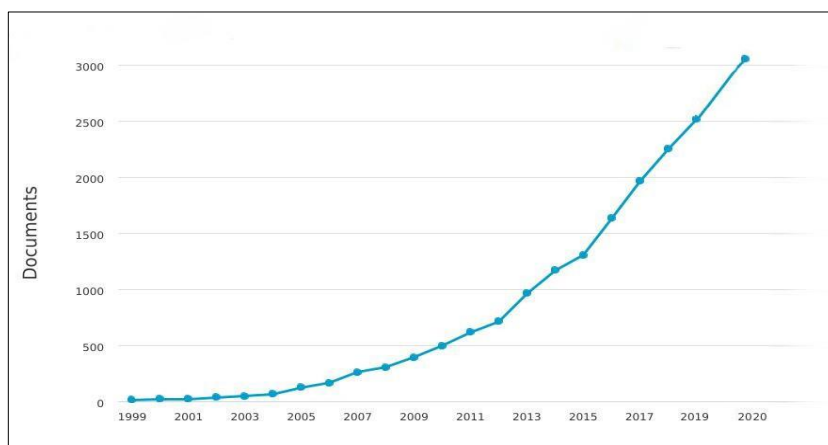


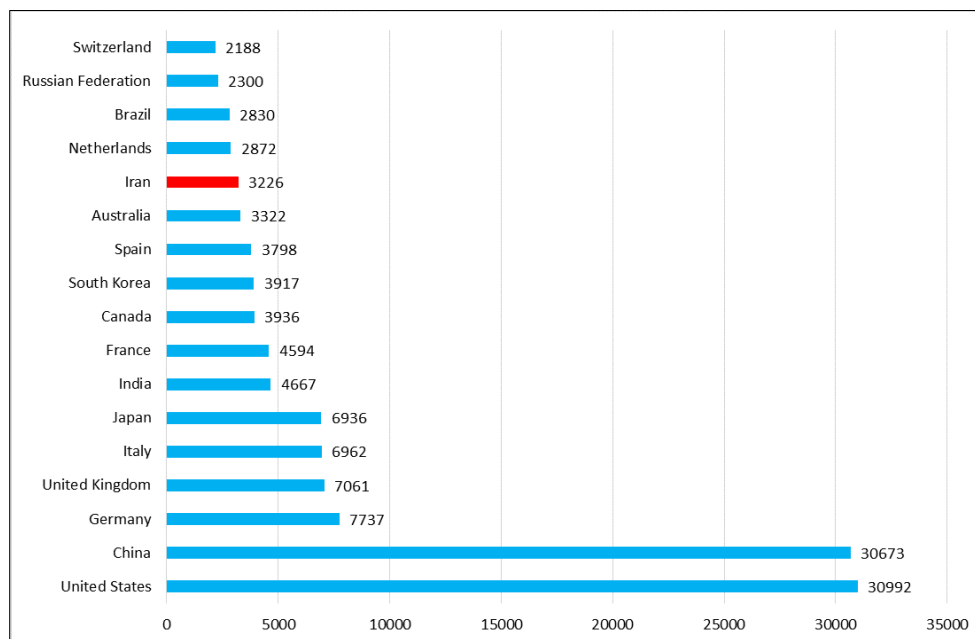
1. An overview of the country's growth in the production of stem cell science and technology and reconstructive medicine

Due to the newness of this field of knowledge and in order to overcome the slowness of the research process compared with the application of knowledge, the “Council for Development of Stem cell Sciences and Technologies” has tried to encourage the existing human resources in this field and also provide the necessary platform for training and growth of young forces in various fields of reconstructive medicine and stem cells (tissue engineering, gene therapy, and cell therapy). On the other hand, thanks to the efforts of scientists and researchers, there has been significant growth in science production in the field of reconstructive medicine in our country. One of the important indicators of scientific growth in the countries is the number of published research articles that have shown growth and progress in that particular field of study. In order to evaluate the production of science, articles published in reputable international journals in the field of stem cells and reconstructive medicine, indexed in the authentic “Scopus” database, were searched with related keywords:

It should be noted that all scientific production that have been carried out in universities and scientific-educational centers of the Islamic Republic of Iran and published by the end of 2021, were reviewed and it revealed that at the end of 2021, the Islamic Republic of Iran ranked 13th in the world and first in the region in the world ranking of Scopus; higher than Turkey, Israel, and other Middle Eastern countries.



