NoBoCap

Pulse report 4: Survey analysis of proposed MDR and IVDR revisions

Project: 101101269 - NoBoCap - EU4H-2022-PJ

Co-funded by the European Union

Contents

List of Figures 4
List of Tables 5
Abbreviations and version history 6
Version history 6
1 Introduction 7
1.1 Purpose and project context 7
1.2 Regulatory context 7
1.3 Proposed changes covered by the survey 8
1.4 Interpreting evidence flexibility 8
2 Methodology 9
2.1 Survey sources and analysis unit 9
2.2 Questionnaire structure and reporting practice 9
2.3 Quantitative analysis and sensitivity checks 9
2.4 Data quality and limitations 10
2.5 Qualitative analysis and confidentiality 10
3 Analysis 11
3.1 About your company 11
Q1 Country of headquarters 11
Q2 Number of employees 11
Q3 Products developed or placed on the market 12
Q4 Current or expected EU regulatory classification 12
Q5 Regulatory stage of the most advanced product 13
Q6 Commercialisation markets 13
3.2 Awareness and general assessment 14
Q7 Familiarity with the proposed revisions 14
Q8 Overall view of the proposed revisions 15
Q9 Expected improvements in the regulatory environment 15
3.3 Assessment of the proposed changes 16
Q10 Value of individual proposed measures 16
Q11 Five measures with the greatest positive impact 18
Q12 Single most important measure 19
Q13 Reasons for the selected priority 20
Q14 Additional changes still needed 20
3.4 NB access and costs 21
Q15 Current or anticipated notified-body challenges 21
Q16 Expected resolution of notified-body challenges 22
Q17 Adequacy of fee reductions 22
Q18 Additional fee or financing support 23
3.5 Software-specific questions 24
Q19 Expected effect of software-classification changes 24
Q20 Whether the changes go far enough 25
Q21 Closest view of the proposed software changes 25
Q22 Additional software improvements 26
3.6 Administrative burden, evidence and post-market obligations 27
Q23 Simplifications expected to reduce the most work 27
Q24 Potential excessive simplification or risks 28
Q25 Explanations of concerns 29
3.7 Competitiveness and company decisions 29
Q26 Conditional company intentions 29
Q27 Expected competitiveness of the revised EU pathway 30
3.8 Remaining gaps and final priorities 31
Q28 Innovation-enabling environment 31
Q29 Important challenges not adequately addressed 31
Q30 One further change for EU policymakers 32
3.9 Data protection and contact information 32

Q31 Data protection consent 32
Q32 Permission to quote written comments 32
Q33 Permission for follow-up contact 32
Q34 Name, Q35 Company name, Q36 Email 32
4 Conclusions 33
4.1 Main findings 33
4.2 Priorities and sufficiency of the proposed changes 33
4.3 Simplification and safeguards 34
4.4 Recommendations for NoBoCap 34
5 Appendices 35
Appendix A Respondent profile and awareness 35
Appendix B Expected effects 37
Appendix C Value of proposed measures 38
Appendix D Priorities and selection sensitivity 38
Appendix E Additional changes and notified-body barriers 40
Appendix F Adequacy and financing 41
Appendix G Software module 42
Appendix H Workload and risks 43
Appendix I Company intentions and competitiveness 45
Appendix J Remaining gaps and permissions 45
Appendix K Survey questionnaire 47
Appendix L References 67

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Health and Digital Executive Agency (HADEA). Neither the European Union nor the granting authority can be held responsible for them.

List of Figures

Figure 1. Q1 Respondents by country (N = 23) 11
Figure 2. Q2 Number of employees (N = 23) 12
Figure 3. Q3 Product types (N = 23; multiple responses) 12
Figure 4. Q4 Regulatory classifications (N = 23; multiple responses) 13
Figure 5. Q5 Regulatory stage (N = 23) 13
Figure 6. Q6 Target markets (N = 23; multiple responses) 14
Figure 7. Q7 Familiarity with the proposed revisions (N = 23) 14
Figure 8. Q8 Overall assessment of the proposed revisions (N = 23) 15
Figure 9. Q9 Expected effects of the proposed revisions (N = 23) 16
Figure 10. Q10 Value of proposed measures, part 1 of 3 (N = 23) 17
Figure 11. Q10 Value of proposed measures, part 2 of 3 (N = 23) 17
Figure 12. Q10 Value of proposed measures, part 3 of 3 (N = 23) 18
Figure 13. Q11 Priority selections (N = 23; multiple responses) 19
Figure 14. Q12 Single most important measure (N = 23; 22 substantive answers) 20
Figure 15. Q14 Additional changes (N = 23; multiple responses) 21
Figure 16. Q15 Current or anticipated notified-body challenges (N = 23; multiple responses) 22
Figure 17. Q16 Expected resolution of notified-body challenges (N = 23) 22
Figure 18. Q17 Adequacy of fee reductions (N = 23) 23
Figure 19. Q18 Additional financing measures (N = 23; multiple responses) 24
Figure 20. Q19 Expected software effects (eligible n = 12) 24
Figure 21. Q20 Whether the software changes go far enough (eligible n = 12) 25
Figure 22. Q21 Perspectives on the software proposals (eligible n = 12) 25
Figure 23. Q22 Additional software improvements (eligible n = 12; multiple responses) 26
Figure 24. Q23 Measures expected to reduce workload (N = 23; multiple responses) 27
Figure 25. Q23 Selection sensitivity (full N = 23; at-most-five n = 17) 28
Figure 26. Q24 Potential risks of excessive simplification (N = 23; multiple responses) 29
Figure 27. Q27 Expected EU competitiveness (N = 23) 31

List of Tables

Table 1. Version history 6
Table 2. Report scope 7
Table 3. Regulatory context for interpretation 7
Table 4. Proposed changes and survey questions 8
Table 5. Questionnaire structure 9
Table 6. Data quality (N = 23) 10
Table 7. Q10 Selected measures concerning dialogue and evidence (N = 23) 18
Table 8. Q19-Q22 Software findings among eligible respondents (n = 12) 26
Table 9. Q26 Expected actions under the proposed revisions (N = 23) 30
Table 10. Respondents' ratings of the proposed MDR/IVDR revision's potential to support innovation 33
Table 11. Five key survey findings (N = 23; software N = 12) 33
Table 12. Suggested discussion priorities 34
Table 13. Q1-Q8 Respondent profile summary (N = 23) 35
Table 14. Q1-Q2, Q5 and Q7-Q8 Profile and general assessment (N = 23) 35
Table 15. Q3-Q4 and Q6 Products, classifications and target markets (N = 23; multiple responses) 36
Table 16. Q9 Expected effects across 15 areas (N = 23) 37
Table 17. Q10 Value of all 21 proposed measures (N = 23) 38
Table 18. Q11 Priority selections and sensitivity subsets (N = 23; n = 17; n = 11) 38
Table 19. Q12 Coded single most important measure (N = 23; 22 substantive answers) 39
Table 20. Q14 Additional changes (N = 23; multiple responses) 40
Table 21. Q15 Current or anticipated notified-body challenges (N = 23; multiple responses) 40
Table 22. Q16 Expected resolution of challenges (N = 23) 41
Table 23. Q17 Adequacy of fee reductions (N = 23) 41
Table 24. Q18 Additional financing measures (N = 23; multiple responses) 41
Table 25. Q19-Q21 Eligible and all recorded answers (n = 12; n = 15) 42
Table 26. Q22 Additional software improvements (eligible n = 12; all recorded n = 14) 43
Table 27. Q23 Measures expected to reduce workload (N = 23; multiple responses) 43
Table 28. Q23 Sensitivity to the five-option limit (N = 23; n = 17) 44
Table 29. Q24 Potential excessive simplification or risk (N = 23; multiple responses) 44
Table 30. Q26 Conditional intentions (N = 23) 45
Table 31. Q27 Expected EU competitiveness (N = 23) 45
Table 32. Q28 Innovation environment scores (N = 23) 45
Table 33. Q12-Q13 and Q25-Q36 Open answers and permissions (N = 23) 46

Abbreviations and version history

AAPOR: American Association for Public Opinion Research; AI: artificial intelligence; CE: European conformity marking; CHERRIES: Checklist for Reporting Results of Internet ESurveys.

DoA: Description of the Action; EC: European Commission; EEA: European Economic Area; EU: European Union.

EU4HS: EU4HealthSolutions; IVD: in vitro diagnostic medical device; IVDR: Regulation (EU) 2017/746; MDCG: Medical Device Coordination Group.

MDR: Regulation (EU) 2017/745; NB: notified body; PMCF: post-market clinical follow-up; PMPF: post-market performance follow-up.

PSUR: periodic safety update report; SME: small or medium-sized enterprise; WP: work package.

MSE: micro and small enterprise. N/A: not applicable.

EUDAMED: European database on medical devices; HADEA: European Health and Digital Executive Agency; IP: Internet Protocol; QMS: quality management system; US: United States.

Version history

The report version history is recorded below. See Table 1.

Table 1. Version history

1.0	16 October 2026	1st draft version	iVita
1.1	23 October 2026	2nd draft version	iVita
1.2	26 October 2026	3rd draft version	iVita
1.3	29 October 2026	Review of 3rd draft version	EU4HS
1.4	29 October 2026	Finan report version	iVita

1 Introduction

1.1 Purpose and project context

This report analyses 23 responses to the NoBoCap survey on the proposed revisions to the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR). It addresses the survey activity assigned to EU4HS and partners under WP5, Task 5.1, in the Description of the Action (DoA). The survey and this reports addressed the key milestone and findings contribute to the Pulse Report by identifying Micro and Small Companies view on the revision and, expected benefits and remaining concerns for discussion within the NoBoCap Community and to inform EU policy. [1, 2]

The report examines which proposed changes respondents value, whether they consider those changes sufficient, which barriers remain, and what further action could support an innovation enabling regulatory environment. The analysis follows the questionnaire from company profile through final priorities and data permissions. Detailed distributions and the full questionnaire are retained in the appendices. [1] See Table 2.

Table 2. Report scope

Project activity	EU4HS survey under WP5 T5.1, DoA Part A, pages 13-14
Survey data	23 submissions
Geographic coverage	Respondents in 10 EU Member States
Regulatory reference	Commission proposal COM(2025) 1023
Practical output	Survey findings, stakeholder priorities and topics for community discussion

Annex 1, Part A (pp. 13-14), places the survey within WP5, Task 5.1, Landscaping of further stakeholders. EU4HS leads this task with BIOVIA, ROHEALTH, IVITA and HBIO. The extension specifies a survey on the new MDR/IVDR proposal, the framework and implementation, from the perspective of the MSE (Micro - Small Enterprises Innovation Community, with partner involvement and community webinars. [2]

1.2 Regulatory context

The European Commission published COM(2025) 1023 on 16 December 2025 to amend the MDR and IVDR and simplify their requirements. On 16 October 2026, European Parliament procedure 2025/0404(COD) was awaiting a committee decision. A draft report and committee amendments had been published. The Commission proposal is the common reference for this survey and is not an adopted final revision. [3, 4, 5, 6]

Respondents assessed proposed changes while also describing current or anticipated implementation difficulties. Results are therefore interpreted against the wording of each question and cannot be treated as endorsement of every provision in the legislative package. See Table 3.

Table 3. Regulatory context for interpretation

MDR and IVDR framework	Context for the current implementation challenges raised in the survey	Applicable law and guidance must be distinguished from proposed changes. [7]
Commission proposal	COM(2025) 1023 and its annexes provide the common substantive reference	Measures remain proposals, subject to the legislative process. [3, 4, 5]
Survey responses	Ratings, reported or anticipated barriers, and conditional intentions	Evidence of stakeholder views, rather than measured implementation outcomes. [1]

The Commission presents the revision as a response to eg. Administrative and Notified Body burden, disproportionate software requirements, uncertain assessment processes and obstacles to innovation. These themes overlap with the questionnaire. This provides context for the questions. [6]

Measures discussed in the questionnaire must be labelled as proposed where they depend on the wider revision. The existing MDR and IVDR, applicable amendments and current guidance remain distinct sources [7].

1.3 Proposed changes covered by the survey

The table summarizes selected proposal themes relevant to the questionnaire. See Table 4.

Table 4. Proposed changes and survey questions

Fees and payment	Minimum fee reductions of 50% for micro manufacturers, 25% for small manufacturers and 50% for orphan devices; deferral for micro and small manufacturers until the relevant assessment activity is finalised.	Q10-Q12 and Q15-Q18: value, priority and adequacy
Assessment and dialogue	Documented dialogue before and after application, together with more transparent and predictable assessment processes.	Q9-Q12 and Q15-Q16: expectations and barriers
Orphan and breakthrough devices	Tailored assessment provisions and expert support for qualifying devices.	Q10-Q12: perceived value and priority
Clinical and performance evidence	More flexible evidence provisions and additional opportunities for expert advice.	Q9-Q10, Q14 and Q23Q25: benefits and concerns
Lifecycle workload	Changes to audits, periodic reporting, documentation and management of device changes.	Q10-Q11 and Q23-Q25: workload and safeguards
Software and classification	Changes to classification provisions and the interaction with AI regulation.	Q19-Q22 and Q24: expected effects and remaining needs

Sources: Commission proposal, annexes and explanatory material. [3, 4, 6]

1.4 Interpreting evidence flexibility

For medical devices, evidence must support the intended clinical claims, safety and performance. For IVDs, performance evaluation connects scientific validity, analytical performance and clinical performance. Respondents' support for greater flexibility does not establish that a particular evidence source is sufficient for a specific device. [3, 8]

The report analyses how respondents value evidence-related changes and which implementation questions remain. It does not define product-specific evidence requirements. In the software module, classification and evidence concerns are reported separately because a change in classification does not by itself demonstrate adequate clinical or performance evidence. [8, 9]

2 Methodology

2.1 Survey sources and analysis unit

The survey export contains 23 submissions and 90 columns, with recorded timestamps from 23 September to 14 October 2026. This is the observed submission period. One submitted response is the analysis unit. The full questionnaire is reproduced in Appendix K.

The questionnaire addresses micro and small medical device and IVD companies, but the received sample is broader. 17 respondents report fewer than 50 employees and stakeholder roles vary. All 23 submissions are retained for the main survey. The software module uses the eligibility instruction stated in the questionnaire. Submission IDs are unique, and nonblank company, email and Internet Protocol (IP) address fields contain no exact duplicates.

The results describe the received responses.

2.2 Questionnaire structure and reporting practice

Reporting draws on transparency principles, CHERRIES guidance for online surveys and the Commission Better Regulation Toolbox. Counts, denominators, missing information and deviations from question instructions are disclosed. These sources guide reporting, they do not make this project survey an official Commission consultation or a representative sample. [10, 11, 12]

The questionnaire introduction emphasises expected simplification benefits, and several questions frame outcomes positively, although negative response options are available. Findings are descriptive. See Table 5.

Table 5. Questionnaire structure

About your company	Q1-Q6
Awareness and general assessment	Q7-Q9
Assessment of the proposed changes	Q10-Q14
Notified-body access and costs	Q15-Q18
Software-specific questions	Q19-Q22
Administrative burden, evidence and post-market obligations	Q23-Q25
Competitiveness and company decisions	Q26-Q27
Remaining gaps and final priorities	Q28-Q30
Data protection, quotation and contact information	Q31-Q36

2.3 Quantitative analysis and sensitivity checks

Percentages are unweighted and rounded to one decimal place, using all 23 responses. Software results use the 12 respondents meeting the questionnaire instruction, with all recorded module answers shown for sensitivity. Multiple-response percentages use respondents and may exceed 100%. Rating categories are grouped explicitly. Q28 is a single 0-10 rating, with the median primary and mean supplementary. N denotes the full sample; n denotes the stated analysis base or category count.

For Q9, improvement combines somewhat and significantly improve; worsening combines the two negative categories. For Q10, high value combines very valuable and essential. Q26 combines the two more-likely categories and, separately, the two less-likely categories. Q27 groups the two more-competitive and two less-competitive categories. Unsure, no change and not-applicable responses remain separate where those options were offered. Q27 retains insufficient experience to compare as a separate category.

Q11 is reported for all 23 respondents, the 17 selecting at most five measures and the 11 selecting exactly five. Q23 also requested up to five options, so its main counts are compared with the 17 responses meeting that limit. Software results use the 12 respondents who selected software or

an AI-incorporating device in Q3. All recorded software-module answers provide a sensitivity comparison. Further descriptive checks consider employee count, regulatory applicability and familiarity with the proposal.

2.4 Data quality and limitations

The sample is small, geographically uneven and includes organisations outside the target headcount group. Employee count alone does not establish EU micro or small enterprise status, which also depends on financial and ownership criteria. Q15 combines experienced and anticipated barriers. Positive expectations and conditional intentions do not establish actual savings, certification speed, investment or patient access effects. [13] See Table 6.

Table 6. Data quality (N = 23)

Q11 and Q12 consistency	Q11: 11 select five, 6 fewer and 6 more; maximum 12. Two Q12 priorities were not selected in the same respondent's Q11.
Q14 export correction	16 select the combined documentation/templates option. Two erroneous PMPF entries have been excluded. All 23 respondents retain at least one questionnaire-defined choice.
Conflicting multi selections	One Q14 record combines substantive and exclusive options; one Q15 record combines challenges with not applicable.
Software eligibility	The form targets Q3 software or AI devices: 12 qualify and answer Q19-Q22. Three others answer Q19-Q21; two answer Q22.
Q28 scale	The supplied questionnaire defines 0 to 10. Observed ratings are 0 to 8; nobody selects 9 or 10.
Open answers	Q13 has 17 nonblank entries; Q25 has 8; Q29 and Q30 have 13 each.
Q23 selection limit	Six respondents exceed the up-to-five instruction; four select five and thirteen select fewer. Maximum: nine selections. All counts are retained, with an at-most-five sensitivity comparison.

2.5 Qualitative analysis and confidentiality

Open answers were read and grouped by recurring issues: affordability, interpretation and accountability, evidence planning, software and updates, surveillance, and niche devices. Text placed under a different question was not silently reassigned.

Q12 single-priority answers were coded by the measure named, keeping unspecified cost reduction separate from notified-body fee reductions.

All 23 respondents consented to processing, 8 permitted aggregated use only, 14 permitted anonymous quotation and one permitted attributed quotation. This report uses aggregate results and paraphrased thematic synthesis without direct respondent quotations or identifiers.

Names, company names, email addresses, IP addresses and submission identifiers are excluded from the report. Q31-Q36 are reported only as aggregate permissions and an explanation of how contact fields are handled.

3 Analysis

The analysis below follows the order of the questionnaire. Unless stated otherwise, the denominator is all 23 respondents. Multiple-response items describe overlapping selections. Full distributions, coding notes and sensitivity comparisons are provided in Appendices A-J. [1]

Question wording and response options are reproduced from the questionnaire in Appendix K. An asterisk marks a required field. [1]

3.1 About your company

***Question 1:** Country of headquarters**

Q1 Country of headquarters

Respondents report headquarters in ten EU Member States: Belgium (8), Romania (4), Greece (3), Lithuania (2), and Bulgaria, Spain, Portugal, Ireland, France and Italy (1 each). This is the geographic coverage of the received responses. See Figure 1.

