



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

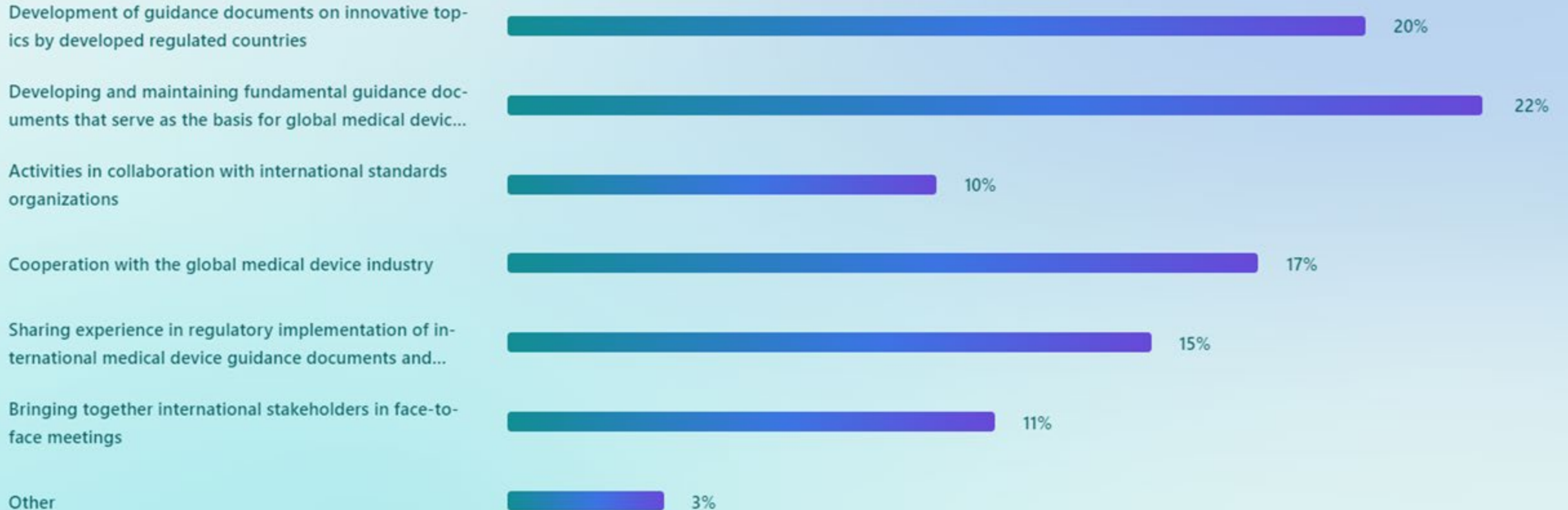
IMDRF Q1. Do you think IMDRF has achieved the objectives and scope of activities listed in the TOR?

