# Making sure you are ready for MDR (2017/745)

A strategic opportunity for Medical Device Manufacturers to improve patient safety, grow revenue streams and stay ahead of the competition

The world is how we shape it

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# Introduction

**Tighter and more stringent Medical Device Regulations (2017/745) from the EU are due to come into force in May 2021. Medical Device Manufacturers may have a plan to meet their legal obligations related to this changing regulation in the short term, but are the solutions they have designed, tested and looking to deploy right and fit for purpose in the long term?**

For example a requirement of MDR (2017/745) is a post market surveillance process must be in place. Those organisations who are reliant on manual processes to fulfil this regulatory obligation may find themselves at a disadvantage. As we know manual processes can be both costly and time consuming.

In the Medical Device market we know regulation which is heavily reliant on manual data processes usually require highly skilled staff to find, retrieve and interpret data, then report information related to what the regulator wants to know. As well as the obvious staffing cost involved in a manual reporting process, having your most skilled staff undertaking administrative tasks can be demoralising for them and reduce focus on other important business objectives.

Additionally a manual process is only as good as the people involved in it. What happens when your business grows and the range of medical devices you manufacture increases? Increased workloads raises the risk of error if you are solely reliant on manual product validation.

This could in turn lead to your products becoming non-compliant and crucially your organisation losing revenue due to the removal of some of your products from the market. Non-compliance of MDR (2017/745) can also lead to heavy fines and damage to your brand.

As you have probably guessed making sure you have the right process, people, technology partners and investments in place to meet MDR obligations is a 'must have' not a 'nice to' have.

***At Sopra Steria we believe those Medical Device Manufacturers who take the time to examine their immediate MDR regulatory reporting requirements whilst thinking about their future business objectives alongside this legislation will be at a distinct advantage from their competitors. By using this time to set up the right processes, recruit the right people for their organisation and work with right technology partners, Medical Device Manufacturers can unlock the power of their organisations data.***

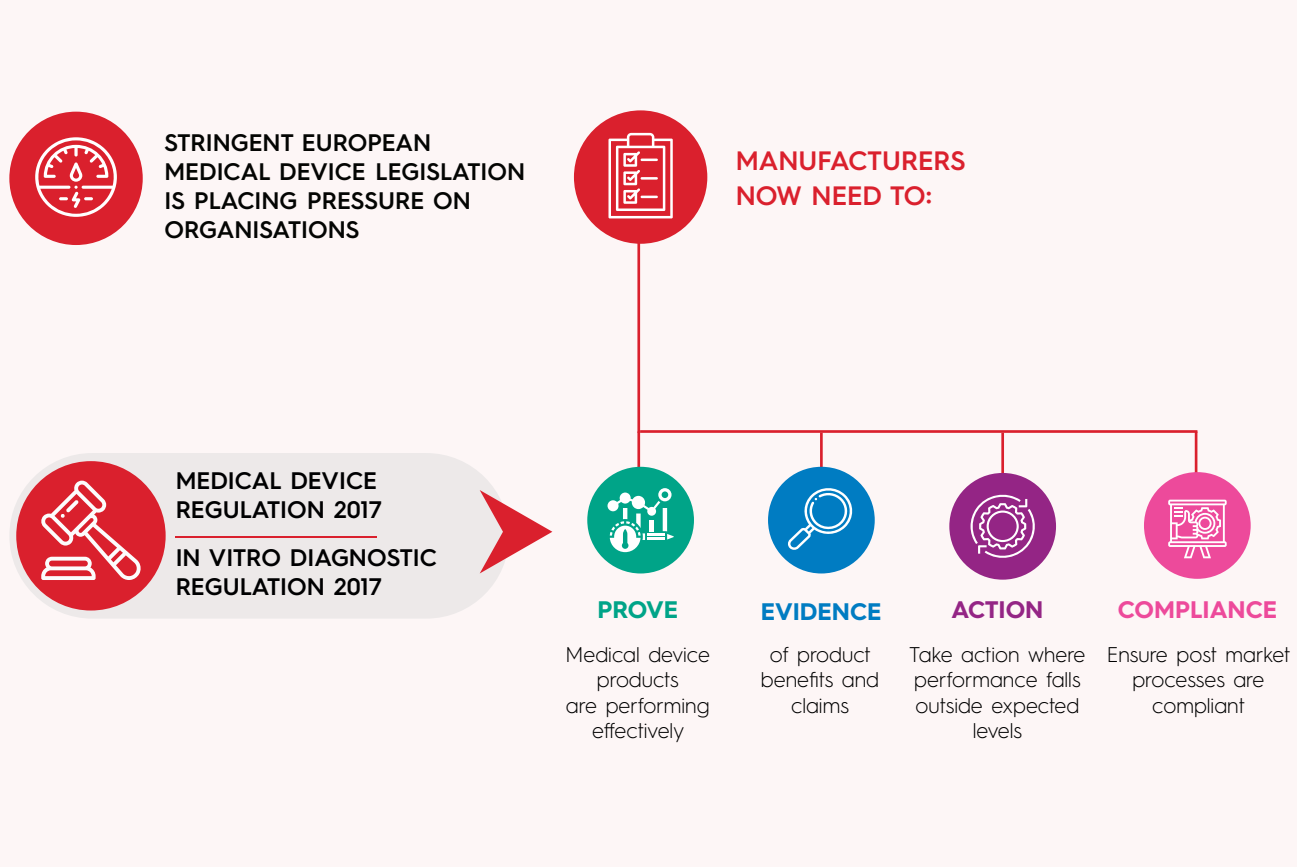
# What will Medical Device Manufacturers need to focus on?