Number of articles in the field of stem cells and reconstructive medicine by 2020 (taken from Scopus database)



Iran ranks 13th in 2020, based on the number of articles published in the world (taken from the Scopus database)

2. Preparation of the infrastructure of laws, instructions and standards for the production of cell therapy products in the Islamic Republic of Iran

Stem cell knowledge in the country is developing with a slight difference compared to developed countries in the world, however, since the standards of the production, accreditation, and commercialization process of stem cell-related products had not yet been fully developed in the country, and these activities remained at the level of research and development until 7 years ago. For this reason, during the past years, diligent efforts were made with the cooperation of the most prominent professors, managers, and senior experts of the Council for Development of Stem cell Sciences and Technologies of the Vice Presidency for Science and Technology, in order to prepare and improve related instructions and regulations to help the Ministry of Health and Medical Education.

Therefore, a large number of technical meetings were held to discuss and exchange opinions and benefit from the experiences of developed countries in this field; for example, “Criteria for registration of biological products” and “Guidelines for the minimum order of cells, tissues and

products based on human cells” were uploaded on the website of the Food and Drug Administration in 2015, and the by-laws on the establishment and operation of reconstructive medicine and cell therapy in public, non-governmental and private hospitals were communicated to all universities and the medical system organizations by the Deputy Minister of Health, Treatment and Medical Education in 2018.

Thus, now the Islamic Republic of Iran has provided the infrastructure of laws and regulations and is able to produce stem cell products and reconstructive medicine with high standards, and is ready to accept foreign investment and participate in the production, transfer, and sale of technology, construction of production infrastructure and training of specialists in target countries besides any required mutual cooperation in this field.

Date of Notification	Regulation
2015	Criteria for registration and import of biological products
2015	Regulations of the National Council for Development and Supervision, for Admission Centers for Hematopoietic Stem Cell Donation and Cord Blood Banks
2015	Guideline for Minimal Manipulation of Human Cell-Based Cells, Tissues and Products
2016	Issuance of the First License for Cell Therapy Services
2018	Regulations for the Establishment and Operation of Reconstructive Medicine and Cell Therapy Center in Public, Non-governmental and Private Hospitals

2019	Guideline for Gene Therapy Products
2019	Industry Guideline for Preclinical Reviews of Cell and Gene Therapy Products

3. Qualitative and quantitative development of stem cell clinical service centers in the country

Currently, nationally licensed cell therapy centers are specialized centers in hematopoietic stem cell transplant centers (bone marrow) that treat a variety of incurable diseases such as congenital hematopoietic diseases, primary immunodeficiency diseases (PID), metabolic diseases, hematopoietic cancers, and solid tumors. A significant number of people in the world suffer from this kind of disease, and in some cases, transplantation of hematopoietic stem cells from a healthy person to a patient is the only option left to save the lives of patients with such diseases.

Hematopoietic stem cell transplantation is very useful in the treatment of cancers and the repair of the hematopoietic system and the body's immune system and can lead to lifelong recovery for the patient. The first hematopoietic stem cell transplant center at Tehran University of Medical Sciences was put into operation in 1990. Currently, 18 centers have been established in prestigious university hospitals across the country.

Hematopoietic stem cell transplantation was initially performed only for adults in the country, but since 2006, a pediatric ward has been set up at Tehran University of Medical Sciences. During the 31 years that hematopoietic stem cell transplants have been performed in the country, about 13,000 patients have benefited from this treatment. Therefore, the Islamic Republic of Iran is now ready to provide advanced bone marrow transplantation or hematopoietic stem cell transplantation in incurable patients, and while accepting patients in the form of health tourism, also can train target groups in friendly countries, and design and set up specialized hematopoietic stem cell transplant centers in such countries.

