Medtech Insight

Informa Pharma Intelligence

How Medtech Is Responding To Changes Set To Reshape The Industry

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INTRODUCTION

The medtech industry faces unprecedented pressures. Among the biggest challenges, and the most urgent, companies must adapt to impending deadlines of the radically revised European regulatory environment. These regulatory changes, which go into full effect in May 2020 for device manufacturers, and May 2022 for in vitro diagnostics manufacturers, have much broader reach and implications than for EU countries only. In parallel, the industry is contending with other changes that are upending established ways of working, from evolving market access, real-world evidence (RWE) and postmarket surveillance requirements, to the effect of US legislation on sales and service teams.

These hurdles have made two points very clear: Change is inevitable, and no medtech company has the resources and expertise to address all challenges to meet its business needs and advance to operational excellence.

For some companies, reality has set in. People and companies live with the knowledge that the immediate regulatory changes are likely to have them pulling certain products or withdrawing from some markets because of product classification changes and rising regulatory barriers, which ultimately threaten access to devices providers rely on and patients need. On a different front, HR, legal and finance are getting involved in commercial operations and support matters as legislation is impacting traditional use of temporary contracted workers for sales and promotion of products, health care provider training, field technical support and more. And, no one can ignore that we live and operate in a connected world, where connected devices can be a source of tremendous data and real-world evidence that provide insights for those who take advantage of the technology.

In isolation, any one of these changes represents a major challenge for medical device and diagnostics companies. Collectively, they are stretching and stressing companies like never before. Faced with these burdens, businesses increasingly are accepting that it is impossible to do everything in-house as they had in the past. The only way to cope is to draw on the resources and expertise of partners that focus and specialize on the tasks medtech companies need to perform.

That narrative, of new, intense pressures driving medtech companies to reimagine their business processes and further leverage domain expert partners, is evident in survey data captured by *Medtech Insight*. The survey results provide a quantitative snapshot of the challenging operating environment in which everyone working in medtech today lives. But where challenges exist, the right strategies and partnerships can help medical technology firms seize opportunities and even end with competitive advantages in their market space.

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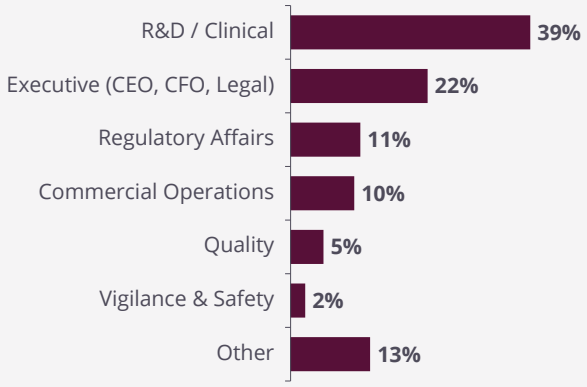
The *Medtech Insight* survey gathered responses from 111 people, around four-fifths of whom work in the medtech industry. A fairly even mix of small, medium and large companies and all the key therapeutic areas are represented. More than half of respondents work for companies based in North America (55%), with the remainder split between Europe (26%) and the rest of the world.

In professional roles, the respondents were skewed toward R&D and clinical functions. Executives make up a little more than one-fifth of the sample. As will be discussed, the sample mix of roles and organizational responsibilities influenced the top-line findings of the survey.

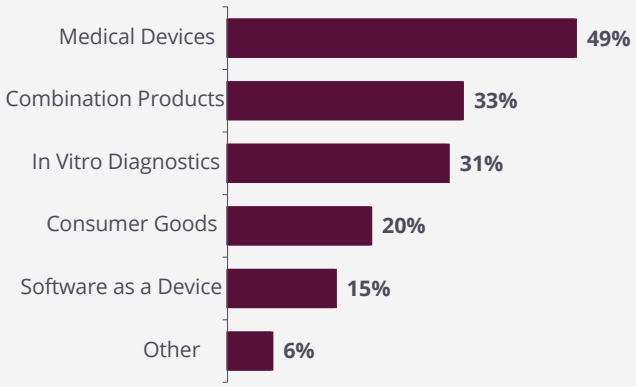
Professional Role



Question: Which of the following best describes your professional role?

Base: All respondents (n=111)

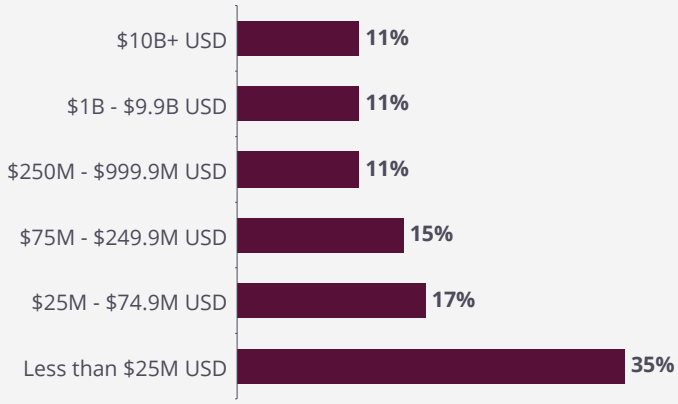
Organizational Medtech Focus



Question: Which of the following best describes the medtech focus of your organization? (Select all that apply.)

