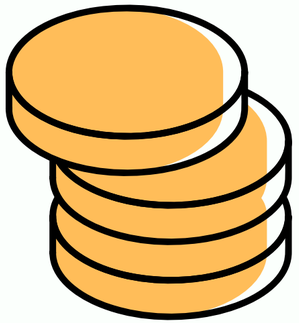
STATE OF THE MEDTECH INDUSTRY

Climedo HEALTH

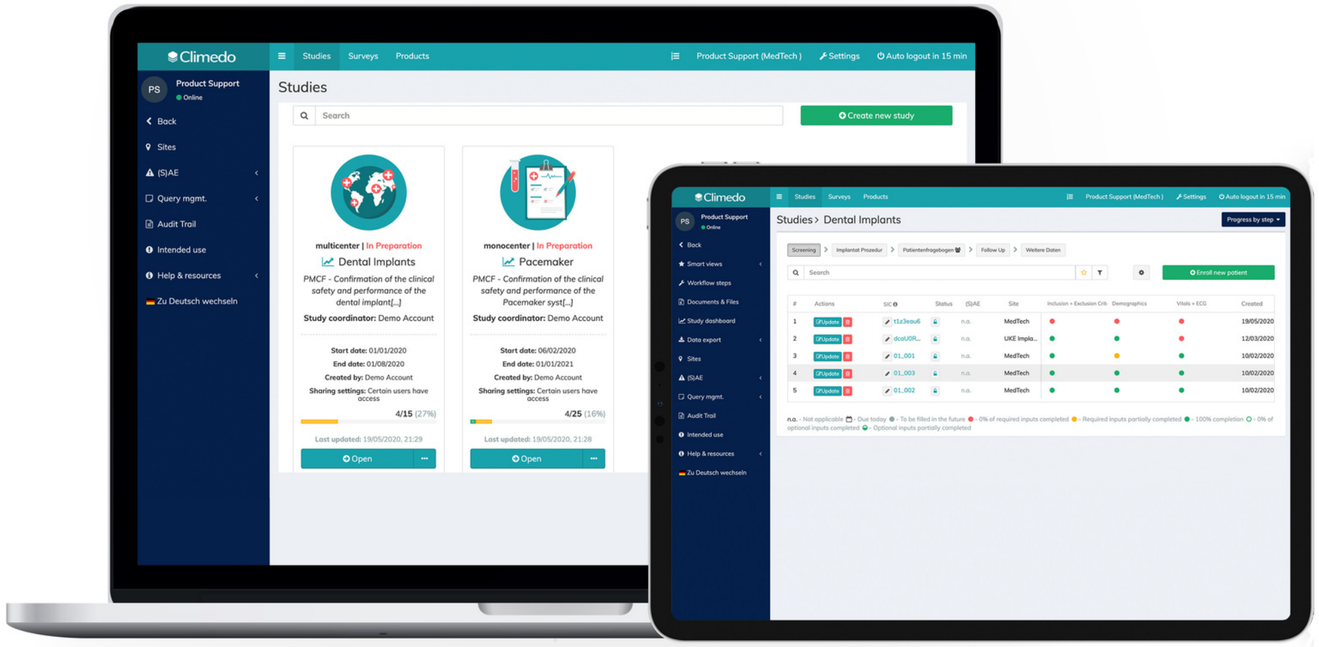


EU MDR Survey
The True Cost of the New Regulation

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, they 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, pharmaceutical companies, CROs, hospitals and patients), Climedo allows for increased performance, better cost-efficiencies – and ultimately – accelerated medical innovation. Learn more at www.climedo.com.



Executive Summary

The delay of the EU MDR's validity date until May 2021 most likely came as a great relief to most medical device manufacturers. Nevertheless, there is a lot of unrest in the MedTech market. In August 2020, Germany's BVMed association called for a one-year delay of the grace period (analogous to the regulation's delay), the swift certification of new Notified Bodies, necessary expert committees for Class III implants, legal acts and missing guidelines, as well as the assurance of a working EUDAMED database.

Following our EU MDR Readiness Survey in March 2020, which showed that many companies were not yet prepared for the new requirements, this survey explores the actual costs of the new regulation for companies. Among other things, we wanted to find out how much time, money and human resources are required to meet the new regulatory demands. In addition, participants were asked which systems they currently use for clinical data capture, how time this clinical data management is and to what extent they have already automated their post-market processes.

The survey was conducted between July and August 2020. In total, around 100 companies took part, the majority of them (77%) medical device manufacturers. For most companies, the EU MDR appears to be a very expensive and complex matter. Almost half of them believe that they will invest more than 5% of their annual turnover in meeting the new requirements. More than two thirds have hired or plan to hire at least one new employee to cope with MDR and more than half are investing more than 5 additional hours per week in meeting the obligations. At the same time, there is still a lot of room for improvement in the digitalization and automation of certain processes, such as PMCF. Only 11% use an EDC solution for their data collection – an essential part of MDR – and 51% have not yet automated any PMCF processes.

If you have any questions or comments, you will find our contact details on the last page of this presentation.