**As we identified in the introduction section of this paper the changing medical device regulations coming into force in May 2021 will place increased responsibilities on manufacturers to demonstrate the following in order to continue to sell medical devices:**

- **Provide evidence that medical devices are performing effectively**
- **Provide evidence that the benefits and claims made by manufacturers are accurate**
- **Ensure that standards, systems and processes supporting post market surveillance are compliant and fit for purpose**
- **That swift and appropriate action has been taken where performance trends fall outside of acceptable levels**

At Sopra Steria we believe the key to successfully meeting these responsibilities is to have a comprehensive data and analytics platform in place to capture and understand everything about your medical devices from concept to manufacturing to where they are being used in real life.

By creating and implementing the right data and analytics platform Medical Device Manufacturing organisations will be able to monitor the performance of each of the manufactured devices quickly and proactively, highlighting any issues before they become a bigger challenge. In addition to creating the right platform an assessment of your current systems and processes is advisable to help quickly identify any issues with your current capabilities and to look for ways to strengthen areas of your business to ensure ongoing compliance.



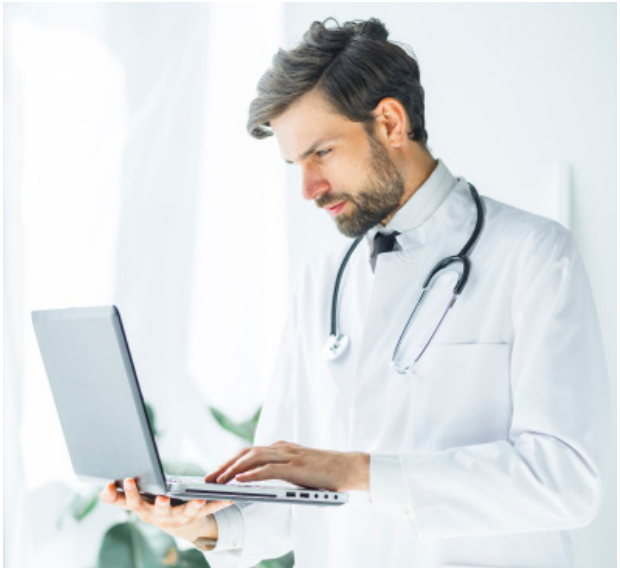
**It all sounds easy right? Unfortunately it isn't. Many Medical Device Manufacturing organisations are simply not ready for the new regulations which are due to come into force in May 2021. A survey by Climedo Health found that:**