In this regard, in the last 3 years, the first hematopoietic stem cell transplant center was designed and set up in the Children's Hospital of Damascus University, Syria.

NO.	Center's Name	NO.	Center's Name
1	Shariati Hospital, Tehran	10	Montaseriyeh Hospital, Mashhad
2	Taleghani Hospital, Tehran	11	Afzalipour Hospital, Kerman
3	Namazi Hospital, Shiraz	12	Amirkela Hospital, Babol
4	Tehran Children's Medical Center	13	Mofid Children's Hospital, Tehran
5	Imam Khomeini Hospital, Tehran	14	Seyed Al-Shohada Hospital, Isfahan
6	Ghazi Tabatabai Hospital, Tabriz	15	Imam Khomeini Hospital, Urmia
7	Imam Reza Hospital, Kermanshah	16	Amir Hospital, Shiraz
8	Shafa Hospital, Ahvaz	17	Mahak Hospital, Tehran
9	Imam Khomeini Hospital, Sari	18	Firoozgar Hospital, Tehran

4. Design and operation of stem cell donation centers

Every year in Iran, a large number of people with leukemia and other incurable diseases who required hematopoietic stem cell transplantation, suffer from the lack of a suitable and compatible cell donor for transplantation, and this number was increasing and transplantation of hematopoietic stem cells from compatible donor family members were the last chance for patients to survive.

To solve this problem, hematopoietic stem cell donation centers were set up in the country. People, who volunteer to donate their own hematopoietic stem cells, can register at admission centers. An initial test of the donor's genetic status is performed. The test results of the candidate are kept confidential except for himself/herself. When needed and if the donor is compatible with the patients in need, the donor is invited to participate in the donation process.

The first admission center in the country was established at Tehran University of Medical Sciences and then a limited number of stem cell donor centers were established in the country, including the Blood Transfusion Organization, Shiraz University of Medical Sciences, Shahid

Beheshti University of Medical Sciences, etc. Now, nearly a decade has passed since the development of the national network of hematopoietic stem cell donors in the country, and Iran, as a member of the WMDA (World Association of Hematopoietic Stem Cell Donors), is able to exchange cells with other countries in the world. Therefore, the Islamic Republic of Iran is ready to design and set up donor centers in the target countries, so that patients in these countries can benefit from donated cells in various ways.

Launching and developing 13 donor centers					
91498 donors in 16 centers					
NO.	Center's Name	Number of donors (HLA Type)	NO.	Center's Name	Number of donors (HLA Type)
1	Tehran University of Medical Sciences • Shariati Hospital	28554 (28554)	8	Isfahan University of Medical Sciences	(189)1031
2	Blood Transfusion Center • Sepas Adult Center	15472 (15472)	9	Mazandaran University of Medical Sciences	315 (175)
3	Mahak (Charity Organization)	8826 (8797)	10	Kermanshah University of Medical Sciences • Imam Reza Hospital	816 (61)
4	Shiraz University of Medical • Motahhari	5780 (4783)	11	Kerman medical university • Afzalipour	152 (60)

	Clinic			Hospital	
5	Tehran University of Medical Sciences Children's Medical Center	2017 (1501)	12	Ahvaz Jondishapur University of Medical Sciences	13 (11)
6	Mashhad University of Medical Sciences Stem cell research and application Headquarter	664 (658)	13	Shahid Beheshti University of Medical Sciences Taleghani Hospital	664 (658)
7	Tabriz University of Medical Sciences	1130 (596)			

5. Design and operation of cord blood banks

Umbilical cord blood is the blood that remains in the placement and in the attached umbilical cord and is thrown away with it after childbirth. In addition to blood cells, this blood is a rich source of hematopoietic stem cells. An important feature of umbilical cord blood cells is that they are not fully developed, including their lymphocytes, which, as a result, is much less likely to reject transplants performed with these types of cells compared to bone marrow transplants. Laboratory studies have shown that umbilical cord stem cells have the ability to differentiate themselves from other cells, and thus can draw new horizons for the treatment of related diseases in the not-too-distant future.

