NAVIGANT

HELPING NOTIFIED BODIES MEET THE REQUIREMENTS OF THE NEW EUROPEAN MEDICAL DEVICES REGULATIONS

The new European Medical Devices Regulations (MDR) and In Vitro Diagnostic Regulations (IVDR) were published in the Official Journal of the European Union and came into force in May 2017, marking the start of the three-year transition period for manufacturers to update their technical documentation and processes to meet the new requirements. Clinical justifications based on device equivalence, a standard practice for decades, is no longer possible especially for high risk devices.

BROADER EXPERTISE REQUIREMENTS

The MDR not only impact manufacturers with its need for improved clinical evidence, impact on product portfolios and device classifications, but has significant implications for Notified Bodies and National Competent Authorities (NCA). Under the strengthened surveillance and increased scrutiny of the NCA, Notified Bodies need to be re-certified under the MDR to retain their designation and ability to issue CE certification during the transition period.

With the increased requirements on manufacturers to produce more clinical evidence for their products, comes increased demands on Notified Bodies to have the capacity and expertise to assess clinical evidence robustly.

Navigant supports a UK Notified Body with our clinical expert panel and the review of clinical evaluation reports for selected new CE markings, renewals and spot audits. We provide a bespoke solution that integrates into the Notified Bodies' existing processes and quality management system meeting the requirements of the MHRA.

Navigant is a global consultancy with decades of experience advising the life sciences sector, providing regulatory, commercial and dispute resolution solutions. Our team members themselves have expertise and experience with clinical investigations of all types. Working closely with CROs this includes experience from the designing and running of large scale randomized trials, non-interventional real world studies, as well as patient reported outcome studies, for drugs, devices and combination products.

CLINICAL EXPERTISE PANEL AND KEY OPINION LEADERS

Our team have a broad experience with academic research, the pharmaceutical and device industry and regulator backgrounds. Interpretation of clinical data is part of our daily work as we support our clients through the regulatory and commercial development of all types of IVDs, companion diagnostics, medical devices and combination products. Because of the in-depth research, we conduct with health care practitioners, we have developed an extensive and established network of key opinion leaders (KOLs), physicians, surgeons and clinicians from specialities covering most of the NBOG codes.

Navigant's solutions for Notified Bodies include:

- Providing clinical expertise through our expert panel
- Assisting with the evaluation of clinical trial data, published literature including systematic reviews and meta-analysis and real world evidence (RWE)
- Supporting the review of manufacturers clinical evaluation reports (CER) for new CE marking, renewals and spot audits of class IIb and class III devices
- Supporting the review of post market clinical investigations (PMCF) and post market surveillance (PMS)
- Providing internal training on understanding clinical investigations and medical statistics for technical reviewers

CASE STUDY 1: INNOVATIVE DEVICE LACK OF SAFETY EVIDENCE LEADS TO DISPUTE WITH MANUFACTURER

CHALLENGE

A US based manufacturer presents difficult to evaluate safety and performance data in their CER for a novel and innovative device. Notified Body denies certification based on incomplete safety data but manufacturer makes formal complaint.

SOLUTION

Navigant brings together expert panel to review clinical aspects of innovative device including all safety and performance data. Navigant expert participates in hearing with manufacturer cross-examining the clinical data and highlighting key gaps.

RESULT

Manufacturer accepts opinion of Navigant expert panel and decision of Notified Body.

CASE STUDY 2: CE RENEWAL OF COMPLEX ORTHOPAEDIC HIP SYSTEM WITH TIGHT TIMELINE

CHALLENGE

Multiple components of a complex orthopaedic hip system are due for their CE mark renewal. Multiple CERs presented with large amounts of clinical trial results, published literature reviews and post market surveillance data.

SOLUTION

Navigant supports in house clinicians to review clinical data for each component and uses orthopaedic expert panel to evaluate literature and safety data.

RESULT

Robust review of performance and safety for all components of the system complete meeting the tight timeline.

CASE STUDY 3: SPOT AUDIT LEADS TO CE MARK CERTIFICATE WITHDRAWAL

CHALLENGE

Spot audit of an established device product range unveils multiple concerns over safety and performance when compared to the state of the art. Notified Body considering withdrawal of CE mark and seeks clinical expert review.

SOLUTION

Navigant review all safety and performance data with clinical expert and discover that published clinical literature was contradictory and did not support the performance of the device Additionally, changes to labelling since the last CE renewal presented a potential safety issue in clinical practice.

RESULT

Notified Body withdraws CE mark from product range supported by Navigant's expert clinical opinion findings. Decision accepted by manufacturer.

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