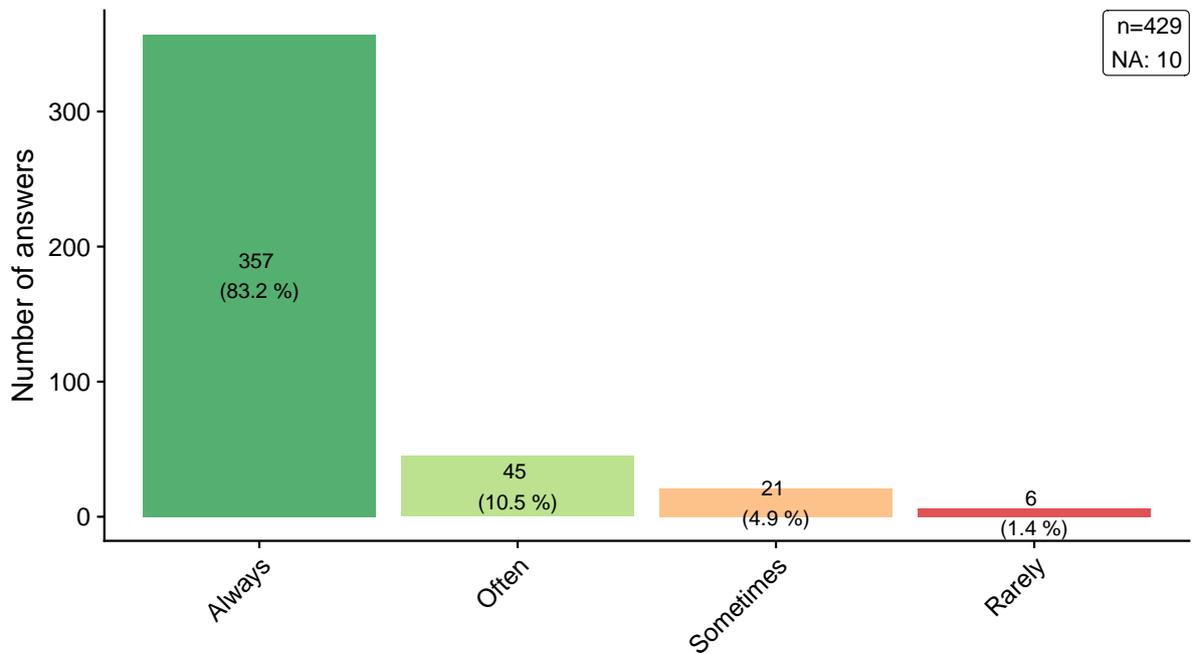


Note: The following two questions were only asked if A10 was answered with 'Yes, several times' or 'Yes, once' (n=439)"

A10a At which stage of the application process? (multiple answers possible)

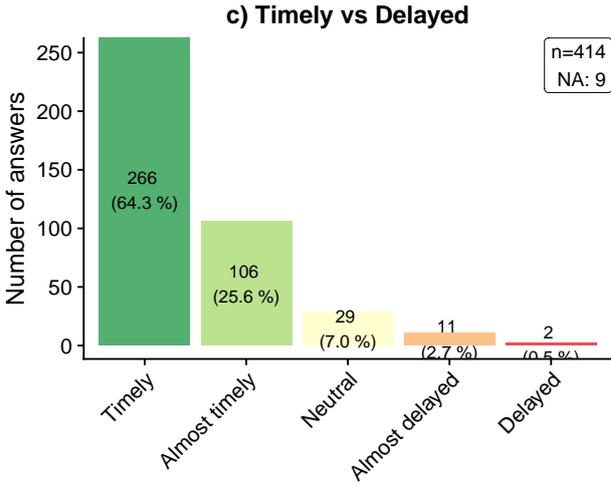
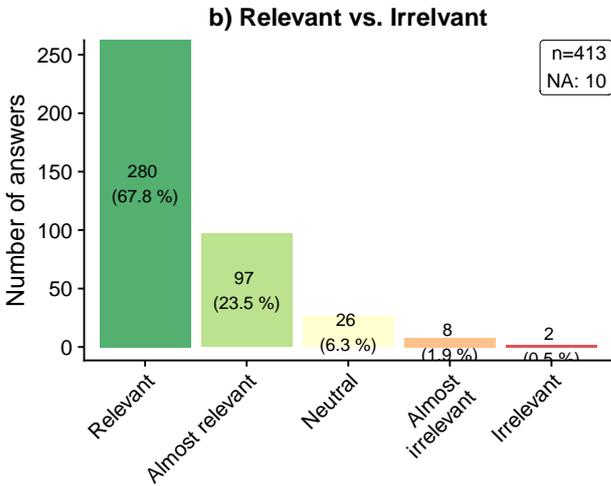
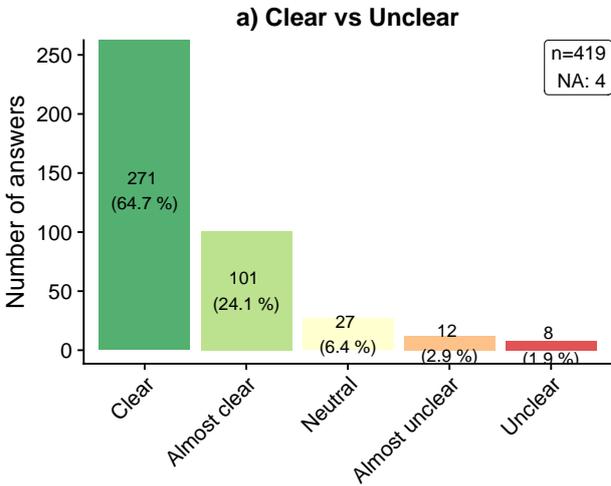


A10b Did you get answers to your request(s)?

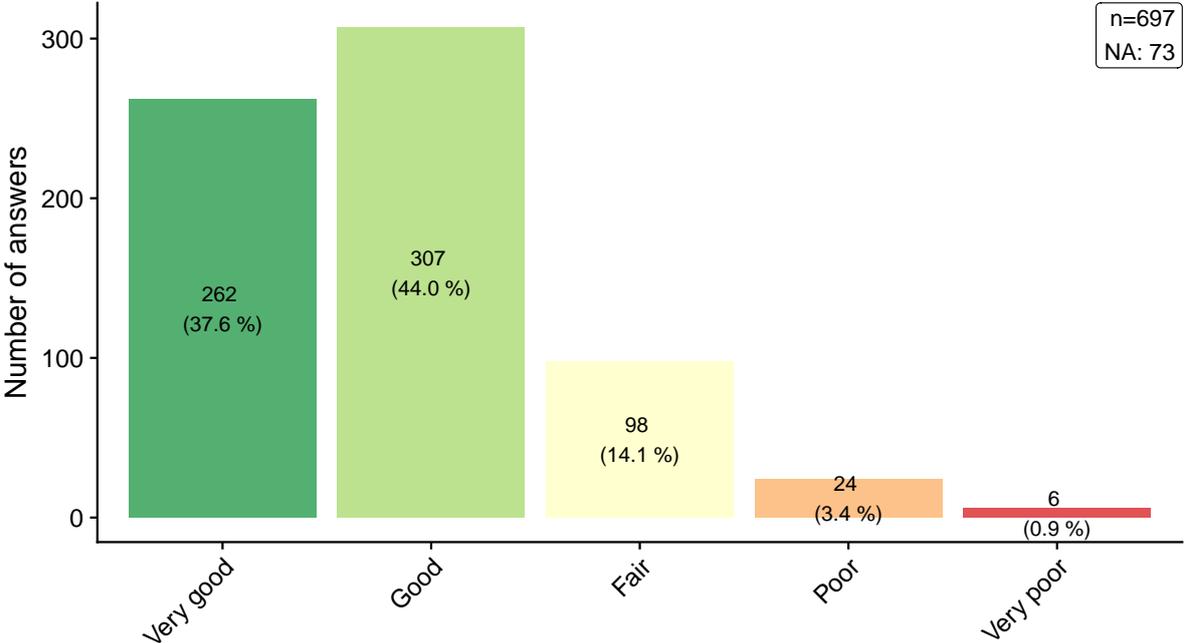


A10c Adjectives that best describe the answers received by Ethics Committee or swissethics

Note: These questions were only asked if the previous questions was answered with 'Always', 'Often' or 'Sometimes' (n=423)



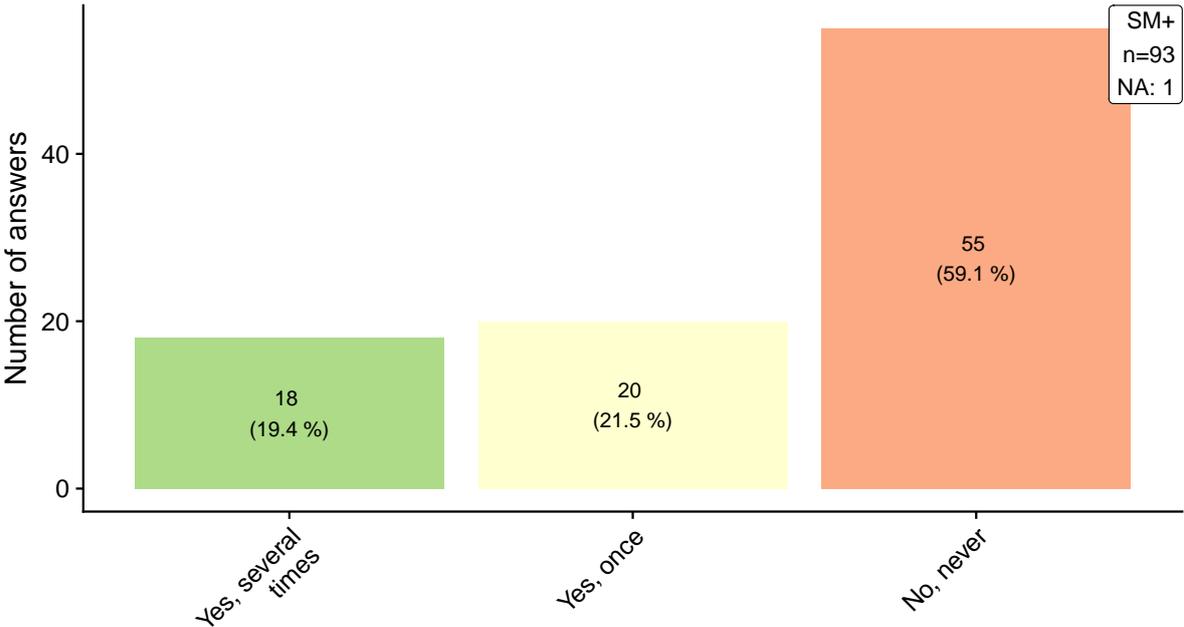
A11 Overall, communication with the Ethics Committee or swissethics concerning your application was ...



Additional Questions concening Swissmedic

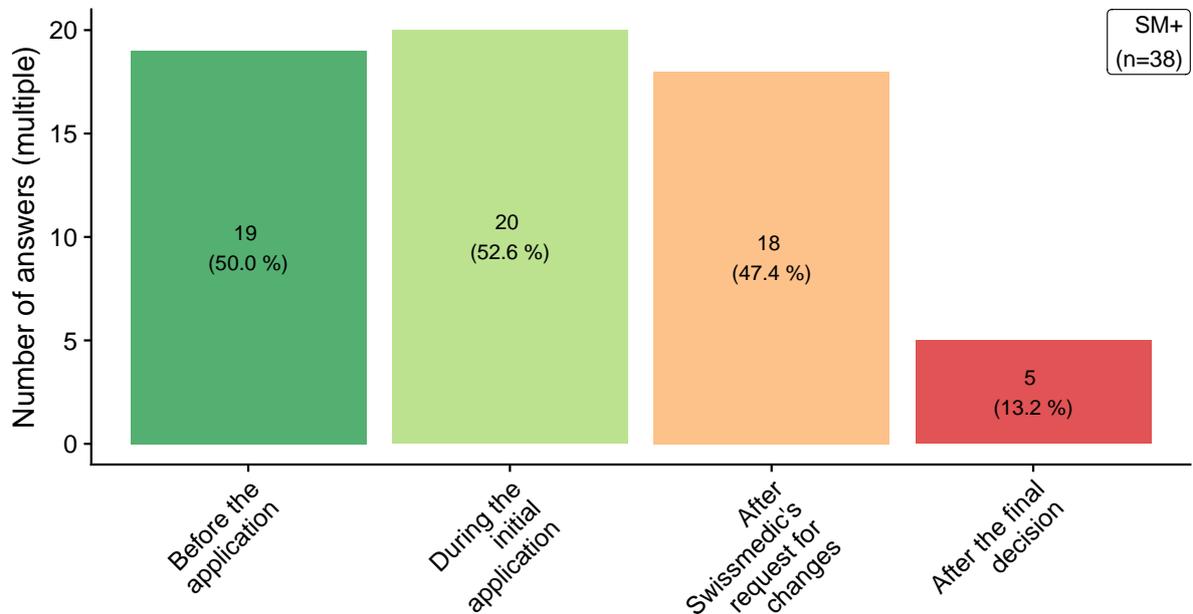
Note: Questions A12 and A13 were only asked for **SM+** (n=94)

A12 When you submitted your project, did you contact Swissmedic for questions or advice?

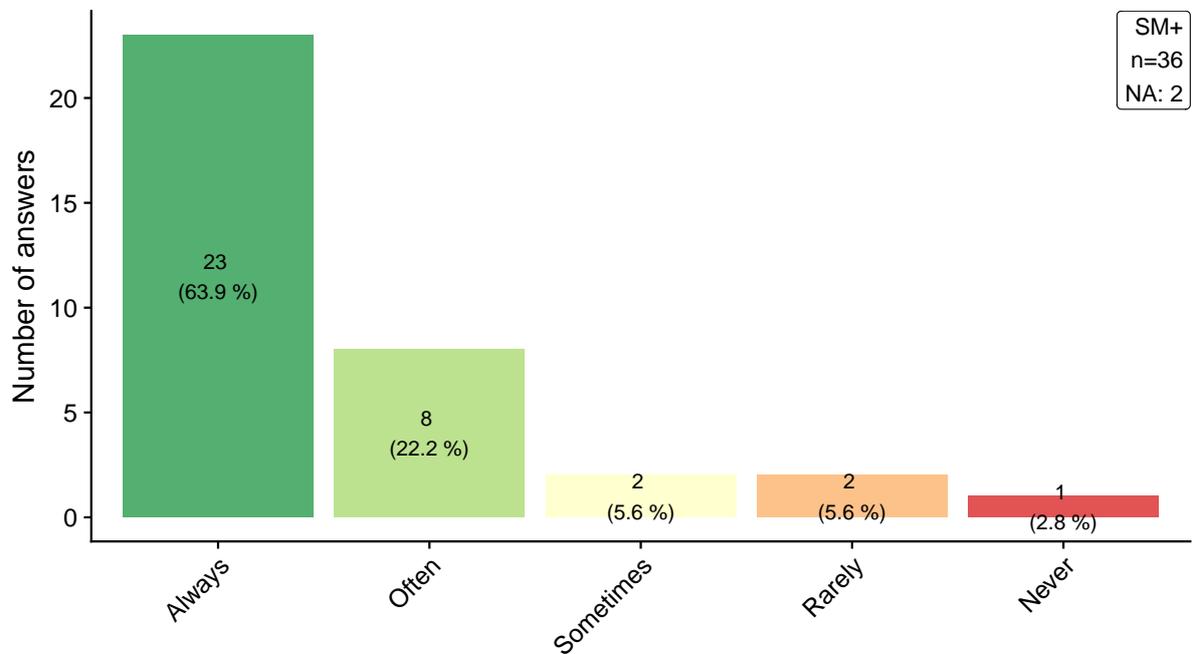


Note: The following two questions were only asked if the previous question A12 was answered with 'Yes, several times' or 'Yes, once' (n=38)"

A12a At which stage of the application process? (multiple answers possible)

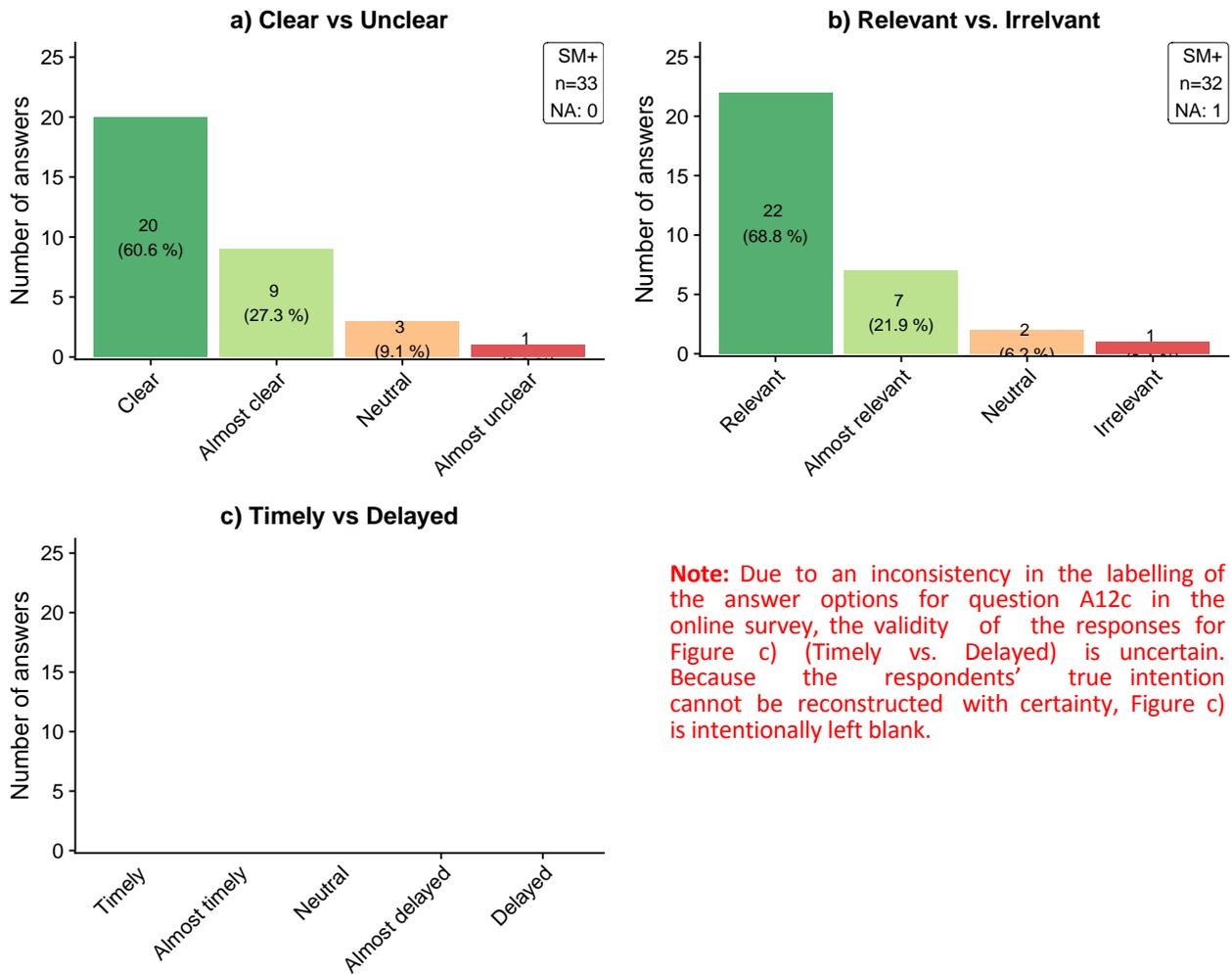


A12b Did you get answers to your request(s)?



A12c Adjectives that best describe the answers received by Swissmedic

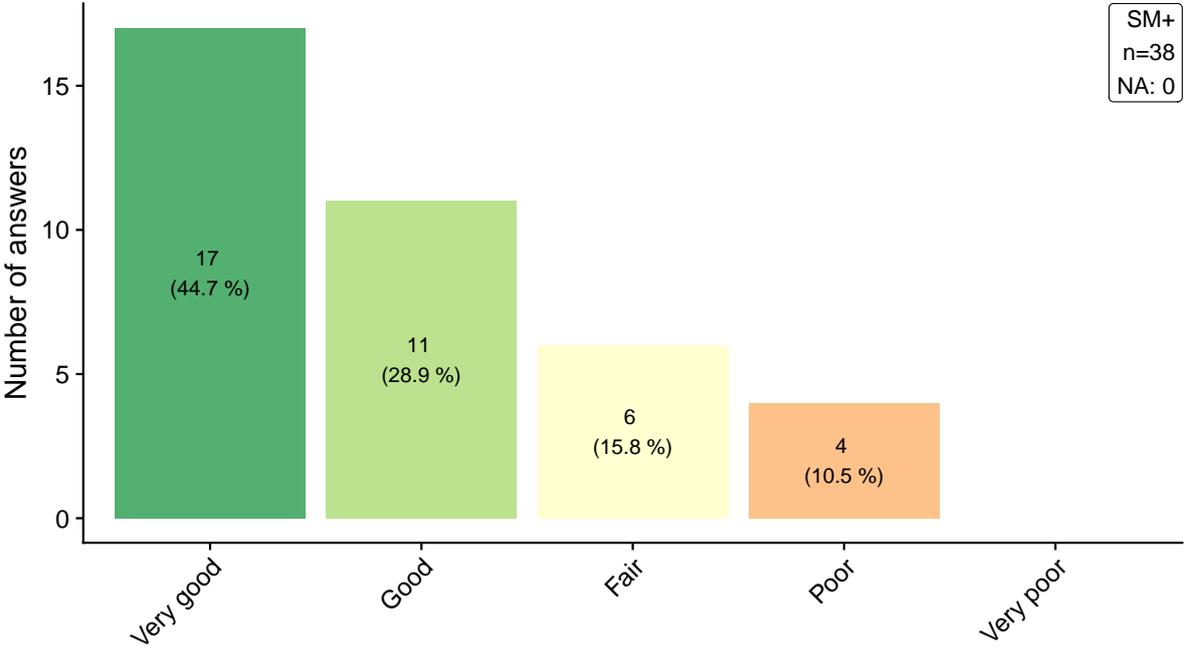
Note: These questions were only asked if the previous question A12.2 was answered with 'Always', 'Often' or 'Sometimes' (n=33)



Note: Due to an inconsistency in the labelling of the answer options for question A12c in the online survey, the validity of the responses for Figure c) (Timely vs. Delayed) is uncertain. Because the respondents' true intention cannot be reconstructed with certainty, Figure c) is intentionally left blank.

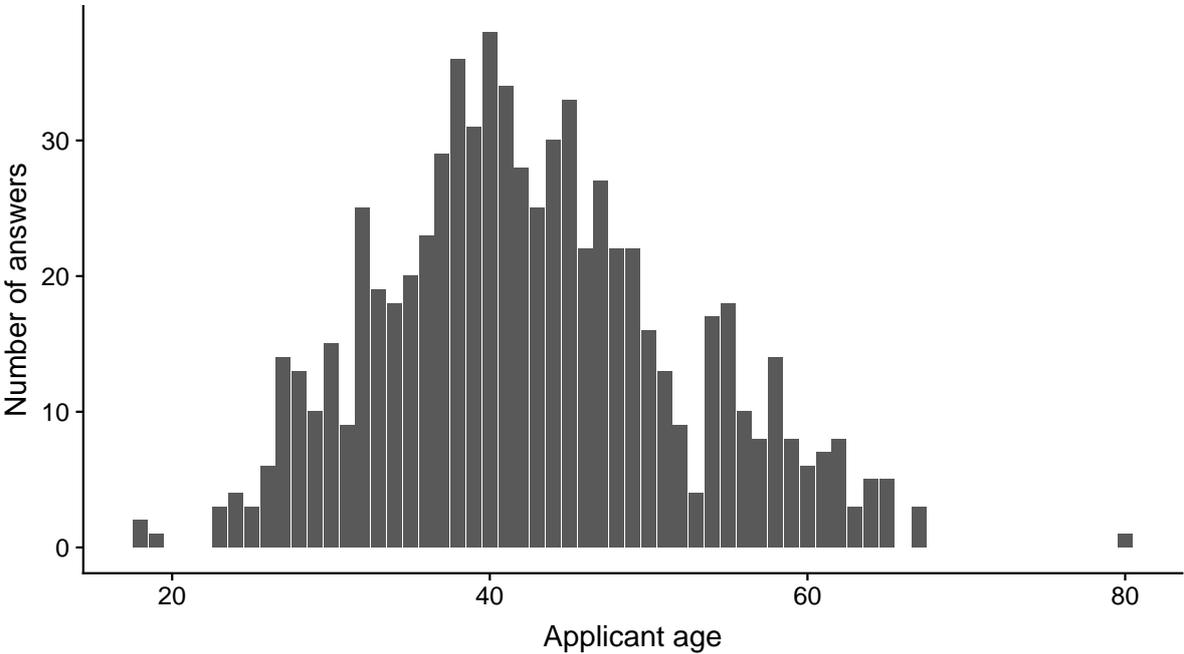
A13 Overall, communication with Swissmedic concerning your application was

...

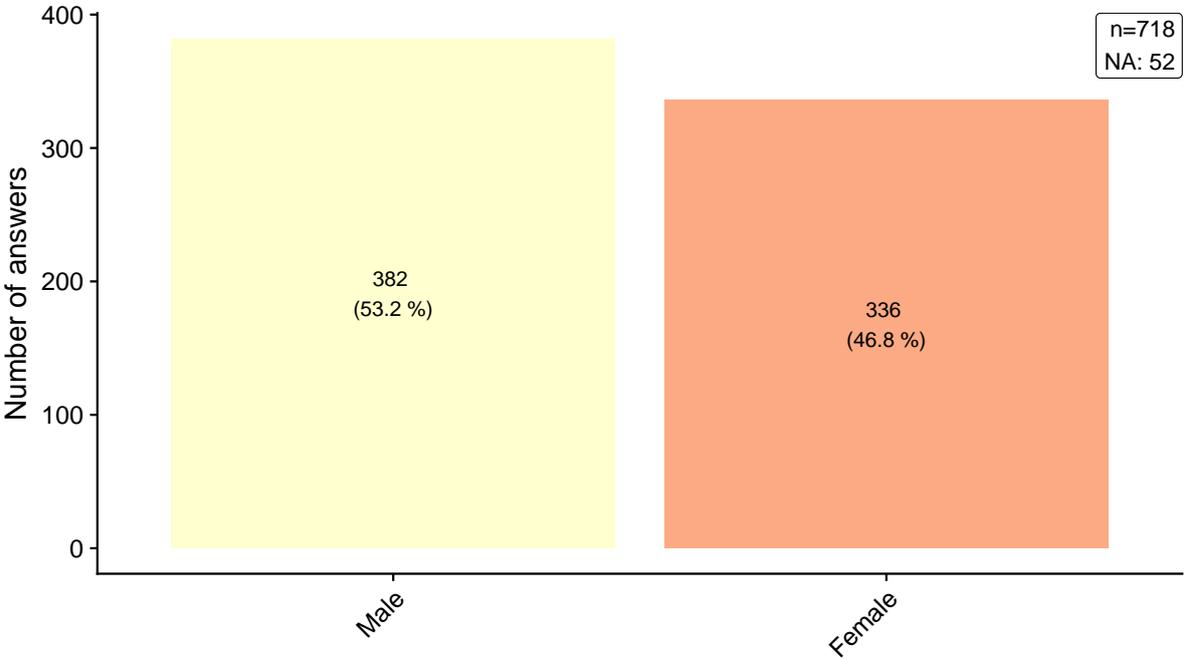


Personal characteristics of respondents

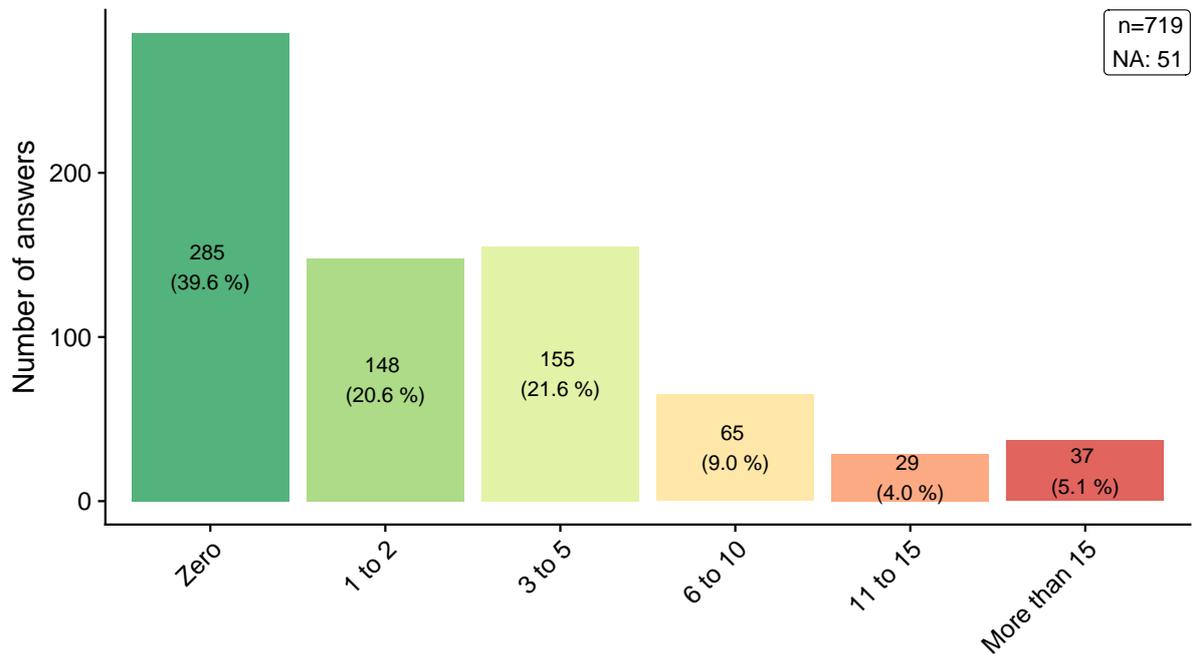
A14 Age



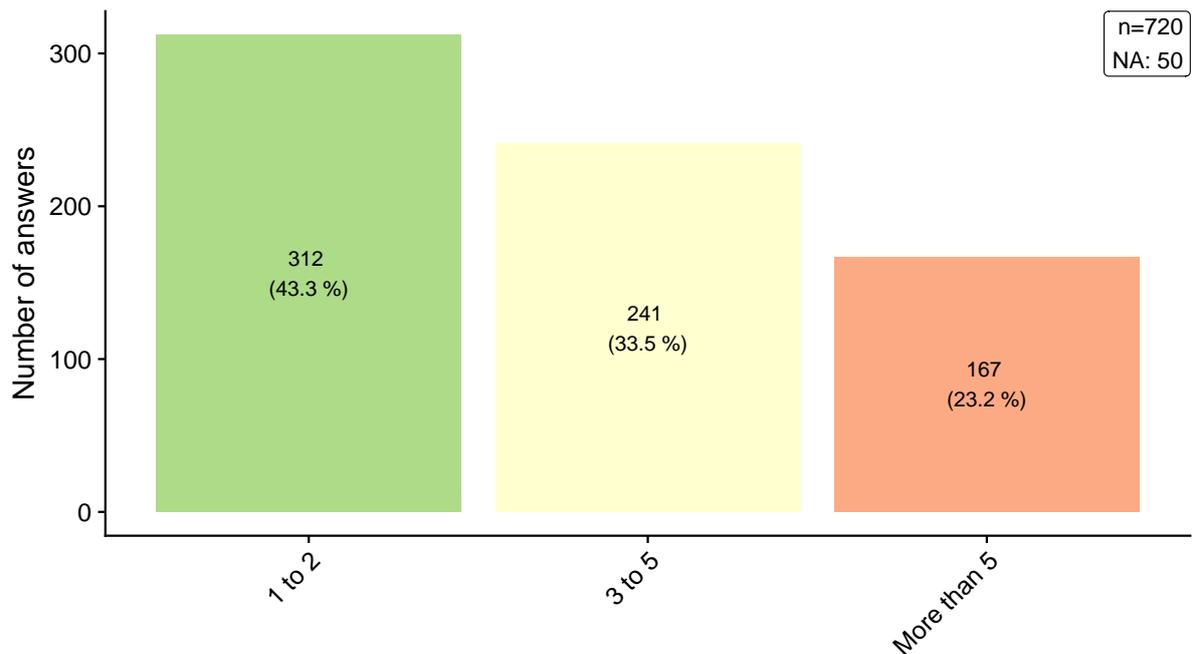
A15 Sex



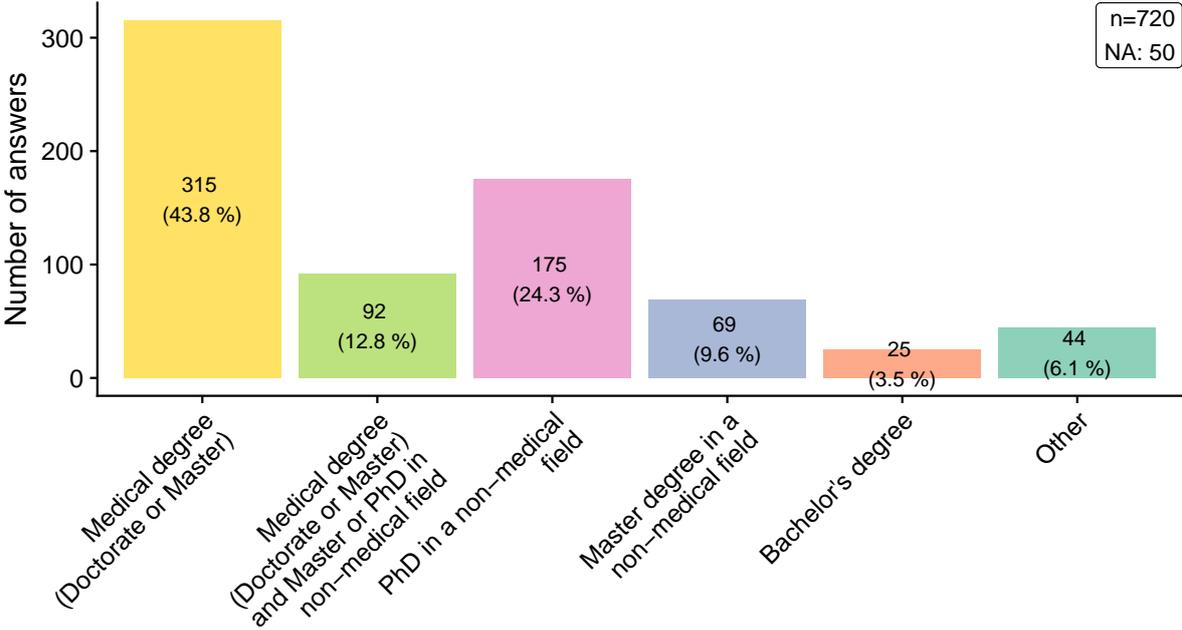
A16 How many research projects have you submitted to Ethics Committees in Switzerland before 1 January 2014 (in any role)?



