

# Overview of Regenerative Medicine in Malaysia

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## Abstract

Regenerative medicine is a fast-evolving discipline that has the potential to revolutionize healthcare through replacements or reparations of damaged tissues and organs. Stem cell therapy and tissue engineering have been the focus of regenerative medicine research and development in Malaysia. However, several challenges related to this field of medicine need to be addressed. Therefore, several different measures had been taken by the Malaysian government includes establishment of the National Committee on Stem Cell Research and Therapy and the issuance of guidelines for the use of stem cells in clinical practice to ensure a better development of the regenerative medicine filed in Malaysia.

**Keywords:** Regenerative medicine, Stem cell therapy, tissue engineering

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Regenerative medicine is a rapidly developing field that has the potential to revolutionize healthcare by replacing or repairing damaged tissues and organs. The field of regenerative medicine includes stem cell therapy, tissue engineering, gene therapy, and other innovative approaches that utilize the body's own mechanisms for healing and regeneration.

Regenerative medicine has the potential to revolutionize the way we treat a wide range of medical conditions, including cancer, diabetes, heart disease, and neurodegenerative disorders. In a nutshell, regenerative medicine application can be divided into:

1. **Tissue engineering:** Tissue engineering involves the use of biomaterials and stem cells to improve, repair and create functional tissues and organs in the laboratory. This approach has been used successfully to create skin, cartilage, and even organs such as the heart and liver from various natural and synthetic biomaterials [1]. However, previous studies addressed the issue of having limited clinical application in the tissue engineering field due to lack of collaboration between medical doctors and biomaterials scientists [1, 2].
2. **Gene therapy:** Gene therapy involves the use of genetic engineering techniques to modify a patient's DNA to treat or prevent a disease such as clustered regularly interspaced short palindromic repeat-associated protein 9 (CRISPR-Cas9) genome editing tool. This approach has been used successfully to treat certain genetic disorders, such as Parkinson's disease, Huntington's disease and Duchenne muscular dystrophy [3]. However, most of the gene therapies application are limited to in vivo and in vitro studies due to ethical consideration in human genetic manipulation [4].
3. **Stem cell therapy:** Stem cell therapy involves the transplantation of stem cells into a patient to replace damaged or

diseased cells. This approach has been used successfully to treat various conditions associated to neurodegenerative disease and macular degeneration. Nevertheless, previous study by Aly<sup>5</sup> highlighted the need to prepare regulatory guideline since there was an increasing number of clinics in providing unproven stem cell- based treatments which could jeopardize patient safety.

In Malaysia, regenerative medicine research and development are gaining momentum, with a focus on stem cell therapy and tissue engineering. This article provides an overview of the regenerative medicine landscape in Malaysia, including the current research, challenges, and government initiatives.

### **Stem Cell Therapy in Malaysia**

Stem cells are undifferentiated cells that have the potential to differentiate into various cell types and have the ability to regenerate damaged tissues. In Malaysia, stem cell research has been ongoing since the early 2000s, with the establishment of the National Stem Cell Centre which responsible for overseeing the ethical, legal, and regulatory aspects of stem cell research and therapy. Since then, several public and private institutions in Malaysia have been conducting stem cell research and providing stem cell therapy. Additionally, Malaysian Stem Cell Registry (MSCR) was also established as a platform for eligible people among public who want to donate their stem cell voluntarily to patients in need.

However, the effectiveness and safety of some of these therapies are still being investigated, and there is a lack of standardized protocols and regulations governing stem cell therapies. A study conducted by Tran et al<sup>6</sup> evaluated the regulation of stem cell therapy in Malaysia and found that there is a need for standardized guidelines and regulations to

ensure the safety and effectiveness of stem cell therapies. The researcher suggested that the Malaysian regulatory bodies involved in regenerative medicine and healthcare such as Ministry of Health (MOH) and National Pharmaceutical Regulatory Agency (NPRA) should establish a more comprehensive regulatory framework to oversee the use of stem cells in clinical practice.

### Tissue Engineering in Malaysia

Tissue engineering is derived from biomedical engineering which involves the use of cells, scaffolds, and growth factors to create functional tissues or organs as shown in Figure 1[7]. In Malaysia, tissue engineering research is primarily focused on skin and bone tissue engineering. Researchers at Universiti Kebangsaan Malaysia (UKM) are developing a 3D- printed scaffold for bone tissue engineering [8]. The scaffold is made of biodegradable materials and can be implanted into the body to stimulate bone regeneration. Past study by Morshed et al<sup>9</sup> investigated the use of tissue engineering for skin regeneration in Malaysia and found a skin substitute using keratinocytes and fibroblasts, which can be used totreat burns and other skin injuries.

