

Additional stratified analysis of selected questions

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) and the accompanying "Full Report".

The report provides additional stratifications of survey responses of selected questions as identified by the *Institut für Politikwissenschaft, Universität Zürich (IPZ)* and *KEK-CDC Consultants*. The original questions from the IPZ are provided in a yellow box at the beginning for each chapter.

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

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List of abbreviations

BASEC	Business Administration System for Ethics Committees
IPZ	Institut für Politikwissenschaft, Universität Zürich (IPZ)
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)
HRO - obs.	Human Research Ordinance, Chapter 2 (observational studies)
HRO - FU	Human Research Ordinance, Chapter 2 ('further use' studies)
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

1 Data management and statistical analysis

The dataset was prepared for analysis using standard plausibility checks (e.g. for quantitative data entered) and by removing questionnaires that were filled in only partially i.e. for less than half of the overall number of applicable questions. This was done separately for Parts A and B. The number of missing answers are denoted with "NA" in the top right corner of each figure. Undefined/missing values in the stratification variable are not shown (e.g. stratification by risk category does not show studies with no risk category, i.e. further use studies). All analyses were conducted using the statistical software R.

- 2 **Question 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.

Question from IPZ / KEK-CDC Consultants: Bei verschiedenen Fragen würde interessieren, ob es Unterschiede gibt je nach Erfahrung des Forschenden sowie nach Forschungsbereich (HFV vs KlinV / Industrie vs Akademie / KlinV A vs KlinV B,C / ggf. Disziplin), zumal mit dem HFG die bewilligungspflichtige Forschung erweitert wurde.

Gibt es Unterschiede in der Beurteilung des Bewilligungsprozesses nach Forschungsbereich and nach Erfahrung?

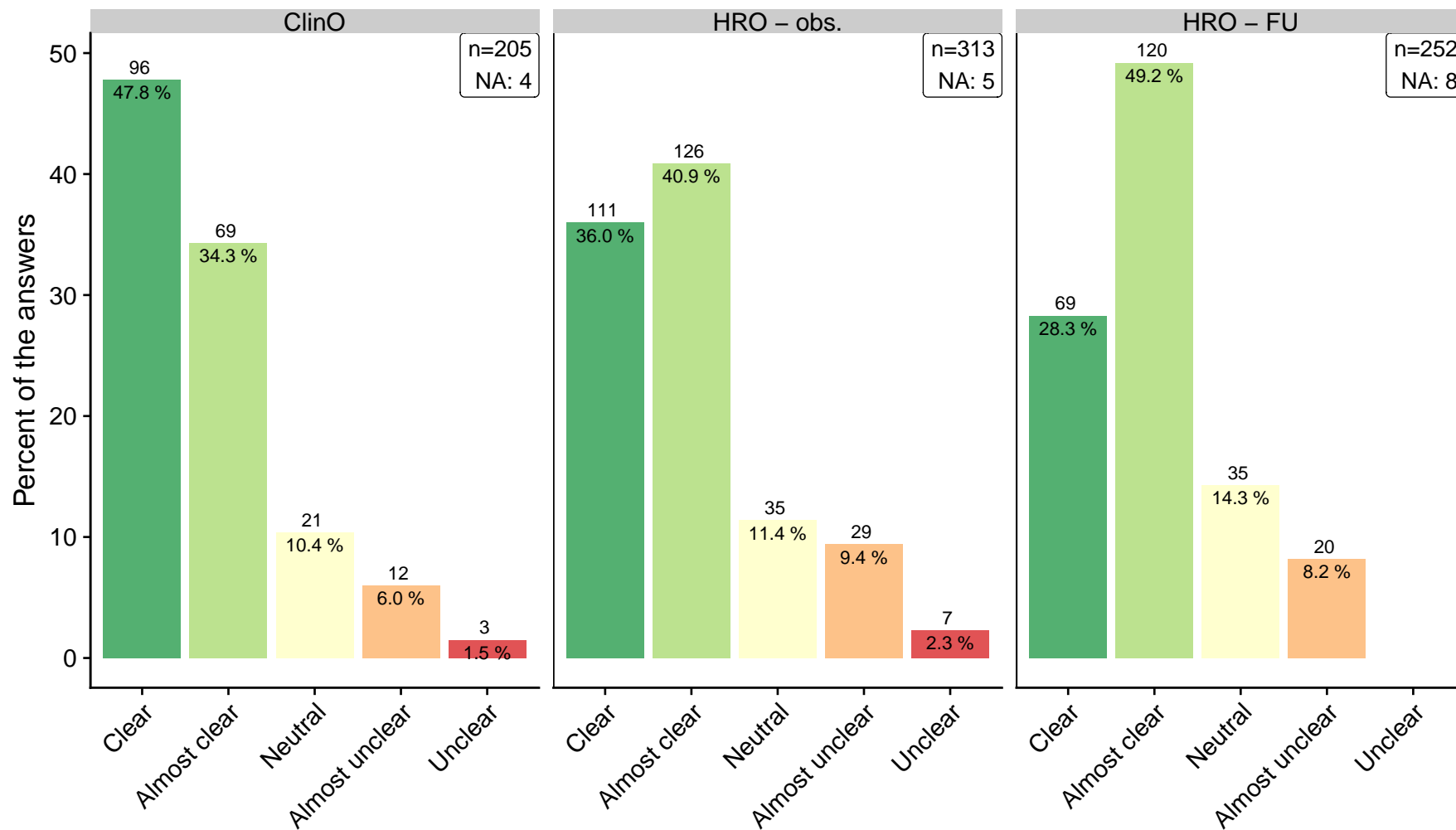
Definition:

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.

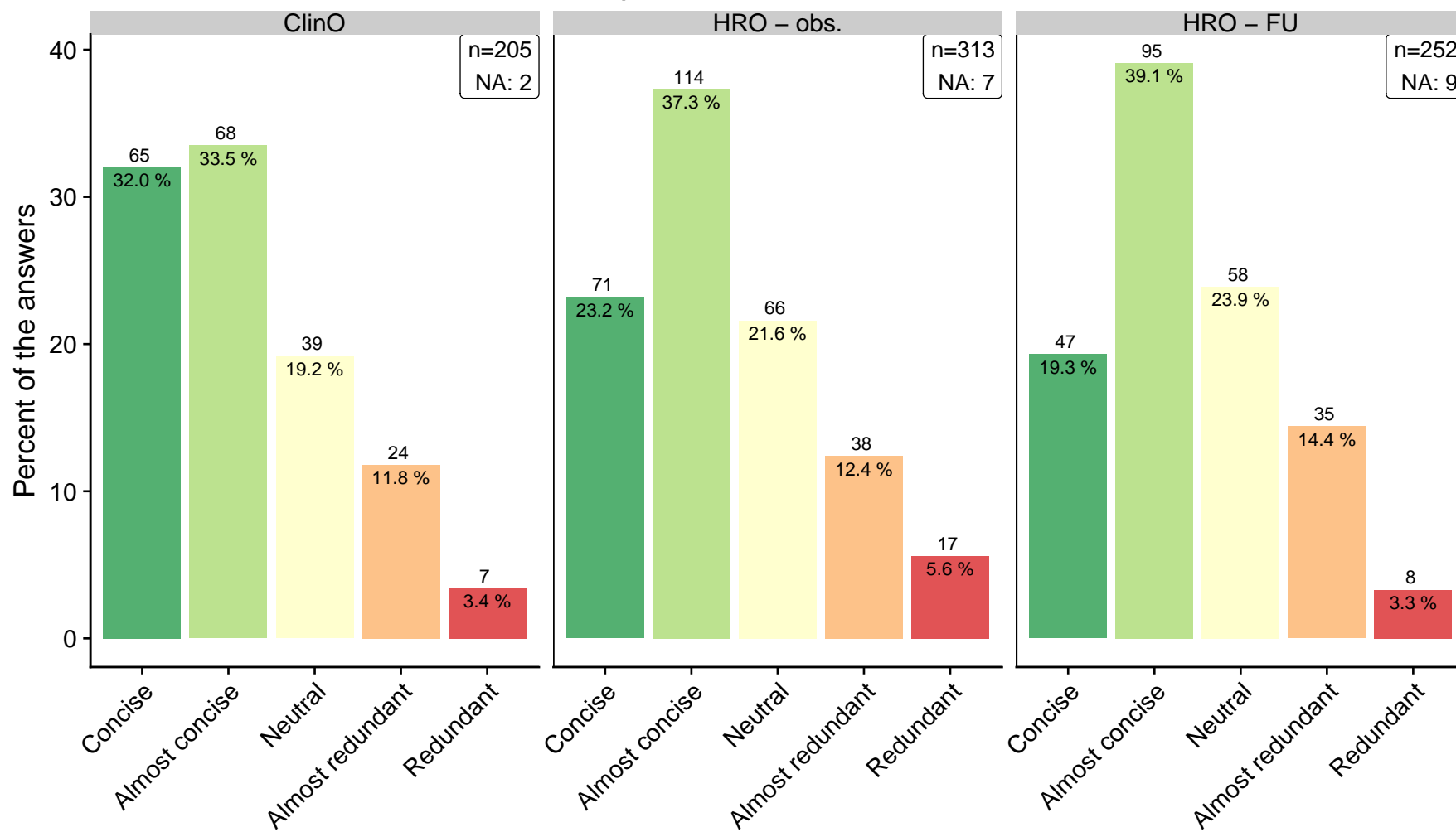
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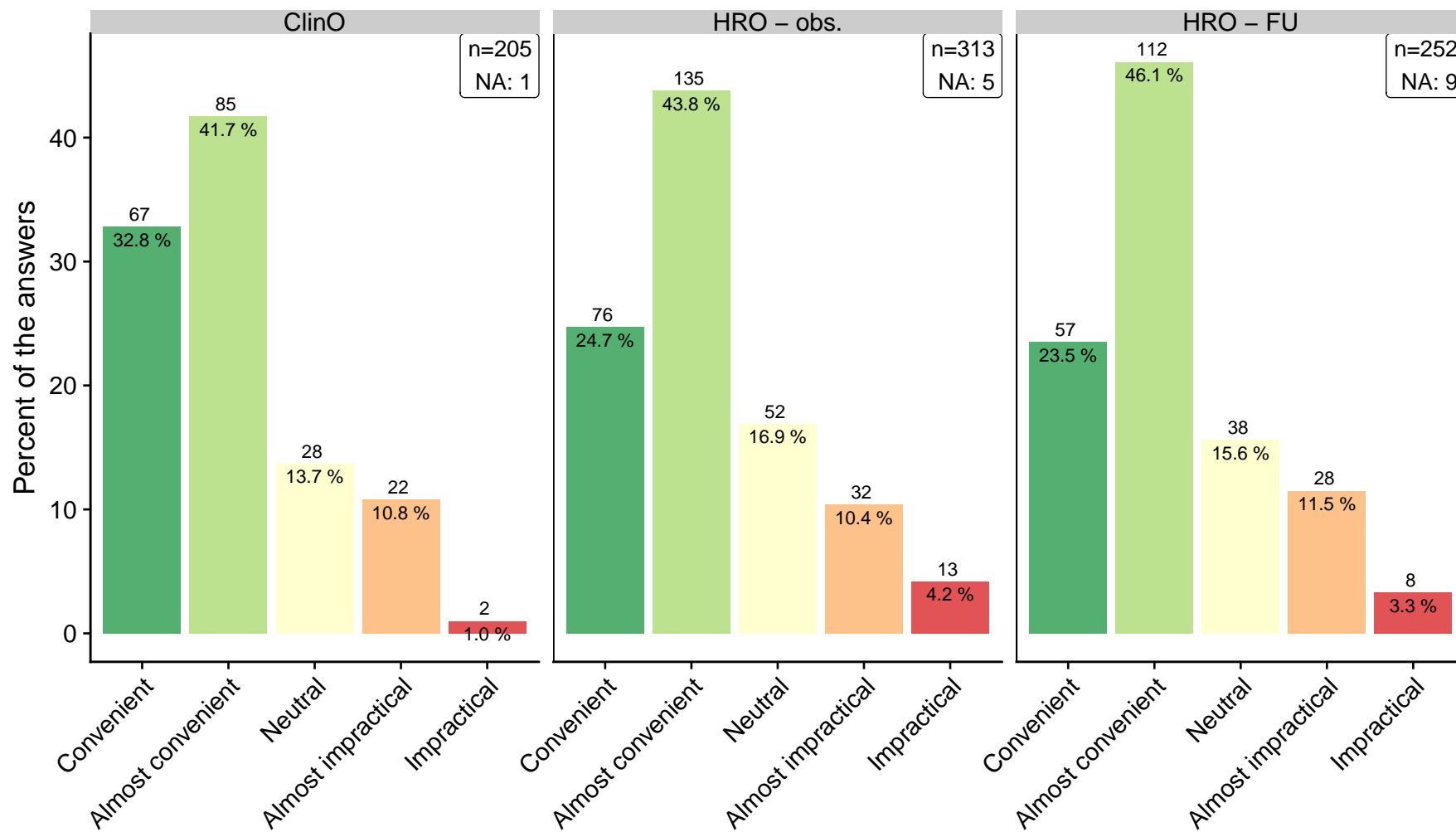
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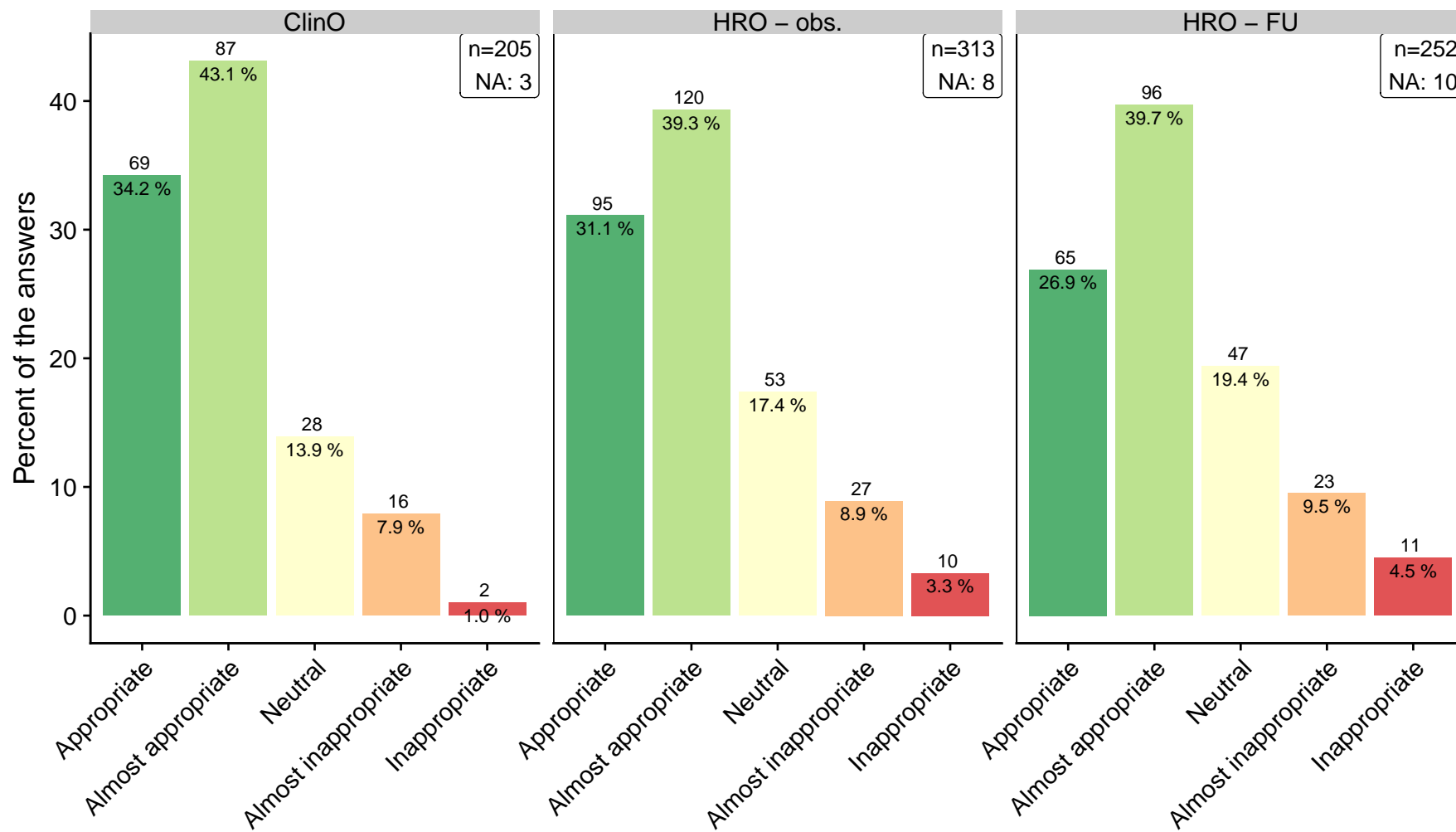
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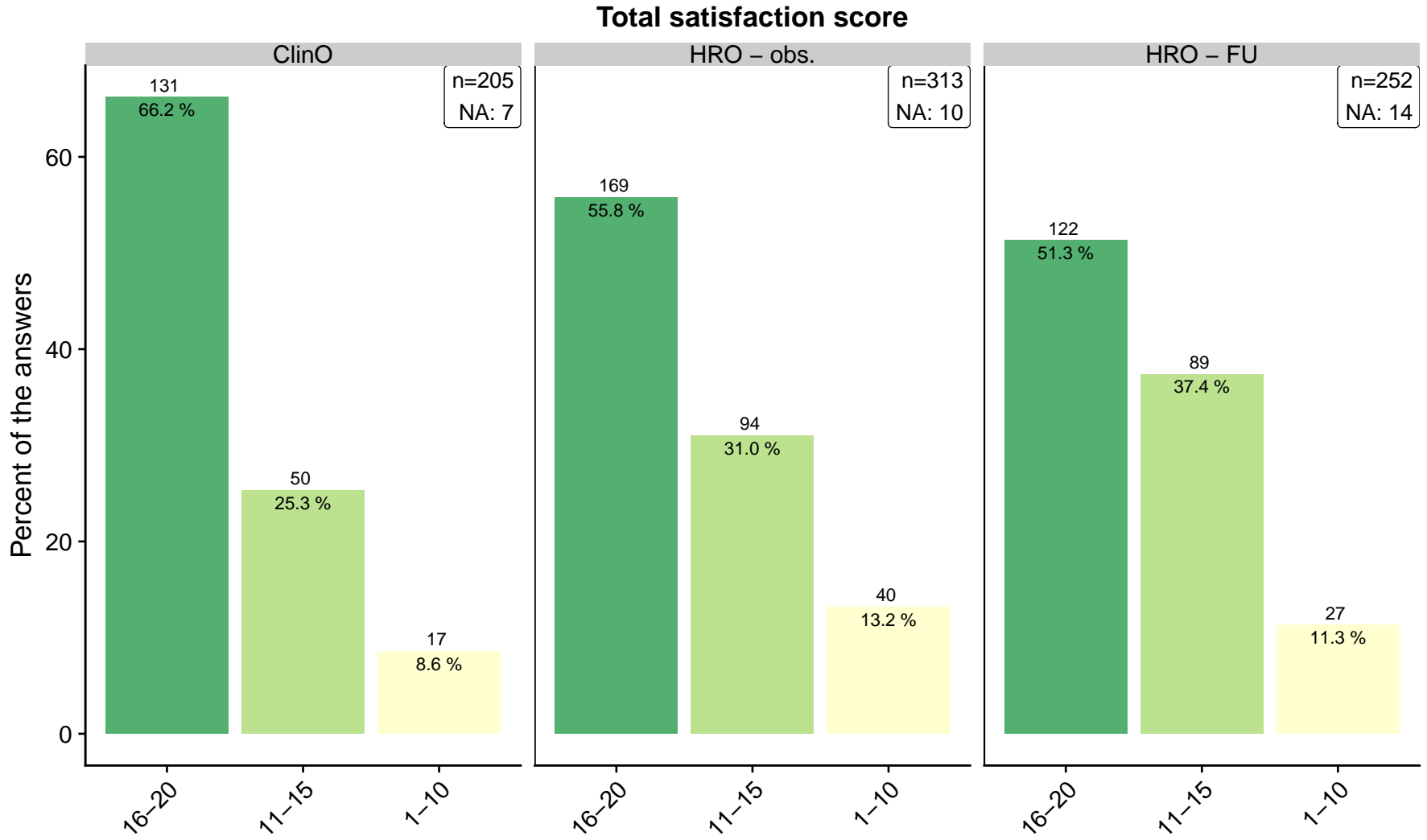


c) Convenient vs Impractical



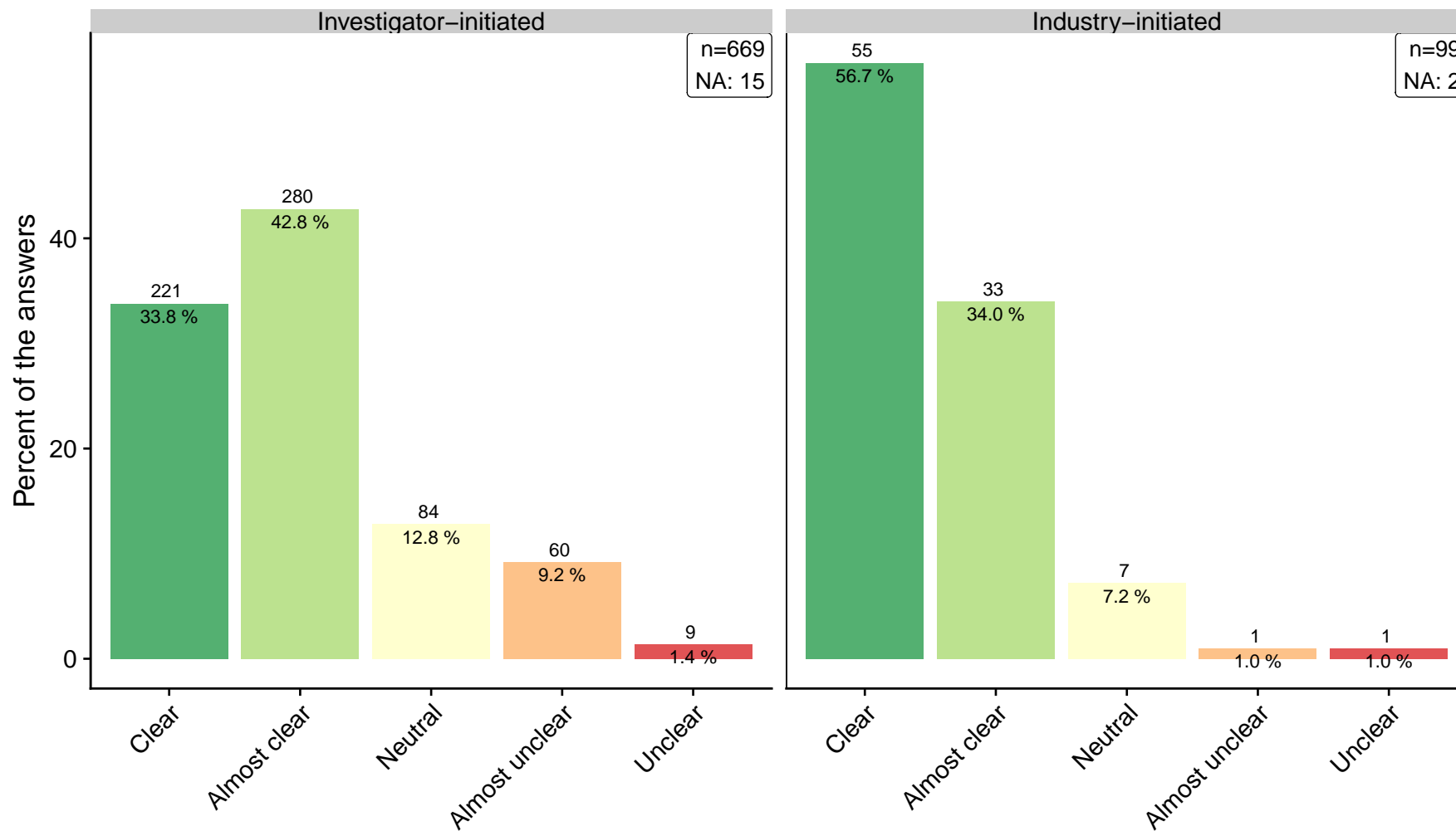
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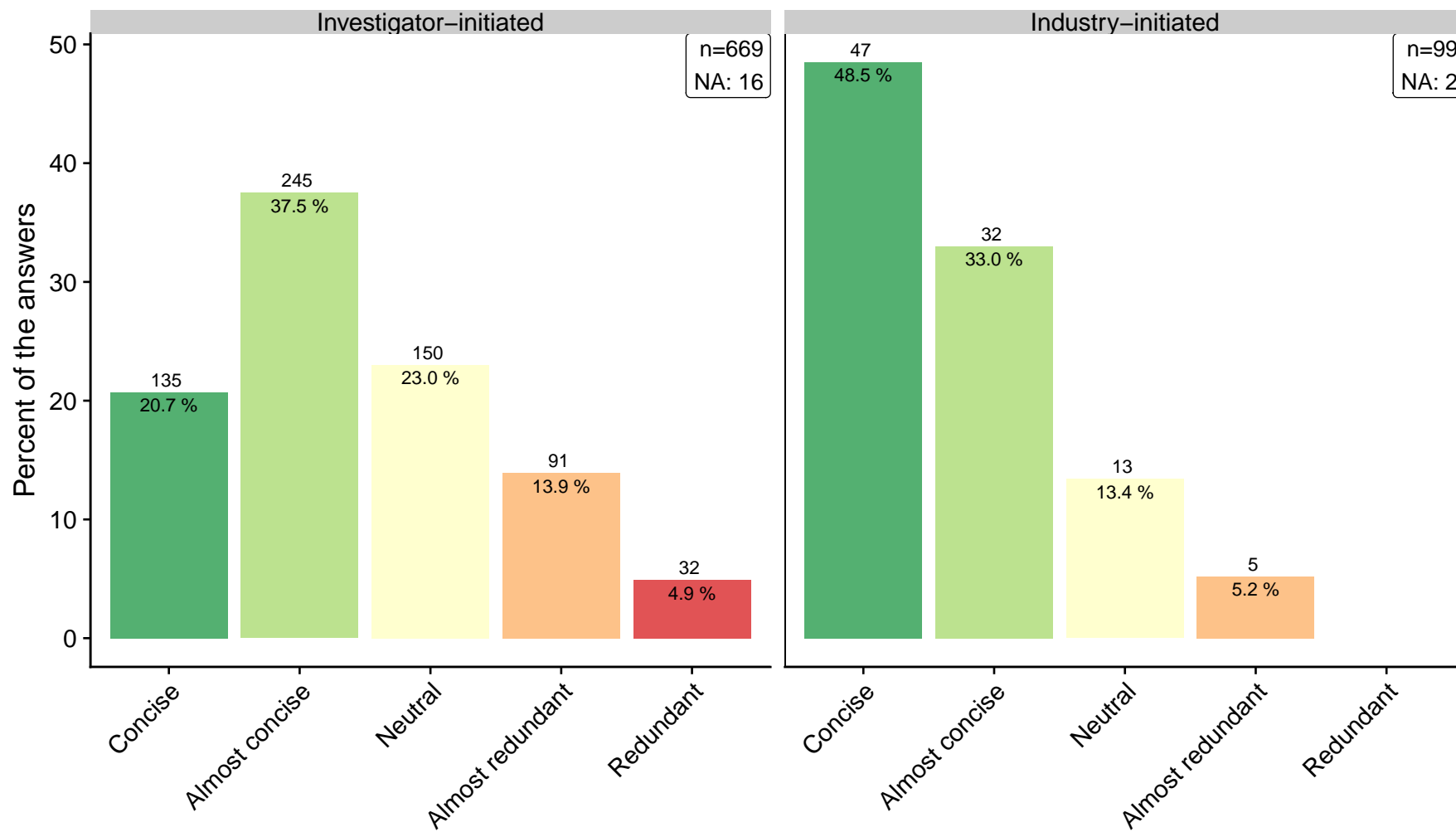


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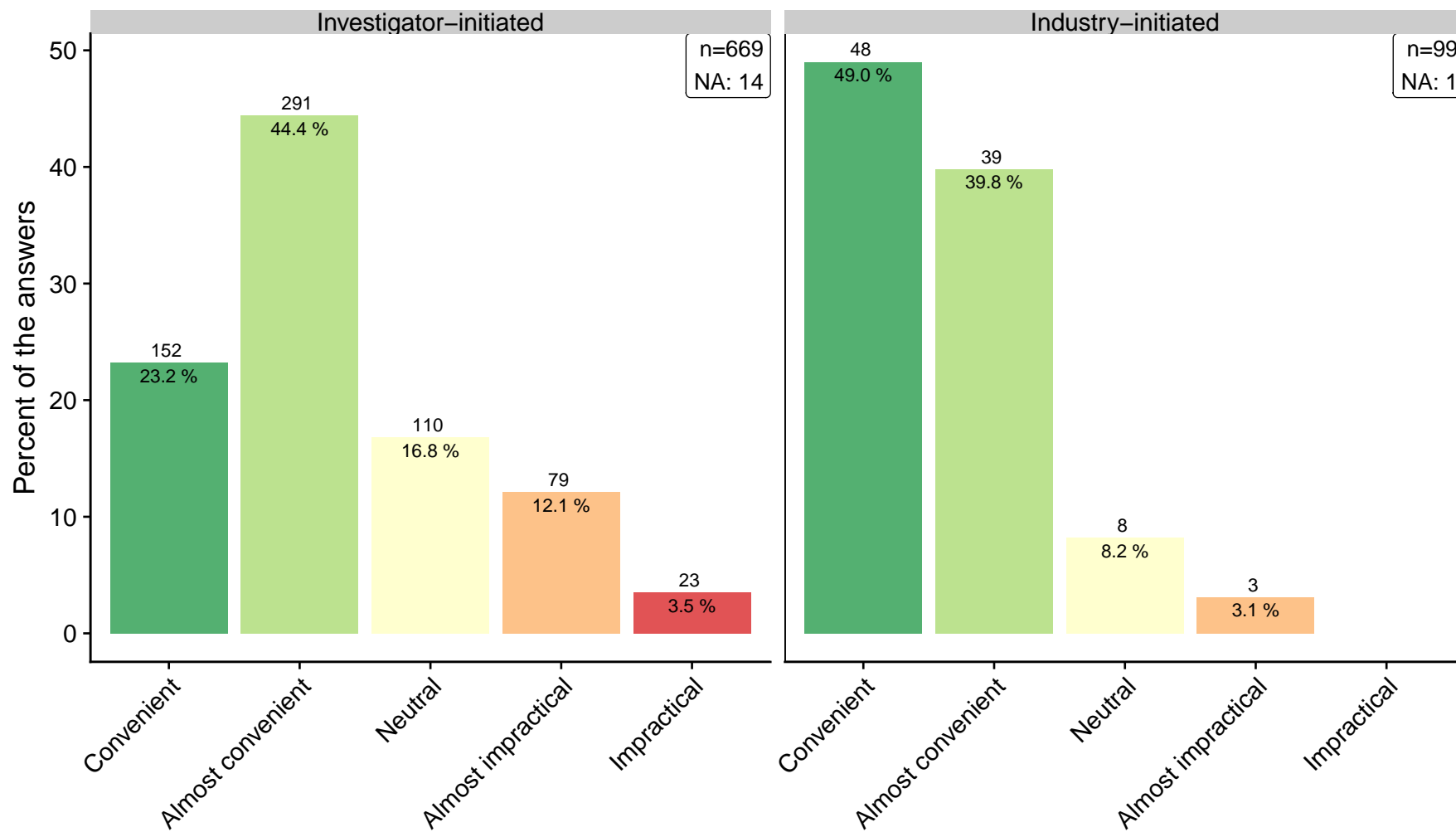
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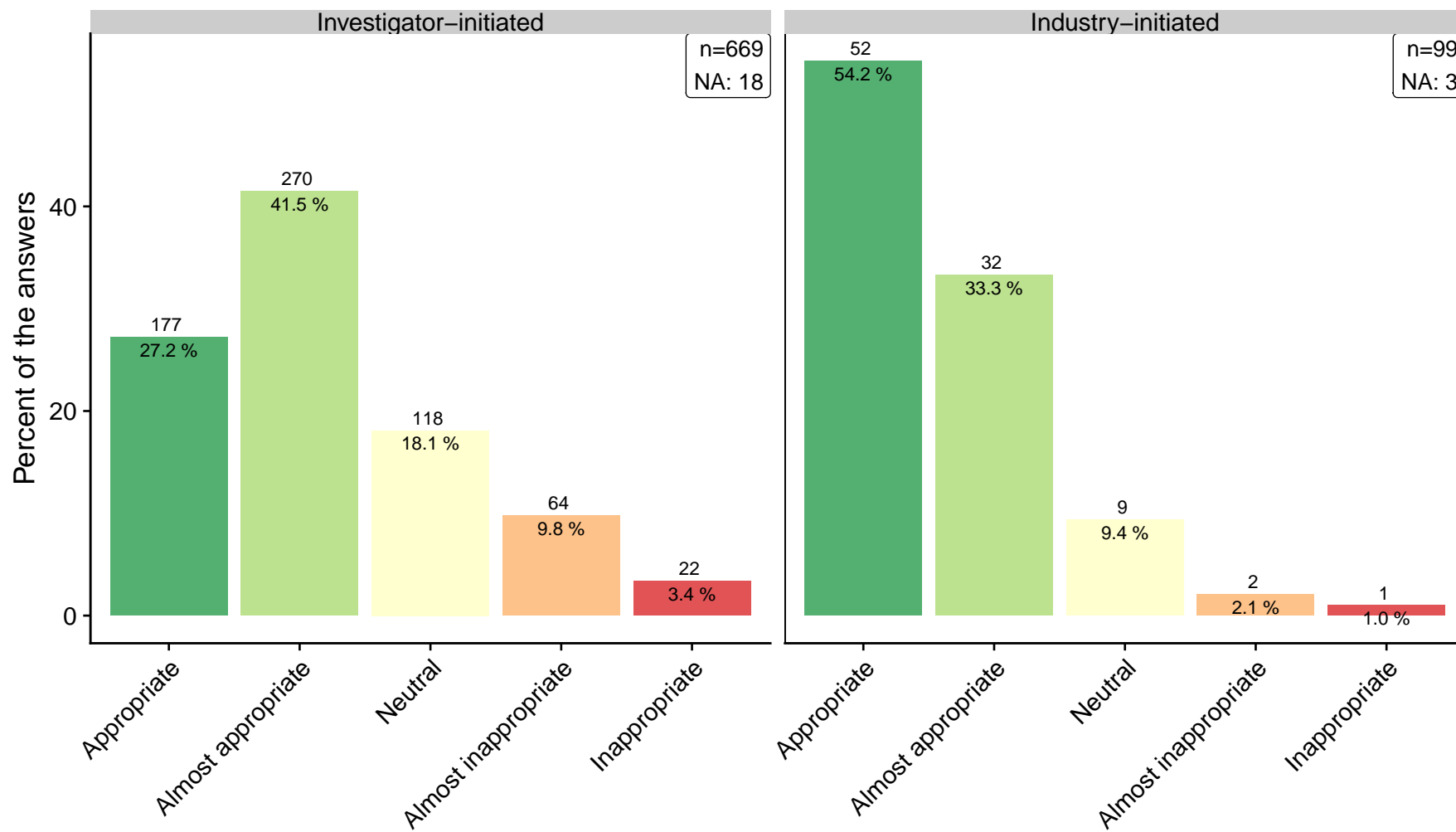
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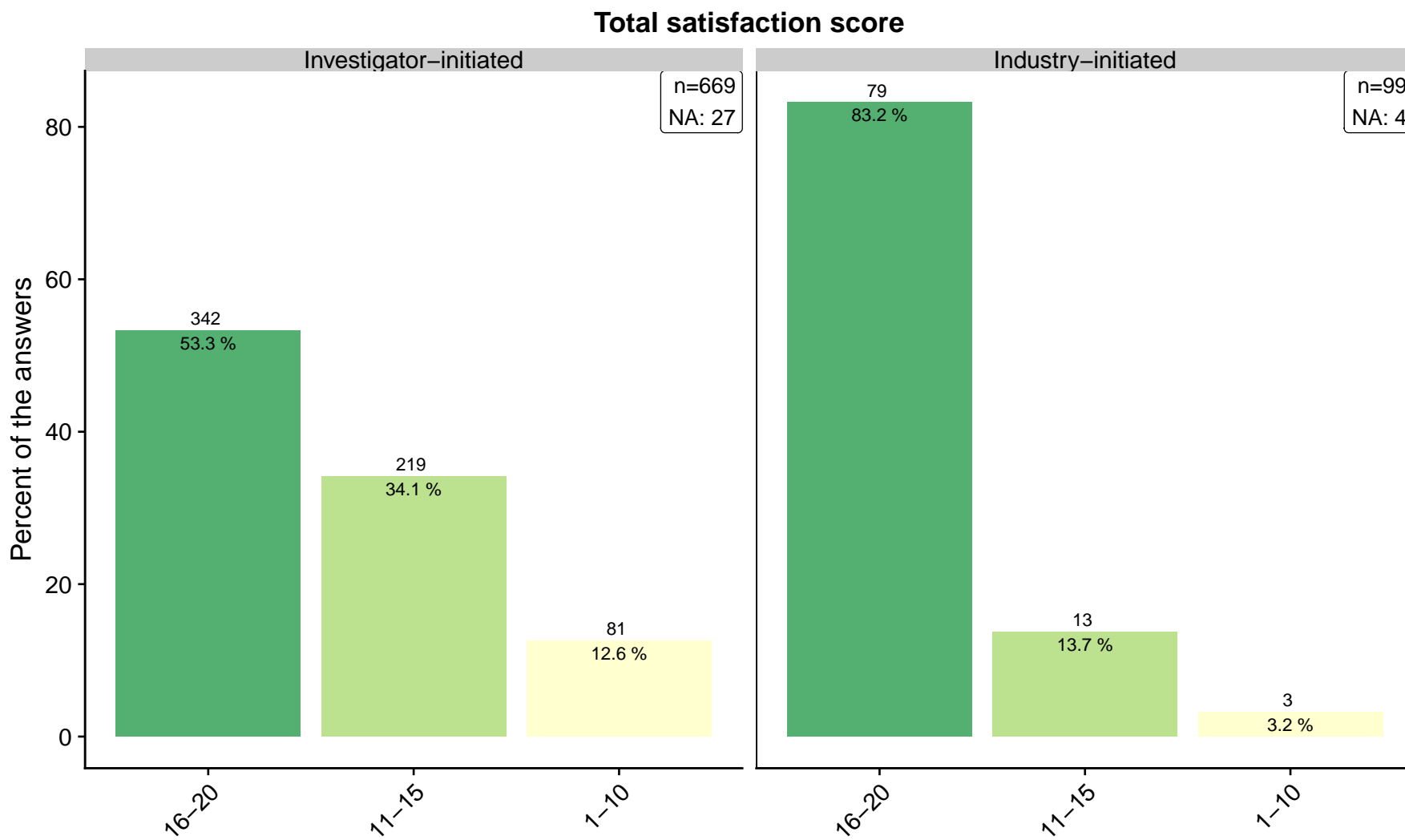


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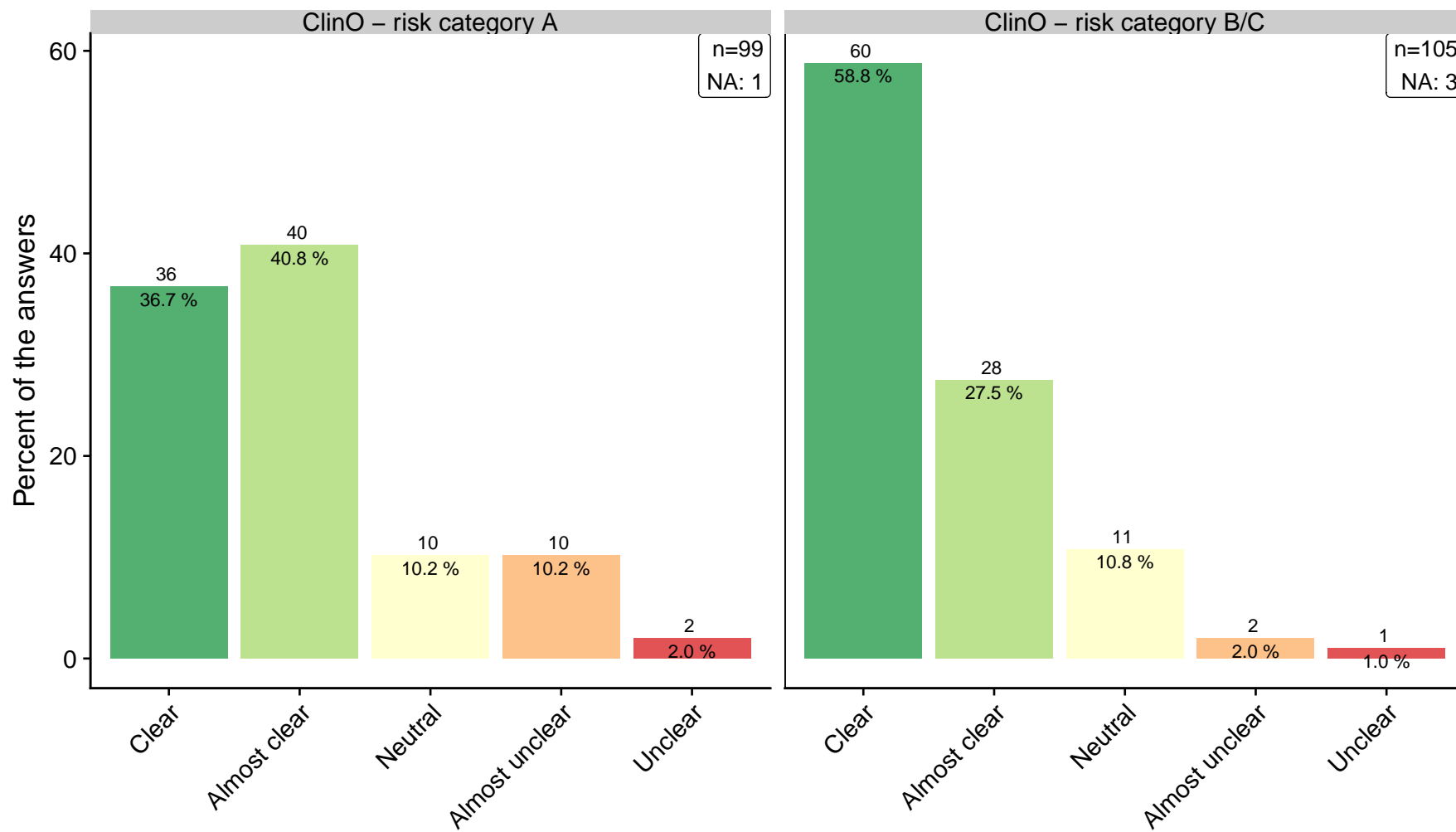
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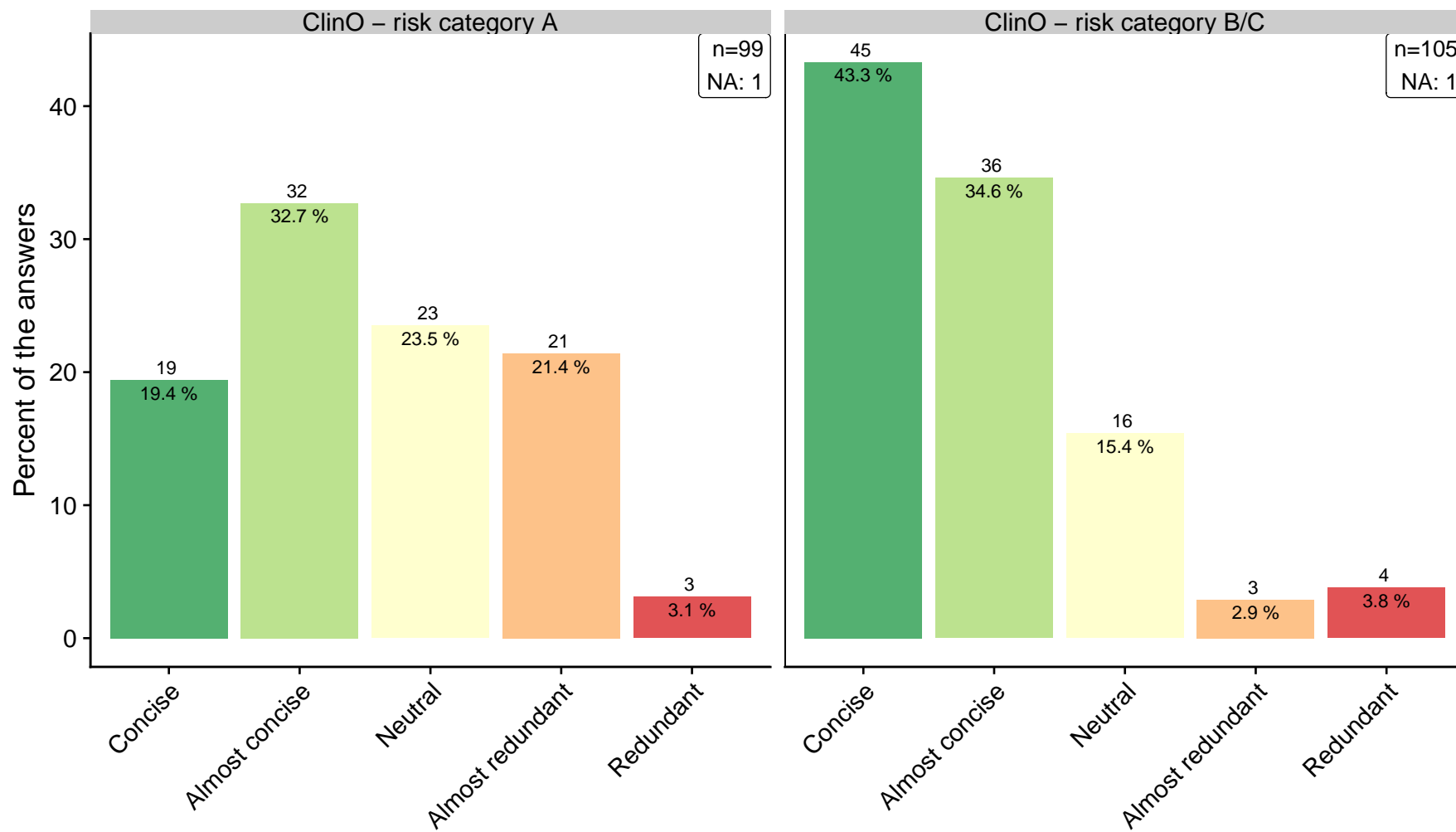


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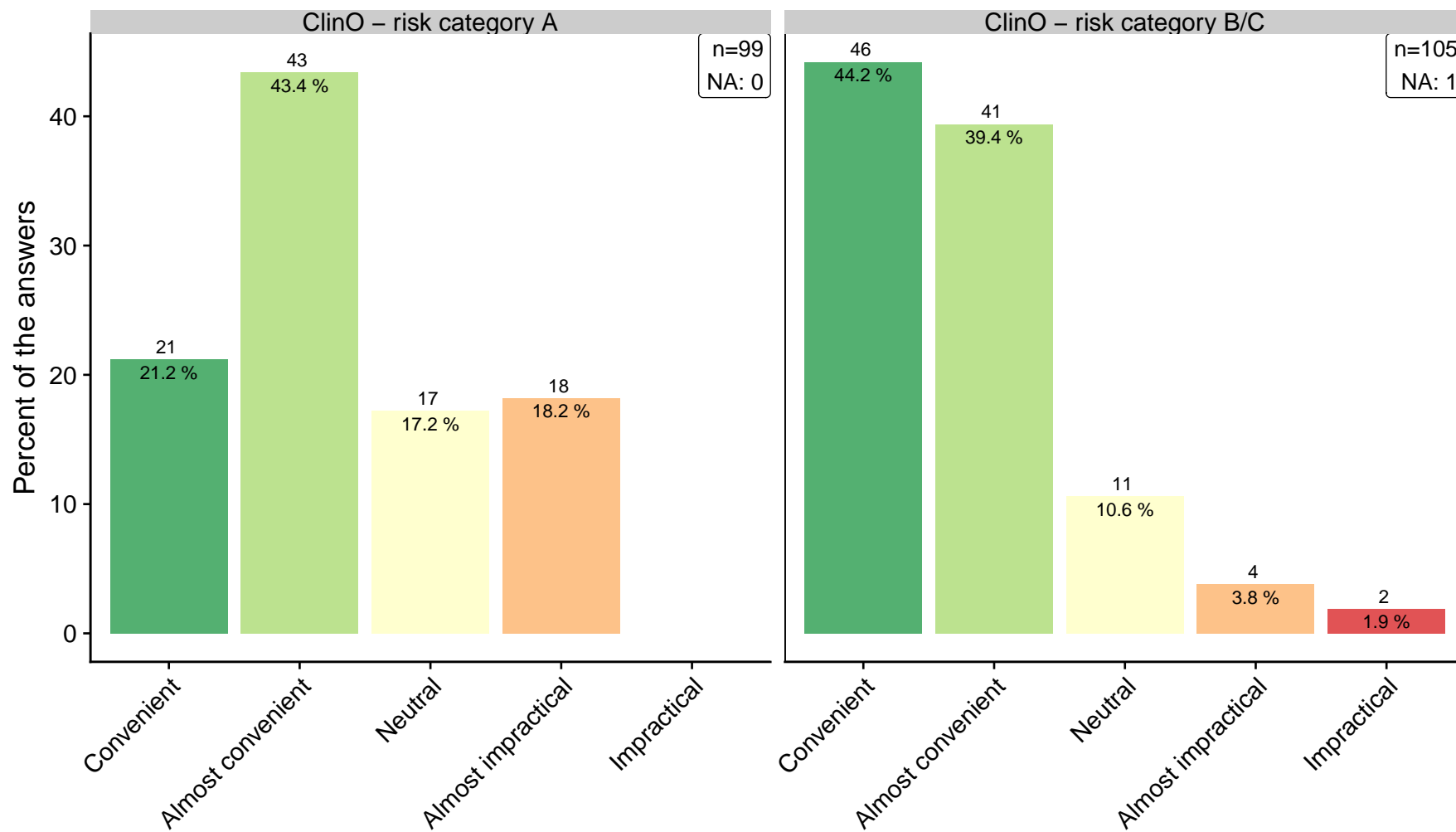
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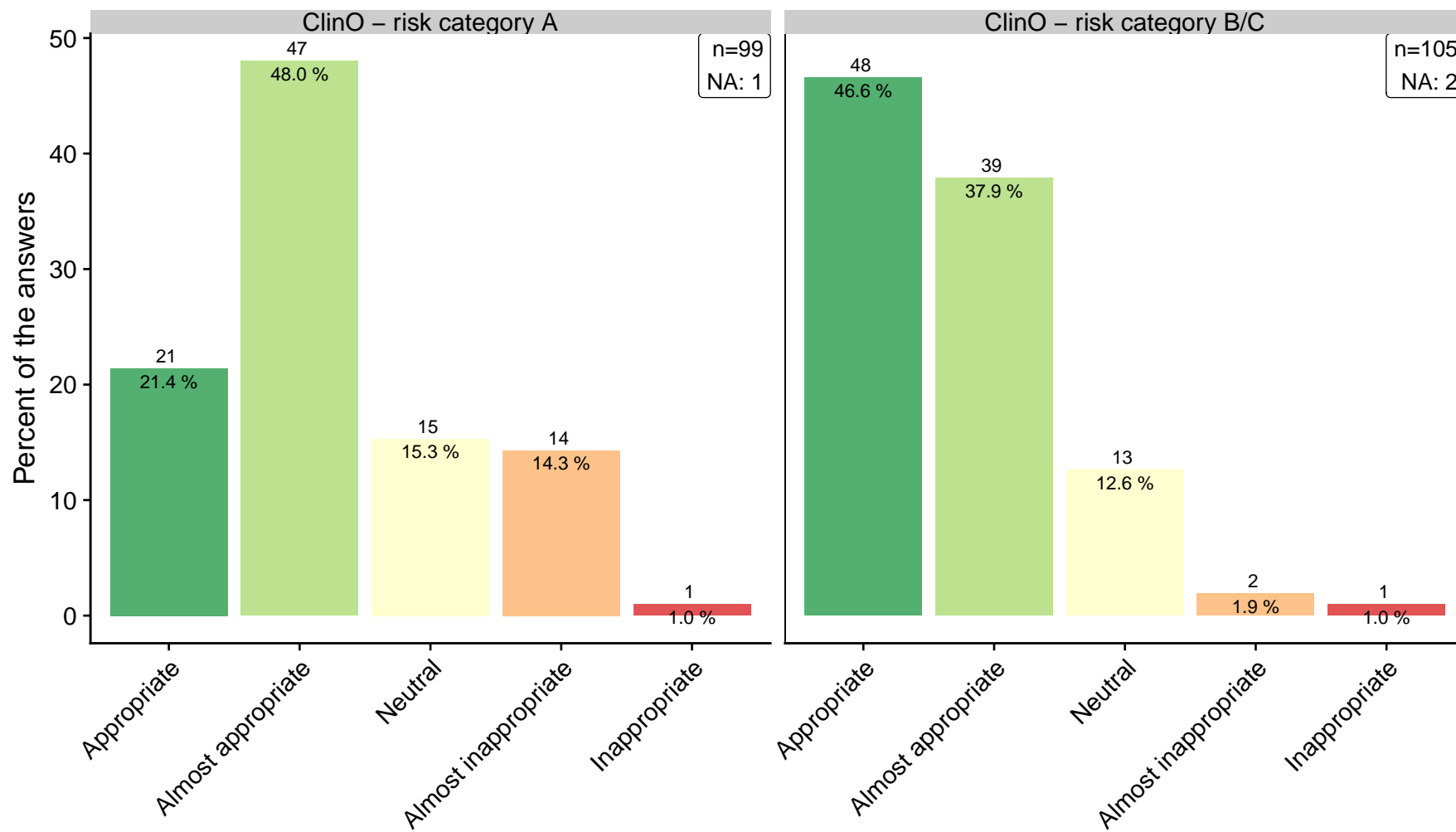
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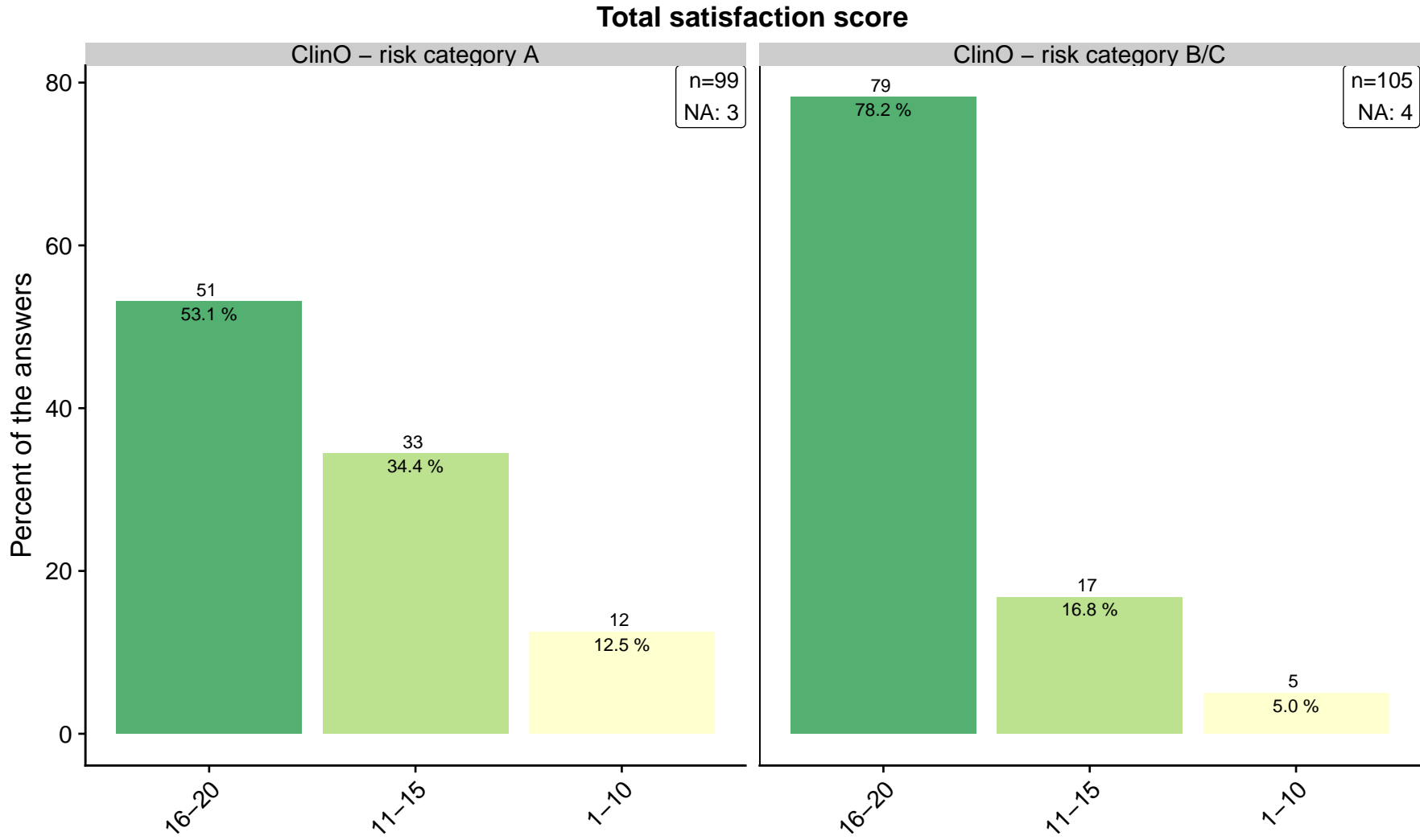


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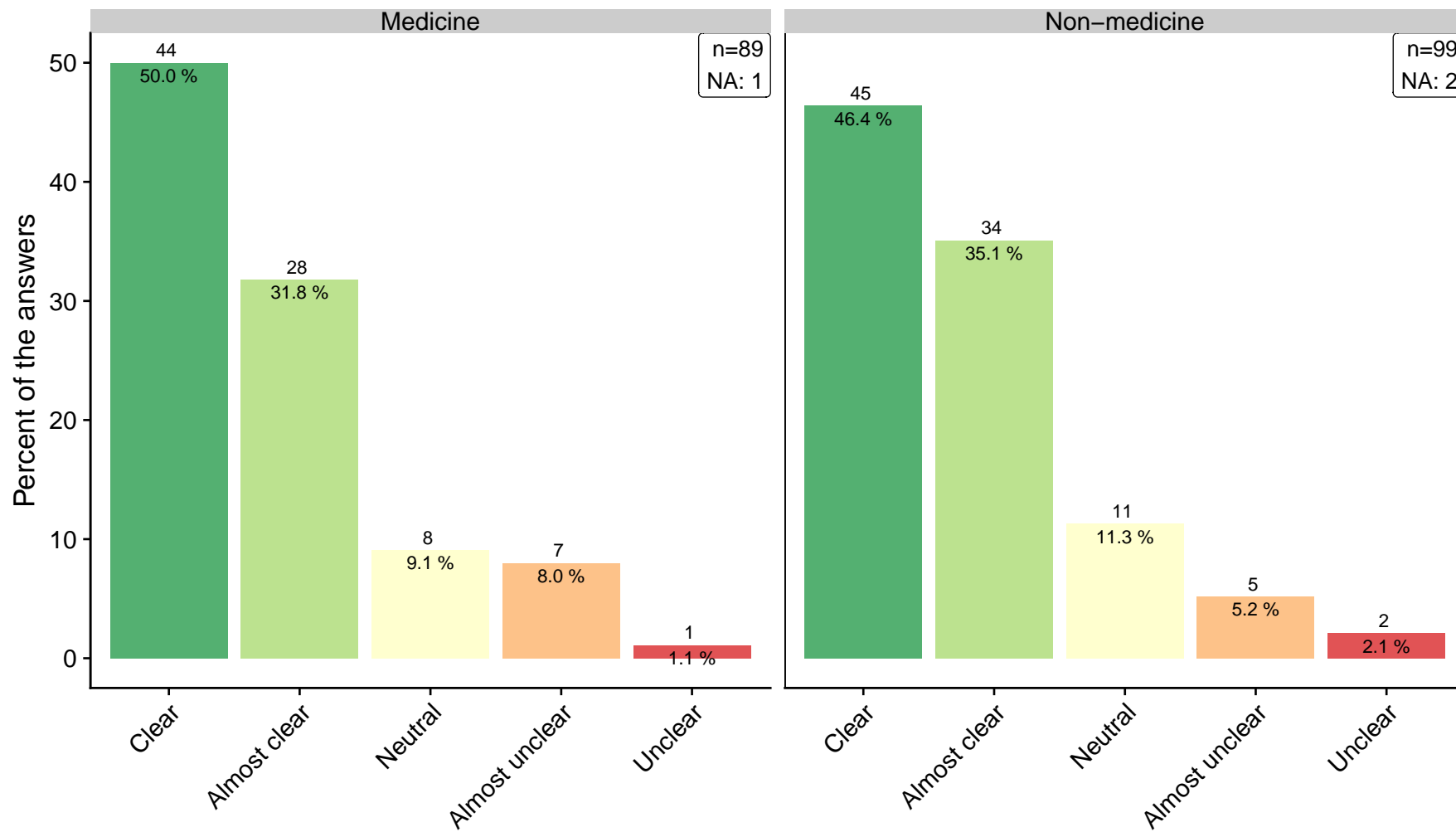
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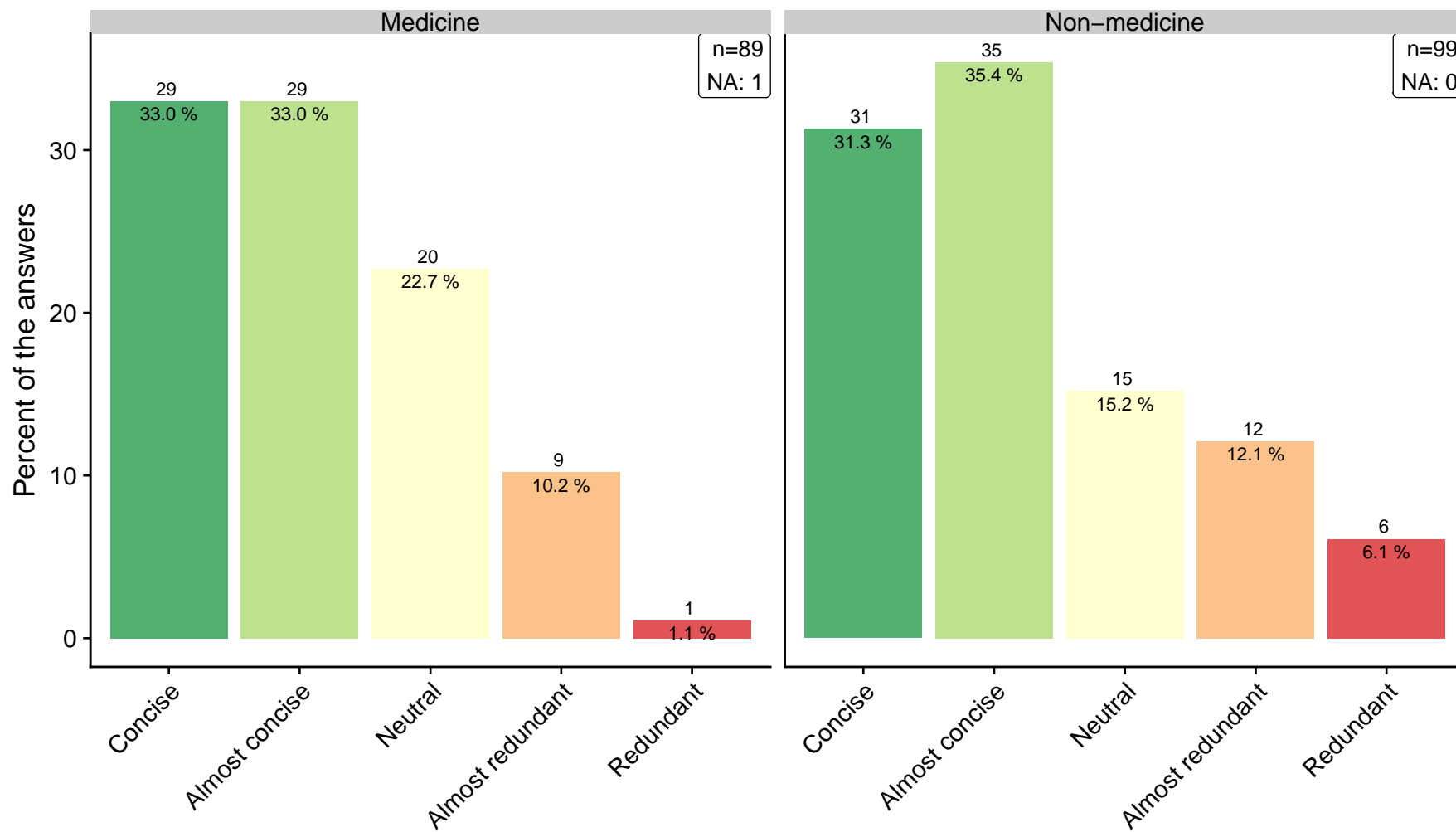


2.1.4 Stratified by field

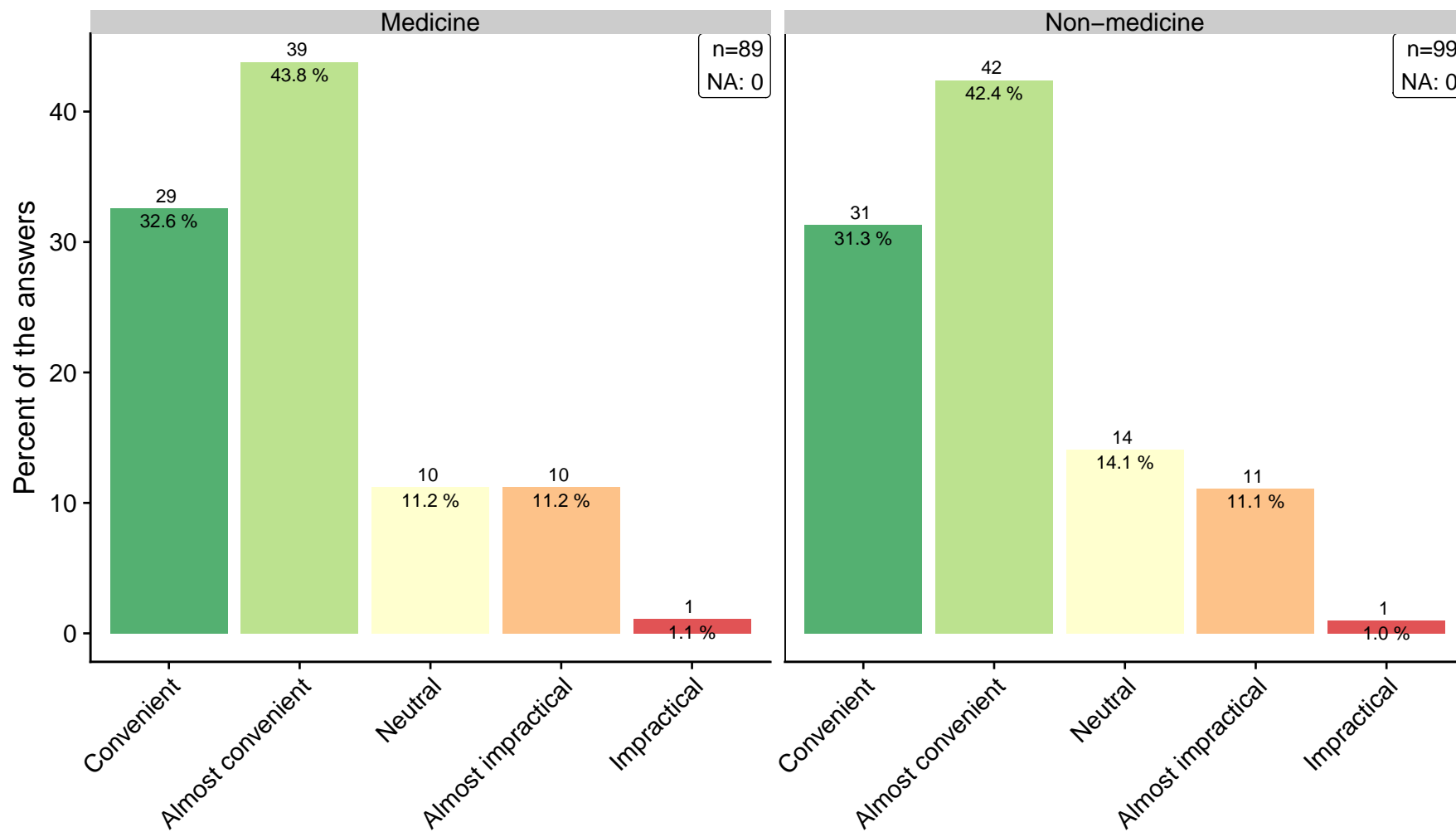
a) Clear vs unclear



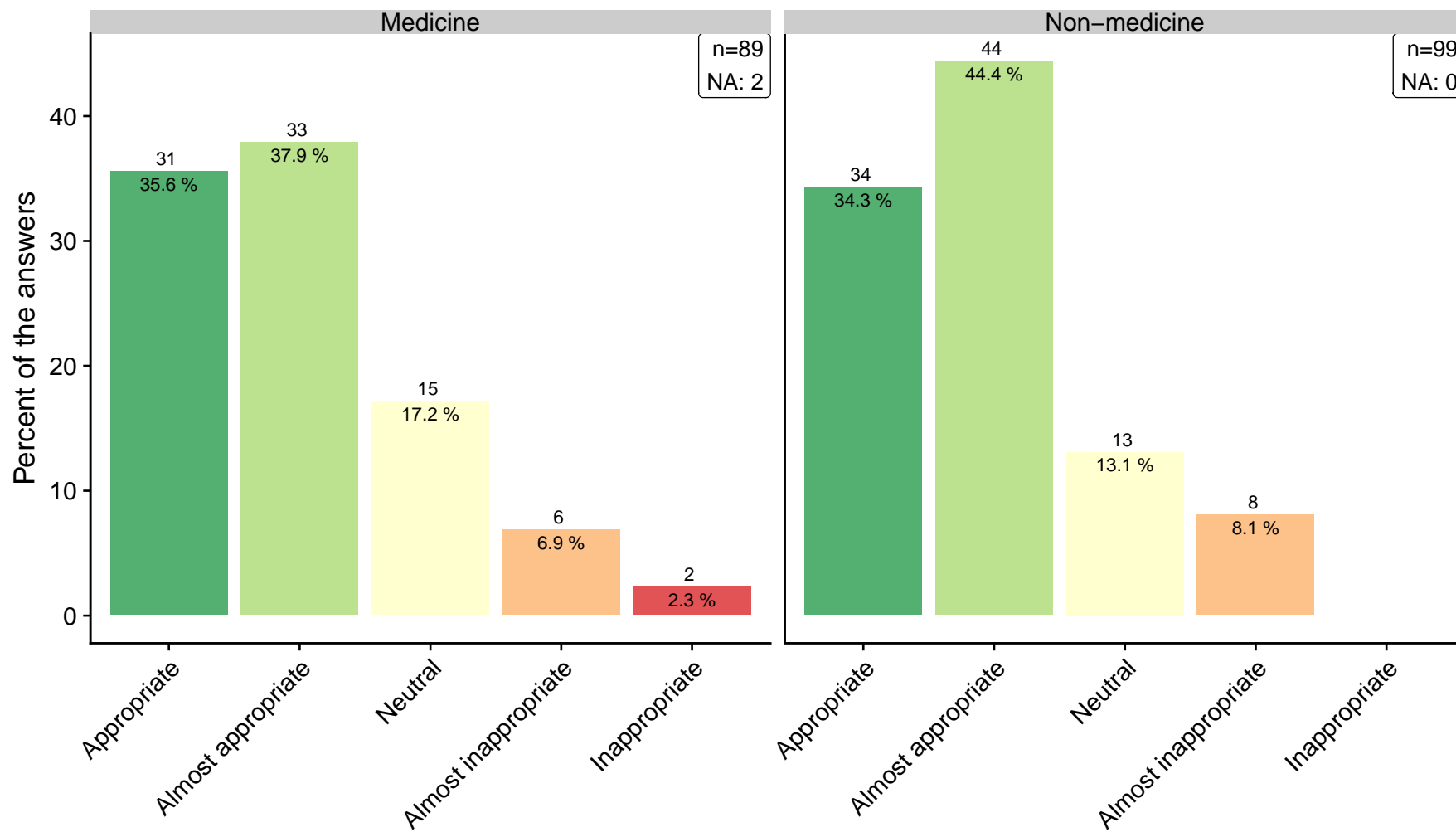
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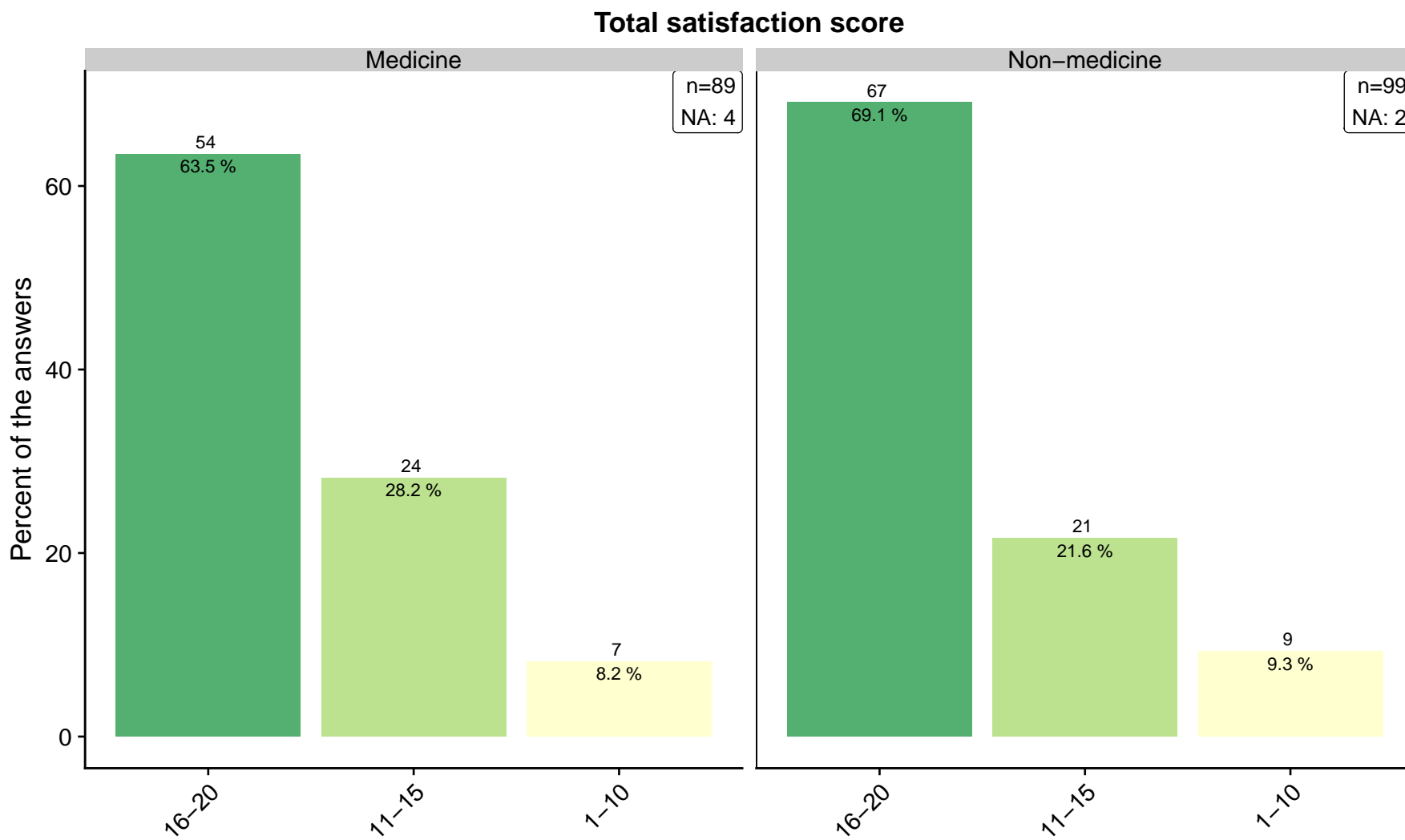


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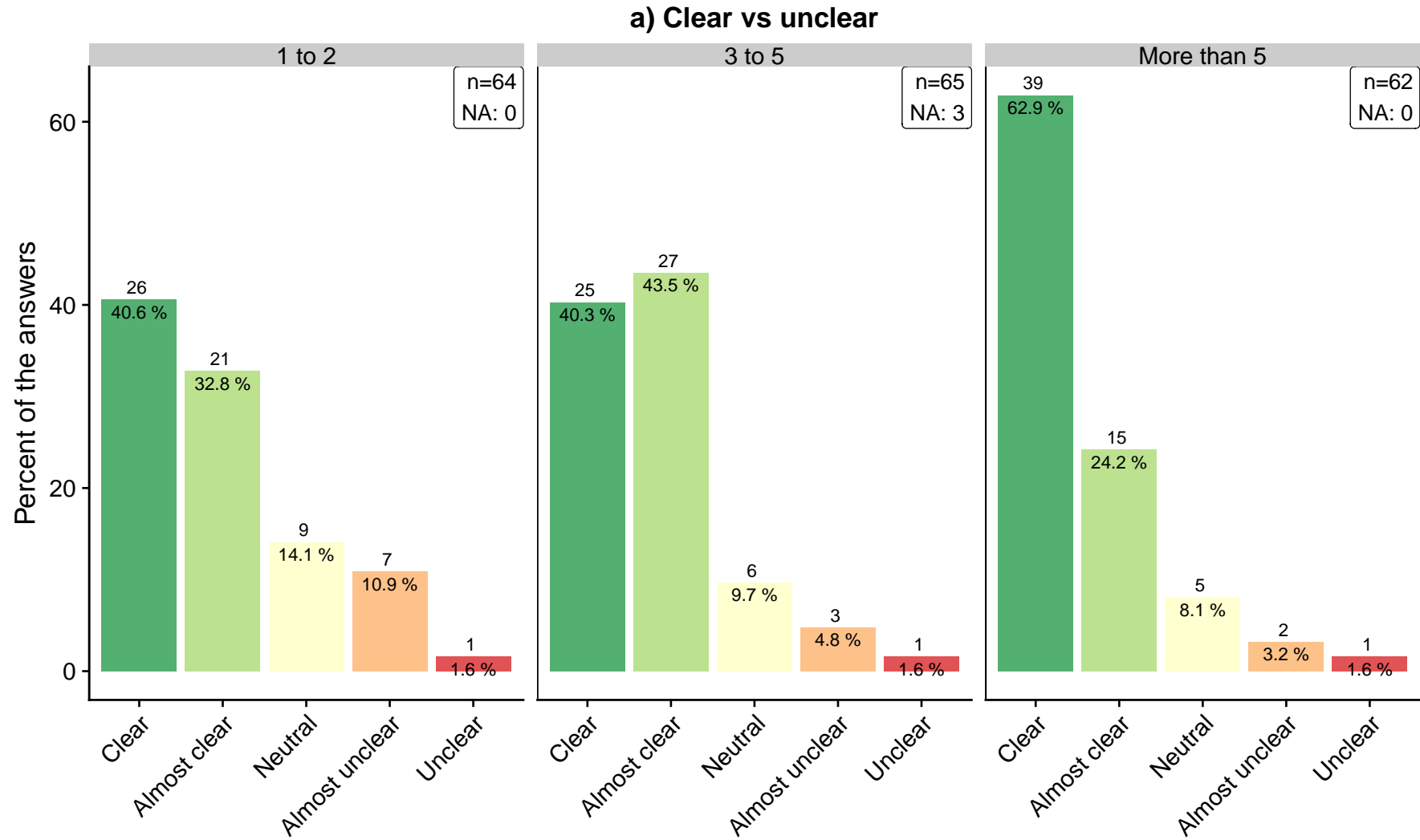
d) Appropriate vs Inappropriate