Base: All respondents; multiple answers permitted (n=111)

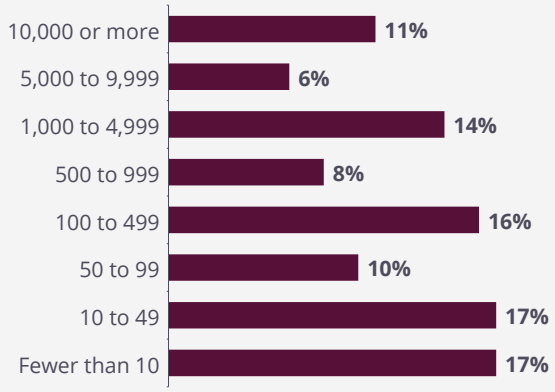
Total Revenue



Question: What is your company's total annual revenue?

Base: All respondents (n=82)

Number of Employees



Question: How many people are employed by your organization, at all locations?

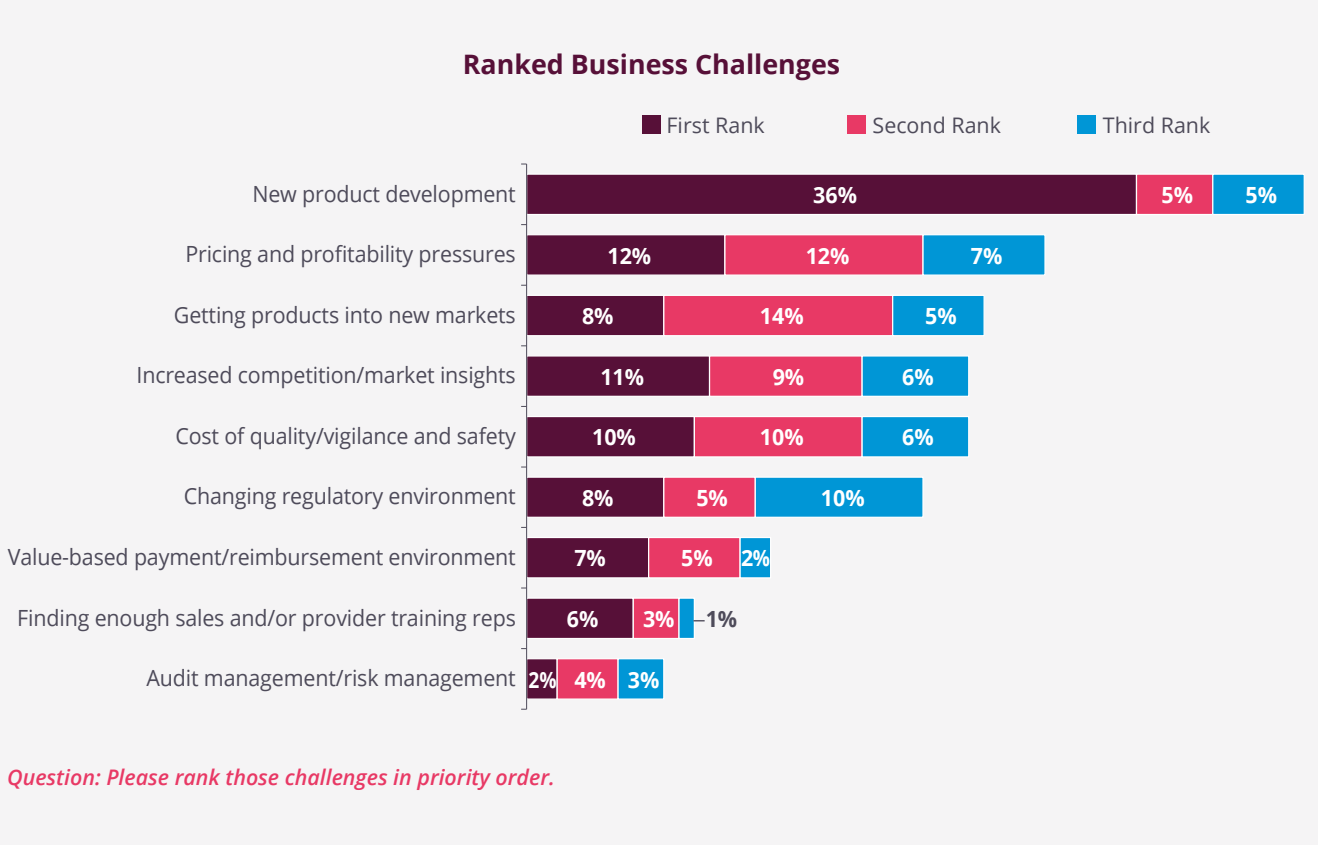
Base: All respondents (n=111)

Across the whole data set, new product development was the top business challenge, with half of the respondents listing it among the biggest issues they face. This is not surprising, considering the industry's focus on innovation at the front end of the product life cycle and that respondents for this particular survey were skewed to research and development and clinical roles. The clinical area is undergoing tremendous change brought by new regulations on product classification, the applicability and need for additional trials, as well as postmarket, real-world data and changes to reporting requirements.

