ONE YEAR AFTER THE DELAY

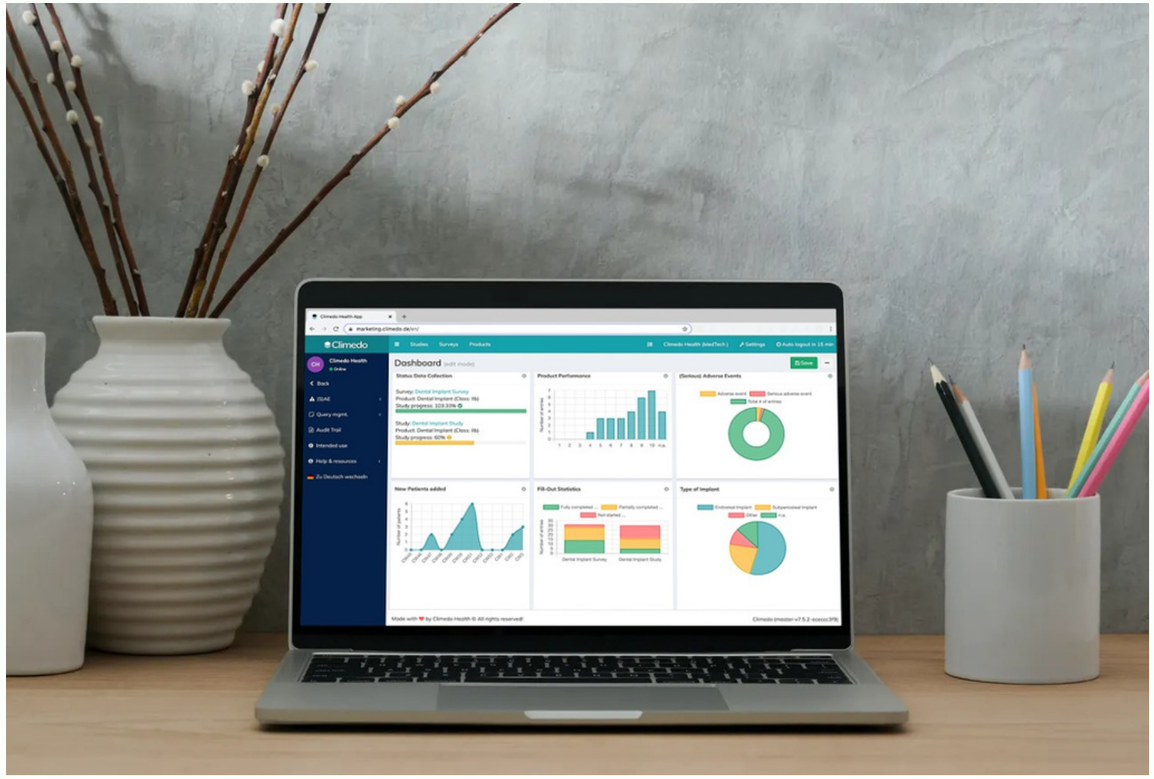
EU MDR Readiness Check 2021

Survey Results

About Climedo Health

Climedo’s mission is to bring the best treatment to every patient by empowering healthcare professionals with intelligent software solutions. Together with Europe’s leading hospitals, we have developed a cloud-based platform for cutting-edge clinical validation and post-market surveillance of medical devices and pharmaceutical products.

By digitally connecting all stakeholders (Medical Device manufacturers, Pharma companies, CROs, hospitals and patients), Climedo allows for increased performance, better cost-efficiencies - and ultimately - accelerated medical innovation. Learn more: www.climedo.com.



Summary

In 2020, we conducted our first survey on the status of EU MDR readiness. The results at the time showed that many medical device manufacturers were not yet prepared for the new regulation. Shortly after the survey was completed, the EU Commission announced the planned postponement of the MDR deadline by one year.

The goal of our new survey, which ran between mid-March and mid-April 2021, was to explore where companies stand now – one year after the postponement –, whether the delay helped and what they would like to see from the EU Commission. Some questions have been taken from last year's surveys ("EU MDR 2020 Readiness Check" and "The True Costs of the EU MDR") and compared to the new results. Some questions are completely new.

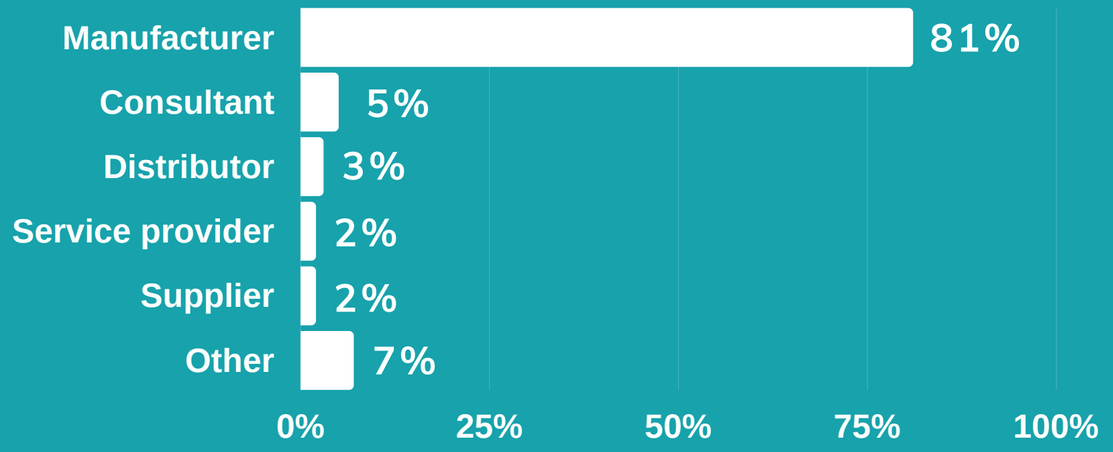
The results from the 115 participants across Europe showed that the new regulation is still **very challenging** for many; in fact, this number has even increased a little. In addition, it seems that the regulation continues to be **very costly** for companies. At the same time, more companies now have an **MDR-certified Notified Body** and many have made use of **virtual audits**. When it comes to clinical data capture, however, most companies still use **Excel sheets and/or paper**. The greatest challenge in **clinical data capture** is the amount of time it consumes. When it comes to benefits of the MDR, **traceability** was cited by the majority of participants. Last but not least, the most affected companies would like to see **clear guidelines** from the EU Commission.

For any questions or comments, you'll find our contact details on the last page of this presentation.

