International

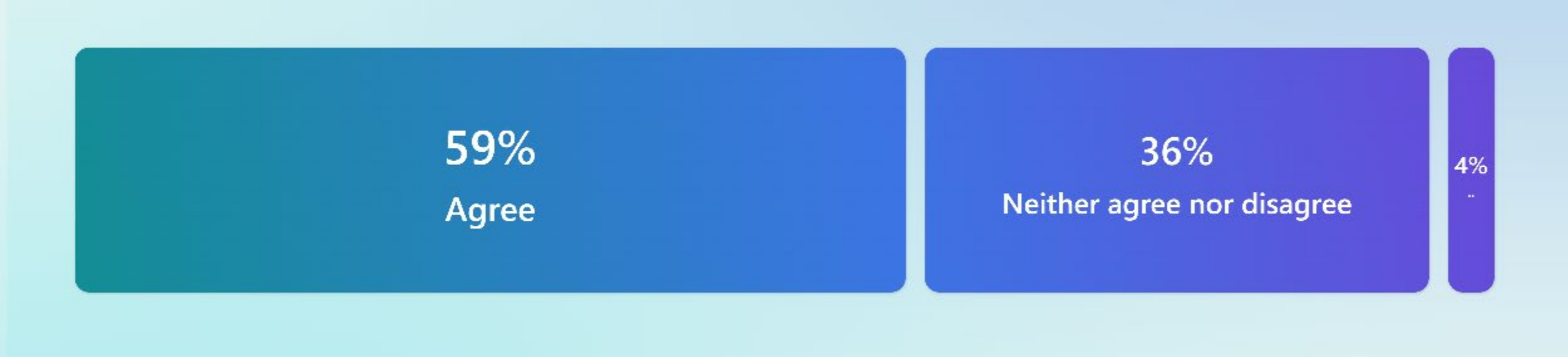
MDCG meeting – Agenda point 6
17-18 December 2024

European Commission
Directorate-General for Health and Food Safety (DG SANTE)
Unit D.3 – Medical Devices