A17 How many research projects have you submitted to Ethics Committees in Switzerland since 1 January 2014 (in any role)?

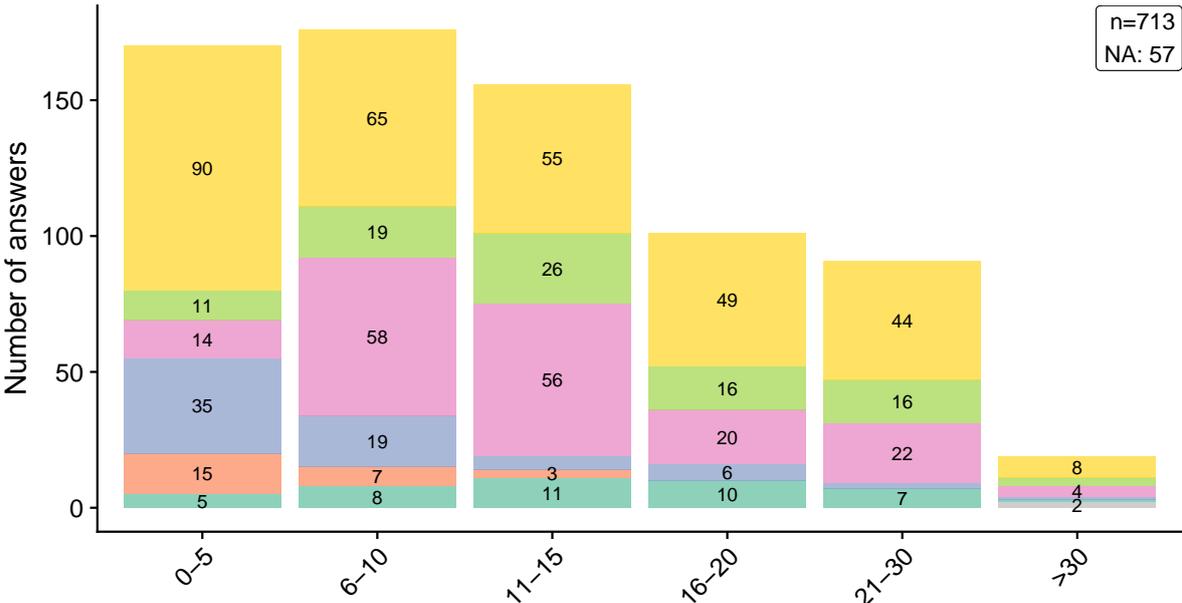


A18 What is (are) your highest professional qualification(s)?



A19 For how long have you been working in research?

- Medical degree (Doctorate or Master)
- Medical degree (Doctorate or Master) and Master or PhD in non-medical field
- PhD in a non-medical field
- Master degree in a non-medical field
- Bachelor's degree
- Other
- NA



A20 Currently, you are working as... (multiple answers possible)

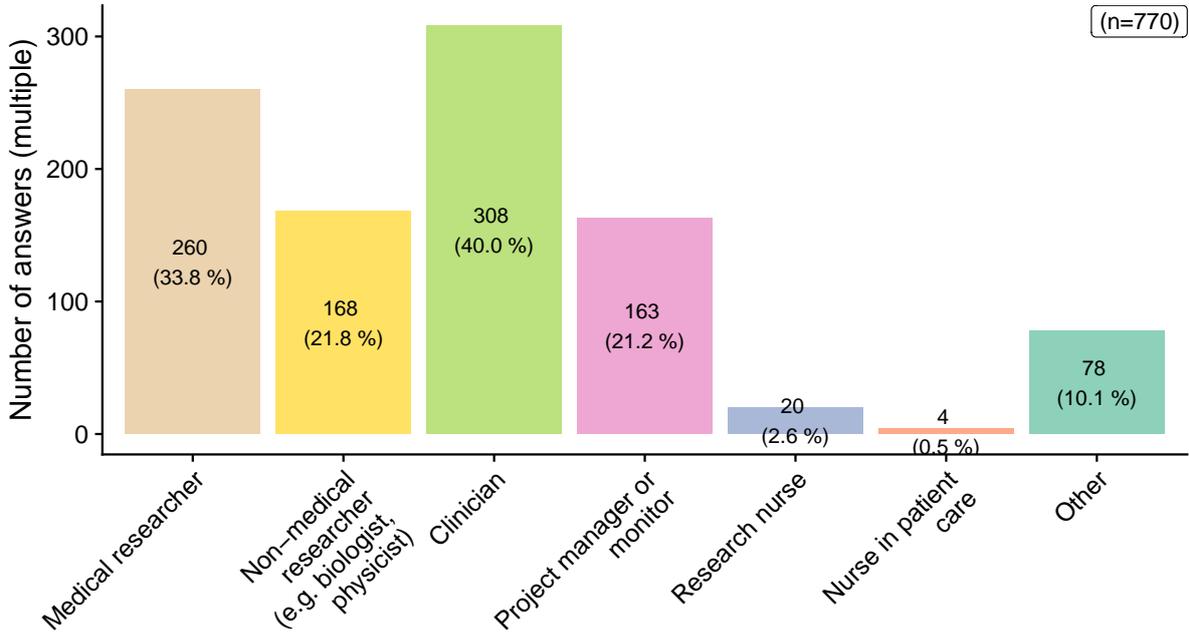
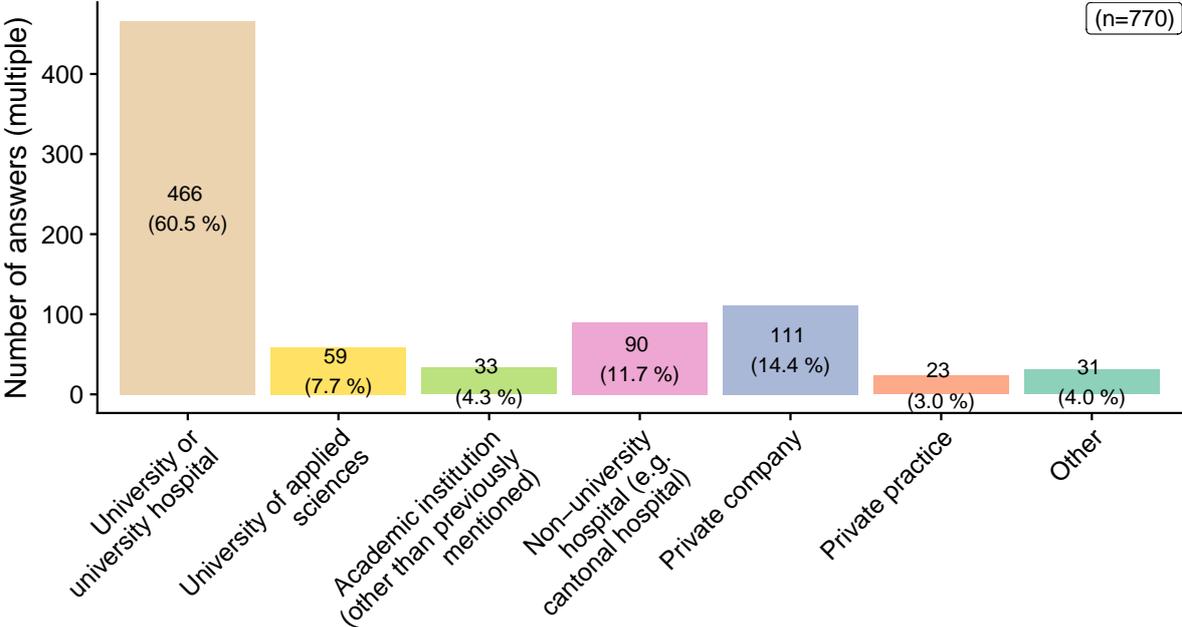


Figure A20.1: Wordcloud of freetext answers provided for 'Other'.

A21 In which area/setting are you working? (multiple answers possible)



A22 In which field of research are you working? (multiple answers possible)

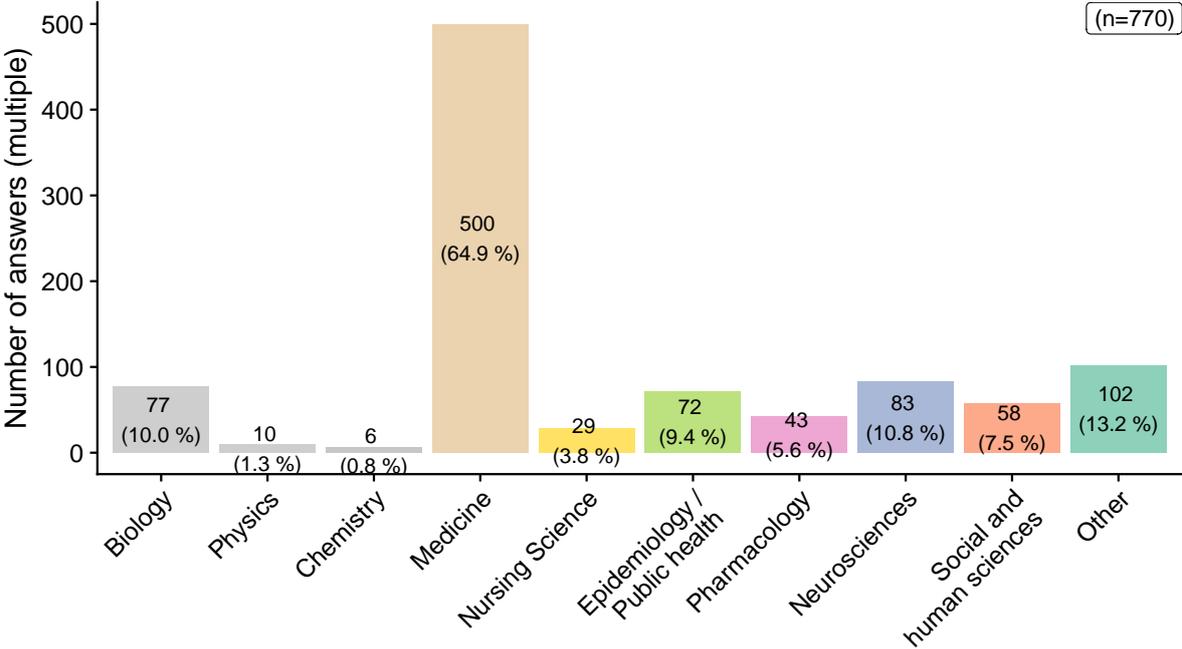
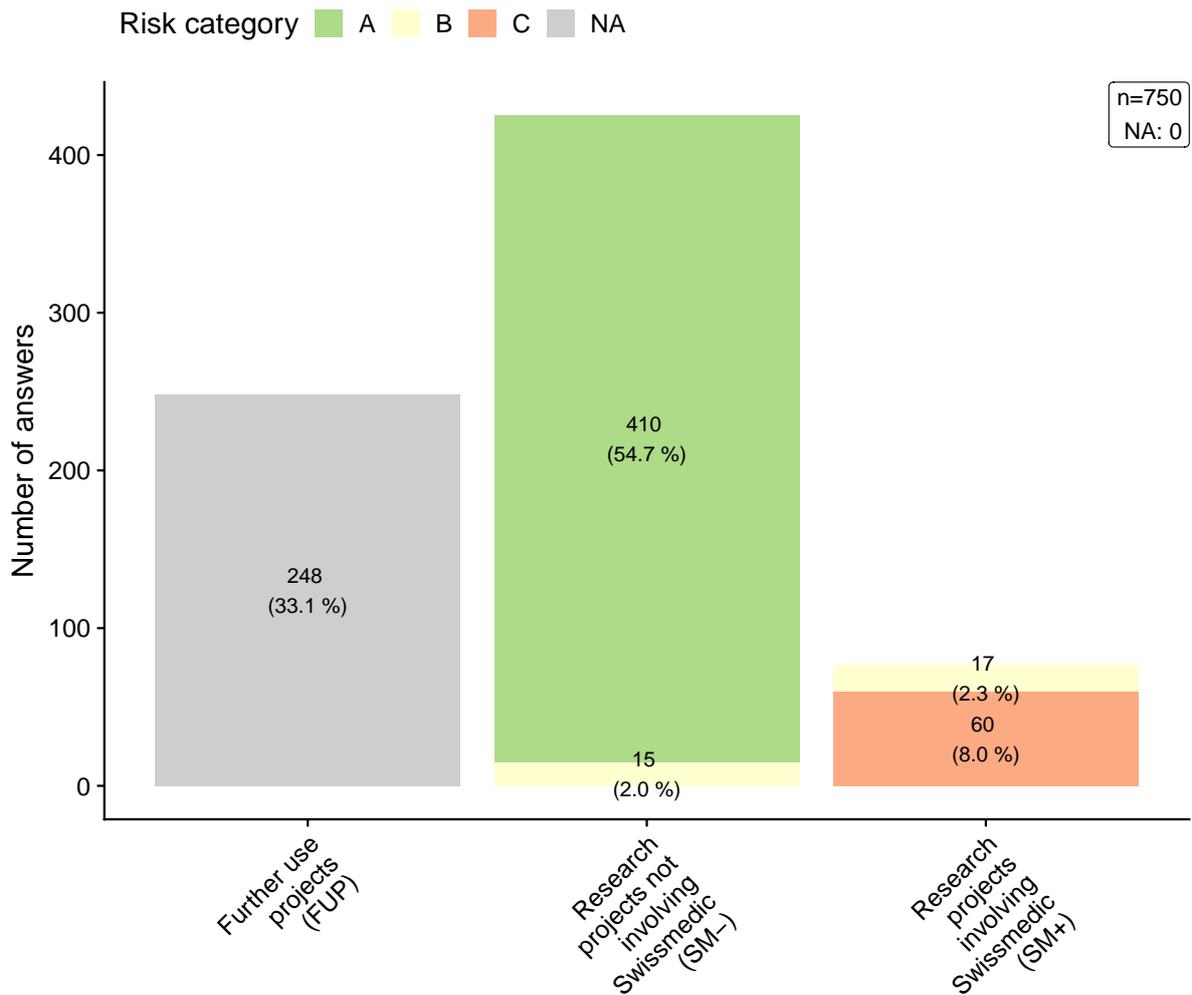


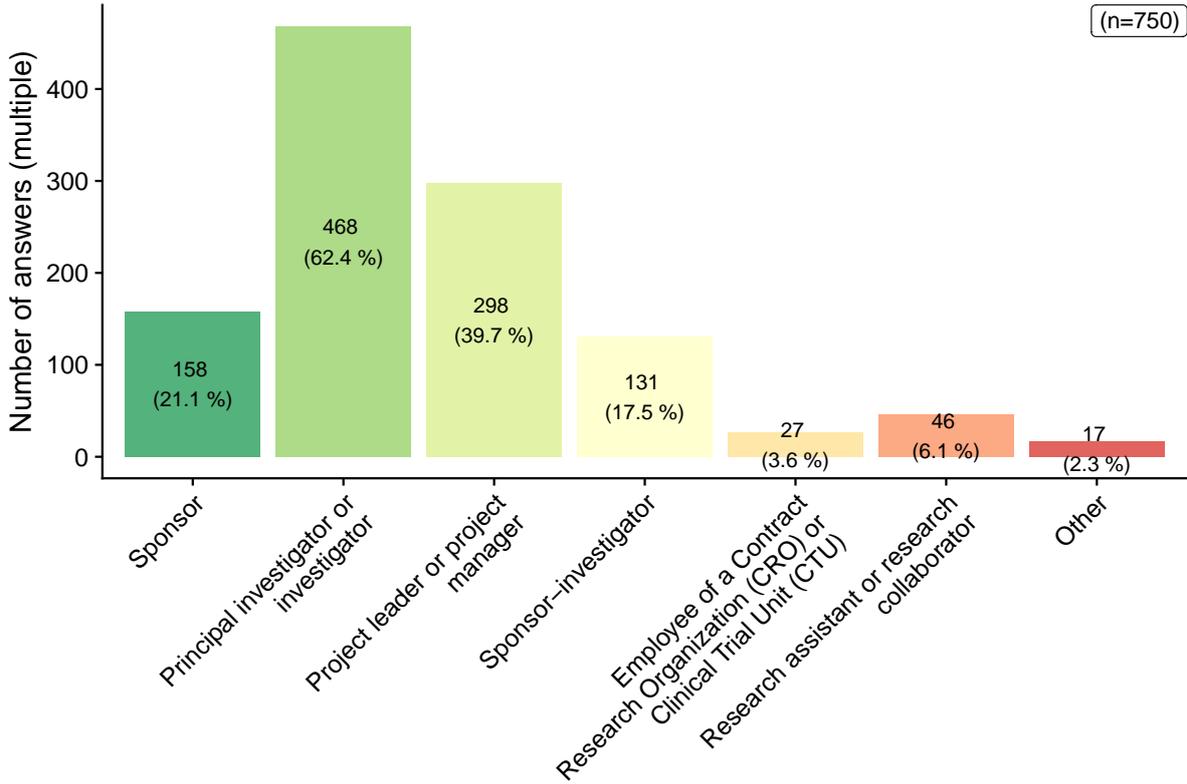
Figure A22.1: Wordcloud of freetext answers provided for 'Other'.

B Questions concerning the opinion about the impact of the HRA and its ordinances on research activities addressed to investigators that take the overall responsibility of research projects (Part B)

Distribution of projects of survey respondents by type of study

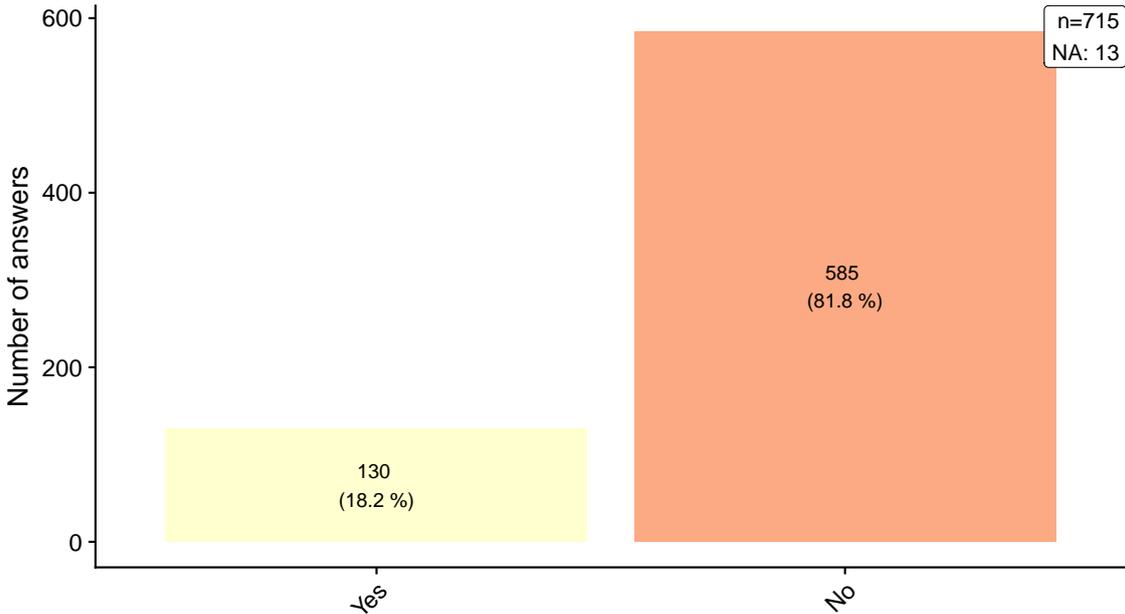


B1 Please indicate your role in project (multiple answers possible)

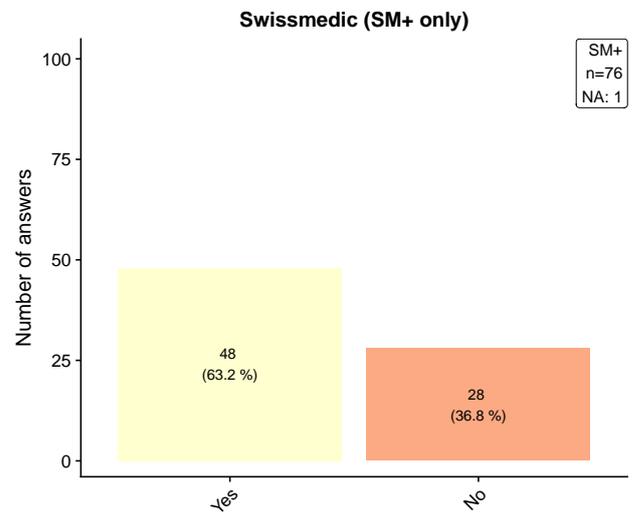
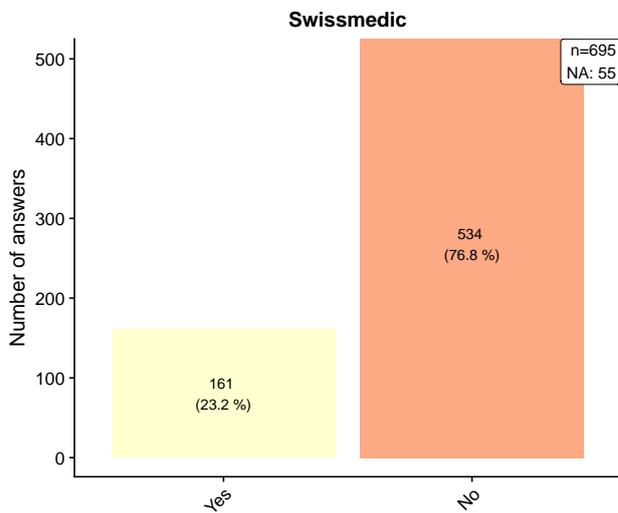
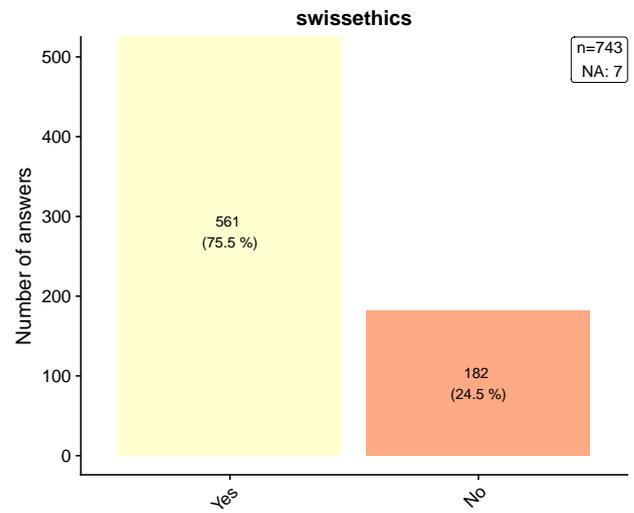
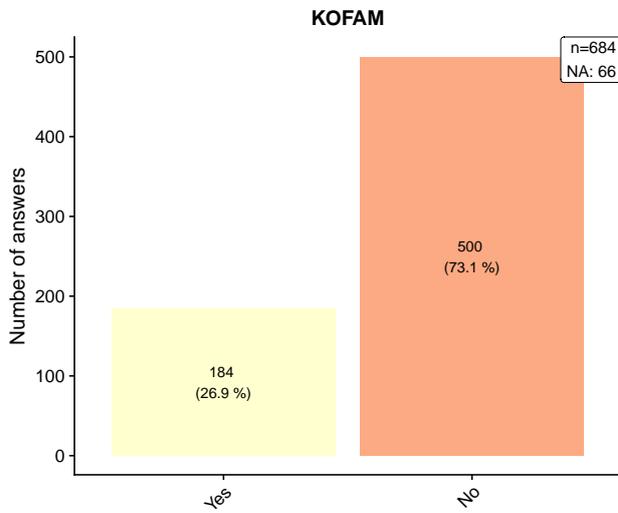


B2 Did you receive any support from a Clinical Trial Unit (CTU) or a Contract Research Organization (CRO) for the design and planning ?

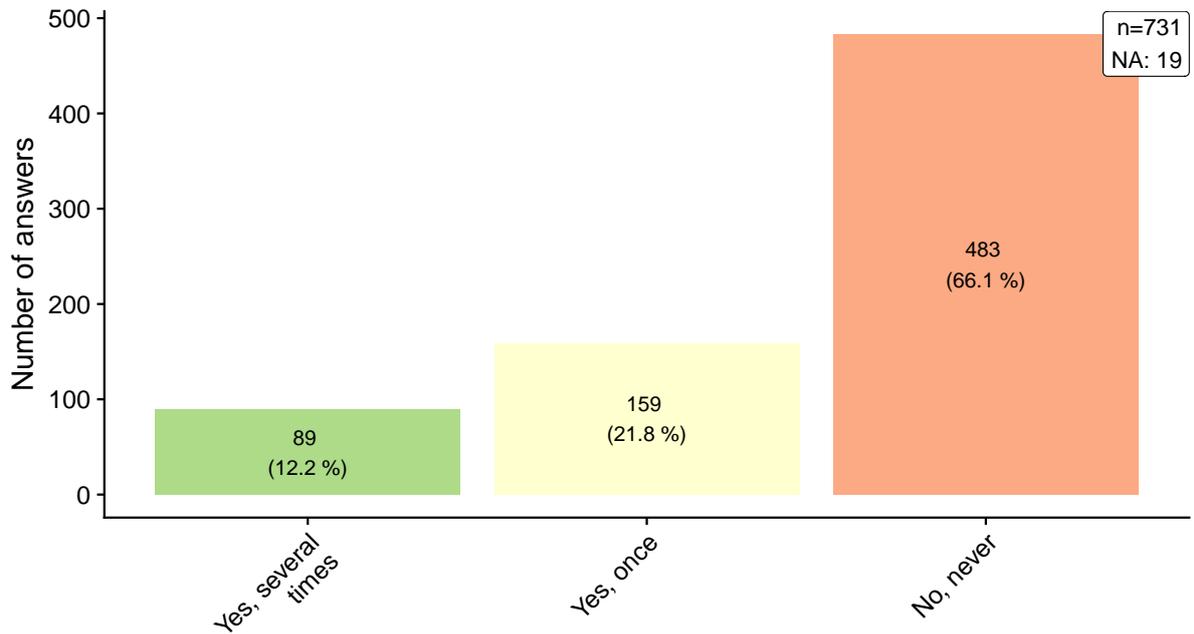
Note: This question was only asked if the applicant was not from CTU/CRO (n=728)



B3 Before and during the design and planning of the project, did you visit the websites of the following organisations?

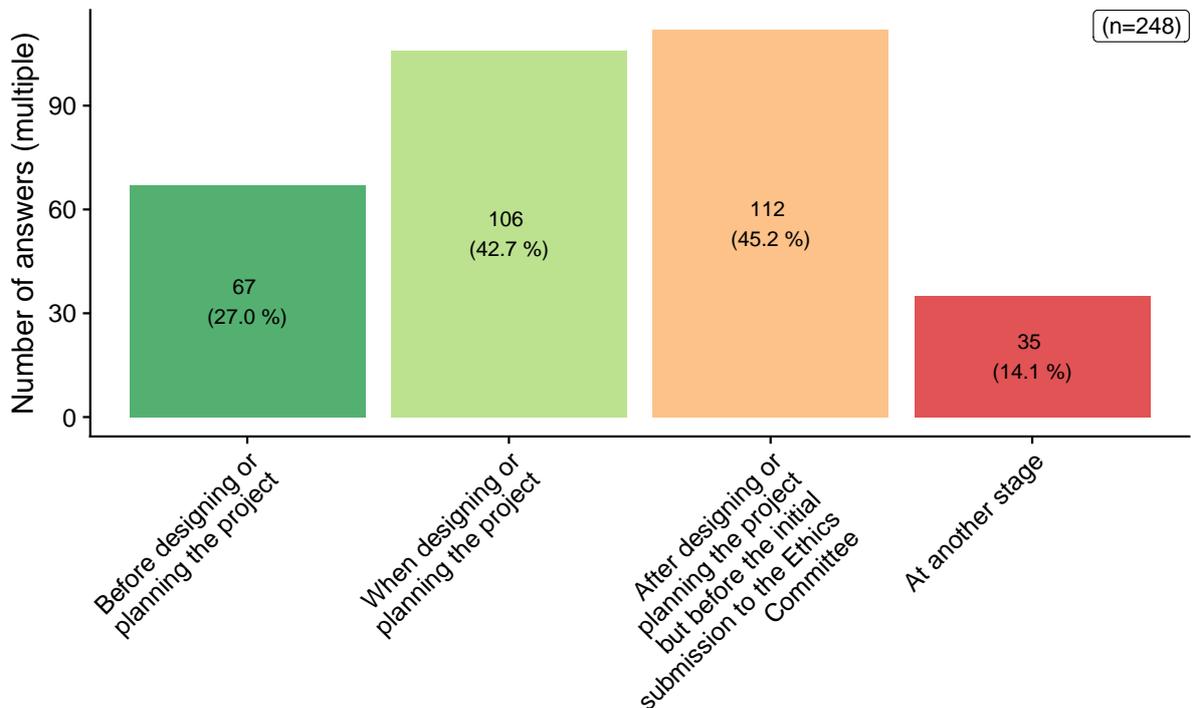


B4 Did you contact the Ethics Committee for questions or advice about the design or planning of your project?

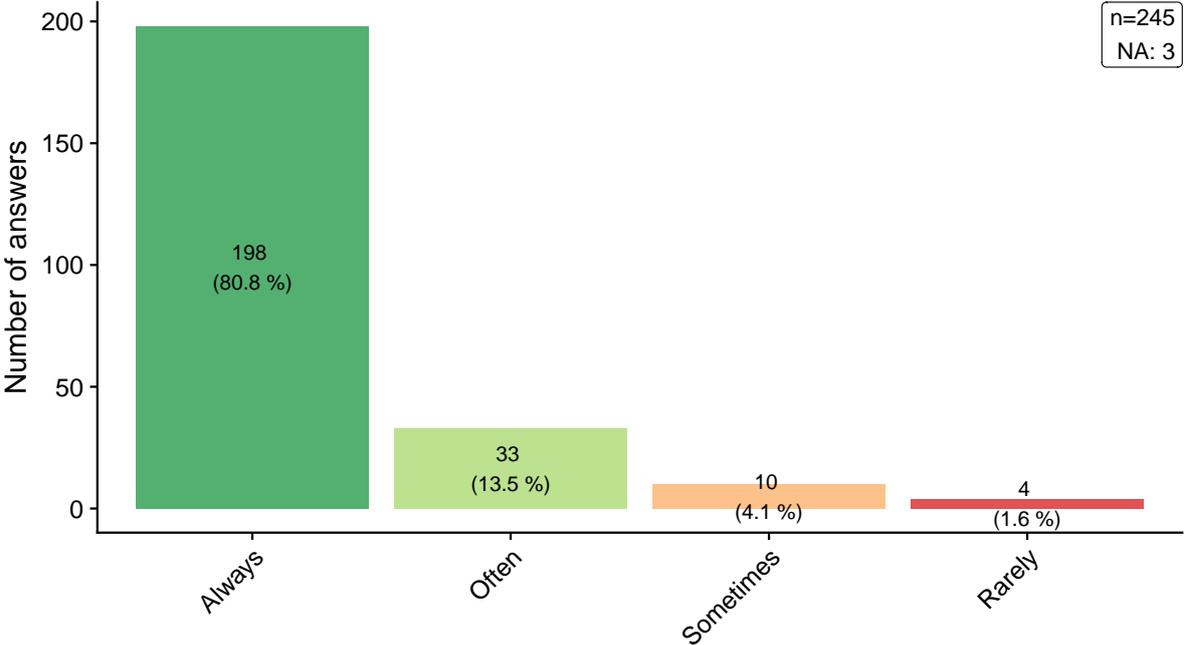


Note: The following two questions were only asked if the previous questions was answered with 'Yes, several times' or 'Yes, once' (n=248)

B4a At which stage of the application process? (multiple answers possible)

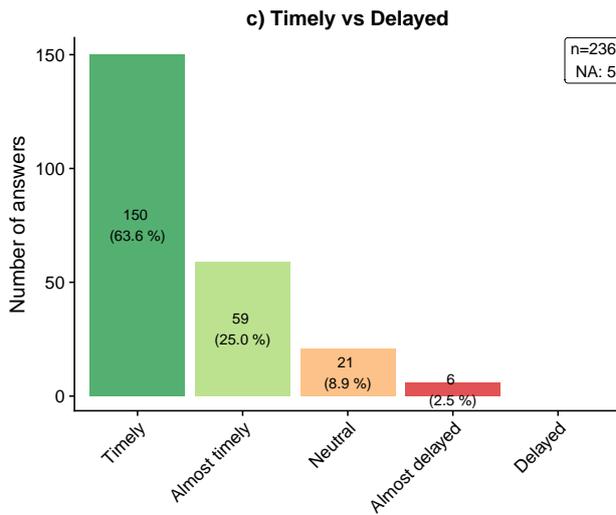
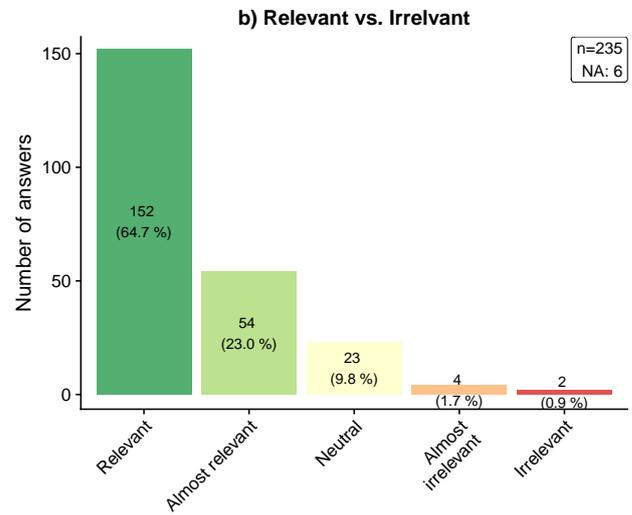
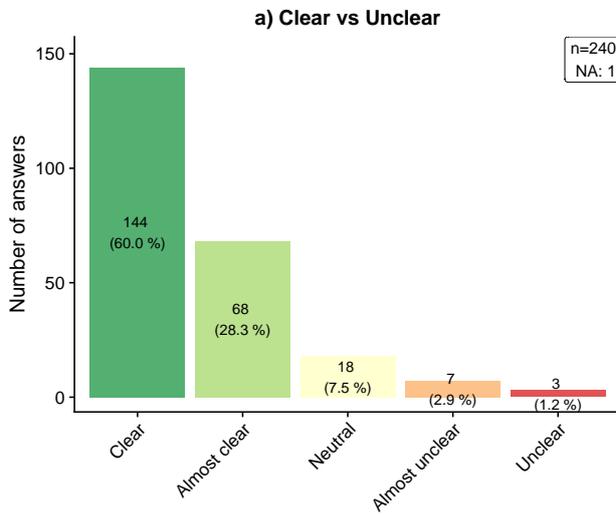


B4b Did you get answers to your request(s)?