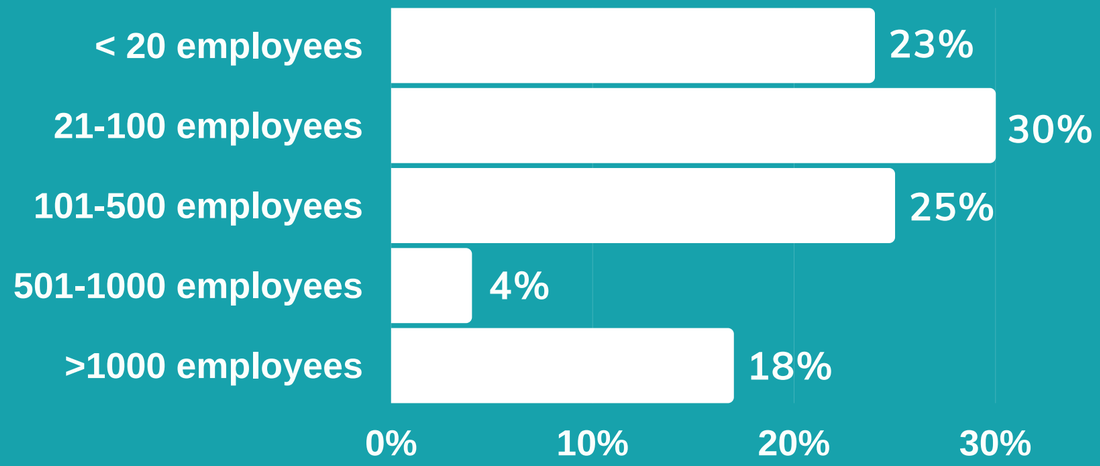
115

Survey participants

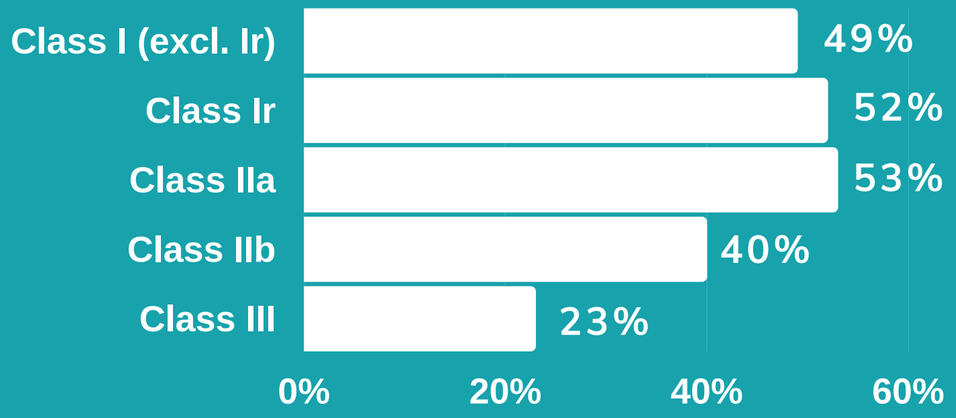
Company type



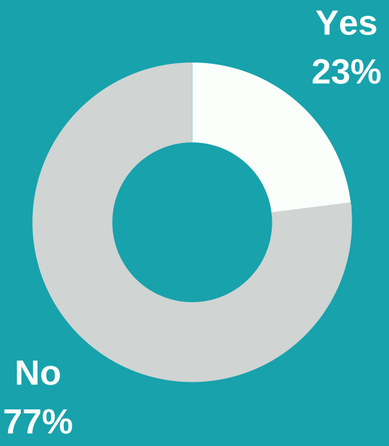
Company size



Device classes*

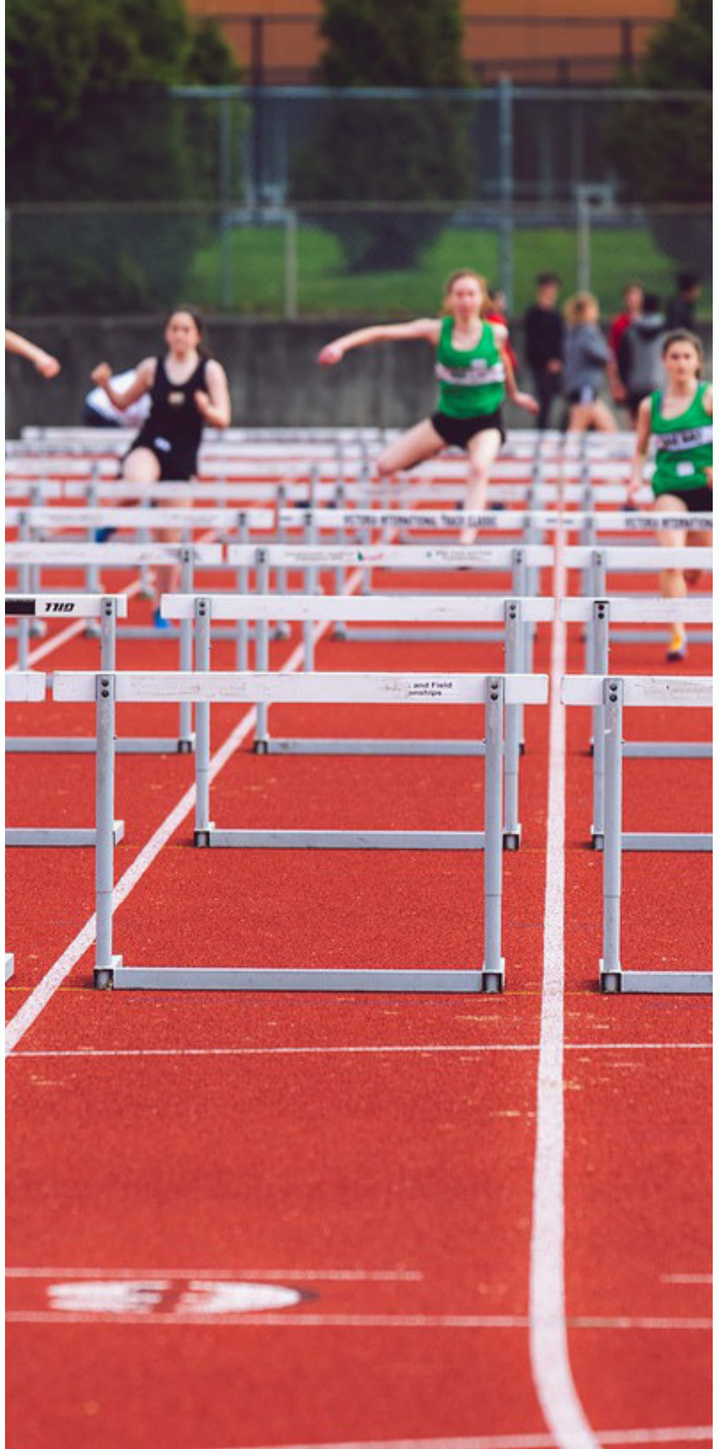


Already EU MDR certified?



*Multiple choice

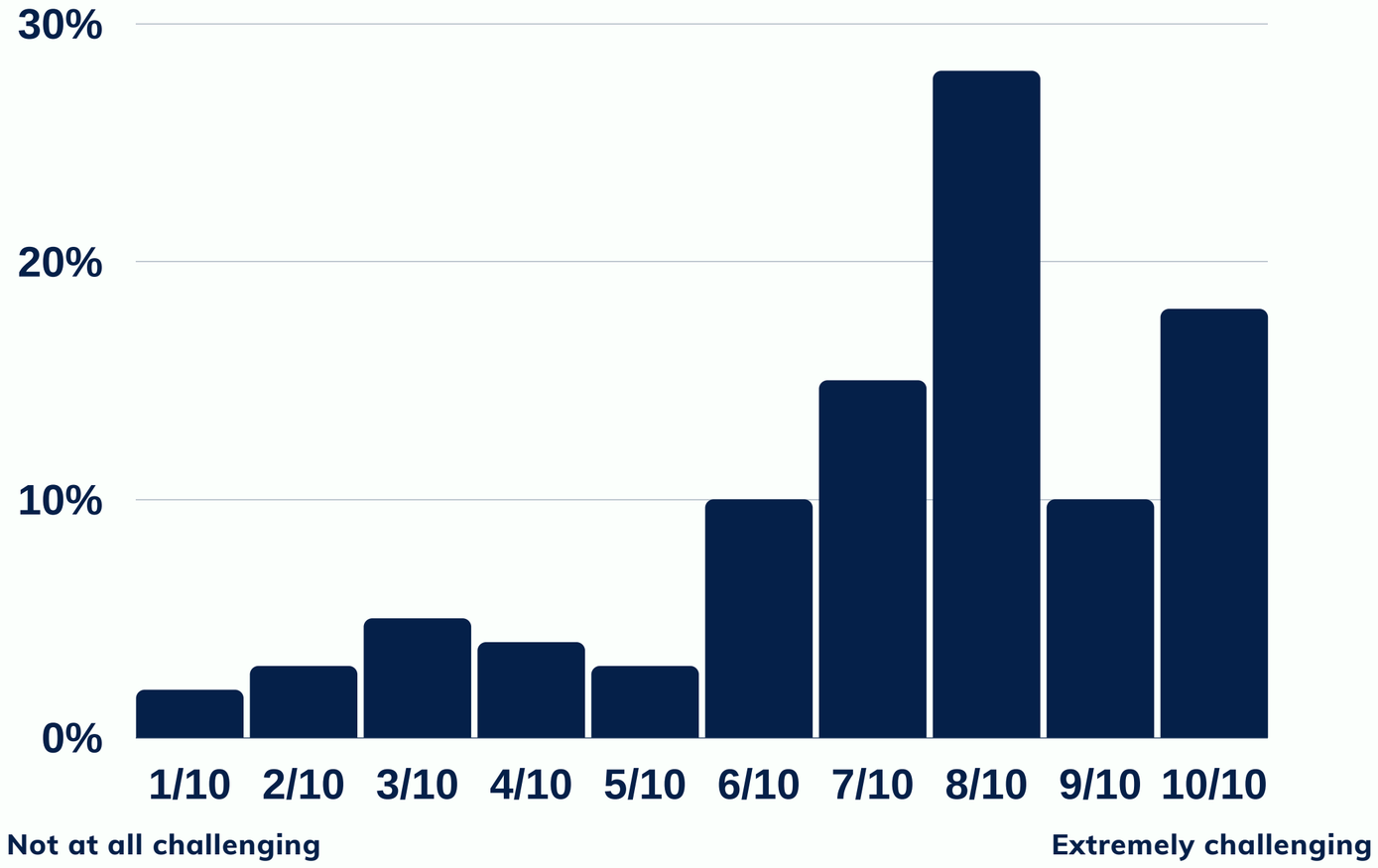
Barriers to EU MDR Implementation



81%

find the EU MDR very challenging. They rated it 6 or higher on a scale of 1 to 10.

How challenging is the EU MDR for your organization?