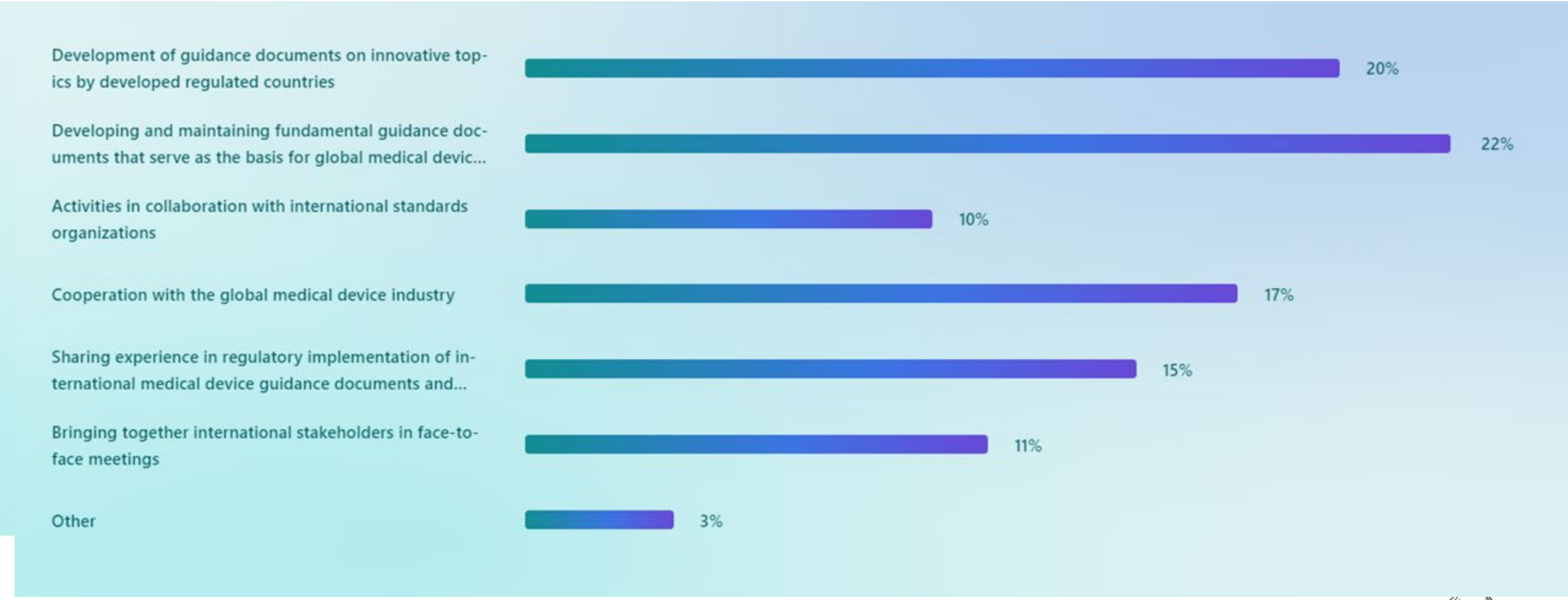
IMDRF Strategic plan survey

European Commission

IMDRF Q1. Do you think IMDRF has achieved the objectives and scope of activities listed in the TOR?



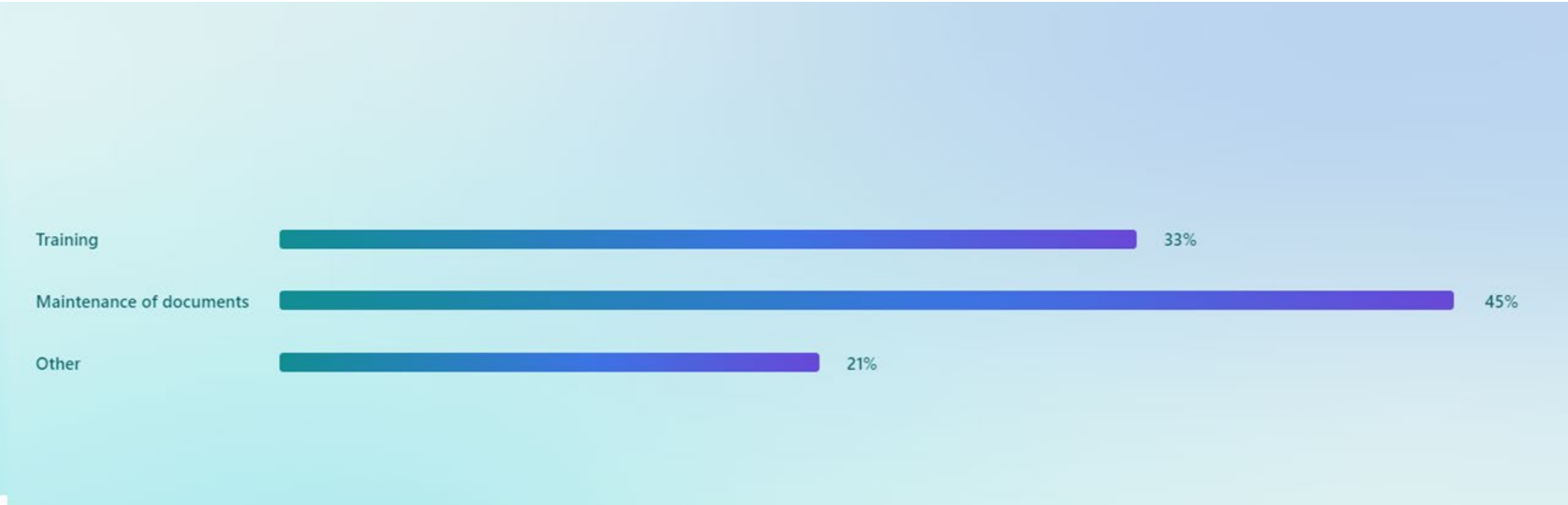
IMDRF Q2. As a core member of IMDRF, what do you think is the strength of IMDRF? Please select all that you think apply.



Q3. Similarly, what do you think are the current challenges for IMDRF? Please select all that you think apply.

IMDRF Q4. Please suggest any initiatives for IMDRF activities that you would like to see established by 2031 when the Strategic Plan (2026-2030) is completed.

IMDRF Q5. What elements are considered necessary for IMDRF to maintain leadership in a world of international medical device regulatory harmonization?



