



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

# Introduction to TBMED

## Boosting Innovation Workwhop

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# MedTech Sector

Healthcare system in EU has to deal with two main and growing problems: **large variation in patient outcomes** and **continuous increase of costs**

New regulation EU 2017/745: **demonstrate safety and performance** through clinical evaluation of the product's **entire life cycle**

Reimbursement approval: **Demonstrate benefit for patients and health systems**

MedTech Sector  
27,000  
companies

95% SMEs  
Mostly  
< 50 employees

Product Lifecycle is  
between 18 to 24  
months

Highest N° patent  
applications on a  
technical field

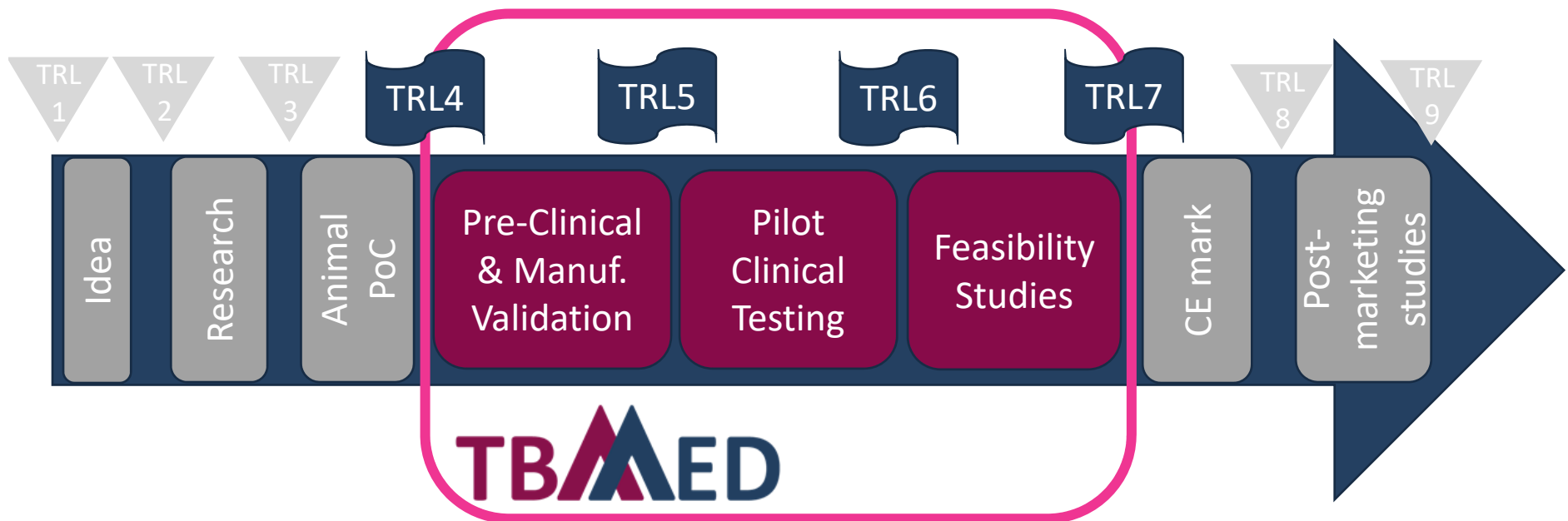
The new scenario represents several challenges for high-tech SMEs to **maintain their competitiveness and innovation capacity**

## Impact & Final Objective

**Increase the access of high-risk medical devices to patients, that due to long reimbursement processes need to wait **up to 6 years** for its availability**

# What is TB MED?

Is an OITB platform that **consist of a connected Network of labs** providing a single entry point to services along the whole value chain **from preclinical development to clinical testing based on Quality-by-Design (QbD) concept.**



