where science and ethics meet

EFGCP eConsent - Ethics Committees Survey Detailed Results

Driven by EFGCP eConsent Database Workstream

In case of questions, please contact Hilde Vanaken
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This deck includes the detailed results of the

EFGCP eConsent Ethics Committees Survey.

For the overall conclusion, please consult the article:

”Understanding Acceptability of eConsent from a Global, Ethical, and Industry Perspective” published in Applied Clinical Trials on 11 October 2024

Survey Methodology

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- The surveys were distributed as on-line surveys from 23 August to 31 December 2023 via the EFGCP team members (+50 organizations), the EFGCP eConsent website and social media posts.
- Team members were asked to distribute the survey further upon their discretion to Ethics Committees/Institutional Review Boards and/or other Vendors/Sponsors. A template distribution email and survey layout document was available.
- The Ethics Committee/Institutional Review Board Survey contained 15 questions, some with multiple questions and multiple parts. All questions were mandatory to complete.
- The scope of the survey and a link to the EFGCP eConsent Glossary of Digital Features was included in the introduction of the survey.
- Survey completion was anonymous but contact details could be provided in order to clarify unclear answers.

Overview of Questions

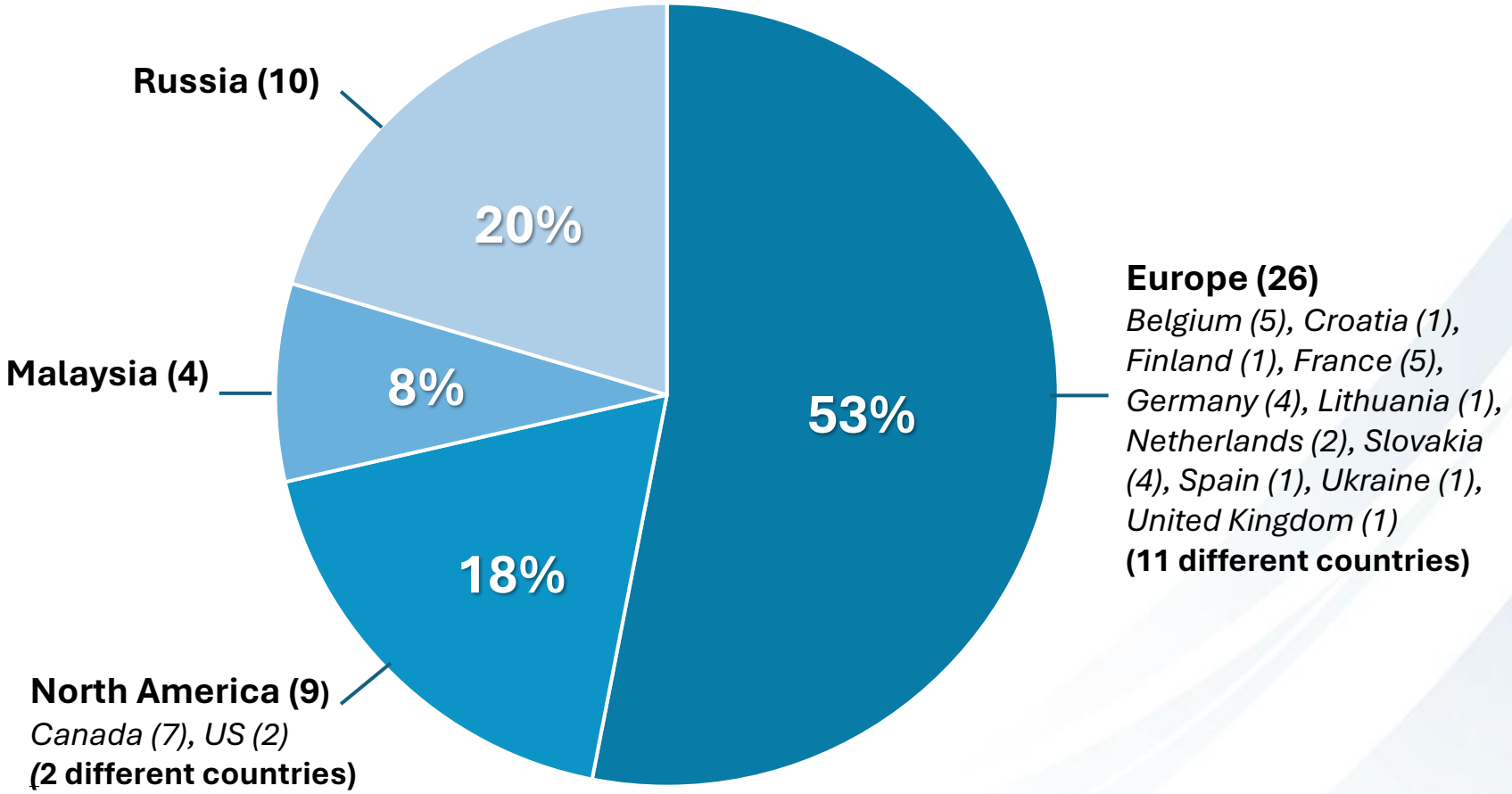
The 15 core questions of ECs/IRBs Survey are shown below. For the sub-questions and various answer options, please see the survey layout document.

#	Questions	Answers
1	Which of the following best describes your organization?	Predefined answers, single choice
2	Please indicate the country in which your Institutional Review Board or Ethics Committee has jurisdiction	Select country
3	Please indicate any relevant locality/state/site in which your Institutional Review Board or Ethics Committee has jurisdiction	Open Answer
4	Please indicate which of these statements best describes your experience with electronic informed consent (eConsent)	Predefined answers, single choice
5	We are interested in understanding how to advance the acceptability of electronic signatures together with electronic informed consent for clinical trials. How important is each of the following features, in your decision to approve the use of eConsent with eSignature	Multiple questions, predefined answers, single choice
6	What is the most important factor driving a decision to approve an eConsent technology in your country/jurisdiction?	Predefined answers, single choice
7	Does your Ethics Committee have a guidance document related to informed consent?	Yes or No
7.1	Is there anything that would need to be adapted in order to accommodate use of eConsent?	Yes or No
8	For each of the consent scenarios below, please consider what the minimum requirement is for signature types in a Phase 1-3 interventional trial	Multiple questions, predefined answers, single choice
9	Do local laws or regulations require that directly identifiable personal data (e.g., names and signatures on consent forms) be hosted locally in your country or region?	Predefined answers, single choice
10	Please describe criteria for storing directly identifiable data outside the country and/or indicate which laws govern the storage of this data	Open Answer
11	Which of these materials is required for submission and approval of eConsent? (check all that apply)	Multiple choice answer
12	Do you have any timeline requirements for archives of eConsent data that exceed the GCP requirements?	Yes/No
13	Are there any differences in expectation for monitoring of eConsent versus paper consent?	Yes/No
14	Would your IRB/EC be supportive of a stipulation in the protocol that consent can only be given electronically?	Yes/No/Other
15	Would you be interested in participating in future research (interviews or focus groups) or initiatives regarding eConsent?	Yes/No