59%
Agree

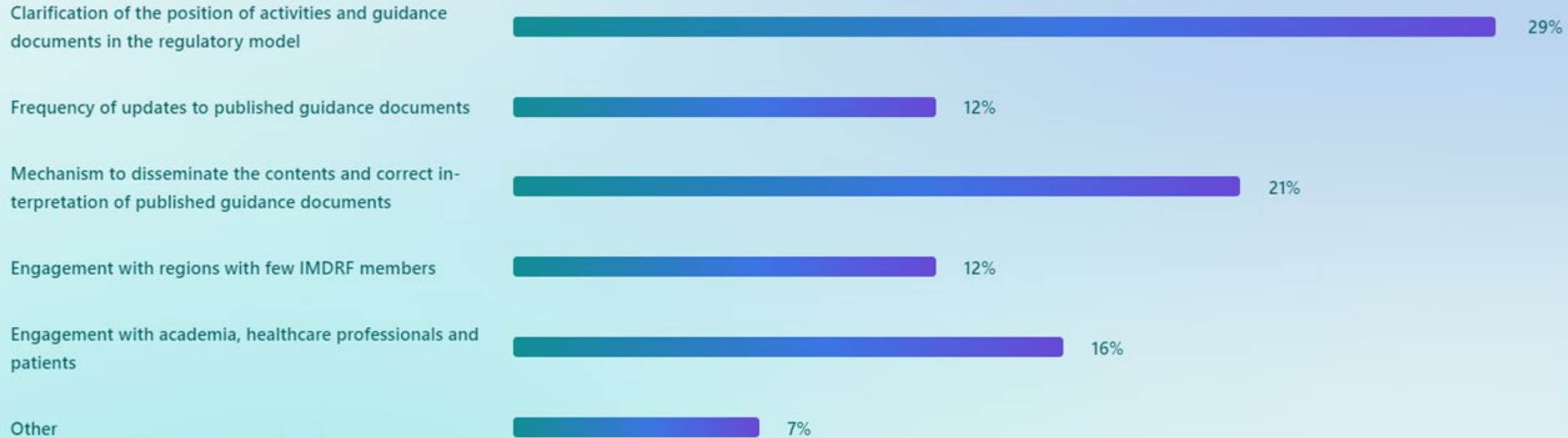
36%
Neither agree nor disagree

4%
..

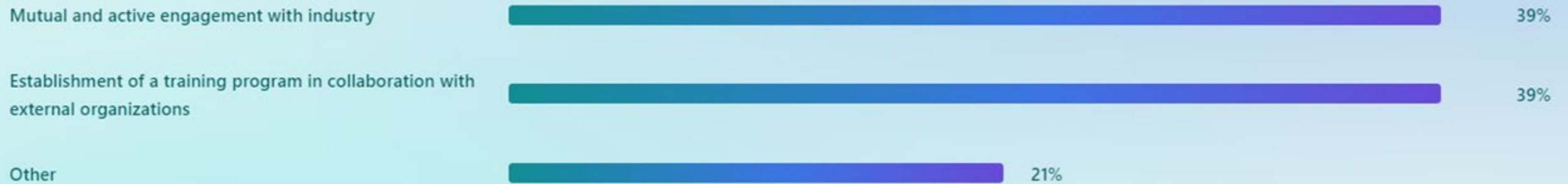
IMDRF Q2. As a core member of IMDRF, what do you think is the strength of IMDRF? Please select all that you think apply.



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.

59%

Foundational and Advanced

40%

Pre-market and Post market



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

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

association manufacturer
competent authority
Trade association
medical technology
Regulator - competent
Industry Association
Competent Authority
European Regulator
medical devices
Authorised Representative



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

71%
Yes

21%
No

7%
..



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

countries
Tome and Principe
GCC countries
Isreal
Republic
Sudan Herzegovina Egypt
Australia **Switzerland** African
Zealand Tome **South Africa** Serbia
Norway Switzerland / UK
RicaDominican RepublicEI
EEA countries



