ecne

White Paper

Overcoming Barriers to European Market Access in 2024

New solutions manufacturers are leveraging to scale the mountain of MDR clinical documentation requirements

As healthcare needs and treatment protocols grow more complex, medical device innovators must evolve to keep pace with customer demands – while also ensuring compliance with expanding industry standards. To capture a more complete picture of device features and capabilities, the European Union (EU) initiated the transition to the Medical Device Regulation (MDR) in 2017, with new requirements and regulatory frameworks to account for emerging quality and safety concerns.[1]

While necessary, this peace of mind often comes at a cost. The MDR introduces countless hoops for medical device innovators to jump through before getting the stamp of approval to sell in the EU. At the core of MDR compliance lies a wide range of clinical documentation requirements that can cause end-to-end budgetary strangleholds as in-house staff try to collect, analyze, submit, and revise the large volume of clinical evidence necessary to achieve compliance – all before the transition period ends in just a few short years.

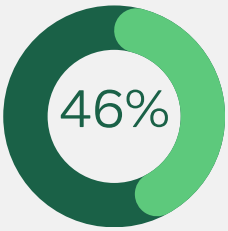
THE CHALLENGE

Evaluating Barriers to MDR Compliance

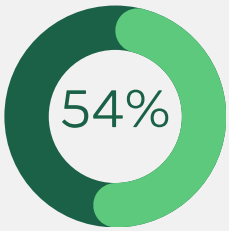
Despite the critical need for stringent regulatory standards, the EU has made it more challenging than ever to get life-saving and life-changing technology into the hands of European clinicians. For some, the added quality assurance will come at the expense of market supply, as smaller companies may lack the necessary resources and financial bandwidth to accommodate the costs of MDR compliance.

Moreover, numerous other factors – including device complexity, quality of pre-existing clinical data, and resources available to the manufacturer – can impact a company's readiness to meet MDR requirements. Thus, it's not uncommon for smaller companies, or those with devices lacking a robust clinical evidence base, to consider pulling their devices from the European market due to the challenges and costs of both initial and ongoing MDR compliance.

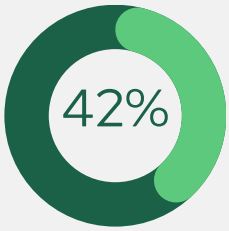
The Volatile State of the EU Medical Device Market



of high-risk device manufacturers report inconsistencies in the volume of clinical data accepted by different notified bodies.[2]



of high-risk device manufacturers have or will remove their devices from the EU market.[2]



of high-risk device manufacturers prioritize launching in other markets before the EU.[2]

Even so, the requirements for ongoing or post-market clinical documentation can be just as large of a hurdle as the initial documentation requirements – if not more so for certain manufacturers. This can be attributed to the MDR's emphasis on a lifecycle approach to regulation, which requires companies to continuously gather and report evidence to ensure the devices remain safe and effective throughout their market life. The need for ongoing clinical evidence, Post-Market Surveillance (PMS) studies, and Post-Market Clinical Follow-Up (PMCF) reports can be especially challenging due to the need for sustained resources, as well as the dynamic nature of clinical evidence and device performance over time.

The #1 Clinical Roadblock on the Path to Compliance

While clinical surveillance as a whole is a time-intensive process, one document stands out as the greatest challenge for medical device companies: the Clinical Evaluation Report (CER). For many, the CER represents the largest threat to MDR compliance, given the unprecedented volume of data required to satisfy the new requirements. According to one survey of MedTech companies, the largest challenge when creating MDR-compliant CERs is the colossal amount of information required to build sufficient clinical evidence.[2] As one of the most complex and costly documents to develop for MDR compliance, the CER must include comprehensive data on the safety and performance of the device, including data from clinical trials, scientific literature, and post-market surveillance.

With pressures mounting to gather and evaluate clinical data in a shrinking window of time, medical device manufacturers are turning to innovative solutions to ensure timely compliance and drive device sales – all while leveraging these challenges to get ahead and secure a higher position in the EU market.

THE SOLUTION

Turning Roadblocks Into Opportunities

With MDR posing a greater threat to market readiness, companies that can efficiently navigate the new requirements are well-positioned to gain a competitive edge, as their devices may be among the few that meet the stringent standards – especially in certain high-complexity device categories. As such, this regulatory transition may be a golden opportunity for innovators to get a leg up in a competitive market, so long as they can optimize time and resources for costly and cumbersome clinical evaluation and surveillance publications.