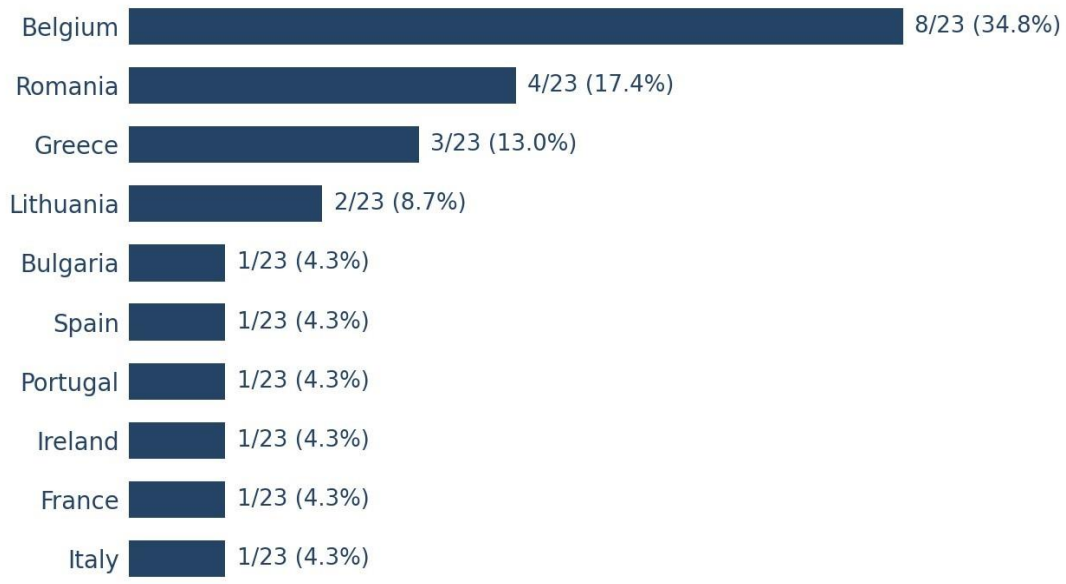


Figure 1. Q1 Respondents by country (N = 23)

Question 2: *How many people does your company employ?**

Q2 Number of employees

Eleven respondents employ 1-9 people and six employ 10-49, giving 17/23 (73.9%) with fewer than 50 employees. One reports 50-249 employees, three report 250 or more and two prefer not to disclose size. The survey therefore mainly reflects smaller organisations by headcount, but it is not confined to them. See Figure 2.

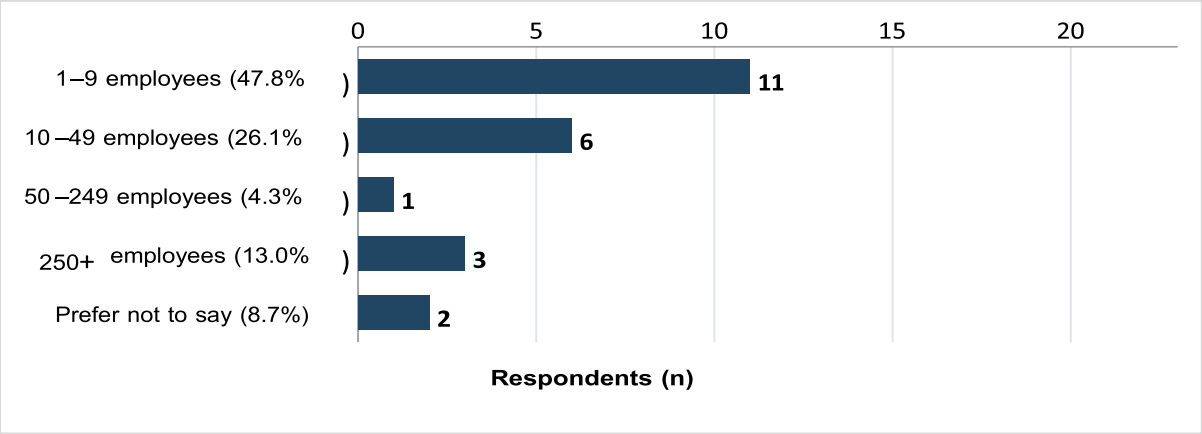


Figure 2. Q2 Number of employees (N = 23)

Employee count alone does not verify EU micro, small or medium-sized enterprise status. Financial and ownership criteria also apply and were not established by the survey. Eligibility for proposed fee support cannot therefore be inferred from the headcount categories. [13]

Question 3: *Which products are you developing or placing on the market?**

Q3 Products developed or placed on the market

AI-incorporating devices, software as a medical device or medical device software, and medical devices excluding standalone software each receive nine selections (39.1%). Seven respondents select IVDs, three companion diagnostics and one a combination product. Five select Other, including unspecified answers and stakeholder activities. Products overlap within respondents; these counts do not describe mutually exclusive company groups. See Figure 3.

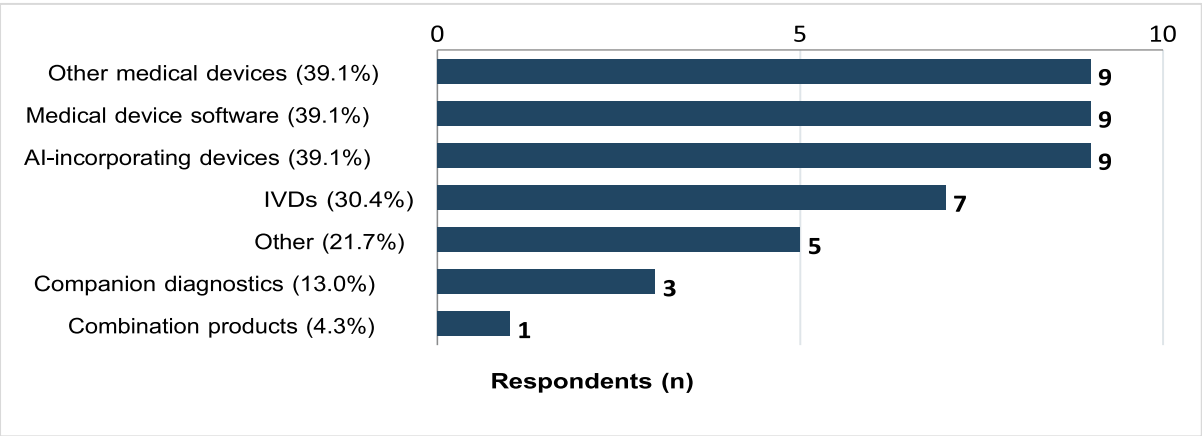


Figure 3. Q3 Product types (N = 23; multiple responses)

Question 4: *What is the current or expected EU regulatory classification of your product(s)?**

Q4 Current or expected EU regulatory classification

MDR Class IIa is the most frequently selected classification, with 11 respondents. MDR Class I and Class IIb each receive four selections. MDR Class III receives two and Class Is, Im or Ir - one. IVDR Class C is selected by three respondents and Classes A and B by two each. No respondent selects IVDR Class D. One reports that classification is not yet determined and one is unsure, four select not applicable. Multiple selections are allowed, so class counts cannot be added to estimate the number of manufacturers. Class Is, Im or Ir is kept separate from Class I. See Figure 4.

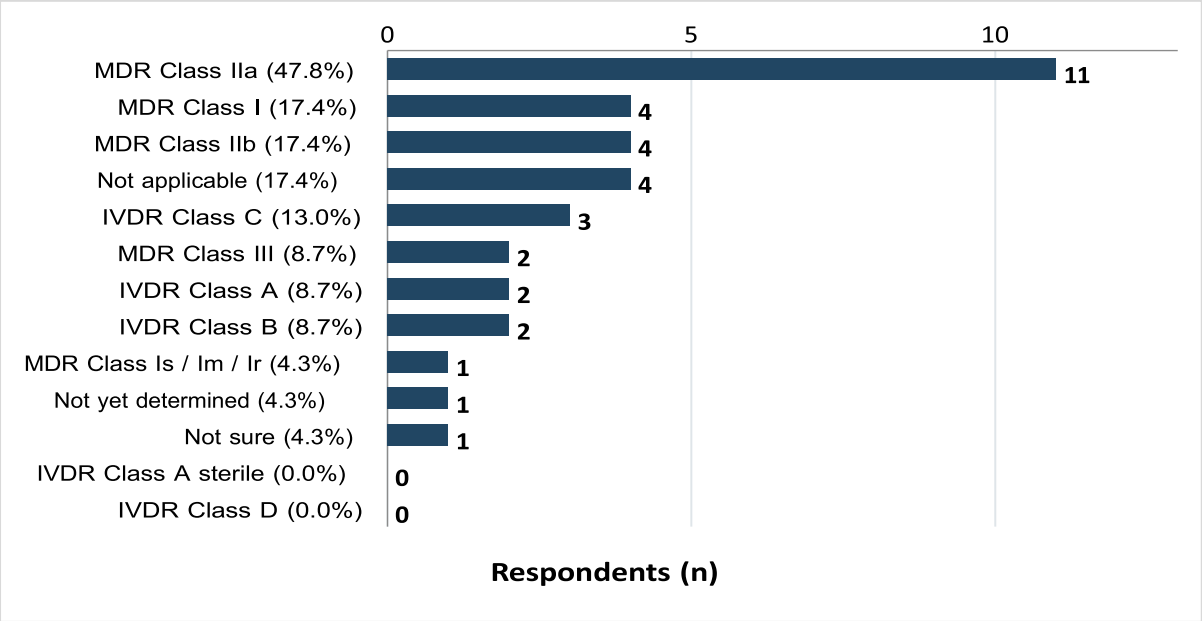


Figure 4. Q4 Regulatory classifications (N = 23; multiple responses)

Question 5: *What is the current regulatory stage of your most advanced product?**

Q5 Regulatory stage of the most advanced product

Ten respondents have a CE-marked product on the EU market and one has CE marking but has not yet launched. Three are undergoing Notified-body assessment, one is preparing for assessment, four are in product development and one is generating clinical or performance evidence. Three select “Other”. The responses combine current market experience with expectations formed before certification; this distinction matters when interpreting barriers and anticipated benefits. See Figure 5.

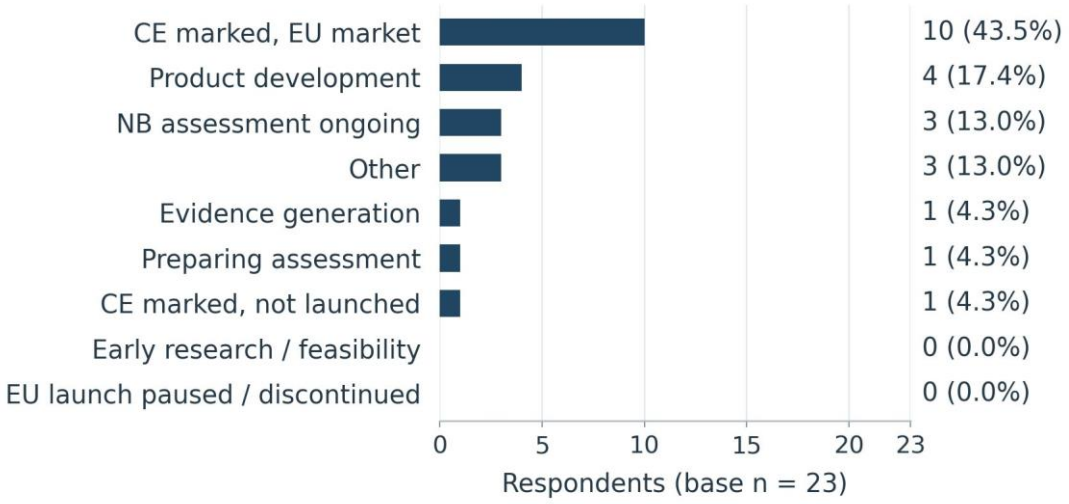


Figure 5. Q5 Regulatory stage (N = 23)

***Question 6**: Which markets are currently part of your commercialization strategy?*

Q6 Commercialisation markets

The EU or EEA forms part of the strategy for 22 respondents (95.7%). Eleven also select the United States, eight the United Kingdom, five Switzerland, four Australia, three Canada and one Japan. Three select other markets and one has not yet determined a market strategy. The strong EU focus coexists with international strategies, which provides context for later comparisons of regulatory competitiveness. See Figure 6.

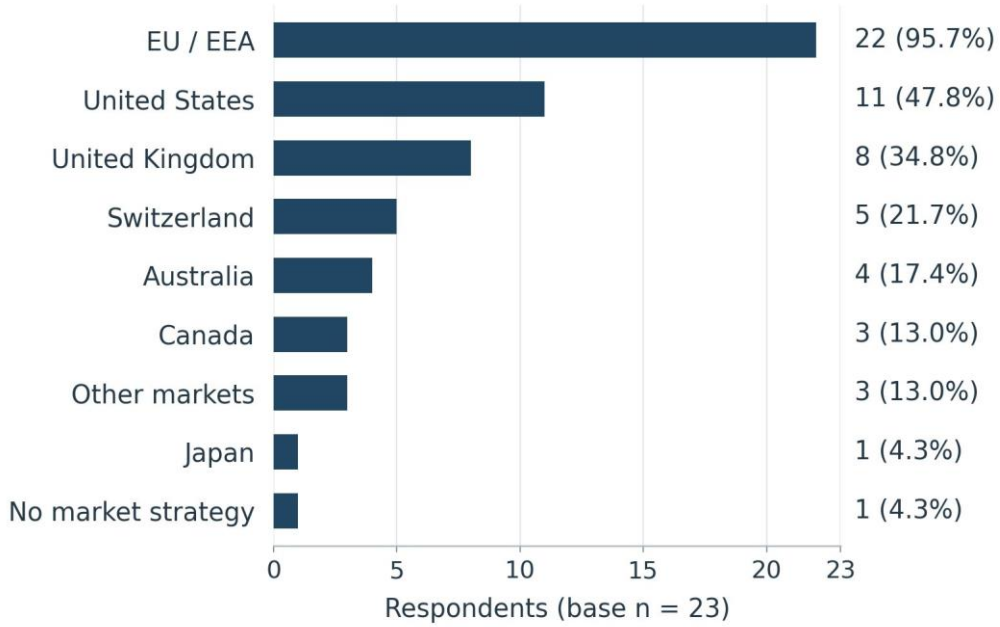


Figure 6. Q6 Target markets (N = 23; multiple responses)

Appendix A gives the complete profile distributions and a summary of the sample. Other responses are not treated as a separate device category.

3.2 Awareness and general assessment

***Question 7**: Before receiving this survey, how familiar were you with the proposed MDR and IVDR revisions?* You can review the revision text here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC1023*

Q7 Familiarity with the proposed revisions

Six respondents (26.1%) had reviewed the proposal in detail, 11 (47.8%) had read summaries or selected provisions and six (26.1%) were aware of the proposal but had not reviewed it. None reports being unaware. Most respondents therefore express views without a detailed review of the complete text. Familiarity is self-reported and does not establish knowledge of individual provisions or current advice routes. See Figure 7.

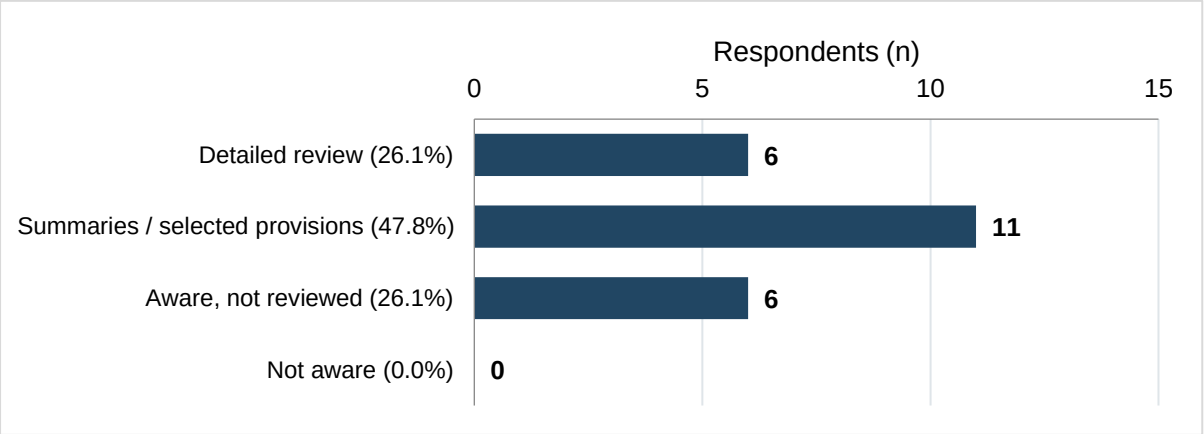


Figure 7. Q7 Familiarity with the proposed revisions (N = 23)

Question 8: *Based on what you know today, what is your overall view of the proposed revisions?**

Q8 Overall view of the proposed revisions

Twelve respondents are somewhat positive and six very positive, giving 18/23 positive responses (78.3%). Three are somewhat negative and two have insufficient information to assess the proposal. No respondent selects very negative or neutral or uncertain. This is a favorable signal within the received sample, not a measure of EU-wide consensus. See Figure 8.

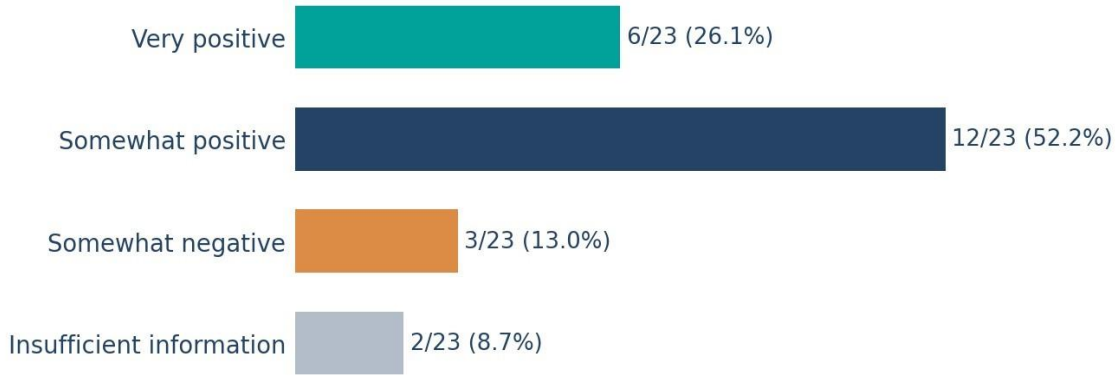


Figure 8. Q8 Overall assessment of the proposed revisions (N = 23)

Positive views occur in all familiarity groups: 5/6 detailed reviewers, 9/11 summary readers and 4/6 aware non-readers. Among respondents with fewer than 50 employees, 12/17 are positive; all four with 50 or more employees and both with undisclosed size are positive. Excluding the four respondents whose classification is not applicable leaves 15/19 positive. These small descriptive checks preserve the broad direction but do not establish a size or knowledge effect or create a verified manufacturer sample.