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

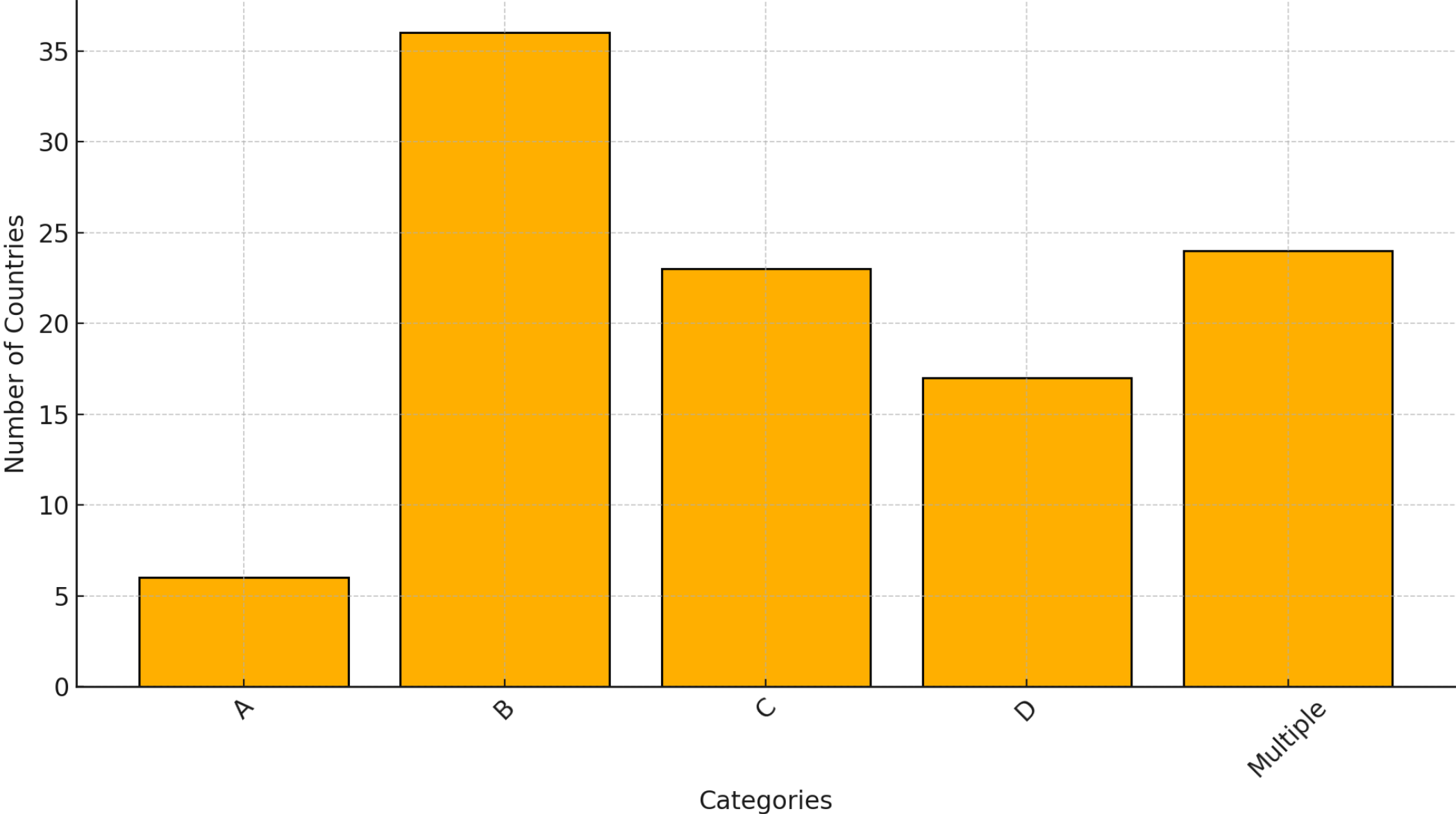


Which types of reliance mechanisms?

- 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):



