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

TBMED: A test bed specialized in the development of Medical Devices according to quality by design.

EuroNanoForum

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cidetec nanomedicine

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TBMED

Open Innovation Test Bed for High-risk Medical Devices

12.07.2019

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 Nº 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 on the market

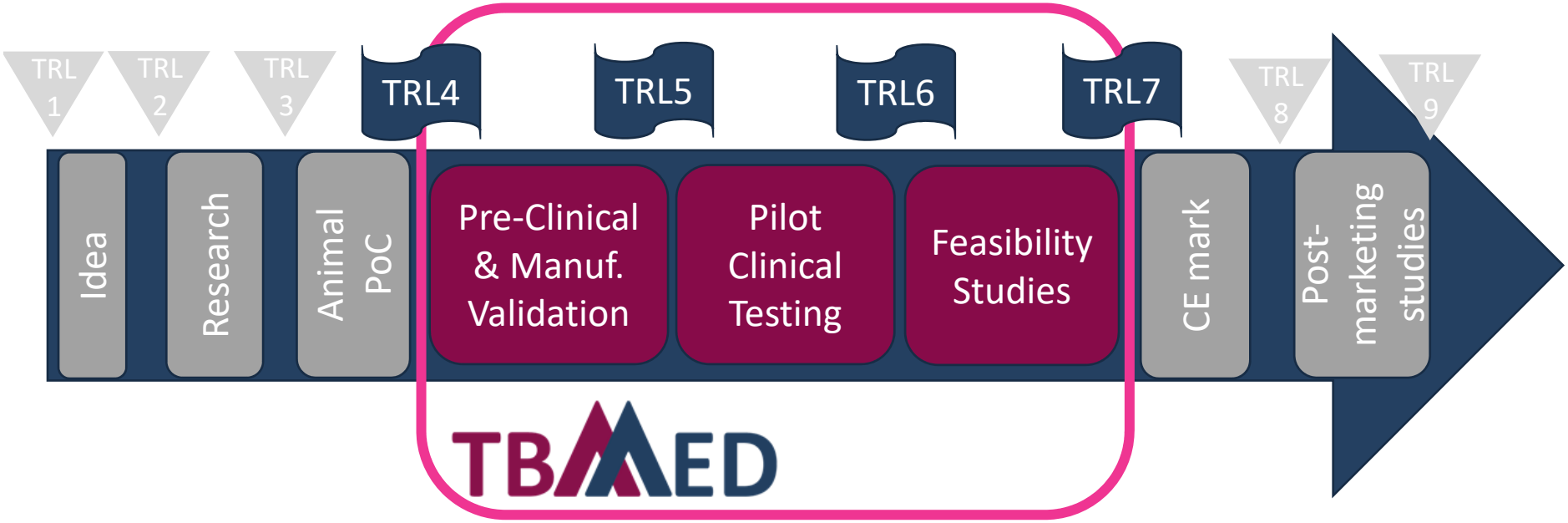
Main Objectives

- **Create a sustainable OITB** specialized in the development of high-risk medical devices and…
- **Adapt** the current **QbD methodology** for the development of high-risk medical devices

- **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.