For this reason, about 15 years ago, centers for storing umbilical cord blood were established in the country, such as the bank of Royan Stem Cell Technology Company, which also operated separately like the admission centers, and the patient had to go and search in different cord blood

banks of the country. In this regard, and due to the high number of patients in need of hematopoietic stem cell transplantation, the cord blood bank of the Blood Transfusion Organization was established with the support of the Council for Development of Stem cell Sciences and Technologies, with the aim of storing and supplying hematopoietic stem cells for patients.

Therefore, today, processing centers for maternity products, especially cord blood, for use in the treatment of diseases are very prosperous and the Islamic Republic of Iran is ready to design and launch these banks in the target countries. One of these banks was established in Oman.

Setting up and developing 3 cord banks		
NO.	Center's Name	Number of donors (HLA Type)
1	blood transfusion Center • Cord blood bank	3588 (3588)
2	Royan Institute • Royan cord blood bank	19186 (19185)
3	Tehran University of Medical Sciences • Cord blood bank	2012 (2012)

6. Comprehensive centers of science and technology of stem cells and reconstructive medicine in the country

Stem cells and reconstructive medicine is an interdisciplinary knowledge that requires the cooperation of specialists in various fields, from clinical specialists to pharmacists, specialists in basic medical sciences, technical engineers and tissue engineering to develop and promote. In recent years, most universities and research centers interested in the subject of stem cells have worked separately and independently, and as a result, most research has been done on a small scale or has not led to a technology clinical service.

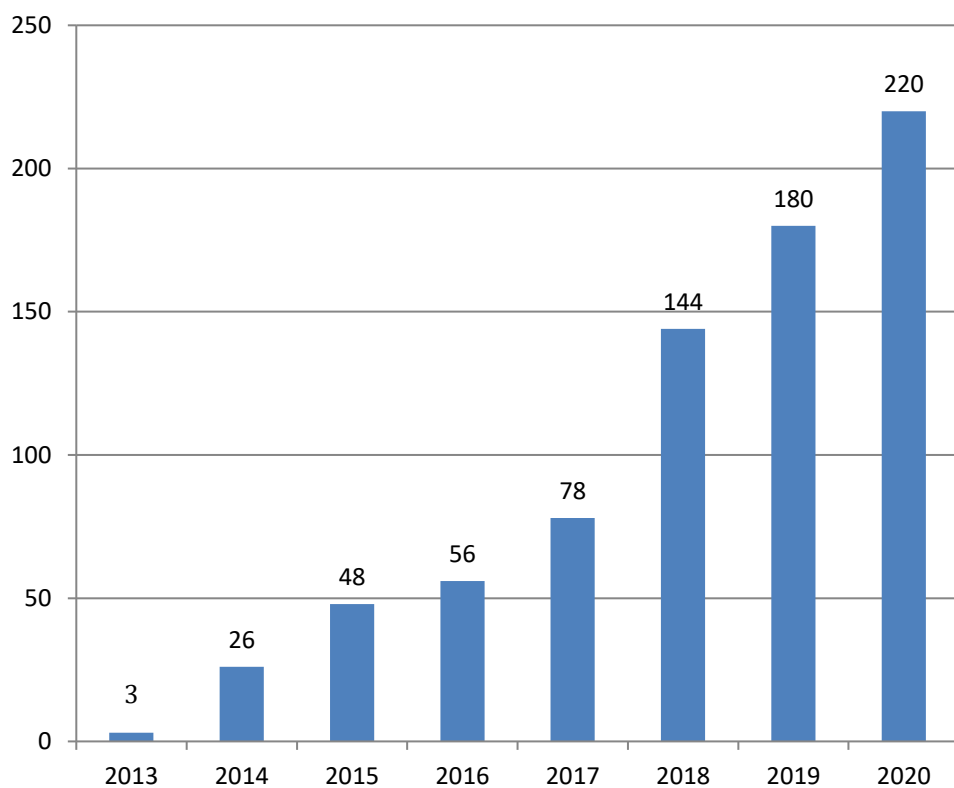
Therefore, the establishment of comprehensive centers of science and technology of stem cells and reconstructive medicine in order to consolidate scientific capacity, manpower, and technical