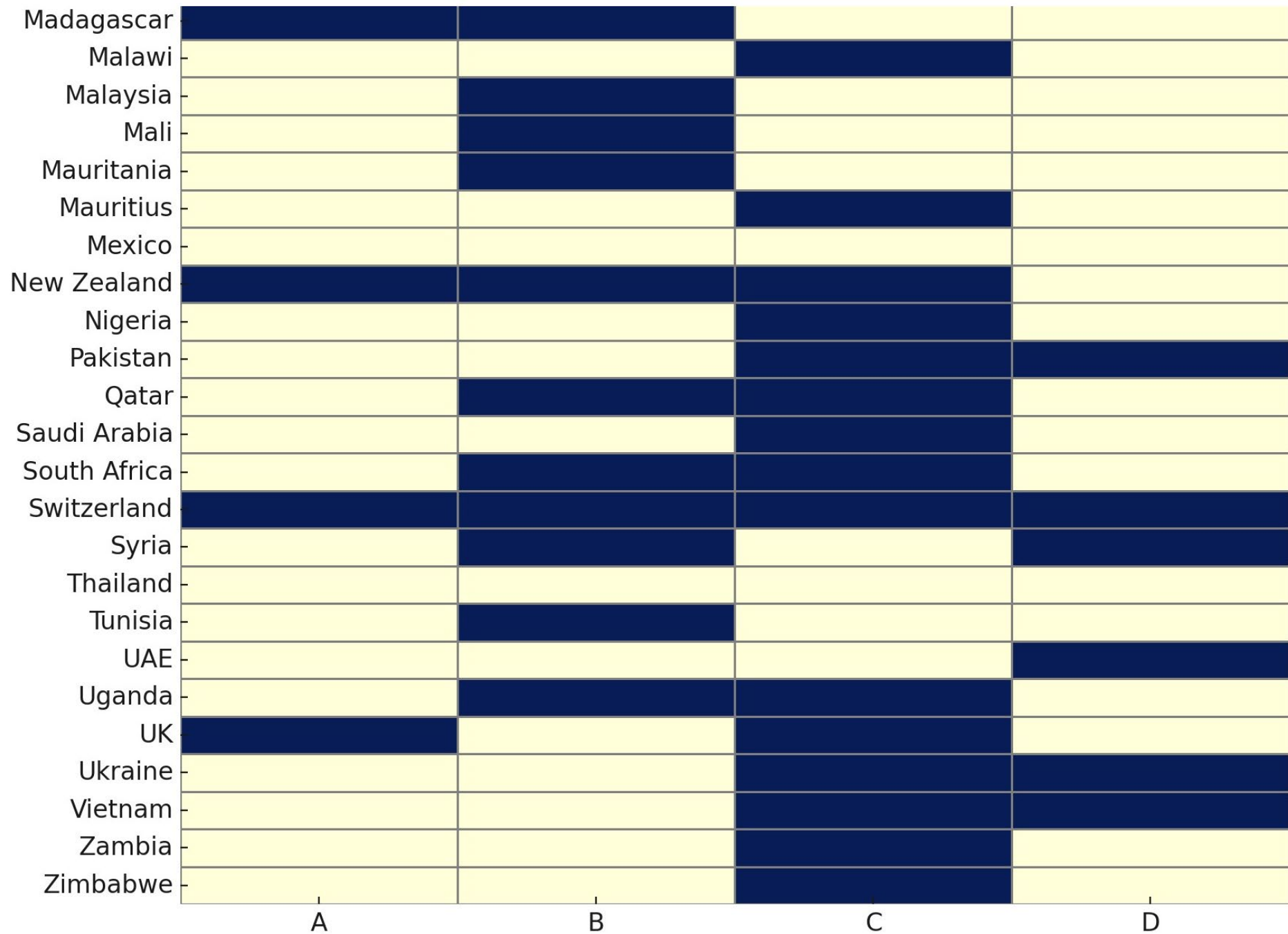
Number of Countries in Each Category



	A	B	C	D
Australia	Light	Dark	Light	Dark
Canada	Light	Dark	Light	Light
China	Light	Light	Light	Light
Egypt	Light	Dark	Light	Dark
Kenya	Light	Dark	Dark	Dark
Morocco	Light	Dark	Light	Dark
Turkey	Light	Light	Light	Dark
Albania	Light	Light	Dark	Light
Algeria	Light	Dark	Light	Light
Angola	Dark	Light	Light	Dark
Argentina	Light	Dark	Light	Light
Azerbaijan	Light	Light	Dark	Light
Bahrain	Light	Dark	Light	Dark
Benin	Light	Dark	Light	Light
Bolivia	Light	Light	Light	Light
Botswana	Light	Dark	Dark	Light
Brazil	Light	Light	Light	Light
Burkina Faso	Light	Dark	Light	Light
Burundi	Light	Dark	Light	Light
Cabo Verde	Light	Dark	Light	Light
Cameroon	Light	Dark	Light	Light
Cuban Republic	Light	Dark	Light	Light
Chad	Light	Dark	Light	Light
Colombia	Light	Light	Light	Light
Comoros	Light	Dark	Light	Light
Costa Rica	Light	Dark	Light	Light
Czech Republic	Light	Light	Light	Light
Ecuador	Light	Dark	Light	Light
Ethiopia	Light	Dark	Dark	Dark
Ghana	Light	Dark	Dark	Light
India	Light	Dark	Light	Light
Indonesia	Light	Dark	Light	Light
Iran	Light	Dark	Light	Dark
Iraq	Light	Dark	Light	Dark
Israel	Light	Light	Dark	Light
Kazakhstan	Light	Light	Light	Light
Kuwait	Light	Light	Light	Dark
Madagascar	Dark	Dark	Light	Light

Categories





Categories



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

57%
No

42%
Yes



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?

