Country Report China – Stem Cell Research

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Introduction

This paper provides an overview of the regulatory, funding and institutional landscape of stem cell research in the People's Republic of China. The document is structured in two parts and three appendices. PART I provides an overview of the current funding landscape for stem cell research in China. It introduces, furthermore, some of the key-projects that have been funded by the Chinese government in recent years, and key-priority areas in the regenerative stem cell field in the recent past, the present and future. PART II provides an overview of the regulatory situation for stem cell research. We have listed (1) regulations for basic research, (2) the regulations for clinical research on human subjects in China (these regulations do not explicitly address clinical stem cell research, but they constitute a set of horizontal regulations that affect experimentations with stem cell-based applications indirectly). Thereafter (3) the regulatory approach for clinical research and applications with stem cells will be explored. An overview will be provided of the currently existing regulatory steps and documents, and some commentary on implementation is provided, if possible. The final appendix provides information on: (1) Key state institutions that affect stem cell research in China. (2) Key research institutes and stem cell biobanks in China. (3) A list of clinics that offer experimental stem cell therapies in China.

PART I: The funding landscape: a provisional sketch

During the last three decades, the promotion of innovation processes in science and technology has been defined as a key driver for economic development in China. China has surpassed Japan as the second largest investor of R&D expenditures in 2006 (US NSF 2012). Drug discovery and regenerative medicine, as has been re-emphasized by premier Wen Jiabao in January 2012, form two key-strategic areas of investment (Qiu 2012).

According to the Cure Report – a 2009 report from the UK Medical Research Council on Sino-UK research collaborations in biomedicine and the biosciences – the Chinese government has between 2005 and 2010 spent between RMB 500 million (USD 63m) and RMB 2 billion (USD 250m) into the development of SC research. The UK in contrast, invested in the two-year period 2006-2007 GBP 30 million (ca. USD 43m) (Cure 2009).

Since the Ninth Five-Year Plan (1997-2001) stem cell research has been endorsed by several governments departments. The largest part of funding has been provided by the National Science Program of the Ministry of Science and Technology, with the "863" program targeting the promotion of high technology research, and the "973" program focusing on the promotion of basic research (in all fields of science) (Cure 2009).

However, grants for stem cell research were also allocated through the Chinese Academy of the Sciences, the National Natural Science Foundation Committee, and other government related departments and organizations (Cure 2009). In the Eleventh Five Five-Year Plan (2007-2011) the “863” program included a funding section for “Stem Cells and Tissue Engineering”, within a wider program that aimed to the development of biological and pharmaceutical technology (China National Center for Biotechnology Development 2011a). This program finished in 2011, with the following PIs having been awarded major grants: ZHOU Qi, WANG Changyong, MA Yue, WU Fang, WANG Yan, LI Lingsong, WANG Ren (*ibid*.).

In the context of the Twelfth Five-Year Plan (2012-2016), the "stem cell therapy clinical translational and applied research program” has been initiated, with money allocated through the “863” program (MOST 2013).

Another important measure for the promotion of stem cell research, has been the formation of the National Stem Cell Advisory Committee (国家干细胞研究指导协调委员会), by the Ministry of Science and Technology in October 2011 (Wang 2011). Through this committee, the ministry aims to:

(1) Further coordinate stem cell research, to make strategic funding decisions (to increase efficiency of the use of national funding resources)
(2) To further create a favourable environment for innovation, to promote high-level training
(3) To strengthen international collaborations, and exchanges, so as to stimulate research into major scientific issues, and major technical breakthroughs

A closely related initiative, also funded by MOST, is the formation of biobanks, which has been set as a key-target in the Twelfth Five Year Plan (2012-2016) (China National Center for Biotechnology Development 2011b).
More specifically, the plan emphasizes the construction of biobanks as repositories for genetic clinical specimen, to:

- develop drug research / pharmaceuticals and for purposes of development biomedical engineering products, as well as for biological breeding.

A standardized clinical information database and biological specimen database shall be established in this respect in Beijing, administered under the Beijing Municipal Science and Technology Commission. The bio-bank shall be hosted by the Capital Medical University. It shall form a repository that contains samples of major disease transmitters (hope have understood this correctly), clinical data and other biological samples (China National Center for Biotechnology Development 2011b).

