UNIVERSITY OF LIVERPOOL | ONLINE PROGRAMMES

New Regulations on Notified Bodies and Conformity Assessment of High-Risk Medical Devices in Europe: Impact on Clinical Investigation from an Industry Perspective

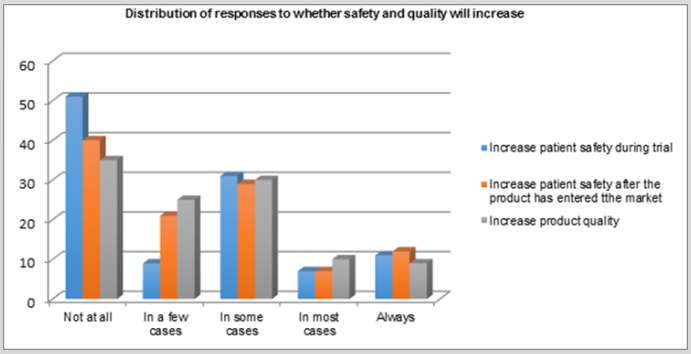
Wenche Grønnvold MSc
Clinical Research Management

Background:
A more rigorous medical device regulation concerning Notified Bodies and clinical evidence are met with controversies. The regulatory revision will not only endeavor improvement of patient safety and product quality, but is expected to have a direct impact on manufacturers by generating higher costs, longer processes to gather a CE mark and increased requirements for clinical evidence. Despite that industry recognizes a need for regulatory improvements, there are uncertainties about the estimated impact the regulatory changes have on European manufacturers.

Aim:
To determine the impact the new regulations on Notified Bodies and conformity assessment have on clinical investigation of implantable medical devices in Europe.

Methods:
Data regarding information to 5 regulatory changes and their impact on different factors of clinical investigation were collected from 22 clinical research specialists working for manufacturers of implantable medical devices. The data were collected through a cross-sectional, quantitative, descriptive survey and analyzed.

Results:
It was determined that burden on costs and resources would be affected the most, while innovations and product development would be negatively affected. Additionally, product quality and patient safety would benefit minimally from the proposed regulatory changes.



Conclusion:
The results obtained are in contrast to the intended aims of the new Medical Device Regulation. The regulations may introduce economic and organizational challenges to manufacturers in Europe, particularly when considering the small- and-medium-sized enterprises. It is moreover debatable whether the goal of strengthening patient safety and allowing for rapid and cost-efficient market access for innovative products will be reached.