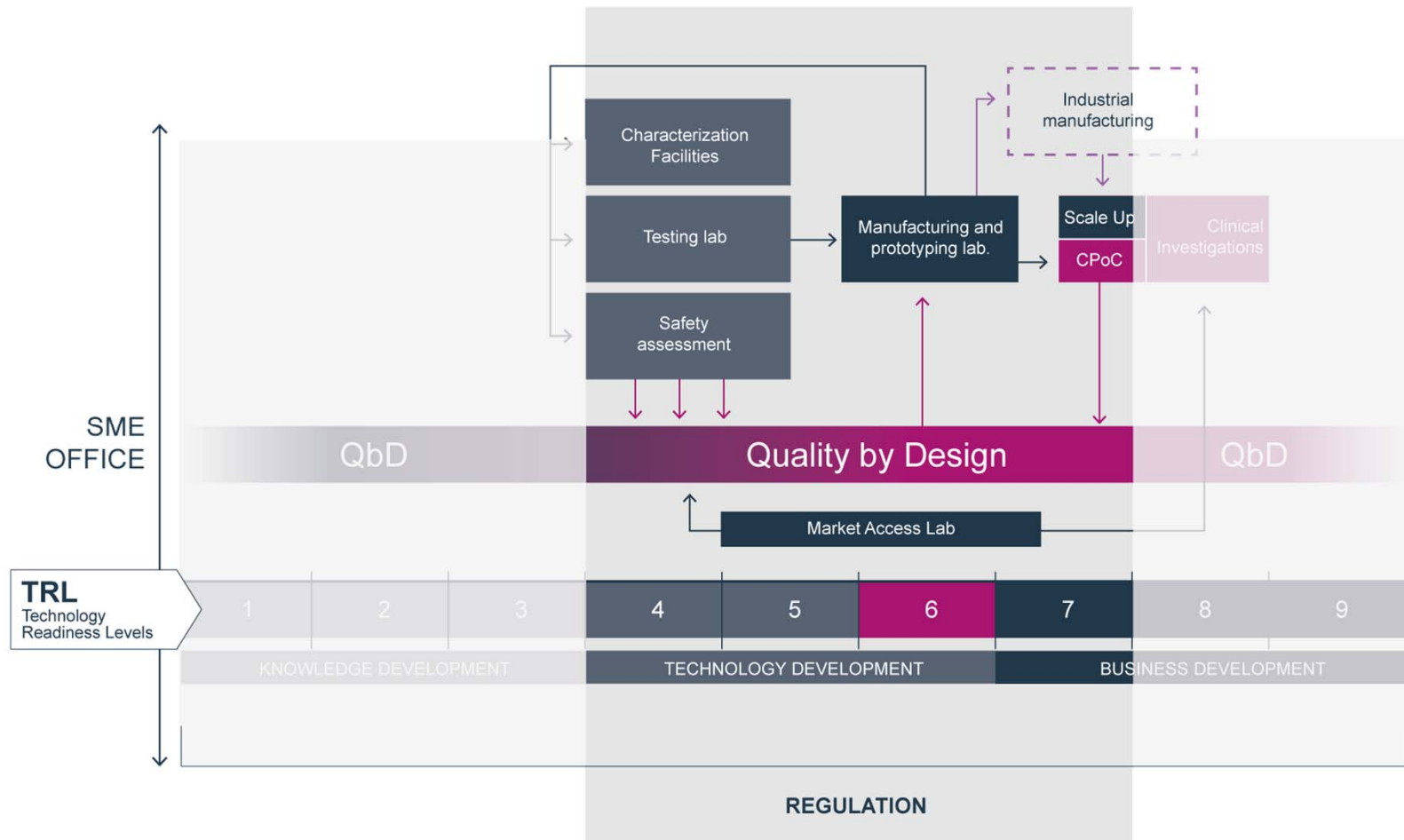
# Objectives



- **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.