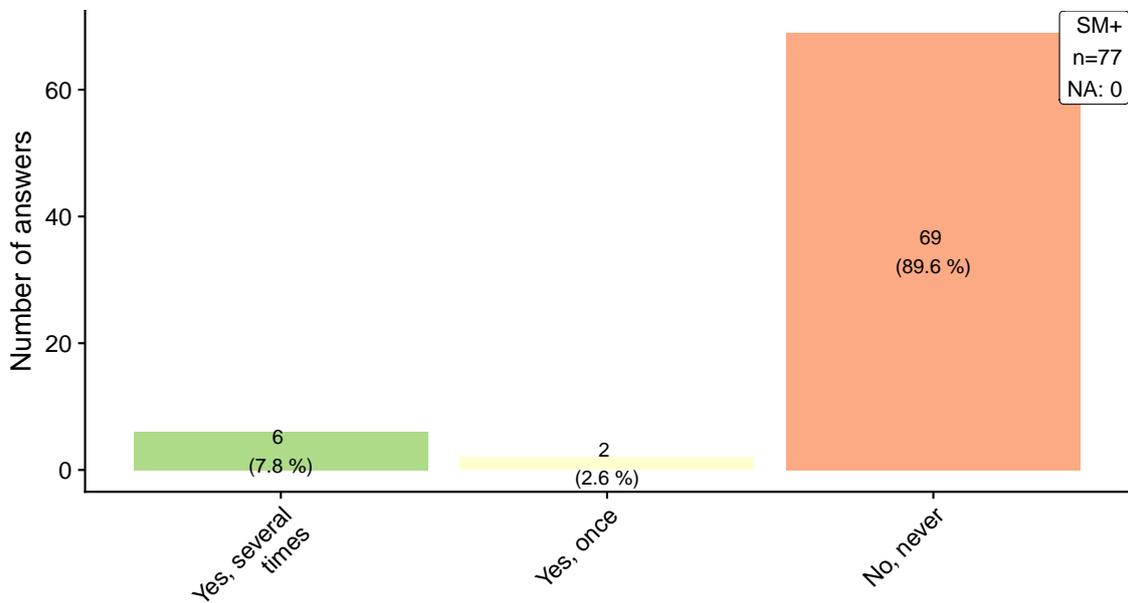
B4c Adjectives that best describe the answers received by Ethics Committee or swissethics

Note: These questions were only asked if the previous question was answered with 'Always', 'Often' or 'Sometimes' (n=241)



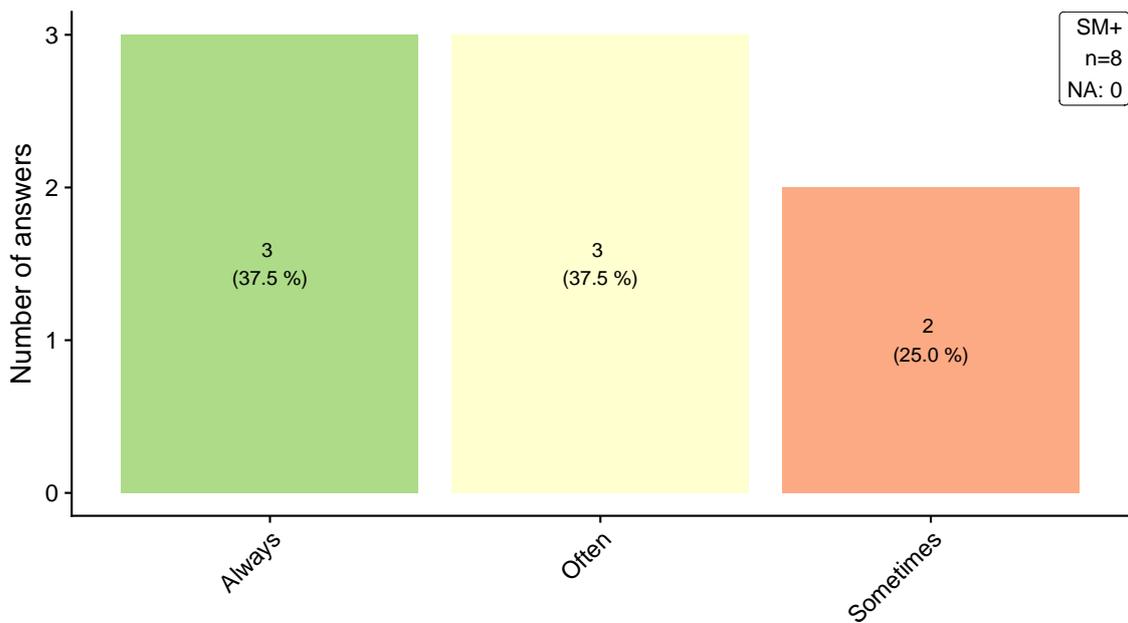
B5 Did you contact Swissmedic for questions or advice about the design or planning of your project

Note: This question was only asked for projects concerning a clinical trial with risk B and C (n=77)

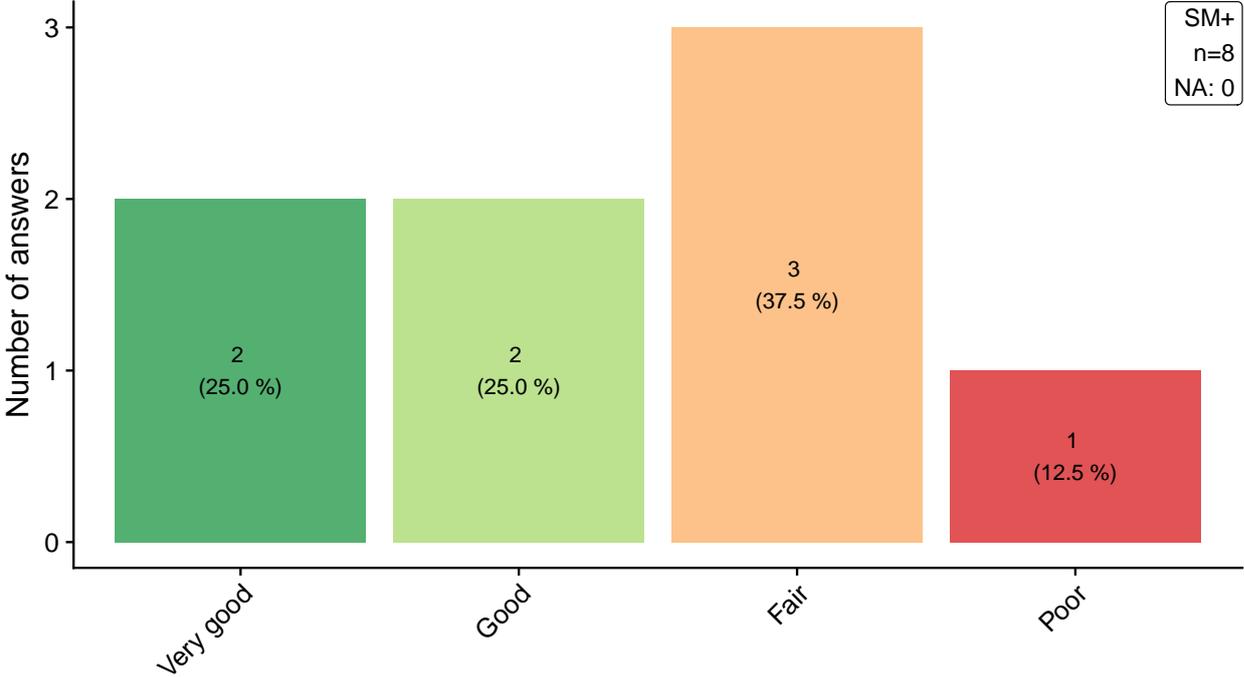


Note: The following two questions were only asked if the previous question was answered with 'Yes, several times' or 'Yes, once' (n=8)

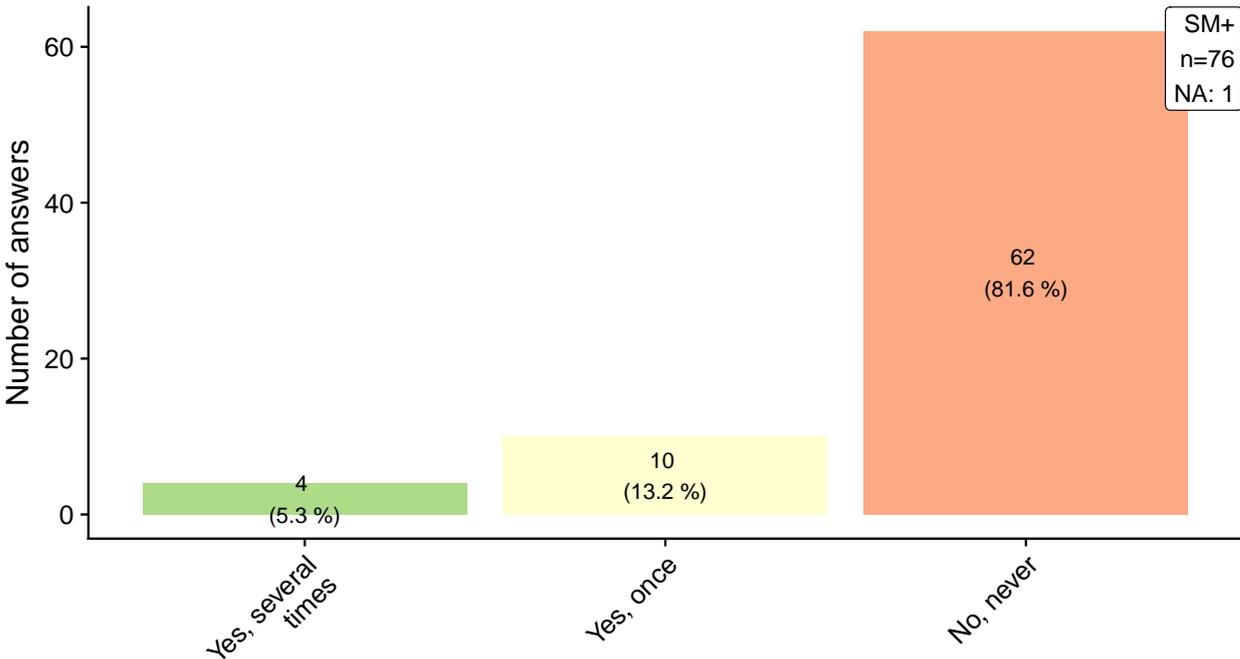
B5a Did you get answers to your request(s)?



B5b Concerning the questions or advice about the design or planning of your project, the communication with Swissmedic was...



B6 Concerning your project, did you experience inconsistencies between the Ethics Committee and Swissmedic?



B6a What were these inconsistencies about?

Yes, several times Many formal requirements are rather futile from both sides, without any consistency. It is impossible to prepare the same contents and to submit them to both EC and SM, despite the fact that they depict the same study!

Yes, several times Protocol design

Yes, several times Classification of the risk status

Yes, several times Reconnaissance du titre de formation GCP. Plusieurs détails formels exigés tantôt par Swissmedic, tantôt par la CER, sur des bases non-concordantes et arbitraires (c'est-à-dire non justifiées par un quelconque règlement).

Yes, once risk category classification discrepancies between ethics committee and swissmedic

Yes, once Swissmedic considers pregnancy as an exclusion criteria for the administration of vitamin D.

Yes, once The discrepancy between categorization of study initially by EK (category B) and Swissmedic (category C) The study was initially submitted to EC by sponsor as category C The study was later re-categorized by EC to category C as requested by Swissmedic

Yes, once Category of the trial.

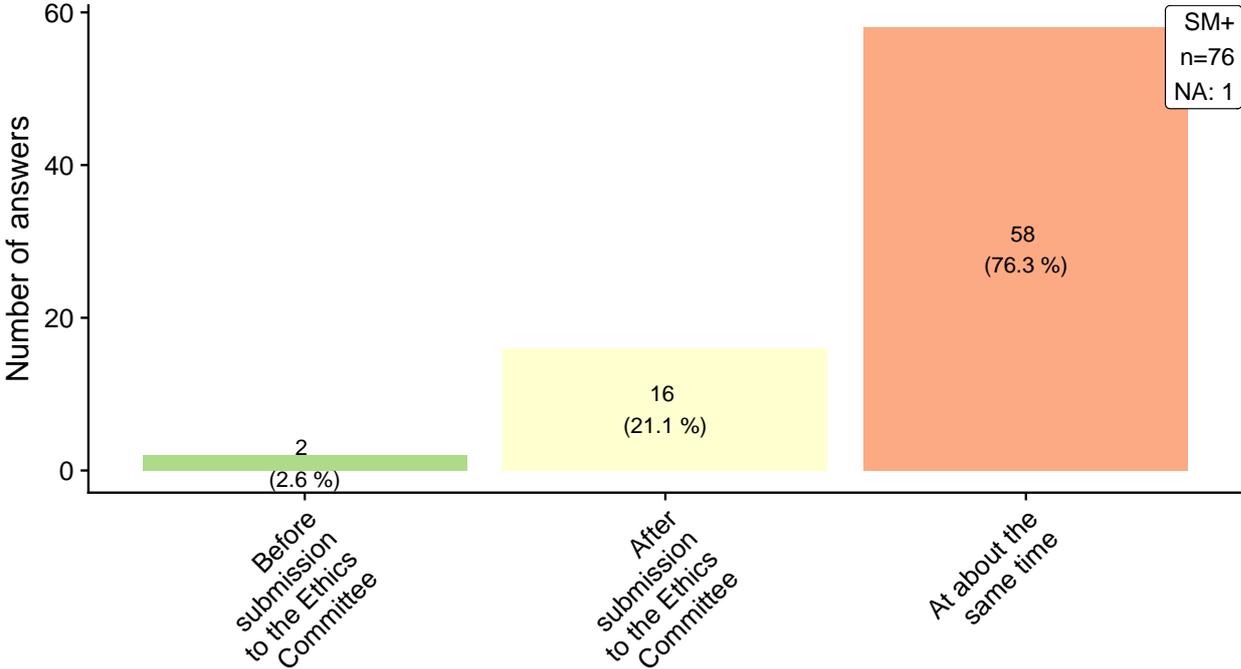
Yes, once Categorization of trials where the compound is approved by Swissmedic for commercial use, but trials are performed with a different formulation/in a different indication/population seems to be interpreted differently by Swissmedic and ECs.

Yes, once After commencing the project, we asked for changes, that were approved by the Ethic's committee. For Swissmedic's information, the documents were sent to them as well. The document was sent back twice for changes that did not need approval by Swissmedic. (1st time: a cover form was not filled in, 2nd time: they requested a CD rom). Whether or not these documents are required is not the question, but I would appreciate a one time feedback with all things, that are missing instead of getting the information in several stages.

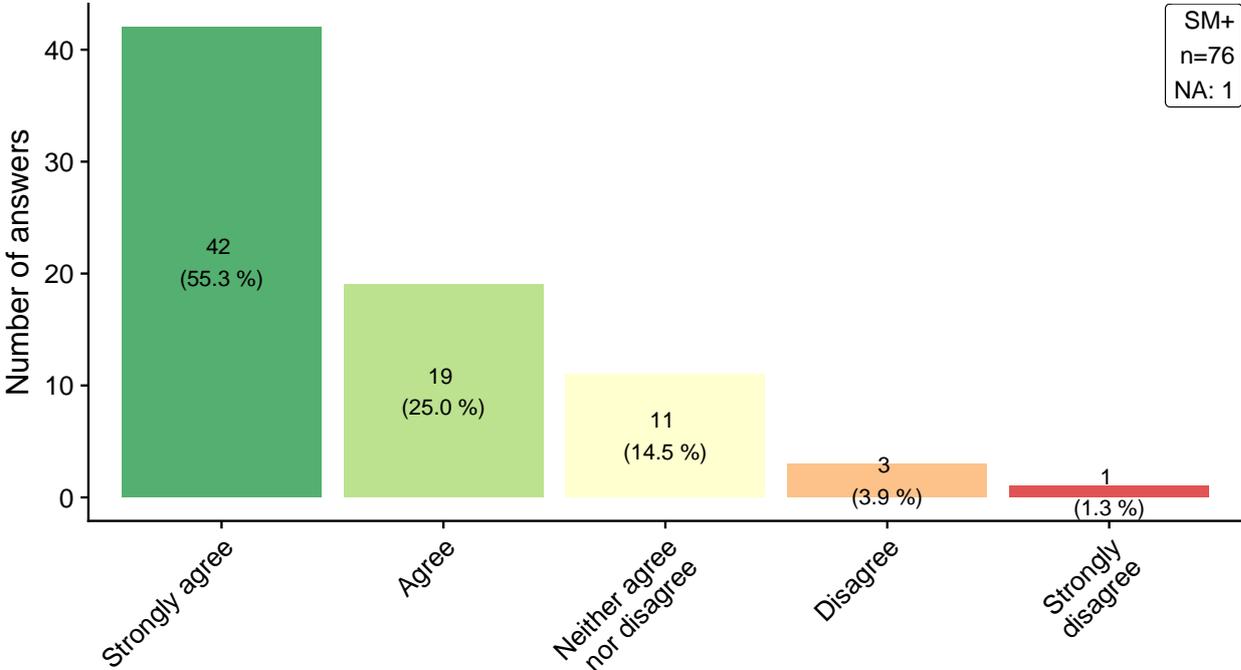
Yes, once about statistics and sample size calculation

Yes, once The involvement of patients of childbearing age
'n' too low

B7 Did you submit the project to Swissmedic...

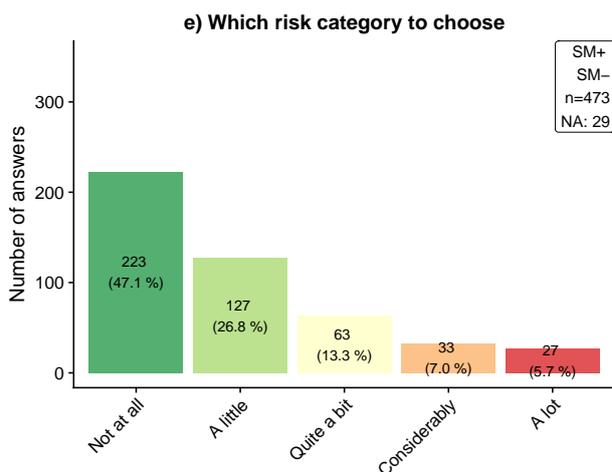
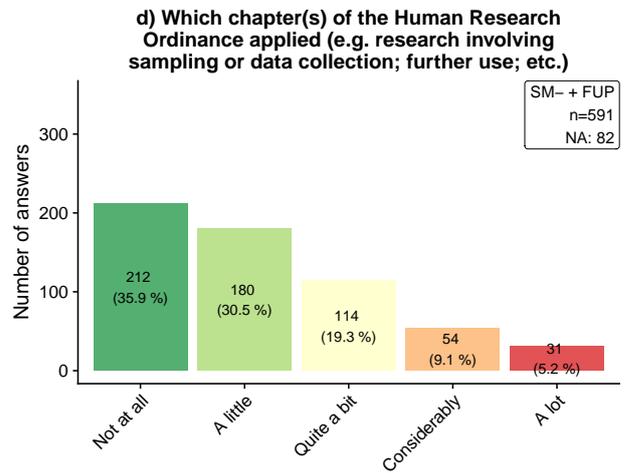
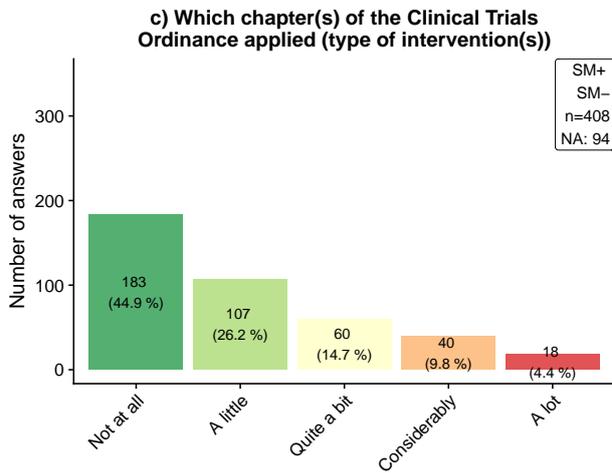
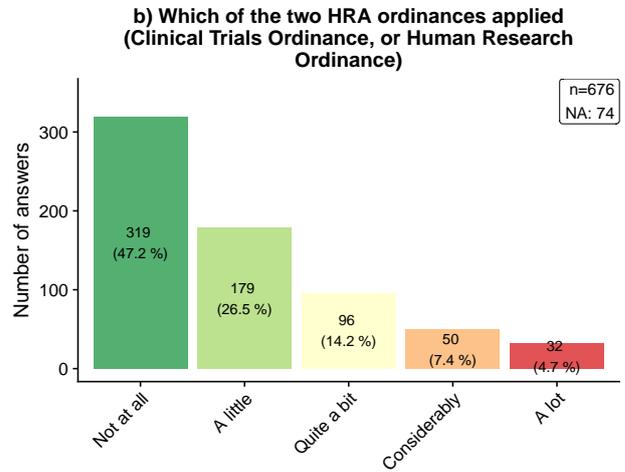
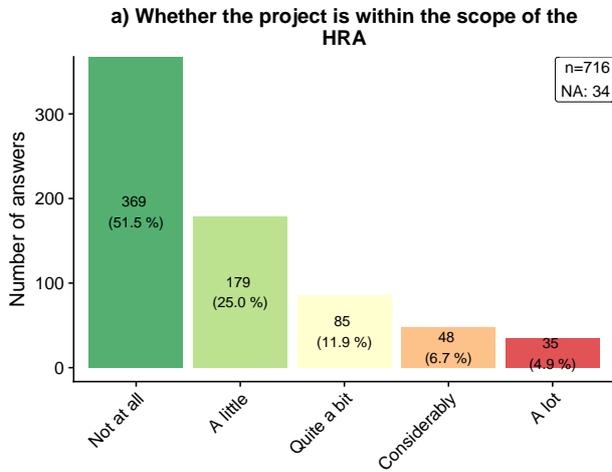


B8 Parallel submission of applications to both Ethics Committee and Swissmedic is an advantage.



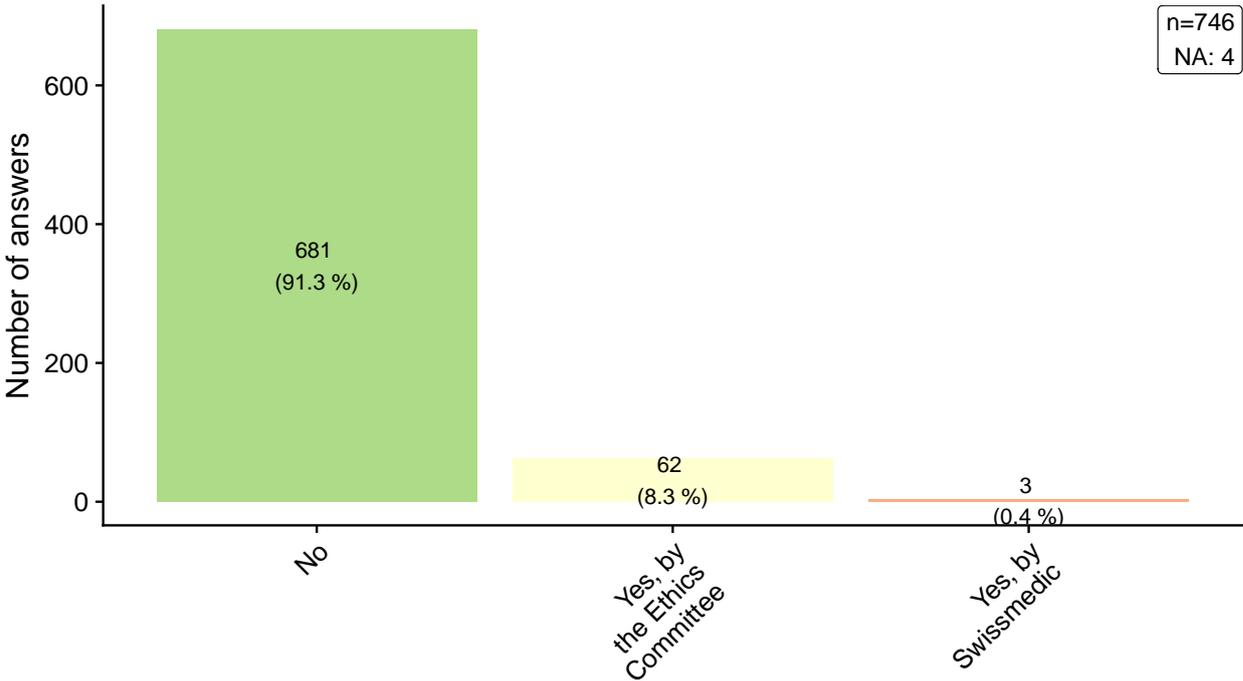
Questions concerning the compliance of the project with the HRA and its ordinances

B9 When designing or planning your project, was it difficult to determine the following aspects?



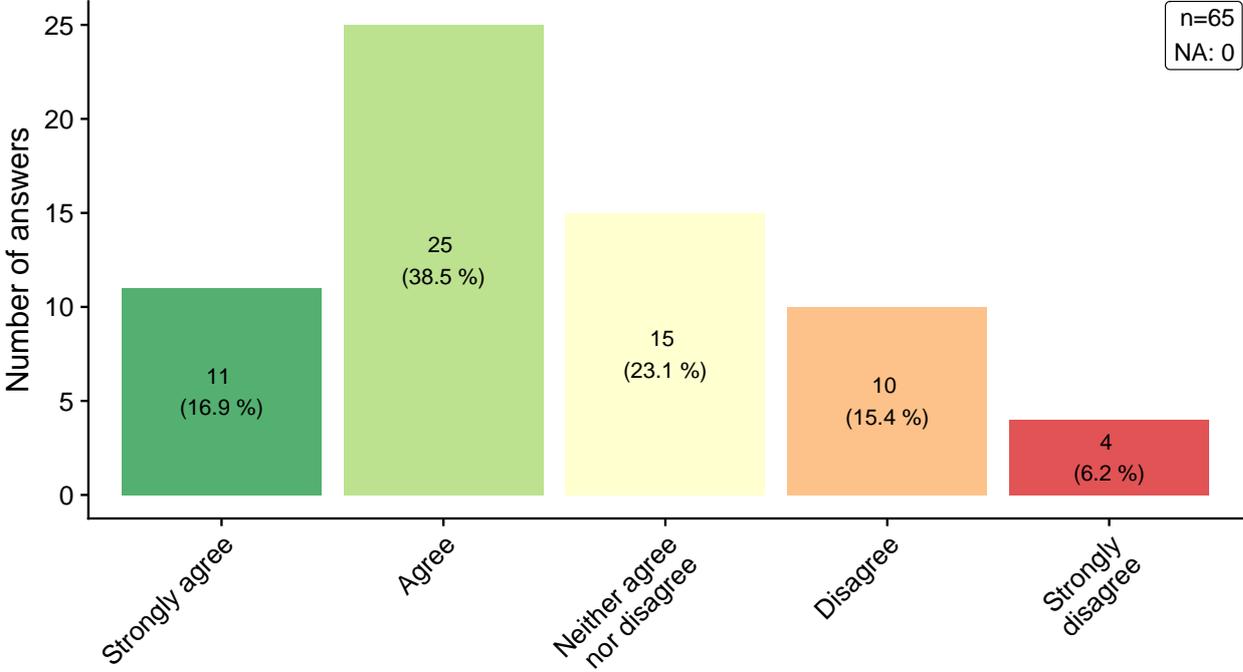
Answers 'Don't know' were attributed to the group NA.

B10 Was the type of study changed after submission?



B10a How much did you agree or disagree with this change?

Note: Asked if previous answer is 'Yes' (n=65)



Why?

Note: This questions was only asked if the previous questions was answered with 'Strongly disagree' or 'Disagree' (n=14)

Strongly disagree The EC does seem to apply too strict interpretations of terms, different from common sense/legislator intent

Strongly disagree Project is aiming towards assessing the impact of physiological factors on the ability of CT to determine coronary calcifications when different CT scanning parameters (tube voltage, tube current) are applied. This has nothing to do with what I'd consider a clinical trial.

Strongly disagree A telephone interview doesnt make the study prospective in my opinion, we had some discussions.

Strongly disagree This harmless project should never produce the paperwork that we had to fill out. It should have received a Unbedenklichkeitserklärung upfront.

Disagree We believe that the ethics committee uses the term 'clinical' differently than common sense and intended by the legislator.

Disagree Too demanding for just 1 phonr call

Disagree NA

Disagree Change of category from first contact and info to submission

Disagree I was surprised that the committee decided that project n°2017-01365 is not a HRA-project.

Disagree A simple blood samling is no clinical trial in my understanding.

Disagree study type and risk classification as done by Swiss Medic was also questioned by the local EC

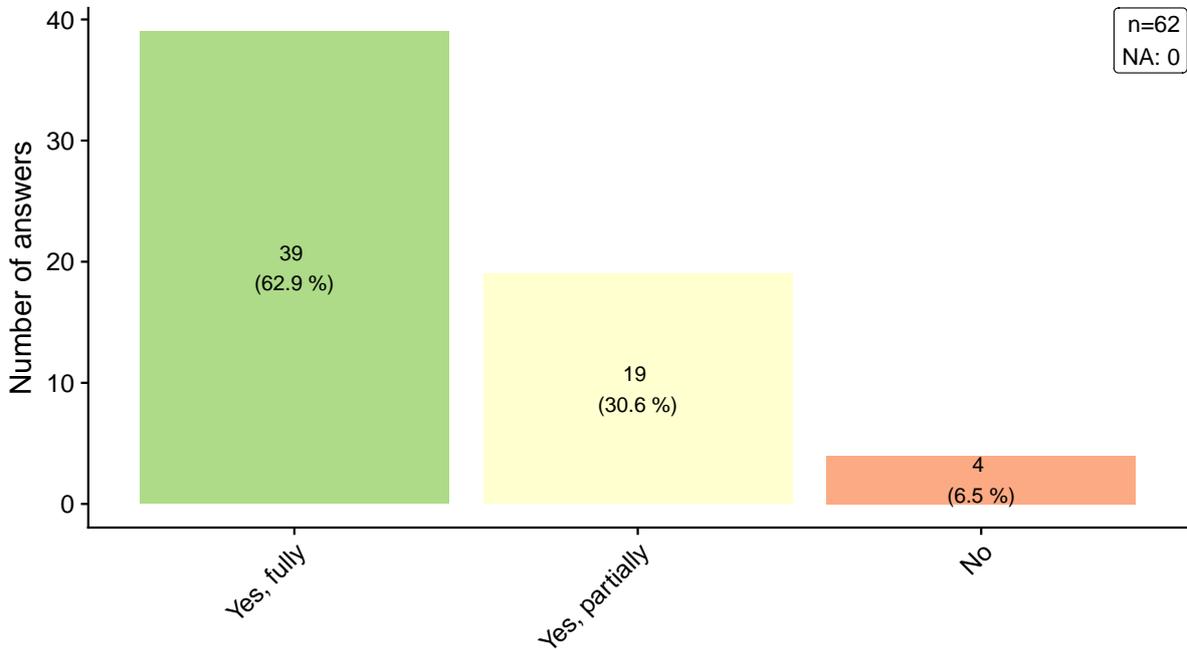
Disagree Because was bad explained in the beginning

Disagree Our reply was: "La classification de l'étude relève des compétences du comité d'éthique. Cependant, nous ne considérons pas notre étude comme un essai clinique. Le but des interventions dans cette étude, c'est-à-dire, les repas standardisés, n'est pas « d'évaluer les effets de ces dernières sur la santé » mais uniquement de diminuer les facteurs confondants (mesure d'étalonnage) afin de pouvoir comparer la réponse en glucose entre les individus. Nous avons expliqué ce point dans le protocole, p.9, dans le paragraphe qui commence par : « This is a cross-sectional ... »"

Disagree Study was a simple follow-up of healthy population with minimal intervention and yet had to be considered a clinical trial

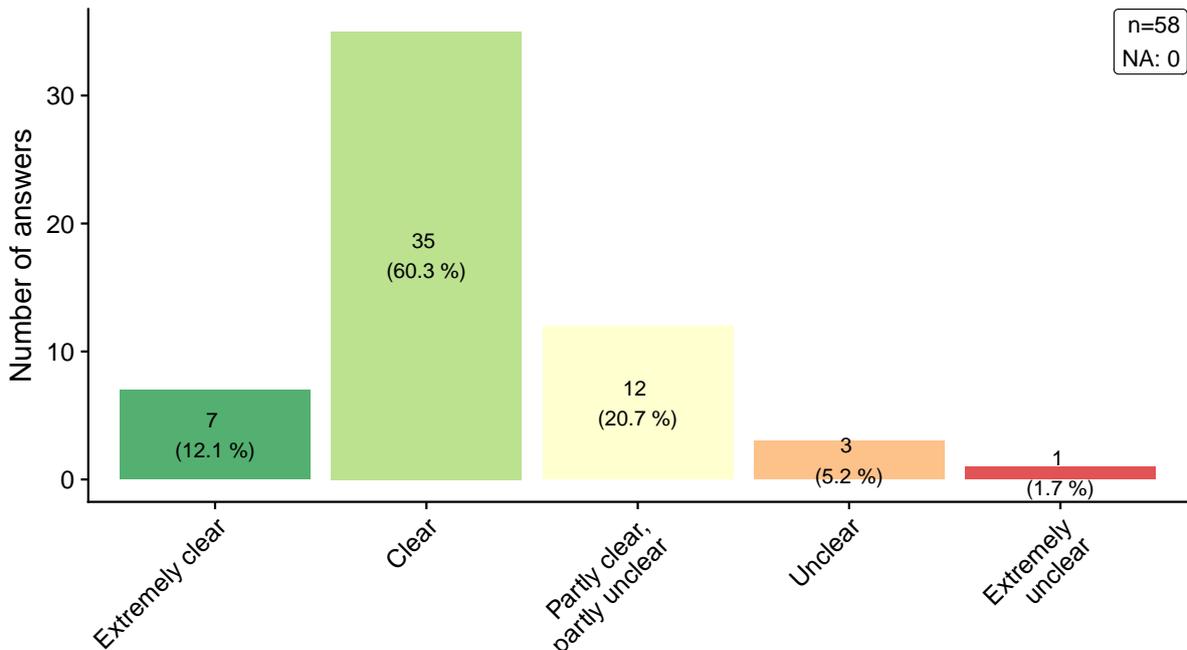
B10b Did the Ethics Committee explain the change?

