

Report on R&D *and* Engineering Capabilities in the *Healthcare Sector in Turkey*



INVEST IN **TÜRKİYE**

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25
yıl

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Dear Readers,

Thanks to the successful macro policies implemented, reforms carried out uninterrupted and political stability achieved under the leadership of President Mr. Recep Tayyip Erdoğan, the Turkish economy reached an average growth of 5.1% between the years 2003-2020. Thus, Turkey managed to become one of the fastest growing economies, ranking 11th largest economy in the world in terms of purchasing power parity as of 2020. In the same period, Turkey established itself as a center for investments in its region by attracting 225 billion USD of foreign direct investments (FDI).

Throughout the pandemic we have been fighting against for the past year, Turkey has been one of the few major economies which prevented economic downsizing and achieved positive growth in 2020 with 1.8% growth data. This pandemic has reminded us of the importance of the healthcare sector and our companies operating there. As a nation, becoming one of the top 10 economies in the world and developing domestic technologies are among our goals. One of the most important pillars of this goal is undoubtedly the healthcare industries. FDIs play a very important role in the progress made by the Turkish healthcare industries and research ecosystem today. Our country has 20 multinational pharmaceutical companies which completed their investments, as well as a constantly improving medical technologies ecosystem advancing towards globalization. With health expenditures exceeding 35 billion USD as of 2019, Turkey is a center that attracts the attention of the global health ecosystem, particularly pharmaceuticals and medical technologies. Furthermore, thanks to its strategic position, Turkey has easy and efficient access to raw materials and markets in its region, as well as young, dynamic and qualified skill power and large production capacity. Our country has the potential to produce in many different sectors and product groups. These production systems are supported with reliable, economical, logistics and commercial services. Due to numerous similar advantages, many leading multinational companies have chosen Turkey as an R&D, design, production, export, logistics center and headquarters. We see the reflections of this situation also in the Turkish pharmaceutical industry, which has been improving itself on daily basis in the field of health biotechnology. The healthcare industry has leveled up thanks to the attractive investment opportunities we offer, contributing to the establishment of a modern ecosystem that meets international standards. Within this framework, the Investment Office of the Presidency of The Republic of Turkey is involved in these efforts by striving to bring new added-value and technology-intensive investments into the ecosystem and enhance the reliability of existing investments.

We believe that this study titled "Healthcare R&D and Technology Ecosystem in Turkey", which the **Investment Office of the Presidency of The Republic of Turkey** has prepared together with **Sistem Global Danışmanlık**, will highlight the investment opportunities in Turkey in the field of healthcare and life sciences, based on concrete examples. This study will fulfill a significant need in the healthcare sector, where the research, science, technology and innovation focuses are most prominent in the world and innovation and progress have the most impact on public health. With this study, we have tried to address the R&D and technology ecosystem in the fields of pharmaceuticals, medical technologies, digital health, medical biotechnology and clinical studies with a holistic approach.

I would like to express my gratitude to all those who have contributed to the preparation of this issue, especially to Sistem Global Danışmanlık, and to all of relevant private sector representatives who have not spared any effort to support our endeavor to bring Turkey to the position it deserves in the international arena. I hope that this study will provide our dear readers with answers to their questions regarding the healthcare industry and investment environment in Turkey.

A. Burak Dağlıoğlu

President

The Investment Office of the Presidency of the Republic of Turkey



We are excited and pleased to present to you the “Report on R&D and Engineering Capabilities in Healthcare”, which has been prepared by the Presidency of The Republic of Turkey Investment Office, aided by the analyses and expertise of Sistem Global Danışmanlık, in order to emphasize the R&D, technology, design and innovation activities of the healthcare industries in Turkey.

This valuable study has been developed to ensure that health sector representatives, investors and other concerned actors operating abroad can access critical information on the Turkish health sector and to be guided on investment processes that may take place. We hope that this study will serve as a motivating reference source.

Summarizing the strengths, R&D efforts and engineering-intensive studies of the Turkish healthcare industry, this report covers the activities of the public and private sectors, research infrastructures, clusters, technoparks, non-governmental organizations and other related organizations, especially in the fields of pharmaceuticals, vaccines, digital health, medical devices, biomedical and clinical studies.

At Sistem Global, we have been acting together with the international companies in Turkey, and the companies with international value coming out of Turkey along many steps from their establishment to their globalization, from forging partnerships to their access to financing for 25 years. We see the value our country boosted on behalf of the health sector. We are proud to offer the private sector, academic and public institutions in this ecosystem growth-oriented professional services in areas such as tax, law, access to finance and intellectual property services.

Now is the time to move on to sustainable added value through qualitative activities based on the significantly increasing infrastructure and intentions!

Hüseyin KARSLIOĞLU

Sistem Global Danışmanlık Chairman of the Board of Directors

The Presidency of the Republic of Turkey Investment Office

Operating directly under the Presidency, the Investment Office responds to the needs of investors who would like to do business and invest in Turkey with a “One Stop Shop” approach, as the only nation-wide public organization that brings together all services related with international investments under a single roof, which are necessary for Turkey’s economic development.

The Office stays in contact from the initial communication with the investor company until -and even after- the completion of the investment project, providing support to investors at every stage needed, such as establishment of companies, obtaining the required permits and licenses, providing information about incentives, incentive applications, land procurement, work and residence permits and coordinated conduct of processes with other related institutions and organizations.

Adhering to the principle of ‘strict confidentiality’ in the performance of the professional services provided to international investors, the Office has a staff of experts who can provide services in English, German, French, Italian, Spanish, Japanese, Russian, Arabic and Chinese, in addition to Turkish. The Office is structured to solve investors’ problems quickly and efficiently and plays an active role in the development of policies and strategies aiming to improve the investment and business environment of our country as well.

Sistem Global Danışmanlık

Established in 1996, Sistem Global Danışmanlık continues to provide close support to its customers with 8 offices in Turkey and 4 offices abroad, with the fresh, innovative and interdisciplinary perspective of more than 350 experts in taxation, regulatory compliance and risk management, engineering and patents.

Sistem Global serves a customer base spanning more than 60 cities in every region of Turkey with its integrated solutions in its main competence areas such as tax consultancy, legislation compliance, risk management, R&D, investment-oriented growth, incentive management and patent and business solutions. In so doing, it has become an industry leader in Turkey, empowered by its business models and cutting-edge digital solutions.

Acting with the mission of making local values available to the world and localizing global experiences for the internationalization and commercialization of R&D in Turkey, Sistem Global helps its customers to expand their business globally through its international offices and aims to expand its sphere of influence worldwide by following new opportunities at every step.

01

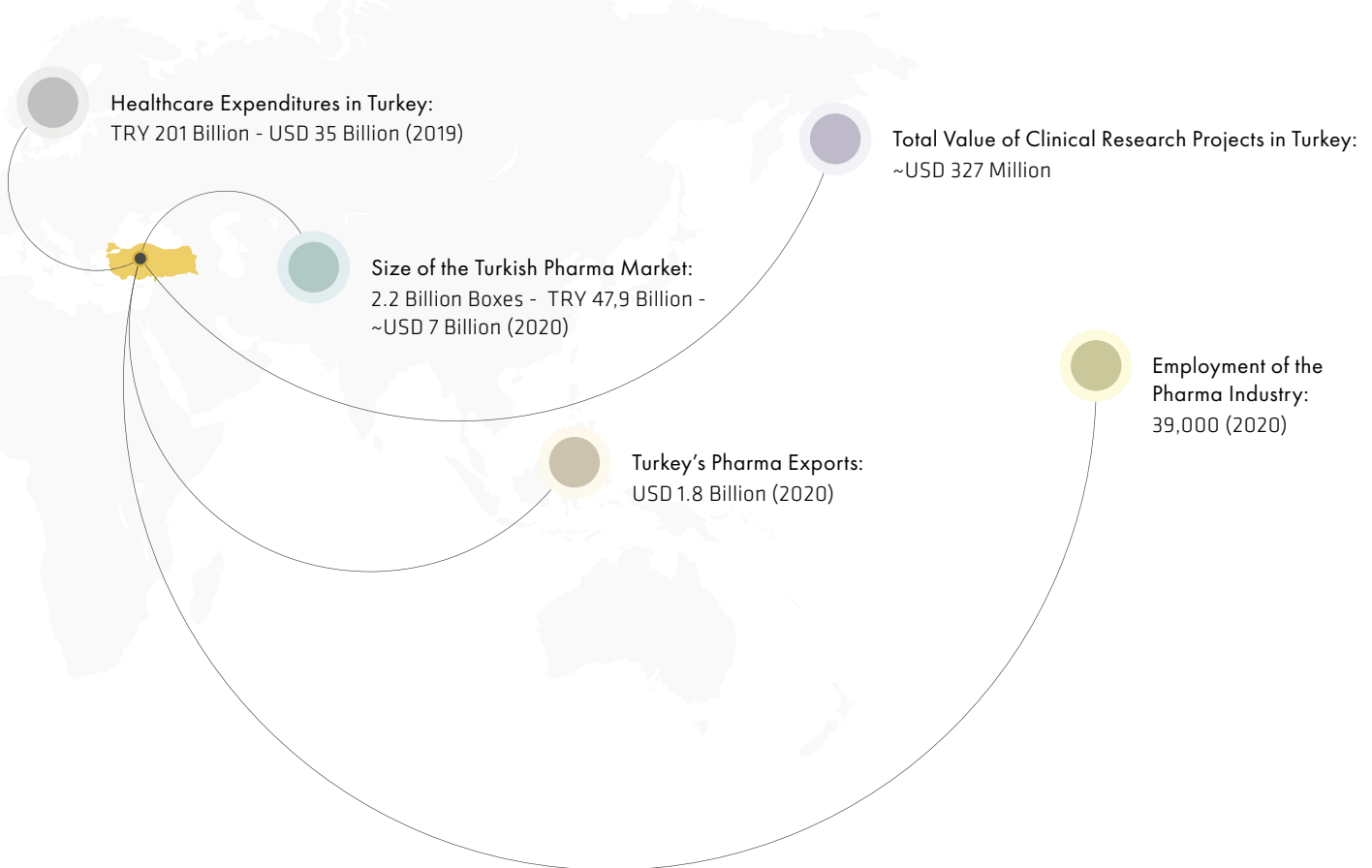
Introduction

Report on R&D and Engineering Capabilities
in the Healthcare Sector in Turkey

INTRODUCTION

The healthcare sector in Turkey is one of the most focused pillars of the diversification process in the Turkish industry and economy. As we approach the 100th anniversary of the Republic, many steps are being taken to increase domestic development and production activities in the fields of pharmaceuticals and medical devices, which have been among the most significant sources of foreign trade deficit for a long time. Considering the social and economic impacts of healthcare industries, the strategic importance of the sector becomes more evident. Turkey demonstrated its determination regarding health reforms with the Health Transformation Program launched in 2004 by the Ministry of Health. The same process marks the beginning of a period when health expenditures increase, and the public sector creates both an infrastructure that supports development and an attractive market through mega projects. Supported also with R&D investments and investments made in innovations in the healthcare industry, these studies have played an important role in the development of the healthcare sector and industries.

Pharmaceutical Industry in Turkey



The Growing Market brings along opportunities

In 2020, Turkey accounted for approximately 1.5% of the global pharmaceutical market, becoming the 18th biggest pharmaceutical market. In the same year, the size of the Turkish pharmaceutical market reached 47.9 billion TL, with an increase of 17.6% compared to 2019.

In 2020, biotechnological products constituted 18.2% of prescription products with a value of 8.4 billion TL over 34.3 million boxes for a 12-month period. The biotechnological pharmaceutical market in question achieved 24% growth in terms of value compared to the previous year. Reference biotechnological pharmaceuticals reached 7.8 billion TL with an increase of 21.8%, while biosimilar pharmaceuticals increased by 50.4%, reaching 938.5 million TL.

In the medical devices sector, the value of the Turkish market reached approximately 2 billion USD in 2020. The market is expected to grow by 7.7% per year on TL basis between 2021 and 2024.

Turkey's domestic production capabilities and opportunities in the field of healthcare are developing

About 470 companies operate in the pharmaceutical sector. As of the end of 2020, there are 83 pharmaceutical and 11 raw material production facilities capable of meeting the highest international standards. 17 of these 83 production facilities and 3 of the 11 raw material production facilities belong to multinational companies. Some of the 20 multinational companies with production facilities in the country include giant companies such as Sanofi, Amgen, Pfizer and Novartis. The pharmaceutical industry alone produces more than 12,000 products while providing employment to more than 39,000 people. The pharmaceutical industry is generally concentrated in and around Istanbul.

The pharmaceutical export volume, which was 1,018 billion USD in 2017, increased by 80%, reaching 1.84 billion USD in 2020. Turkish pharmaceutical producers export to 170 countries, including EU, Middle East and North Africa (MENA) region and CIS countries.

According to the Turkish Medicines and Medical Devices Agency, there are approximately 1,000 producers, around 2,300 importers and 700 companies engaged in both import and production activities in the medical device industry. It is known that approximately 40%, 20% and 10% of the producer companies are based in Istanbul, Ankara and Izmir respectively, while the rest of them mostly carry out their activities in the cities of Adana, Konya and Samsun.

Healthcare transformation, increased satisfaction and business opportunities

With the healthcare transformation program whose first phase was implemented between 2003 and 2016, significant progress has been achieved in the main indicators related to public health. In this period, the average life expectancy increased from 72 to 78.6; infant mortality rate, which represents the number of infant deaths per one thousand live births, decreased from 29 per thousand in 2003 to 9.1 per thousand in 2019. As part of the efforts to facilitate access to healthcare services, numerous public hospitals have been built, while significant progress has been achieved in terms of not only quality standards, but also patient satisfaction, thanks to city hospital projects.

Furthermore, the rapidly growing healthcare tourism sector is one of the drivers of the sector, with the number of tourists increasing from 552,000 in 2018 to 660,000 in 2019. Turkey aims to become one of the world's 2 healthcare tourism centers that host most patients and to host 1.5 million tourists in 2023. Large health campus investments are among the country's most important trump cards to achieve these goals. It is estimated that a market of approximately 20 billion USD will be created in this area when the goals set are achieved.

Considered as a strategic sector, the healthcare sector is supported with priority incentives

The healthcare sector and related industries are indicated among the sectors and product groups eligible for 'priority investment incentives' in the investment incentive system and the privilege to benefit from the supports provided for the 5th region is granted, regardless of the incentive region of the province where the project will be carried out. More than 70% of the total investment amount of the investments made in the fields of pharmaceuticals, medical devices and biotechnology is supported with incentive elements such as corporate tax reduction, social security premium employer's share and interest support in the years following the investment, as well as VAT and customs duty exemptions during the investment.

In addition to investment incentives, 55 companies operating in the fields of healthcare, medical devices and pharmaceuticals officially gained R&D Center status as of January 2021 and their research and development activities are constantly supported. Many healthcare and biotechnology companies operating in technoparks also benefit from the advantages offered by these zones, advancing towards becoming one of the leading countries in the race to develop and produce health technologies.

As stated above, this report aims to reveal the R&D, technology, design and innovation activities of the Turkish healthcare industries, which have become one of the most important players in the healthcare industry of the country and surrounding markets over the years, thanks to their production and marketing capabilities. Detailed information about the competencies of the Turkish healthcare industry, which aims to become dominant in the global healthcare market by leveraging its strengths, is provided under the relevant headings.