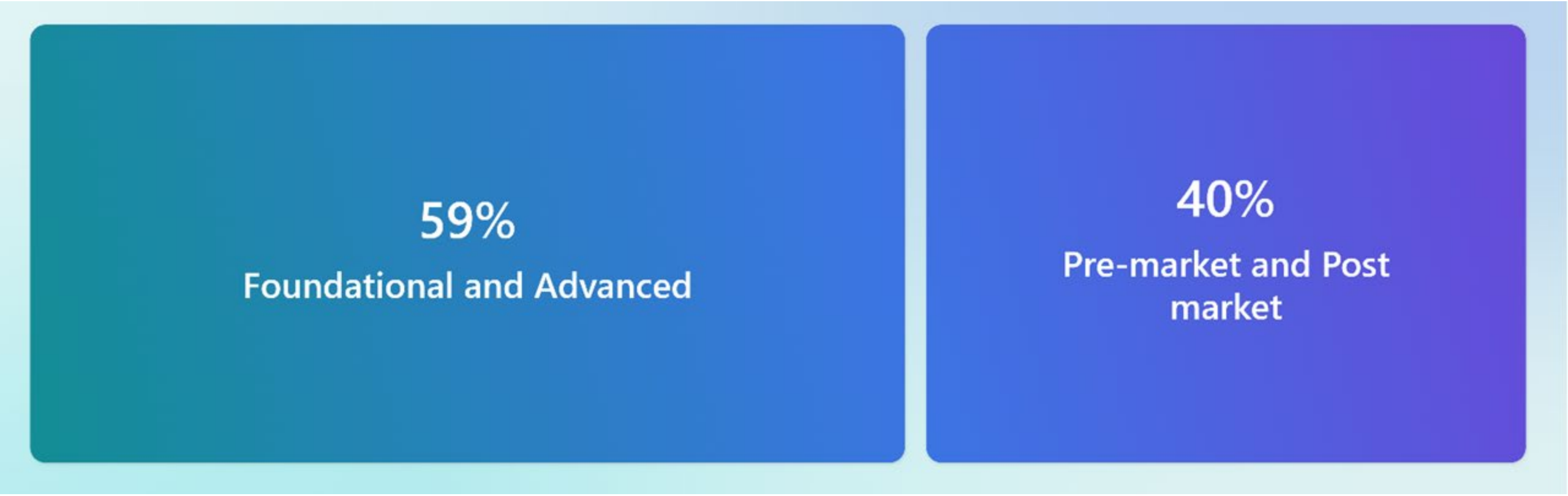
IMDRF Q6. If there are any foundational IMDRF/GHTF documents that you think IMDRF should especially continue to update, please list them in detail.

- Classification
- MD Clinical Evidence
- PMS
- IVD Clinical Evidence
- UDI

IMDRF Q7. If there are any innovative topics that you think IMDRF should tackle in the future as a group of highly regulated countries or organizations, please list them in detail.

- AI Clinical Evaluation
- Breakthrough technologies
- Electronic submissions
- IVD clinical evidence
- Predetermined change control plans

IMDRF Q8. What approach do you think is desirable to classify priority topics we are going to identify in the Strategic Plan? Select what you think applies.



IMDRF Q9. In your opinion, what strategic priorities / topics should the EU pursue at IMDRF level?