Note: Asked if question B10 was 'Yes, by the Ethics Committee' (n=62)



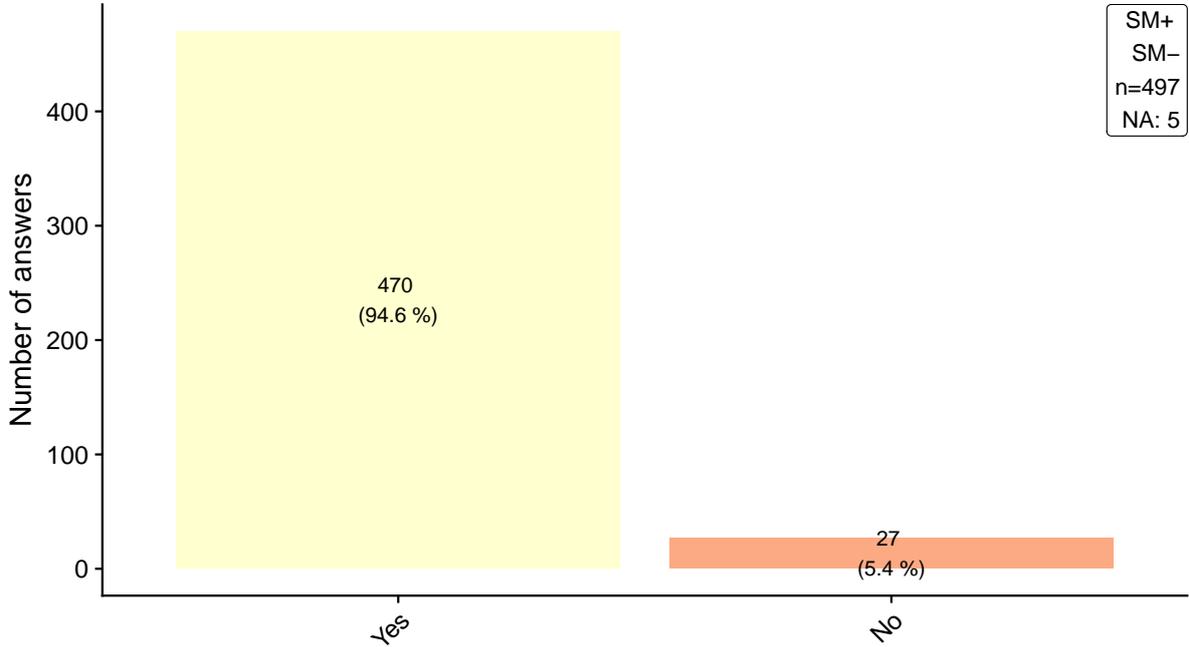
Was the explanation clear for you?

Note: Asked if previous answer was not 'No' (n=58)



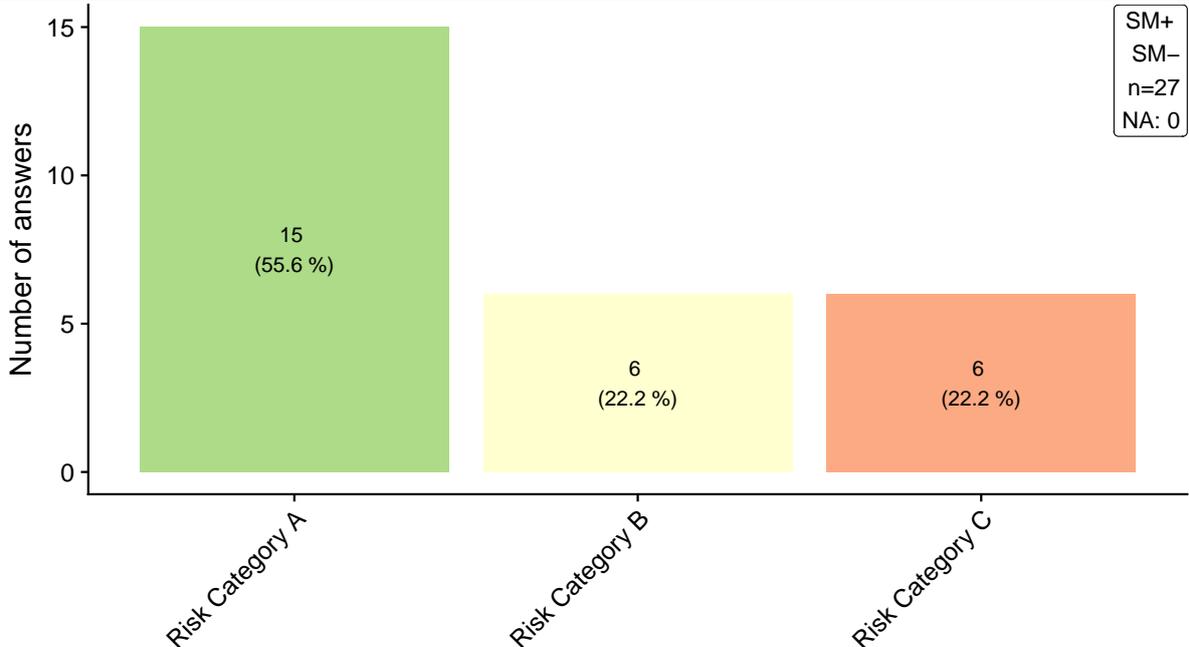
B11 Did the Ethics Committee accept the risk category you indicated?

Note: Question B11 was performed on **SM+** and **SM-** (n=502)

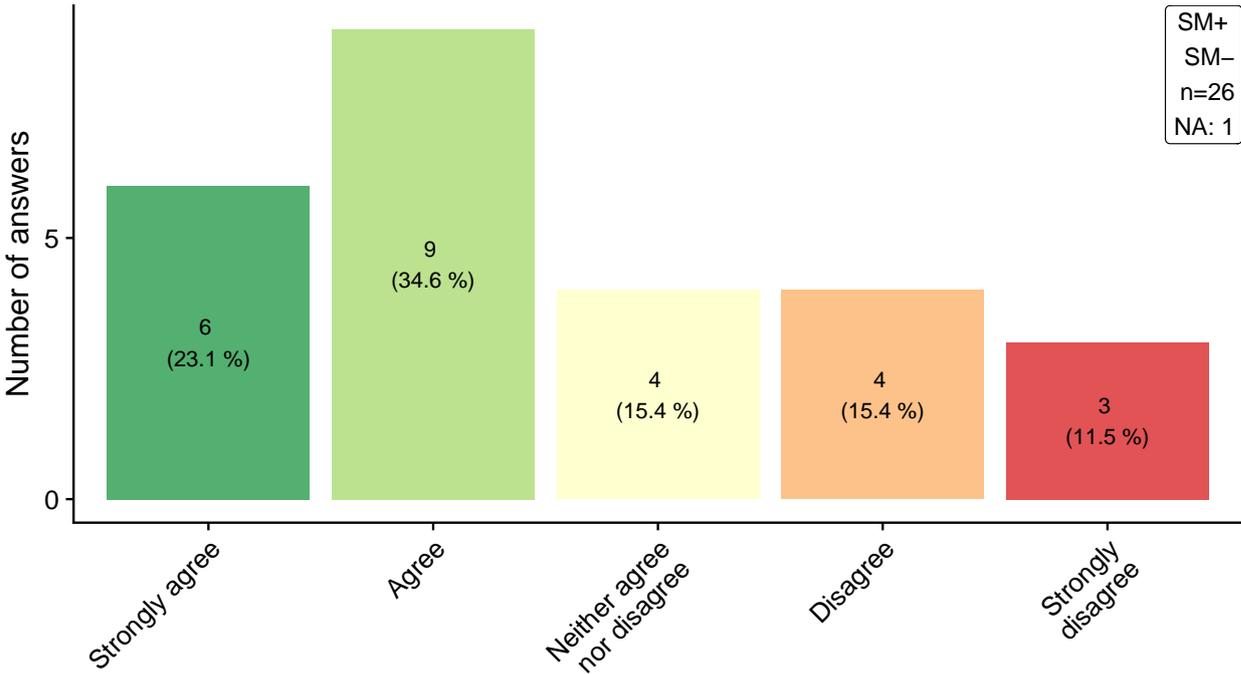


B11a How did you initially classify your project?

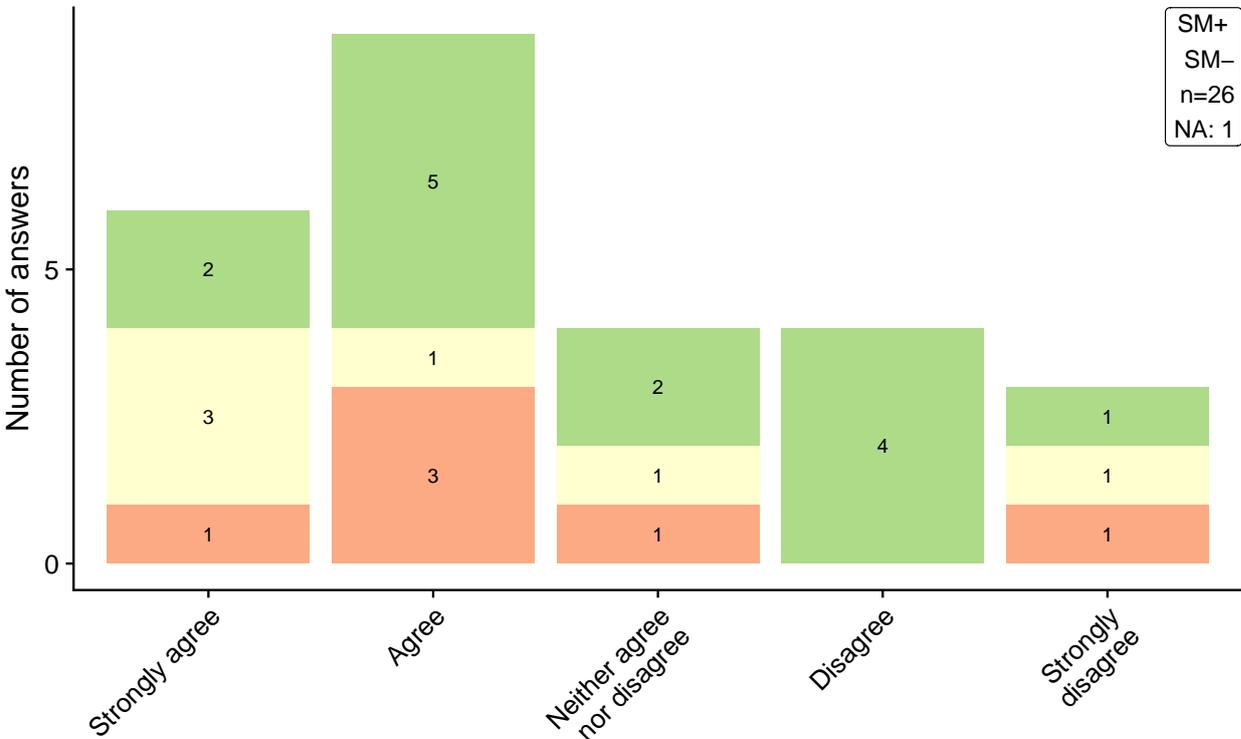
Note: Asked if B11 is answered with 'No' (n=27)



B11b Do you agree with the final classification by the Ethics Committee?



Initial risk category ■ Risk Category A ■ Risk Category B ■ Risk Category C



Why?

Strongly disagree NA

Strongly disagree Project initially submitted as category C, reclassified by EC to category B. However, Swissmedic required study to be classified as category C, which is the final category of study.

Strongly disagree they did not understand the purpose of our project

Disagree As a manufacturer of CE-marked medical devices for the extemporaneous preparation of platelet-rich plasma (PRP), we expected to have our study falling into category A. The Ethics Committee (following discussion with Swissmedic) decided to consider the product under investigation a magistral preparation and to classify it as a Category C trial. Because PRP is prepared from the patient's own blood, it is not applicable to give dose or information specific to pharmaceutical products.

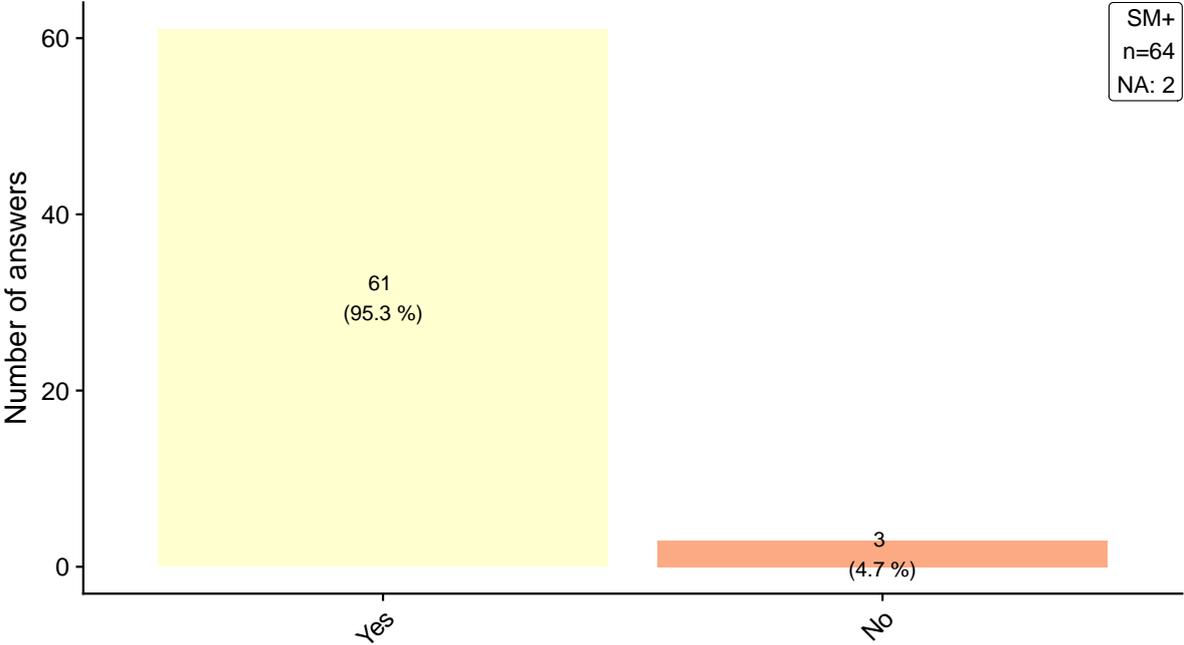
Disagree Even after asking the ethics committee and getting a response, the decision for re-classification seems arbitrary.

Disagree I think that our project, even if it involves minors, doesn't entail more than only minimal risks

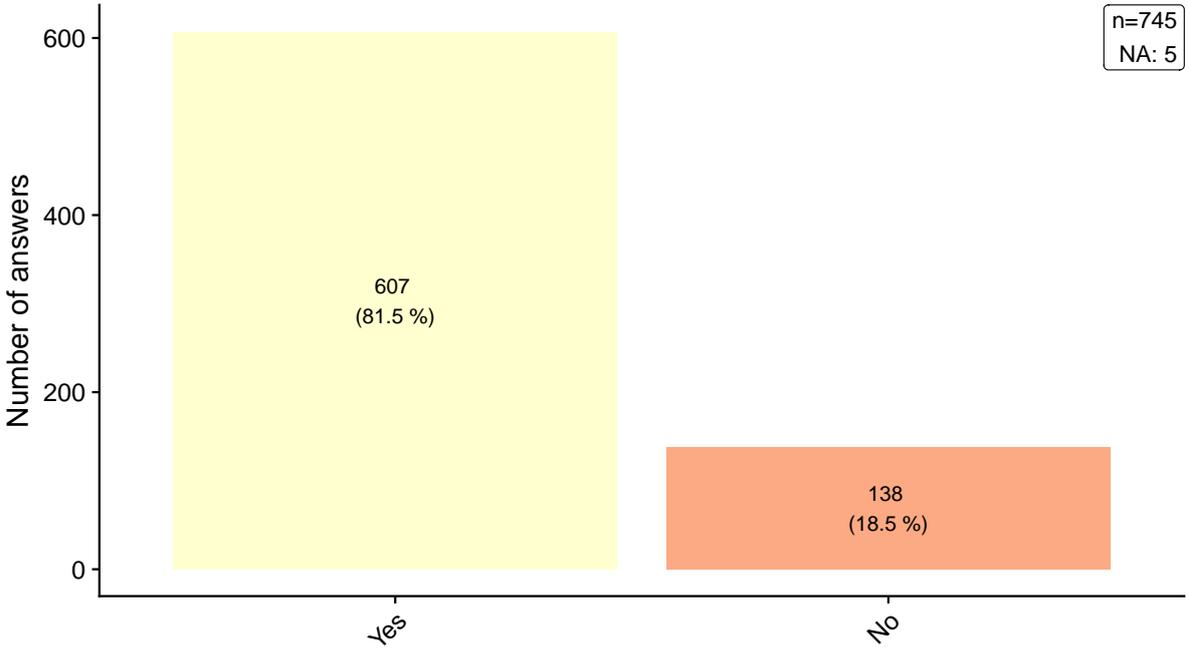
Disagree We do not think it is a category C risk

B11c Did Swissmedic also accept the risk category you indicated?

Note: Asked for **SM+** if B11 is answered with 'Yes' (n=66)

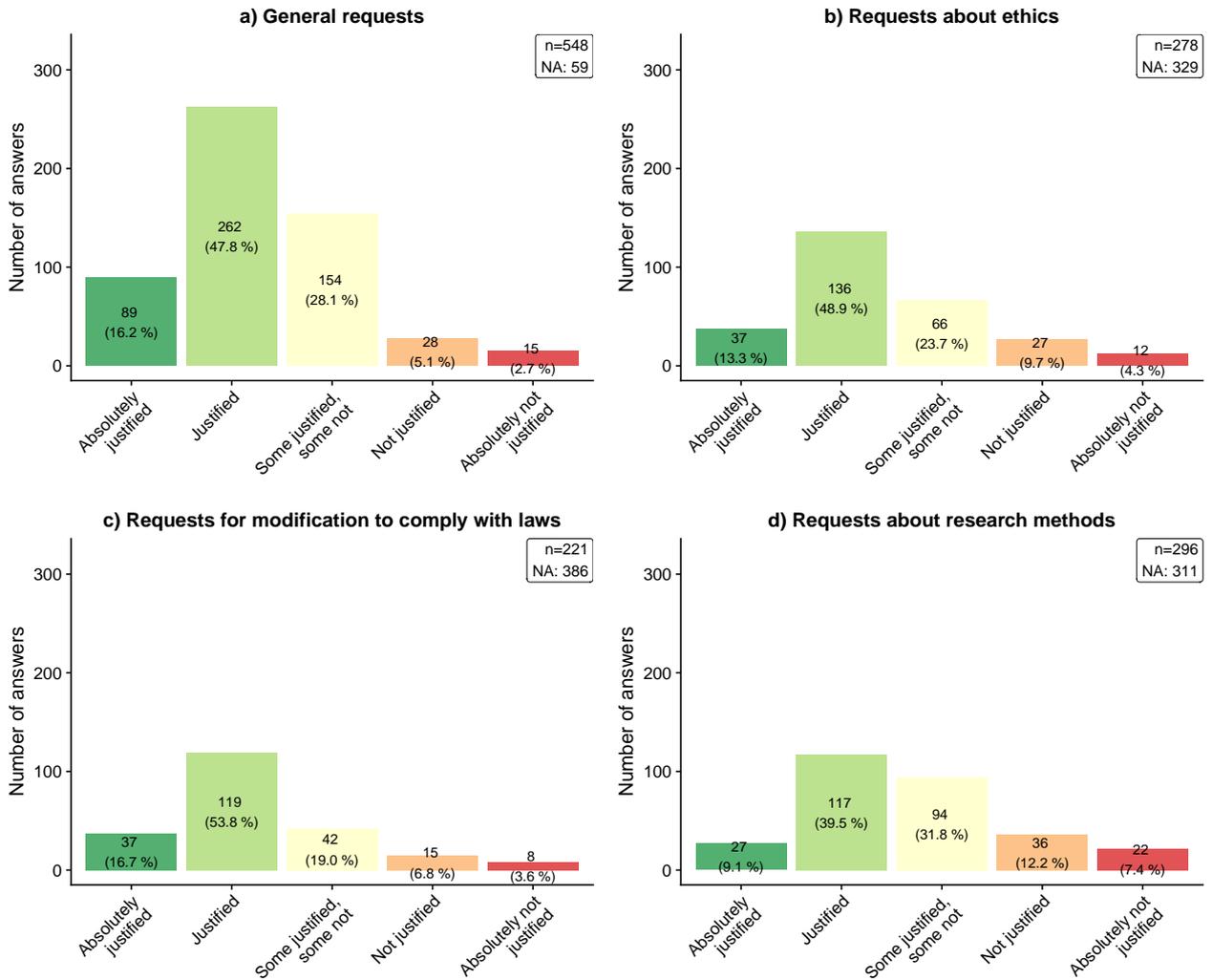


B12 In the first decision letter, did the Ethics Committee attach additional charges or conditions, or requested modifications before approval?



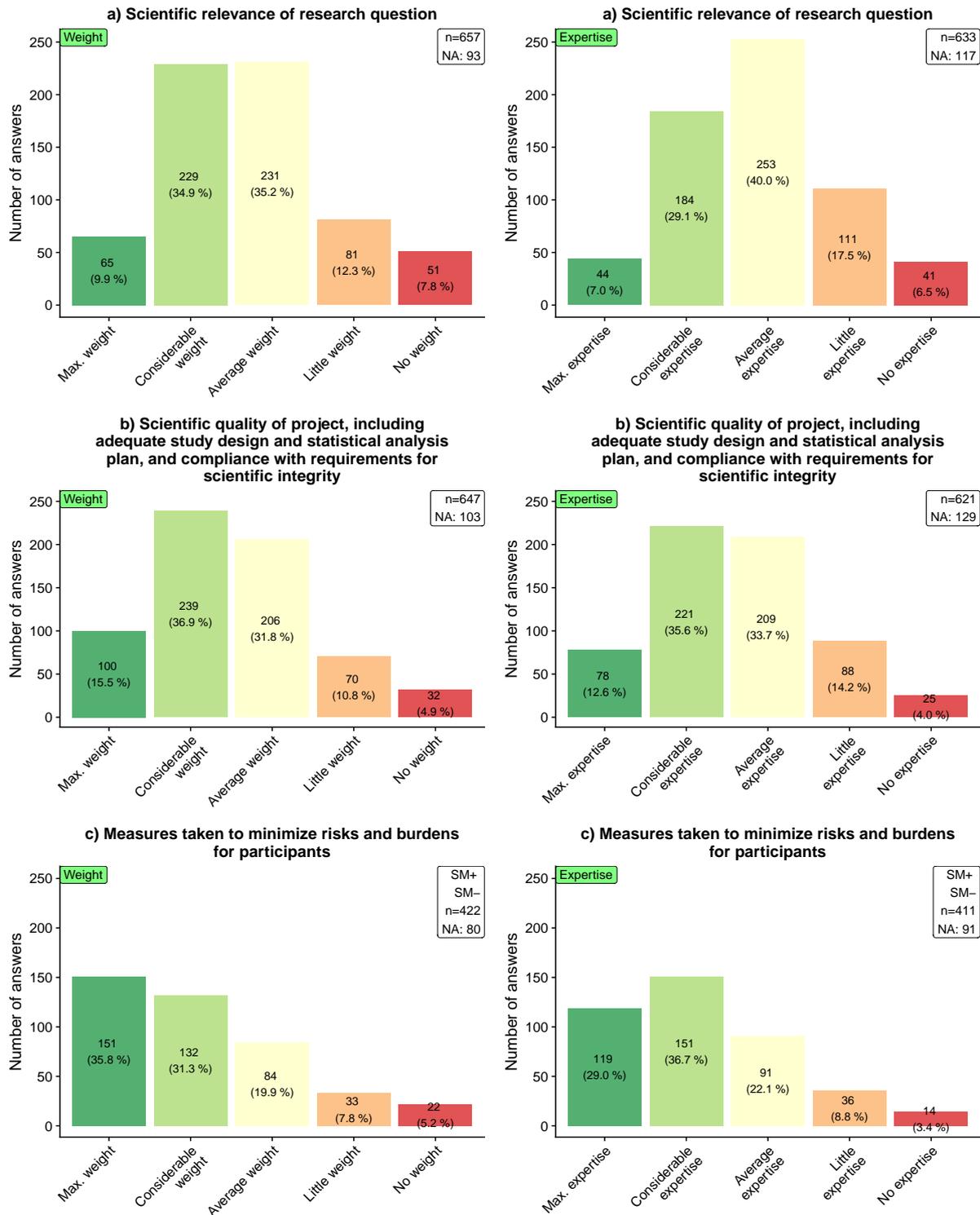
B13 Please rate whether you think these requests were justified

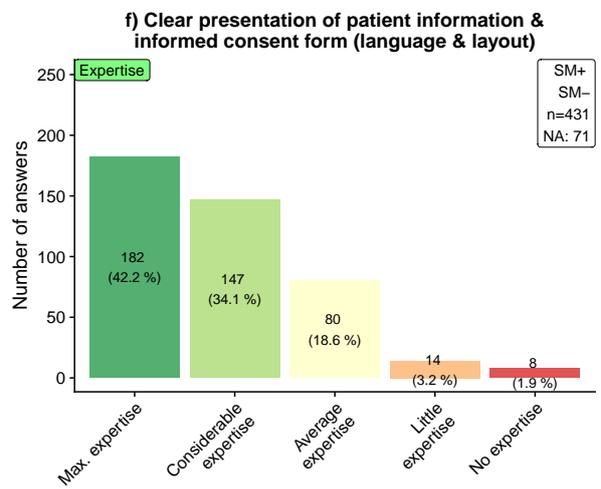
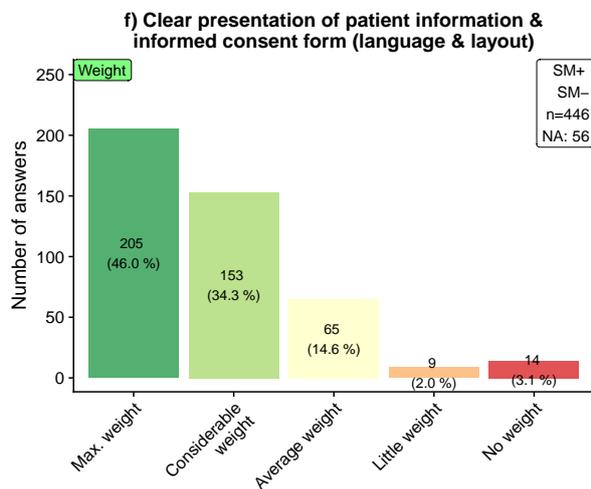
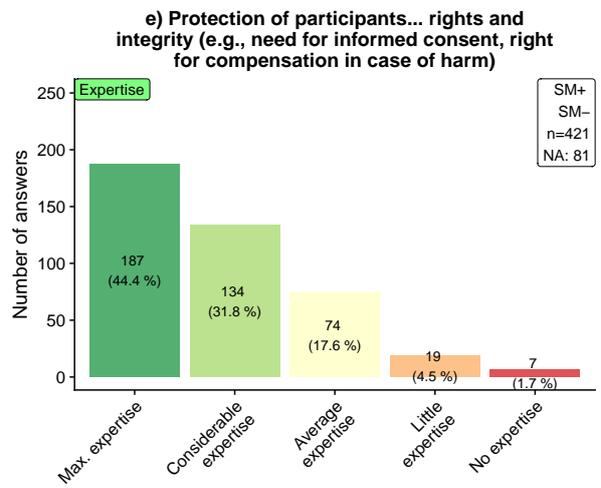
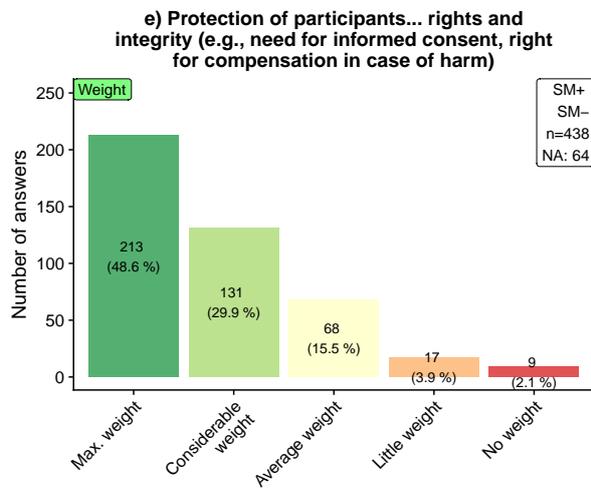
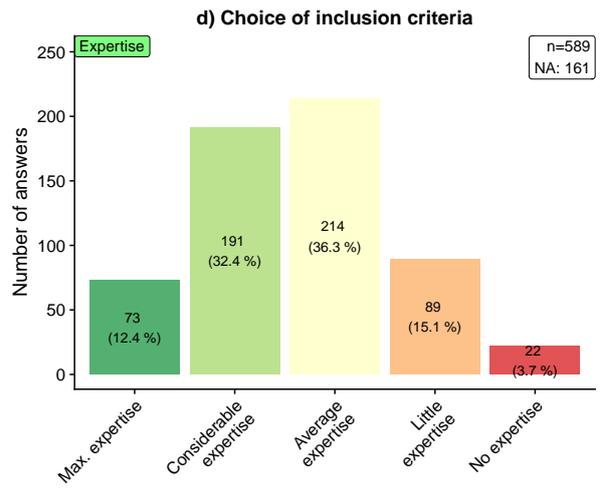
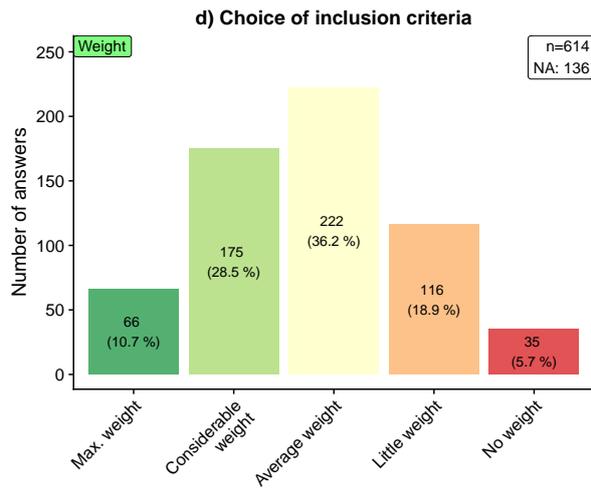
Note: Asked if B12 is answered with 'Yes' (n=607)