and laboratory equipment and support the establishment of knowledge-based companies and technology centers, was included in the Council program, and the supporting national approved projects were carried out with the approach of fair distribution of resources in the country, which is currently being implemented, monitored and evaluated. In this regard, and based on the announcement of the Supreme Council of the Cultural Revolution on the formation of 10 major medical sciences regions in the country, comprehensive centers have been established with the support of the Council for Development of Stem cell Sciences and Technologies and the participation of the country's universities of medical sciences in some large regions, which will act as one of the most important regional structures for the development of stem cell science and technology. These centers will focus on all four aspects of education, research, human resource development, and especially the production of technology, services, and medical products. The establishment of comprehensive centers, in addition to leading to the growth of science, will also increase the employment of specialists and graduates of related fields.

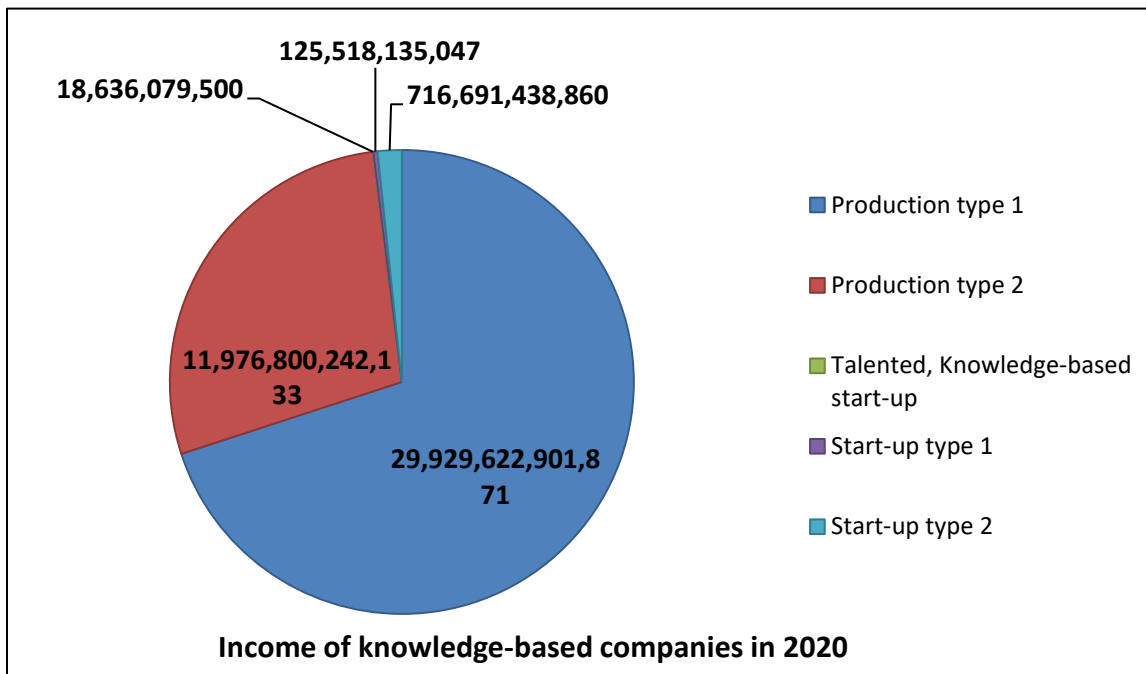
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7. Significant development and growth of the number of knowledge-based companies, readiness to export, transfer and sell technology