*Question 9: To what extent do you expect the proposed revisions to improve the EU regulatory environment for your company?**

Q9 Expected improvements in the regulatory environment

The strongest expectation concerns the ability to introduce product updates or changes: 18/23 (78.3%) expect improvement. Fifteen respondents (65.2%) expect improvement in each of compliance cost, cost predictability, assessment-timeline predictability, administrative and documentation workload, and post-market surveillance and follow-up workload.

For each of time to CE marking, clarity of requirements, and clinical or performance evidence requirements, 14 respondents (60.9%) expect improvement. For each of the ability to launch innovative products in Europe and to keep existing products on the EU market, 13 respondents (56.5%) expect improvement. For each of duplication and the availability of internal regulatory resources or need for external consultants, 12 respondents (52.2%) expect improvement. Eleven of 23 respondents (47.8%) expect access to an appropriate notified body to improve.

Investment expectations are more cautious: seven expect improvement, seven no meaningful change, two worsening, five are unsure and two report non-applicability. For clinical or performance evidence, 14/23 is the primary figure; excluding the four uncertain answers would raise the percentage from 60.9% to 73.7% (14/19) without adding positive responses. No respondent marks that item not applicable.

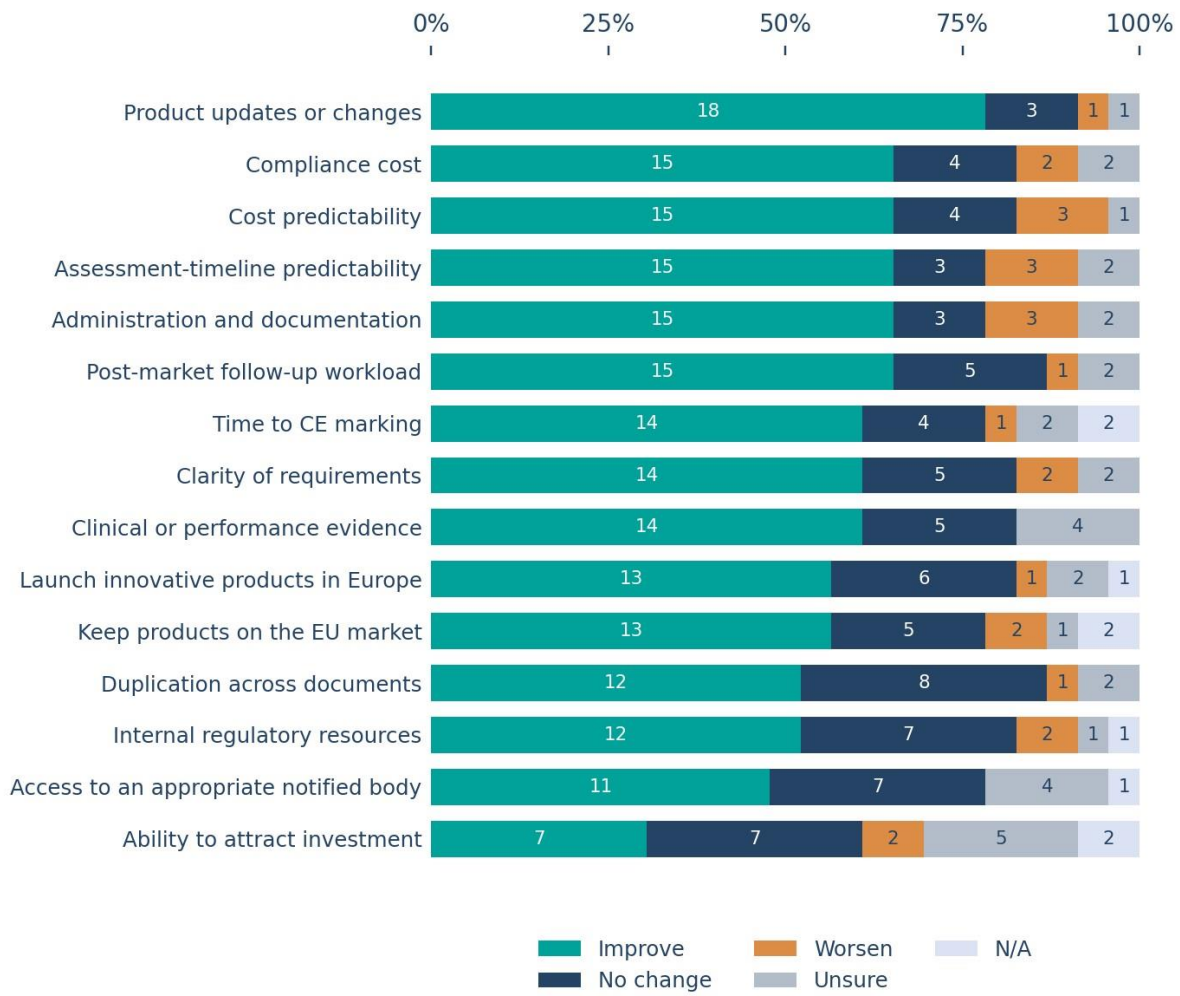


Figure 9. Q9 Expected effects of the proposed revisions (N = 23)

3.3 Assessment of the proposed changes

*Question 10: How valuable would each of the following proposed changes be for your company, if adopted and implemented as intended?**

Q10 Value of individual proposed measures

Across all 21 measures, very valuable or essential ratings range from 15/23 (65.2%) to 21/23 (91.3%). Less frequent surveillance audits, reduced PSUR update frequency and electronic submissions each receive 21 high-value ratings. Reduced NB fees, predictable assessment processes and timelines, and proportionate lower or medium-risk assessment each receive 20.

Structured NB dialogue receives 19 high-value ratings. Fee deferral, remote audits, simpler safety and performance summaries, flexible evidence, greater use of non-clinical evidence, and clearer change control each receive 18. Dispute resolution, proportionality for well established technologies and breakthrough pathways each receive 17. Common templates and early expert-panel advice receive 16 each. Public fee lists, PMCF integration into clinical evaluation and orphan or small-population pathways each receive 15.

Fee reductions and predictable processes share the highest essential-only count, at 15 each. Fee deferral follows with 14. Essential-only counts distinguish intensity without assigning arbitrary numerical weights to ordinal answers. Broad perceived value is different from selecting a limited set of priorities or expressing willingness to pay. See Figure 10, Figure 11 and Figure 12.

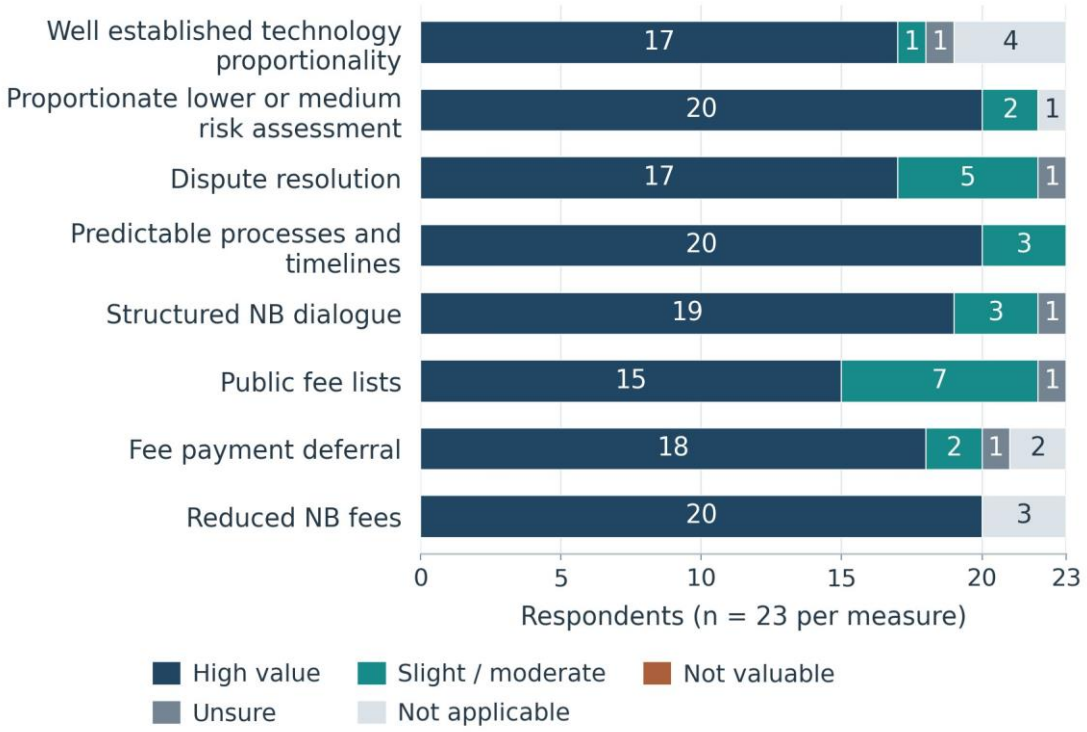


Figure 10. Q10 Value of proposed measures, part 1 of 3 (N = 23)

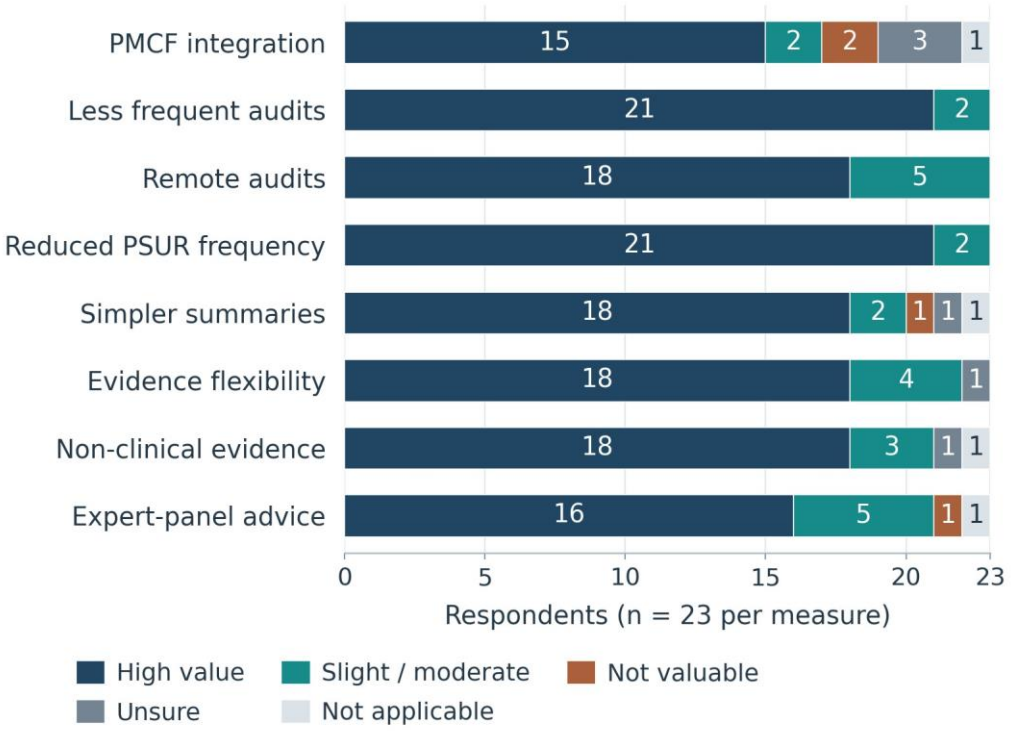


Figure 11. Q10 Value of proposed measures, part 2 of 3 (N = 23)

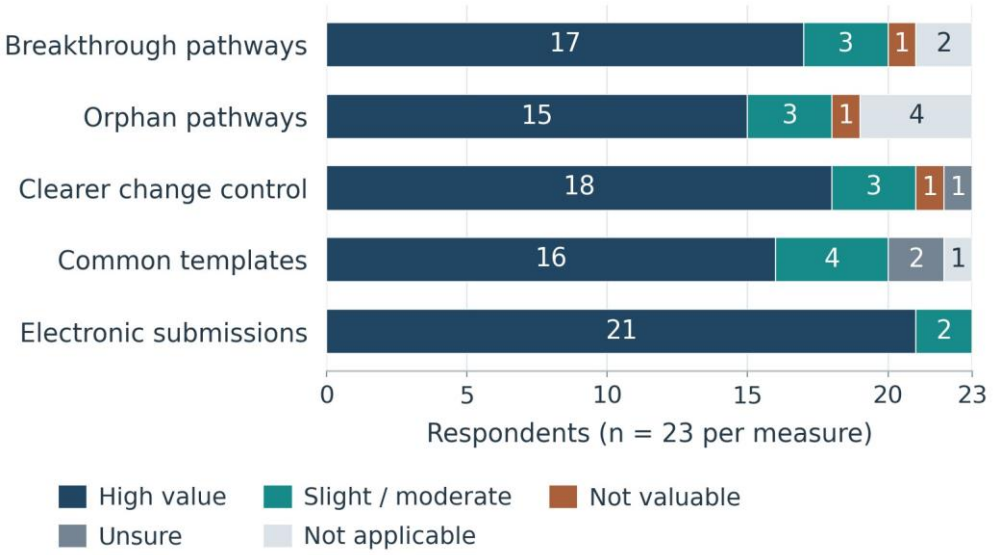


Figure 12. Q10 Value of proposed measures, part 3 of 3 (N = 23)

Appendix C reports all 21 measures. High ratings show perceived value, while Q11 asks respondents to select priorities. Both questions are retained to avoid overstating a preferred policy interpretation. See Table 7.

Table 7. Q10 Selected measures concerning dialogue and evidence (N = 23)

Structured NB dialogue	19/23 (82.6%)	1 unsure; 0 not applicable
Flexibility in evidence for safety and performance	18/23 (78.3%)	See full distribution in Appendix C
Greater use of non-clinical evidence	18/23 (78.3%)	See full distribution in Appendix C
Breakthrough pathways	17/23 (73.9%)	0 unsure; 2 not applicable
Early expert panel advice	16/23 (69.6%)	0 unsure; 1 not applicable
Orphan or small population pathways	15/23 (65.2%)	0 unsure; 4 not applicable

High ratings for dialogue and evidence-related measures support further examination of procedural expectations, scientific evidence questions and which body can address each. Appendix C gives the distribution for every measure.

Question 11: *Which five proposed measures would have the greatest positive impact on your company?**

Q11 Five measures with the greatest positive impact

Reduced NB fees lead with 18/23 nominations (78.3%), followed by less frequent surveillance audits with 12, clearer change control and structured dialogue with 11 each, and reduced notified-body involvement for certain lower- and medium-risk devices with ten. EU harmonisation receives eight. Fee deferral, remote audits and public fee lists each receive seven. The full distribution is shown in the figure and Appendix D. See Figure 13.

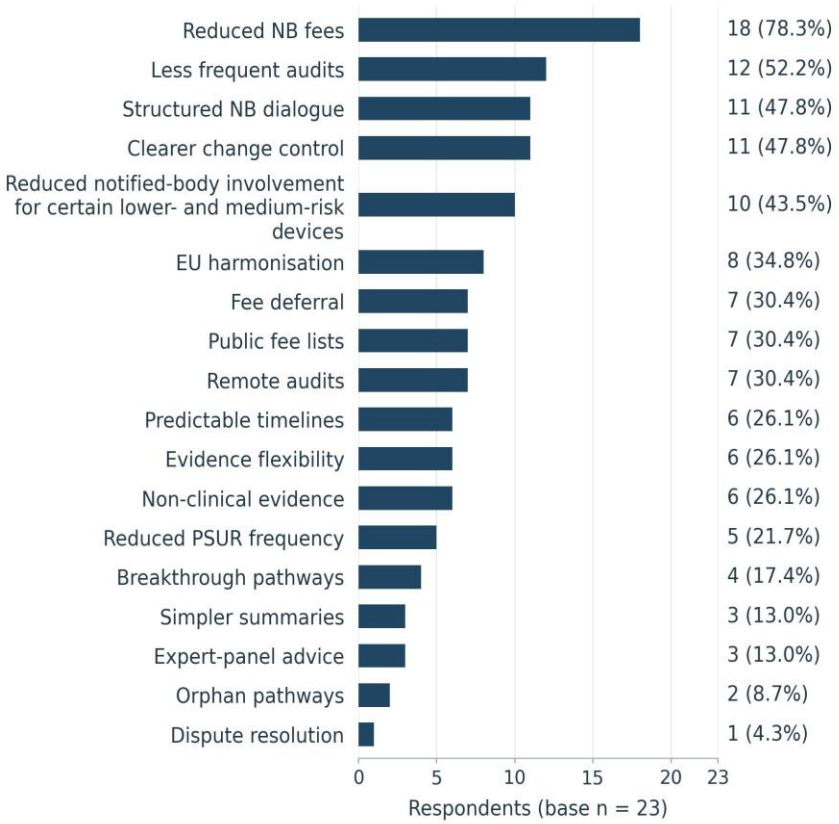


Figure 13. Q11 Priority selections (N = 23; multiple responses)

The figure presents all 18 proposed measures for the full sample (N = 23), showing the number and percentage of respondents selecting each measure. All recorded selections are retained, including those from respondents who selected more than five measures. Percentages use N = 23 as the denominator and do not sum to 100% because multiple selections were recorded.

Eleven respondents select exactly five measures, six select fewer and six select more, with a maximum of 12. Fee reductions remain first among those selecting at most five (12/17) and exactly five (8/11). Other positions change. All three expert-panel advice nominations come from respondents exceeding five choices, so that item is better interpreted alongside Q10 ratings and written explanations. Appendix D compares the full sample with respondents selecting at most five measures and those selecting exactly five. These groups overlap and are not independent samples.

Fee reductions are nominated by 15/17 respondents with fewer than 50 employees, 2/4 with 50 or more and 1/2 with undisclosed size. Excluding four respondents who report no applicable regulatory classification leaves 15/19 fee nominations. These checks support the recurring affordability theme without establishing differences between company-size groups.

Question 12: *Of the measures you selected, which single measure is most important?**

Q12 Single most important measure

The 22 substantive answers identify NB fee reductions seven times, structured dialogue four times, lower-risk proportionality or reduced notified-body involvement three times, and predictable processes and timelines twice. Unspecified lower cost, expert-panel advice, change control, EU harmonisation, an orphan pathway and reduced PSUR frequency are each named once. One response is a non-substantive dash.

Two priorities, one fee reduction and one PSUR-frequency nomination, were absent from the corresponding Q11 selections. Q12 is retained as written rather than forced to match Q11. Unspecified cost reduction is kept separate from fee reductions.