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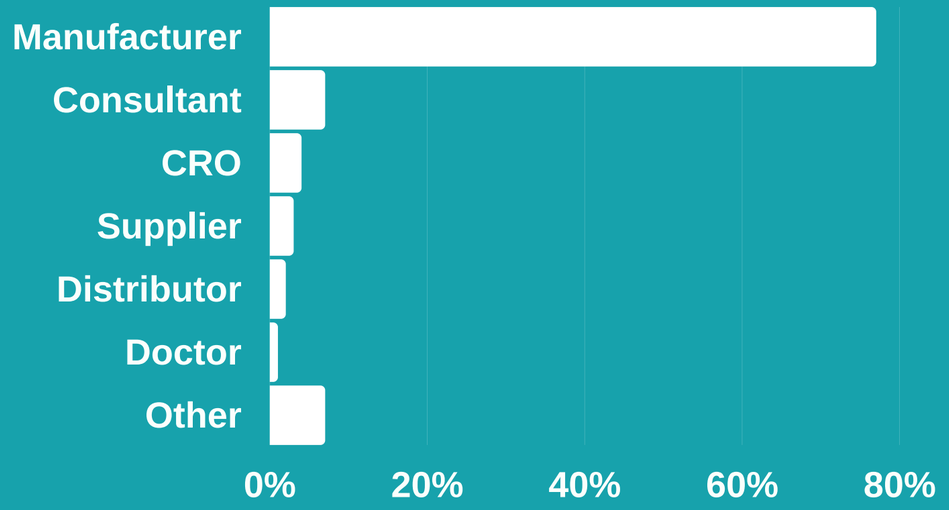
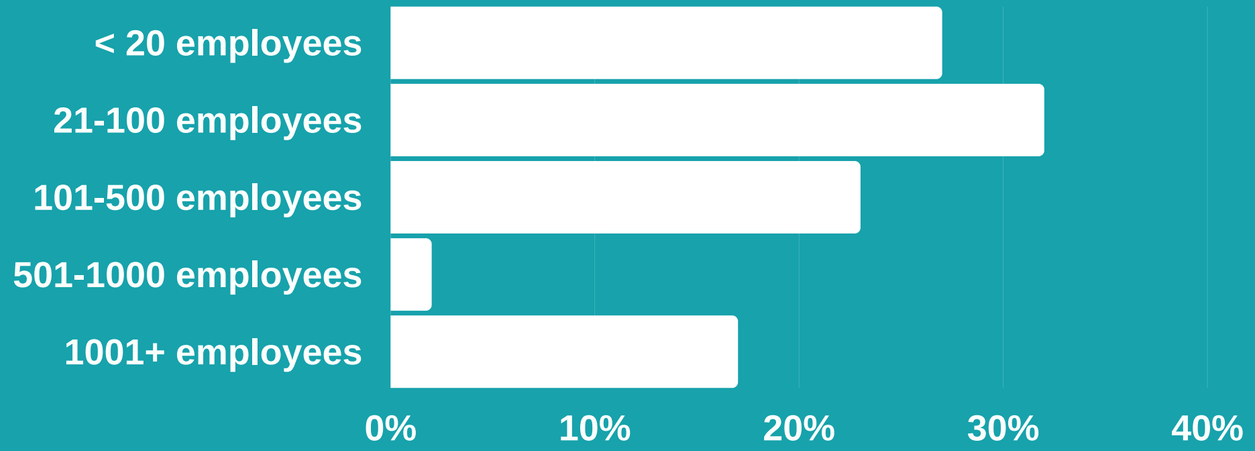
Survey Participants

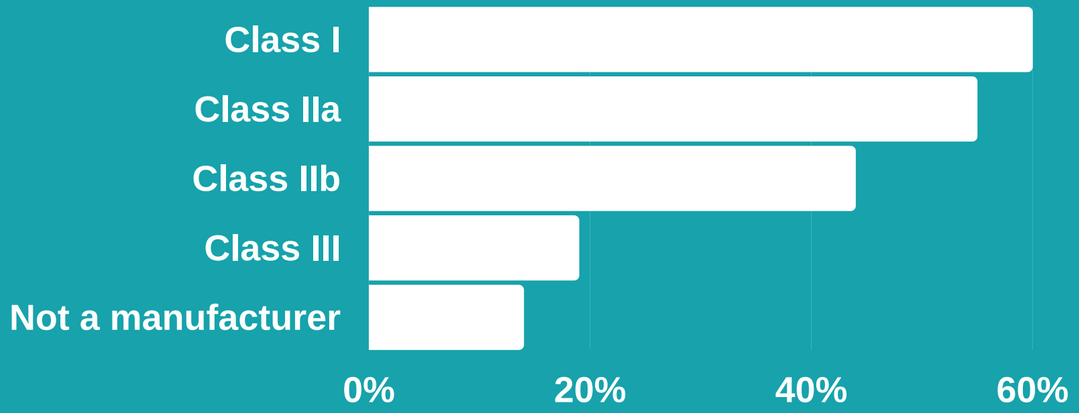
Company / profession



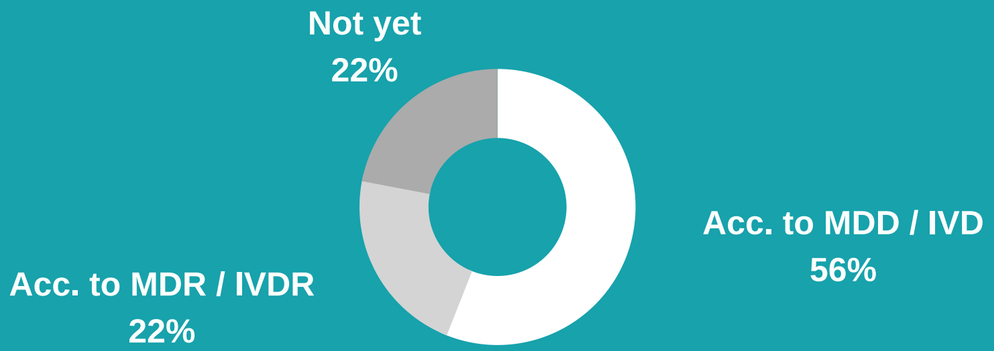
Company size



Device risk class*



Already certified?