Results Analysis

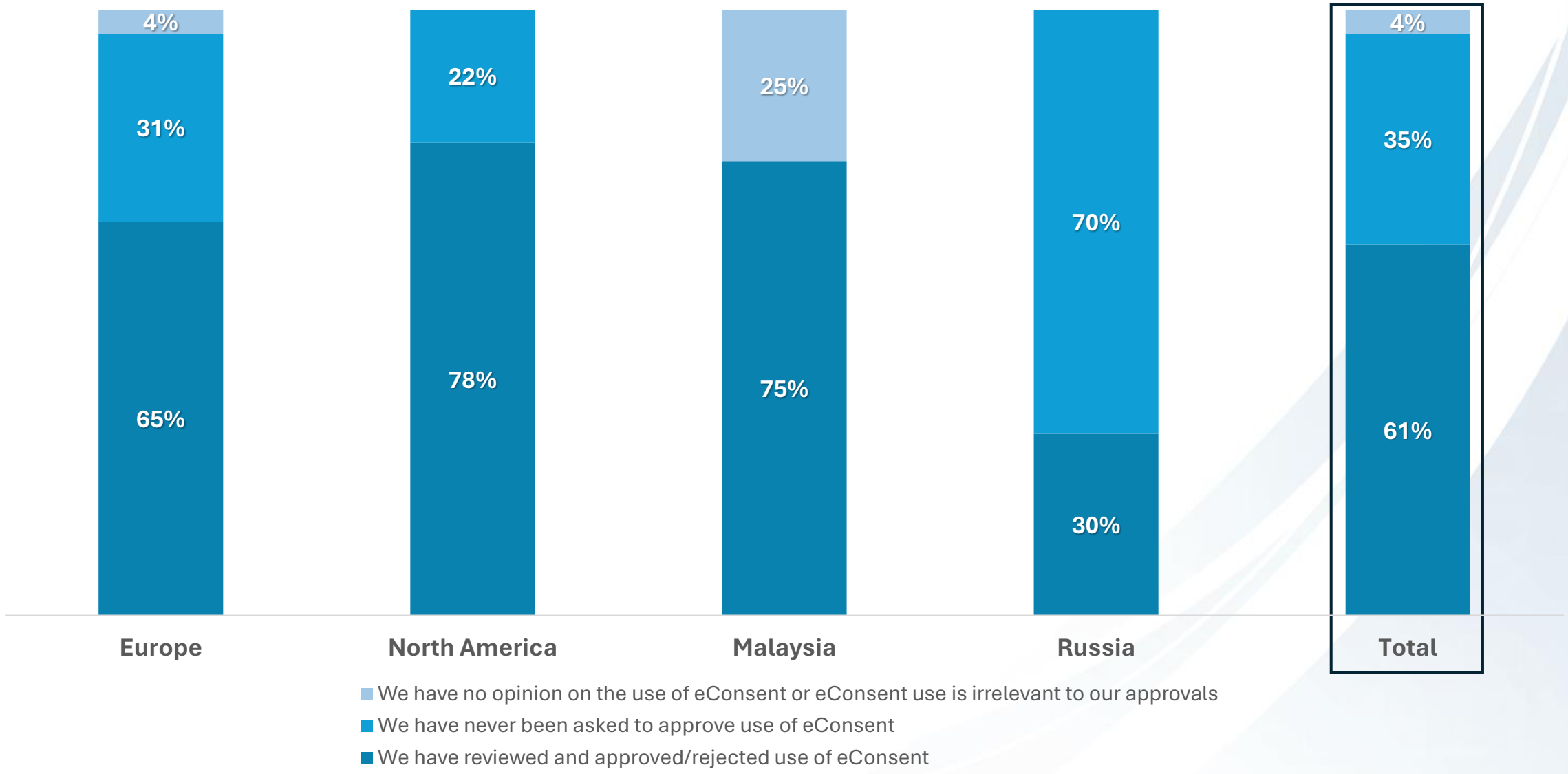
Survey Respondents - Regional Distribution (Q2)