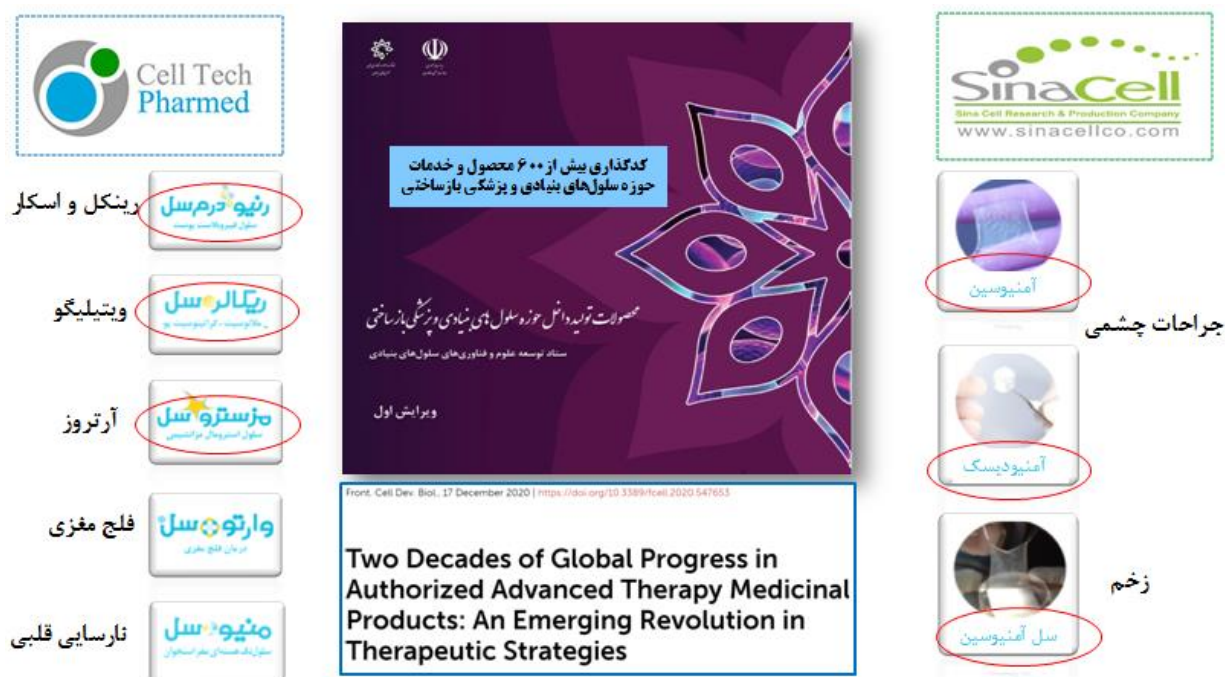
Stem cell science and technology has reached a stage of growth and prosperity that can gradually enter the field of export, including the export of technology and products. It should be noted that by the end of 2021, more than 190 knowledge-based companies in the field of stem cell science and technology have been organized. In this regard, active companies in this field are ready to attract foreign investment, and also to cooperate with the target countries in the field of transfer and sale of stem cell technology and reconstructive medicine by participating in the production process.



Number of companies active in the field of reconstructive medicine in the different fields of raw materials, equipment and devices, product production and processing, genetic manipulation, tissue engineering and gene therapy in Iran



✓ Production of over 600 products based on stem cells and regenerative medicine



List of services available to present to target countries

NO.	Title	Application
1	Design and operation of hematopoietic stem cell transplant centers	Treatment of cancer and 70 types of incurable diseases
2	Design and operation of stem cell donation centers and cord blood bank	Treatment of incurable diseases
3	Design and operation of centers for providing cell therapy and reconstructive medicine services	Treatment of diseases
4	Design and operation of comprehensive stem cell and regenerative medicine centers	Education, research and training of graduate students, and technology development
5	Participation in domestic production, design and establishment of production centers for cellular products in abroad, attracting foreign investment, transfer and sale of technology	International economic cooperation

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