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What are the hurdles before stem cell research?

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The pioneering research of Nobel Laureates Sir John Gurdon and Dr Shinya Yamanaka on reprogramming adult stem cells has opened new avenues in stem cell research. Several APAC countries are taking major leaps in this domain. However, their path is filled with a lot of struggle as they face numerous hurdles.

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Mr Vasant S Gaikwad of GBI Research, while speaking in this regard, says, "Inadequate research funding, unknown therapeutics outcomes and reproducibility issues in clinical trials, poor understanding of underlying mechanism, and lack of patient awareness about stem cell therapies and its potential applications are some of the key factors that hinder the growth of stem cell therapy market."

Dr Deepak Srivastava of Gladstone Institutes notes that the length of time and capital resources required are the biggest challenges. "An average of 12 years and over $1 billion (is required) to successfully bring an experimental drug from research to market," he says.

To add to these, there is a still evolving regulatory environment in most countries. Clinics offering unproven and unfounded stem cell treatments can put patient's health at risk, often for little or no benefit, adds Professor Martin Pera of Stem Cells Australia. "Responsible scientists in the field have repeatedly called for tight regulation of stem cell therapies, which, being experimental, should almost always be carried out in the context of a clinical trial after appropriate preclinical studies have demonstrated safety and efficacy in model systems," he says.

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Mr Gaikwad says that the possible harmful risk associated with unapproved stem cell therapies are making regulatory agencies and patients skeptical about potential of stem cell therapies, necessitating the need for controlled clinical studies to provide evidence on safety and efficacy claims of such therapies.

Unapproved stem cell therapies, claiming to treat a myriad of disease conditions, are being offered in various counties all over the world. "Each year, thousands of foreigners are arriving to APAC countries to seek stem cell therapies which they can't receive in their own countries, where clinical data on safety and efficacy of stem cell therapies are necessary for their approval. Treatment with unapproved stem cell therapies, lacking proven clinical data, can pose safety risk to the patients," he says.

However, governments and health authorities are slowly but surely waking up to the problem. Last year, the US Food and Drug Administration (FDA) warned consumers about unapproved stem cell therapies. In 2012, government of China ordered to halt unapproved stem cell treatments and clinical trials.