49 EC/IRB Respondents of 15 Different Countries

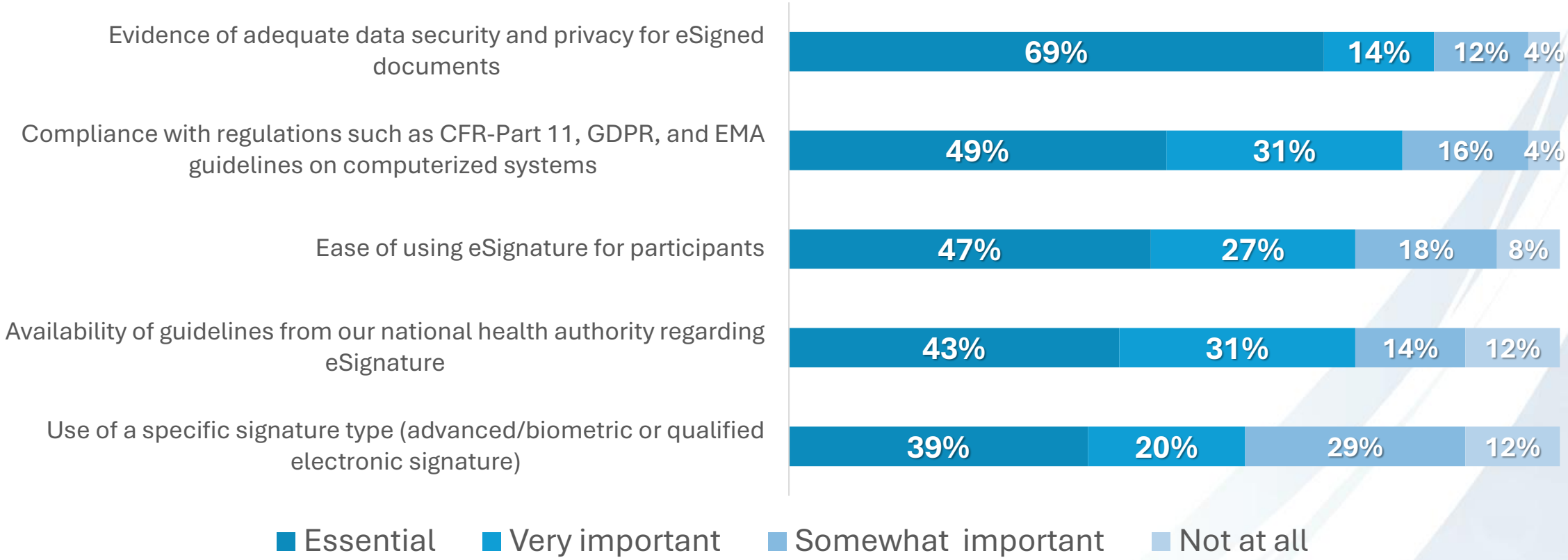


Note - Q1 (type of EC/IRB organization) is added in the back up slides as the question was confusing/unclear for several EC respondents.

EC/IRB Experience with eConsent (Q4)



Importance of Different Variables to Approve eConsent with eSignature (Q5)



Note – in the survey, “features” instead of “variables” was used

Most Important Factor to Drive Decision to Approve eConsent (Q6)

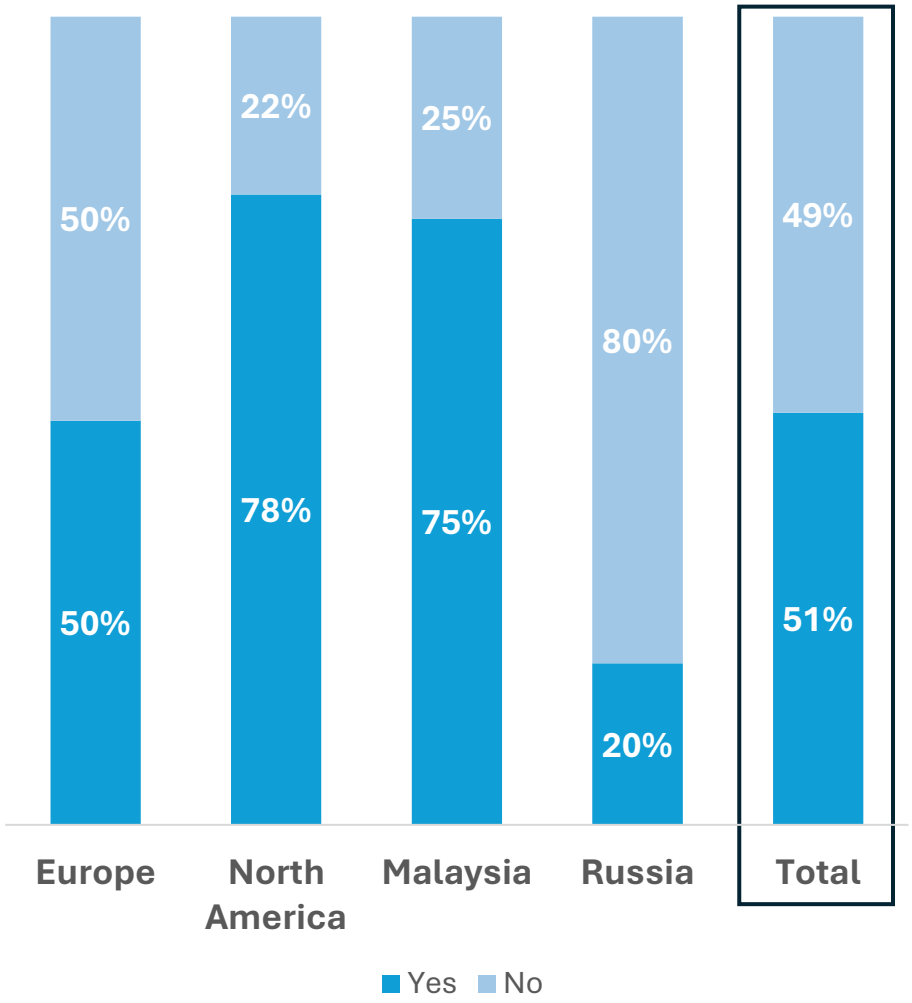
- Knowing the process allows for a true informed consent procedure without removing the interaction between physician and participant
- Patient-centricity, i.e., patients first
- The regulatory body within my country accepts eConsent technology
- Knowing it is accounted for in site guidance document, i.e., Standard Operating Procedures (SOPs)
- That there is easy access to the technology and documentation/training
- That it enables decentralized trials
- Other

Other (free text field): *Combination on ease of technology use and patients' ability to utilize/understand the eConsent; Both regulatory acceptance, and local privacy policies permitting storage of identifiable information externally from the institution; Increase recruitment of participants into studies; Sponsor decision; Whether it is appropriate for the study in question - this depends on a range of factors.*

* In the article, “investigator” instead of “physician” was used to be consistent and avoid different terminologies throughout the text