### Challenges in Regenerative Medicine in Malaysia

Despite the progress made in regenerative medicine research and development in Malaysia, several challenges need to be addressed. One of the main challenges includes the lack of definite understanding on ethical guideline among ethics committee which involve conceptual framework, safety and efficacy in conducting research associated to regenerative medicine [4, 10, 11]. Subsequently, ethical issue in regenerative medicine may impede the application of research grant for the research study funding. Consequently, this will create a huge gap for researchers to design and conduct acceptable clinical trials on regenerative medicine besides time and cost-consuming procedures.

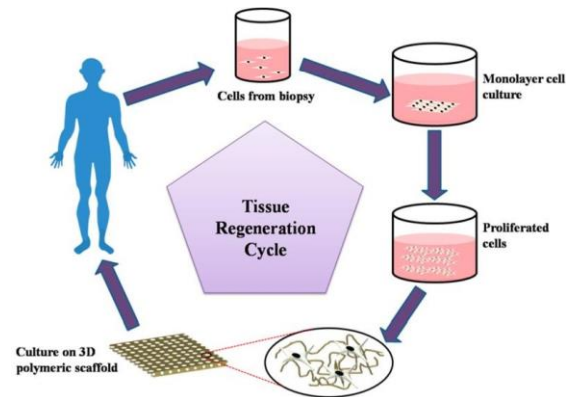


Figure 1: Basic principle procedure for tissue engineering [7]

Another challenge is the shortage of skilled personnel, particularly in the area of stem cell research and therapy. The demand for stem cell therapy is increasing, but there is a shortage of trained personnel to provide these therapies. This shortage is due to the limited fund, specialized equipment, lack of formal training programs and educational opportunities in regenerative medicine in Malaysia [12].

### Regulatory Framework for Regenerative Medicine in Malaysia

The regulatory framework for regenerative medicine in Malaysia is still evolving, and there is a need for standardized guidelines and regulations to ensure the safety and effectiveness of regenerative medicine products. In 2009, MOH has issued guidelines for the regulation of stem cells in clinical practice. The guideline was prepared by Stem Cell Research and Ethics Subcommittee of National Stem Cell Committee in collaboration with Medical Development Division of the Ministry of Health to develop policies, requirements, framework and guidelines for stem cell research and therapy in Malaysia [13]. Nevertheless, Gopalan et al<sup>14</sup> revealed that the guideline is inefficient in providing good ethical governance of the technology and suggest to provide more comprehensive stem cell therapy guideline that align to Guideline for Stem Cell Research and Clinical Translation (ISSCR) for more relevant and advanced regenerative medicine application.

Additionally, National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health which was established in 1978 to help protect public's healthcare by ensuring approved therapeutic substances and meet the guideline before marketed locally. With the increasing awareness of the importance of regenerative medicine, NPRA has prepared Malaysian Guidance Document and Guideline for Cell and Gene Therapy Products (CGTPs) in 2016 which help to facilitate and provide guidance for regenerative medicine application [15]. However, Imran et al<sup>12</sup> argued that the guideline needs to be specific and focused since it was too brief.

Furthermore, the Malaysian Bioeconomy Development Corporation (Bioeconomy Corporation) has been established under the purview of Ministry of Science, Technology and Innovation (MOSTI) since 2005 to promote the development of biotechnology and life sciences in the country. Bioeconomy Corporation provides funding, resources, and support to biotech companies and research institutions in Malaysia, including those involved in regenerative medicine research.

### Conclusion

In conclusion, regenerative medicine is a promising field that has the potential to transform healthcare by providing new and innovative treatments for a wide range of conditions. In Malaysia, regenerative medicine research and development are gaining momentum, with a focus on stem cell therapy and tissue engineering. However, there are still several challenges that need to be addressed, including the lack of funding and trained personnel, and the need for standardized guidelines and regulations for the use of regenerative medicine products. The government of Malaysia has taken steps to address these challenges, including the establishment of the National Committee on Stem Cell Research and Therapy and the

issuance of guidelines for the use of stem cells in clinical practice.

Overall, the future of regenerative medicine in Malaysia looks promising, and further investment and research in this field have the potential to benefit not only Malaysians but also the global healthcare community.

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