- **More than three quarters (77%) consider the new regulation to be "very challenging"**
- **The main challenges identified were "lack of clarity regarding the new requirements" and "increased resources and costs"**
- **Around one third believe that compliance with EU MDR will cost them more than 5% of their annual turnover**
- **Only 26% have a fully MDR-compliant QMS**
- **34% do not yet have a Notified Body or are currently switching NBs**
- **Almost half do not (yet) have a PMS plan**
- **Many companies still use paper (48%) and / or Excel spreadsheets (69%) for clinical data collection**

So what does this survey tell us? It says Medical Device Manufacturers need to start taking notice of MDR (2017/745) as time is passing quickly. Standing still or taking little or no action is not an option. In addition to not being regulatory compliant many Medical Device Manufacturers are actually missing an opportunity to make sense of their organisations data to improve patient safety, access new revenue streams and gain a competitive advantage.

# What will happen if Medical Device Manufacturers take no action?

**Poor planning and inadequate processes could be hugely detrimental to Medical Device Manufacturers businesses and the customers who purchase their products. Some of the key risks organisations could face as a result of non-compliance include:**



## Customers

Patient safety will be severely comprised as a result of poor quality products. This will lead to dissatisfied customers and an increase in class action litigation where customers have been impacted negatively by products provided by manufacturers.

## Safety and Quality

Non-compliance will also lead to the risk of reduced levels of safety management leading to poor levels of product quality. What would have been deemed 'acceptable' safety management will no longer be deemed adequate, eroding customer confidence in your products and brand and leading them to look elsewhere.

## Business Implications

Products which are deemed to be non-compliant will not be certified and will be taken off the market. And organisations are finding that there are significant financial penalties for non-compliance. For example a leading medical company has already incurred settlement costs in excess of $4bn following the ASR metal-on-metal implants issue and their failure to disclose and address the problem when they first became apparent.

# Sopra Steria's approach to MDR Compliance

**To help Medical Device Manufacturers meet their regulatory compliance requirements and unlock the power of the data they hold in their organisation Sopra Steria have developed a simple four step solution. The solution has been specifically designed to help organisations overcome their challenges related to MDR.**

We start with a 'health check' of your current MDR set up. Once the 'health check' is completed we will work with you to create and implement a solution which is right for your organisation both now in the short term to make sure you are compliant for May 2021 but also help your organisation plan for the future based on the data you already hold.

