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EU MDR is in effect. Now what?



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Who this guide is for

If you're looking to stay compliant and build a successful regulatory strategy, this guide is for you. It's been written for:

- Medical device manufacturers
- Clinical data professionals
- Regulatory affairs professionals

What you'll learn

- The basics of EU MDR
- Who EU MDR impacts
- When EU MDR takes effect
- EU MDR's impact on clinical data collection
- How to collect EU MDR-compliant clinical data

What is the European Medical Device Regulation?

In May 2021, EU MDR replaced the EU's Medical Device Directive (93/42/EEC) and Directive on Active Implantable Medical Devices (90/385/EEC). Manufacturers selling medical devices within the EU must adhere to these new regulations to ensure their products are safe to use.

After a one-year delay due to the pandemic, the European Medical Devices Regulation 2017/745 (EU MDR) is now in effect. EU MDR is a regulatory framework for medical devices produced in or supplied to Europe. It replaces the Medical Device Directive (MDD), which has been in effect since the 1990s; the Active Implantable Medical Devices (AIMD); and the In-vitro Diagnostic Directive (IVDD). It also ushers in major changes in how medical device manufacturers obtain CE Marking and maintain access to the European market.



CE Marking: Represents a manufacturer's declaration that products comply with the EU's New Approach Directives for health, safety, and environmental protection standards.

The goal: Safety, traceability, and transparency

The goal of EU MDR is to improve patient safety, traceability, and transparency throughout the medical device lifecycle. EU MDR aims to establish a standard and consistent regulatory framework for medical devices to ensure a high level of health and safety while supporting innovation. The new regulations aim to weed out subpar medical products before reaching the European market.

In a move toward increased uniformity, EU MDR:

- Enforces stricter pre-market control of high-risk devices.
- Adds a new risk classification for diagnostic medical devices.
- Increases transparency by providing a comprehensive EU database of medical devices (Eudamed).
- Includes aesthetic products with similar characteristics and risk profiles as equivalent medical devices.

Other aims of EU MDR include:

- Better device traceability through the supply chain.
- Added use of real-world device-use data collection.
- Improved coordination between the EU Member States.

The challenge: Re-classification and re-registry

EU MDR may be a more effective regulatory process than its predecessors—but it is also more extensive and complicated. The impact of EU MDR on the medical device industry is massive, given that all medical devices on the market must be re-classified and re-registered. The new rigorous regulatory process will trigger organizational and practical issues for all stakeholders involved.

Additionally, many devices may be reclassified to a higher device class, which may require more clinical data. EU MDR also opened the way for legislators to impose high fines on companies that do not meet the specified standards. The result? Many medical device manufacturers are scrambling to comply with these new requirements. Here's what to know.

The impact: More clinical data collection

EU MDR applies to any manufacturer producing or supplying medical devices to Europe. It brings significant regulatory change, including:

- Requiring the re-classification and re-registration of all medical devices currently on the market.
- Outlining new clinical data requirements for (maintaining) certification of medical devices.
- Requiring more clinical data collection throughout the product's life cycle.
- Raising the bar for the level of required evidence.

To comply with EU MDR and its focus on real-world clinical evidence, companies must generate more documentation for health authorities and conduct new clinical studies. Of course, these all impact costs, processes, outsourcing, and other business functions.



Post-market surveillance and Post-market clinical follow-up

Post-market surveillance (PMS)

EU MDR requires manufacturers to actively collect post-market surveillance (PMS) data on a device's quality, performance, and safety over its entire lifetime. Of course, this concept isn't entirely new—regulatory bodies have required PMS in pharmaceutical trials for quite some time. But collecting post-market clinical follow-up (PMCF) data requires a substantial investment from manufacturers.

Post-market surveillance (PMS): The practice of monitoring the safety of a device after its release on the market.

Post Market Surveillance (PMS) Report: A report containing data on PMS measures and their results. It includes what data has been collected; what conclusions have been drawn regarding the risk and benefits of the product; and whether the collected data is sufficient to confirm the ongoing safety and performance of the product within its intended purpose.

Medical device manufacturers must update their PMS procedures. With the launch of EU MDR, there have been notable changes to:

- PMS planning and implementation.
- Vigilance reporting.
- Periodic Safety Update Report (PSUR).
- The handling of field safety corrective actions.
- The timeline for adverse event (AE) reporting (decreased from 30 to 15 days).



Post-market clinical follow-up (PMCF)

Manufacturers must also include a Post-Market Clinical Follow-up (PMCF) Plan to meet MDR targets. PMCF aims to ensure quality, performance, and safety data collection throughout a device's life cycle, especially in a post-market setting.

Post-market clinical follow-up (PMCF): An active collection of clinical experience data from a device after its market release. Activities range from data analysis from existing device registrations to conducting a new clinical investigation.

Under EU MDR, manufacturers should perform PMCF studies throughout a device's lifecycle. Manufacturers with CE Marked devices should prepare PMCF studies to comply with MDR requirements. Manufacturers use PMCF studies to collect safety information on and validate the clinical performance of a device. These are often:

- Customized studies such as investigator-initiated studies (IIA).
- Economic impact studies.
- Registries.
- Prospective or retrospective trials based upon the intended use and indication for use under evaluation.