Furthermore, four national level stem cell banks have been founded under the Chinese Academy of the Sciences (*ibid*.):

- (1) Beijing Municipality Stem Cell Bank
- (2) Southern Stem Cell Bank, in Guangzhou
- (3) Stem cell bank of the Chinese Academy of the Sciences, Shanghai
- (4) East China Stem Cell Bank (also in) Shanghai

One of the authors of this report was in 2008 reported, furthermore, that a five-year government grant was provided for the foundation of five human embryonic stem cell banks. One of these five banks, in Changsha, should be specialized in the banking of disease-specific stem cells lines. The current status and exact functions of these banks would have to be explored in further research.

An open question is at this moment also what the role (a) of provincial and municipal governments is in funding stem cell research. Unclear is furthermore, the role of (b) foundations and (c) private investors and companies, in the financiering of translational stem cell research and/ or experimental for-profit clinical applications. Regarding the latter group, private investors and companies, active investment activity can be expected, since the application of (non-systematically proven or completely unproven) experimental stem cell therapies, constitute important market opportunities in China.

PART II: Regulatory Situation

I. Basic Research

The following regulations have been issued in China, to govern basic research with stem cells. Both of these regulations focus on human embryonic stem cell research only. The first concerns the sourcing of human embryos and ova in the context of IVF clinics. The second addresses the specific conditions under which human embryos can be produced and used for research. No regulation exists currently that addresses (a) somatic cell nuclear transfer techniques for research purposes (i.e. "therapeutic cloning"), (b) basic or preclinical research with iPS cells, and (c) research with human-animal hybrids.

(1) 2001-2003, MOH: The Ethics Guiding Principles for Assisted Reproductive Technology

This regulation addresses stem cell research, by stipulating that all ART institutions must set up ethics committees, and that these committees must approve applications of human embryos to be donated for research (Hu, Min and Wei 2011; Cure 2009). The regulation affects the supply of embryos, ova and fetal tissue for research also in the following ways: (i) by stating that the buying and selling of human eggs, embryos or fetal tissues is prohibited, (ii) by restricting the use of embryos for research to super-numerous embryos in the context of an IVF treatment, and by explicitly prohibiting the creation of IVF embryos for research only, (iii) by specifying that embryos and gametes must be voluntarily donated, on the basis of informed consent, and (iv) by forbidding hormonal super-stimulation, to harvest more eggs. This regulation is backed up by punitive measures: IVF clinics or ART centers can loose their license if they violate these guidelines (Cure 2009).

(2) 2003, MOH/MOST: The Ethics Guiding Principles for hESC research

《人胚胎干细胞研究伦理指导原则》

Human embryonic stem cell (hESC) research is regulated with these principles at a national level, through ministerial guidelines. The core aspects of this regulation are that: (i) embryos are not allowed to be used for hESC after 14 days post conception, (ii) embryos used for research can not be implanted in human beings (prohibition of human reproductive cloning). The principles demand, furthermore, that institutions that are involved in hESC form an ethics committee that details regulatory rules and exact conditions under which research can be conducted.

Criticism of existing basic research regulation from the National Ethics Committee of the MOH

These principles have been criticized by the National Ethics Committee of the MOH in China because (a) they do not introduce a registration or licensing system of research institutes or clinics that conduct hESC research, (b) because they are not backed up by law, and (c) no clear control pathways for the principles are provided. Plans and efforts to revise this regulation, from the side of the MOH National Ethics Committee, are ongoing (Zhai 2007).

II. Clinical Research

It follows now an overview of the regulations, laws and institutions, that play a role (or are foreseen to play a role) for clinical stem cell research. This process is still evolving. Before briefly discussing this regulatory approach, I will introduce however an overview of the regulations and laws that govern research on human subjects in China, of which some do – indirectly – also impact on experimental clinical research and applications.

II.a. Regulations for human subject research (affects clinical SC research horizontally)

The following provides an overview of existing regulations for human subject research. These regulations are not designed for clinical trials with stem cells, but they affect clinical research that involves stem cell-based applications indirectly (i.e. as horizontal regulations).

(1) Review of clinical research and review by Ethics Committees / hospital-internal IRBs

(a) Foundation of a national-level ethics committee

The MOH 'Ethics Committee on Biomedical research involving human subjects' was founded in 1998, and renamed in 2000 as 'Medical Ethics Expert Committee'. The committee comprises since a reform in 2007 – 17 members from multi-disciplinary background.