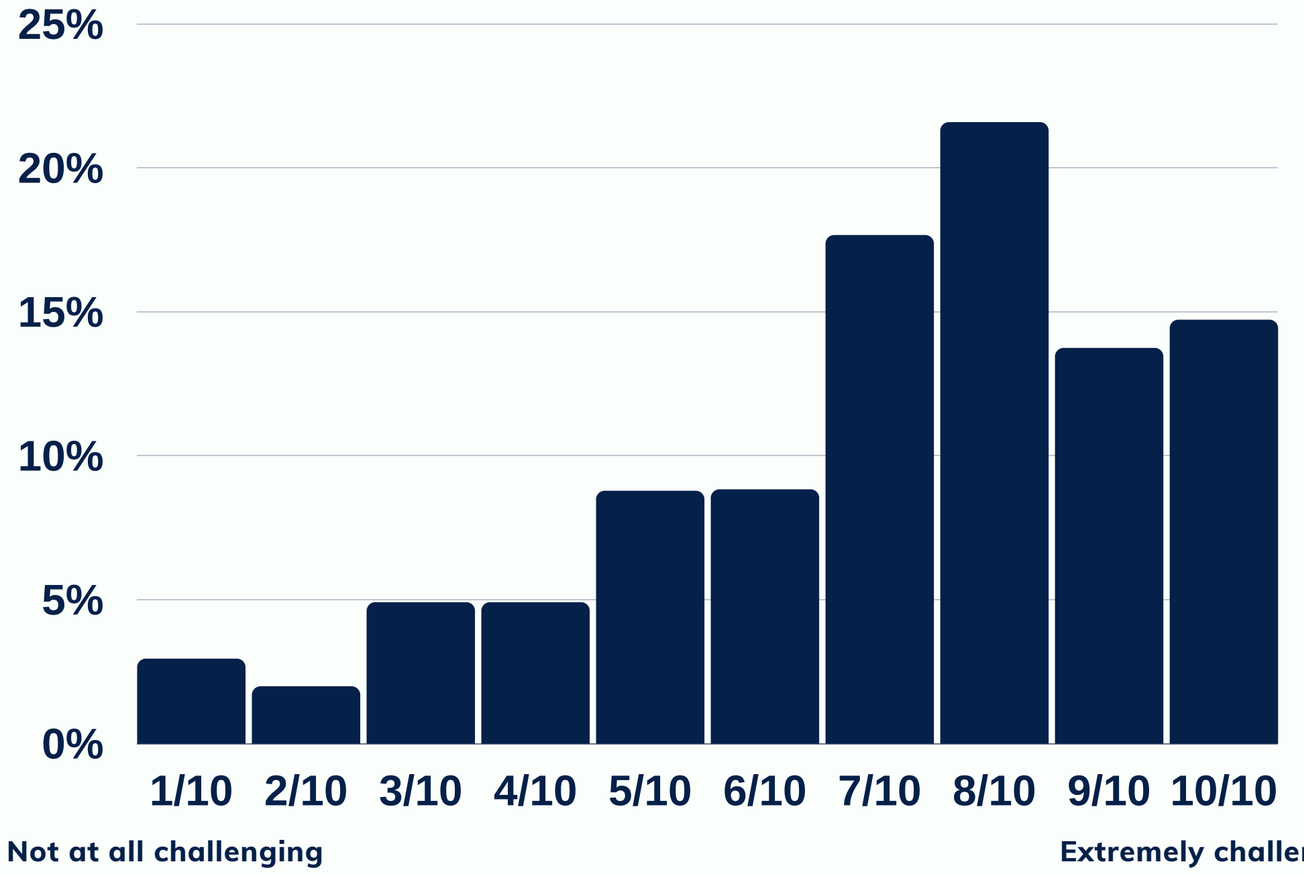


In 2020

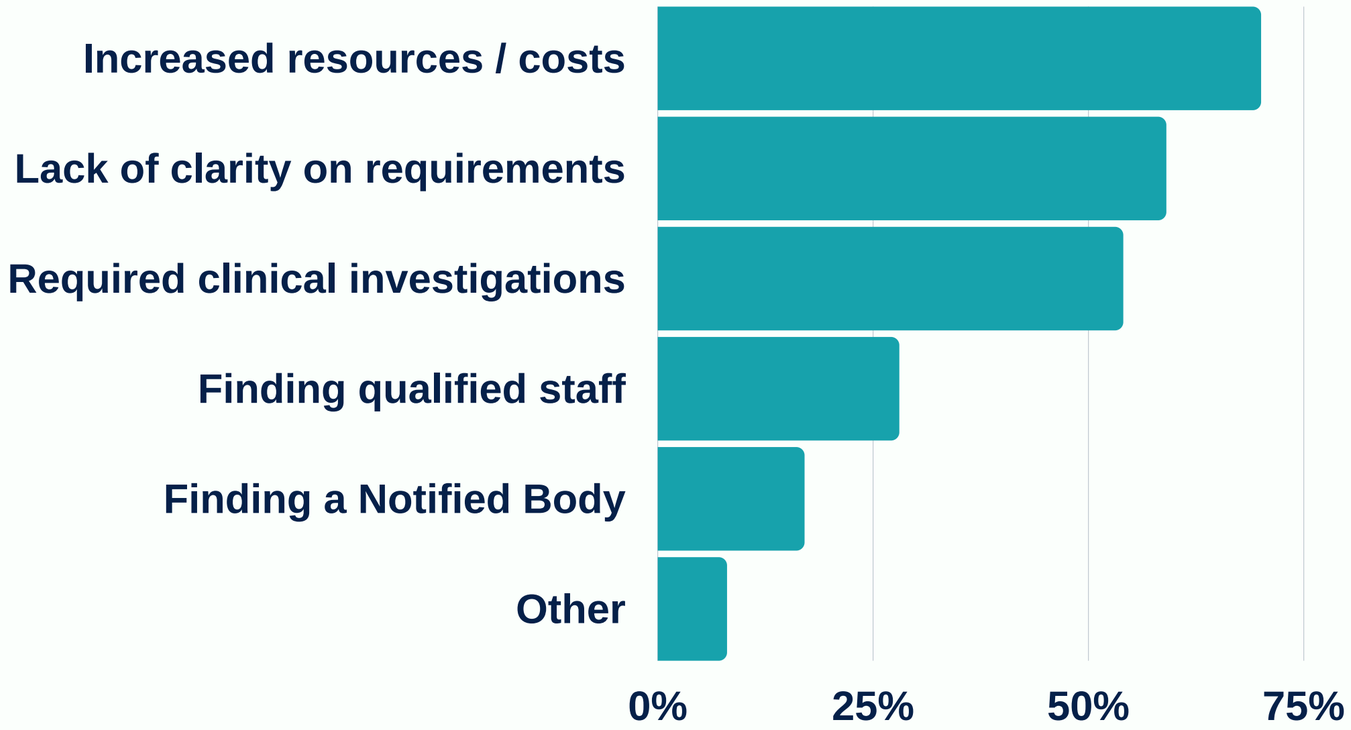
77%

found the EU MDR very challenging.

Comparison to 2020



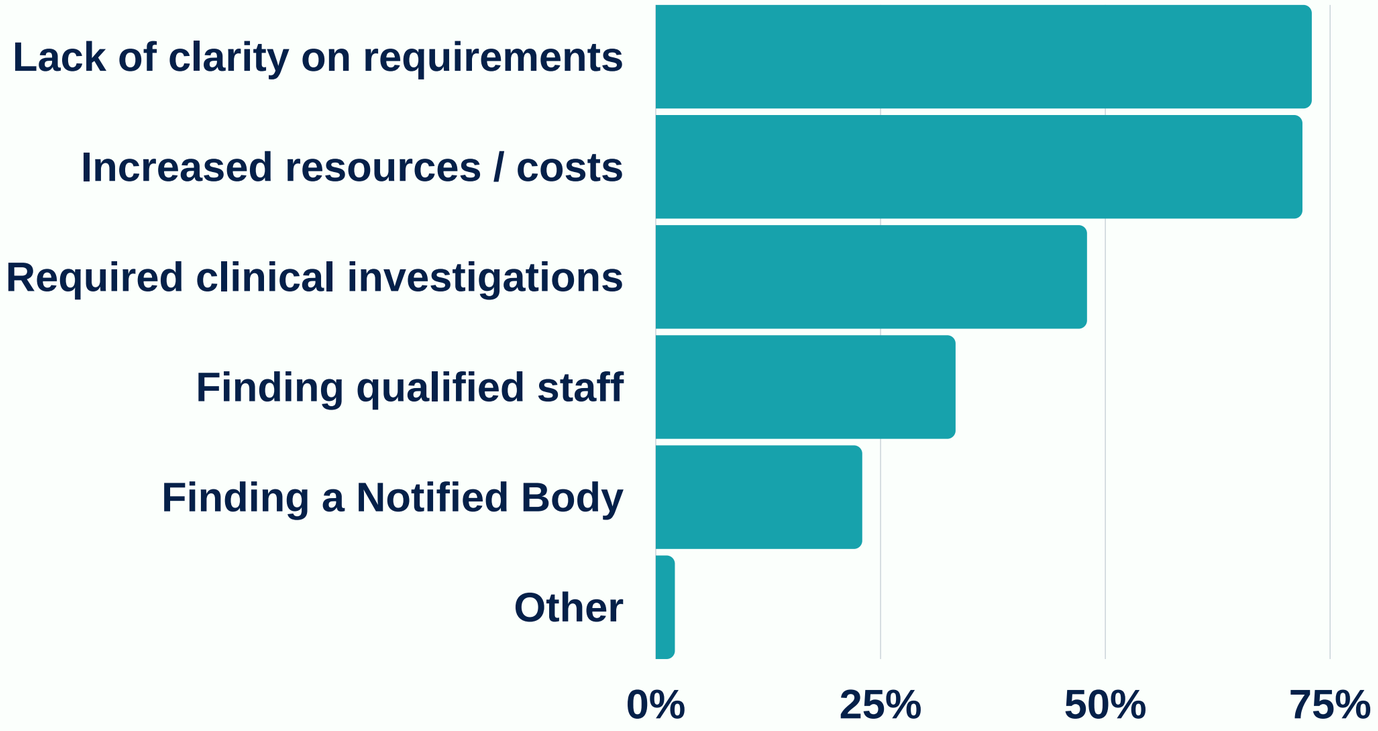
Which are your greatest challenges?*



*Multiple choice

"Increased resources / costs" (70%) and "Lack of clarity" (59%) were considered to be the greatest challenges for companies.

Comparison to 2020



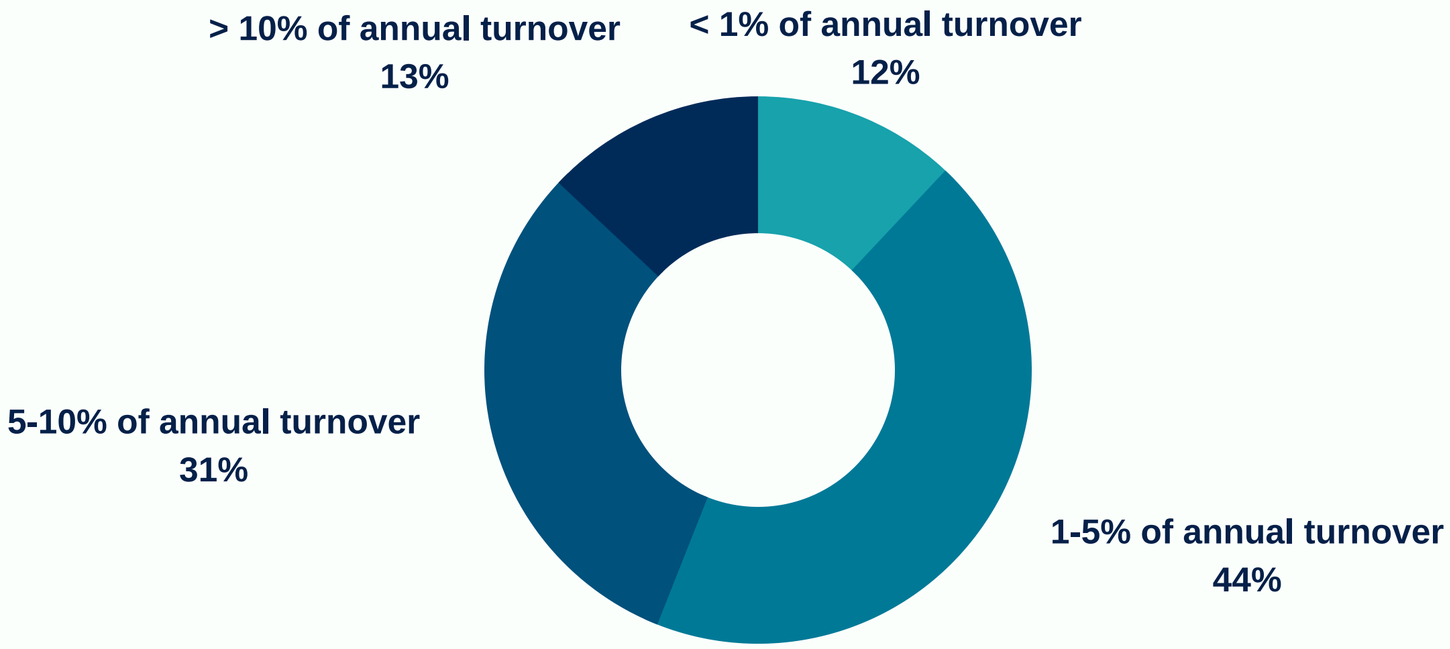
*Multiple choice

In 2020, "Lack of clarity" (73%) and "Increased resources / costs" (72%) were the greatest challenges.

