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Regulatory Prospects of Clinical Trials with Stem Cells

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ABSTRACT: Importance of stem cell therapies is increasing at a rapid rate due to various benefits and a wide range of applications. However, challenges such as the application of untested therapies are also accompanying the increased need for stem cell therapies. This research has been focussed on analysing different prospects of regulations associated with clinical trials using stem cells. Different types of challenges faced in clinical trials using stem cells have been identified. Capability of regulations of stem cell clinical trials to mitigate such challenges has been defined in this research. Apart from this, different regulations prevailing in different countries have also been analysed in this research.

I. INTRODUCTION

1.1 Research Background

Stem cells are considered to be the raw materials of human body as it leads to the formation of diversified cells possessing specialised functionalities. Stem cells form daughter cells within specific suitable conditions developed either within human body or a controlled environment in a laboratory (Mayoclinic, 2023). Daughter cells developed from the stem cells develop stem cells or diversified cells that possess specialised functions and only daughter cells possess such abilities.

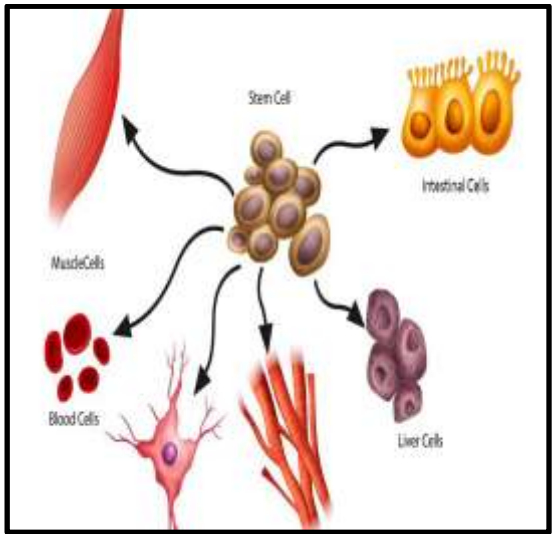

Figure 1.1: Stem cell
(Source: Mayoclinic, 2023)

Cells located in different parts of the body and performing diversified activities are formed by the daughter cells. Cells formed by daughter cells are such as “blood cells”, “brain cells”, “heart cells”, “muscle cells” or “bone cells” (Mayoclinic, 2023). This ability of stem cells to form diversified cells increases its importance concerning clinical trials.

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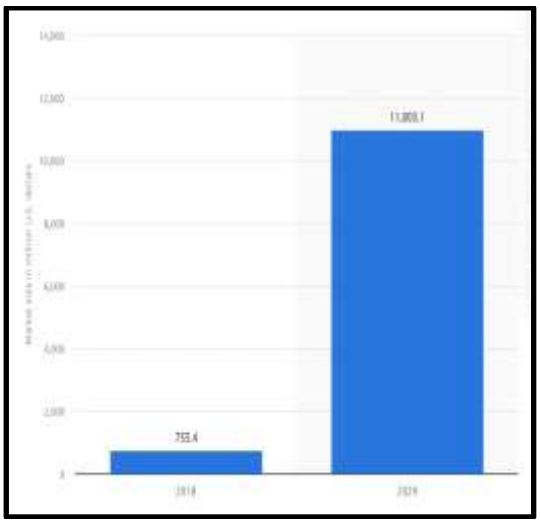

Figure 1.2: Stem cell market size forecast
(Source: Statista, 2021a)

Ability of stem cells to form different types of cells in the human body has led to various clinical advancements. For instance, stem cells have aided in improving understanding about disease occurrence, development of healthy cells required for making replacement of damaged cells, and for trying newly developed medicines (Stanford Medicine, 2023). This signifies the role of stem cells in medical advancement. Due to the medical benefits of stem cells, the market size of stem cell therapy was $755.4 million in 2018 and is projected to grow to $11 billion by 2029 (Statista, 2021a). Proper regulations are necessary for controlling the applications and improving outcomes of this growing segment of medical treatments.