02

Pharmaceutical Industry

Report on R&D and Engineering Capabilities
in the Healthcare Sector in Turkey



PHARMACEUTICAL INDUSTRY

An analysis of the healthcare ecosystem in Turkey in the last 10 years indicates a rapid increase in entrepreneurship activities and development of their R&D structures in Turkey by large scale companies, in parallel with the increasing investment and support mechanism.

In terms of the position of the Turkish pharmaceutical industry in the world today, it is observed that the industry ranks 18th in the world with a value of 7 billion USD. The Turkish pharmaceutical industry continues to provide services with more than 12,000 products produced at 83 facilities in accordance with international standards, with approximately 470 establishments and 39,000 employees. Oncological drugs account for the biggest volume among drugs.

The Turkish pharmaceutical industry has decades of history, resulting an industry strongly committed to the protection of international quality standards. Thanks to the quality of the country's human capital and state-of-the-art technology, on par with the products produced in developed markets, the footprint of Turkish pharmaceuticals currently extends to more than 170 countries, including the Commonwealth of Independent States (CIS), North Africa and the Middle East, and European Union countries.

Good Manufacturing Practices (GMP), which is a set of rules that ensure the production and control of medicines in accordance with quality standards, were accepted in our country in 1984 and pharmaceutical facilities were accredited by both the Ministry of Health and the competent authorities of countries such as the United States, Germany, Denmark, England, Japan and Gulf countries.

In terms of R&D Activities;

- The R&D incentives provided by the government have led the way for R&D.
- Thanks to localization policies, a great majority of conventional medicines are now produced in Turkey.
- Cooperation of the public sector-universities-industry is encouraged and increasing.
- A significant number of qualified students and personnel are trained in the field of health, especially in Biology, Molecular Biology and Genetics, and Medicine.
- The research infrastructure encouraged for life sciences, biomedicine and genetics provides end-to-end coverage of activities in target discovery, leading new discoveries, preclinical trials, clinical research and go-to-market.

Furthermore, the industry stands out with the dynamic and young skill pool it is supported by, as well as its favorable demographics.

Vaccine and Drug Development R&D Ecosystem



Note: The image is provided for visualization purposes and does not include all stakeholders in the field.

A. PUBLIC SECTOR

TÜBİTAK has supported 3347 R&D and innovation projects with total budgets exceeding 2.5 billion TL (in 2020 prices) for the development of innovative technologies in the field of healthcare since 2012. Within the scope of the programs carried out by TEYDEB, support decisions have been taken for 1,179 projects of 795 companies/universities in the healthcare sector from 2015 to date. The total budget of these projects is over 1 billion TL and approximately 500 million TL grant support has been provided as of the end of August 2020.

Calls focused on Vaccine and Pharmaceutical Technologies, which were published by TÜBİTAK between 2019-2020:

Priority R&D and Innovation Subject	Priority Products and Technologies
Priority R&D and Innovation Subject	Support will be granted to technological development and innovation projects with Technological Readiness Level between 4 and 8 for the development of vaccines and immunological products, which are frequently used in our country but not domestically produced, and which are critical for national security.
Pharmaceutical Technologies	Blood and blood products
	Innovative/reference drugs: New molecule discovery
	Controlled/targeted medicine delivery systems for Cancer and Autoimmune Diseases
	Biotechnological and biosimilar drugs

2,145 projects with a total budget of approximately 1.3 billion TL were supported in the field of healthcare by TÜBİTAK Academic Research Funding Programmes Directorate (ARDEB) between September 2012-2020. In addition to these projects, the 5 major projects supported by ARDEB's Public Sector Research Grant Committee (KAMAG) in the field of health between 2012-2020 September have a total budget of approximately 205 Million TL. KAMAG also supports 18 projects with a total budget of 19 million TL for the development of vaccines and drugs as part of the "Covid-19 Turkey Platform" established during the Covid-19 pandemic.

Year	Number of Project Applications	Number of Projects Decided to be Supported	Budget of Projects Included within the Scope of the Support (Million TL)	Grant Support Amount (Million TL)
2015	584	199	379,8	132,5
2016	307	112	102,2	85,7
2017	408	194	169,5	80,6
2018	531	236	264,9	81,7
2019	609	192	306,9	92,9
2020 September	758	246	204,0	25,5

Source: [Tubitak](#)

TÜSEB (Presidency of Health Institutes of Turkey)

TÜSEB, which supports R&D Projects for the production of medicines, has published many calls in the field of pharmaceutical development.

The aim of the projects within the scope of the call is to ensure that biotechnological molecules, therapeutic agents, biosimilars, gene therapies and immunotherapeutics that are developed, produced and commercialized in different structures such as peptide/protein, fusion protein, monoclonal antibody, antibody-drug conjugates are developed and produced in Turkey at world standards, thus creating technological experience in this field and contributing to the country's economy with innovative products.

Subject of the Call	Period	Number of Calls
Drug Development	2019-2020	5
Diagnostic Kit Development	2019-2020	3
Medical Device	2019-2020	3
Other Medical Applications	2019-2020	4

List of calls opened by TÜSEB in the years 2019-2020

TÜBİTAK MAM

Pioneering projects for the development of domestic biotechnological drugs at international standards are carried out at TÜBİTAK Marmara Research Center (MAM) Genetic Engineering and Biotechnology Institute (GMBE). As a result of the studies carried out in the institute, patents were obtained for original, mouse-derived recombinant antibodies developed against vascularization, which plays an important role in the spread of cancer. As a good example of the studies within the Institute, patent-registered antibody structures were humanized and their cancer-preventing properties were demonstrated in clinical studies, with the project for the development of humanized antibodies to stop tumor vascularization (DAKINAT). Activities for the completion of clinical studies to ensure that these studies result in anti-cancer drugs offered to the market are still ongoing.

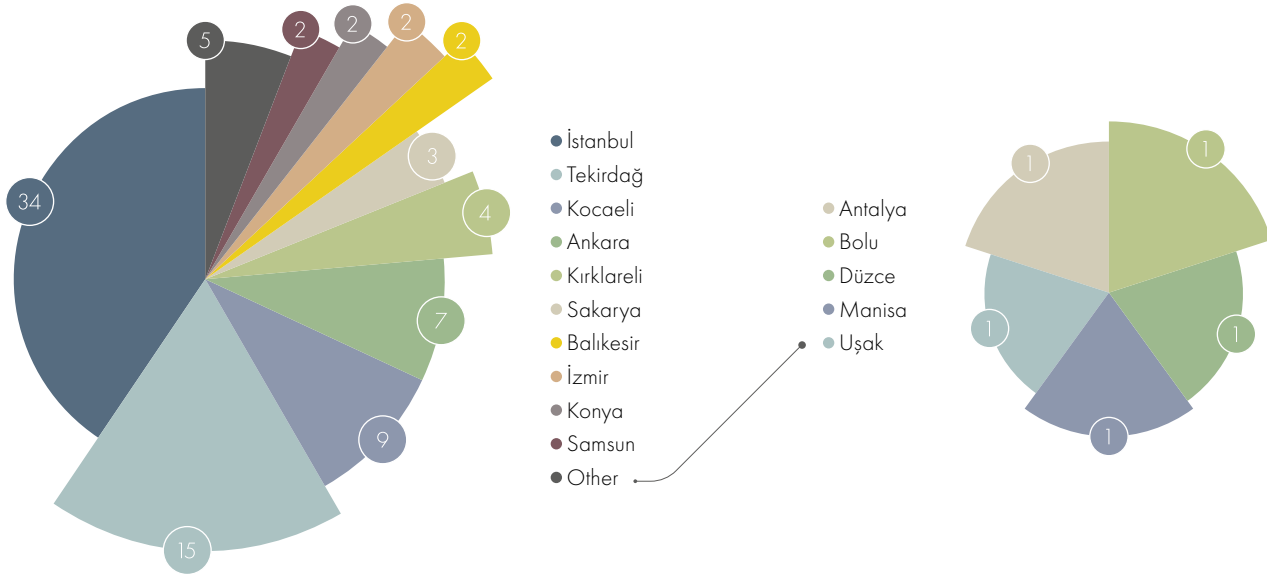
The project for the development of a domestic biosimilar drug for cancer treatment (BIOSIM) is carried out within the Institute with the aim of developing Turkey's first domestic biosimilar cancer drug, through the partnership of the public sector, R&D and domestic pharmaceutical industry. Furthermore, the "Development of gene and drug carrying, new targeted dendritic nanostructures in colon cancer treatment" project, which will reduce the side effects of chemotherapy in healthy tissues and multi-drug resistance in patients with colon cancer, one of the most common cancer types, is in progress.

In coordination with the Presidency, the Government of the Republic of Turkey added the concept of developing original drugs to its agenda and determined action plans to achieve this goal. The country's goals for 2023 include implementation of an "enterprise" model that paves the way for the development of "national drugs". The purpose of this model is to create an innovation environment through a "pool of enterprises" that brings together molecule developers, government researchers, universities, technoparks, small-scale companies and big pharmaceutical companies.

B. PRIVATE SECTOR (Enterprise, Start-up, SME, Large Scale, etc.)

Number of Pharmaceutical Production Facilities Approved by TITCK

November 2020 (n=85)



There are a total of 12 raw material production facilities approved by TITCK. Albia, Atabay, Bionom, Deva Gensenta, Koçak, Konya Şeker, Med-Mar, Neutec, Sandoz, Toprak and Ulkar (Nobel) are companies engaged in production activities in this field.

Furthermore, there are a total of 10 radiopharmaceutical facilities approved by TITCK. Eczacıbaşı(5), Kamrusepa, Samyoung, Mediceck, Moltek, Nukleon and TAEK are sector stakeholders with production facilities in this area.

There are a total of 9 advanced treatment medical product facilities approved by TITCK. Acıbadem Labcell, Anadolu Medical Center, Ankara University Stem Cell Institute, At-Gen Cell Technology, Erciyes University Genome and Stem Cell Center, Onkim Stem Cell Technologies, Liv Hospital, Florence Nightingale Hospital and Yaşam Bankası TAEK are also important organizations that feed the research ecosystem.

Source: TITCK

There are many significant private sector organizations that operate in the field of pharmaceuticals in Turkey. Some of them are as follows:

Deva Holding A.Ş.

DEVA, which started its operations in 1958, is one of Turkey's well-established pharmaceutical producers. Being awarded an R&D certificate in 2010, DEVARGE develops innovative new forms and products with high added-value with its staff of more than 300 expert scientists, laboratories equipped with up-to-date technologies and comprehensive equipment park.

DEVARGE, which is capable of developing products in all pharmaceutical forms, is built on a total area of 7,000 m² comprised of a pre-formulation and pilot production site, synthesis and scale-up laboratories, stability cabinets, analytical development laboratories, biotechnology laboratories, oncologic and hormone development laboratories, raw material, packaging material and finished product warehouse, analysis laboratories and CMC documentation archives.

DEVA was selected the best R&D company in the pharmaceutical industry at the 4th Private Sector R&D Centers Summit organized by the Ministry of Science, Industry and Technology in 2015. DEVA has been given the Golden Mortar "Best R&D Award", which is one of the most prestigious awards of the pharmaceutical and pharmacy sector, three times with 3 different products.

Abdi İbrahim İlaç San. ve Tic. A.Ş.

As Turkey's first accredited pharmaceutical R&D Center, Abdi İbrahim R&D Center possesses the capability and infrastructure to develop pharmaceuticals through inhalation technologies and nanotechnological methods, with the aim to respond to the evolving and developing needs of the national and international pharmaceutical industries.

The R&D Center is focused on studies for developing innovative products, achieving high success rates in bioequivalence studies, expedition of reference product development processes, as well as developing value added products and preparation of Common Technical Document files for not only Turkey, but also Europe and other regions. Know-how is transferred through the joint projects implemented with scientific organizations in Turkey and abroad, in addition to the projects carried out within the company.

The formulations used in innovative products are: Orally Disintegrating Tablets, Multilayer Tablets, Nanotechnology and Dry Powder Inhalers. Furthermore, the company provides services in a total of 13 treatment areas, including antianemic, antibacterial/antiviral, dermatology, endocrine and metabolism, gastrointestinal, cardiovascular, NSAID and myorelaxants, ophthalmology, nervous system, respiratory system, urogenital system, as well as food supplements, vitamins and minerals.

Koçak Farma İlaç ve Kimya San. A.Ş.

With respect to the production of pharmaceuticals and their active ingredients, Koçak Farma pioneers the development of the domestic pharmaceutical industry, by putting the advanced technologies owned by a limited number of pharmaceutical producers in the world into use in our country and by obtaining the patents of inventions realized as a result of R&D studies, especially in the fields of oncology, biotechnology and hormones.

Koçak Farma has been meeting the tuberculosis drug needs of the Ministry of Health for 45 years. Furthermore, Koçak Farma was granted the "domestic investment incentive award in oncology" by the Ministry of Health of Turkey in 2013 and 2016, due to its contributions to the treatment of cancer patients.

Koçak Farma conducts studies on Conventional Products, Biotechnological Products (Insulins, Monoclonal Antibodies) and Vaccines (Bacterial and Viral) and Anti-Serums in its R&D center.

Studies regarding inactive COVID-19 Vaccine and Hyper immune serum are ongoing in the BSL3/ABSL3 laboratories approved by the Ministry Health within Koçak Farma R&D Center approved by the Ministry of Industry and Technology.

Koçak Farma successfully continues its R&D works on insulin and insulin analogs, monoclonal antibodies (Mabs), bacterial and viral vaccines and plasma proteins with recombinant DNA technology. Investments and studies regarding the production of insulin and monoclonal antibodies from the cell have been completed. R&D studies for the vaccines have been completed and studies for commercial production are in progress.

İlko İlaç San. ve Tic. A.Ş.

İLKO İlaç aims at using 'innovative' and life-saving products that extend people's lives, while creating a difference in the production of pharmaceuticals, thus adding value to the industry. To this end, İLKO İlaç carries out its activities at two R&D Centers:

Established in Hacettepe University Technology Development Zone in 2009, İLKO ARGEM is a pioneering and exemplary R&D investment made on this scale within the Technology Development Zone, by establishing an infrastructure through the cooperation between university and industry on R&D in Turkey. İLKO ARGEM consists of four departments: analytical, formulation, patent and clinical research. The innovative technologies subject to the studies at the center are conventional tablet and capsule technology, modified release systems, multilayer tablet technology, orally disintegrating tablet technology and topical systems.

İLKO İlaç carries out its R&D studies regarding biotechnological products at the İLKO ARGEM Biotechnology Center, which it established in Technopark Istanbul in 2015. As one of the first biotechnology-specific R&D structures in Turkey, the center continues its activities to develop biotechnological drugs by means of recombinant DNA technology. Currently, studies are carried out on biosuperior, nanobiosuperior, biosimilar and new generation biotechnological products at the center, which aims to develop biotechnological products for cancer and cancer-related diseases in the first stage.

Sanovel İlaç San. ve Tic. A.Ş.

Sanovel, which has been operating in the pharmaceutical industry for more than 30 years, is one of the leading representatives of the Turkish pharmaceutical industry with its more than 1,200 employees and 55 R&D employees today.

Sanovel Pharmaceuticals operates with its products in the fields of Cardiovascular system, Respiratory system, Central nervous system, Gastrointestinal system, Antidiabetics, Antihistaminics, Antiasthmatics, Analgesics, Antivirals, Antifungals and Antibiotics.