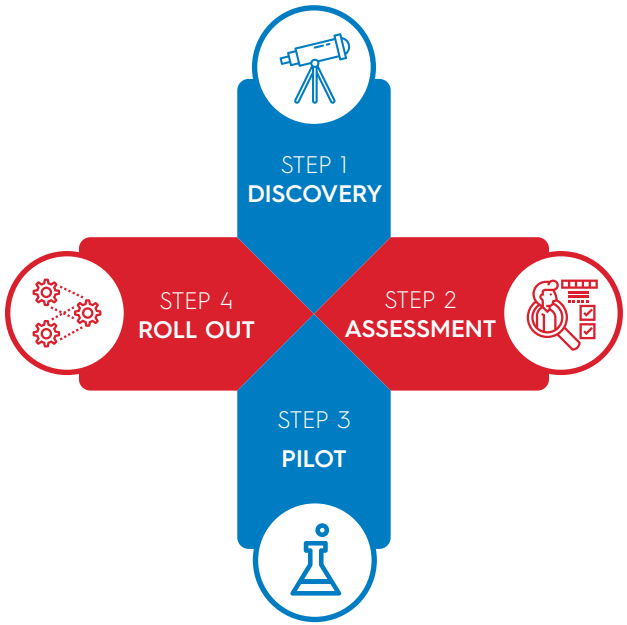
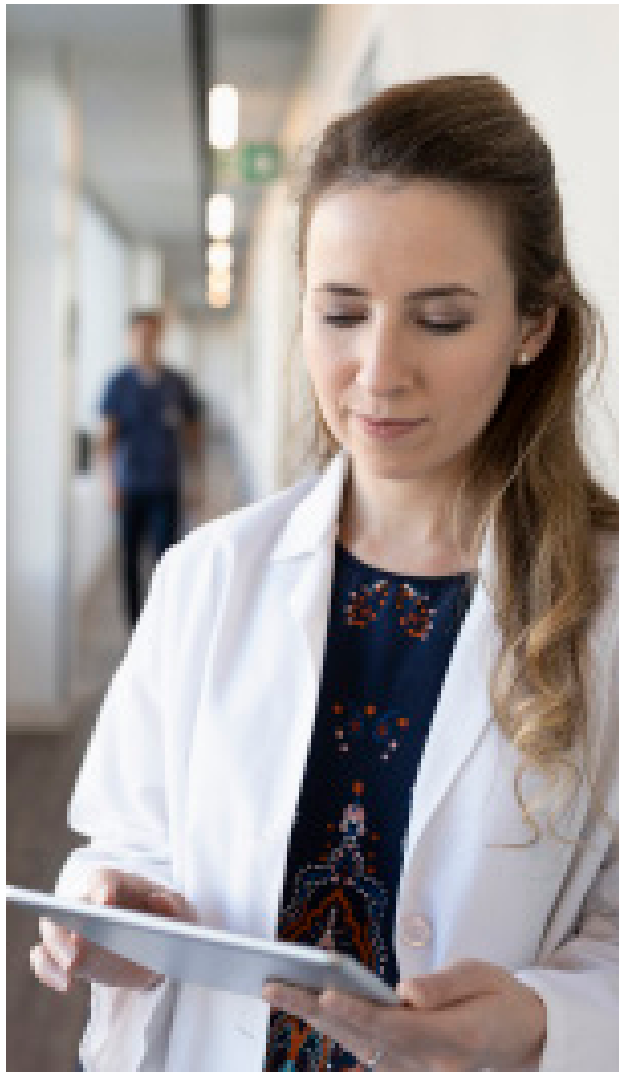


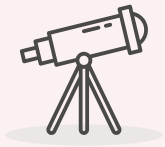

*Figure 1 - Our 4 step approach to MDR compliance*

**As you can see in the diagram above our solution is a proven 4 step process which has been tried, tested and implemented at a top 10 global Medical Device Manufacturer:**



# Our 4 step approach to MDR compliance

## STEP 1 : DISCOVERY



### Discovery Activities

Initial high-level discovery activities (time boxed)

### Assessment Workbook

Based upon our Post-Market Assessment Workbook

## STEP 2 : ASSESSMENT

We'll work with you to undertake an initial assessment and provide you with a summary understanding on where you are with meeting your MDR post market surveillance obligations. Highlighting improvements and efficiencies you need to make.

**The initial MDR assessment will include:**

- Summary of challenges including data reporting and analytics
- The key findings of the assessment
- A proposal of future work
- The key recommendations

## STEP 3 : PILOT

Once you've had chance to digest the assessment report we'll develop a proof of concept which will deliver working illustration of functional capability against a scoped subset of your business needs.

### MDR Pilot Phase

- Tailored to your organisations needs
- We'll base it on your existing technology stack
- This will help to avoid disruption and unnecessary cost

## STEP 4 : ROLLOUT

The final part of getting you and your organisations MDR ready is to work with you to configure a tailored solution which is future proofed – ensuring you are compliant now and in the future.