And will use Quality by Design, improving the development process

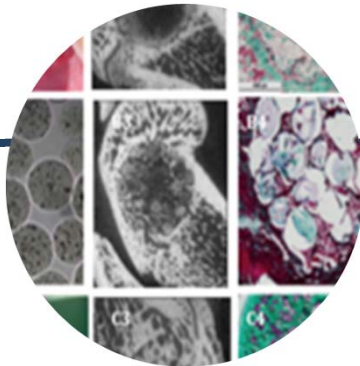


# Scientific Objectives

## Technology

- GlycoBone® for Sinus floor augmentation
- GlycoBone® for Peri-implantitis
- Keratoprosthesis
- Magnetic nanoparticles for hyperthermia in colorectal cancer
- AMF device

TRL before	TRL at the end of the project
6	7
4	6/7
3	6
3	5
4	5



**Glycobone**

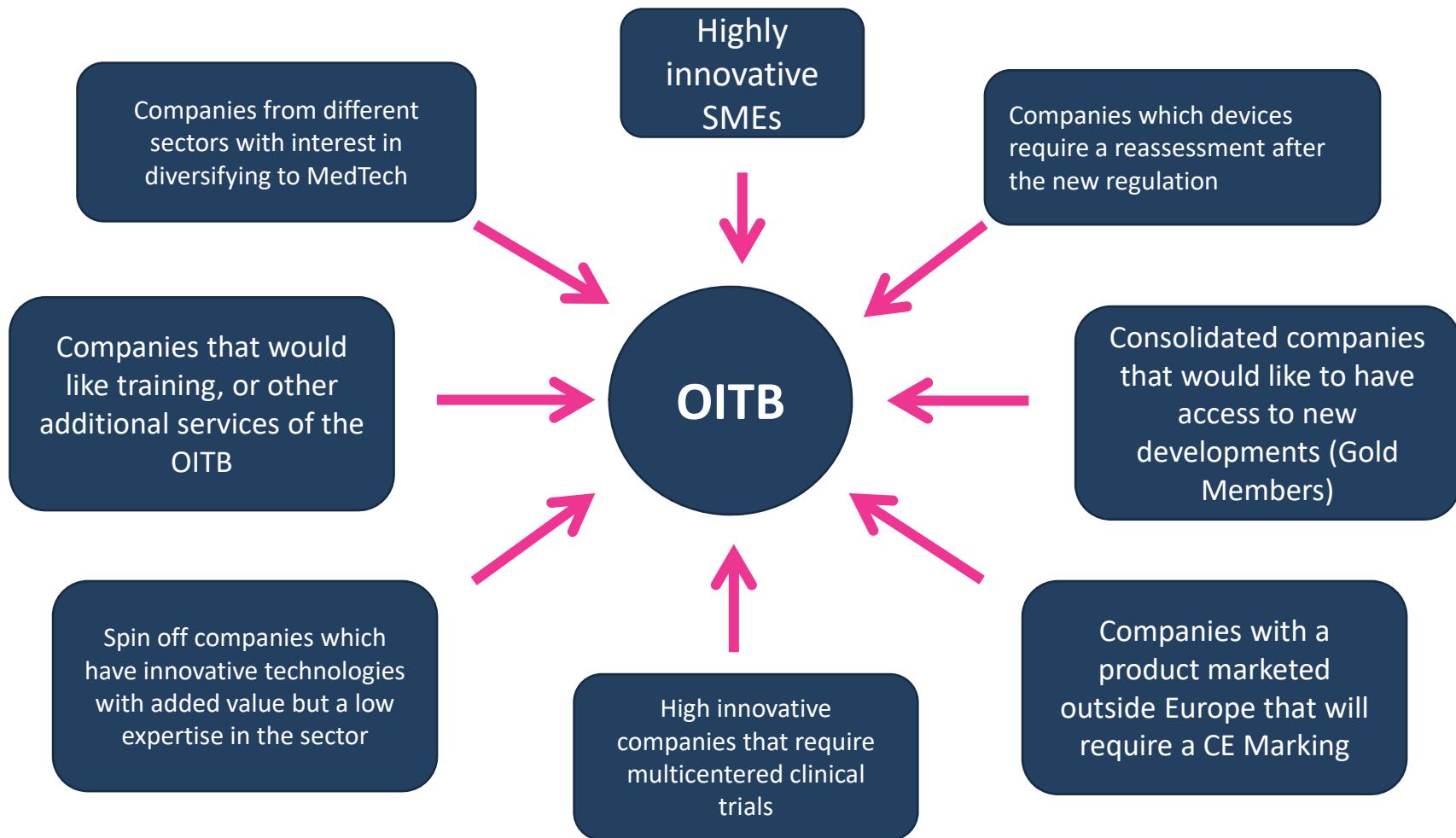


**Keratoprosthesis**



**Magnetic nanoparticles and Alternating Magnetic Field for hyperthermia**

## For which users is created TBMED?





# What do we offer?



## FINANCING

- Venture Capital Access