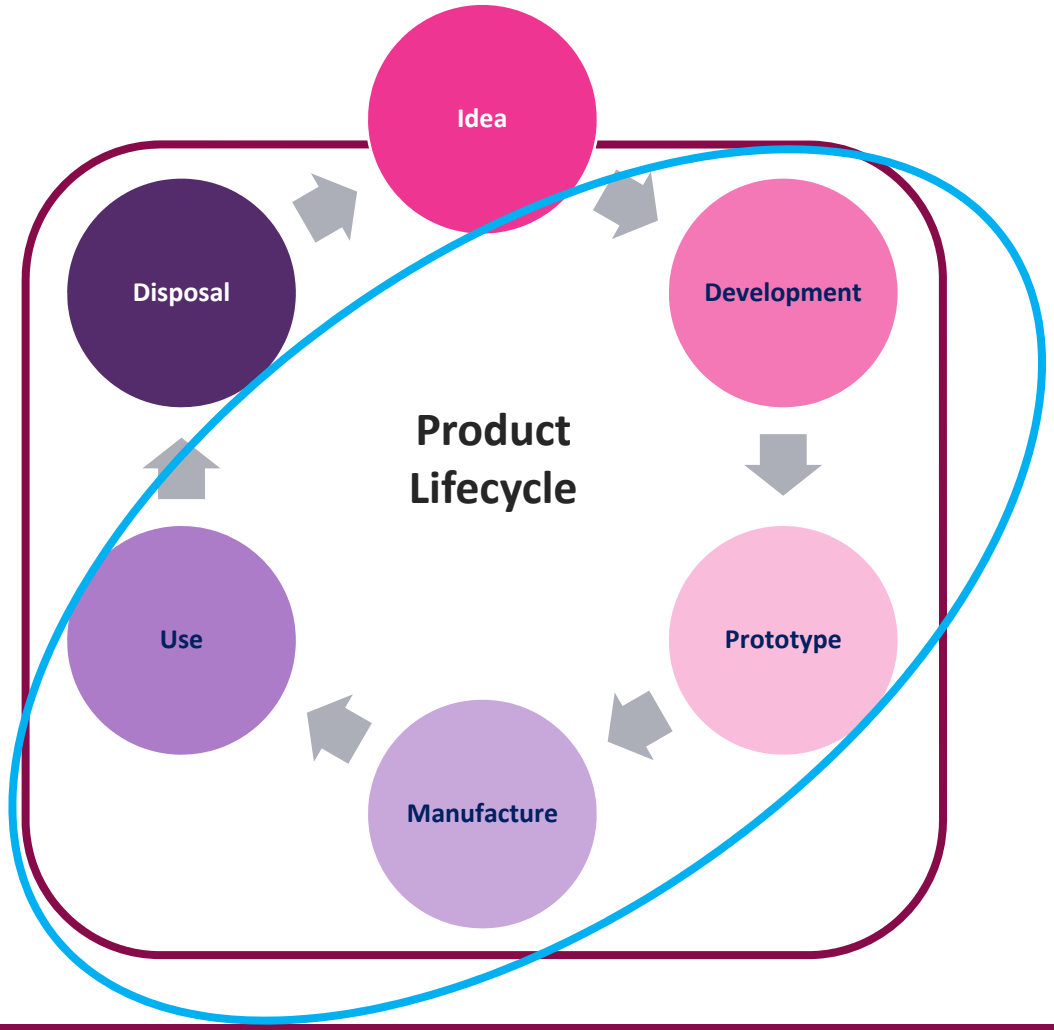
What is TBMED?