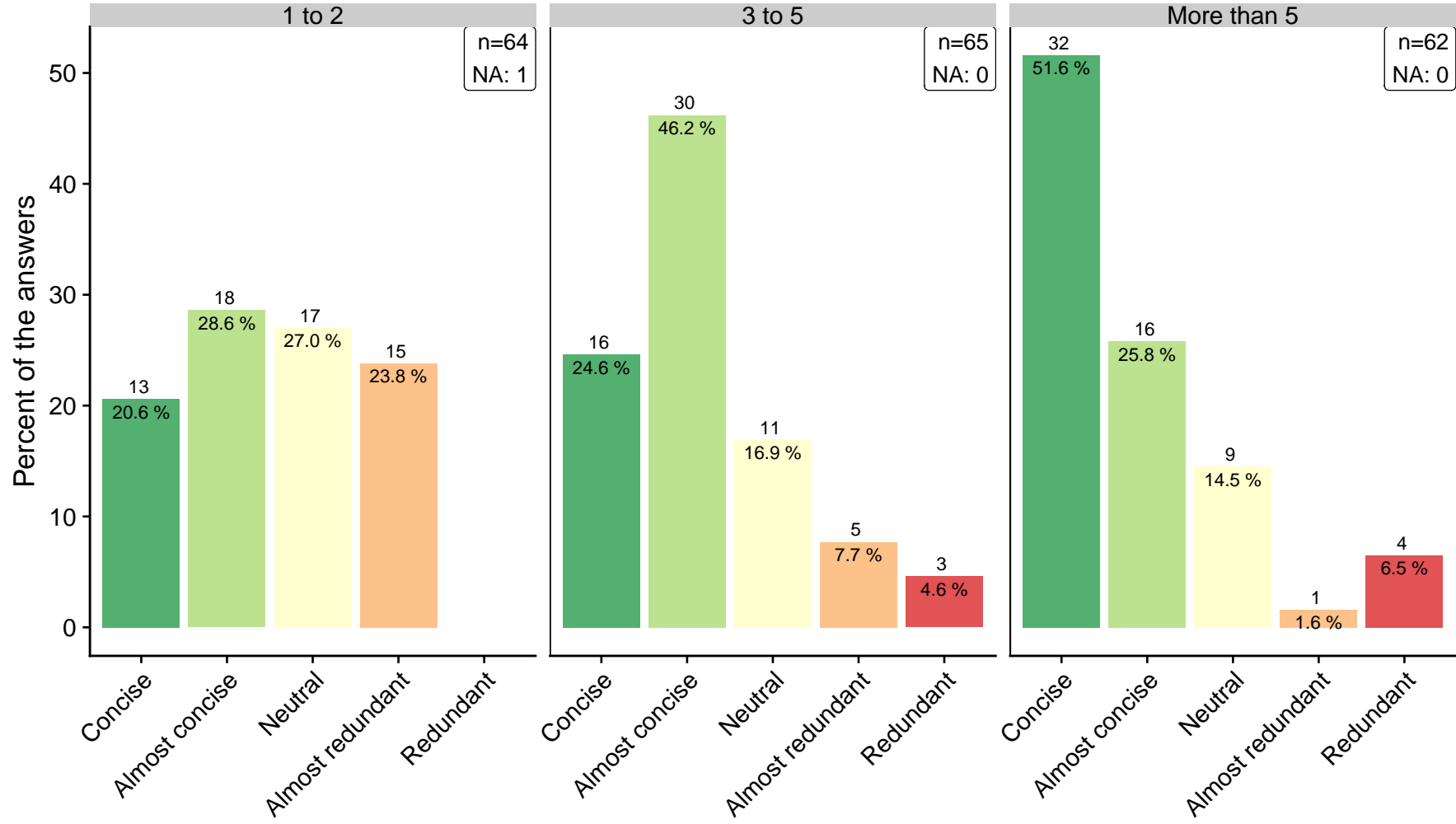


2.2 Feedback on application stratified by experience of the researcher

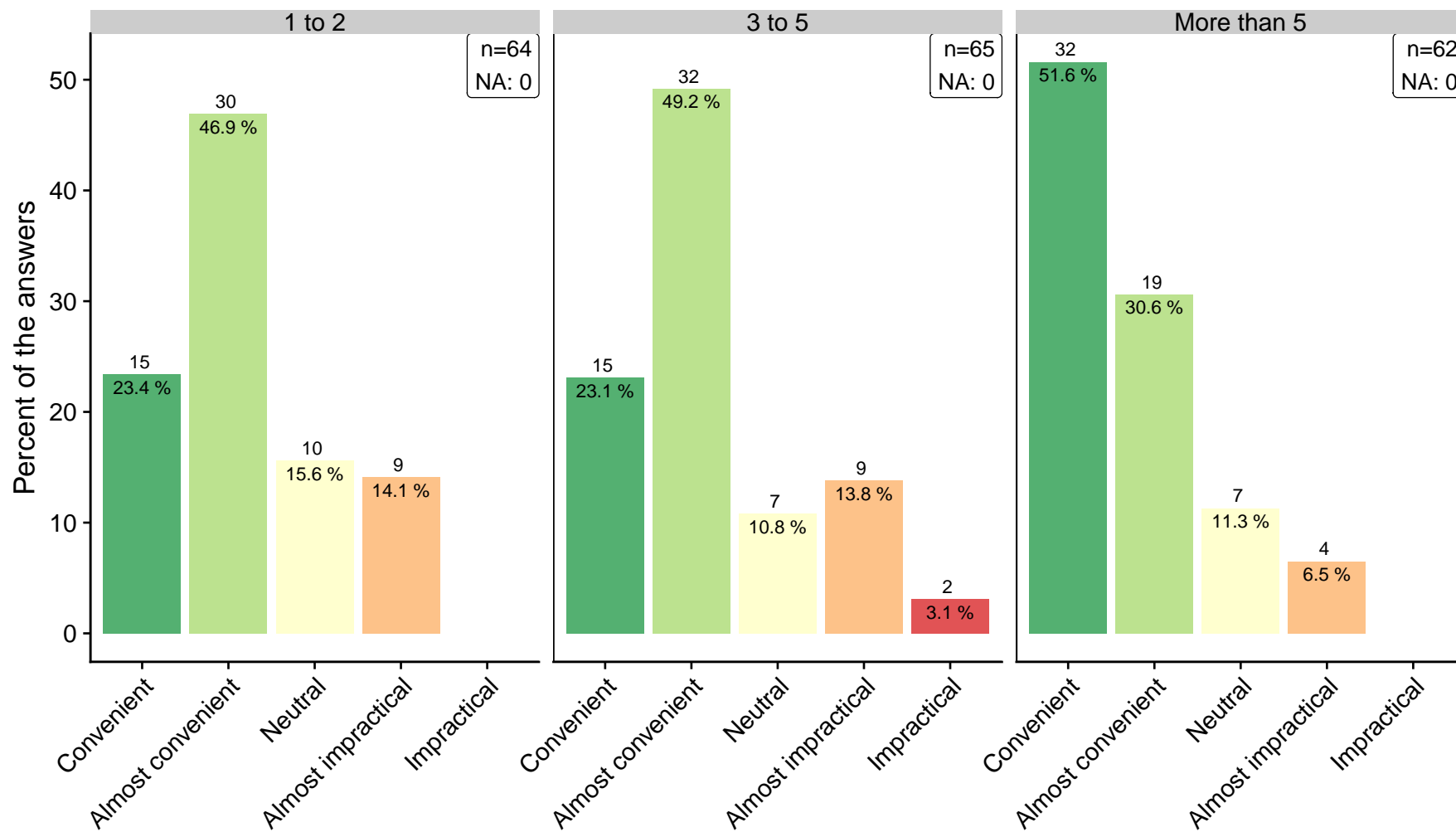
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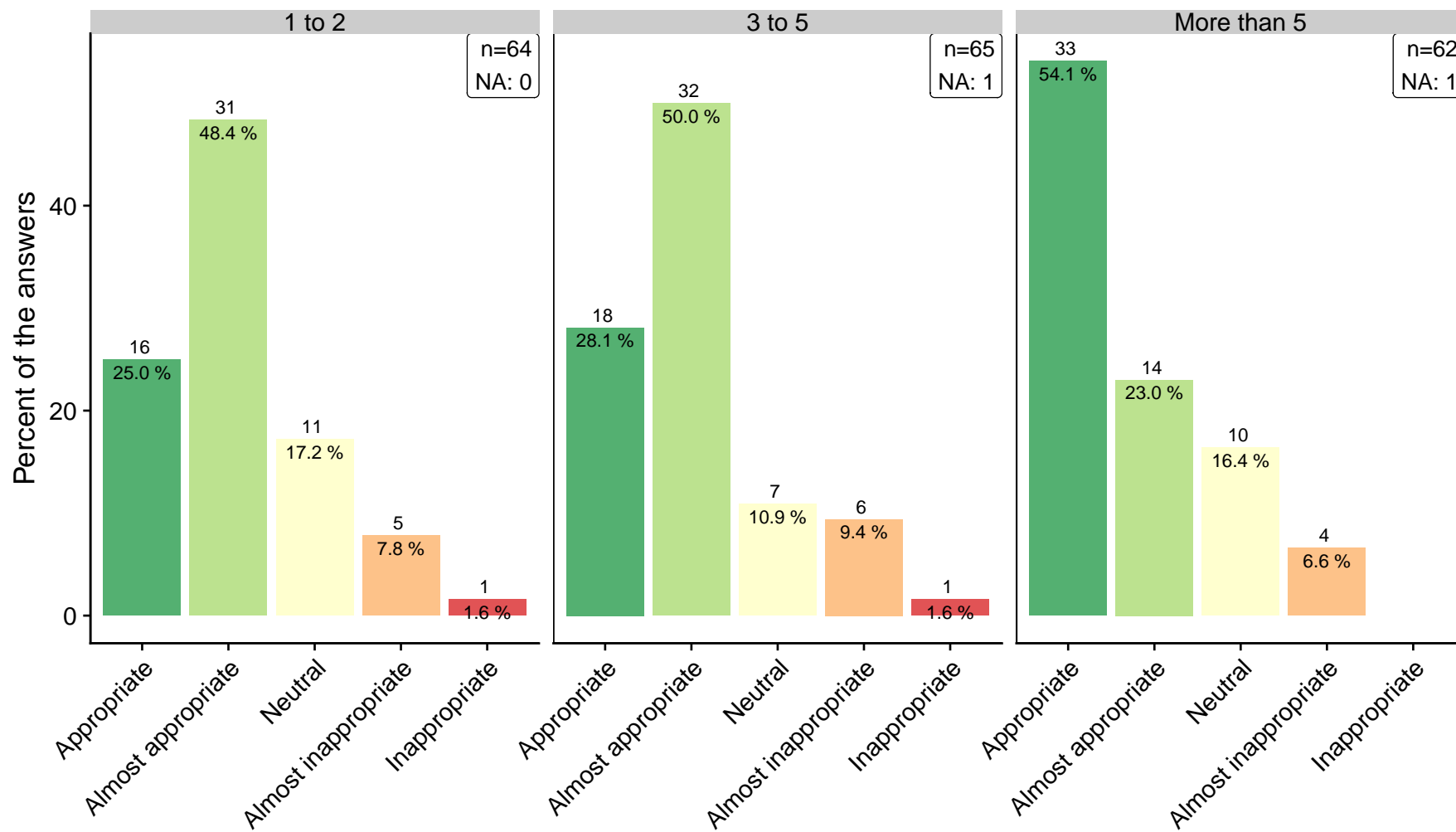
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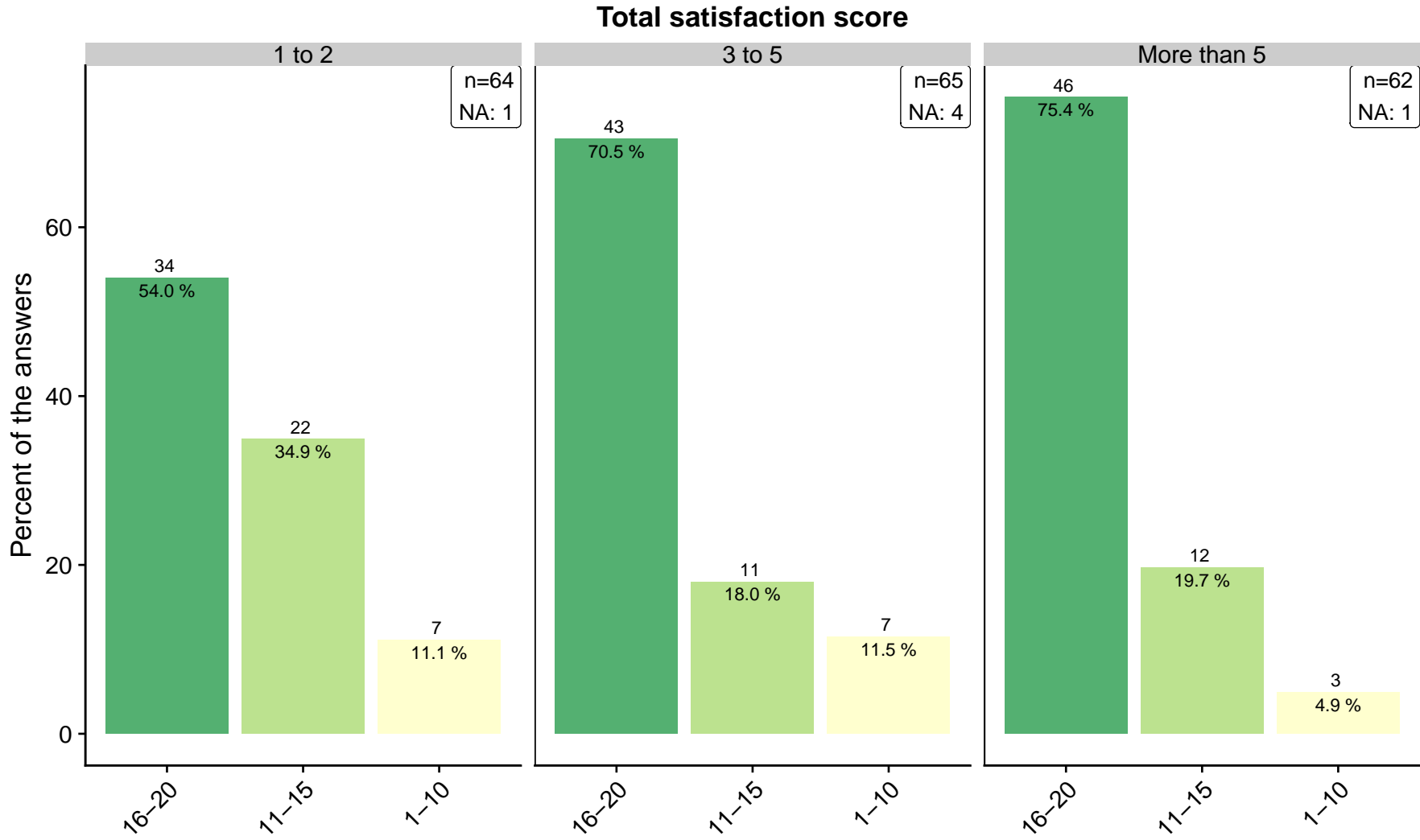


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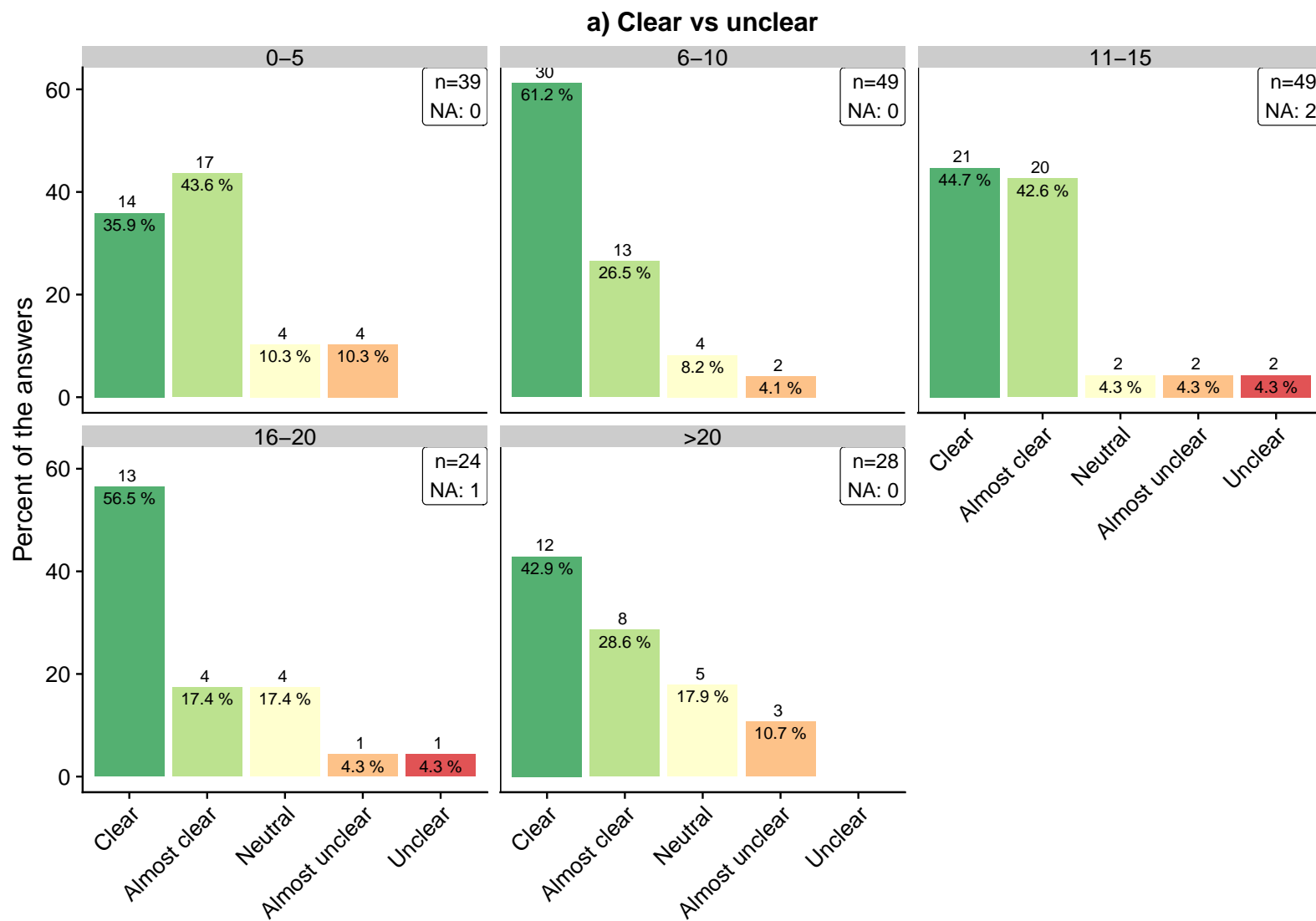


d) Appropriate vs Inappropriate

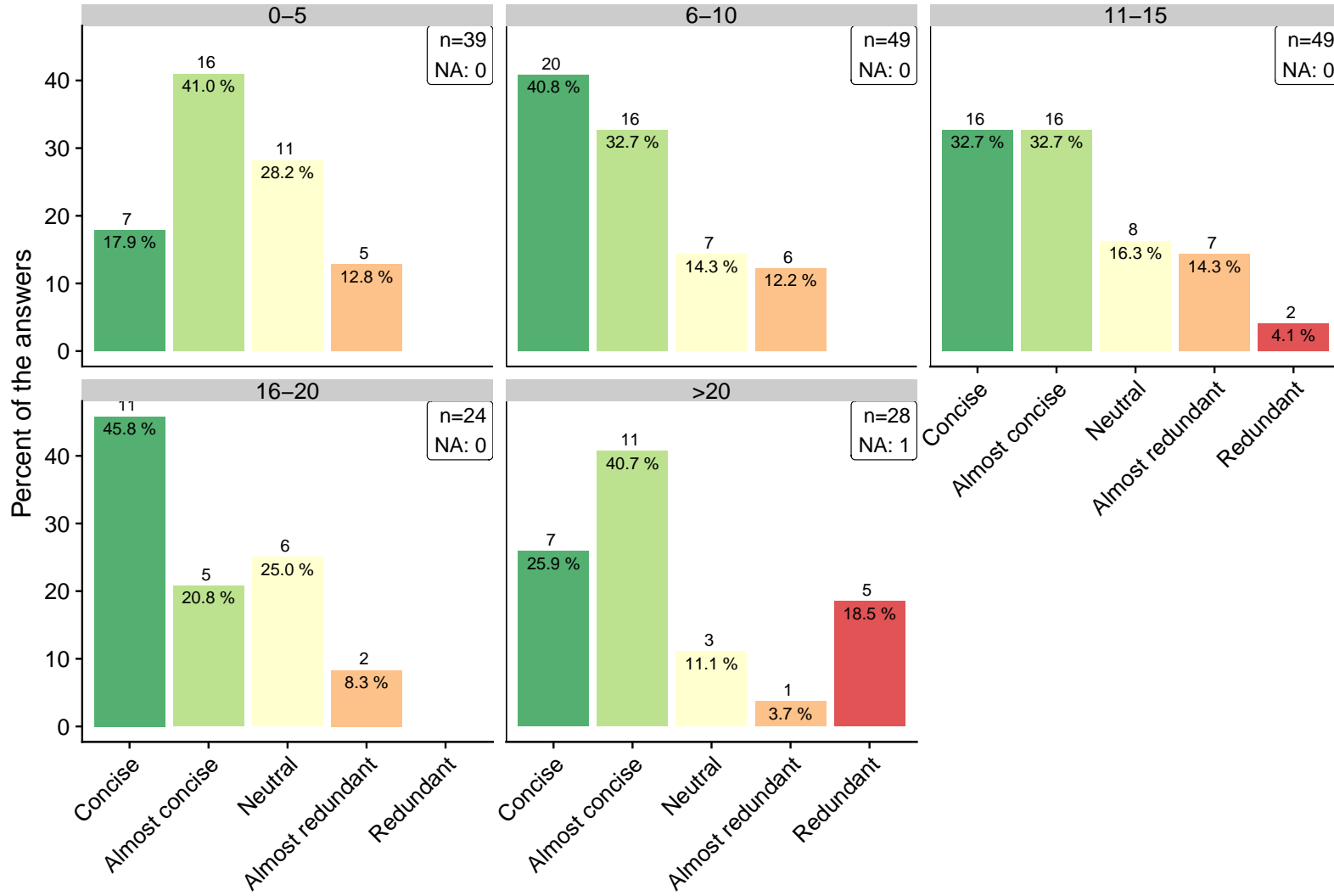


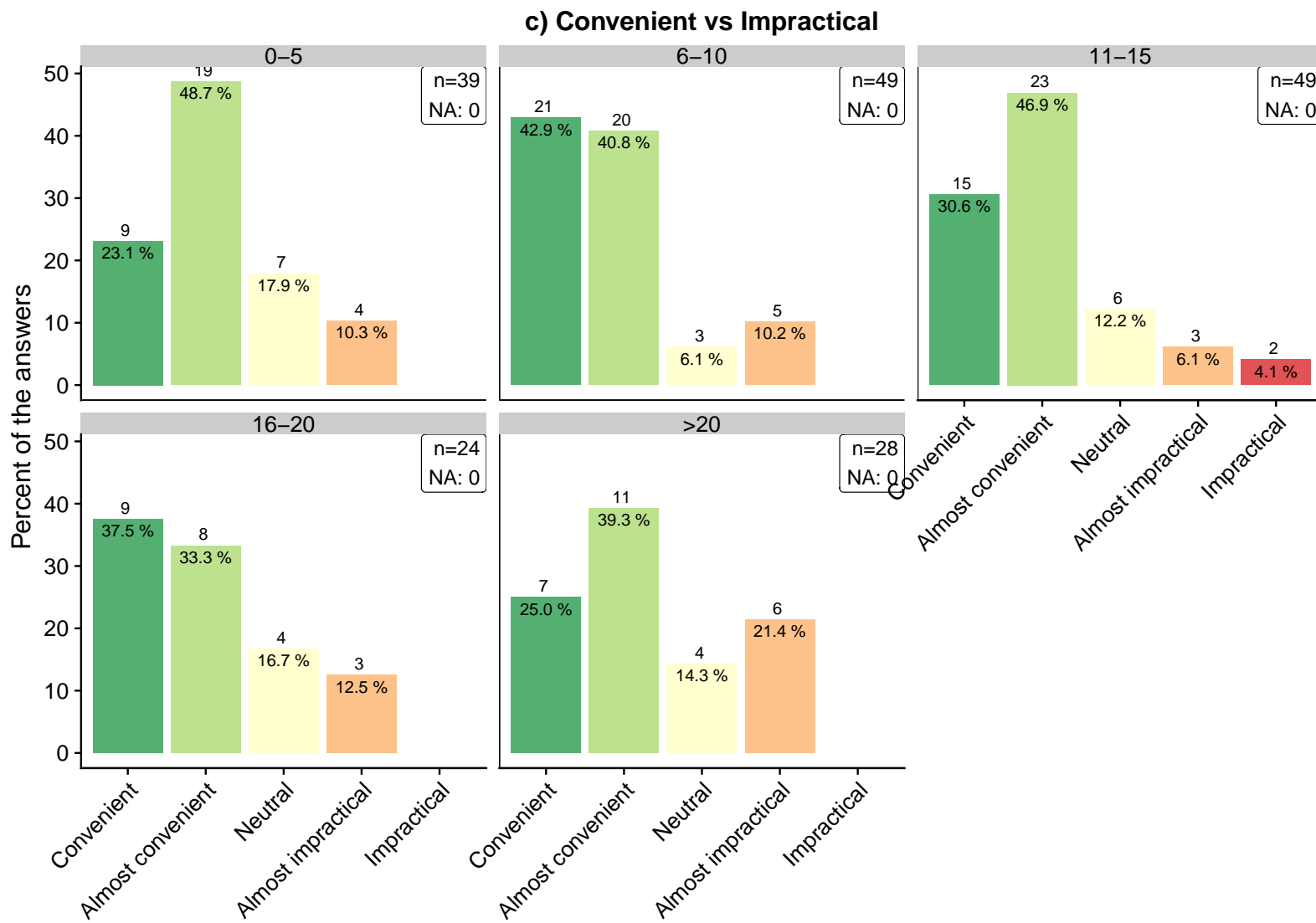


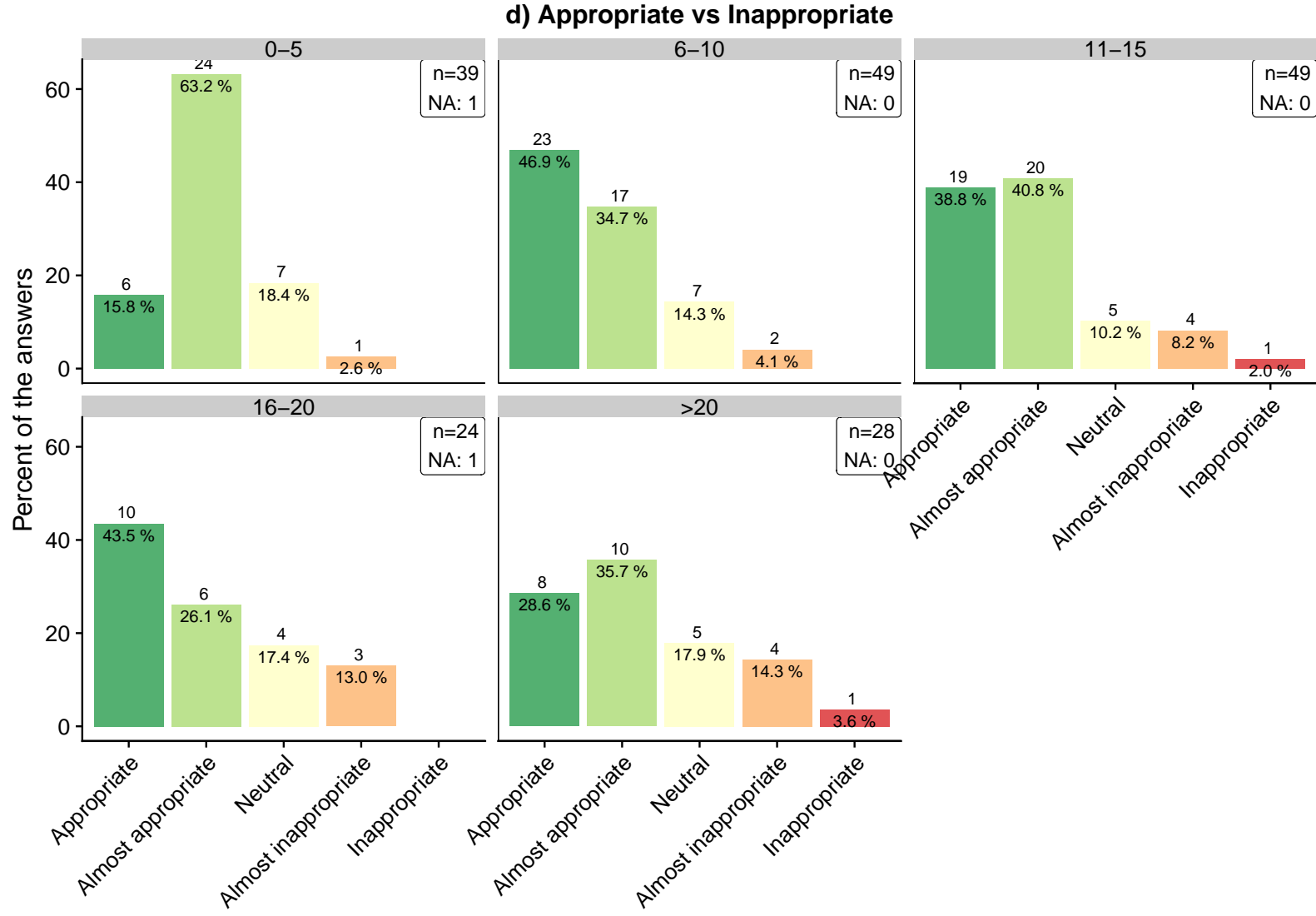
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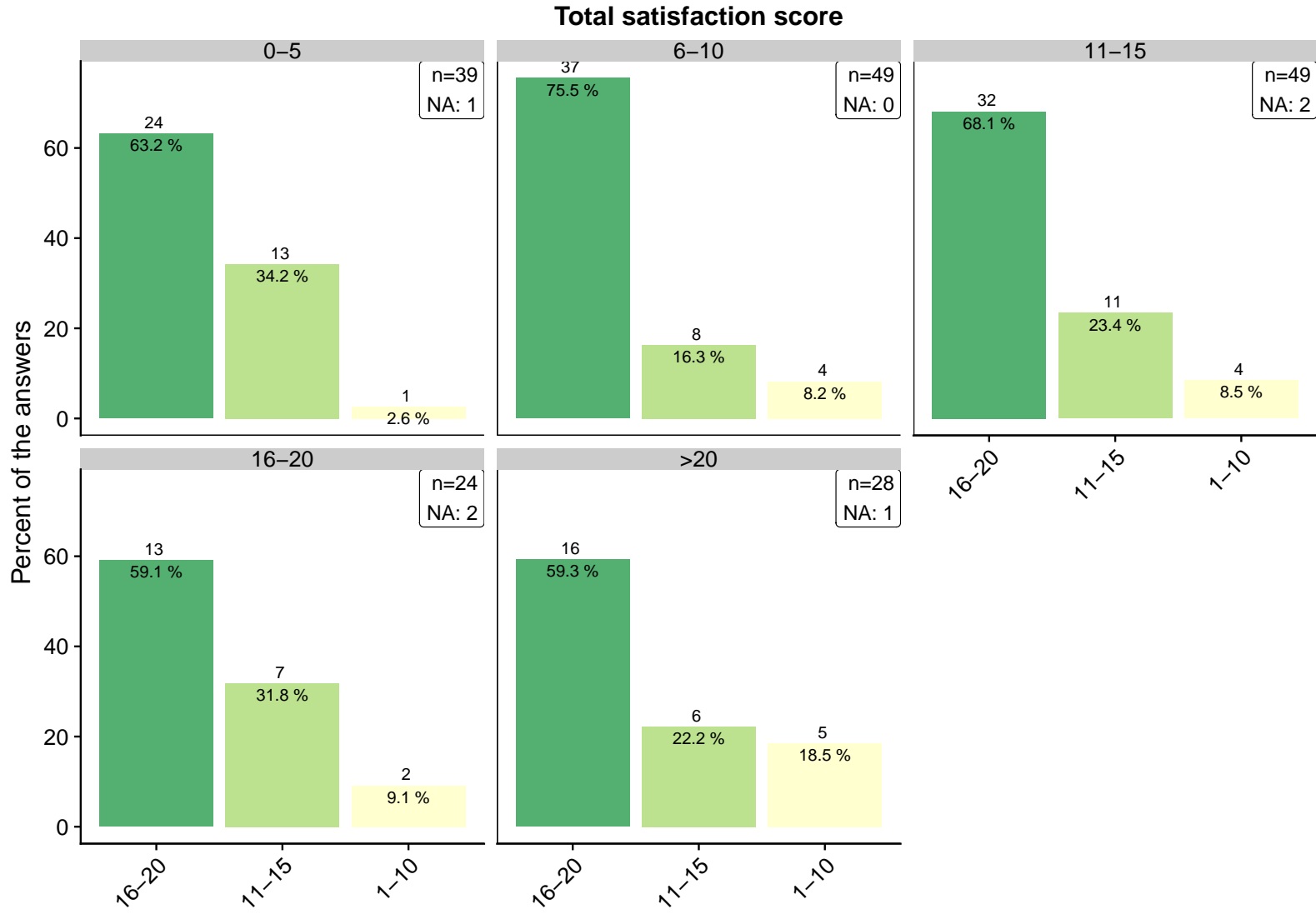


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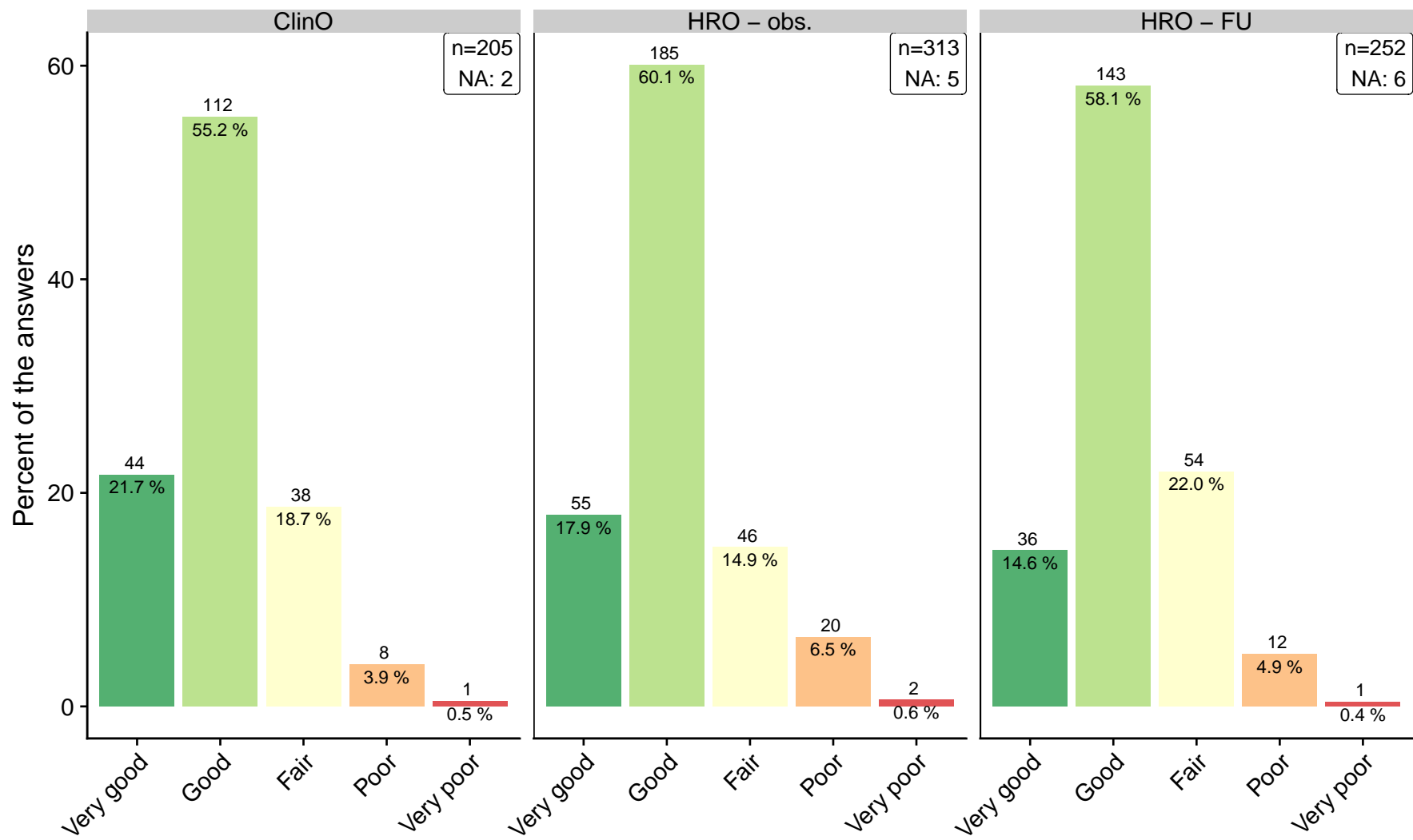


3 Question A5: The overall application process was ...

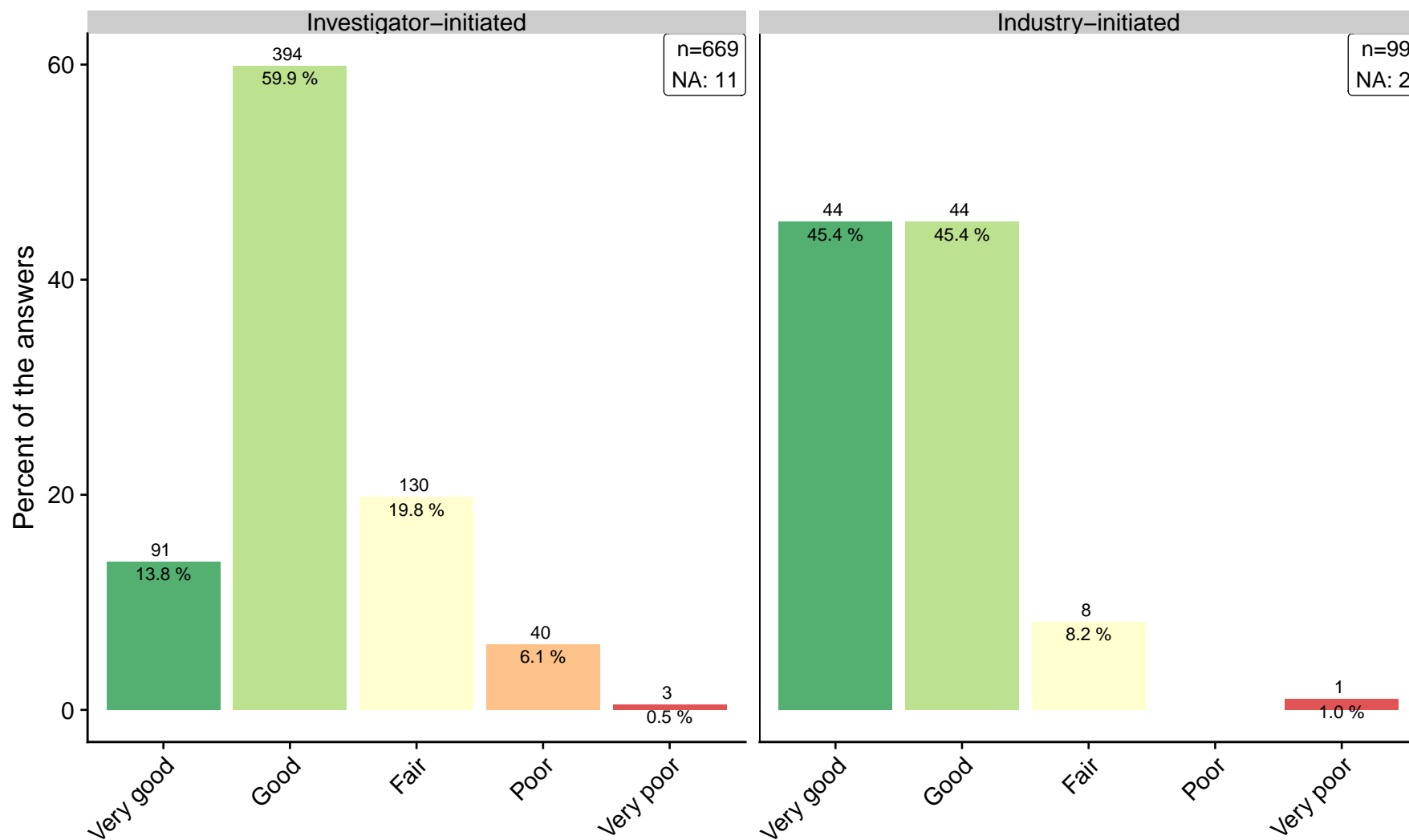
Question from IPZ / KEK-CDC Consultants: Gibt es Unterschiede in der Beurteilung des Bewilligungsprozesses nach Forschungsbereich and nach Erfahrung?

3.1 Feedback on application stratified research details

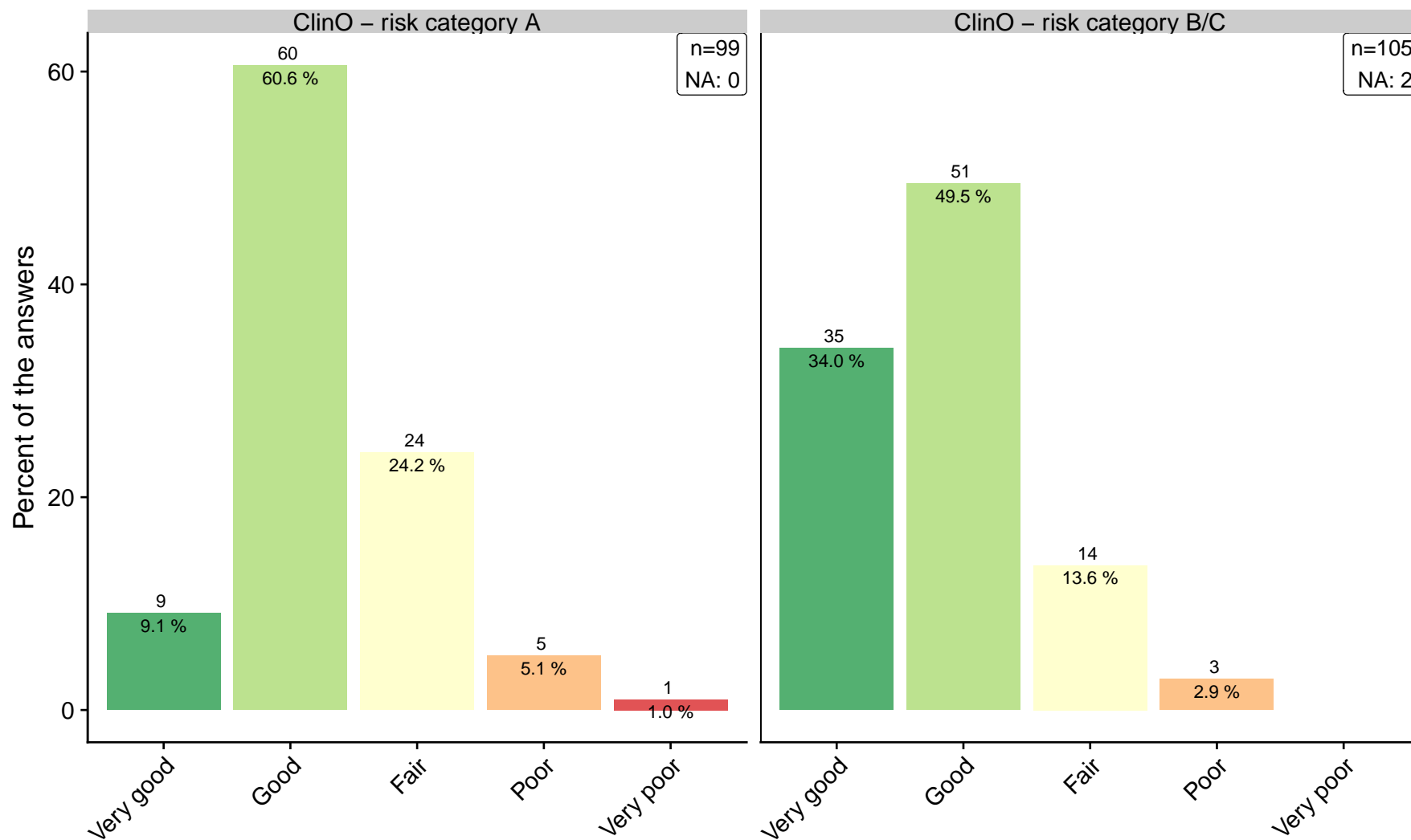
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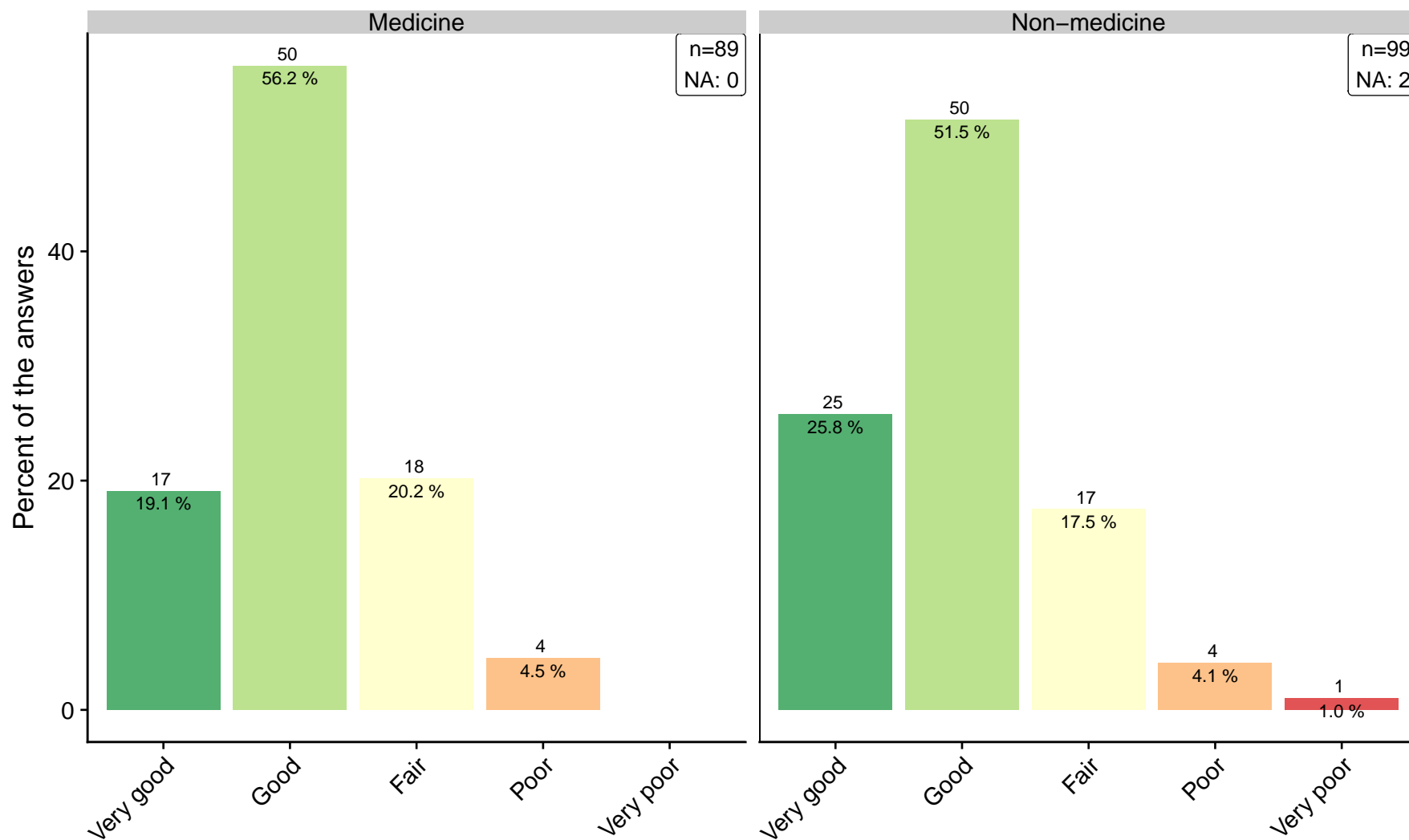
3.1.2 Stratified by initiator



3.1.3 Stratified by risk category

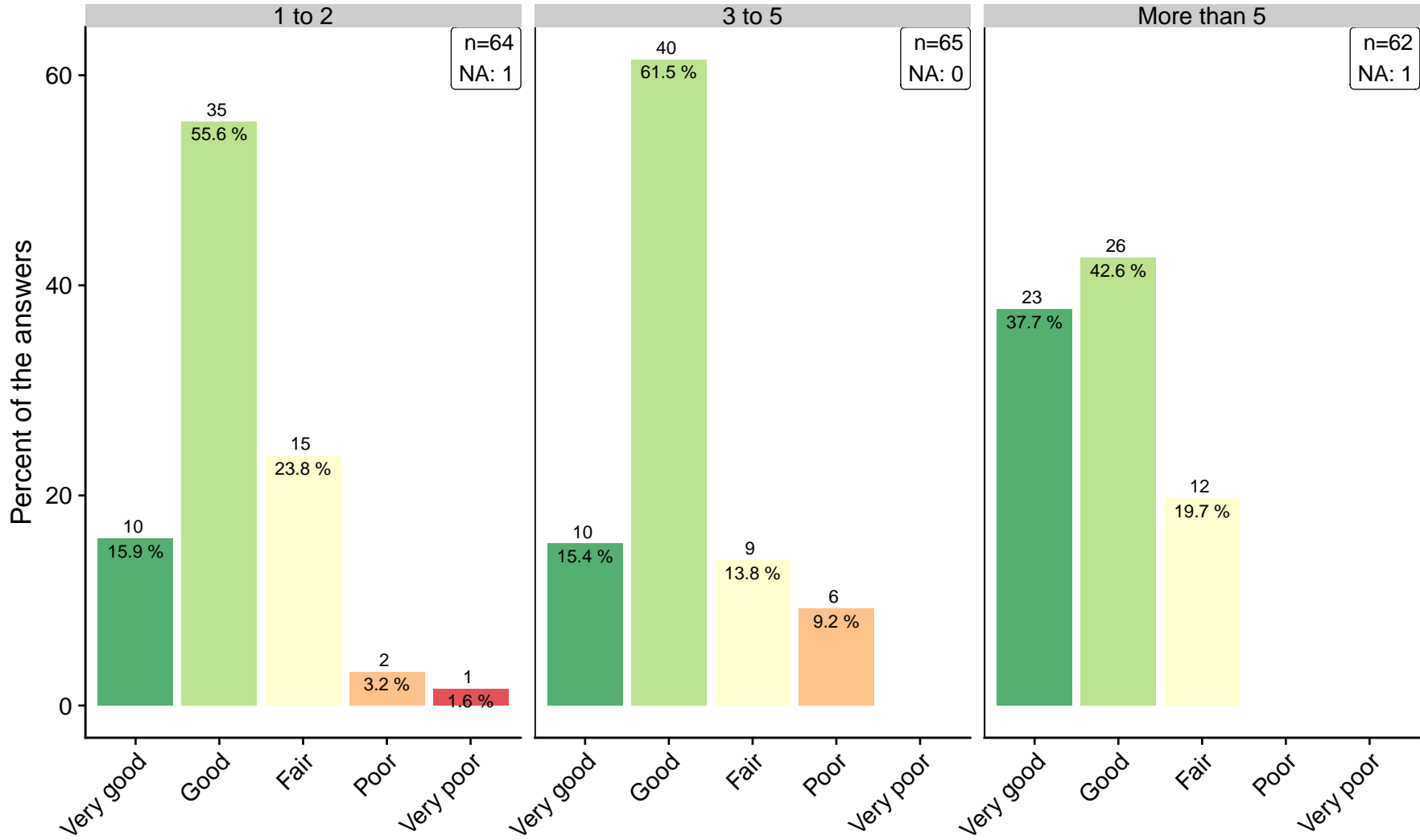


3.1.4 Stratified by field

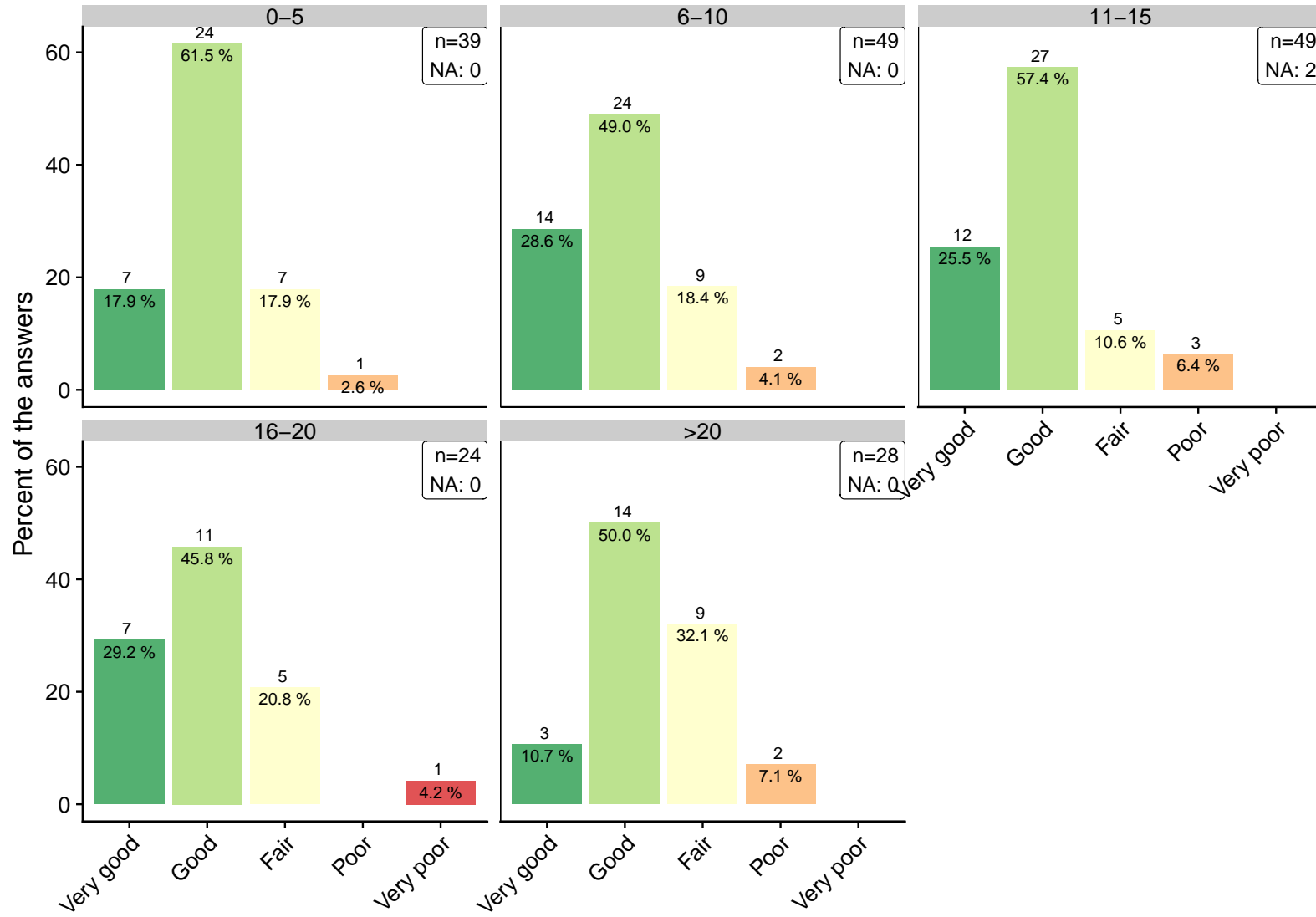


3.2 Feedback on application stratified by experience of the researcher

3.2.1 Stratified by number of submitted EC projects since HRA



3.2.2 Stratified by years working in research

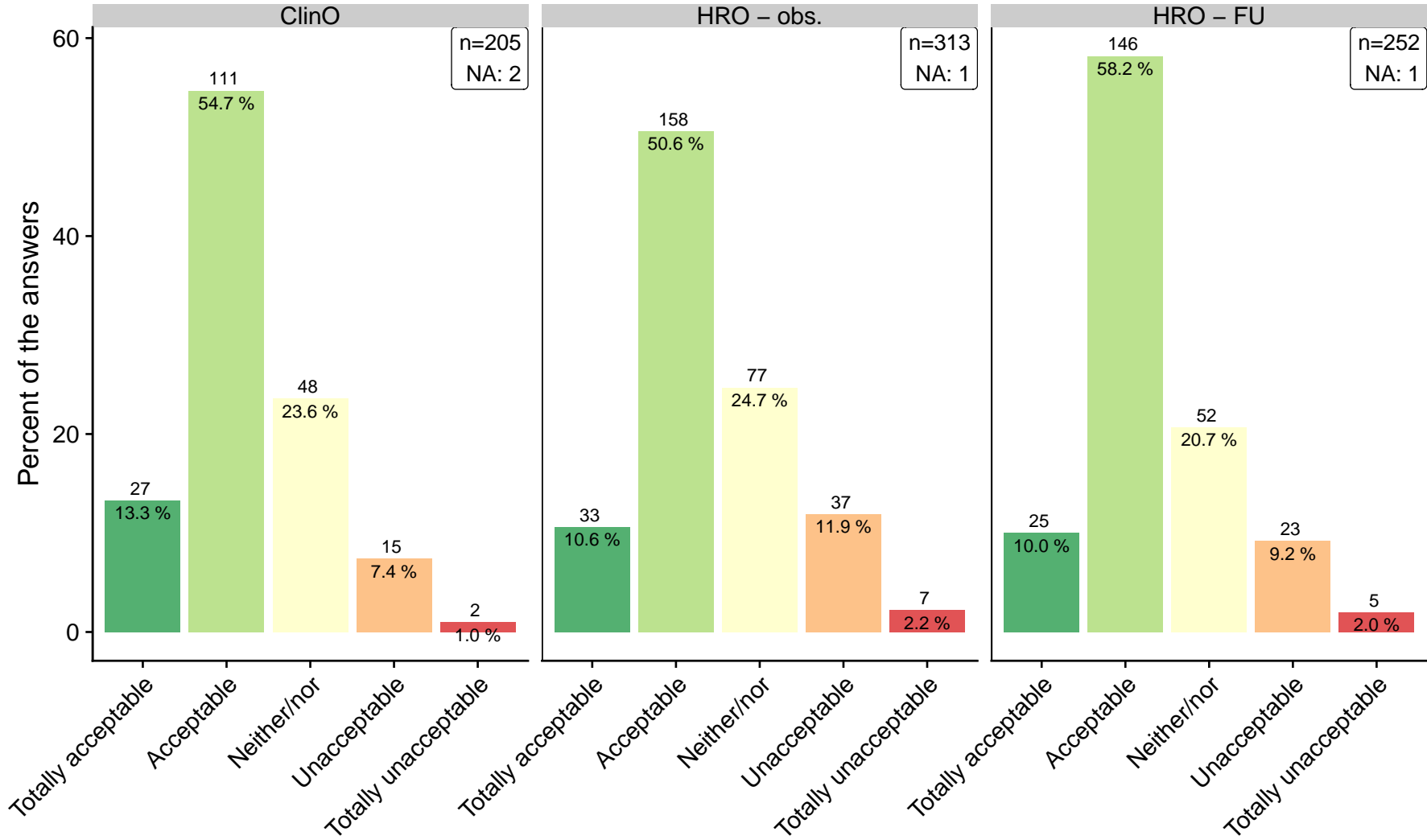


4 Question A7: In your opinion, the number of documents that you needed to upload was ...

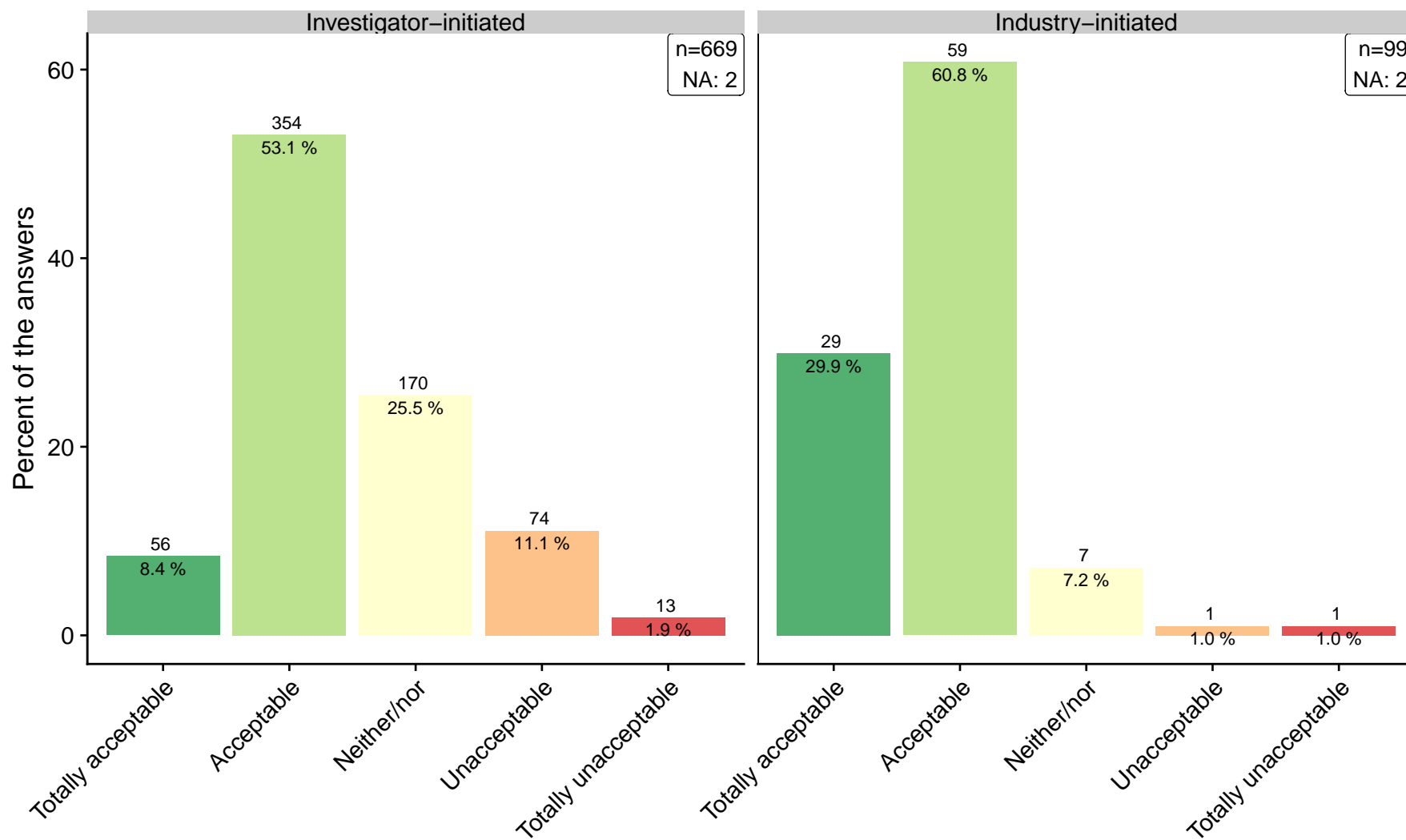
Question from IPZ / KEK-CDC Consultants: Gemäss den Befragten scheint die Anzahl der einzureichenden Dokumente akzeptabel zu sein, wenn auch die Befragten häufig den Aufwand bzw. Redundanz der Informationen bemängeln. Gibt es hier Unterschiede nach Forschungsbereich? Nach Erfahrung?

4.1 Feedback on application stratified research details

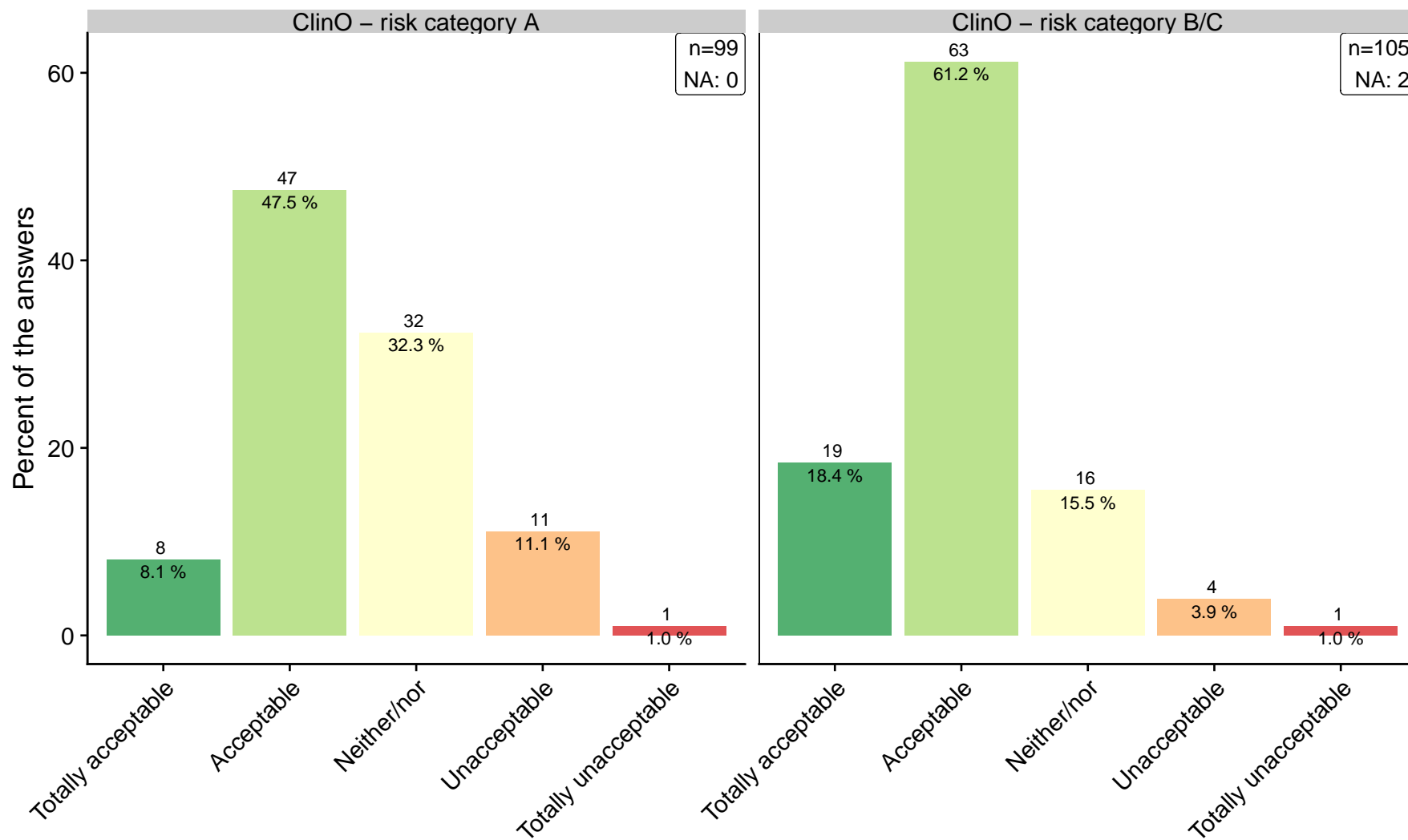
4.1.1 Stratified by research type



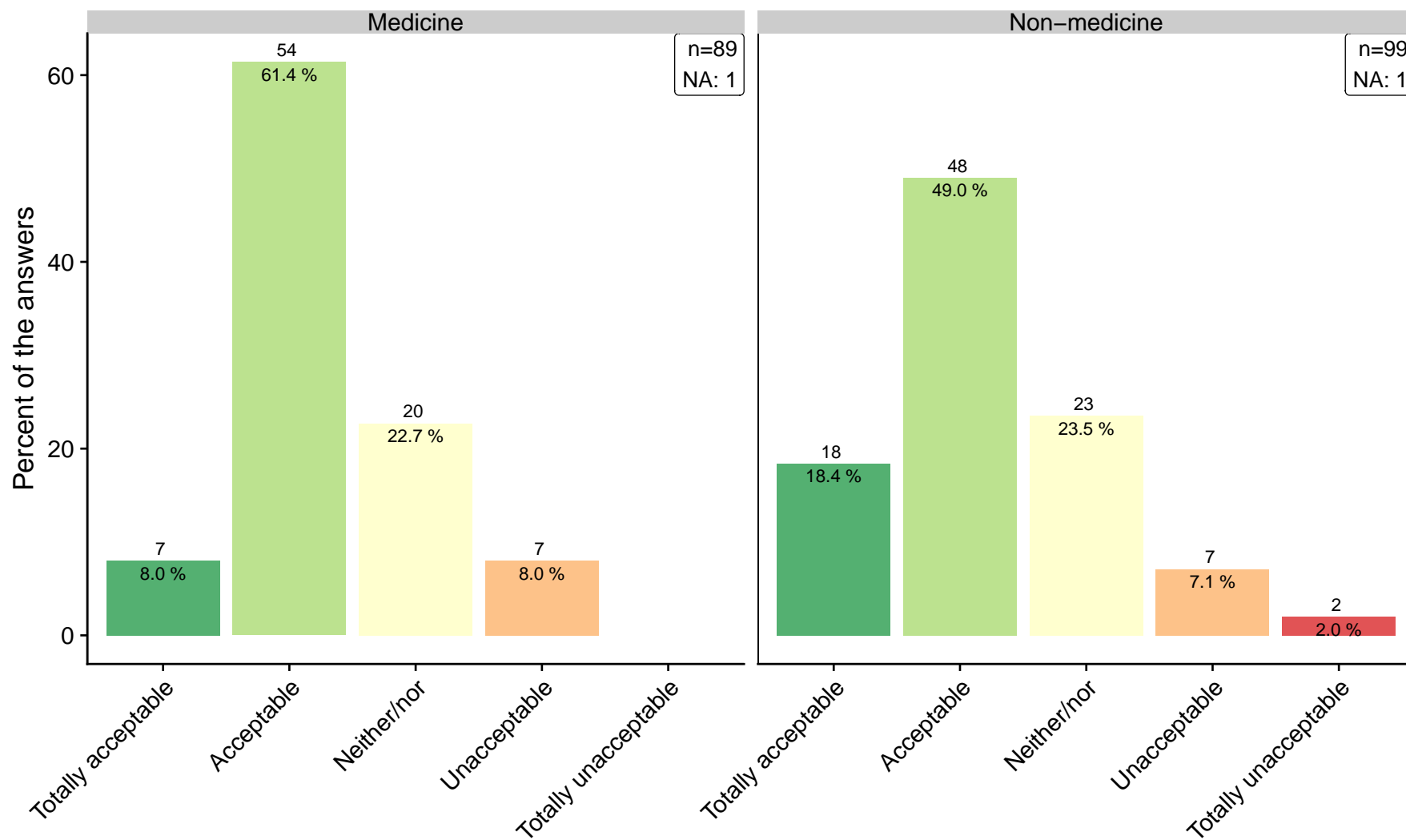
4.1.2 Stratified by initiator



4.1.3 Stratified by risk category

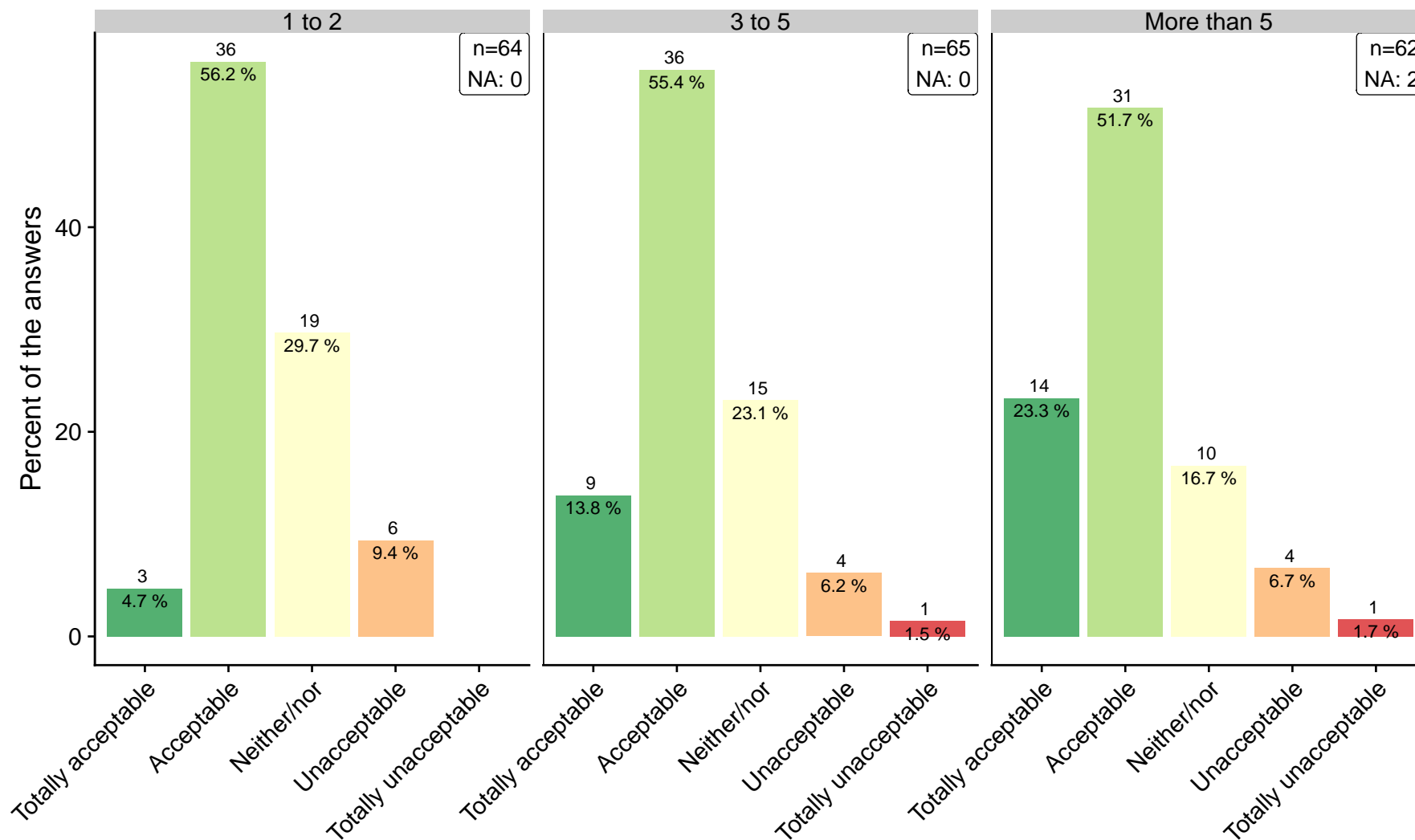


4.1.4 Stratified by field

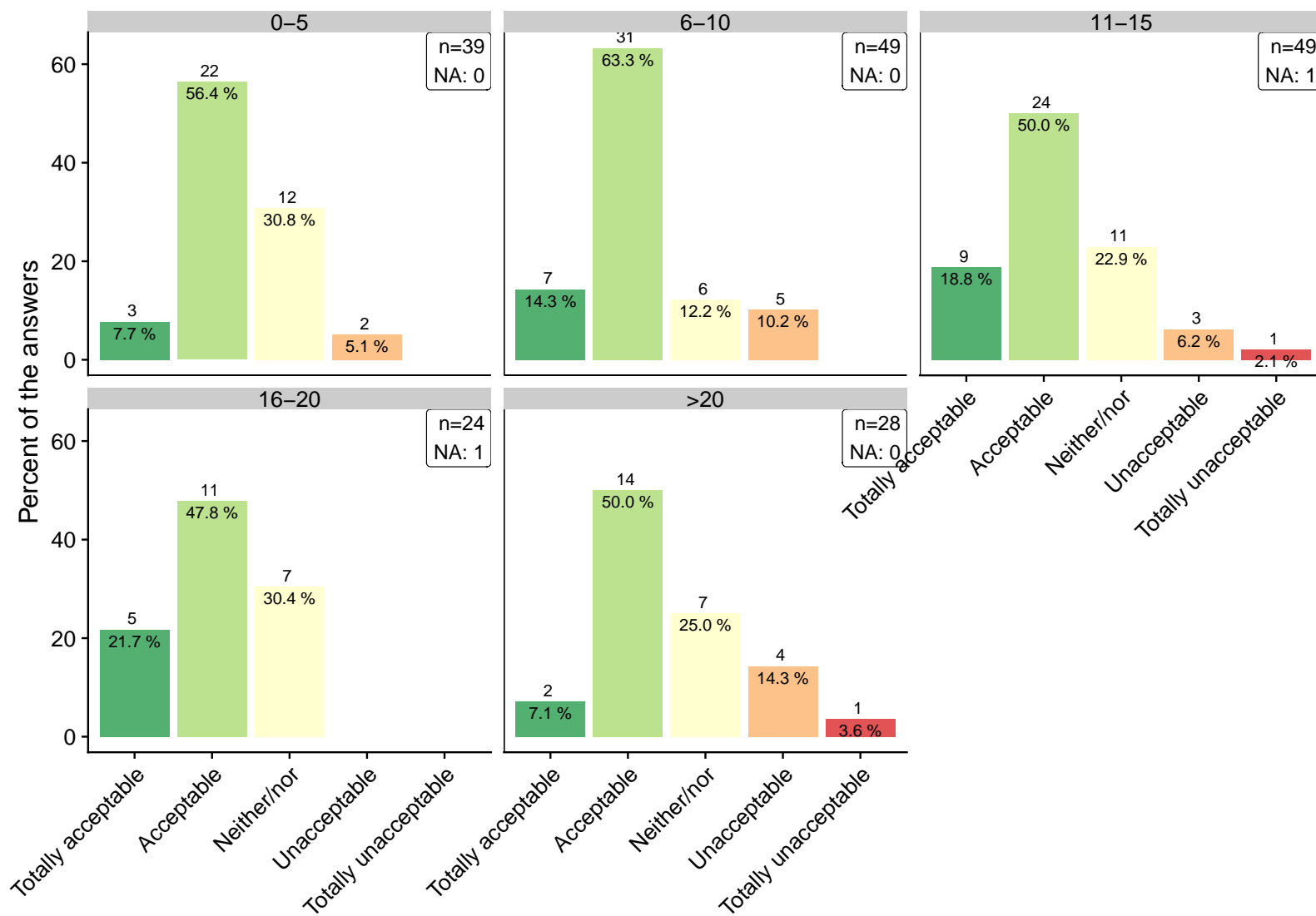


4.2 Feedback on application stratified by experience of the researcher

4.2.1 Stratified by number of submitted EC projects since HRA



4.2.2 Stratified by years working in research

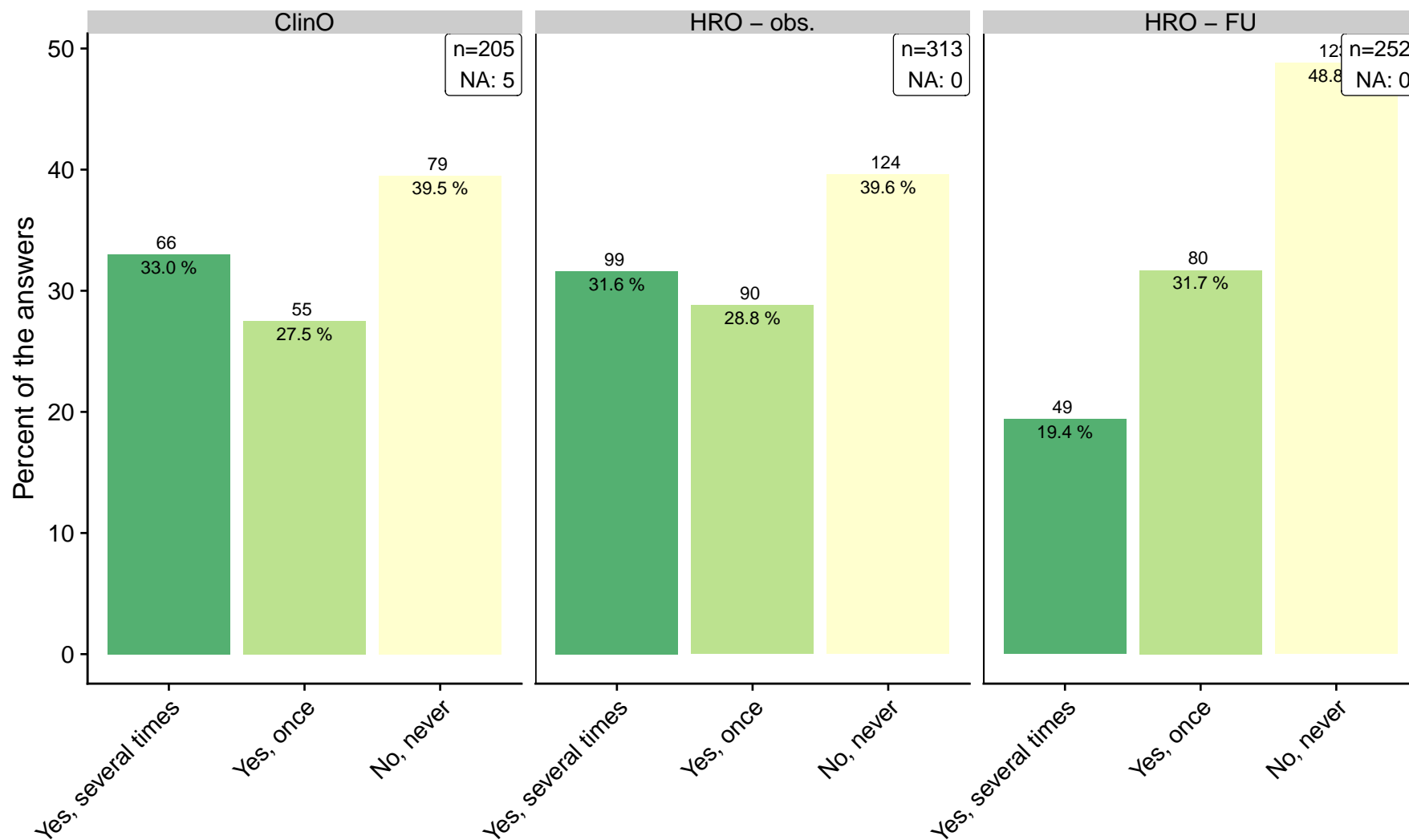


5 Question A10: When you submitted your project, did you contact your Ethics Committee or swissethics for questions or advice?