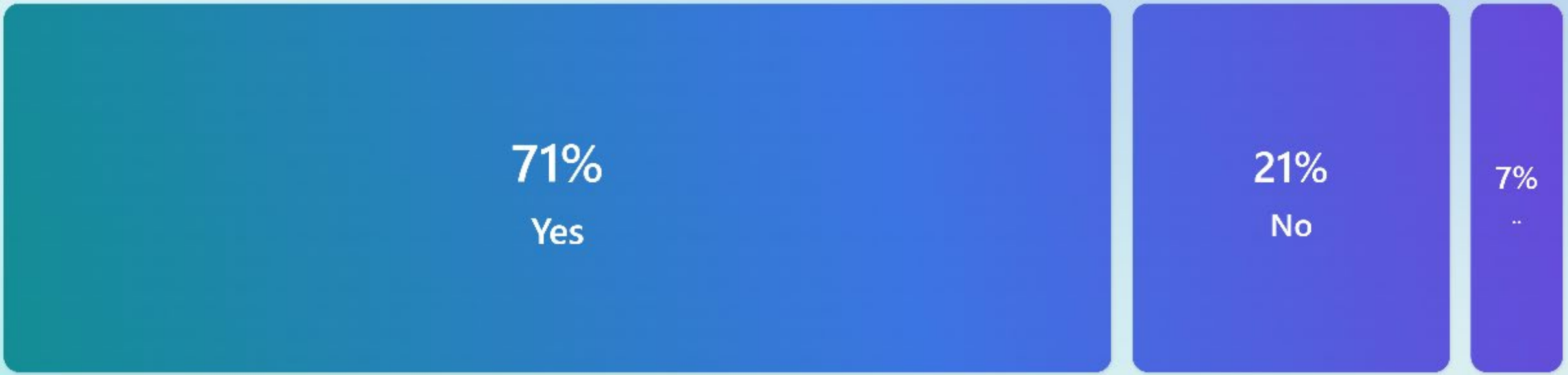
- Promote EU PMS requirements
- EU AI requirements
- PCCP, change management
- Reliance playbook – maintain EU role in the world
- Training programs
- IVD Clinical Evidence
- Adverse event reporting and PMS reporting

Results of the Survey on Reliance

European Commission

Role (e.g., regulator, notified body, EU association manufacturer, importer, authorised representatives, healthcare professional, etc.):

Are you aware of any non-EU countries that rely on EU medical device / IVD certificates as part of their regulatory framework?

