Research Professionals-CRO Case Study

Accelerating Submissions Under New EU Medical Device Regulations (MDR)

Research Professionals (RP) is a leading GCP compliant contract research organization (CRO) based in Hungary (EU Member) with operations in Poland, Czechia, Romania and Bulgaria, serving customers from across Europe and the globe. www.rp-cro.com

Introduction

With the implementation of the updated EU MDR regulations in 2021 and 2022, medical devices that have a CE (Conformité Européenne) mark that predates the new regulations must be reviewed for conformity with the new standards. In addition, new medical devices coming onto the market will have to meet the new requirements, in many cases supported by clinical data, where it wasn't previously required. Those medical device-based products that are found not to conform with the updated EU MDR, must update and refile their submission in order to maintain or receive their CE mark. The original deadline for this transition process was May 24, 2024, but has been extended to December 31, 2027, for higher risk devices and December 31, 2028, for medium and low risk assets. In many cases this refiling process will require the generation of additional clinical data, a new ethics submission and completion of a longer, more complex submission to EU regulatory authorities (RAs). Finding a responsive CRO with the knowledge, experience, and capabilities to help customers quickly navigate through this complex regulatory process to maintain their critical CE mark can be a challenge to today's pharmaceutical, biotech and medical device companies.

Background

Sponsor companies are seeking CROs with a strong understanding of the new requirements of the EU MDR as it applies to medical device products. Sponsor companies know they need to conduct a conformity assessment and complete the scope of work required to submit the filing to regulators in the near future or risk losing their CE mark and medical device approval. If the assessment demonstrates the need to perform additional clinical studies, having a knowledgeable and flexible CRO with experience in conducting and managing the study programs for this specific purpose are critical. Regulatory bodies may be more cautious and stricter in how they apply the new regulations, while they gain practical experience in overseeing the new EU MDR regulations. In addition, the regulations are fundamentally more complex and take significantly more time and effort to prepare and apply for submissions. All of these issues combined, point to the importance of finding an EU based CRO that has practical applied knowledge of how to efficiently advance these specialized studies to completion. It also means having cooperative communications with the regulatory authorities and the right ethics boards can help to keep medical device filings on track for sponsor companies.

Strategy

As the new EU MDR regulations were approaching finalization, RP-CRO took a strategic approach to studying them and developing an efficient process to support MDR filings for its customers. Critical

features of their MDR study service plan included structuring and managing studies that were designed specifically to meet the EU MDR requirements and include only the activities needed to efficiently advance them to completion. Research Professionals CRO had already established strong relationships with local ethics boards and European regulatory authorities, which became even more necessary to work through the challenges of interpreting the new EU MDR requirements as applied to customer medical device products.

RP-CRO Study Metrics in EU MDR

Research Professionals CRO established its specialized EU MDR expertise through successfully filing numerous medical device filings for customers. Research Professionals successfully submitted more EU MDR submissions on its own, than did all global CROs in Hungary combined.

Research Professional CRO EU MDR License Applications Experience

Status of submissions (as of May 2023)	Article	Number of submissions	Indication
Approved	Article 62	5	- vascular implant (HU) - dental surgery (HU) - cardiology x2 (HU) - cardiology (CZ)
	Article 74	1	- dental implant (HU)
Under RA evaluation	Article 62	1	- cardiology (PL)
Applied	Article 62	1	- cardiology (HU)

Key Points

- RP-CRO has submitted the most EU MDR regulatory submissions for customers in Hungary and has the same capabilities in Poland and Czechia.
- RP-CRO submitted a cardiology MDR trial submission procedure in only six working days, from receiving the sponsor's initial request to the completion of the ethics board submission.
- RP-CRO had the critical processes, quality systems, and regulatory knowledge in place to manage EU MDR license applications efficiently and successfully for its medical device customers.

Results

RP-CRO had the foresight to prepare for the implementation of new and more strict EU MDR regulations in advance. By putting the right processes, and system in place to efficiently handle these specialized regulatory requirements ahead of time, Research Professionals CRO was ideally positioned to efficiently advance sponsor medical device products through the increasingly complex and lengthy regulatory process. RP-CRO expertise and proven track record of successfully supporting EU MDR clinical study requirements and submission preparation services, provides sponsor companies with the confidence that their medical device product is well supported in the new regulatory environment. This specialized MDR knowledge, combined with RP-CRO's well-established clinical trial capabilities allow its customers to meet the new European regulatory requirements quickly and confidently for their medical device products.