# Does Your Wound Care Clinical Data and Digital Health Strategy Fully Comply with the New Medical Device Regulation?

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Regulation (EU) 2017/745 on medical devices (MDR) has replaced both Directives (93/42/EEC and 90/385/EEC) as of the 26th May 2021. Key now for medical device manufacturers is understanding how this new MDR affects the conduct of clinical investigations, the collection and collation of efficacy and effectiveness data, and clinical reporting. It is fair to say that the transition to the new MDR presents complex challenges. The shortage of regulatory experts, notified bodies (NB), and an absence of transition strategies have further compounded the problem. The impact on organisations and stakeholders alike is immense as the new regulations are reshaping the wound care research arena.

It is important to note the general differences and improvements related to clinical investigations under the new Regulation (EU) 2017/745 (MDR) as compared to the Directives 93/42/EEC and 90/385/EEC. The first difference is regarding the type of the law. A Directive is a legislative act that sets out a goal that all EU countries must achieve. A Regulation, as opposed to a Directive, is a binding legislative act that must be applied in its entirety across the EU. In simple terms, this means that the rules are applied in an identical manner throughout the EU. A clinical investigation is defined by the MDR as any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device (Article 2(45) of the MDR).

The new Regulation introduces major changes to how medical device manufacturers obtain CE Marking and maintain access to the European market. Under the MDR, sponsors will need to comply with more stringent requirements for **pre-market clinical evaluation (PMCE)**. The new regulations have an increased demand for clinical evidence, safety, and performance. As a result, introducing more rigorous procedures for authorizing multicenter clinical investigation. The rationale, objectives, design methodology and conduct documentation, monitoring, and electronic systems will need to be critically assessed in the **clinical investigation plan (CIP)**. The CIP sets out the rationale, objectives, design methodology, monitoring, conduct, record-keeping and the method of analysis for the clinical investigation. It contains, in particular, the information as laid down in the MDR. It also places greater emphasis on transparency and traceability of medical devices throughout the lifecycle and supply chain.

Medical devices on the market may need to be reclassified and reregistered. Some of the wound care devices may be reclassified to a higher class, which mandates additional clinical data requirements. The largest impact of the new regulation is on Class IIb and III products. Previous clinical evaluation reports based on literature analysis will require clinical investigation and/or a **post-market clinical follow-up (PMCF)** study. Furthermore, there are no grandfathering provisions. Thus, manufacturers will no longer be able to use the clinical data of substantially equivalent device for registration.

One of the fundamental changes is that wound care device studies must also show clinical benefit along with safety and efficacy. Clinical benefit needs to be expressed in meaningful, measurable, and patient-relevant clinical outcomes. Additionally, manufacturers will need to collect **post-marketing surveillance (PMS)** data, including performance and quality measures over the device's lifetime. The PMS will need to be set up for each device, which will include incident reporting, customer feedback and complaints.

Medical device manufacturers and distributors are at a crossroads regarding the following two key points: 1) whether to keep the device on the market and 2) how much clinical data is deemed to be sufficient? While there is no single best approach, the consensus is to have a life cycle risk-based management approach when evaluating a company's product portfolio. It may not be beneficial to invest in a product that is near the end of its life cycle. For devices that fall within the high-risk category, a prospective or a registry study will be essential to meet the data requirements. Sponsors may still need to augment existing data with smaller studies to address gaps in clinical evidence. For instance, gaps in clinical data for a class III device will likely result in a returned dossier, sending the sponsor back to the start line. Thus, a comprehensive clinical data strategy is paramount before submitting the technical dossier to the notified body.

PMS is a long-term obligation that require significant planning and cost considerations. There is no doubt that sponsors will need to increase investment in technology to procure appropriate systems and software for ensuring provisions for data requirements. Up to this point, many organizations have been able to get by on legacy systems which may no longer suffice.

The shift towards long term maintenance necessitates a more efficient solution for data storage, management, monitoring, and for an audit trail across the life cycle. Cloud-based solutions can facilitate easier collaboration with outsourcing partners, and regulatory authorities. Leveraging eConsent, **electronic patient-reported outcome (ePRO)**, and integrated real-time reporting may help accelerate progress towards the new clinical evidence requirement.

If you are finding yourself with more questions than answers, you are not alone. The teams at eKare and Real Healthcare Solutions (RHS) are focused on helping companies to align their clinical data strategy to meet the necessary clinical evidence requirements. eKare has supported over 150 clinical studies, offering immense experience in both pre-market clinical evaluation and post-market clinical follow-up. With ekare's fully integrated cloud-based platform, research sponsors can standardize wound assessment, increase patient engagement, and accelerate clinical research. Follow the link below to learn more about how eKare can help maximise the value of collected data across wound care studies:

**Collecting High Quality Data for Research**

**Effortlessly Integrate with EHR or EDC**

**Enable Patient and Provider Engagement**

**Analyze Data with Gauss®**


**eKare inSight Technical Specs**

If you need support on research design, protocol development, clinical evaluation or developing a quality evidence portfolio, look no further. RHS offers end to end support for clinical in-market evaluations and full NHS research application. RHS can support you in developing robust clinical investigation plans, identify centers of excellence, appoint suitable primary / chief investigators, and ensure compliance with good clinical practice standards. For a closer look at the new regulation and to explore how Real Healthcare Solutions (RHS) can support your clinical evidence journey, check out Research Reset or contact info@realhealthcaresolutions.co.uk.

## Key Takeaways

- The main objective of the new regulation is to improve the health and safety level by ensuring products are current to state of art technology and scientific knowledge.
- Many wound care devices, including legacy products, may need to be recertified.
- A life cycle risk-based management approach is essential for evaluating product portfolios.
- The safety and performance parameters of medical devices are now, more than ever, under scrutiny.
- The new regulations have an increased demand for clinical evidence, safety, and performance.
- Given the increased requirements on safety and reliability, sponsors need to increase investment in technology to procure appropriate systems and software for ensuring provisions for data requirements.

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*The article has been reviewed and edited by Jack Slovick. Jack has worked in the medical device and diagnostics industry since 1981. Throughout his career, he has gained a variety of experiences in regulatory, quality, and clinical services. He currently works as the Founder and Managing Director of Methodize, helping companies bring medical devices and in-vitro diagnostics to market.*



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