While the industry's prevailing challenge, the changing regulatory environment, scored higher by executive respondents, in this survey it was only ranked as a top challenge by 27% of respondents. Increased competition even ranked higher.

Although all of these top challenges are interwoven to some degree, and rooted or tied to the impact industry regulations are imposing, the results here were lower than expected, to some degree based on the specialized roles that are responsible for the regulatory changes and companies turning to outside expert parties to manage many aspects of the process.

Analysis of a subset of the data, plus responses to subsequent questions support that the regulations are a far bigger issue for medtech than the overall data imply. The changing regulatory environment was the second-biggest issue among respondents in executive positions, the people best placed to have a comprehensive view of the challenges facing a company.



Question: Please rank those challenges in priority order.

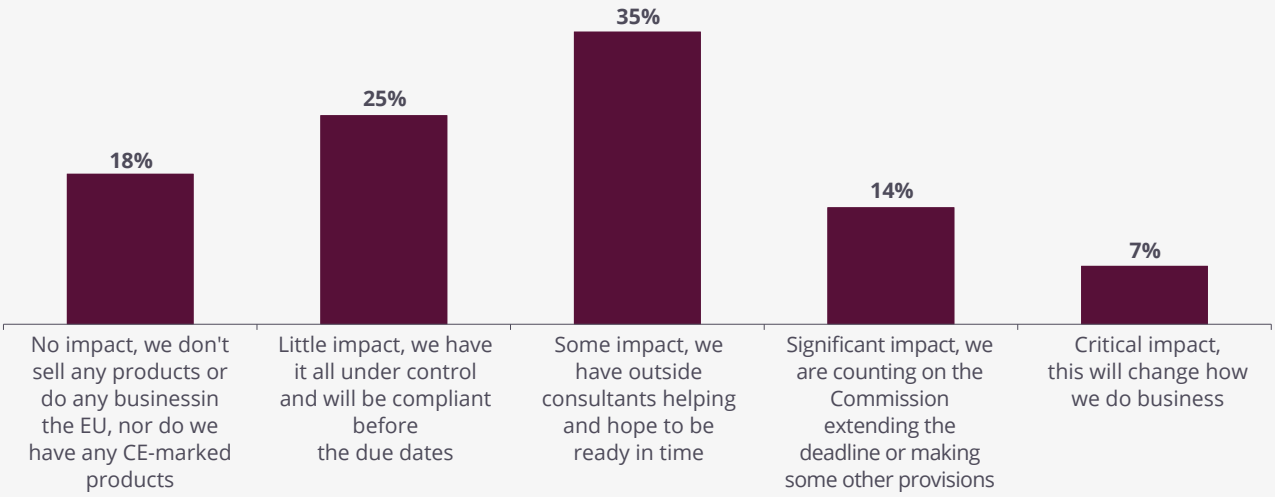
The divergent views of executives and other workers about the impact of new regulations is evident in other parts of the data. Almost 40% of executives with operations in the EU said the impending Medical Device Regulations will have a significant or critical impact on their businesses. Many of these executives still believe and are counting on the European Commission to mitigate the lack of certified Notified Bodies and shortage of time between now and May 2020, for example, by extending the deadline and/or offering some form of additional grandfathering.

Less than 25% of executives with EU operations think they have the regulatory situation under control. The remaining respondents "hope" everything will work out, showing the vast majority of executives who are exposed to the regulations have some level of concern about their impact.

The broader data set suggests people working in clinical and, in particular, commercial operations are less concerned about the regulations, showing still

how siloed workers and processes are as opposed to executives who have oversight across their companies. When firms without EU operations are excluded from the data, less than one-third of all respondents think they have the changing regulatory environment under control.

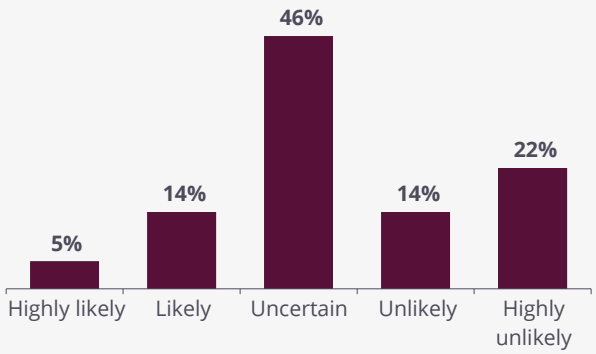
Business Impact of Changing Regulations (MDR/IVDR)



Question: How would you characterize the impact of changing regulations (MDR/IVDR) on your business?