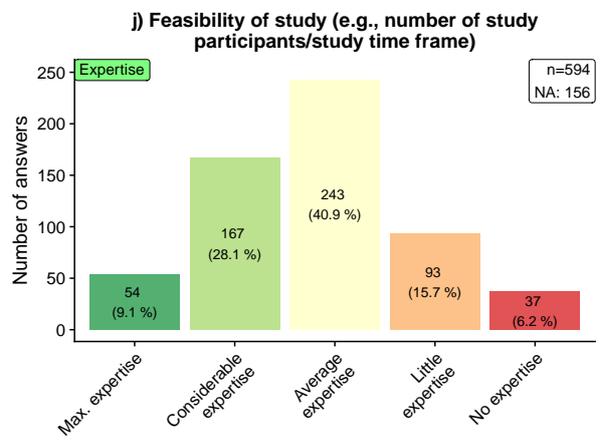
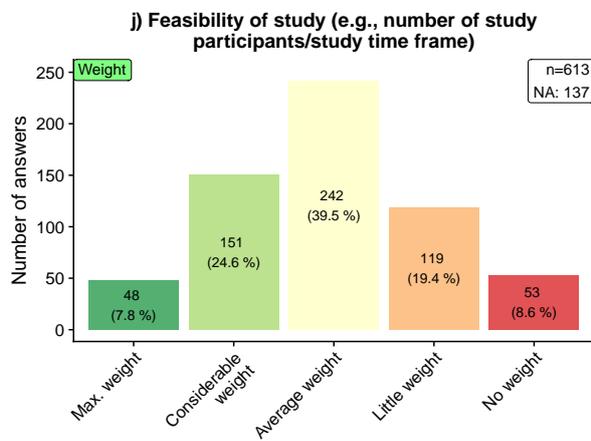
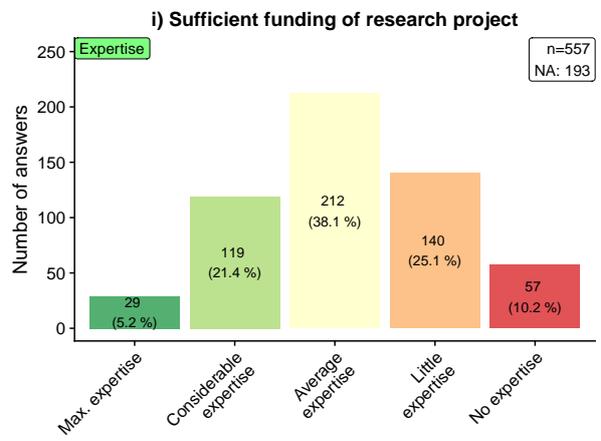
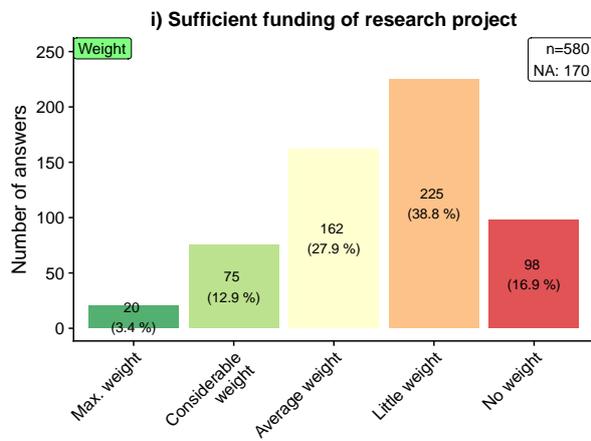
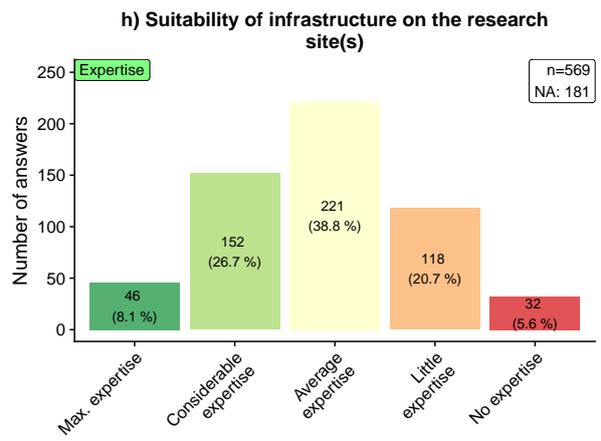
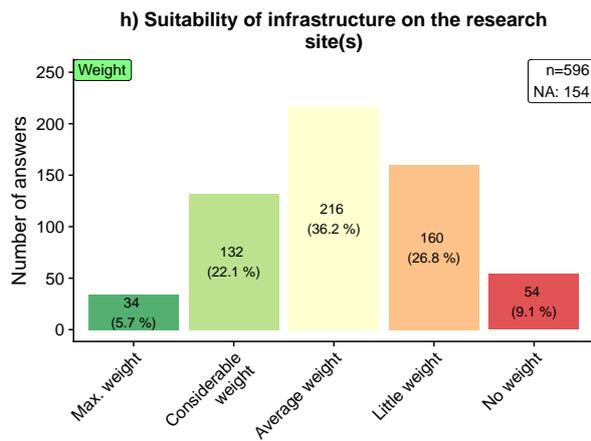
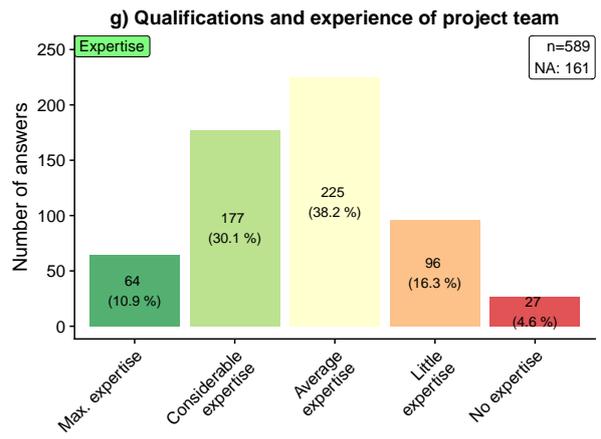
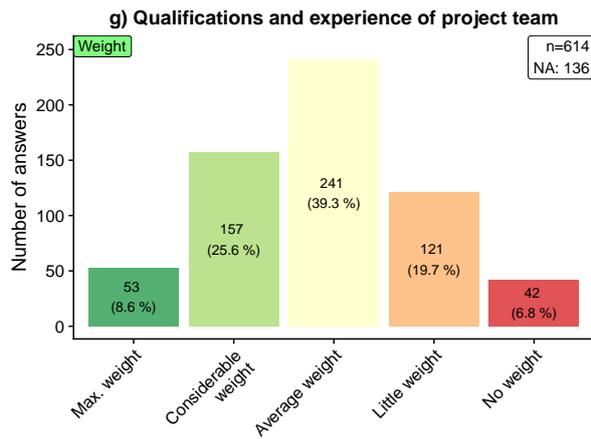


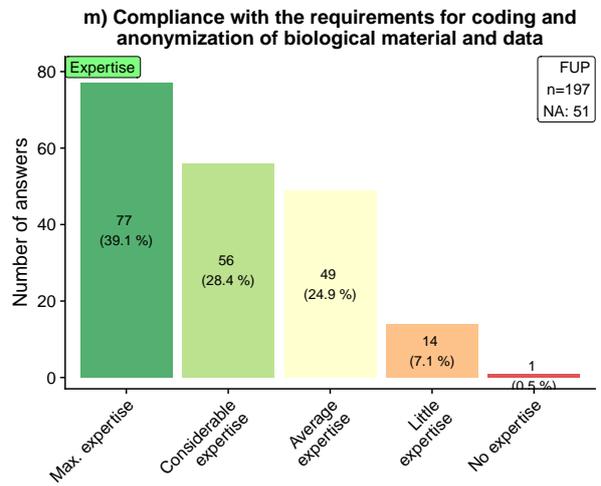
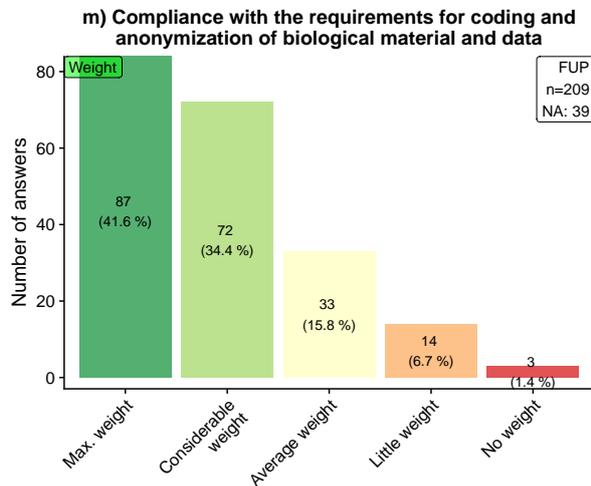
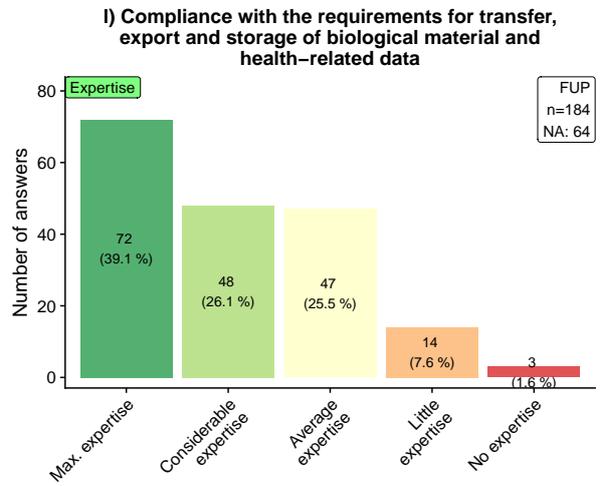
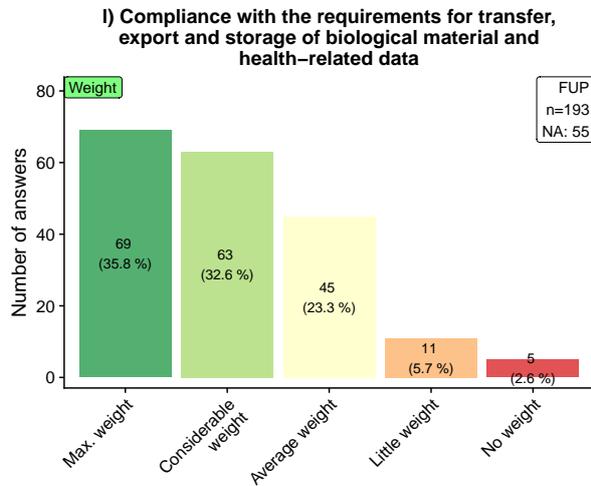
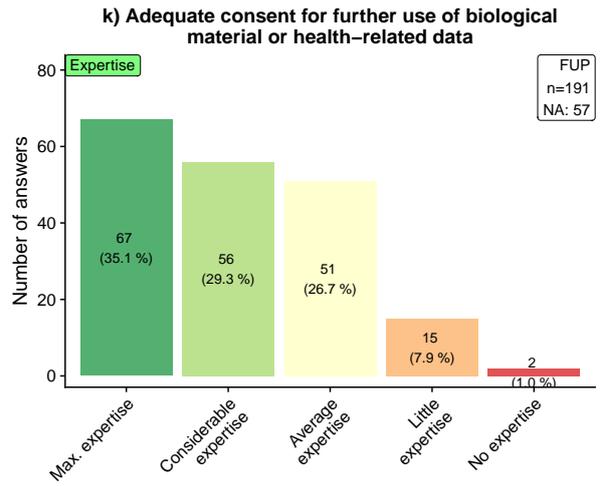
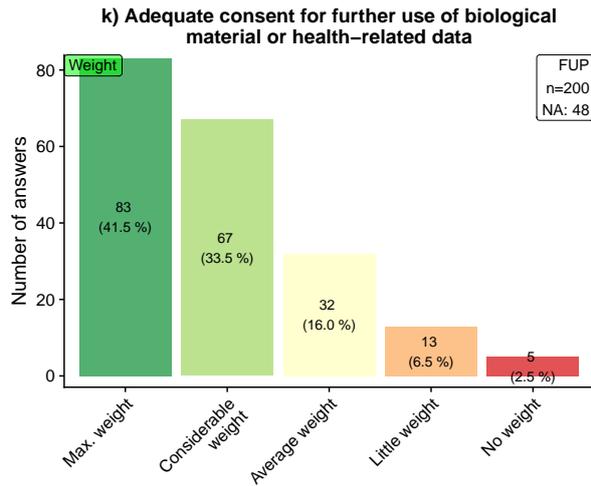
The answers 'No such request by EC' have been attributed to the group NA.

B14 Here is a list of aspects from the HRA or its ordinances that could have been considered by Ethics Committees (EC) when assessing your project. In your opinion, (left) how much weight did the EC give to these aspects, and (right) how much expertise did the EC have to assess these aspects? Please rate each aspect independently.



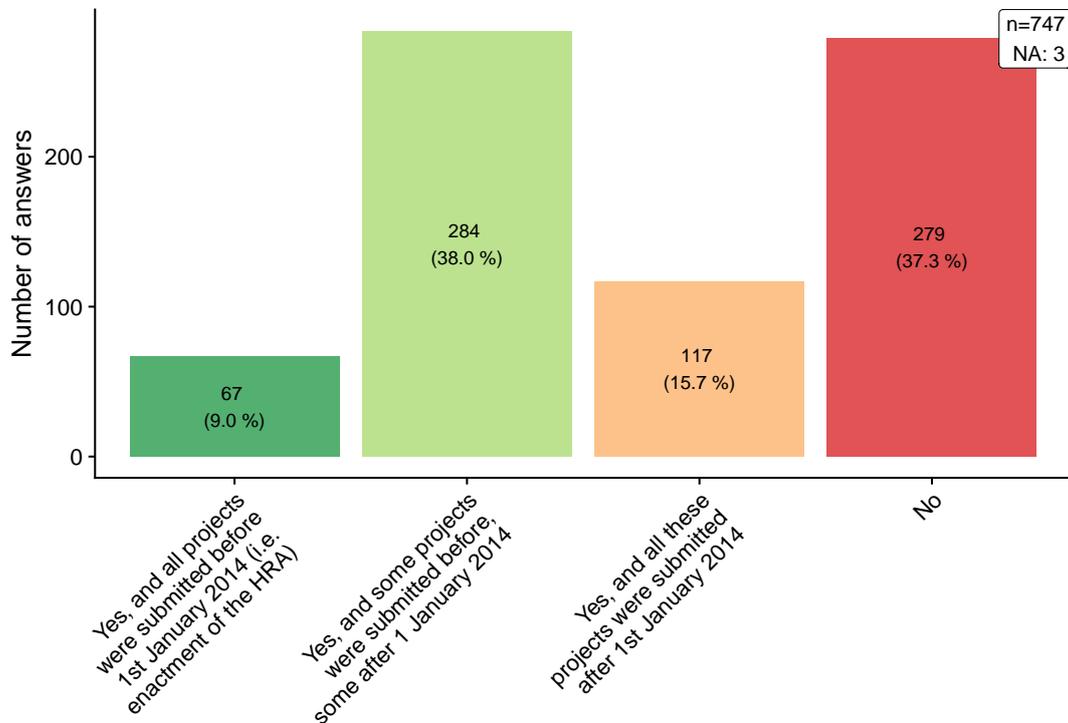






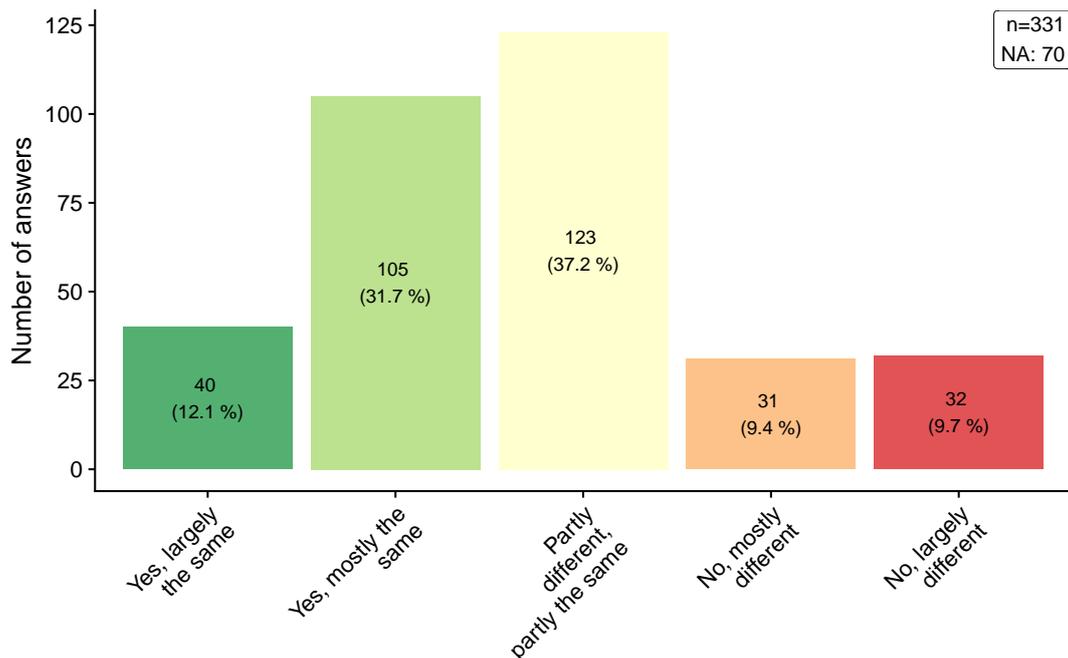
Concerning your experience with Ethics Committees in general...

B15 In the past, did you submit research projects to Ethics Committees in Switzerland, other than the one that has decided on this project?

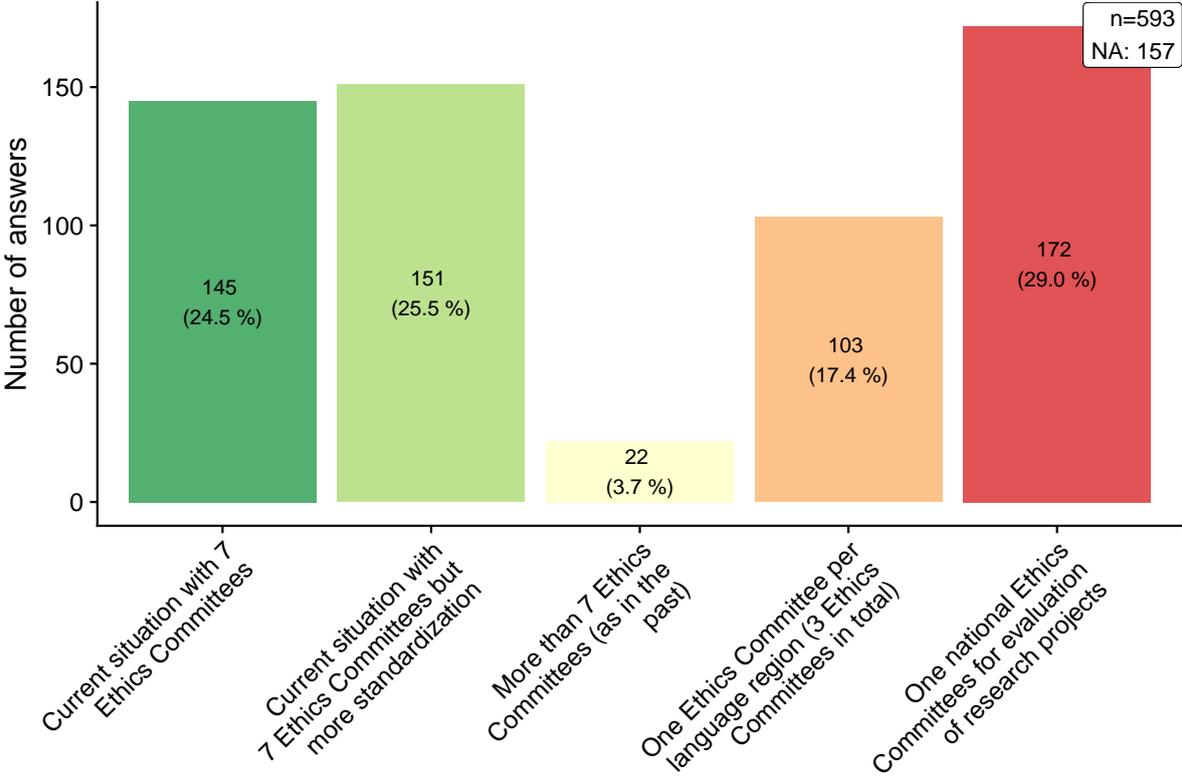


B16 In your opinion, do the seven Ethics Committees in Switzerland evaluate research projects according to a common standard?

Note: Asked if answer to B15 was that some or all projects were submitted after 2014 (n=401)

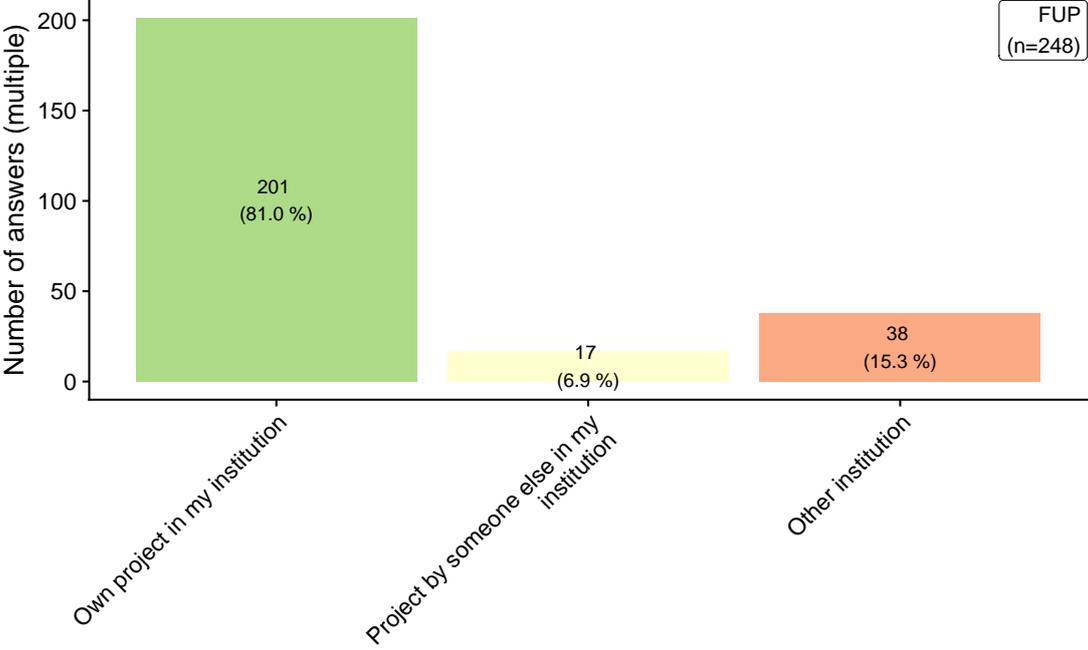


B17 From the following options, which one do you prefer?



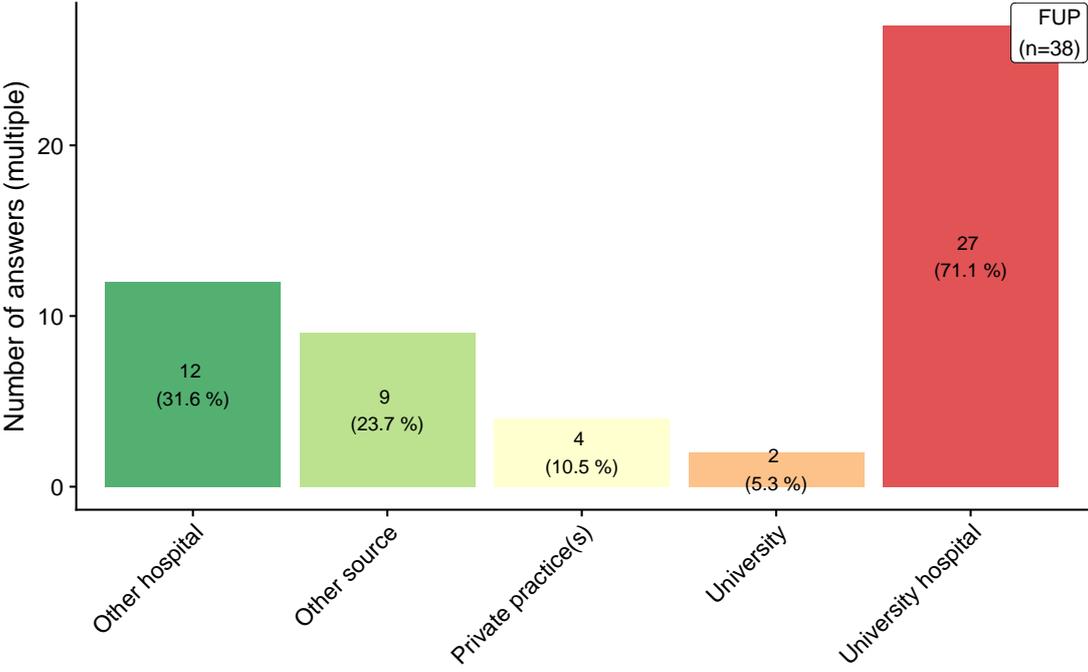
Questions concerning further use of biological material or health-related data specifically

B18 From which institution(s) did you get the biological material or the health-related data (multiple answers possible)

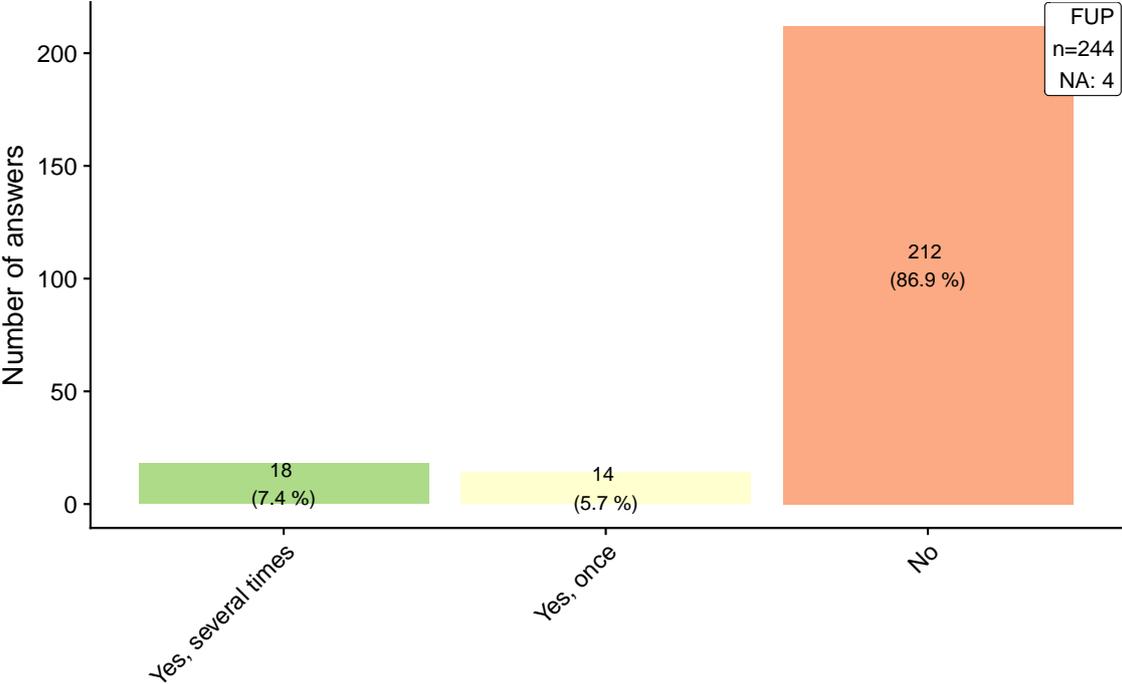


If "Other institution" (multiple answers possible)

Note: Asked if B18 is answered with 'Other institution' (n=38)

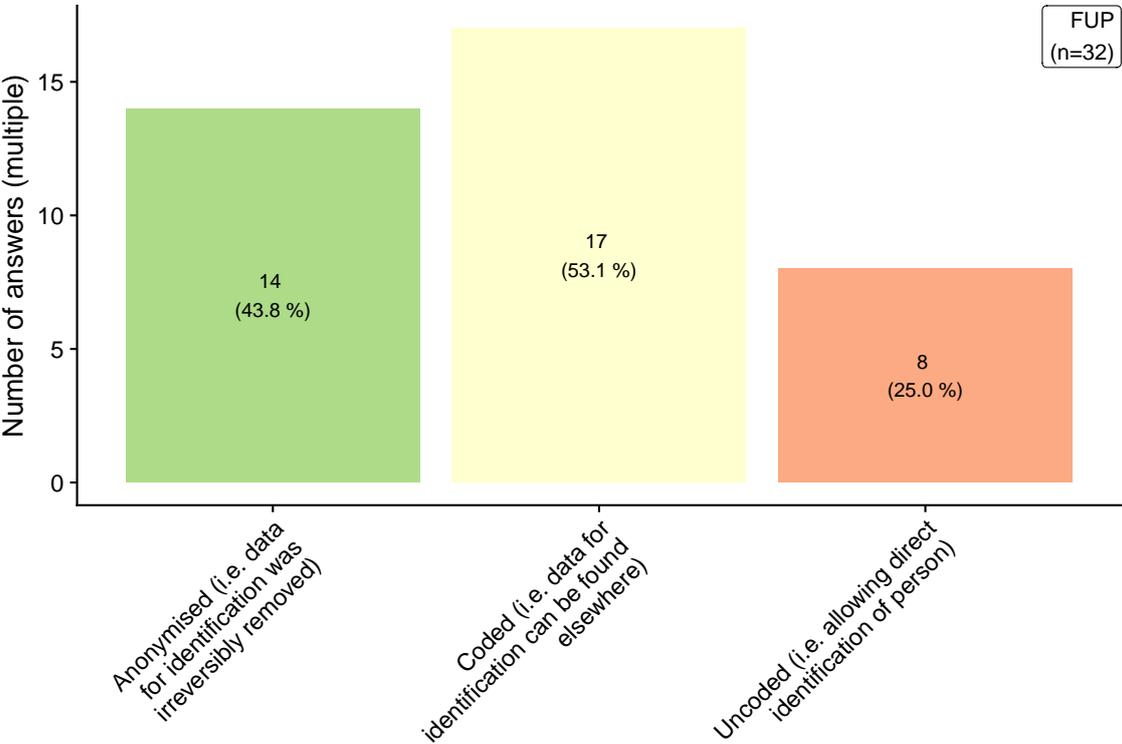


B19 Since 1 January 2014, have you used biological material or data from other countries for this project or another project?



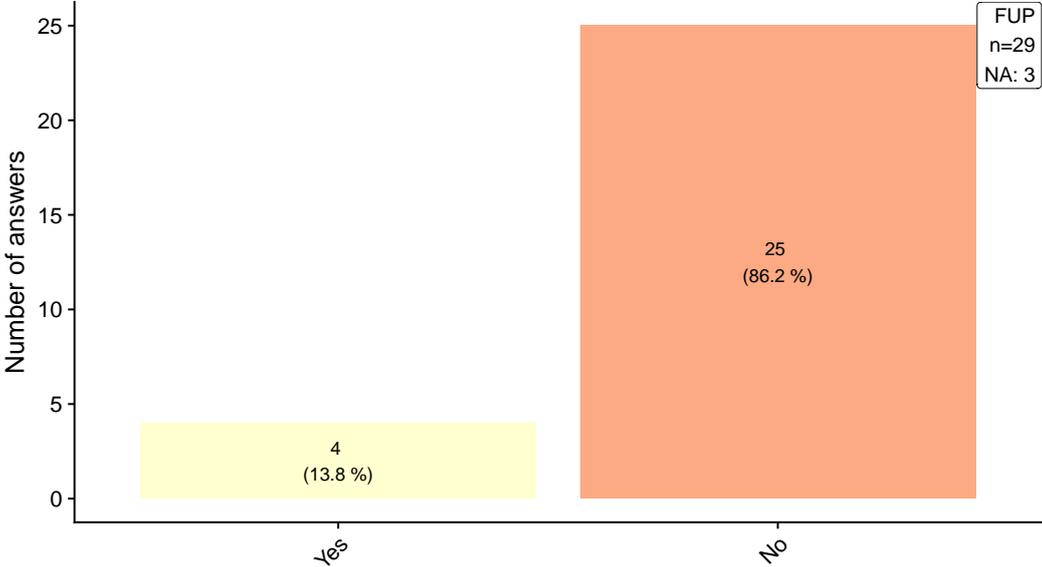
B19a Was this biological material or these data ... (multiple answers possible)

Note: Asked if B19 is answered with 'Yes' (n=32)

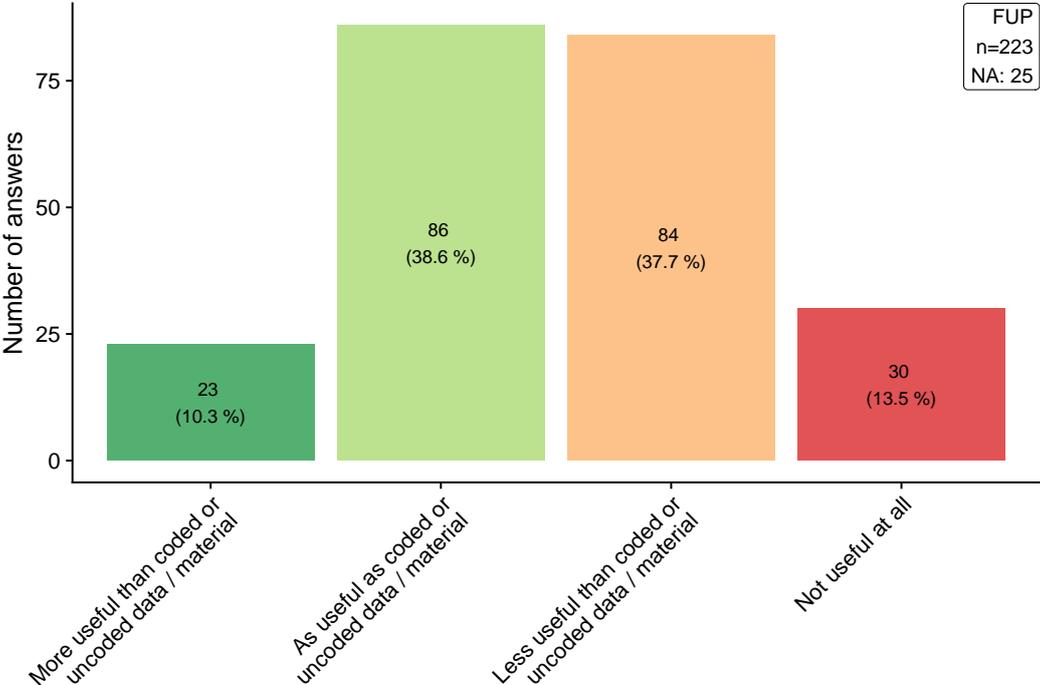


B19b Has the use of biological material or data from other countries ever caused problems with the authorisation of one of your research projects in Switzerland?