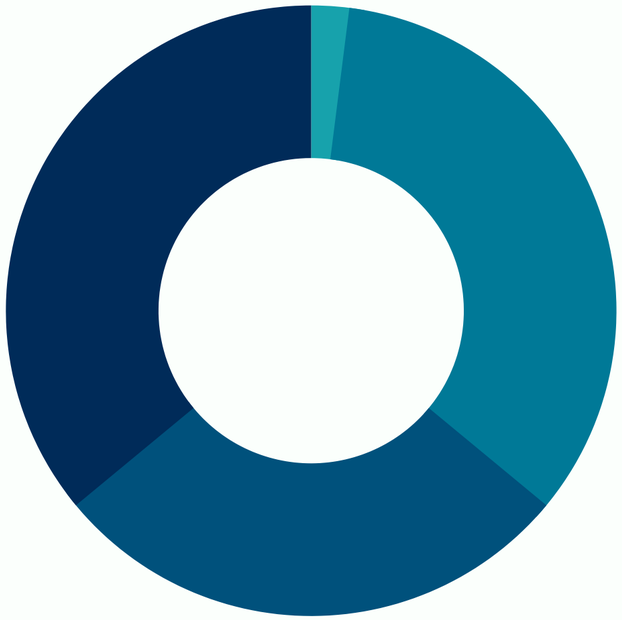
44%

believe that the EU MDR will cost their company more than 5% of their annual turnover.

How much additional cost do you think your company will incur due to the EU MDR?



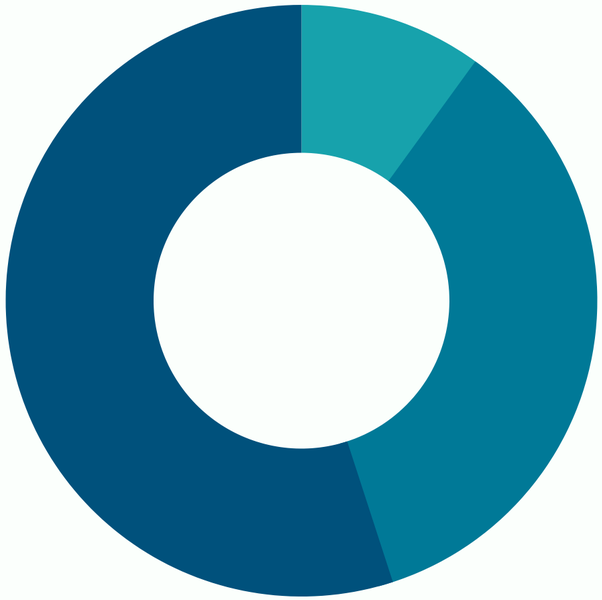
How many additional hours per week do you invest or plan to invest in meeting EU MDR requirements?



64%

invest more than 5 additional hours per week in meeting the EU MDR requirements.

Comparison to 2020



In 2020,

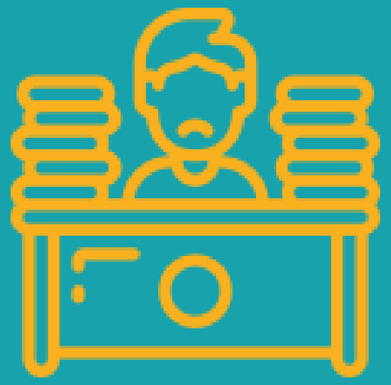
55%

invested more than 5 additional hours per week in meeting the EU MDR requirements.

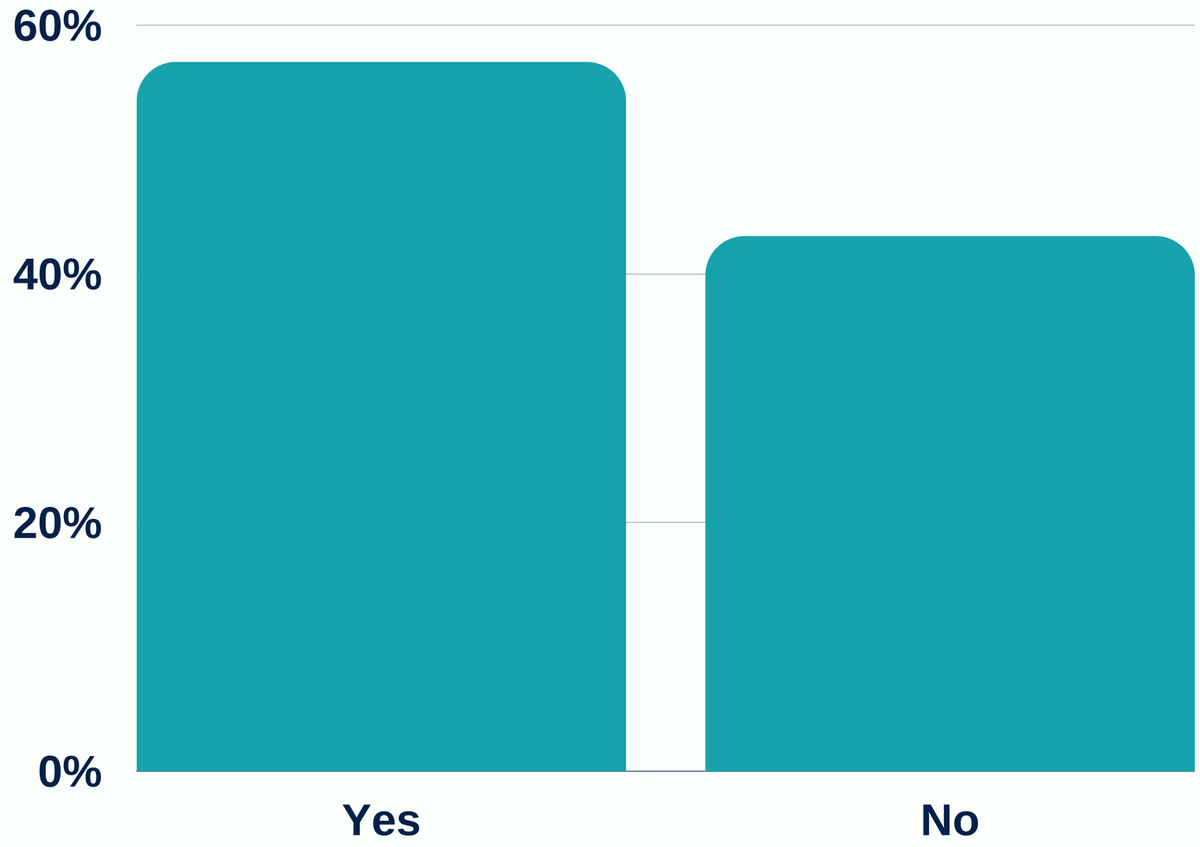
EU MDR Delay and Status of Notified Bodies

For **43%**

the EU MDR delay has not made their daily work any easier.



Has the postponement of the MDR made your work any easier?



Additional comments for "Yes" (57%) 👍

"The effort itself is of course the same, but there is more time available to master the challenges conscientiously."

"The time pressure, especially for the class I products, has been reduced a little."

"With limited resources, it always helps to have more time; it makes planning much easier. The extra time also helps the EU to publish guidance documents. There are more best practices to follow."

"More time for technical documentation."

"More time to implement the requirements and more time for the Notified Body to become certified."

"Timelines were extended; demands became clearer."

Additional comments for "No" (43%) 👎

"Expenditures have already been made, but Notified Bodies are taking longer to be certified, which delays the time to market."

"The postponement only reordered priorities, but did not relieve the pressure."

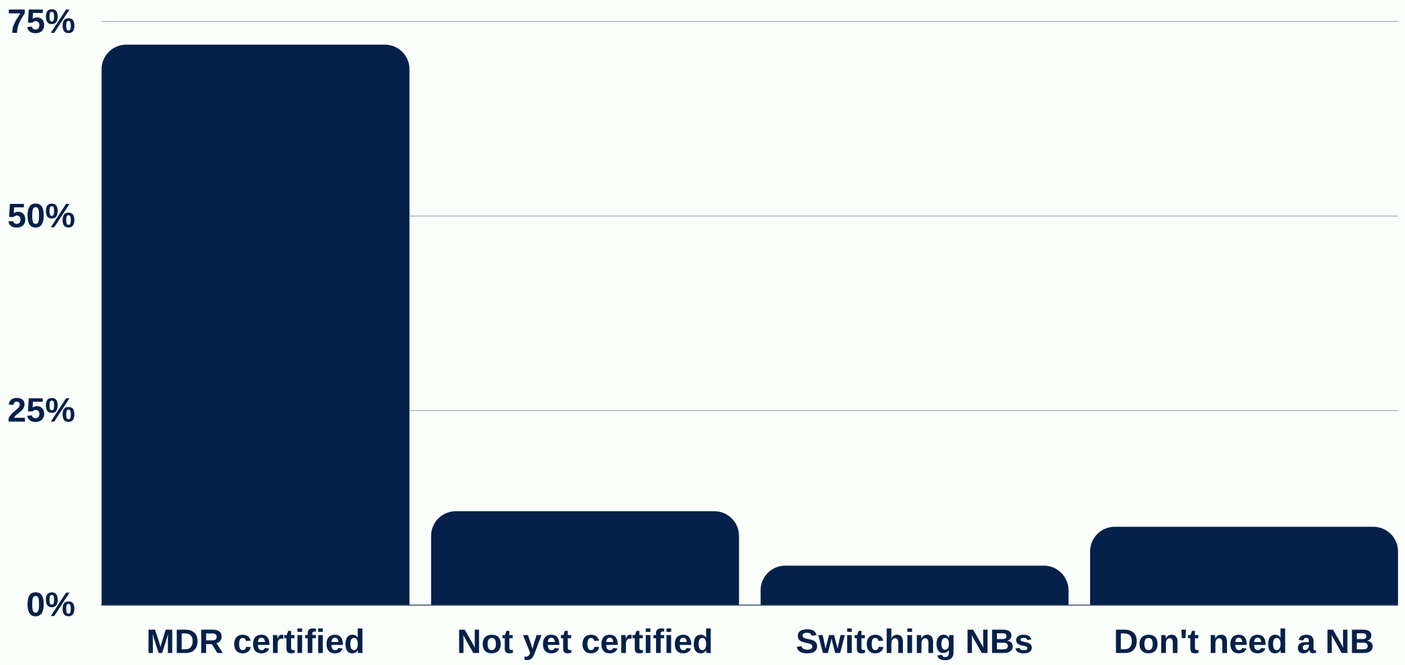
"Ambiguities remain, still too few Notified Bodies."

"We already had the MDR audit before the postponement date."

"The postponement has resulted in R&D or PM resources being put on short time and the company has temporarily reduced the priority on MDR."