Post-market clinical follow-up (PMCF):

- For a quick primer on PMCF, consult our whitepaper "PMCF in 5 Steps."
- To learn how to use ePRO and physician surveys to collect MDR-compliant data in a PMCF study, consult our blog post "6 Steps for Using ePRO & Physician Surveys to Fulfill MDR PMCF."
- Ready to consider a PMCF technology solution? Click here to learn more.



When will EU MDR come into effect?

Some elements of EU MDR are already in effect. In general, companies had until May 26, 2021 to meet the new regulations, and current CE-registered products have until 2024 to re-register under the MDR.

Key MDR dates:

May 25, 2017
MDR officially replaced MDD with a target implementation date of May 26, 2020.

April 24, 2020
Due to COVID-19, the Official Journal of the European Union published the first formal amendment to MDR, which delayed the implementation date from May 26, 2020, to May 26, 2021. This amendment also legally allows for an extra year of conformity review under the MDD and Active Implantable Medical Devices Directive (AIMDD).

May 26, 2021
Compliance deadline for most devices.

May 26, 2024
Compliance deadline for either reusable surgical instruments, Class I sterile products, or Class I devices with a measuring function.

For more details on the regulations, visit the European Commission website.

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What is EU MDR's impact on clinical data collection?

EU MDR substantially impacts medical device clinical data requirements both pre- and post-market. It creates more stringent clinical evidence requirements to ensure more significant health and safety for patients through transparency and traceability. Also, governing bodies aim to close previous loopholes that allowed devices to enter or stay on the market without sufficient post-market clinical evidence.

Overall, conducting medical device clinical trials in Europe can be challenging as the MDR contains approximately 300 line items. Thankfully, many match up with the ISO 14155 regulations or standards, so there's a harmonization effort. (For example, the Annex 15 of the MDR outlines protocol for pre-market clinical investigations aligns with the ISO 14155.)

Hoping to collect device data directly from patients? Not so fast.

In Europe, the hurdle is relatively high for a manufacturer to get direct access to a patient to collect medical device data due to the General Data Protection Regulation (GDPR). However, there are exceptions. Suppose a user can find a device at the local drugstore. In that case, it may be possible to go directly to the patient if the legal requirements for GDPR, Health Insurance Portability and Accountability Act (HIPAA) and Good Clinical Practice (GCP) are followed.

It also may be possible to obtain explicit consent from patients willing to be contacted by the manufacturer for further research; however it's vital to understand the ethical requirements involved in that possibility. In such a case, the patient must remain informed of changes, and the manufacturer must be as transparent as possible.

ISO 14155: According to ISO.org, these principles address "good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes."

General Data Protection Regulation (GDPR): A regulation in EU law on data protection and privacy in the European Union (EU) and the European Economic Area (EEA) aimed at giving individuals control over their personal data.



Understanding medical device classifications

Under EU MDR, “grandfathering” of devices is no longer possible. The MDR’s requirement for increased clinical evidence means many manufacturers will need to certify or recertify devices—even Class I medical devices.

All medical devices fall under a category of the medical device classification system. Classification is based on the degree of control required to assure the safety and effectiveness of the various types of devices. Medical device classification determines what needs to be done before you a product can be sold—and therefore is a big component of how much time and money is required to bring a device to market.

Classification of medical devices

Class I

Class I medical devices are non-invasive devices or equipment that present minimal potential for harm to the patient or user. Examples include bandages, canes, or compression stockings.

Class Is

Class Is is a sub-group of similarly non-invasive devices and include sterile devices. Examples include examination gloves, oxygen masks, and stethoscopes.

Class Im

Class Im devices are considered low-risk and encompasses measuring devices. Examples include thermometers and non-invasive blood pressure machines.

Class II

This category includes everything from home pregnancy tests to wheelchairs.

Class IIa

Class IIa devices are low-to-medium risk devices. These may be installed within the body for a short time, between an hour to 30 days. Examples include catheters and hearing-aids.

Class IIb

Class IIb devices are typically medium-to-high risk which may be installed within the body for 30 days or longer. Examples include equipment for intensive care monitoring and ventilators.

Class III

Class III devices are high risk, implanted, or used to sustain or support life. Examples include orthopaedic implants, pacemakers, deep brain stimulators, and prosthetic heart valves.

What data points need to be collected and reported?

With EU MDR, the quantity and type of data that manufacturers collect depends on the risk class of the medical device:

Class I devices (low risk)

- Class I may require involvement of Notified Body if they:
  - are sterile
  - have a measuring function
  - are re-usable surgical instruments
- These devices must demonstrate evidence for safe use and summarize any report of adverse events or risks reported (e.g., allergic reactions to the material) and corrective actions (e.g, use warnings or material change for certification and recertification).
- Manufacturers must also create and maintain a post-market surveillance report (PMSR) that can be made available for a national competent authorities' request.