1.2 Research Rationale

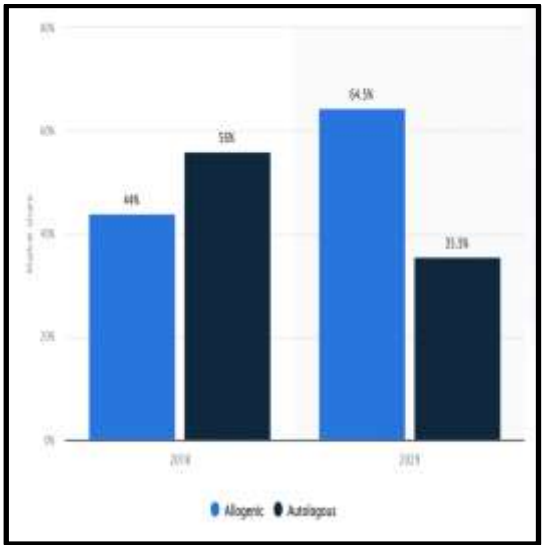

Figure 1.3: Market share of different types of Stem Cell treatment
(Source: Statista, 2021b)

Necessity of regulations guiding application of stem cells within clinical trials has been concerned as an issue in this research. This is an issue as stem cells are utilised in different manners and aid in diversified medical advancements. Treatments using stem cells are divided into two types: Allogeneic, where cells from a donor are used and Autologous, where own cells are used (Statista, 2021b). Rate of application for these two types of medical treatment is changing over time. Allogeneic treatments are predicted to increase from 44% in 2018 to 64.5% by 2029 and Autologous treatments have been predicted to decrease from 56% in 2018 to 33.5% by 2029 (Staitsta, 2021b). This signifies the importance of regulations for clinical trials of stem cells as an increase in the number of clinical trials is evident in the current context of medical research. This research has shed light on regulatory aspects associated with clinical trials including stem cells.

1.3 Research Aim

This research aims to analyse the regulatory aspects associated with utilisation of Stem Cells within clinical trials.

1.4 Research Objectives

- To analyse the significance of regulations for challenges associated with clinical trials of stem cells.
- To identify different types of regulations prevailing globally for guiding stem cell usage in clinical trials.
- To provide recommendations for improvement of stem cell usage regulations in clinical trials.

II. RESEARCH METHODOLOGY

Different types of tools and techniques are required to be used in research for acquiring desired outcomes. Methodology provides information about tools and techniques used in current research.

2.1 Search Strategy

Secondary data collection has been included in this research. Selection of a suitable search strategy is significant for improving opportunities for selecting suitable articles for this research. Keywords have been used to improve the

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opportunity to find relevant articles for this research and avoid irrelevant articles (Nikolopoulou, 2022). Keywords selected for this research include "stem cells", "clinical trials", "regulations", and "stem cell application regulations". Incorporation of these keywords has aided in finding the most suitable articles for this research. Apart from this, "Boolean operators" which include words such as "AND", "OR", and "NOT" have been utilised to provide a path to the literature search (Harari et al. 2020). Incorporation of "AND" and "OR" has aided in further refinement of search process. The application of "NOT" has aided in avoiding irrelevant articles from appearing in the search results in this research.

2.2 Database Selection

Selection of a database plays a crucial role in selecting most suitable articles for research. Articles for this research have been searched from Google Scholar to access multiple databases. The most popular databases for medical studies include "PubMed", "CINAHL", "Embase", and "Scopus" (Justesen et al. 2021). A database of PubMed has been utilised in this research for finding relevant articles.

2.3 Inclusion and Exclusion Criteria

A large number of articles are acquired while performing search procedures using specific keywords in research. Inclusion and exclusion criteria aid in improving search results by specifying the area of search and restricting expansion of the search area (Nikolopoulou, 2022). Articles that have been published before 2019 have been excluded from this research. This strategy has been developed for avoiding outdated information being included in this research. Apart from this, articles that have been published by renowned authors have only been included in this research for improving credibility of this research. Articles containing duplicate or redundant information have been excluded from this research. Implementation of these inclusion and exclusion criteria has enhanced opportunities for information collection.

2.4 Data Screening and Extraction

Data screening and extraction procedures are significant for improving outcomes of research. Data screening aids in identification of information that is not necessary for research objectives but, can impact the results of the research (Huebner et al. 2020). This type of information is excluded from this research through the data screening procedure. On the other hand, data have been extracted from the articles selected for this research by implementing abstract screening followed by a thematic analysis procedure.

2.5 Data Analysis

The data analysis procedure is significant for research to meet objectives of the research. Information is extracted from relevant articles to fulfil requirements of research objectives through a data analysis procedure (Lochmiller, 2021). Thematic data analysis technique has been incorporated in this research as qualitative information has been collected. Different themes have been developed based on the research objectives for extracting crucial information from selected articles. This information has aided in fulfilling the research objectives.