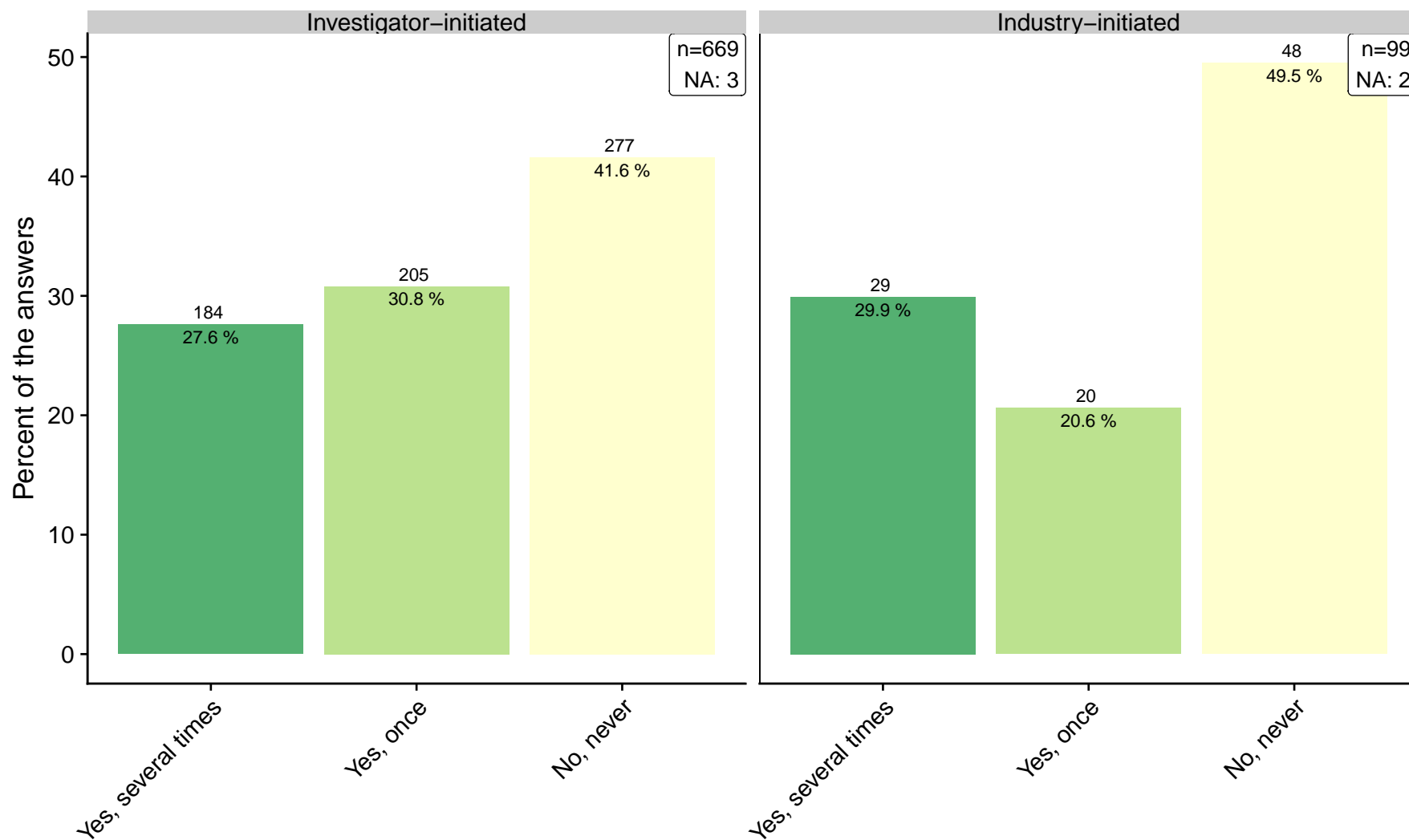
Question from IPZ / KEK-CDC Consultants: Gibt es Unterschiede in Kontakt nach Erfahrung oder Forschungsbereich?

5.1 Feedback on application stratified research details

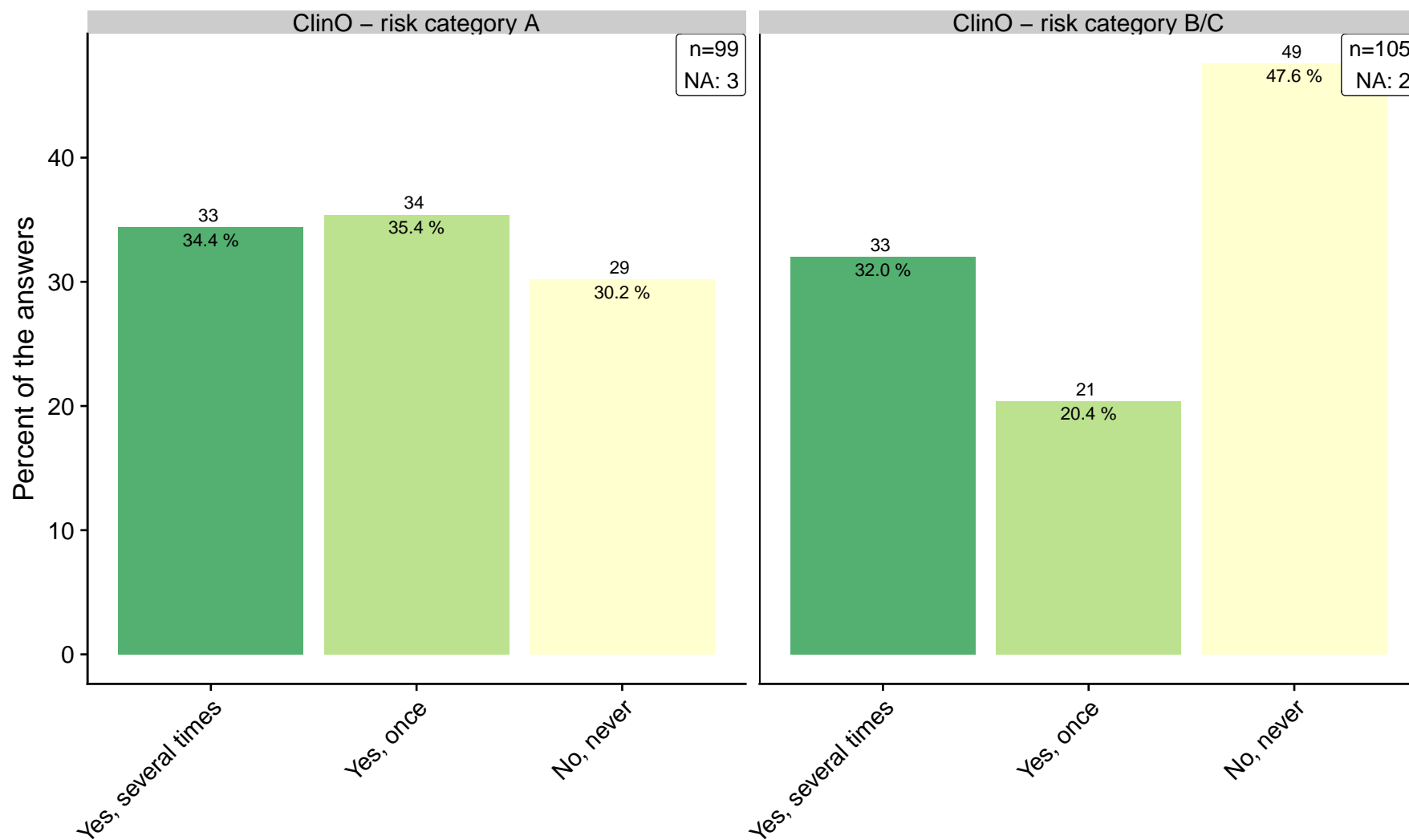
5.1.1 Stratified by research type



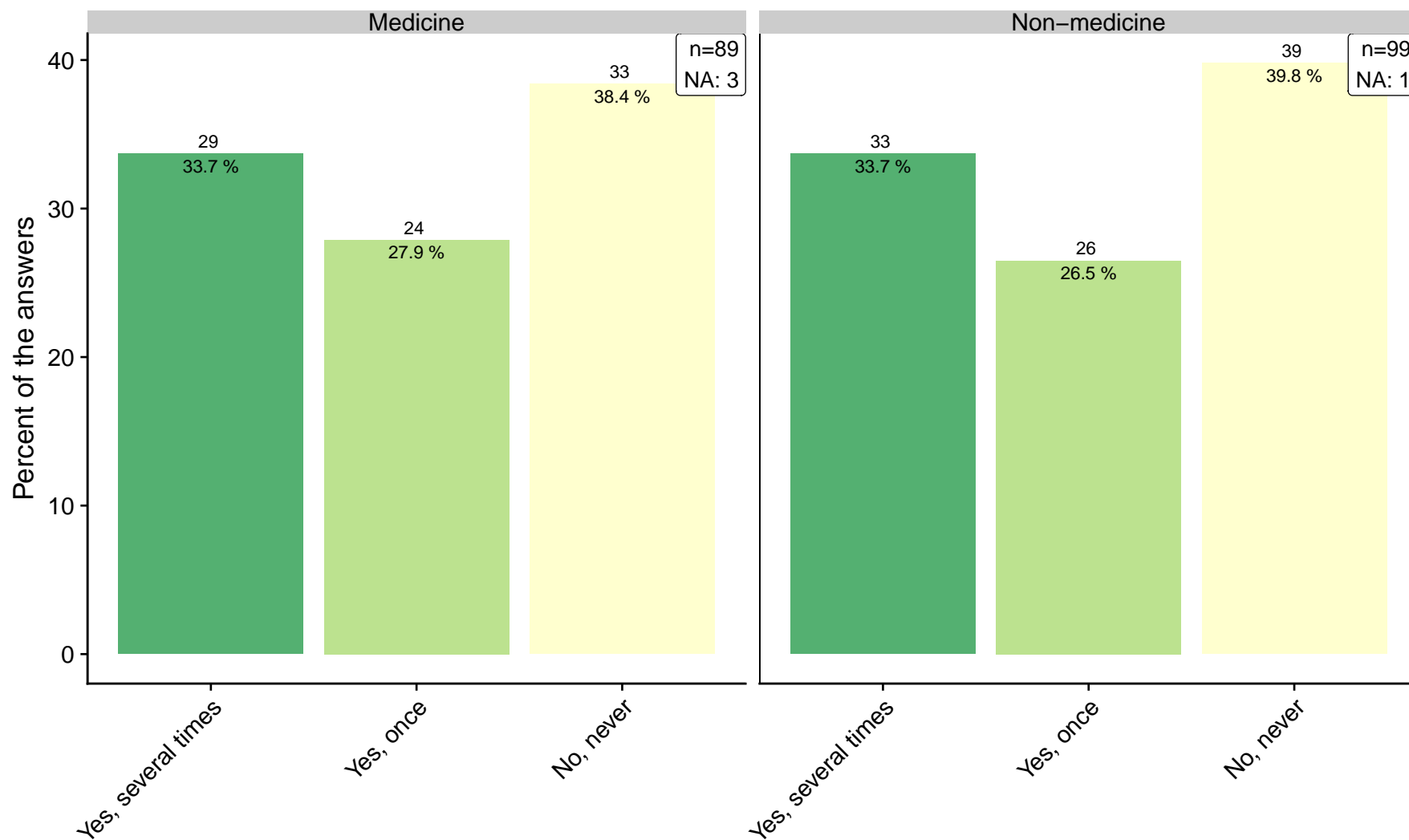
5.1.2 Stratified by initiator



5.1.3 Stratified by risk category

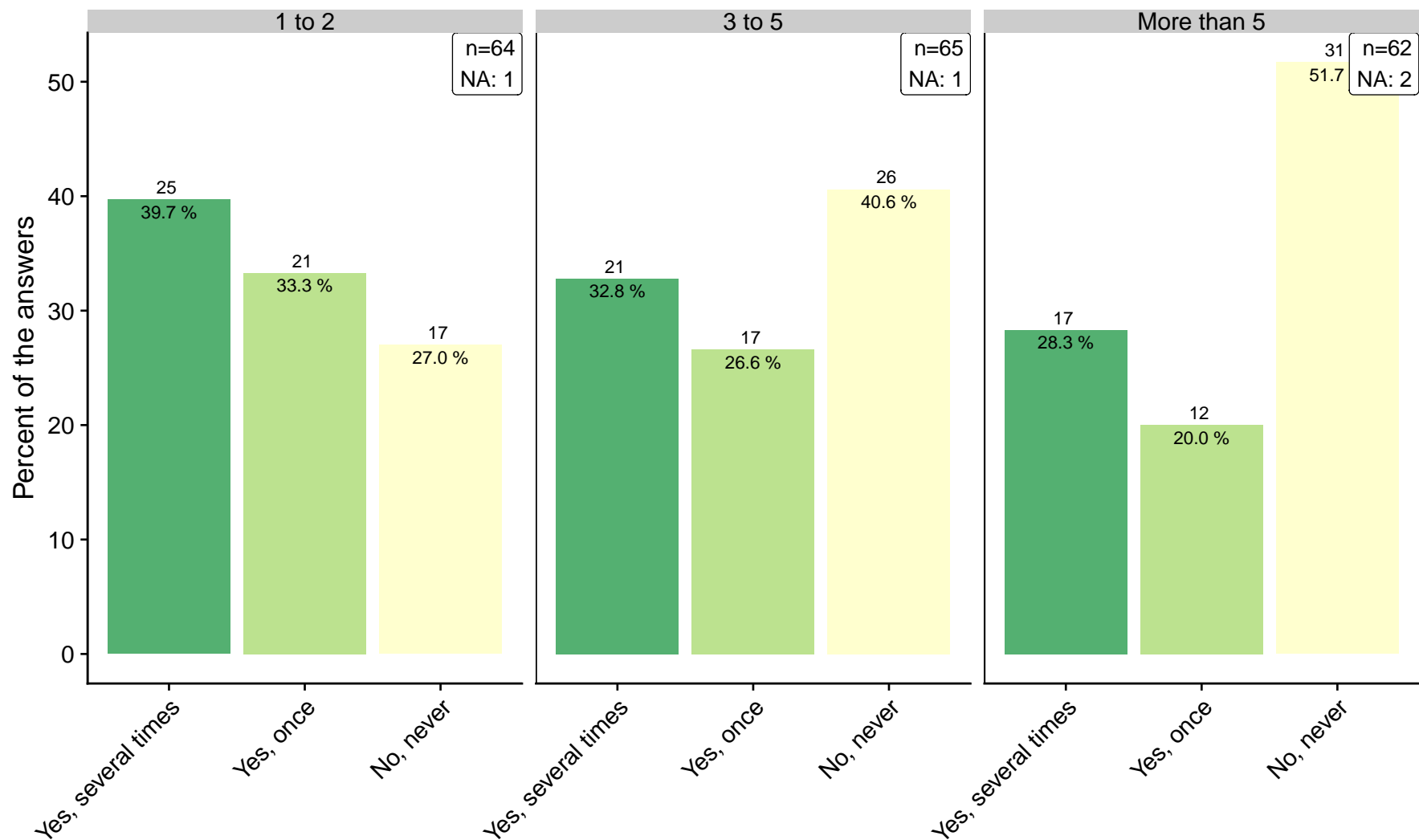


5.1.4 Stratified by field

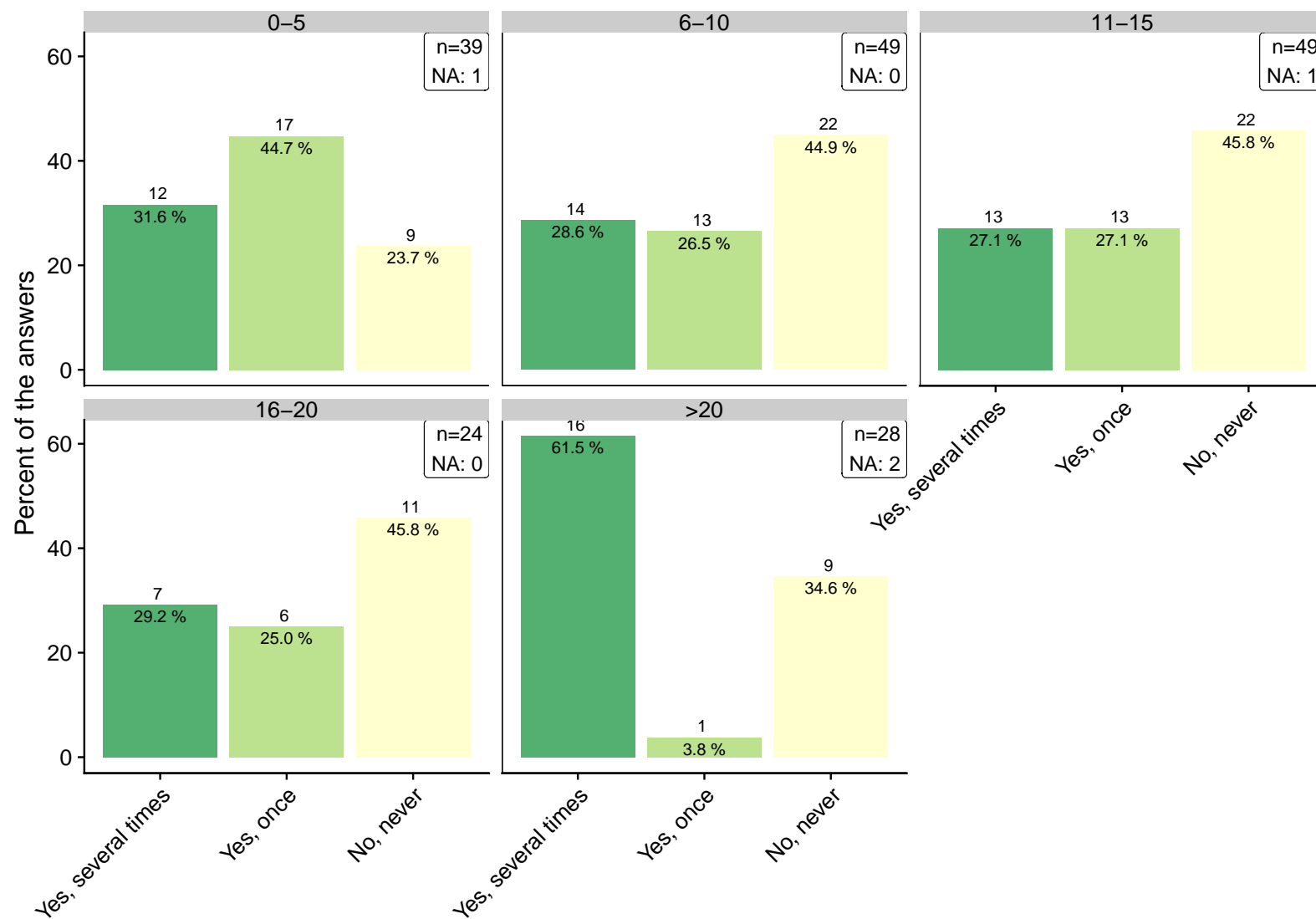


5.2 Feedback on application stratified by experience of the researcher

5.2.1 Stratified by number of submitted EC projects since HRA



5.2.2 Stratified by years working in research



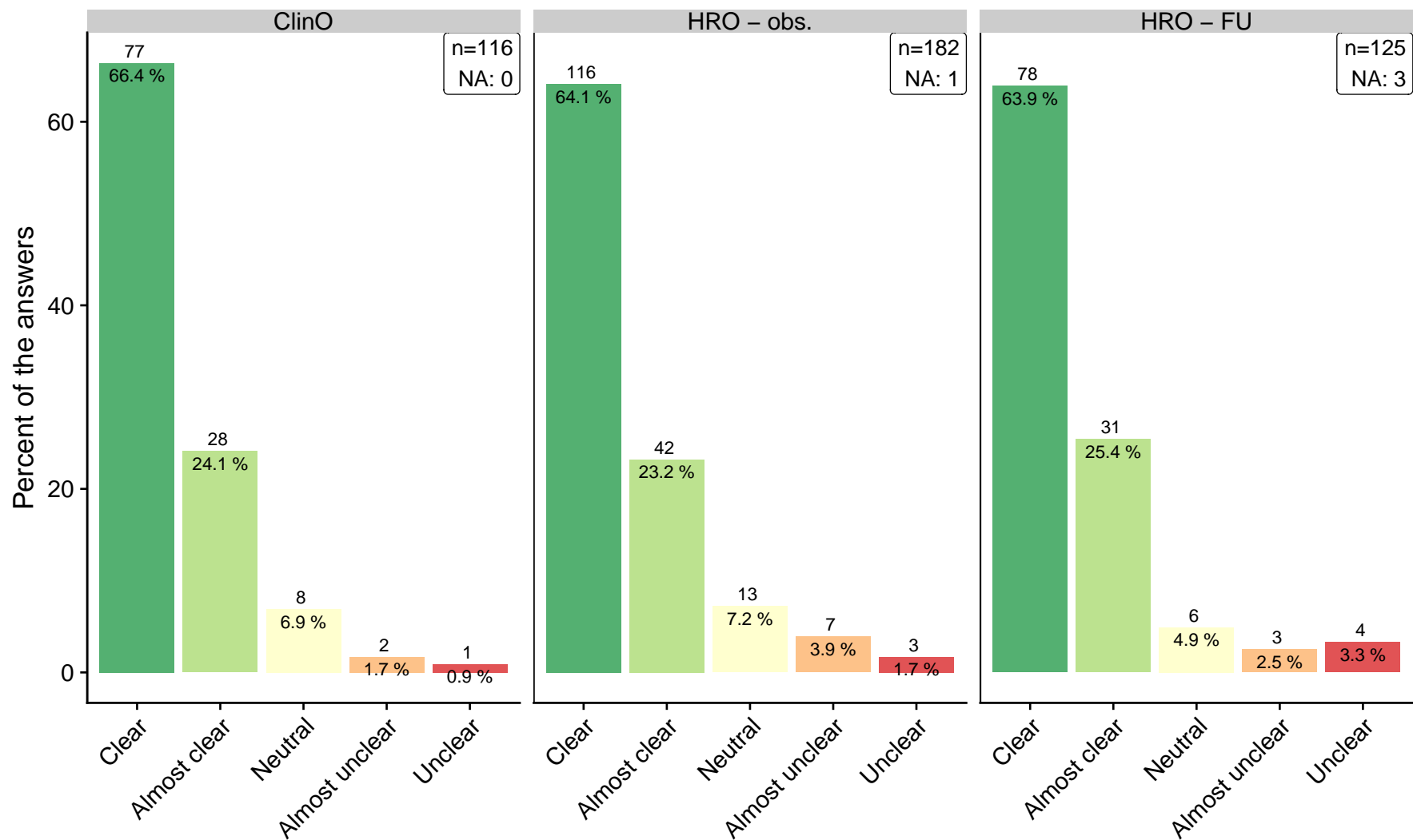
6 Question A10c: Adjectives that best describe the answers received by Ethics Committee or swissethics

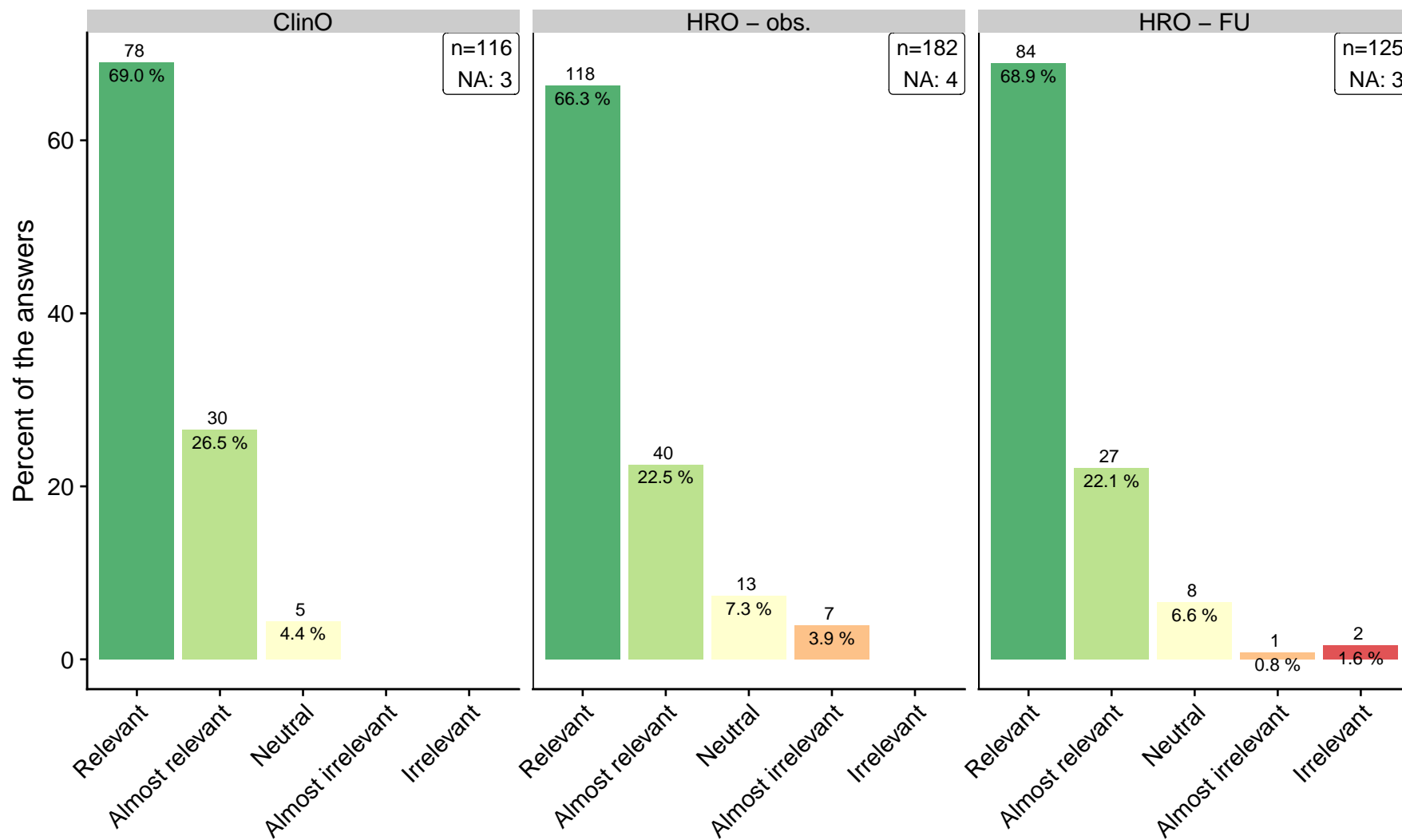
Note: These questions were only asked if the previous questions was answered with 'Always', 'Often' or 'Sometimes' (n=423)

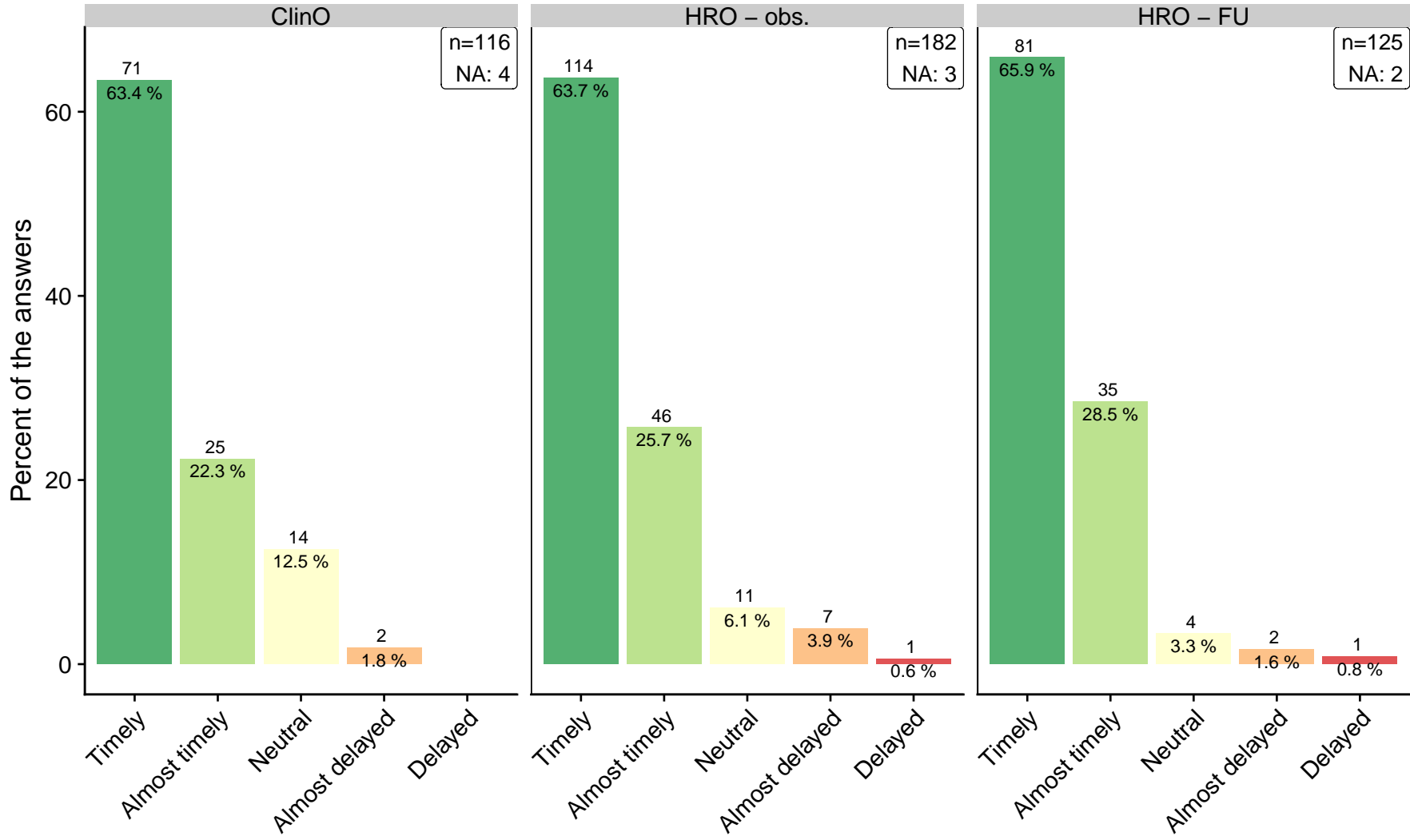
Question from IPZ / KEK-CDC Consultants: Gibt es Unterschiede in Kontakt nach Erfahrung oder Forschungsbereich?

6.1 Feedback on application stratified research details

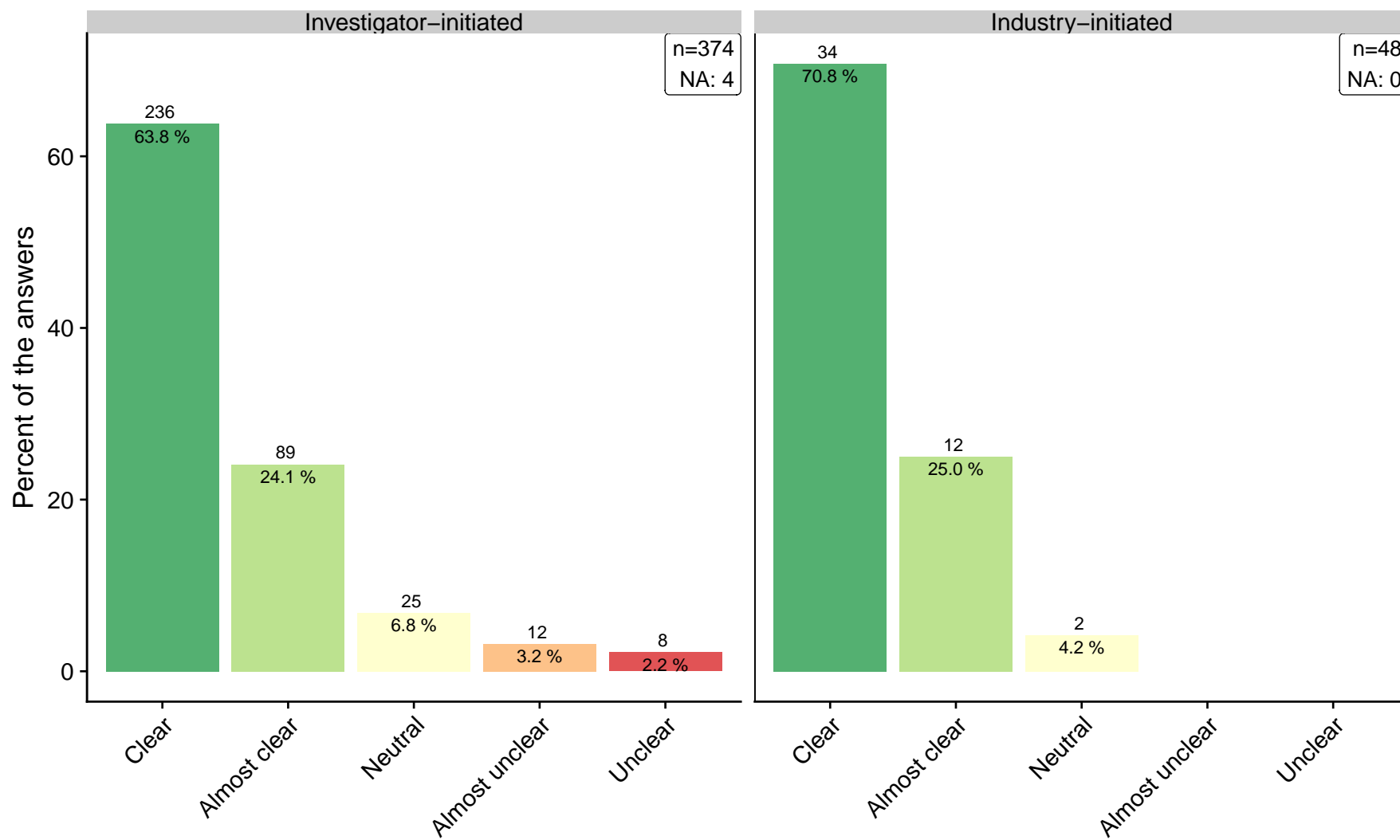
6.1.1 Stratified by research type

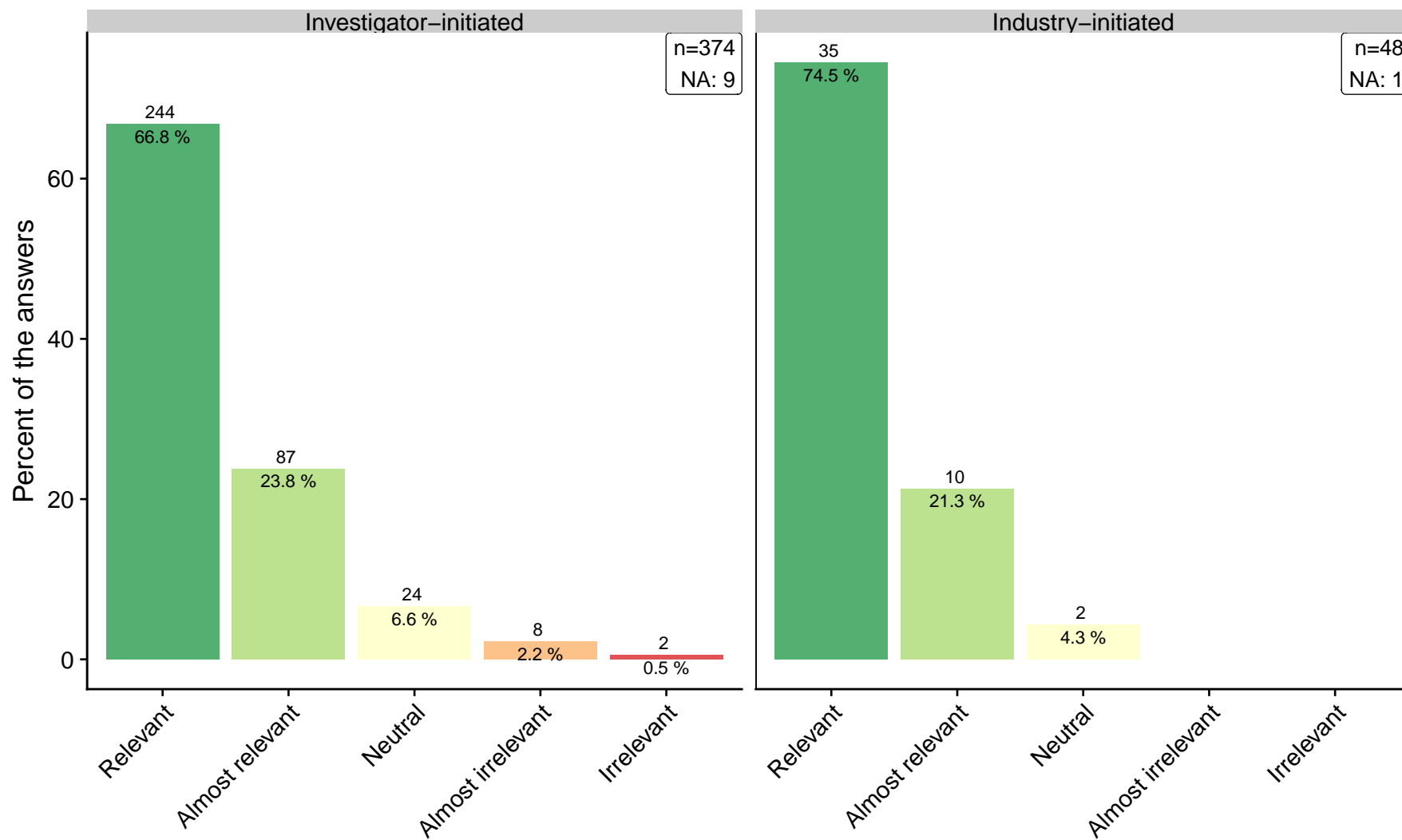


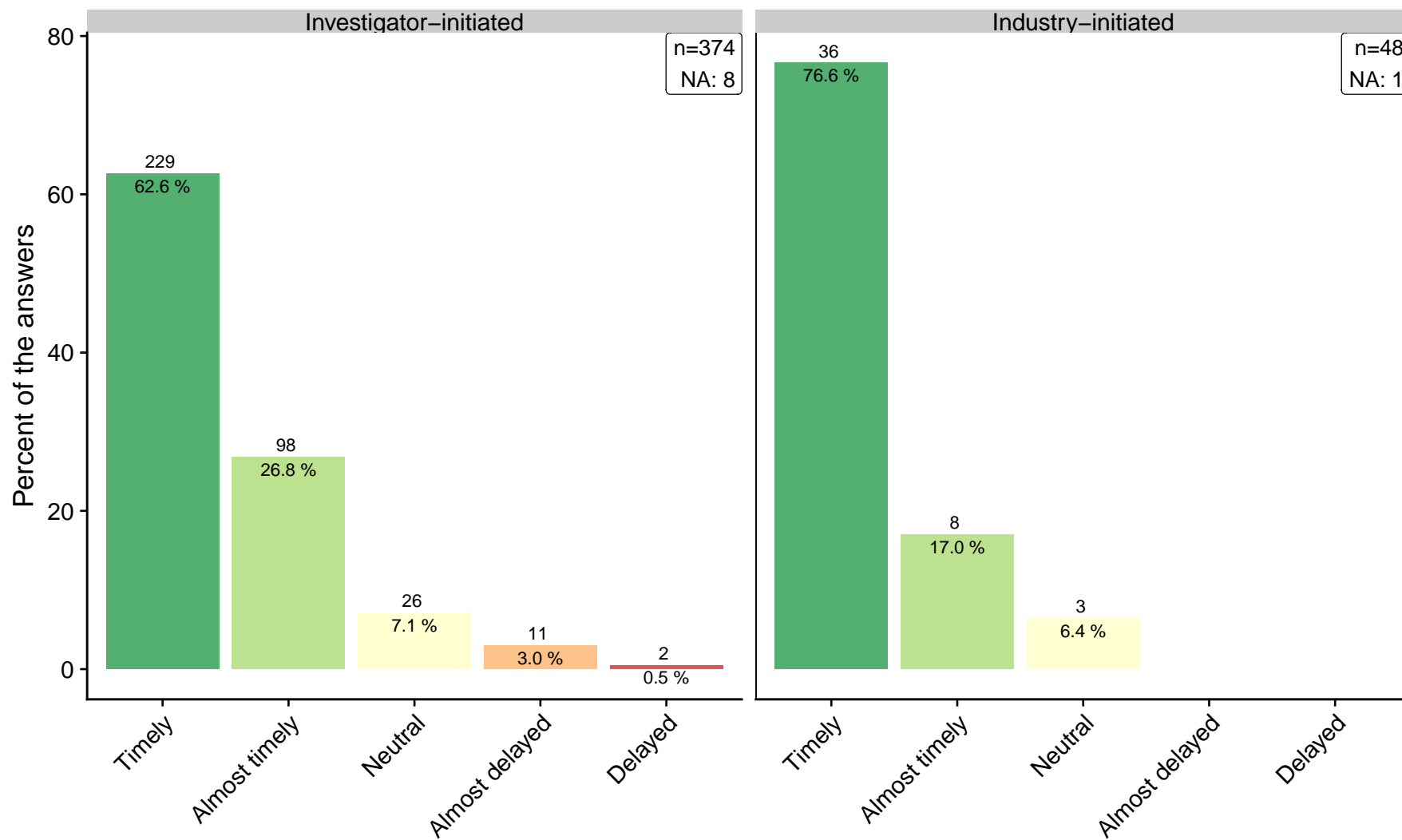




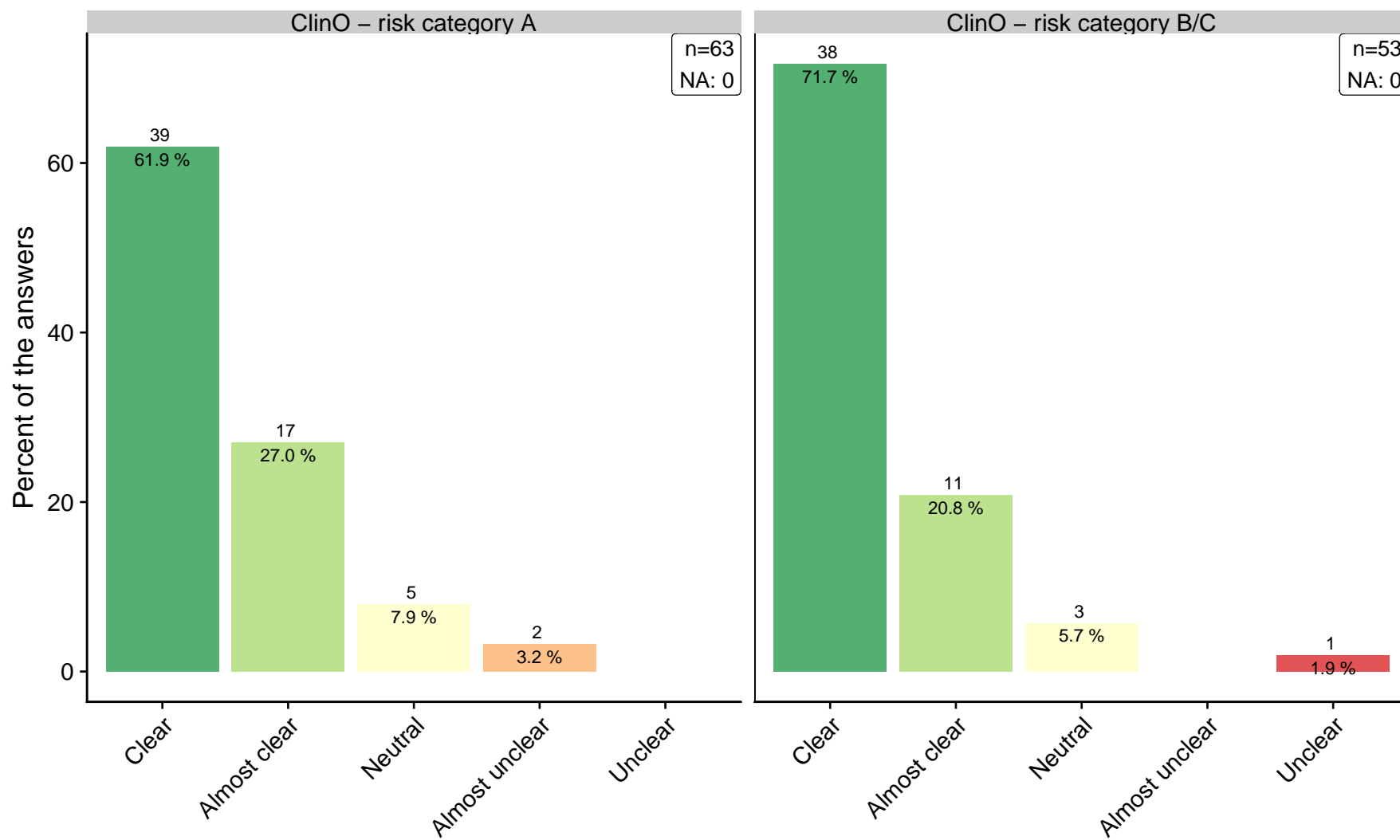
6.1.2 Stratified by initiator

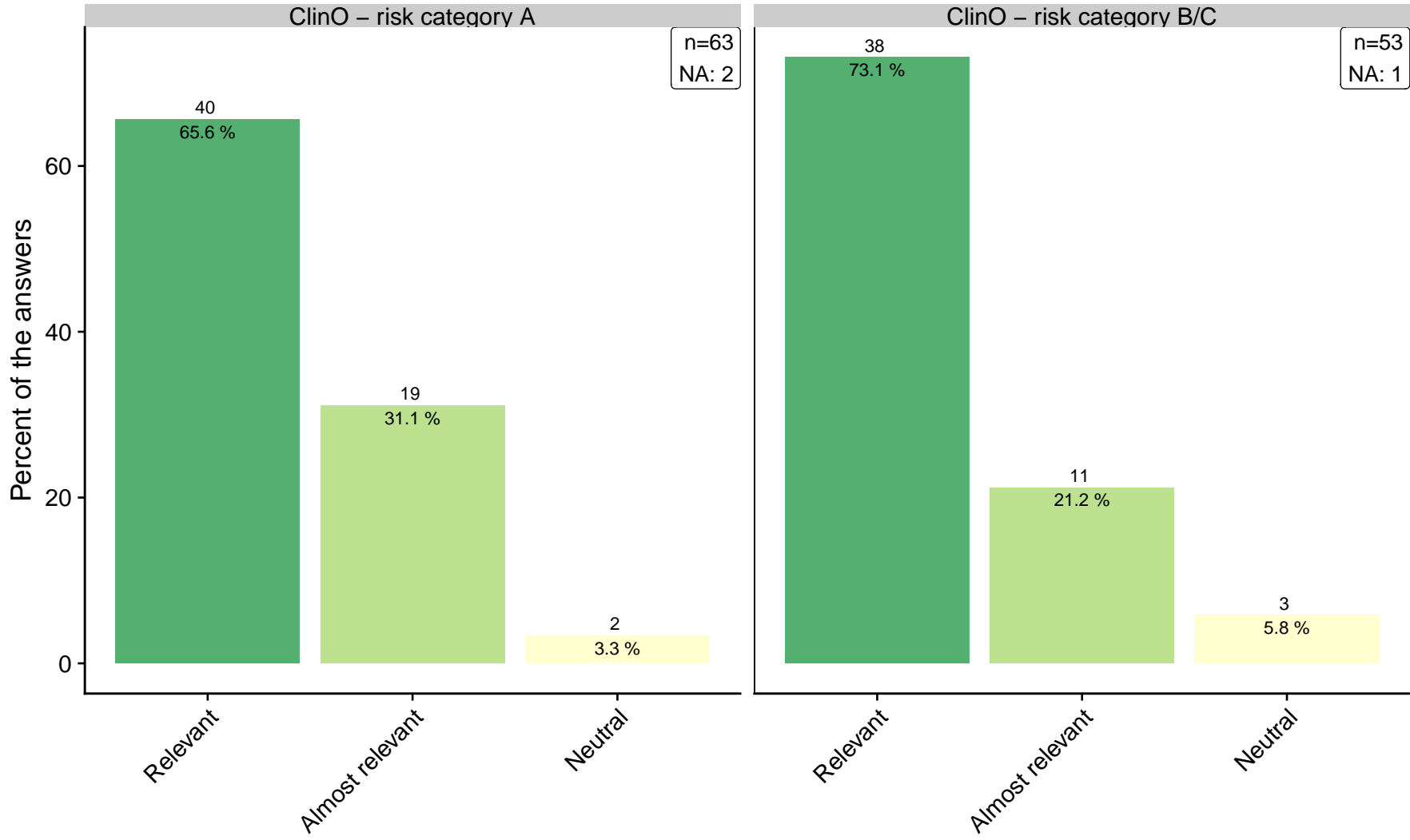


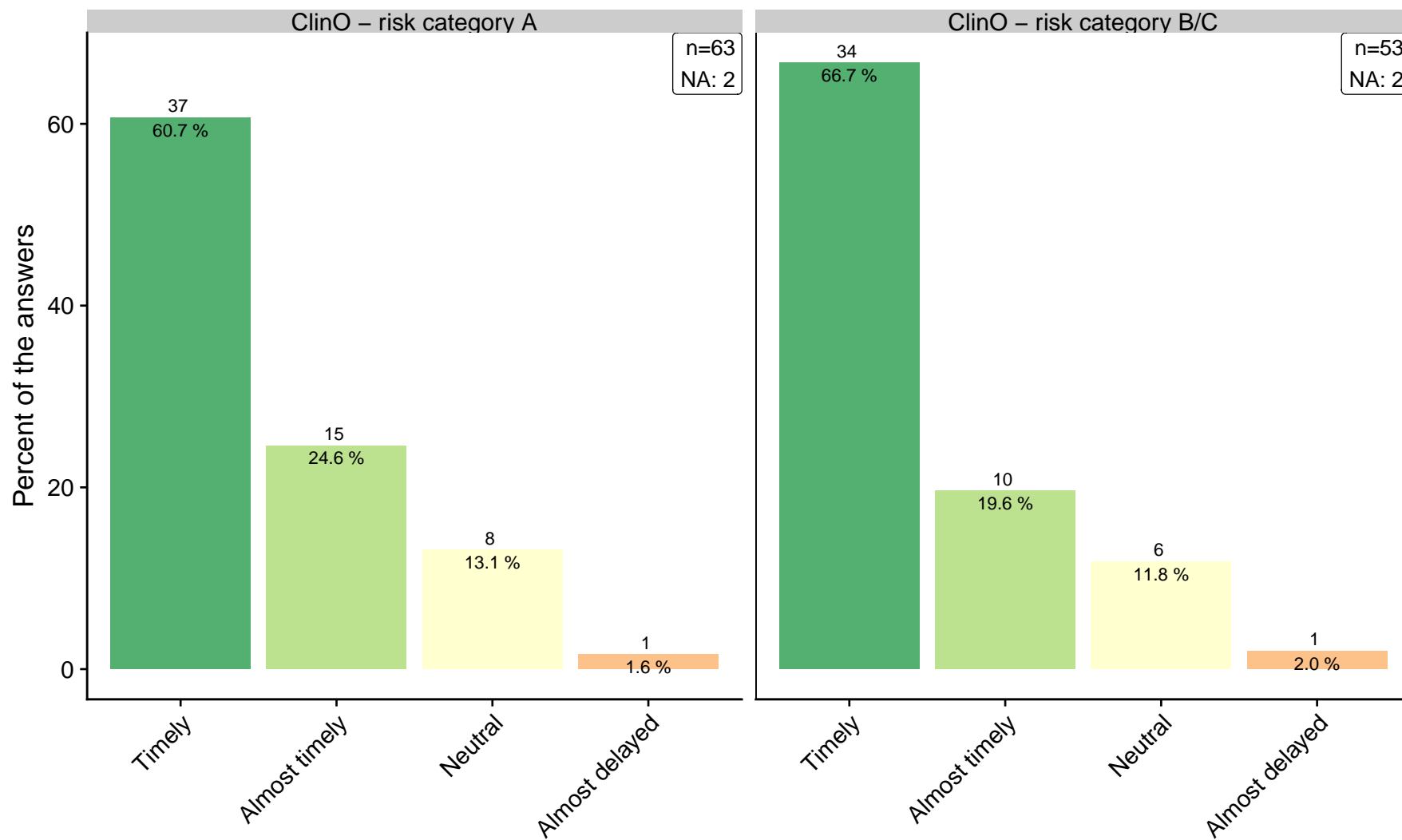




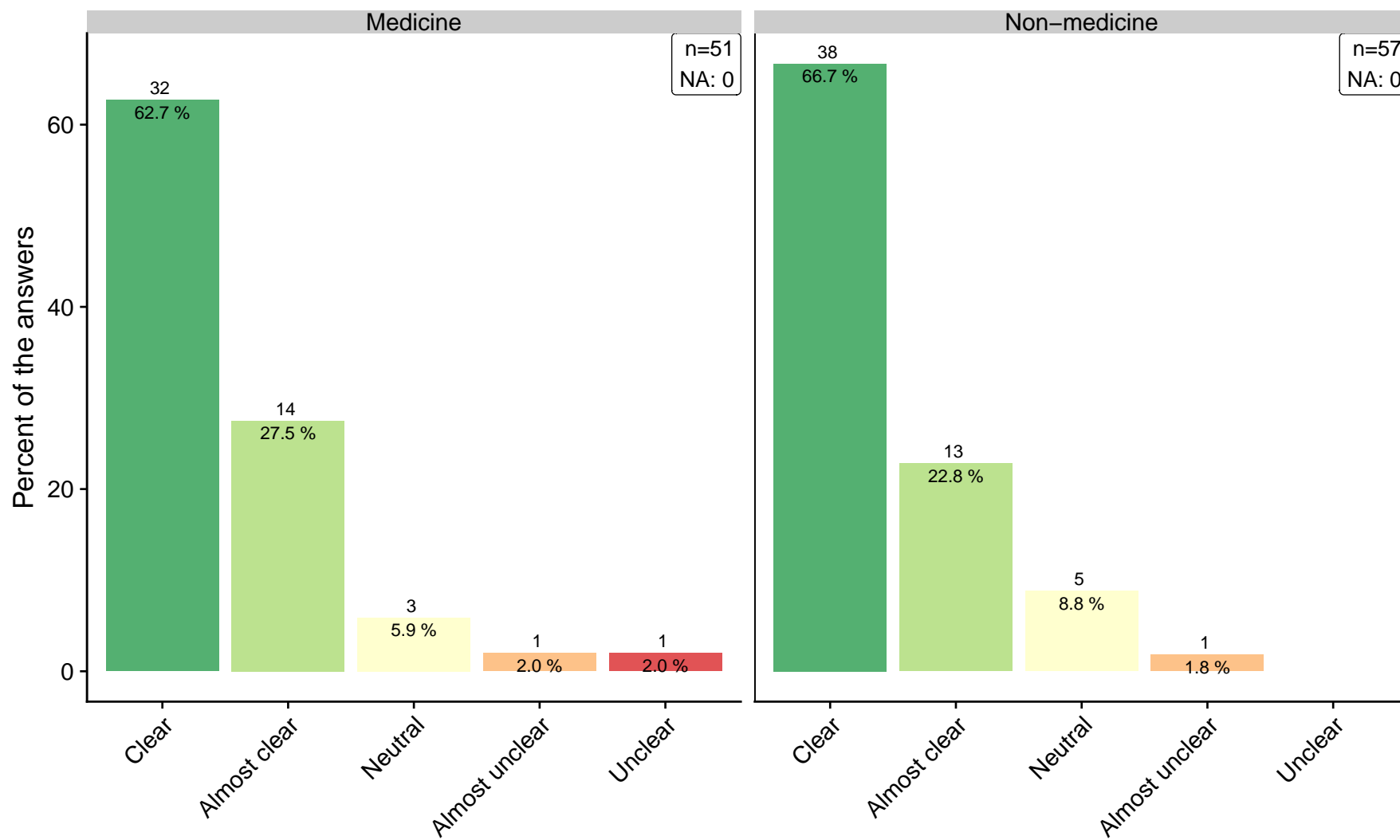
6.1.3 Stratified by risk category

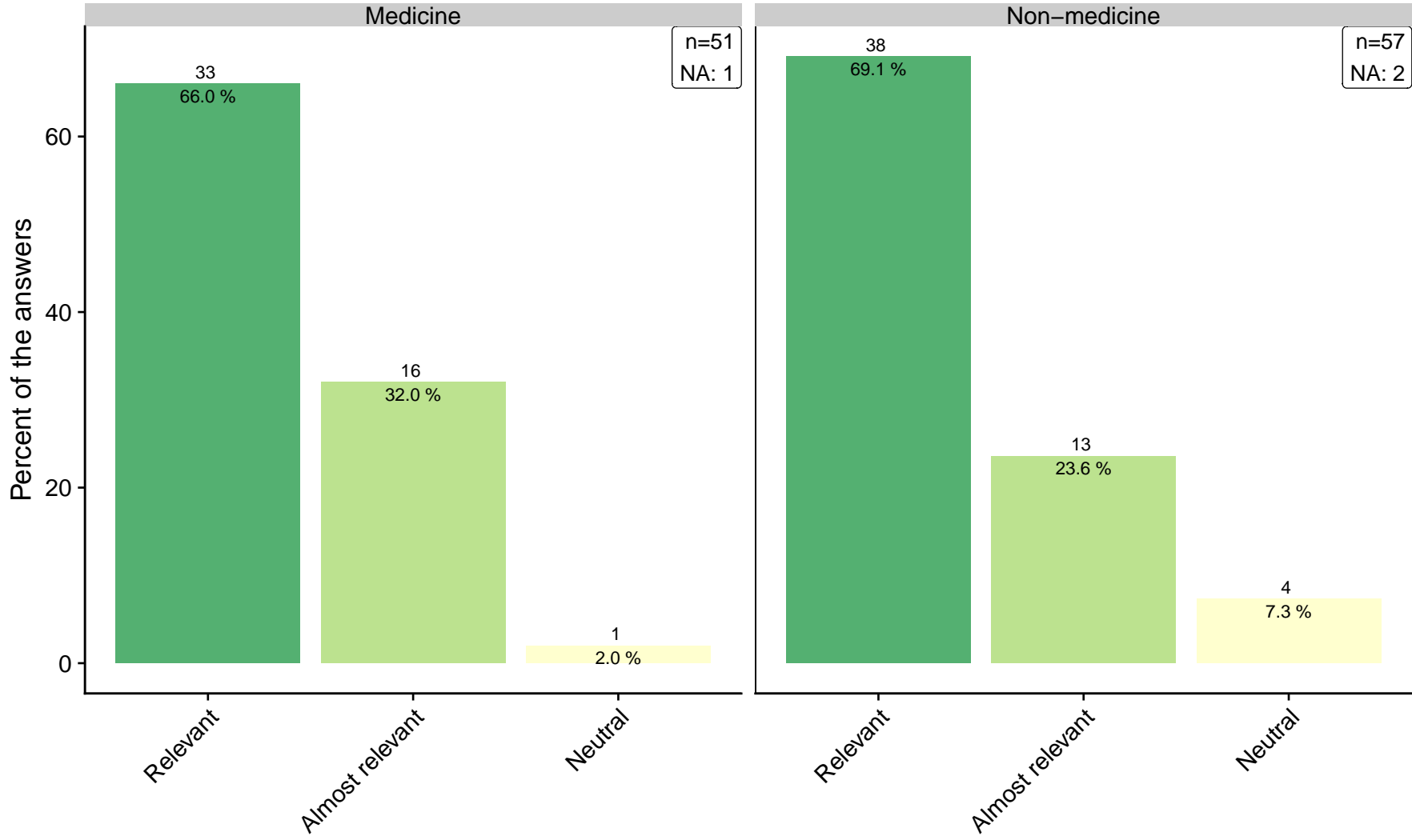


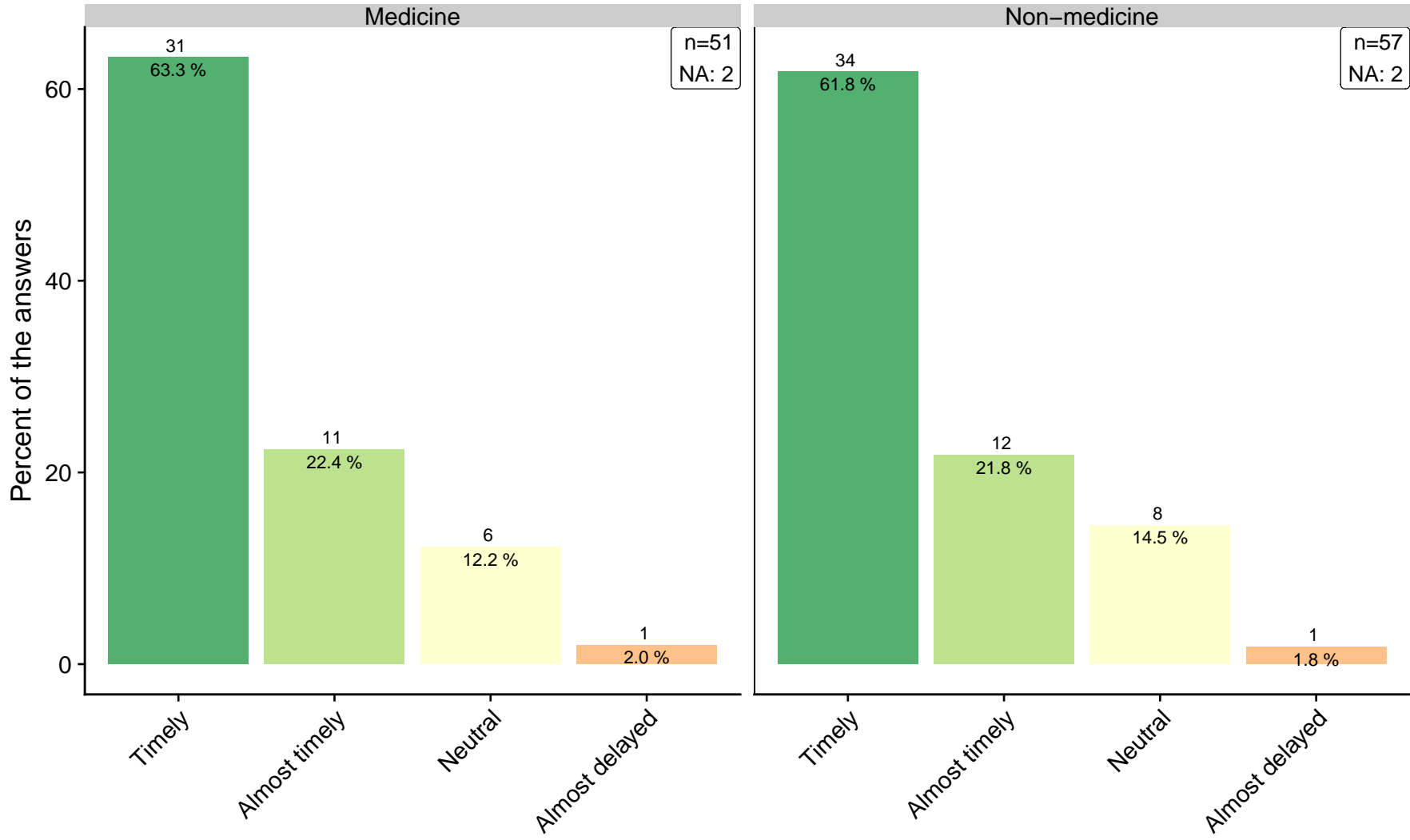




6.1.4 Stratified by field

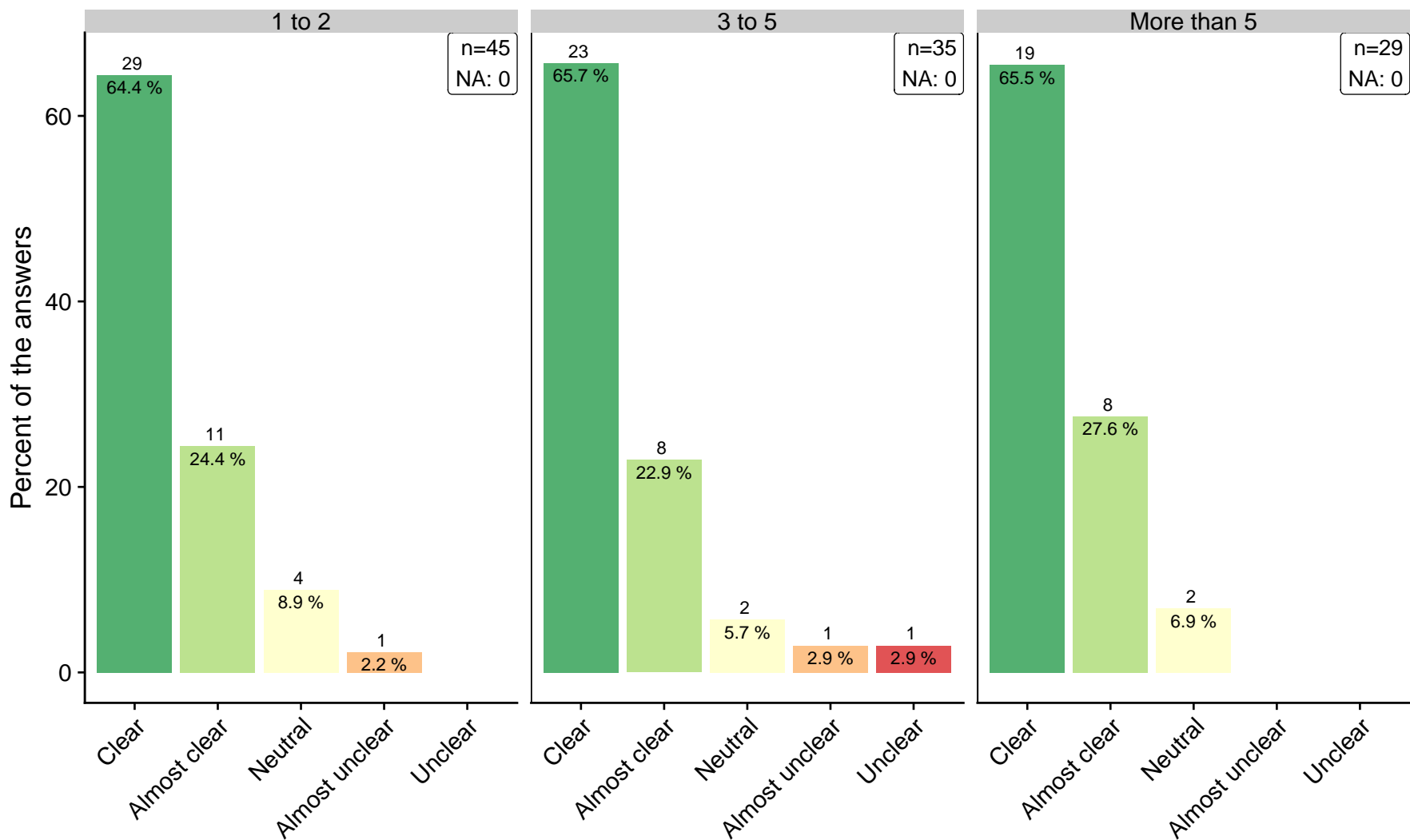


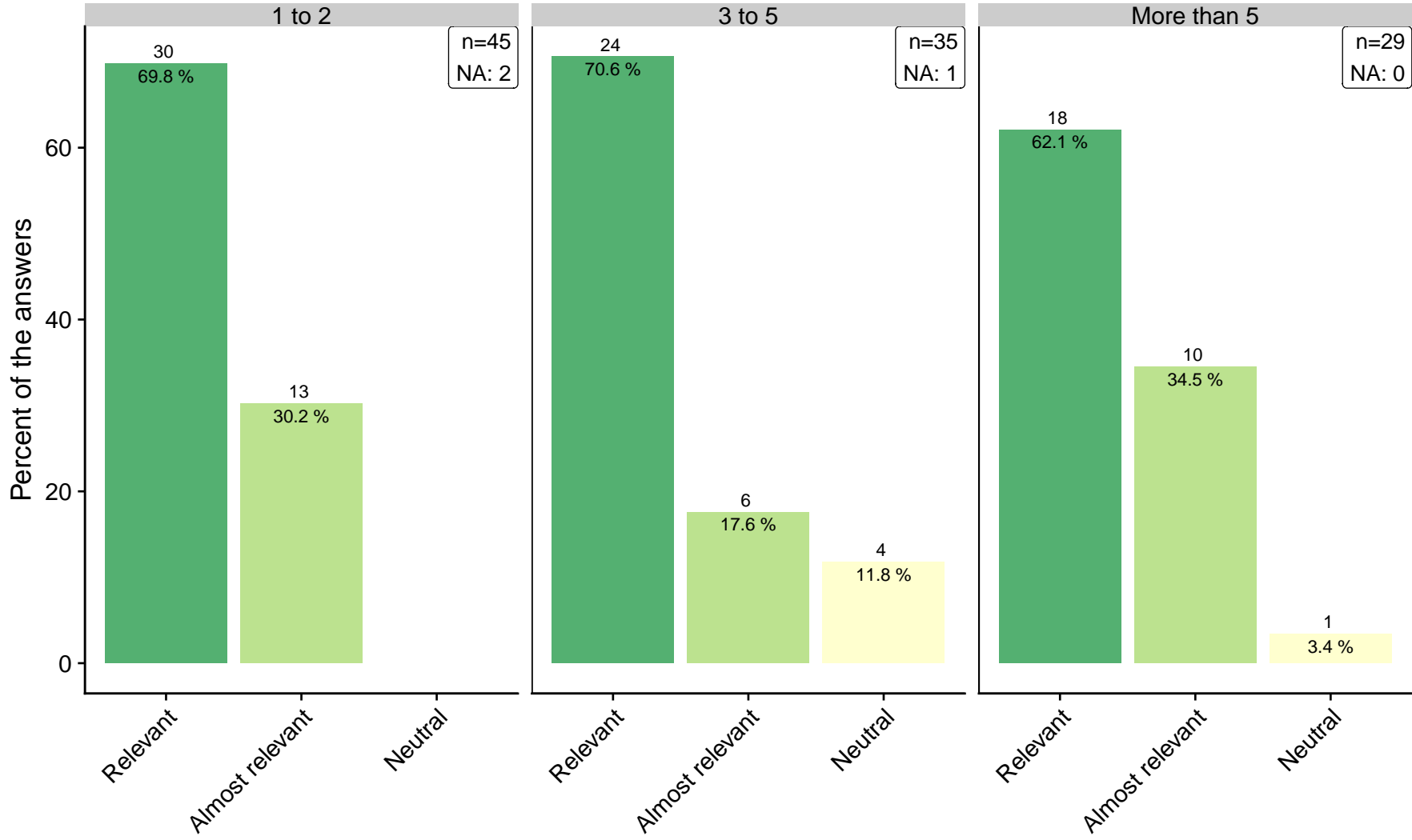


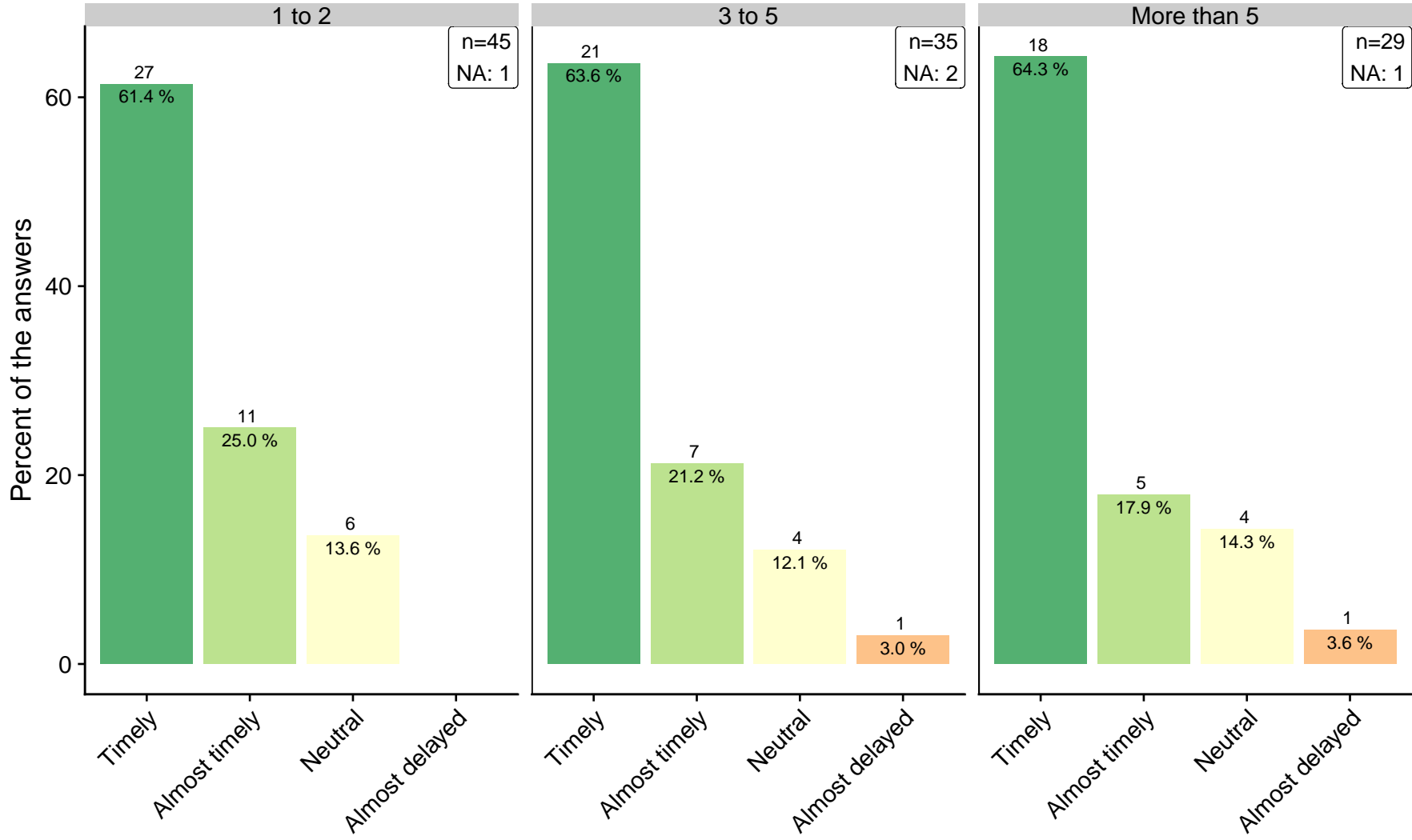


6.2 Feedback on application stratified by experience of the researcher

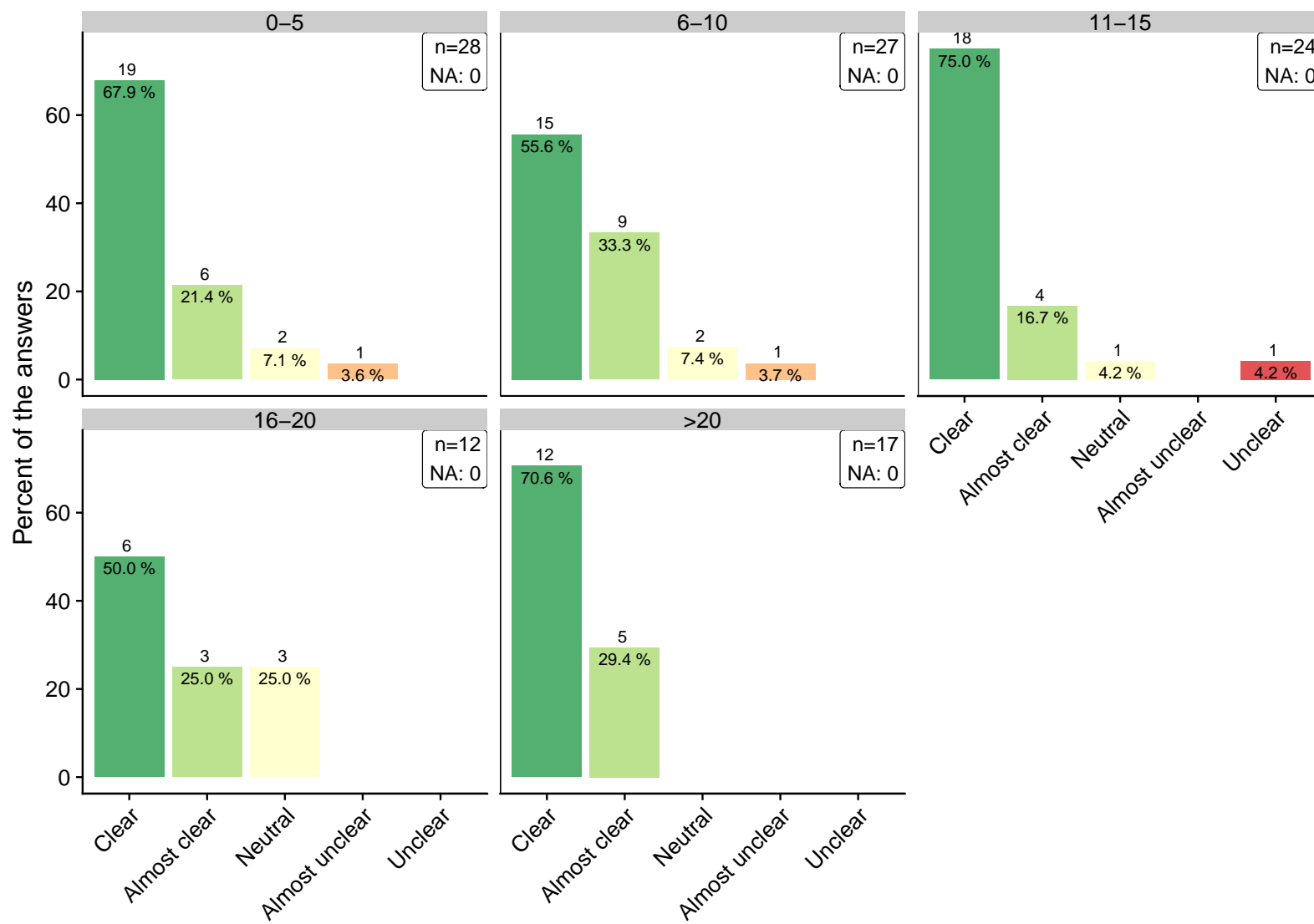
6.2.1 Stratified by number of submitted EC projects since HRA

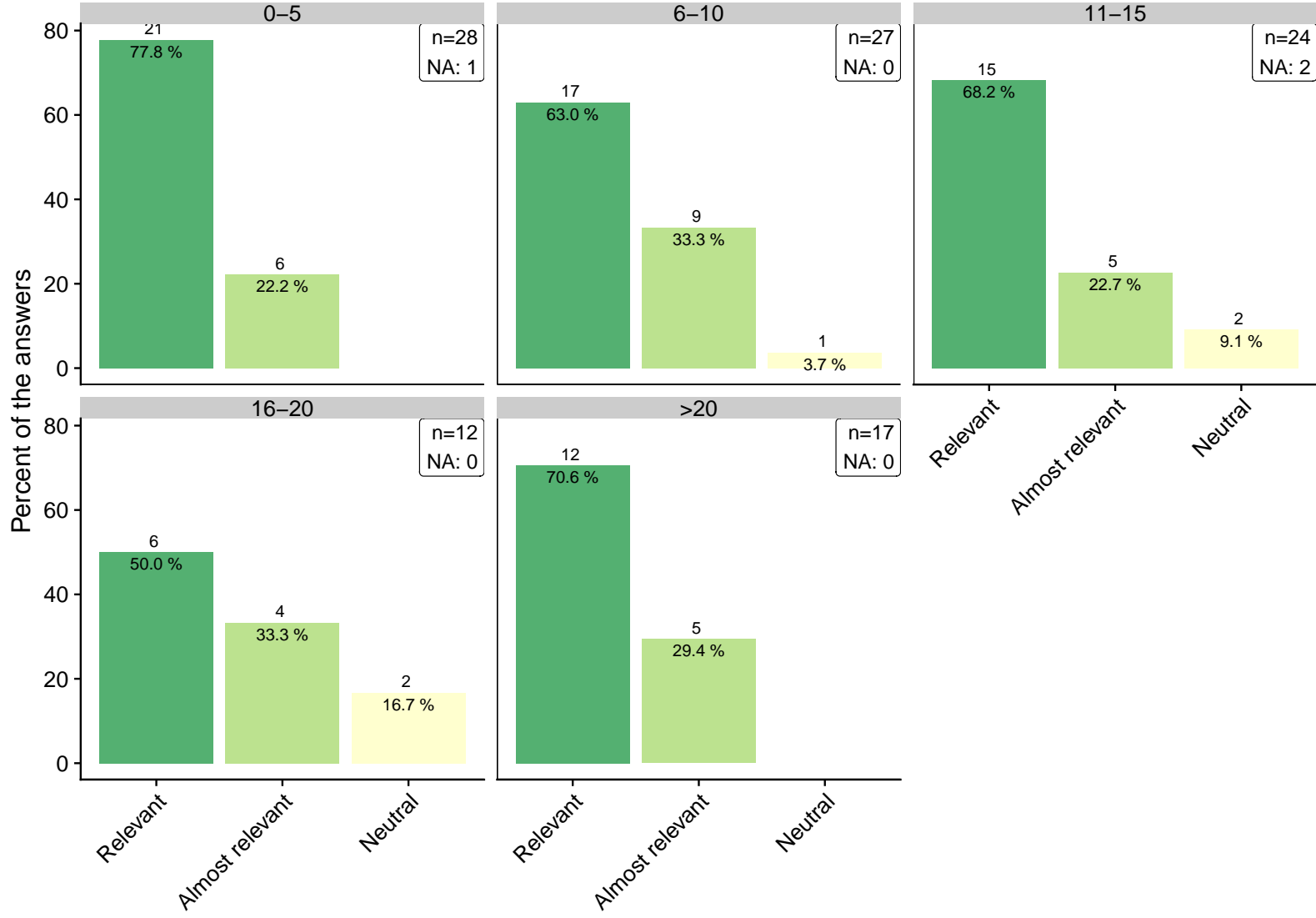


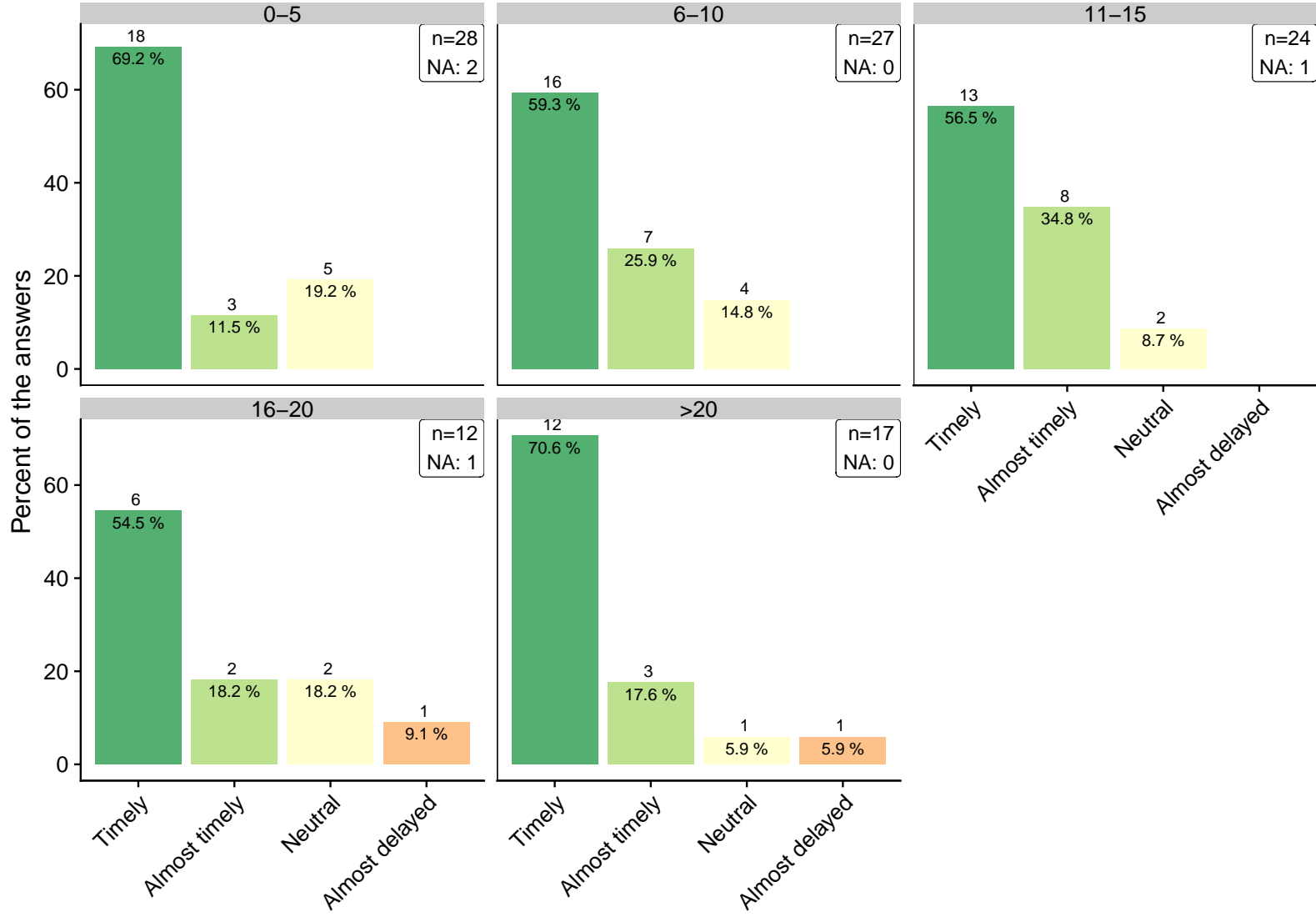




6.2.2 Stratified by years working in research





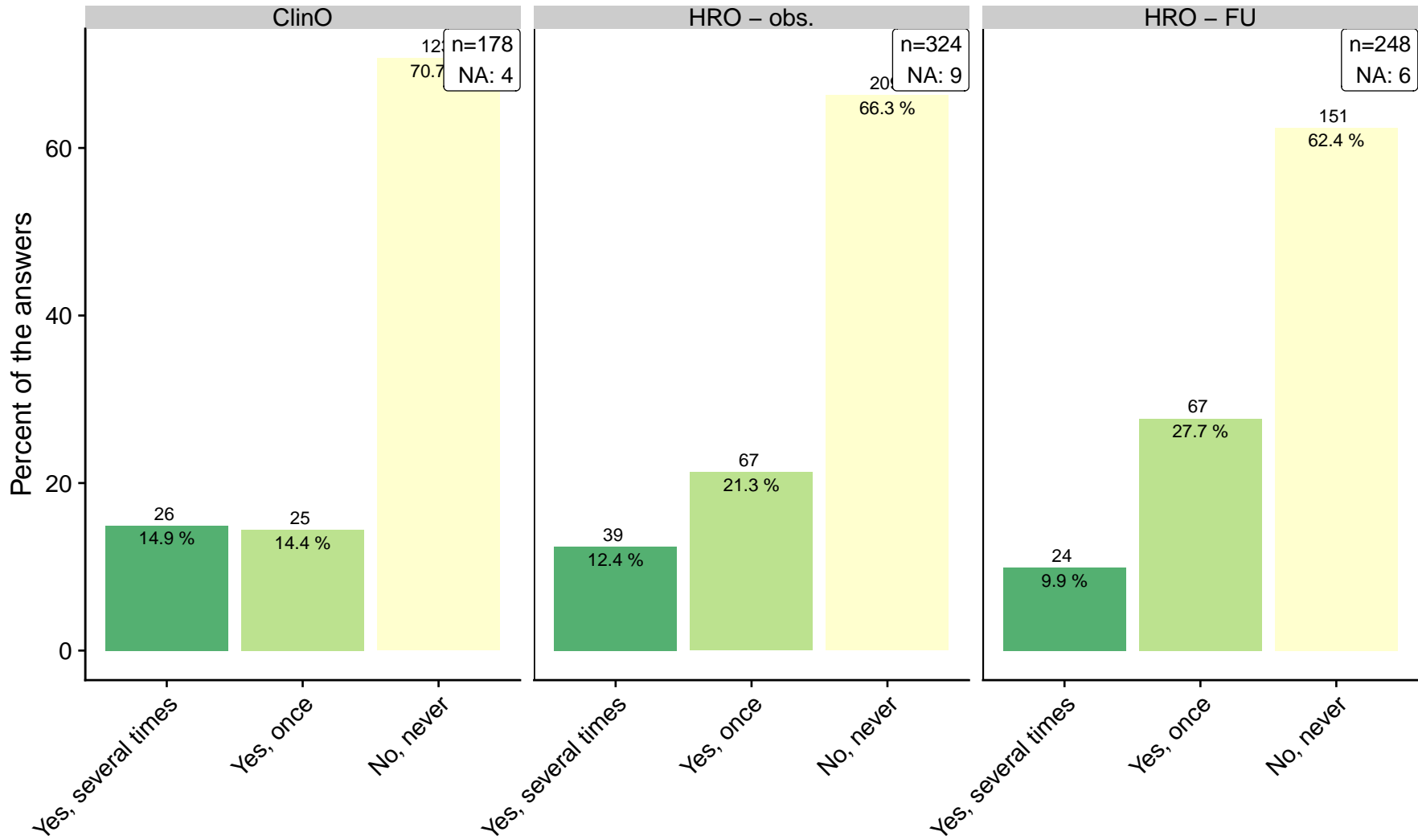


7 Question B4: Did you contact the Ethics Committee for questions or advice about the design or planning of your project?