Note: Asked if B19 is answered with 'Yes' (n=32)



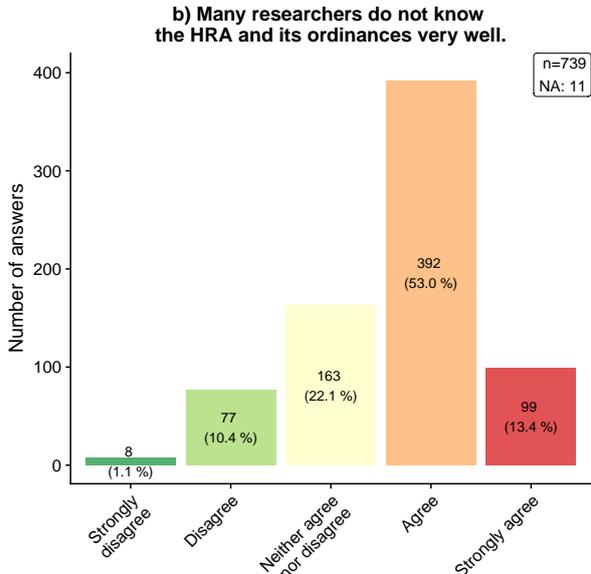
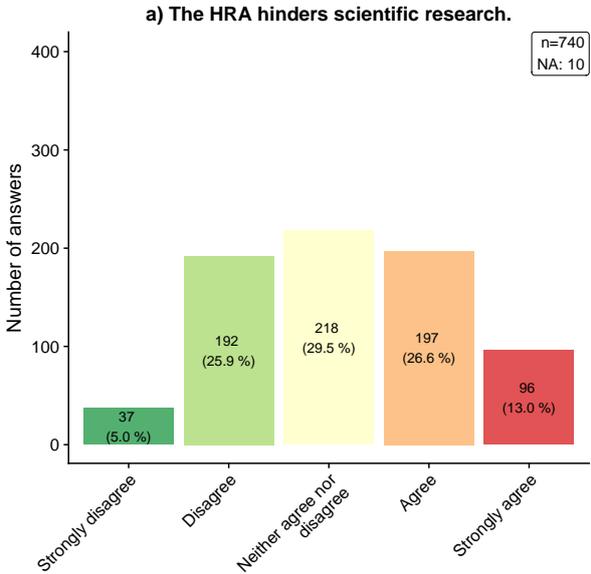
B20 In medical research, health-related data and biological material can be used either in anonymised, coded or uncoded form. To obtain or work with such data/material the current legal requirements are less strict with anonymised as compared to coded or uncoded data/material. In your field of research, how useful are anonymised data/material to obtain meaningful results?



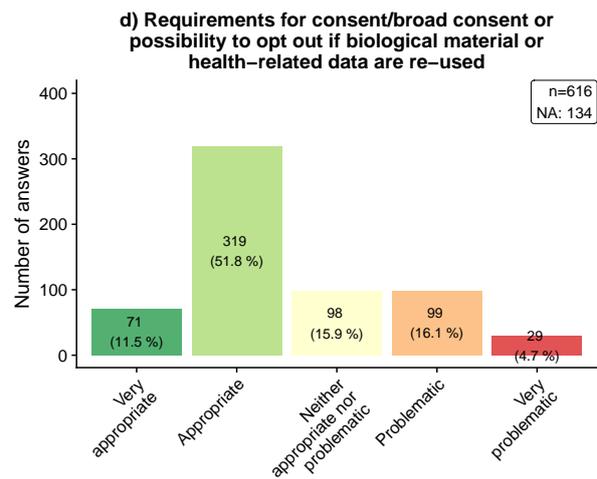
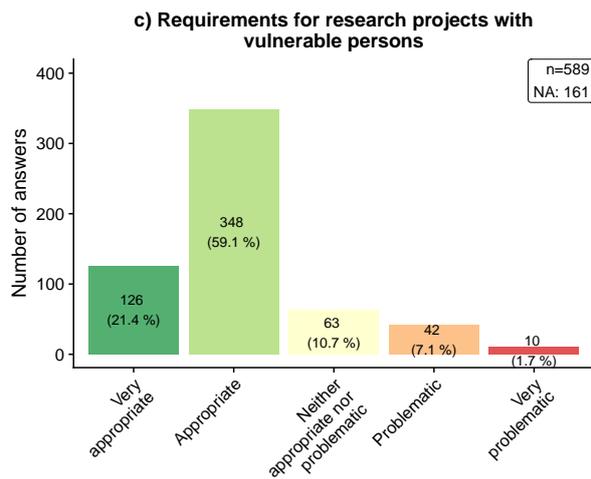
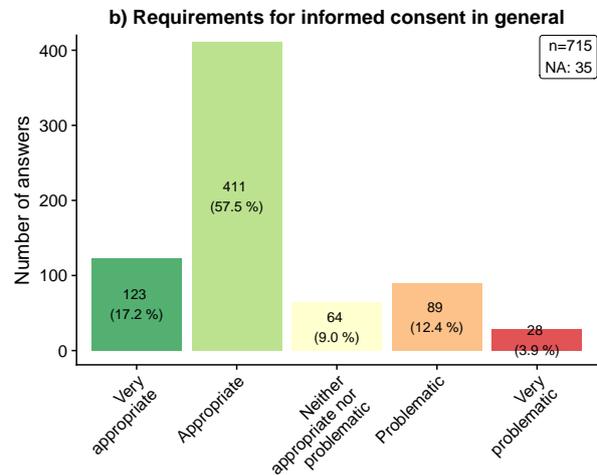
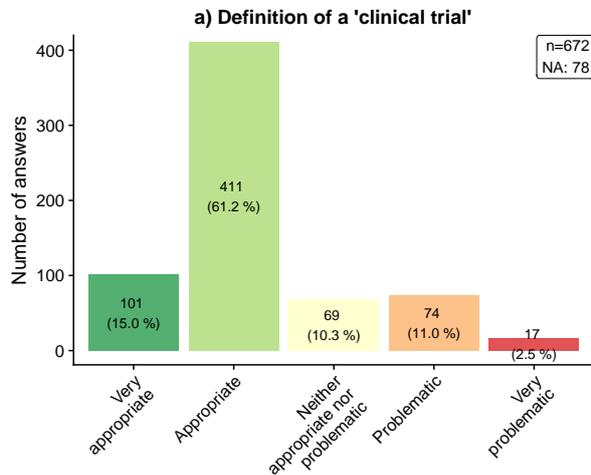
25 answers 'I don't know' were attributed to the group NA.

In the following questions we are interested in your opinion about the Swiss laws regarding research on human beings (HRA and ordinances) and how they are applied to research projects in general (i.e. not only to your project).

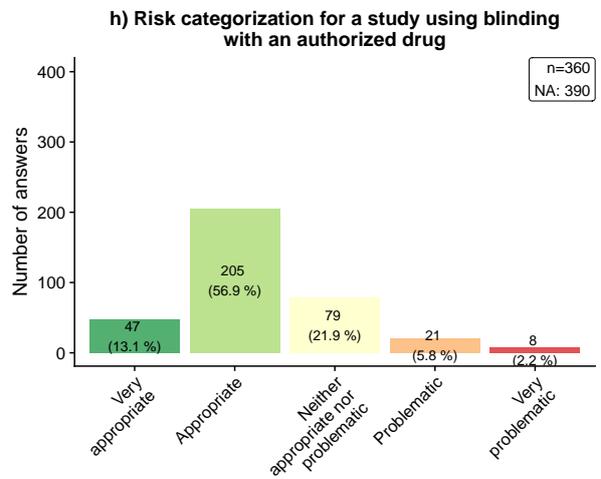
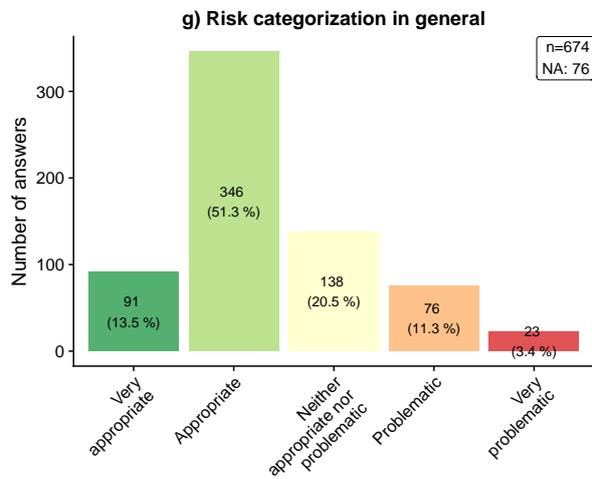
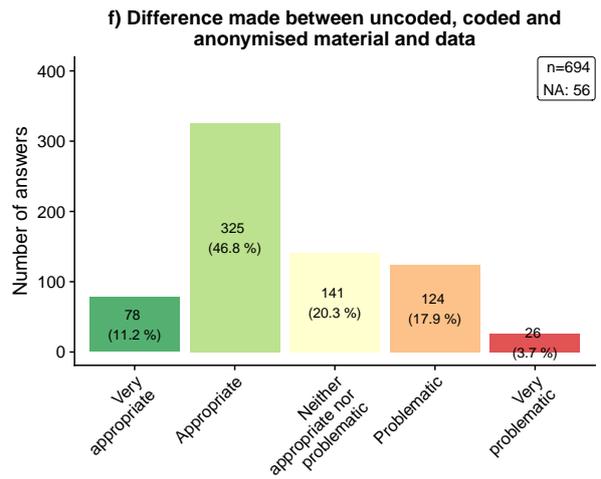
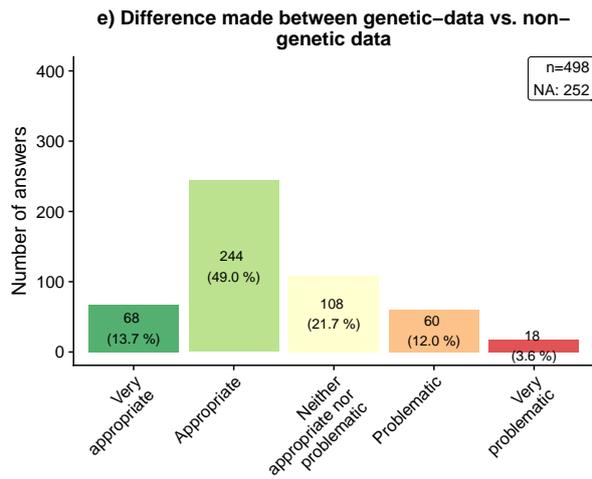
B21 Here are two statements that you could hear in discussions about the HRA. For each statement, indicate your level of (dis)agreement.

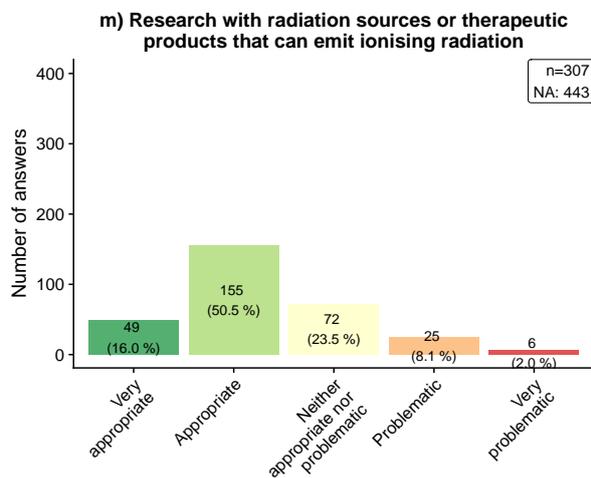
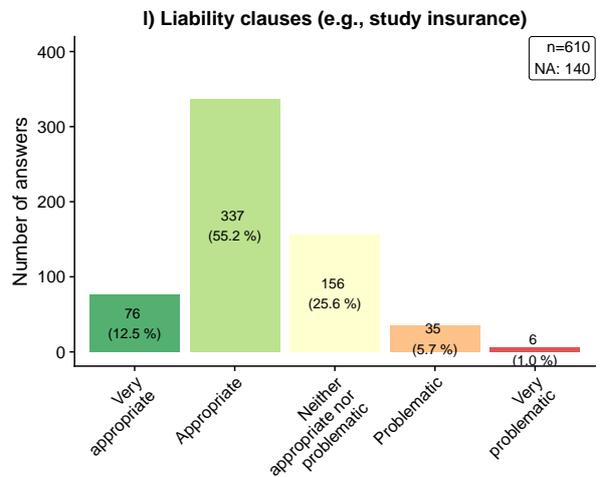
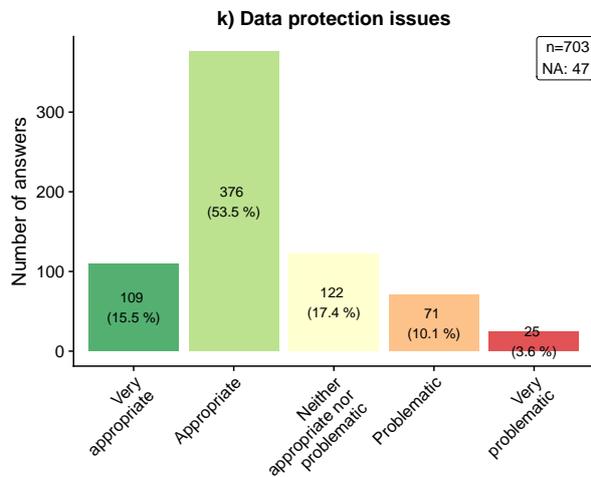
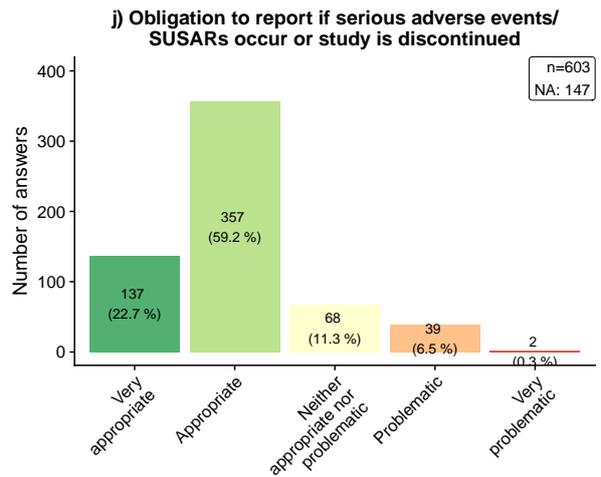
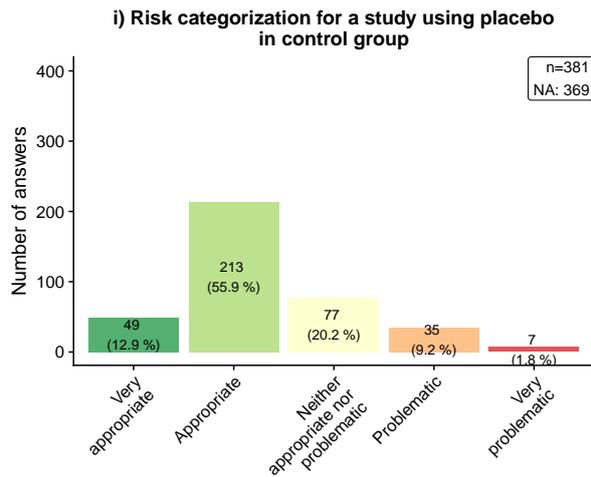


B22 Below is a list of different aspects that are usually covered by human research regulations. In your opinion, are these aspects appropriately regulated in the Human Research Act and its ordinances?



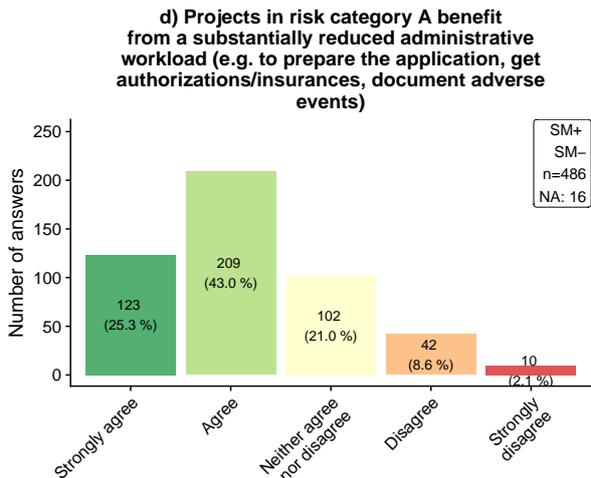
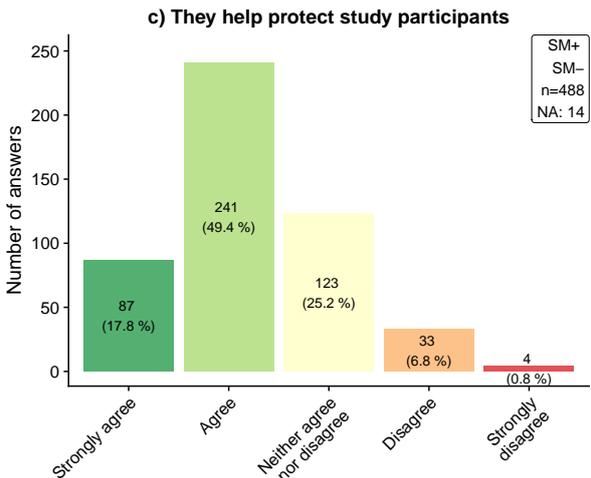
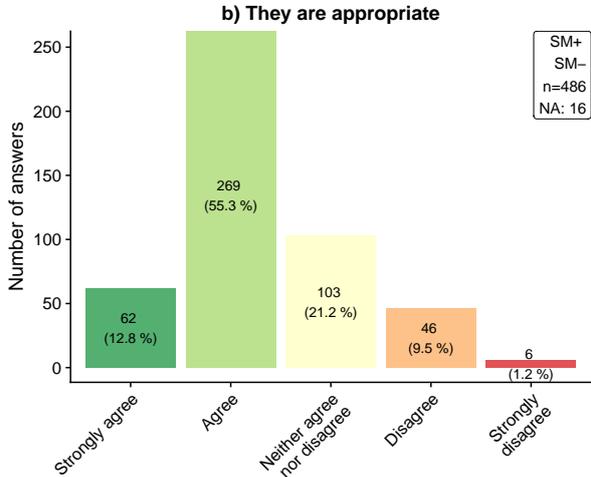
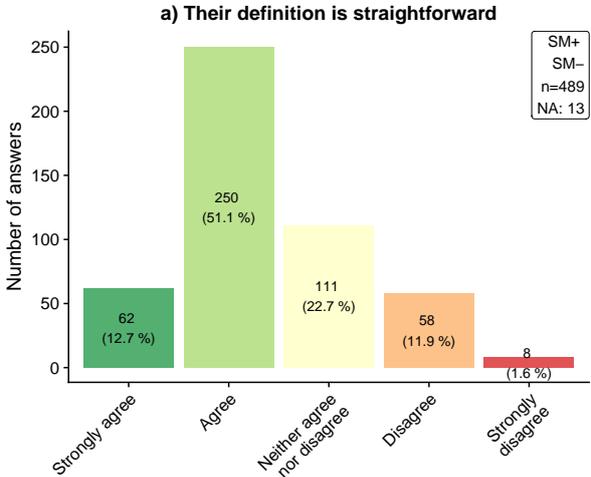
The answers 'I have no experience with this aspect' have been attributed to the group NA.





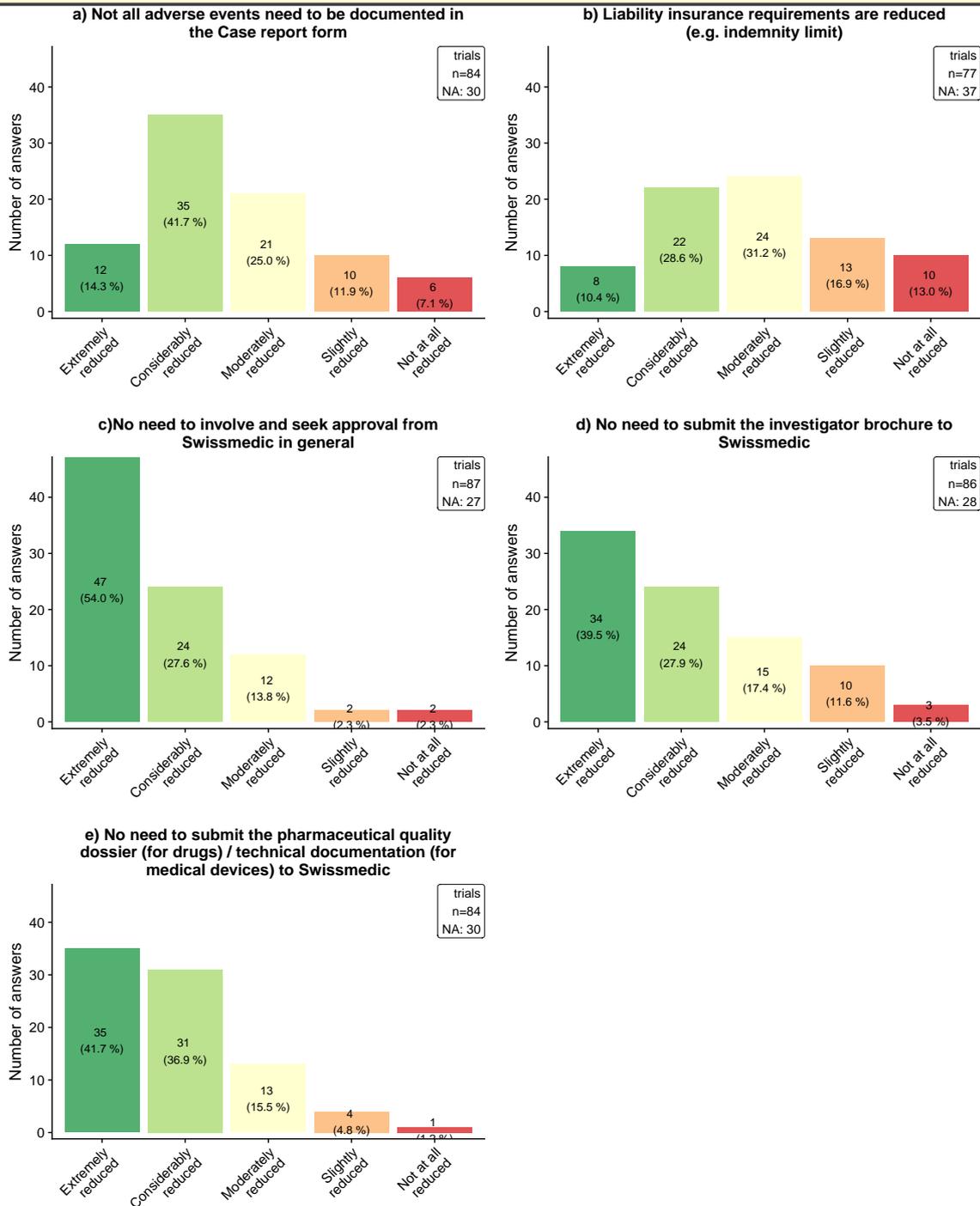
Questions concerning risk categories specifically

B23 Do you agree/disagree with the following statements regarding the risk categories A, B and C?



B24 Clinical trials in risk category A benefit from a number of reduced legal requirements defined by the HRA, compared to those in risk category B or C. According to your experience with submitting research projects, to which extent do the following aspects help reduce the administrative workload?

Note: Only asked to researchers submitting a clinical trial involving medicinal products or medical devices (n=114).



Questions concerning comparison with other countries

B25 Do you think that the regulations of the HRA and its ordinances are perceived as more burdensome than comparable laws in other countries? For instance, think of international partners who might have complained about Swiss laws since 1 January 2014.

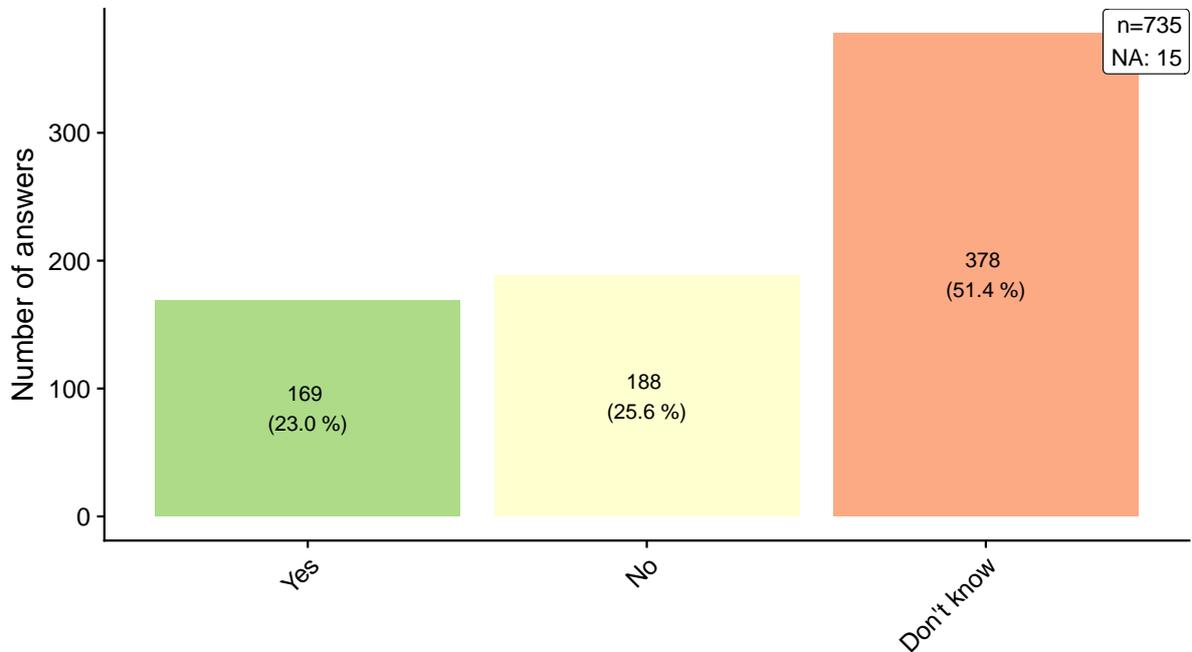


Table B25: Stratification of the answers.

		N	HRA perceived as burdensome?					
			Yes		No		Don't know	
			n	%	n	%	n	%
Project group	Further use projects (FUP)	245	69	28	56	23	120	49
	Research projects not involving Swissmedic (SM-)	415	84	20	102	25	229	55
	Research projects involving Swissmedic (SM+)	75	16	21	30	40	29	39
Project type	Clinical trial (ClinO)	175	37	21	58	33	80	46
	Research with persons (HRO Chapter 2)	315	63	20	74	23	178	57
	Further use (HRO Chapter 3)	245	69	28	56	23	120	49
Initiator	Investigator-initiated	651	161	25	140	22	350	54
	Industry-initiated	82	8	10	48	59	26	32
	Not specified	2	0	0	0	0	2	100
Role	(Principal) investigator	521	133	26	114	22	274	53
	Sponsor	72	12	17	39	54	21	29
	Project leader/manager	87	16	18	17	20	54	62
	Research assistant/collaborator, Other	24	3	12	6	25	15	62
	CRO/CTU	18	0	0	9	50	9	50
	Not specified	13	5	38	3	23	5	38
All		735	169	23	188	26	378	51

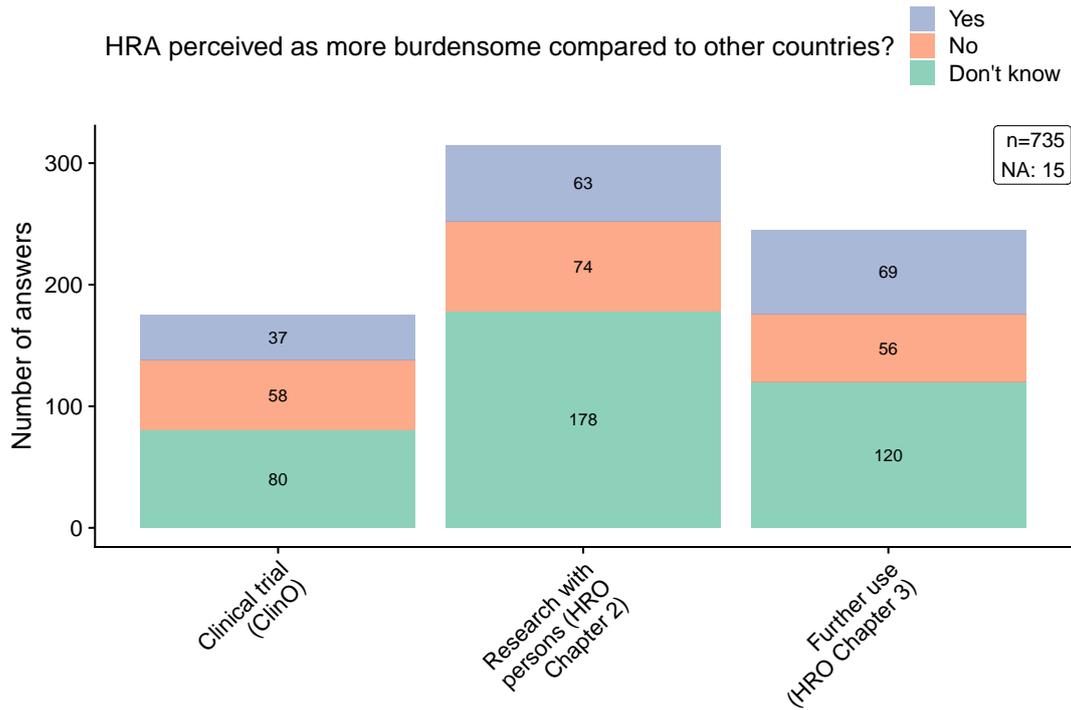


Figure B25.1: Stratification by project group

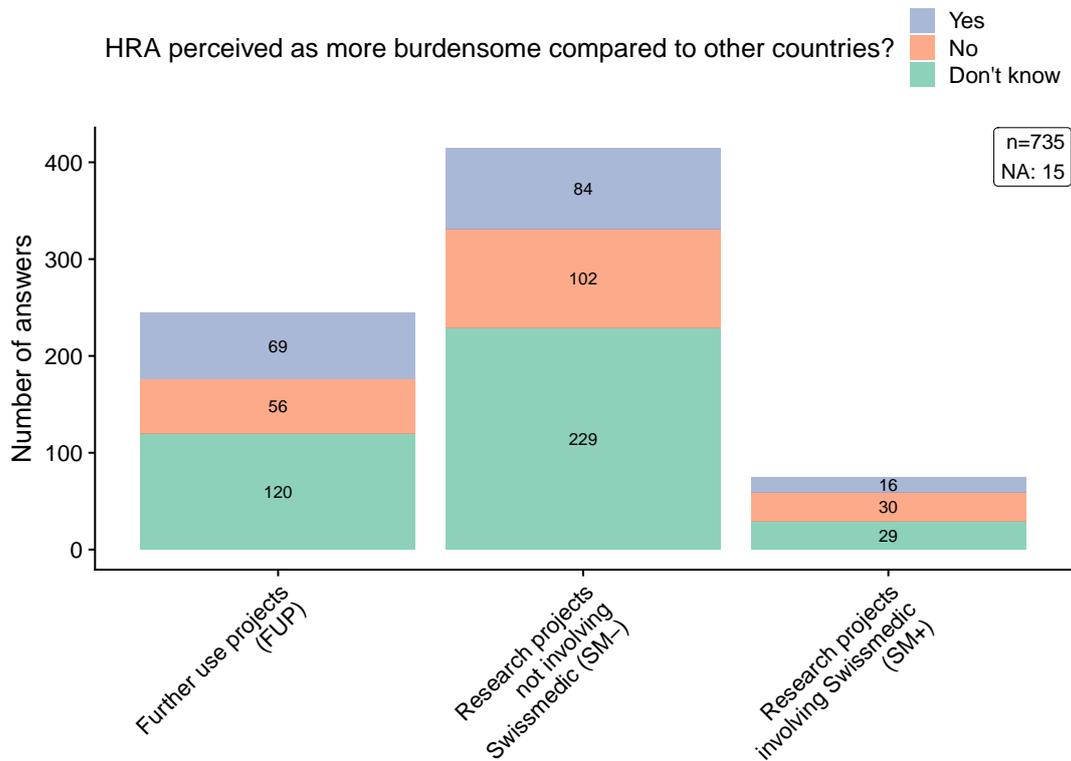


Figure B25.2: Stratification by project type

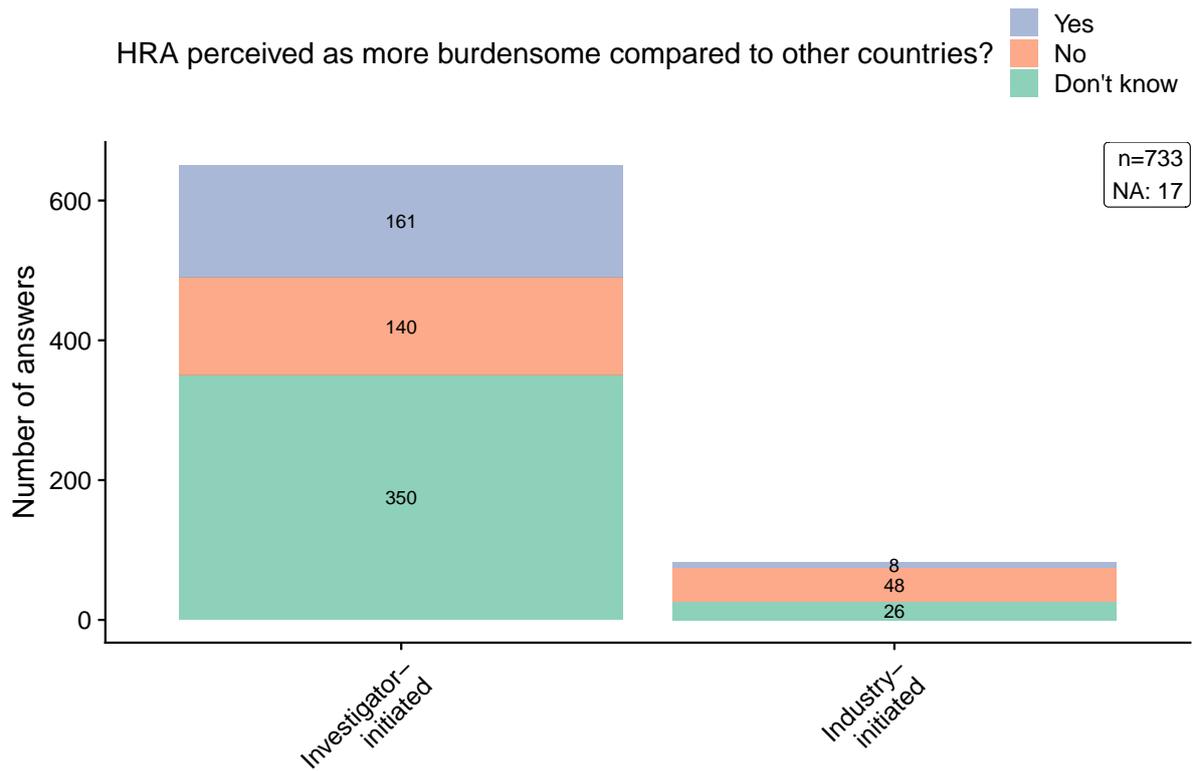


Figure B25.3: Stratification by project initiator

B25a If B25 = Yes: About which aspects, please specify ...

