Question-based development of high-risk medical devices: A proposal for a structured design and review process.

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Abstract

The recent introduction of the European Medical Device Regulation poses stricter legislation for manufacturers developing medical devices in the EU. Many devices have been placed into a higher risk category, thus requiring more data before market approval, and a much larger focus has also been placed on safety. For implantable and Class III devices, the highest risk class, clinical evidence is a necessity. However, the requirements of clinical study design and developmental outcomes are only described in general terms due to the diversity of devices. A structured approach to determining the requirements for the clinical development of high-risk medical devices is introduced, utilising the question-based development framework, which is already used for pharmaceutical drug development. An example of a novel implantable device for haemodialysis demonstrates how to set up a relevant target product profile defining the device requirements and criteria. This can then be used to define specific questions to be answered during clinical development, based upon 5 general questions as specified by the question-based framework. The result is a clear and evaluable overview of requirements and methodologies to verify and track these requirements in the clinical development phase. Development organisations will be guided to the optimal route, also to abandon projects destined for failure in an early stage to minimise development risks. Moreover, the framework facilitates communication with funding agencies, regulators and clinicians, while highlighting remaining "known unknowns" that are to be answered in the post-market phase after sufficient benefit has been established relative to the risks.

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