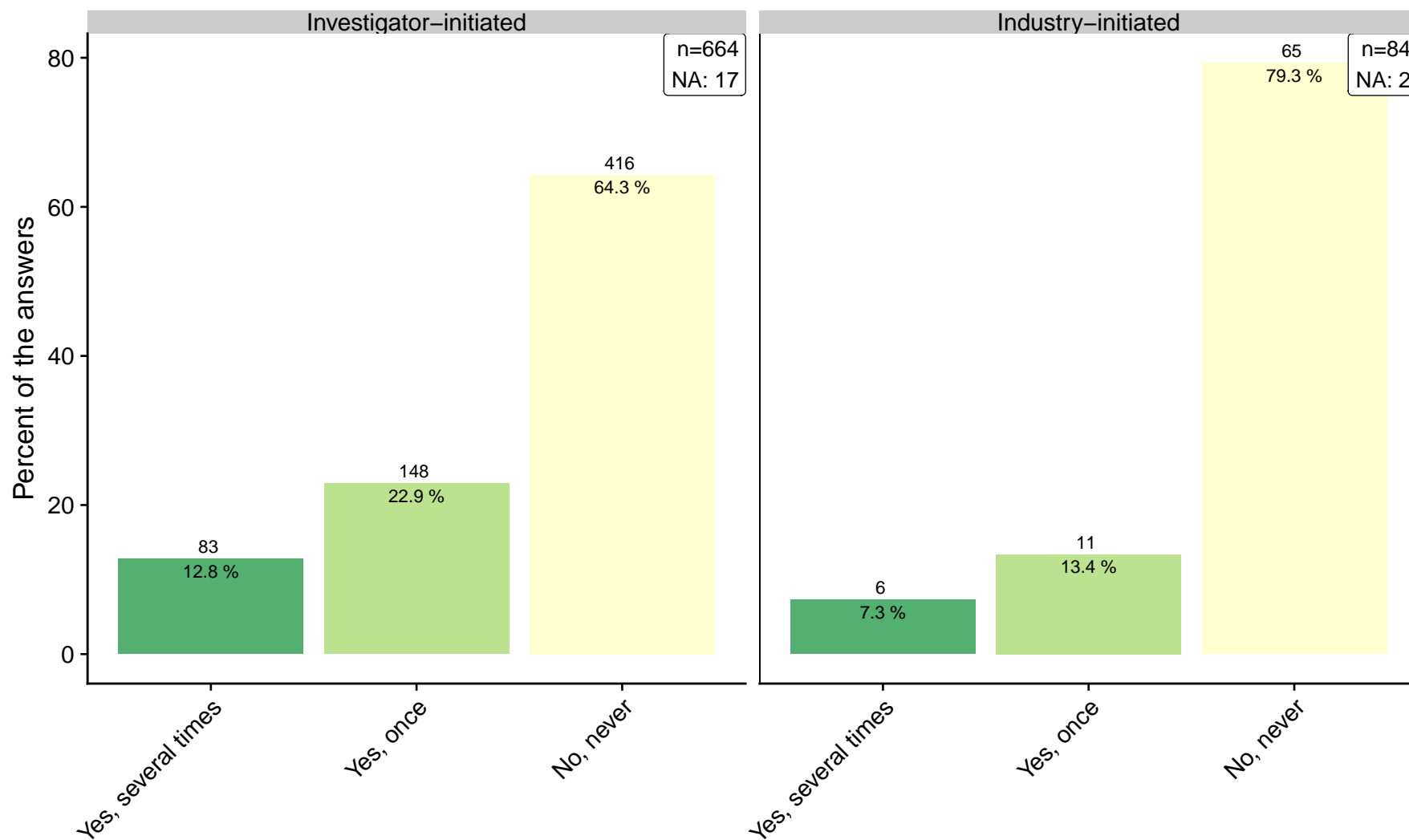
Question from IPZ / KEK-CDC Consultants: Gibt es Unterschiede in Kontakt nach Erfahrung oder Forschungsbereich?

7.1 Feedback on application stratified research details

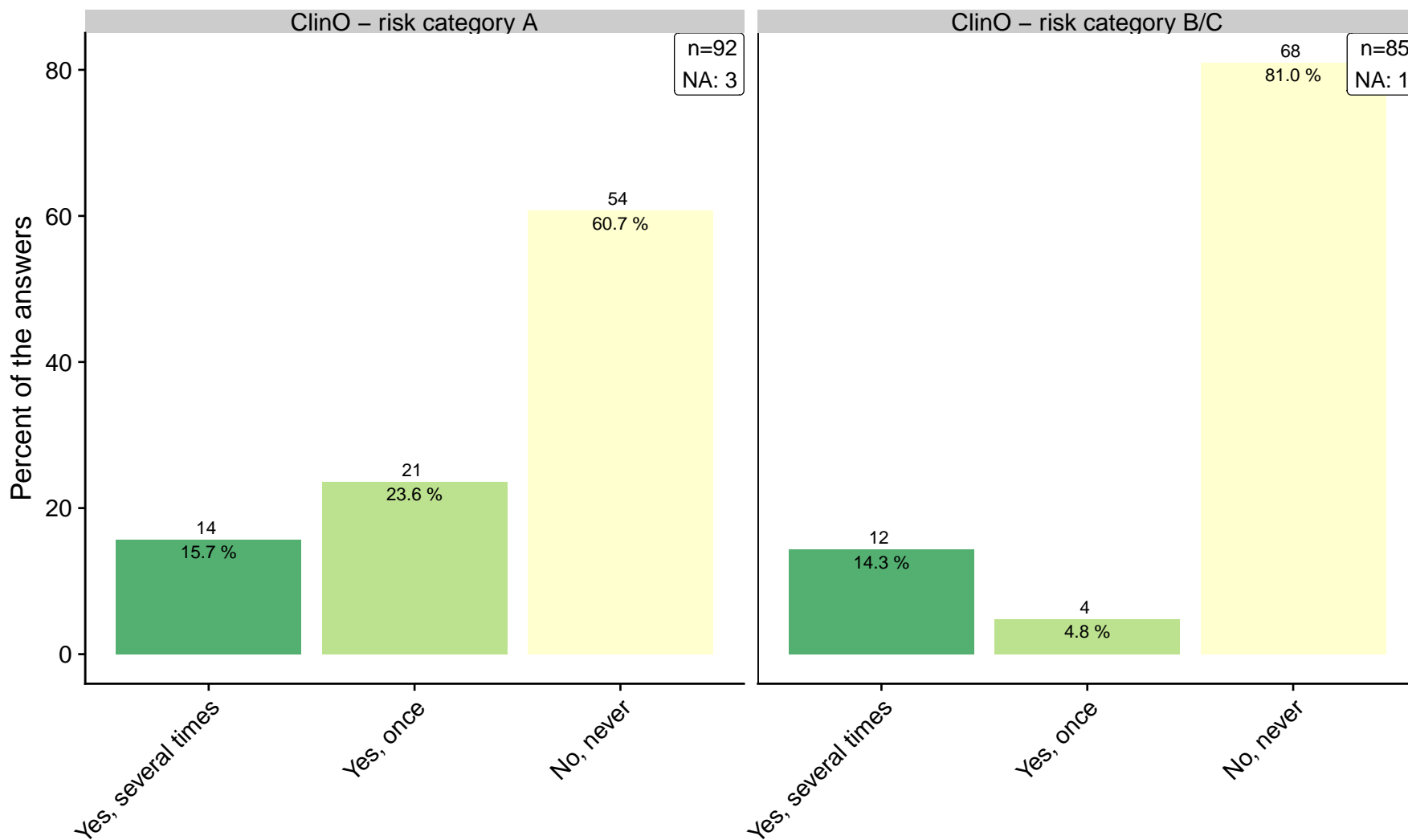
7.1.1 Stratified by research type



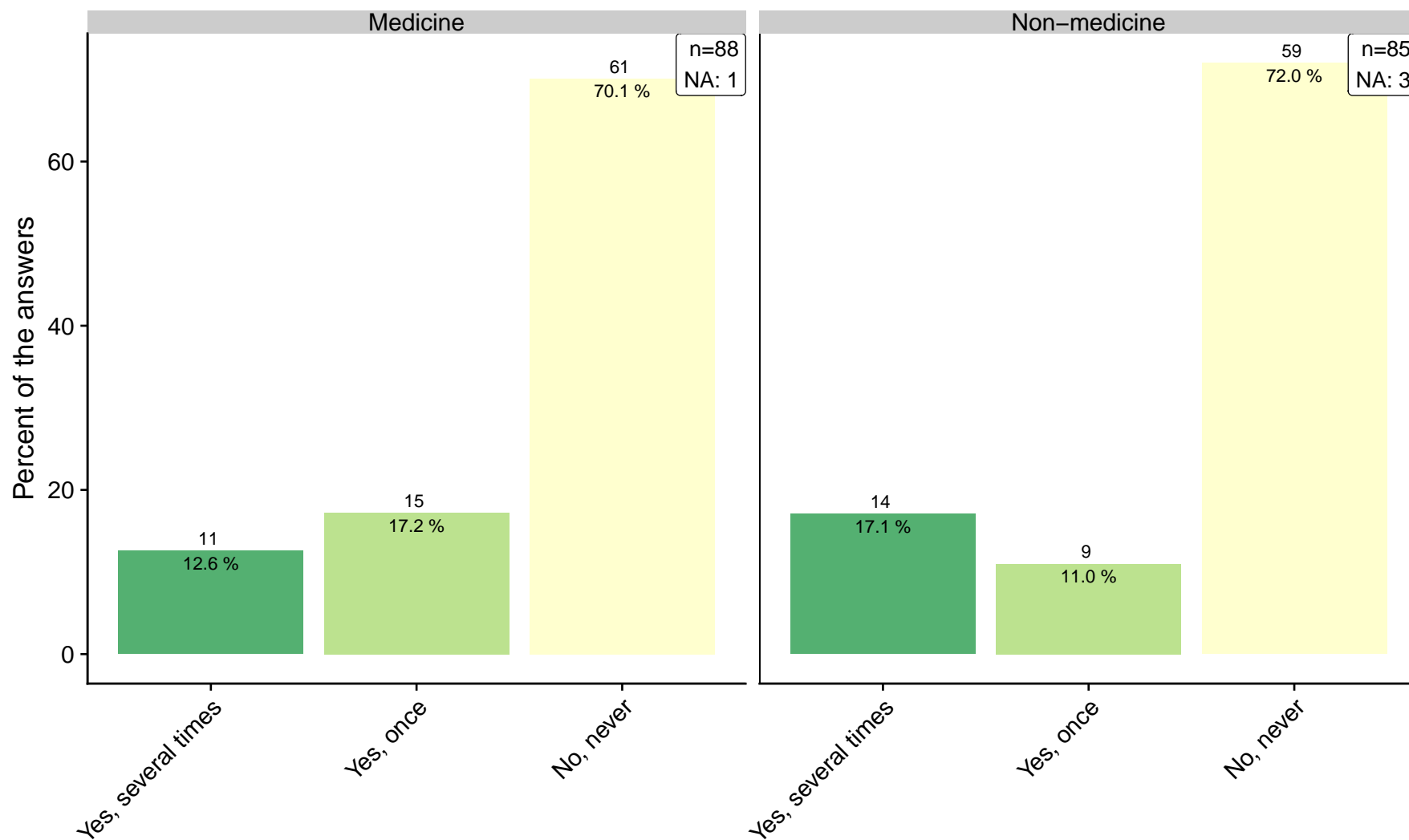
7.1.2 Stratified by initiator



7.1.3 Stratified by risk category

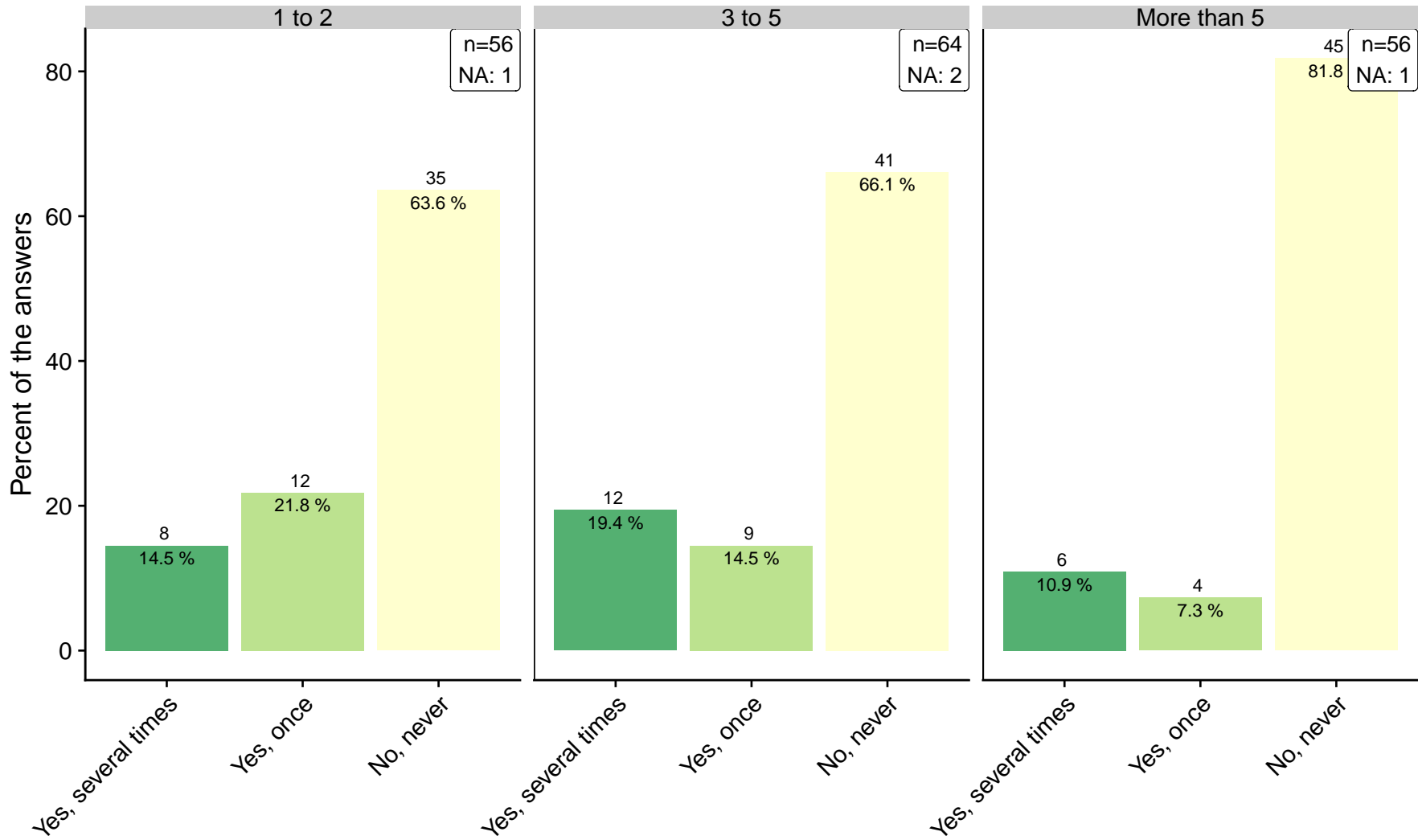


7.1.4 Stratified by field

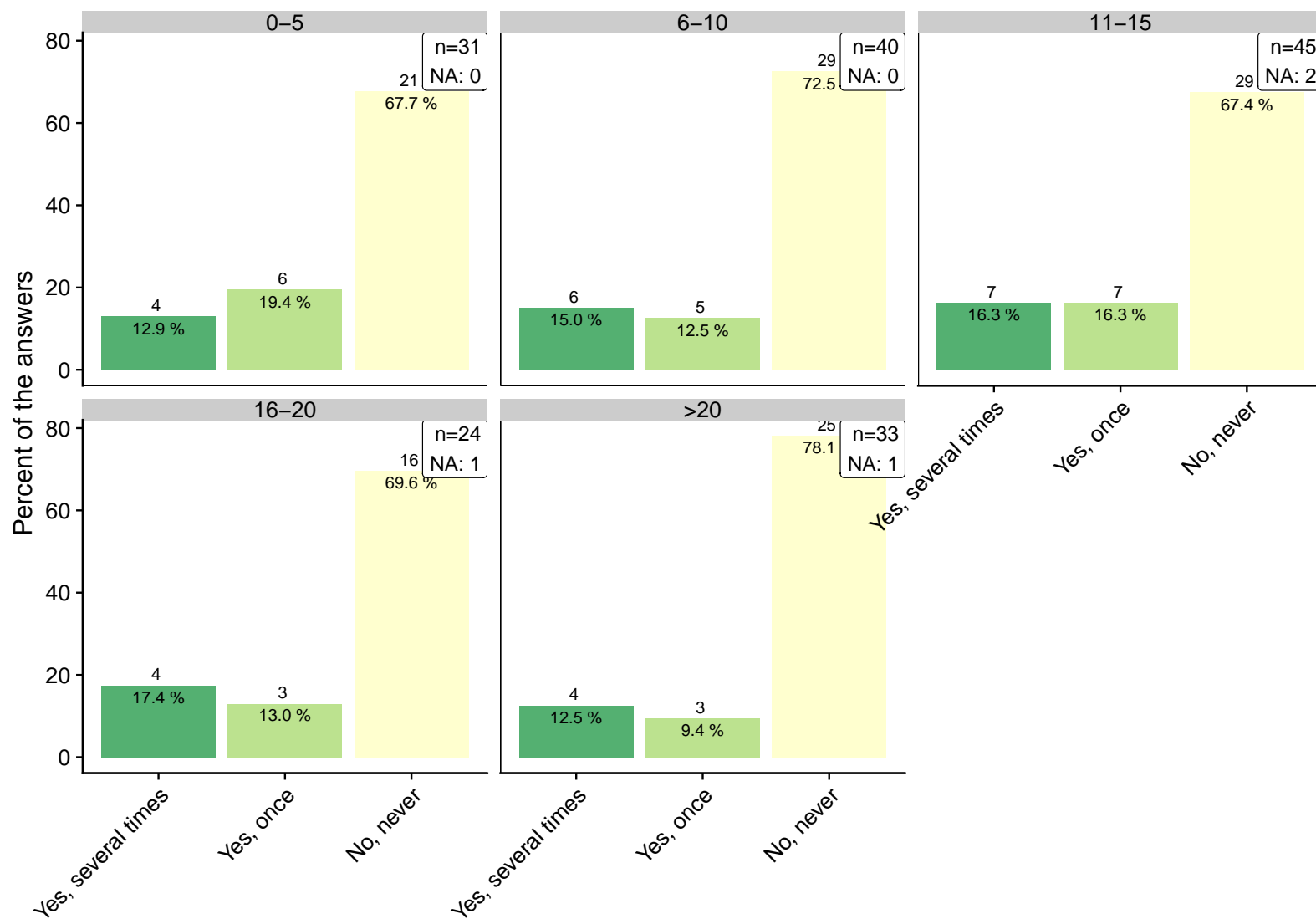


7.2 Feedback on application stratified by experience of the researcher

7.2.1 Stratified by number of submitted EC projects since HRA



7.2.2 Stratified by years working in research



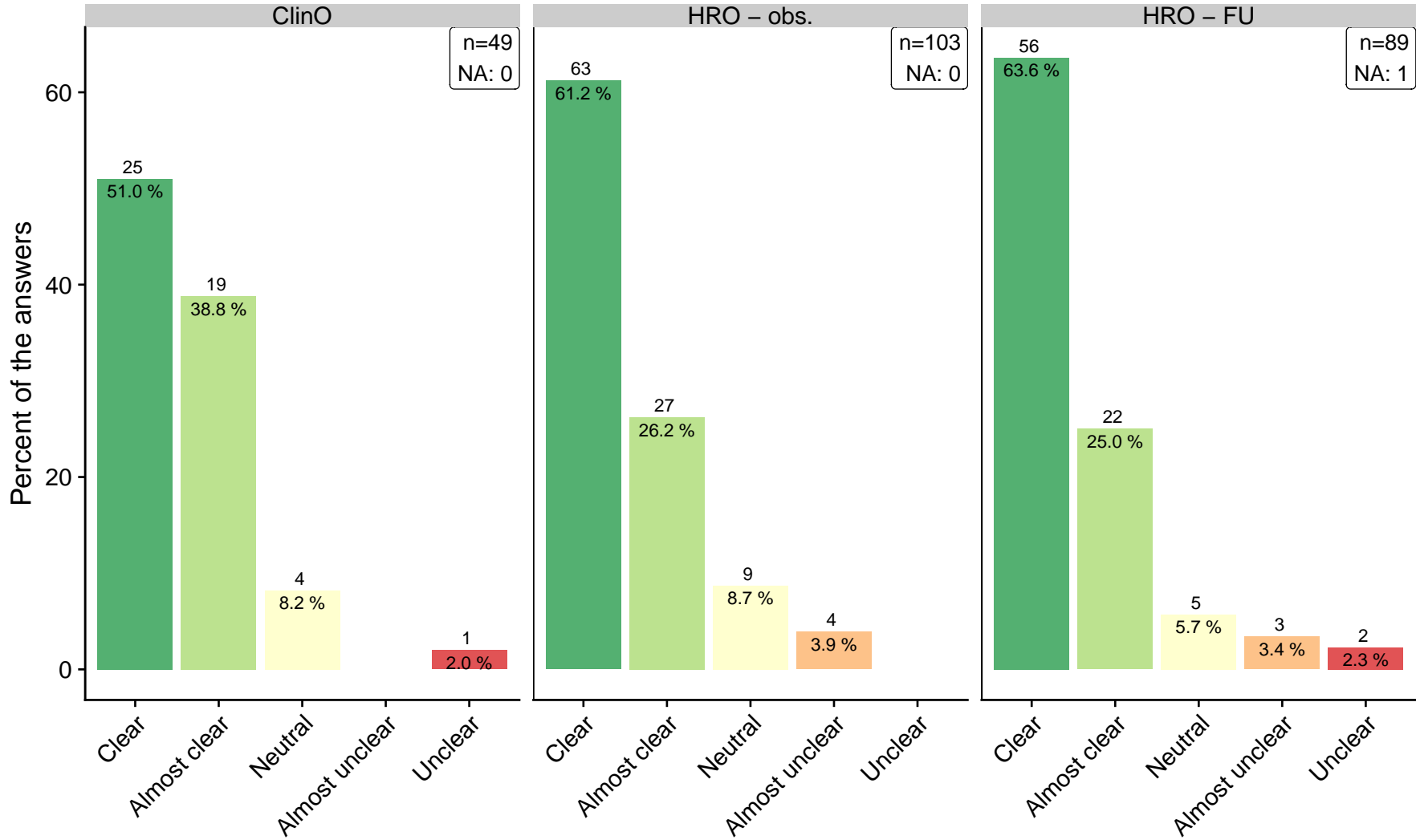
8 Question B4c: Adjectives that best describe the answers received by Ethics Committee or swissethics

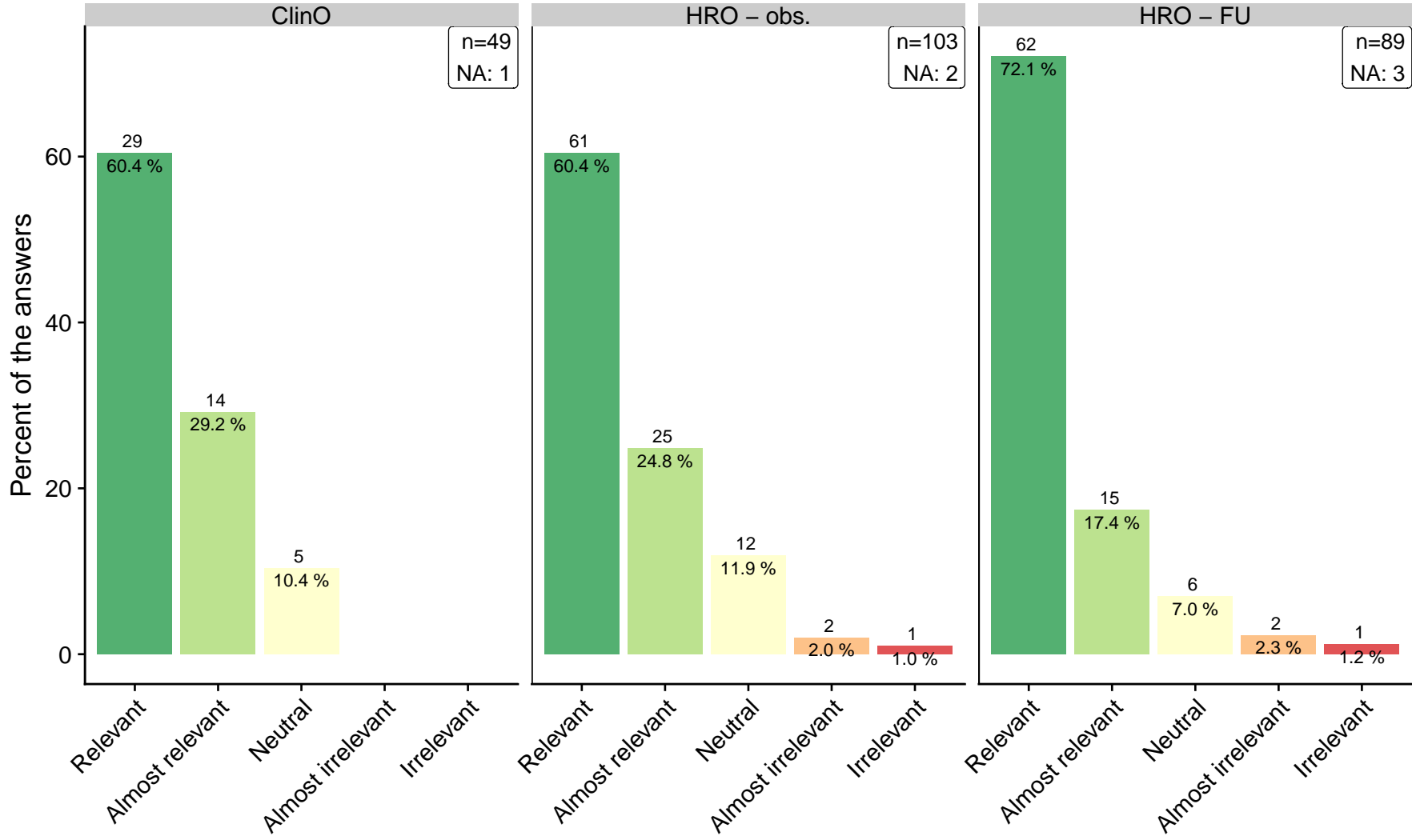
Note: These questions were only asked if the previous question was answered with 'Always', 'Often' or 'Sometimes' (n=241)

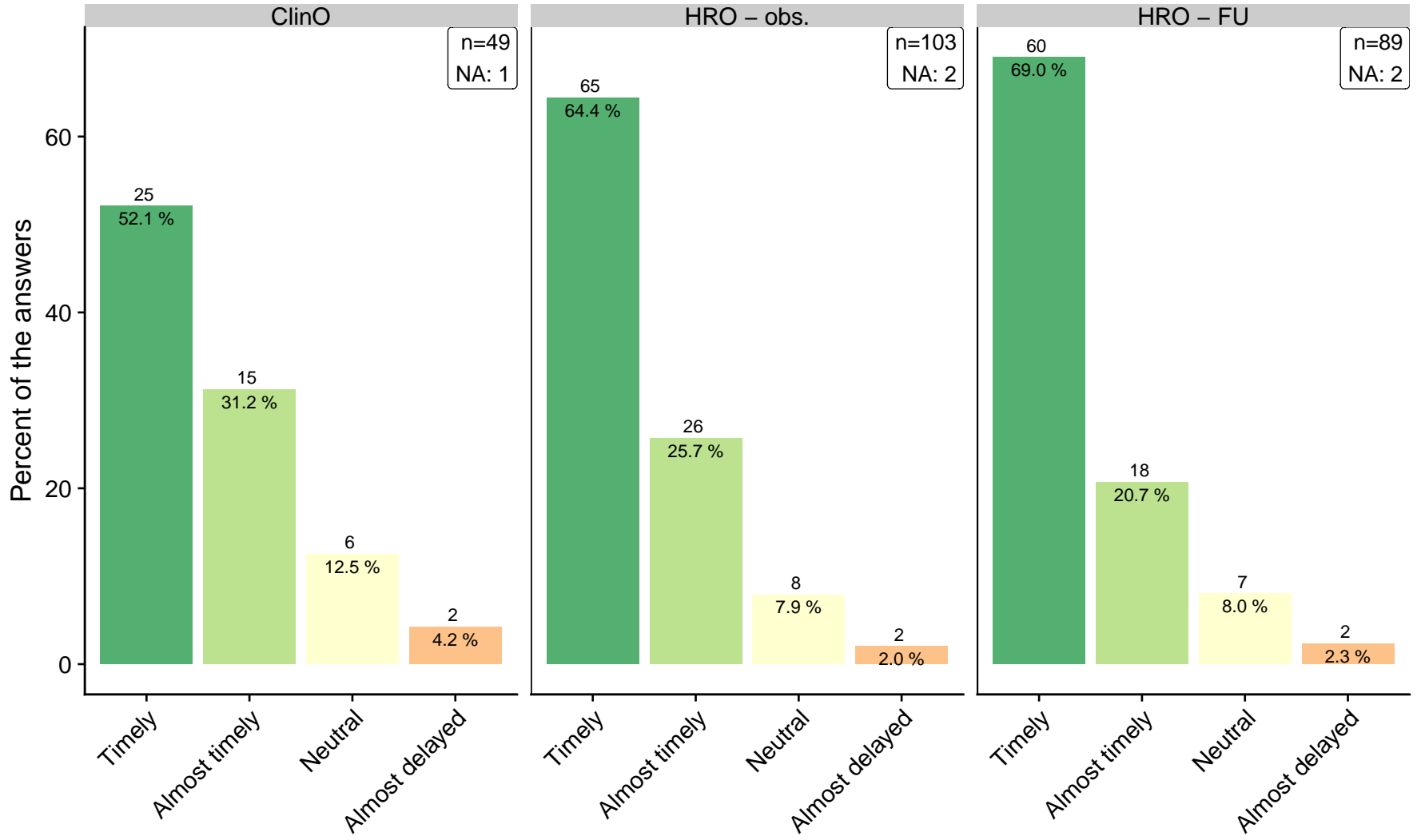
Question from IPZ / KEK-CDC Consultants: Gibt es Unterschiede in Kontakt nach Erfahrung oder Forschungsbereich?

8.1 Feedback on application stratified research details

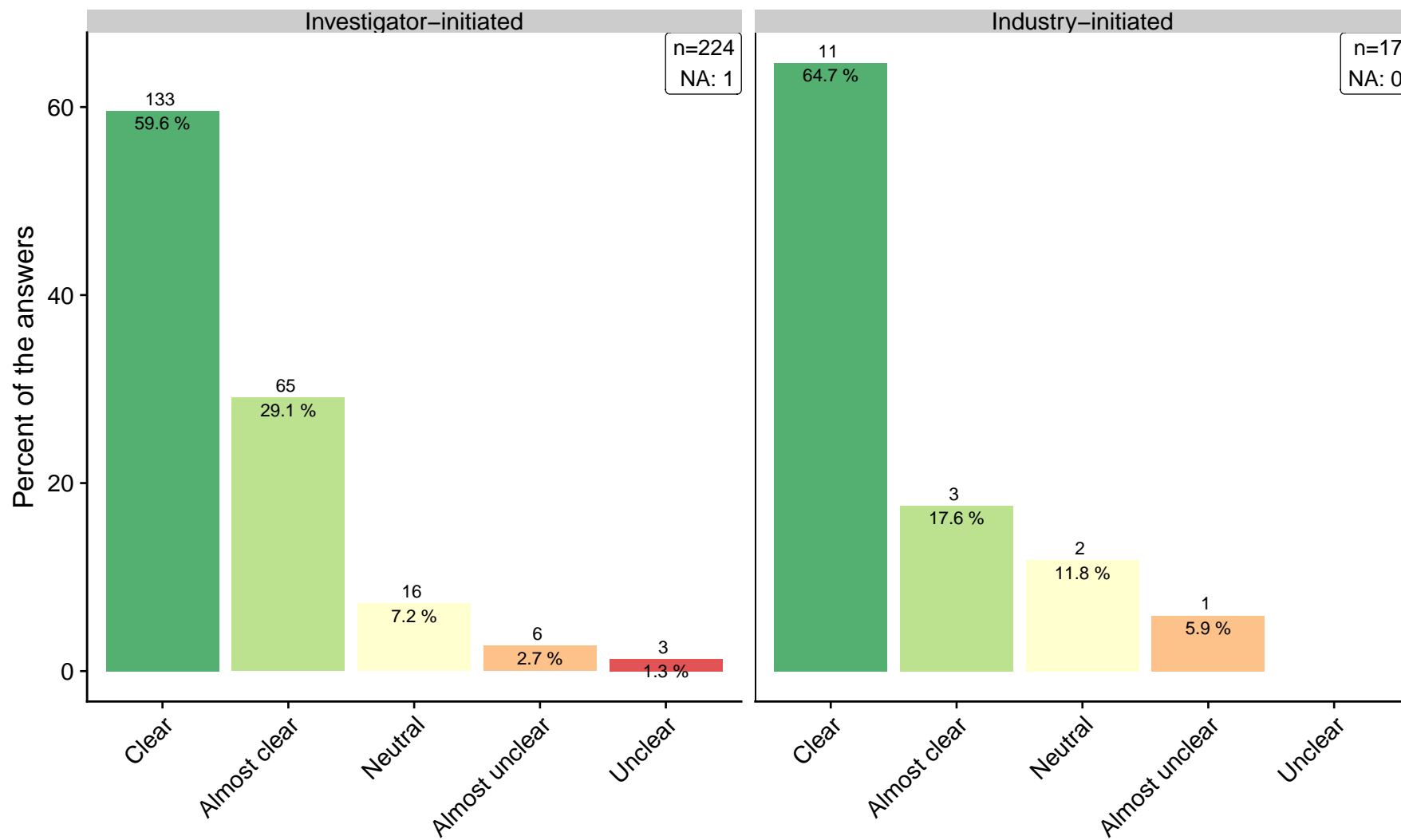
8.1.1 Stratified by research type

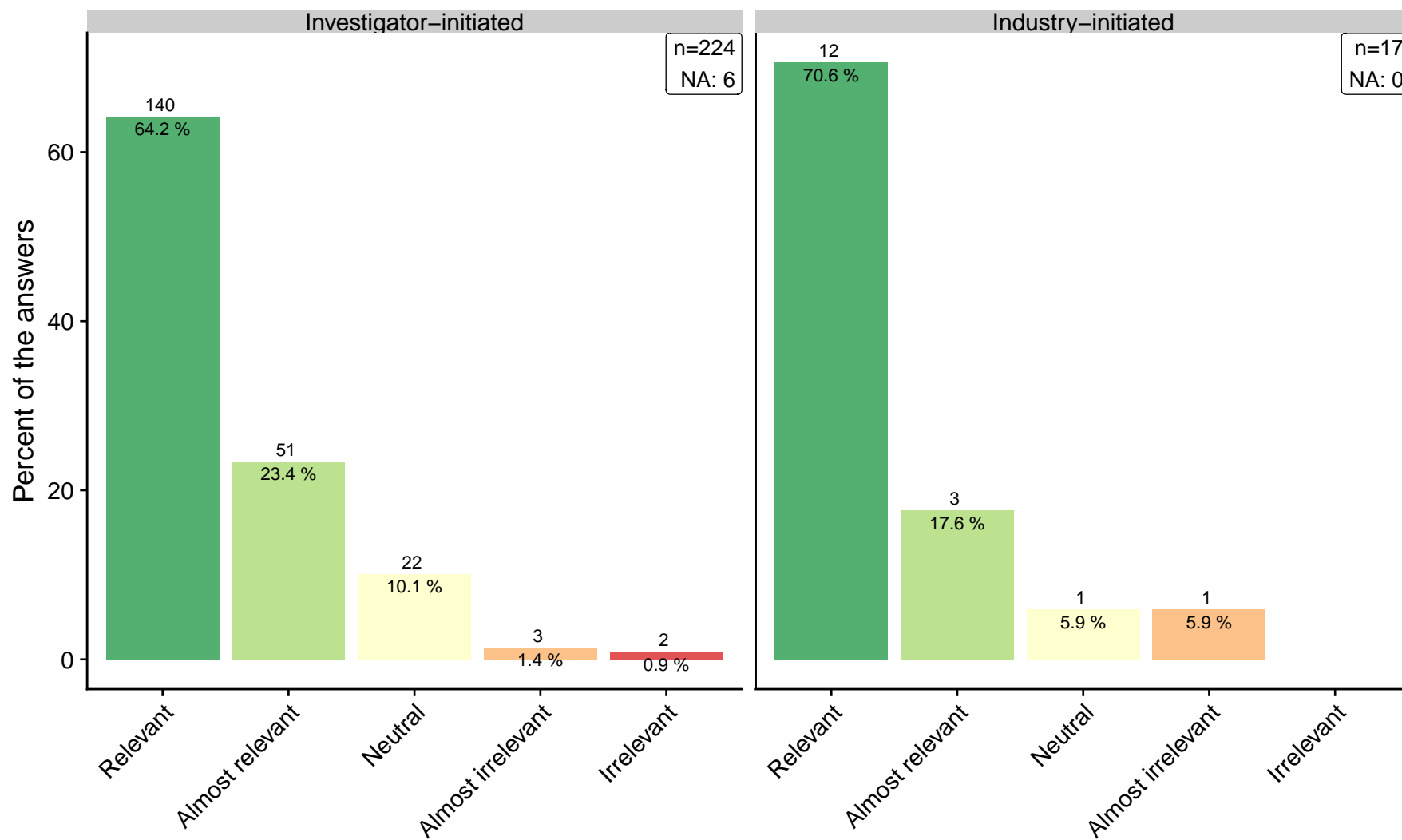


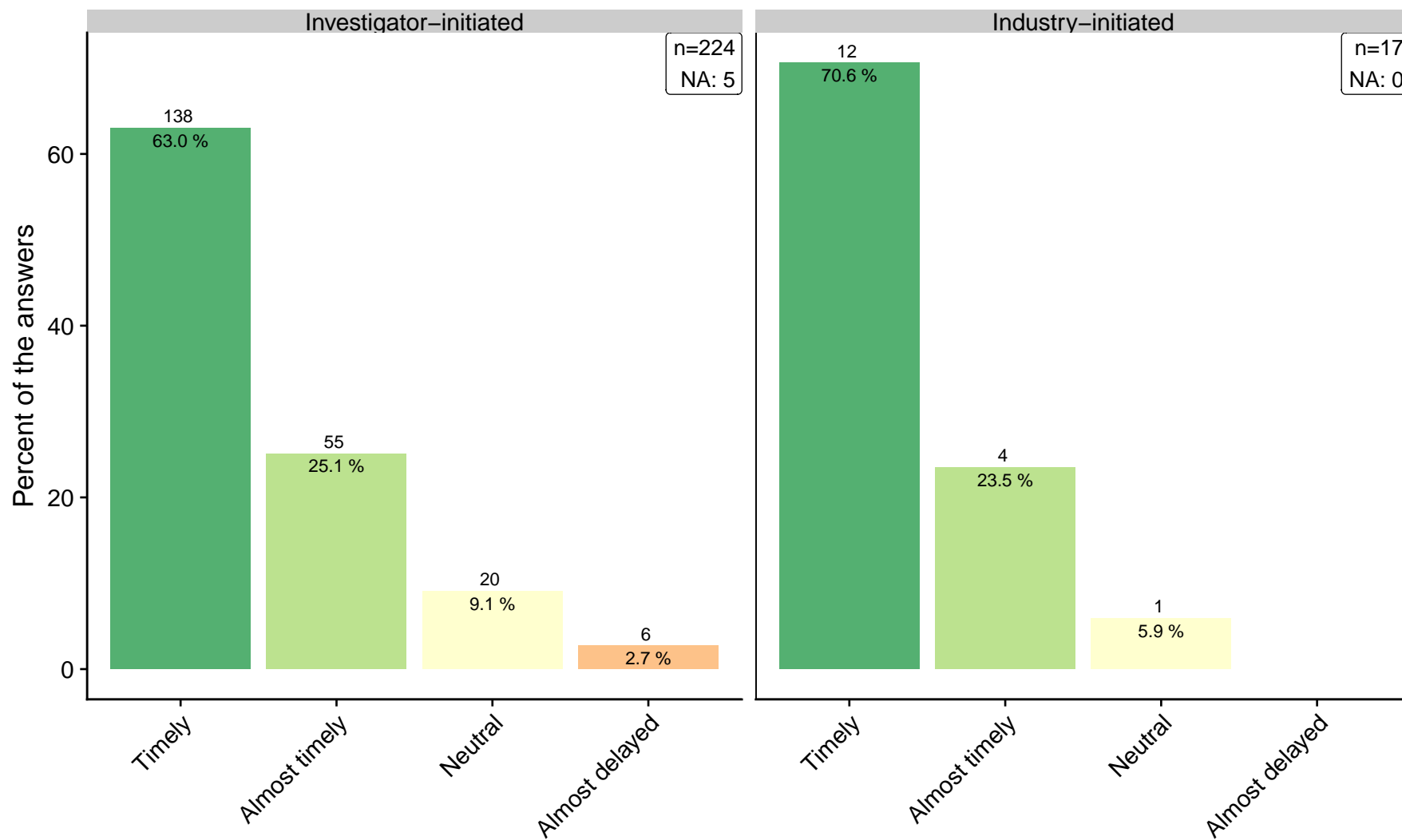




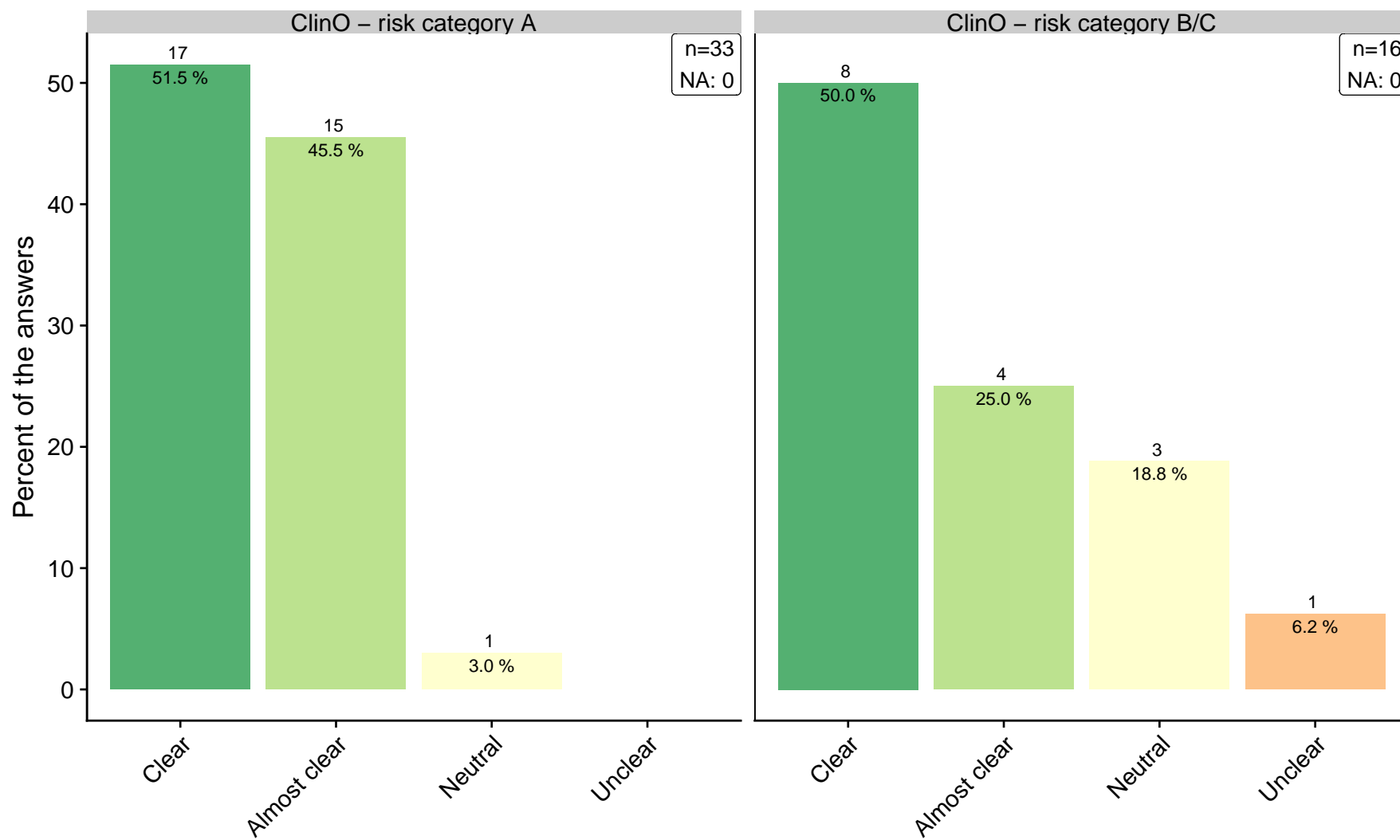
8.1.2 Stratified by initiator

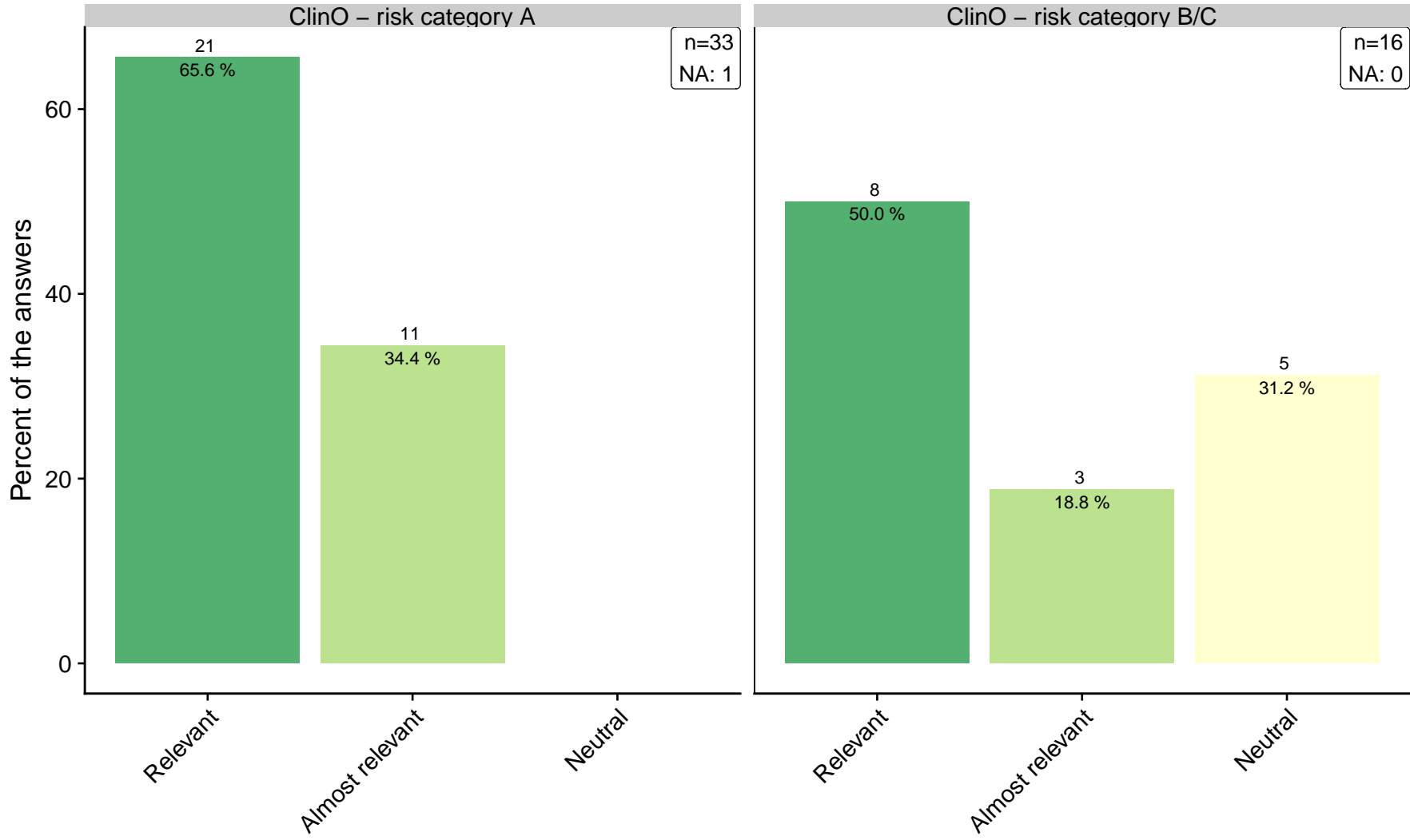


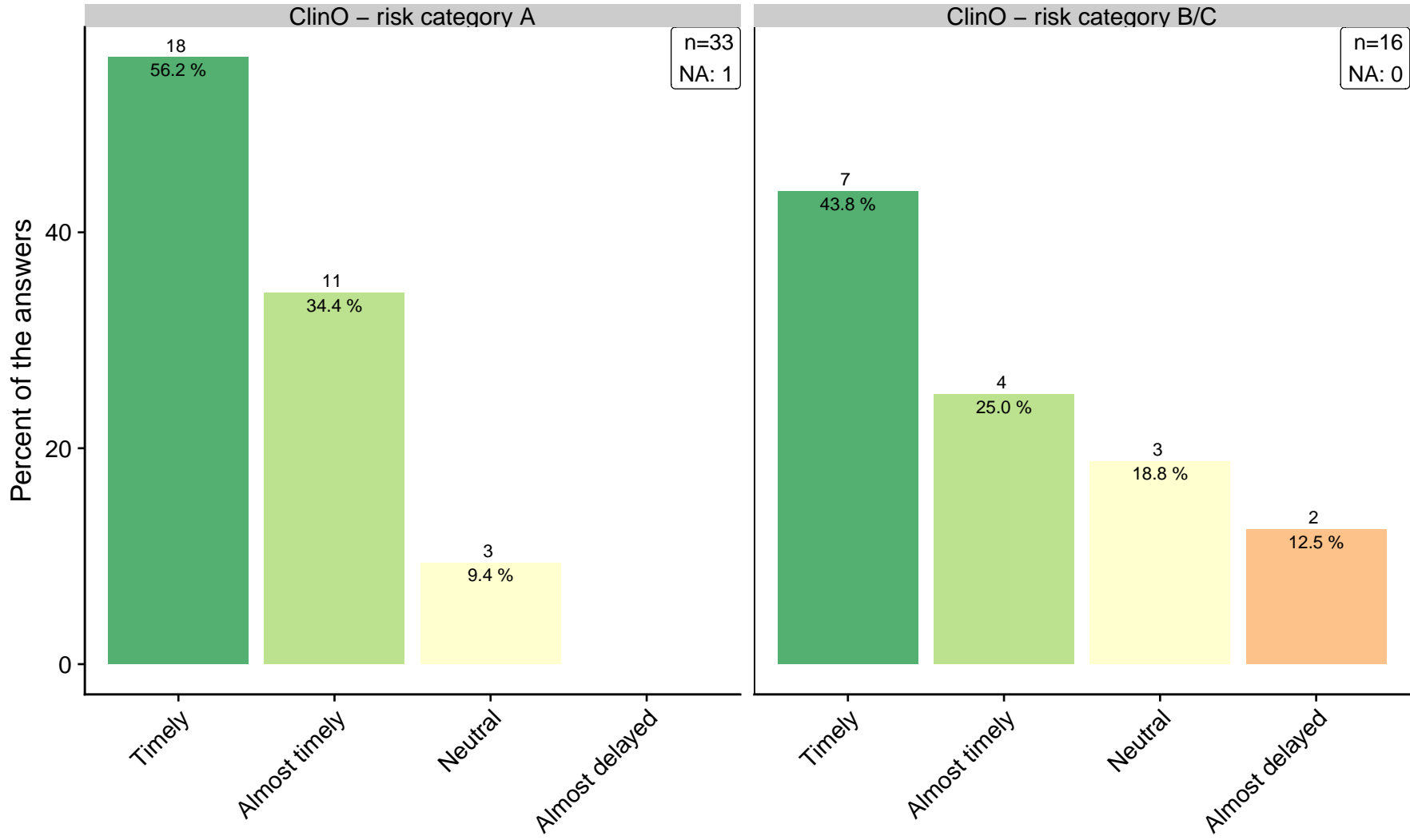




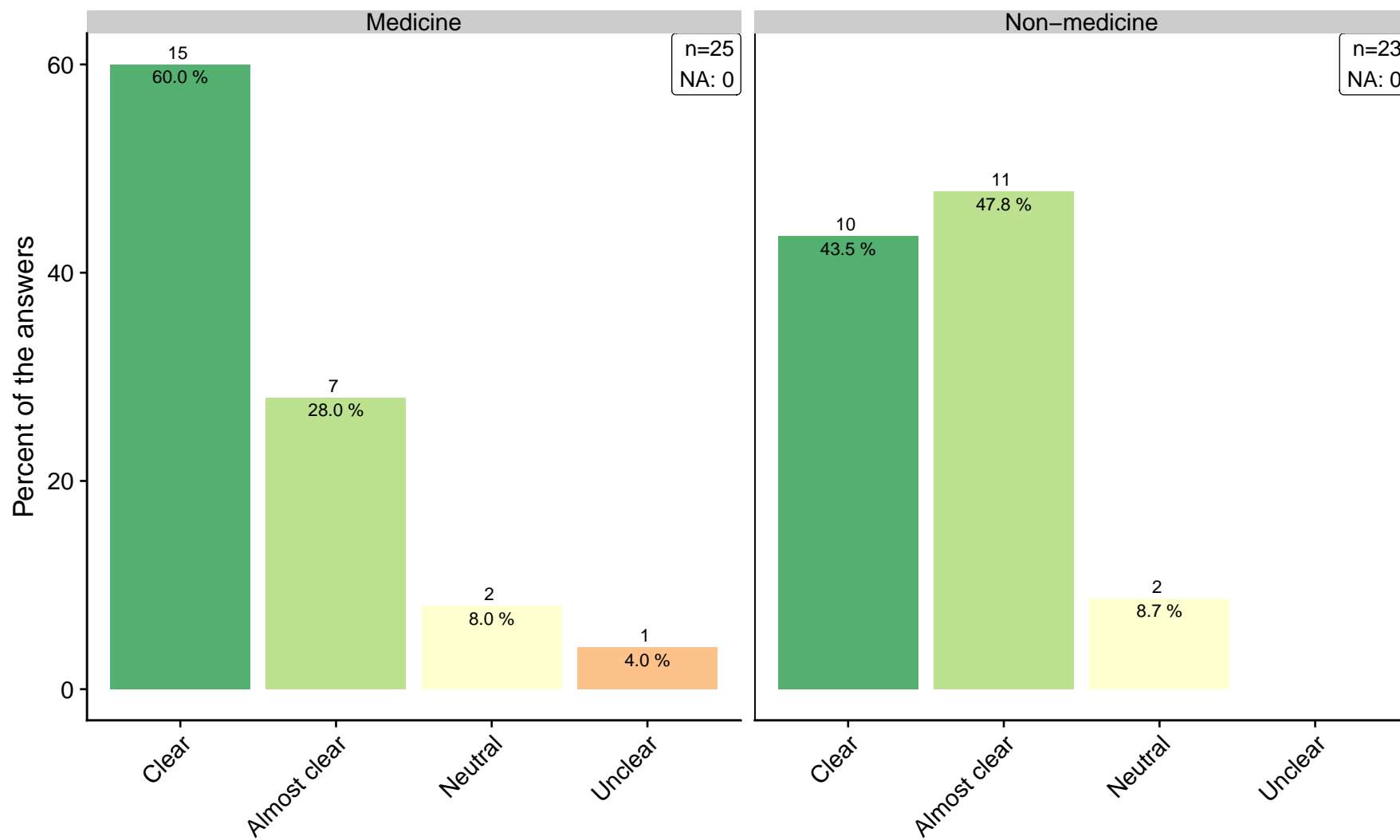
8.1.3 Stratified by risk category

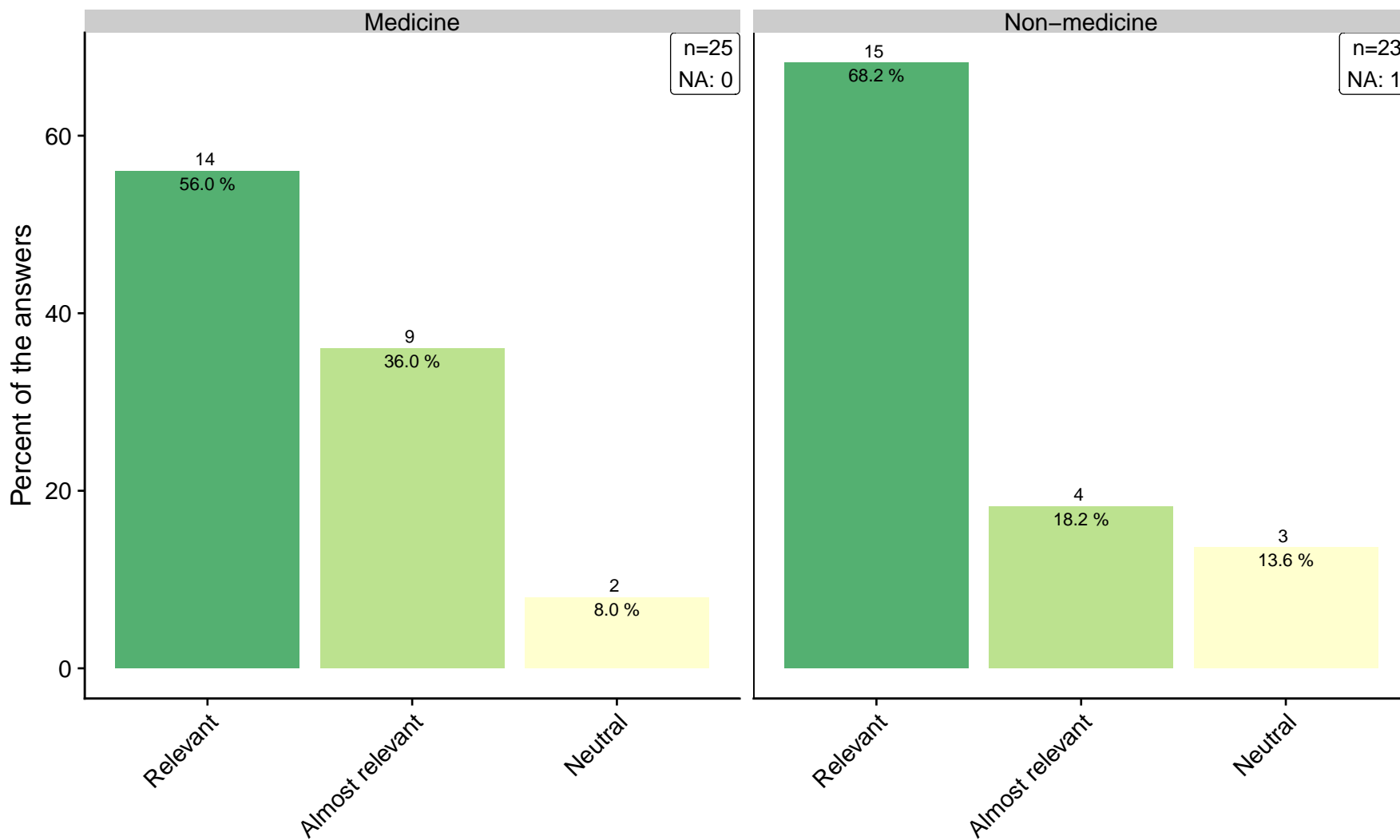


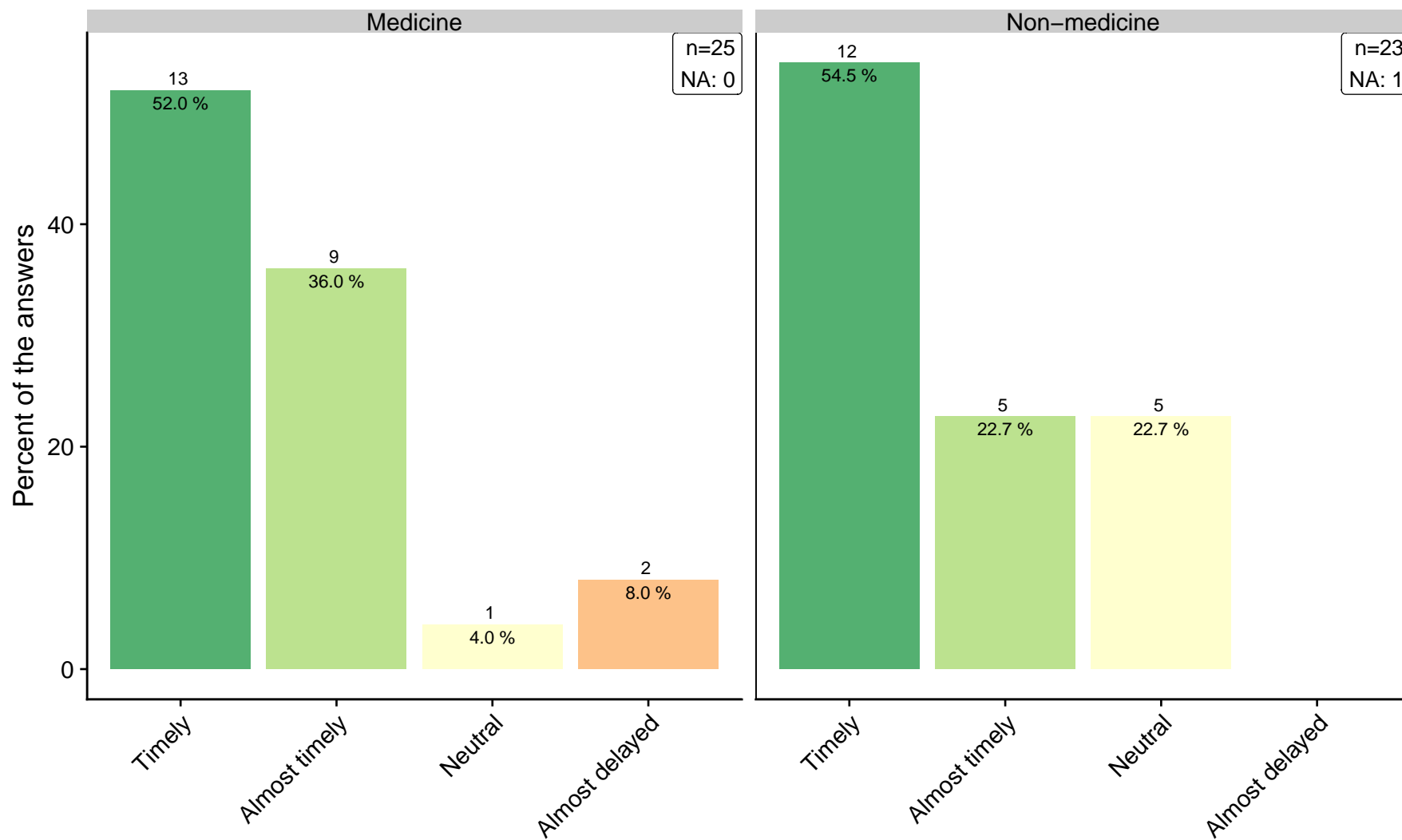




8.1.4 Stratified by field

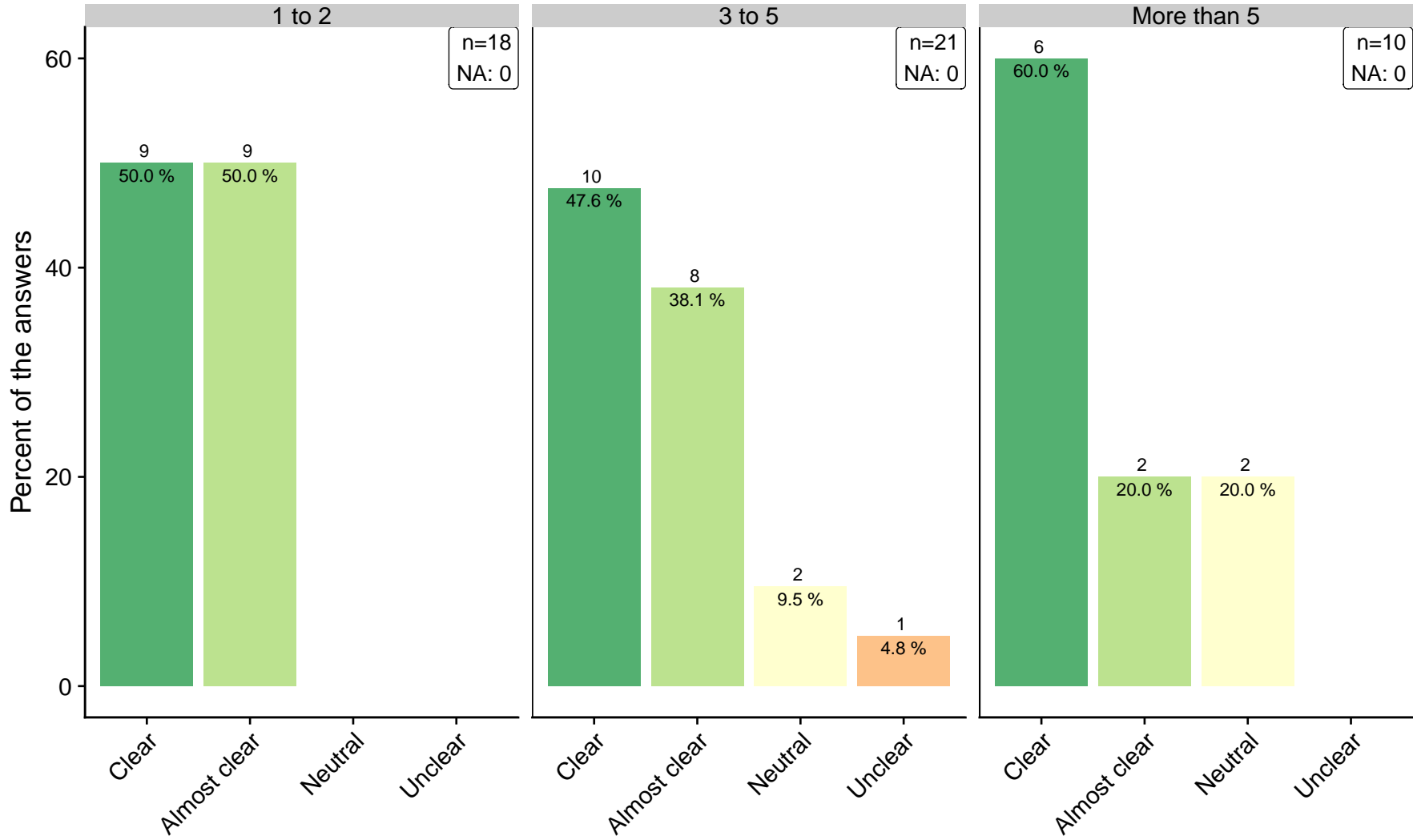


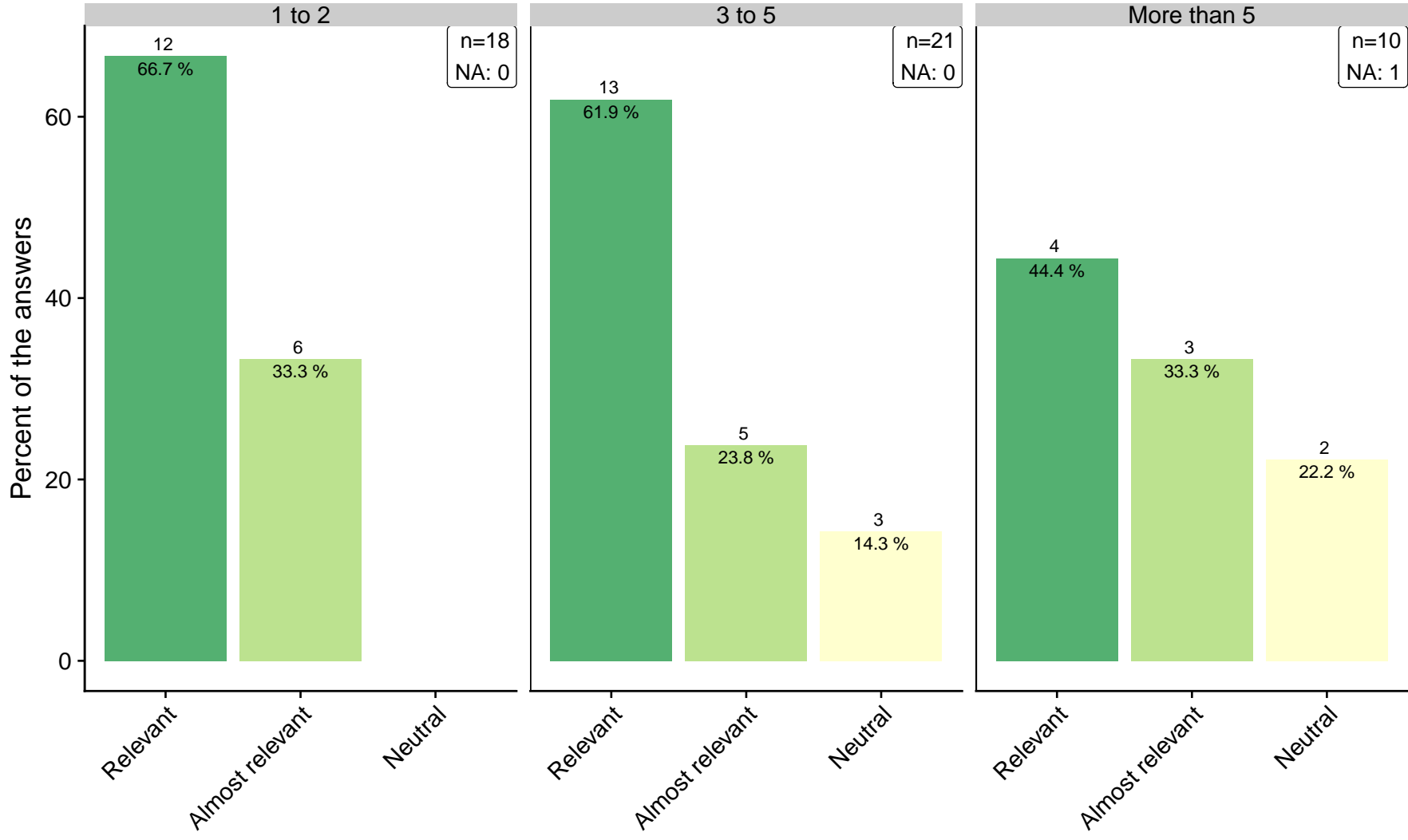


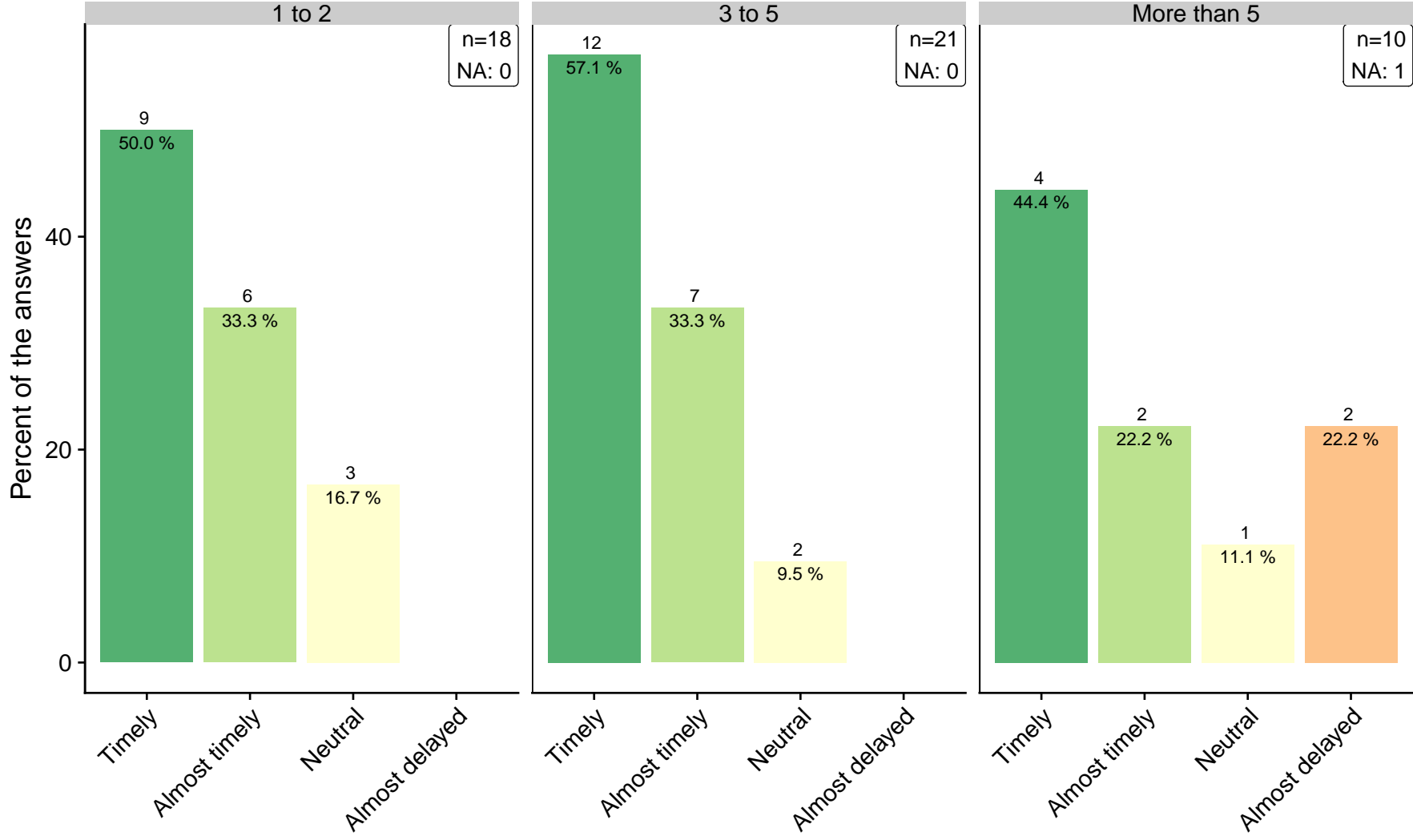


8.2 Feedback on application stratified by experience of the researcher

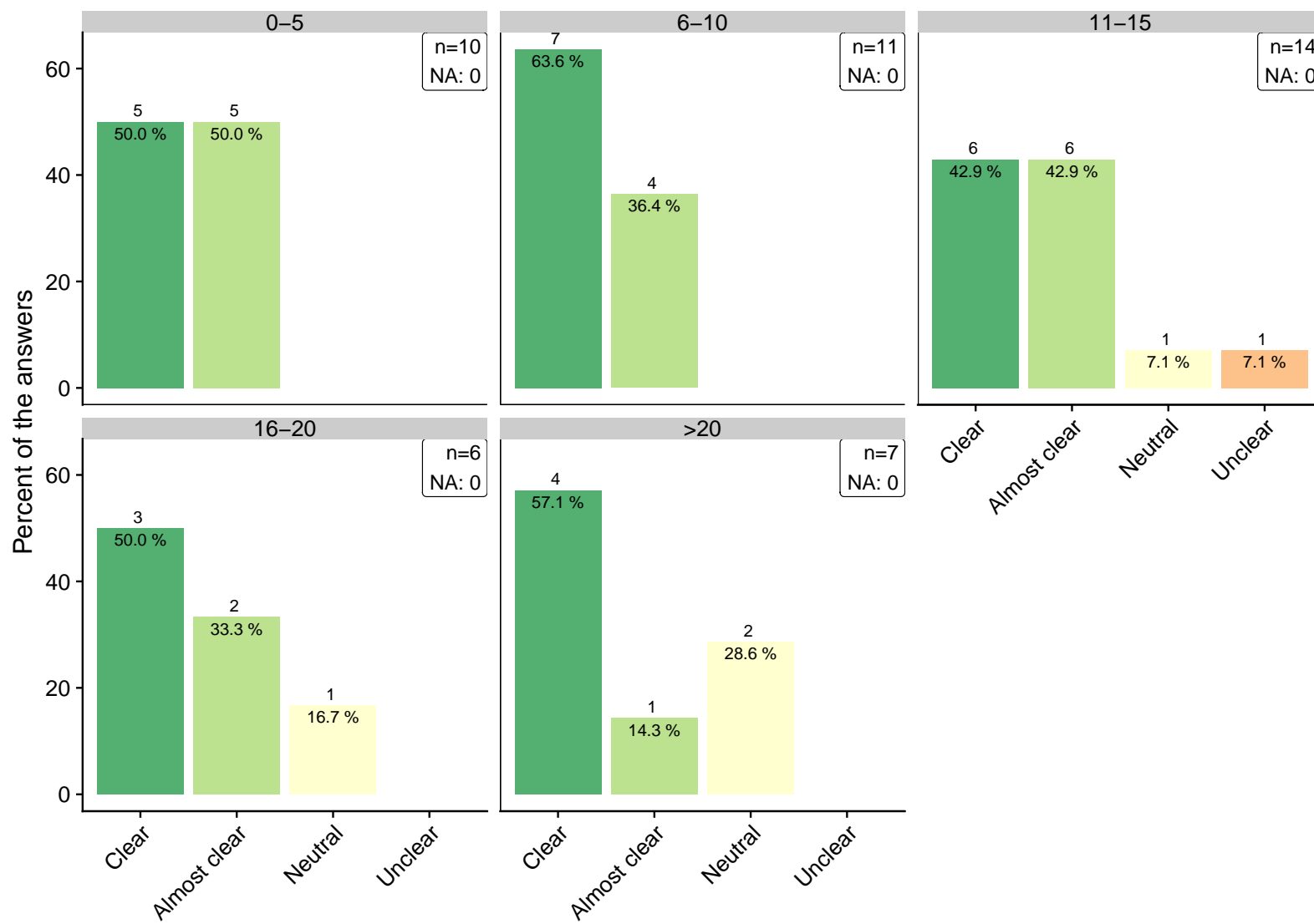
8.2.1 Stratified by number of submitted EC projects since HRA