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.**



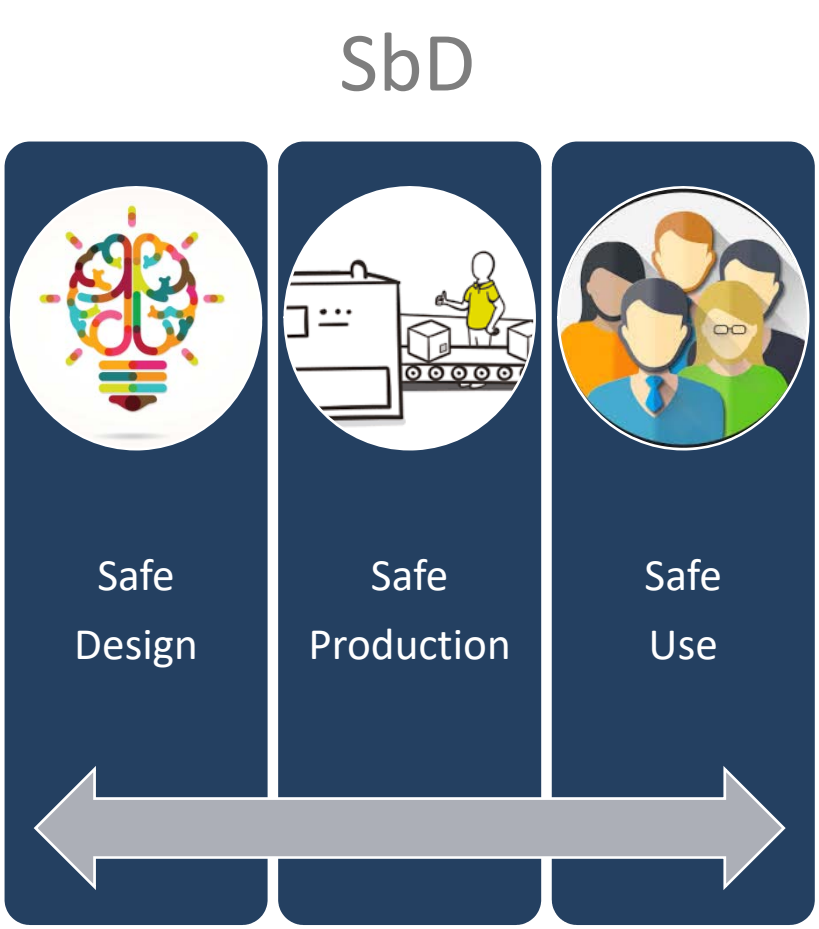
Safe & Quality by Design

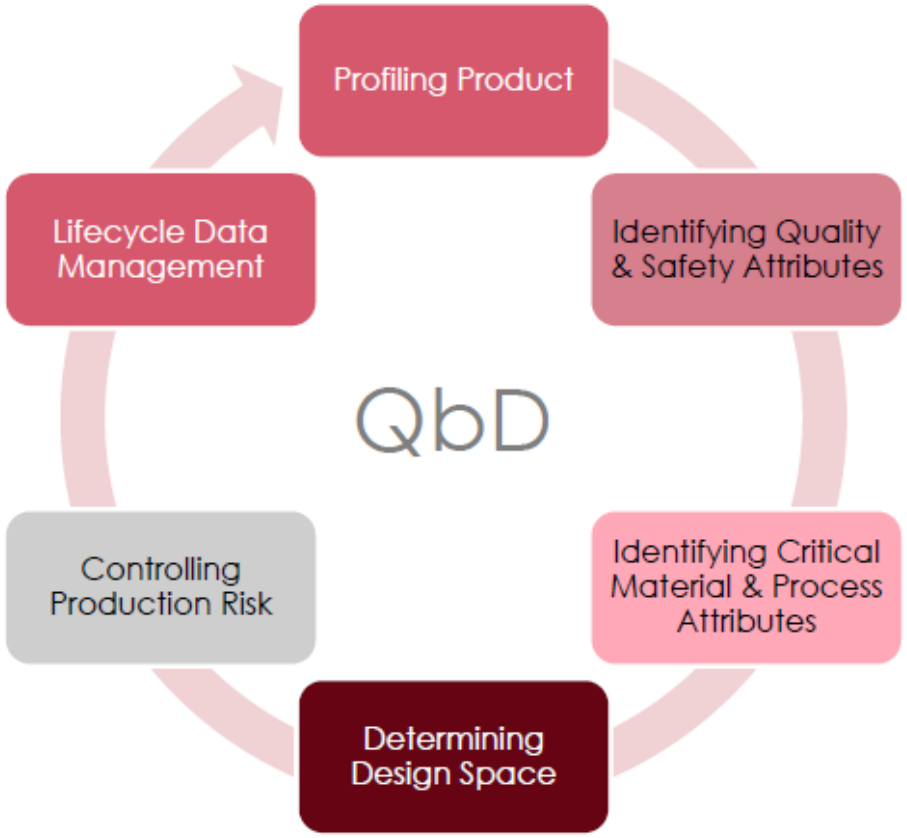
Safe
By
Design



Quality
By
Design

Safe & Quality by Design



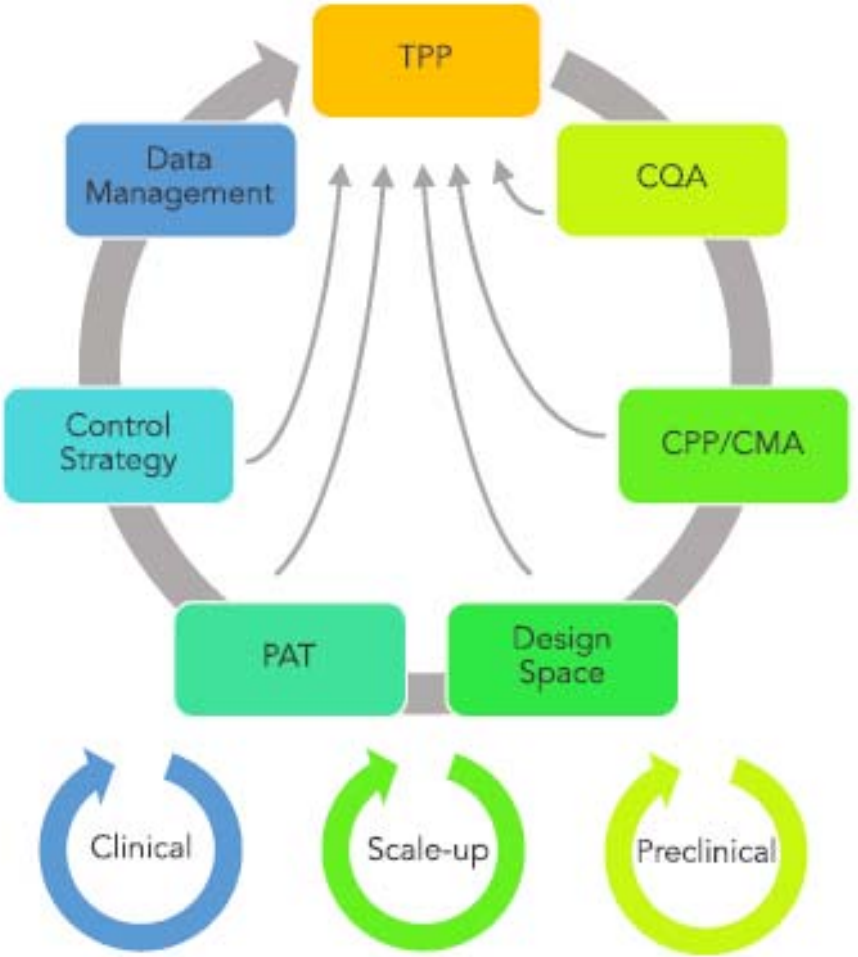


Safe & Quality by Design

Both methodologies have several points in common:

- Both have to be considered and implemented from the very beginning of the development
- Both are related to most of the life cycle of the product
- Both use risk analysis tools in their core
- Both are methods that will help to “fail early” in the process in order to improve the development

Quality by Design



CQA: Critical Quality Atribute CPP: Critical Process Parameter CMA: Critical Material Atribute PAT: Process Analytical Technology

Quality by Design

1 - TPP (Target Product Profile)

Intended Use	• Clinical Treatment of Actinic Keratosis (Precancerous Skin Lesions)
Device Description	• A new device to control light signal in realtime during a treatment session
Expected efficacy	• Better Reduction of Tumor than PDT without control