Base: All respondents (n=111)

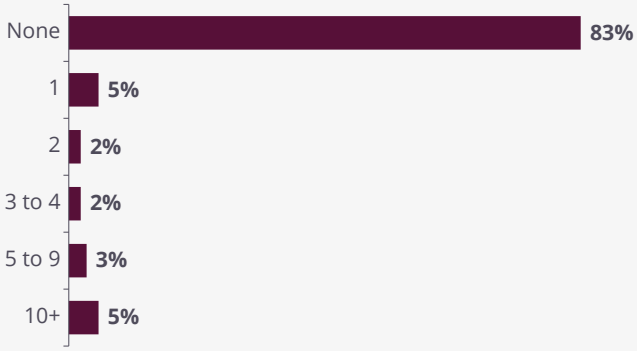
Likelihood of Pulling Select Products Rather than Obtain New Certificates for Them



Question: How likely is your company to pull select products from the market rather than obtain new certificates for them?

Base: All respondents (n=111)

of Products Already Reclassified under the New MDR/IVDR



Question: Approximately how many of your products have been reclassified under the new MDR/IVDR?

Base: All respondents (n=111); write-in responses were coded into the above categories.

The responses to other questions flesh out why the EU regulations are a huge deal for the industry. Faced with the need to recertify products in compliance with the new, tougher rules, almost 20% of respondents expect to withdraw devices from the market rather than go through the revised regulatory process. Just 36% of respondents believe it is unlikely they will need to withdraw products.

Companies have begun reclassifying products to comply with the new regulations, thereby enabling them to continue selling the devices, but there is still a lot of work to do, impacted by the lack of approved Notified Bodies. Across the whole data set, 83% of respondents said they are yet to reclassify any products. Among executives, that figure is 75%, potentially more representative of the real-world situation, yet still staggering.

Companies have begun reclassifying products to comply with the new regulations, thereby enabling them to continue selling the devices, but there is still a lot of work to do, impacted by the lack of approved Notified Bodies.

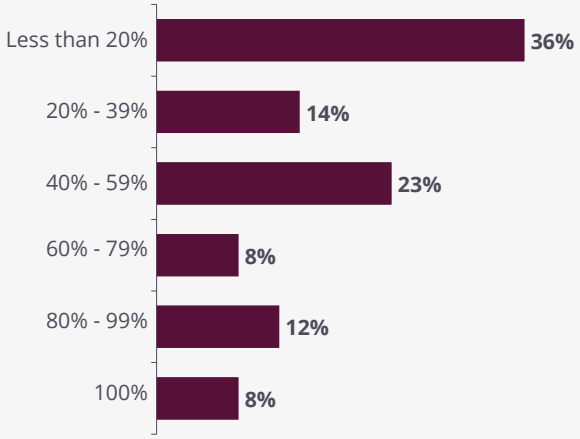
The low proportion of respondents who are confident they will keep all their products on the market after the EU regulations come into full effect is indicative of the additional burdens imposed by the rules.

A significant minority of respondents think they currently capture less than 20% of the data required by the new regulations. Half the respondents believe they currently capture less than 40% of the required data. Just 8% think they already capture all of the data. That suggests the industry recognizes it has a major data deficiency problem.

In some cases, companies will need to conduct additional clinical trials to remedy data deficiencies. Most respondents expect to need to run a new trial to get at least one product recertified under the rules. More than one in 10 respondents expect to carry out new trials for more than 50% of their products. As shown by the previous slide some companies expect to drop products rather than perform the extra work.

Certainly, the impact of further postmarket data capture, additional periodic and safety reporting, and audit scrutiny resulting from the new regulations will be felt by all affected companies.

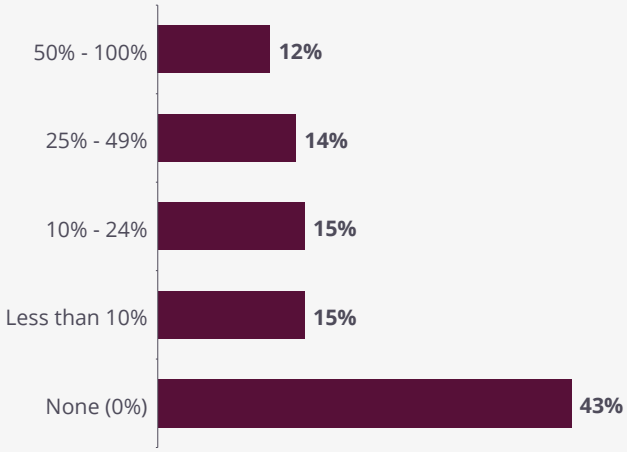
% of Data Required by the New MDR Already Captured by Respondent Companies



Question: What percentage of data required by the new MDR does your company already capture?

