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White Paper

Tackling the MDR Transition

Overcome Barriers to Compliance With Efficient, Scalable, and Comprehensive Clinical Documentation Solutions

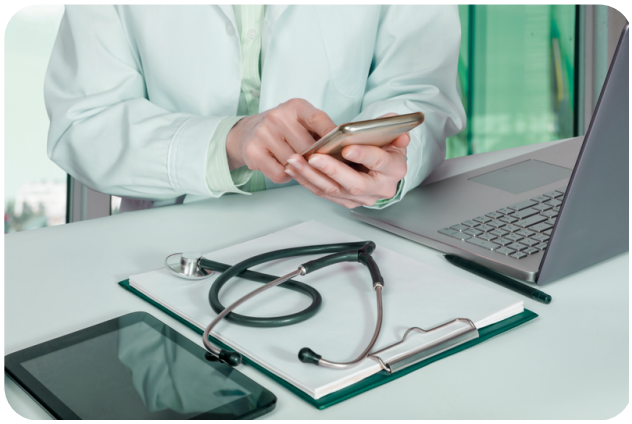
Understanding the New Medical Device Landscape

The Race Between Innovation and Regulation

Since 1993, the Medical Device Directive (MDD) stood as the flagship legal and regulatory framework that defined the medical device landscape in the European Union (EU).[1] However, recent decades bore witness to rapid advancement in product design and functionality, ushering in a new – and far more complex – era of medical device innovation. As device technology evolved at a rapid pace, medical device innovators turned to software solutions and specialized manufacturing protocols to further innovate and enhance their product offerings. These modern advancements fell outside the realm of MDD jurisdiction, bringing to light the critical need for updated regulatory requirements.

The Medical Device Regulation (MDR), officially enacted in May of 2017, seeks to close the widening gaps in the MDD framework through robust end-to-end regulatory oversight.[2] To keep pace with device innovation, the MDR employs a variety of requirements to ensure device safety and compliance, including:[2]

- **Expanded scope and classification of medical devices**
- **Stringent regulatory and clinical evidence requirements**
- **Heightened involvement of notified bodies**
- **Close surveillance throughout the post-market period and the entire product life cycle**



Although a crucial necessity in the medical device regulatory space, the MDR places enormous pressure on companies to meet a laundry list of new requirements to get to market and maintain certification. The clinical evaluation and documentation process is a notorious bottleneck in the MDR certification process, as many struggle to deliver the scope of data and clinical evidence required in systematic literature reviews (SLRs), global value dossiers (GVDs), Clinical Evaluation Reports (CERs), Post-Market Clinical Follow-Up Reports (PMCFRs), and other regulatory documents.

Put simply, many medical writing teams lack the deep understanding of the new regulatory and clinical landscape needed to effectively synthesize clinical evidence in a fair and objective manner. Even before MDR went into effect, lack of expertise was a concern during the research, documentation, and writing process. Now, the need for highly skilled medical writers is higher than ever.

THE CHALLENGE

Five Hurdles on the Path to MDR Regulatory Compliance

Clinical evidence and documentation lie at the heart of MDR compliance. To avoid certification delays and stay on time and within budget, medical device companies must take the necessary steps to master these processes and tackle the challenges associated with MDR compliance.

MDR Documentation Requirements by Device Class

	Class I	Class IIa	Class IIb	Class III
Clinical Evaluation Report (CER)	✓	✓	✓	✓
Post-Market Surveillance Plan (PMS Plan)	✓	✓	✓	✓
Post-Market Surveillance Report (PMS Report)	✓	✗	✗	✗
Post-Market Clinical Follow-Up Plan (PMCF Plan)	✓	✓	✓	✓
Post-Market Clinical Follow-Up Report (PMCF Report)	✓	✓	✓	✓
Periodic Safety Update Report (PSUR)	✗	✓	✓	✓
Summary of Safety and Clinical Performance (SSCP)	✗	✓	✓	✓

Challenge | Shrinking Notified Body Resources and Bandwidth

Medical device companies aren't the only stakeholders impacted by MDR. The transition substantially increases demand for notified body services, creating additional bottlenecks as companies seek conformity assessments at an unprecedented pace. Even with extended transition periods and legacy devices, notified bodies are burning the midnight oil to evaluate a substantially greater number of products, including:[2]

- In vitro medical devices
- Medications with an integral device
- Ancillary medicinal substances
- Absorbable devices
- Borderline products

Moreover, the industry may soon face a shortage of notified bodies with the required expertise in MDR standards, leading to critical delays in the certification process. This scarcity puts the onus on companies to work closely with notified bodies to ensure a smooth transition through additional training to help both entities understand and adapt to the new regulatory requirements.

> The MDR increased the number of medical device definitions from 11 to 71.[3]

Challenge | Limited Availability and Traceability of Data

The mere existence of clinical evaluation and post-market surveillance data isn't enough, according to the MDR. Now, companies must improve the traceability and availability of their device data throughout the entire product life cycle. This task is nearly impossible to perform with rudimentary data management workflows. Improving data integrity in accordance with MDR requires updated systems and optimized processes to facilitate efficient data storage, management, and retrieval.