(b) The 2007 'Regulation on ethical review of biomedical research involving human subjects' 《涉及人的生物医学研究伦理审查办法（试行）》

A draft regulation on Ethical Review of Medical Research involving human subjects was drafted in 1998, but was due to controversies failed to be endorsed (Hu, Min and Wei 2011). It was issued by the MOH only in 2007. According to this regulation – all

– research on human subjects has to occur under review of ethics committees at the level of research institutes and hospitals. It specifies details for how informed consent procedures have to be structured. This regulation is of fundamental importance to clinical stem cell research and applications, because it requires mandatory EC approval at the level of medical institutions that engage in these activities.

(2) The 1994 Regulation on the Government of Medical Institutions

This regulation has been passed by the state council in 1994. It clarifies that informed consent is required for performance of surgical operations, special investigations, and special (experimental) treatments. It sets out, furthermore, a number of rules for medical institutions, such as for instance, that approval documents for treatments, can not be 'inherited', if the owner, or name of a hospital changes. This regulation is of some relevancy for clinical SC research, in particular institutes that offer for-profit therapies. The Jilin Silicon Valley Hospital, for instance, was criticized by the media on the basis of this regulation. Reason: the hospital had changed its name and proprietor, but the same approval license was used (issued by a local and a provincial health bureau) to attract patients (approval documents were publicly displayed on the internet).

(3) The 1999 Drug Clinical Trial Regulations Law on Practicing Doctors

This regulation protects patients by stating that doctors who violate a patient's privacy or conduct experimental interventions without informed consent, will be legally persecuted. I have not yet heard of cases where this regulation was applied, in the context of SC based for experimental treatments. In theory, however, this regulation applies to doctors who fail to sufficiently inform patients, or who violate a patient's privacy (Cure 2009). In other words, patients could sue doctors who offered experimental stem cell treatments based on fraudulent claims, on the basis of this regulation.

(4) The 2001/2001 Drug Administration Law / Regulations for implementation of the drug

This law has been passed by the National People's Congress. It covers the use of pharmaceutical products in research as well as practice. It clarifies that GCP and GMP standards must be followed. (Cure 2009).

This regulation (if I understand it correctly – need for verification by CIs in China) is of relevancy to hospitals that conduct clinical trials with SC in the context of an SFDA monitored IND application. These hospitals would, according to this regulation require GCP certification, obtained through the procedures set out above. Other clinical trials or forms of experimentation – that are conducted outside of the jurisdiction of the SFDA do – not require to be carried out in GCP accredited hospitals, and the regulation is for these hospitals redundant.

(5) The 1999-2003 SFDA good clinical practice standards (药物临床试验质量管理规范)

These SFDA GCP standards were issued in a first version in 1999, and in a second more complete version in 2003. Both were issued by the SFDA. The SFDA GCP standards specify procedures for the accreditation of medical institutions, to take part in drug trials. They require that each hospital in human subject research acquire GCP certification (Cure 2009). An interesting feature is that GCP certification is based on examinations of high-level clinical staff (heads of department). They emphasize strict informed consent and strict review by ethics committees, and include provisions on how IRBs should be composed and be organized. The Chinese GCP standards, draw actively on the now internationally handled ICH GCP standards. (Cure 2009). These SFDA GCP standards are of relevancy to hospitals that conduct clinical trials with SC in the context of an SFDA registered IND application.

II. b. The evolving regulatory approach for clinical SC research

It follows now an overview of the evolving regulatory approach for clinical SC research and applications in China. Three regulatory documents shall be discussed: (1) The 2009 May 1 Regulation; (2) a 2010 draft regulation; (3) the January 6 2012 notification for clinical stem cell research and application.

1. The 'May 1 2009 regulation' and its impact

On May 1 2009 the MOH promulgated the "Management Measures for the Clinical Use of Medical Technologies" [医疗技术临床应用管理办法], a regulation that classified a range of new medical technologies and procedures into three categories. Stem cell transplant technology was grouped into category III, which included technologies considered as risky, ethically controversial and in need of clinical verification (Chen 2009). To implement the regulation the MOH assigned five institutions (ibid.: 271), among them the Chinese Medical Association, the Chinese Hospital Association and the Chinese Doctors Association. According to an associate of the MOH in Beijing, clinics that used SC transplantation technology were summoned to register at these institutions. These organizations in turn were assigned to grant licenses on the basis of newly formed assessment criteria and review and inspection committees. In practice, this regulation has not yet been implemented for SC transplantation technologies. As stated by a senior SC scientist, who as a member of the Chinese Doctors Association was involved in the formulation of review criteria, there were widespread disagreements among experts of the assigned five institutions, over the precise characteristics of these criteria, over feasible implementation pathways, as well as the extent to which the situation should be controlled.