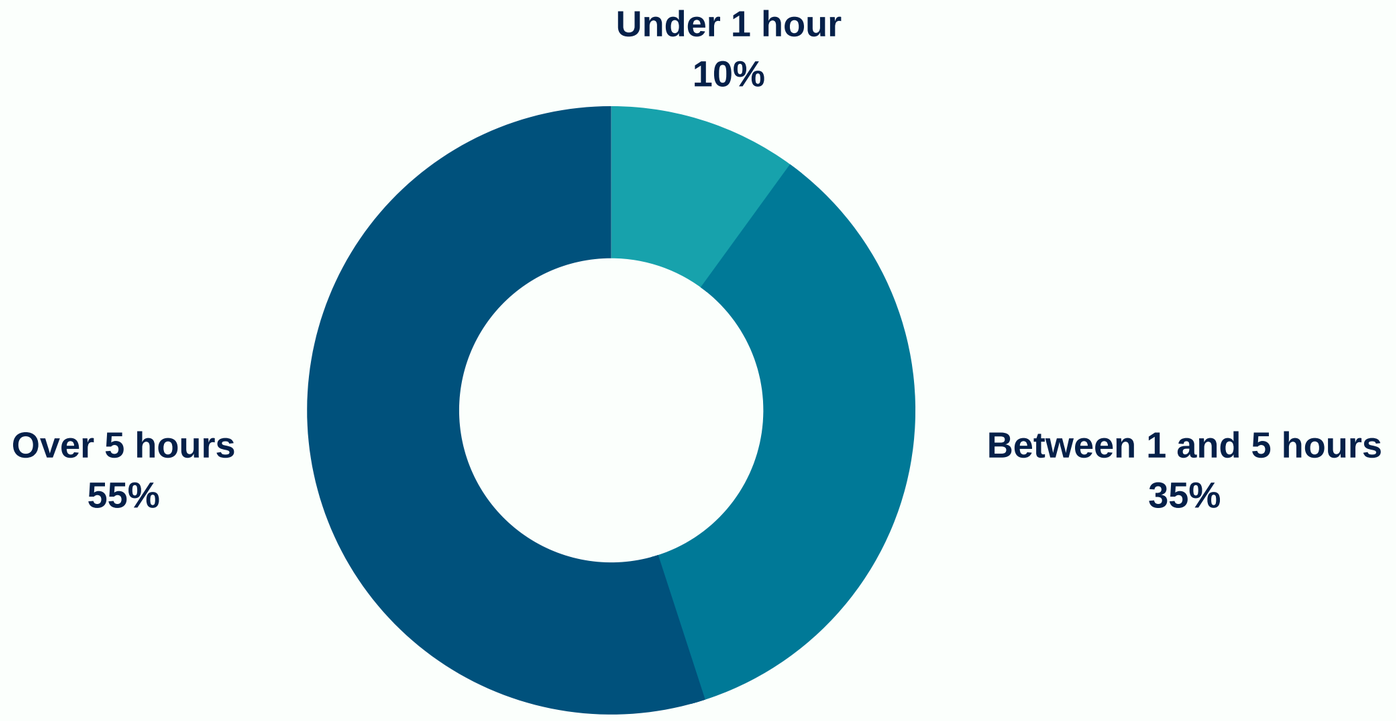
*Multiple choice

Implications of the EU MDR for Companies

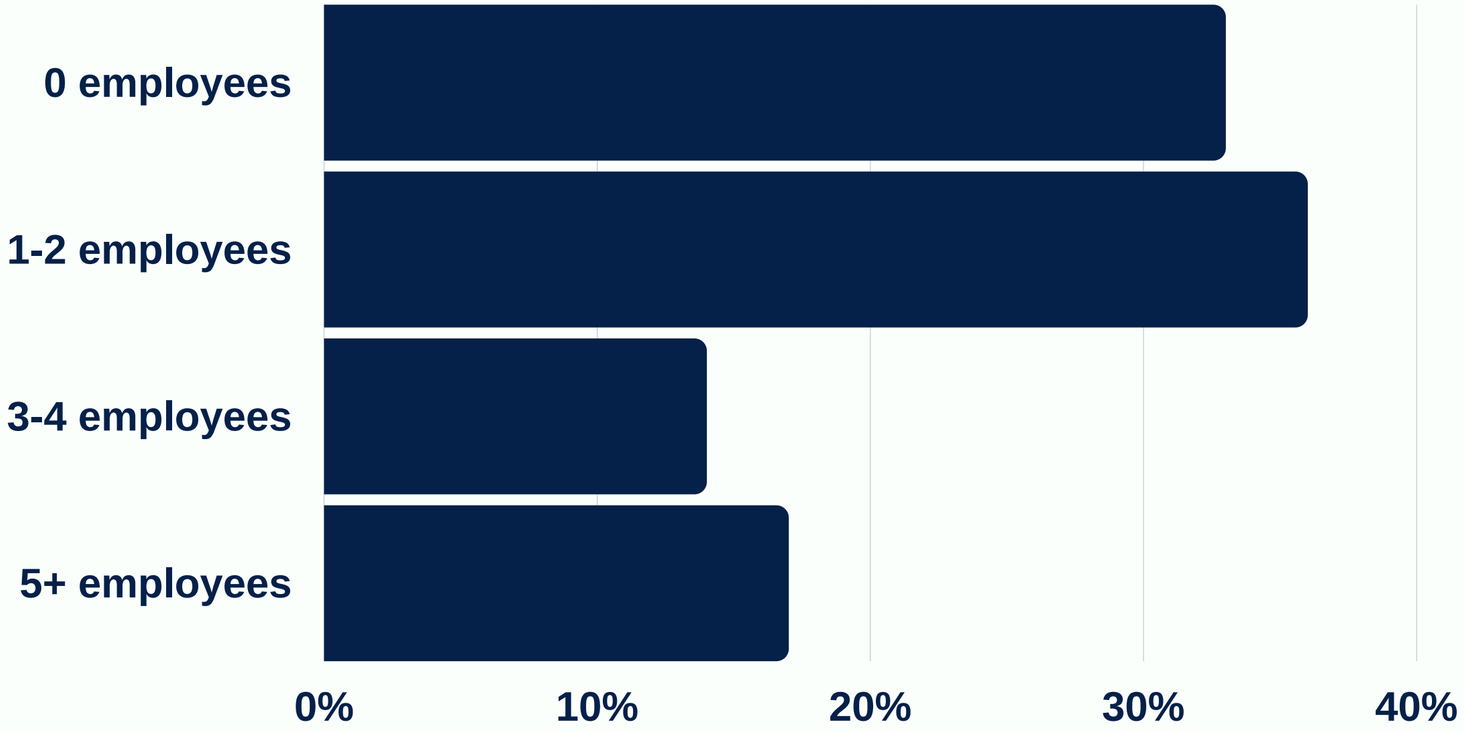
55%

invest more than 5 additional hours per week in the fulfilment of the MDR demands.

How many additional hours per week are you investing or do you plan to invest in the fulfilment of the EU MDR demands?



How many new employees have you hired or do you plan to hire to manage the EU MDR requirements?