- Monitor
- Track
- Report

- Focussed on the key challenges identified by the assessment and the pilot phase
- To ensure you are able to monitor, track and report on all your medical devices easily
- You'll have an effective solution in place which will help you manage your compliance challenges now and in the future

# Our overall approach to MDR compliance

## Discovery Phase

The initial discovery phase will focus on gathering all the relevant information, data and documentation including meeting with key stakeholders within your organisation to ensure we have everything we need to perform a thorough assessment.

## Assessment Phase

We will work with you to undertake an initial assessment of your post-market surveillance processes, platforms and data to provide you with a summary understanding on where you are in relation to meeting your MDR post market surveillance obligations.

**We'll provide you with a report of the MDR assessment which will include:**

- **Summary of challenges including data reporting and analytics**
- **The key findings of the assessment**
- **The key recommendations**
- **A proposal of future work**

## Pilot Phase

Once you've had chance to digest the assessment report we will develop a proof of concept which delivers a working illustration of functional capability against a scoped subset of your business needs. It will be tailored to your business based on your existing technology environment to help avoid disruption and unnecessary cost.

## Rollout

The final part of helping you and your organisation to become MDR ready is to work with you to configure a tailored solution which is future proofed. This ensures you are compliant now and in the future. The solution will focus on the key challenges identified in the assessment and pilot phase. Once in place your organisation will have a solution which will allow you to monitor, track and report on all your medical devices easily and effectively.

As we have recognised earlier in this paper early detection and resolution of incomplete or inconsistent data is key to making sure your organisation is MDR (2017/745) compliant. Faster identification of trends and changes in product performance by collating data from multiple sources and replacing manually intensive processes also enables manufacturers to take action faster to improve product quality.

Quick and easy access to diverse structured and unstructured data reduces time spent manually searching for and retrieving information. The creation of a foundational data platform to satisfy ongoing regulatory and safety requirements coupled with automated connection to master data sources (to ensure information is always timely and accurate) and a common portal for access to all relevant product performance data across the portfolio can automate manually intensive processes to address evolving compliance, analysis and reporting workloads whilst avoiding significant increases in resource costs.

# How Sopra Steria Data and Analytics experts can help your organisation to succeed with MDR

**Sopra Steria have a number of Data and Analytics experts who can help Medical Device Manufacturers to put in place effective measures and solutions which will help them meet their compliance obligations and unlock a range of business benefits including:**

## Demonstrate compliance

Prove ongoing compliance with MDR regulations through robust systems and reporting which can track all your devices.

## Protect and grow revenue

Through tracing, monitoring and reporting you will be able to make sure your products stay on the market, protecting your revenue. Your revenue will grow as you adopt this to new products you bring to market, ensuring they are fully compliant.

## Industry leader in medical device safety

You will be seen as an industry leader in the management of medical device safety. Enhancing your brand reputation with regulators, peers and most importantly your customers.

## Moving ahead of your competition

You will be able to move ahead of your competition who may not have a thorough and robust response to MDR in place.

## Use tech, data and analytics

You will be able to use technology, data and analytics to simplify your processes and demonstrate patient pathway savings.

## Unlocking value

Our approach will help you unlock the value from your data and support more tailored and successful R&D and Sales and Marketing activity.

# Client Focus | How we helped one of the world's largest Medical Device Manufacturers become MDR 2017/745 ready

## The Challenge

Recently we have worked with a top 10 global Medical Device Manufacturer to harness poly-structured data to provide better business decisions, enable proactive regulatory compliance and significantly reduce the time and effort expended searching for information. This organisation identified the necessity to replace manually intensive processes to enhance patient safety, drive sales, remain compliant, and make better use of expensive internal resources.

## Our Solution

Sopra Steria adopted a multi-step approach, initially undertaking a consulting assessment of the organisations key post-market and clinical-evidence challenges. This enabled the project team to understand and document business drivers, propose a set of recommendations and, ultimately, both prove (via a proof-of-value exercise and pilot) and release the enabling technology to take this organisation forward on its compliance journey.