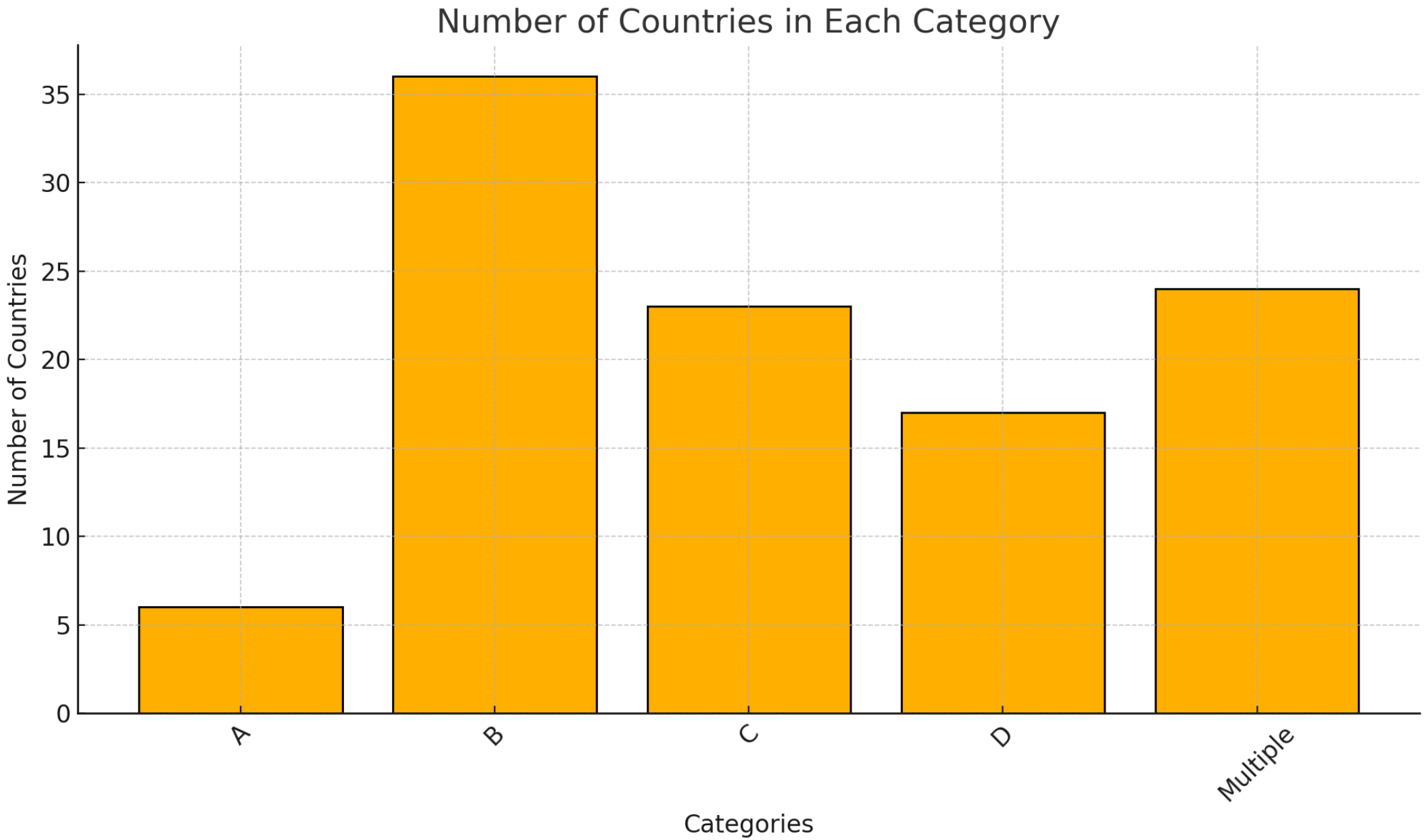


If yes, which non-EU countries do you know that practice reliance on EU medical device certificates?

- Complete reliance
- Expedited assessment (partial reliance)
- Registration only requirement
- Adapted reliance
- Other

Which types of reliance mechanisms?

A. **Complete reliance:** No additional assessment, full acceptance of EU certificates.
B. **Expedited assessment (partial reliance):** Limited review based on EU certificate with a focus on local regulatory aspects.
C. **Registration-only requirement:** Local registration based on EU certification without additional technical assessment.
D. **Adapted reliance:** Modifications or supplementary requirements based on EU certificates.
E. **Other** (please specify):


