Challenge based learning (CBL)

Building a pre-clinical research plan to enter into a clinical trial to heal peripheral nerve damage

Note for teachers: A CBL user guide can be found at www.jandeboerlab.com/TissueEngineering with instructions and tips to run an effective CBL teaching session.

Background and vision

The ultimate goal of tissue engineering is to apply tissue engineered products in the clinic to cure patients. Product development has its classical trajectory going from in vitro experiments to preclinical proof of principle in animals and finally a carefully designed clinical study in man. To move tissue engineered products to the market, one has to prove that these products are feasible, effective and safe. The decision of the regulatory bodies to approve a clinical trial to test a tissue engineered product depends on research data that scientists have acquired over the years. It is our vision that every scientist should have a well-designed pre-clinical research plan to accelerate and expedite the step into clinical research.

Motivation and stakeholders

Exploratory clinical trials provide information on efficacy of tissue engineered product. A clear and detailed regulatory framework for TE products needs to be followed to enter into clinical experimentation. This regulatory framework has evolved over time and now many countries have comparable regulatory requirements to allow the use of TE products around the world. Therefore, tissue engineers should consult the regulatory bodies as early as possible to develop tissue engineered products. Their definitions, regulations and documentation provide guidance in preclinical and clinical development. To build a pre-clinical research plan, researchers should consider the needs, requirements and regulatory, financial and technical boundary conditions defined by stakeholders such as all scientists involved in product development, the patients who are treated with the product and clinicians who apply it and the product manufacturers.

Problem Definition

The European Medical Agency (EMA) has issued regulatory guidelines for the implementation of tissue engineered products but the scientific path towards the approval of the first clinical trial depends on the type of product one wants to put in the market. There is a lack of awareness in the tissue engineering community to carefully integrate EMA regulation as the basis of the design of pre-clinical research.

Challenge

To design the preclinical research plan to convince EMA to test a therapeutical strategy to heal a critical-sized peripheral nerve defect with a biomaterial of choice and iPSC-derived neurons.

Learning framework

Reading the Clinical Translation chapter and related literature will help you to understand:

1. How EMA decides on the approval of a clinical trial.
2. The set of regulations EMA uses to make the decision.
3. The current bottlenecks and most common challenges in the approval of tissue engineered products.

For a more focused examination of the challenge, read scientific literature and create a mind map to include information about the following:

4. The phases of research prior to a clinical trial.
5. The critical and quantifiable experimental evidence needed to make the transition from in vitro to pre-clinical research.
6. The safety and efficacy data required by EMA to enter into a clinical trial.

End product

A three-minute video explaining the solution of your challenge. Please include your motivation and the steps to execute your solution.