

# MEDICAL SCIENCES JOURNAL

## REVIEW

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## Trends and Prospects of Stem Cell Research in China<sup>△</sup>

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**Key words:** stem cell; policy; regulations; China

**Abstract** Great progresses have been made in fundamental and clinical stem cell research in China in recent years. The official policy on stem cells, which was announced in 2015, seems as the spring of stem cell therapy in China. However, the regulation, governance, and management of clinical expectations are still challenging. This review summarized the current stem cell research and development in the field, as well as its rapidly evolving commercial, regulatory and ethical environment in China. As expected, the prospects of stem cells in China look prospective.

Chin Med Sci J 2016; 31(2):116-120

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**T**WO decades ago, small molecule compounds, which had been long predominated in the pharmaceuticals industry, were revolutionised by biological products including recombinant hormones, soluble receptors and antibodies. Nowadays,

stem cell therapy brings us a novel approach to treat complex diseases, especially the ones that traditional medications have little clinical effect on. Clearly, there is a growing consensus, amongst policy analysts and scientists alike, that China is now playing an increasingly important role in the scientific, clinical and commercial development of stem cell research.

Stem cells are present both during embryonic development (embryonic stem cells) and in the adult body (adult stem cells). With the characteristics of self-renewal and rapid

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Received for publication April 30, 2016.

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△Supported by the National Soft Science Research Program of China (2013GXS4B083).

proliferation, they could differentiate into multiple types of functional cells and have potential clinical application in regenerating human tissues and organs. As for such versatile therapeutic potential and great economic value, stem cell research has been vigorously supported for many years in China. As a result, significant progresses have been made in fundamental and clinical research. Furthermore, plenty of companies related to stem cells have grown up and integrated into an industrial chain. In 2015, the first official policy on stem cells was announced, which further encouraged stem cell research in the field of the translational research. This review summarized the current stem cell research and development in the field, as well as its rapidly evolving commercial, regulatory and ethical environment in China. From here, we look ahead to assess the probability of China's emergence as a global player in the increasingly internationalized business of stem cell biomedicine.

## **THE DYNAMIC STEM CELL RESEARCH IN CHINA: TRENDS IN STEM CELL RESEARCH FROM 2001 TO 2015**

The stem cell field has grown very rapidly over the past two decades, and continues to be one of the most exciting aspects of biomedical research. China started its own stem cell research and the translational research as early as 2001. Generally, it could be summarized into three different stages: quickly commence, slow down bottleneck and fast development.

### **Quickly development of stem cell research in China**

In 2001, the Ministry of Health in China decided to set up five to ten banks of umbilical cord blood stem cells nationwide.<sup>1</sup> This event indicated the beginning of industrialization for human stem-cell technologies. With the support from the programs of 973 and 863, as well as the national key scientific and technological projects, stem cell technology has rapidly growing in the period of 'the 11th Five-Year Plan' (2006-2010) and 'the 12th Five-Year Plan' (2011-2015). Especially, in 2012, to push in the global stem cell market at all costs, the Ministry of Science and Technology announced the 'National Major Scientific Research Program on Stem Cells during the Period of the 12th Five-Year Plan',<sup>2</sup> which showed the determination of China on the development of stem cell technology. In the meantime, motivated by the great potential economic and strong social benefits that were brought by the stem cell industry, many more regions got involved in the stem cell industrialization. Then, in the next several years, seven banks of umbilical cord blood stem cell were established in different

areas in China. In the meantime, stem cell science has been drawn numerous funding and facilities by national, provincial, and municipal governments.

### **Defective policies and regulations postponed the development of stem cell technology**

Growing needs of social and economic benefits promoted a rapid development of stem cell technology. And more opportunities of the stem cell market were provided for China due to the policy restrictions on stem cell research in the US. But this rapid development also created contradiction. (1) Stem cell research has been driven by investment until now. The actual profit is relatively low. Thus, stem cell technology has tremendous risks and uncertainty. (2) Incomplete laws and regulations lead to blind development. Some companies and medical institutions even committed fraud treatments. An expanded number of hospitals and clinics in several cities have been even offered stem cell therapies for treatment of diseases ranging from cancer and Alzheimer's disease to spinal cord injuries. However, those treatments had little or no scientific evidence, and some were still under clinical trial. Even worse, a few of these involved some large general hospitals where patients paid thousands- or even tens of thousands- for treatments that were advertised online, which attracted both local patients of China and those from overseas, sparking what experts said is dubious type of medical tourism. However, patients usually went away with little or no improvement with most of them died. Therefore, China Food and Drug Administration (CFDA) suspended all unapproved stem cell projects and decided to neaten the clinic related stem cell research for one year.<sup>3</sup> This caused the down-stream applications of stem cell technology to be stalled for a while.

### **Chinese stem cell technology in high-speed developing period**

The contradiction between rapid development and a lack of standard and supervision caused irregular growth and chaos everywhere in China. Improving the regulation system and enhancing the supervision has become the key to solve these problems. Therefore, in March 2013, the Ministry of Health and CFDA issued the draft of 'The stem cell clinical trials management approach (Trial)', 'The stem cell clinical trials research foundation management approach (Trial)' and 'Quality control of stem cell preparations and guidelines for clinical research (Trial)'.<sup>4</sup>

As expected, 'The stem cell clinical trials management approach (Trial)', which attracted the most attention on stem cell research, was officially announced on July 20th 2015.<sup>5</sup> This policy gave a clear direction for stem cell

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