Number of Countries in Each Category
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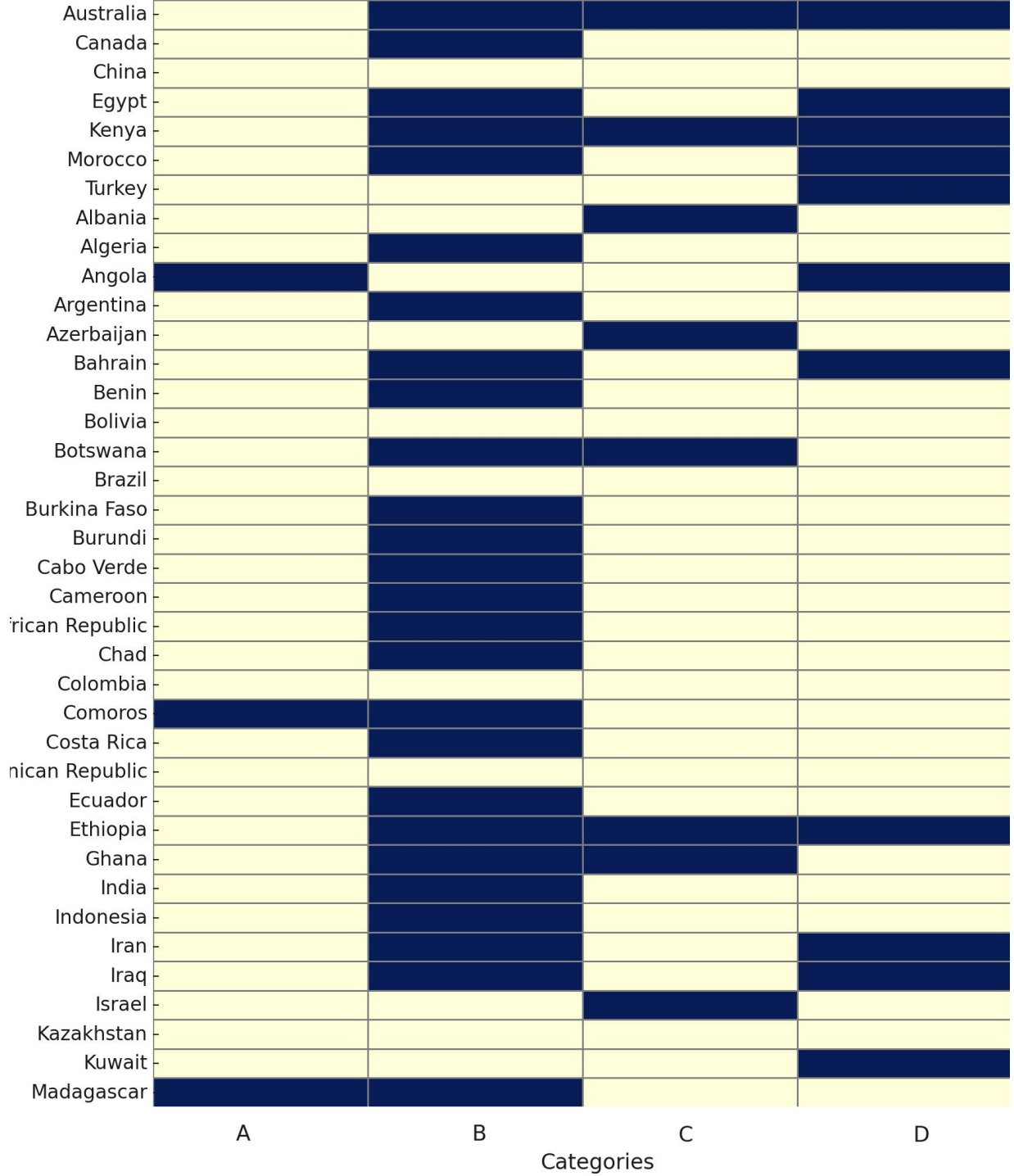
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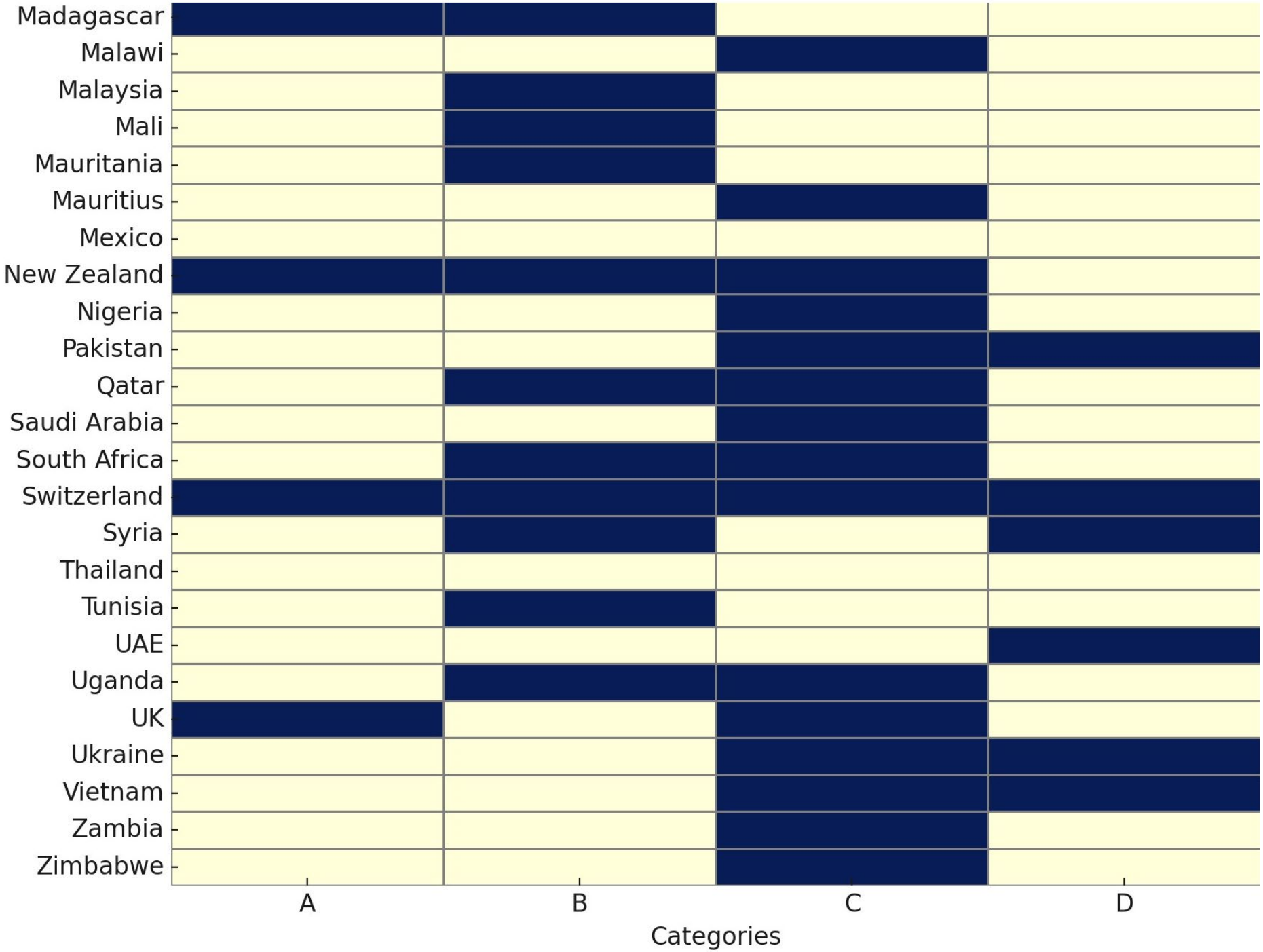
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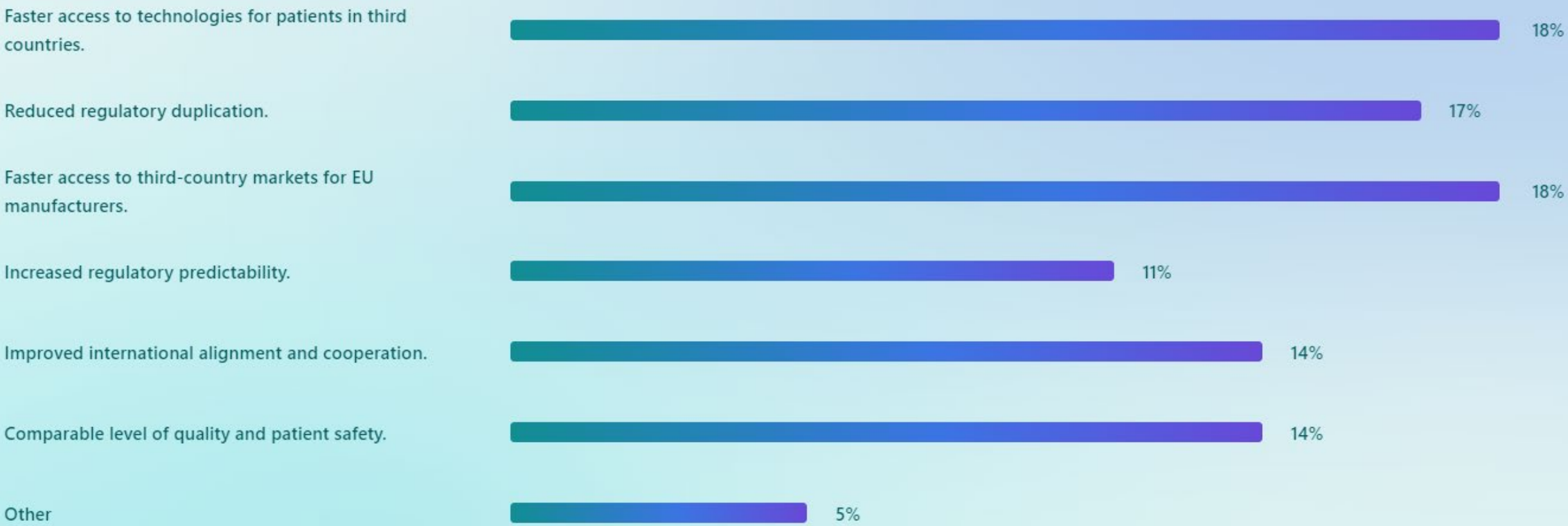
Categories