In the R&D Center of Sanovel İlaç, studies for the development of drugs in almost all pharmaceutical forms are carried out with the aim to compete globally in the pharmaceutical sector.

Onko İlaç San. ve Tic. A.Ş.

Onko Koçsel İlaç R&D Center, which was approved by the Ministry of Science, Industry and Technology in 2015, operates as the first oncological R&D center in Turkey which uses isolator technology and can perform commercial production with GMP license when necessary. Having collaborated with TÜBİTAK and various universities, Onko Koçsel İlaç has developed a total of 16 products to date. 8 of these projects are completed, while 5 of them are still in progress. There is one project in the application stage and two ongoing projects within the scope of the SAYEM project carried out in cooperation with universities. Currently, there are 9 products which have been developed by the R&D department and licensed. Licensing procedures for 11 products are still in progress. Onko İlaç carries out its R&D activities with a team of 25 qualified personnel including pharmacists, chemists and chemical engineers.

Atabay Kimya San. ve Tic. A.Ş.

Atabay continues its research and development studies to produce active pharmaceutical ingredients and medicines for human use that contain those ingredients, to be used in the treatment of important diseases. The main fields covered by these studies include antivirals, drugs used in the treatment of thromboembolism, drugs used in the treatment of difficult infections, drugs used in the treatment of fungal infections, biotechnological products and oncological drugs. The R&D Center, which was accredited by the Ministry of Technology and Industry of the Republic of Turkey in 2019, develops new products based on traditional herbal medicine, biotechnology and pharmaceuticals. It is involved in the development of university - industry collaboration projects with 8 major universities of our country, as well as strategic R&D projects carried out with the national public R&D center, TÜBİTAK Marmara Research Center.

Atabay has also developed the first domestic GMP approved cell bank in the biotechnological pharmaceutical development, in addition to the small molecule active ingredient synthesis and production. The commercialization processes have been started for this biosimilar project, which has been conducted with the support of TÜBİTAK KAMAG. Developed in 2012, 'Enoxaparin Sodium' is considered one of the first biological drugs developed in our country.

Nobel İlaç Sanayii ve Tic. A.Ş.

Nobel İlaç operates with the aim of developing effective, safe, innovative and economical products which ensure patient compliance and allow them to live a healthier and higher quality life and putting these products at the service of human health all over the world, with the efforts of its 72 R&D personnel.

The R&D strategy of Nobel İlaç is based on developing innovative products by conducting studies in accordance with the company's strategies. 95% of the product portfolio of Nobel İlaç and all its pharmaceutical formulations licensed in 39 countries have been created as a result of the studies carried out at the R&D Center.

Within the scope of its studies carried out at the R&D Center, Nobel İlaç also continues working hard on new drug discovery researches and drug raw material synthesis processes, in addition to the research and development studies for human medicinal products that are basically equivalent products. Products are obtained within the framework of two key pharmaceuticals disciplines within the company: active pharmaceutical ingredients (API) in the field of pharmaceutical chemistry and new and equivalent drugs as finished products in the discipline of pharmaceutical technology.

As the owner the first file selected among 28 applications of 23 companies submitted to the "Development and Manufacturing of Biosimilar Drugs Domestically" project launched under the leadership of TÜBİTAK, at Nobel İlaç MARTEK Biotechnological Drugs Facility, Nobel aims to become an important part of the biotechnology ecosystem with its new production investment.

R&D Centers

Name of the R&D Center	Province	Name of the R&D Center	Province
Abdi İbrahim İlaç San. ve Tic. A.Ş.	İstanbul	Novagenix Biyoanalitik İlaç Ar-Ge Mer. San. ve Tic. A.Ş.	Ankara
Ali Raif İlaç San. A.Ş.	İstanbul	Onko İlaç San. ve Tic. A.Ş.	Kocaeli
Argis İlaç San. ve Tic. A.Ş.	Ankara	Pharmactive İlaç A.Ş.	Tekirdağ
Arion İlaç San. ve Tic. A.Ş.	İstanbul	Polifarma İlaç San. ve Tic. A.Ş.	Tekirdağ
Arven İlaç San. ve Tic. A.Ş.	İstanbul	Sanofi İlaç San. ve Tic. A.Ş.	Kırklareli
Atabay Kimya San. ve Tic. A.Ş.	İstanbul	Sanovel İlaç San. ve Tic. A.Ş.	İstanbul
Berko İlaç ve Kimya San. A.Ş.	İstanbul	Santa Farma İlaç San. A.Ş.	Kocaeli
Bilim İlaç San. ve Tic. A.Ş.	Kocaeli	Teknovet İlaç San. ve Tic. A.Ş.	Tekirdağ
Biofarma İlaç San. ve Tic. A.Ş.	İstanbul	Turgut İlaçları A.Ş.	Kocaeli
Deva Holding A.Ş.	Tekirdağ	Turktıpsan Sağlık Turizm Eğitim ve Tic. A.Ş.	Ankara
Era Pharma Analitik Çöz. ve İlaç San. Tic. A.Ş.	İstanbul	Tüm-Ekip İlaç A.Ş.	İstanbul
Farmatek İlaç San. ve Tic. A.Ş.	Kırklareli	Ulkar Kimya San. ve Tic. A.Ş.	Tekirdağ
Gen İlaç ve Sağlık Ürünleri San. ve Tic. A.Ş.	Ankara	Vefa İlaç San. ve Tic. A.Ş.	İstanbul
Gensenta İlaç Sanayi ve Ticaret A.Ş.	İstanbul	Vem İlaç San. ve Tic. A.Ş.	Tekirdağ
İlko İlaç San. ve Tic. A.Ş.	Ankara	World Medicine İlaç San. ve Tic. A.Ş.	İstanbul
Koçak Farma İlaç ve Kimya San. A.Ş.	Tekirdağ	Zade Vital İlaç Kimya Gıda San. ve Tic. A.Ş.	Konya
Kurtsan İlaçları A.Ş.	Balıkesir	Nobel İlaç San. ve Tic. A.Ş.	Düzce
Total R&D Personnel		1603	
Total R&D Expenditure		424 Million TL	



VACCINE STUDIES

In 2015, the Ministry of Health invited tenders with a guarantee to purchase the Adult Tetanus-Diphtheria Vaccine on the condition that it is produced in Turkey. The winners of the tender were BULBİO-Bulgaria (BB) and TURK İlaç ve Serum San. A.Ş., which entered into a partnership and completed the studies for the establishment of an antigen production facility and a vaccine filling facility for the Tetadif vaccine to be produced in Turkey, at the end of 2018.

Similarly, having won the 3-year purchase tenders for Conjugated Pneumococcal Vaccine (CPV) in 2010 and 2014, Pfizer has been formulating and performing the filling processes of Prevenar 13 vaccine in Turkey since 2013. The filling processes of the quadrivalent and pentavalent combined vaccines of the company Sanofi Pasteur have been carried out by the Turkish Pharmaceutical company Birgi Mefar since 2011. In the current situation, with the advantage provided within the scope of nationalization projects, the public sector grants 100% reimbursement support by guaranteeing the purchase of vaccines, for the development and production of 13 vaccines in the national vaccine program.

The scorpion venom antiserum and the trivalent snake venom antiserum produced by the company Vetal Serum in Adıyaman were licensed by the Turkish Medicines and Medical Devices Agency (TİTCK) in 2012 and 2014 respectively and are produced in quantities sufficient to meet Turkey's needs. Equine diphtheria, tetanus and scorpion antisera are currently produced and used within the Ministry of Health of Turkey, General Directorate of Public Health.

Koçak Farma, which is one of the companies operating in the field of vaccines, has a BSL-3 laboratory and GMP compliance certificate in the production of vaccines and medicines for human use. It has been working intensively on vaccines for about 6 years. Development studies continue for many vaccines, especially rabies vaccine, BCG vaccine and varicella vaccines. The vaccines have reached the clinical research stage and phase studies are ongoing.

Studies for Developing Vaccine Against COVID-19

Since 11 March 2020, when the first case was diagnosed, scientific studies were started in addition to the measures taken in accordance with the recommendations of the Ministry of Health Science Committee, high-quality services provided at public-universities and private hospitals designated as pandemic hospitals and contact tracing works, as part of the efforts to fight COVID-19. The virus isolation process, which constitutes the first step for producing vaccines and medicines against the new coronavirus, was carried out by Prof. Dr. Aykut Özkul and his team from Ankara University, Faculty of Veterinary Medicine, Department of Virology and Biotechnology Institute and Prof. Dr. Aykut Özdarendeli and his team from Erciyes University, who sequenced the 30 kB genome of the SARS-CoV-2 Virus using the new generation sequencing technology and obtained its gene map. Institutions such as the Presidency of Health Institutes of Turkey (TÜSEB), the Scientific and Technological Research Council of Turkey (TÜBİTAK) and the Istanbul Development Agency (ISTKA) have initiated calls regarding the development of diagnostic kits, vaccines and drugs, as well as the socio-economic effects of the virus as part of the efforts to fight COVID-19. COVID-19 Turkey platform was established, ensuring the assembly of 436 researchers from 49 different institutions and organizations. Thanks to this union, 17 projects focused on vaccine and drug development began to be carried out. Phase studies have been initiated for the three innovative vaccine candidates obtained as a result of the studies.

C. RESEARCH INFRASTRUCTURES

Some Important Laboratories in Turkish Universities and the Number of Their Employees

LABORATORY NAME	AFFILIATED INSTITUTION	NUMBER OF EMPLOYEES
Anadolu University Rectorate Plant, Pharmaceutical and Scientific Research Application and Research Center Laboratory	Anadolu University	14
Ege University Drug Development and Pharmacokinetic Research Application Center (Argefar) Bioanalytical/Biosimilar/Biocidal Laboratories	Ege University	12
İstanbul University-Cerrahpaşa Veterinary Faculty Pharmaceutical Research and Development Laboratory	İstanbul University - Cerrahpaşa	7
Yeditepe University Faculty Of Pharmacy Pharmaceuticals, Cosmetics and Medical Devices R&D and Analysis Laboratories	Yeditepe University	6
Karadeniz Technical University Drug and Pharmaceutical Technology Application and Research Center (Ilafar) Laboratory	Karadeniz Technical University	4

D. ACADEMY

In the light of the 2019-2020 data in Turkey, the number of students continuing their education in the field of Health Science is provided in the table below;

How Many Universities Have an Institute of Health Sciences?	103
What is the Total Number of Students Studying at Institutes of Health Sciences? (Graduate+Doctorate)	35.947

Source: <https://istatistik.yok.gov.tr/>

Based on the 2019-2020 data in Turkey, the following table provides the number of academics working in higher education programs providing undergraduate education in the field of Health Sciences, by field of education and training;

Department Name	Total Number Of Academics (Professor + Associate + Doctor + Academic Staff + Research Assistant)
Biology	3438
Biochemistry	3548
Chemistry	1836
Chemical Engineering and Processes	961
Pharmacy	155
Medical Diagnostics and Treatment Technology	1569
Medicine	29197

Source: <https://istatistik.yok.gov.tr/>

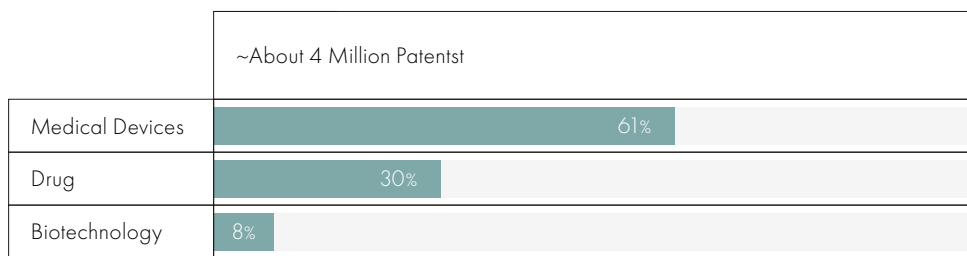
F. INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS (IIPR)

IIPR activities are key for protecting the outputs of the R&D activities performed by companies in the field of health, just as in other areas.

In addition to the brands and designs of companies, patent and utility model applications in particular are among the most fundamental steps for standing out in the sector. In other words, companies make efforts to create a monopoly by protecting their inventions through patents and utility models in the field of health as well.

It is observed that approximately 4 million of the patent applications published in the database of the European Patent Office are made in the field of health. When these applications are categorized among themselves, applications from the pharmaceutical sector account for 30% of the total applications.

Pharmaceuticals, medical technologies and biotechnology are considered as the main pillars of the health sector in Turkey. The sub-categories of medical technologies and biotechnology are further analyzed in the following parts of the report.



Number of Patent Applications in Sectoral Fields in the Last 10 Years

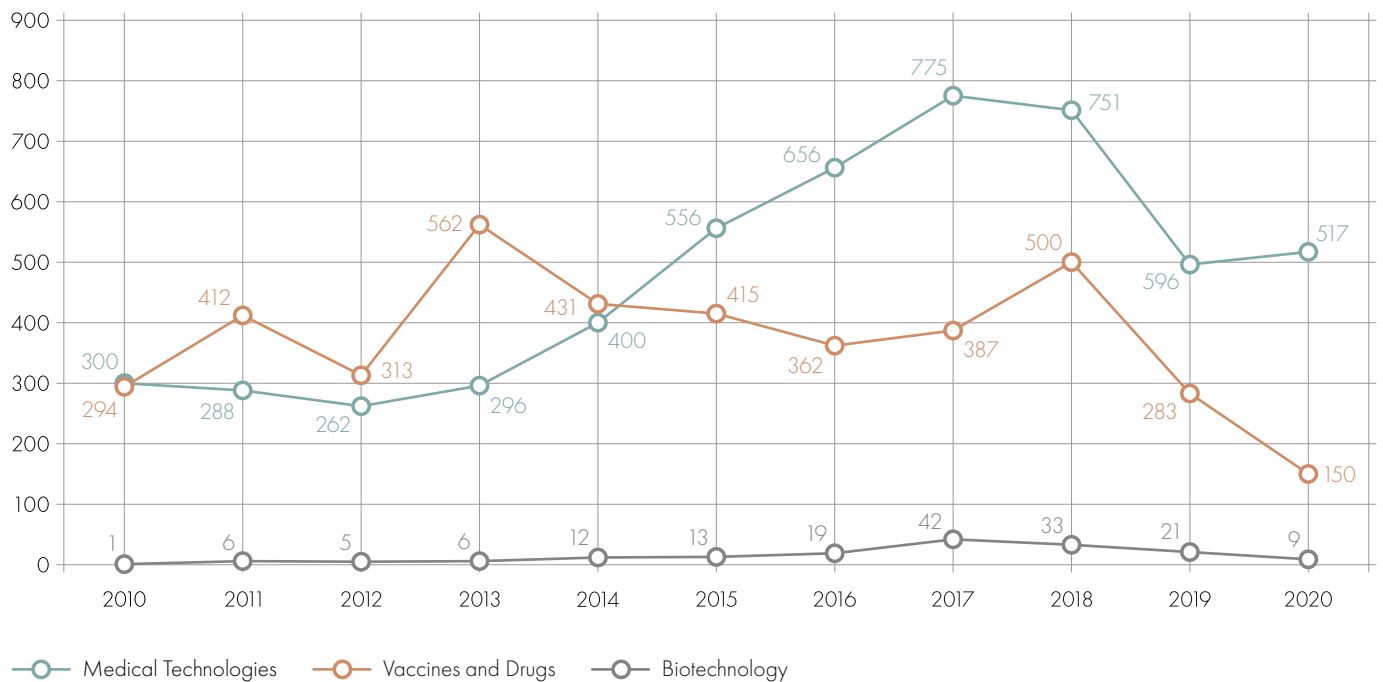







Figure 1. Trends Relating to the Number of Patent Applications in the Fields of Medical Technologies, Pharmaceuticals and Biotechnology

The Figure 1 shows the priority patent application trend in Turkey which originates from the pharmaceutical sector. Patent applications in the field of medical technologies display a faster rising trend than the patent applications in the fields of pharmaceuticals and biotechnology.