A key MDR requirement companies must become proficient in is the Unique Device Identification (UDI) system. UDIs utilize internationally accepted numbers and alphanumeric characters to enable rapid, unambiguous identification of specific devices present on the market.[2] While efficient post-launch, implementing and managing UDIs for every device is a time- and resource-intensive task necessitating updated labeling, packaging, and information systems.

Challenge | Rising Cost of Compliance and Disrupted Market Access

The move to MDR doesn't just consume additional staff time – there are significant costs associated with generating the level of clinical evidence and documentation needed to comply with the new requirements. Small and medium-sized enterprises (SMEs) may struggle to absorb these costs and allocate sufficient resources to meet these stringent documentation requirements, which, in turn, could potentially impact their ability to bring products to market.

Zooming out, these financial and operational roadblocks have the potential to majorly disrupt market access. Companies that sell their devices in the European market jeopardize device sales without proactive solutions to mitigate these risks. Moreover, the sheer volume of resources needed to invest in and expand human resources and technology infrastructure poses a serious threat to any company's bottom line. By the time companies receive approval to sell in the EU, they may already be operating in the red, putting even more pressure on sales and marketing efforts to offset these costs.

> The MDR increased the number MDR compliance costs can consume over 5% of the company[4]

Challenge | Narrowing Bottlenecks in Clinical Evaluation & Post-Market Surveillance

In addition to SLRs and GVDs, medical device companies must also implement robust strategies to ensure their CFRs and PMCFRs deliver accurate and scientifically sound representation of clinical evidence. Prior to MDR initiation, companies invested countless hours and resources into preparing these documents. Now, the stakes are even higher due to:

- **Lack of robust and high-quality data.** Incomplete, inaccurate, or outdated data can lead to flawed conclusions, impeding both clinical evaluation and post-market surveillance efforts.
- **Small sample sizes or limited diversity in patient populations.** This can affect the generalizability of clinical trial results, making it difficult to apply clinical findings to broader patient groups. The lack of data generalizable to the European population is a common challenge in MDR submissions.
- **Ineffective study design.** Poorly constructed clinical trials or post-market surveillance studies often fail to address key questions or adequately capture relevant information. Flaws in study design and implementation can undermine the validity and reliability of results.
- **Limited long-term follow-up.** Without close surveillance and follow-up of device performance across long periods of time, clinical trials and post-market studies can suffer from a limited understanding of device functionality and safety in the long term, especially for chronic conditions.

Tackling these MDR hurdles requires a strategic, proactive, and multidisciplinary approach that leverages both internal capabilities and external collaboration. Together, researchers, clinicians, regulatory experts, and industry professionals can successfully adapt the industry as a whole to this new regulatory framework. Without a smooth transition, device profits may fall, and, more alarming, EU patients may not be able to access the groundbreaking technology they need to achieve positive outcomes.

THE SOLUTION

Fast Track Compliance With MDR Specialists

Despite taking the first steps toward MDR compliance, such as intensive training programs and new technology solutions, medical device companies still face a long road ahead of time- and budget-consuming process improvements to achieve compliance. As a result, more company leaders are turning to outsourced solutions to meet MDR requirements while avoiding the costs of a ground-up in-house regulatory transformation.

While some have investigated artificial intelligence (AI) as a potential solution, the industry is reluctant to involve automation in the research and writing process. The critical flaw with AI systems is the potential to inadvertently perpetuate bias in the clinical data. If training algorithms are, at any point, inaccurate or unreliable, the AI will apply those models to downstream data analytics and synthesis. Ultimately, concerns around data security, integrity, and accountability position AI as an unviable, if not incomplete, alternative to the human eye. Writers may find value in AI-assisted organization and formatting, but MDR regulatory documents require distinctly human elements: creativity, critical thinking, complex clinical interpretation, contextual understanding, deep knowledge of regulatory nuances, and baseline ethical judgment.

Far and away, the most time- and cost-effective way to meet every MDR documentation requirement is to partner with an outside team of medical device regulatory and clinical specialists. Rather than stressing your in-house team with a deluge of regulatory requirements, leverage an extra set of hands to move your publications across the finish line with full peace of mind that the research, data, and conclusions have been thoroughly scrutinized and verified by subject matter experts.

Every company needs an expert regulatory partner to guarantee compliance and streamline submissions. **For medical device innovators, ECNE Research is that partner.** With over 150 years of combined clinical, academic, and industry experience across the healthcare spectrum, ECNE Research stands apart as the ideal partner for medical device companies looking for a stress-free MDR transition. Book a free consultation to learn how our custom medical writing and clinical research consultancy solutions can help you eliminate roadblocks on your journey to MDR compliance.

Book a Free Consultation

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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

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