→ See answers to this freetext field in the Appendix.

B26 Have you ever been excluded from an international multi-site study because of the perceived hurdles caused by legislation in Switzerland?

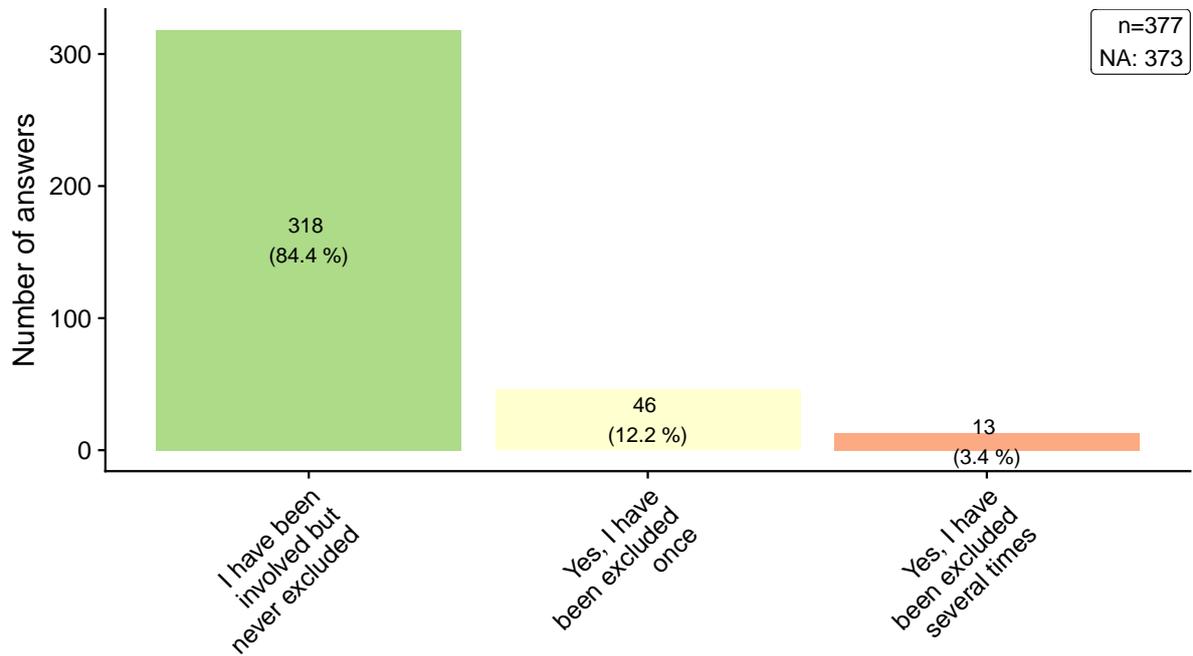


Table B26: Stratification of the answers.

		N	Have you ever been excluded?					
			No		Yes, 1x		Yes, >1x	
			n	%	n	%	n	%
Project group	Further use projects (FUP)	129	101	78	23	18	5	4
	Research projects not involving Swissmedic (SM-)	189	161	85	22	12	6	3
	Research projects involving Swissmedic (SM+)	59	56	95	1	2	2	3
Project type	Clinical trial (ClinO)	116	105	91	8	7	3	3
	Research with persons (HRO Chapter 2)	132	112	85	15	11	5	4
	Further use (HRO Chapter 3)	129	101	78	23	18	5	4
Initiator	Investigator-initiated	306	251	82	43	14	12	4
	Industry-initiated	70	66	94	3	4	1	1
	Not specified	1	1	100	0	0	0	0
Role	(Principal) investigator	250	200	80	42	17	8	3
	Sponsor	52	49	94	3	6	0	0
	Project leader/manager	39	37	95	0	0	2	5
	Research assistant/collaborator, Other	10	8	80	1	10	1	10
	CRO/CTU	16	15	94	0	0	1	6
	Not specified	10	9	90	0	0	1	10
All		377	318	84	46	12	13	3

B26: 358 answers 'I have not been involved in international studies' were attributed to NA.

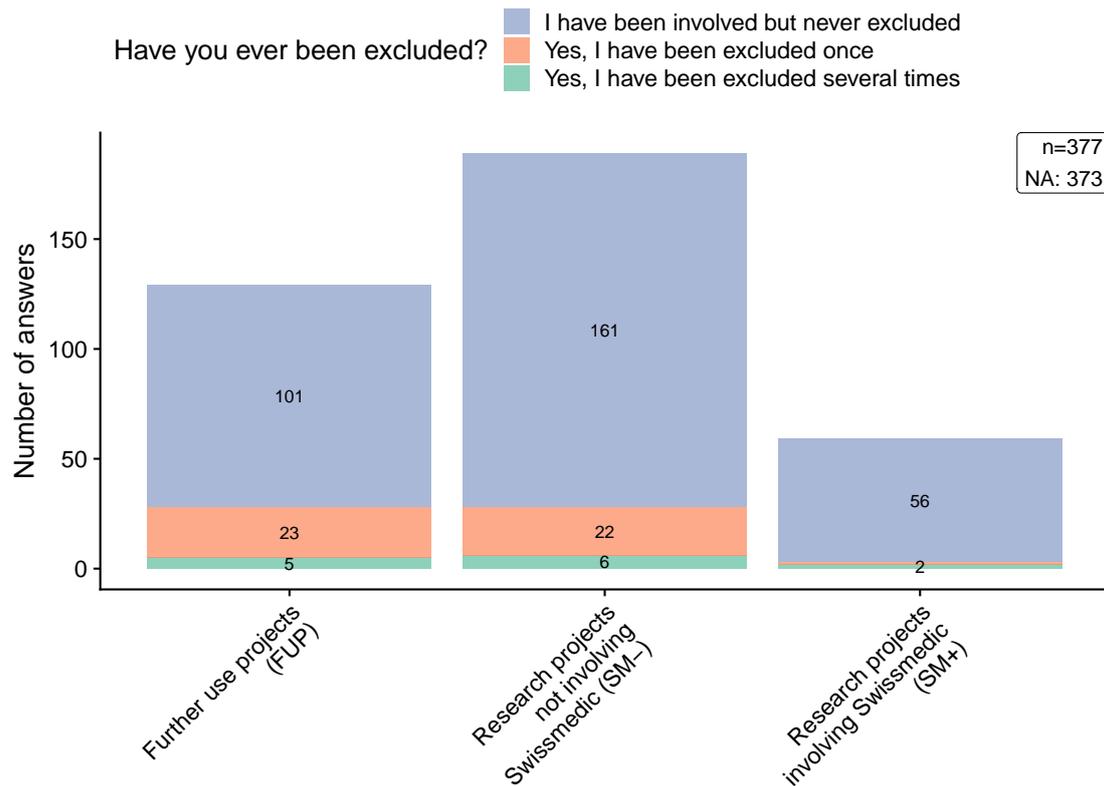


Figure B26.1: Stratification by project group.

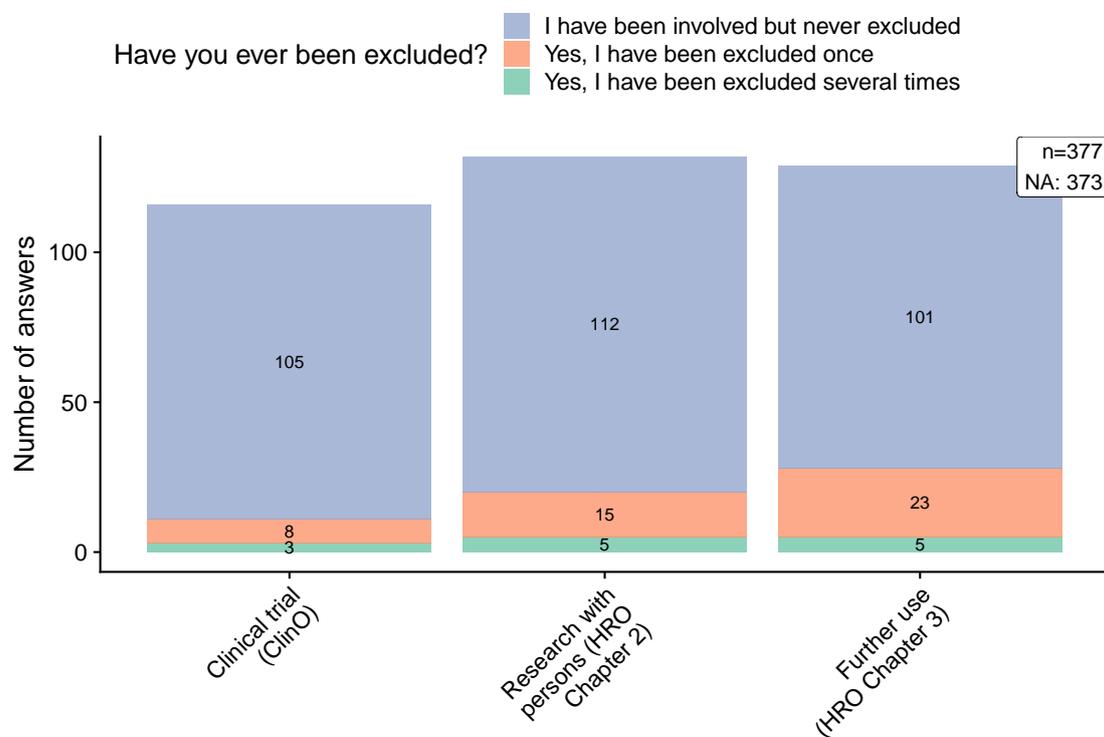


Figure B26.2: Stratification by project type.

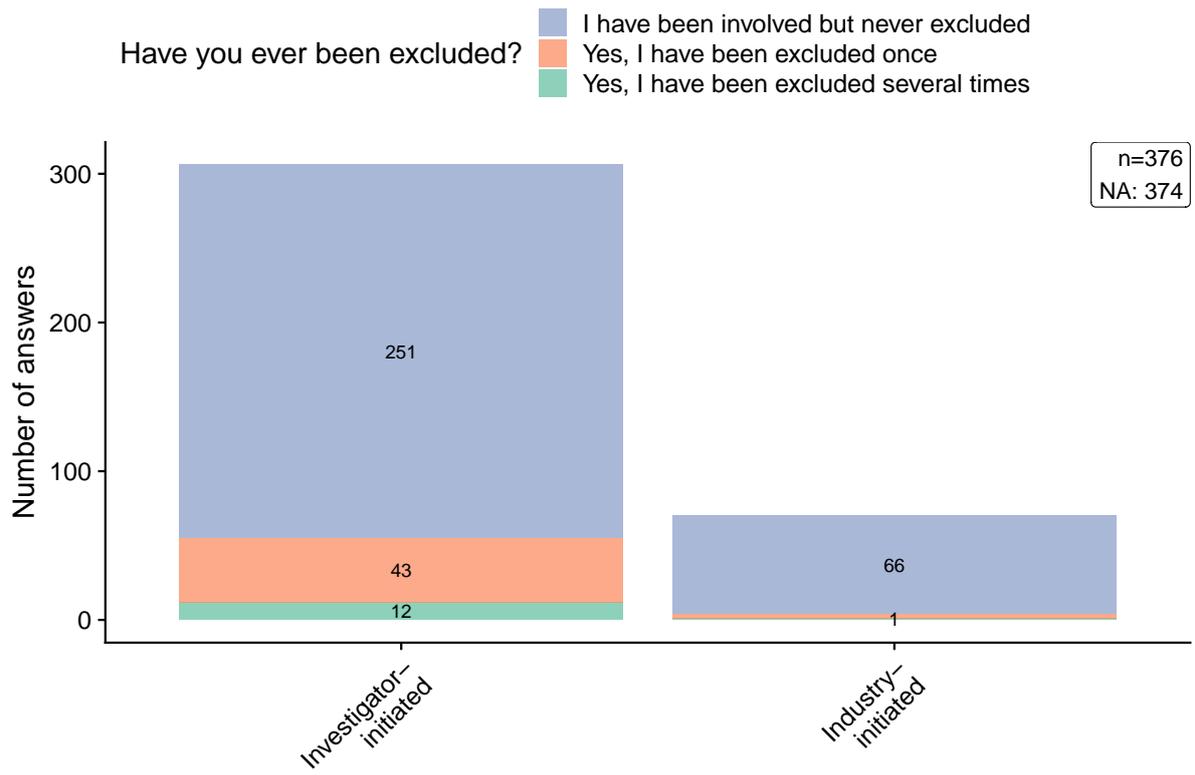


Figure B26.3: Stratification by project initiator.

B27 Have you ever decided to conduct a research project in another country and specifically not in Switzerland?

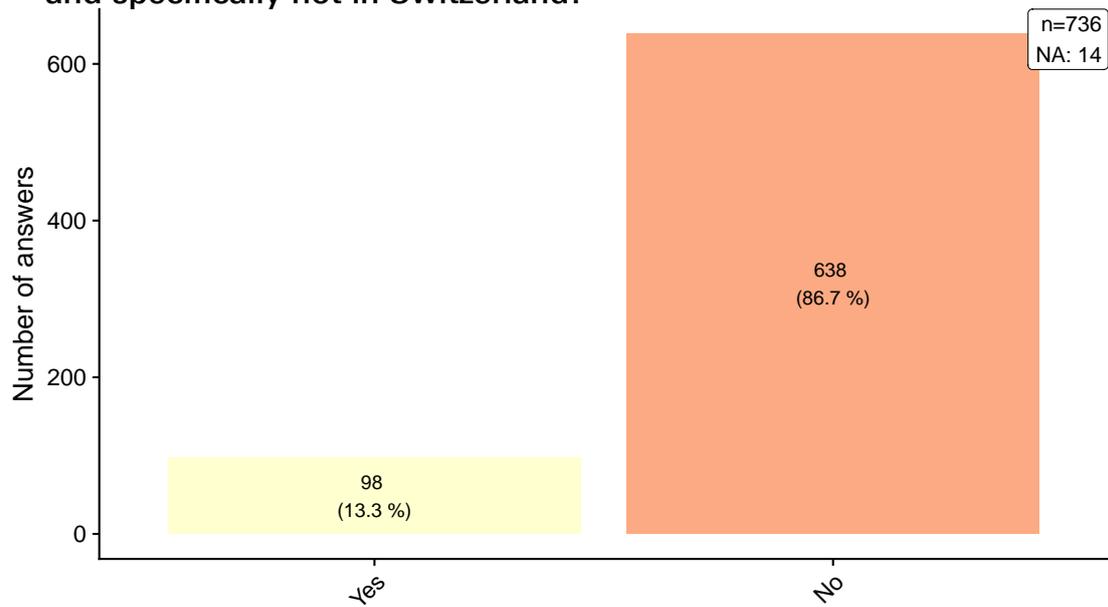


Table B27: Stratification of the answers.

		N	Research in another country?			
			Yes		No	
			n	%	n	%
Project group	Further use projects (FUP)	245	33	13	212	87
	Research projects not involving Swissmedic (SM-)	417	55	13	362	87
	Research projects involving Swissmedic (SM+)	74	10	14	64	86
Project type	Clinical trial (ClinO)	173	24	14	149	86
	Research with persons (HRO Chapter 2)	318	41	13	277	87
	Further use (HRO Chapter 3)	245	33	13	212	87
Initiator	Investigator-initiated	653	85	13	568	87
	Industry-initiated	81	13	16	68	84
	Not specified	2	0	0	2	100
Role	(Principal) investigator	523	70	13	453	87
	Sponsor	72	12	17	60	83
	Project leader/manager	87	8	9	79	91
	Research assistant/collaborator, Other	24	2	8	22	92
	CRO/CTU	18	4	22	14	78
	Not specified	12	2	17	10	83
All		736	98	13	638	87

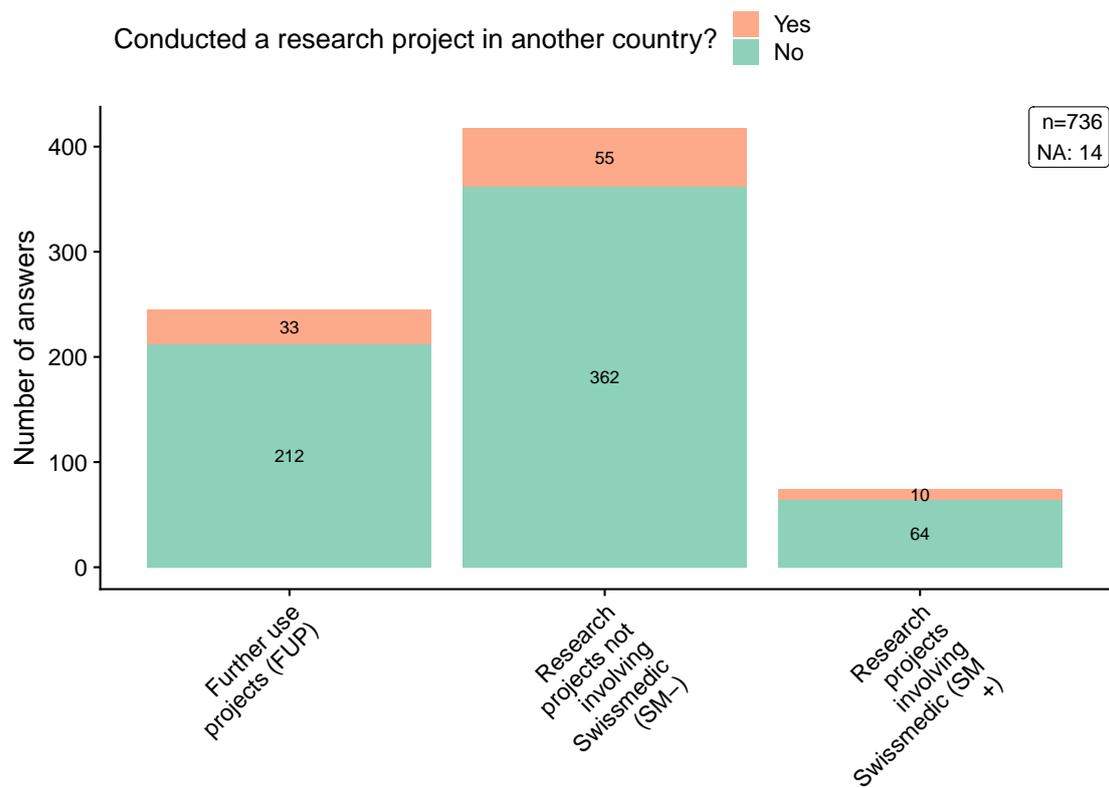


Figure B27.1: Stratification by project group.

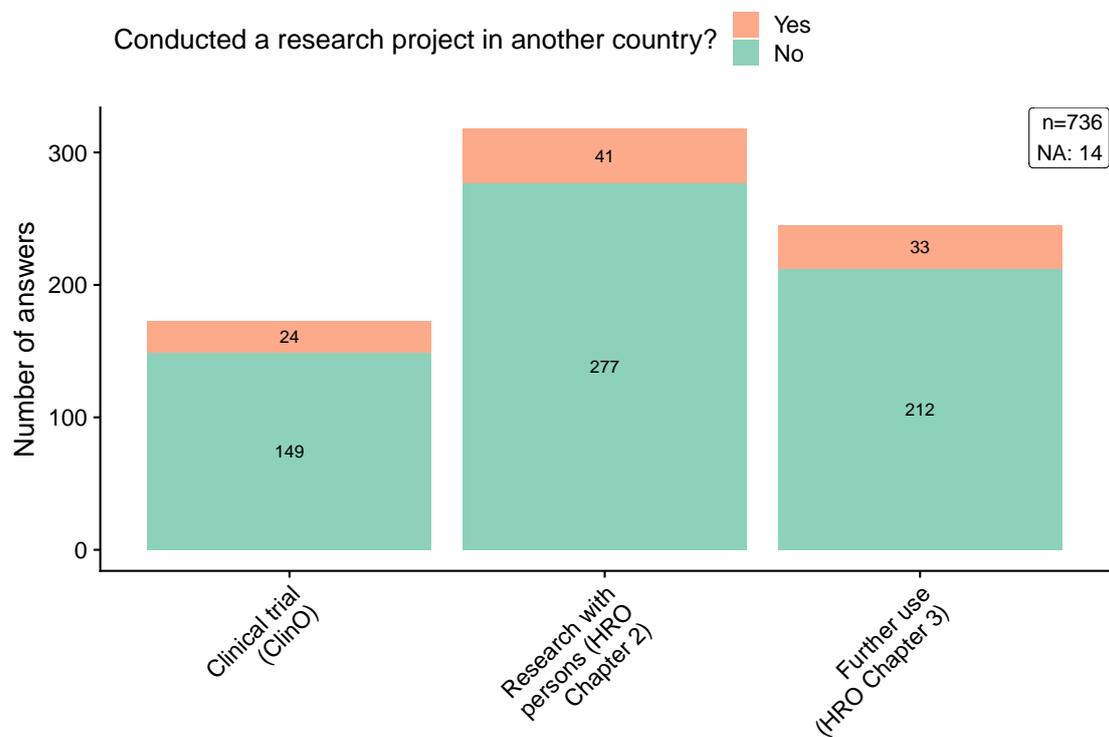


Figure B27.2: Stratification by project type.

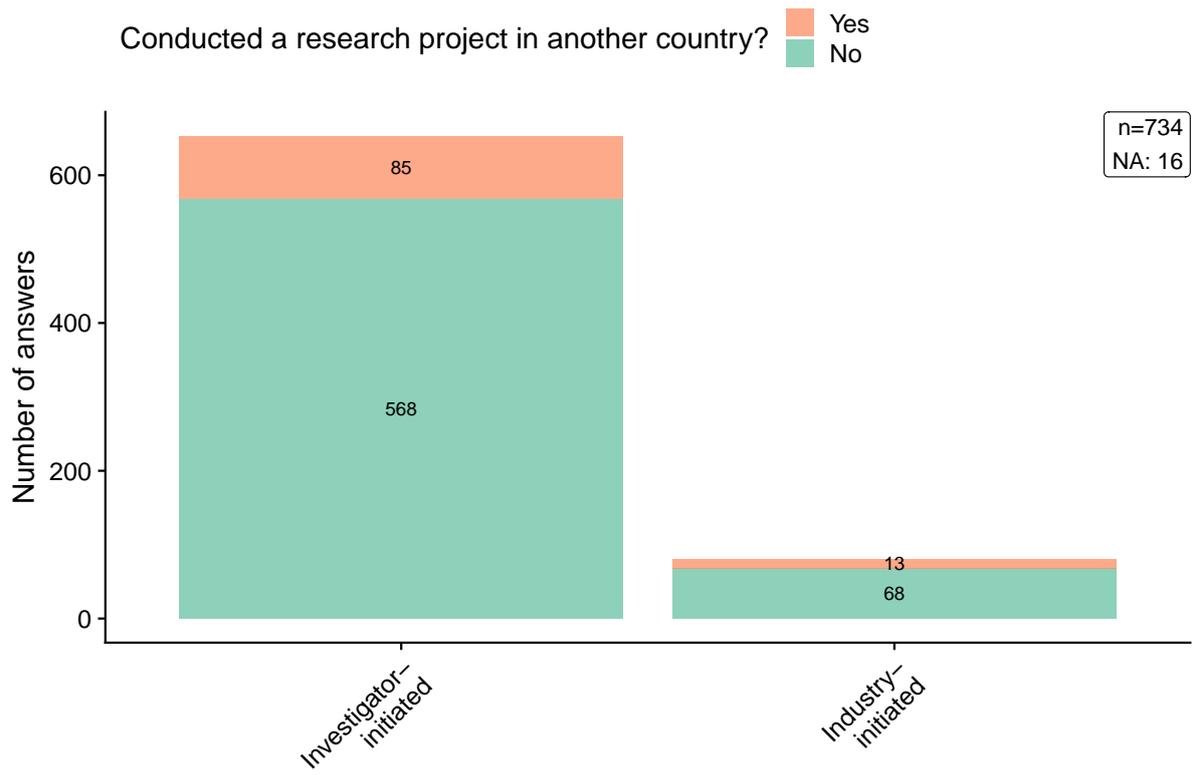


Figure B27.3: Stratification by project initiator.

B27a What were the reasons? (multiple answers possible)

Note: Asked if B27 is answered with 'Yes' (n=98)

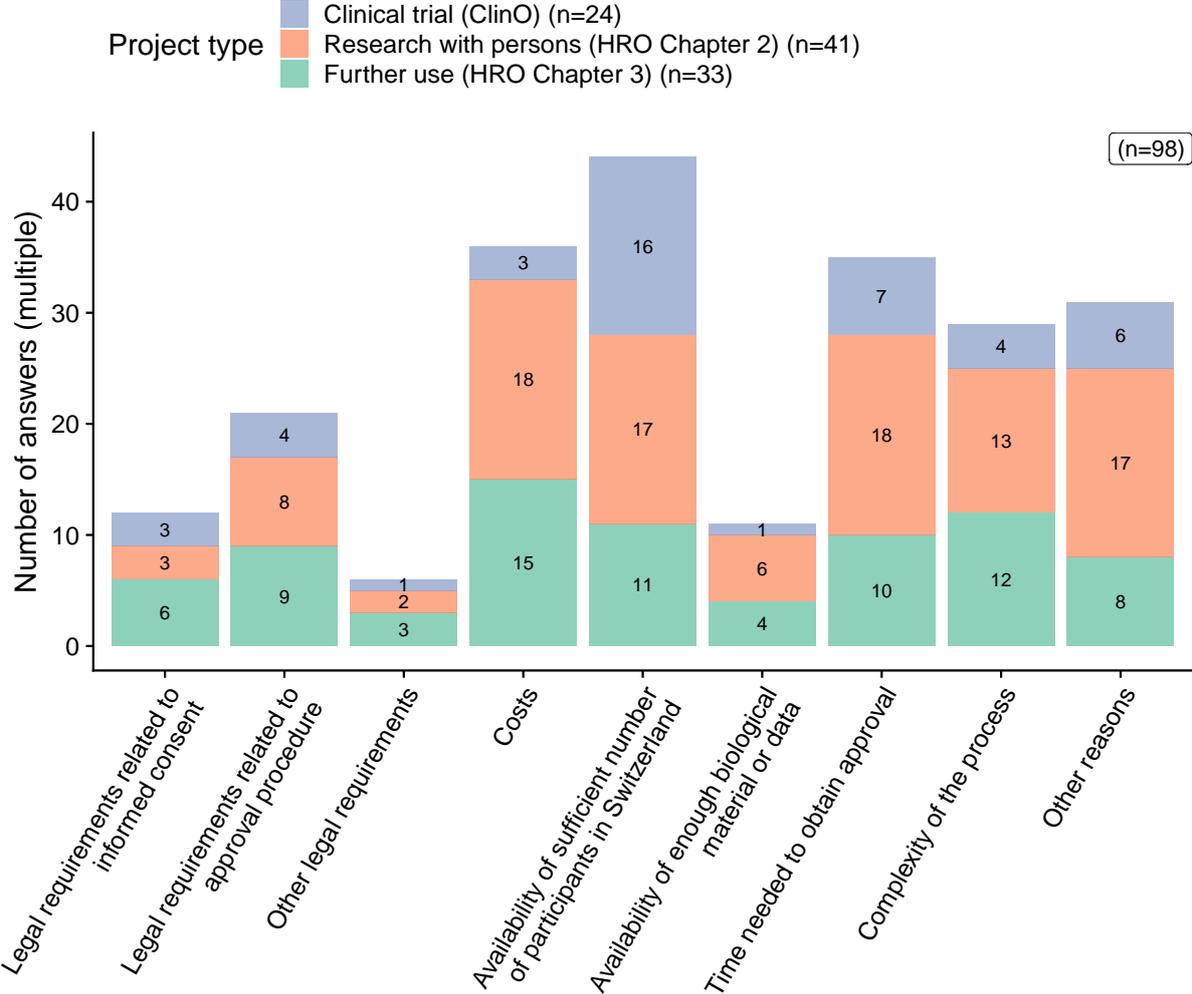


Figure B27a.1: Stratification by project type.

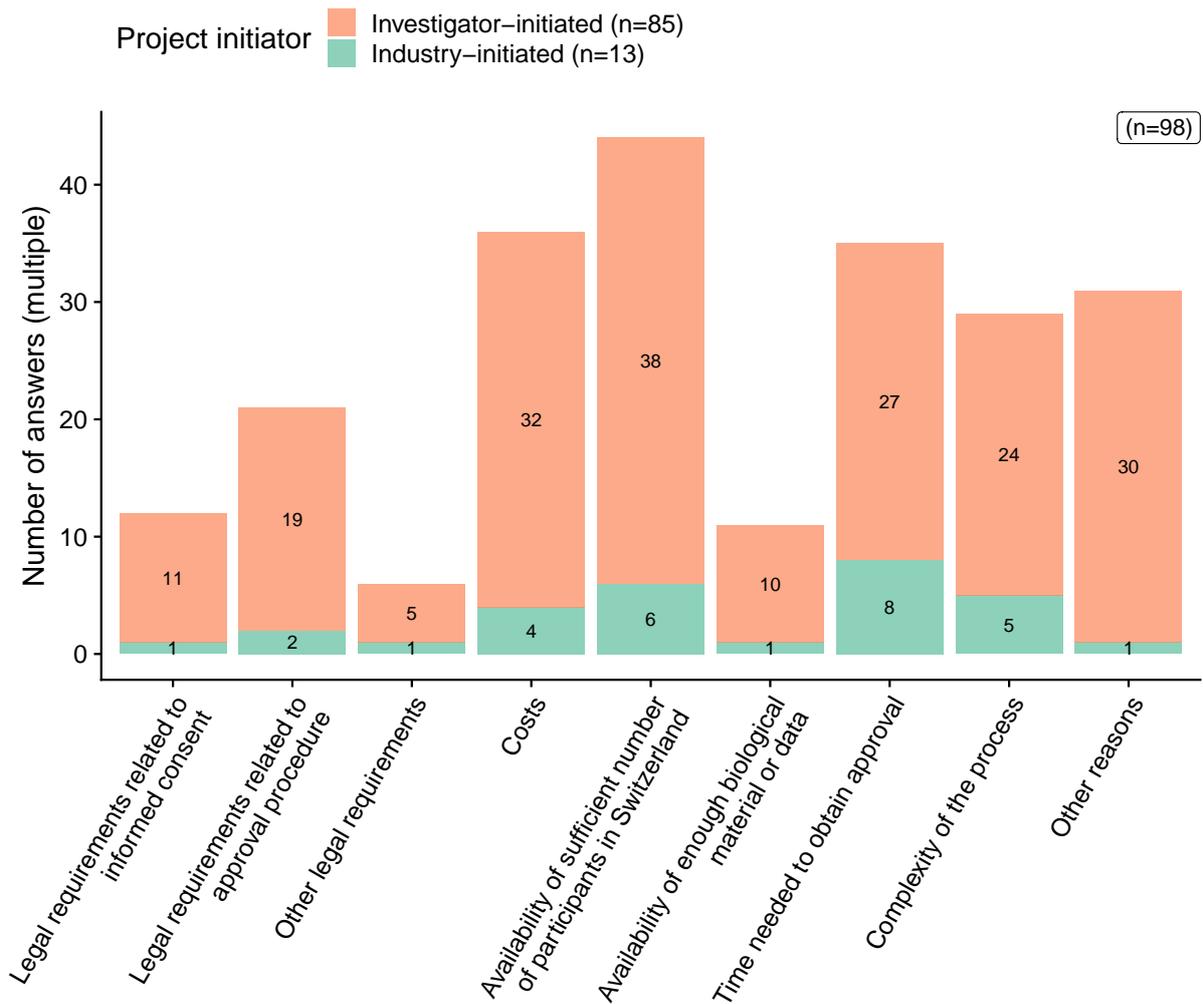


Figure B27a.2: Stratification by project initiator.