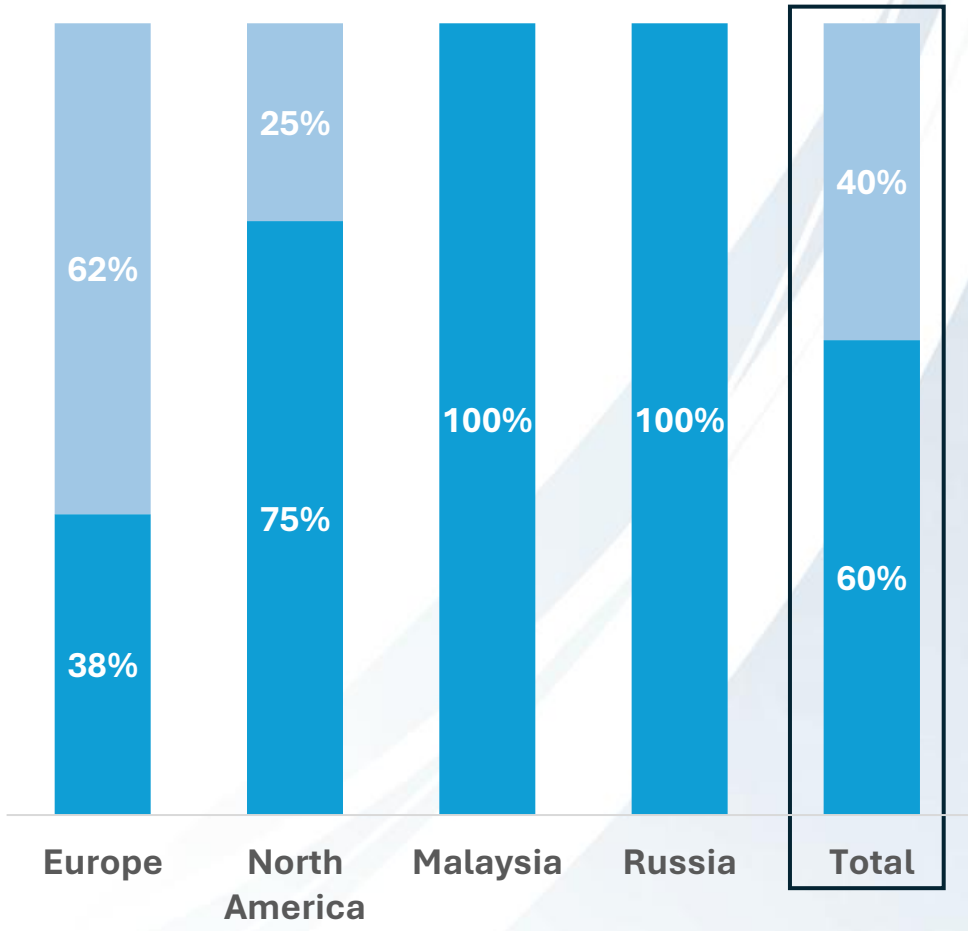
Guidance Document on ICF Available and Updates for eConsent needed (Q7, Q7.1)

ICF Guidance Document Available

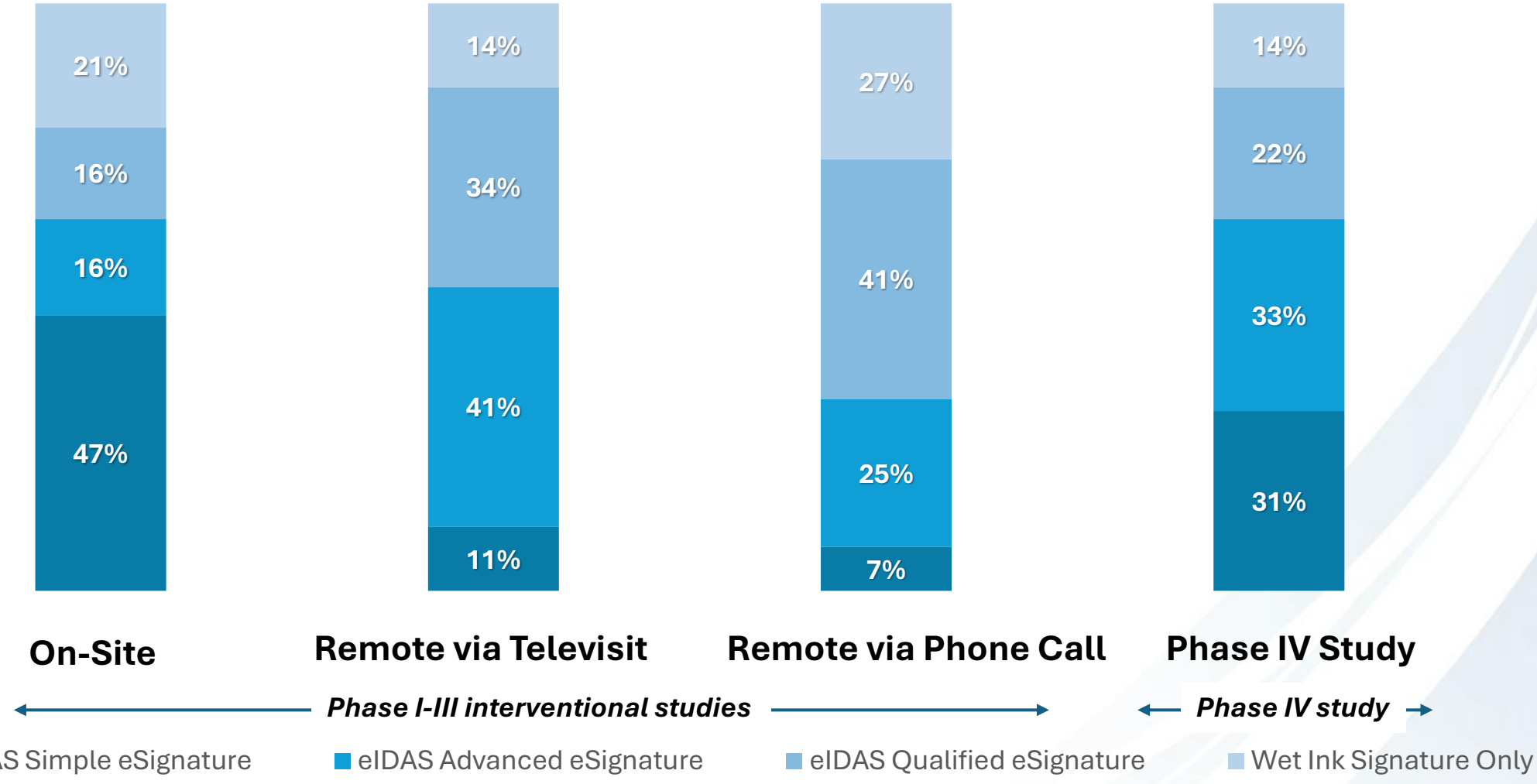


If yes

Guidance updates needed for eConsent?