Base: All respondents (n=111)

% of Products Requiring a New Trial for Recertification under MDR



Question: What percentage of your products will require a new trial in order to re-certify them under MDR?

Base: All respondents (n=111)

The need to conduct additional clinical trials to meet EU requirements is placing burdens on R&D teams that are already straining to adapt to other changes. In many cases, the need to focus on regulatory and quality is impacting the time and resource availability for innovation.

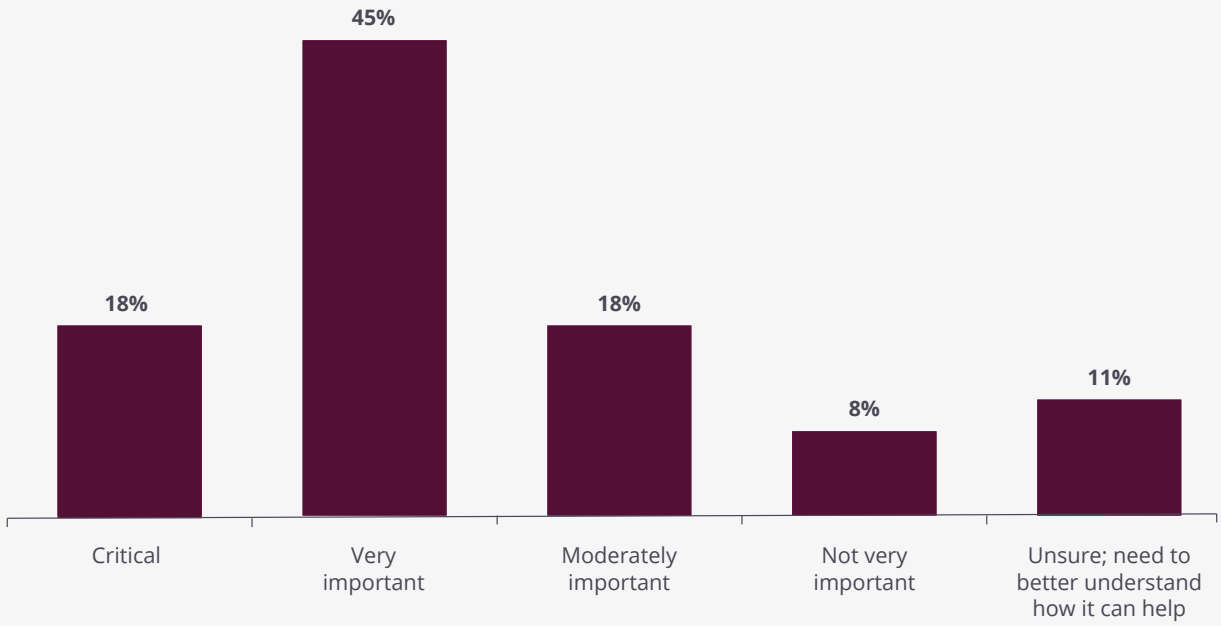
Additionally, in today's emerging era of value-based health care, safety, efficacy and quality data that used to be sufficient to get products to patients in even the most demanding of market access environments are falling short. Payers want to see stronger evidence of need and the positive effect that is delivered.

Apparent is the importance companies are placing on real-world evidence (RWE). Such evidence can persuade payers and providers to cover and use products by showing how they positively affect outcomes in the real world.

Likewise, almost two-thirds of respondents think RWE in clinical trials is very or critically important. However, people are far less certain about how to act on this knowledge. More than two-thirds of respondents are unsure how RWE can help them, are just starting to learn how to use the real-world evidence, or are finding their activities constrained by limited access to high-quality data.

Less than 20% of all respondents said RWE in trials has been the cornerstone of their activities for some time, although that figure shot up to 33% among executives, once again suggesting siloed workers may have led to an artificially low overall survey result, and the need for companies to better orchestrate across business processes.