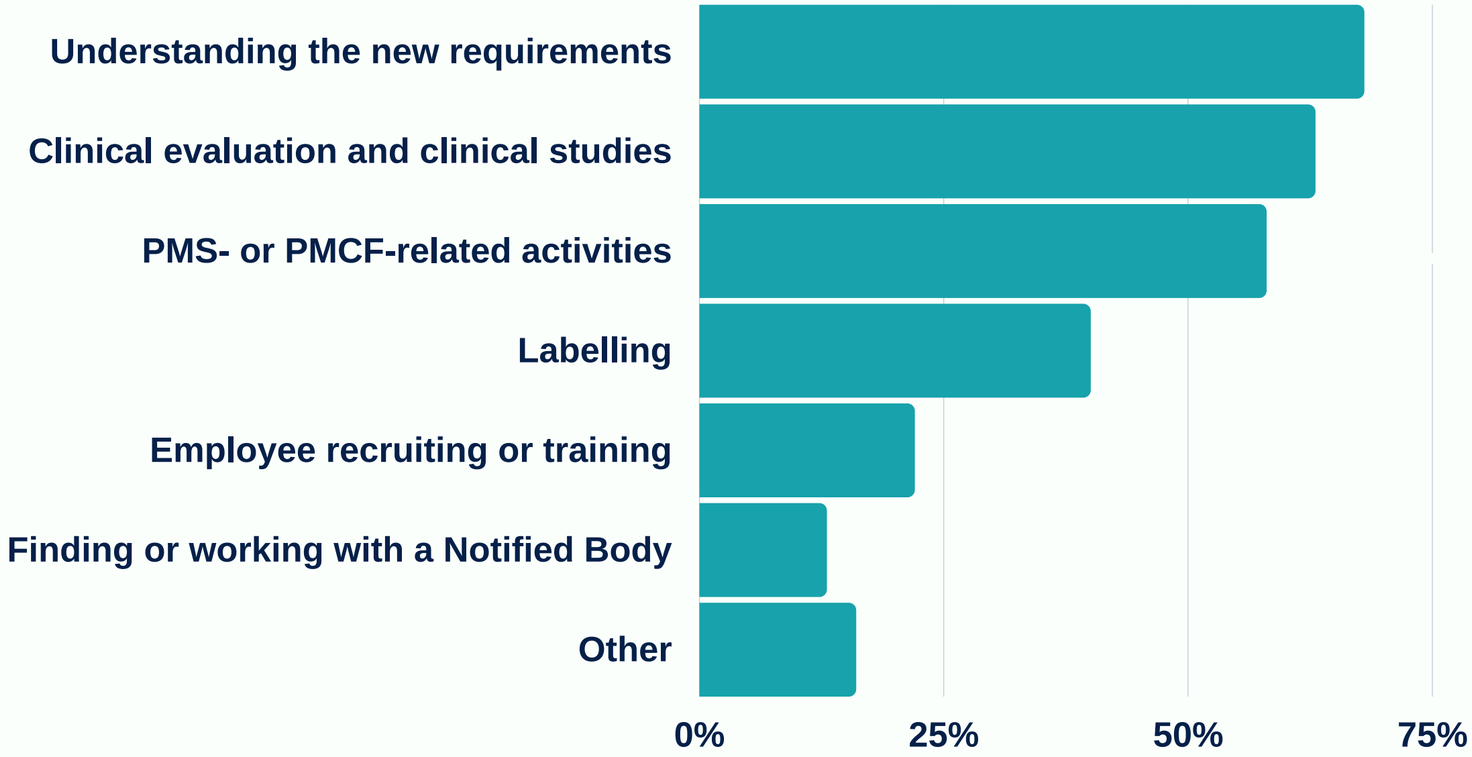
67%

have hired or plan to hire at least one new employee due to the EU MDR.

68%

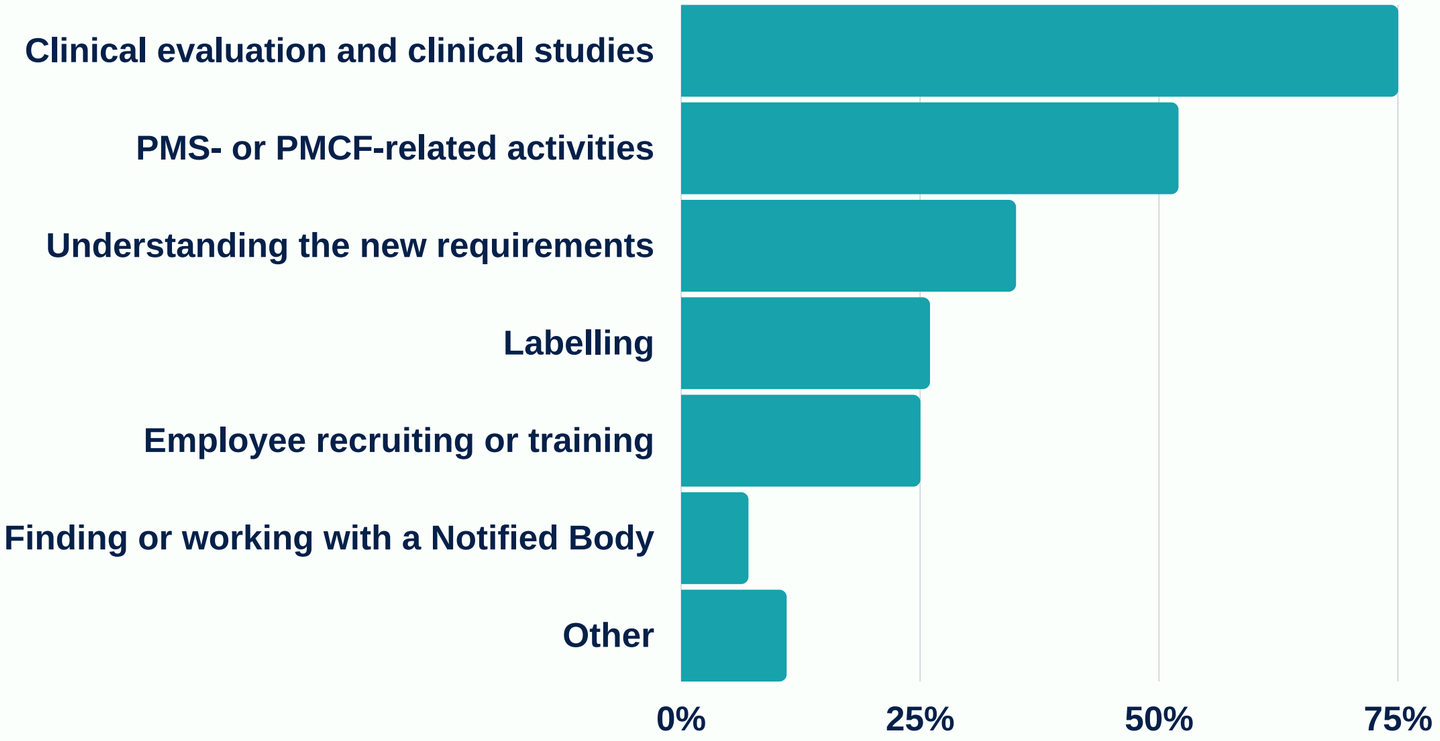
invest most of their time in understanding the new requirements.

