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TBMED

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

Newsletter Issue N° 3

Dear reader,

With this issue, we welcome you to our first special edition with a focus on the five steps to develop a medical device. Providing a full set of services to guide developers in the process is TBMED's major goal. To this end, TBMED intends to prepare a set of tutorials in the future to give developers direction and hands-on advice. Find out more about what is coming next in this newsletter.

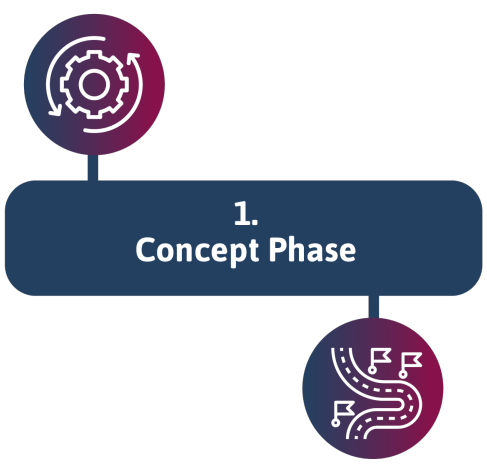
The five phases of developing a medical device

It has never been easy to develop a medical device (MD). This is particularly true for high-risk medical devices affected by the EU's current regulation 2017/745.

The entire process of developing such a device can be divided into different phases with particular tasks to be performed to reach the specific objectives.
In a combined effort of different institutions, TBMED is aiming to provide a full set of high-quality services covering all development steps starting at TRL3 up to TRL7.

This includes the following five phases:

1. Concept Phase

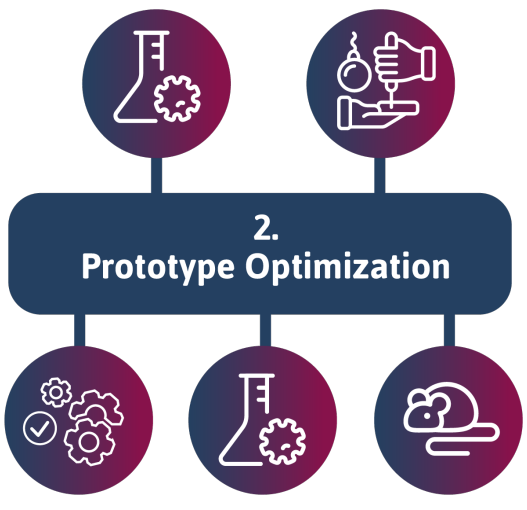


Technology transfer is a core activity of this phase in order to check reproducibility of the device. However, a market analysis & regulatory roadmap should also be prepared at this stage to ensure viability.

2. Prototype Optimization

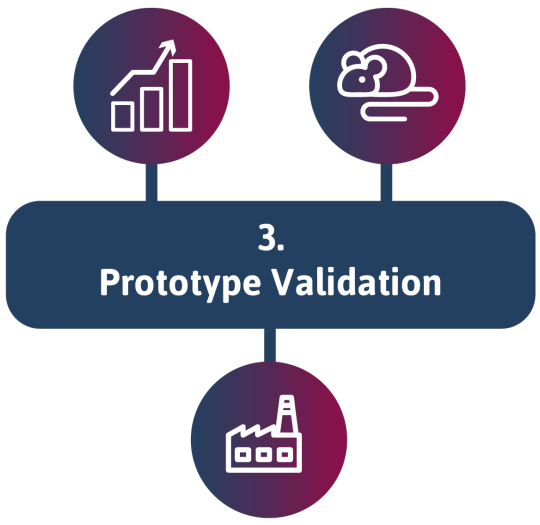
In this phase, we do not only optimize the prototype and its manufacturing process, but we also propose a Quality Control (QC) strategy and a biological evaluation plan. A Health Technology Assessment (HTA) meeting is held to verify the alignment of the device with the current market needs.

Remember that TBMED has a strong focus on Quality by Design (QbD)! Applying the QbD methodology can help to optimize the time and cost of the device development. In addition, it could improve the robustness of the manufacturing process.



Look out for our tutorial on QbD!
It is planned to go public on the website in May 2021.

3. Prototype Validation



This phase includes the scaling up of the manufacturing process under ISO13485-like conditions as well as different *in vitro* and *in vivo* tests under GLP to prove the safety and efficacy of the device. A second HTA meeting will help to define the end points for the clinical studies as well as different aspects to take into account for the reimbursement process.

■ Look out for our support material on HTA meetings. It is planned to go public on the website in the course of April 2021.

4. Clinical Proof of Concept

In order to continue with the validation of the device a small clinical study (Clinical Proof of Concept) must be carried out. TBMED will help with all the documentation, submission and approval processes of the regulatory bodies. A follow-up of the study will also be done. A risk analysis constitutes a mandatory part of this documentation. In our experience, companies have many doubts on how to perform it. Inside TBMED we have experts who can help you with it.

■ A tutorial with advice on how to approach a risk analysis is planned to go public on the website in June 2021.

5. Clinical Investigations

Finally, once the first results are obtained, a larger clinical trial, in some cases multinational, could be required. TBMED will help with all the related topics such as documentation, submission and approval processes of the regulatory bodies.

Upcoming events

MedTechForum - Online event taking place on April 20-22, 2021

EuroNanoForum - Online conference taking place on May 5-6, 2021

■ Stay tuned about future events.

We hope that you enjoyed our special edition. Follow us on Twitter and visit our website for the upcoming tutorials.

TBMED on Twitter

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