Class IIa devices (low to medium risk)

- These devices must show strict equivalence to an existing device; otherwise, clinical evidence of safety and efficacy might require certification.
- These devices require a PMCF, which might incorporate registry study data. Notified Bodies (NB) govern these studies.
- Manufacturers must submit data from the PMCF and other real-world sources as part of a PSUR and include a risk assessment and information on use volume every other year.

Class IIb implantable and Class III devices (medium to high risk)

- These devices require clinical evaluation for certification and recertification.
- Manufacturers must submit PSUR reports to NBs, including the results of approved PMCF studies, at least once a year.



How should you collect EU MDR-compliant clinical data?

The more stringent clinical evidence requirements of EU MDR mandate more clinical data than the previous regulations. As discussed earlier, EU MDR clinical data requirements might impact up-classified medical devices and result in some devices' reclassification and reregistration.

Providing clinical data for a significantly increased number of medical devices—whether data collection occurs on a predicate device, during pre-CE clinical trials, or PMCF studies—presents a significant challenge for most manufacturers. However, meeting EU MDR targets is achievable with proper planning and the assistance of tools such as a robust and compliant clinical trial platform to aid in data collection, management, and reporting.

The importance of preclinical research

One of the first challenges for medical device manufacturers is setting up the preclinical research phase to demonstrate that the device's technical characteristics meet safety and biocompatibility standards. This phase is known as the prototype stage and includes verification and validation, an early version, and not-for-human use.

At the preclinical research stage, manufacturers test device prototypes in controlled laboratory settings using in vitro (for example, in a test tube) and in vivo (for example, in a living organism) methods.

The goal of any preclinical phase is to gather sufficient data for analysis to move the device along the path to market. Consult our blog post "Jumpstart Your Medical Device Preclinical Phase" for more information on this critical data collection phase.



A technology-driven data collection strategy

Under EU MDR, medical device manufacturers typically collect a larger quantity of data. A large quantity of data is only useful if you can manage it and understand its value. A robust data management system accelerates this task and facilitates compliance, even with constantly changing regulations. It can also keep track of multiple data streams.

If your company is overwhelmed by increased demand for data, consider a new technology solution. The best system can streamline the data collection and distribution process and ensure that your company is prepared for and thrives under EU MDR. And while adapting to stricter regulations like EU MDR might be initially burdensome, manufacturers who comply quickly and thoughtfully will be able to bring their products to market faster and advance global health more easily.

Because medical device companies wanting to market in Europe are expected to conduct PMCF trials for any new device introduced to the market, there are higher development and operational costs. Medical device manufacturers need an easy-to-configure, self-service clinical trial platform to reduce the time it takes to go live with a trial and positively impact their overall R&D budget. Here's what to look for.

Ease of use

Look for **an accessible and self-service platform** that empowers both novice and experienced users to design and build eCRFs. Make sure it's easy to collect and manage data while having control over the whole process.

Clean study data is a crucial component to timely database lock, and ultimately, study success. Data capture technology with such features as **direct input validation, edit checks,** and **automation** to capture only clean study data is critical. A user-friendly system will minimize data entry errors—a significant advantage in saving valuable time and money.

Data integration (e.g., sensors & wearables)

Integrating data from clinicians, patients, and devices in one connected platform can help save time and alleviate resourcing pressures. **An open API architecture** can be essential for connecting sensors, wearables, and other devices dierectly to your EDC, a process called eSource. This direct flow of laboratory results, vital signs, and other clinical data eliminates the need for double documentation and reduces the chance of errors with manual transcription of data.

Find an EDC system that **directly integrates data from numerous sources including:**

- Electronic case report form (eCRF)
- Electronic patient-reported outcome (ePRO)
- Electronic clinical outcome assessment (COA)
- Laboratory data
- Device data
- Wearables

Security and compliance

Meet EUMDR regulatory and compliance certifications on **a private and secure infrastructure**. Ensure adherence to privacy regulations including the General Data Protection Regulation (GDPR, EU). Make sure your tech choice's organization and data centers have been **audited for information security compliance** and granted **ISO 27001 certifications.**

Ecosystem partners

To speed up a study, look for a tech solution with **proven partnerships with industry-leading patient enrollment and recruitment companies**. This enables sponsors to expedite their clinical trials through streamlined workflows for patient enrollment, data collection and engagement.

Reporting and analytics (RWE)

Ask for a **helpful dashboard** to project, interpret and action study specific data and key performance indicators at a glance. Choose from customized or standardized reports displaying core site performance tracking, such as:

- Participant recruitment rates
- Data collections
- Verification progress
- Query and issue management

In summary

The expense, technical complexity, and market implications of EU MDR result in high compliance costs for medical device manufacturers in the EU market. Thousands of companies are working to meet the new EU MDR, but many struggle to find a strategy that meets their needs.

But as a researcher, you want to focus on the science, not the admin. That's where Castor's self-service technology comes in. It helps researchers skip the complexity and get straight to designing and running clinical trials centered on the patient experience. It's a clinical research platform uniquely designed to help medical device companies conduct regulatory-compliant and patient-centric research effortlessly.

Castor ranks among the top 5% of EDCs for shortest build times, with more than 90% of studies being deployed within 4 weeks without the need for extensive training. Want to learn more about it can be configured for your medical device trial? Get in touch with our team today.