It is known that pharmaceutical and vaccine studies have increased in our country due to the Covid-19 pandemic, which broke out in 2020, and accordingly, the number of patent applications are estimated to increase in the following years. As the pharmaceutical industry is one of the first sectors established in Turkey, a strong response was given to the pandemic and vaccine/drug studies were started swiftly. Therefore, this situation is deemed to herald a significant growth in the sector.

In terms of the priority applications made in the field of health in Turkey, it is observed that pharmaceutical companies are in top ranks. The top 5 institutions/organizations which made the most patent applications in the pharmaceutical and vaccine sector in the last three years are Sanovel İlaç, Mahmut Bilgiç and İstanbul University, Bülent Karaağaç and Abdi İbrahim.

Organization		Number of Patent Application
	Sanovel İlaç Sanayi ve Ticaret Anonim Şirketi	210
	Neutec İlaç Sanayi Ticaret Anonim Şirketi	206
	İstanbul Üniversitesi	202
	Bilim İlaç Anonim Şirketi	89
	Abdi İbrahim İlaç Sanayi ve Ticaret Anonim Şirketi	60

20 Companies/Institutions Which Made The Most Patent Applications In The Pharmaceutical Sector

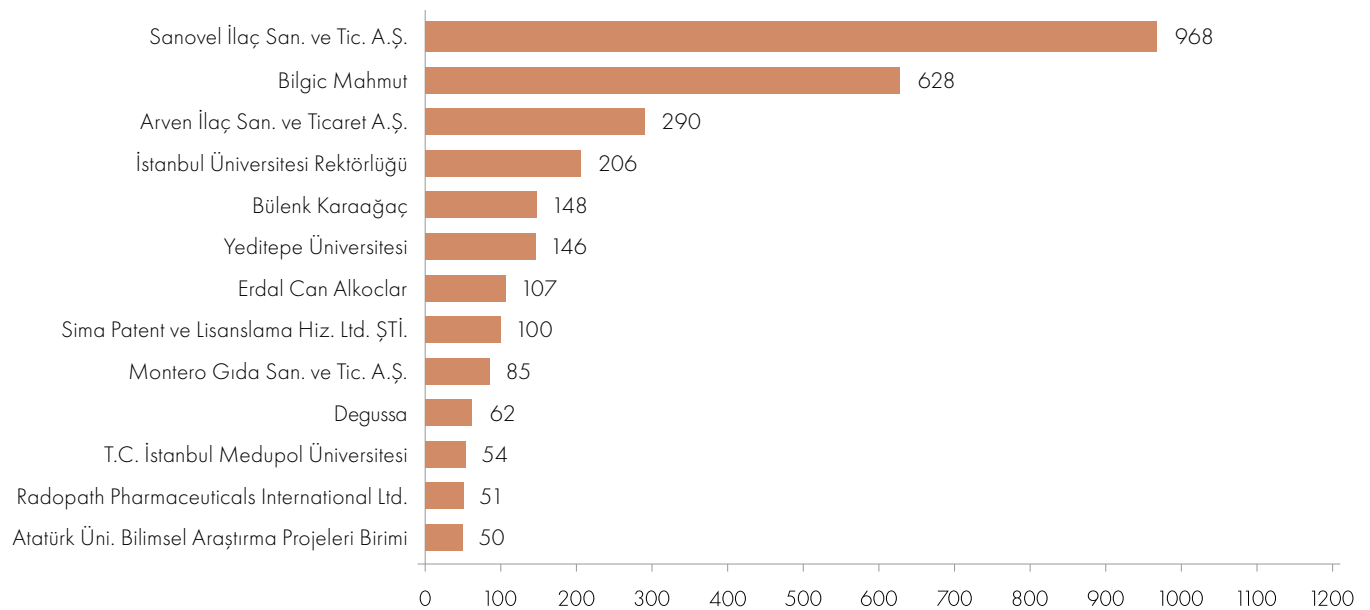


Figure 2. Number of Patent Applications Made by the Top 20 Surging Institutions/Persons in the Pharmaceutical Sector

The Figure 3 shows the numbers of patent applications made by the top 20 institutions and organizations in the pharmaceutical sector. The established backgrounds of the pharmaceutical companies in the sector demonstrate Turkey's power in the field, while the presence of numerous universities, institutions and organizations in the sector indicates the strong potential.

03

Medical Technologies

Report on R&D and Engineering Capabilities
in the Healthcare Sector in Turkey

MEDICAL TECHNOLOGIES

With a population of 83 million people, Turkey is a growing market for medical technologies and healthcare services. The Ministry of Health is responsible for planning and implementing the country’s healthcare policy and is also the biggest provider of healthcare services. Turkey spends 4.5% of its GDP on healthcare services, which corresponds to an amount of 30 billion USD in 2018. Although this rate is relatively low when compared to the OECD average of 8.8%, it indicates that there is room for growth in healthcare expenditures.

1. Digital Healthcare

The economic burden created by the world’s healthcare system, the complexity and high number of the problems faced by it, as well as the changing expectations regarding healthcare services have increased the efforts to restructure the whole system. As underlined by the World Economic Forum, “provision of healthcare services under the current model is not sustainable”. Utilization of digital technologies has become a must for effective management of the costs in the healthcare system, increased quality and efficiency of the healthcare services, ability to provide preventive healthcare services and increased life quality.

Some Important Projects Implemented by the Ministry of Health Towards Digitalization

Main Service-Oriented Information and Technology Projects	Description	Usage Statistics
e-Nabiz Personal Health System	E-Nabiz, which is an application of the Ministry of Health of Turkey, is Turkey’s reliable personal health record system where you can manage your personal health information.	Number of Registered Persons: 20 Million +
e-Report System (National Reporting Information System-URBS)	An “e-Report System” is developed to ensure that all reports issued by the healthcare institutions affiliated to the Ministry (birth, disability, driver, rest, status report, etc.) are delivered electronically with e-signature.	Number of Areas of Use: Reports specific to 12 areas can be supplied via the system;
Telemedicine/Teleradiology System	The Telemedicine System of the Ministry of Health of Turkey is a system that allows accessing images of radiological examinations on the web 24/7, reporting of these images, teleconsultations between radiologists, evaluation of medical images and reports in terms of quality, and their sharing with citizens through the e-Nabiz application.	Integrated Hospital: 2002
Central Physician Appointment System (“MHRS”)	The application allows receiving outpatient services by setting appointments with the health institutions affiliated to the Ministry of Health of Turkey. Currently implemented in Turkey, MHRS is one of the 20 fundamental public services accepted by the EU within the scope of the “Transformation in Healthcare Project”.	Number of Appointments: 264 Million +
Health Information Network (SPA)	The Health Information Network (SBA) Project system allows the inclusion of all departments of the Ministry in the closed circuit private health network, through the execution of services relating to the procurement, establishment, maintenance and support of the data circuits established between the central and provincial units of the Ministry by using multi-point access technologies.	



A. PUBLIC SECTOR

Digitalization Steps in Healthcare Services

The digitalization journey of healthcare services in Turkey dates back to 1990s. Drastic initiatives in health informatics were accelerated with the Transformation in Healthcare Program ("SDP") which was launched in 2003. Within this framework, the Health-Net project was implemented with the widespread use of HBYS, projects such as Central Physician Appointment System ("MHRS") were initiated and applications such as MEDULA were implemented upon the establishment of the Social Security Institution (SSI). The Drug Monitoring System ("ITS"), which tracks the whole process of drugs from producers to citizens and which was implemented in 2010, soon became a successful example worldwide and was even exported to Saudi Arabia in 2017. One of the purposes of digitalization of healthcare services is to improve the medical decision making processes by obtaining more and better data and the decision support system ("KDS") was implemented in 2007 and developed over time within this framework.

Another significant transformation concerning health data was achieved with the introduction of e-Nabiz application. E-Nabiz is an application where citizens and healthcare professionals can access to the health data collected from health organizations, via internet and mobile devices and has increased the speed and quality of diagnosis and treatment processes. E-Nabiz is also recognized over the world as a comprehensive, broad health information infrastructure that facilitates communication between patients and doctors and allows people to safely access their health data over the internet.

Digital Hospitals

Certification and processes relating to digital hospitals are carried out by the organization titled Healthcare Information and Management Systems Society ("HIMSS"). HIMSS uses the globally accepted accreditation and standard model from 1 to 7 to determine the level reached by hospital that apply, by evaluating their digital processes, and rewards the hospitals which have completed their digital processes up to level 6 and 7.

As of the current period which corresponds to the last quarter of 2020, we have 177 EMRAM level 6 and 3 level 7 hospitals, as well as 10 0-EMRAM level 6 hospitals and 2 level 7 hospitals in the criteria determined for oral and dental hospitals. The following table demonstrates the support programs provided by TÜBİTAK and TÜSEB in the Digital Health Sector in the past.

Priority Areas of TÜBİTAK Calls for the Year 2019-2020

Priority Technology Area	Number of Calls	Priority R&D and Innovation Subjects
Digital Technologies in Healthcare	5	<ul style="list-style-type: none"> • E-Health Applications • ICT Based Innovative Medical Devices • Big Data and Data Analytics in Healthcare • Neurotechnology and the Human Brain • Artificial Intelligence in Healthcare

B. PRIVATE SECTOR

Digitalization in the field of healthcare accelerated particularly due to the Covid-19 pandemic, thus the Medical Technology Sector has rapidly gained momentum. Furthermore, this moment is expected to increase exponentially. As proof of this expectation, the applications developed after the Covid-19 process by a few private health groups are provided in the following table;

Number of the Company	Name of the Application	Description
ACIBADEM	Online Doctor	Thanks to the "Online Doctor Consultation" application of Acibadem, if you cannot go the hospital, you can consult your doctor online by setting an appointment from where you are and have your medical check or diagnosis and examination procedures (where necessary) done during a video call.
MEMORIAL	e-Doktor	Accessible from every corner in Turkey, doctors at Istanbul, Ankara, Antalya, Kayseri and Diyarbakir hospitals provide services in the e-Doctor application. While all branches are available in the e-Doctor service, there are some situations excluded from the scope as well.
ANADOLU SİGORTA	Online Health Consultation	Anadolu Sigorta has also started to provide 24/7 free health consultation services to all individual and corporate private health insurance holders. Within the scope of this service, individual and corporate insurance holders can make live video calls 24/7 by logging in with their TR ID number from the "live doctor call button" on Anadolu Sigorta website.
MLPCARE	VideoKlinik	VideoKlinik (VKlinik) is designed to be simple and effective. It allows patients to be examined from home. Thanks to the application which has contracted with 122 hospitals and 2,173 doctors to date, you can have a video call with your doctor without going to the hospital and share reports, images or files about your situation with your doctor.

Wearable Technology and Device Start-Ups

- **BRACEHEALTH**: Established by Çağlar Aksu with the support of TÜBİTAK in 2018, Bracehealth offers a wearable hardware and mobile application solution that measures the involuntary tremors of Parkinson's patients and provides continuous follow-up. Thus, it becomes much easier to follow the treatment applied to the individuals and it is ensured that the treatment is based on numerical data instead of subjective comments. Çağlar Aksu, the Founder of Bracehealth, states that they are currently in testing and certification stage and aim to offer the product for sale at the end of the year after completing these processes. Mentioning that they received a seed investment of 75,000 TL from Proline Ventures in 2016, Aksu said, "We have been eligible for the TÜBİTAK 1,512 support and there was another cash inflow of 150,000 TL".
- **ORTHERO**: Established in 2012 by Aydın Dikkulak, Ferit Güler, Efe Turhan and Seyyid Bucak in ITU ARI Technocity, Orthero adds a new dimension to orthodontic treatments. Orthero offers a treatment method without using braces, which brings the teeth of patients into the ideal shape, with the first domestic, custom-made transparent apparatus in Turkey. The Co-Founder of Orthero Efe Turhan says that they have changed the expensive and slow services provided by foreign brands, which have dominated the sector for many years. "Our monthly capacity is 15,000 models. We have produced more than 300,000 models to date. We have attracted a total investment of 4.5 million TL," says Turhan. Having closed 2018 with a turnover of 7 million TL, the company targets 50% growth this year. Its target turnover for the next three years is 30 million TL.
- **TİON HEALTH**: Established by Berkay Şamiloğlu, Tion Healthcare develops wearable sensors in the form of stickers for purposes of diagnosis, treatment and follow-up in the field of healthcare. The Tion application, developed by the company for the diagnosis of heart arrhythmia, produces diagnostic tags supported by artificial intelligence and uses this technology to detect arrhythmias in the field of cardiology.

Artificial Intelligence Start-ups

- **ALBERT HEALTH**: Established in 2018 by Serhat Uzun, Ensar Güneşdoğdu and Serdar Gemici, Albert Health is one of the start-ups operating for the healthcare sector. Albert owns 20% of Siemens' corporate venture capital Next47, an artificial intelligence-based voice health assistant that helps chronic patients take their medications on time and at the right dose, and 6% of the global accelerator Techstars. Serdar Gemici states that they are planning to launch the product this month and have recently started the tests with Acıbadem Health Group. "We have attracted investments in the total amount 150,000 USD. We are aiming to become a health platform with 500,000 daily active users in Europe, generating annual turnover in the amount of 2 million EUR and providing services in English, German and French within three years," adds Gemici.
- **YEŞİL SCIENCE**: Founded in 2015 by Dr. Yusuf Yeşil, Yesil Science develops solutions for the production of visual technologies such as augmented reality (AR), virtual reality (VR), 3D drawing, animations and the applications of technologies such as artificial intelligence (AI) in the field of healthcare. Using augmented reality technology with its Augmentify product, the company aims to make invisible, molecular medical processes understandable. It adds a new dimension to the classical medical narratives by transferring drug mechanisms and effects to holographic models. "We have contacted companies in our target market and have now completed our first major business. We aim to do business with 15 companies, 5 of which are global companies within this year," says Dr. Yusuf Yeşil, the Founder of Yesil Science.
- Artificial intelligence, in addition to the initiatives mentioned previous, biotechnology initiatives in the field of healthcare:
- weWALK, manufacture of smart canes for the visually impaired, 3D digital body scanning Digime3D, women's health monitoring and analysis application PepApp, manufacturer of microbial biopeptides Nanomik extends the shelf life of foods and digital pathology Virasof.