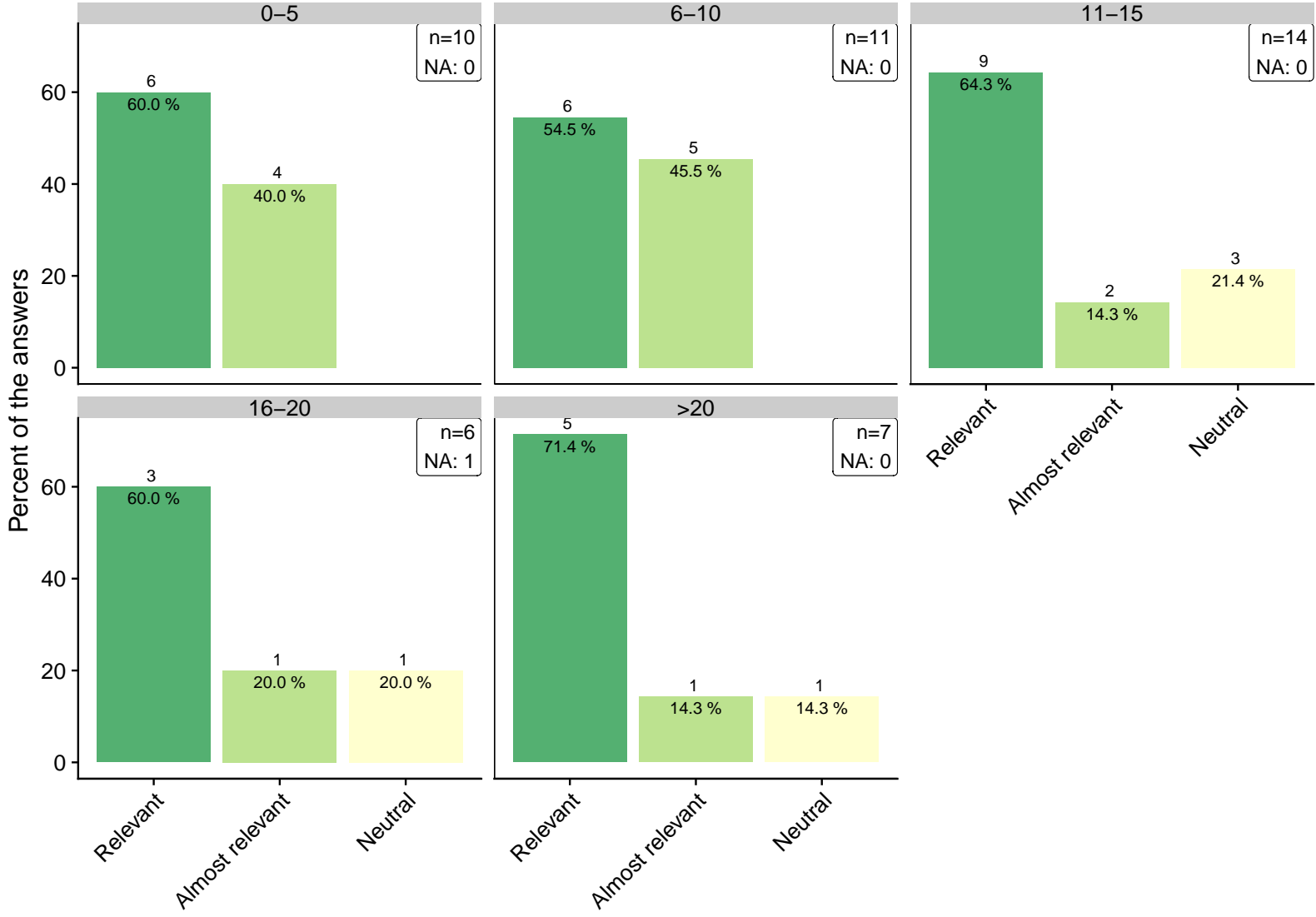


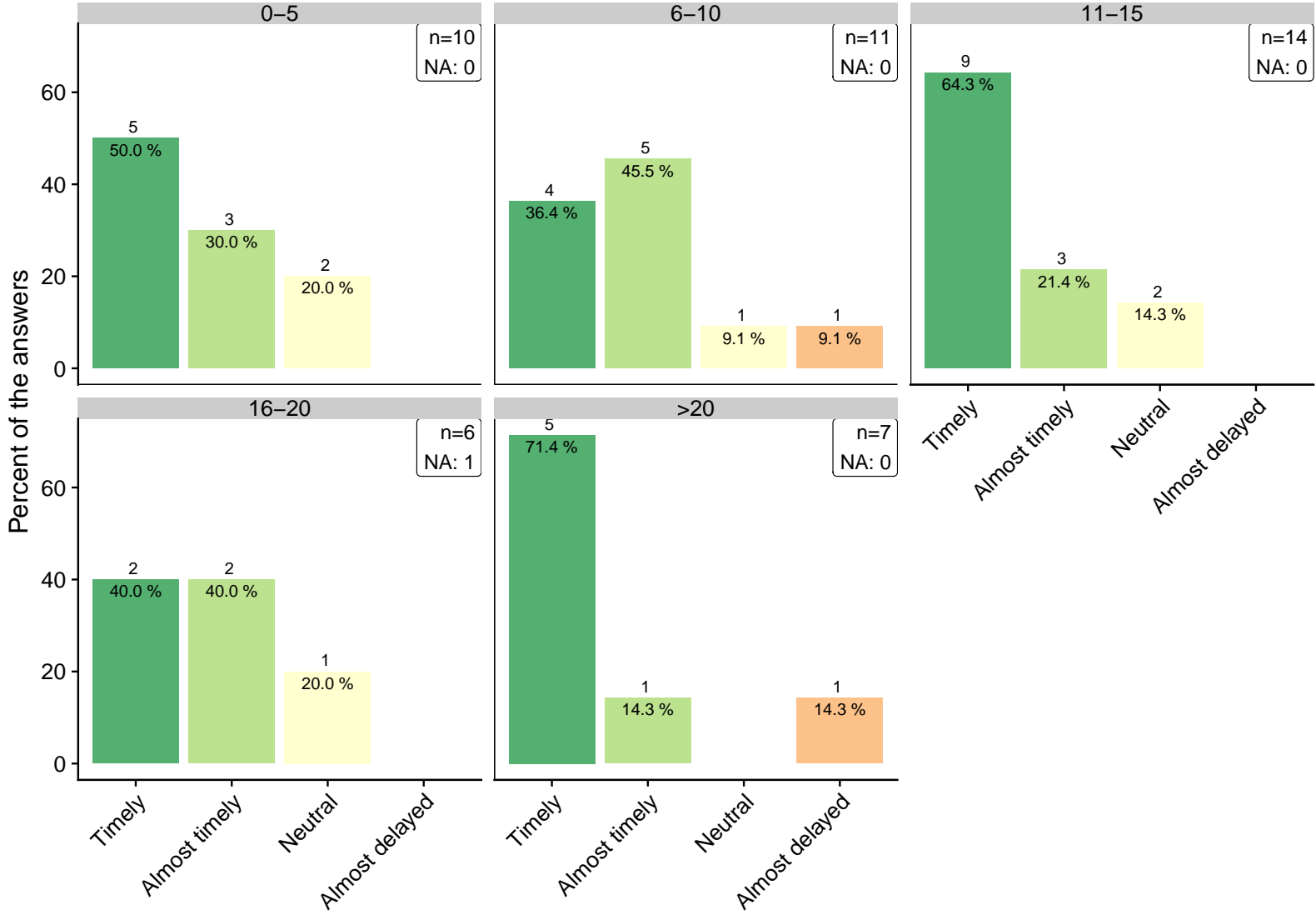




8.2.2 Stratified by years working in research







9 Question B9: Questions concerning the compliance of the project with the HRA and its ordinances - When designing or planning your project, was it difficult to determine the following aspects?

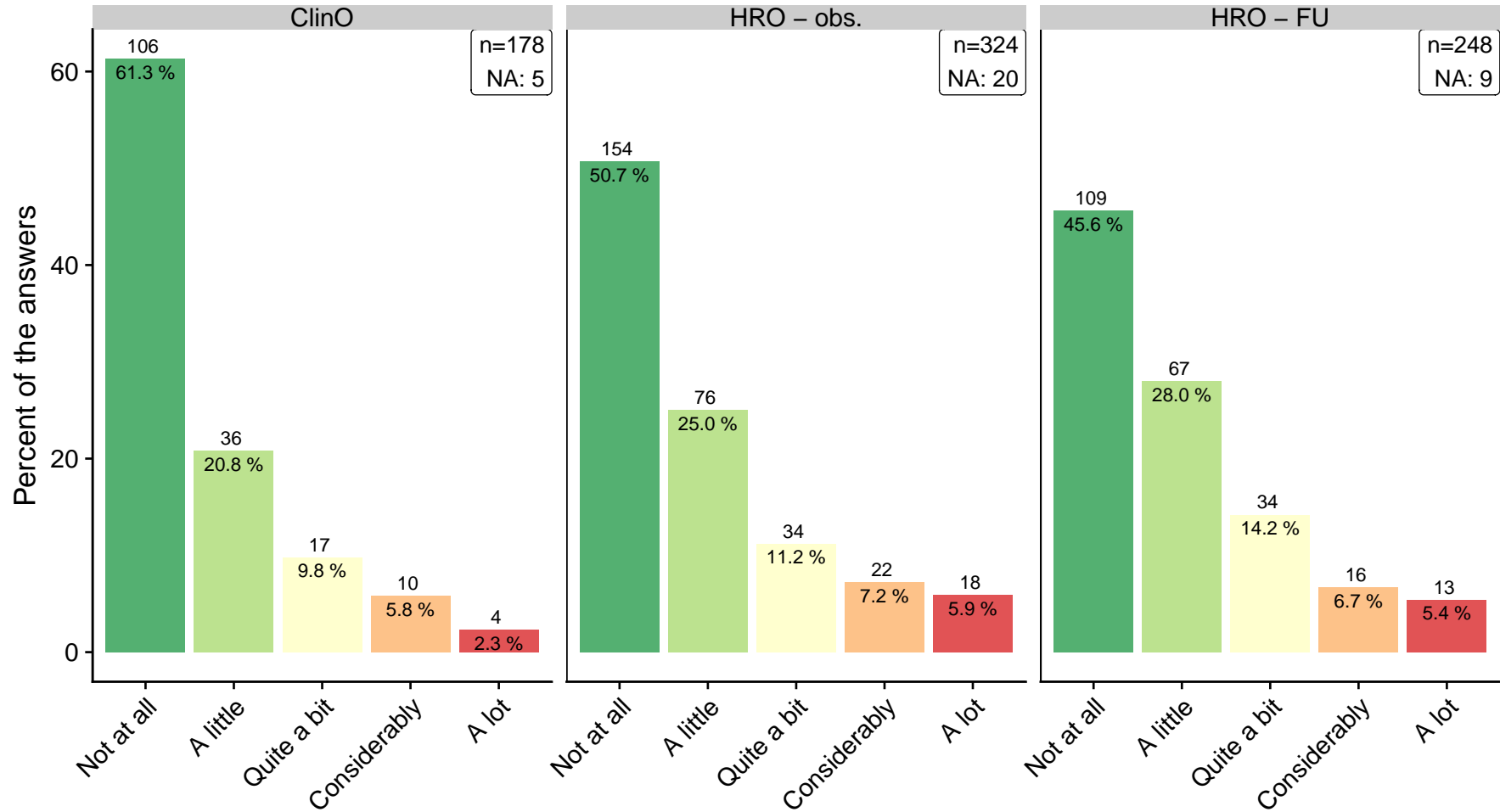
Question from IPZ / KEK-CDC Consultants: Haben sich bestimmte Forschungsbereiche bei der Bestimmung der genannten Aspekte (Geltungsbereich, Risikokategorie etc.) besonders schwer getan?

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

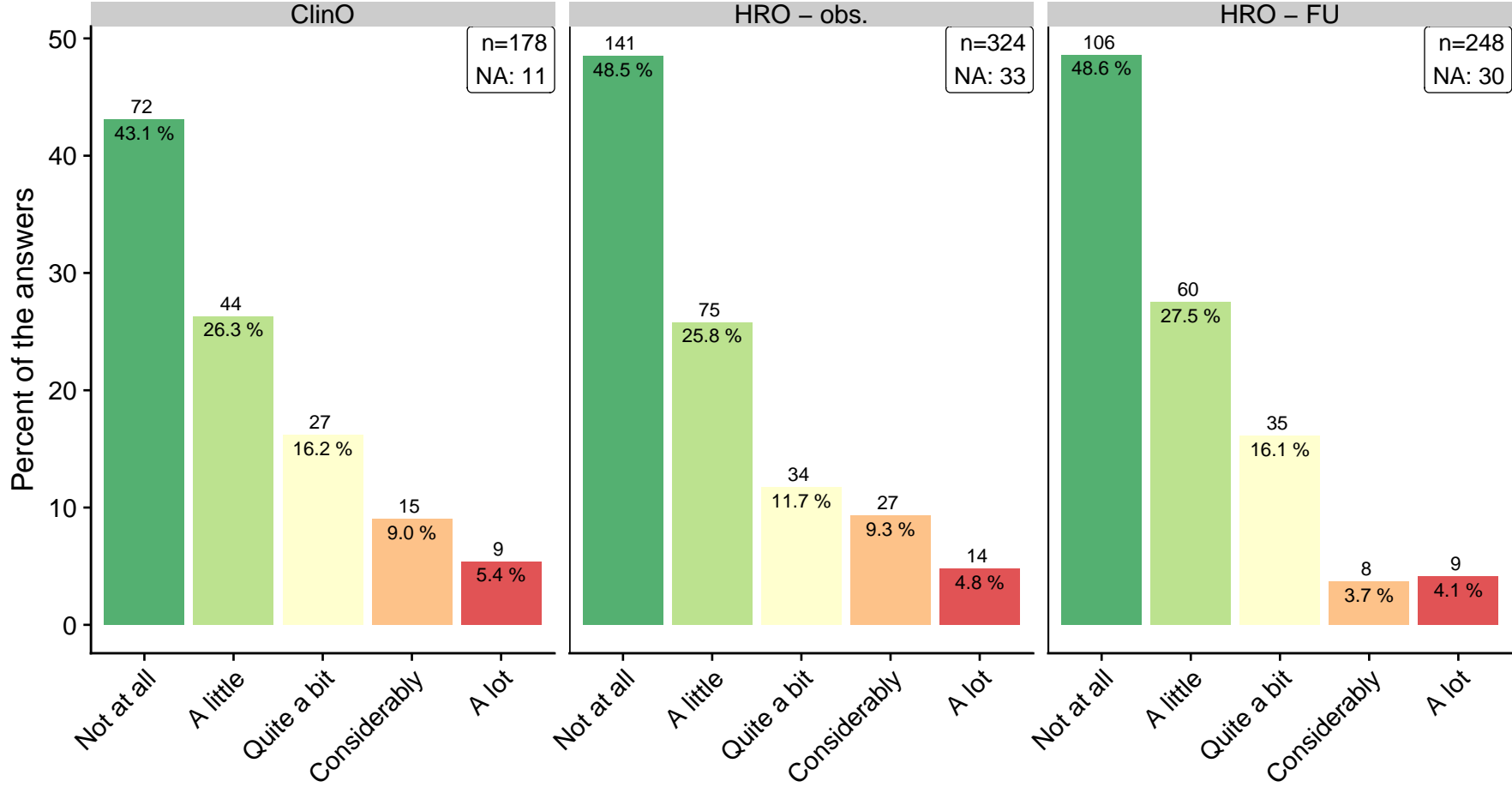
9.1 Feedback on application stratified research details

9.1.1 Stratified by research type

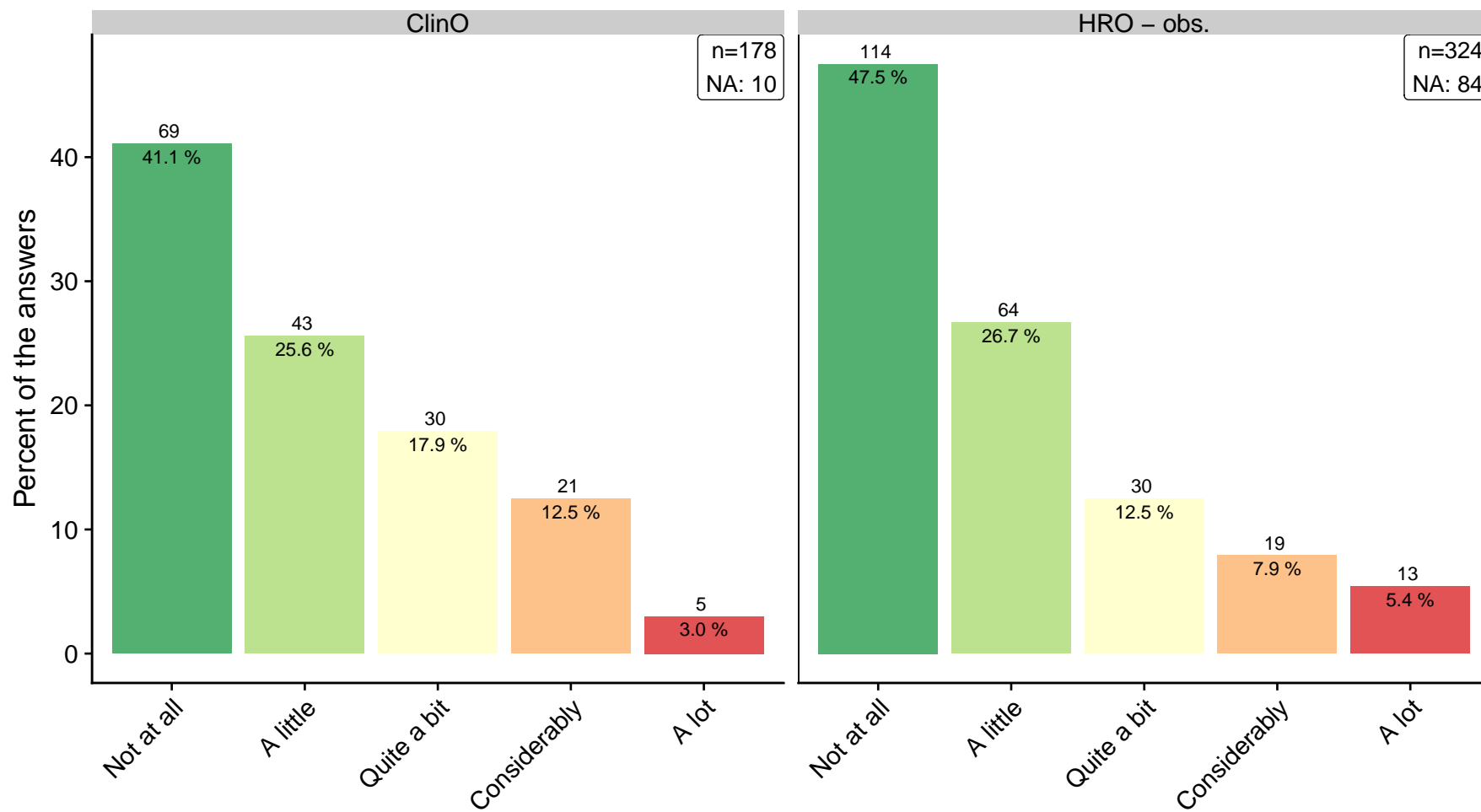
a) Whether the project is within the scope of the HRA



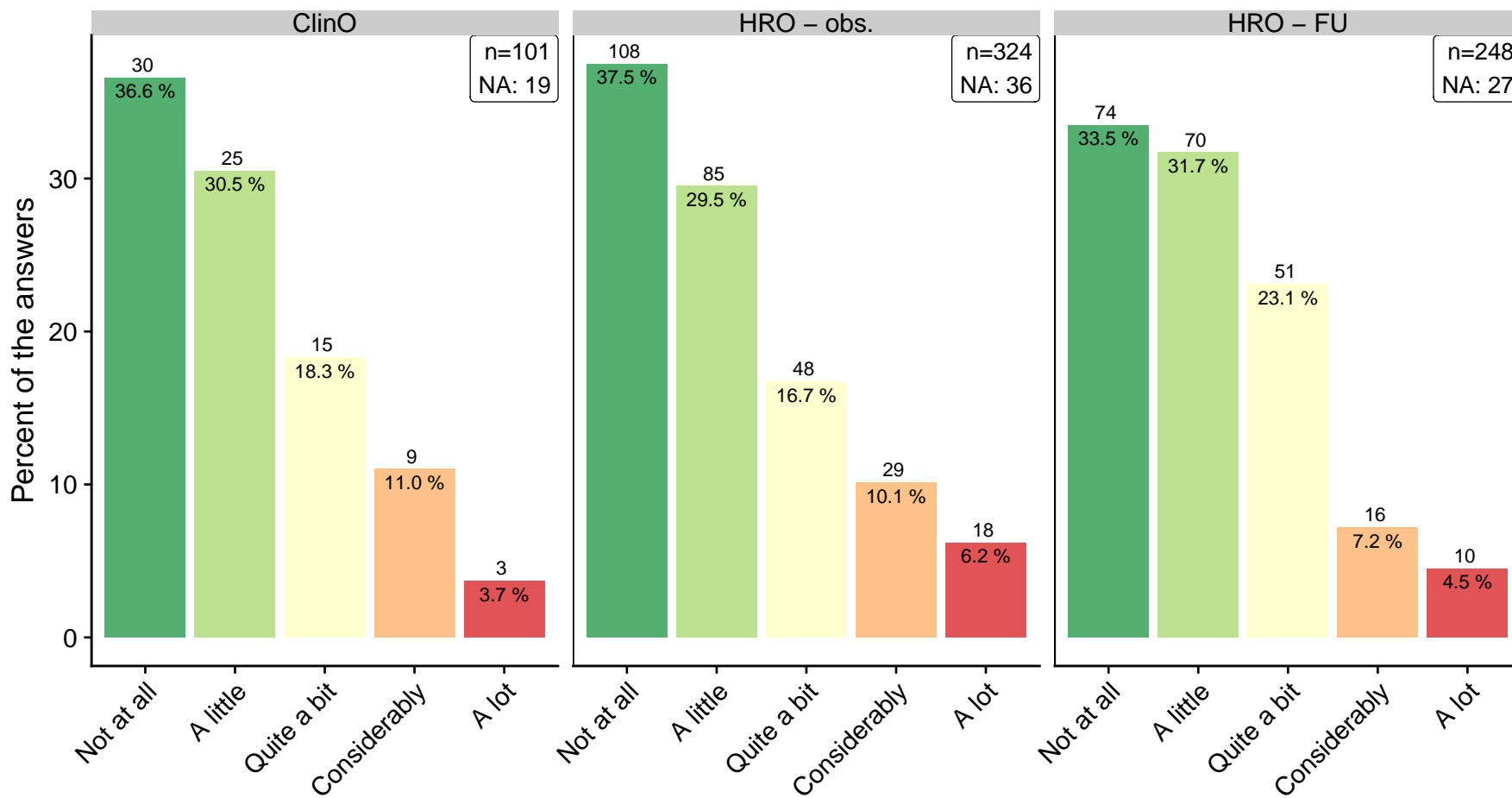
b) Which of the two HRA ordinances applied (Clinical Trials Ordinance, or Human Research Ordinance)



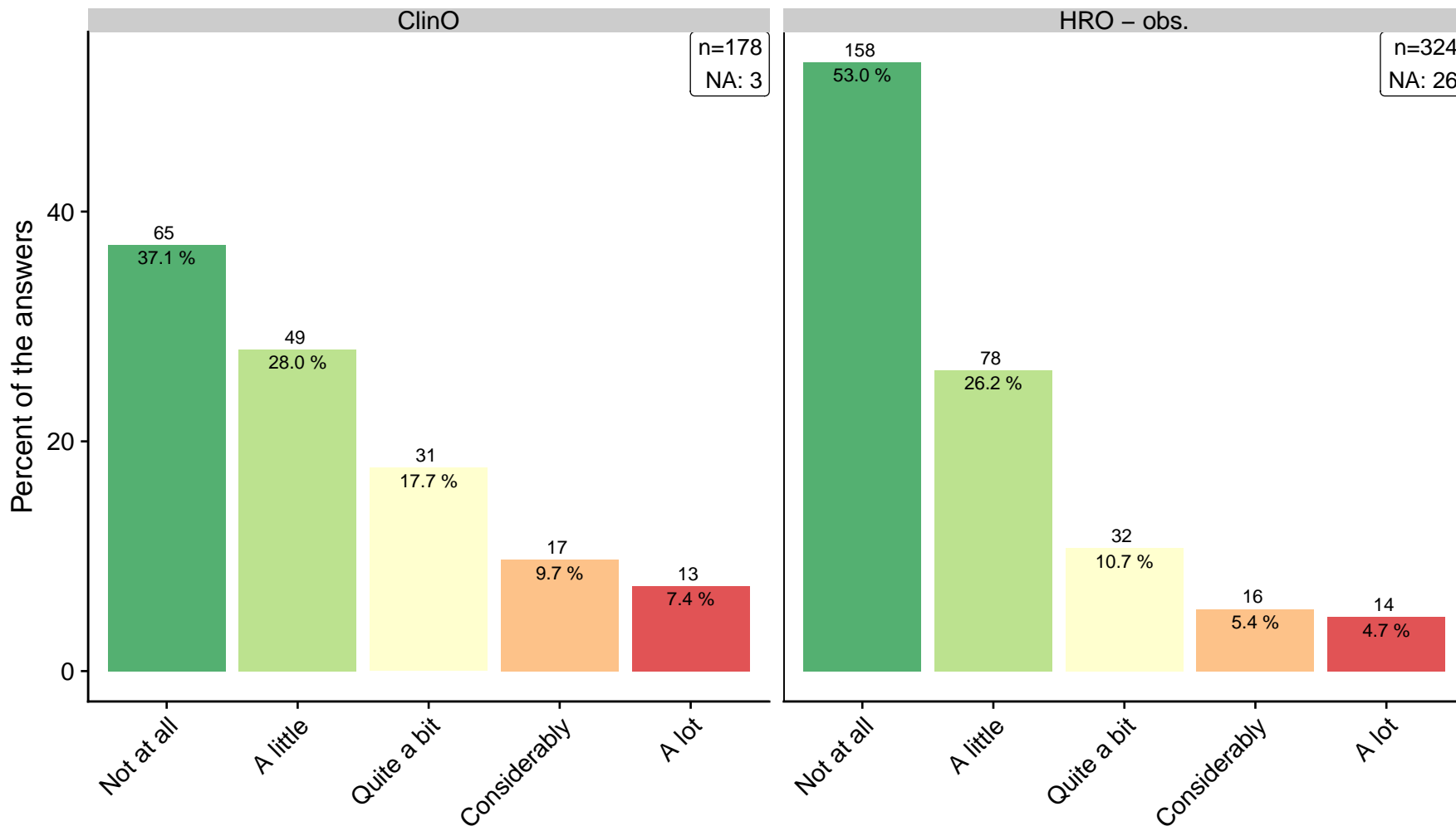
c) Which chapter(s) of the Clinical Trials Ordinance applied (type of intervention(s))



d) Which chapter(s) of the Human Research Ordinance applied (e.g. research involving sampling or data collection; further use; etc.)

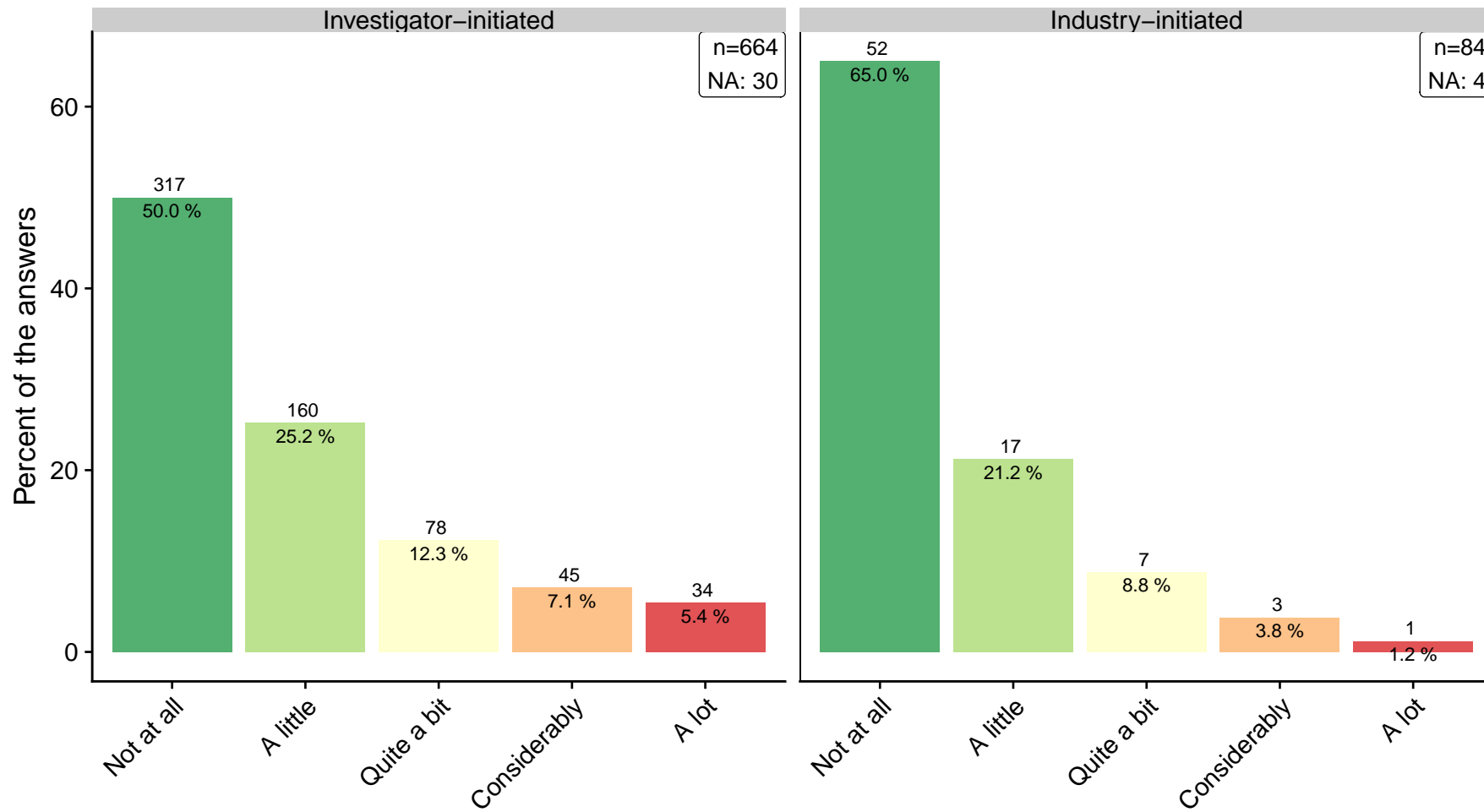


e) Which risk category to choose

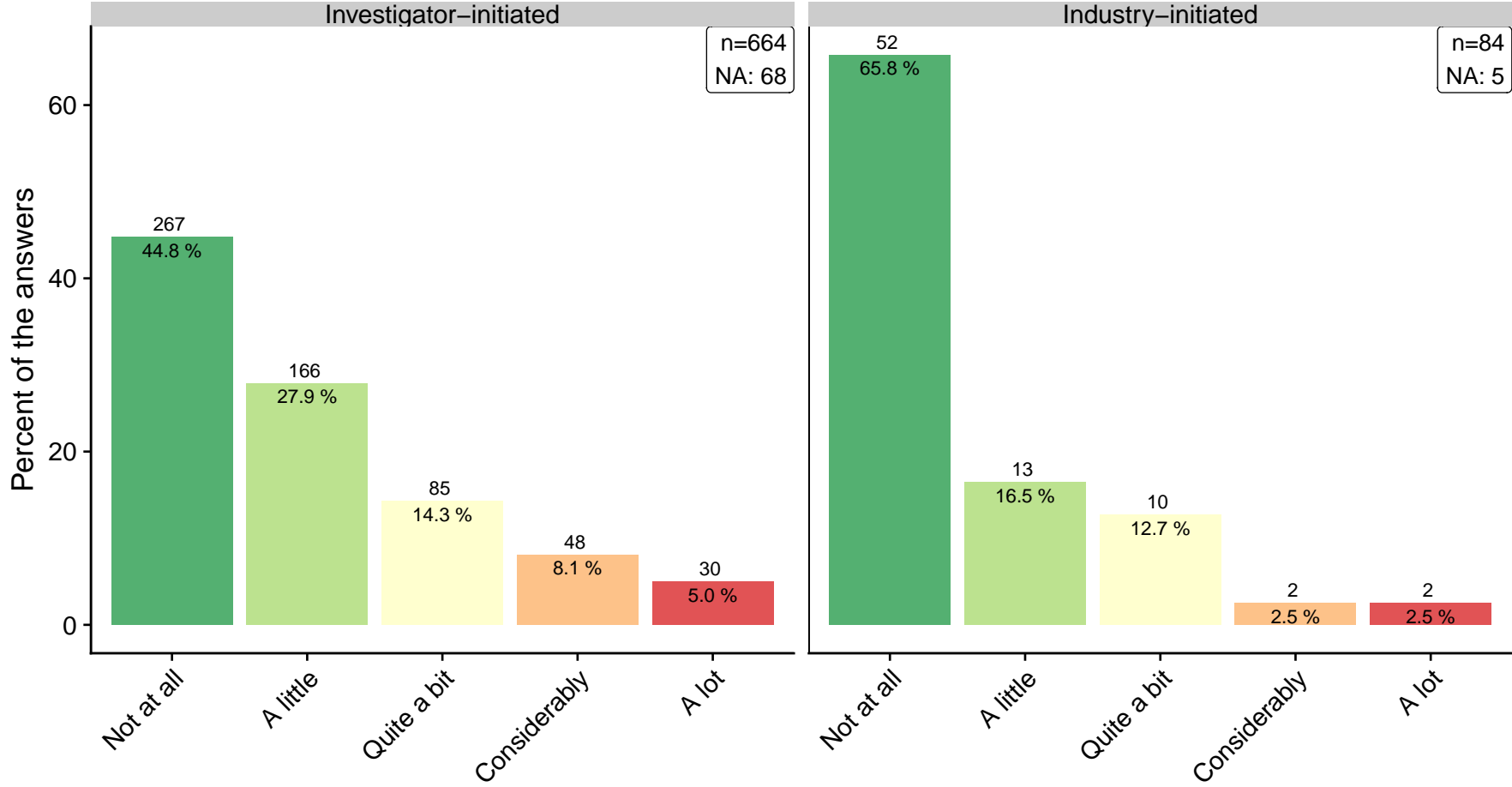


9.1.2 Stratified by initiator

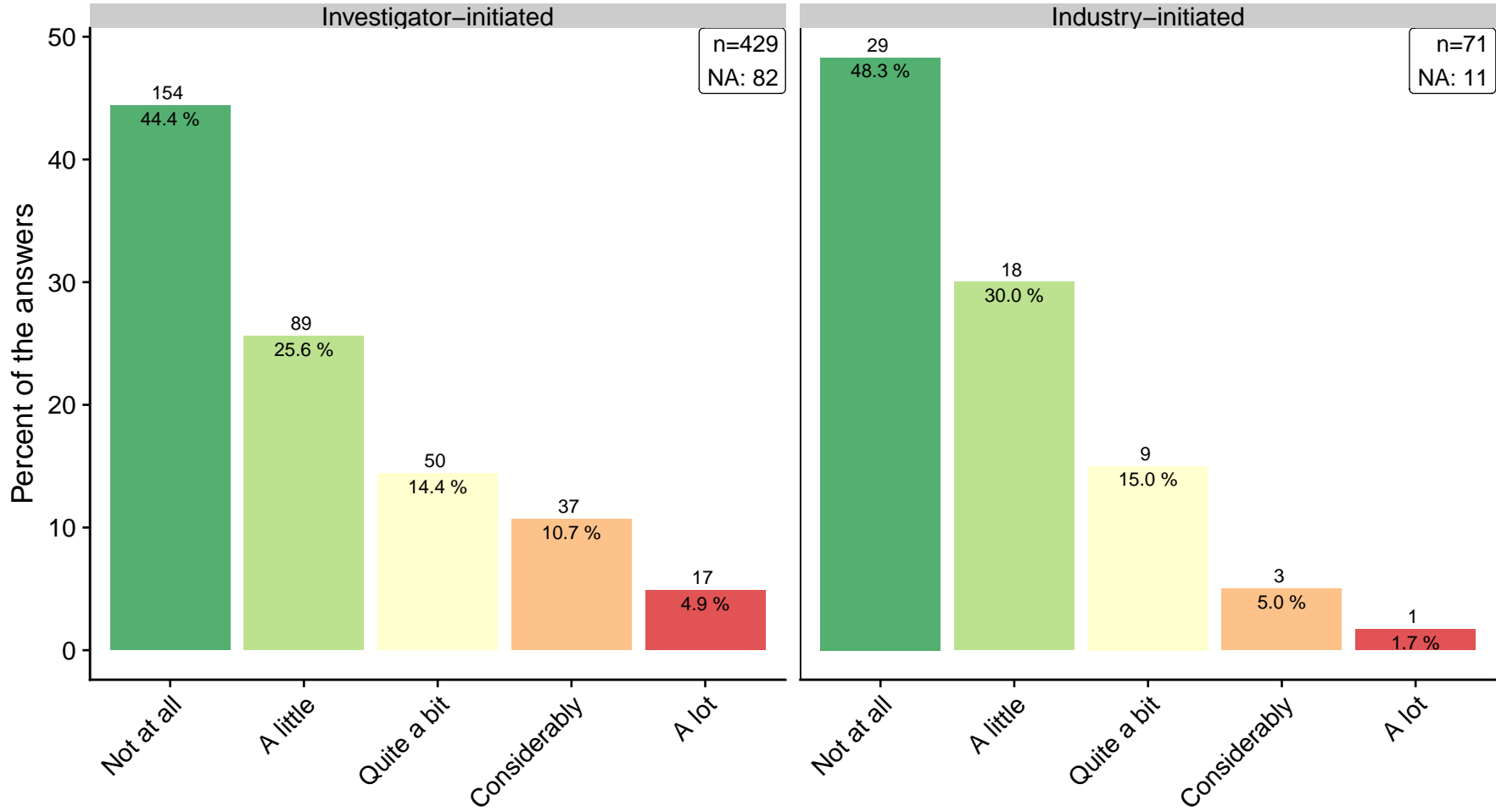
a) Whether the project is within the scope of the HRA



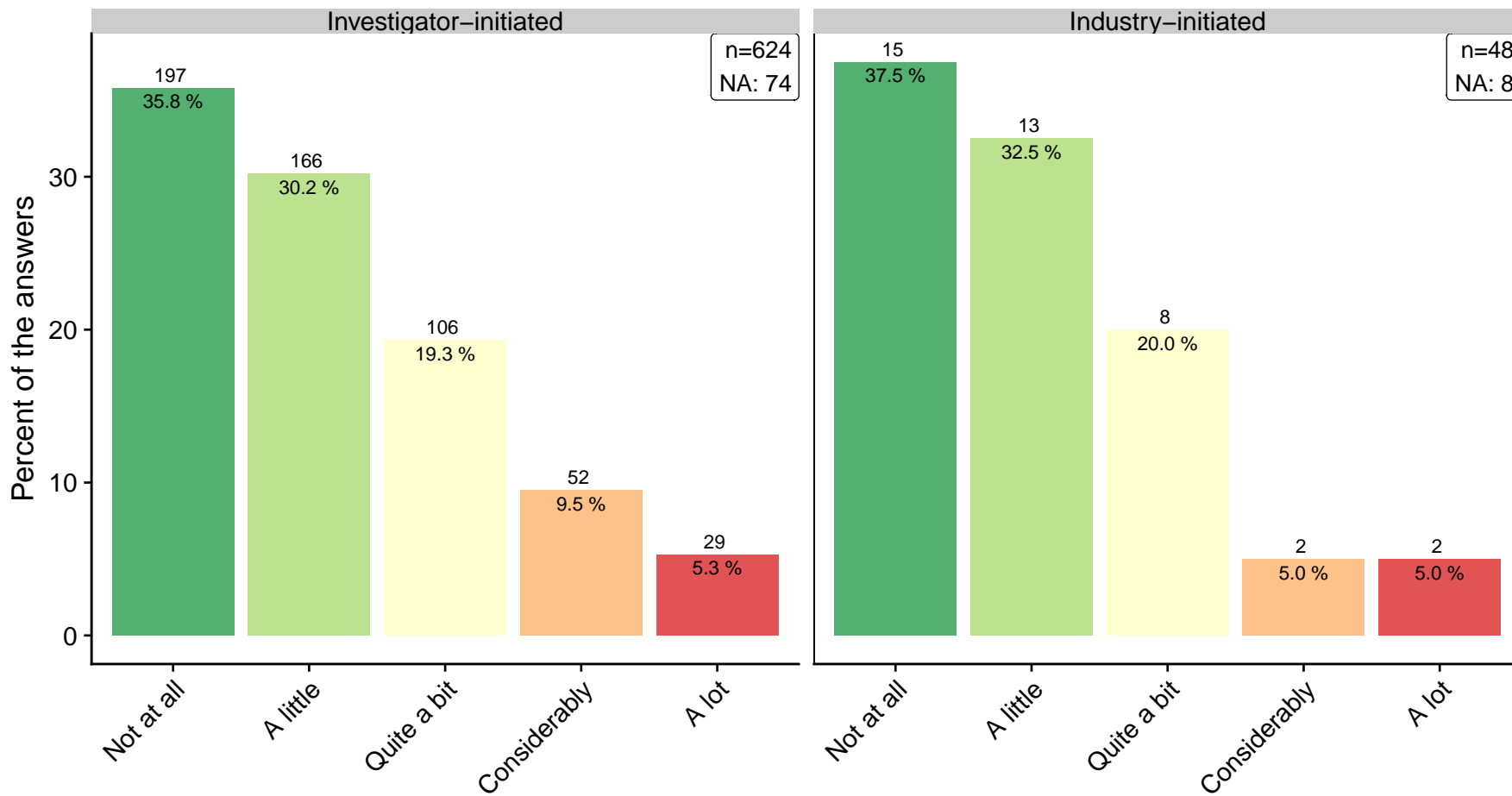
b) Which of the two HRA ordinances applied (Clinical Trials Ordinance, or Human Research Ordinance)



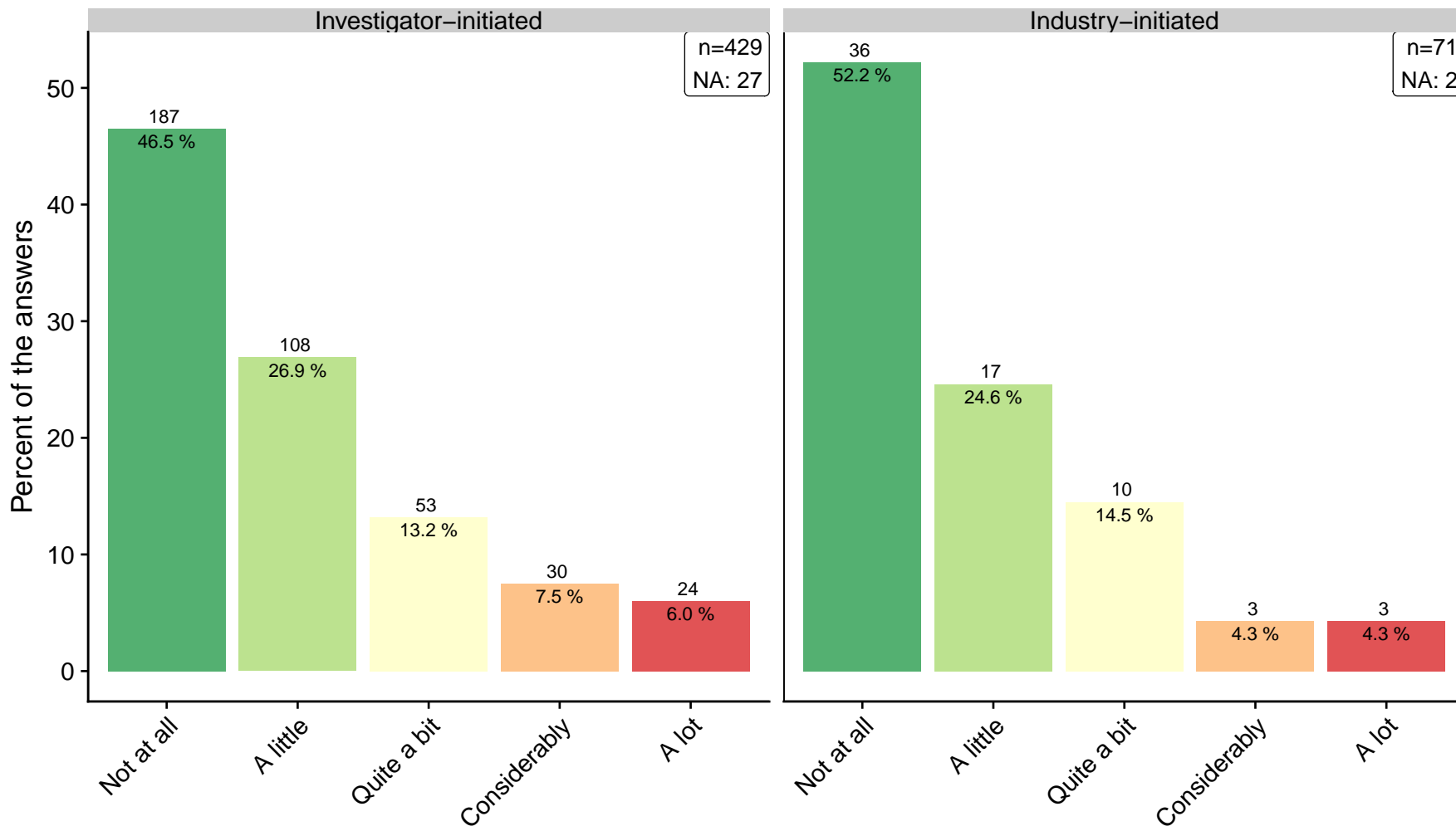
c) Which chapter(s) of the Clinical Trials Ordinance applied (type of intervention(s))



d) Which chapter(s) of the Human Research Ordinance applied (e.g. research involving sampling or data collection; further use; etc.)

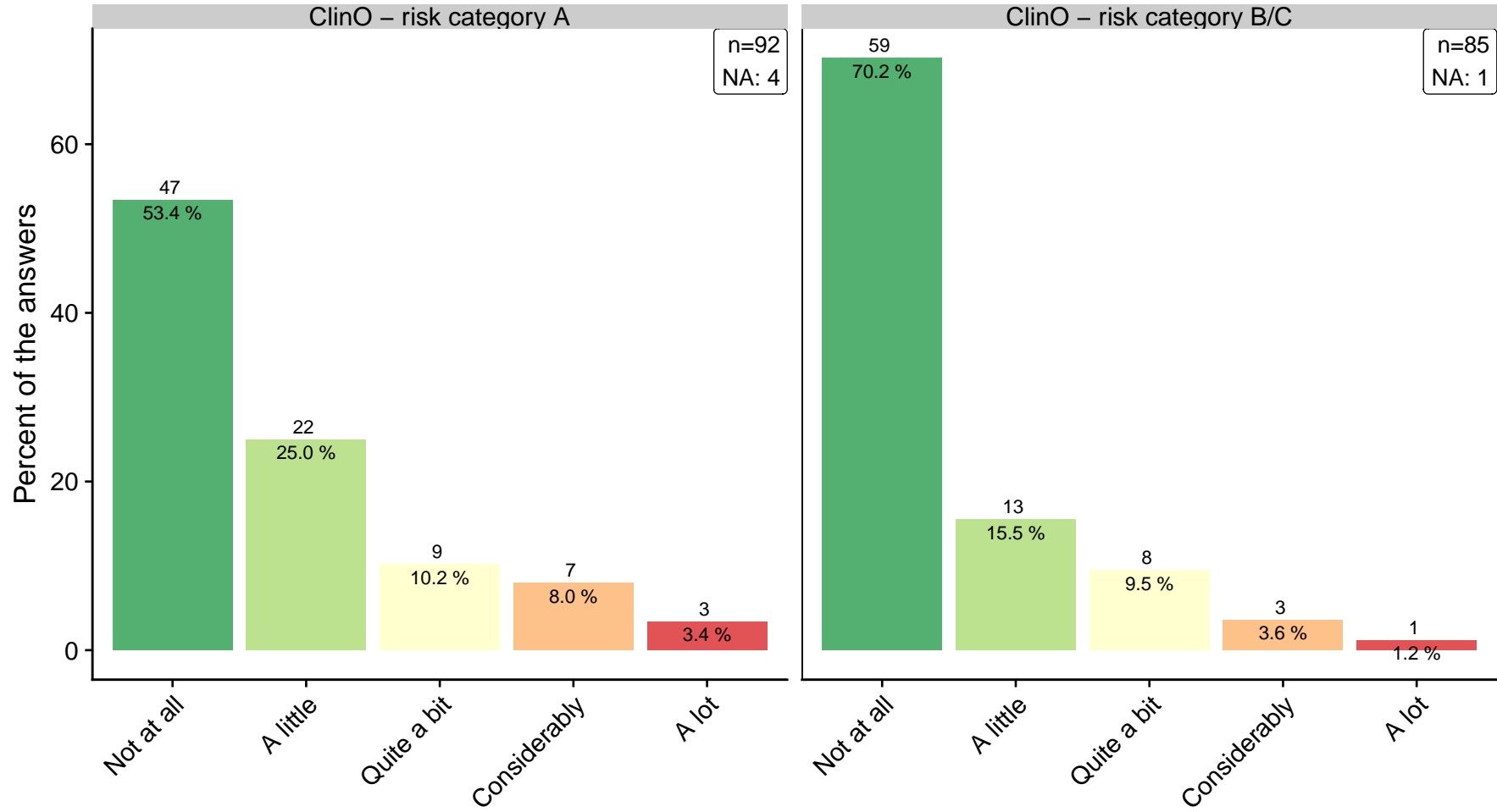


e) Which risk category to choose

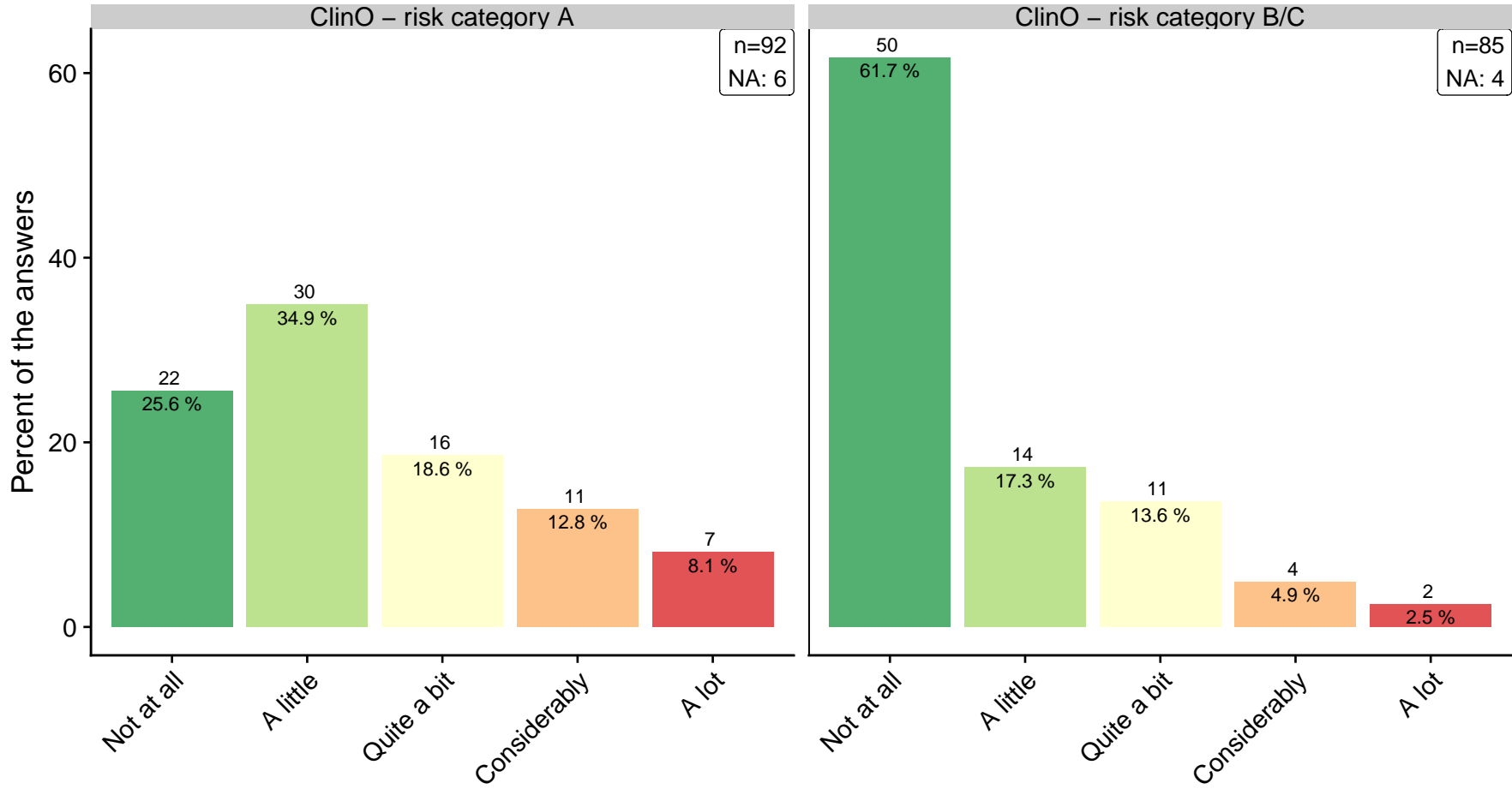


9.1.3 Stratified by risk category

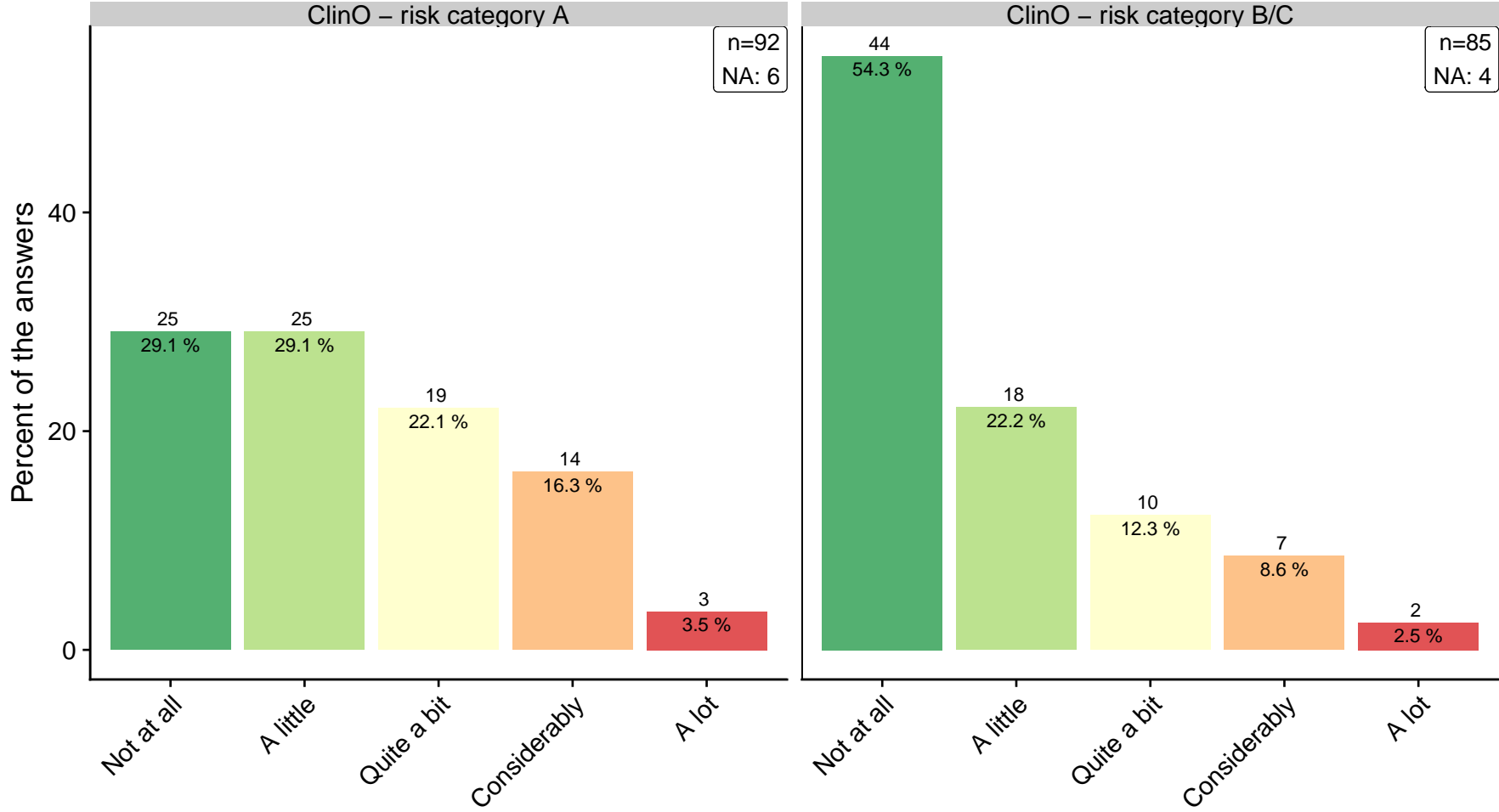
a) Whether the project is within the scope of the HRA



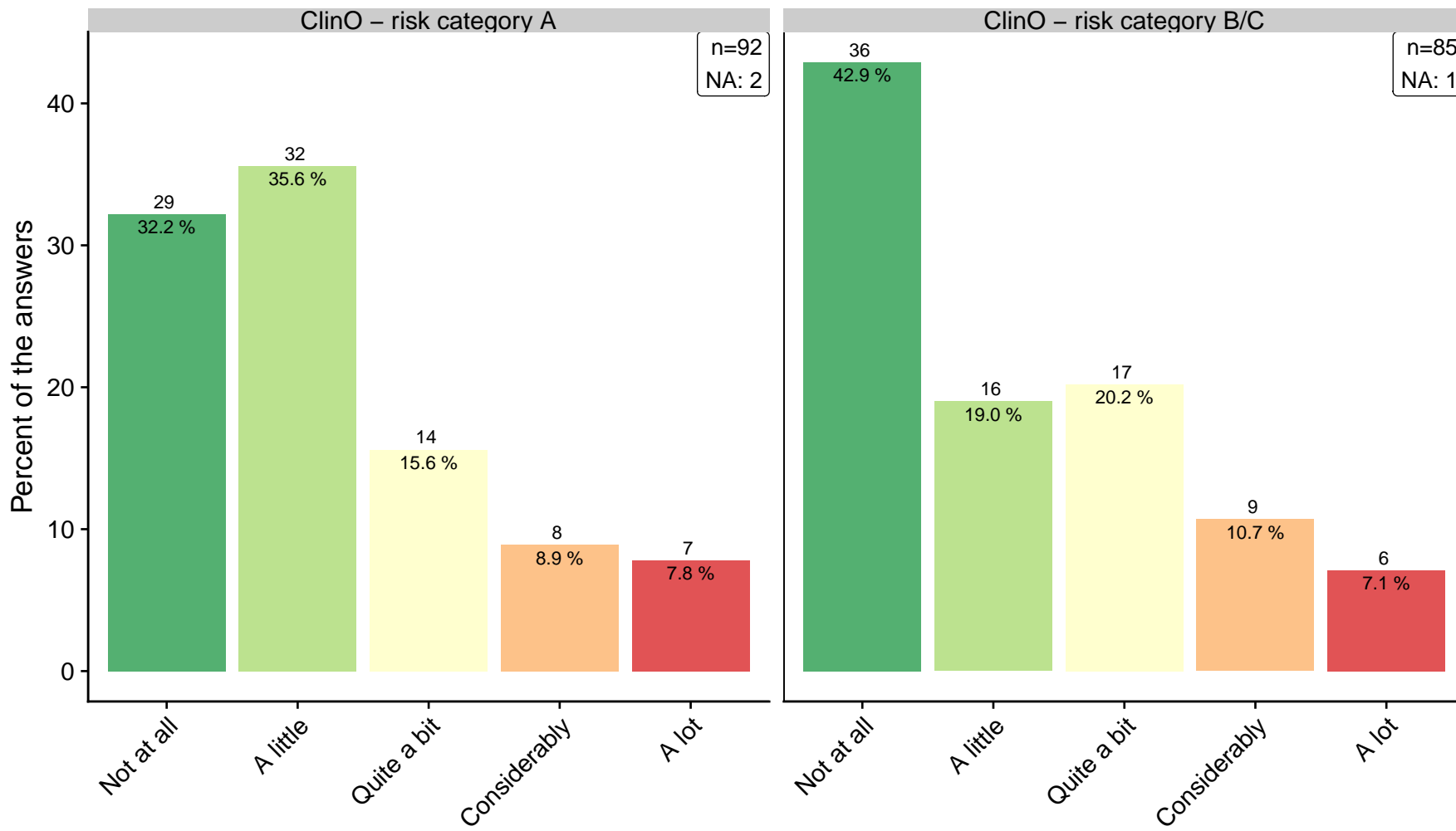
**b) Which of the two HRA ordinances applied
(Clinical Trials Ordinance, or Human Research
Ordinance)**



c) Which chapter(s) of the Clinical Trials Ordinance applied (type of intervention(s))

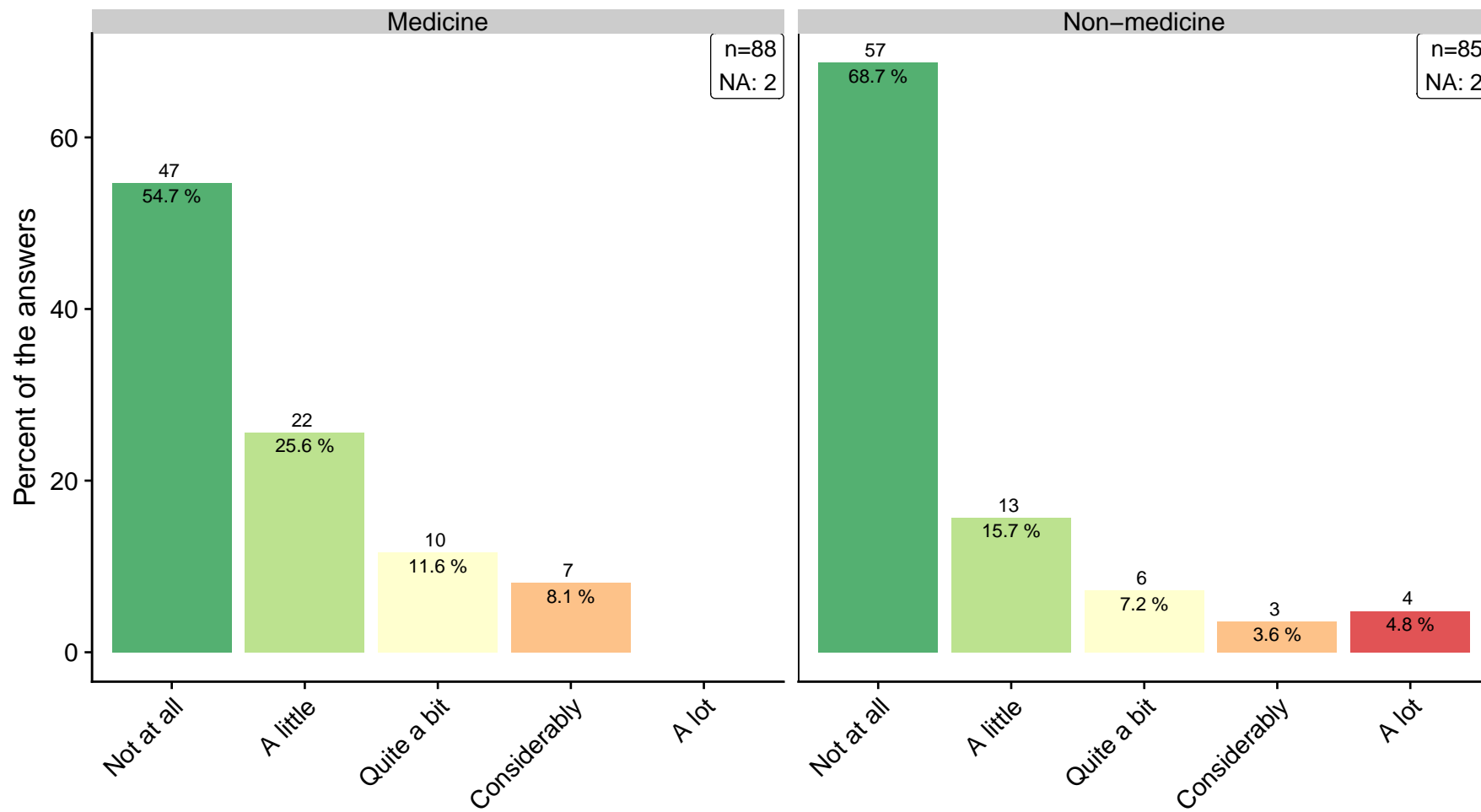


e) Which risk category to choose

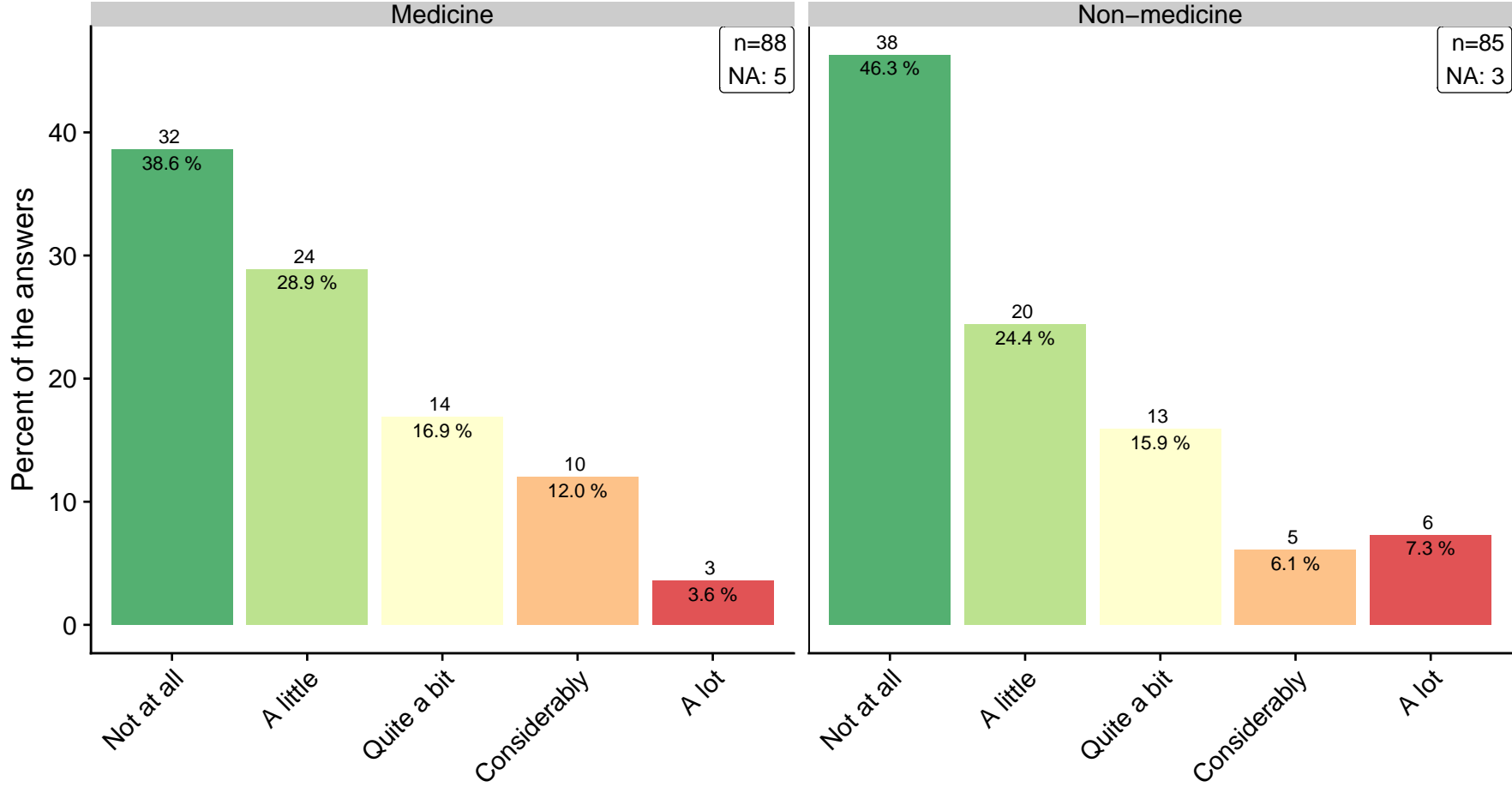


9.1.4 Stratified by field

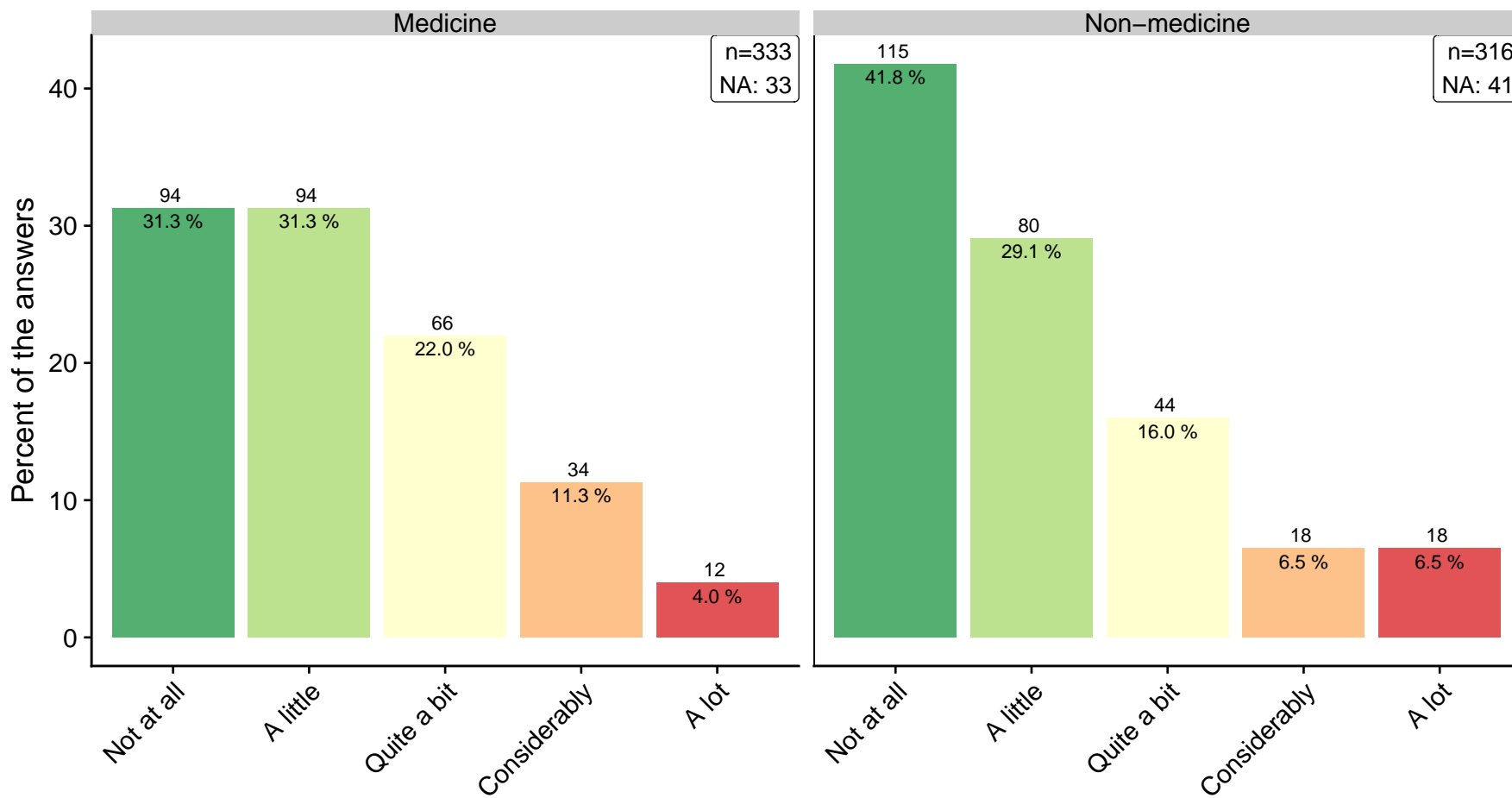
a) Whether the project is within the scope of the HRA



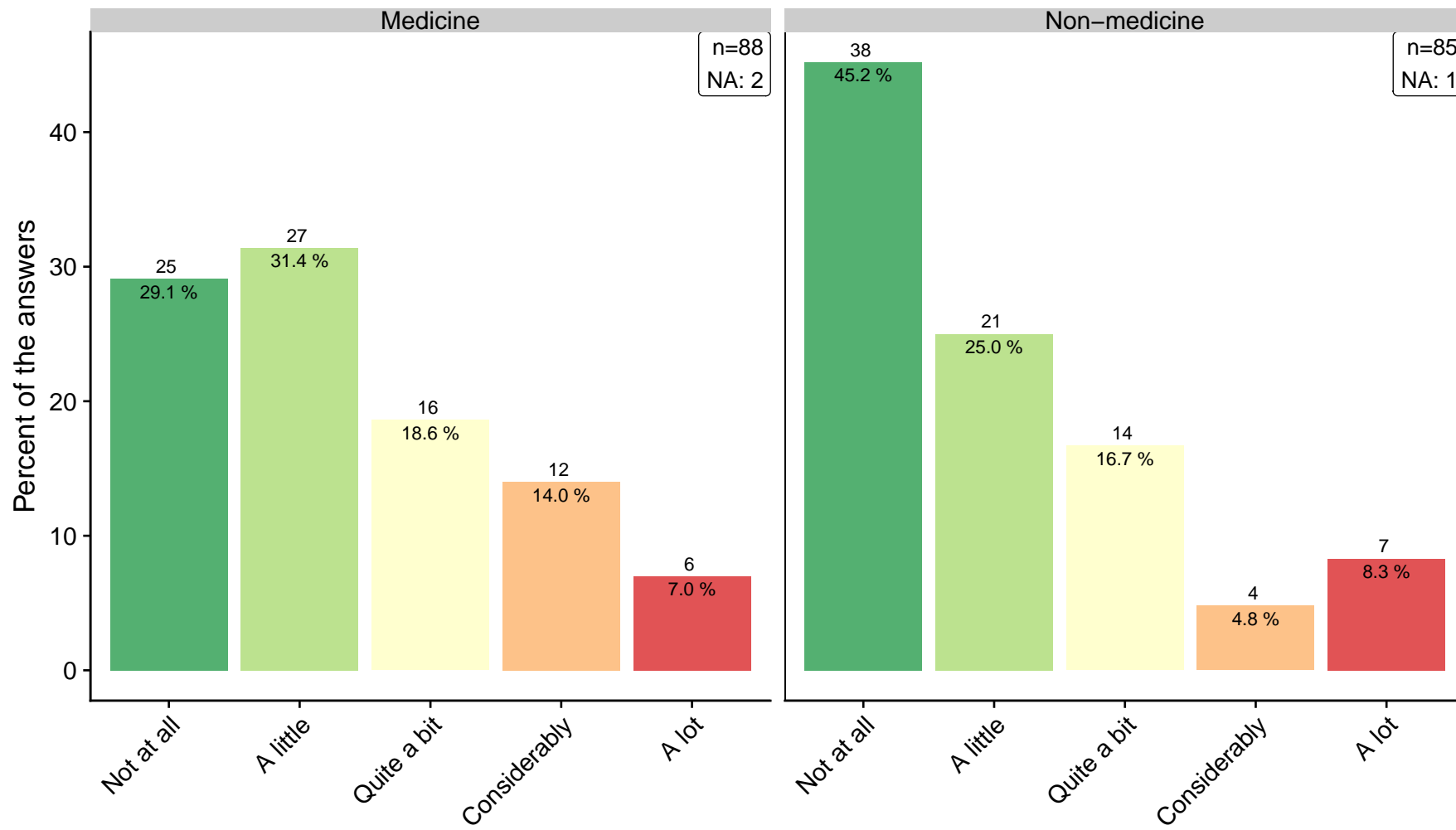
b) Which of the two HRA ordinances applied (Clinical Trials Ordinance, or Human Research Ordinance)



d) Which chapter(s) of the Human Research Ordinance applied (e.g. research involving sampling or data collection; further use; etc.)