"The focus in the last 12 months was primarily on maintaining the ability to supply pandemic-relevant products at short notice."

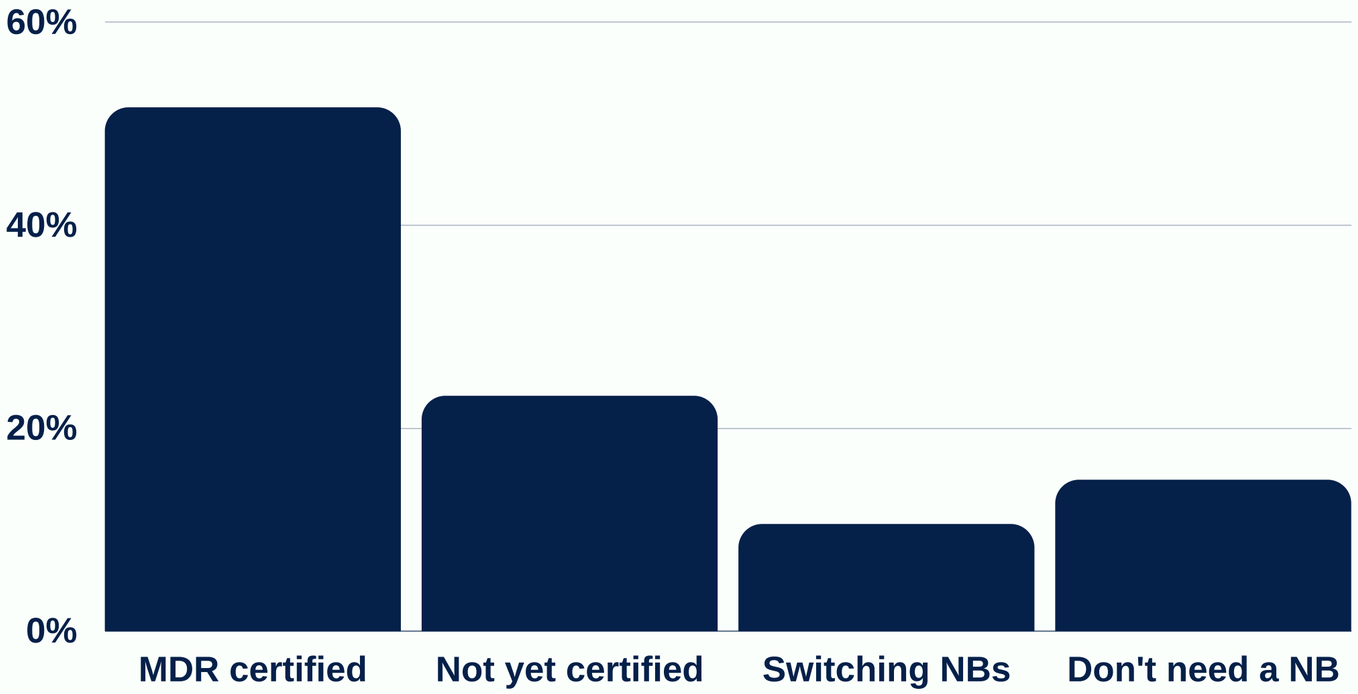
What is the status of your Notified Body (NB)?



72%

already have an MDR-certified Notified Body.

Comparison to 2020



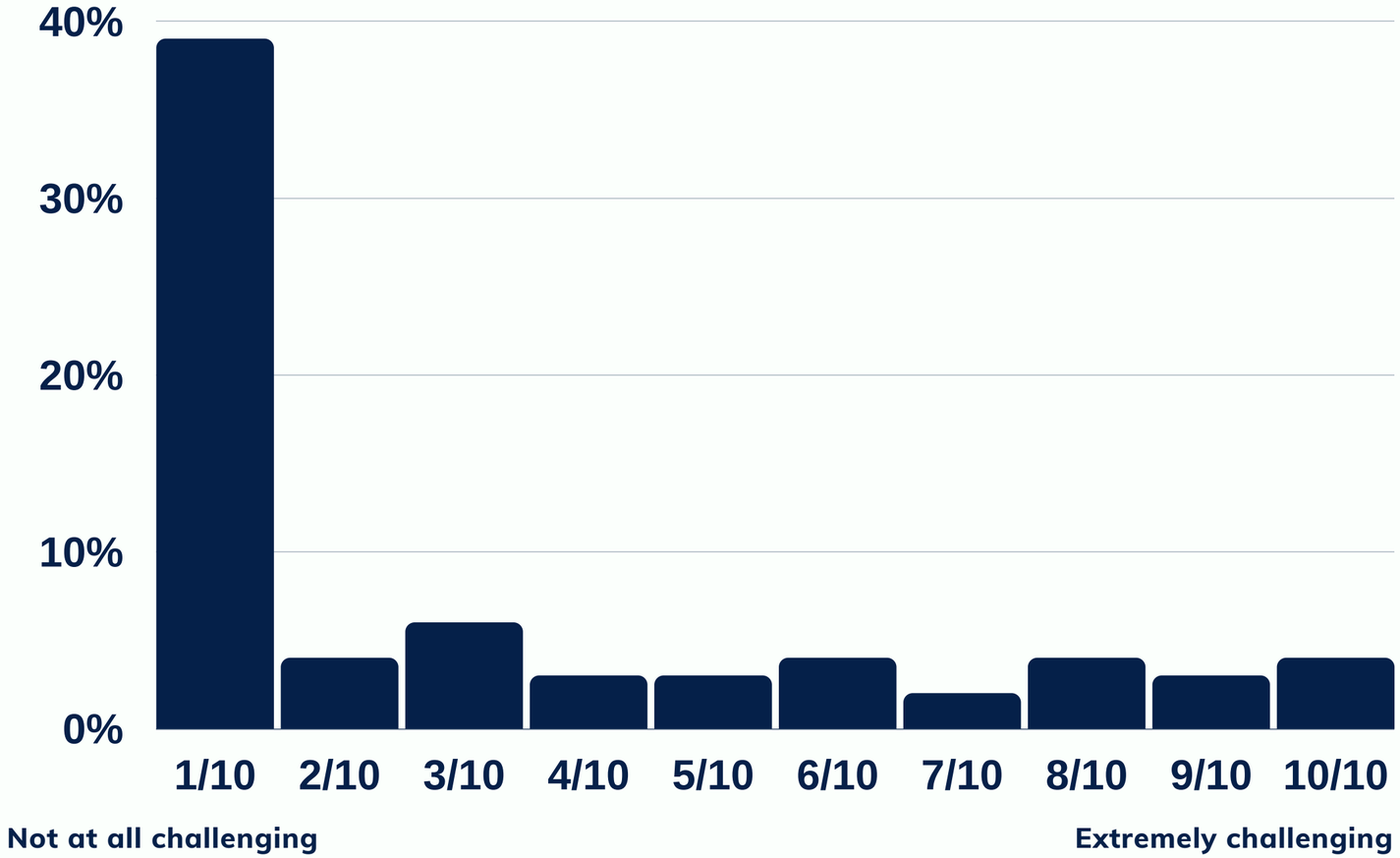
In 2020,

52%

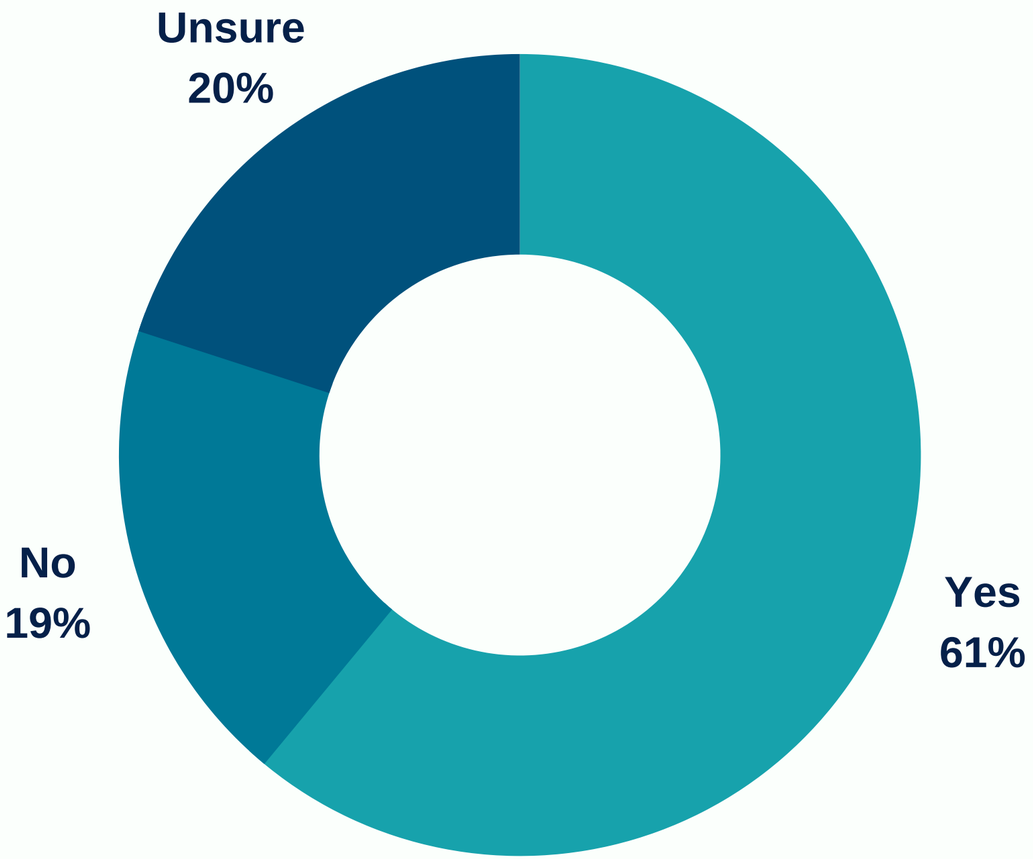
had an MDR-certified Notified Body.

For **39%**
it was not at all challenging to find a Notified Body.

How challenging was it for you to find an MDR-certified Notified Body?

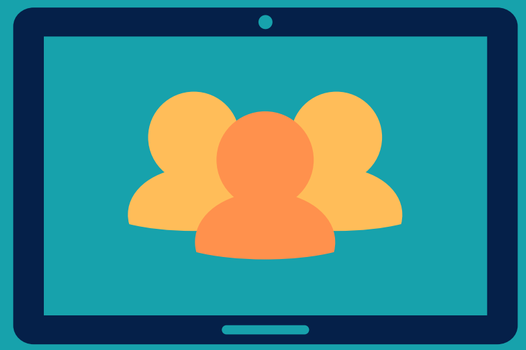


Have you made use of virtual audits or do you plan to?