83%

Yes

16%

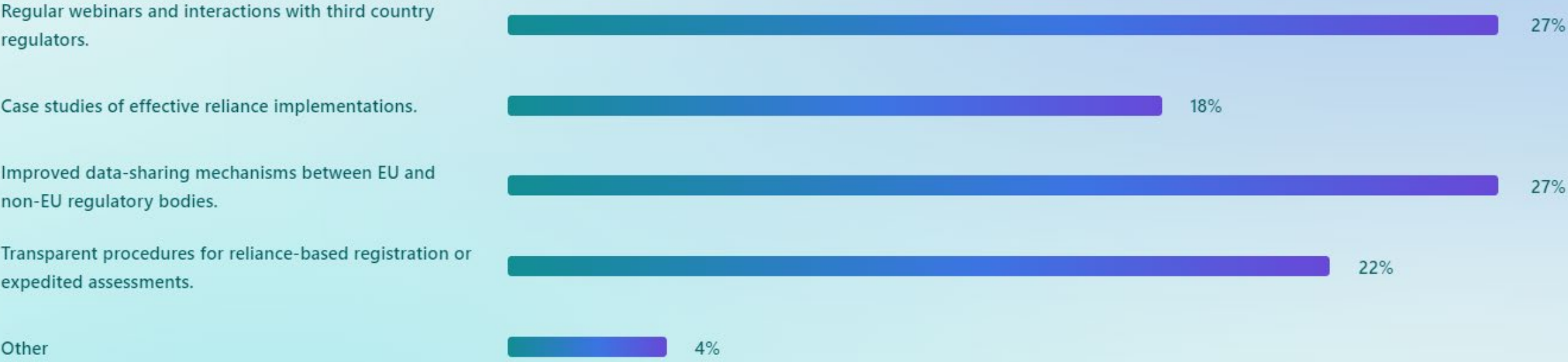
No



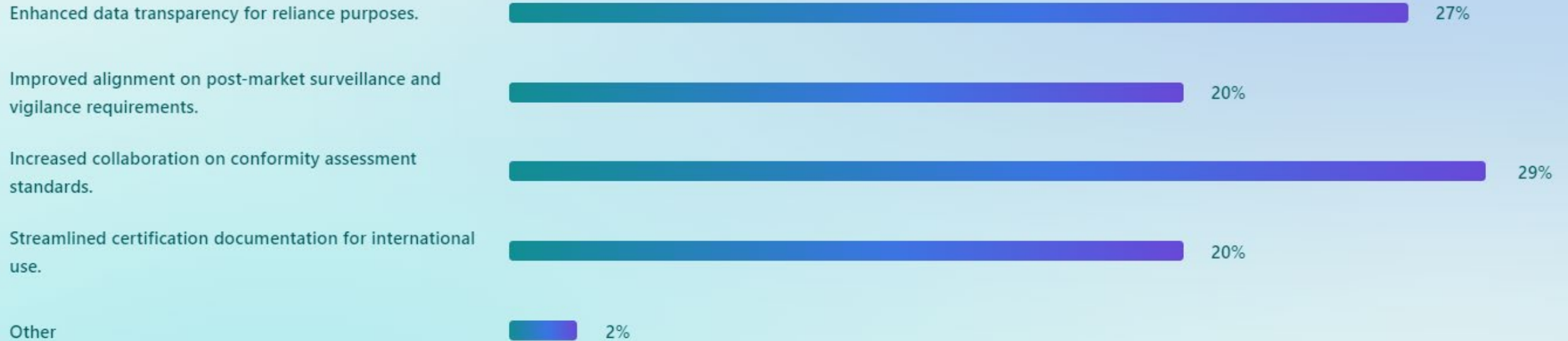
In your view, what are the primary benefits of third-country reliance on EU medical device/IVD certificates? (Please select all that apply)



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?

reliance mechanisms
promotion of reliance
device registrations
markets than the EU
CE mark
EU industry
playbook on reliance
EU legislation
nonEU reliance
reliance options
forms of reliance
EU exports
EU authorities
EU countries
EU regulators
CE certificate
EU business
template for CFS



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...



A word cloud centered around the terms 'MDSAP' and 'EU'. The words are arranged in a circular pattern, with 'MDSAP' and 'EU' being the largest and most prominent. Other words include 'countries', 'reliance', 'regulatory approvals', 'GSPR requirements', 'IVDR', 'Essential Principles', 'MDSAP countries', 'EU's efforts', 'eg ISO', 'EU legislation', 'MDSAP certificates', 'EU funding', 'Medical Device', 'member of the IMDRF', 'Recognition Agreements', 'aligning', 'devices in Australia', and 'membership in the MDSAP'.

membership in the MDSAP
devices in Australia
aligning
countries
Essential Principles
MDSAP countries
IVDR
MDSAP EU
reliance
regulatory approvals
GSPR requirements
EU's efforts
eg ISO
EU funding
EU legislation
MDSAP certificates
Medical Device
member of the IMDRF
Recognition Agreements