Which areas are you spending the most time on?*



*Multiple choice

Which areas will cost you the most money?*



*Multiple choice

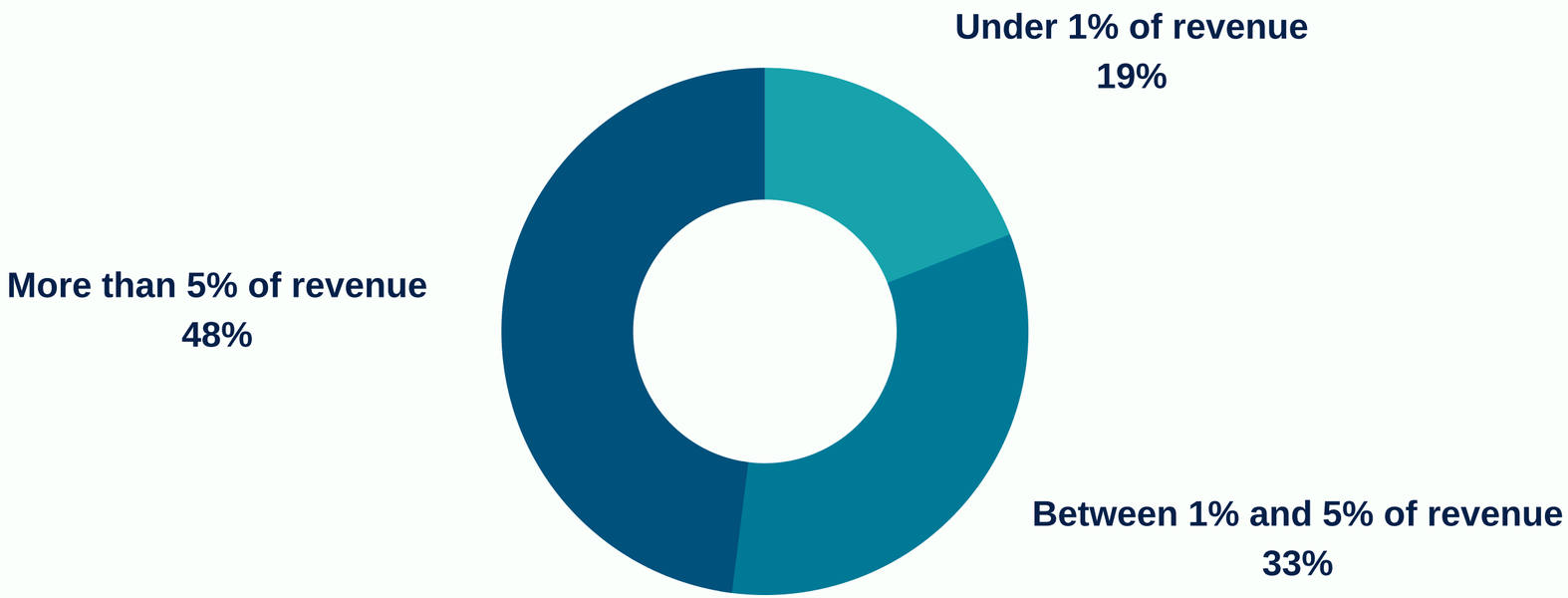
75%

believe that clinical evaluation and clinical studies will cost them the most money.

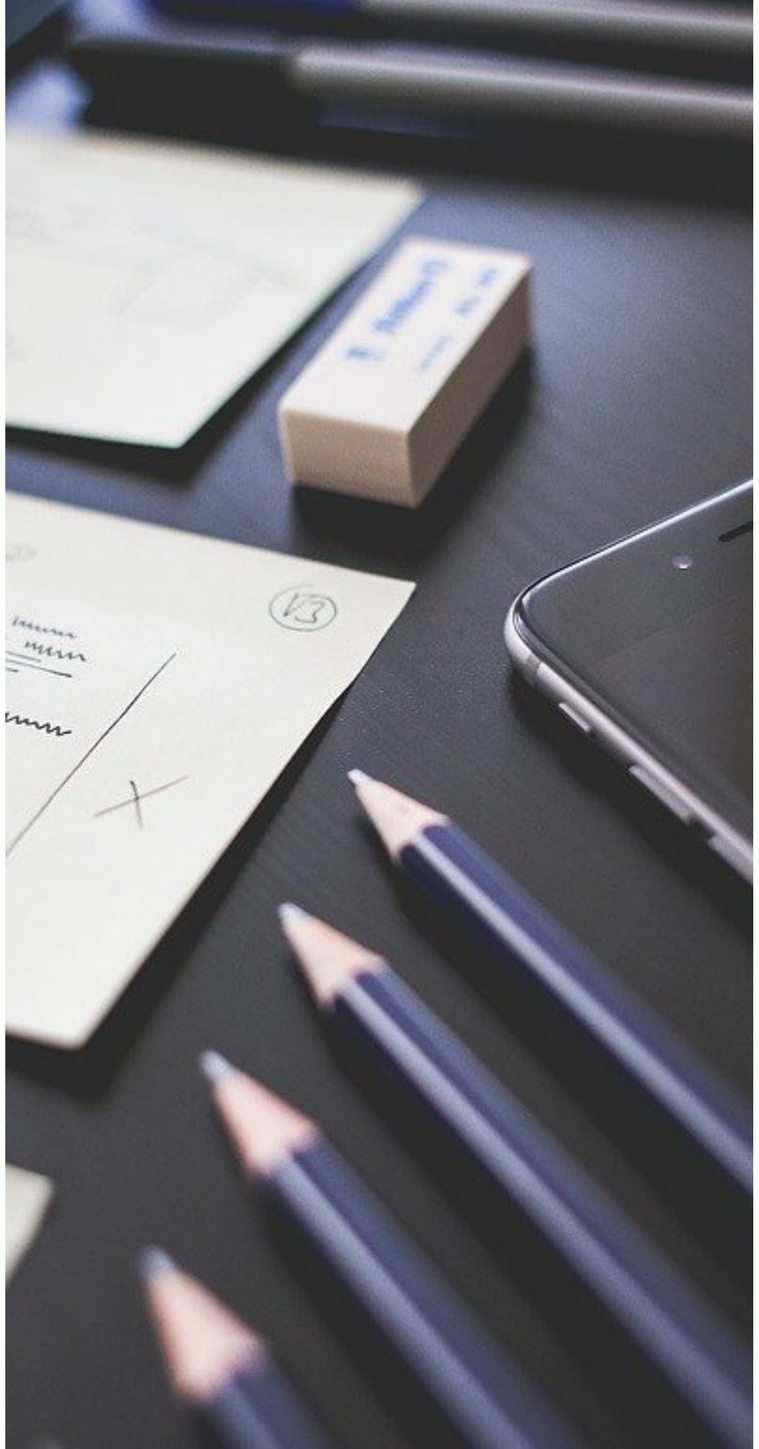
48%

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

How much do you think the EU MDR will cost your company in total (in % of annual company revenue)?



