

**UNIVERSITI TEKNOLOGI MARA**

**SOMATIC GENE THERAPY IN  
HUMAN: MALAYSIAN  
REGULATORY FRAMEWORK &  
*SHARĪ'AH* PERSPECTIVE**

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## ABSTRACT

As a powerful new tool in the arena of biomedicine, human genome editing medical technologies have received an explosion of interest recently. As this powerful biological tool can be used either for fundamental basic research, as well as for somatic or disease correction, it is considered to be very important. Genome editing tools and techniques can be applied to the treatment of diseases such as somatic gene therapy. As Somatic Gene Therapy is applied clinically in humans, it is common that the application of this new technology will entail its own set of benefits, risks, ethical and societal implications (ELSI) which are subject to debate and discussion. The Malaysian regulatory framework concerning Somatic Gene Therapy is not comprehensive and inadequate. As far as the existing guidelines for Somatic Gene Therapy are concerned, there are several loopholes, and the monitoring is not adequate and effective. Thus, this study is conducted to analyse the medical and legal aspects of Somatic Gene Therapy in humans within Malaysian regulatory framework. The legislation on human Somatic Gene Therapy in the UK, EU as well as USA have also been analysed to see to what extent the current legislation in those countries serve as the best concerning Somatic Gene Therapy. Given that Islam is an official religion of Malaysia, by virtue of Article 3 of the Federal Constitution. A special emphasis is given to the use of Somatic Gene Therapy technology from the *Shari'ah* perspective. This study further evaluates the regulation in the UK, EU, and USA on Somatic Gene Therapy from the Islamic point of view. In this study, a doctrinal legal analysis is used to obtain data. Reference has been made to numerous statutory provisions, legislation, and judicial opinions as a source of data. In addition to collecting primary data, selected experts were interviewed using purposive sampling. A semi-structured interview was conducted with medical experts in the field of somatic gene therapy clinical application, representatives from government bodies as well as *Shari'ah* experts on fatwas. In light of these findings, Malaysia needs a comprehensive model to follow in order to effectively regulate Somatic Gene Therapy for humans. In conclusion, this study found that the experiences of developed nations, particularly the UK, EU, and the United States, which have been at the forefront of Gene Therapy application along with established statutory legislation overarching Somatic Gene Therapy, can provide valuable guidance for Malaysia when determining its own policy. This study provides some recommendations which are considered as fundamental and pertinent to legislating Somatic Gene Therapy in Malaysia. The recommendations addressed are meant not only to national policymakers and scientific investigators and sponsors of gene therapy products but also to public and private research institutions, patients and wider communities.

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# CHAPTER ONE

## INTRODUCTION

### 1.1 Background of Study

Technology and science have significantly impacted human life over the years, changing the world in its entirety. In order to stay on top of this modern world landscape and technological wave, Malaysia has also placed science and technology at the top of its agenda. In order to accomplish this, Malaysia has spent the past eight years strengthening its biotechnology ecosystem, developing its local industry, and carving out its niche as one of Asia's prestigious biotechnology hubs (International Business Review Asia Group, 2019), as outlined in Vision 2020 and the National Biotechnology Policy (hereinafter referred to as NBP). The Malaysian government has continued to promote science and technology (S&T) as key factors for the economy, with a primary goal of creating an advanced society through S&T.

Among the key aspects of biotechnology development addressed in the NBP are priority areas, legal, safety, financial, and other factors. It also provides nine areas of priority for industry development. There are four thrust areas in this initiative: healthcare biotechnology development (thrust 2), industrial biotechnology development (thrust 3), research and development, and technology acquisition (thrust 4). The National Biotechnology Division of the Ministry of Science, Technology and Innovation (MOSTI) has therefore led the national agenda by developing strong intellectual property and protection to facilitate research and development, technology development, and promotion of biotechnology programs based on global standards and best practices (International Business Review Asia Group, 2019; Kuen, 2012; Malaysian Biotechnology Corporation, 2010; Rozhan Abu Dardak, 2019).

For the purpose of strengthening the biotechnology planning process and achieving Vision 2020, the Economic Planning Unit has developed a comprehensive approach under the 8th Malaysia Plan (2001-2005) and 9th Malaysia Plan (2006-2010), highlighting this competitive advantage as well as its potential to contribute up to 5% of the country's GDP by 2010 to the sustainability and welfare of the economy. (International Business Review Asia Group, 2019; Mohd Fuaad Said et al., 2013). A