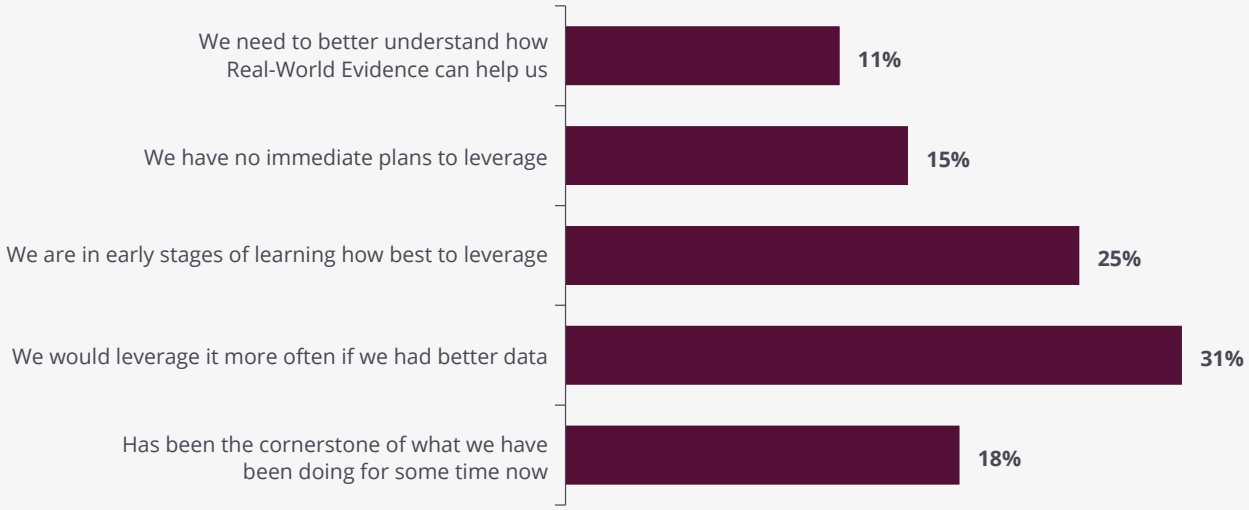
Importance of Real-World Evidence in Current Trials



Question: How important is Real-World Evidence in your current trials?

Base: All respondents (n=111)

Organizational Position with Regard to Leveraging Real-World Evidence in Trials



Question: Which of the following best reflects your company's position with regard to leveraging Real World Evidence in its trials?

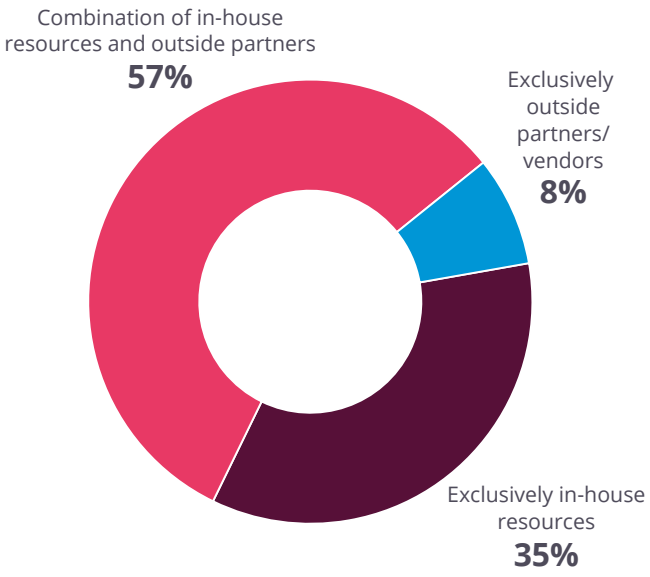
Base: All respondents (n=111)

The need to access better RWE and learn how to use evidence-based data and analytics is driving medtech companies to work with outside partners that are experts in the area. Among the surveyed organizations that use RWE, close to two-thirds rely at least partly on outside partners and vendors, although only 8% exclusively use third parties.

That finding is in line with the use of outside partners in medtech clinical trials. Although three-quarters of surveyed companies still deploy some internal resources to support clinical trials, the data suggest it is now relatively rare for businesses to do everything themselves.

If representative of the real world, the survey findings suggest medtech, an industry that traditionally outsourced relatively little work, now recognizes that the best way to handle rising complexity is to leverage the expertise of third parties.

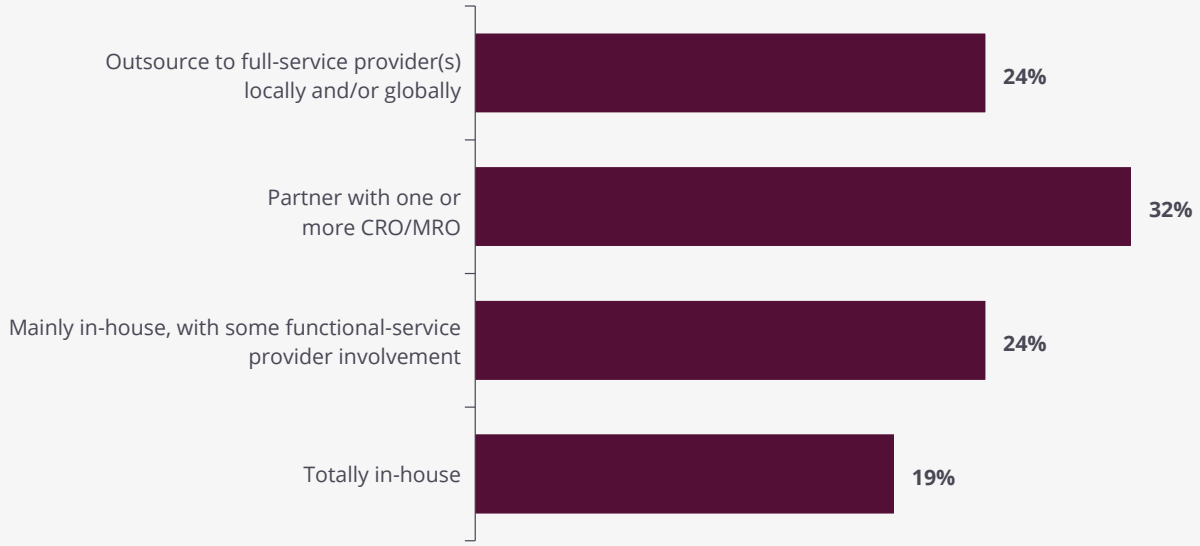
Means of Capturing & Analyzing Post-Market Data