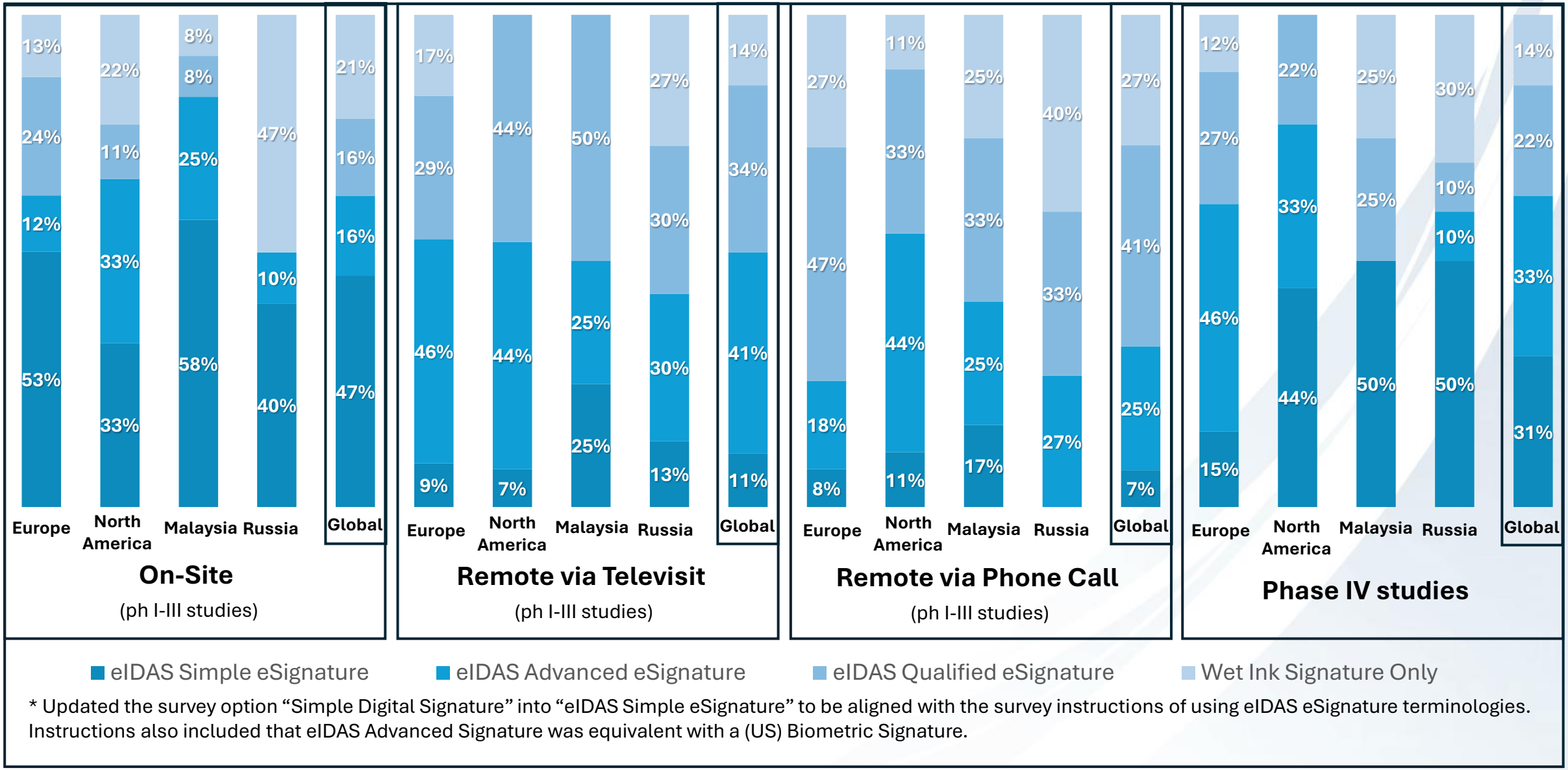


Minimum Signature Type Required (Q8) – Global



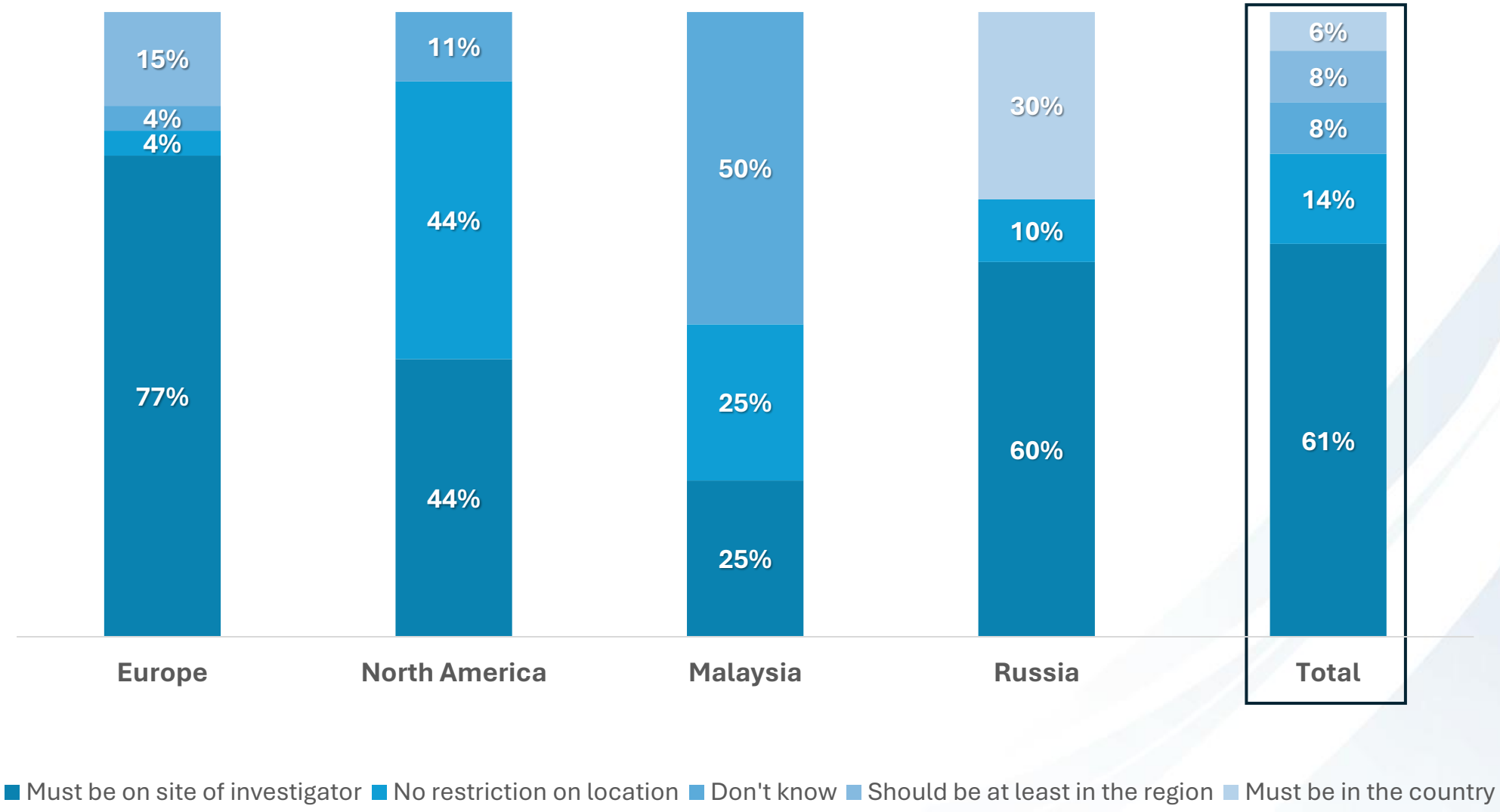
* Updated the survey option “Simple Digital Signature” into “eIDAS Simple eSignature” to be aligned with the survey instructions of using eIDAS eSignature terminologies. Survey instructions also included that eIDAS Advanced Signature was equivalent with a (US) Biometric Signature.