Mobile Healthcare Start-ups







- **LIFECARE Mobile Health**: Established in ODTU Teknokent in 2018 by Büşra Özcan, Lifecare is a product combining smart technologies and design to offer a solution for weight problems. Lifecare is comprised of a personal body analysis device, a mobile application connected to the device and a dietitian control panel. Thus, communication, follow-up and control between the client and dietitian is ensured in the most accurate and efficient manner according to the personal analysis results. "We will prepare to enter the French market for three months as part of the Le Village acceleration program in France at the end of 2019. Afterwards, we aim to enter the developing remote health monitoring systems in the UK," says Büşra Özcan.
- **VIVOO Mobile Health**: Established in 2017 by Gözde Büyükcaraoğlu and Miray Tayfun, Vivoo is an application that enables people to make healthier decisions and explains the needs of the body to them. This app gives people nutritional and lifestyle advice based on their urine. Launched in January 2019, Vivoo has reached more than 2,000 users to date. Vivoo Co-Founder Gözde Büyükcaraoğlu underlines that they have received investments from 2 of the 3 largest investment networks in the world.

Note: The aforementioned initiatives have been described as representations of the entrepreneurial activities in the sector, and hundreds of health technology initiatives in the ecosystem have not been included.

Name of Technopark	Number of Companies Engaged in Health Informatics
Yıldız Technopark	23
Teknopark İstanbul	26
İtü Arı Teknokent	12
Odtü Teknokent	36

C. RESEARCH INFRASTRUCTURES

Table 4: Relevant Laboratories in Turkey

LABORATORY NAME		AFFILIATED INSTITUTION
 ACIBADEM ÜNİVERSİTESİ	Acıbadem Mehmet Ali Aydınlar University Faculty of Health Sciences Laboratories	Acıbadem Mehmet Ali Aydınlar University
 BAŞKENT ÜNİVERSİTESİ	Başkent University Health Innovation Center	Başkent University
	İstanbul University Technology Transfer Center Three-Dimensional Medical And Industrial Design Laboratory (Tetlab)	İstanbul University
	Istanbul Yeni Yüzyıl University Life Sciences And Technologies Laboratory	İstanbul Yeni Yüzyıl University
	Middle East Technical University (Metu) Informatics Institute Health Informatics Kansil Laboratory	Middle East Technical University
	Sabancı University Three-Dimensional Bioprinting Laboratory (G-157-A)	Sabancı University

D. ACADEMY

New departments are opened at different universities every day for the younger generations to generate employment in the Medical Technology Sector, which will become prevalent in the coming years. **Main examples in Turkey are:**

Table 5: Universities in Turkey with Departments Related to Medical Technology

PROGRAM	UNIVERSITY
Health Informatics Master's Program	Üsküdar University, Bahçeşehir University, Hacettepe University, Gazi University, Marmara University, Middle East Technical University, University of Health Sciences, Zonguldak Bülent Ecevit University, Necmettin Erbakan University
Biostatistics and Medical Informatics	Acıbadem University, İstanbul University, Karadeniz Technical University, Beykent University, Medeniyet University, Akdeniz University, University of Health Sciences, Bolu Abant İzzet Baysal University, On Dokuz Mayıs University, Giresun University, Kocaeli University, Dokuz Eylül University, Mersin University, Eskişehir Osmangazi University, Yozgat Bozok University, Trakya University
Medical Engineering	Karabuk University, Acıbadem University
Biomedical Engineering	Afyon Kocatepe University, Ankara University, Çukurova University, Düzce University, Erciyes University, İnönü University, Başkent University, Beykent University, Fatih Sultan Mehmet Vakıf University, Işık University, İzmir Democracy University, İstanbul Arel University, İzmir Katip Çelebi University, Kastamonu University, Kocaeli University, Pamukkale University, Samsun University, Tekirdağ Namık Kemal University, Yıldız Technical University, Zonguldak Bülent Ecevit University, Bahçeşehir University, İstanbul Medipol University, İstanbul Yeni Yüzyıl University, İzmir University of Economics, Tobb University of Economics and Technology, Yeditepe University, Eastern Mediterranean University, Near East University

Some projects developed by the academics and students of TÜBİTAK and Acibadem University in representation of these departments and/or programs:

Project Manager	Department	Project	Project Team	Program	University
Prof. Dr. Meltem Müftüoğlu	Medical Biotechnology	Investigation of Effects of Mitochondria-targeted Drug-Loaded Nanocarrier Systems on Colon Cancers with Damaged DNA Mismatch Repair	Yasemin Uzuner (Researcher), Özgül Gök (Researcher), Devrim Özarlan (Consultant), Meryem Sedef Erdal (Consultant)	TÜBİTAK 1001	Acibadem University
Doç. Dr. Halime Kenar	Medical Engineering	In vitro Development of Functional Human Heart Muscle-Coronary Vascular Model by Three-Dimensional Bioprinting	Deniz Yücel (Consultant), Şadan Yavuz (Consultant), Ayşe Karson (Researcher),	TÜBİTAK 1001	
Doç. Dr. Emel Timuçin	Biostatistics and Medical Informatics	Machine Learning-Based New Gene Discovery and Development of a Drug Repositioning Platform for Improving Immunotherapy Efficacy in Cancer	İlknur Melis Durası (Researcher), Günseli Bayram Akçapınar (Researcher), Gökçen Eren (Consultant)	TÜBİTAK 1003 Priority Areas R&D Projects Support Program	
Prof. Dr. Osman Uğur Sezerman	Biostatistics and Medical Informatics	Detection of Response to Neoadjuvant Therapy in Triple Negative Locally Advanced Breast Cancer by Mathematical Models and Animal Experiments	Meltem Müftüoğlu (Researcher), Gül Başaran (Researcher)	TÜBİTAK Bilateral Cooperation Programs	



E. INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS (IIPR)

In the healthcare sector, 64% of the published patents among the patent applications made from Turkey are related with medical technologies.

Patent Applications In The Field Of Medical Technology In The Last Ten Years

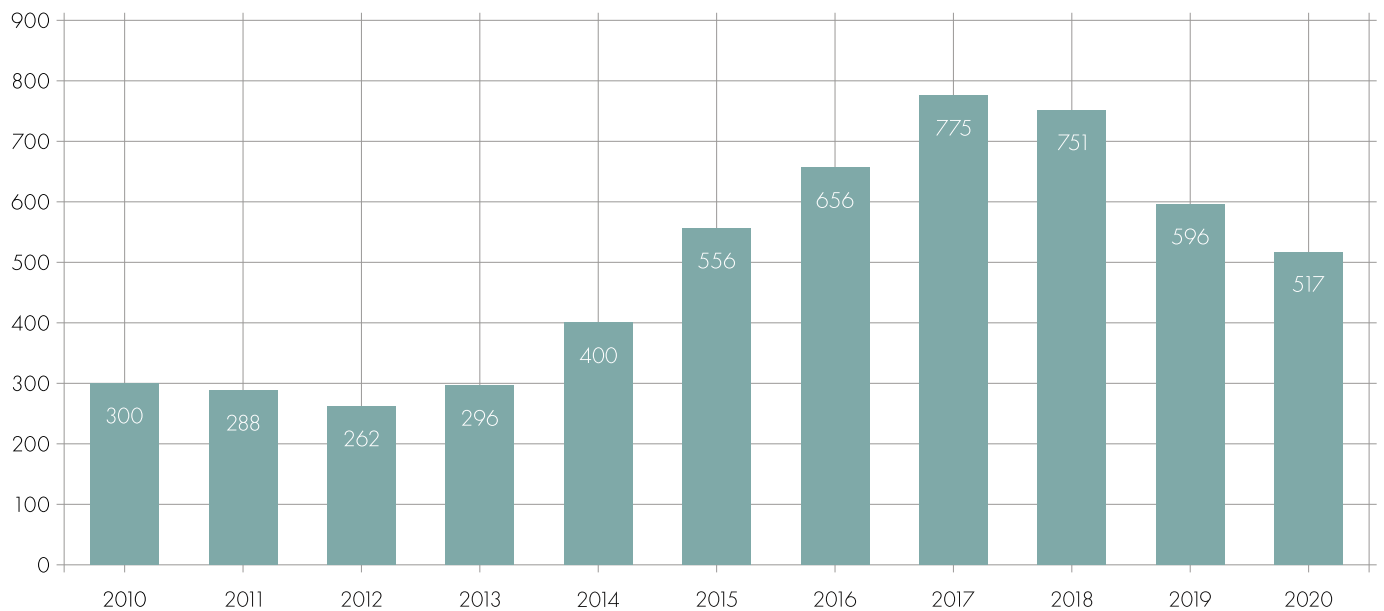


Figure 3. Number of Patent Applications in the Field of Medical Technologies in the Last 10 Years

The yearly analysis of the patent applications in the field of medical technology indicates an increasing trend, as shown in figure 5. In the Turkish healthcare sector, the top 20 institutions/persons that have filed the highest number of patent applications related to medical technologies have been examined.

Leading Institution/Persons In Patent Applications In the Field of Medical Technologies

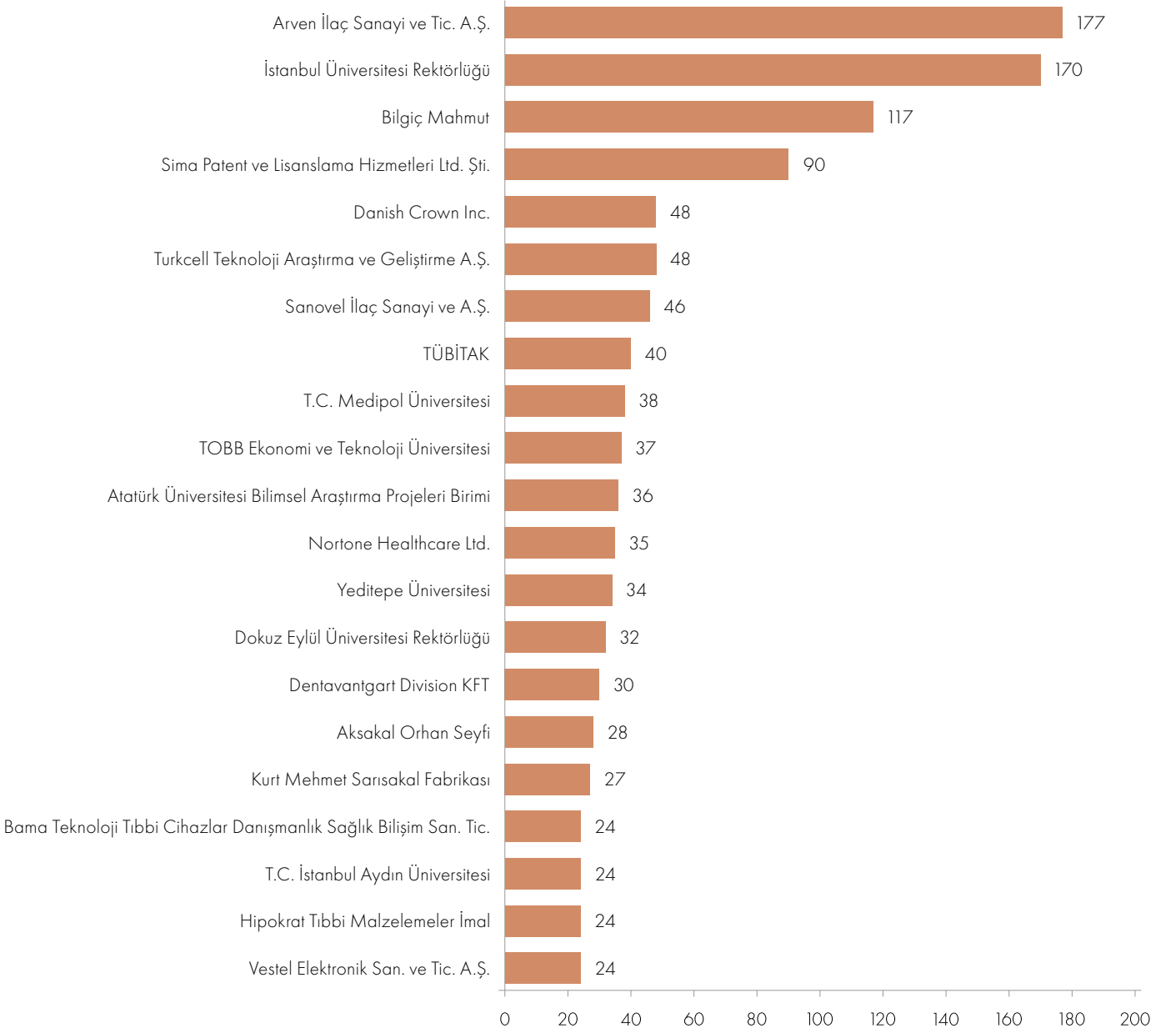


Figure 4. Leading Institution/Persons in Patent Applications in the Field of Medical Technologies

The Figure 6 shows the numbers of patent applications made by the top 20 institutions and persons. In terms of the right holders of the applications made in the field of medical technologies, pharmaceutical companies and universities stand out, while the presence of companies and institutions such as TÜBİTAK, Turkcell and Vestel is also noteworthy.

It is observed that the main players of the sector in medical technologies are universities and many universities carry out studies in the sector.

Leading Universities in Patent Applications in the Field of Medical Technologies

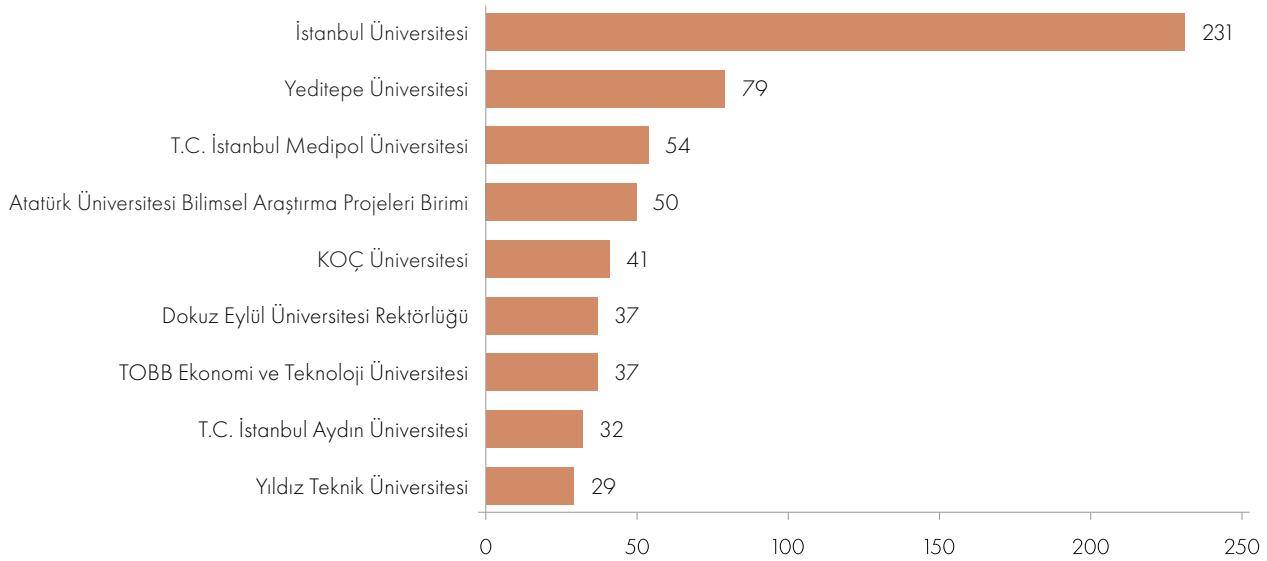


Figure 5. Leading Universities in Patent Applications in the Field of Medical Technologies

Istanbul University is by far the leading institution in the sector with its applications, while it is observed that the number of applications of other universities is not very diverse. In the heat map of the patent applications in the field of medical technology in 2017 and afterwards as shown in Figure 7, Istanbul University and Vestel stand out.