Question: How does your company currently go about capturing and analyzing post-market data?

Base: Respondents currently capturing and analyzing post-market data (n=91)

Approach to Conducting Majority of Clinical Trials



Question: How do you conduct the majority of your clinical trials?
Base: All respondents (n=111)

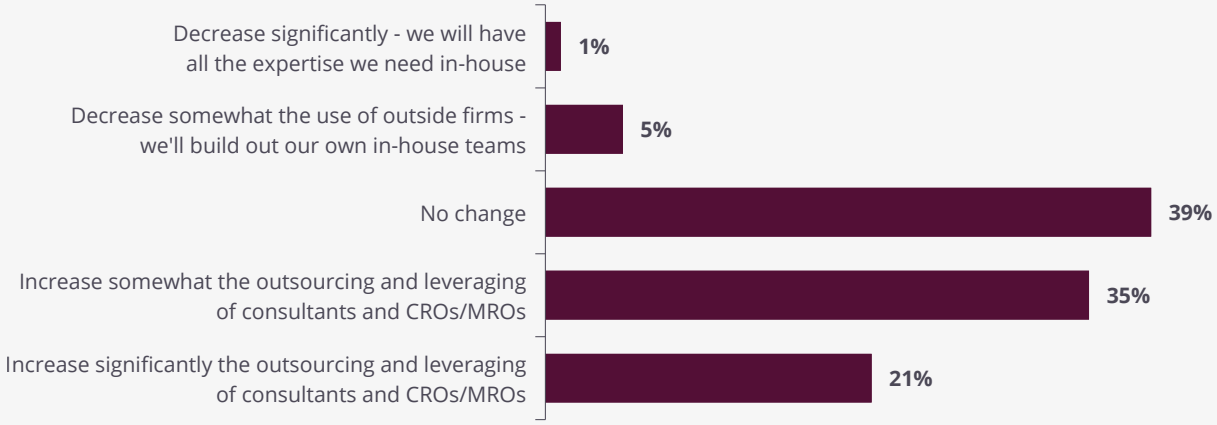
Other aspects of the survey responses lend weight to the trend that medtech is turning to outsourcing as leverage, from the 56% of respondents who are working with third parties to prepare for the EU regulations, to the equally high proportion of respondents who plan to somewhat or significantly increase their reliance on outside clinical development partners over the next two years.

Across the whole data set, 56% of respondents said they plan to increase clinical trial outsourcing. At 67%, the proportion of executives who plan to increase outsourcing is higher still. The executive responses may provide the most accurate forecast as they are from the people best placed to know how their companies' clinical trial strategies will change in the coming years. Almost 30% of the surveyed executives plan to significantly increase their use of CROs and other third parties.

The findings reflect rising clinical development resourcing requirements. To access and stay in the EU and related markets, companies will increasingly need to have clinical data, making it necessary to run more trials than in the past. At the same time, emerging medtech opportunities in markets such as China are moving businesses into challenging regions in which they have reduced R&D infrastructure or expertise, and thus need to rely on experienced partners with local knowledge that can provide resources and assistance. Finally, in all regions, changing market access evidence requirements are forcing clinical development groups to capture and analyze new, expanded and unfamiliar types of data.

Faced with the need to retool clinical trial teams to cope with this new normal, a rising number of companies are identifying outsourcing as the most efficient way to access the required resources and expertise.