Minimum Signature Type Required (Q8) – Per Region

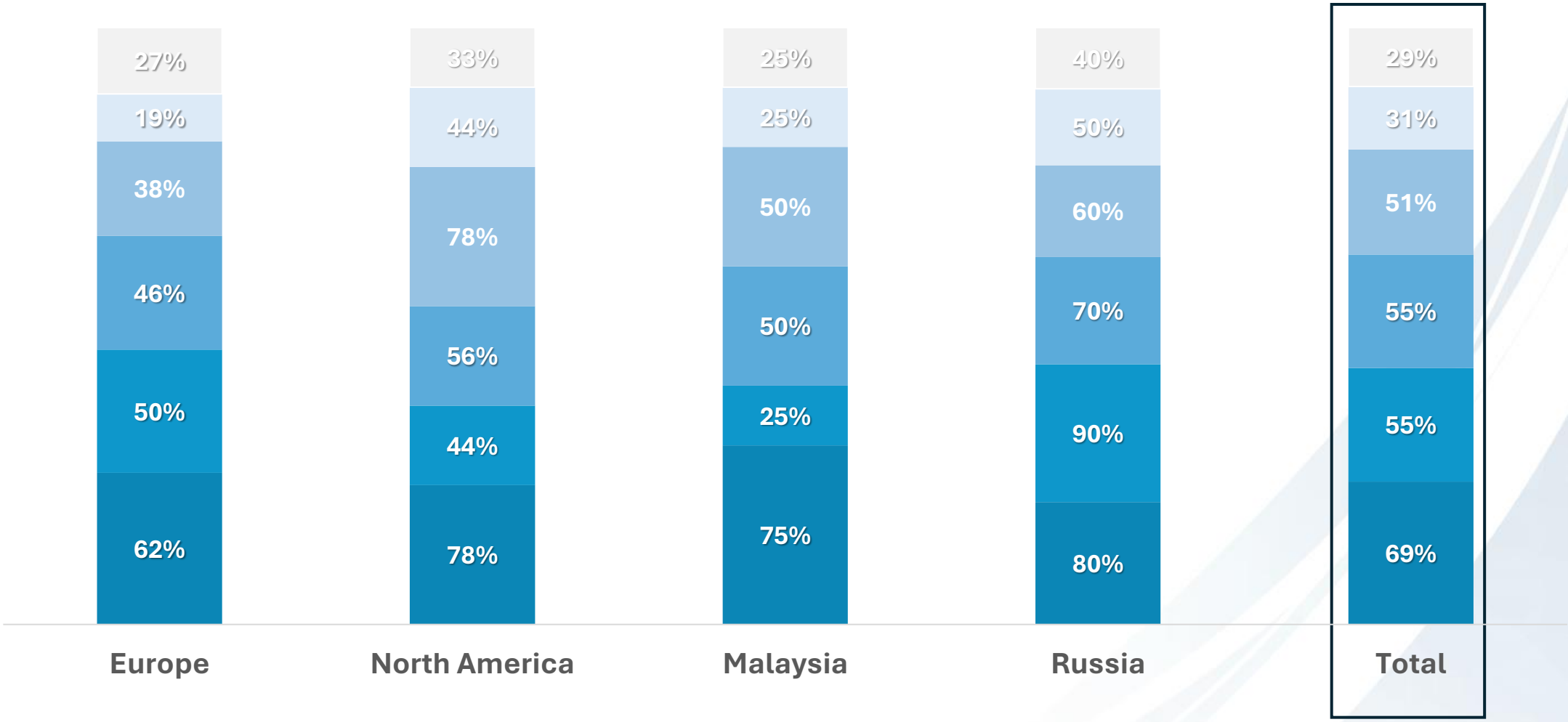


* Updated the survey option “Simple Digital Signature” into “eIDAS Simple eSignature” to be aligned with the survey instructions of using eIDAS eSignature terminologies. Instructions also included that eIDAS Advanced Signature was equivalent with a (US) Biometric Signature.