Five Stepping Stones to a Successful Transition

While MDR presents substantial roadblocks to the European market, particularly with extensive documentation requirements and ongoing compliance needs, it als offers unprecedented opportunities for manufacturers to differentiate themselves and become a market leader – and it begins with demonstrating excellence in safety, efficacy and compliance. Follow these best practices to set your company up for a successful and efficient MDR transition:

1. **Be proactive with notified bodies.** Set your team up for success by engaging with notified bodies early, establishing continuous dialogue to clarify expectations and ensure that all documentation meets the required standards.
2. **Invest in quality data management.** Implement robust systems for data collection, management, and analysis to streamline the process of generating documentation that adheres to compliance standards.
3. **Take a lifecycle approach to compliance.** Adopt a lifecycle approach to device management, embedding compliance throughout every stage of the device's life – from product design through post-market surveillance.
4. **Leverage and build expertise.** Ensure that staff are well-trained and have a deep understanding of MDR requirements, and engage with regulatory experts to help navigate the complexities of compliance.
5. **Stay on top of post-market surveillance and clinical follow-up.** Establish proactive systems for PMS and PMCF studies to continuously gather the necessary clinical evidence to support the safety and efficacy of your device.

Forging Strategic Compliance Partnerships

Why Manufacturers Outsource Clinical Documentation

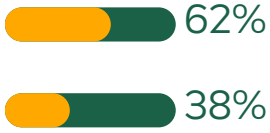
Simply put, MDR compliance is often too costly and time-consuming for certain companies seeking to sell their devices in the EU. However, the answer isn't just to pull devices from the market. Instead, countless manufacturers are leveraging new relationships to avoid compliance hurdles altogether. Despite the complexities of MDR compliance, these challenges have unlocked opportunities for strategic partnerships with clinical research organizations, data management firms, and other regulatory specialists. These business collaborations pave the way for new opportunities to continually optimize the data collection and compliance workflows crucial to ongoing compliance.

Over 60% of high-risk medical device companies outsource CER production.[2]

Topping the list of innovative compliance partners is clinical research organizations. These specialized entities provide end-to-end support for every document needed to successfully complete the MDR transition, from CERs and systematic literature reviews (SLRs) to PMS and PMCF studies. These partnerships are a game-changer for manufacturers struggling to optimize their clinical documentation, especially for small and midsize enterprises. In fact, one survey found that over 60% of high-risk medical device companies outsource the production of their CERs due to lack of internal expertise and/or limited time and resources needed to generate and maintain the required documentation.[2]

Did you know? The EU Commission is conducting a public consultation in Q3 of 2024 to determine whether MDR is fit for purpose and efficient. Ensure a prompt response to any new changes by partnering with a medical device compliance partner like ECNE Research.

Why do manufacturers outsource CER generation?[2]



With the right partnerships in place, medical device manufacturers can simultaneously tackle MDR compliance hurdles while also generating a competitive advantage against companies that have yet to leverage these innovative solutions. With a clinical research partner like ECNE Research, manufacturers can benefit from a hassle-free compliance experience, knowing that a team of clinical, academic, and healthcare compliance experts are working diligently to produce top-quality clinical documents throughout every stage of a device's market life. Book a free consultation to explore how our suite of clinical research solutions can help your company cost-effectively overcome challenges with MDR compliance and get ahead in the EU market.

Book a Free Consultation at
ecneresearch.com/book-consultation

About Us

At ECNE Research, we are committed to providing high-quality medical writing services and clinical research solutions to all types of healthcare organizations to bridge the evidence-practice gap and play our part in ensuring that ground-breaking technology and pharmaceutical treatments are available to those who need them most, leading to better care and outcomes for patients, clinicians, and institutions.

ECNE Research is not just a medical writing service, but a trusted business advisor with in-depth expertise in medical writing and clinical evaluation. We offer customized solutions, establish strong relationships, and deliver high-quality medical documentation. With our team of clinical scientists from various healthcare domains, ECNE Research consistently delivers high-quality medical documentation that surpasses industry standards, optimizing efficiency and reducing costs for clients.

www.ecneresearch.com

Sources

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.) (OJ L 117 05.05.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj)
2. Kearney B, McDermott O. The Challenges for Manufacturers of the Increased Clinical Evaluation in the European Medical Device Regulations: A Quantitative Study. Ther Innov Regul Sci. 2023;57(4):783-796.