EURICE
EUROPEAN RESEARCH AND PROJECT OFFICE GMBH

Factsheet

TBMED

ACRONYM TBMED

FULL TITLE A testing bed for the development of high-risk medical devices

PROGRAMME Horizon 2020/H2020-NMBP-HUBS-2018

CONTRACT NUMBER 814439

ABSTRACT TBMED will establish an open innovation testing bed specialized in the development of high-risk devices (≥Class IIb). Due to a long reimbursement processes, patient access to innovative high-risk medical devices in Europe can take four times longer than in the U.S. In addition to this, the new regulations will stricter ex-ante controls for this type of devices. This scenario represents a big challenge for European high-tech SMEs (representing 95% of the MedTech sector in Europe) to maintain their competitiveness and innovation capacity. TBMED will provide an integral service to accelerate the development of medical devices reducing time to market, covering technology development from TRL4-7 based on Quality-by-Design (QbD) concept and business management services. QbD concept enhances product and process understanding together with process control, based on robust scientific knowledge and quality risk management.

Once operating (M37) the OITB will integrate: 1) an SME office that will provide business advice and IP management, 2) services on regulation, early health technology assessment advice and QbD, 3) a biomaterial synthesis lab, 4) characterization facilities, 5) a testing lab for in vivo and in vitro efficacy testing, 6) safety assessment and 7) clinical testing. Three case studies will be used to validate the concept and will help to establish the OITB: 1) An osteoinductive hydrogel, 2) Keratoprosthesis and 3) Magnetic NPs for hyperthermia. TBMED consists of 13 complementary partners composed by 1 Industry and 2 SMEs developers of 4 different medical devices used as case studies, 5 RTD institutions experts in the development of medical devices, 1 SME expert in QbD methodology, 2 RTD Institutions that will provide the access to a hospital network with experience in regulation, health technology assessment and clinical investigation design and testing and 2 consultancy (SME) experts on business plan development, IPR management and communication activities.

DURATION 56 months (01/01/2019 – 31/08/2023)

PROJECT FUNDING 8.480.543,89 €

COORDINATOR

Dr Iraida Loinaz
Fundación Cidetec
Donostia-San Sebastián, Spain
Email: iloinaz@cidetec.es

PARTNERS

- Fundación CIDETEC, Spain
- AJL Ophthalmic S.A., Spain
- EURICE - European Reseach and Project Office GmbH, Germany
- Institut National de La Santé et de la Recherche Médicale, France
- Société Industrielle Limousine d'Application Biologique, France
- Universidad de Zaragoza, Spain
- nanoScale Biomagentics SL, Spain
- Fraunhofer Gesellschaft zur Foerderung der Angewandten Forschung e.V., Germany
- National University of Ireland Galway, Ireland
- ECRIN European Clinical Research Infrastructure Network, France
- Fundación Vasca de Innovación e Investigación Sanitarias, Spain
- Antares Consulting S.L., Spain

CONTACT AT EURICE

Janine Jost
Senior Project Manager
Heinrich-Hertz-Allee 1
66386 St. Ingbert, Germany
Phone: +49 6894 3881331
Email: j.jost@eurice.eu

WEBSITE www.tbmed.eu