2. The 2010 Draft Regulation

In 2008 the Science and Education unit of the MOH authorized an expert committee of medical ethics chaired by Prof Chingli Hu, to develop a comprehensive draft regulation for clinical research and applications with human SC in China. After a two-year consultation and preparation process, a draft was submitted to the MOH in

October 2010. This proposal has subsequently been under internal consideration, and is expected to form the foundation of a finalized version that is expected soon.[1]

A central premise of this draft is the promotion of standardized and rigorous scientific forms of clinical SC research (Hu 2010: 27). It asks for methodical preclinical studies and the generation of reliable safety data, as well as standardized clinical trials that precede clinical applications (27). These trials shall be subject to approval and review procedures under the MOH and the SFDA (which since 2008 has been a subunit of the MOH). Only qualified and licensed hospitals would be able to provide approved clinical applications (37). Furthermore, the draft stipulates that the quality and safety of used cells must be subjected to reliable controls and documentation (32). Medical institutions that violate these principles will be forced to stop SC-based clinical trials or applications for a period of five years (37).

The draft specifies approval and review procedures for three central forms of clinical research and applications with SC. First is approval of clinical trials and applications of *stem cell based drug products*, i.e. standardized batch products based on amplification of cells from one or multiple donors. Responsibilities for evaluation and market approval of these 'off-the-shelf' SC products (commonly regarded as the most risky treatment form with SC) shall be handled by the SFDA, and be based on systematic preclinical studies and closely reviewed Phase I-III clinical trials (36). Second is approval of clinical trials and applications of *modified SC from a single donor to single recipient*. With reference to the 2009 regulation these treatment forms were defined as medical technology. Regulatory distinctions are made in this respect between autologous/allogeneic SC, and minimally/extensively manipulated SC. Approval of minimally processed autologous SC, which are seen as the least risky group of cells, shall occur through the MOH Bureau of Medical Administration. More extensively manipulated cells, particularly from allogeneic sources, shall be approved by the MOH Bureau of Science and Education. Application and review procedures shall be handled by the thirty-one province-level sub-branches of the MOH, with the MOH in Beijing as the central supervising agency. Third is approval of *experimental therapeutic approaches with SC*. Experimental for-profit applications shall be strictly delimited. In accordance with article 35 of Helsinki Declaration first-in-human experimental treatments with SC shall be allowed, but in a low number of patients, and according to clear approval criteria. Applications and oversight shall occur through specialized ethics committees, at the provincial MOH branches.

With this draft regulation, a clear step toward international harmonization has been set into motion. In regulating medical procedures with SC proportionate to risk, for example, the Chinese draft regulation follows essentially the approach that is also taken in the EU (Faulkner 2009: 641). Differences exist, however, with respect to terminology and the allocation of responsibilities. In the EU, all experimental medical procedures with SC (including autologous SC for non-homologous use) have since 2007 been classified as *advanced therapy medicinal products*. These are regulated under the centralized auspice of the European Medicines Agency (EMA) (*ibid*. 2009; EMA 2012). The 2010 draft regulation for China, on the other hand, follows a slightly different strategy. For one thing, approval procedures are divided between the categories 'medical products' and 'medical technologies. For the other thing, responsibilities are not done by a centralized drug regulatory agency, but split across three administrational units of the MOH, each with its own subsidiary branch

[1] This information is based on a presentation of this draft regulation, generously provided by Prof Chingli Hu and his team in Shanghai, on January 21, 2011.

organizations at a provincial level. Since the draft regulation is likely to still undergo significant revisions, it is too early to say what the implications of these differences for processes of regulatory harmonization and international collaborations will be. Further research into these directions, together with a focus on local implementation, will be of interest.

3. The January 2012 notification

On January 6 2012, the MOH issued a regulatory document called 'Notification on Self-Evaluation and Self-Correction Work regarding the Development of Clinical Stem Cell Clinical Research and Applications' [关于开展干细胞临床研究和应用自查自纠工作的通知].[2] With this document an initial one-year phase of a more comprehensive regulatory approach has been initiated, whose precise details have not yet been publicized. In the January 2012 document, four subsequent stages of this forthcoming approach have been announced: self-evaluation (*zicha*), self-correction (zijiu), re-certification (*chongxin renzheng*), and standardized management (*guifan guanli*).