Heat Map of the Patent Applications in the Field of Medical Technology in the Last 8 Years	2012	2013	2014	2015	2016	2017	2018	2019	2020
Sanovel İlaç Sanayi ve Ticaret A.Ş.	63	131	109	118	46	84	106	33	7
Bilgç Mahmut	129	79	5	2					
Bülent Karaağaç	14	64	8	29	28	2	3		
Arven İlaç Sanayi ve Ticaret A.Ş.		124	30	39	30	29	14	12	
İstanbul Üniversitesi Rektörlüğü			23	24	36	62	43	15	6
Erdal Can Alkoçlar		32	23						
Montero Gıda Sanayi ve Ticaret A.Ş.		45	2	8	17	15	30	4	
Yeditepe Üniversitesi	2	13	46	11	13	31	30	12	3
T.C. İstanbul Medipol Üniversitesi					9	17	21	7	
Atatürk Üniversitesi Bilimsel Araştırma Projeleri Birimi					2	3	20	19	5
Türkcell Teknoloji Araştırma ve Geliştirme A.Ş.	2	2				6	20	10	
Koç Üniversitesi	17	13	10						
Dokuz Eylül Üniversitesi Rektörlüğü						10	14	10	5

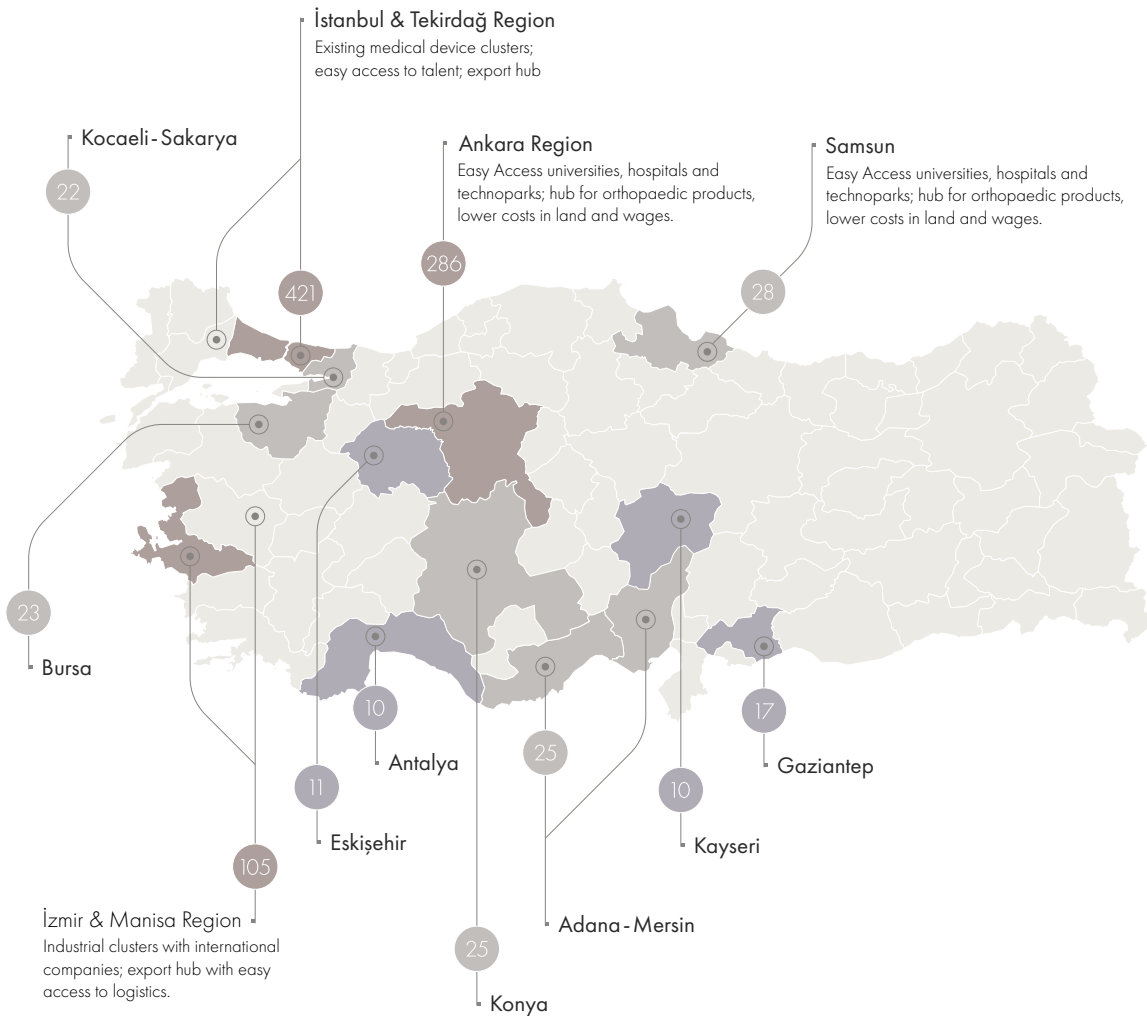
Figure 6. Heat Map of the Patent Applications in the Field of Medical Technology in the Last 8 Years

It is observed that Istanbul University, Koç University, Istanbul Medipol University, Yeditepe University, Atatürk University Scientific Research Projects Unit and Dokuz Eylül University have taken part in patent applications in the field of medical technology in the last 8 years. It is seen that Istanbul University, Yeditepe University and Dokuz Eylül University have been actively continuing their applications in the field in the last 3 years.

2. MEDICAL DEVICES

The medical devices sector is marked by rapid changes. The development and changes in the sector is affected by the fact that the products in the sector are open to innovation and the quick applicability of the technological developments arising from other disciplines to the medical device technology. In this respect, developments in fields such as information and communication technologies, medical genetics and molecular biology, nanotechnology-materials-composite materials also affect medical technology in the medium and long term. The most important goals include encouraging and spreading the production of medical devices with high added value by increasing the confidence in our domestic products in the field of medical devices in Turkey and achievement of a competitive medical device market with medical companies spread out across the country, where all resources are used efficiently, through the improvement of the public-university-industry cooperation.

Table 6 : Distribution of the Medical Device Manufacturing Companies by Province



Source: 'Medical Technologies Sector Report, English Publication, Investment Office

A. PUBLIC SECTOR

According to the 11th Development Plan; "The main purpose is to increase our competitiveness in the global market and to bring our country to a higher position in the value chain in the pharmaceutical and medical devices sector."

According to the policies, first of all, the competencies of TÜSEB in the pharmaceutical and medical device industry will be increased and in addition to the R&D, production and training activities, TÜSEB will finance Start-ups, set up simulation centers, join partnerships with other companies with its corporate structure when necessary, act as leader in the establishment of health valleys and health technologies development zones, and enable the development of export-oriented products with higher added-value. Health technology development zones, where supports for clustering are provided, will be established. To sum up, the purpose of initiating projects which will grow the ecosystem and increasing the supports provided to entrepreneurs and SMEs by the state is to create an integrated ecosystem growing organically in the Medical Device Sector in Turkey.

Plans for Domestic Production of Medical Devices

The ‘Health Industries Steering Committee’, which was established pursuant to a Presidential circular for increasing domestic production in our country and which is comprised of members from the Ministry of Health, Ministry of Science, Industry and Technology, Ministry of Economy, Ministry of Development, Ministry of Finance, Undersecretariat of Treasury, TÜBİTAK, Social Security Institution and Turkish Medicines and Medical Devices Agency, is continuing its efforts for the domestic production of medical devices.

The following table demonstrates the support programs provided by TÜBİTAK, KOSGEB and TÜSEB in the Medical Devices Sector in the past.

Program	Call	Call End Date	Objective of Call
TK - Applied Project Cooperation in the Field of Diagnostic Kits	Call Regarding Applied Project Cooperation in the Field of Diagnostic Kits	10/4/2019 12:00:00 AM	The purpose of the cooperation activities to be carried out within the scope of this call is to obtain exportable products capable of competing in the international market and to reduce foreign dependency.
TC - Applied Project Cooperation Program in the Field of Medical Devices and Biomaterials	Call Regarding Applied Project Cooperation Program in the Field of Medical Devices and Biomaterials	10/17/2019 12:00:00 AM	The purpose of this call is to support projects for the development of all kinds of medical devices and biomaterials that can be used for prevention, early diagnosis and treatment, support and monitoring of diseases and to reduce the difficulties faced by patients.
TÜBİTAK 1003	1003-Sab-Tchz-2017-2 Innovative Medical Devices for Diagnosis, Treatment and Support Purposes	1/19/2018 5:30 PM	The purpose of this call is to fund projects in the following three groups for the application of tools and technologies which will be developed for early and effective diagnosis and treatment of diseases.
KOSGEB	KOSGEB Technoinvestment		4 million 200 thousand TL of the 6 million TL support to be supplied from KOSGEB’s TECHNOINVESTMENT package will be repaid. 1 million 800 thousand TL will be given to businesses as a grant.
TEYDEB	Biomedical Equipment Technologies		Medical Products whose Domestic Production is Critical Innovative Implants New Generation Prosthesis and Orthotics Innovative Ophthalmology Devices Innovative Medical Imaging Systems Robotic Surgery Technologies
TEYDEB	Diagnostic Science / Diagnostic Kits		Development of Domestic Diagnostic Kits

B. PRIVATE SECTOR (Enterprise, Start-up, SME, Large Scale, etc.)

There are 17 R&D Centers relating to Healthcare and Medical field in Turkey. Some important R&D centers which will assist in the development of the Medical Device sector are provided in the following table:

Name of R&D Center

Anatolia Tanı ve Biyoteknoloji Ürünleri Araştırma Geliştirme San. ve Tic. A.Ş.
 Bıçakçılar Tıbbi Cihazlar San. ve Tic. A.Ş.
 Ertuğç Özcan Sağlık Tesisleri ve Tıbbi Cihazlar İnş. San. ve Tic. A.Ş.
 Meditera Tıbbi Malzeme San. ve Tic. A.Ş.
 TST Rakor ve Tıbbi Alet. San. ve Tic. Ltd. Şti.

Companies with international capital, which aim at constant development with their innovative missions and visions in the medical device sector in Turkey and possess R&D capabilities adaptable to the changing sector are provided in the following table;



MEDICAL DEVICE INITIATIVES

- **DAPGENOMİK:** BDAPGenomik was established in 2017, with the joint venture of Prof. Dr. Elif Damla Arısan, Prof. Dr. Ajda Çoker Gürkan and Assoc. Dr. Pınar Obakan Yerlikaya, who are faculty members of Istanbul Kultur University, Molecular Biology and Genetics Department. The Company operates under the 'Nutrilena' brand. "We focused on the nutritive aspect of breast milk and developed a diagnostic kit to identify the content of breast milk in relation to nutrition," says Prof. Dr. Elif Damla Arısan. The Company continues developing its business model with the first support it received from Telos Angels after its stage performance at the finale of ITU Bigg Bang.
- **GENZ BIOTECH:** Founded in 2016 by Umut Ağyüz, Genz Biotech developed a test which does not interpret cancer with the relationships established between genetics and cancer and which reveals a person's advantages and disadvantages in the light of their DNA and genetic information. The Company is the producer of fastest and cheapest test for cancer pre-screening and has attracted a 200,000 USD investment from StartersHub.
- **PONS:** The device developed and named 'Pons' by the brothers Soner and İlker Hacıhaliloğlu allows the detection of cerebral hemorrhage from patients' eyes. Thanks to its mobile ultrasound 'probe' and the associated image processing and data analysis software, Pons notifies the hospital of the risk of cerebral hemorrhage before the patient reaches the hospital, with the image taken over the eye. Studies are currently being carried out to transform the system into a wearable technology such as glasses. Pons, whose preliminary clinical tests have started in the USA and Germany, is planned to be fully used by end users towards the end of 2020.
- **TARABİOS:** Tarabios is an initiative whose studies were commenced five years ago upon doctors' demands for measurement of blood coagulation parameters with a portable device with the accuracy of laboratory devices. The studies that started at Koç University Optical Microsystems Laboratory developed with the investment of the high-tech investment company Inventram and have now become a technology protected by patents all over the world. Prof. Dr. Hakan Ürey, the Co-Founder of Tarabios states that the product will positively contribute to a great number of people, considering that more than 1 billion blood coagulation tests are performed annually. He also adds that the market was worth more than 1 billion USD and included very few players when they started this initiative. "We aim to go on new investment tours by completing the clinical tests," says Ürey.
- **ULTRALAB LTD:** Founded in 2018 by Burhan Eyüboğlu, Emre Özüm and Furkan Küçük, Ultralab has developed two products for the healthcare sector. One of them is Ubeat, a platform for pregnant women. The platform consists of a fetal heart monitor and a mobile application. It allows expectant mothers to listen to their babies' heartbeats at any time and share them on social media. The second product is a mobile ultrasound device called 'Soundcam' that can operate on smart phones. Emre Özüm mentions their recent work which will allow early diagnosis from ultrasound images. "It is estimated that medical image processing software will reach a market size of approximately 2.5 billion USD in 2020. That is why we are continuing to work in this field as well," adds Özüm.

Digital Health Initiatives in Turkey

Medical Devices

Human Health

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Telehealth / Online Counselling

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Mental Health

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Medical Imaging

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Women's Health

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Wellness

Biotech and R&D

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Hospital Management

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Virtual Assistant









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E-learning & Virtual Reality

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Table 7. Map of Digital Health Initiatives in Turkey

C. RESEARCH INFRASTRUCTURES

LABORATORY NAME		INSTITUTION
	Ankara University Faculty of Medicine - Physiology Department Brain Imaging Laboratory	Ankara University
	Dokuz Eylül University Bioizmir Calibration and Medical Device Test Laboratory	Dokuz Eylül University
	İstanbul Medipol University Health Science and Technologies Research Institute Innovative Microscope Technologies Laboratory	İstanbul Medipol University
	Koç University Faculty of Science Live Cell Imaging Microscopic Laboratory	Koç University
	Koç University Faculty of Science Microscope Laboratory	Koç University
	Koç University Automated Multi-Purpose Live Cell Imaging Laboratory	Koç University
	Marmara University Faculty of Technology Electrical-Electronics Engineering Department Biomedical Imaging and Diagnostic Laboratory	Marmara University
	Yeditepe University Faculty of Pharmacy Pharmaceuticals, Cosmetics and Medical Devices R&D and Analysis Laboratories	Yeditepe University

Note: The table does not include all research infrastructures in the field and has been shared for representation purposes.

HEALTHCARE INDUSTRIES TRANSFORMATION AND RESEARCH PLATFORM (SEDAP)

Objective: It is an institution program that aims to ensure the growth and commercialization, even branding of the innovative initiatives in the field of healthcare. The Turkish Medicines and Medical Devices Agency ranks start-ups, guides them according to their needs, provides consultancy services regarding the legislation and brings together start-ups and investors.