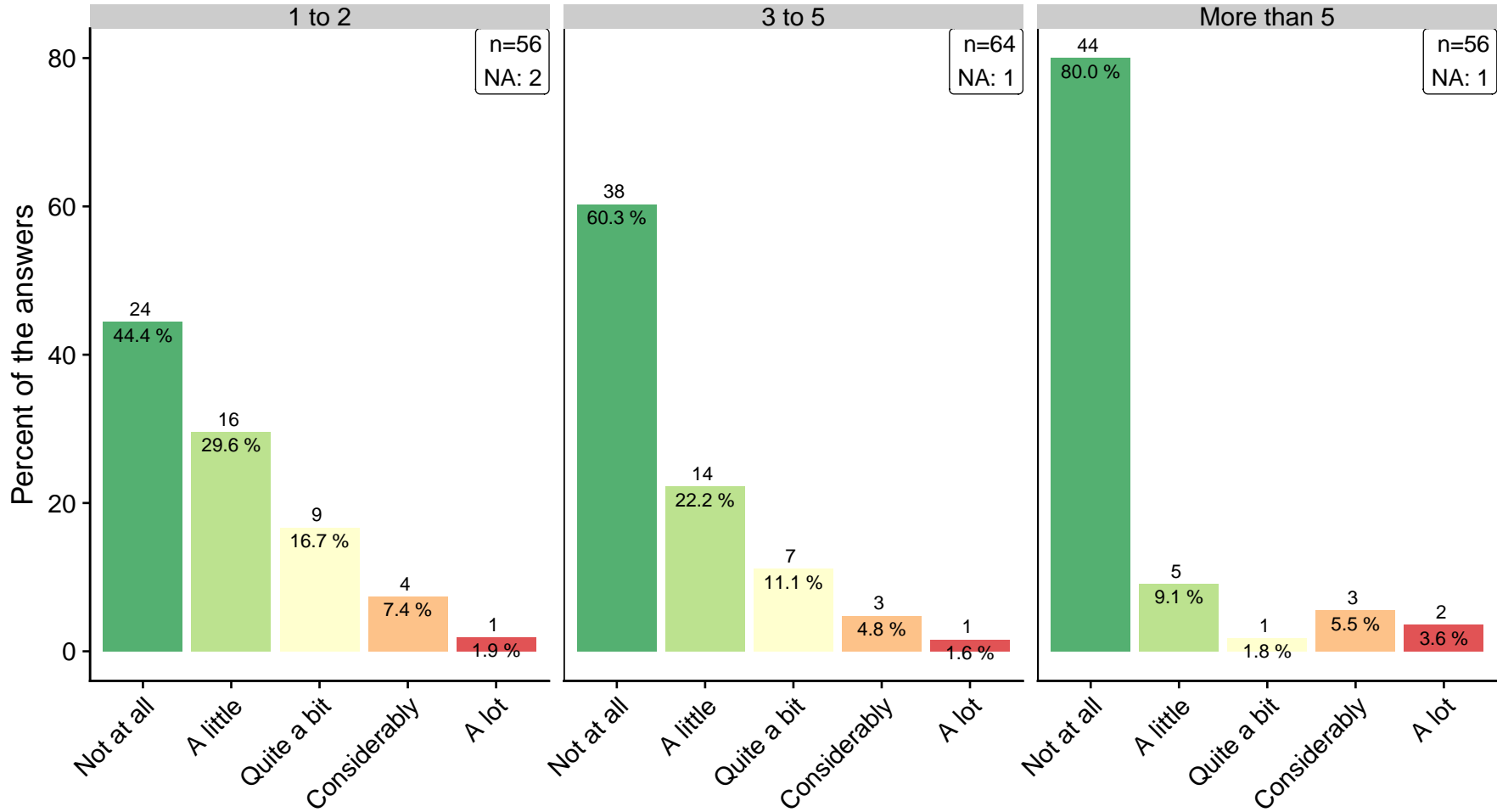
e) Which risk category to choose



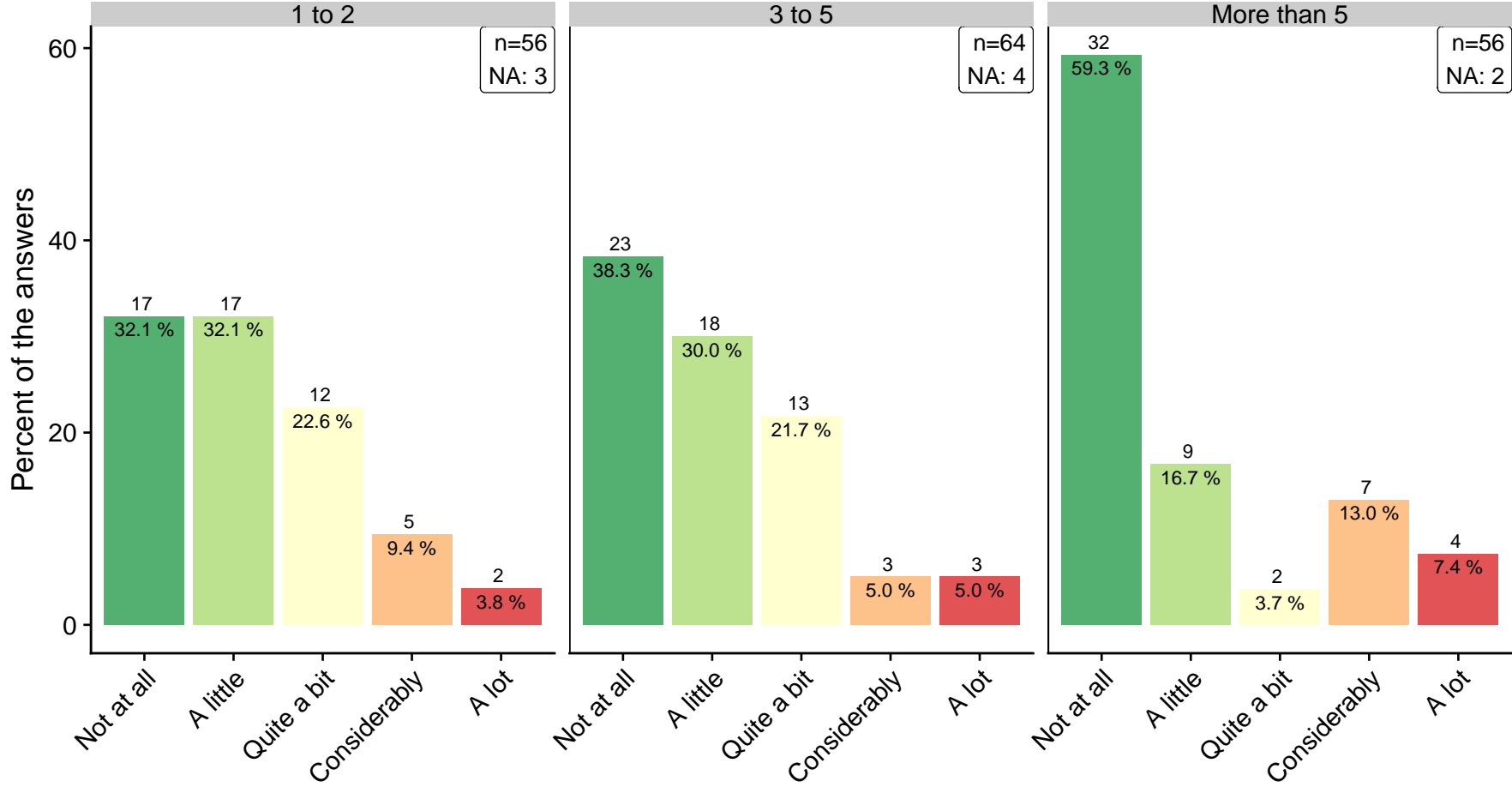
9.2 Feedback on application stratified by experience of the researcher

9.2.1 Stratified by number of submitted EC projects since HRA

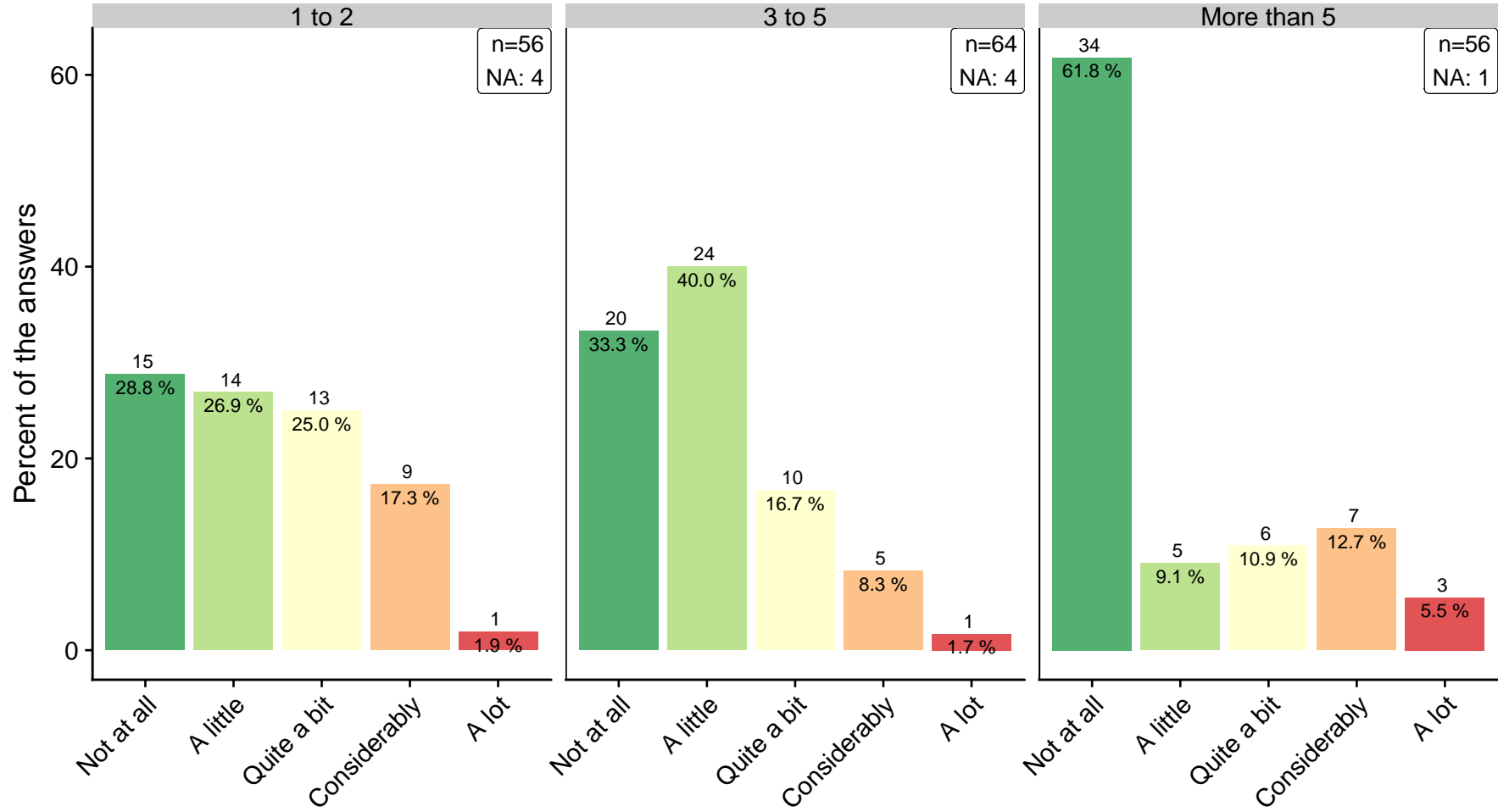
a) Whether the project is within the scope of the HRA



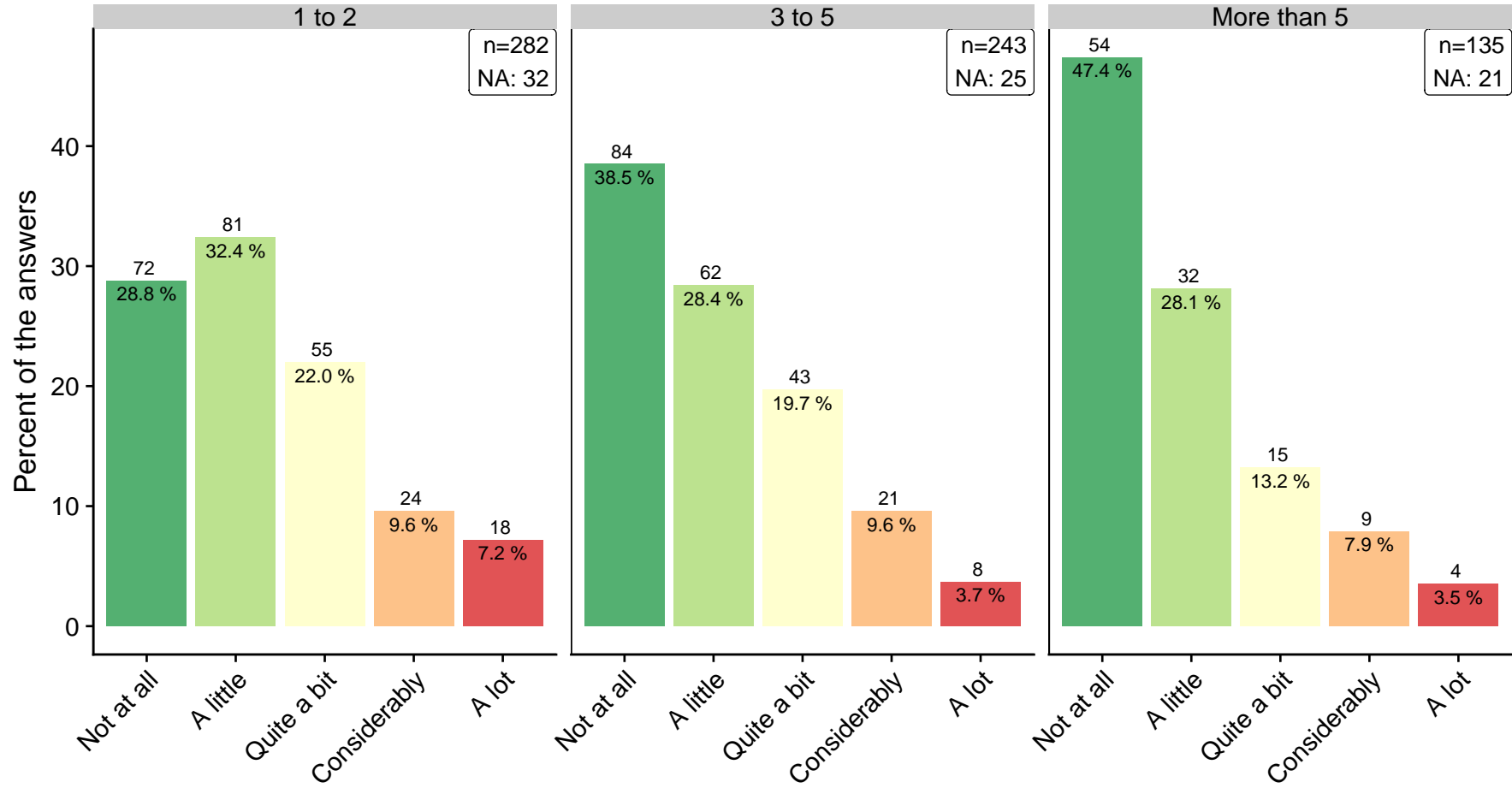
b) Which of the two HRA ordinances applied (Clinical Trials Ordinance, or Human Research Ordinance)



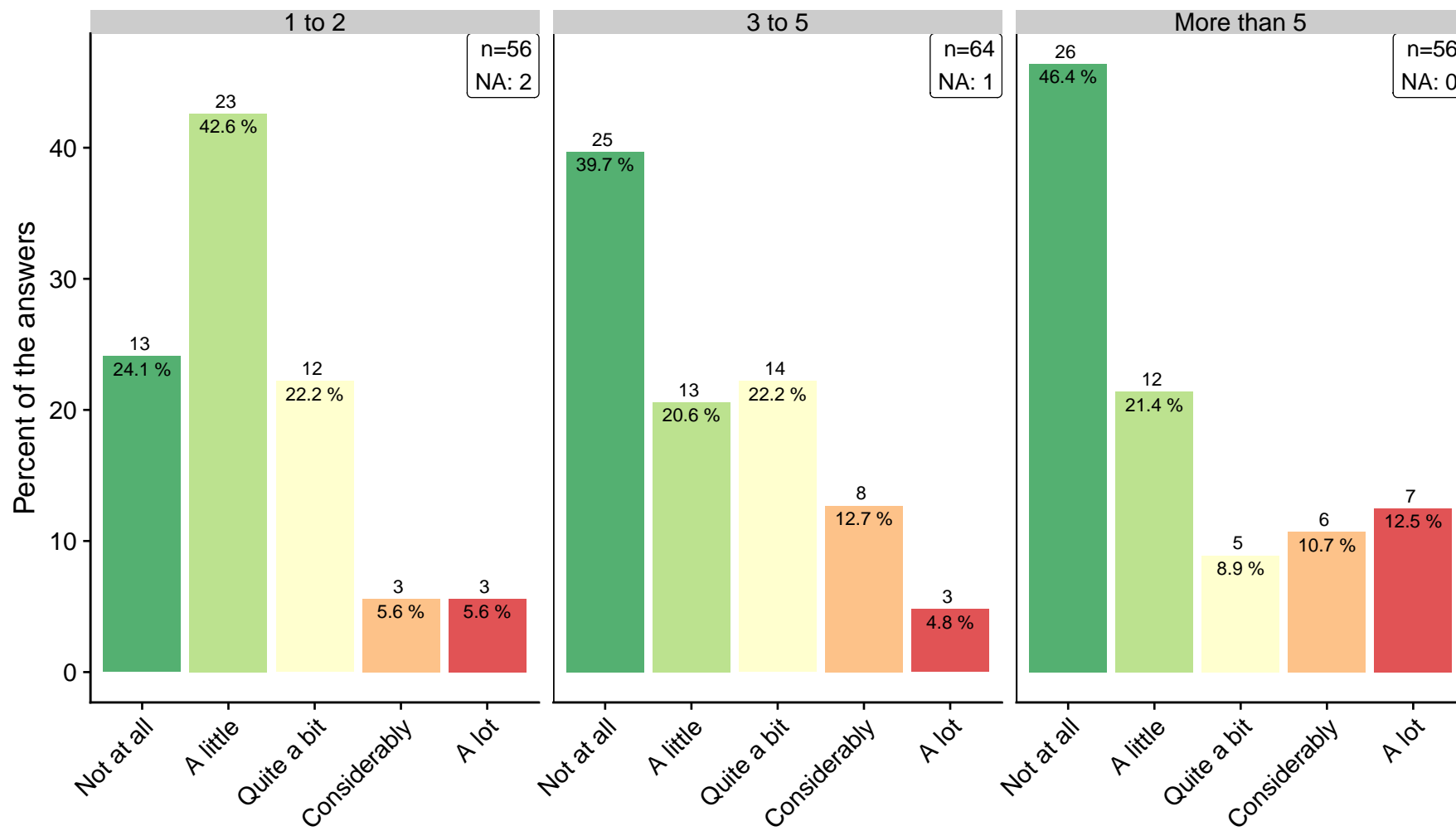
c) Which chapter(s) of the Clinical Trials Ordinance applied (type of intervention(s))



d) Which chapter(s) of the Human Research Ordinance applied (e.g. research involving sampling or data collection; further use; etc.)

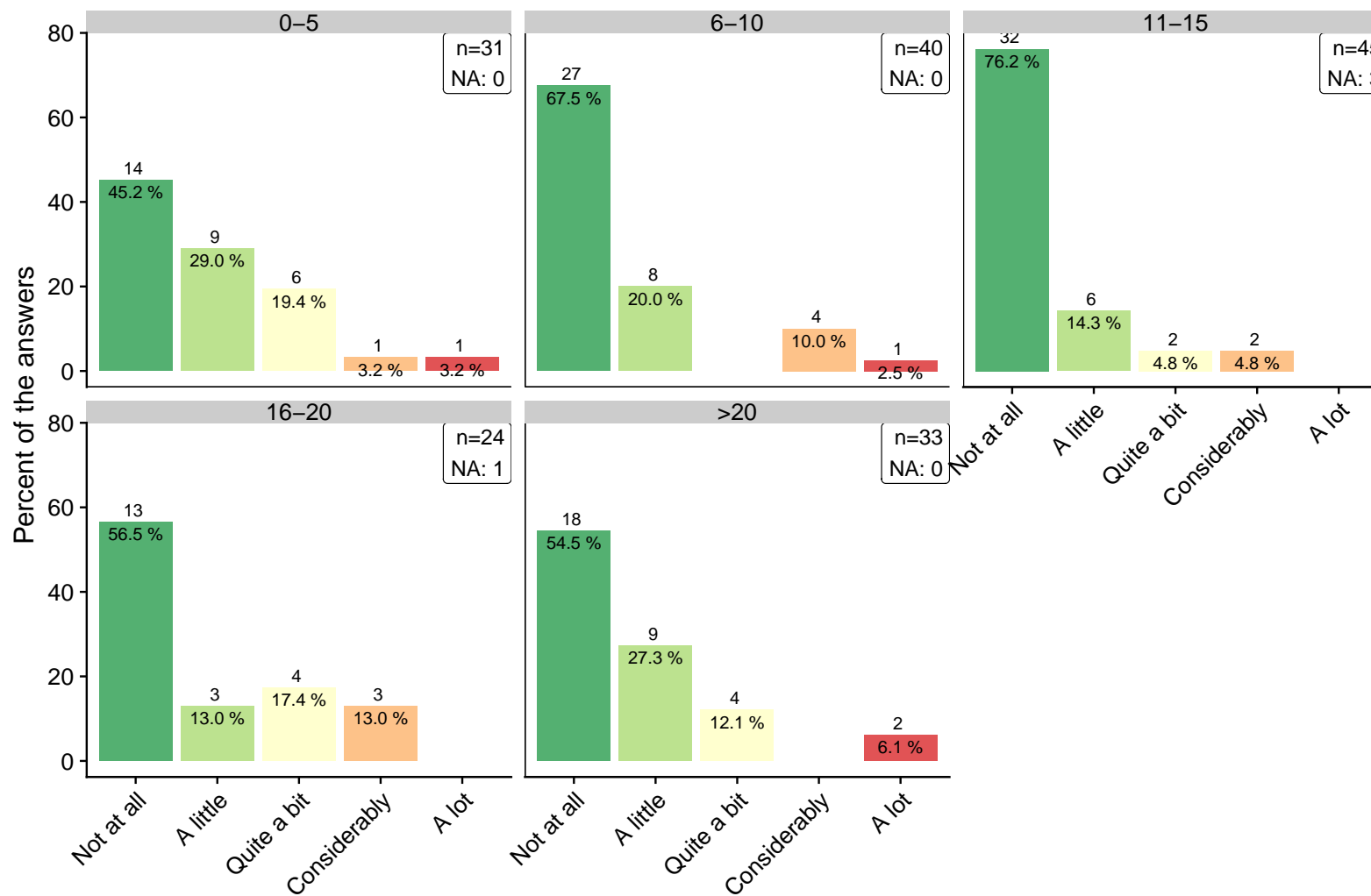


e) Which risk category to choose

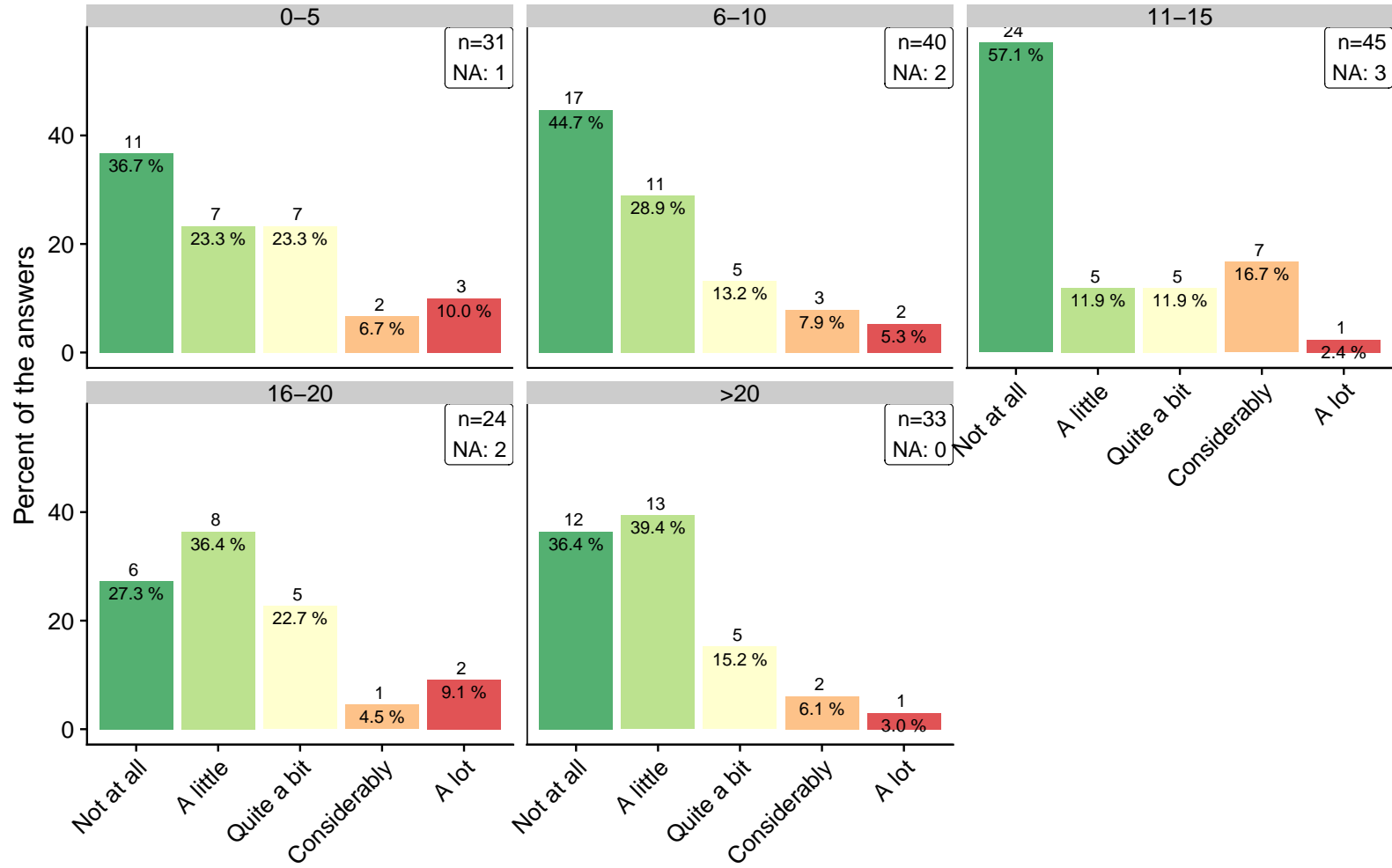


9.2.2 Stratified by years working in research

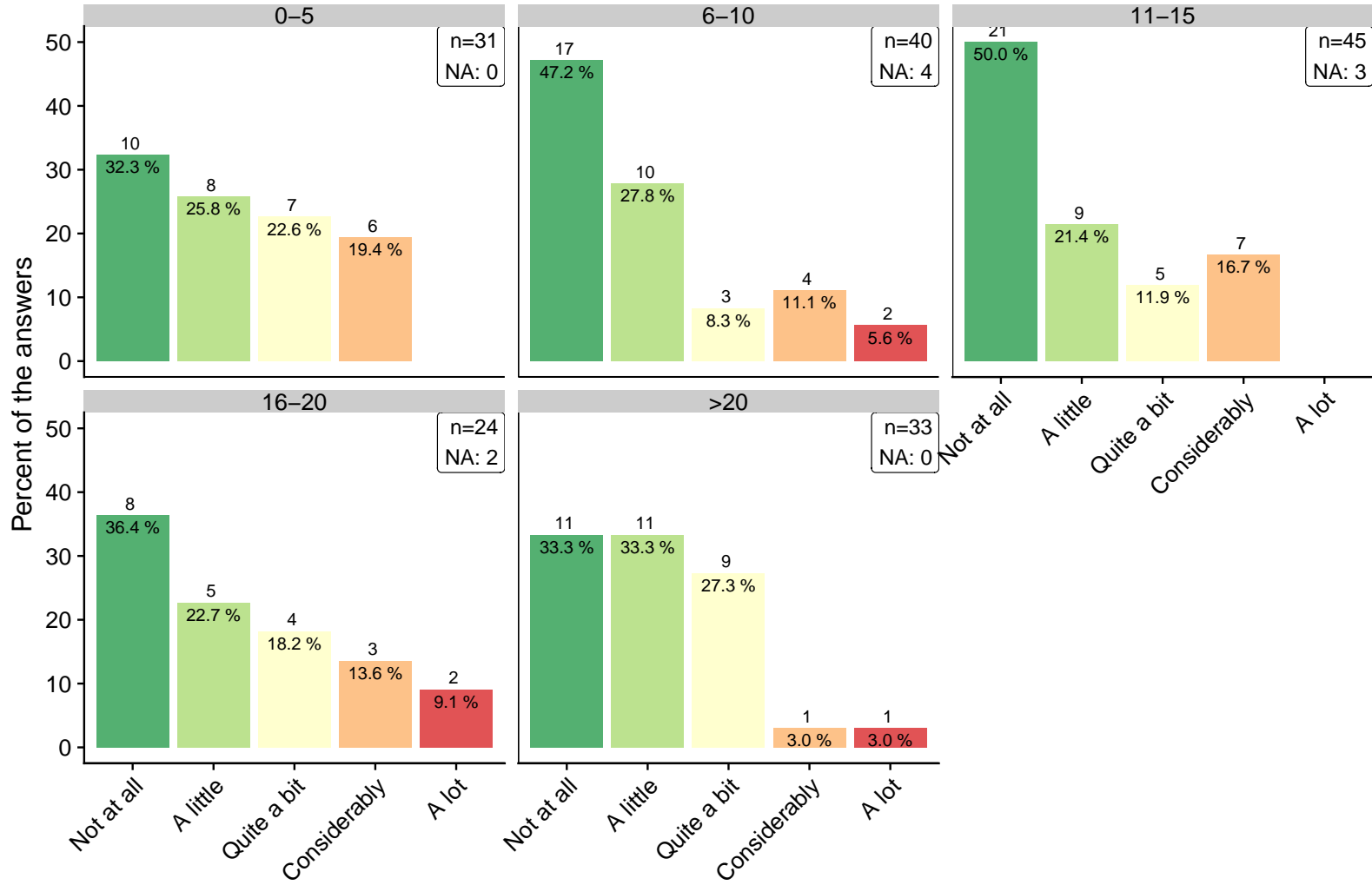
a) Whether the project is within the scope of the HRA



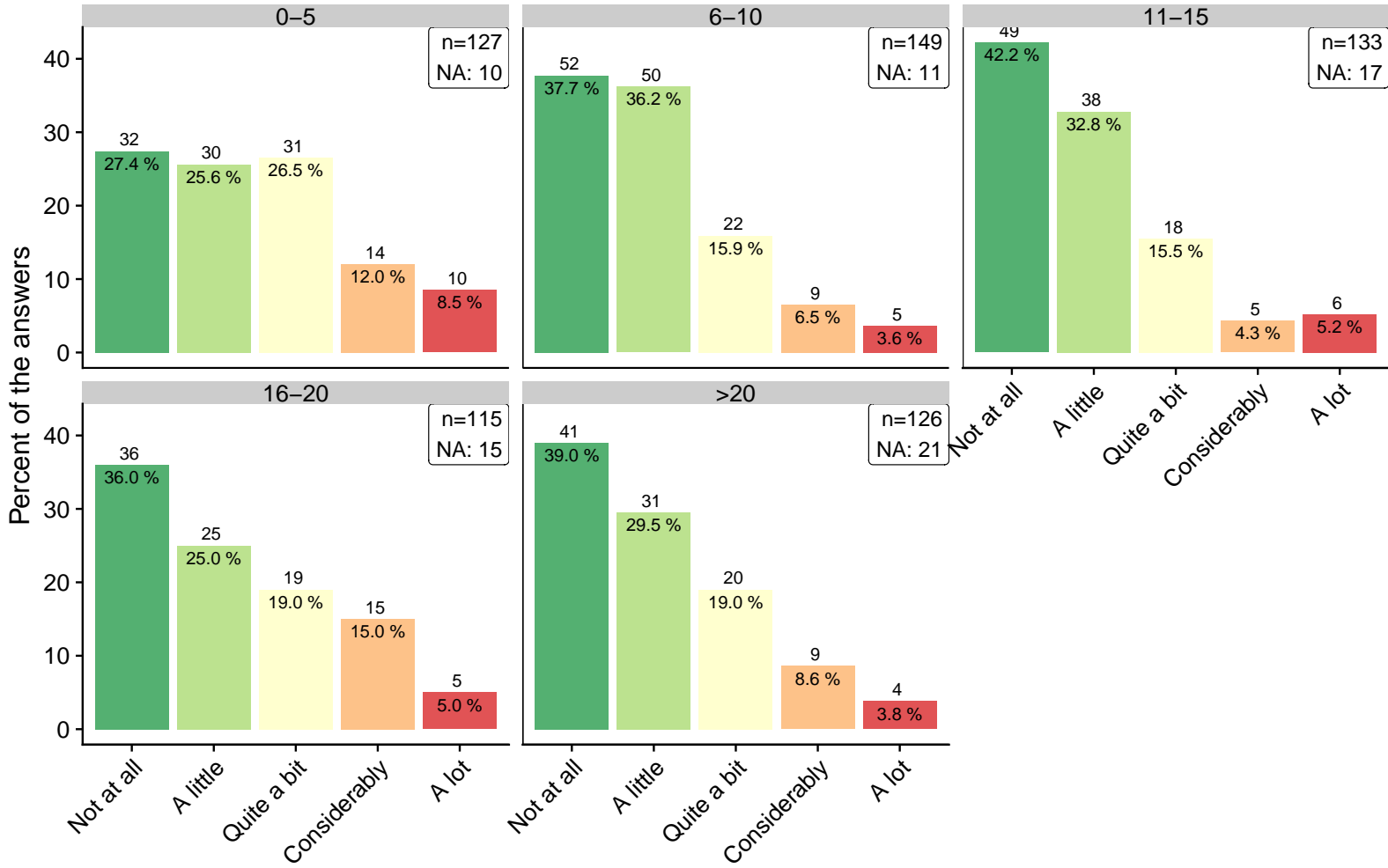
**b) Which of the two HRA ordinances applied
(Clinical Trials Ordinance, or Human Research Ordinance)**



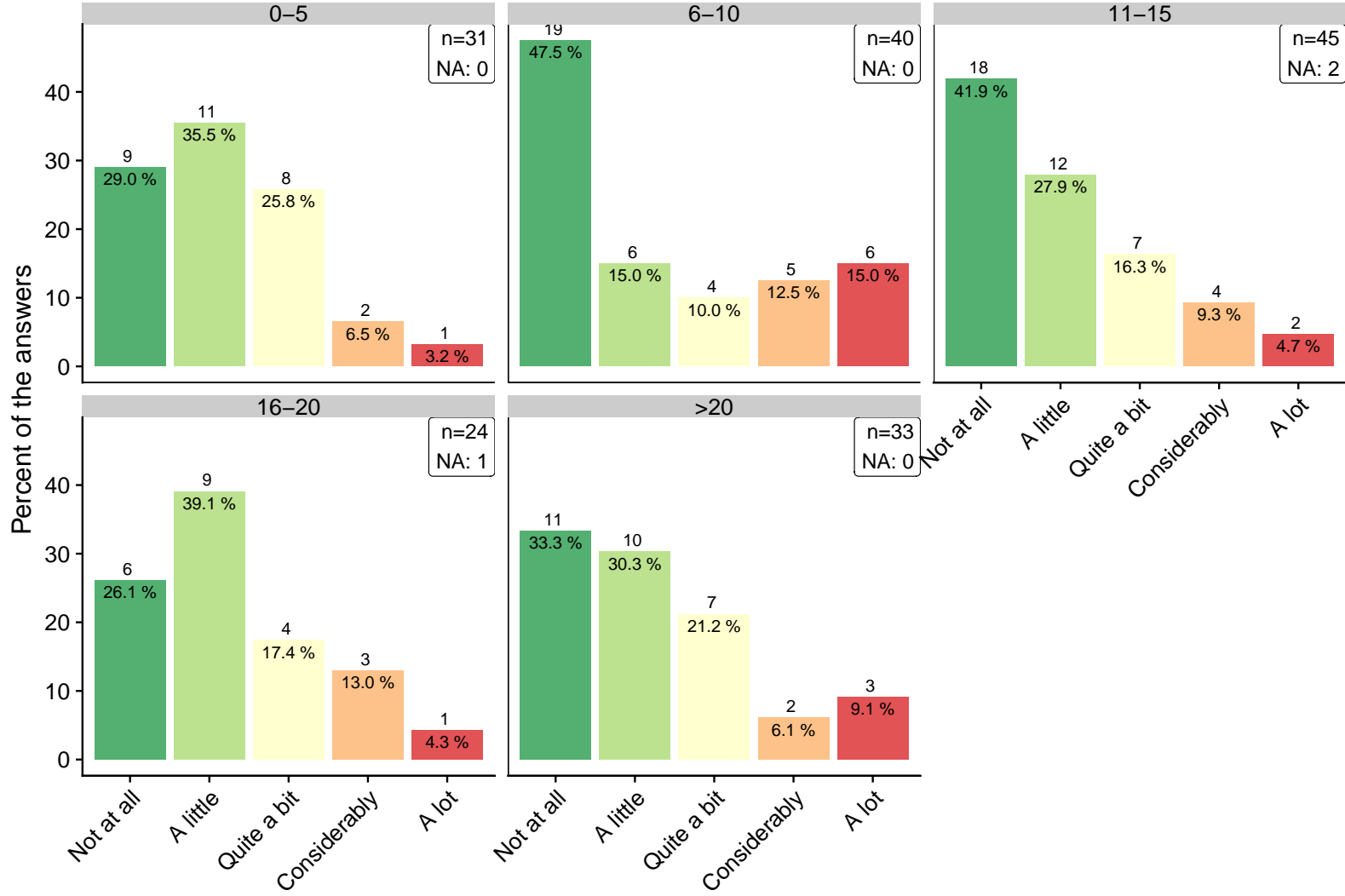
c) Which chapter(s) of the Clinical Trials Ordinance applied (type of intervention(s))



d) Which chapter(s) of the Human Research Ordinance applied (e.g. research involving sampling or data collection; further use; etc.)



e) Which risk category to choose

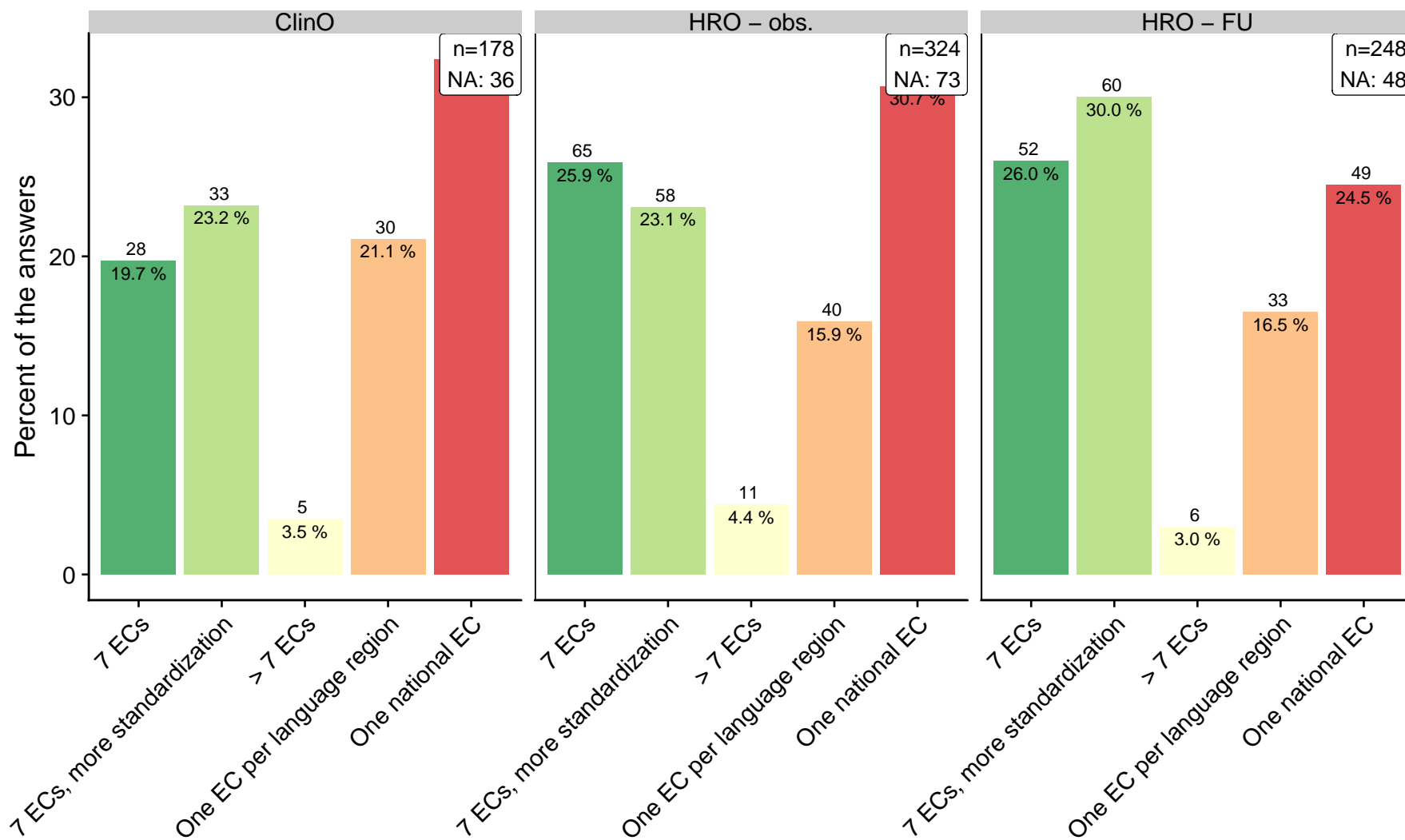


10 Question B17: From the following options, which one do you prefer?

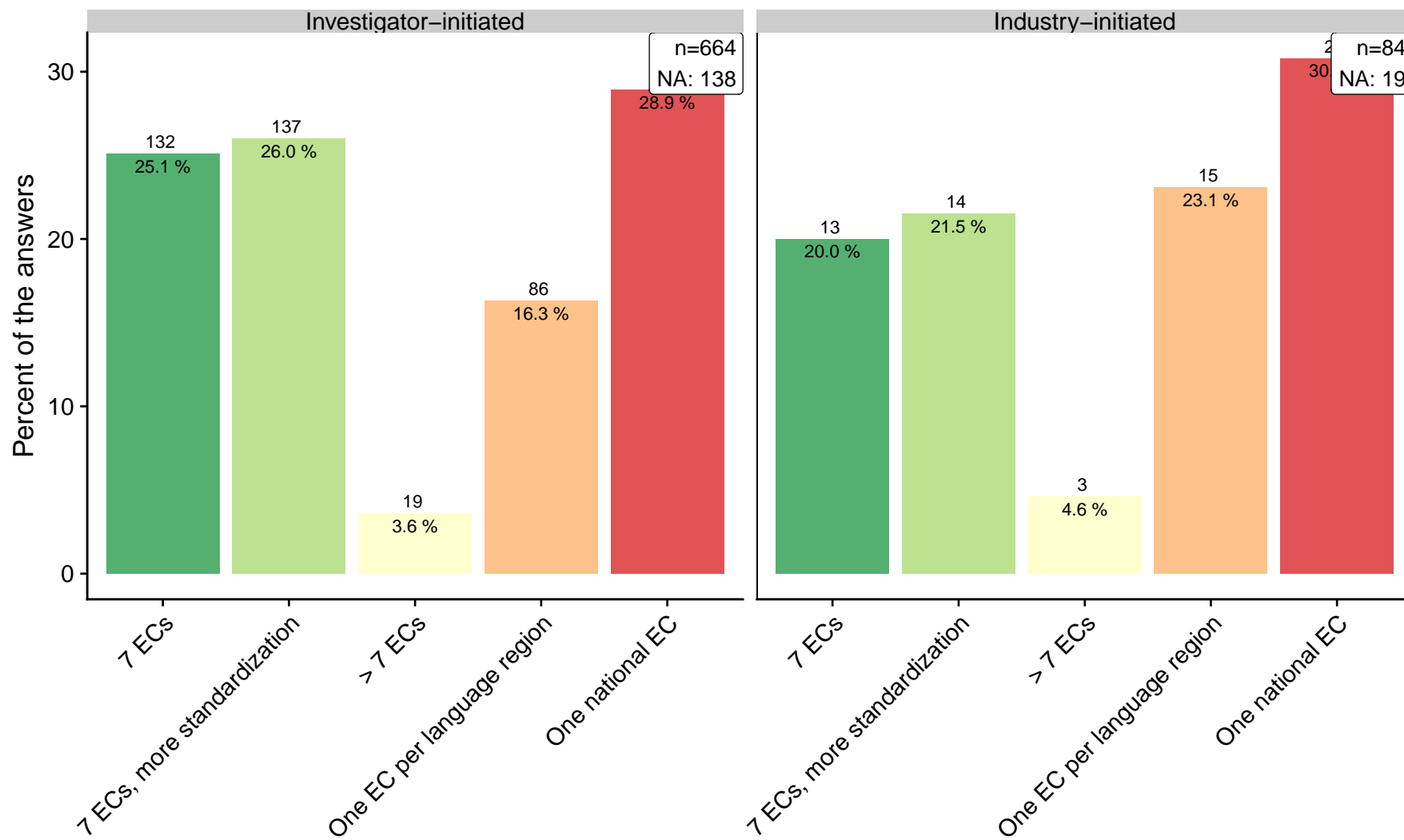
Question from IPZ / KEK-CDC Consultants: Gibt es Unterschiede nach Forschungsbereich oder Hintergrund zur Einstellung ggü einer bzw. mehrere EK?

10.1 Feedback on application stratified research details

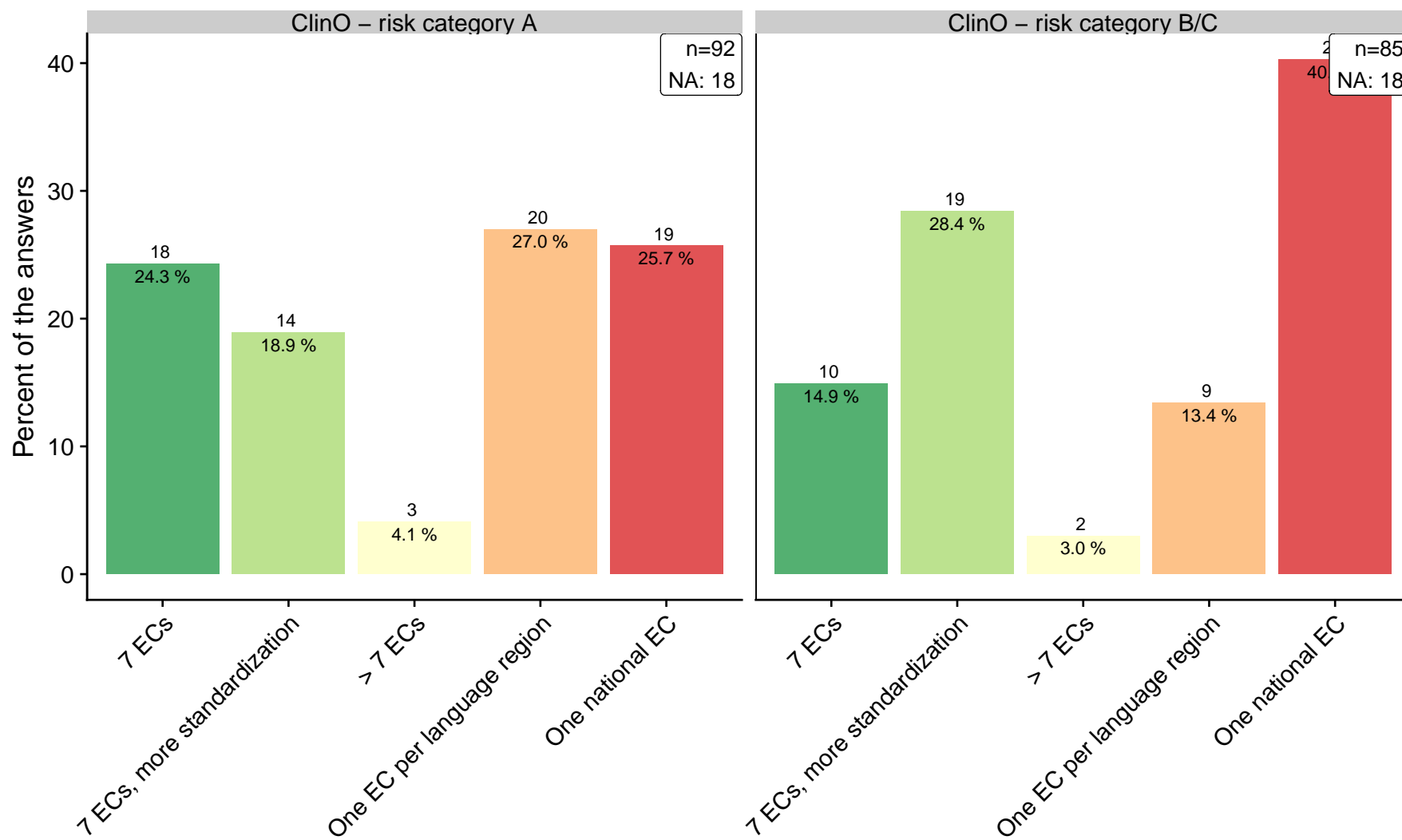
10.1.1 Stratified by research type



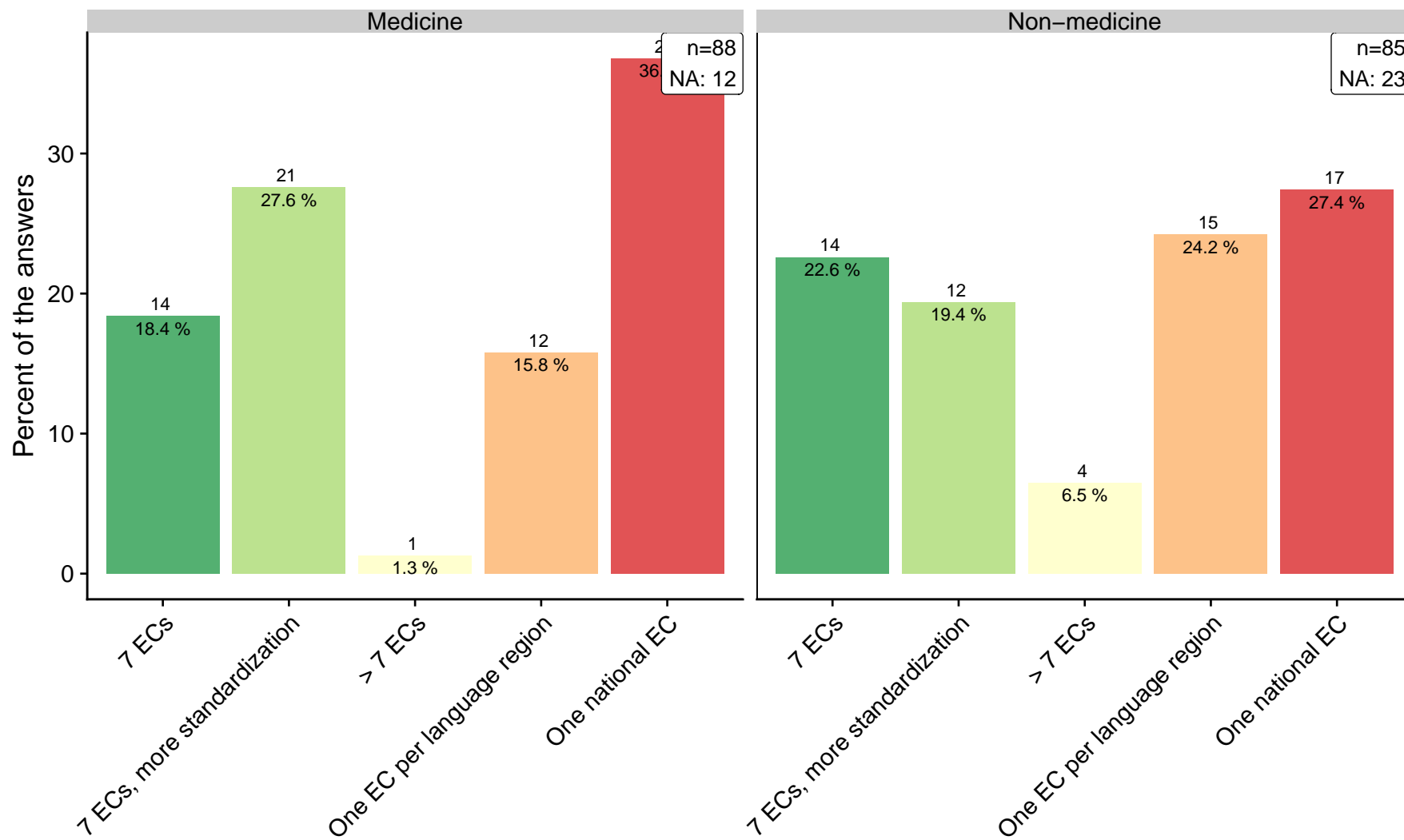
10.1.2 Stratified by initiator



10.1.3 Stratified by risk category

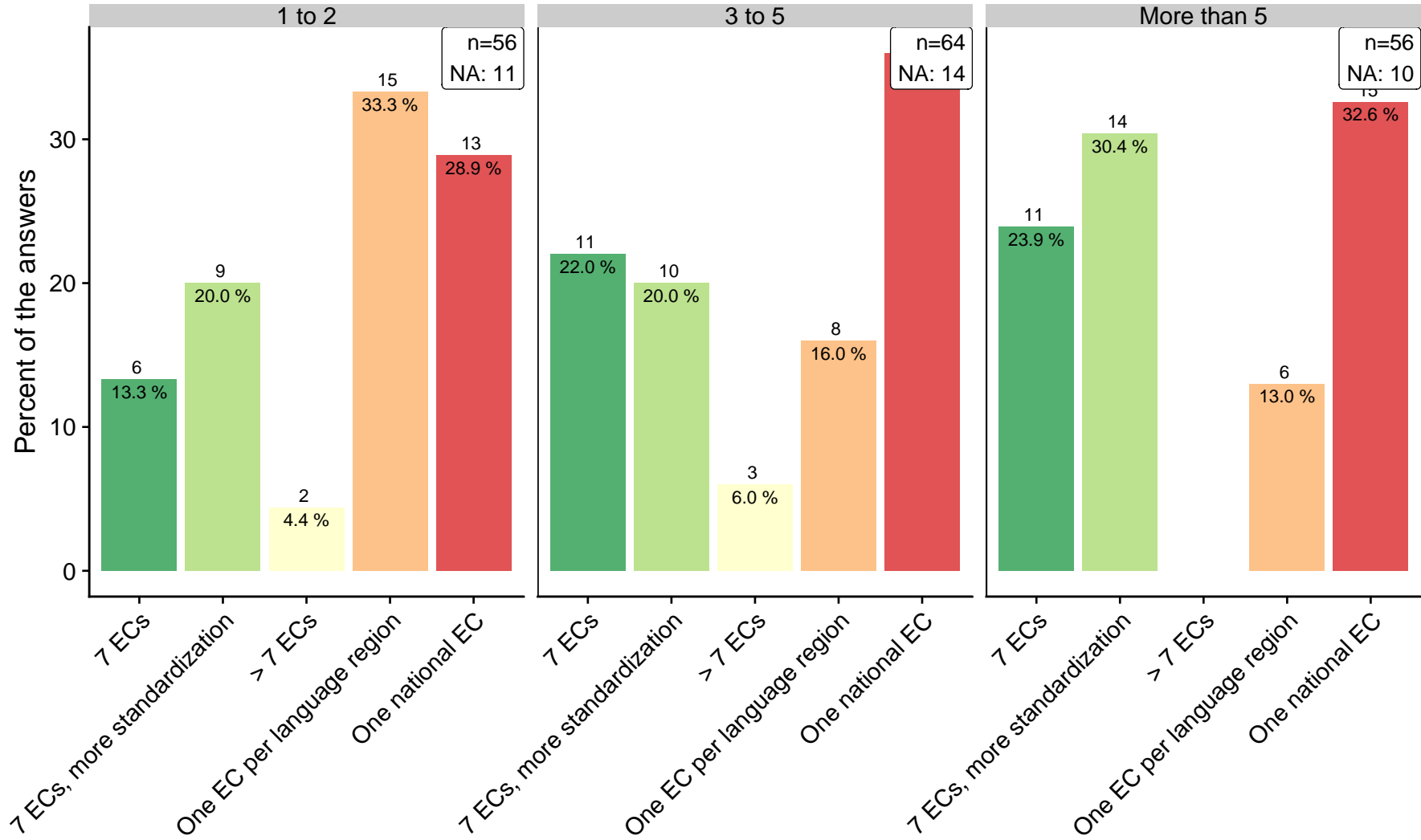


10.1.4 Stratified by field

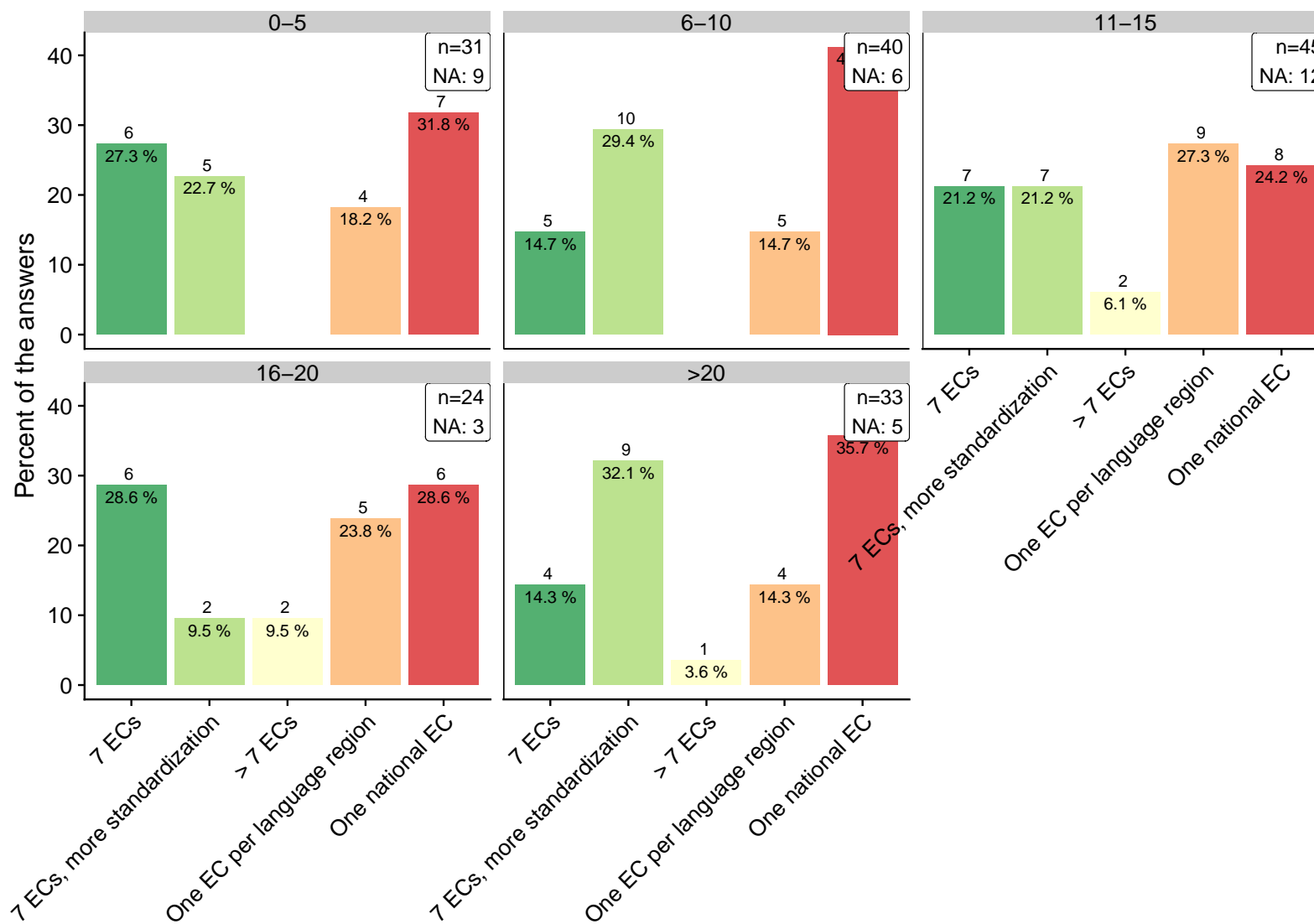


10.2 Feedback on application stratified by experience of the researcher

10.2.1 Stratified by number of submitted EC projects since HRA



10.2.2 Stratified by years working in research



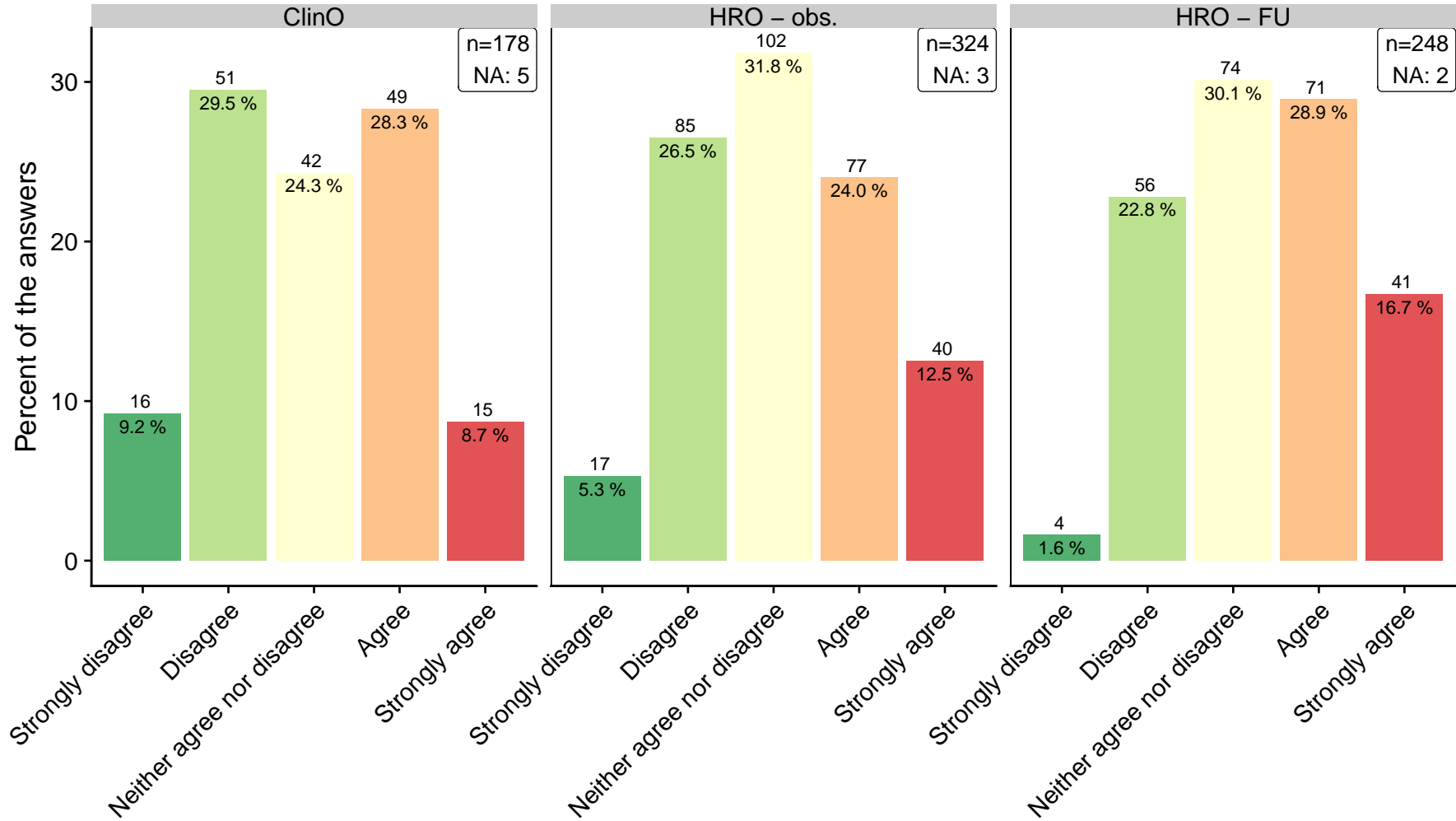
- 11 **Question B21a: Here are two statements that you could hear in discussions about the HRA. For each statement, indicate your level of (dis)agreement.**

Question from IPZ / KEK-CDC Consultants: Gibt es Unterschiede nach Forschungsbereich oder Erfahrung zu den beiden Fragen? Wie ist Frage B21b generell zu interpretieren? Wenn sich daraus schliessen lässt, dass die Forschenden kaum Kenntnisse haben, wie sind dann die Fragen zur «Appropriateness» der Regelung des HFG (B22) zu interpretieren?

11.1 Feedback on application stratified research details

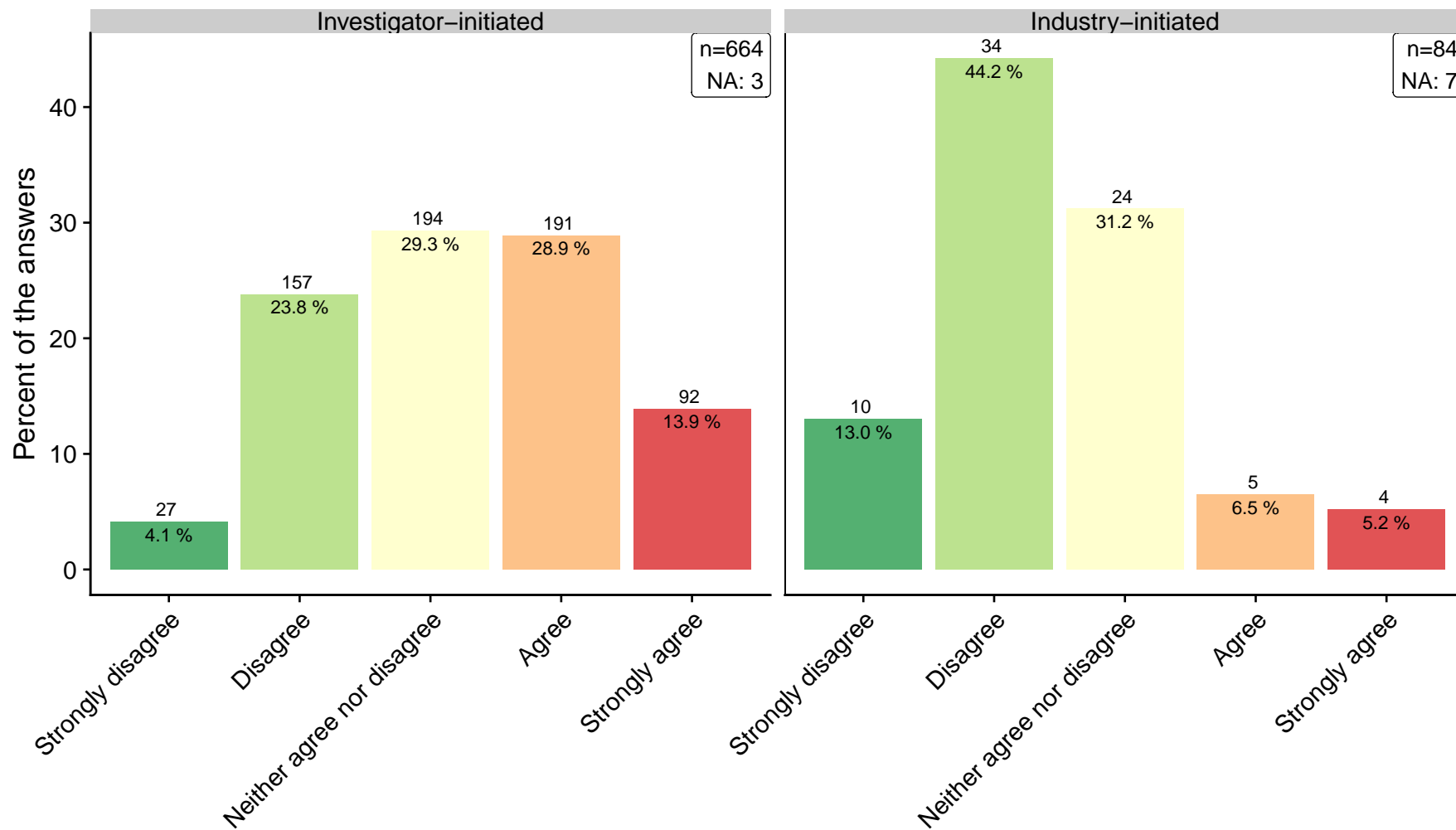
11.1.1 Stratified by research type

a) The HRA hinders scientific research.



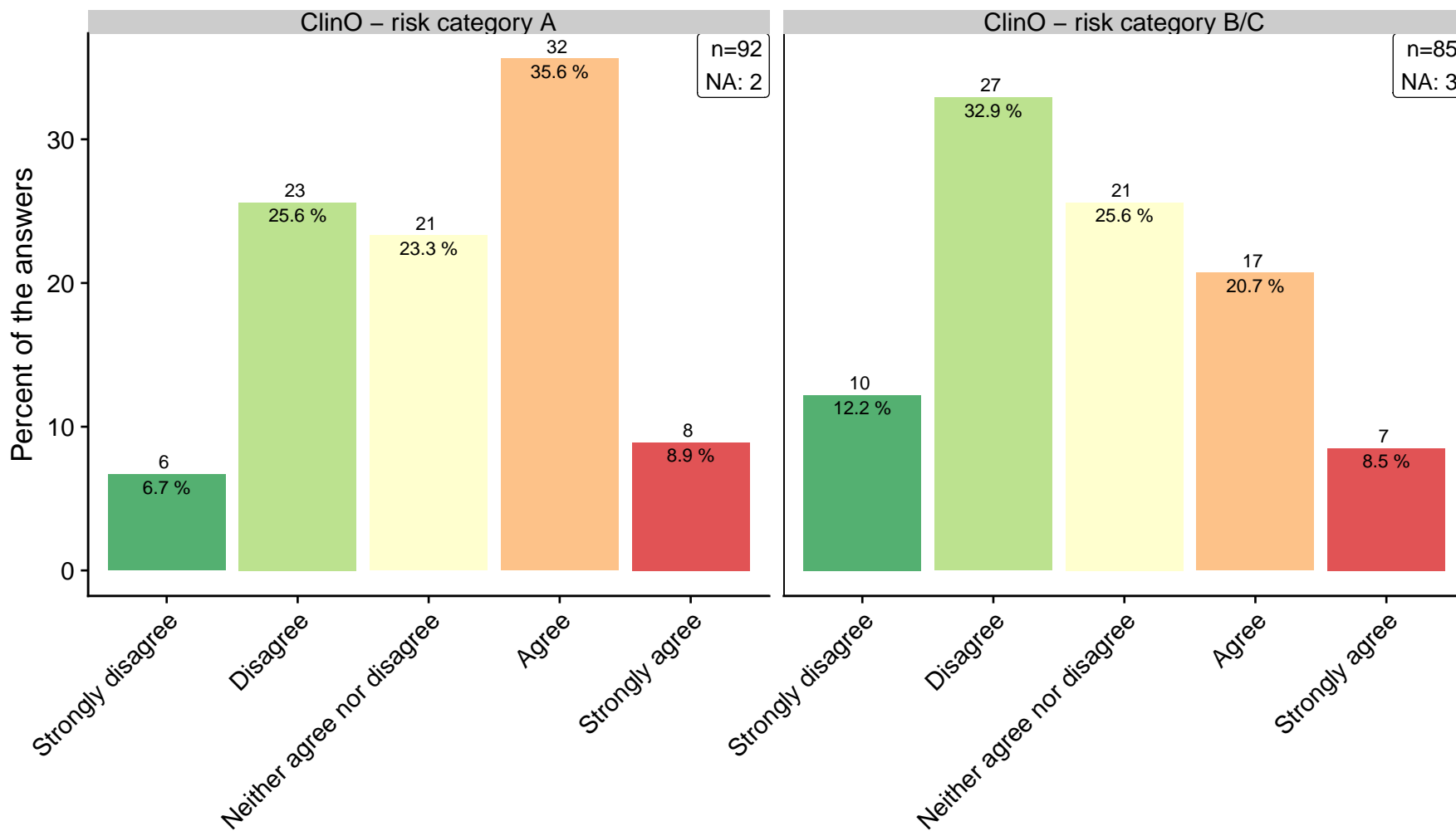
11.1.2 Stratified by initiator

a) The HRA hinders scientific research.



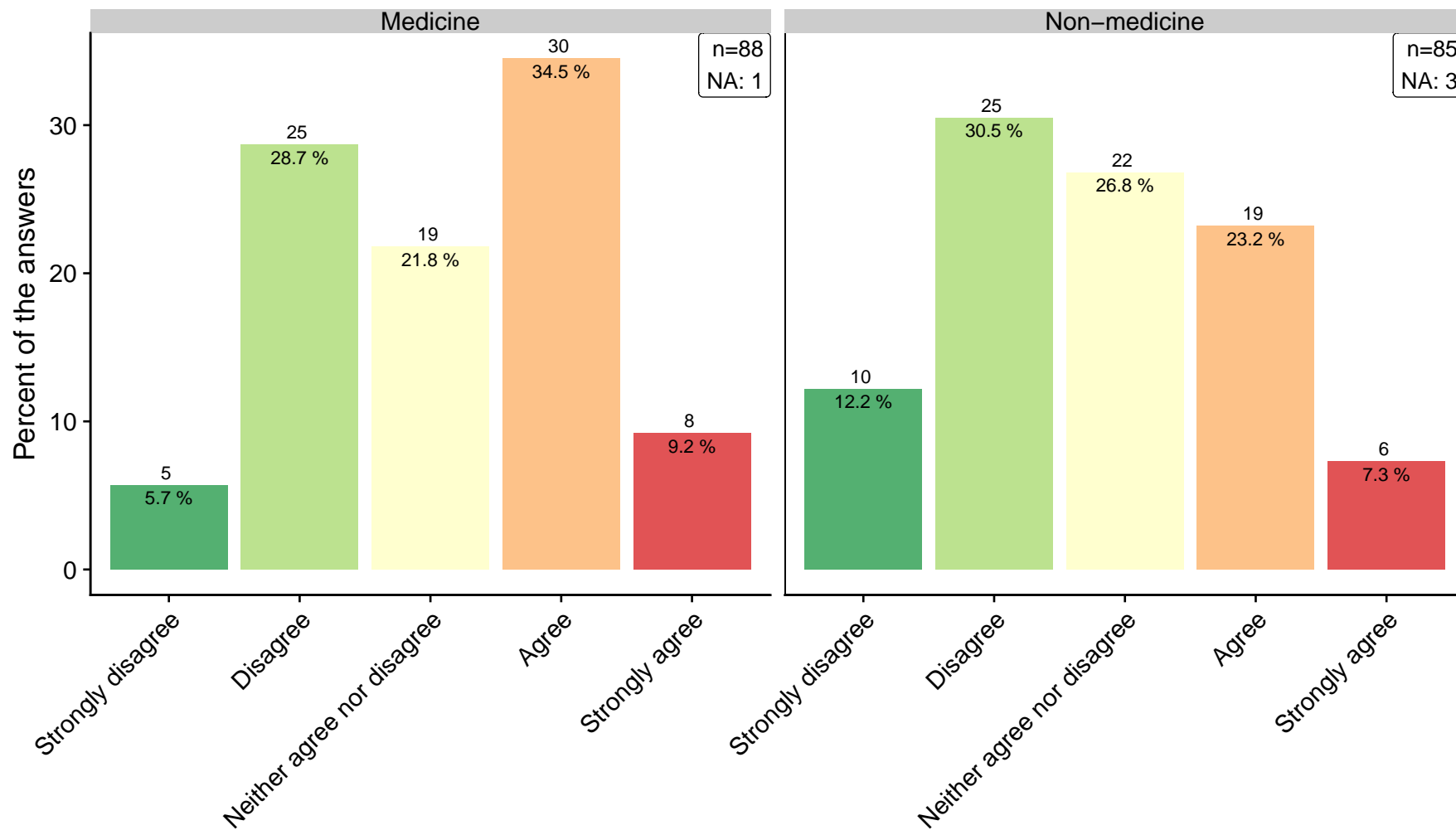
11.1.3 Stratified by risk category

a) The HRA hinders scientific research.