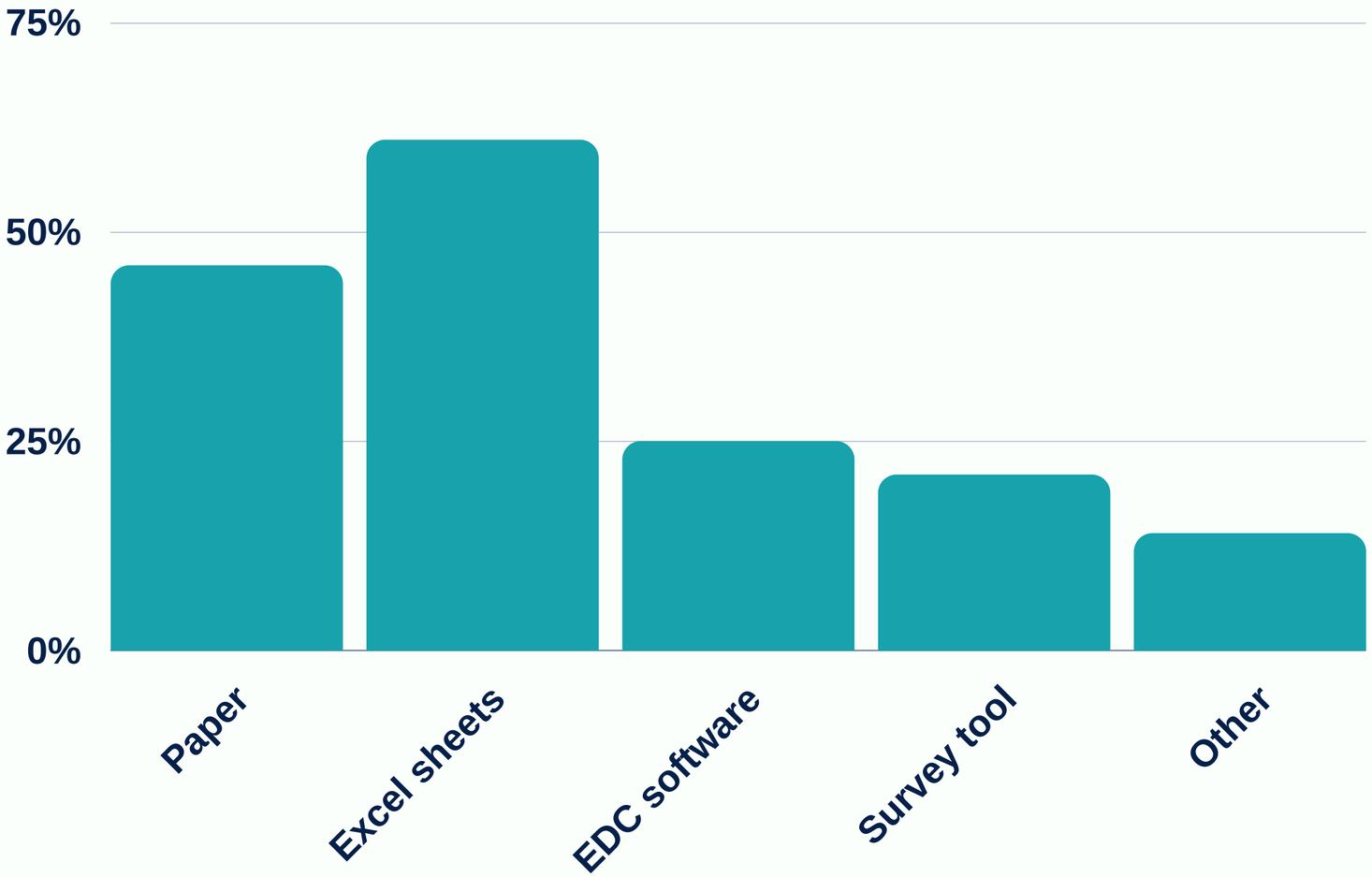
61%

have made use of virtual audits or plan to do so.



Clinical Data Capture

Which system(s) do you use for your clinical data capture?*



*Multiple choice

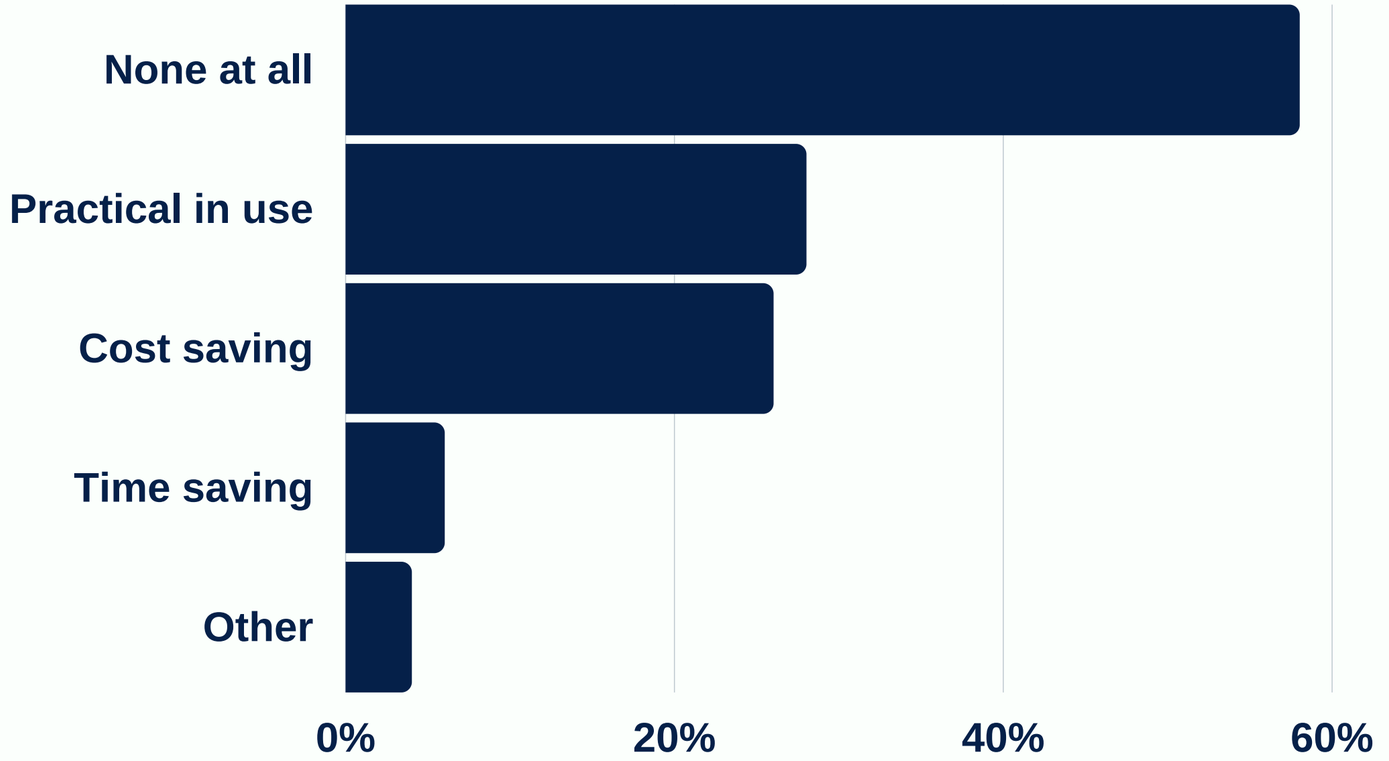
Just

25%

use an Electronic Data Capture system for their clinical data capture.

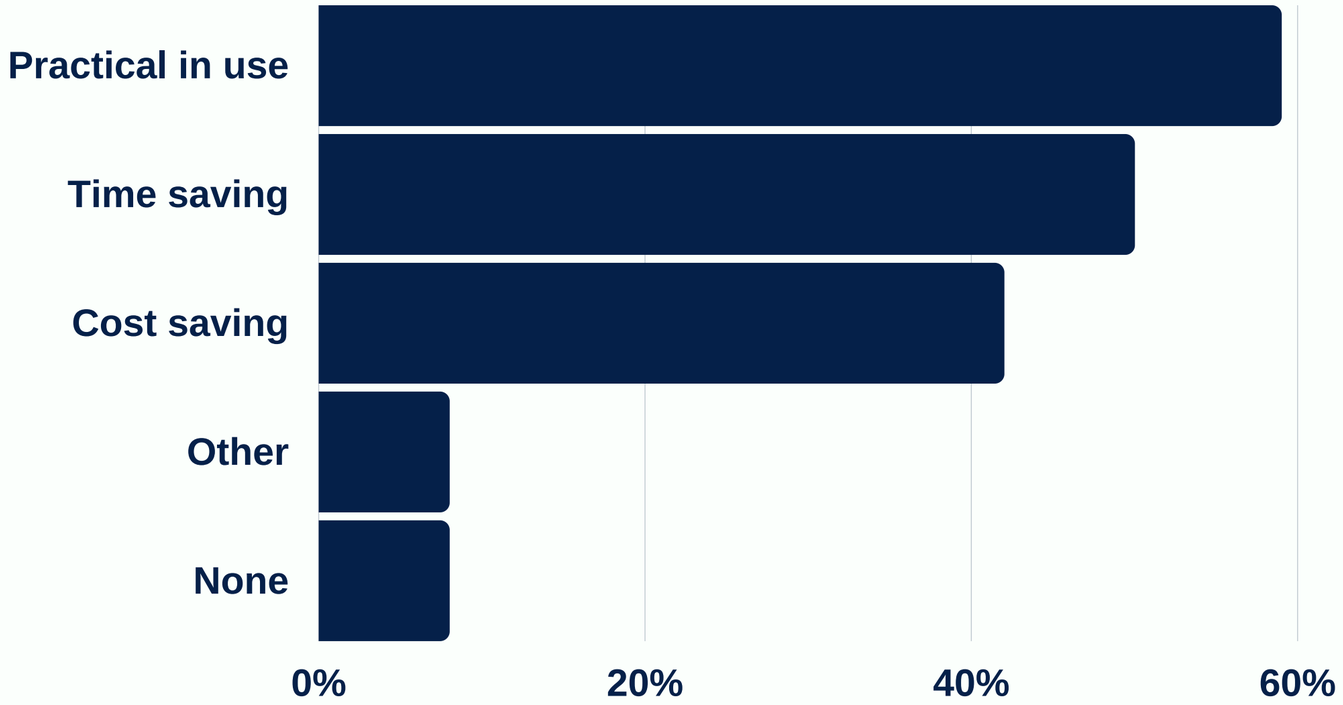
58% see "No benefits at all" in the usage of paper and/or Excel, and 28% find them "Practical in use."