Clinical Data Capture and Management



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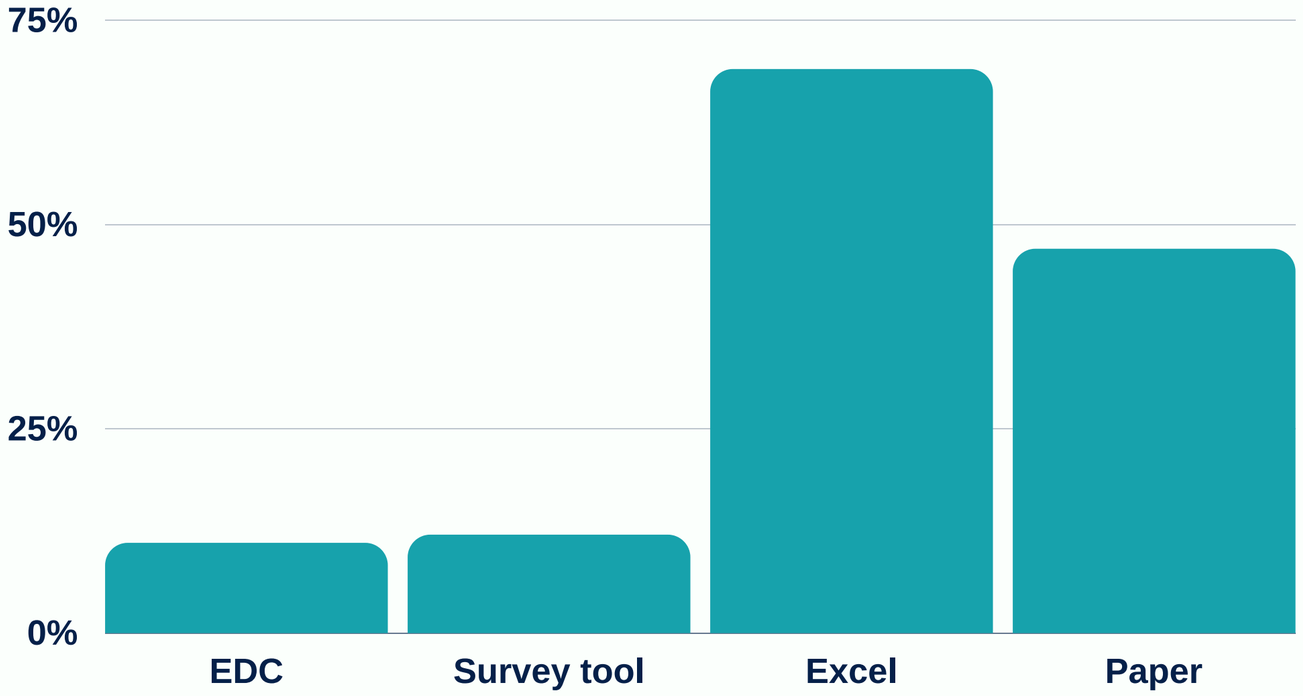
69%

use Excel and

47%

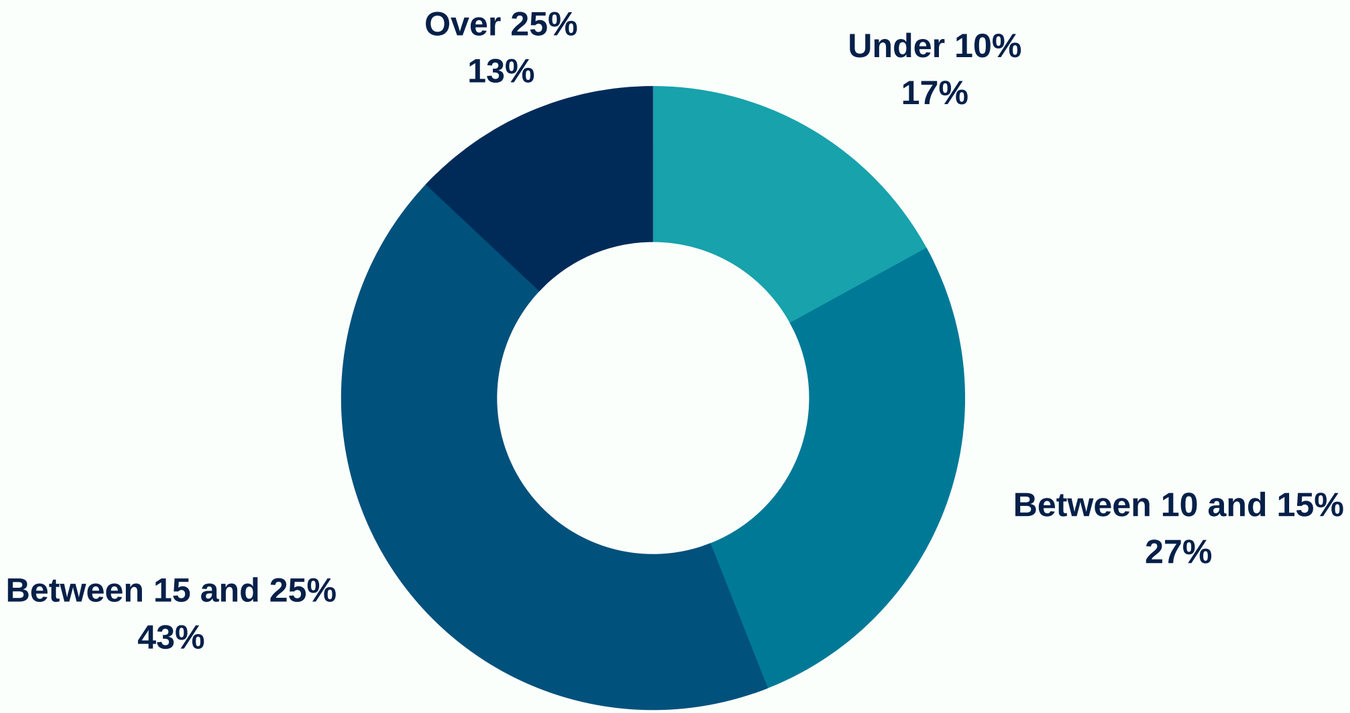
use paper for their clinical data capture.