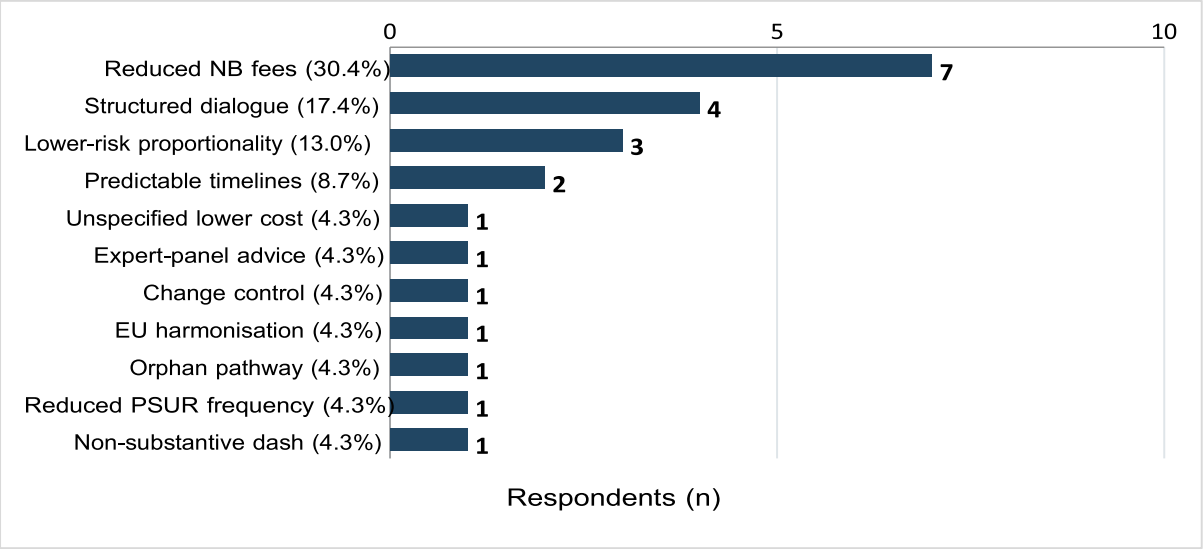


Figure 14. Q12 Single most important measure (N = 23; 22 substantive answers)

The full coding is in Appendix D. See Figure 14.

Question 13: *Why is this measure particularly important to your company? Please describe the expected effect where possible, for example on cost, time to market, internal workload, evidence generation, investment, notified-body access, product availability or commercialisation decisions.*

Q13 Reasons for the selected priority

Seventeen respondents provide a nonblank explanation. The comments link fees and recurrent audit costs to limited cash, pre-revenue development, resources available for research and development, and the viability of low-volume products. They distinguish assessment charges from the potentially larger cost of generating evidence. Early advice is valued as a way to reduce the risk of committing to an evidence programme that later proves inadequate and to make timelines and investment discussions more realistic.

Further explanations concern uncertain reviewer expectations, inconsistent interpretations, lengthy assessment, difficult communication, and the need for clear rules when software or AI models change. Niche devices and small patient populations raise questions about feasible evidence generation and continued availability. Some entries simply repeat a measure rather than explain it. These accounts describe respondent experiences and concerns.

Taken together, the explanations support distinguishing finance for evidence generation, finance for conformity assessment and finance for continued compliance. They also support transparent process expectations, reasoned feedback and usable dispute or complaint routes.

Question 14*: Which additional changes would still be needed for the revised MDR and IVDR framework to work effectively for your company? The previous questions concerned changes included in the European Commission's proposal. The following question asks whether any further changes may still be needed.*

Q14 Additional changes still needed

Further proportionality for lower-risk products is selected by 18/23 (78.3%). Sixteen (69.6%) select the combined option on integration of clinical or performance evaluation and post-market documentation and consistent use of common templates. Clearer PMCF criteria receive 13 selections (56.5%), a once-only submission principle 12 (52.2%), and further proportionality for wellestablished technology devices under the MDR 10 (43.5%).

Four "Other answers" (17.4%) concern clearer wording, software qualification or Rule 11, alignment between medical-device and AI requirements, and the orphan threshold.

The findings support practical guidance on proportionality and coherent documentation. They do not establish that PMCF should routinely be waived or that a classification change removes the need for adequate clinical or performance evidence. See Figure 15.

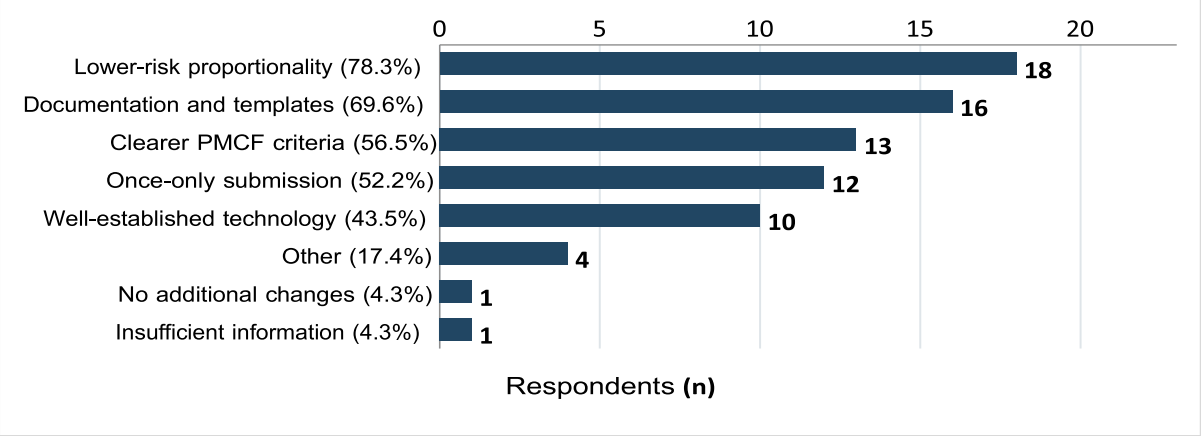


Figure 15. Q14 Additional changes (N = 23; multiple responses)

3.4 NB access and costs

Question 15: *What notified-body challenges does your company currently experience or anticipate?**

Q15 Current or anticipated NB challenges

High total cost is selected by 20/23 (87.0%). Limited pre-submission dialogue, long waiting periods before application or submission, and unpredictable fees each receive 13 selections (56.5%); unclear or changing timelines receive ten (43.5%). Other selections concern different interpretations between bodies (six), insufficient technology expertise (four), changing notified body (three), identifying a body with the right scope (two), and bodies not accepting new clients (one). Three Other responses raise documentation workload, consistency within a body and local availability.

Two respondents select not applicable, including one who also selects substantive challenges. All choices are retained. Appendix E gives the full distribution. See Figure 16.

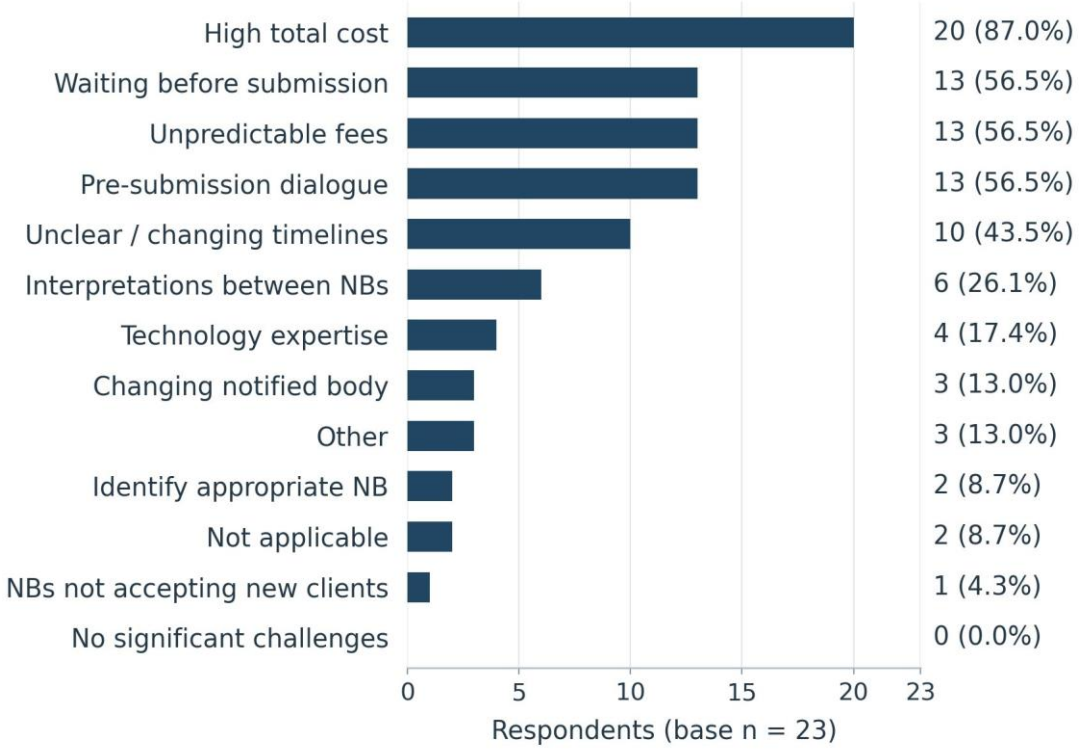


Figure 16. Q15 Current or anticipated notified-body challenges (N = 23; multiple responses)

Question 16: *To what extent would the proposed notified-body measures resolve the challenges you selected?*

Q16 Expected resolution of notified-body challenges

Ten respondents expect the proposed measures to resolve challenges to a moderate extent and five to a large extent. Together, 15/23 (65.2%) expect at least moderate resolution. Five expect only limited resolution and three are unsure. Nobody selects completely or not at all. Respondents anticipate help, but do not report complete resolution of their challenges. See Figure 17.

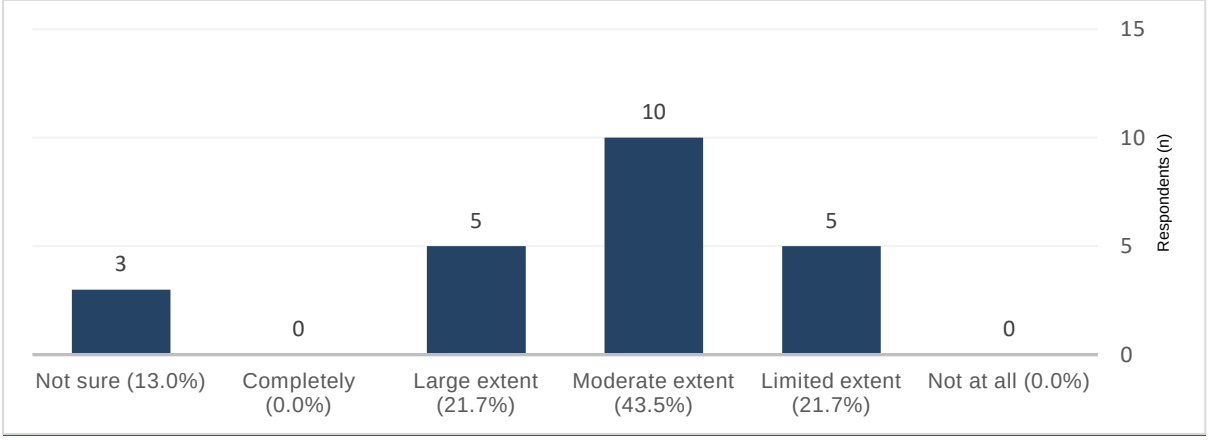


Figure 17. Q16 Expected resolution of notified-body challenges (N = 23)

Question 17:*How adequate are the proposed notified-body fee reductions for micro and small companies?*

Q17 Adequacy of fee reductions

10 of 23 consider the proposed fee reductions fully or largely adequate, 6 partly adequate, 2 inadequate and 2 prefer another mechanism; 2 report non-applicability and one is unsure. Among

the 17 reporting fewer than 50 employees, 9 consider the reductions fully or largely adequate, 4 partly adequate, 2 inadequate, 1 prefers another mechanism and 1 reports non-applicability. This subgroup is closer to the stated audience, but headcount does not verify fee eligibility. The findings show mixed adequacy, rather than general sufficiency or insufficiency. See Figure 18.

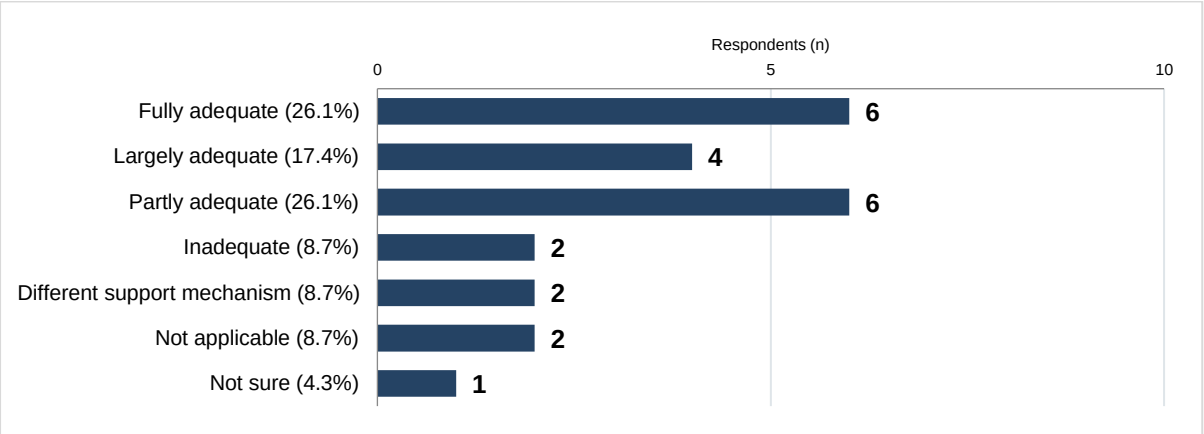


Figure 18. Q17 Adequacy of fee reductions (N = 23)

The proposal discussed in the survey includes minimum reductions of 50% for micro manufacturers, 25% for small manufacturers and 50% for orphan-device assessments, alongside fee-payment deferral until the relevant assessment activity is completed. These are proposed provisions, not benefits demonstrated by the survey or verified entitlements for individual respondents. [3]

Question 18: *What additional fee or financing measures would be most helpful?*

Q18 Additional fee or financing support

Fee caps for defined assessments, EU or national vouchers for conformity assessment, and grants for clinical or performance evidence each receive 12 selections (52.2%). Reduced early scientific or regulatory advice fees receive 11; reduced follow-up certification and surveillance fees eight; public standardised fee structures seven; milestone-linked payments six; deferral until certification five; larger percentage reductions four; and instalments three. One Other response concerns harmonised reimbursement.

These preferences extend beyond a single discount: respondents seek support for evidence preparation, assessment and recurring compliance, as well as clearer prices and payment timing. Appendix F reports Q16-Q18 in full. See Figure 19.

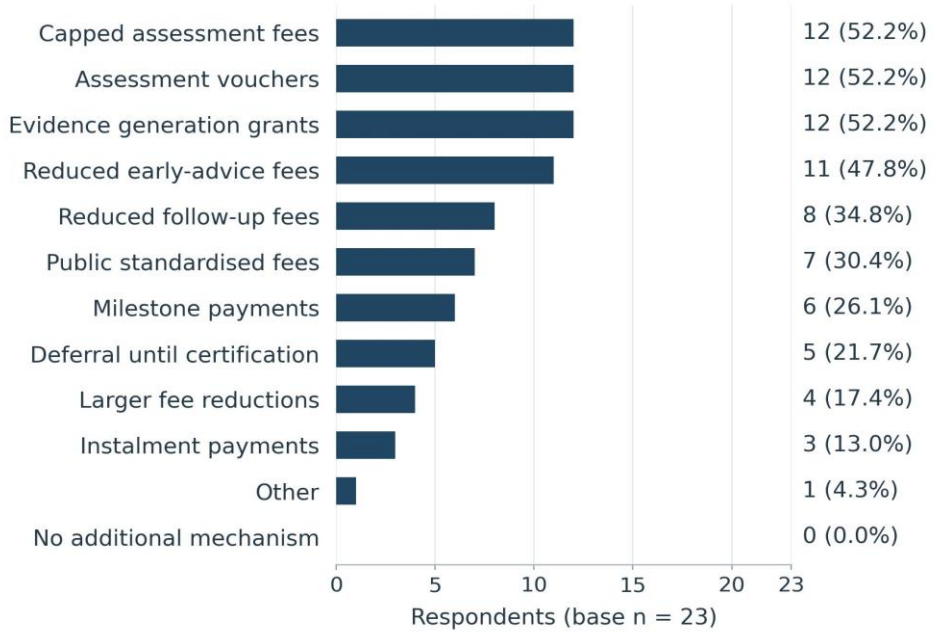


Figure 19. Q18 Additional financing measures (N = 23; multiple responses)

3.5 Software-specific questions

The questionnaire directs Q19-Q22 only to respondents selecting medical device software or an AI-incorporating device in Q3. Twelve meet this rule and all 12 answer the module. Three additional respondents answer Q19-Q21 and two answer Q22. The eligible group is primary; Appendix G retains all recorded answers as a sensitivity comparison. Blank answers are not negative opinions.

Question 19: How do you expect the proposed changes to the classification of medical device software to affect your company?

Q19 Expected effect of software-classification changes

This section is only for people who replied "Software as a Medical Device," "medical device software," or "device incorporating artificial intelligence" to question #3.

Eight of the 12 eligible respondents expect a positive effect: six moderate, one significant and one limited. One respondent expects no meaningful effect, one expects a negative effect, one selects "not applicable", and one is unsure. Across all 15 recorded answers, ten expect a positive effect. The direction is similar, but the broader group includes respondents outside the questionnaire instruction. See Figure 20.

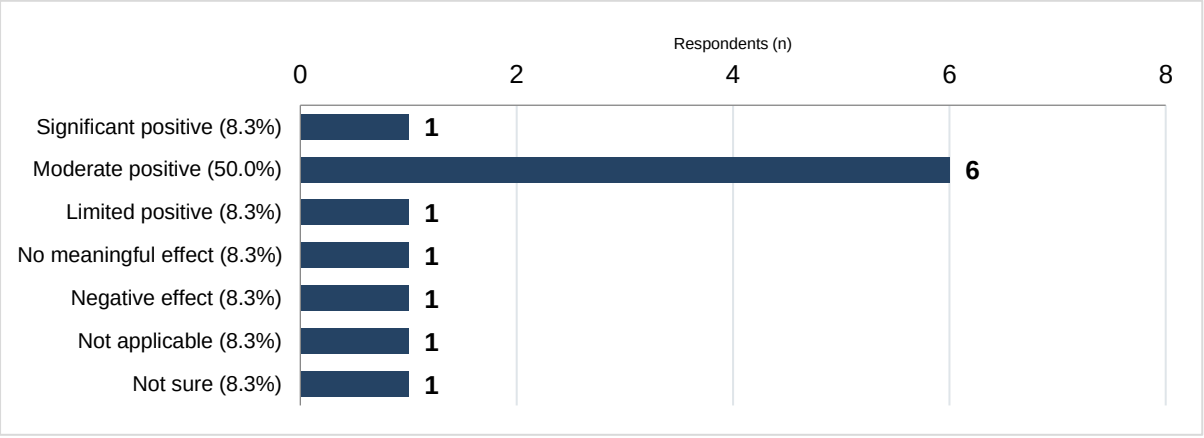


Figure 20. Q19 Expected software effects (eligible n = 12)

Question 20: Do the proposed software-classification changes go far enough?

Q20 Whether the changes go far enough

Five eligible respondents answer no, four partly and three are unsure; none answers yes. Thus, 9/12 (75.0%) consider the changes only partly sufficient or insufficient, despite 8/12 expecting a positive effect in Q19. Across all recorded responses, 11/15 answer partly or no and four are unsure. Positive effect and perceived sufficiency are separate findings.

