Case Study

Cardiovascular Device Company Exceeds Patient Enrollment Goals Six Months Ahead of Schedule

Learn how a medical device company scaled its post-market trial for cardiovascular grafts and patches to meet new EU MDR requirements during the global pandemic.

The situation: fresh data for EU MDR compliance

Medical device manufacturers are using all available resources to meet European Union Medical Device Regulation (EU MDR) requirements, which took full effect in May 2021, with a transition period until May 2026.

To meet EU MDR post-market surveillance requirements, a large cardiovascular medical device manufacturer needed post-market data on its cardiovascular grafts and patches. The data produced from that study would not only ensure compliance with new regulations, but also inform development of new products.

The manufacturer had no shortage of prospective clinical trial participants. What the company did need was a global CRO to manage study activity across several countries. When a global pandemic disrupted the original plan, a robust site network, a reliable clinical operations team, and overall agility became paramount to the study's success.

THE STUDY: POST-MARKET SURVEILLANCE

The manufacturer partnered with IQVIA MedTech to conduct a prospective and retrospective post-market non-interventional study on five types of devices. The devices included two knitted vascular grafts, two woven vascular grafts, and a knitted cardiovascular patch.

The study included patients who either had received one of the five devices in the past five years or who would receive one of the devices from study launch onward. Patients were divided into five cohorts according to device type.

Primary outcome measures were 30-day or in-hospital mortality within one year of implant and graft leakage. The sponsors collected data on device performance at 30 days, with ongoing follow-up through 10 years.

The study included a total of 1,665 patients.

The challenge: navigating a sudden detour

The manufacturer knew it could easily meet its enrollment goal of 1,000 participants. The devices were part of standard treatment at healthcare facilities across Europe, including leading teaching hospitals throughout France and Germany.

The manufacturer partnered with IQVIA MedTech to execute the study on time and on budget, with the highest-quality data. It needed a CRO partner with the resources to activate sites across multiple European countries. It also needed a partner that could enroll and manage five large cohorts through screening, discharge, and follow-up.

To ensure high efficiency and quality, IQVIA MedTech deployed a team of expert clinical research associates (CRAs) to oversee multiple data-intensive processes at trial sites. The CRAs assigned were fluent in the native languages of those sites.

However, the COVID-19 pandemic prompted country-wide and regional lockdowns in early and late 2020. The restrictions on healthcare facilities compromised sites in the UK and Italy.

To keep the study on track, the manufacturer needed to replace those sites, and fast.

Solution: leverage a robust network of sites, domain expertise, and technology

IQVIA MedTech leveraged its global site network not once, but twice. First, to select and activate the initial group of sites; second, to find new facilities to replace UK and Italy sites.

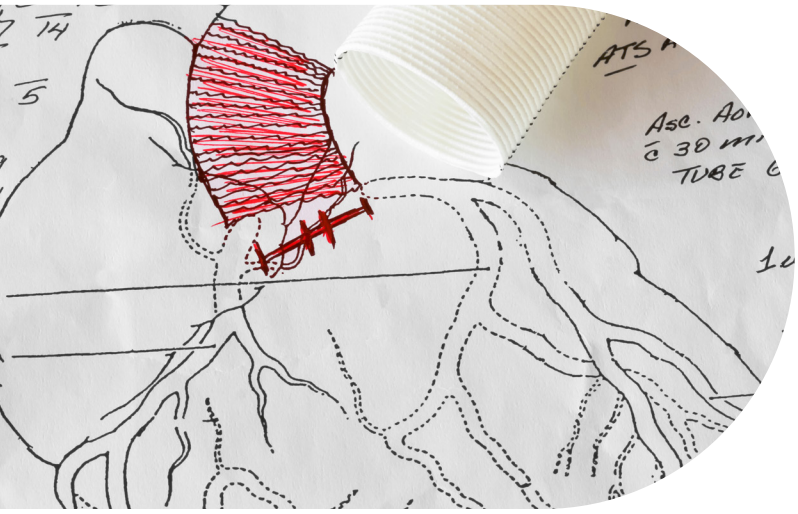
Because IQVIA MedTech employs associates worldwide, it easily secured CRAs in each country. Enlisting full-time IQVIA employees to oversee site activities helped ensure consistency during the trial and led to stronger relationships between the manufacturer, the site, and the CRO. Not only did they manage heavy workloads, but they also took on additional duties as the number of patients grew.

While the sites in Hungary and the Netherlands enrolled 34 and 35 patients, respectively, the sites across France and Germany cared for many more: 708 in France and 445 in Germany.

All sites leveraged the IQVIA MedTech Research Management Platform to accelerate data capture for clinical trial participants across geographic locations. The manufacturer also used the platform's interface to easily report outcomes to stakeholders, maximizing efficiency.

About the Research Management Platform:

- Complied with applicable local and global data privacy regulations
- Provided a flexible EDC system to collect, store, and preserve health data
- Simplified the data capture and review process, including 15+ case report forms per patient
- Translated CRF in local language when needed
- Generated robust and interactive reporting dashboards



The results: ahead of schedule

The manufacturer not only achieved its enrollment goals but surpassed them by seven months ahead of schedule, enrolling more than 1,600 patients in the study. The remarkable speed and success of the enrollment allowed the manufacturer to pause two study arms, resulting in significant time and cost savings.

In addition to achieving early enrollment, IQVIA MedTech completed regulatory submissions. IQVIA MedTech diligently submitted study start-up documentation to Regulatory Authorities (RAs) in Germany, the Netherlands, Belgium, and Hungary, acknowledging the local requirements of each EU country as well as meeting the overarching requirements of EU MDR.

The combined achievements of successful enrollment, accurate regulatory submissions, and the pivotal role played by the CRAs were vital to the overall success of the launching this post-market study.

1,665 patients enrolled
(1,335 in Europe, 300 in North America)
66% over target
6 months ahead of schedule

First site activated
January 2021

Last site activated
May 2022

5 CRAs in Europe
Conducted 60 visits (and counting)
Monitored 1,600 informed consent forms
Reviewed 15 case report forms (per patient)

The current state

Enrollment remains ongoing for two study arms. The manufacturer plans to conduct an interim data analysis at one year. Follow-up visits will continue for 10 years, which means ongoing source data review (SDV) and data management.

Medical device companies have faced multiple hurdles in recent years due to the COVID-19 pandemic and the EU MDR transition. Fortunately, this cardiovascular device manufacturer is equipped with the comprehensive data it needs to comply with regulations, with many targets hit well ahead of schedule.

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Why partner with IQVIA MedTech?

Accelerate clinical development by intelligently connecting data, technology, and expertise

GLOBAL FOOTPRINT

With expansive global footprint paired with local expertise, IQVIA MedTech enables manufacturers to select the right sites for their studies and helps ensure a reliable study team throughout the duration of the trial.

CARDIOVASCULAR EXPERTISE

Through our Cardiovascular Center of Excellence, IQVIA MedTech brings strong scientific and medical expertise, deep therapeutic insights, and unrivaled clinical trials experience.

ADVANCED TECHNOLOGIES

From electronic data capture (EDC) to powerful visualizations and reporting, IQVIA MedTech clinical trial technologies help to simplify workflows and deliver cross-study insights, faster.

460+ **Class I-III device trials conducted across 61 countries.**

170+ **Cardiovascular studies in the past 5 years.**

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