

“Stem cell research moving towards clinical practices”

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Q: What is the scope of stem cell therapy in treating various ailments?

Stem cell therapy has already changed and saved thousands of lives around the world. The therapy has proved to be effective in treating dangerous diseases like cardiac failure, Parkinson's, diabetes, Autism, Alzheimer, Cerebral Palsy, Eye disorders and various other life threatening diseases. All these diseases are not caused by something going wrong within a cell or organ, but are caused by complete loss of a specific cell type. Stem cells have the prospect of a cure as they offer the

opportunity to put back into the body brand new functioning cells to replace those which have been damaged or degenerated.

Q: What are the business prospects in India? How big is the market and growth?

Stem cells hold great promise and potential for both basic sciences and medicine. Stem cells could be a major branch of medical treatment and eventually become a standard of care and practice in a few years.

With the global development of stem cell technology in research as well as clinical applications, it is very obvious that the field is making very large leaps to revolutionize the conventional approach of treating medicines and testing various drugs. The Stem Cell Research Forum of India says the stem-cell industry may grow at 15 percent reaching a billion-dollar industry by 2017. The field of stem cell biology and regenerative medicine is rapidly moving towards translational research and eventually to clinical practice in India. Since stem cells have the potential to be differentiated into any type of cell, they offer promise for treatments for a wide range of disease conditions. These include damage to the brain, spinal cord, skeletal muscles and the heart. Stem cell therapy is still in clinical trial stage for most of these indications. Hopefully it should become a standard therapy in the near future. Stem cells will be available as off-the-shelf product in the near future for treating various unmet medical needs. Majority of these products will be based on adult stem cells. Human mesenchymal stem cells, isolated from various post natal and adult human tissues, will become an attractive tool for their potential in cell therapy and will hit the market in the near future. New up-scaling technologies will emerge for mass production of stem cells without losing their inherent 'stemness' properties, thereby making stem cell products affordable.

Q: Are stem cell banking and stem cell therapy linked to each other? Please explain the difference?

Stem cells have the potential to develop into many different kinds of human tissue cell. This means they can, for certain illnesses, be introduced into the body as 'spare parts' to repair faulty cells or organs. This has spawned a new industry, private stem cell 'banks'. These banks are selling a mightily optimistic promise, that somewhere in the future stem cells could prove a miraculous cure-all: a person's own deep-frozen healthy stem cells might be defrosted to cure them of heart disease, diabetes, cancer, arthritis and Alzheimer's. Stem cell banking has become routine practice for many families throughout the world for treatment of a variety of diseases, or for future therapeutic uses which are currently in their research phase.

Stem cell therapy on the other hand also known as regenerative medicine, promotes the reparative response of diseased, dysfunctional or injured tissue using stem cells or their derivatives. It is the next chapter of organ transplantation and uses cells instead of donor organs, which are limited in supply. Stem cells grown in labs are manipulated to specialize into specific types of cells, such as heart muscle cells, blood cells or nerve cells. The specialized cells can then be implanted into a person.

Q: What are the latest techniques behind stem cell processing and stimulation?

Innovations are taking place very rapidly in the field of cell separation and cell preparations. We employ the latest closed system cell separator in the world called Sepax 2 which is the only system that ensures the sample is completely sterile and consistently give viability of more than 93 percent.

Q: How is Advancells doing as a company and your journey so far?

We have been experiencing double digit growth since inception. Our focus is to raise the general awareness of the people towards the therapy and with increasing awareness we are not only seeing more patients but we are now being approached by a lot of doctors who wish to get associated with us.

Q: Have the regulatory norms around usage of stem cell treatment been eased? What is the latest on this?

In India, the Central government has been trying to introduce a set of rules for regulating this medical technology since last seven years. In 2007, the Department of Biotechnology (DBT) and Indian Council of Medical Research (ICMR) jointly formulated the National Guidelines of Stem Cell Research and Therapy. Subsequent to that, the health ministry had set up a National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) and an Institutional Committee for Stem Cell Research and Therapy (IC-SCRT) to regulate and oversee the activities of this sector. Institutions and investigators carrying out research on human stem cells must be registered with NAC-SCRT through IC-SCRT. This is the first step towards streamlining the stem cell research in the country.

It takes a long time to get approval for conducting stem cell clinical trials in India. The regulatory approval process for conducting clinical trials for stem cell based products is evolving and the government bodies are involved in publishing a new

guideline for the use of human adult stem cells for therapy and product. The new guideline will address the development, manufacturing and quality control for stem cell therapy and product.

The existing guidelines for Stem Cell Research and Therapy (2007) address ethical and scientific concerns to encourage responsible practices in the area of stem cell research and therapy. The guideline categorizes stem cell studies into three main groups, covering permissible, restricted and prohibited research. All institutions and investigators carrying out research on human stem cells, existing and newly derived stem cell lines generated in India or in other countries should have prior approval and should be registered with NAC-SCRT through IC-SCRT.