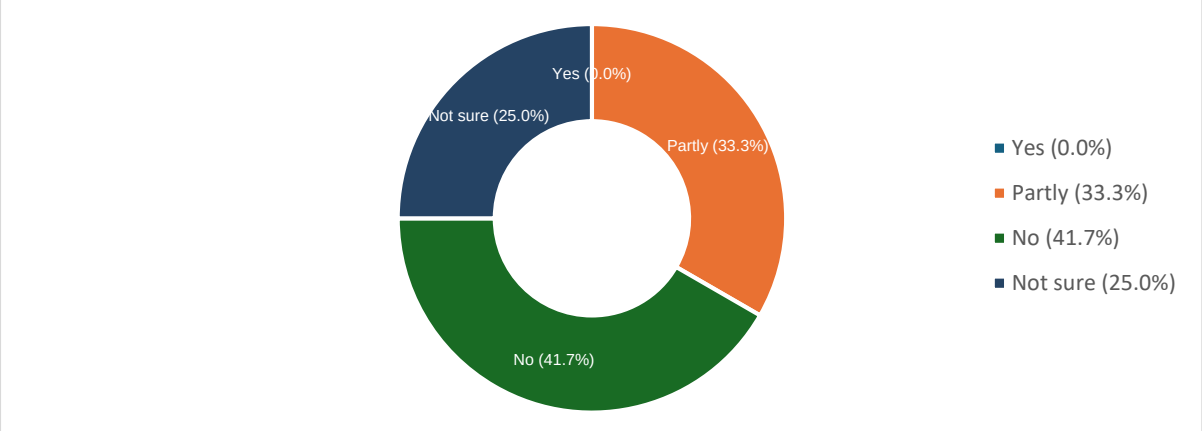


Figure 21. Q20 Whether the software changes go far enough (eligible n = 12)

***Question 21**: Which statement is closest to your view?*

Q21 Closest view of the proposed software changes

Four eligible respondents identify unclear or inconsistent interpretation as the main challenge; three favour additional lower-risk software categories qualifying as Class I. One considers that the changes achieve an appropriate risk-based balance, one identifies the assessment process as the main challenge, one provides another interpretation concern and two are unsure. This distribution indicates that classification thresholds, interpretation and assessment practice all require attention. See Figure 22.

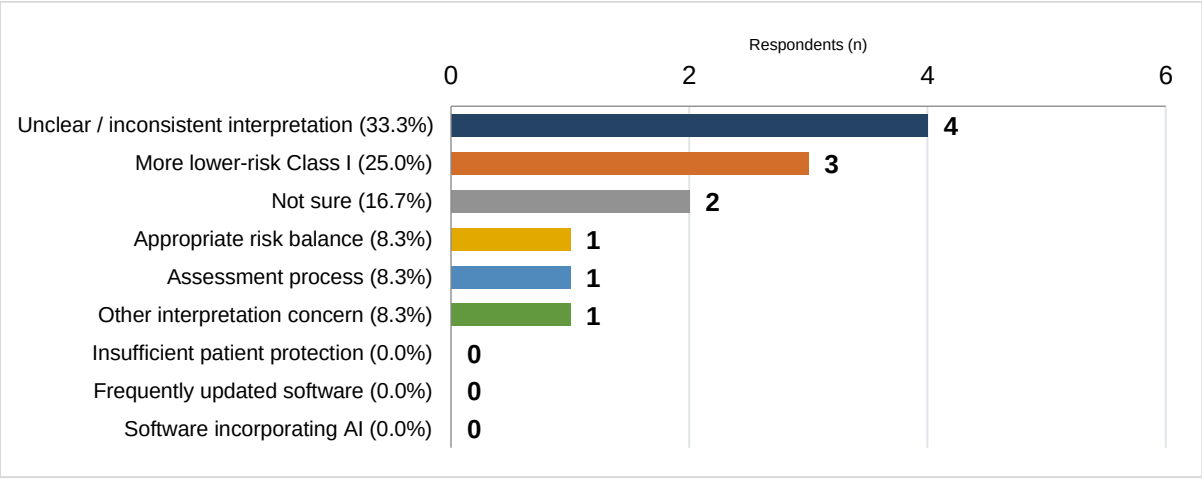


Figure 22. Q21 Perspectives on the software proposals (eligible n = 12)

***Question 22**: Which additional improvements are needed for medical device software?*

Q22 Additional software improvements

Table 8. Q19-Q22 Software findings among eligible respondents (n = 12)

Do the changes go far enough	Partly 4/12; no 5/12; unsure 3/12; yes 0/12	Positive effects and perceived sufficiency are different questions.
More categories eligible for Class I	9/12 in Q22 (75.0%)	A request for broader proportionality, not evidence that down-classification is clinically justified.
Clearer criteria and examples	7/12 in Q22 (58.3%)	Worked examples and consistent interpretation are practical priorities.
Alignment with the EU AI Act	8/12 in Q22 (66.7%)	Developers need a coherent view of overlapping obligations.
Clearer treatment of updates	7/12 in Q22 (58.3%)	Evidence planning must account for software versioning and change assessment.

Beyond the leading items in the table, six of the 12 eligible respondents seek consistent classification decisions across Member States, five clearer criteria for significant changes, four greater acceptance of simulation or other non-clinical evidence and four greater acceptance of real-world evidence. Software-specific assessment timelines and early advice each receive three selections; faster access to software expertise and predetermined change-control plans each receive two.

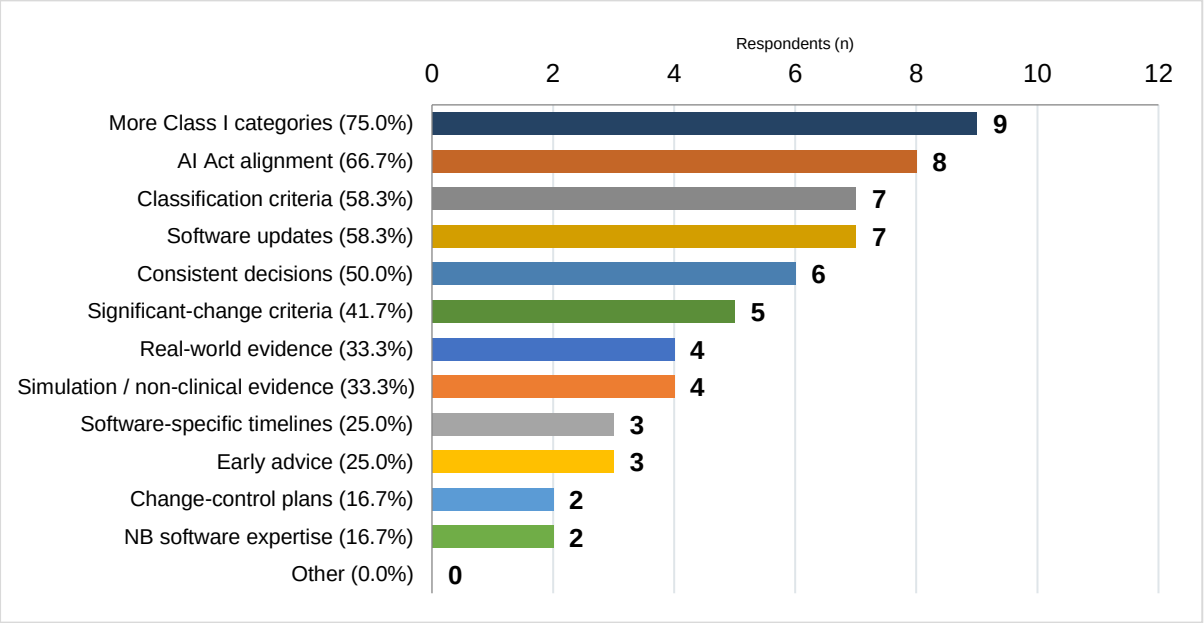


Figure 23. Q22 Additional software improvements (eligible n = 12; multiple responses)

The request for more Class I categories is a preference for broader proportionality, not evidence that down-classification is clinically justified.. Examples should distinguish valid clinical association, technical performance and clinical performance, and help respondents prepare focused questions for the appropriate authority. They should not assume that AI functionality determines class or that every software update requires the same evidence. [9] See Figure 23. See Table 8.

3.6 Administrative burden, evidence and post-market obligations

***Question 23**: Which proposed simplifications would reduce the greatest amount of work for your company?**

Q23 Simplifications expected to reduce the most work

Reduced PSUR frequency receives 12/23 selections (52.2%). Integration of PMCF findings into clinical evaluation, fewer routine surveillance assessments and greater reliance on non-clinical evidence each receive ten. Simplified clinical-investigation or performance-study requirements, simpler safety and performance summaries, and greater reliance on existing or equivalent-device data each receive nine. Remote audits receive eight; reduced technical-documentation sampling and electronic submissions seven each; and clearer change control six. Two respondents expect none of the options to materially reduce workload.

Although Q23 instructs respondents to select up to five options, six select more than five, with a maximum of nine. Among the 17 meeting the limit, PMCF integration leads with seven selections; PSUR frequency, fewer surveillance assessments and simpler study requirements each receive six. The leading order therefore changes. Appendix H presents the full counts. These are expected workload benefits, not measured hours saved or a basis for changing an individual device's evidence obligations. See Figure 24 and Figure 25.

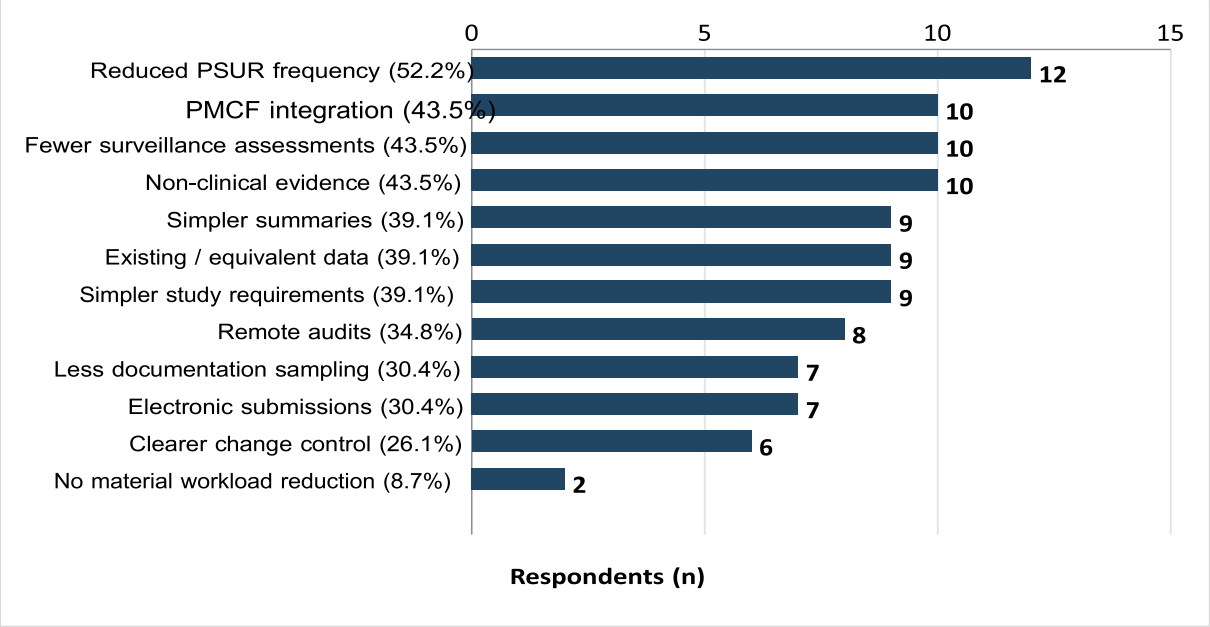


Figure 24. Q23 Measures expected to reduce workload (N = 23; multiple responses)

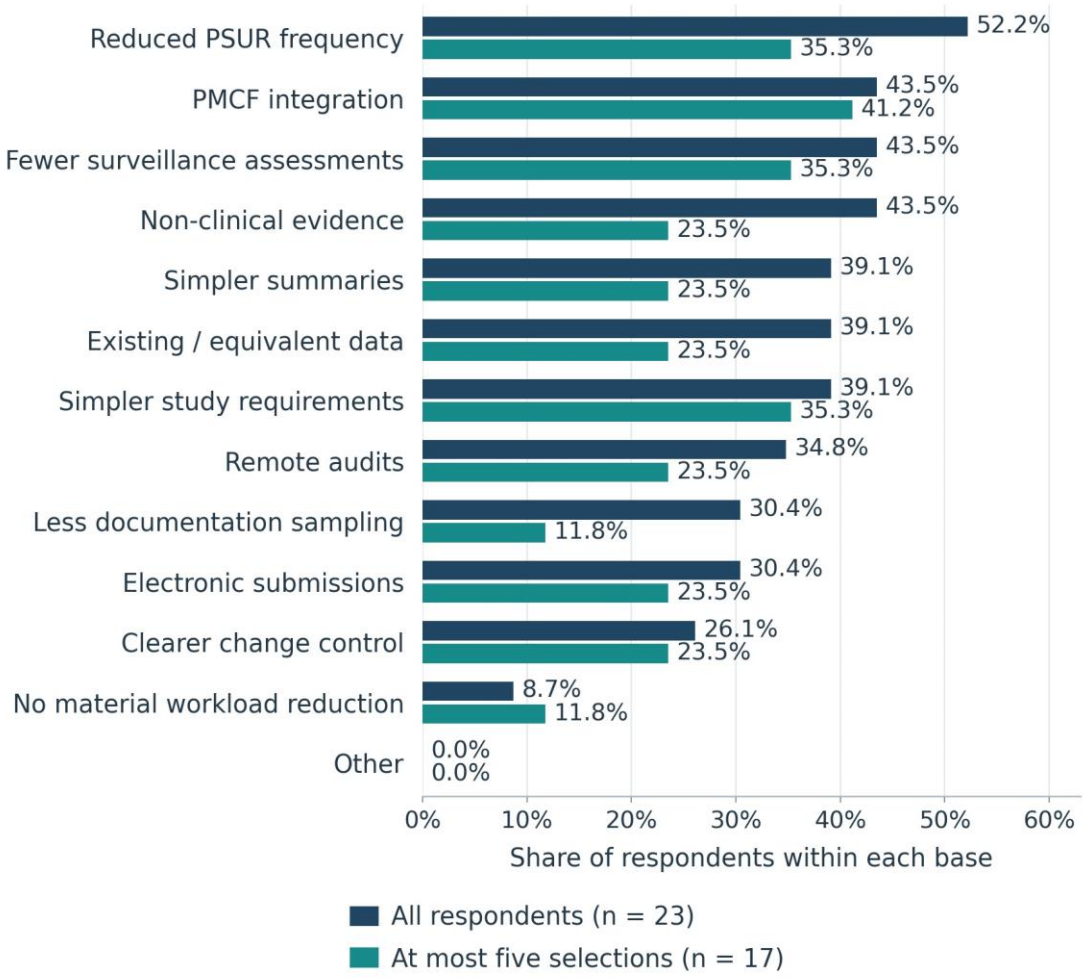


Figure 25. Q23 Selection sensitivity (full N = 23; at-most-five n = 17)

Question 24: *Where do you believe the proposal may simplify requirements too much or create a potential risk?*

Q24 Potential excessive simplification or risks

Fifteen respondents identify at least one substantive risk, five see no significant risk and three are unsure. Clinical or performance evidence, particularly for novel technologies, receives eight selections; vigilance reporting seven; oversight of AI and frequently updated software six; and cybersecurity, maintenance and vulnerability management five.

Device classification and reduced audit frequency each receive four selections. Remote audits, reduced notified-body involvement and post-market surveillance each receive three. Oversight of changes to certified devices or quality-management systems and breakthrough or orphan-device pathways each receive two. Multiple risks may be selected by one respondent, so percentages must not be added.

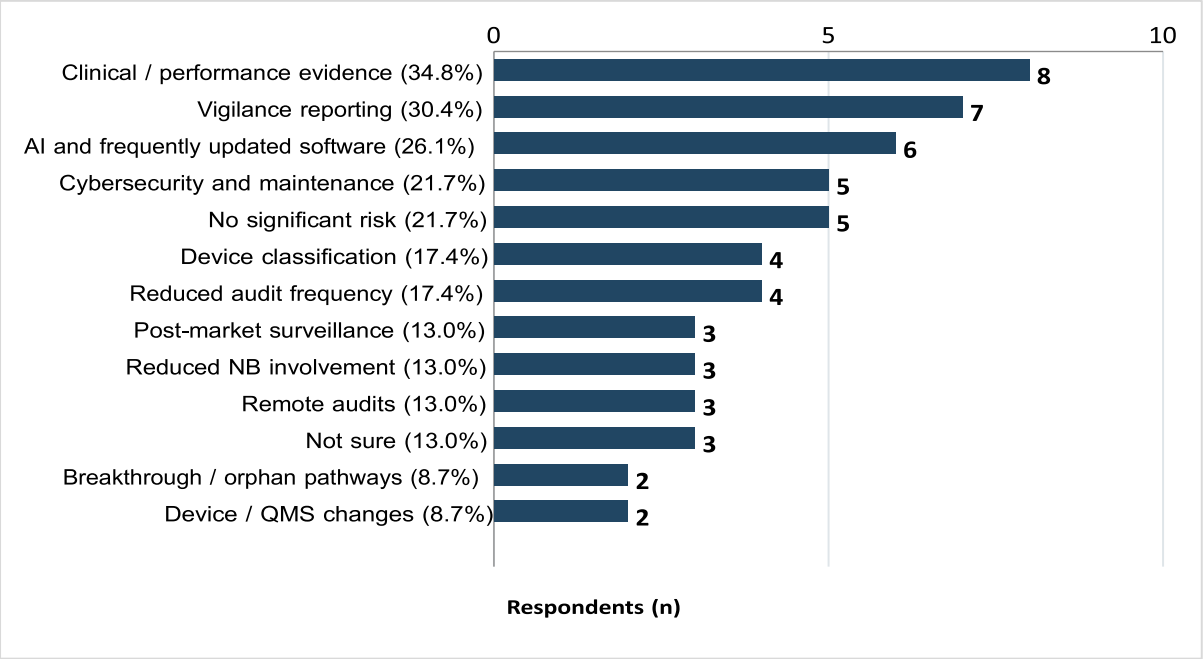


Figure 26. Q24 Potential risks of excessive simplification (N = 23; multiple responses)

Support and concern overlap within respondents. Four identify reduced audit frequency as a concern, 12 nominate less frequent audits in Q11, and two do both. Fourteen of the 18 respondents positive about the overall proposal identify at least one risk. Thirteen of the 18 seeking greater lower-risk proportionality also identify a risk. These overlaps support examining the conditions for acceptable simplification; they do not establish clinical harm or safe thresholds.

Question 25: *Please explain any concern you selected.*

Q25 Explanations of concerns

Eight respondents provide nonblank explanations. Themes include ambiguity in Rule 11 wording, clearer cybersecurity requirements and international consistency, and maintaining adequate analytical and clinical validation for novel diagnostic technologies. The comments also request greater accountability and usable complaint mechanisms for notified-body processes. These are respondent concerns and proposals, not independently verified legal or operational findings.