III. RESULTS AND DISCUSSION

3.1 Presentation of Thematic Analysis

Theme 1: Challenges such as complexity of therapies, and untested nature of therapies are faced in clinical trials with stem cells

Therapies including stem cell application have become significantly popular due to range of benefits associated with it. However, increased demand for stem cell treatments has given rise to serious challenges to clinical trials using stem cells. According to Barker et al. (2018), the most significant challenges associated with clinical trials including stem cells are complex nature of the therapies and application of untested therapeutic techniques. Complex nature of stem cell treatments has given rise to confusion among researchers. On the other hand, increased demand for stem cell therapies has led to various stances on the application of such therapies without proper testing (Barker et al. 2018). This has resulted in increased risk for the patients being provided with the first stage of clinical trials with untested stem cell therapies. Suitable regulations are necessary for avoiding such challenges and reducing risks for the patients participating in clinical trials.

Theme 2: Regulations for clinical trials of stem cells are significant for challenges faced in clinical trials

Challenges faced in clinical trials including stem cell application include the complex nature of therapies as well increased risk of participants. According to Castillo-Aleman et al. (2021), number of clinical trials including stem cells by both government as well as private

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organisations is increasing rapidly. This is resulting in significant concerns for an increased number of risks for the individuals involved in clinical trials with stem cells. As stated by Castillo-Aleman et al. (2021), regulatory guidelines have been developed for reducing risk and improving effectiveness of clinical trials including stem cells. Hence, the regulatory guidelines are essential for maintaining culture and standards of clinical trials while maintaining safety of the participants.

Theme 2: Diversified regulations are associated with stem cell usage in clinical trials globally

Clinical trials including stem cells are being performed in different countries across the globe which is leading to the development of diversified regulations associated with clinical trials of stem cells. Apart from this different bodies in different countries are responsible for developing guidelines governing clinical trials including stem cells. According to Lahiry et al. (2019), guidelines for clinical research using stem cells have been provided in India through "National Guidelines for Stem Cell Research 2017". Moreover, "The Indian Council for Medical Research" and "The Department of Biotechnology" were responsible for the development of such guidelines. As stated by Gao & Gao (2022), a framework for regulating stem cell research in China is provided in "Administrative Measures on Stem Cell Clinical Research (AMSCCR)". This framework provides guidelines on clinical research done using stem cells in China. On the other hand, medical applications of medical products developed using stem cells are guided by the "Drug Administration Law (DAL)" in China. These regulations are significant for mitigating the challenges faced in clinical research using stem cells.

3.2 Key Findings

Articles that have been selected for information extraction have provided information about different aspects of regulations for clinical research using stem cells. Challenges faced in clinical trials using stem cells such as increased risk of untested therapies of stem cells being administered have been identified. Impacts of such challenges can be severe leading to death of individual participants in clinical trials. Apart from this, importance of regulatory frameworks governing clinical trials with stem cells has also been deduced from this research. Diversified regulations and frameworks prevail in different countries governing clinical trials with stem cells. Specific examples of such guidelines or frameworks have also been included in this research. Exploration of such aspects has led to development of an understanding of different regulatory aspects of stem cell clinical trials.

3.3 Discussion

Thematic analysis of the selected articles has provided crucial insights into the necessity and types of regulations governing stem cell applications in clinical trials. As stated by Barker et al. (2018), the increased demand towards performing research activities using stem cells has increased frequency of challenges. Challenges have been identified to be of diverse categories relating to clinical trials incorporating stem cells. As pointed out by Barker et al. (2018), administration of untested therapies including stem cells has been among the most significant challenge for stem cell clinical trials. This has resulted in increased risk among individuals participating in clinical trials of stem cell treatments. Apart from this, complex nature of stem cell treatments has also resulted in challenges in proper administration and monitoring of stem cell therapies (Barker et al. 2018). These challenges have raised significant concerns among administrative bodies governing stem cell research. Regulations developed for governing stem cell application in clinical trials are significant for mitigating the challenges faced in clinical trials. As mentioned by Castillo-Aleman et al. (2021), the number of trials has significantly increased due to the involvement of both government and private organisations in stem cell clinical trials. This has enhanced necessity of stem cell clinical trial regulations. Diversified regulations implemented in different countries have also been identified. For instance, "National Guidelines for Stem Cell Research 2017" provides guidelines on clinical trials including stem cells in India (Lahiry et al. 2019). Hence, it can be said that diversified aspects of regulations governing stem cell clinical trials have been explored in this research.

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