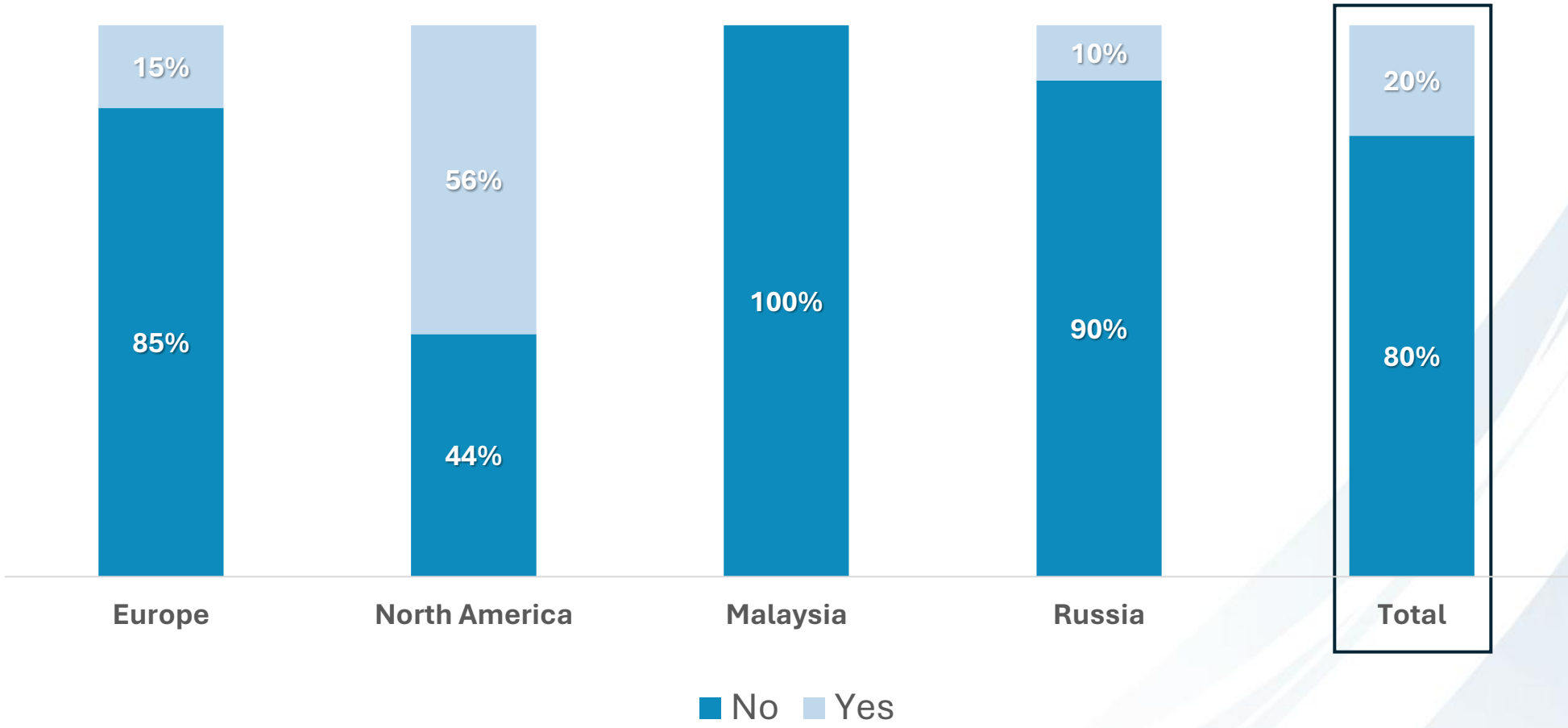
Hosting of Personal Data Requirements, Laws or Regulations (Q9)



eConsent Submission Material (Q11)



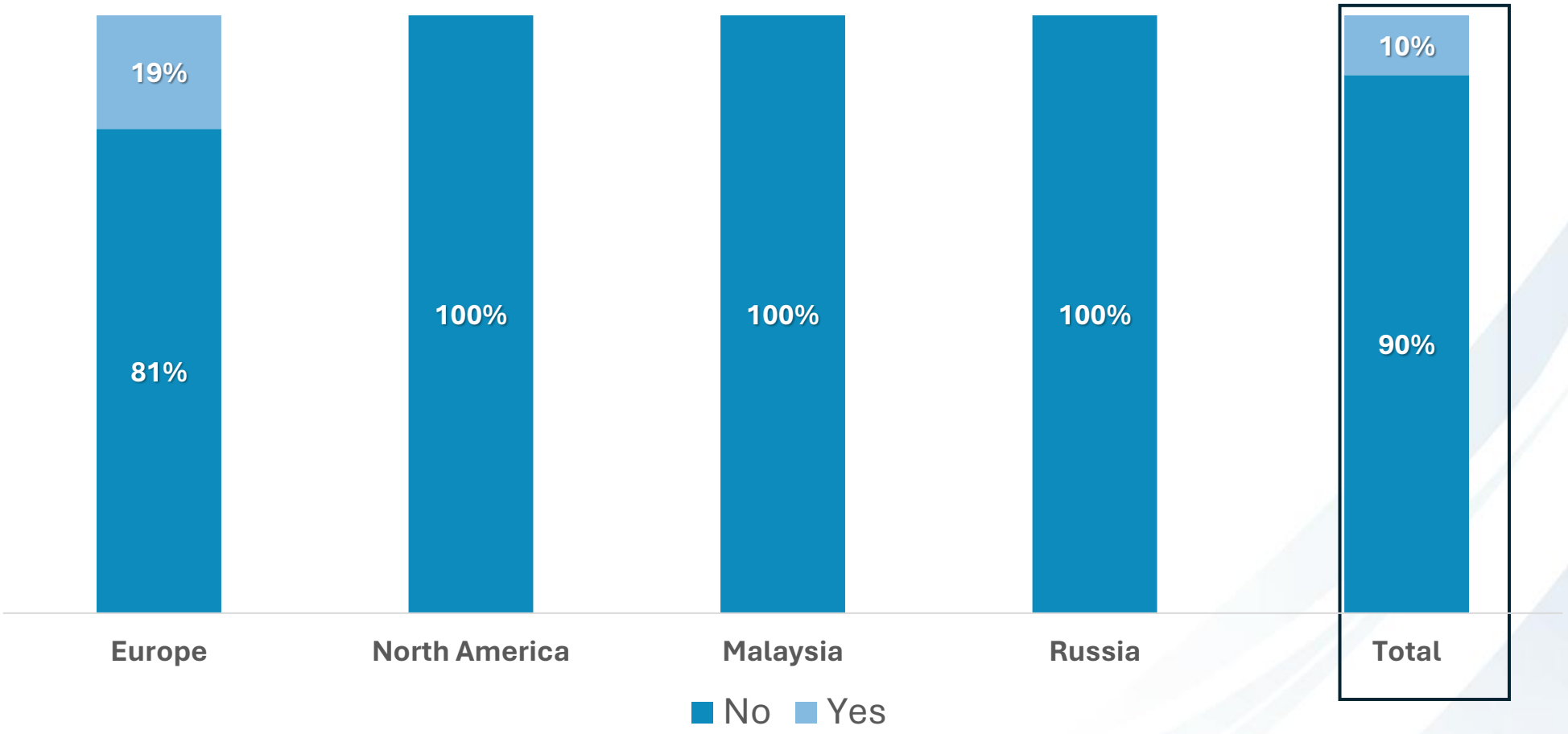
Any eConsent Archival Timelines Requirements that exceed GCP requirements (Q12)



Additional notes:

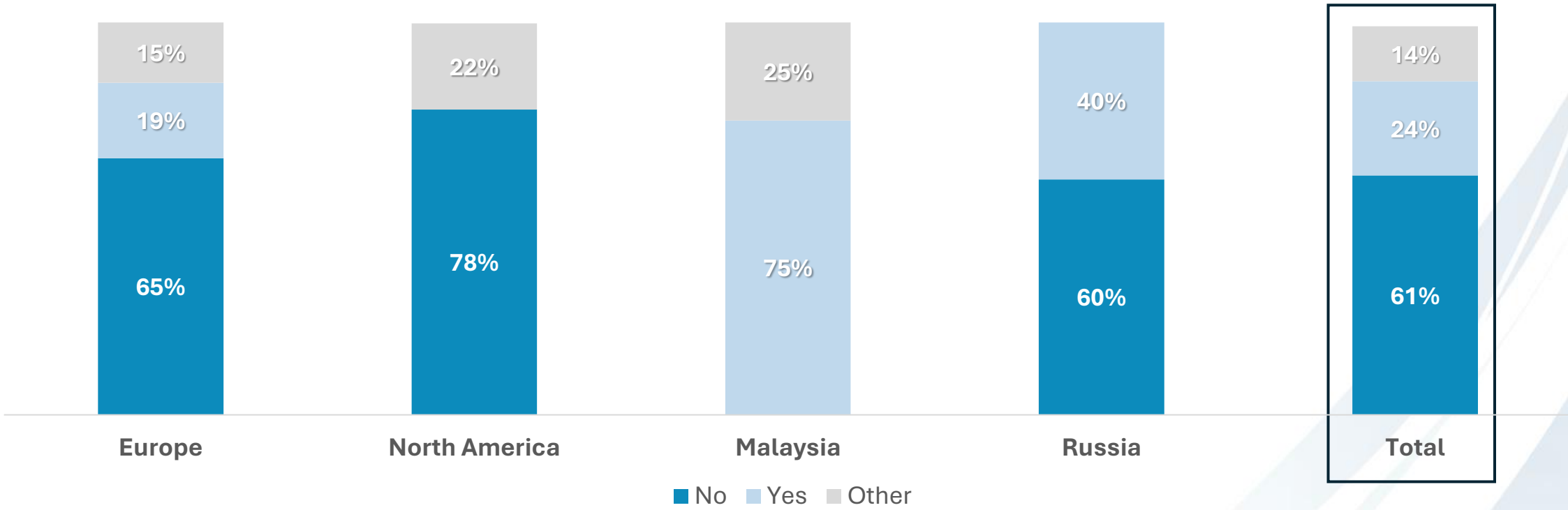
- ICH GCP archival guidelines set a minimum standard of 2 years for the retention of essential documents post-trial but there might be additional country-specific or internal requirements.
- 56% US “yes” (5 of 9 US respondents): 3 respondents indicated 15 years (Canadian legislation) and 2 respondents indicated 2 years (FDA regulations).

Any eConsent Monitoring Requirement Different From Paper Consent (Q13)



19% European EC respondents (5) represent 1 of 5 Belgian, 2 of 4 German, 1 of 1 Finish and 1 of 1 Croatian Ethics Committees

Supportive that consent can only be given electronically (Q14)



- **Other comments (Europe):** Not suggested/assessed yet by our MREC, positive, If legal regulations are adapted, Only if paper ICF is impossible for the conduct of the trial otherwise paper back-up needs to be provided (e.g. pandemic situation). eIF can be stipulated as the preferred way of consenting within the protocol.
- **Other comments (North America):** Paper alternative not necessarily a requirement. Participants must be provided with a true and accurate copy of the ICF signed, It depends on your demographic and target regions. If justified, yes. Caveat: Some folks in rural areas don't have a computer, or wifi, or even an email address and the REB would not want to restrict access to trials based on electronic capabilities.
- **Other comments (Asia):** Should allow flexibility both e-consent & wet ink according to subject preference,
- **Other comments (Russia):** not applicable

This work was the result of the EFGCP eConsent Database Workstream. Many thanks to all organizations that contribute and completed the EFGCP eConsent Ethics Committees Survey.

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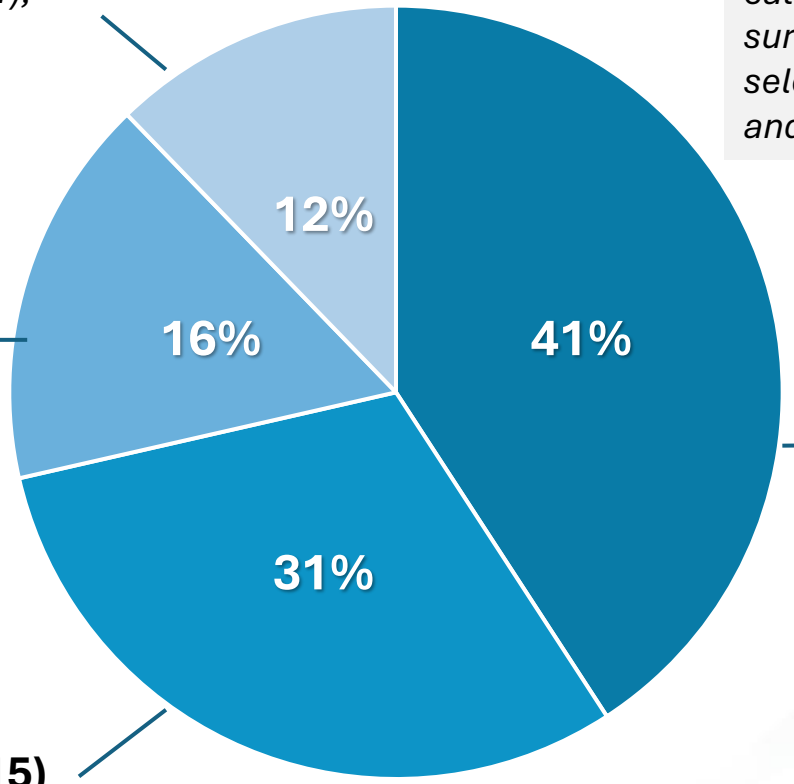
Back up slide

Survey Respondents - Organization Type and Country of Jurisdiction (Q1, Q2)

49 EC/IRB Respondents of 15 Different Countries

Central/Independent IRB (6)
Croatia (1), France (2), Malaysia (1), Slovakia (1), United Kingdom (1)

There might have been some confusion in the categories and way how they were described in the survey. For example, several European and Asian ECs selected local IRBs instead of ECs outside the US, and for central IRBs, only non-US countries are listed



EC outside the US not linked with Acad/Medic Institute (8)
Belgium (1), Canada (1), Finland (1), Germany (1), Lithuania (1), Russia (1), Slovakia (2)

EC outside US, linked with Acad/Medic Institute (20)
Belgium (4), Canada (5), France (2), Germany (3), Malaysia (1), The Netherlands (2), Russia (2), Slovakia (1)

Local IRB (Acad/Medic Institute) (15)
Canada (1), France (1), Malaysia (2), Russia (7), Spain (1), Ukraine (1), US (2)