Some Medical Device Initiatives on the Platform;

KOÇ UNIVERSITY RESEARCH CENTER FOR TRANSLATIONAL MEDICINE (KUTTAM)

Supported within the scope of the Ministry of Development's University Infrastructure Support Project, Koç University Research Center for Translational Medicine (KUTTAM) was established for the purpose of conducting advanced scientific research on biomedical device production and maximizing university-industry cooperation with respect to the production of high value-added, state-of-the-art medical devices and innovative products in Turkey. Academics working in the Faculty of Medicine, Faculty of Science, Faculty of Engineering and Social Sciences, who have proved their competence globally in the fields of basic sciences and applied sciences, work together under the umbrella of KUTTAM, making efforts to develop high value-added, state-of-the-art medical devices and innovative products. Koç University Health Education Application and Research Center, which started its operations in 2015, provides a great and unique opportunity for conducting the clinical researches of biomedical devices developed by KUTTAM, working together with producers in the clinical researches required to develop medical devices, and operation of the mechanisms that provide feedback to domestic producers for innovation relating to product improvement.

Some projects of KUTTAM which are currently in progress are provided in the following table;

PROJECT	FINANCING ORGANIZATION
Studies for Development of Biomarker for Early Stage Diagnosis by Detecting Circulating Cancer Stem Cells in Pancreatic Ductal Adenocarcinoma	TÜBİTAK TB.ARDEB.1003
Studies for Development of Biomarker for Early Stage Diagnosis by Detecting Circulating Cancer Stem Cells in Pancreatic Ductal Adenocarcinoma	TÜBİTAK ARDEB 1003
3D Evaluation of Liver Fibrosis and Cirrhosis by Clarifying and Fluorescent Microscopy	TÜBİTAK ARDEB 1001
Development of Artificial Intelligence Algorithms for the Analysis of Corneal in Vivo Confocal Microscopy Images"	TÜBİTAK Teydeb 1511
Integrated electronic skin for prosthesis	TÜBİTAK.2232
COVID 19 diagnostic kit development project	TÜSEB

MEDICAL DEVICE SECTOR AFTER COVID-19

A story of national mobilization initiated by Arçelik, Biosys, Baykar and Aselsan by combining their powers with the start of Covid-19;

Companies in Charge of the Project	Companies that Support the Project	The Objective of the Project
Engineers of Biosys, the domestic developer of intensive care ventilators, Baykar, a leading manufacturer of UAV, Aselsan and Arçelik work together on the project.	Akim Metal, Aksan, Dora, Femsan, PSC, Serdar Plastik, Teknokauçuk and Tombak.	15% of people infected with coronavirus get sick. Of this 15%, the 20% gets sick to the extent that intensive care is necessary. This means that 7,500 intensive care respirator devices are needed for every 1 million people. However, in Turkey, there are 50 intensive care ventilators for only every 100,000 people. This number is insufficient as demonstrated by the above data, particularly under such extraordinary circumstances. That is why four sector leaders came together and initiated a national mobilization, starting the mass production of domestic intensive care ventilators to save the lives of as many people as possible, when the pandemic reached its peak.

Furthermore, almost 10 Turkish diagnostic companies developed COVID-19 tests to date.

- **ANATOLIA GENEWORKS:** Based in Istanbul, Anatolia Geneworks exports kits to 20 countries, including Europe. The Company develops kits which are called 'Real Time PCR' and which can provide real-time measurements of virus material on patient samples.
- **RTA LABORATUVARLARI :** RTA Laboratories, which were granted R&D Center Certificate by the Ministry of Science, Industry and Technology of Turkey in 2017, continues its R&D and Production activities under Güler Yatırım A.Ş. The company has an R&D laboratory suitable for studies based on molecular biology-genetics and immunology-serology.
- **BIOKSEN :** Bioeksen is a company in ITU ARI Technocity, which offers effective solutions for various fields in molecular biology and R&D Technologies. In addition to solutions for the rapid diagnosis of viral and bacterial pathogens in the fields of human and animal health and food safety, the company develops projects on obesity, athlete genetics, genotyping of fungal and viral pathogens, and the development of nanobiotechnology-based biosensors that can be used in the field without devices.

- **GENKORD:** Contributing to biotechnology researches with numerous institutions and scientists in Turkey, Genkord serves as a biotechnology, tissue engineering and cryopreservation institution. In addition, the company also provides cryopreservation services based on special needs and demands.
- **SENTROMER:** Sentromer DNA Teknolojileri, which is based in the Maslak campus of Istanbul Technical University, operates as a biotechnology company developing and producing synthetic oligonucleotides and rapid diagnostic kits. Carrying out its activities in its laboratories in ITU ARI Technocity and İstinye ABC Plaza, Sentromer DNA Teknolojileri offers an extraordinary variety of rapid diagnostic kits and analysis services by using synthetic DNA products designed and produced by itself in humans and model organisms.
- **DIAGEN:** Specialized in Molecular Biology and Genetics, Diagen provides design, development, production, supply, storage, marketing, sales and after-sales support services of research and diagnostic reagents in the field of human, animal, food and environmental health.
- **NUCLEOGENE:** Nucleogene is based in Istanbul and develops products for medical and industrial use by using biotechnological methods. In addition, the company works on product and high-security diagnostic methods for the healthcare and food industries.
- **DS BIO ve NANO TEKNOLOJİ:** Based in Ankara, DS Bio ve Nano Teknoloji provides services in the fields of nano technology, genetics and software.

TGB companies also worked hard during this period and produced innovative products to combat Covid-19. Companies operating within 26 TDZs across Turkey have implemented 165 products and projects as part of the efforts to combat Covid-19.

04

Biomedical

Report on R&D and Engineering Capabilities
in the Healthcare Sector in Turkey



BIOMEDICAL

Studies to prepare the “2015-2018 Biotechnology Strategy and Action Plan of Turkey” were initiated on 3 April 2013 to ensure that the biotechnology sector in our country has a sustainable and effective structure, given the increasing strategic importance of biotechnology in the world and the developments experienced in the field.

In the final document, “Becoming one of the leading countries of the world by increasing the level of technological knowledge and value-added production in the field of biotechnology” is determined as the vision, while the general purpose is described as; “making our country a center of attraction which can develop technologies and produce innovative products with high added value that are suitable for global competition, by developing the capacity of the R&D and innovation ecosystem in the field of biotechnology.”

Strengths Of The Health Biotechnology In Turkey

- Prioritization of investments to be made in the field of biotechnology and their inclusion within the scope of support in Turkey,
- Increase in product oriented R&D activities in health biotechnology,
- Participation of Turkey in European Union Framework Programs,
- Presence of competent universities, training and research hospitals and experienced academics in our country,
- Presence of special departments such as Biotechnology, Bioengineering and Biomedical Engineering,
- Presence of qualified young population, students and research assistants interested in the field,
- Increasing number of academicians, entrepreneurs and companies interested in the field,
- Establishment of Technology Transfer Offices in universities and the increase in the number of these offices,
- Increase in supports relating to the protection of intellectual property rights,
- The capacity and advanced production infrastructure of the domestic pharmaceutical industry in the conventional pharmaceutical production,
- Formation of sufficient knowledge in the production of diagnostic kits,
- Operation of many multinational companies which carry out a major part of the biotechnological pharmaceutical R&D and production activities in the world and possess vast knowledge in this field in Turkey,
- Increased access to doctors and treatment thanks to the transformation in healthcare program,
- Presence of a Clinical Research Legislation in line with effective international standards,
- Relatively lower costs of production and clinical researches compared to the US and many European countries.

A. PUBLIC SECTOR

In the Biotechnology Strategy and Action Plan Monitoring Report of Turkey, the targets achieved and processes continued by the Ministry of Health in the field of health biotechnology and the targets reached by the Ministry of Industry and Technology can be listed as follows;

Action	Responsible Ministry	Studies Conducted
R&D, clinical research, licensing and production processes of biotechnological products to be developed in Turkey will be harmonized with the regulations of EMA (European Medicines Agency) and/or FDA (The United States Food and Drug Administration) at international standards.	Ministry of Health	The legislation on Veterinary Health Medical products has been harmonized with the European Union. Places of production of a number and quality suitable for the production of biotechnology veterinary medical products have been contributed to our country. Furthermore, biosimilar workshops are held.
A work group will be formed to define the biotechnological products to be developed and produced in Turkey on the basis of product/treatment group.	Ministry of Health	A workshop was held regarding the production of the second domestic vaccine in Turkey and it was decided to carry out the production through technology transfer for the Hepatitis A vaccine. Preliminary proposals of companies were collected, meetings were held with the relevant Ministries and the projects were presented.
Products and areas where biotechnological support and incentives will be provided for diseases that are specific to Turkey and that have unmet medical treatment needs will be determined.	Ministry of Health	Within the scope of the action, the "R&D Infrastructure Analysis and Contributions of the Health Economy in Turkey" project was created. Visits were made to countries which are advanced in biotechnology and the reports presented were examined in detail. Commissions were set up for the diseases that can be encountered in Turkey and the related diseases were identified. Calls were opened jointly with TÜBİTAK in relation to these diseases.
A work group which will improve the investment environment and increase competitiveness for clinical researches in our country will be formed.	Ministry of Health	A work group was formed and the action plan was realized.
Internationally accredited analysis laboratories will be established in pilot regions and universities for immunogenicity and other analyzes of biotechnological products.	Ministry of Industry and Technology	Some steps have been completed and the completion rate is increasing.
Research infrastructures in the field of biotechnology will be supported.	Ministry of Industry and Technology	Studies were carried out to strengthen the cooperation of METU Micro Electro Mechanical Systems (MEMS), Bilkent National Nanotechnology Research Center (UNAM), Sabancı University Nanotechnology Research and Application Center (SUNUM) and Izmir Biomedicine and Genome Center (IBG) with the industry.

There are also significant projects carried out by TÜBİTAK MAM and the Presidency of TÜBİTAK in the field of biotechnology. The most prominent ones among these projects are as follows:

Priority R&D Subjects of TÜBİTAK Calls for the Year 2019-2020

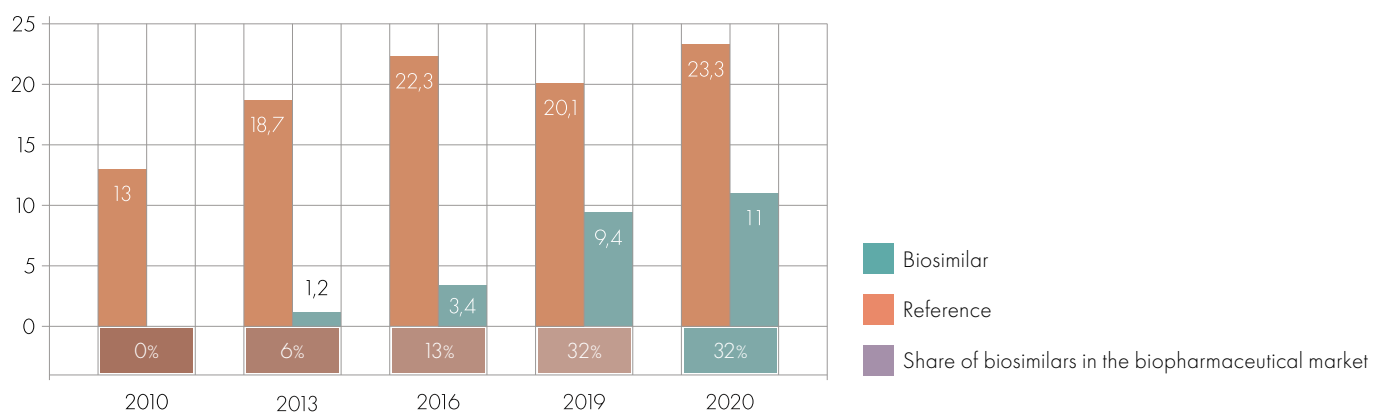
Priority Technology Areas	Number of Calls	Priority R&D and Innovation Subjects
Bionanotechnology and Biomaterials	3	Personalized Medicine-Diagnostics, Diagnostic and Monitoring Technologies
		Innovative Medical Consumables
		Regenerative Medicine and Artificial Tissues/Organs

B. PRIVATE SECTOR

In 2019, 1,692 people worked in biotechnology activities. 18.8%, 25%, 38.7% and 6.6% of them had doctorate, graduate, undergraduate, college degrees respectively, while 10.9% had completed high school or lower education. The number of full-time equivalent employees in biotechnology activities was 1,350 in 2019.

Biotechnological drugs accounted for 18.2% of prescription drugs, reaching 8.4 billion TL, and 34.3 million boxes were sold in 2020. In the same period, reference biotechnological drugs reached 7.8 billion TL with an increase of 21.8%, while biosimilar drugs increased by 50.4%, reaching 938.5 million TL. As it can be seen in the following chart, biotechnological drug sales, which were about 13 million boxes in 2010, reached about 35 million boxes as of 2020; biosimilar drugs, which increase their share every year, accounted for more than 1/3 of the total biopharmaceutical market. It is believed that the increase in the market share of biosimilars, which are considered to be more economical for the public finance and consumers' budgets, will continue to increase with the biosimilar development and production activities in our country.

Turkish Biopharmaceuticals Market · Million Boxes



Source: IQVIA, IEIS

As October 2020, 7% of the biotechnological pharmaceutical market was comprised of domestically produced products in the first 10 months of the year. The products of 6 domestic producers (Arven, Atabay, Drogan, Hasbiotech, Koçak, Vem İlaç) and 1 foreign investor (Celltion Healthcare) which were produced in Turkey were delivered to patients. In addition to the products already on the market, there are domestically developed drugs that are currently in development, licensing or clinical research stages. According to the data of Biotechnological Pharmaceutical Platform of Turkey, studies are carried out to launch 39 biosimilar, 2 reference biotechnological and 1 biosuperior drugs that are domestically produced, by 2024.

R&D activities of some companies are summarized below to exemplify the activities carried out in this field by the Turkish pharmaceutical industry, which has invested more than 1.1 billion USD in biopharmaceutical production to date, according to the data of BPP:

- **ABDİ İBRAHİM:** The leading company of the Turkish pharmaceutical market began to operate AbdiBio production facility, which was designed entirely for the production activities and processes of biotechnological drugs, in 2018. With this facility, where approximately 1 billion TL was invested, a production infrastructure that enables all biopharmaceutical processes from cell bank to final product was set up in a closed area of 13,500 square meters. The facility has an annual production capacity of 11 million liquid vials, 9 million syringes, 22 million cartridges and 1 million lyophilized vials. Being one of our country's leading pharmaceutical companies with 4,600 employees and a turnover of 640 million USD, Abdi İbrahim exports products to more than 60 countries in addition to its production facilities in Kazakhstan and Algeria, which demonstrates its export potential in the field of biopharmaceuticals as well. The Company is continuing the activities to develop biosimilars eligible for competition in the world markets, as well as its strategic cooperation and investments in the field of biopharmaceuticals. Abdi İbrahim acquired the 83-year-old pharmaceutical company OM Pharma, which is based in Switzerland, the leading country of the pharmaceutical sector, together with a Swiss joint venture group. After the acquisition, Abdi İbrahim became the owner of 28.5% of OM Pharma's shares. Thus, Abdi İbrahim went down in history as the first and only Turkish pharmaceutical company to establish a strategic partnership with a European pharmaceutical company. The company also continues to cooperate with talented enterprises and companies, especially in the Far East countries.
- **ARVEN İLAÇ:** The Company started its activities in 2013 with its main focus on biotechnological drugs and respiratory treatment group with Toksöz Group, which is one of the strongest groups of the sector. For this purpose, it continues its activities at the R&D facilities set up in Selimpaşa and the production facility in Kırklareli, which is established on an area of 30,000 m² and which began to operate in 2017. The Company is the developer of Fraven with the active ingredient Filgrastim, the first biosimilar developed from the cell to the end product in our country and released to the market, and this result obtained from its 8 years of development activities constitutes an important example to explain its capabilities. Fraven, whose pre-clinical studies and clinical studies were started in 2012 and 2014 respectively, began to be commercially produced in 2016. The company's R&D Center in Istanbul houses a Microbial USP Room, a mammalian USP room, a DSP room, an instrumental laboratory, a bioassay laboratory, a molecular biology and characterization laboratory, and buffer preparation, weighing, washing and storage rooms. The company has a microbial production line for the production of biotechnological active ingredients and continues its studies for the production of mammalian active ingredient production in parallel with its R&D studies.
- **ATABAY:** Being one of the important companies in the production of pharmaceuticals and active ingredients since 1939, Atabay has been taking significant steps in the field of biopharmaceuticals since 2013. The Company, which invested in the establishment of a biopharmaceutical R&D facility in Acıbadem Istanbul and sterile prefilled syringe filling facilities in 2013, continued these works with Biotechnology R&D and Pilot Production Facility investments in 2016.