- Co-development
- Partnering for Grant proposals



## BUSINESS SUPPORT

- Business Consultancy services
- Networking
- Market Access / Regulatory

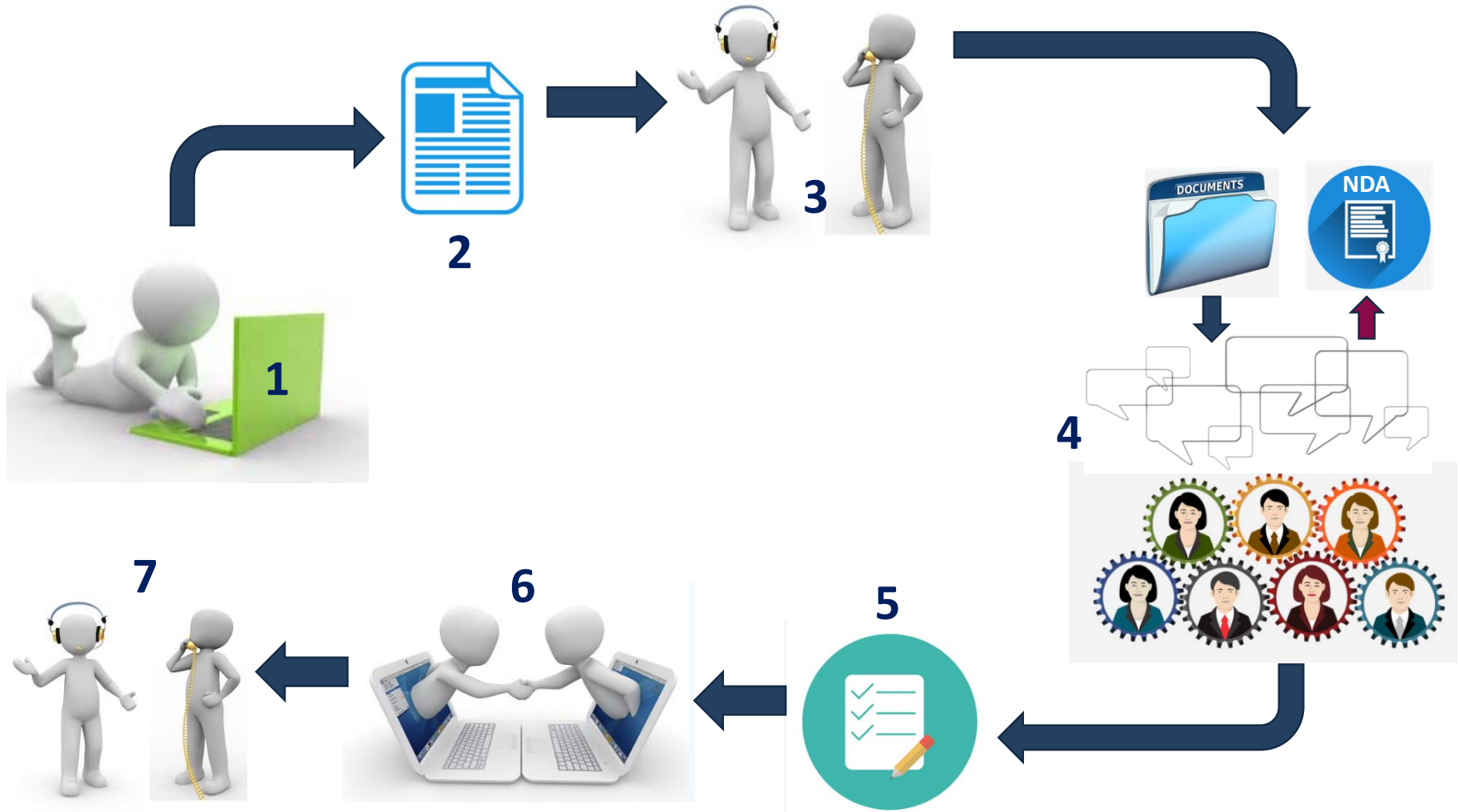


## TECHNOLOGY DEVELOPMENT

- Efficacy Testing
- Safety Testing
- Characterizaion
- Prototyping
- Upscaling



# Customer Journey

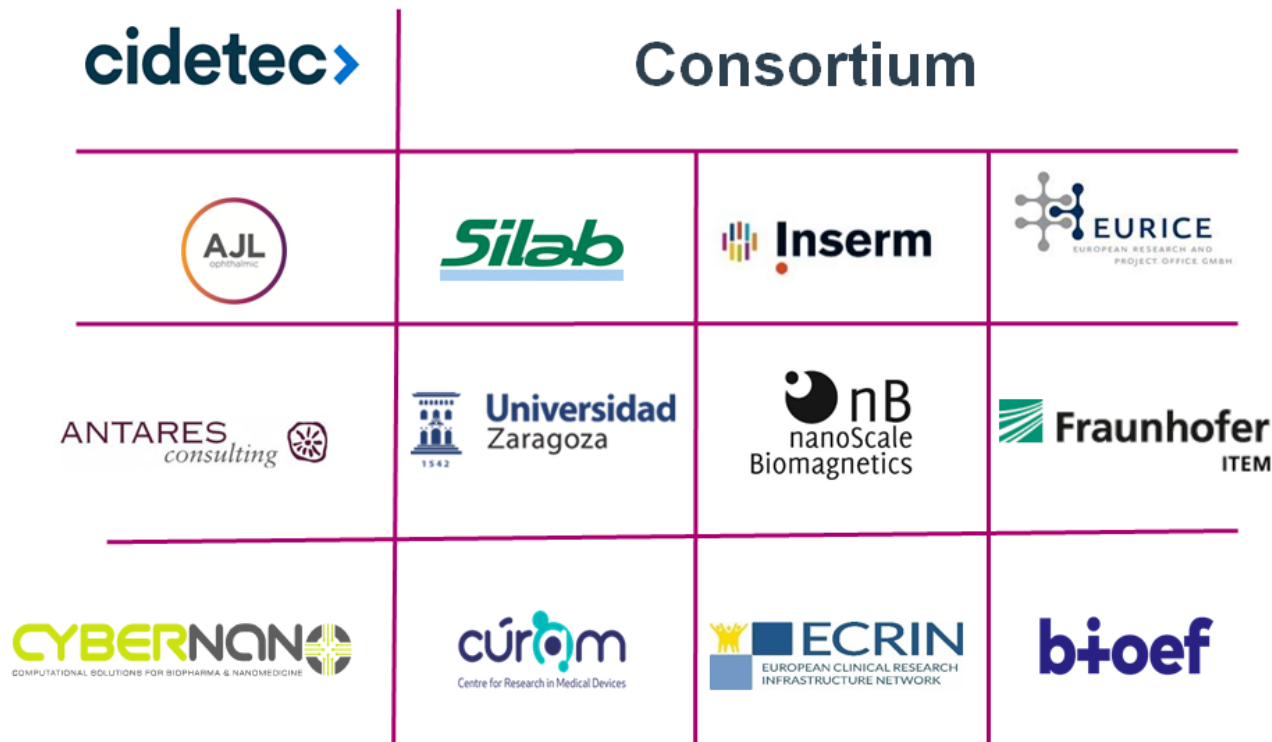


# Competitive Advantages

- First to Market (First OITB specifically created for MDs)
- Single Entry Point service (easy to use, KAM to guide you through the process)
- High Quality Providers ( carefully selected based on past records)
- Sound Methodology (QbD)
- Service adapted at customer needs (wide range of services)
- It covers the complete value chain including clinical trials
- Easy-to-use and integral virtual platform to manage customer and internal interaction

# Who is TB MED?

- ◆ 5 research groups, 5 SMEs, 1 Industry and 2 Hospitals, with significant track record in knowledge creation and innovation that have joined forces to guarantee a successful outcome





**Thank You!**



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