The initial one-year phase that is set out in the 2012 document, however, addresses only the first two of these stages: self-evaluation and self-correction. Self-evaluation of the hospitals that carry out SC-based clinical research and applications shall occur in the following way. First, clinics are required to fill in the 'Self-Evaluation Form for Inquiry into Conditions of Stem Cell Clinical Research and Applications'.[3] In this form, clinics are asked to report truthfully on previously and currently developed kinds of clinical research and applications with stem cells. Information is requested on (1) types of cells and forms of cell-processing, (2) the disease types for which cells have been used, (3) forms of ethics and regulatory approval mechanisms, (4) informed consent procedures, (5) information on risks and experienced problems, (6) sources of funding and patient fees, (7) number of patients experimentally treated, and (8) publications or summarizing reports from clinical trials or other types of clinical studies. Second, this information is evaluated by province-level MOH workgroups, which are coordinated by the 'Stem Cell Clinical Research and Application Standardization and Rectification Work and Leadership Group', co-founded by the MOH and SFDA in Beijing (paragraph 2). The task of these province-level workgroups is to appraise the incoming data, to produce summarizing reports to Beijing (paragraph 4), and during later stages, to play an active role in the implementation and enforcement of the regulation (paragraph 2).

Self-correction means that all institutes that have not yet received approval, either by the MOH or the SFDA, must stop clinical stem cell research or application activities until approval has been obtained. Institutes that continue to carry out unauthorized clinical research or applications have been announced to be targeted as focal points for rectification (paragraph 2). On the other hand, clinical trials for stem cell products that have obtained approval by the SFDA are expected to act in strict accordance with the requirements set out by the SFDA, and in compliance with the Chinese GCP standards (paragraph 2). The document has announced that no

[2] http://www.moh.gov.cn/publicfiles/business/htmlfiles/mohkjjys/s3582/201201/53890.htm
[3] This document has been put on the MOH website.
http://61.49.18.65/publicfiles///business/cmsresources/mohkjjys/cmsrsdocument/doc13829.docx
Translations of these two documents can be requested from the author of this article per email.

registration applications will be accepted by the MOH or the SFDA until July 1 2012 (paragraph 2). Information on how applications for registration will be handled, however, has not been provided in the text. Uncertainty also remains as to how non-compliance will be dealt with, and which role the MOH and its province-level workgroups will play in this. It is not clear, furthermore, whether military hospitals (that operate under the command of the Health Department of the Army General Logistics Department), will be subjected to the same review and approval procedures as state hospitals, or whether a different regulatory approach shall apply.

4. The March 2013 announcement of three inter-related draft regulations

On March 7 2013, the MOH has published on its website, three documents that summarize, and introduce to the public, the basic structure and central regulatory instruments of three inter-related draft regulations, that have been developed by the MOH for the regulation of clinical stem cell research and applications, in recent months. In contrast to initial media coverage (Zornoza 2013), these documents do not constitute the regulatory draft documents themselves, but they provide comprehensive summaries of the three draft regulations, that introduce the underlying rationale of the forthcoming regulatory framework, its purposes, central regulatory premises, and implementation structure. From these documents it becomes clear, that each of the three draft regulations, consists of ca 35 to 40 articles, that address different aspects of the review and approval procedures, for clinical stem cell research and applications (details will follow below).

The summaries of the draft regulations have been published on the website of the MOH for the purpose of public feedback and commentary. The public dissemination of the introductory summaries of the three draft regulations, constitutes the first publicly visibly step toward regulatory intervention of clinical stem cell research and applications in China, since the above-mentioned January 6 2012 notification. The announcement and summary of the three draft regulations, represent the first move toward realization of the third and the fourth of the four regulatory phases that were announced by the MOH in the 'January 6 2012 notification' (above): "re-certification" [chongxin renzheng] and "standardized management" [guifan guanli] (following from phases one and two: "self-evaluation" [zicha] and "self-correction" [zijiu], which were initiated in the course of 2012.