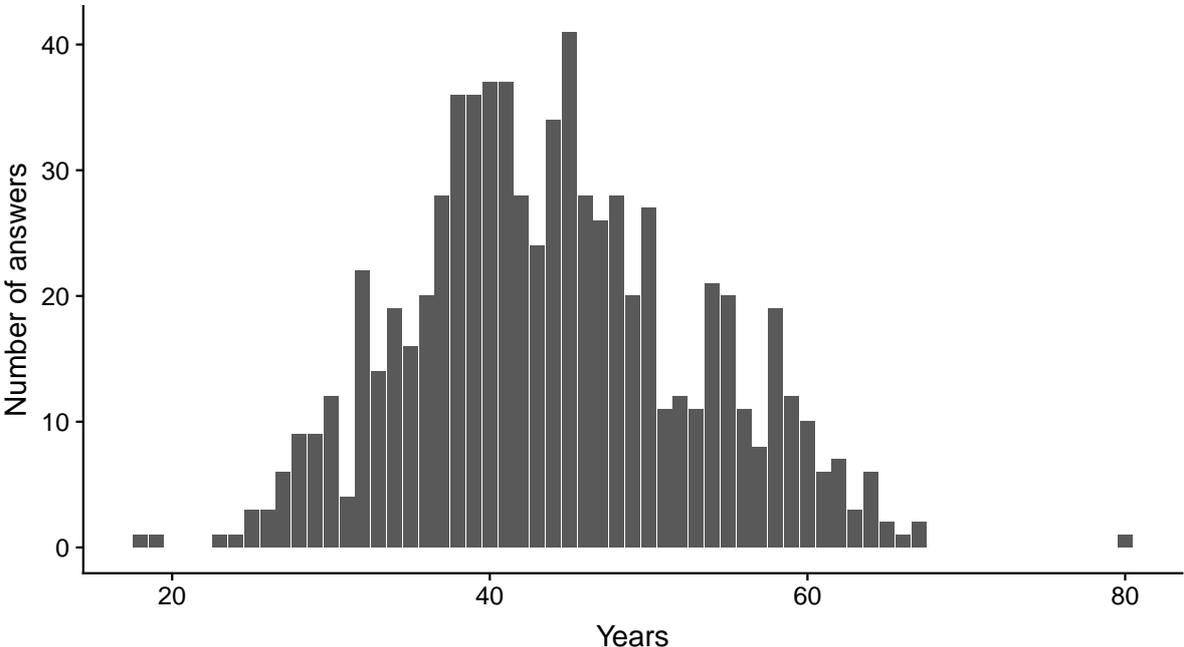
Freetext answers if B27a = "Other reasons":

- Scientific expertise and collaborators
- did a fellowship abroad
- EC requirements around CTAs; there is work to be done (a common consensus has to be agreed, current situation is limiting industry led clinical research in Switzerland) Switzerland is not competitive in this regard
- During my fellowship overseas
- co-operation with a partner outside Switzerland
- Research-management was given up in Horizon2020 call to partners outside from CH
- During my Fellowship in France

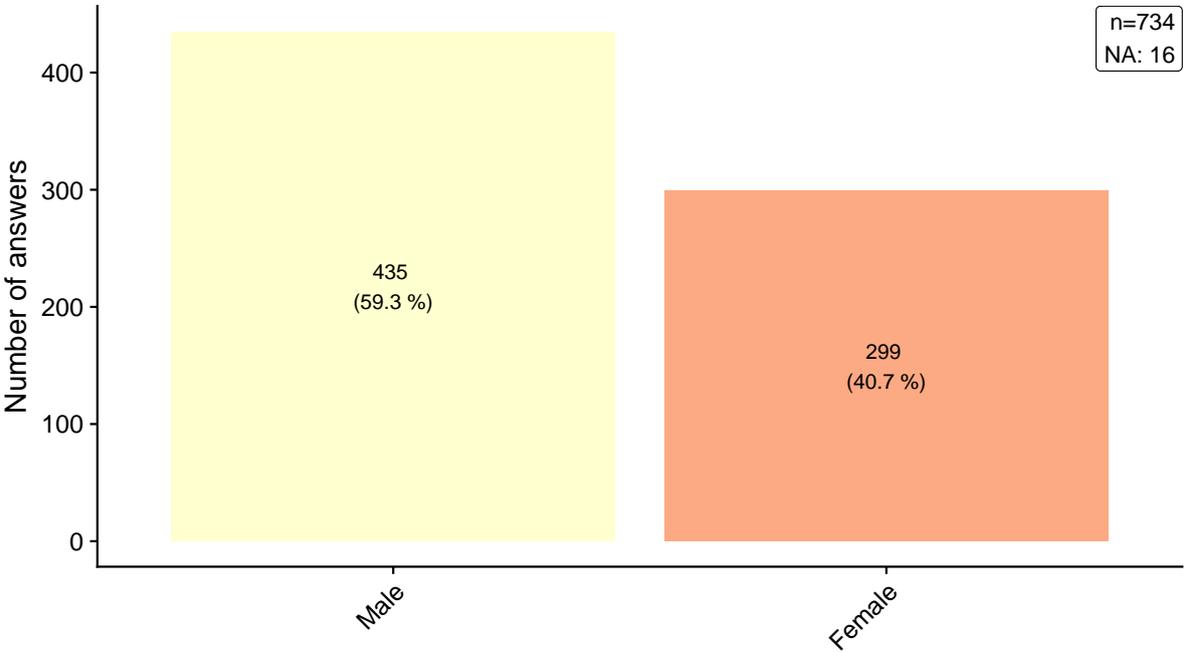
- I am moving back to my home country.
- The research question was more appropriate for that alternative setting
- clinical partners in different country
- cooperation, lower salary
- research stay abroad
- Basic research in a collaboration laboratory for knowledge exchange.
- work outside of switzerland
- Genetic association studies require reference data, ideally from the population that the individuals under study belong to. In Switzerland, I am not aware that reference population genetic data exist, making impossible to conduct such studies in Switzerland.
- I have been living there
- research at high altitude in the Andes in collaboration with international consortium
- scientific collaborations
- patient specific allocations in germany
- During my fellowship overseas
- Home university
- Research for a post doc abroad.

Personal characteristics of respondents

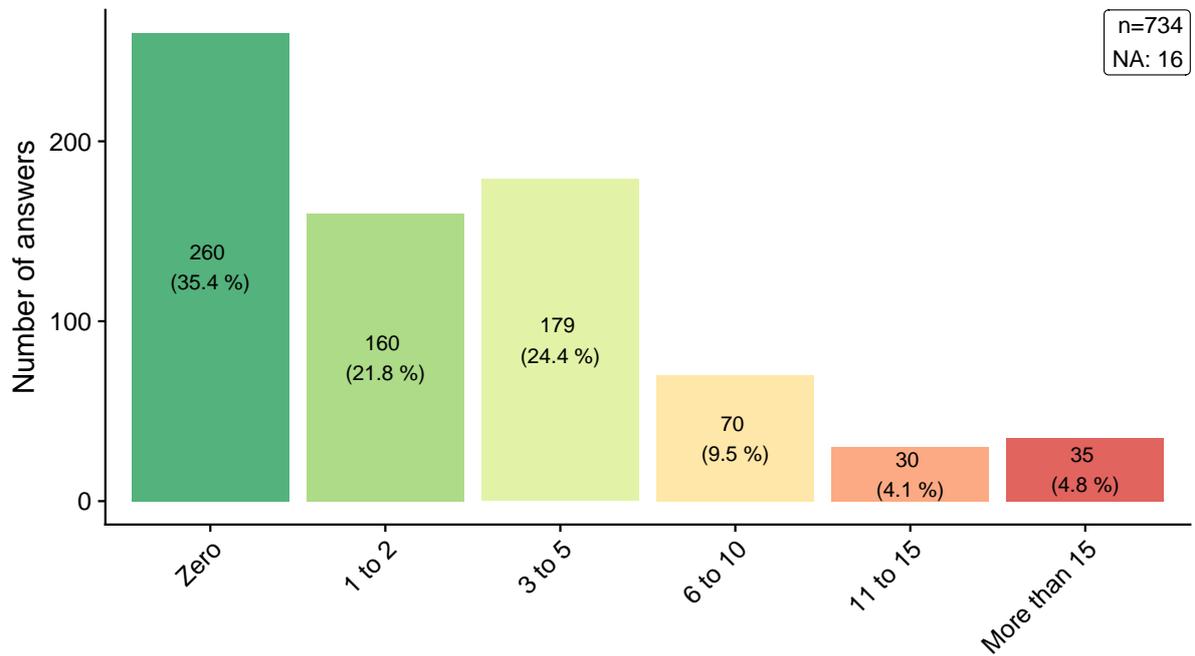
B30 Age



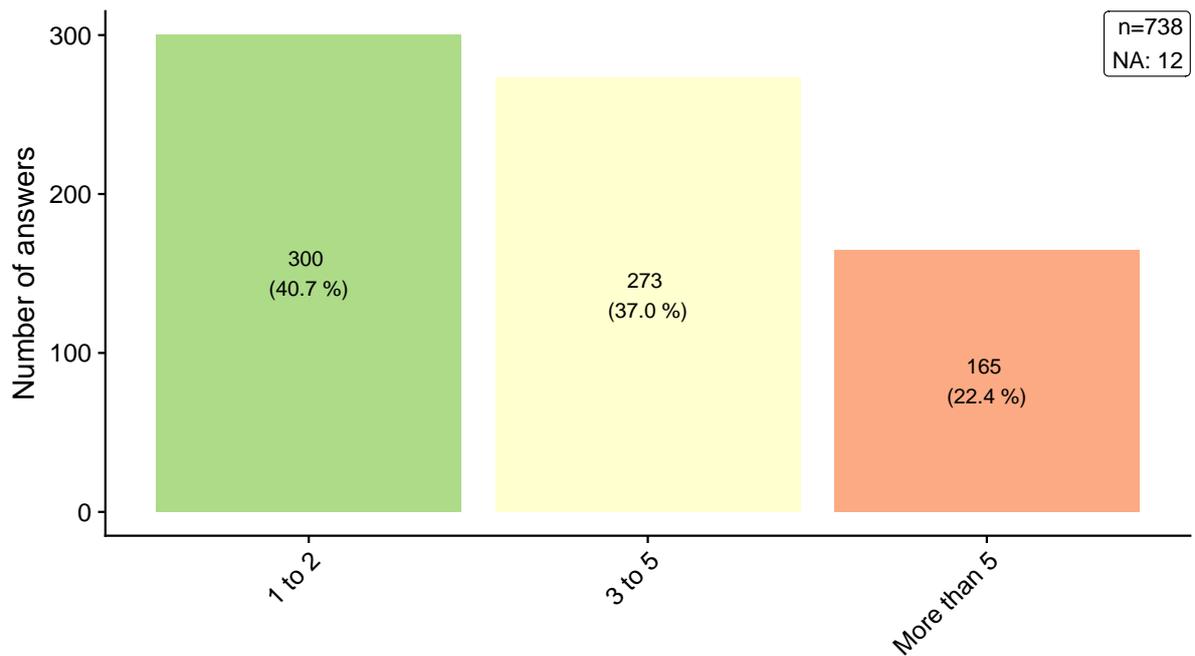
B31 Sex



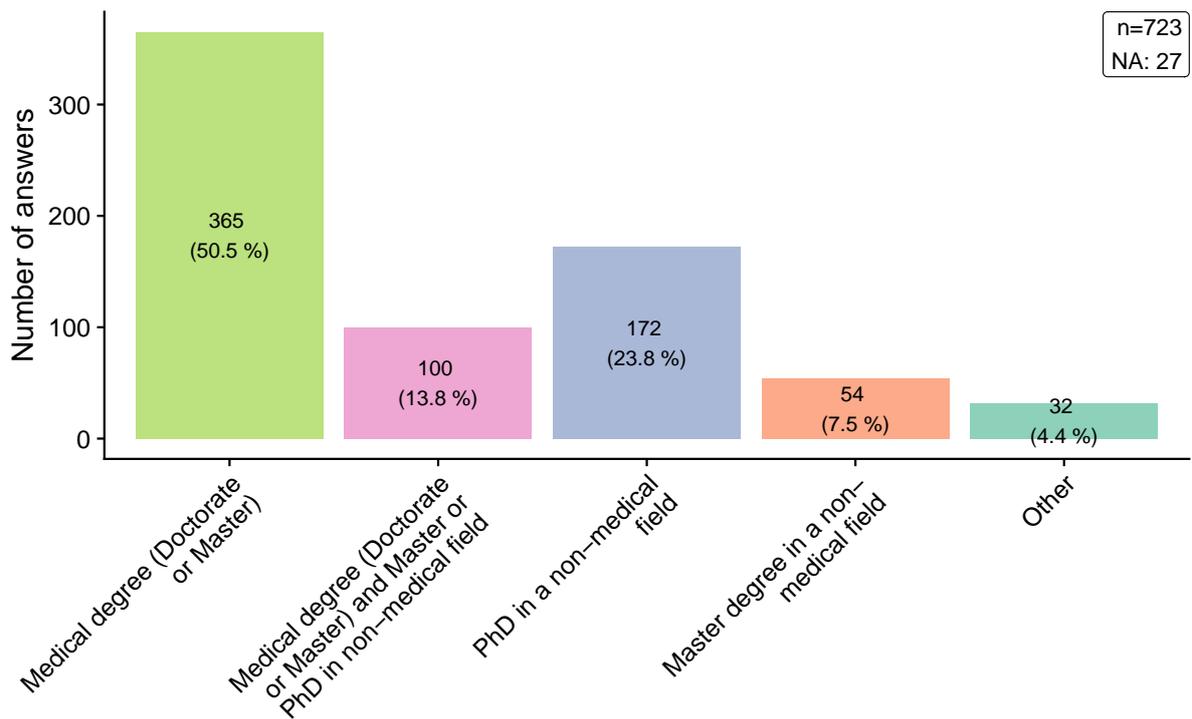
B32 How many research projects have you submitted to Ethics Committees in Switzerland before 1 January 2014 (in any role)?



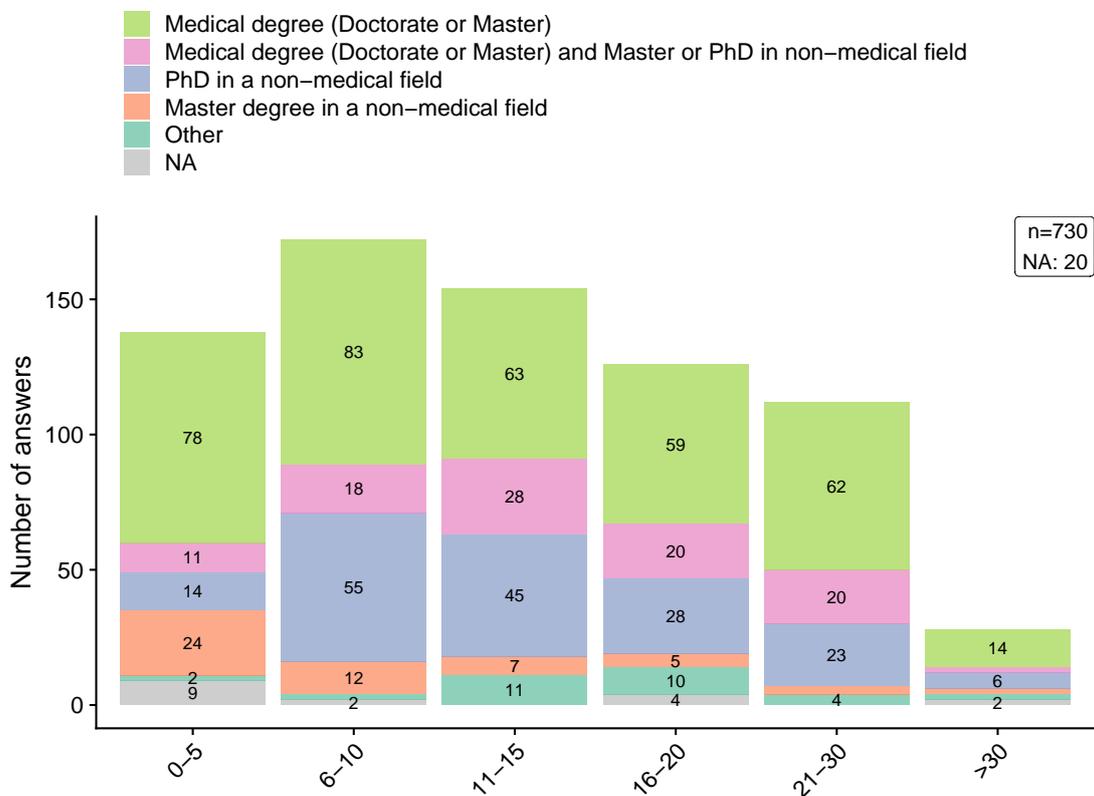
B33 How many research projects have you submitted to Ethics Committees in Switzerland since 1 January 2014 (in any role)?



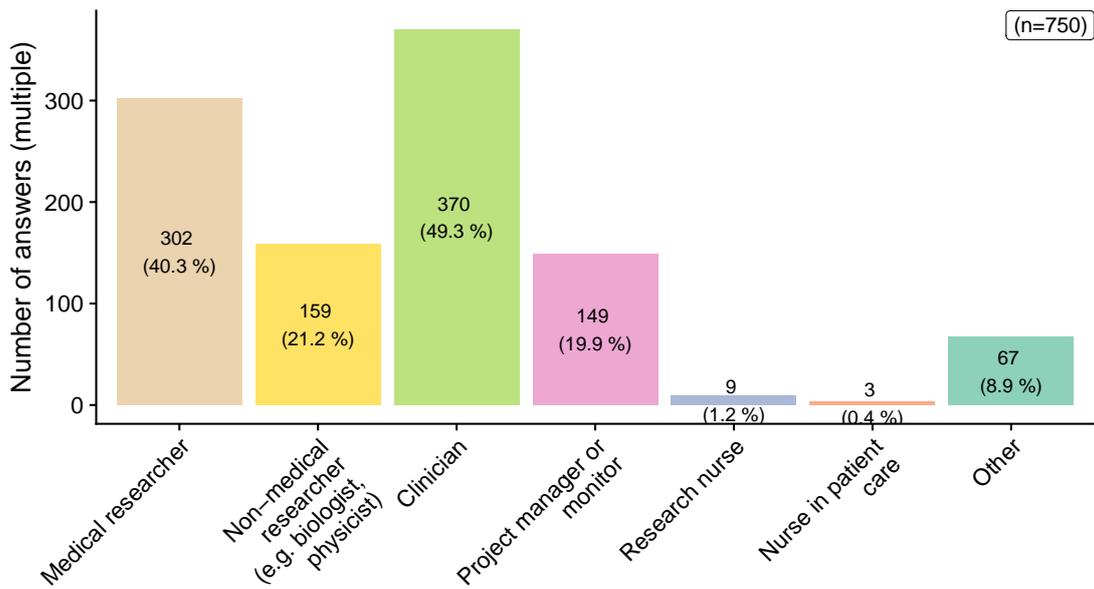
B34 What is (are) your highest professional qualification?



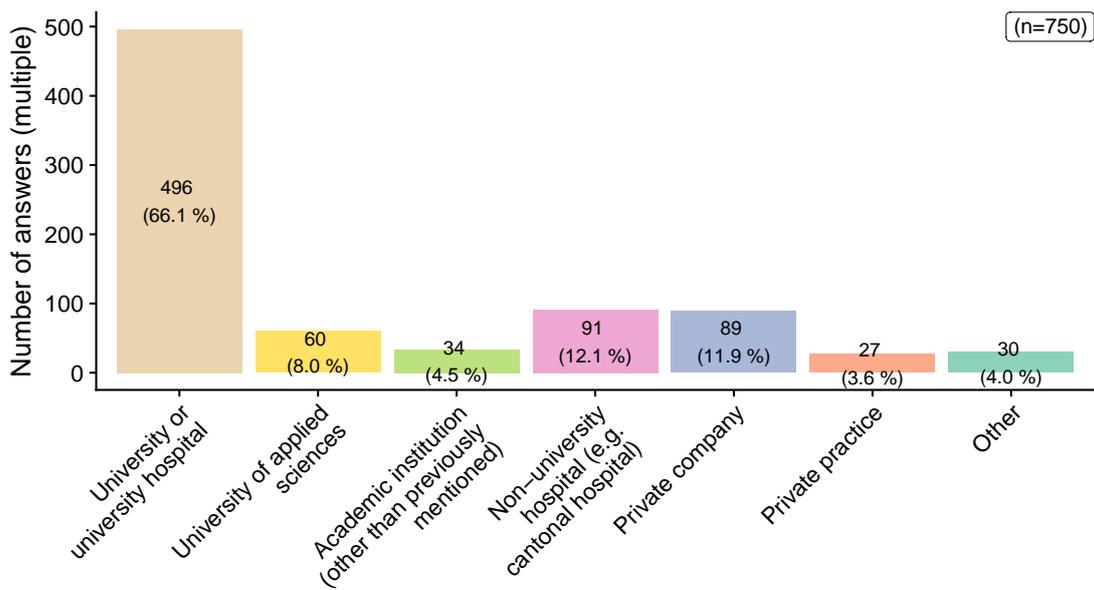
B35 For how long have you been working in research?



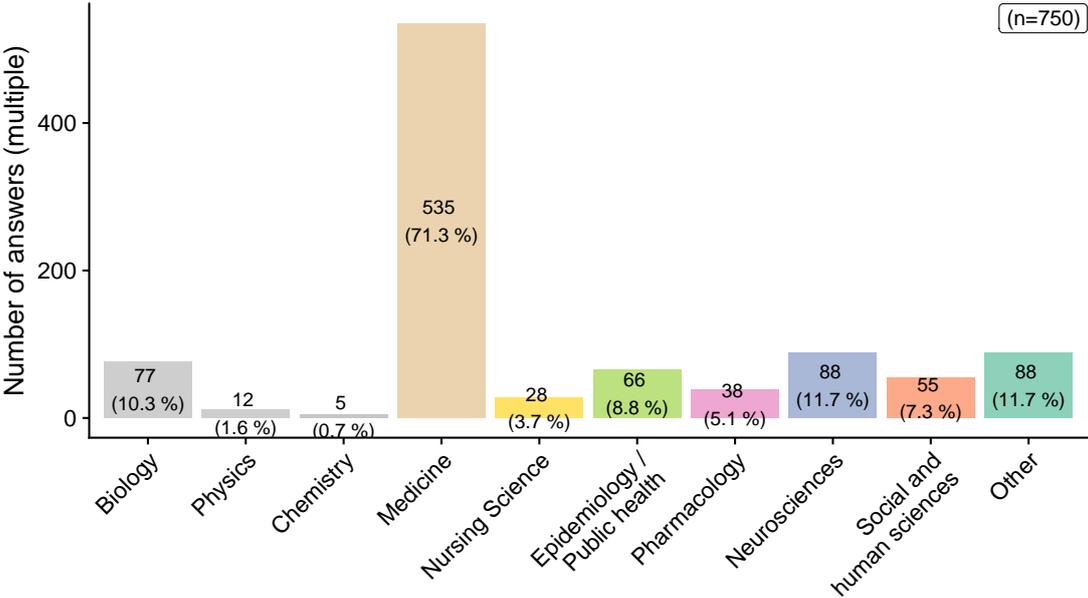
B36 Currently, you are working as a... (multiple answers possible)



B37 In which area/setting are you working? (multiple answers possible)



B38 In which field of research are you working? (multiple answers possible)



C Appendix

i Stratifications of type of study by total score of satisfaction

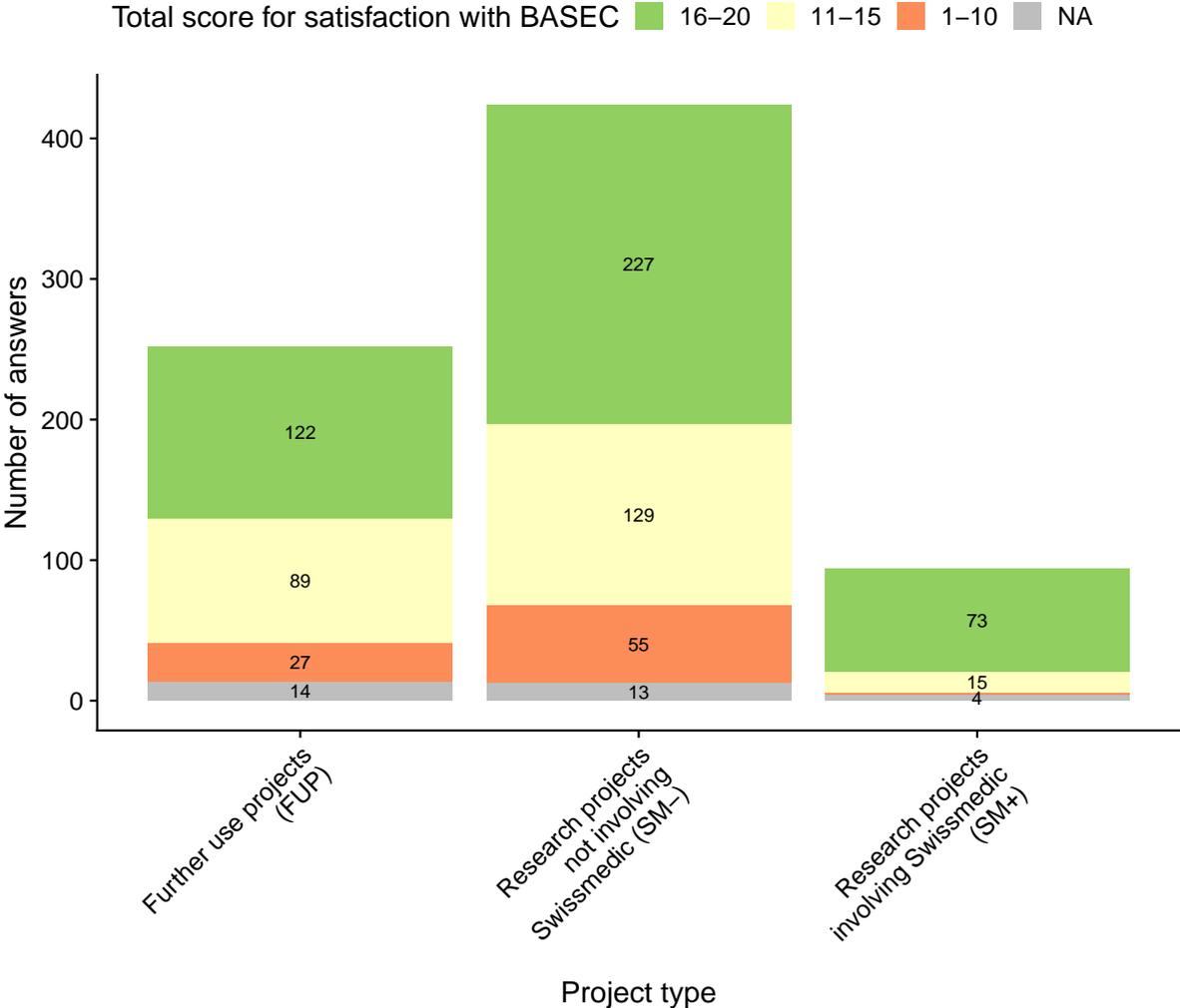


Figure Ci.1: Satisfaction per project group.

Total satisfaction score. higher scores correspond to higher satisfaction.

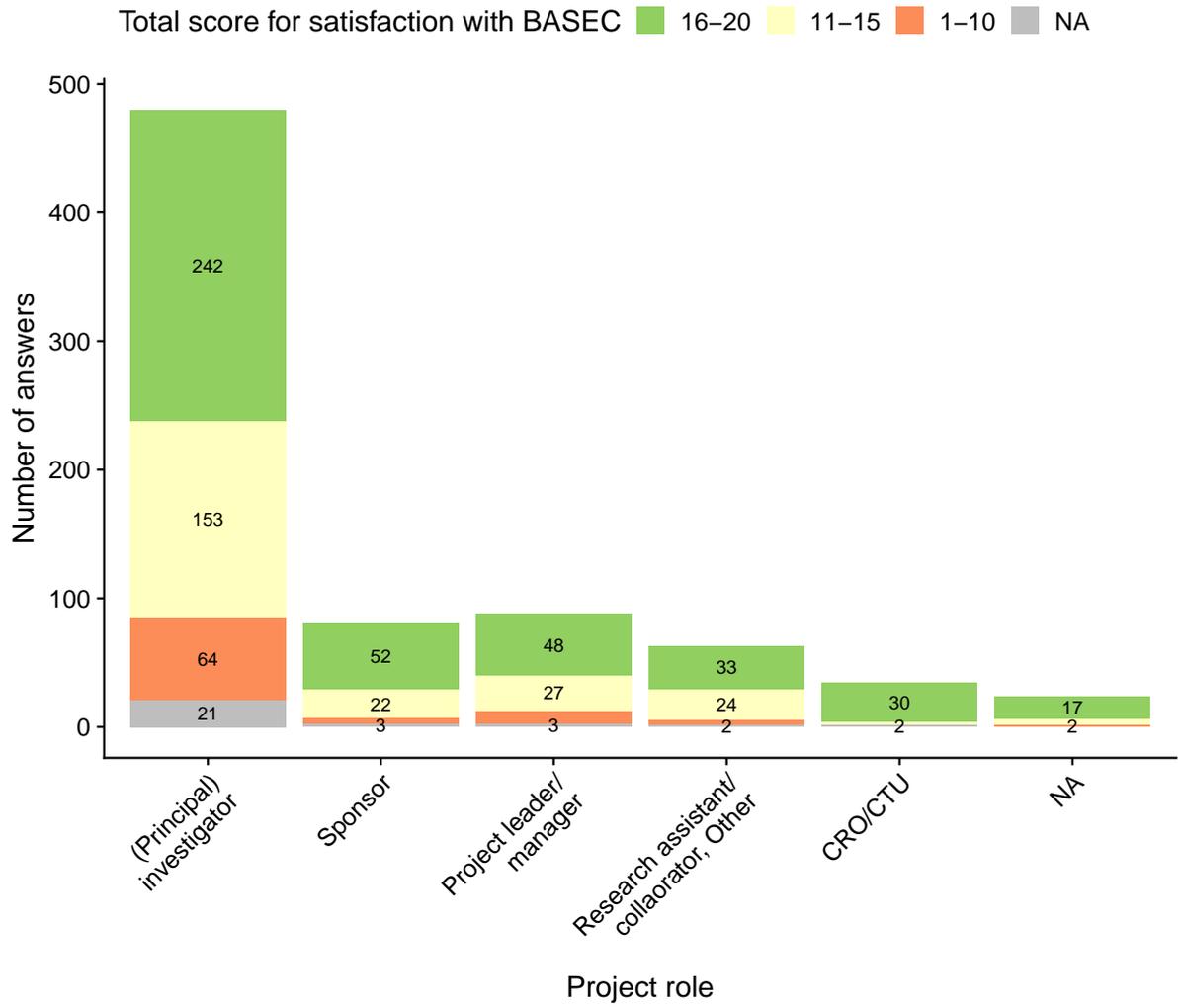


Figure Ci.2: Satisfaction per role.

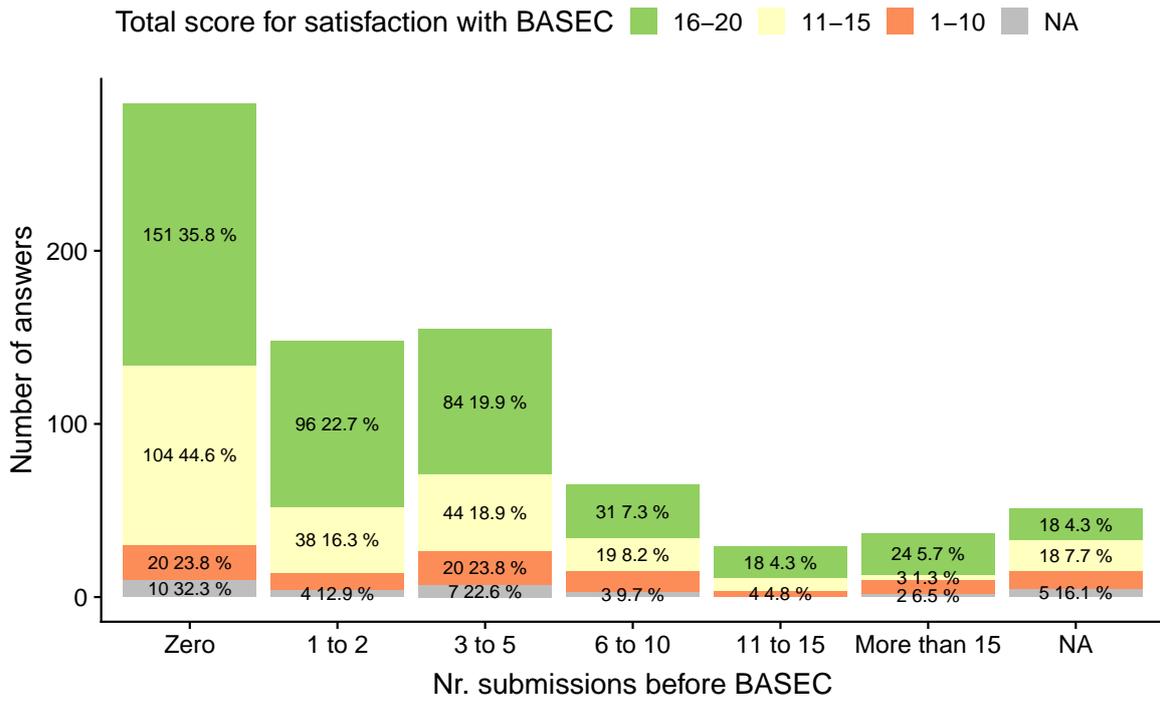


Figure Ci.3: How many research projects have you submitted to Ethics Committees in Switzerland before 1 January 2014?

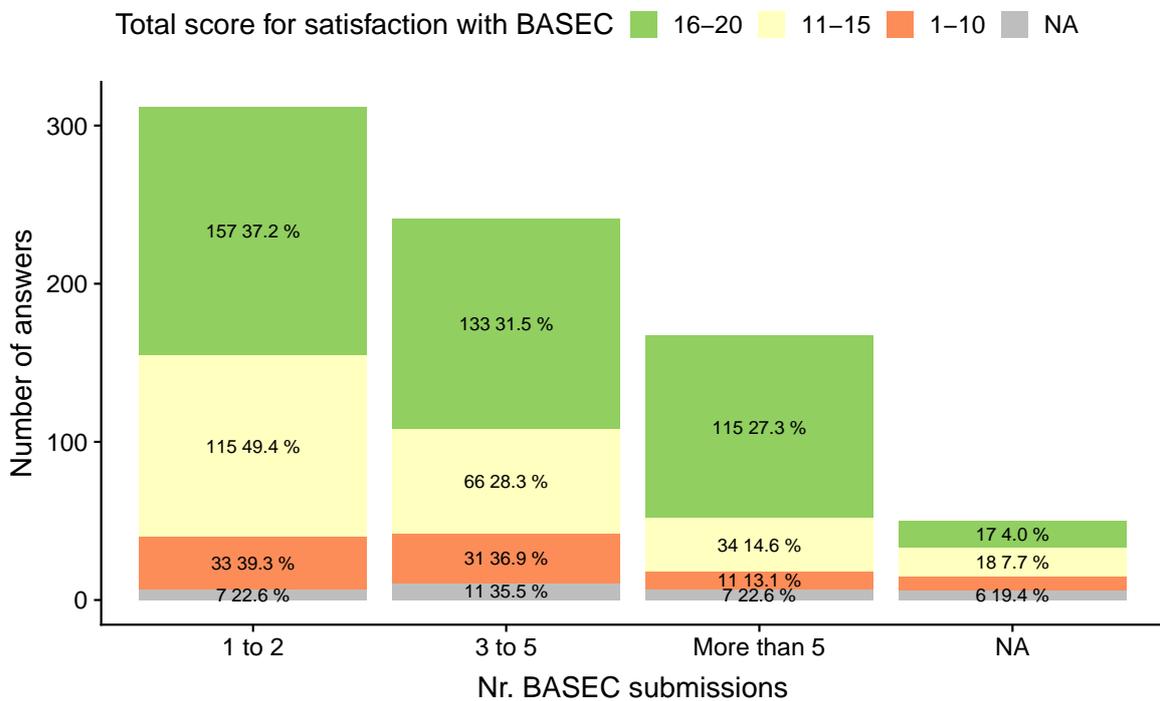


Figure Ci.4: How many research projects have you submitted to Ethics Committees in Switzerland after 1 January 2014?