Views on audits differ. Some favour less frequent, cheaper or remote audits; others consider onsite observation of company culture valuable and suggest a combination of remote and physical review. The comments therefore do not justify a uniform assumption that one audit format is always preferable. Some answers repeat an option or are non-substantive; no thematic prevalence percentage is assigned.

The analytical implication is to relate evidence flexibility to intended claims and remaining uncertainty. Proportionate use of existing, non-clinical or post-market evidence can be discussed alongside the consequence of an incorrect conclusion and the studies or follow-up needed to resolve uncertainty. For IVDs, scientific validity, analytical performance and clinical performance remain distinct considerations. [8]

3.7 Competitiveness and company decisions

Question 26: *If the proposed revisions were adopted as currently drafted, how would they affect the likelihood that your company would undertake the following actions?**

Q26 Conditional company intentions

This question asks how company actions would change if the revisions were adopted as drafted. It measures stated intentions under a hypothetical policy condition, not observed decisions.

Developing a new medical device or IVD in Europe receives the most positive responses, at 17/23 (73.9%), followed by seeking initial EU access at 15/23 (65.2%). For each of keeping existing products in the EU, launching in the EU first, and conducting clinical or performance studies in Europe, 14 respondents report being more likely to do so. These signals are stronger than intentions to seek external investment (ten) or add regulatory staff or expertise (seven).

For prioritising the United States or another non-EU market, six are more likely, seven less likely and seven report no effect; two are unsure and one reports non-applicability. This mixed result does not establish that reform would shift companies uniformly toward or away from Europe. Appendix I retains every positive, negative, neutral, uncertain and non-applicable response. See Table 9.

Table 9. Q26 Expected actions under the proposed revisions (N = 23)

Develop a new medical device or IVD in Europe	17/23 (73.9%)
Seek initial market access in the EU	15/23 (65.2%)
Keep existing products available in the EU	14/23 (60.9%)
Launch new products in the EU before other markets	14/23 (60.9%)
Conduct clinical or performance studies in Europe	14/23 (60.9%)
Partner with a European hospital or research organisation	12/23 (52.2%)
Seek external investment	10/23 (43.5%)
Invest in additional regulatory staff or expertise	7/23 (30.4%)
Prioritise the United States or other non-EU markets	6/23 (26.1%)

Question 27: In comparison with other markets relevant to your company, how competitive would the revised EU pathway be?

Q27 Expected competitiveness of the revised EU pathway

In Q27, 10 respondents expect greater EU competitiveness in suitability for micro and small companies; 9 each for clarity of requirements and suitability for innovative products; 8 for cost; 7 for speed; and 6 each for predictability and advice. None of the seven dimensions has a positive majority of all 23 responses. Between 3 and 5 respondents per dimension report insufficient experience to compare. Comparisons therefore reflect heterogeneous perceptions, not benchmarking of equivalent regulatory submissions.

The strongest positive count is suitability for micro and small companies (10/23, 43.5%). For speed, seven expect the EU to be more competitive, six comparable, six less competitive and four lack sufficient experience. For predictability, eight expect comparability and six greater competitiveness. The detailed distributions in Appendix I make clear that broad support for reform in Q8 does not imply a positive majority on international competitiveness. See Figure 27.

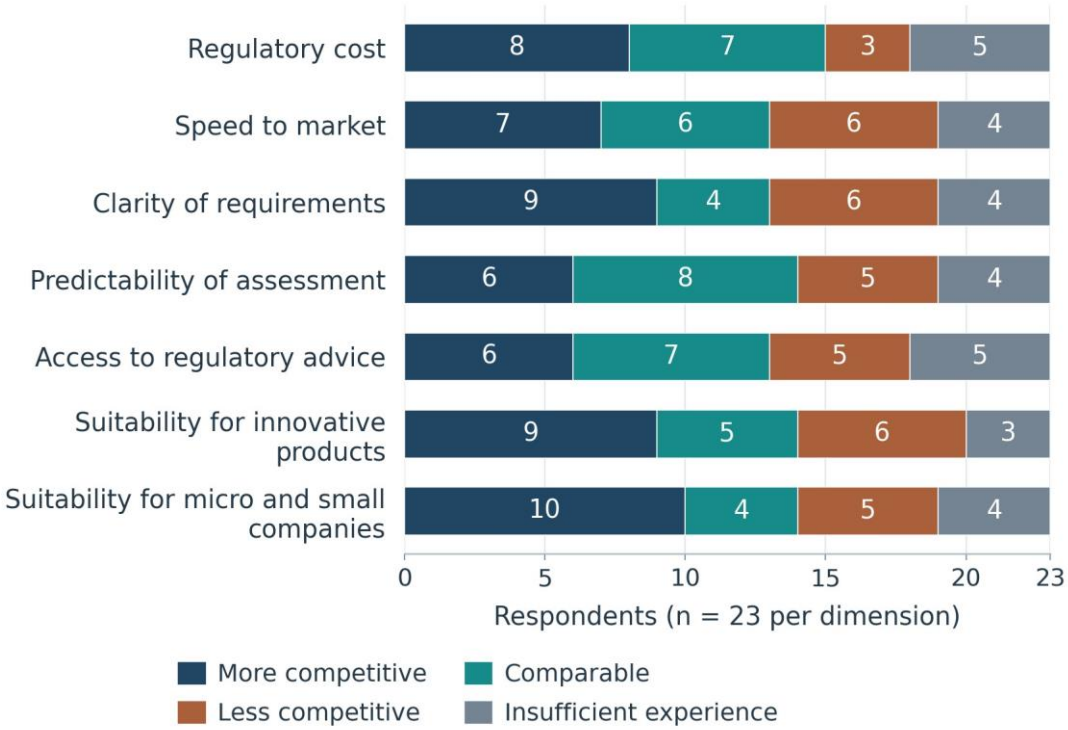


Figure 27. Q27 Expected EU competitiveness (N = 23)

3.8 Remaining gaps and final priorities

*Question 28: Overall, how far do the proposed revisions go towards creating an innovation-enabling regulatory environment for micro and small companies?**

Q28 Innovation-enabling environment

The supplied questionnaire defines Q28 from 0, meaning no innovation-enabling environment, to 10, meaning a fully innovation-enabling environment. The median is 6/10 and the supplementary mean is 5.48/10. 15 respondents choose 6-8, 1 chooses 5 and 7 choose 0-4; none chooses 9 or 10. These ratings indicate perceived room for improvement. They are not a validated index or a measure of how much regulatory reform has been completed.

The scale runs from “does not create an innovation-enabling environment at all” to “fully creates one”. Appendix J reports all scores, including the unselected values of nine and ten. The rating complements the question-specific results; it is not a validated composite index.

***Question 29:** What important challenge for micro and small companies is not adequately addressed in the proposal?*

Q29 Important challenges not adequately addressed

Thirteen respondents provide nonblank answers. Recurring concerns are the total cost of obtaining and maintaining certification, the burden relative to product revenue or a limited portfolio, and financing evidence generation, technical validation and quality-management work before assessment. Respondents also seek regulatory consultation that is affordable or publicly supported, more proportionate documentation for small organisations, and clearer treatment of lower-risk software.

Further comments concern assessment timelines, reviewer consistency, the basis for nonconformities, and accountability or complaint follow-up. Niche products and small patient populations raise particular concerns about continued availability and the limited benefit of document sampling for companies with very few products. Some responses are general or nonsubstantive.

Question 30: *If you could recommend one further change to EU policymakers, what would it be?*

Q30 One further change for EU policymakers

Thirteen respondents provide nonblank answers. Suggestions include binding assessment timelines, more consistent and substantiated reviews, clearer oversight and EU-level complaint follow-up. Financing proposals include accessible support for evidence generation and preparation for conformity assessment before launch. Other suggestions seek clearer structure and greater alignment with international approaches, including US terminology or processes for AI and cybersecurity.

Software-related suggestions favour proportionate access for lower-risk products, use of real world or post-market evidence, and avoidance of duplicative medical-device and AI obligations. Suggestions concerning IVDs and small populations include extending well-established technology principles, reviewing orphan thresholds and the treatment of in-house devices or subcontracted manufacture, and strengthening market surveillance to support fair competition and continued niche-product availability.

These are stakeholder proposals for policy discussion. Generic answers, statements of uncertainty and entries without a recommendation remain part of the response-count record but do not support a substantive policy conclusion.

3.9 Data protection and contact information

Question 31: *Data protection consent**

Q31 Data protection consent

All 23 respondents consent to processing their personal data for the purposes described in the survey notice.

Question 32: *May NoBoCap quote your written comments?**

Q32 Permission to quote written comments

Eight permit aggregate analysis only, 14 permit anonymous quotation and one permits quotation with company identification. The report uses aggregate findings and paraphrased thematic synthesis throughout; no direct respondent quotations or identifying details are reproduced.

Question 33: *May NoBoCap contact you regarding your response?*

Q33 Permission for follow-up contact

Eleven respondents permit follow-up contact and 12 do not. Any subsequent follow-up should respect these choices and be recorded as a separate source of evidence.

Question 34-36: *Name; Company name; Email*

Q34 Name, Q35 Company name, Q36 Email

These fields collect contact and organisational identifiers. They are not analytical outcomes and are excluded from the published results. Appendix J consolidates the permission counts; contact details are not reproduced.

4 Conclusions

4.1 Main findings

The overall conclusion in striving for an innovation enabling regulatory environment is that the proposed revision the respondents marked as follow with most indicating a level 6 in a scale of 0 to 10.

Table 10. Respondents' ratings of the proposed MDR/IVDR revision's potential to support innovation (0–10 scale)

Score	0	1	2	3	4	5	6	7	8	9	10
Number of respondents	1	1	1	1	3	1	7	3	5	0	0

The survey shows support for the revisions among the 23 respondents, whereby they expressed that EU or EEA forms part of the strategy for 22 respondents (95.7%) and more likely to seek initial EU access at 15/23 (65.2%) and to keep existing products in the EU, and conducting clinical or performance studies in Europe. These signals are stronger than intentions, based upon the current MDR/IVDR proposed revision, to seek external investment.

The respondent also expect a positive impact on the resolution of notified-body challenges at least to a limited degree and 2/3 to a moderate to large extend, whereby the survey reconfirmed the challenges as reported in previous pulse report present still today.

Alongside requests for further improvements. Affordability is the strongest recurring priority across questions, predictable assessment, useful dialogue and proportionality also matter. A reduced PSUR frequency and PMCF integration, fewer surveillance assessment are most reported to have the highest impact on the administrative burden.

The mixed sample supports a focused stakeholder views of companies interested to commercialize products in Europe and engaged with the evolving regulatory environment. companies. An active involvement of companies with software as medical device and AI inclusion was seen. It does however not establish the position of all micro and small manufacturers or of the European innovation community who still remain disconnected. See Table 11.

Table 11. Five key survey findings (N = 23; software N = 12)

1. Affordability	20/23 report or anticipate high NB costs; 18/23 select fee reductions in Q11.	Cost is a consistent priority, including in the Q11 sensitivity checks.
2. Predictability and dialogue	20/23 highly value predictable processes; 19/23 highly value structured NB dialogue.	Respondents want clearer assessment expectations and useful exchange.
3. Proportionality and safety	18/23 seek more proportionality for lower-risk (software) products; 13 of these 18 also identify a potential risk of excessive simplification.	Requests for reduced burden while securing a recognized safety profile overlap within respondents.
4. Software concerns	9/12 in the questionnaire-defined software or AI group say partly or no; that changes for far enough, none says yes.	A special attention is required for companies with software as medical devices and AI, Hereby also a fast evolving international competitive regulatory environment
5. Investment expectations	Q9: 7/23 expect improvement, 7 no change, 2 worsening, 5 are unsure and 2 report non-applicability.	The survey does not demonstrate a financing or market access effect.

4.2 Priorities and sufficiency of the proposed changes

Cost is prominent in reported or anticipated barriers, the Q11 nominations and the coded single priority in Q12. Fee reductions remain the leading Q11 selection in both sensitivity subsets. This

consistency supports treating affordability as a central discussion topic, while the survey provides no estimate of the amount of savings needed or achievable.

High value and sufficiency are distinct. In Q16, 15/23 expect the NB measures to resolve challenges at least moderately, including 5 to a large extent; none selects completely. This indicates anticipated help with continuing gaps. In Q17, fee reductions are fully or largely adequate for 10/23 overall and 9/17 in the fewer-than-50-employees subgroup. For software, 8/12 expect positive effects, yet 9/12 say the changes go only partly or not far enough; none says yes. These distributions support further discussion without implying that respondents expect no benefit.

The broad value ratings are highest for reduced audit and PSUR frequency and electronic submissions, at 21/23 each. Fee reductions remain the leading Q11 priority under both sensitivity restrictions. In Q23, however, the workload-priority order changes when responses exceeding five options are excluded. The survey supports a cluster of practical priorities rather than a precise, stable hierarchy across every measure.

4.3 Simplification and safeguards

13 of the 18 respondents requesting greater lower-risk proportionality also identify a potential area of excessive simplification. The overlap supports examining how simplification would work and which safeguards respondents require. Concerns cover evidence, vigilance, AI-enabled software and cybersecurity. They do not establish clinical harm, safe evidence thresholds or a basis for product-specific exemptions.

The strongest conditional intention is new device or IVD development in Europe (17/23), but no competitiveness dimension receives a positive majority of all 23 responses.

The realization of an innovation enabling regulatory environment given the revision is implemented is seen as median with reaching six out in a scale from zero to ten . Together, these findings indicate perceived potential and continuing gaps, rather than demonstrated gains in attracting investment, access or competitiveness, for which further measures will be required.

4.4 Recommendations for NoBoCap

The findings can inform further EU and EU4Health activities and focus of community exchange under T5.1. The actions below are recommendations for consideration derived from the current analysis.

Table 12. Suggested discussion priorities

Costs and financing	High total NB cost: 20/23; fee reductions in Q11: 18/23.	Separate assessment fees, evidence generation costs and payment timing; clarify why support is considered insufficient.
Predictability and dialogue	High value for predictable processes: 20/23; structured dialogue: 19/23.	Clarify expected milestones, procedural questions and opportunities for useful exchange, dialogue
Software implementation	9/12 in the software or AI group say partly or no to the question of proposed changes go far enough.	Use examples to examine classification, updates and interaction with AI requirements.
Evidence and safety	18/23 highly value evidence flexibility. Of 18 requesting lower-risk proportionality, 13 also identify a potential risk.	Discuss how proportionality could preserve adequate evidence and oversight.
Lifecycle requirements	Audits, PSUR frequency and electronic submissions each receive 21/23 highvalue ratings.	Clarify which burdens respondents expect to fall and which monitoring activities remain necessary and can be optimized

For evidence planning, separate procedural questions for notified bodies from scientific questions that may require different expertise. Use device-specific examples to examine intended claims, remaining uncertainty, acceptable data and proportionate follow-up. For software, use examples of classification, updates and overlapping requirements rather than broad assumptions about all AI-enabled products. See Table 12.

5 Appendices

Appendices A-J retain the detailed analysis tables and sensitivity comparisons. Appendix K reproduces the survey questionnaire, and Appendix L lists the references. Counts and percentages are descriptive. Where categories are shortened, their grouping is explained beside the relevant table. N/A means not applicable. The original response workbook remains the source for ungrouped answer categories. [1]

Appendix A Respondent profile and awareness

All counts use n = 23. Profile items Q3, Q4 and Q6 allow multiple responses. Categories are shortened for readability; no individual identities are included. See Table 13, Table 14 and Table 15.

Table 13. Q1-Q8 Respondent profile summary (N = 23)

Employee count	1-9: 11; 10-49: 6; 50-249: 1; 250 or more: 3; undisclosed: 2	17/23 report fewer than 50 employees. This is not a verified EU micro or small enterprise classification.
Product profile	AI-enabled devices: 9; device software: 9; other medical devices: 9; IVDs: 7; companion diagnostics: 3	Multiple selections allowed; groups overlap. The sample includes other stakeholder activities.
Development stage	CE marked and on market: 10; CE marked, not launched: 1; NB assessment: 3; preparing submission: 1; development: 4; evidence generation: 1; other: 3	Respondents combine current market experience and anticipated challenges.
Market strategy	EU or EEA: 22; United States: 11; United Kingdom: 8	An EU focus is strong, but several organisations pursue multiple markets.
Proposal familiarity	Detailed review: 6; summaries or selected provisions: 11; aware but not reviewed: 6	Opinion does not imply detailed knowledge of the proposal or of current advice routes.

Table 14. Q1-Q2, Q5 and Q7-Q8 Profile and general assessment (N = 23)

Q1 Country	Belgium	8	34.8%
Q1 Country	Bulgaria	1	4.3%
Q1 Country	Romania	4	17.4%
Q1 Country	Spain	1	4.3%
Q1 Country	Greece	3	13.0%
Q1 Country	Portugal	1	4.3%
Q1 Country	Lithuania	2	8.7%
Q1 Country	Ireland	1	4.3%
Q1 Country	France	1	4.3%
Q1 Country	Italy	1	4.3%
Q2 Employees	10 to 49 employees	6	26.1%
Q2 Employees	1 to 9 employees	11	47.8%
Q2 Employees	Prefer not to say	2	8.7%
Q2 Employees	250 or more employees	3	13.0%
Q2 Employees	50-249 employees	1	4.3%
Q5 Stage	CE marked and on the EU market	10	43.5%
Q5 Stage	Other:	3	13.0%
Q5 Stage	On-going conformity assessment with an NB	3	13.0%

Q5 Stage	Preparing for conformity assessment	1	4.3%
Q5 Stage	Product development	4	17.4%
Q5 Stage	Clinical or performance evidence generation	1	4.3%
Q5 Stage	CE marked but not yet commercially launched	1	4.3%
Q5 Stage	Early research or feasibility	0	0.0%
Q5 Stage	Product launch in the EU has been paused or discontinued	0	0.0%
Q7 Familiarity	Summaries or selected provisions	11	47.8%
Q7 Familiarity	Detailed proposal review	6	26.1%
Q7 Familiarity	Aware but not reviewed	6	26.1%
Q7 Familiarity	I was not aware of the proposal	0	0.0%
Q8 Overall view	Somewhat positive	12	52.2%
Q8 Overall view	Somewhat negative	3	13.0%
Q8 Overall view	Very positive	6	26.1%
Q8 Overall view	Insufficient information	2	8.7%
Q8 Overall view	Very negative	0	0.0%
Q8 Overall view	Neutral or uncertain	0	0.0%

Table 15. Q3-Q4 and Q6 Products, classifications and target markets (N = 23; multiple responses)

Q3 Products	Device incorporating artificial intelligence	9	39.1%
Q3 Products	Software as a Medical Device or medical device software	9	39.1%
Q3 Products	Medical device, excluding standalone software	9	39.1%
Q3 Products	In vitro diagnostic medical device	7	30.4%
Q3 Products	Companion diagnostic	3	13.0%
Q3 Products	Combination product	1	4.3%
Q3 Products	Other responses	5	21.7%
Q4 Class	MDR - Class IIa	11	47.8%
Q4 Class	Not applicable	4	17.4%
Q4 Class	MDR - Class IIb	4	17.4%
Q4 Class	MDR - Class I	4	17.4%
Q4 Class	IVDR - Class C	3	13.0%
Q4 Class	IVDR - Class B	2	8.7%
Q4 Class	IVDR - Class A	2	8.7%
Q4 Class	MDR - Class III	2	8.7%
Q4 Class	Classification is not yet determined	1	4.3%
Q4 Class	MDR - Class Is, Im, or Ir	1	4.3%
Q4 Class	Not sure	1	4.3%
Q4 Classification	IVDR - Class A Sterile	0	0.0%
Q4 Classification	IVDR - Class D	0	0.0%
Q6 Markets	European Union or EEA	22	95.7%
Q6 Markets	United States	11	47.8%
Q6 Markets	United Kingdom	8	34.8%
Q6 Markets	Switzerland	5	21.7%

Q6 Markets	Australia	4	17.4%
Q6 Markets	Canada	3	13.0%
Q6 Markets	No market strategy has yet been determined	1	4.3%
Q6 Markets	Japan	1	4.3%
Q6 Markets	Other responses	3	13.0%

“Other responses” combines all Other categories, including unspecified and stakeholder activities; it is not a separate device category. Class Is, Im or Ir is retained separately from the general Class I option. No respondent selected IVDR Class D in the exported data.