For paper and/or Excel: Which benefits do you see in the system(s)?*



*Multiple choice

For EDC-Software: Which benefits do you see in the system?*

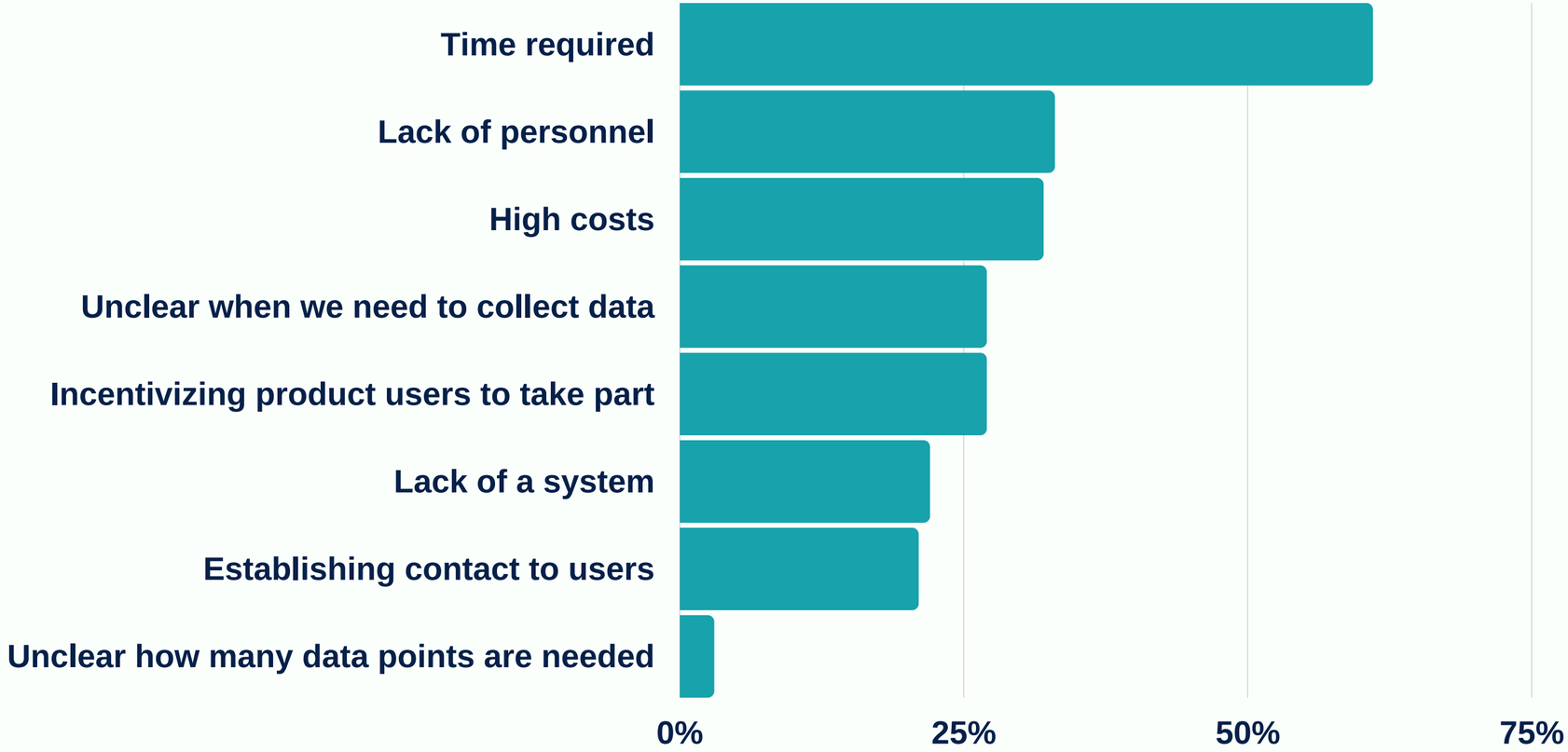


*Multiple choice

59% find EDC Software to be "Practical in use" and 50% find it to be "Time saving" .

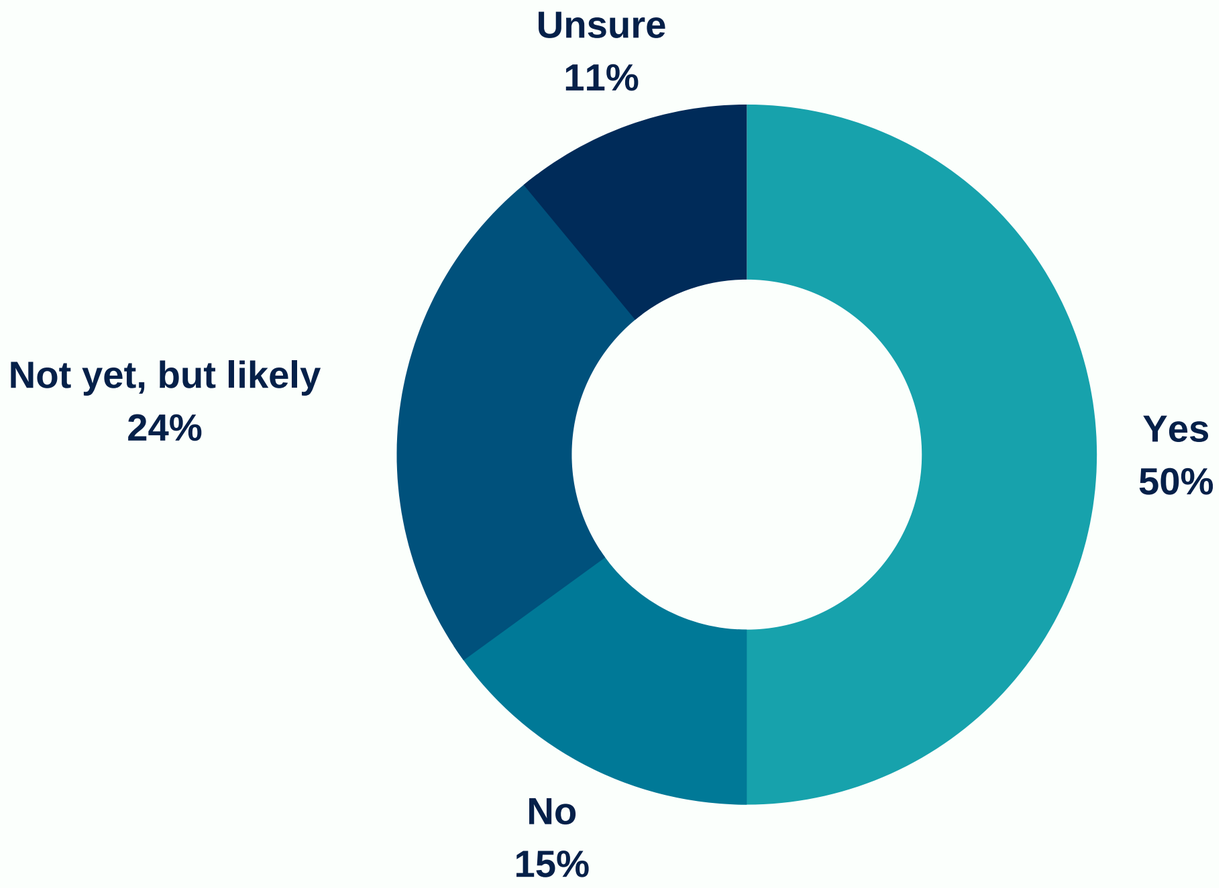
The greatest challenges in clinical data capture are "Time required" (61%), "Lack of personnel" (33%) and "High costs" (32%).

Which challenge(s) do you face in terms of your clinical data capture?*



*Multiple choice

Do you need to conduct PMCF activities?



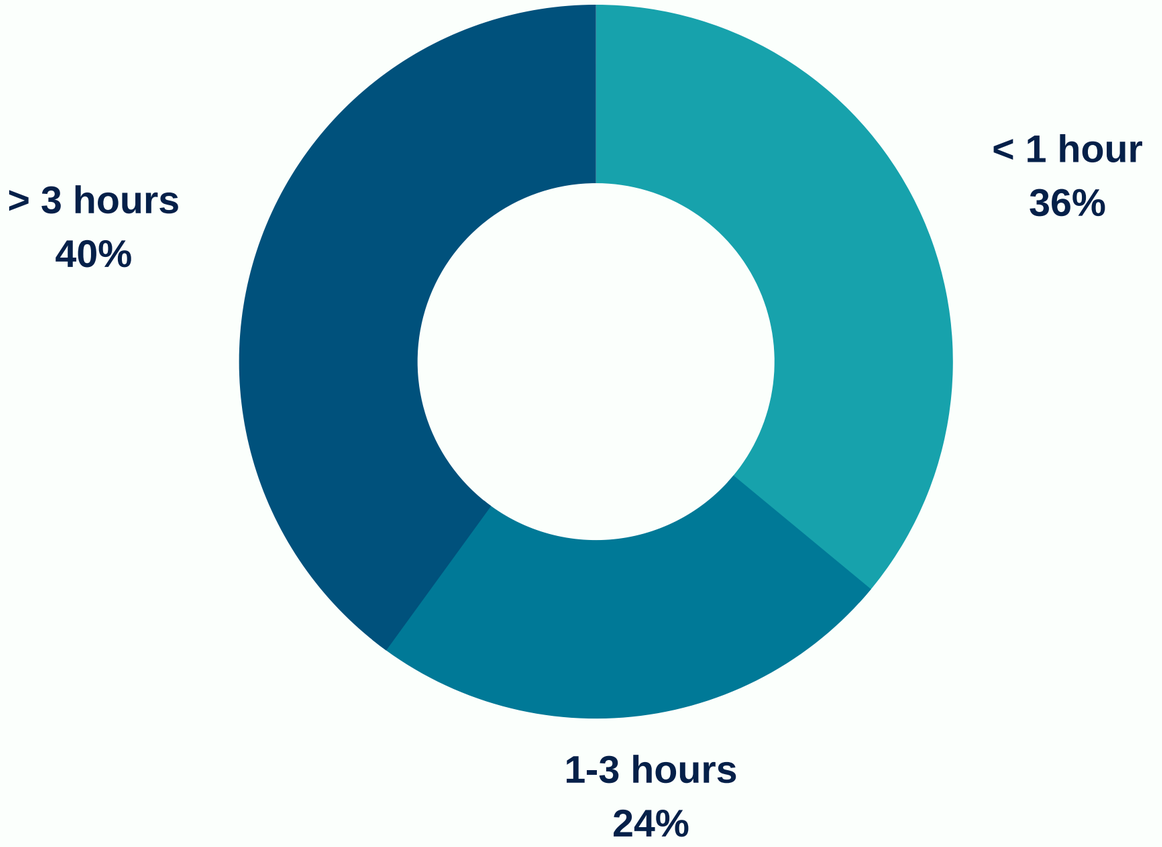
50%

need to conduct PMCF activities.