Quality	• A better control of the inter-individual responses
Contraindication	• The PDT treatment is very painful
Pre-clinical Testing	• Proof of *in vivo* feasability
Clinical Studies	• Not yet
Potential economic value	• Reduced cost and compact design

Quality comprises: Reliability, durability, aesthetics, usability

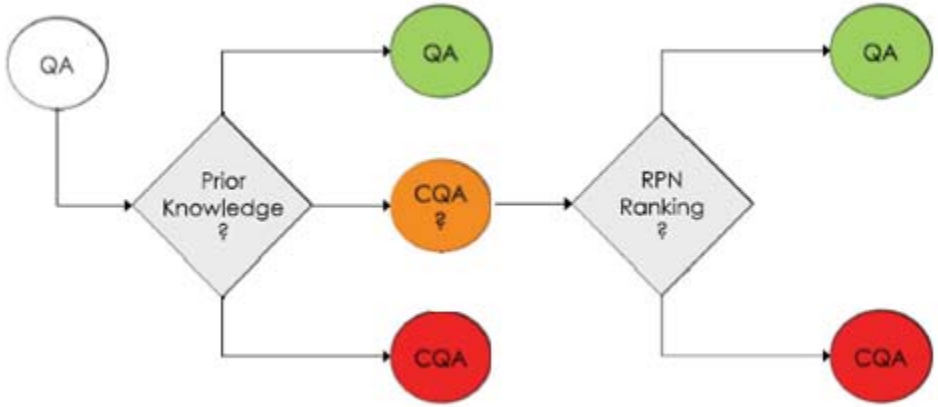
CQA: Critical Quality Atribute CPP: Critical Process Parameter CMA: Critical Material Atribute PAT: Process Analytical Technology

Definition of CQAs

Category	QA	Efficacy		Safety		Quality		Compliance		Criticity
		Severity	Occurrence	Severity	Occurrence	Severity	Occurrence	Severity	Occurrence	
Biological	Biocompatibility									
	Cell adhesion in the skirt									
	Cell proliferation									
	Entrapment efficiency									
	Control of inflammation									
Physicochemical	Presence of leachables									
	Surface topography (microscale) in the optic									
	Humidity/Water content									

- A first qualitative round, based on prior knowledge

- If there are “oranges”:

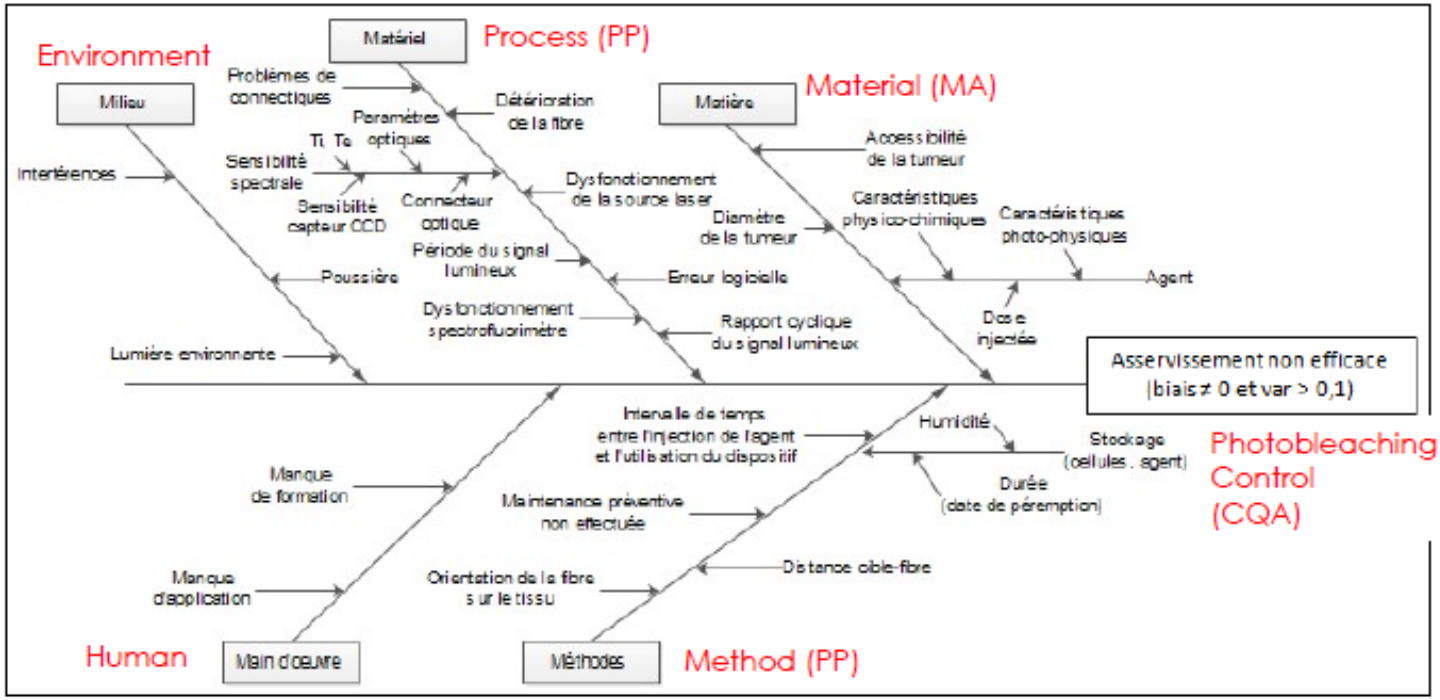


RPN= Severity x Ocurrence

RPN: Risk Priority Number

MAs, PPs and Design Space

MA & PP Screening : Ishikawa Diagram



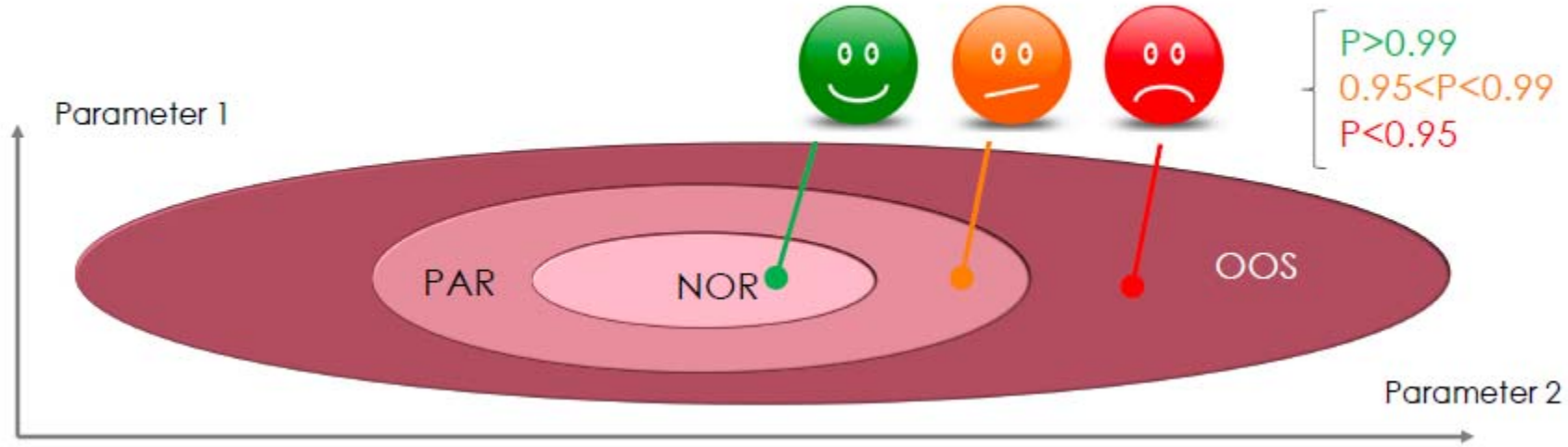
- PPs
- MAs

MAs, PPs and Design Space

- **PPs**
- **MAs**

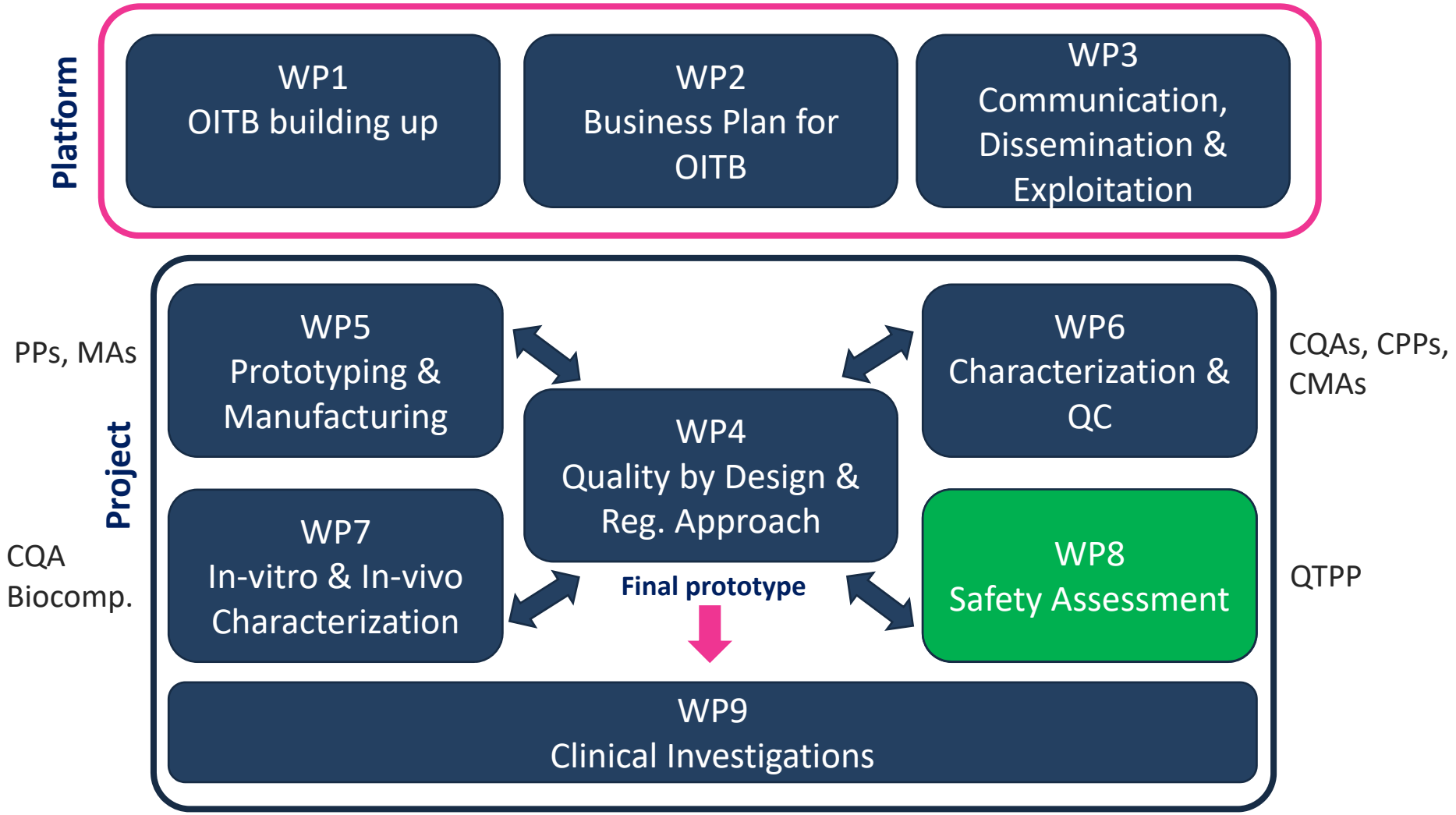
→ **DoE** using Plackett-Burman →

- **CPPs**
- **CMAs**



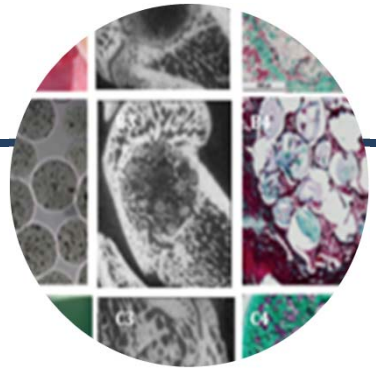
NOR: desired region PAR: product acceptable region but correccions required OOS: Out of Specifications

Work Packages



Scientific Objectives

Technology	TRL before	TRL at the end of the project
GlycoBone® for Sinus floor augmentation	6	7
GlycoBone® for Peri-implantitis	4	6/7
Keratoprosthesis	3	6
Magnetic nanoparticles for hyperthermia in colorectal cancer	3	5
AMF device	4	5