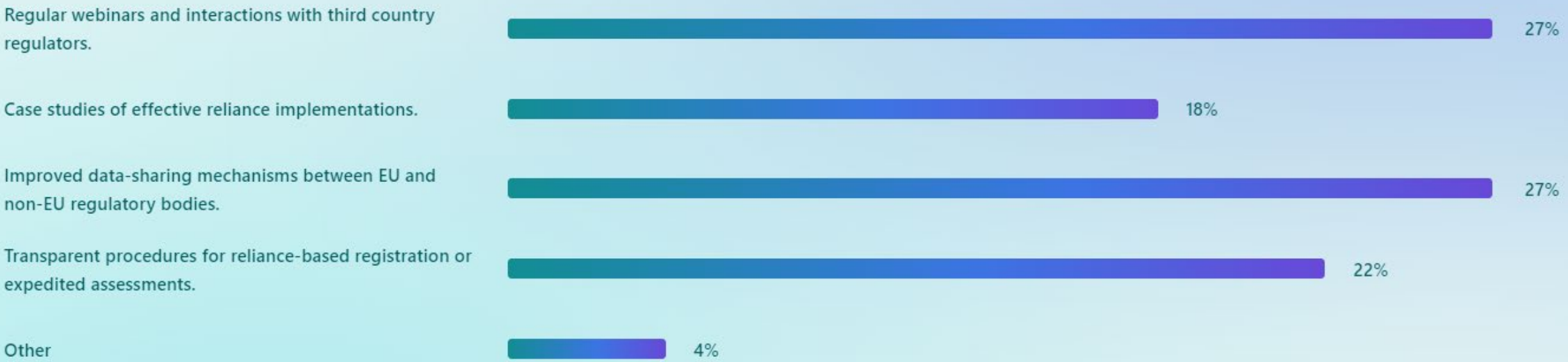
Does your organisation interact with third countries practicing reliance on the EU?