40%

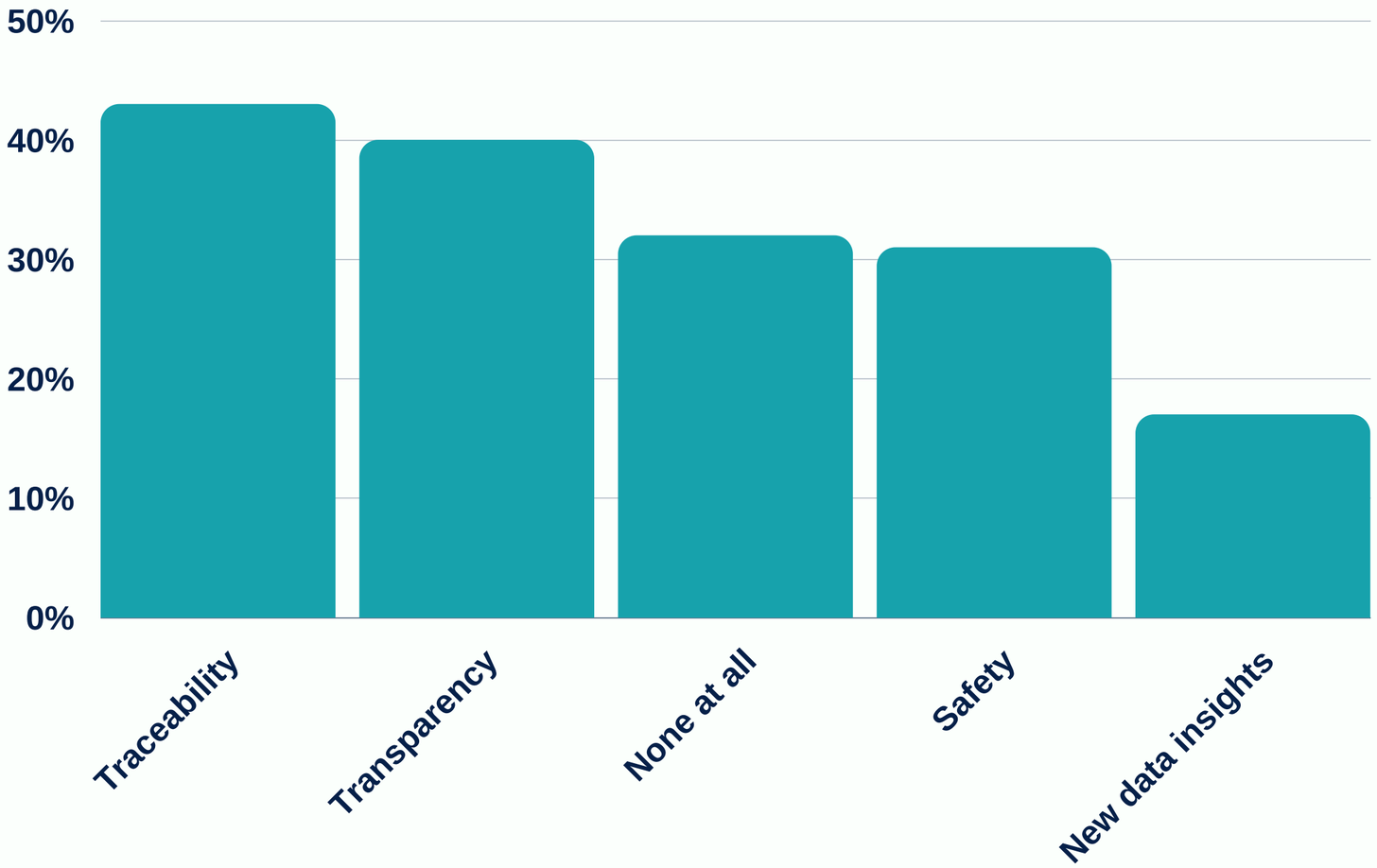
spend more than 3 hours per week communicating with stakeholders.

How much time per week do you spend communicating with relevant stakeholders in your PMCF studies?



A Look at the Future

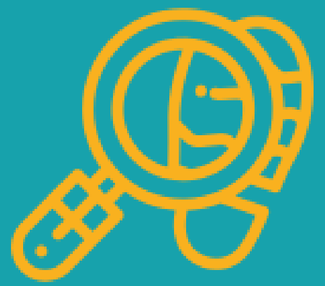
Which advantages do you see in the EU MDR?*



*Multiple choice

43%

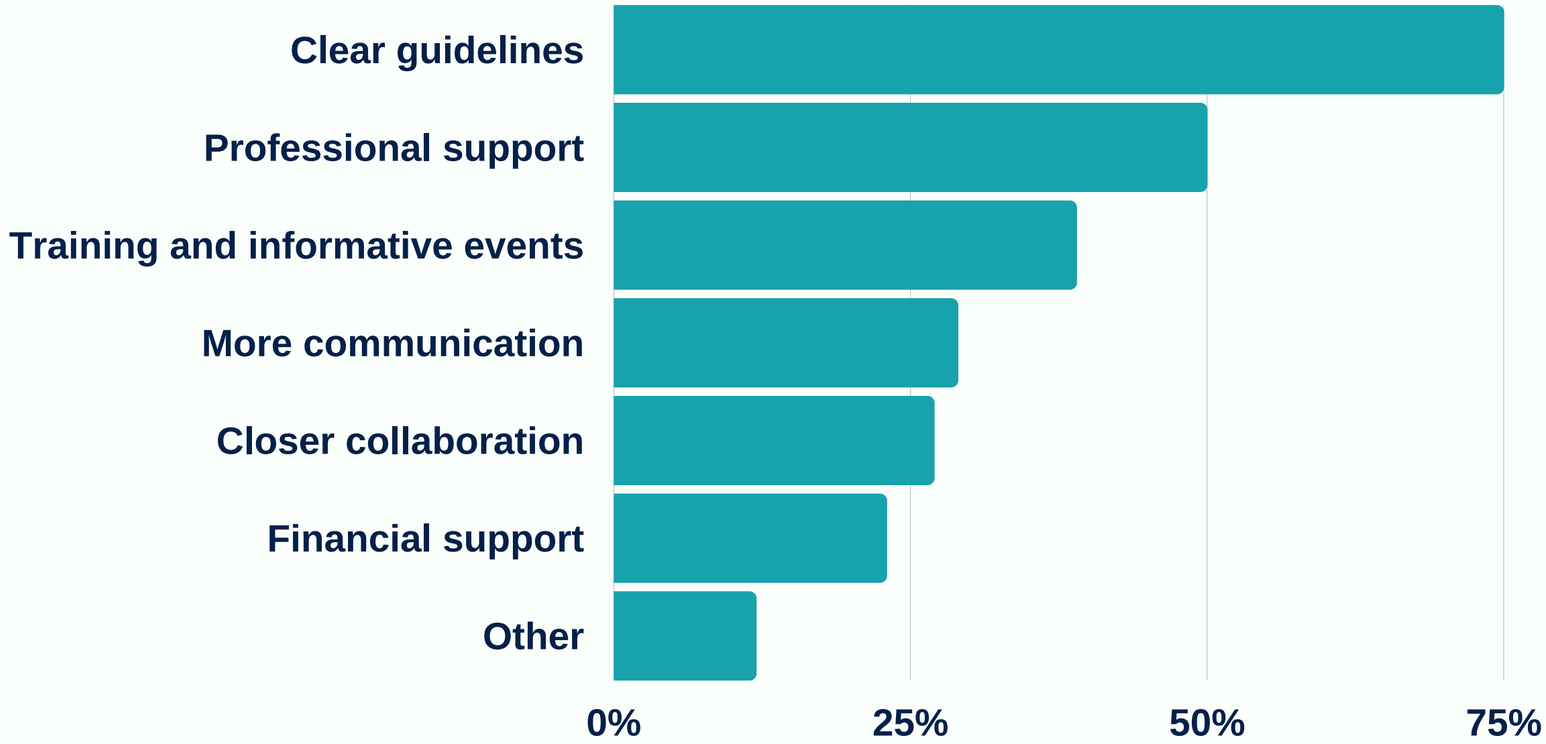
consider "Traceability" to be the greatest advantage of the EU MDR. 32% see "No benefits at all".



75%

would like to see "Clear guidelines" from the EU Commission, and 50% want more "Professional support".

What would you like to see from the EU Commission?*



*Multiple choice

Is there anything else you would like to share with us?

"Especially for Class I products, the MDR appears to overshoot the target."

"Very time-consuming process with unclear future. Lack of practical understanding about what hospitals need. Could lead to a shortage of products in EU hospitals."

"The MDR is well-intentioned, but it's becoming a bureaucratic monster due to accreditation and certification. It leads to products being discontinued and no longer available to patients."

"In Europe, we miss the equivalent of interactions proposed by the FDA, like pre-submission meetings. This would be really efficient in terms of innovation processes, patient benefits and translation of technologies into clinical solutions."

"The MDR is an additional burden on companies, making them less and less competitive compared with Asian manufacturers."

"The Commission is not practice-oriented."

Want to learn more about digitalizing your clinical data capture for the EU MDR? Get in touch!

Catherine Higginson

Marketing Manager
catherine.higginson@climedo.de
+49 89 3220 9394 7

Johann Weier

Account Executive
johann.weier@climedo.de
+49 151 74 35 1854

Amelie Fink

Account Manager
amelie.fink@climedo.de
+49 175 95 08 654

Climedo Health GmbH
Schellingstr. 109a
80798 Munich
Germany
info@climedo.de
+49 89 32209394 0