



An Open Innovation test bed for the development of high-risk medical devices

[www.tbmed.eu](http://www.tbmed.eu)

## TBMED vision

The EU research project TBMED sets out to tackle two of the most pressing issues in the EU healthcare system: the large variation in patient outcomes and the continuous increase in costs which result in an urgent need to create and incorporate value in healthcare. However, new EU regulations regarding medical devices classified as high-risk impose great challenges especially on smaller European companies which are the core target group of TBMED.

Thus, TBMED aims to **support med-tech companies** in the development of high-risk medical devices by reducing their time-to-market for the European sector.

For this purpose, TBMED will establish an **Open Innovation Test Bed (OITB)** consisting of a **connected network of labs** providing a single entry point to services along the whole value chain from preclinical development to clinical testing. **The entire process is based on a Quality-by-Design (QbD) concept.**

## Objectives

The objectives of the project are:

- TBMED will provide an integral service to accelerate the development of MDs **reducing time to market** for technological developments from TRL4 (proof of concept) to TRL7 (clinical investigations)
- **Increase the quality and reduce the risk** of the MDs and facilitate subsequent clinical testing
- **Build the arguments to demonstrate real benefits** (value/final outcomes) of the new devices to increase their success in entering the market.
- **Reduce cost and variability** of the manufacturing process and the **speed of product release to the market** by carrying out statistically designed experiments for process validation.

The OITB will be developed during the course of the project and will become a commercially available platform after the project is finished providing services in areas such as technology development, business support and financing.

## Case studies

Three case studies have been selected to develop the platform:

- GlycoBone®: An injectable ready-to-use scaffold tailored for oral bone defect reconstruction to be validated in two different indications.
- Keratoprosthesis: a biocompatible and flexible synthetic cornea
- Hyperthermia treatment for pancreatic cancer, based on magnetic nanoparticles and alternating magnetic field

## Consortium

The TBMED consortium consists of 13 partners from 4 European countries comprising 2 universities, 5 research organizations, 5 SMEs and 1 large industrial partner, all of them chosen for their expertise and high track-record in their specific field of research.