4 ways the Medical Device Regulation will impact your device studies

By Matthias Havenaar, *M.Phil.*

06/06/2018



Medical device companies targeting the EU market are being confronted with significant regulatory changes for market access. As of May 25th 2017 the Medical Device Regulation (MDR) has replaced the long standing Medical Device Directive (MDD). The impact of the MDR to the medical device industry is substantial. Markedly, the new regulation will require a re-registration and re-classification of all medical devices currently on the market. Companies are given until May 26th 2020 to meet the new regulations. Current CE registered products are given until 2024 to re-register under the MDR.

What does this mean for your company? It means that new product development should have a (clinical) strategy in place with the MDR in mind. It also means you will need to do a conformity assessment for all your devices currently on the market, be it a syringe or a pacemaker, or remove the product from the market. Additionally, more products will be considered to be a medical device. Make sure this does not take you by surprise. The change from `directive` to `regulation` means that legislators can now impose significant fines on companies that do not meet the regulations.

The MDR outlines new clinical data requirements for (maintaining) certification of medical devices. Besides requiring more clinical data collection throughout the product's lifecycle, it also raises the bar for the level of evidence that is required. Below we've outlined four ways the MDR will impact your clinical study requirements:

1) More devices will require clinical investigation

The biggest impact of the MDR is on Class I and II products. Under the MDR, many devices will be re-classified to a higher device class, impacting their clinical data requirements. A clinical evaluation report, previously based on an analysis of literature, might suddenly require clinical investigation and/or post market clinical follow-up. For example a mobile app transmitting cardiovascular data, previously Class I now falls under Class IIb. Another example, mechanical heart valve sizers will be moved up not one class but two, from Class I to Class III. Make sure you are informed about the new classifications and corresponding clinical requirements of your products.

2) Equivalence will be harder to demonstrate

Traditionally, device companies have been able to use clinical data of an equivalent device for its registration. This has saved the industry billions of euros in replicating clinical studies. Fortunately, this principle does not change under the MDR. However, the bar on equivalence criteria is raised. Devices need to be equivalent with respect to technical, biological and clinical properties. In addition, the manufacturer needs to demonstrate it has access to the equivalent device data, which significantly limits its usability. These criteria were also added in the most recent revision of the guidance on the clinical evaluation (MEDDEV 2.7.1 rev. 4). When data-demonstrating equivalence is not available, clinical investigation is necessary.

3) Device studies should demonstrate clinical benefit

Where medical device clinical studies previously aimed to demonstrate safety and performance, studies under the MDR will now also need to show the clinical benefit to patients. This means that clinical trials should be designed with completely different end-points, more complex study setups, and potentially larger sample sizes. Additionally, clinical investigation plans should include details on prevention of scientific bias. For example, randomization, independent monitoring/auditing, power, objective endpoints, etc.

4) More focus on post-market surveillance

While post-market surveillance (PMS) is mentioned in the MDD, its requirements were not clearly defined. The MDR now clearly outlines what is required from manufacturers. A PMS system shall be used to actively gather and analyse data on the quality, performance, and safety of the device throughout its lifetime. The system should be based on a PMS plan and to be outputted in a report. In addition Class II and III devices should prepare yearly for periodic safety update reports (PSUR) containing the analyses of the PMS data gathered, including data from post-market clinical follow-up.



How to process the new clinical data?

The MDR will significantly increase clinical data requirements for your company. Clinical data collection should be compliant with Good Clinical Practice (GCP), such as set out under ISO 14155. GCP requires informed consent, patient privacy protection, and safe data-processing. This has been further intensified under the new General Data Protection Regulation (GDPR).

Traditionally, device companies have relied on paper-based Clinical Research Forms (CRF) to fulfill their clinical data requirements. The downside of paper-based CRF is that this data needs to be entered manually into a data analysis packages. This is error prone. Managing an audit trail is virtually impossible.

In order to make clinical data collection more manageable and cost effective, many companies have moved to an electronic data capture (EDC) system. Castor EDC offers an electronic data capture platform for medical devices and a consent management tool called MyConsent.

The benefit of using a platform such as Castor is that it is has all the quality & security systems in place to protect patient data. It allows strict user management and includes an audit trail to comply with Good Clinical Practice. Having all data on a single platform enables your company to have full control of your clinical data.

Interested in learning more about Castor EDC? Request a demo now.