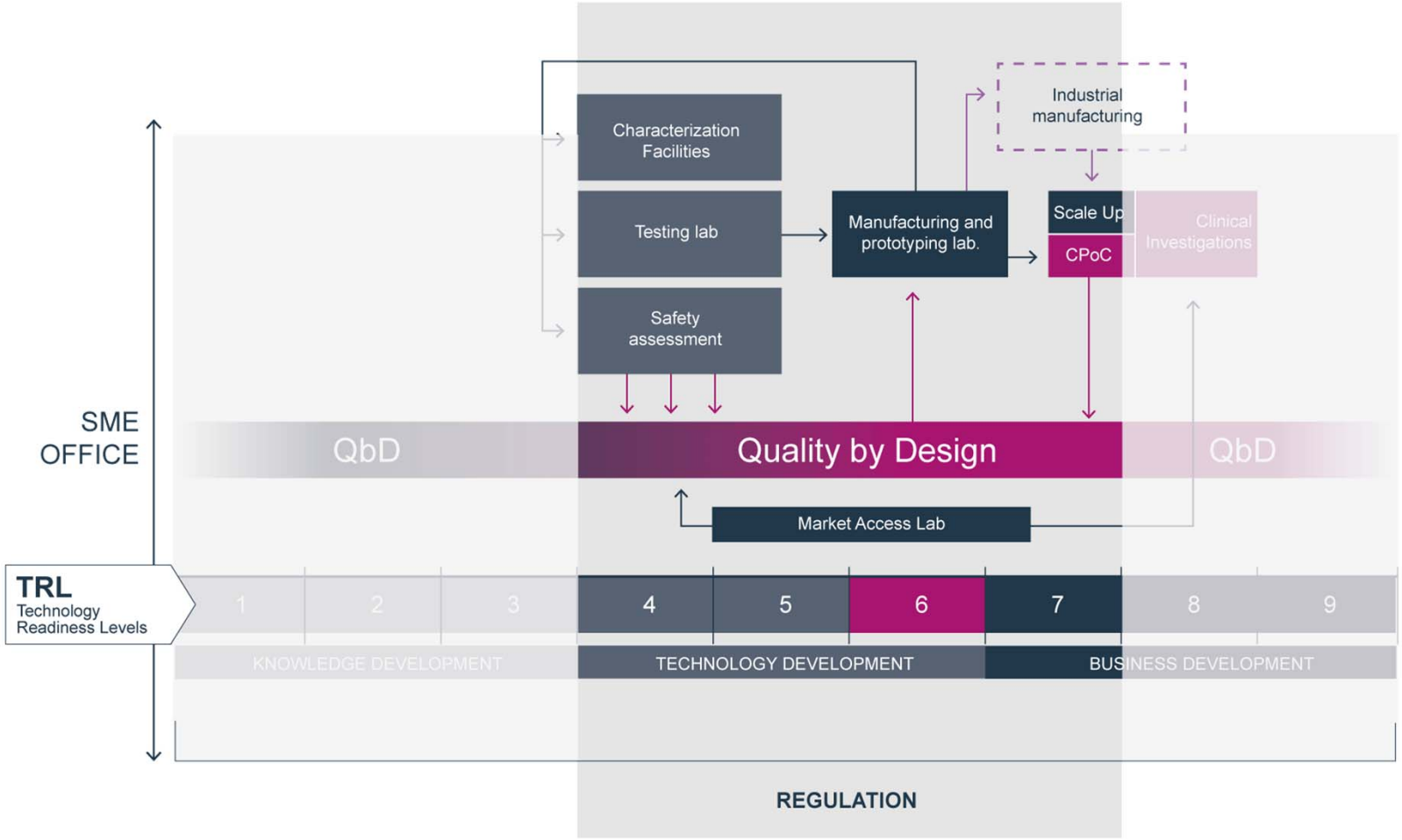


Glycobone

Keratoprosthesis

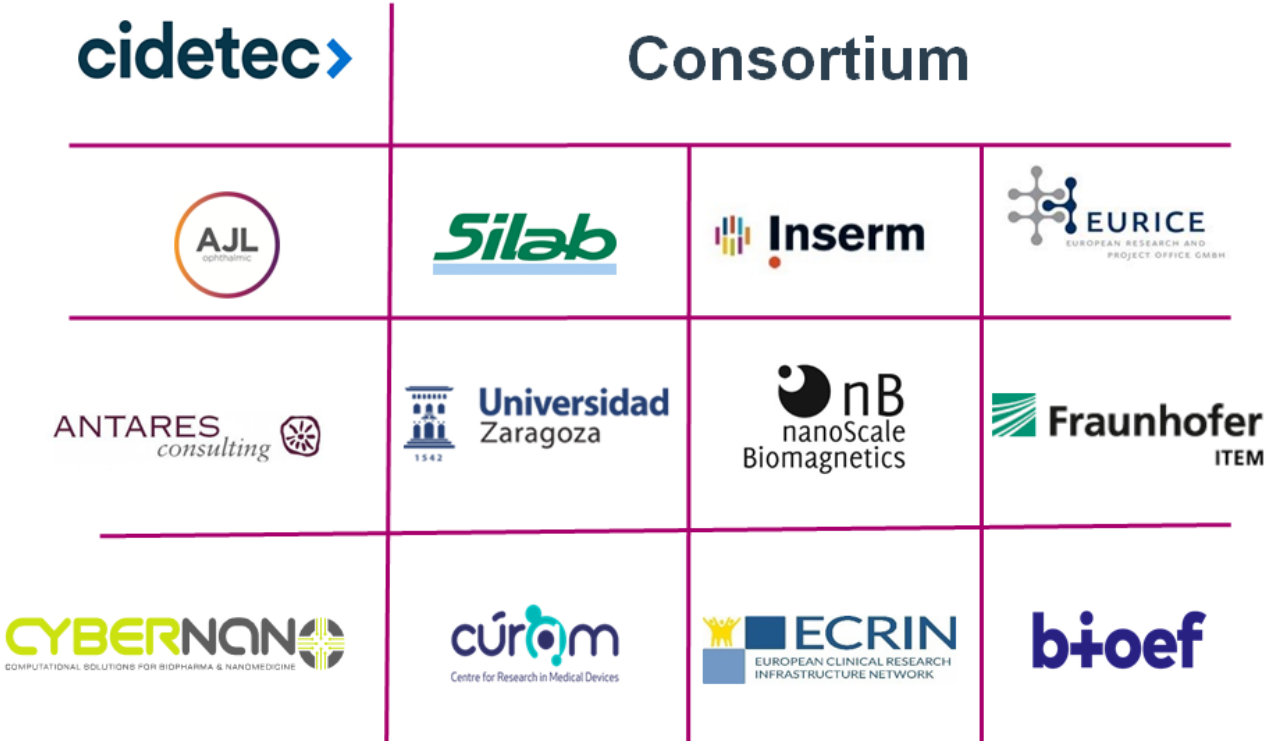
Magnetic nanoparticles and Alternating Magnetic Field for hyperthermia

- We use **quality by design** to improve the different services that we provide:



Who is TBMED?

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



Thank You!

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