The titles of the three draft regulations are as follows:

1. Stem cell clinical trial research management methods [ganxibao linchuang shiyan yanjiu guanli banfa]
2. Stem cell clinical trial research basic management methods [ganxibao linchuang shiyan yanjiu jidi guanli banfa]
3. Guidance principles for stem cell preparation, quality control and preclinical research [ganxibao zhiji zhiliang kongzhi he linchuangqian yanjiu zhidao yuanze]

The most important points in these three documents are as follows:

(1) Approval of stem cell based therapeutic applications must be based on phase I, II and III clinical trials

(2) In the context of these trials it will not be allowed to charge patients for money
(3) Clinical trials must be approved by ethics committees, and designed specifically administrational units, that involve review by expert committees, as formed by provincial and national level units of the MOH, and the SFDA
(4) Clinical stem cell trials must be based on, and will be approved on the basis of, solid preclinical evidence, that established the safety and therapeutic potential of a candidate application
(5) Stem cell clinical trials must be conducted in line with the SFDA's 'Good Clinical Practice Standards' (药物临床试验质量管理规范), and related regulatory documents
    a. This means that hospitals and/ or departments that conduct stem cell trials, must be qualified as GCP hospitals, by the SFDA (will require verification)
(6) Stem cell clinical trials must be conducted in accordance with ethical norms, as laid down in the '2007 Interim Regulation on the Ethical Review of Biomedical Research involving Human Subjects' (涉及人的生物医学研究伦理审查办法（试行）), and the Ethics Guiding Principles for hESC research （人胚胎干细胞研究伦理指导原则）
(7) Stem cell collection, separation, purification, amplification, certification, packaging, storage and transport of stem cells that are used for clinical trials, must occur in accordance with GMP standards.
    a. Staff must be trained in these procedures, and GMP compliance of laboratories and related technologies and equipment must be certified
(8) The regulation applies to all types of stem cell research and regulations, with the exception of hematopoetic stem cells, and related products
(9) Application and review procedures for stem cell clinical trials
    a. Medical institutions must apply at specifically designed report units
    b. The report units distribute the application to the province level branches of the MOH and SFDA for formal examination and review
    c. The province level review is followed by a national-level review procedure, through the 'Stem Cell Clinical Research and Application Regulation Management Work and Leadership Group', which is co-founded by the MOH and SFDA and situated in Beijing (this group is also designated in the document as "the office")
    d. In The Office the application is reviewed by expert committees, and experts brings site visits to clinics, as part of the review process
    e. Following this, applications are accepted, or rejected.
(10) Clinical trials must be conducted in phase I-III format, if there are indicated of serious adverse events, these must be reported to Ethics Committees and The Office, and the trials must be immediately stopped
(11) Progress reports of the trials must be submitted to The Office on a 12 months basis
(12) Punishment procedures are specified, that hold institutions and personnel that violate regulatory provisions, directly responsible. Legal persecution will occur under the existing drug management law.

Appendix:

I. Key state institutions that affect stem cell research in China

(1) Ministry of Science and Technology (MOST) / China

(2) The China Centre for Biotechnology Development

- Has been established under MOST in 1983, to promote innovation processes in biotech, and related commercialization.
- Helps to oversee and handle administrative tasks for MOST, especially in the context of the 863 and 973 funding programs.
- The office for Human Genetic Materials Management is also housed by the China Centre for Biotechnology Development.

(3) The Chinese Academy of the Sciences (manages several national key-institutes in basic science, among which biology, with a key focus also on disease research and drug development)

(4) The Ministry of Health

- Oversees and funds all forms of clinical research /clinical translation processes, as well as clinical applications
- Medicine research and applications are regulated through three various subunits of the MOH
    - The SFDA
    - Bureau of Science and Education (Kejiao Si)
    - Bureau of Medical Administration (Yizheng Si)
- Since 2009 there is also a new office for the monitoring and registration of serious adverse events after approval, which also operates under the supervision of the MOH

(5) The Chinese Medical Association (CMA)

- Plays a leading role in medical education, training and professional exchanges
- Oversees 82 specialty societies
- Publishes over 70 medical journals
- Is also occasionally involved in regulatory processes

Comment: The CMA is to our knowledge currently not involved in the regulation or oversight of stem cell-based clinical research.

2. Research institutes and stem cell biobanks

- Four national level stem cell banks under the Chinese Academy of the sciences:

    (1) Beijing Municipality Stem Cell Bank
    (2) Southern Stem Cell Bank, in Guangzhou
    (3) Stem cell bank of the Chinese Academy of the Sciences, Shanghai
    (4) East China Stem Cell Bank (also in) Shanghai

Clinics that offer experimental for-profit therapies

- Beijing cell permeable rehabilitation center
- Qingdao SC therapy and rehabilitation center
- Chongqing stem cell therapy center
- Beike Biotech
- Jilin Silicon Valley Hospital
- Tiantan Puhua Hospital
- Etc.

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