Which sytem(s) do you currently use for capturing PMCF-related clinical data?*



*Multiple choice

In % of the total time spent on your clinical studies or PMCF activities, how much time is roughly spent on documentation and data management?



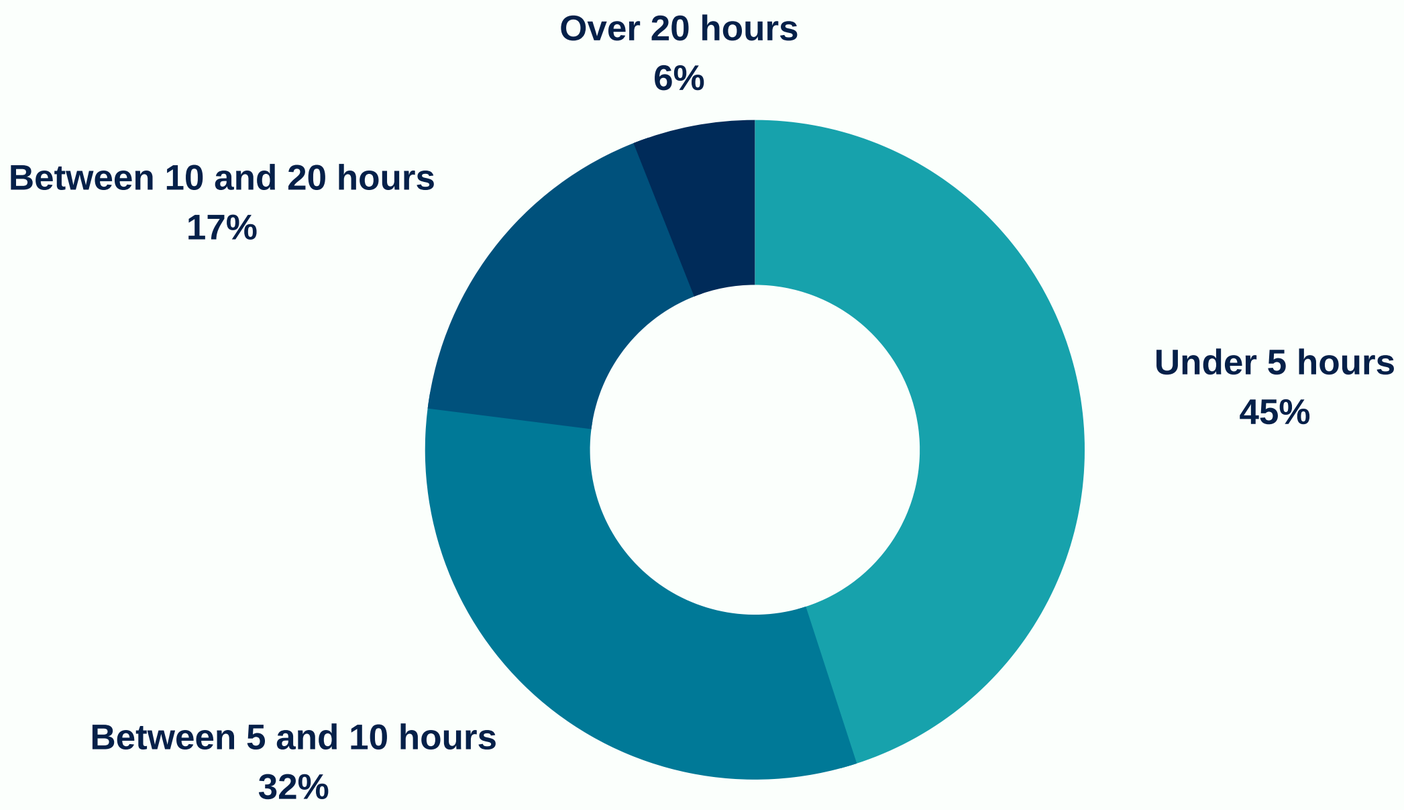
83%

invest more than one tenth of their time needed for clinical studies or PMCF in documentation or data management.