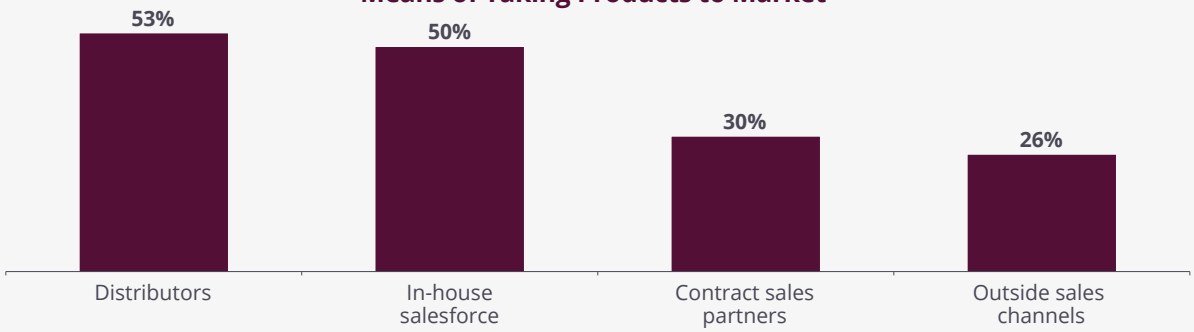
Change in Reliance on Outside Partners over the Next 2 Years



Question: Within the next two years, how will your company's reliance on outside experts/partners in conducting clinical trials change?

Base: All respondents (n=111)

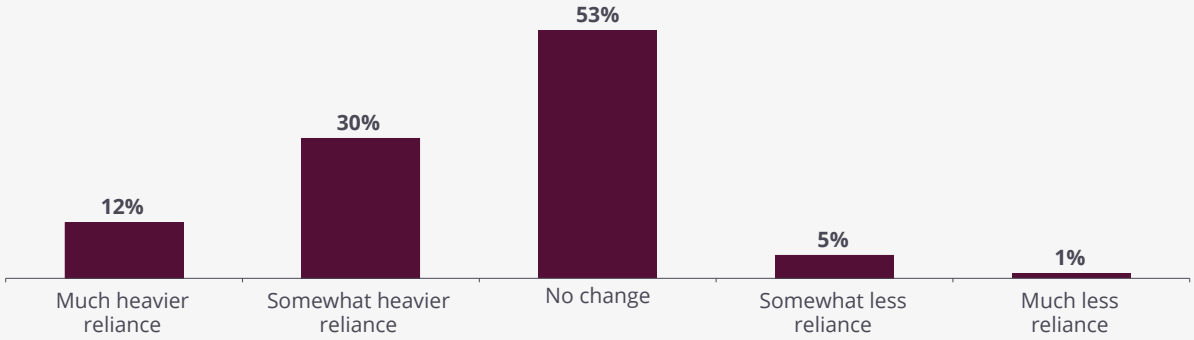
Means of Taking Products to Market



Question: How does your company take its products to market? (Select all that apply.)

Base: All respondents (n=111); multiple answers permitted.

Change in Reliance on Outside Training Partners –Next 3 Years



Question: How will your company's reliance on outside training partners change over the next 2-3 years?

Base: All respondents (n=111)

The responses to other questions suggest different forces are driving medtech companies to partner on other activities. The survey found 30% of companies already rely on contract sales partners to get products to market. Another question revealed 42% of respondents plan to rely more heavily on outside partners to train health care professionals on the use of their products over the next three years. Similar leverage can be applied for field technical support functions as well.

There are reasons to think the companies that already use contract partners for sales and training are at the leading edge of a big shift in how medtech products are commercialized. They can move new products into new markets and thus to patients faster, without the overhead and lead time from conducting recruiting, hiring and training themselves. They receive the expertise of health care professionals and gain the ability to easily flex up and ramp down as their business shifts.

Many companies traditionally contracted sales and training staff in the US as independent 1099-based workers, making it easier to scale capacity up and down to meet demands. However, legislation on 1099 contractors has changed, forcing firms to reconsider the HR, legal and financial implications of traditional practices and the structure of their workforce or those that serve them as agents of the company. When properly structured, outsourcing can provide significant resources, expertise and leverage and is set to rise.

CONCLUSION

These are extraordinary times for the medtech industry. Practices that have served companies well for years or even decades are being rendered ineffective or non-compliant by forces outside their control. The rapid pace at which these forces are converging means companies risk being swept away by the tides of change.

The survey data suggest leadership teams at medtech companies recognize the risks and know that business as usual is not a viable strategy. These firms know they need to rapidly gain access to the resources that are essential for success in the modern medtech industry. For a growing number of companies, that means looking beyond their company walls for expertise and support; for all companies, if they are to be competitive it means better leveraging of technology, breaking down business silos, orchestrating across business processes and driving operational excellence.

About IQVIA MedTech

IQVIA MedTech, part of IQVIA™ (NYSE:IQV), is dedicated to supporting the needs of the Medical Device and In Vitro Diagnostics industry, focusing on the orchestration of "concept to market" business processes to improve patient care. IQVIA MedTech Solutions are powered by the IQVIA CORE™, delivering unique and actionable insights and execution capabilities at the intersection extensive domain expertise, transformative technology, and large-scale analytics. IQVIA is a leading global provider of innovative technology solutions, advanced analytics, and contract research services. Learn more at **iqviamedtech.com.**