Appendix B Expected effects

Q9. Counts, n = 23 for every item. Improve combines “somewhat” and “significantly improve”; worsen combines the two worsening categories. Uncertain and non-applicable answers remain visible. Percentages use all 23 respondents as the denominator. See Table 16.

Table 16. Q9 Expected effects across 15 areas (N = 23)

Cost of regulatory compliance	15	4	2	2	0	65.2%
Predictability of costs associated with regulatory process	15	4	3	1	0	65.2%
Time required to obtain CE marking	14	4	1	2	2	60.9%
Predictability of conformity-assessment timelines	15	3	3	2	0	65.2%
Clarity of regulatory requirements	14	5	2	2	0	60.9%
Access to an appropriate NB	11	7	0	4	1	47.8%
Administrative and documentation workload	15	3	3	2	0	65.2%
Duplication across regulatory documents and assessments	12	8	1	2	0	52.2%
Ability to introduce product updates or changes	18	3	1	1	0	78.3%
Clinical or performance evidence requirements	14	5	0	4	0	60.9%
Post-market surveillance and follow-up workload	15	5	1	2	0	65.2%
Ability to attract investment	7	7	2	5	2	30.4%
Ability to launch innovative products in Europe	13	6	1	2	1	56.5%
Ability to keep existing products on the EU market	13	5	2	1	2	56.5%
Availability of internal regulatory resources / need for external consultants	12	7	2	1	1	52.2%

The grouped positive percentage is descriptive, not a scale score or a test of whether one dimension is significantly better than another. A response of “not applicable” is not treated as a negative opinion. The primary denominator stays constant so that differences in applicability are not concealed.

Where wording is shortened, “no change” means “no meaningful change”. These are grouped aggregate distributions; they are not weighted averages of an ordinal scale.

Appendix C Value of proposed measures

Q10. Counts, n = 23 per item. High value combines “very valuable” and “essential”; slight or moderate combines “slightly” and “moderately valuable”. The essential-only count is included in high value. See Table 17.

Table 17. Q10 Value of all 21 proposed measures (N = 23)

Reduced NB fees	20	15	0	0	0	3
Fee payment deferral	18	14	2	0	1	2
Public fee lists	15	7	7	0	1	0
Structured NB dialogue	19	11	3	0	1	0
Predictable processes and timelines	20	15	3	0	0	0
Dispute resolution	17	7	5	0	1	0
Proportionate lower- or medium-risk assessment	20	11	2	0	0	1
Well-established technology proportionality	17	11	1	0	1	4
PMCF integrated into clinical evaluation	15	7	2	2	3	1
Less frequent surveillance audits	21	10	2	0	0	0
Greater use of remote audits	18	7	5	0	0	0
Reduced PSUR frequency	21	11	2	0	0	0
Simpler safety and performance summaries	18	9	2	1	1	1
Flexible safety and performance evidence	18	8	4	0	1	0
Greater use of non-clinical evidence	18	10	3	0	1	1
Early expert panel advice	16	10	5	1	0	1
Breakthrough pathways	17	9	3	1	0	2
Orphan or small population pathways	15	9	3	1	0	4
Clearer change control	18	11	3	1	1	0
Common templates	16	9	4	0	2	1
Electronic submissions and digitalisation	21	11	2	0	0	0

High value ranges from 15/23 (65.2%) to 21/23 (91.3%). Essential-only counts help distinguish intensity without assigning arbitrary numeric weights to the response categories. The complete answer categories remain available in the original export.

Appendix D Priorities and selection sensitivity

Q11. Primary counts are all recorded nominations. Six responses exceed the choose-five instruction; six select fewer than five. Subset columns are sensitivity checks, not replacements for the primary sample.

Table 18. Q11 Priority selections and sensitivity subsets (N = 23; n = 17; n = 11)

Reduced fees	18	12	8
Less frequent audits	12	9	6
Change control	11	7	4
Structured dialogue	11	6	6
Reduced NB involvement for certain lower- and mediumrisk devices	10	8	6

EU harmonisation	8	5	4
Fee deferral	7	4	3
Remote audits	7	5	2
Public fee lists	7	3	2
Evidence flexibility	6	3	3
Non-clinical evidence	6	5	5
Predictable timelines	6	2	2
PSUR frequency	5	3	3
Breakthrough pathways	4	1	0
Expert panel advice	3	0	0
Simpler summaries	3	2	1
Orphan pathways	2	1	0
Dispute resolution	1	1	0

READING NOTE: Q11 allows multiple responses. Six respondents selected more than five measures and six fewer than five; all 23 respondents are retained in the primary analysis. At most five selections: n = 17; exactly five: n = 11. Subsets overlap and are not independent groups. See Table 18 and Table 19.

Table 19. Q12 Coded single most important measure (N = 23; 22 substantive answers)

Reduced notified-body fees	7
Lower cost without a specified instrument	1
Lower-risk proportionality or reduced notified-body involvement	3
Structured dialogue	4
Predictable processes and timelines	2
Expert-panel advice	1
Change control	1
EU harmonisation	1
Orphan pathway	1
Reduced PSUR frequency	1
Non-substantive dash	1

There are 22 substantive Q12 answers and one dash. Two priorities, one fee reduction and one PSUR frequency, were not among the corresponding Q11 selections. Coding retains Q12 as written; text from other questions is not substituted. Reduced NB fees and unspecified lower cost remain separate categories.

Q13 has 17 nonblank explanations. The question-specific thematic analysis appears in Section 3.3.

Appendix E Additional changes and notified-body barriers

Table 20. Q14 Additional changes (N = 23; multiple responses)

Further proportionality for lower-risk products	18	78.3%
Documentation integration and common templates (one compound option)	16	69.6%
Clearer criteria for PMCF requirements or reduction	13	56.5%
Once-only submission principle	12	52.2%
Further proportionality for well-established technology devices under the MDR	10	43.5%
No additional changes are needed	1	4.3%
Not enough information to assess	1	4.3%
Other responses	4	17.4%

Percentages use all 23 respondents. Multiple selections were allowed. The documentation/templates item is one compound option. The two erroneous PMPF export entries are excluded because PMPF was not a questionnaire option. All 23 respondents retain at least one questionnaire-defined choice. One response includes both exclusive options alongside a substantive choice; its questionnaire-defined choices are retained as recorded. See Table 20 and Table 21.

Table 21. Q15 Current or anticipated notified-body challenges (N = 23; multiple responses)

High total cost	20	87.0%
Limited opportunity for pre-submission dialogue	13	56.5%
Long waiting periods before application or submission	13	56.5%
Unpredictable fees	13	56.5%
Unclear or changing timelines	10	43.5%
Different interpretations between notified bodies	6	26.1%
Insufficient expertise in our technology	4	17.4%
Difficulties associated with changing NB	3	13.0%
Not applicable	2	8.7%
Difficulty identifying an NB with the appropriate scope	2	8.7%
Notified bodies not accepting new clients	1	4.3%
Other responses	3	13.0%
No significant notified-body challenges	0	0.0%

One respondent selected “not applicable” alongside substantive challenges. Q15 does not separate experienced barriers from anticipated barriers.

Appendix F Adequacy and financing

Table 22. Q16 Expected resolution of challenges (N = 23)

Not at all	0	0.0%
To a limited extent	5	21.7%
To a moderate extent	10	43.5%
To a large extent	5	21.7%
Completely	0	0.0%
Not sure	3	13.0%

Table 23. Q17 Adequacy of fee reductions (N = 23)

Partly adequate	6	26.1%
Largely adequate	4	17.4%
Not applicable because our products do not require notified-body involvement	2	8.7%
Fully adequate	6	26.1%
The proposal should use a different fee-support mechanism	2	8.7%
Inadequate	2	8.7%
Not sure	1	4.3%

Table 24. Q18 Additional financing measures (N = 23; multiple responses)

A maximum or capped fee for defined conformity-assessment activities	12	52.2%
EU or national vouchers for conformity-assessment costs	12	52.2%
Grants for clinical or performance evidence generation	12	52.2%
Reduced fees for early scientific or regulatory advice	11	47.8%
Reduced fees for follow-up certification and surveillance activities	8	34.8%
Public and standardised fee structures	7	30.4%
Payment linked to defined milestones or deliverables	6	26.1%
Payment deferred until certification is completed	5	21.7%
Greater percentage fee reductions	4	17.4%
Instalment-based payment	3	13.0%
Other responses	1	4.3%
No additional mechanism is needed	0	0.0%

Q18 describes requested support. It does not establish that any named voucher, grant or fee cap is currently offered to these respondents. See Table 22, Table 23 and Table 24.

Appendix G Software module

Eligible: the 12 respondents selecting software or AI devices in Q3; all answer Q19-Q22. All recorded: 15 respondents in Q19-Q21 and 14 in Q22. See Table 25 and Table 26.

Table 25. Q19-Q21 Eligible and all recorded answers (n = 12; n = 15)

Q19	No meaningful effect	1	2
Q19	Moderate positive effect	6	6
Q19	Significant positive effect	1	2
Q19	Negative effect	1	1
Q19	Not applicable to our software	1	1
Q19	Limited positive effect	1	2
Q19	Not sure	1	1
Q20	No	5	5
Q20	Partly	4	6
Q20	Not sure	3	4
Q20	Yes	0	0
Q21	Other interpretation concern	1	1
Q21	The main challenge is not classification, but unclear or inconsistent interpretation	4	4
Q21	The proposed software-classification changes achieve an appropriate riskbased balance	1	2
Q21	Additional lower-risk software categories should qualify as Class I	3	3
Q21	Not sure	2	4
Q21	The main challenge is not classification, but the conformity-assessment process	1	1
Q21	Some proposed lower classifications may not provide sufficient patient protection	0	0
Q21	The proposal does not adequately address software that is updated frequently	0	0
Q21	The proposal does not adequately address software incorporating artificial intelligence	0	0

Both groups have zero Yes responses to Q20. Table 25 compares the eligible and all-recorded groups; Figure 21 in Section 3.5 presents the eligible respondents. The all-recorded group includes the eligible respondents and is not independent.

Table 26. Q22 Additional software improvements (eligible n = 12; all recorded n = 14)

More software categories eligible for Class I	9	10
Clearer classification criteria and examples	7	9
Better alignment between MDR or IVDR and the EU AI Act	8	9
Clearer treatment of software updates	7	8
Consistent classification decisions across Member States	6	6
Clearer criteria for determining whether a change is significant	5	5
Greater acceptance of simulation, in silico or other non-clinical evidence	4	5
Greater acceptance of real-world evidence	4	5
Software-specific conformity-assessment timelines	3	4
Early advice on classification and evidence requirements	3	3
Faster access to notified bodies with software expertise	2	2
Predetermined change-control plans	2	2
Other	0	0

Positive effects in Q19: 8/12 eligible versus 10/15 overall. Partly/no in Q20: 9/12 versus 11/15. The broad conclusion persists. Q22 includes 12 eligible and 2 additional answers; 9 records are blank. Missing answers are not negative opinions.

Appendix H Workload and risks

Table 27. Q23 Measures expected to reduce workload (N = 23; multiple responses)

Reduced frequency of Periodic Safety Update Reports	12	52.2%
Integration of post-market clinical follow-up findings into the clinical evaluation report	10	43.5%
Fewer routine surveillance assessments	10	43.5%
Greater reliance on non-clinical evidence	10	43.5%
Simplified clinical-investigation or performance-study requirements	9	39.1%
Reduced requirements for summaries of safety and clinical or performance information	9	39.1%
Greater reliance on existing or equivalent-device data	9	39.1%
Remote audits	8	34.8%
Reduced technical-documentation sampling	7	30.4%
Electronic submission of information and documents	7	30.4%
Clearer change-control requirements	6	26.1%
None would materially reduce our workload	2	8.7%
Other	0	0.0%

Q23 permits up to five options. Six responses exceed this limit, four select exactly five and thirteen select fewer. All 23 are retained for the primary distribution. The table below compares all respondents with the 17 meeting the limit. See Table 27, Table 28 and Table 29.

Table 28. Q23 Sensitivity to the five-option limit (N = 23; n = 17)

Reduced frequency of Periodic Safety Update Reports	12	6
Integration of post-market clinical follow-up findings into the clinical evaluation report	10	7
Fewer routine surveillance assessments	10	6
Greater reliance on non-clinical evidence	10	4
Simplified clinical-investigation or performance-study requirements	9	6
Reduced requirements for summaries of safety and clinical or performance information	9	4
Greater reliance on existing or equivalent-device data	9	4
Remote audits	8	4
Reduced technical-documentation sampling	7	2
Electronic submission of information and documents	7	4
Clearer change-control requirements	6	4
None would materially reduce our workload	2	2
Other	0	0

Table 29. Q24 Potential excessive simplification or risk (N = 23; multiple responses)

Clinical or performance evidence, particularly for novel technologies	8	34.8%
Vigilance reporting	7	30.4%
Oversight of AI-enabled devices and software that changes or is updated frequently	6	26.1%
Cybersecurity, software maintenance and vulnerability management	5	21.7%
I do not currently see a significant risk	5	21.7%
Device classification	4	17.4%
Reduced frequency of audits	4	17.4%
Not sure	3	13.0%
Remote audits	3	13.0%
Reduced notified-body involvement	3	13.0%
Post-market surveillance	3	13.0%
Oversight of changes to certified devices or quality-management systems	2	8.7%
Breakthrough or orphan-device pathways	2	8.7%
Other	0	0.0%

Fifteen respondents identify at least one substantive risk; five see no significant risk and three are unsure. Specific risks overlap. Figure 26 in Section 3.6 illustrates the risk selections. Q25 contains eight nonblank explanations, discussed in Section 3.6 without respondent quotations.

Appendix I Company intentions and competitiveness

Counts, n = 23 per item. In Q26, more and less combine the two respective likelihood categories. In Q27, more and less combine the respective competitiveness categories. See Table 30 and Table 31.

Table 30. Q26 Conditional intentions (N = 23)

Develop a new device or IVD in Europe	17	3	1	1	1
Seek initial market access in the EU	15	5	0	1	2
Keep existing products in the EU	14	4	1	1	3
Launch new products in the EU first	14	6	1	1	1
Conduct clinical or performance studies in Europe	14	5	1	2	1
Invest in regulatory staff or expertise	7	10	3	2	1
Seek external investment	10	7	1	3	2
Partner with European hospitals or research organisations	12	6	1	2	2
Prioritise US or other non-EU markets	6	7	7	2	1

Table 31. Q27 Expected EU competitiveness (N = 23)

Cost	8	7	3	5
Speed	7	6	6	4
Clarity	9	4	6	4
Predictability	6	8	5	4
Access to advice	6	7	5	5
Suitability for innovative products	9	5	6	3
Suitability for micro and small companies	10	4	5	4

Appendix J Remaining gaps and permissions

Table 32. Q28 Innovation environment scores (N = 23)

Respondents	1	1	1	1	3	1	7	3	5	0	0

The questionnaire scale is 0 (does not create an innovation-enabling environment at all) to 10 (fully creates one). Median: 6/10; supplementary mean: 5.48/10; observed range: 0-8. No respondent selects 9 or 10. The rating expresses opinion, not percentage completion of reform. See Table 32 and Table 33.

Q29 and Q30 each contain 13 nonblank entries. The question-specific synthesis appears in Section 3.8.

Table 33. Q12-Q13 and Q25-Q36 Open answers and permissions (N = 23)

Q12 single priority	23 nonblank; 22 substantive; one dash
Q13 reasons for the priority	17 nonblank
Q25 explanations of concerns	8 nonblank
Q29 remaining challenges	13 nonblank
Q30 further recommendations	13 nonblank
Q31 processing consent	23 consent
Q32 quotation permission	8 aggregate use only; 14 anonymous quotation; 1 attributed quotation
Q33 follow-up contact	11 yes; 12 no
Q34-Q36 identifiers	Names, companies and emails excluded from published results

No respondent identifiers or verbatim comments are published.

Appendix K Survey questionnaire

The first draft records project confirmation on 16 October 2026 that the full questionnaire was used for all 23 respondents. The supplied form is reproduced below across separate pages for readability, with matrix headers repeated. Question wording and visible response options are unchanged.



The European Commission has proposed revisions to the Medical Devices Regulation and In Vitro Diagnostic Medical Devices Regulation. The proposal aims to simplify requirements, reduce administrative burden, improve the predictability and cost-efficiency of conformity assessment, and support innovation while maintaining patient safety. [eur-lex.europa.eu] The aggregated results will be used to develop a report on the proposed MDR/IVDR revisions and further leveraged in conferences and events where this input is pertinent.

NoBoCap is gathering the views of micro and small medical device and IVD companies to understand:

- which proposed changes would make the greatest practical difference;
- whether the changes go far enough;
- what concerns or barriers remain; and
- whether additional measures are needed to create an innovation-enabling regulatory environment in Europe.

Estimated completion: approximately 12 to 15 minutes, depending on the answers provided.