If you answered No to Question #6, would you be open to support the EU representation in building bilateral relations with third countries to facilitate their uptake / continued reliance?

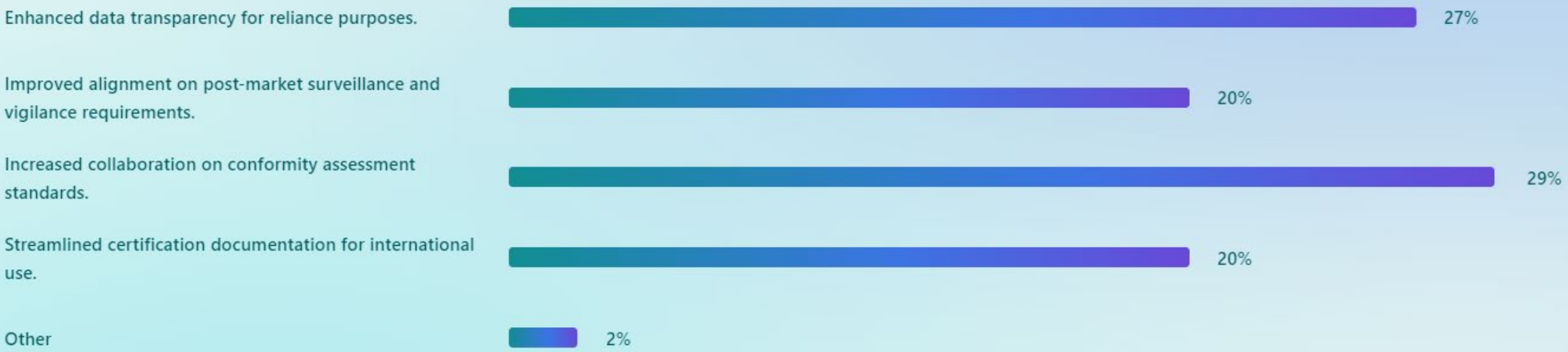
In your view, what are the primary benefits of third-country reliance on EU medical device/IVD certificates? (Please select all that apply)



What additional information or guidance would support more effective interaction with third countries practicing reliance on EU medical device certificates? (Please select all that apply)



In your opinion, which areas of the EU medical device framework could better support third-country reliance?



Do you have any additional comments, observations, or suggestions related to third-country reliance on EU medical device / IVD certificates?

Do you have any additional comments, observations, or suggestions for the EU to consider? E.g. possibilities for the EU to practice reliance itself on...