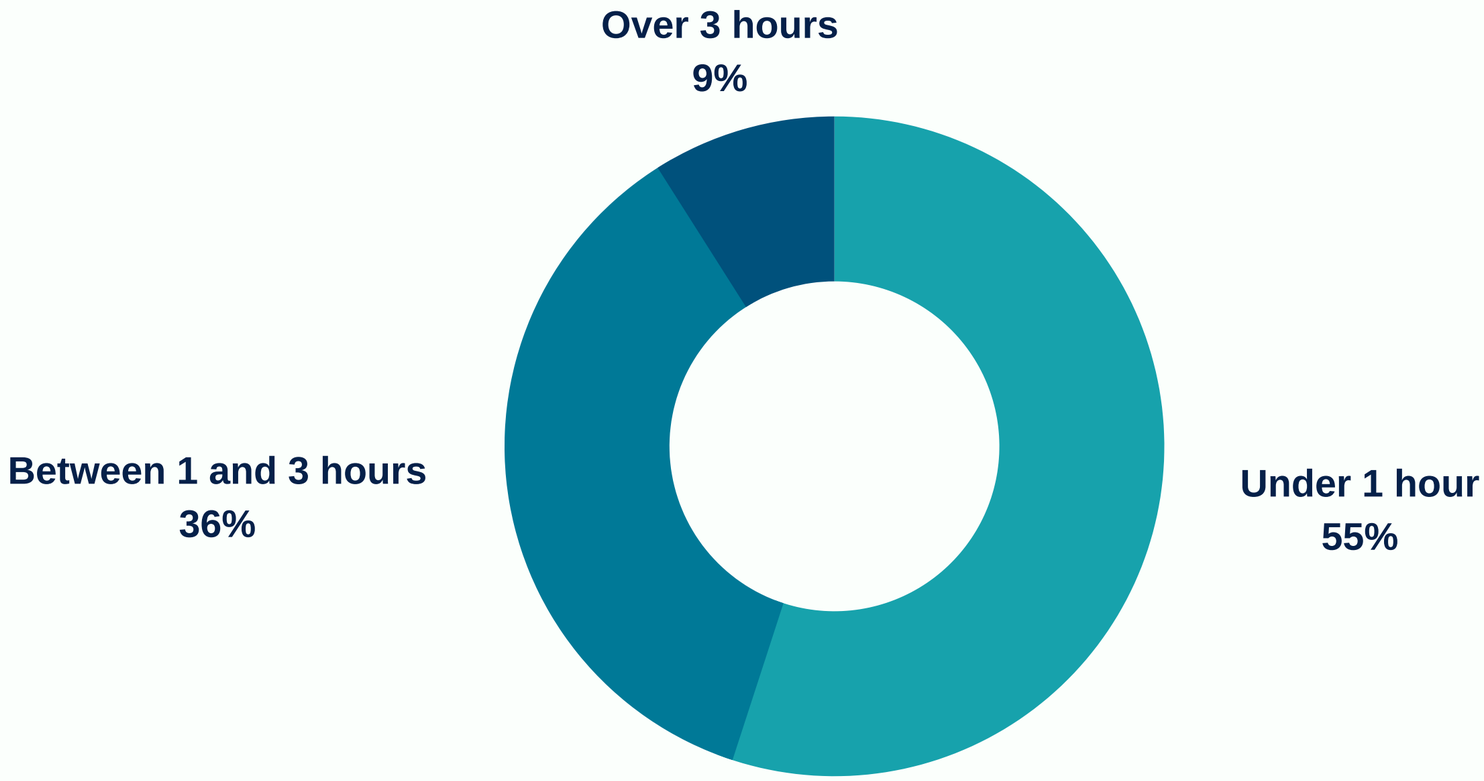
55%

spend more than 5 hours per user on onboarding for a new PMCF study.

How much time in total per user do you spend on onboarding for a PMCF study?



How many hours per week do you spend communicating with relevant stakeholders of your PMCF studies?



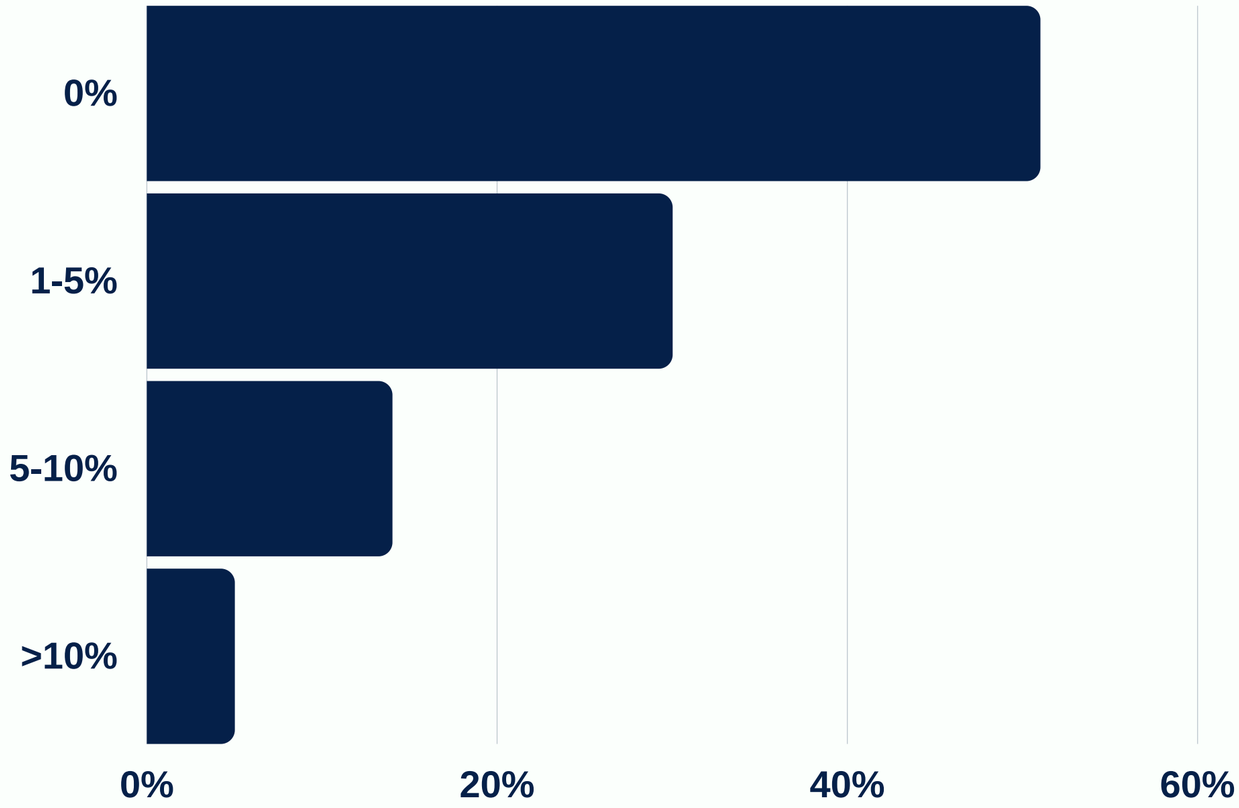
45%

spend more than 1 hour per week communicating with relevant stakeholders of PMCF studies.

51%

do not yet have any automated PMCF processes in place.

What percentage of your PMCF processes is currently automated?



Conclusion

The results show that the EU MDR clearly requires considerable resources from manufacturers. Despite the postponement, it's important to not lose any time now in order to avoid major backlogs in 2021.

On the one hand, the EU Commission must take action here and create the necessary framework to ensure that the system is operational, manufacturers can actually switch to MDR and that their bringing new products to market is not hindered. On the other hand, manufacturers can also take action themselves in certain areas: By switching to digital solutions for clinical data capture, many processes can be automated, which in turn saves valuable time and money. An EDC solution is also proven to be much less error-prone than paper or spreadsheets. However, most survey participants do not yet seem to make use of this potential.

We therefore strongly recommend that MedTech companies continue with their MDR planning and, if they have not already done so, consider the benefits of a digital system. Only this way is it possible to ensure that crucial data collection requirements are met and medical devices can remain on the market.

We hope that the results could offer you some new insights. Furthermore, we're happy to accompany you your journey towards an EDC solution and are always there for you, even in challenging times. Please don't hesitate to reach out if you have any questions. You'll find our contact details on the next slide.

Want to learn more about the EU MDR or automated PMS processes? Get in touch!

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