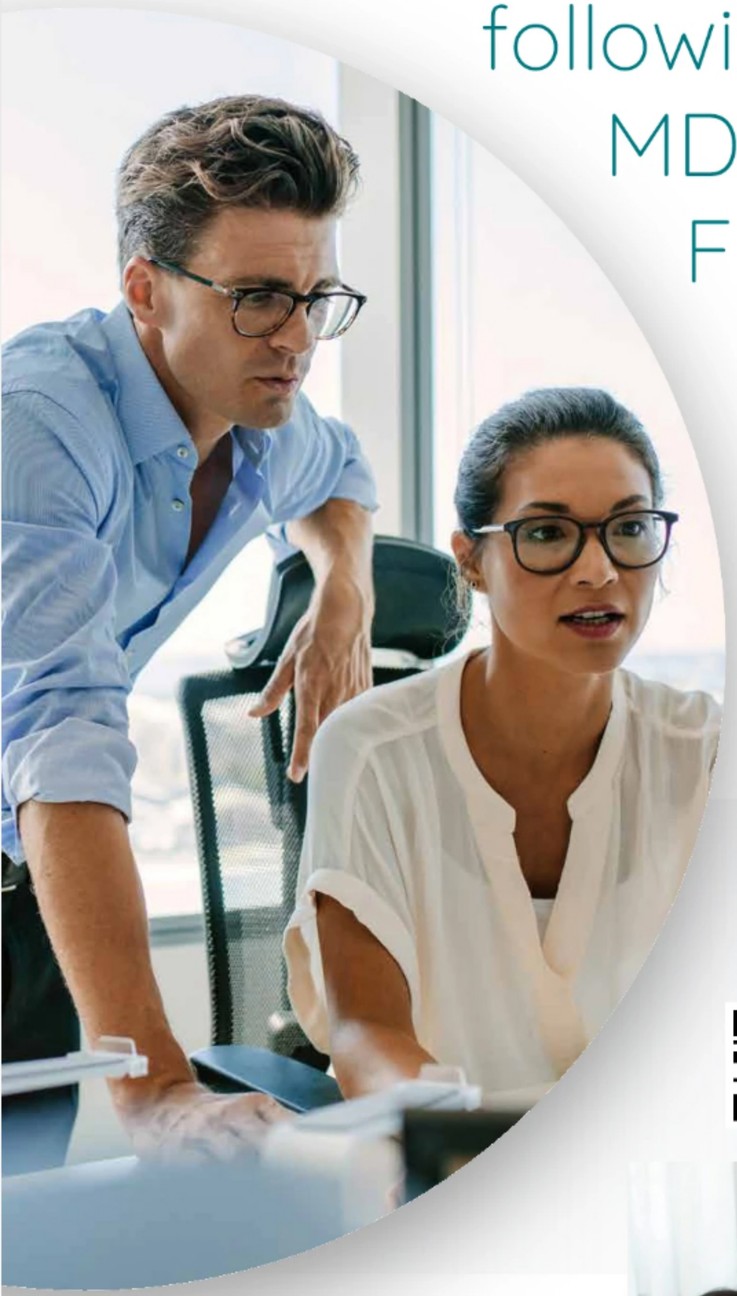
The survival of devices following EU-MDR and FDAs more stringent scrutiny on clinical data



It has been predicted that 50% of all medical device products on the European market will vanish after the MDR curtain has fallen. This produces huge opportunities for companies that are proactive and understand that MDR is not a problem but rather an opportunity.

The biggest impact on life for medical device companies following MDR will be in the clinical evidence that will need to be collected or produced. And there is no time like the present. All devices on the market need to have their post-market-surveillance in place according to MDRA already. Keep in mind, that this is one way to collect further clinical data.

Updated regulations such as the European Commission's MDR, and recent signals from the FDA, mean closer scrutiny of clinical data. As a result, there are more stringent requirements to issue regular, accurate updates including Clinical Evaluation Reports, Post-Market Clinical Follow-Ups, and Period Safety Update Reports. If device manufacturers are not in compliance, they may face both legal and commercial consequences. Be on top of the requirements and you will be one or more steps ahead of your competitors.

If you are uncertain about the value of the clinical data you collected under the MDD, and if you are uncertain about what you will need to produce to be MDR compliant then start with a GAP analysis and updating your clinical evaluation.

It is hard for medical device manufacturers to find the right partner for clinical development. It is not unusual to test pharma competent CROs, both global and local, without receiving the required support that is part of understanding the particulars of the medical device field. There is a huge difference between clinical development in pharma and medical device. Without the correct knowledge any investment in clinical evidence will be in vain. For that reason, in 2020 Key2Compliance decided to start a new business area, Clinical Development. "We did not want to call ourselves a CRO as a lot of medical device and in vitro diagnostic companies unfortunately have bad experience in working with typical pharma CROs", says Jan Hellqvist, CEO at Key2Compliance.

> Our most important asset is our dedicated staff. Our team consists of specialists from all over the world, with long and broad expertise in all aspects of the development of medical devices and in vitro diagnostics. It is the team that makes the difference!
>
> Jan Hellqvist – CEO

One of the usual practices of pharma CROs, include: 30-50% down payment at the signing of the contract, out of scope invoicing, payment according to plan and not according to progress. If a small or mid-size medical device manufacturer contracts a global CRO they will get junior staff with a 30-40% staff turnover, and the person involved in starting your study will not be involved at the end of the study, which is costly both from a relationship and competence aspect. "This is not the way we want to work at Key2Compliance and the reason to why we have decided to call ourselves a Clinical Development partner in medical device and in vitro diagnostics", says Jan Hellqvist.

Key2Compliance have hand-picked an experienced team of device experts forming a full-service team that can support you with your clinical investigation, clinical evaluation, post market clinical follow up, performance study and much more. At the start of a collaboration, we will always recommend doing a GAP analysis to evaluate what you have and to help you develop a regulatory and a clinical strategy to set the road from where you are to success.

"We can support you in fully outsourced projects or work as an integrate part of your team - always with focus and competence needed in your clinical development", says Maria Lindgren, Director Clinical Development. "We have all the skills you need such as Project Leaders, CRMs, CRAs, CTAs, Statisticians, Data Managers, Device Vigilance experts, Medical Advisors and Medical Writers. We have a digital set-up with effective eCRFs, eTMF so all documentation in your investigation is placed safely online" says Maria Lindgren.

Key2Compliance can do both local and global projects through a network of more than 30 000 experienced freelancers. Using a freelancer network instead of a global CRO will save you money, time and give you experienced support where you need it.

Contact us for a discussion about how we can help you reach your road to success.

Watch our video and get a glimpse of what key2compliance is all about!

Key2Compliance is a full-service partner to small and mid-size medical service and in vitro diagnostic companies with services including Quality Assurance, Regulatory, Biological Evaluations & Toxicology, Clinical Development, GxP services and Training & Courses. We also support a large number of pharmaceutical companies with courses and training, custom made competence development, quality assurance and training and consultancy within the entire GxP area.

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