11.1.4 Stratified by field

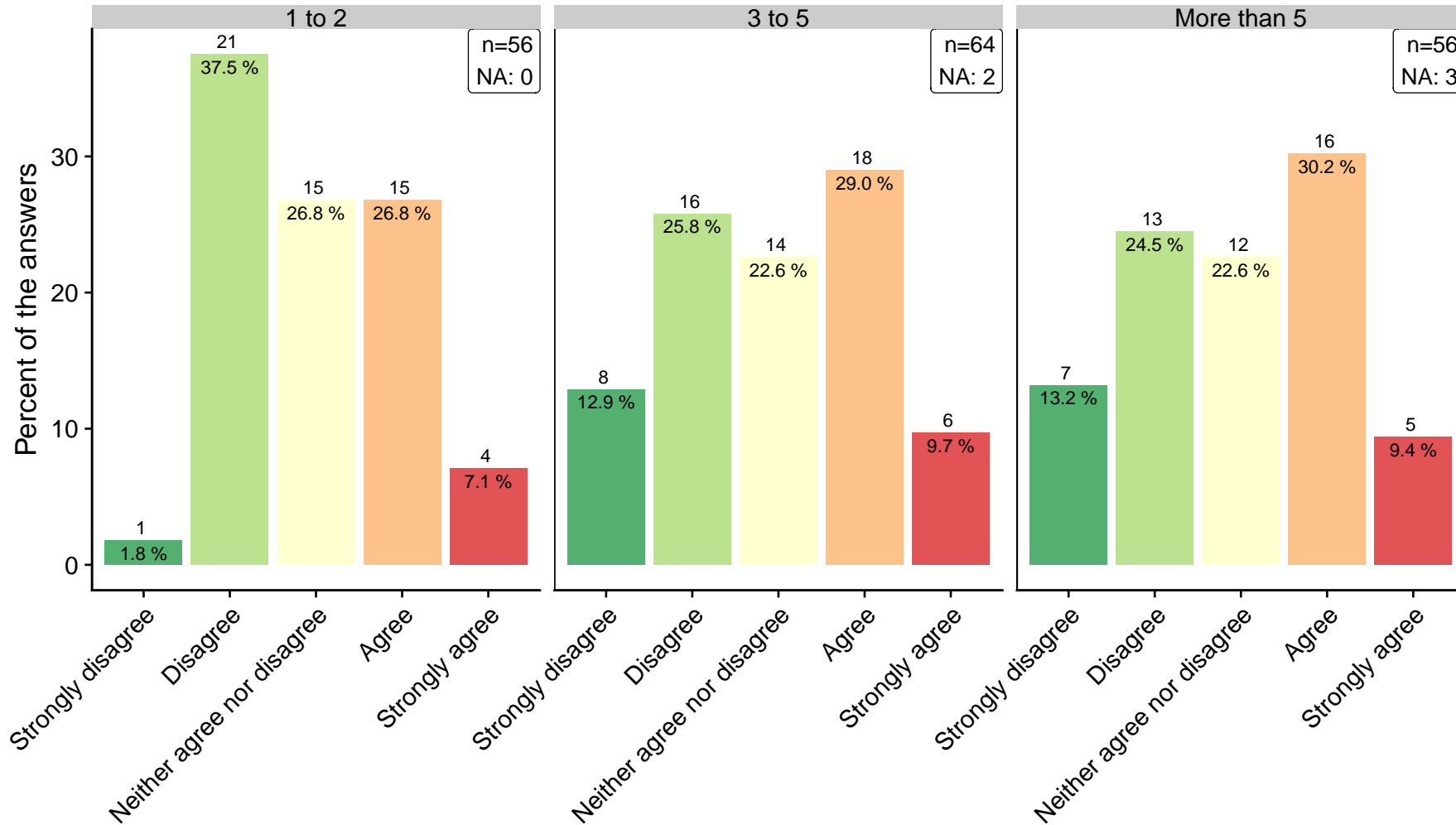
a) The HRA hinders scientific research.



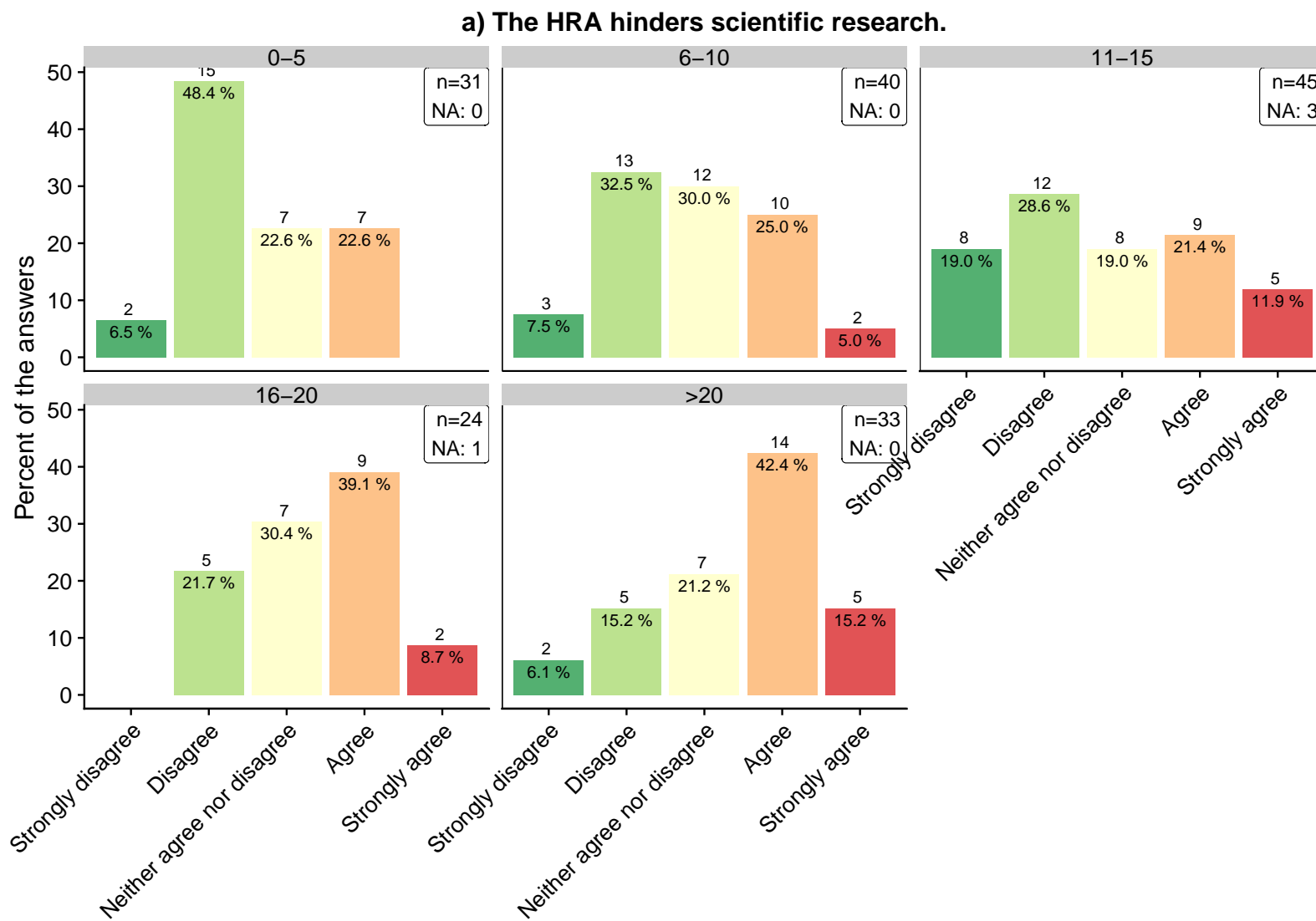
11.2 Feedback on application stratified by experience of the researcher

11.2.1 Stratified by number of submitted EC projects since HRA

a) The HRA hinders scientific research.



11.2.2 Stratified by years working in research



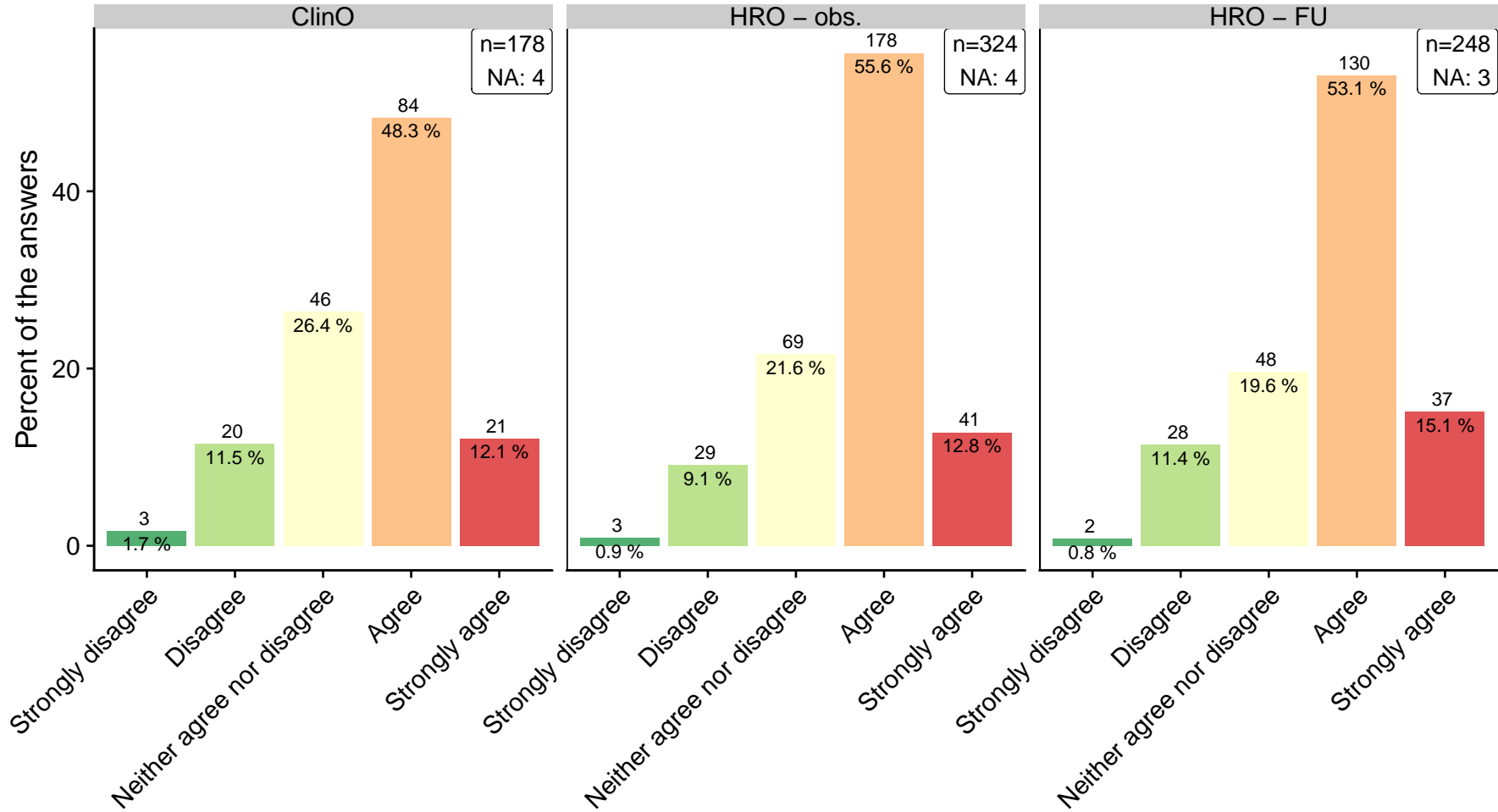
12 Question B21b: Here are two statements that you could hear in discussions about the HRA. For each statement, indicate your level of (dis)agreement.

Question from IPZ / KEK-CDC Consultants: Gibt es Unterschiede nach Forschungsbereich oder Erfahrung zu den beiden Fragen? Wie ist Frage B21b generell zu interpretieren? Wenn sich daraus schliessen lässt, dass die Forschenden kaum Kenntnisse haben, wie sind dann die Fragen zur «Appropriateness» der Regelung des HFG (B22) zu interpretieren?

12.1 Feedback on application stratified research details

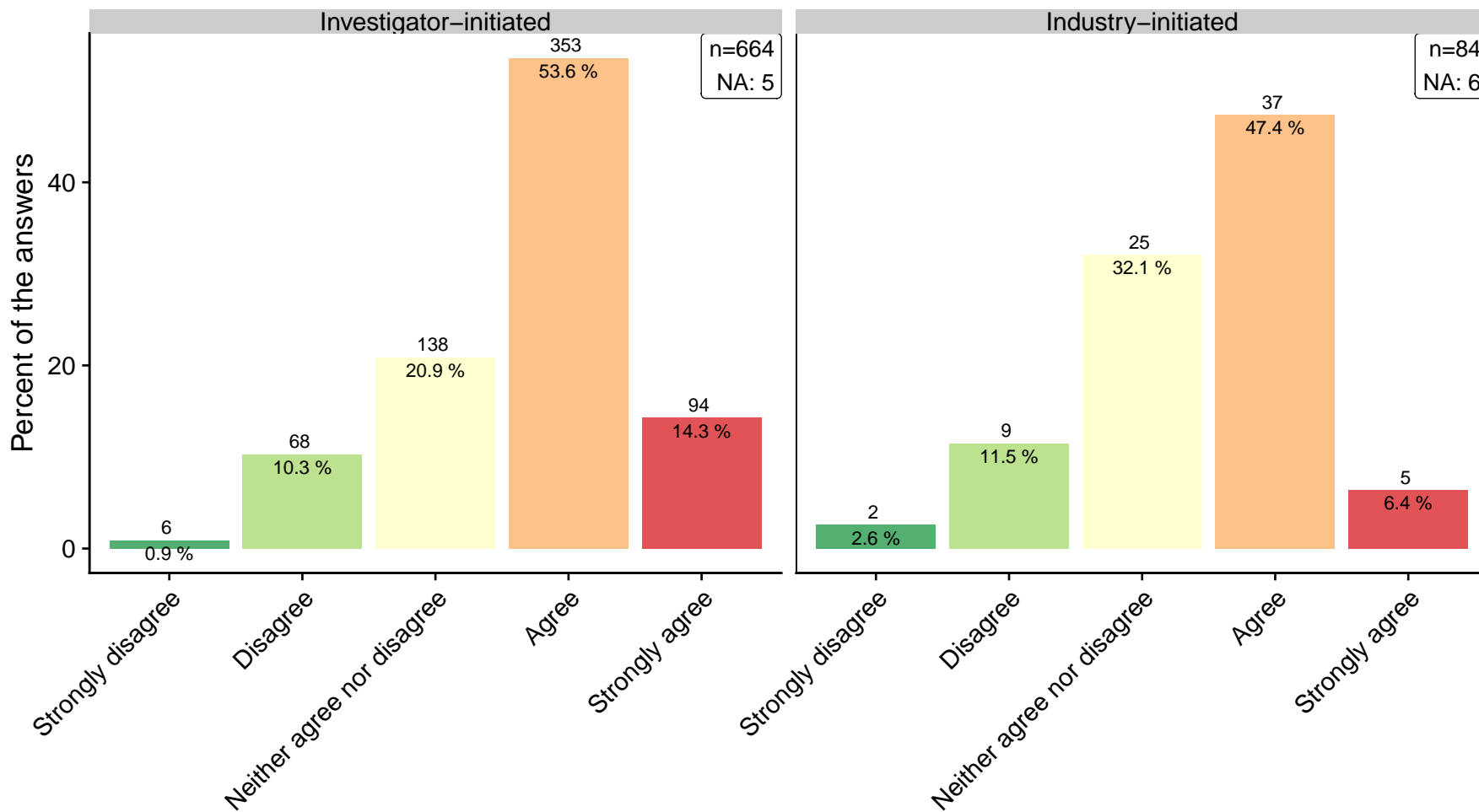
12.1.1 Stratified by research type

b) Many researchers do not know the HRA and its ordinances very well.



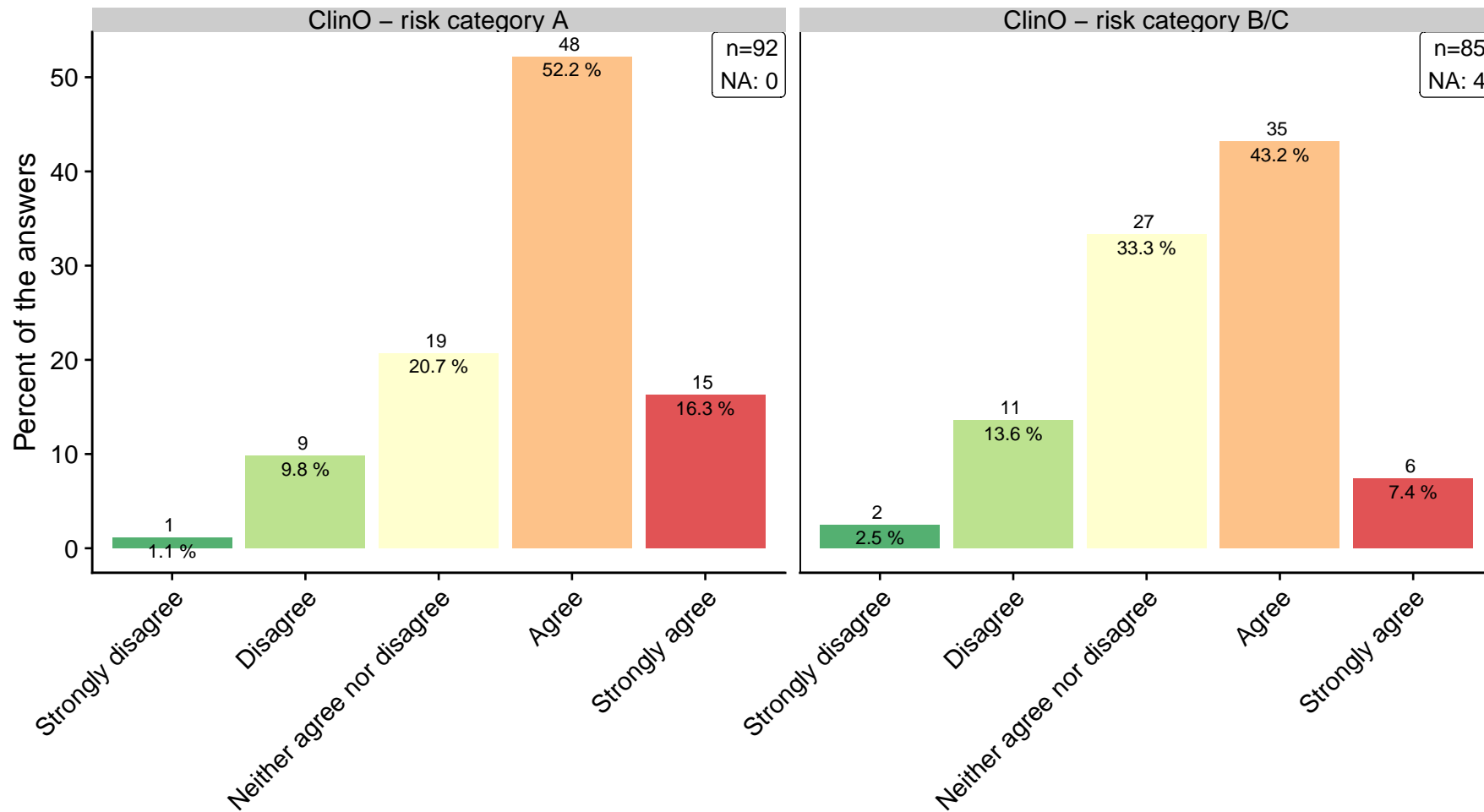
12.1.2 Stratified by initiator

b) Many researchers do not know the HRA and its ordinances very well.



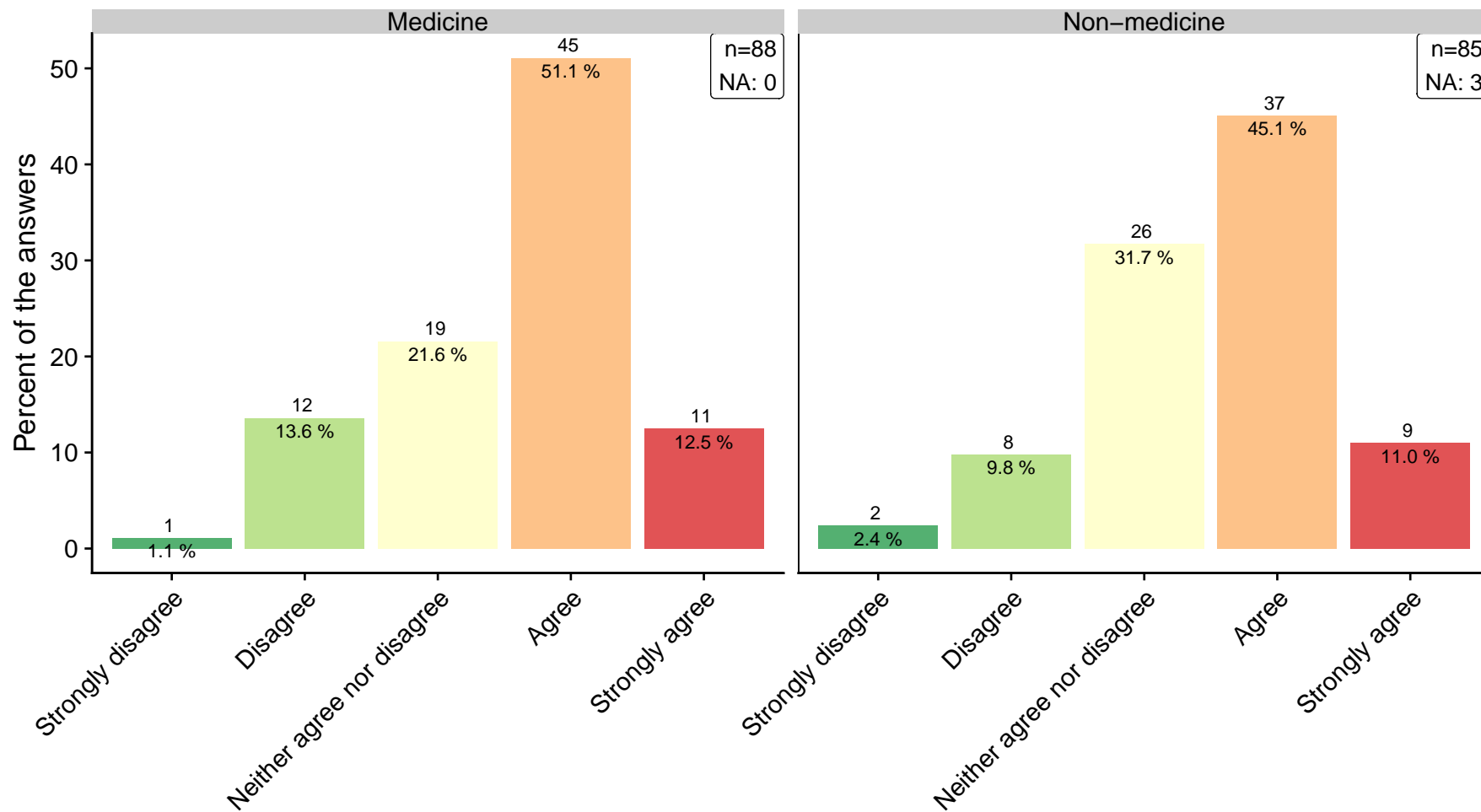
12.1.3 Stratified by risk category

b) Many researchers do not know the HRA and its ordinances very well.



12.1.4 Stratified by field

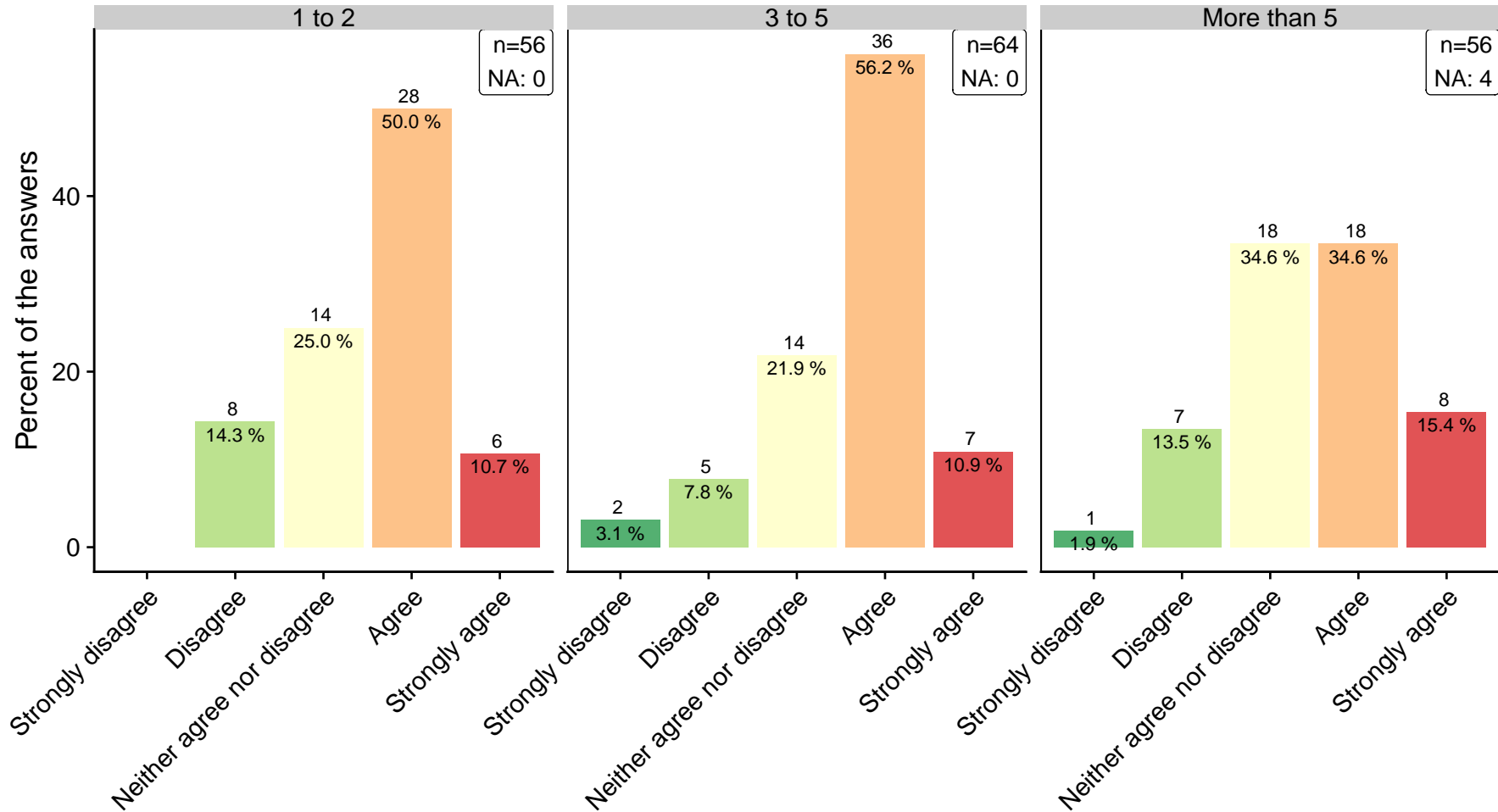
b) Many researchers do not know the HRA and its ordinances very well.



12.2 Feedback on application stratified by experience of the researcher

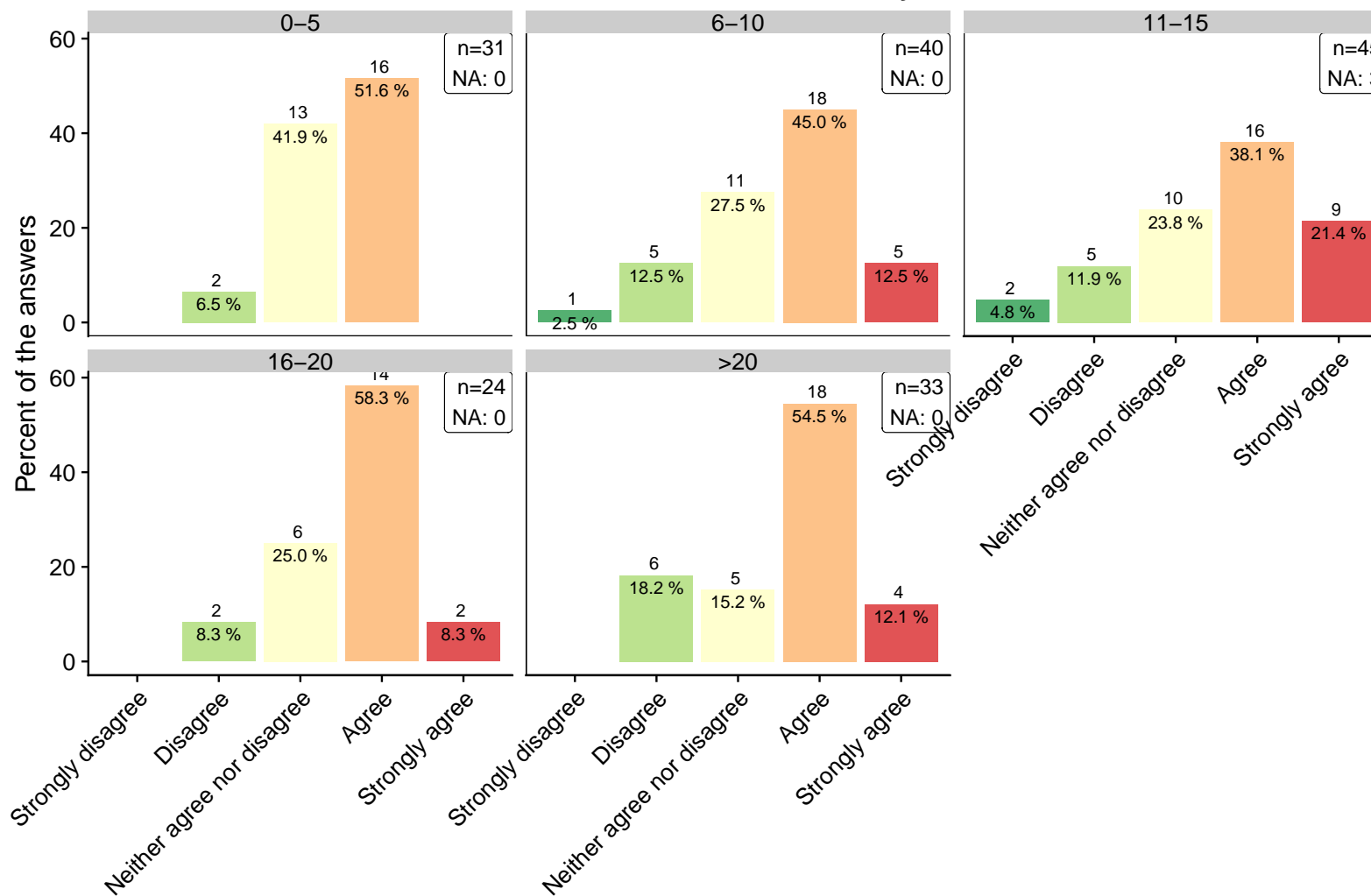
12.2.1 Stratified by number of submitted EC projects since HRA

b) Many researchers do not know the HRA and its ordinances very well.



12.2.2 Stratified by years working in research

b) Many researchers do not know the HRA and its ordinances very well.



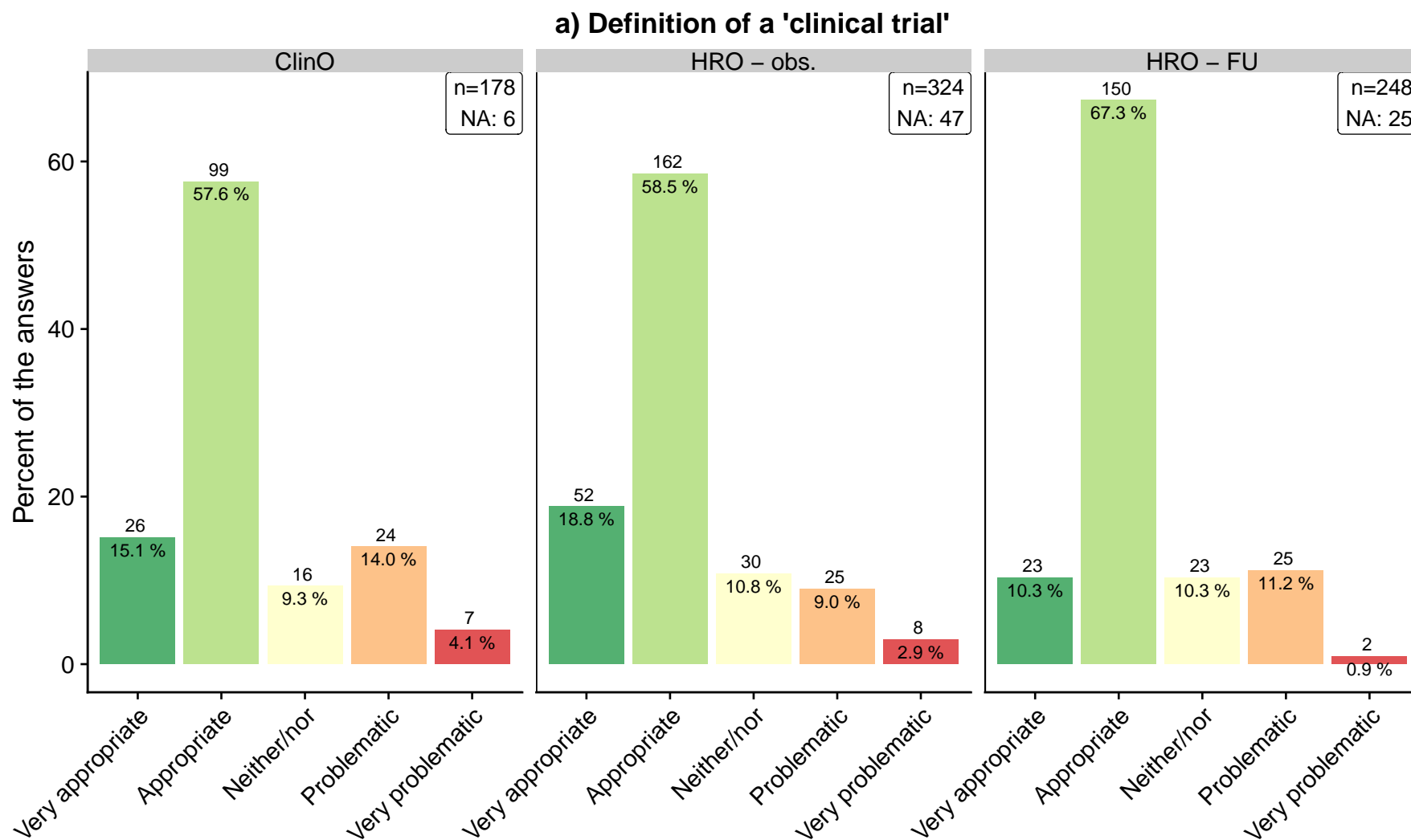
- 13 Question B22 a-f: Below is a list of different aspects that are usually covered by human research regulations. In your opinion, are these aspects appropriately regulated in the Human Research Act and its ordinances?

Question from IPZ / KEK-CDC Consultants: Gibt es Unterschiede nach Forschungsbereich? Gibt es eine bestimmte Gruppe, die Mühe hat mit der Definition des «klinischen Versuchs» (B22a)? (nicht-medizinische Disziplinen, HFV-Forschende). Wie beurteilen Personen die Anforderungen für Forschungsprojekte mit vulnerablen Personen, die auch ein solches eingereicht haben?

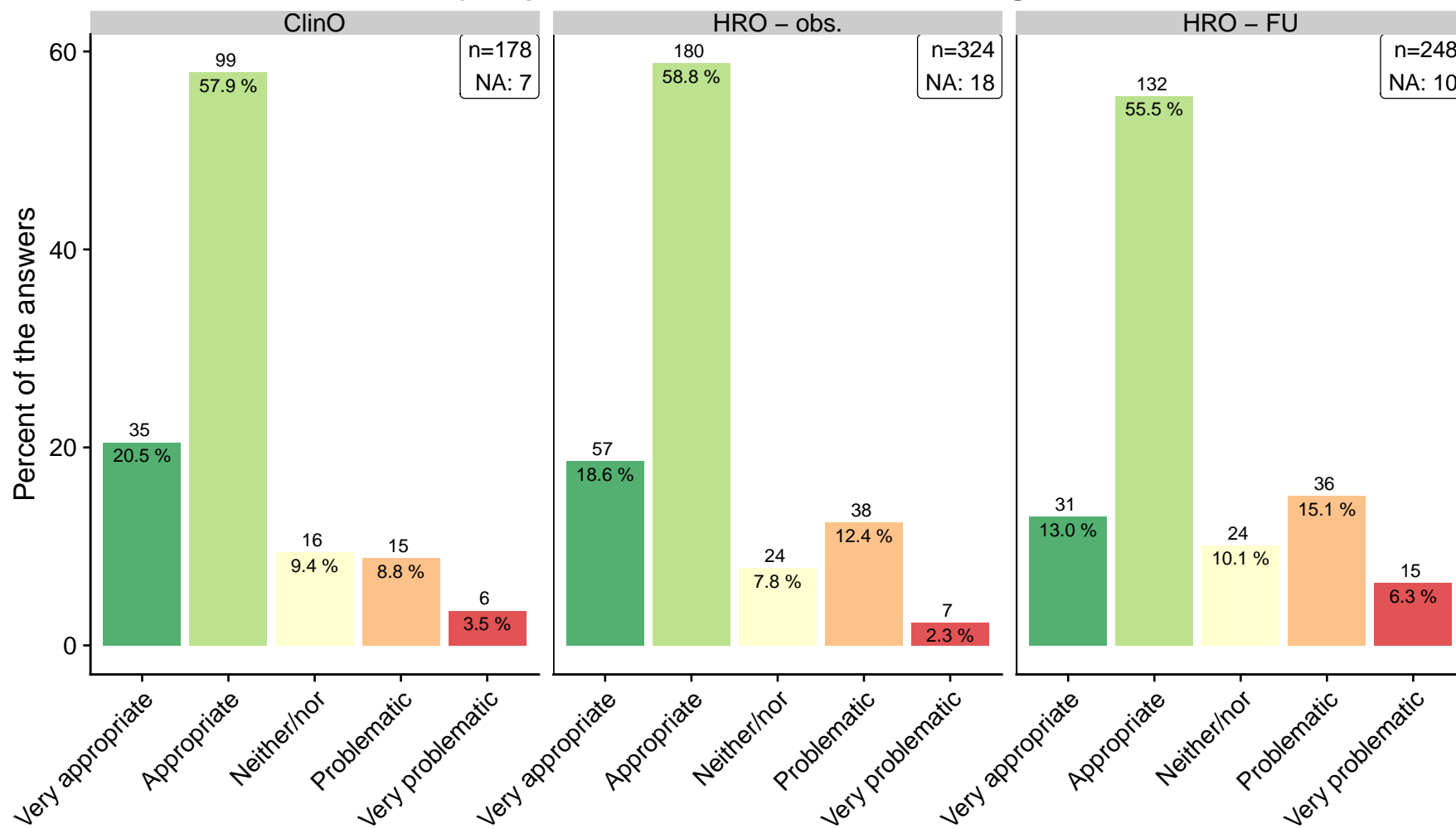
The answers 'I have no experience with this aspect' have been attributed to the group NA.

13.1 Feedback on application stratified research details

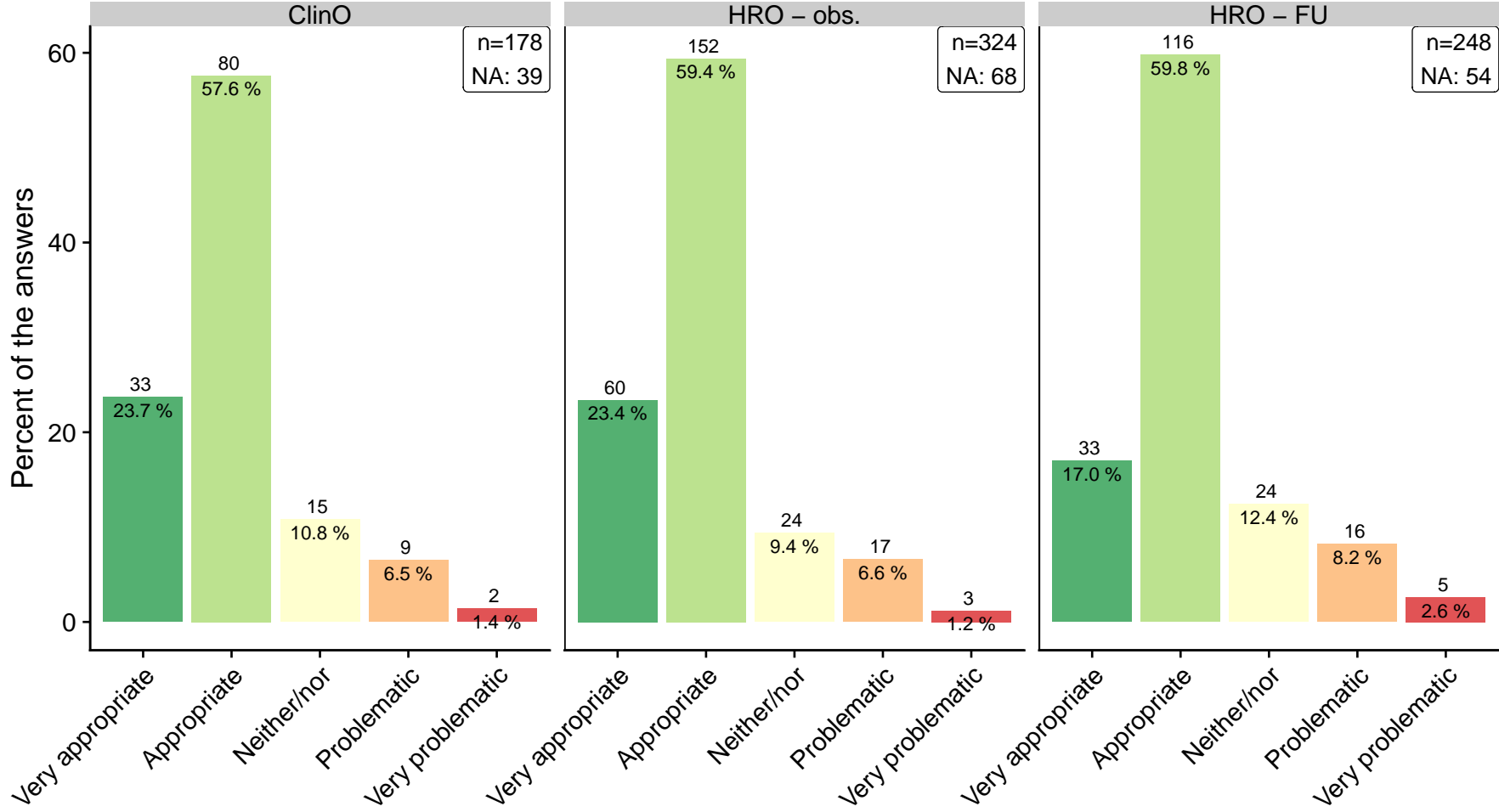
13.1.1 Stratified by research type



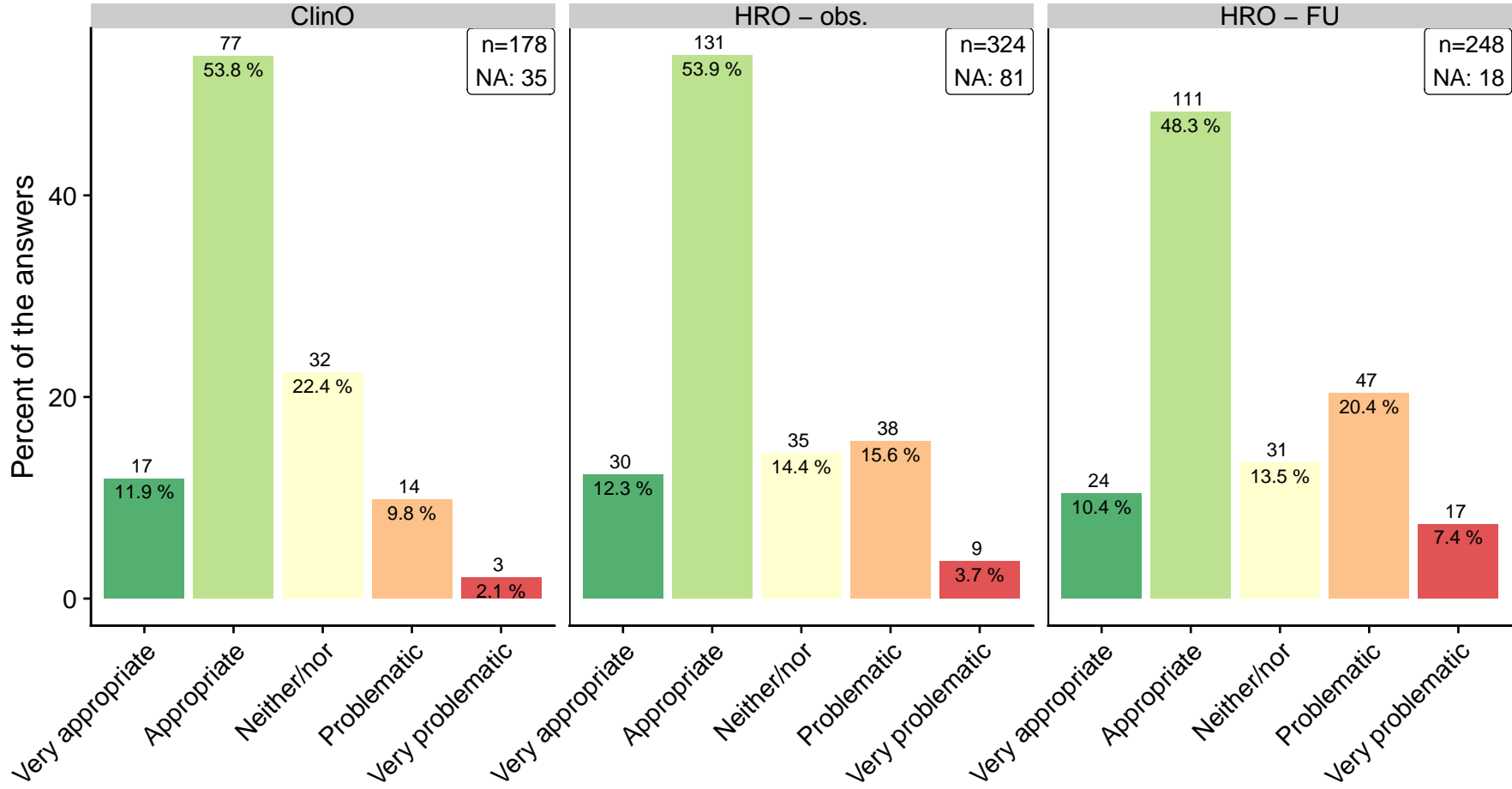
b) Requirements for informed consent in general



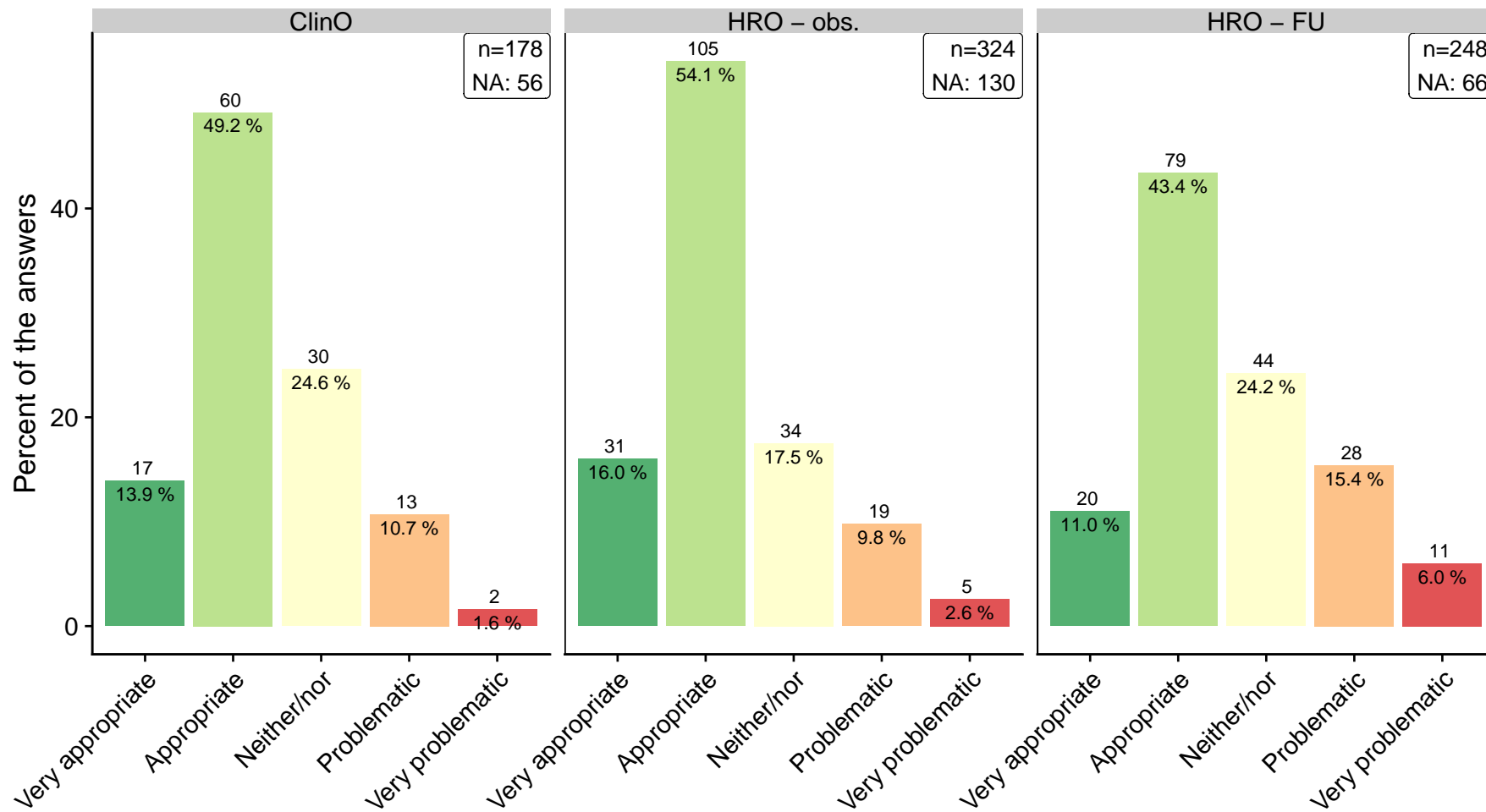
c) Requirements for research projects with vulnerable persons



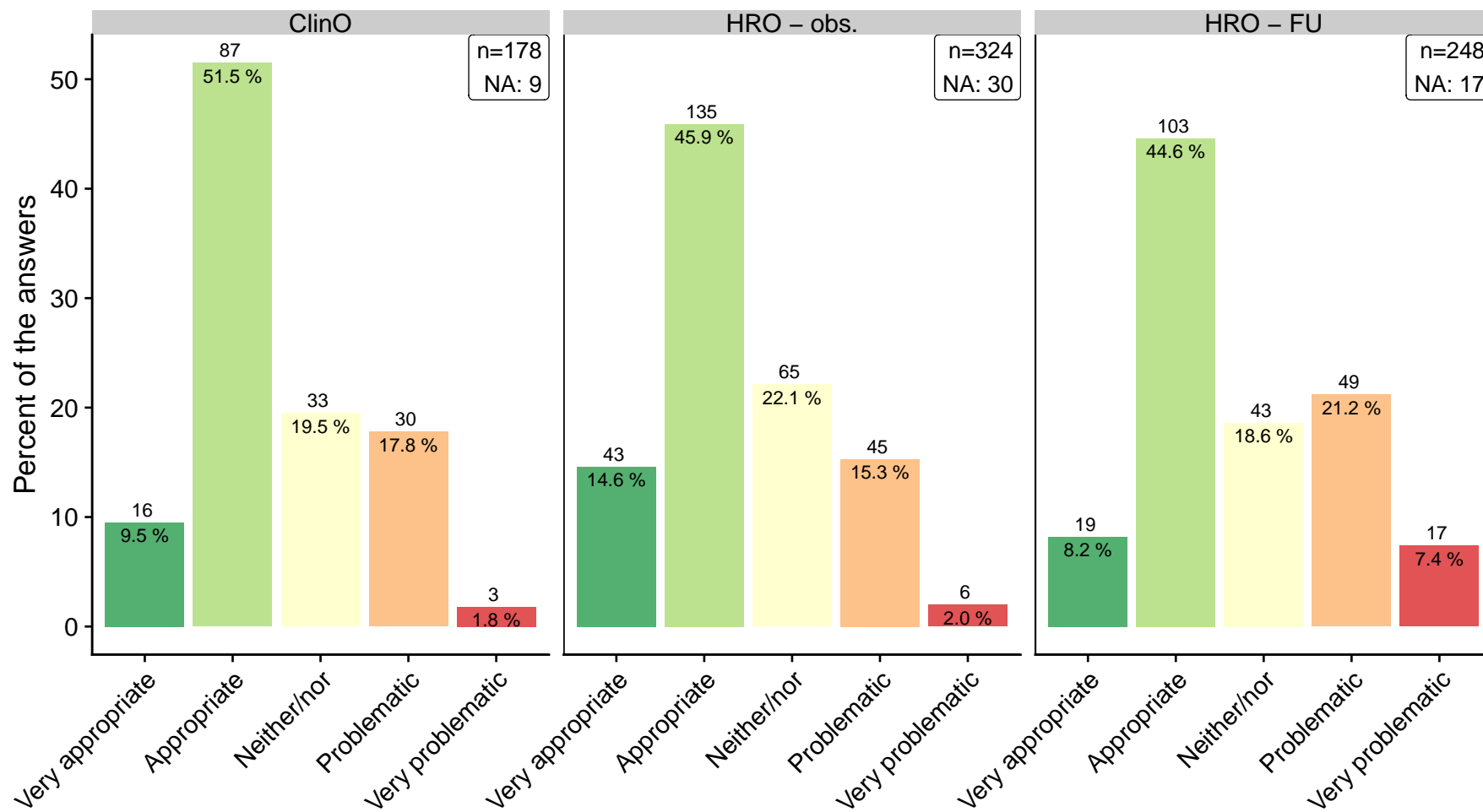
d) Requirements for consent/broad consent or possibility to opt out if biological material or health-related data are re-used



e) Difference made between genetic-data vs. non-genetic data

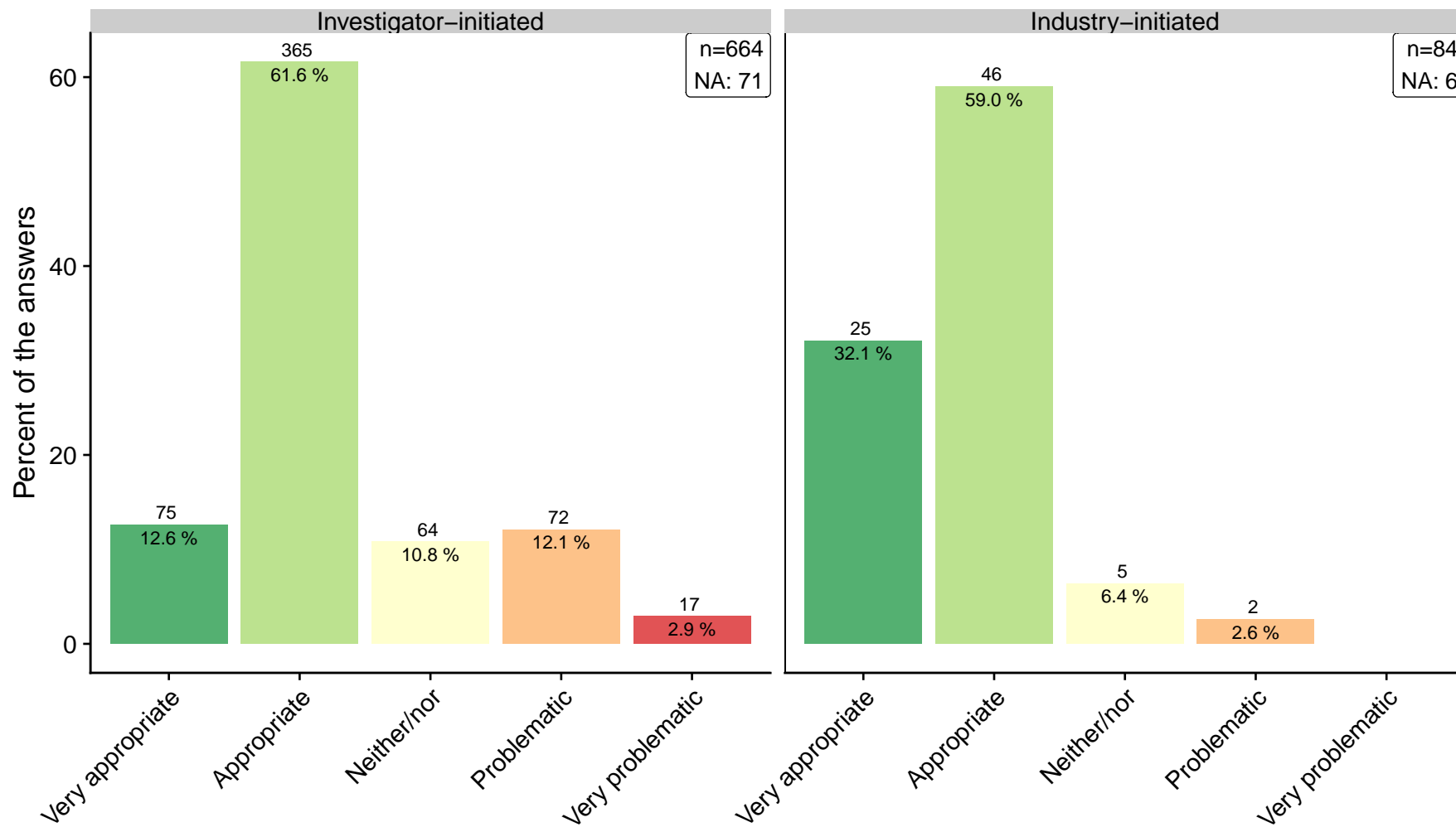


f) Difference made between uncoded, coded and anonymised material and data

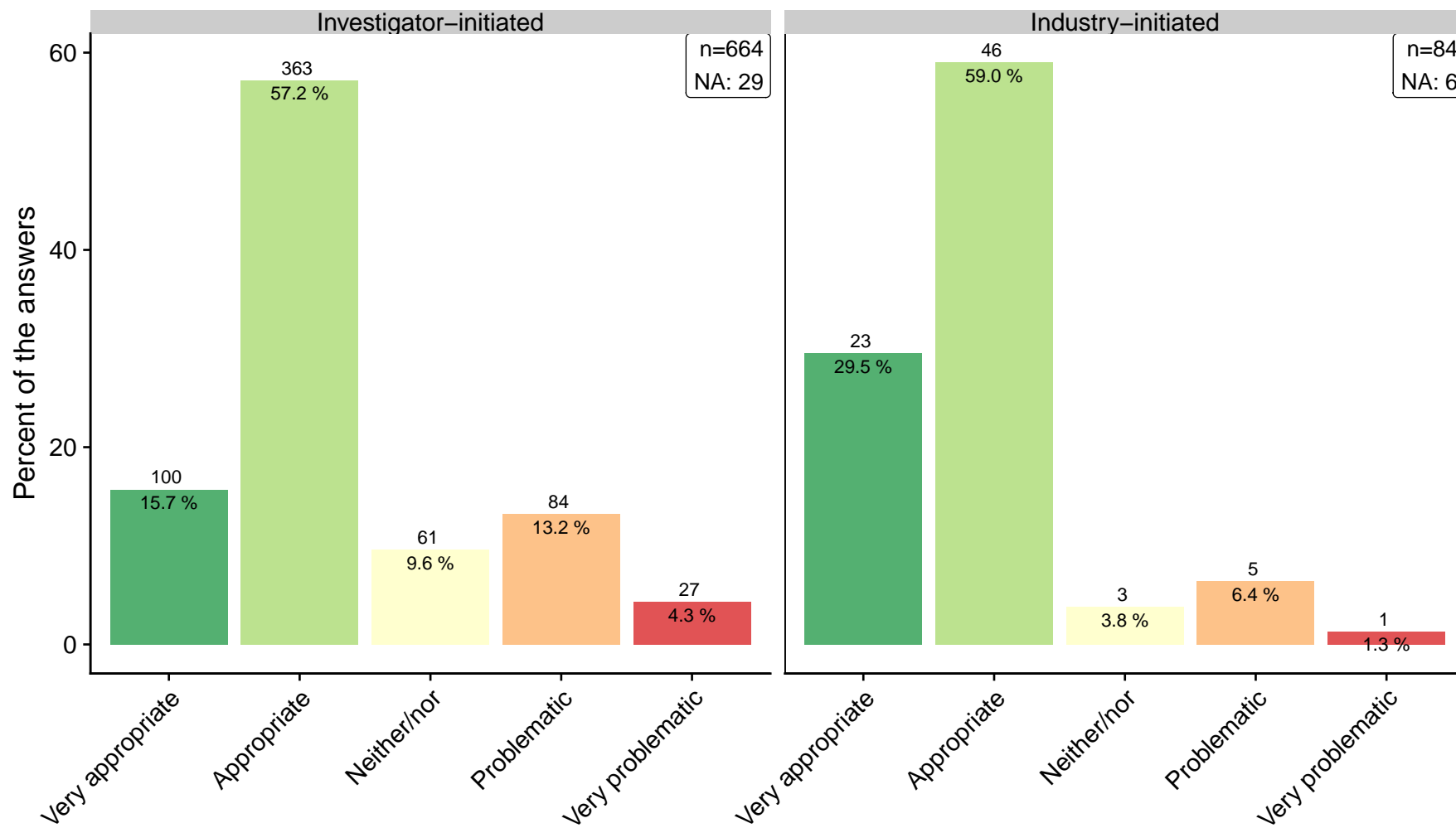


13.1.2 Stratified by initiator

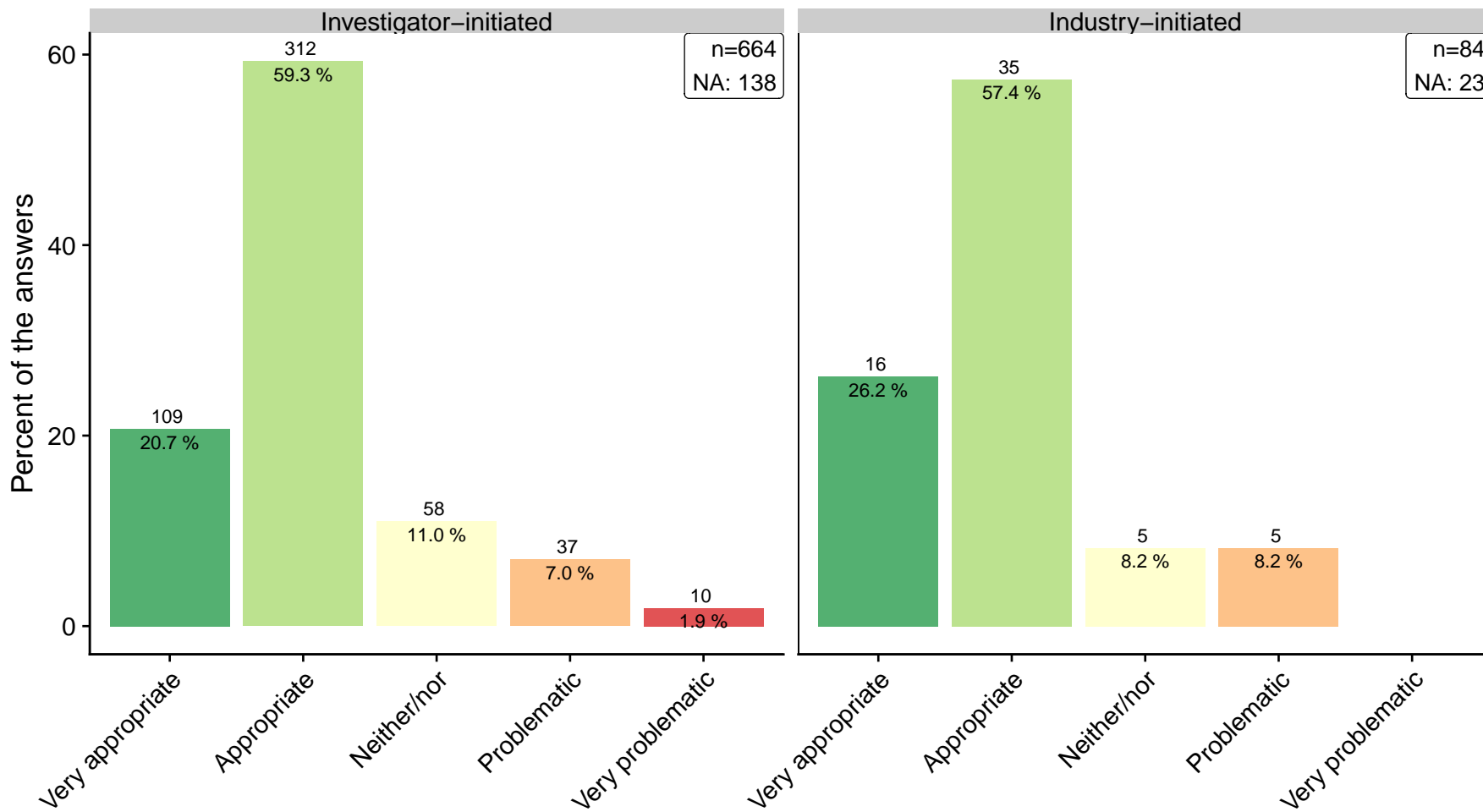
a) Definition of a 'clinical trial'



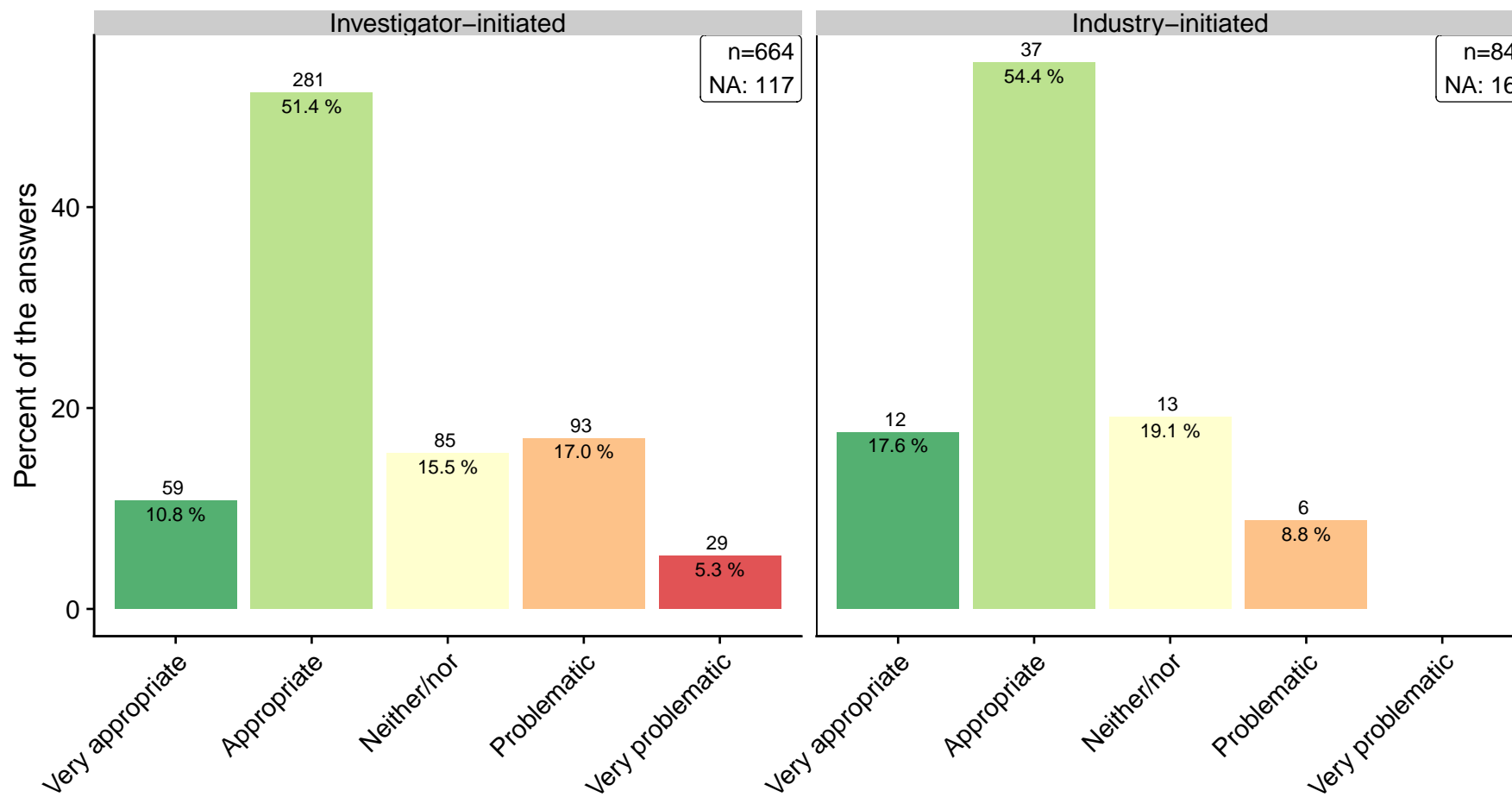
b) Requirements for informed consent in general



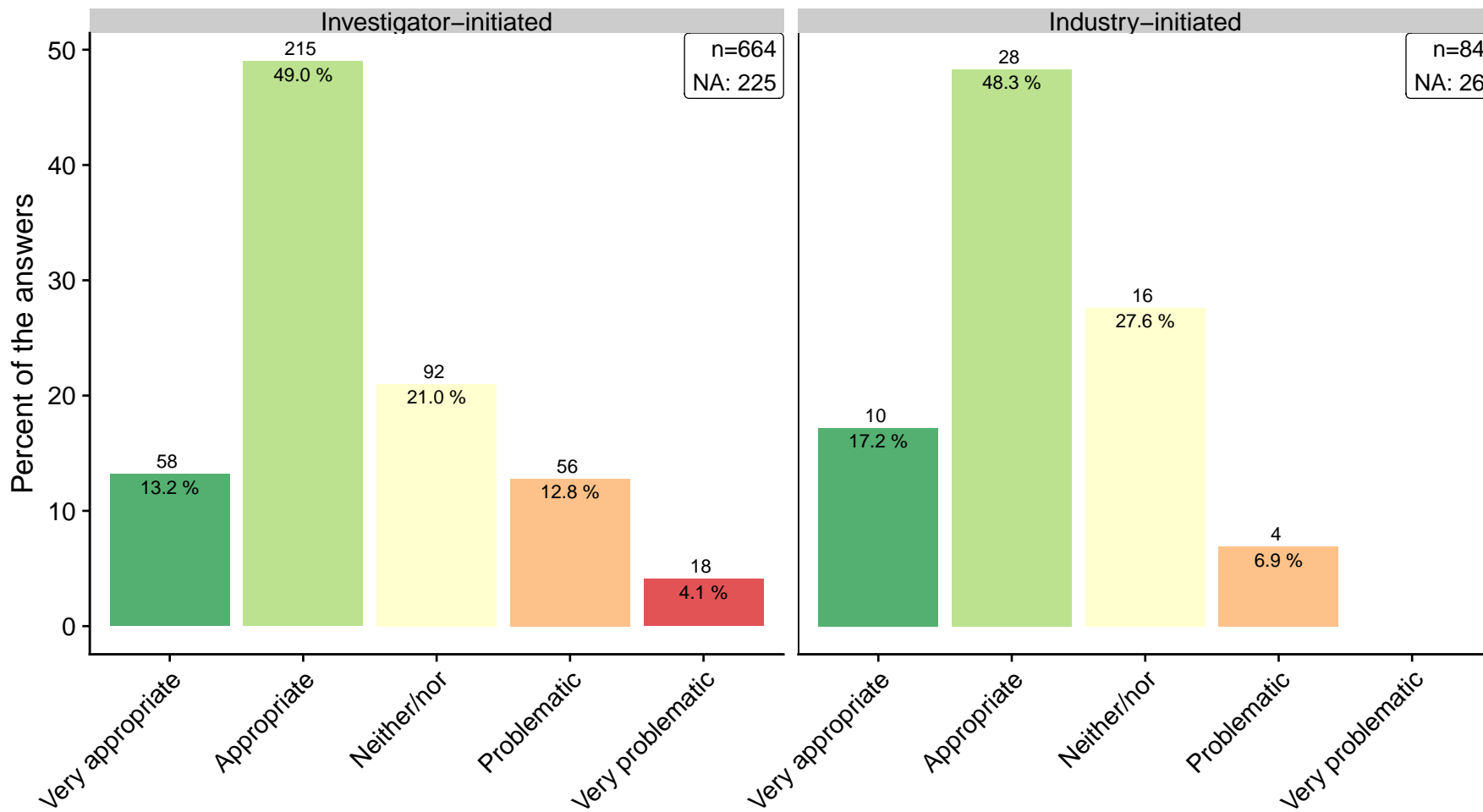
c) Requirements for research projects with vulnerable persons



