MDOT

Support for Conformity Assessment of Medical Devices

MDOT - Medical Device Obligations Taskforce

Start date:	1-1-2019
Runtime:	60 months
End date:	31-12-2023
EC Funding:	EC Horizon 2020
Coordinator:	Fraunhofer Gesellschaft zur Foerderung der Angewandten Forschung E.V.

General information:

The new Medical Device Regulation (MDR) requires testing that is costly and may threaten the competiteness of Europe's innovation SMEs. The EU-funded MDOT project will develop a series of coordinated procedures to support SMEs to bring testbeds and device innovations to the level of clinical evaluation. The project will enable conformity assessment using a database procedure and access to medical device testing data through a secure and transparant platform. MDOT will perform joint evaluations of commonly used parts and devices and develop advanced testing methods focusing on inhalation technology, neural implants and orthopaedic devices. The project envisages the platform as a meta-network aiming to protect medical technologies innovation and economic vigou, limit animal testing and support MDR's vision of patient safety.

Vision and impact:

The aim of the EU project MDOT is to reduce the burden on medical device manufacturers: the regulatory requirements they have to meet have increased considerably, since the Medical Device Regulation (MDR) came into force.

Funded with 8.3 million euros over a period of five years, a platform shall be developed to support small and medium-sized manufacturers of medical devices in the conformity assessment of their products. This will include development of three demonstrator technologies in the fields of inhalers, neural implants, and coatings for hip replacement implants.

MDOT is addressing medical device manufacturers' need for support with the obligatory conformity assessment, which has been exacerbated by the EU regulation 2017/745 (Medical Device Regulation, MDR for short). Under this regulation, coming into force at the end of May 2020 and replacing the Medical Device Directive (MDD), all existing medical devices need to undergo reassessment of their risk class, require more comprehensive documentation and increased clinical testing. To reduce the burden on medical device manufacturers, the consortium is developing a platform aimed at simplifying the process by establishing a database that will include data on regulatory affairs and testing up to clinical evaluation and clinical studies.

To demonstrate usability of the platform, it is addressing three technologies as a starting point: inhalers for pre- and early-term neonates, 3D-printed neural implants, and coatings for orthopaedic prostheses that reduce the wear of particles in the patient's tissue. Test beds for these technologies are being developed and upgraded to ensure safety and long-term stability of devices and materials – aspects particularly important for implants. Future extension of the platform towards other medical device sectors is planned.

Project Website:

www.mdot.eu

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