About your company

1. Country of headquarters*

Required field

Appendix K Survey questionnaire continued

2. How many people does your company employ?*

- ○ 1 to 9 employees
- ○ 10 to 49 employees
- ○ 50-249 employees
- ○ 250 or more employees
- ○ Prefer not to say

3. Which products are you developing or placing on the market?*

- ☐ Medical device, excluding standalone software
- ☐ Software as a Medical Device or medical device software
- ☐ Device incorporating artificial intelligence
- ☐ In vitro diagnostic medical device
- ☐ Companion diagnostic
- ☐ Combination product
- ☐ Other

4. What is the current or expected EU regulatory classification of your product(s)?*

- ☐ MDR - Class I
- ☐ MDR - Class Is, Im, or Ir
- ☐ MDR - Class IIa
- ☐ MDR - Class IIb
- ☐ MDR - Class III
- ☐ IVDR - Class A
- ☐ IVDR - Class A Sterile
- ☐ IVDR - Class B
- ☐ IVDR - Class C
- ☐ IVDR - Class D
- ☐ Classification is not yet determined
- ☐ Not sure
- ☐ Not applicable

Appendix K Survey questionnaire continued

5. What is the current regulatory stage of your most advanced product? *

- ○ Early research or feasibility
- ○ Product development
- ○ Clinical or performance evidence generation
- ○ Preparing for conformity assessment
- ○ On-going conformity assessment with a notified body
- ○ CE marked but not yet commercially launched
- ○ CE marked and on the EU market
- ○ Product launch in the EU has been paused or discontinued
- ○ Other

6. Which markets are currently part of your commercialization strategy?

- ☐ European Union or EEA
- ☐ United Kingdom
- ☐ Switzerland
- ☐ United States
- ☐ Canada
- ☐ Japan
- ☐ Australia
- ☐ Other markets
- ☐ No market strategy has yet been determined

Awareness & General Assessment

7. Before receiving this survey, how familiar were you with the proposed MDR and IVDR revisions? *

- ○ I had reviewed the legislative proposal in detail
- ○ I had reviewed summaries or selected provisions
- ○ I was aware of the proposal but had not reviewed it
- ○ I was not aware of the proposal

You can review the revision text here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC1023

Appendix K Survey questionnaire continued

8. Based on what you know today, what is your overall view of the proposed revisions? *

- ○ Very negative
- ○ Somewhat negative
- ○ Neutral or uncertain
- ○ Somewhat positive
- ○ Very positive
- ○ I do not yet have enough information to assess the proposal

9. To what extent do you expect the proposed revisions to improve the EU regulatory environment for your company? *

	Significantly worsen	Somewhat worsen	No meaningful change	Somewhat improve	Significantly improve	Not applicable	Not sure
Cost of regulatory compliance	○	○	○	○	○	○	○
Predictability of costs associated with regulatory process	○	○	○	○	○	○	○
Time required to obtain CE marking	○	○	○	○	○	○	○
Predictability of conformity-assessment timelines	○	○	○	○	○	○	○
Clarity of regulatory requirements	○	○	○	○	○	○	○
Access to an appropriate notified body	○	○	○	○	○	○	○
Administrative and documentation workload	○	○	○	○	○	○	○

Appendix K Survey questionnaire continued

	Significantly worsen	Somewhat worsen	No meaningful change	Somewhat improve	Significantly improve	Not applicable	Not sure
Duplication across regulatory documents and assessments	○	○	○	○	○	○	○
Ability to introduce product updates or changes	○	○	○	○	○	○	○
Clinical or performance evidence requirements	○	○	○	○	○	○	○
Post-market surveillance and follow-up workload	○	○	○	○	○	○	○
Ability to attract investment	○	○	○	○	○	○	○
Ability to launch innovative products in Europe	○	○	○	○	○	○	○
Ability to keep existing products on the EU market	○	○	○	○	○	○	○
Availability of internal regulatory resources / need for external consultants	○	○	○	○	○	○	○

Appendix K Survey questionnaire continued

Assessment of the proposed changes

10. How valuable would each of the following proposed changes be for your company, if adopted and implemented as intended?*

	Not valuable	Slightly valuable	Moderately valuable	Very valuable	Essential	Not applicable	Not sure
Reduced notified-body fees for micro and small manufacturers	○	○	○	○	○	○	○
The possibility for micro and small manufacturers to defer notified-body fee payments until the relevant conformity-assessment activity is completed	○	○	○	○	○	○	○
Publicly available notified-body fee lists	○	○	○	○	○	○	○
More structured dialogue with notified bodies before and after submission	○	○	○	○	○	○	○
More predictable conformity-assessment processes and timelines	○	○	○	○	○	○	○

Appendix K Survey questionnaire continued

	Not valuable	Slightly valuable	Moderately valuable	Very valuable	Essential	Not applicable	Not sure
A dispute-resolution mechanism for disagreements between manufacturers and notified bodies	○	○	○	○	○	○	○
More proportionate documentation and notified-body assessment requirements for specified lower- and medium-risk devices and IVDs	○	○	○	○	○	○	○
More proportionate clinical-evidence, documentation and conformity-assessment requirements for well-established technology devices under the MDR	○	○	○	○	○	○	○
Integration of PMCF findings into the updated clinical evaluation report instead of requiring a separate PMCF evaluation report	○	○	○	○	○	○	○

Appendix K Survey questionnaire continued

	Not valuable	Slightly valuable	Moderately valuable	Very valuable	Essential	Not applicable	Not sure
Less frequent surveillance audits where there are no safety concerns	○	○	○	○	○	○	○
Greater use of remote audits	○	○	○	○	○	○	○
Reduced frequency of Periodic Safety Update Report updates, depending on the device or IVD risk class	○	○	○	○	○	○	○
Reduced scope and simplified requirements for summaries of safety and clinical performance or summaries of safety and performance	○	○	○	○	○	○	○
Greater flexibility in the evidence used to demonstrate safety and performance	○	○	○	○	○	○	○
Greater use of non-clinical evidence, including in silico testing and computational modelling	○	○	○	○	○	○	○

Appendix K Survey questionnaire continued

	Not valuable	Slightly valuable	Moderately valuable	Very valuable	Essential	Not applicable	Not sure
Early scientific or regulatory advice from expert panels	○	○	○	○	○	○	○
Adapted pathways for breakthrough devices	○	○	○	○	○	○	○
Adapted pathways for orphan devices or devices intended for small patient populations	○	○	○	○	○	○	○
Clearer rules for implementing product or quality-management-system changes after certification	○	○	○	○	○	○	○
Development and consistent use of common templates and technical guidance across notified bodies	○	○	○	○	○	○	○
The possibility to prepare and submit technical documentation, reports and other required documents digitally, including in structured formats	○	○	○	○	○	○	○

Appendix K Survey questionnaire continued

11. Which five proposed measures would have the greatest positive impact on your company? *

- [ ] Reduced notified-body fees for micro and small manufacturers
- [ ] The possibility for micro and small manufacturers to defer notified-body fee payments until the relevant conformity-assessment activity is completed
- [ ] Publicly available notified-body fee lists
- [ ] More structured dialogue with notified bodies before and after submission
- [ ] More predictable conformity-assessment processes and timelines
- [ ] A dispute-resolution mechanism for disagreements between manufacturers and notified bodies
- [ ] Reduced notified-body involvement for certain lower- and medium-risk devices
- [ ] Less frequent surveillance audits where there are no safety concerns
- [ ] Greater use of remote audits
- [ ] Reduced frequency of Periodic Safety Update Reports
- [ ] Simpler requirements for summaries of safety and clinical or performance information
- [ ] Greater flexibility in the evidence used to demonstrate safety and performance
- [ ] Greater use of non-clinical evidence, including in silico testing and computational modelling
- [ ] Early scientific or regulatory advice from expert panels
- [ ] Adapted pathways for breakthrough devices
- [ ] Adapted pathways for orphan devices or devices intended for small patient populations
- [ ] Clearer rules for implementing product or quality-management-system changes after certification
- [ ] Greater harmonisation of regulatory interpretation across EU Member States

12. Of the measures you selected, which single measure is most important? *

13. Why is this measure particularly important to your company?

Please describe the expected effect where possible, for example on cost, time to market, internal workload, evidence generation, investment, notified-body access, product availability or commercialisation decisions.

Appendix K Survey questionnaire continued

14. Which additional changes would still be needed for the revised MDR and IVDR framework to work effectively for your company?

- ☐ A once-only submission principle, so that information already provided to EUDAMED, a notified body or a competent authority does not need to be resubmitted unnecessarily
- ☐ Clearer and harmonised criteria for when PMCF activities are required, may be reduced or are not necessary
- ☐ Further integration of clinical/performance evaluation and post-market documentation Consistent use of common templates by notified bodies
- ☐ Further proportionality for lower-risk products
- ☐ Further proportionality for well-established technology devices under the MDR
- ☐ No additional changes are needed
- ☐ Not enough information to assess
- ☐ Other

The previous questions concerned changes included in the European Commission's proposal. The following question asks whether any further changes may still be needed.

Notified-body access and costs

15. What notified-body challenges does your company currently experience or anticipate?*

- ☐ Difficulty identifying a notified body with the appropriate scope
- ☐ Notified bodies not accepting new clients
- ☐ Long waiting periods before application or submission
- ☐ Unclear or changing timelines
- ☐ Unpredictable fees
- ☐ High total cost
- ☐ Different interpretations between notified bodies
- ☐ Limited opportunity for pre-submission dialogue
- ☐ Insufficient expertise in our technology
- ☐ Difficulties associated with changing notified body
- ☐ No significant notified-body challenges
- ☐ Not applicable
- ☐ Other

Appendix K Survey questionnaire continued

16. To what extent would the proposed notified-body measures resolve the challenges you selected?

- ○ Not at all
- ○ To a limited extent
- ○ To a moderate extent
- ○ To a large extent
- ○ Completely
- ○ Not sure

17. How adequate are the proposed notified-body fee reductions for micro and small companies?

- ○ Fully adequate
- ○ Largely adequate
- ○ Partly adequate
- ○ Inadequate
- ○ The proposal should use a different fee-support mechanism
- ○ Not applicable because our products do not require notified-body involvement
- ○ Not sure

18. What additional fee or financing measures would be most helpful?

- ☐ Greater percentage fee reductions
- ☐ A maximum or capped fee for defined conformity-assessment activities
- ☐ Public and standardised fee structures
- ☐ Instalment-based payment
- ☐ Payment linked to defined milestones or deliverables
- ☐ Payment deferred until certification is completed
- ☐ EU or national vouchers for conformity-assessment costs
- ☐ Grants for clinical or performance evidence generation
- ☐ Reduced fees for early scientific or regulatory advice
- ☐ Reduced fees for follow-up certification and surveillance activities
- ☐ No additional mechanism is needed
- ☐ Other

Appendix K Survey questionnaire continued

Software-specific questions

This section is only for people who replied "Software as a Medical Device," "medical device software," or "device incorporating artificial intelligence" to question #3.

The proposal adapts certain MDR classification rules with the intention of moving some software into lower risk classes. This directly reflects the software concern raised in the company response in the email chain. [eur-lex.europa.eu]

19. How do you expect the proposed changes to the classification of medical device software to affect your company?

- ○ Significant positive effect
- ○ Moderate positive effect
- ○ Limited positive effect
- ○ No meaningful effect
- ○ Negative effect
- ○ Not applicable to our software
- ○ Not sure

20. Do the proposed software-classification changes go far enough?

- ○ Yes
- ○ Partly
- ○ No
- ○ Not sure

Appendix K Survey questionnaire continued

21. Which statement is closest to your view?

- ○ The proposed software-classification changes achieve an appropriate risk-based balance
- ○ Additional lower-risk software categories should qualify as Class I
- ○ Some proposed lower classifications may not provide sufficient patient protection
- ○ The main challenge is not classification, but unclear or inconsistent interpretation
- ○ The main challenge is not classification, but the conformity-assessment process
- ○ The proposal does not adequately address software that is updated frequently
- ○ The proposal does not adequately address software incorporating artificial intelligence
- ○ Not sure
- ○ Other

22. Which additional improvements are needed for medical device software?

- ☐ Clearer classification criteria and examples
- ☐ More software categories eligible for Class I
- ☐ Consistent classification decisions across Member States
- ☐ Clearer treatment of software updates
- ☐ Clearer criteria for determining whether a change is significant
- ☐ Predetermined change-control plans
- ☐ Better alignment between MDR or IVDR and the EU AI Act
- ☐ Greater acceptance of real-world evidence
- ☐ Greater acceptance of simulation, in silico or other non-clinical evidence
- ☐ Faster access to notified bodies with software expertise
- ☐ Software-specific conformity-assessment timelines
- ☐ Early advice on classification and evidence requirements
- ☐ Other

Appendix K Survey questionnaire continued

Administrative burden, evidence and post-market obligations

23. Which proposed simplifications would reduce the greatest amount of work for your company?*

- [ ] Reduced frequency of Periodic Safety Update Reports
- [ ] Integration of post-market clinical follow-up findings into the clinical evaluation report
- [ ] Reduced requirements for summaries of safety and clinical or performance information
- [ ] Reduced technical-documentation sampling
- [ ] Fewer routine surveillance assessments
- [ ] Remote audits
- [ ] Clearer change-control requirements
- [ ] Electronic submission of information and documents
- [ ] Greater reliance on existing or equivalent-device data
- [ ] Greater reliance on non-clinical evidence
- [ ] Simplified clinical-investigation or performance-study requirements
- [ ] None would materially reduce our workload
- [ ] Other

Select up to 5 options.

Appendix K Survey questionnaire continued

24. Where do you believe the proposal may simplify requirements too much or create a potential risk?

- [ ] Device classification
- [ ] Clinical or performance evidence, particularly for novel technologies
- [ ] Post-market surveillance
- [ ] Vigilance reporting
- [ ] Reduced notified-body involvement
- [ ] Reduced frequency of audits
- [ ] Remote audits
- [ ] Breakthrough or orphan-device pathways
- [ ] Cybersecurity, software maintenance and vulnerability management
- [ ] Oversight of changes to certified devices or quality-management systems
- [ ] Oversight of AI-enabled devices and software that changes or is updated frequently
- [ ] I do not currently see a significant risk
- [ ] Not sure
- [ ] Other

25. Please explain any concern you selected.

Appendix K Survey questionnaire continued

Competitiveness and company decisions

26. If the proposed revisions were adopted as currently drafted, how would they affect the likelihood that your company would undertake the following actions?*

	Much less likely	Somewhat less likely	No effect	Somewhat more likely	Much more likely	Not applicable	Not sure
Develop a new medical device or IVD in Europe	○	○	○	○	○	○	○
Seek initial market access in the EU	○	○	○	○	○	○	○
Keep an existing product on the EU market	○	○	○	○	○	○	○
Launch in the EU before launching in another market	○	○	○	○	○	○	○
Conduct clinical or performance studies in Europe	○	○	○	○	○	○	○
Invest in additional regulatory staff or expertise	○	○	○	○	○	○	○
Seek external investment	○	○	○	○	○	○	○

Appendix K Survey questionnaire continued

	Much less likely	Somewhat less likely	No effect	Somewhat more likely	Much more likely	Not applicable	Not sure
Partner with a European hospital or research organisation	○	○	○	○	○	○	○
Prioritize the United States or another non-EU market	○	○	○	○	○	○	○

27. In comparison with other markets relevant to your company, how competitive would the revised EU pathway be?

	Much less competitive	Somewhat less competitive	Comparable	Somewhat more competitive	Much more competitive	We do not have sufficient experience to compare
Regulatory cost	○	○	○	○	○	○
Speed to market	○	○	○	○	○	○
Clarity of requirements	○	○	○	○	○	○
Predictability of assessment	○	○	○	○	○	○
Access to regulatory advice	○	○	○	○	○	○
Suitability for innovative products	○	○	○	○	○	○
Suitability for micro and small companies	○	○	○	○	○	○

Appendix K Survey questionnaire continued

Remaining gaps and final priorities

28. Overall, how far do the proposed revisions go towards creating an innovation enabling regulatory environment for micro and small companies? *

- ○ 0 - Does not create an innovation-enabling environment at all
- ○ 1
- ○ 2
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9
- ○ 10 - Fully creates an innovation-enabling environment

29. What important challenge for micro and small companies is not adequately addressed in the proposal?

30. If you could recommend one further change to EU policymakers, what would it be?

Appendix K Survey questionnaire continued

Data Protection Notice

31. Data protection consent*

☐ I have read the Data Protection Notice and consent to the processing of my personal data for the purposes described in the Notice.

32. May NoBoCap quote your written comments?*

○ Yes, my comments may be quoted and my company may be identified
○ Yes, my comments may be quoted without identifying me or my company
○ No, please use my response only in aggregated analysis

33. May NoBoCap contact you regarding your response?

○ Yes
○ No

34. Name

First Name | Last Name

35. Company name

36. Email

Save and Resume Later

Submit Form

Powered by Formstack Create your own form ›

Appendix L References

[1] Survey sources: FeedbackontheproposedMDRIVDRrevisions_Data_all_23(1).xlsx (23 submissions); Survey-on-the-proposed-MDR-IVDR-revisions(1).pdf (full questionnaire reproduced in Appendix K). Project documents.

[2] NoBoCap. Grant Agreement No 101101269, Annex 1, Description of the Action, Part A, pp. 13-14, WP5 T5.1 and additional EU4HS activities during the extension. Supplied file: Annex 1 - Description of the action (part A) (1) (1).pdf. Project document.

[3] European Commission. COM(2025) 1023 final, 16 December 2025. Proposal amending the MDR and IVDR and related legislation. Fee provisions: Article 1(40), proposed MDR Article 50(2). Available at: https://health.ec.europa.eu/document/download/25e7ea7c-cab3-40cf-86d9-d11f5e7744d8_en?filename=md_com_2025-1023_act_en.pdf

[4] European Commission. Annexes 1 to 2 to COM(2025) 1023 final, 16 December 2025. Proposed changes to the MDR and IVDR annexes. Available at: https://health.ec.europa.eu/document/download/dc018bdb-8c09-4a2e-8763-043b594703f7_en?filename=md_com_2025-1023_annex_en.pdf

[5] European Parliament. Legislative Observatory, procedure 2025/0404(COD): status and parliamentary documents. Available at: https://oeil.europarl.europa.eu/oeil/en/procedure-file?reference=2025/0404(COD)

[6] European Commission. Questions and answers on simpler and more effective rules for medical devices, 16 December 2025. Available at: https://ec.europa.eu/commission/presscorner/api/files/document/print/en/qanda_25_3078/QANDA_25_3078_EN.pdf

[7] European Commission. Medical devices regulations overview: current framework and the targeted revision proposal. Available at: https://health.ec.europa.eu/medical-devices-new-regulations/overview_en

[8] Medical Device Coordination Group. MDCG 2022-2: Guidance on general principles of clinical evidence for In Vitro Diagnostic medical devices (IVDs), January 2022. Available at: https://health.ec.europa.eu/document/download/f373538f-939c-472f-9536-436b6ddac085_en?filename=mdcg_2022-2_en.pdf

[9] Medical Device Coordination Group. MDCG 2020-1: Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software, March 2020. Available at: https://health.ec.europa.eu/document/download/19d9e24f-2808-4e00-bfeb-75892047407d_en?filename=md_mdcg_2020_1_guidance_clinic_eva_md_software_en.pdf

[10] AAPOR. Disclosure Standards. Section III of the Code of Professional Ethics & Practice (April 2021). Available at: https://aapor.org/standards-and-ethics/disclosure-standards/

[11] Eysenbach, G. Improving the Quality of Web Surveys: The Checklist for Reporting Results of Internet E-Surveys (CHERRIES). Journal of Medical Internet Research, 2004, 6(3): e34. Available at: https://www.jmir.org/2004/3/e34/

[12] European Commission. Better Regulation Toolbox, December 2025, Chapter 7: Stakeholder consultation, in particular Tool 54, Analysing data and informing policymaking. Available at: https://commission.europa.eu/document/download/7b10fdd6-a992-4c65-b23d-185d45a5589f_en?filename=BR+Toolbox+-+Dec+2025+-+Chapter+7.pdf

[13] European Commission. SME definition: staff, financial thresholds and treatment of enterprises that are part of a group. Available at: https://single-market-economy.ec.europa.eu/smes/sme-fundamentals/sme-definition_en