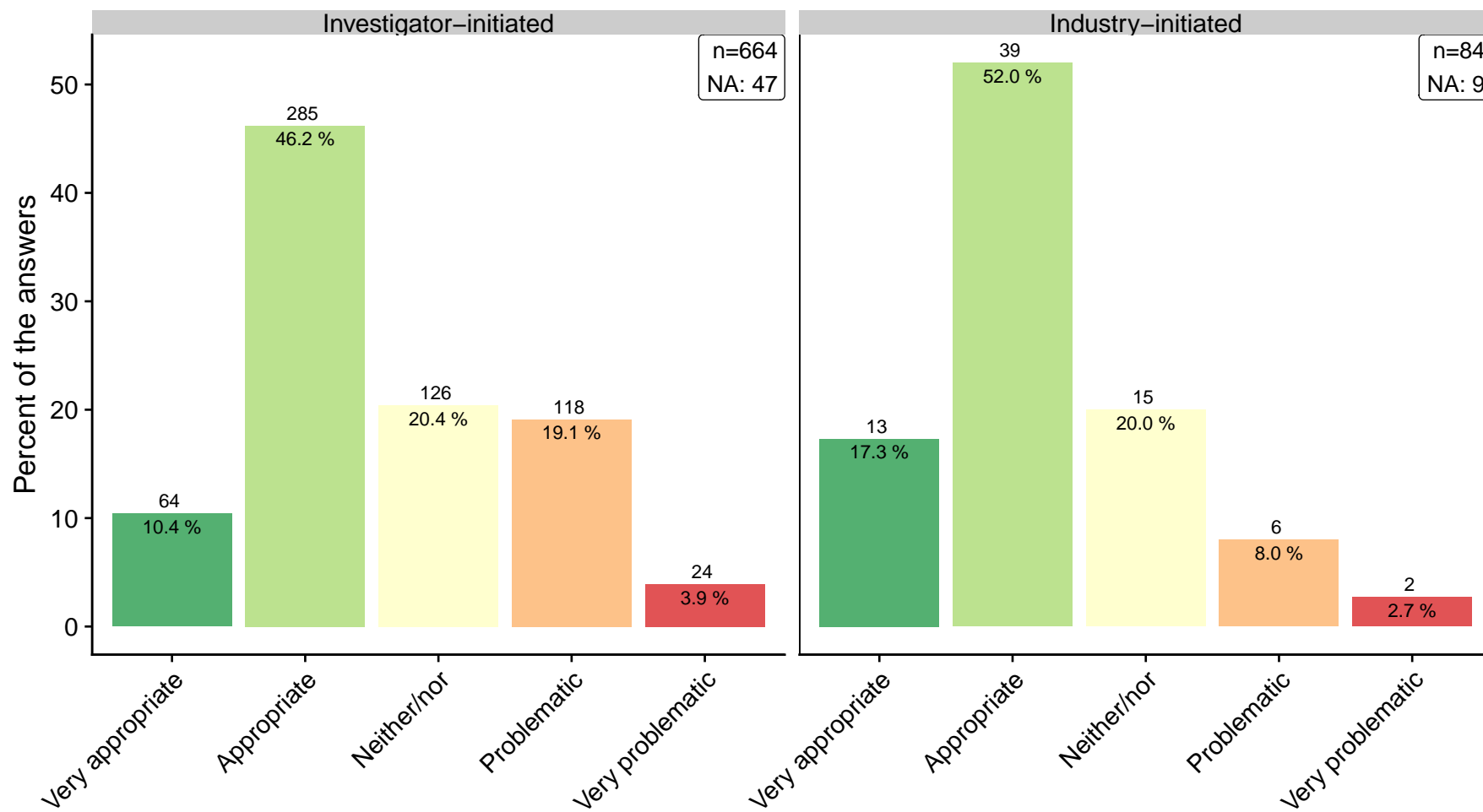
d) Requirements for consent/broad consent or possibility to opt out if biological material or health-related data are re-used



e) Difference made between genetic-data vs. non-genetic data

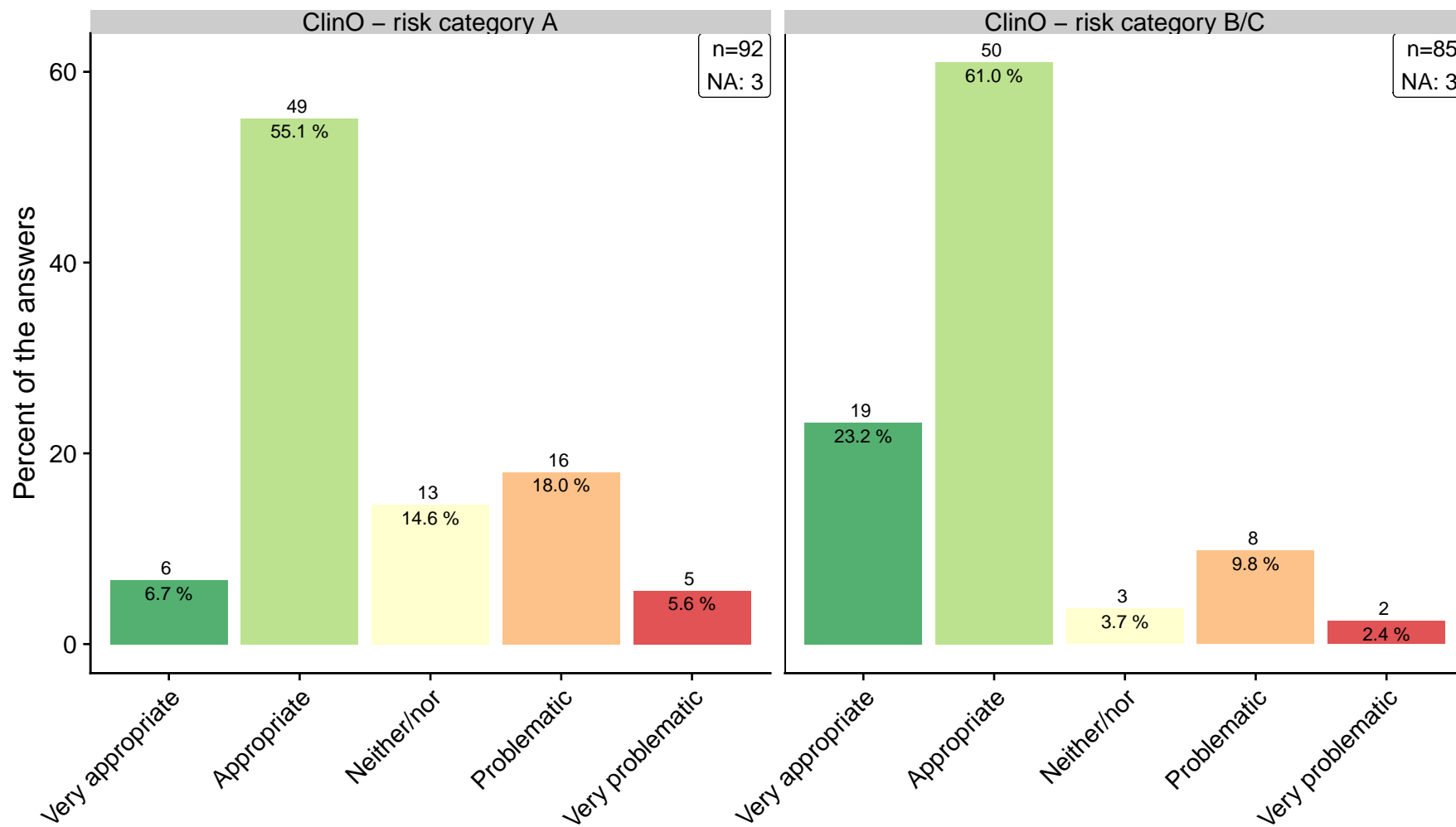


f) Difference made between uncoded, coded and anonymised material and data

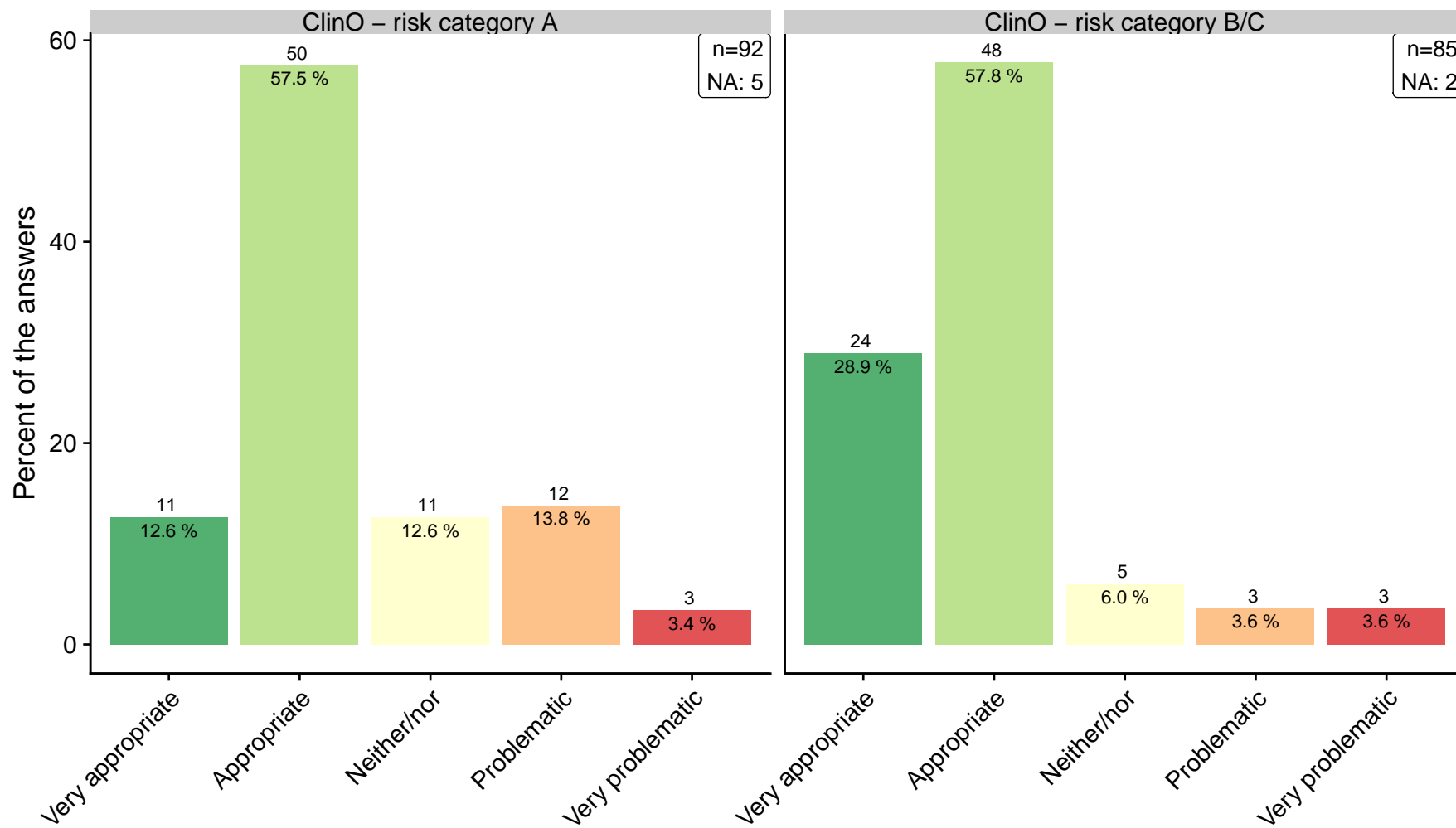


13.1.3 Stratified by risk category

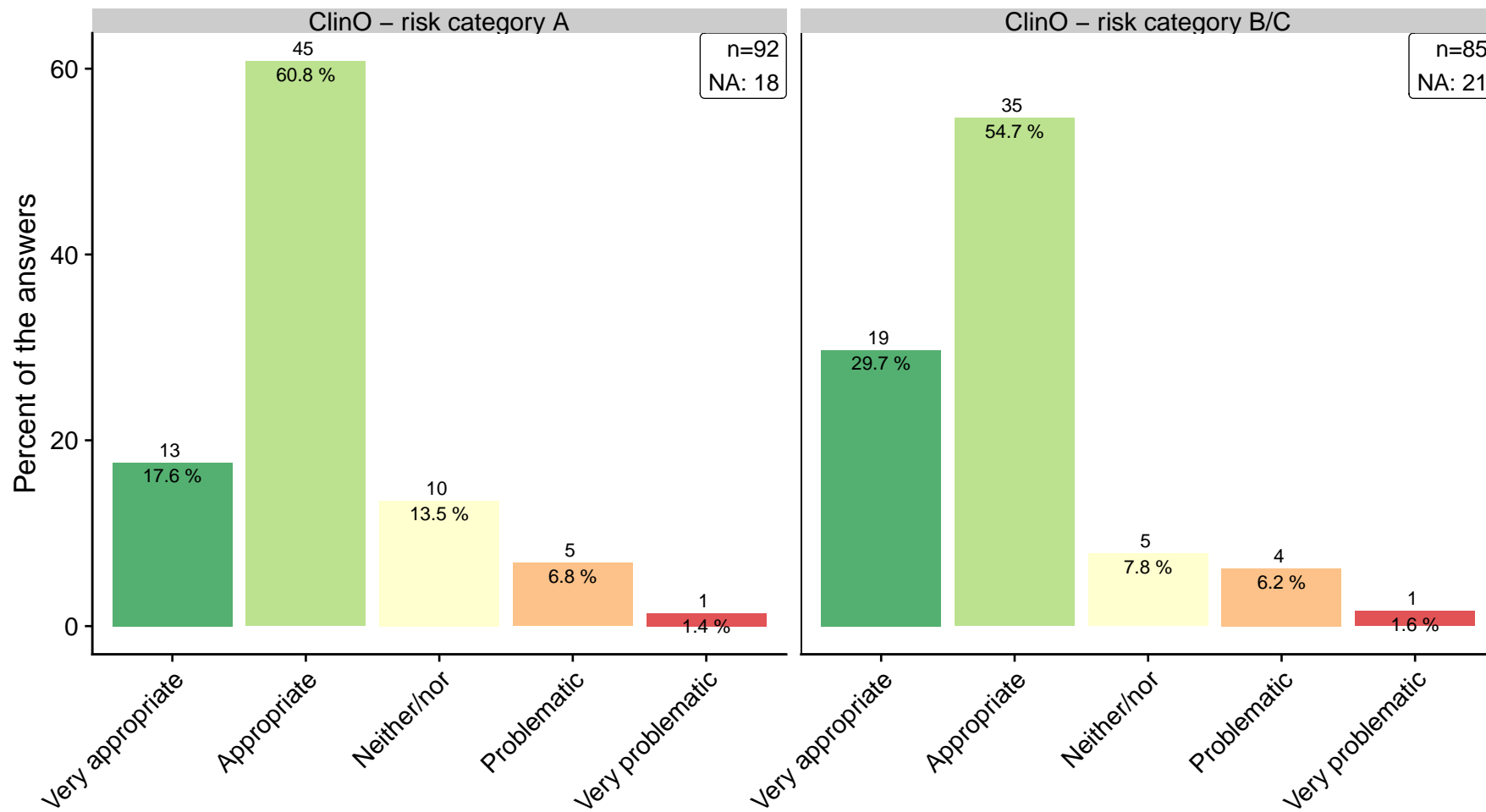
a) Definition of a 'clinical trial'



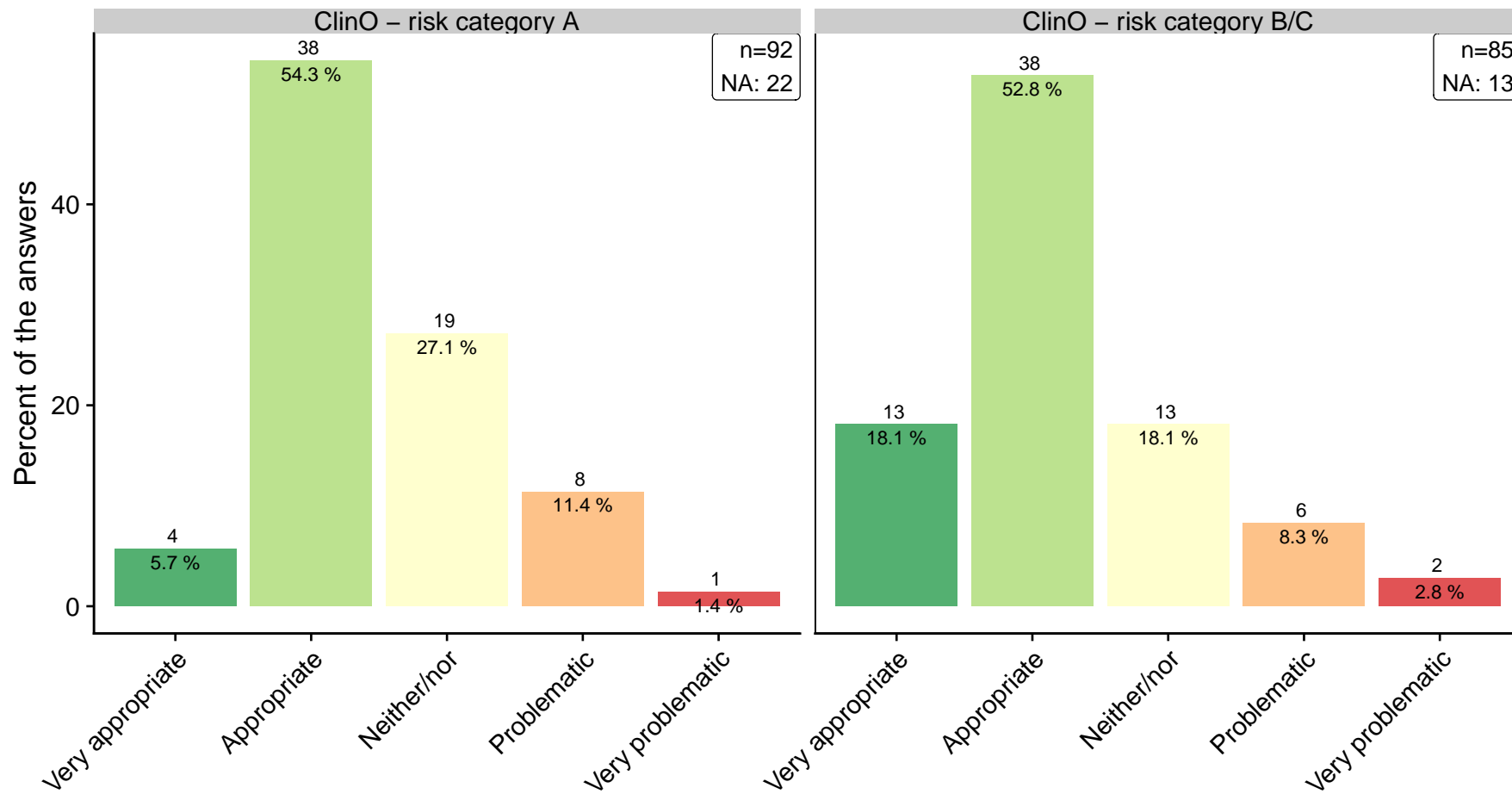
b) Requirements for informed consent in general



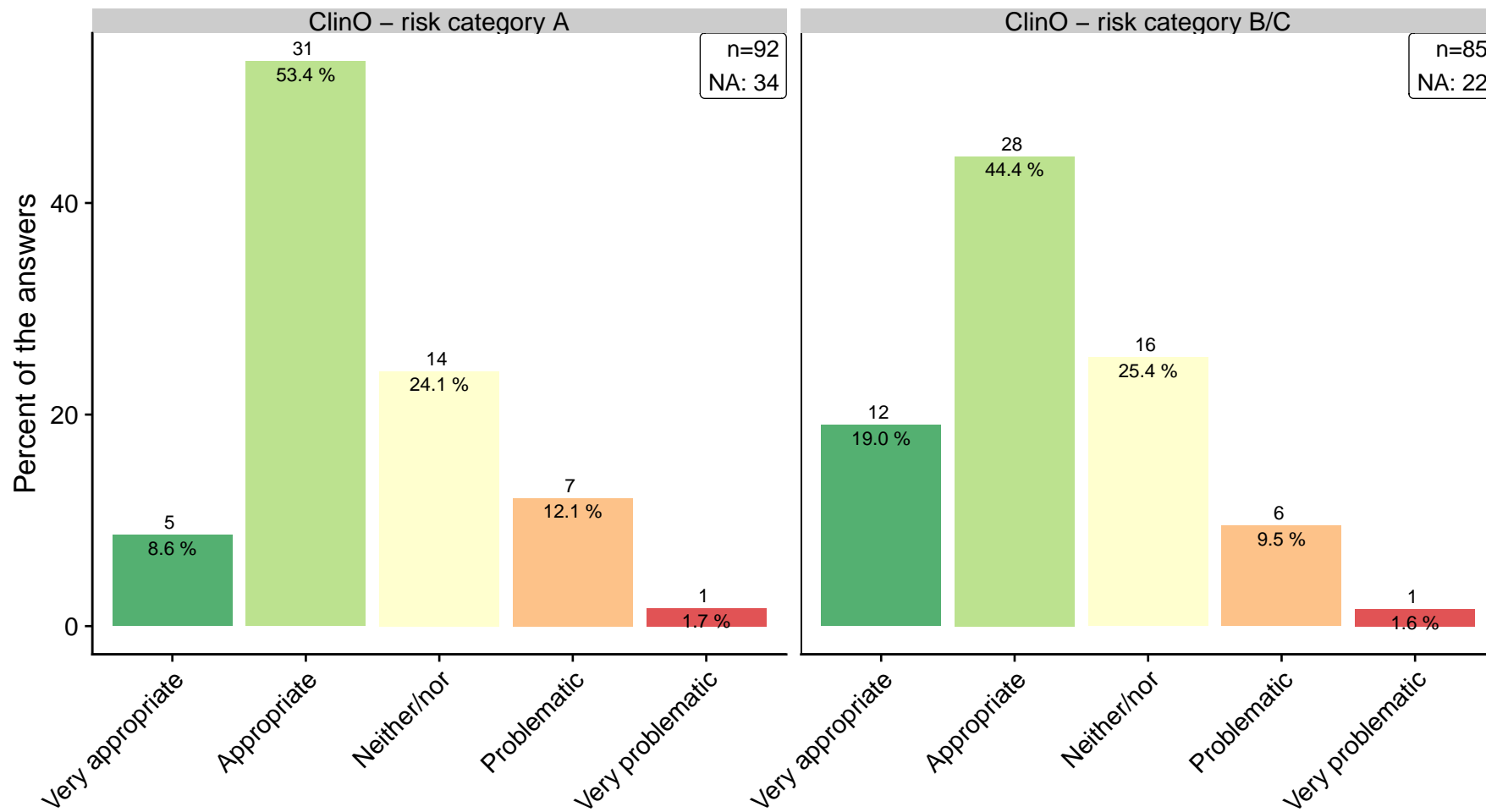
c) Requirements for research projects with vulnerable persons



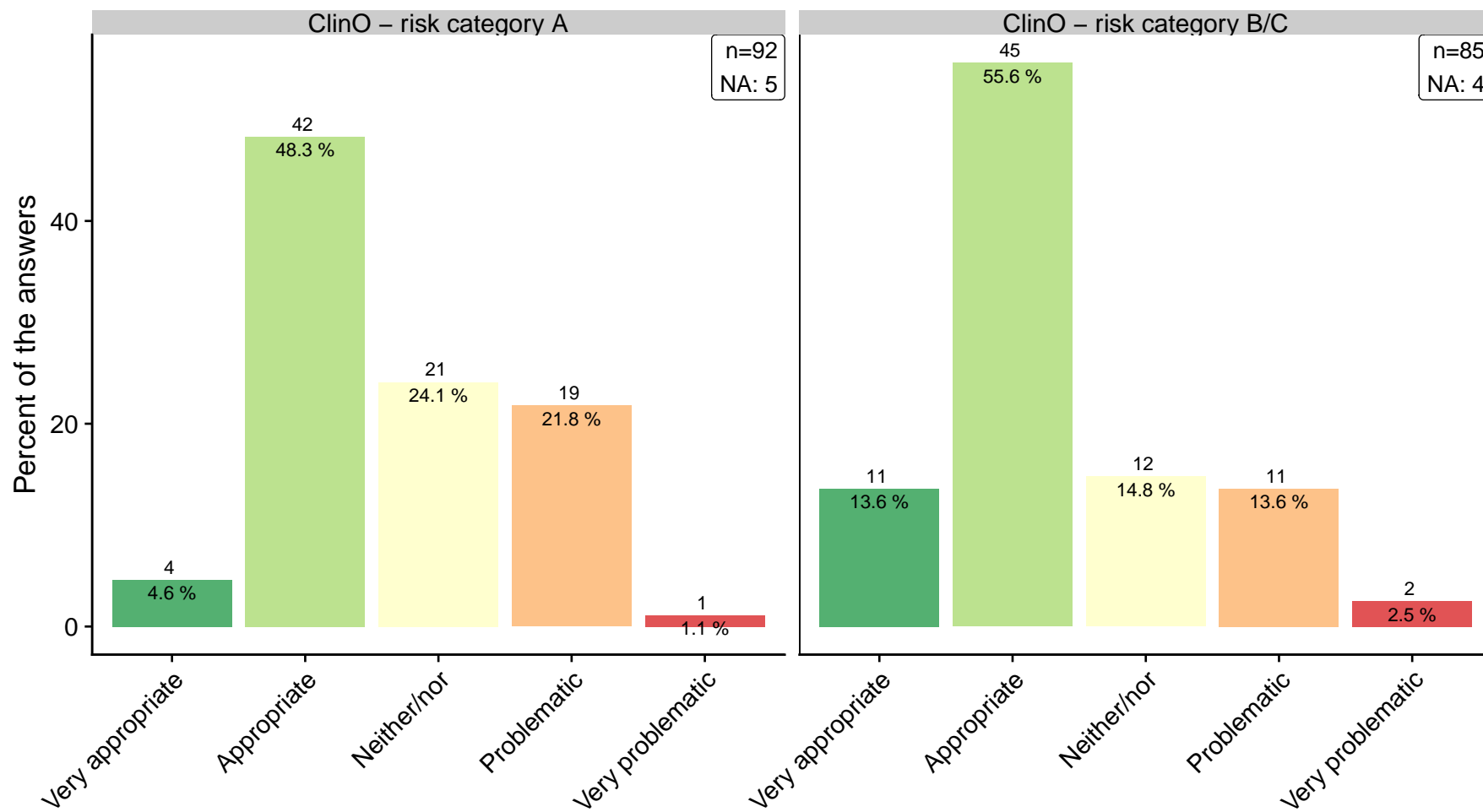
d) Requirements for consent/broad consent or possibility to opt out if biological material or health-related data are re-used



e) Difference made between genetic-data vs. non-genetic data

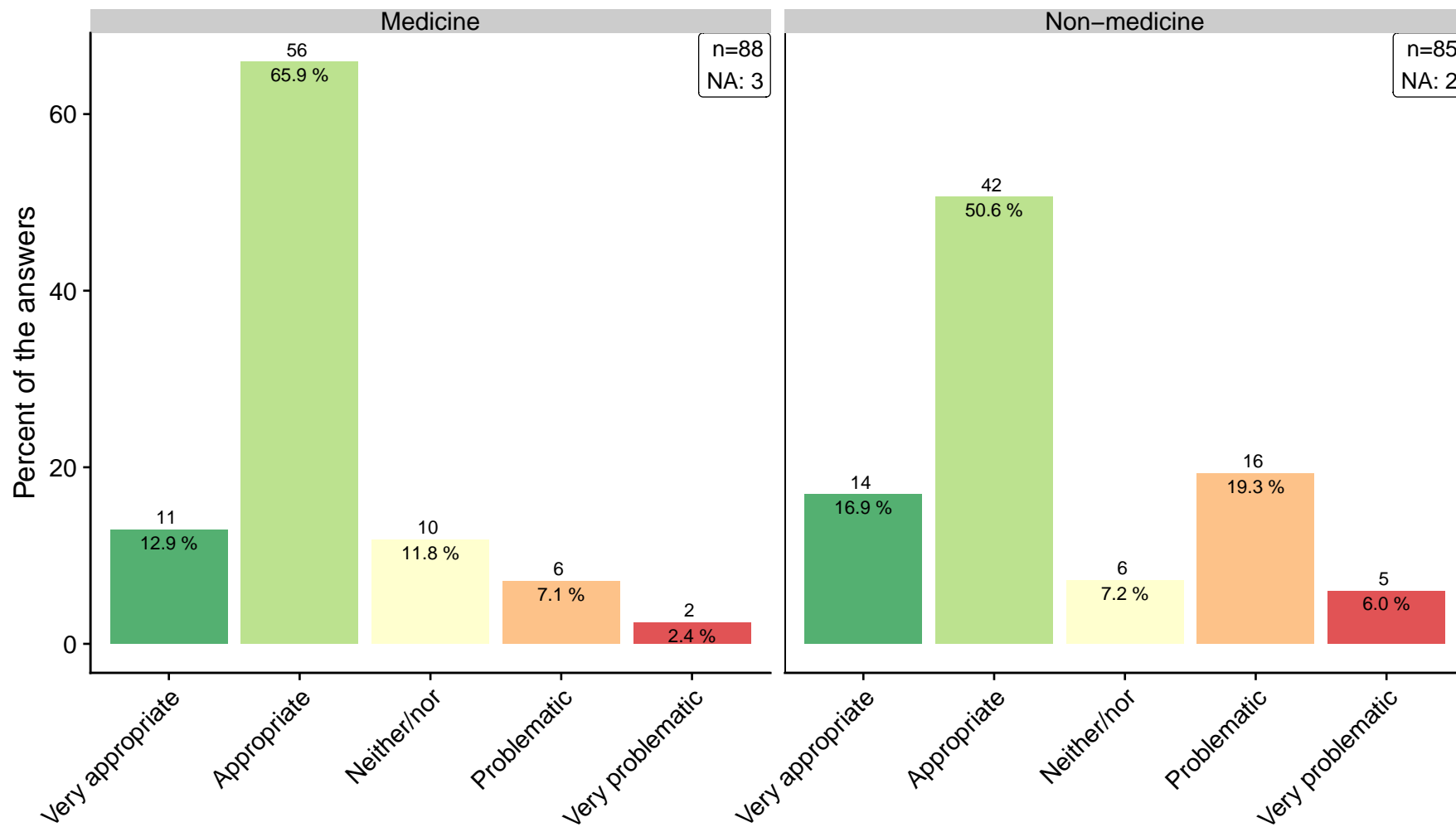


f) Difference made between uncoded, coded and anonymised material and data

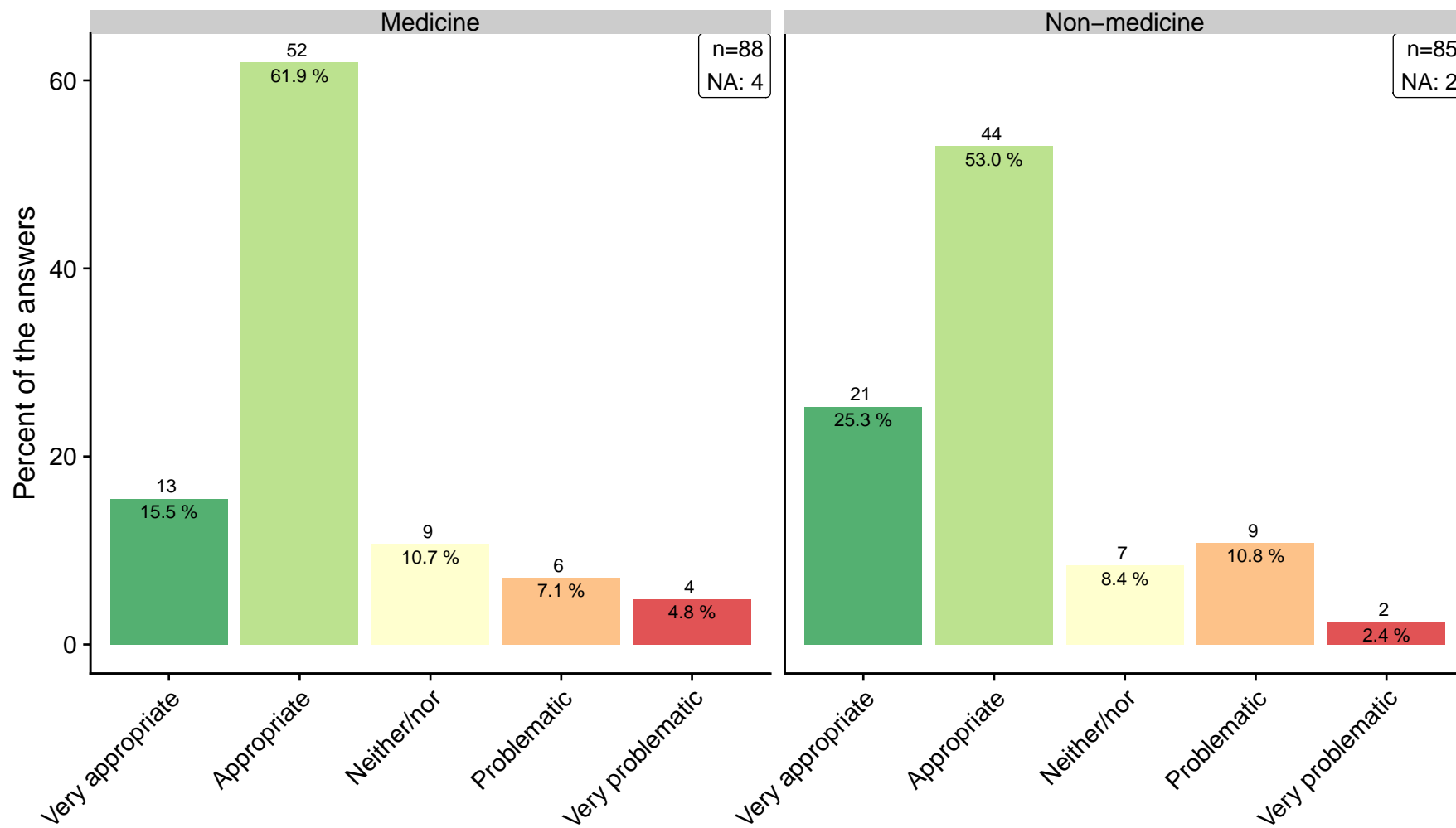


13.1.4 Stratified by field

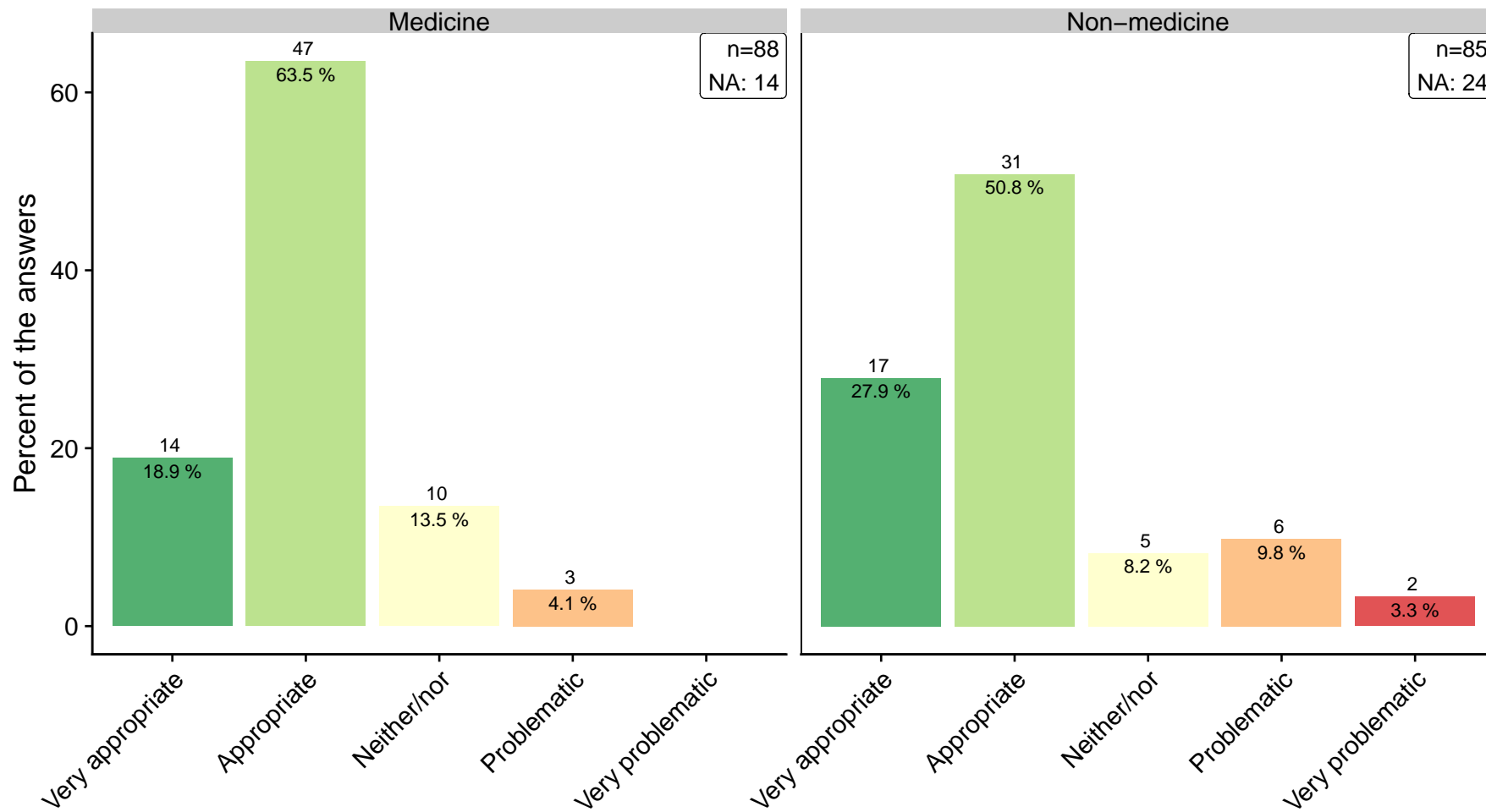
a) Definition of a 'clinical trial'



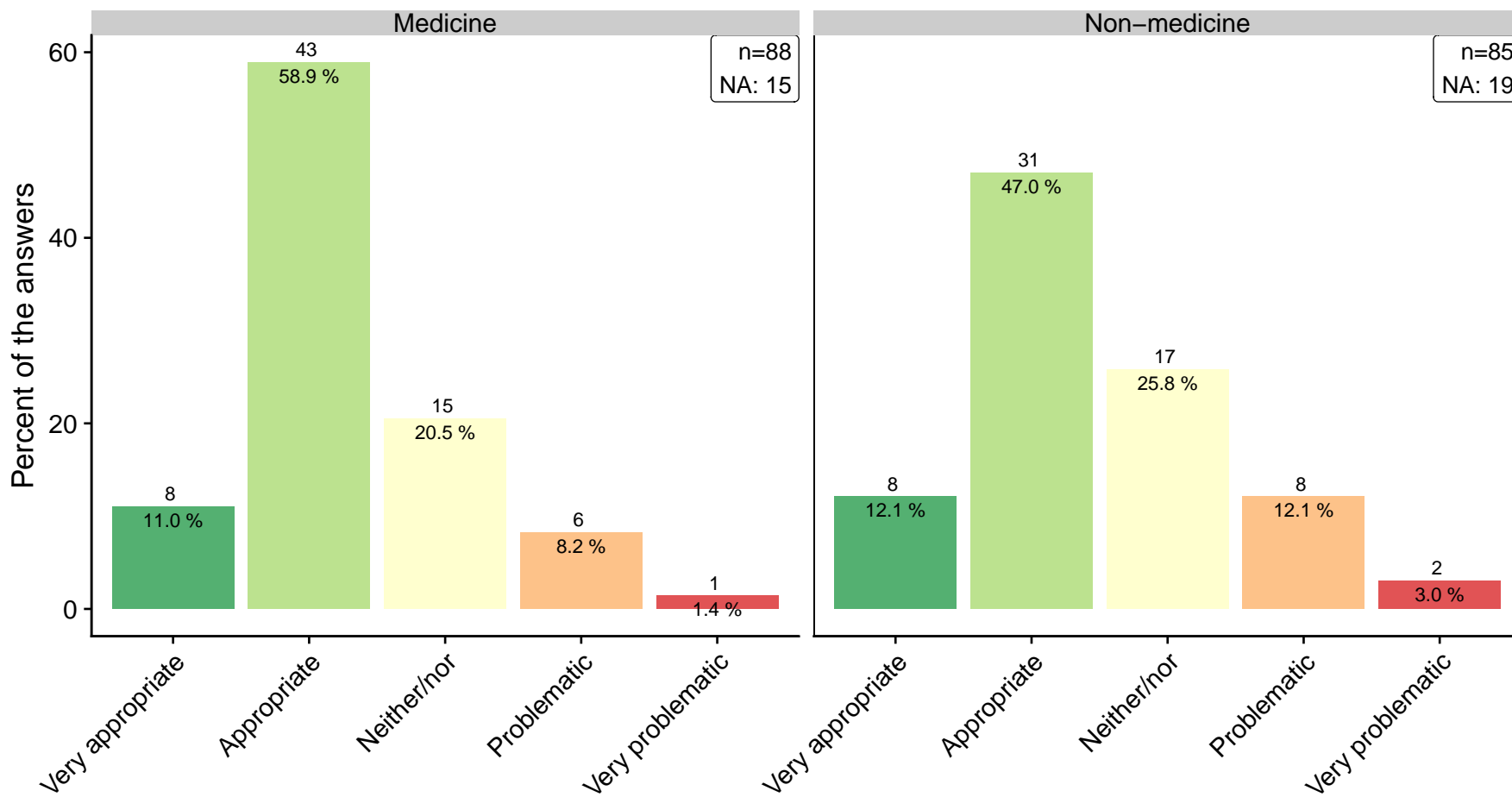
b) Requirements for informed consent in general



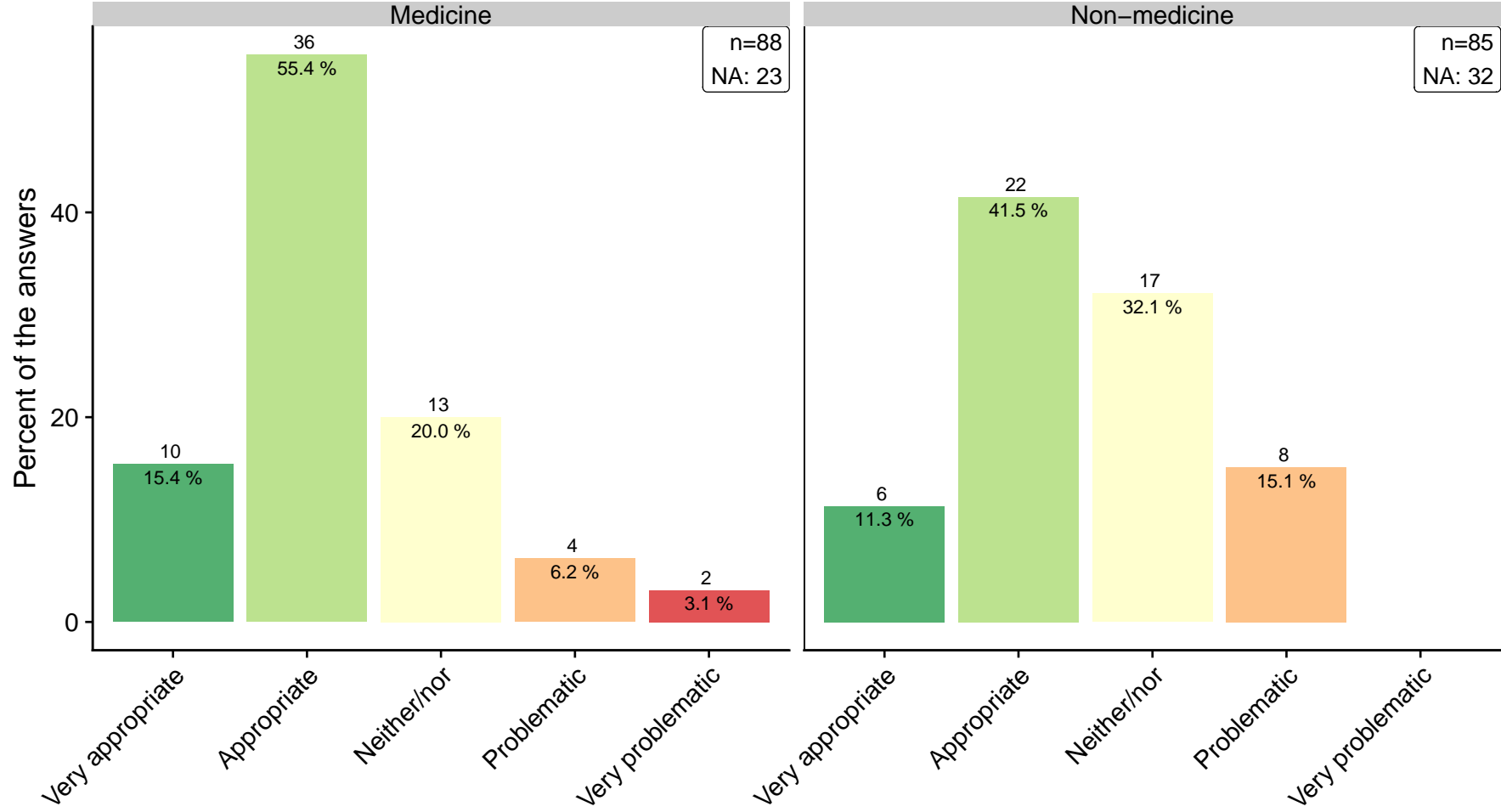
c) Requirements for research projects with vulnerable persons



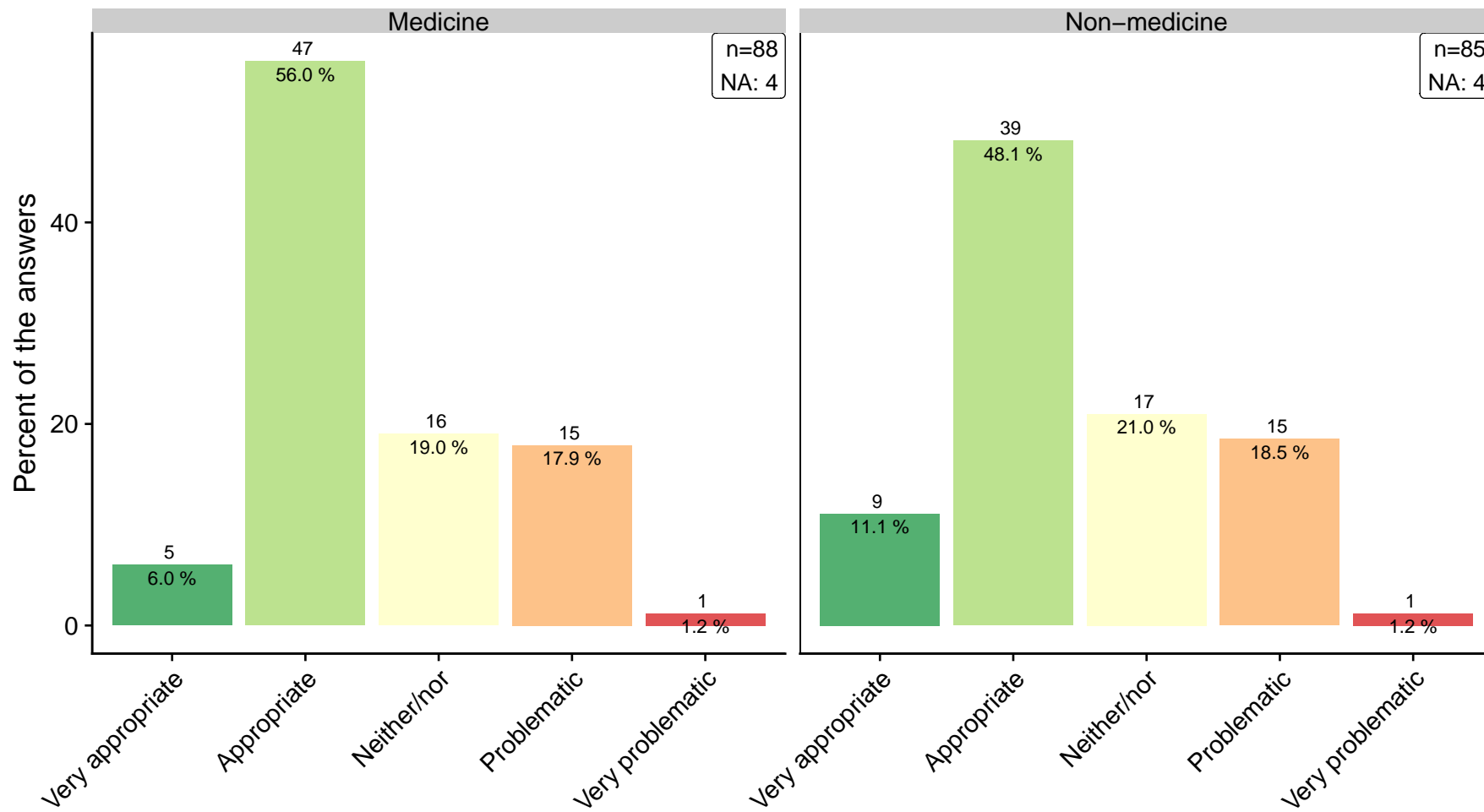
d) Requirements for consent/broad consent or possibility to opt out if biological material or health-related data are re-used



e) Difference made between genetic-data vs. non-genetic data

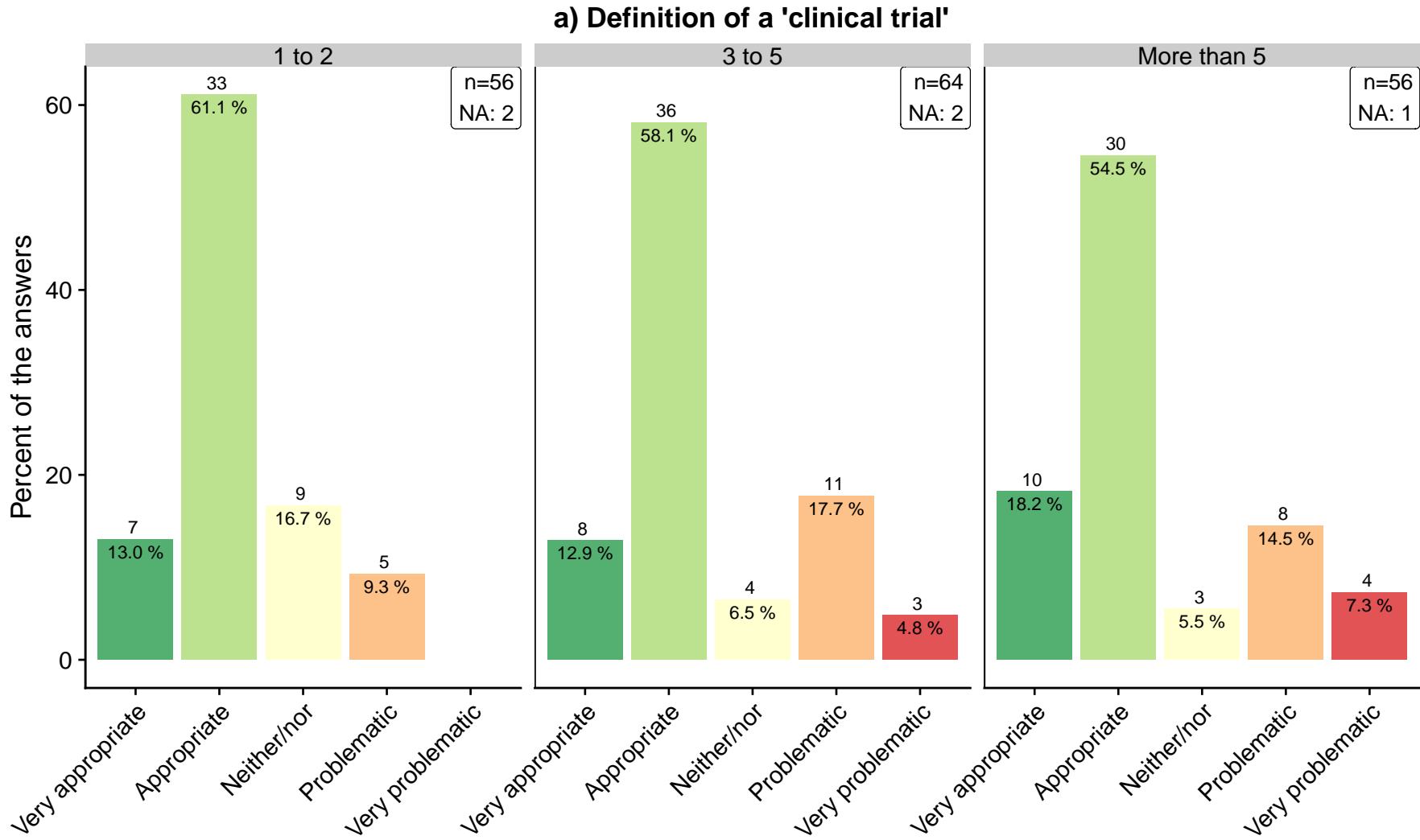


f) Difference made between uncoded, coded and anonymised material and data

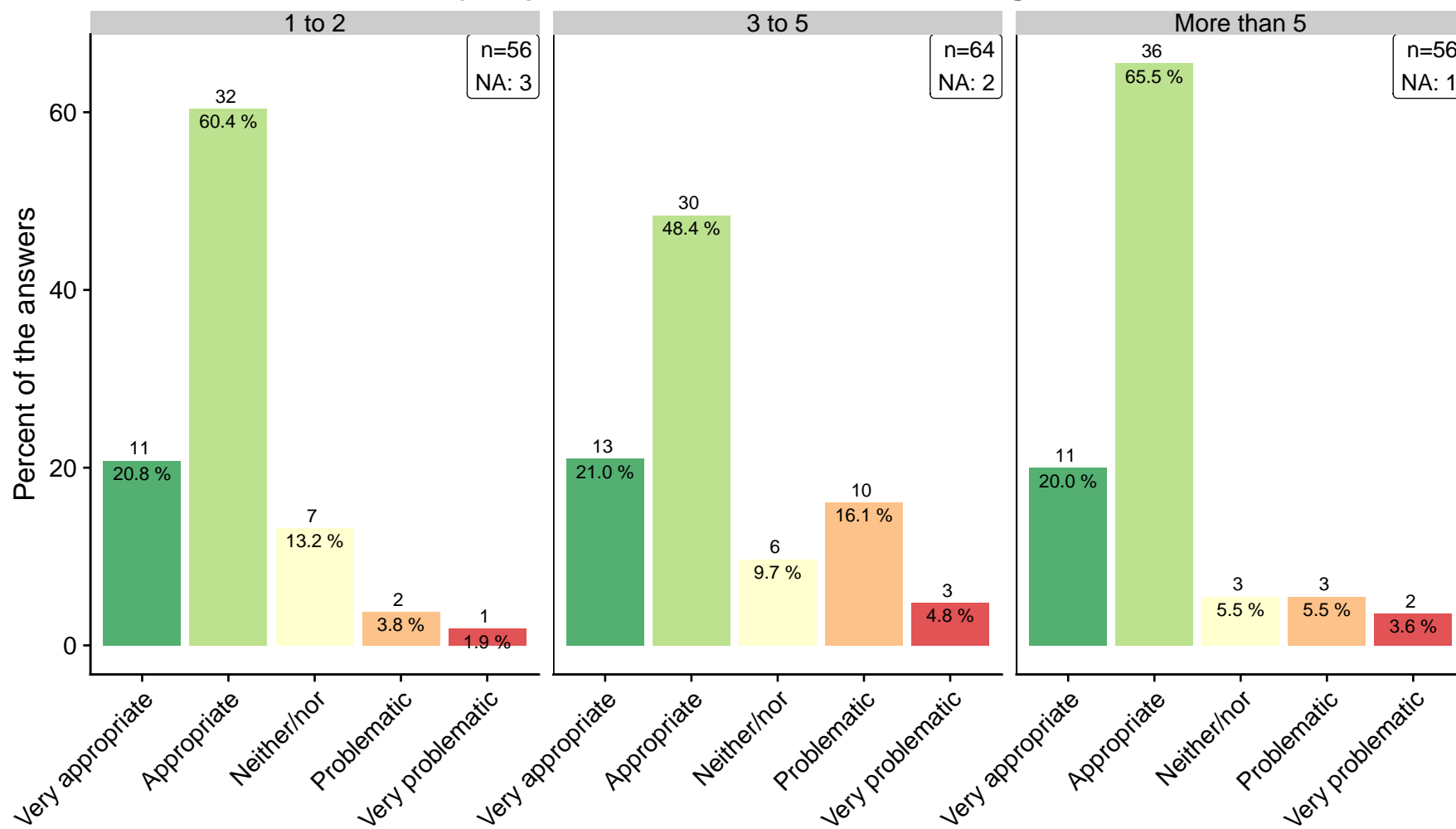


13.2 Feedback on application stratified by experience of the researcher

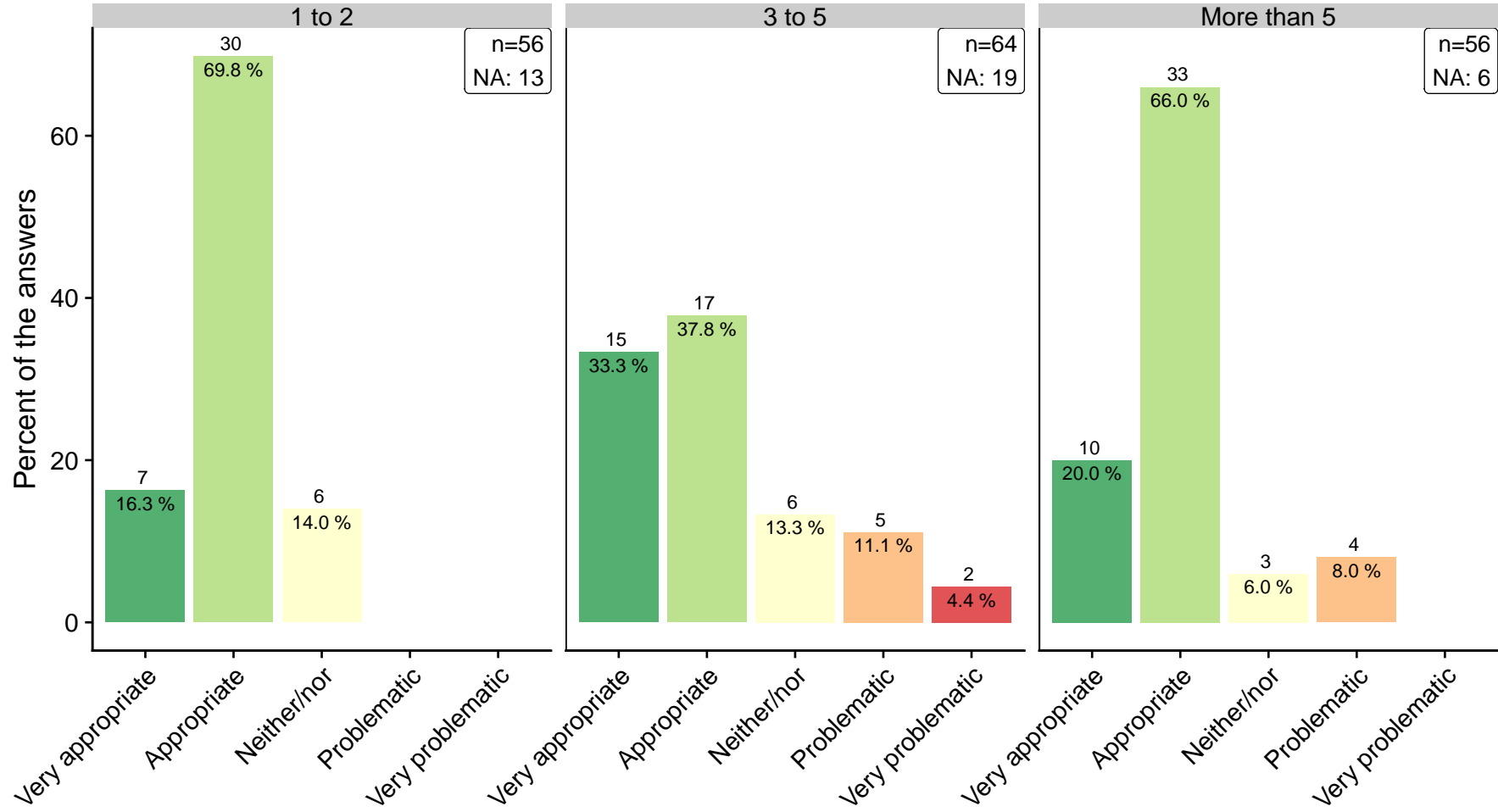
13.2.1 Stratified by number of submitted EC projects since HRA



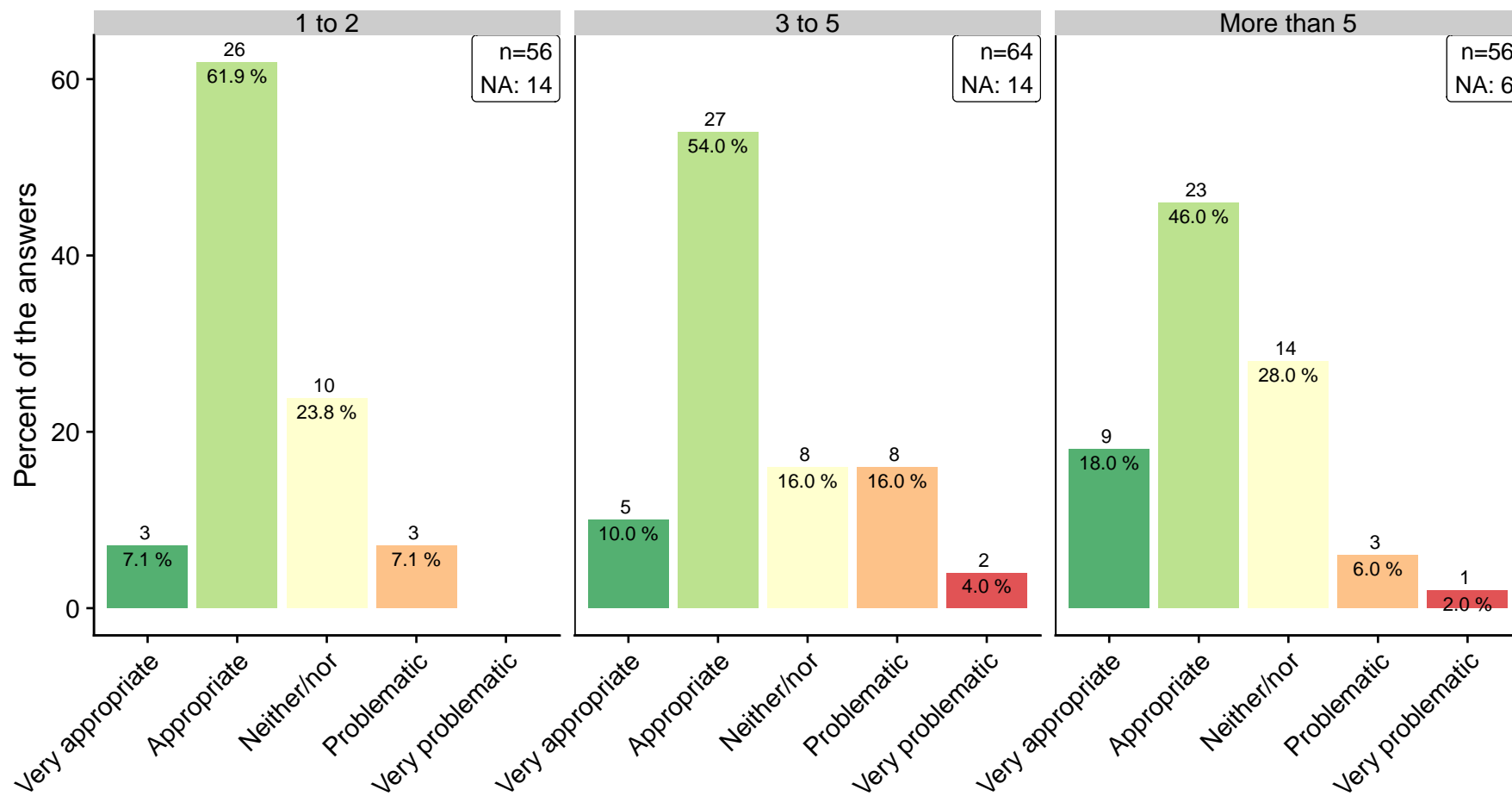
b) Requirements for informed consent in general



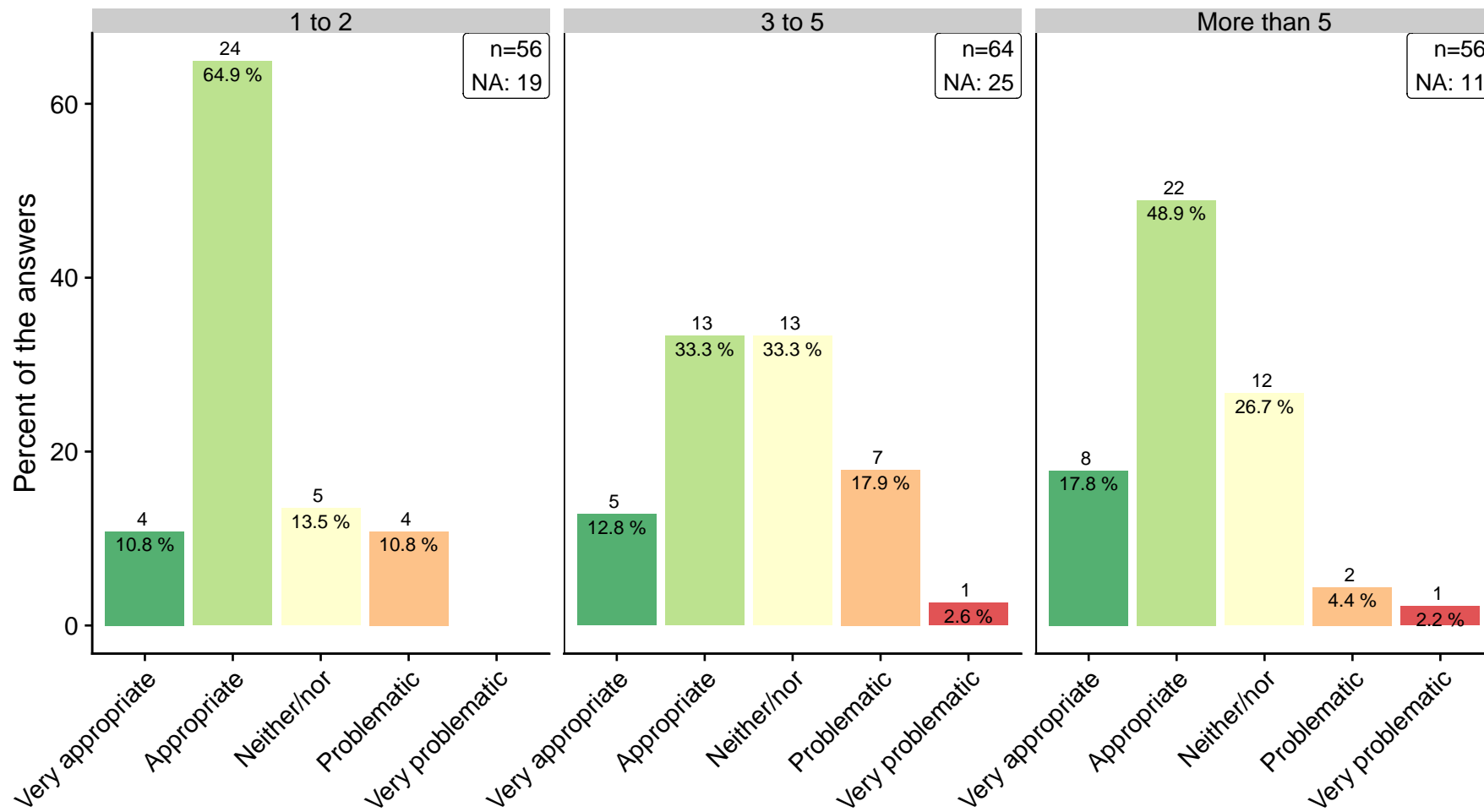
c) Requirements for research projects with vulnerable persons



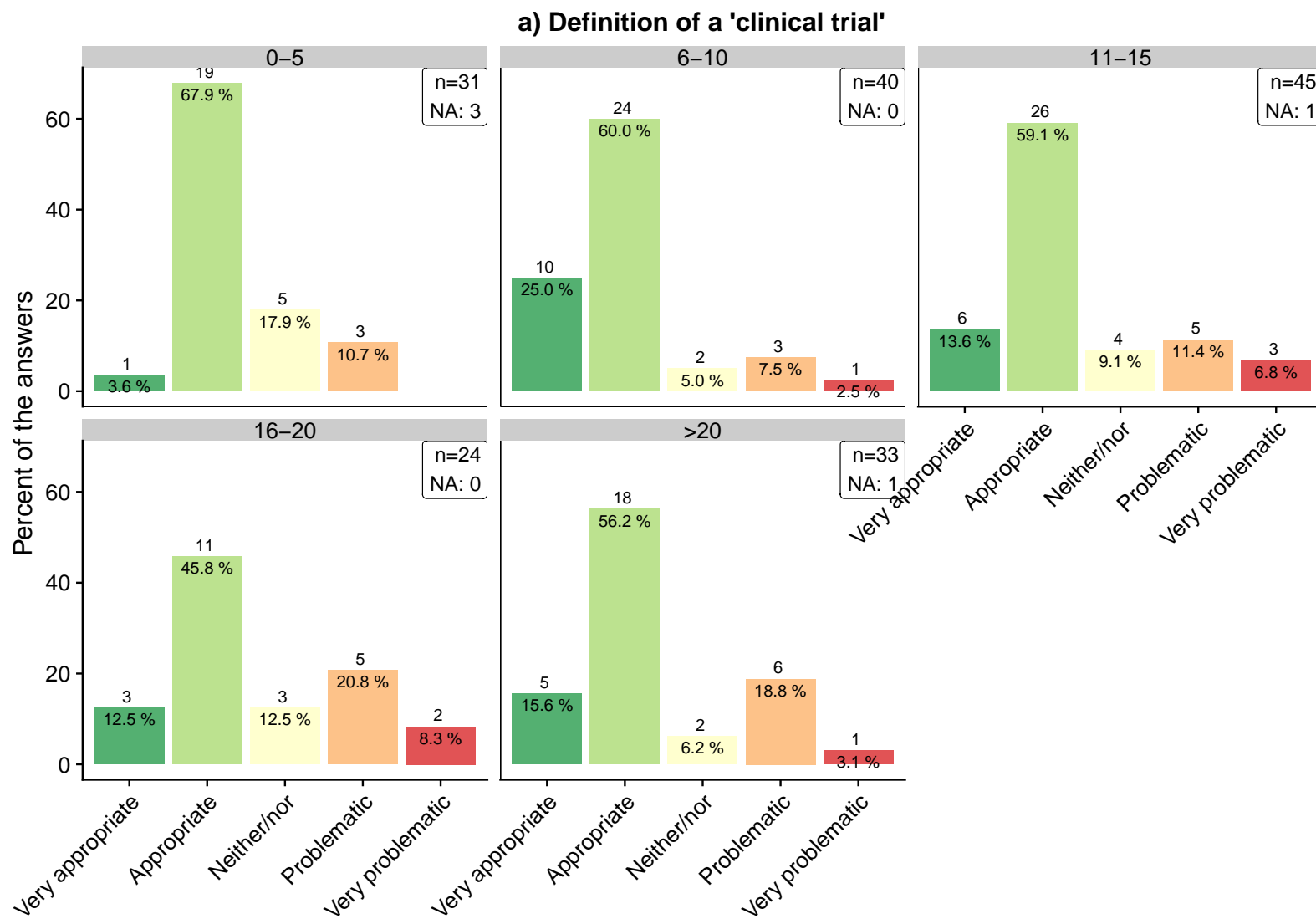
d) Requirements for consent/broad consent or possibility to opt out if biological material or health-related data are re-used



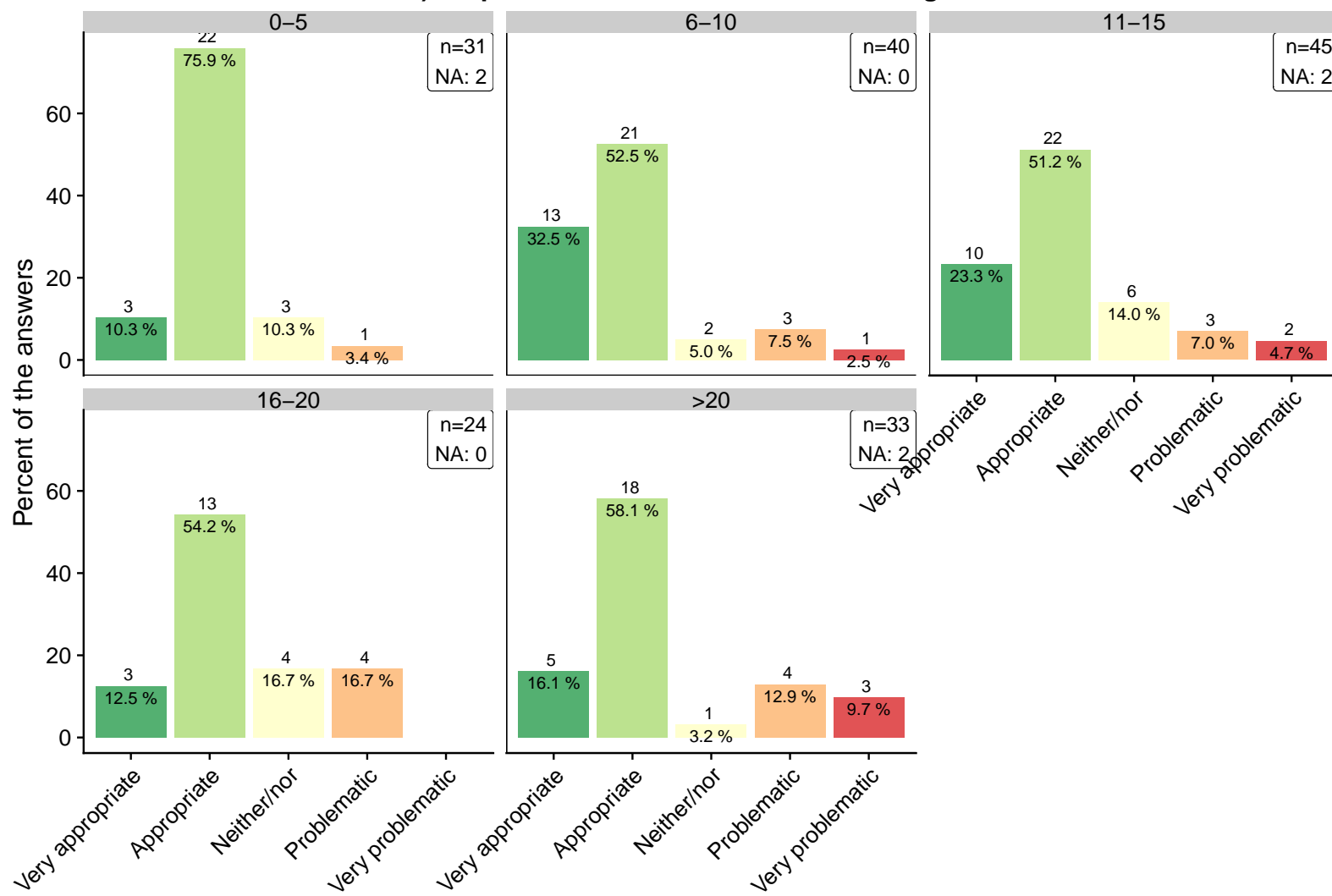
e) Difference made between genetic-data vs. non-genetic data



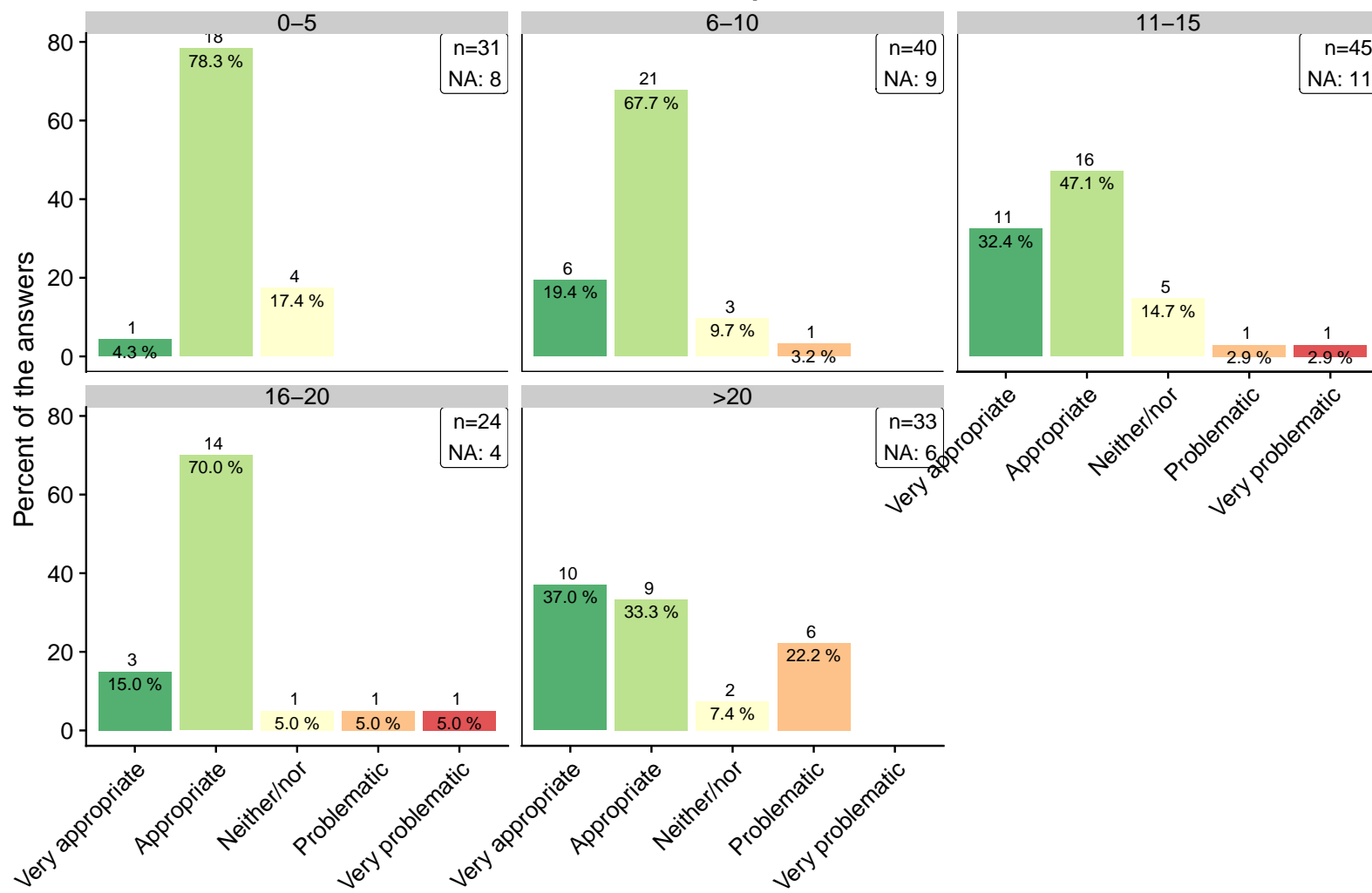
13.2.2 Stratified by years working in research



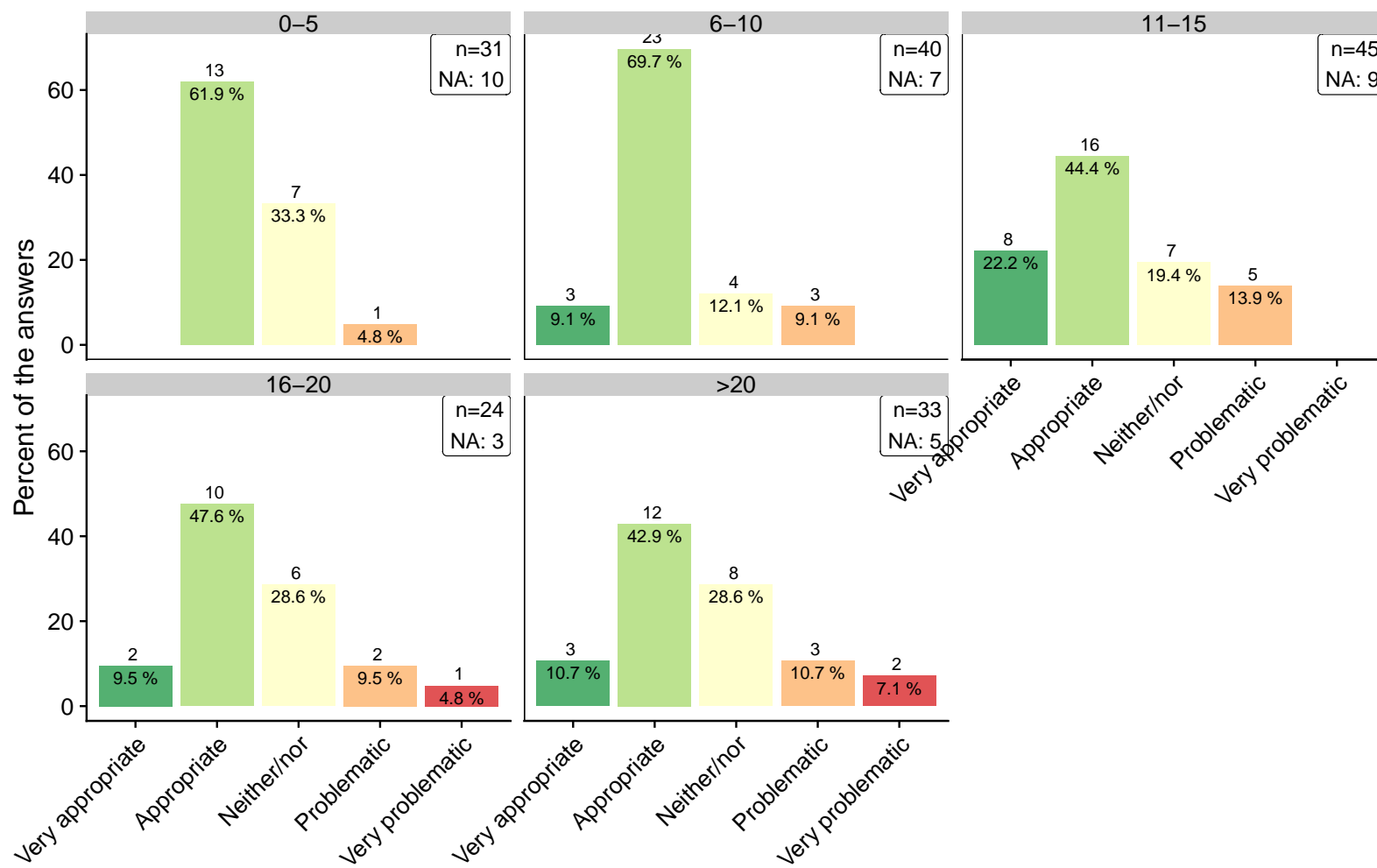
b) Requirements for informed consent in general



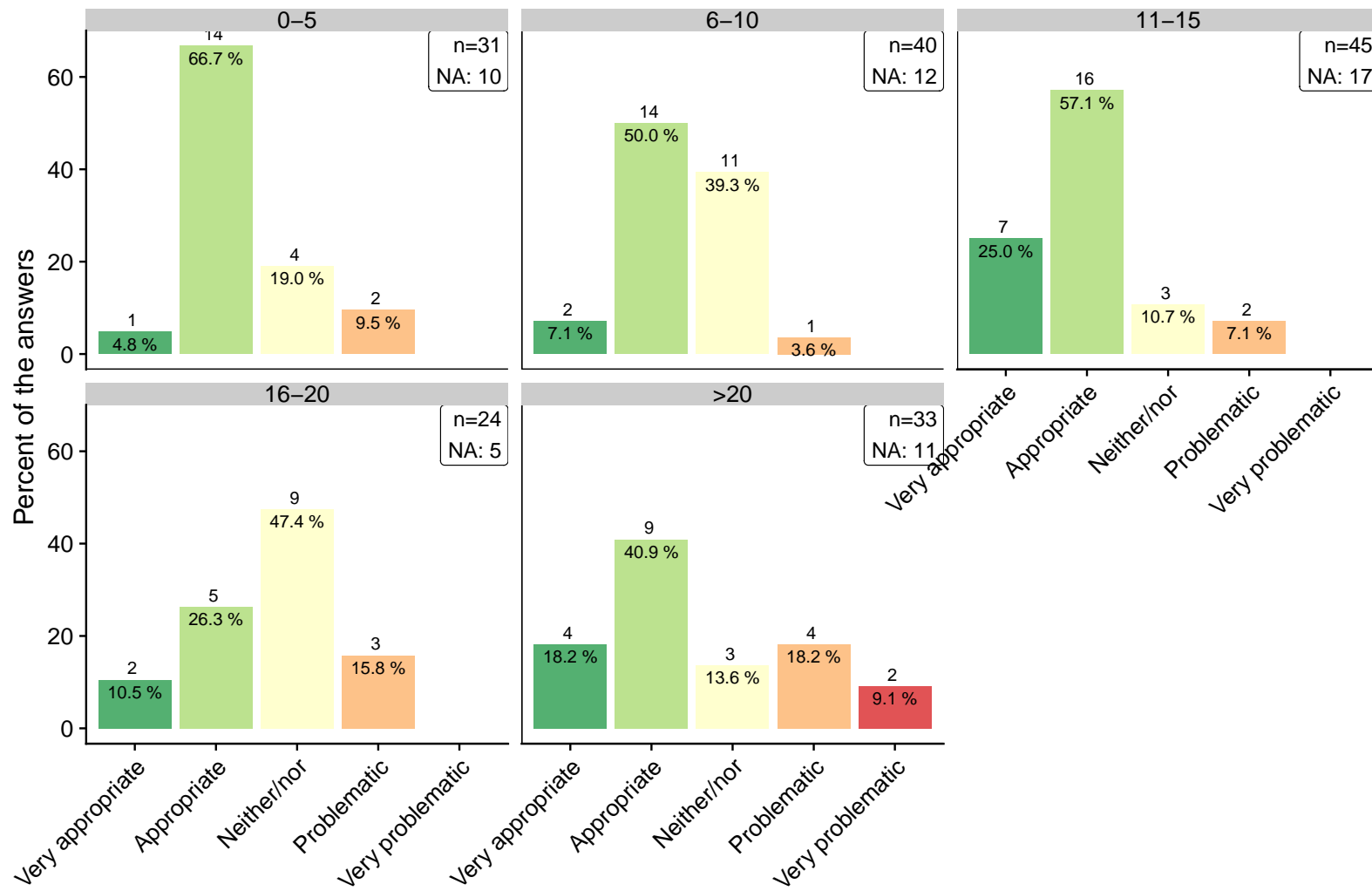
c) Requirements for research projects with vulnerable persons



d) Requirements for consent/broad consent or possibility to opt out if biological material or health-related data are re-used



e) Difference made between genetic-data vs. non-genetic data



13.2.3 Stratified by whether study of respondent included vulnerables

c) Requirements for research projects with vulnerable persons – dependent on whether the study of the respondent included vulnerables