**A secure solution was developed in close consultation with the organisation which comprised of:**

- **A NoSQL platform, enabling collation and management of flexibly structured data content from all relevant data sources**
- **A custom-built web-based application (PMI Portal) providing users with access to search, discovery, and reporting capabilities**
- **Three-tier architecture: database; application; and web-based presentation tier**
- **Data is drawn daily from internal and external sources. It is ingested, modelled and enriched directly using the MarkLogic Data Hub Processing Framework**

The solution was delivered through an agile SCRUM framework allowing the organisation to maintain its position as a world-leading evidence led organisation whilst enabling continual achievement of evolving compliance obligations.

## The Results

This organisation now has a single source for all relevant product performance data in support of its product portfolio. It enables the company to comply with regulatory requirements to take proactive action and provide relevant information early in the product lifecycle.

The solution's ability to intelligently ingest and sort content on relevance is helping the business to assure the very best clinical outcomes. It continuously monitors, validates and communicates patient safety and clinical benefits.

**Other significant benefits include:**

- **95%** reduction in time spent searching for and retrieving information
- **Potential labour saving** of 50+ people resources through the solution
- **Ability to search, find,** consolidate and analyse content quickly
- **A single solution** for all relevant clinical, scientific research & post-market surveillance data
- **Replaces manual processes** with Google-style search and quick, easy access to data
- **Utilises machine learning capabilities** to refine and enrich incoming content

# Why should you choose Sopra Steria to help you achieve MDR compliance?

**As we have demonstrated throughout this paper our team at Sopra Steria puts the business challenge at the heart of any project, ensuring all parties and stakeholders understand the objective and business context, regardless of role, seniority or geographic location. Our Medical industry expertise coupled with our trusted digital delivery capability gives you access to a trusted technology partner who understands the changing regulatory requirements in the Medical Device Manufacturing industry.**

With this our collaborative, integrated, and business outcome focused delivery approach fosters flexibility and agility to allow for proactive failure of candidate ideas in the journey to a business solution which facilitates a positive outcome. Our team work with our clients business stakeholders to understand the full context of their challenges to determine resulting solutions which facilitate positive business outcomes.

Any analytically orientated solution necessitates data as its forming foundational cornerstone and so our team engage collaboratively to ensure business stakeholders recognise the importance of:

- **Data of good quality and so any upstream areas which may necessitate remediation**
- **Data variety i.e. spanning any structure and format available**
- **Value of externally data available through partners, industry and open data sources**

***Our skilled team have both breadth and depth of skills and experience with certifications in technologies provided by world class technology partners including Microsoft, Oracle, IBM, SAS, SAP, Google and Amazon.***

# Final thoughts

**We know that the tightening of Medical Device Regulations poses a significant challenge and risk to manufacturers. With the recent deadline extension, organisations have a unique opportunity to ensure they have the foundations in place to meet the new regulations.**

Additionally it should be recognised that it's not just a regulatory risk Medical Device Manufacturers are facing but also a financial, brand and customer satisfaction one if they fail to plan properly for MDR 2017/745.

**All Medical Device Manufacturers need to ensure that they:**

- **Have the right systems and processes in place**
- **Are able to fully utilise the data and analytics capabilities within their organisation**
- **Can audit their current approach to identify any risks and gaps hindering potential compliance**
- **Can replace and / or complement existing manual processes with faster and more efficient automated systems and processes**

As we have established in this paper it isn't enough to simply plan for the MDR (2017/745) regulations.

Medical Device Manufacturers need to put in place a robust plan, the right processes, and have access to the right technology partners if they are going to use this regulatory change as a springboard to unlock strategic opportunity from the data they hold within their organisation.

# More Information

To request a complimentary MDR discovery session that will provide you with summary findings and a recommendations report please email **Fiona Petrie** at **fiona.petrie@soprasteria.com.**

We look forward to working with you.

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