Upon the successful development and production of the bioengineering antibodies in partnership with İTÜ MOBGAM and Marmara University in 2015, the company launched a biotechnology project with the support of TÜBİTAK KAMAG 1007. In addition to cell line development, process development and scale growth, detailed analytical works are carried out within the company. Atabay has also implemented a new cGMP facility dedicated to microbial production and development. Atabay continues to work on enzyme production, antibody fragments and other biosimilars using microbial fermentation.

- **NOBEL İLAÇ:** Nobel was established in 1964 as a company with entirely domestic capital. Currently, Nobel operates with a total of five production facilities, three located in Turkey and the other two located in Kazakhstan and Uzbekistan, while continuing its promotion and sales efforts through its own organizations in 20 countries. With a staff of 3,000 experts specialized in their field, Nobel exports its qualified products produced at international standards to approximately 50 countries.

The headquarters of Nobel İlaç, which carries out its production and R&D activities in Düzce and Gebze and raw material production in its facilities in Çerkezköy, is located in Istanbul. Nobel established one of the most important high-tech pharmaceutical facilities of Turkey, with its GMP-compliant production facility which has a closed area of 800 square meters and 2x1000 L reactor capacity in TÜBİTAK Marmara Technopark. Activated in 2019, the facility is the only biotechnology cell process development facility that brings together all functions under a single structure in the region. The facility, which can produce 40 series of biotechnological drugs with its annual production capacity of 4 biotechnological products and 2,000 L, will make a significant contribution to the development of domestic production in this field.

As the owner the first file selected among 28 applications of 23 companies submitted to the 'Domestic Development and Production of Biosimilar Pharmaceuticals' project launched under the leadership of TÜBİTAK, Nobel aims to become an important part of the biotechnology ecosystem with its new production investment. With the new investment of 4x2000 L, a significant contribution will be made to the production of mammalian cell-derived active ingredient production, as well as the biopharmaceutical development capacity of our country.

- **CENTURION İLAÇ:** Centurion İlaç, which started its activities in 1979, works on domestic production and widespread accessibility of modern treatment alternatives, production of high-tech vaccines in our country, development of national and patented molecules, and the generation of qualified human resources with its R&D and Production Facility.

Having implemented the first biological and biotechnological production facilities of Turkey on a closed area of 15,000 square meters, Centurion İlaç has a current annual production capacity of 15 million vials, 6 million syringes and 5 million cartridges. The two existing production lines are for the production of plasma and hospital injectables and biotechnological products. New line investments are also planned for vaccines and biosimilar cell production. The company cooperates with leading companies from all over the world in the field of biosimilars, orphan drugs and vaccine products, and develops joint projects in the fields of innovative treatment. Outside of the Turkish market, export related activities were commenced in 2017 and the company started to provide services to foreign markets as well.

- **KOÇAK FARMA:** Koçak Farma was established in 1971. The company manufactures conventional drugs, biotechnological/biological drugs, intravenous (I.V.) solutions and active pharmaceutical ingredients (API). Koçak Farma's Production facilities in Çerkezköy Organized Industrial Zone are established on an area of 140,000 m² and have a closed area of 100,000 m² and a production capacity of 500 million units/year. As one of the important players in the sector with more than 2000 employees, the company has made significant progress with its vaccine development and production capabilities as well. According to 2019 data of ISO 500, Koçak is the second biggest player of the Turkish pharmaceutical industry with approximately 1.5 billion TL sales revenues from annual production. Koçak Farma exports its products to more than 50 countries with EU GMP certificates.

Koçak Farma launched the first biosimilar product produced in Turkey, Oksapar, a sterile prefilled syringe product, to the market in 2012. In February 2017, Turkey's first biosimilar insulin, Glarin, which was produced by Koçak Farma, was introduced to the market. Since 2010, Koçak Farma has been engaged in R&D studies for the production of insulin analogues starting from the cell with recombinant DNA technology in its R&D center approved by the Ministry of Industry and Technology. In this process, the insulin analogs insulin glargine and insulin lispro were produced from the cell using recombinant DNA technology in the production facilities of Koçak Farma. The necessary facilities for the pilot and industrial production of the insulin glargine and insuling lispro developed at Koçak Farma's R&D center from the clone have been established. Having a fermentation capacity of 13,000 L, the production facilities are among the leading facilities in the world.

Koçak Farma produced anti-rabies anti-serum and continues to work on the production of tetanus, snake and scorpion antisera at its anti-serum production facilities.

- **Closed Area of the Biotechnological Production Facility:** 40.000 m²
- **Additional Employment to be Generated by the Investment:** 780 People
- **Purpose of Use of the Facility:** Biotechnological Pharmaceutical Production (Insulins, Monoclonal Antibodies, Miscellaneous Vaccines)
- **Amount of Investments Made to Date:** 200,000,000 USD

Company : Geen Biyoteknoloji

Problem : Difficulty experienced in performing genetic operations

Solution : They developed a system named GeenOS to facilitate the performance of generic operations. For easy performance of genetic operations, the main systems of live cells are controlled with a standard virus program.

Value : The system called GeenOs is operable only by sending simple commands. It enables simultaneous performance and verification of multiple modifications, instead of using dozens of kits and trials for a single genetic modification.

Company : Ozsrc Genetik Biyoteknoloji

Problem : Problems experienced in the process of diagnosing cancer

Solution : Development of new molecular genetic kits and biosensors that will facilitate the diagnosis of cancer.

Value : Accelerating the early detection process.

Company : Vivosens Biyoteknoloji

Problem : Problems experienced in the process of diagnosing E.coli

Solution : A portable biosensor platform which will ensure quick detection of E.coli, one of the world's most common bacteria, is being developed.

Value : Development of a product which will recognize various biomolecules on a portable system by simply changing the apparatus and allow you to view the results instantly from your smart devices.

C. RESEARCH INFRASTRUCTURES

Some research infrastructures established in Higher Education Institutions and Public Institutions and operating in the field of biotechnology and the activities carried out in these infrastructures are as follows;



Name of the Center:

Ankara University Institute of Biotechnology

Sub-Fields of the Projects :

Molecular breeding in national plant gene resources, creation of genetic diagnosis databases; biomarker development; association mapping in gene sources; phenotype and genotype associations such as marker-based selection; genome/functional genomics for abiotic-biotic stress conditions; transcriptome and gene expression analyses; monoclonal antibody production, vaccine development; molecular marker; identification of genes/molecules targeted by drugs; biosimilars; recombinant peptides and vaccine production and advanced researches

<https://biotek.ankara.edu.tr/>



Name of the Center:

Boğaziçi University Center for Life Sciences and Technologies

Sub-Fields of the Projects :

Computational biology and bioinformatics, smart drug delivery systems (drug carrier surface applications, Water Soluble Drug Delivery Systems)

<https://lifesci.boun.edu.tr/>

**Name of the Center:**

Dokuz Eylul University Izmir International Biomedicine and Genome Institute

Sub-Fields of the Projects:

Stem cells, biomarker development, nanobiosensors, biomaterials research, intervertebral disc development, biotechnological drug development, biosimilar production

<http://ibg.deu.edu.tr/>

**Name of the Center:**

Ege University Pharmaceutical Sciences Research Laboratory

Sub-Fields of the Projects:

Studies at the molecular level on the formation mechanisms of some diseases, studies to explain disease mechanisms, studies to design different controlled release systems

<http://fabal.ege.edu.tr/>

**Name of the Center:**

Turkish Biotechnology Institute

Sub-Fields of the Projects:

The purpose of the Institute is to establish research centers that will serve in the field of health science and biotechnology and support the existing ones, to coordinate R&D activities for products by encouraging cooperation between universities, public and private sectors and to develop the biotechnology ecosystem in our country by providing project support to researchers through project calls. To this end, TBE initiated the Turkey Genome Project for early diagnosis of rare genetic diseases, complex diseases and cancers and implementation of personalized treatments to improve public health. In addition, the Institute provides support for projects in respect of regenerative medicine, stem cell, gene and cellular treatment activities, production of the biotechnology products (vaccines, monoclonal antibodies, hormones, plasma and plasma products, coagulation factors, insulin, etc.) that the country primarily needs and development of medical devices and diagnostic kits. It also leads international cooperation and joint studies in order to train young scientists.

<https://www.tuseb.gov.tr/tbe/>

**Name of the Center:**

Hacettepe University Center for Pediatric Stem Cell Research and Development

Sub-Fields of the Projects:

Stem cell, Stem cell technologies, biomaterial/material-stem cell interaction, genetic modification, cloning, cancer stem cell/microenvironment targeting, bioreactors

<http://www.pedistem.hacettepe.edu.tr/>

**Name of the Center :**

TÜBİTAK MAM Genetic Engineering and Biotechnology Institute

Sub-Fields of the Projects :

Biopolymer technology and tissue engineering controlled drug release technology, nanostructures and their biological applications, human cell technology (stem cell production, primary cell production, in vitro toxicity and biocompatibility studies) genomic and proteomic studies related to human diseases, development of recombinant antibody and peptide structures, vaccine technology (development of classical and recombinant vaccines), molecular immunology

<https://gmbe.mam.tubitak.gov.tr/>

**Name of the Center:**

TÜBİTAK BİLGEM (Advanced Genomics and Bioinformatics Research Group)

Sub-Fields of the Projects :

Compression of Genomic Data, Computational Biomarker Discovery in Genomic, Proteomic and Metabolomic Data, Metagenomic Studies, Analysis of Copy Number Variations (CNV) from Exome Data, Sequence Alignment, Genome Combination, Medium and Large Insertion and Deletion Detection, Cancer Marker Development, Molecular Modeling Digital Design, Development of 'Prenatal Diagnosis from Maternal Blood' Kits for Detection of Down Syndrome and Similar Genetic Disease Signs, Evaluation of All Genome Linkage Analysis Data by Pathway and Network, Evaluation of Next Generation Sequencing Data by Pathway and Network, Haplotype Analysis

<https://igbam.bilgem.tubitak.gov.tr/tr/index.html>

**Name of the Center:**

Middle East Technical University Molecular Biology and Biotechnology R&D Center

Sub-Fields of the Projects:

Genomics; genetic modification; biotechnological enzyme production, food microbiology, food control, nanobiosensors, medical imaging, vaccines, antibodies, antisera, new active ingredient development, biochemical system modeling, drug production and controlled release systems, biomaterials research, polymorphism research,

<https://merlab.metu.edu.tr/tr/molekuler-biyoloji-ve-biyoteknoloji-ar-ge-merkezi>

**Name of the Center:**

Istanbul Medipol University Regenerative and Restorative Medicine Research Center

Sub-Fields of the Projects :

Regenerative medicine (nervous system regeneration, cardiovascular system regeneration, epimorphic regeneration, stem cell and cancer relationship, biocompatible materials, prosthesis and bioimplants Rehabilitation, neuromodulation, microbiome, complementary medical applications), genomics, proteomics, cell culture,

<https://www.medipol.edu.tr/akademik/arastirma-merkezleri/saglik-bilim-ve-arastirma-enstitusu?cat=14>

**Name of the Center:**

İzmir Institute of Technology Biotechnology and Bioengineering Research and Application Center (BİYOMER)

Sub-Fields of the Projects :

Pharmaceutical production and controlled release systems, development of biotechnological drugs/new drugs/vaccines, antibodies, antisera and new active ingredients, biological enzyme production and biomaterial research, nanobiosensors

<https://biyomer.iyte.edu.tr/>

Dokuz Eylül University İzmir International Biomedicine and Genome Institute; Established within Dokuz Eylül University with 150 million TL investment support supplied from the Directorate of Strategy and Budget of the Presidency of Turkey and other resources, the Institute is the first and only international biomedicine and genome center of Turkey. Turkey's largest and most advanced research center iBG-izmir has advanced devices used for the first time in Turkey, therapeutic cell and drug production areas, biobank and genome analysis departments.

D. INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS (IIPR)

In the healthcare sector, 3% of the patents published among the priority patent applications made in Turkey are related with biotechnology. Analyzes of the patent applications in the field of biotechnology on yearly basis indicates a rising trend. Although the number of applications made has still not reached satisfactory levels, the progress made since 2010 is an indication of great development.

Patent Applications In The Field Of Biotechnology In The Last 10 Years

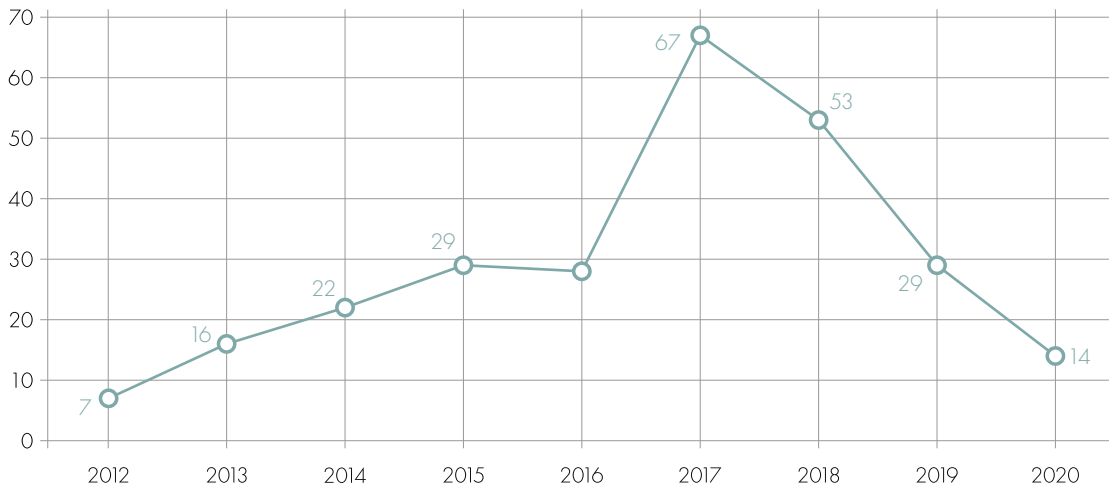


Figure 7. Patent Applications in the Field of Biotechnology in the Last 8 Years

The number of patent applications made by leading institutions/organizations that made patent applications in the field of biotechnology is shown in Figure 10. The top institutions in biotechnology patents relating to health are Istanbul University, Yeditepe University and TÜBİTAK. The low number of the applications made in the field of biotechnology and the companies that make these applications demonstrates that the field is open to development.

Leading Institution/Persons In Patent Applications In The Field Of BIOTECHNOLOGY

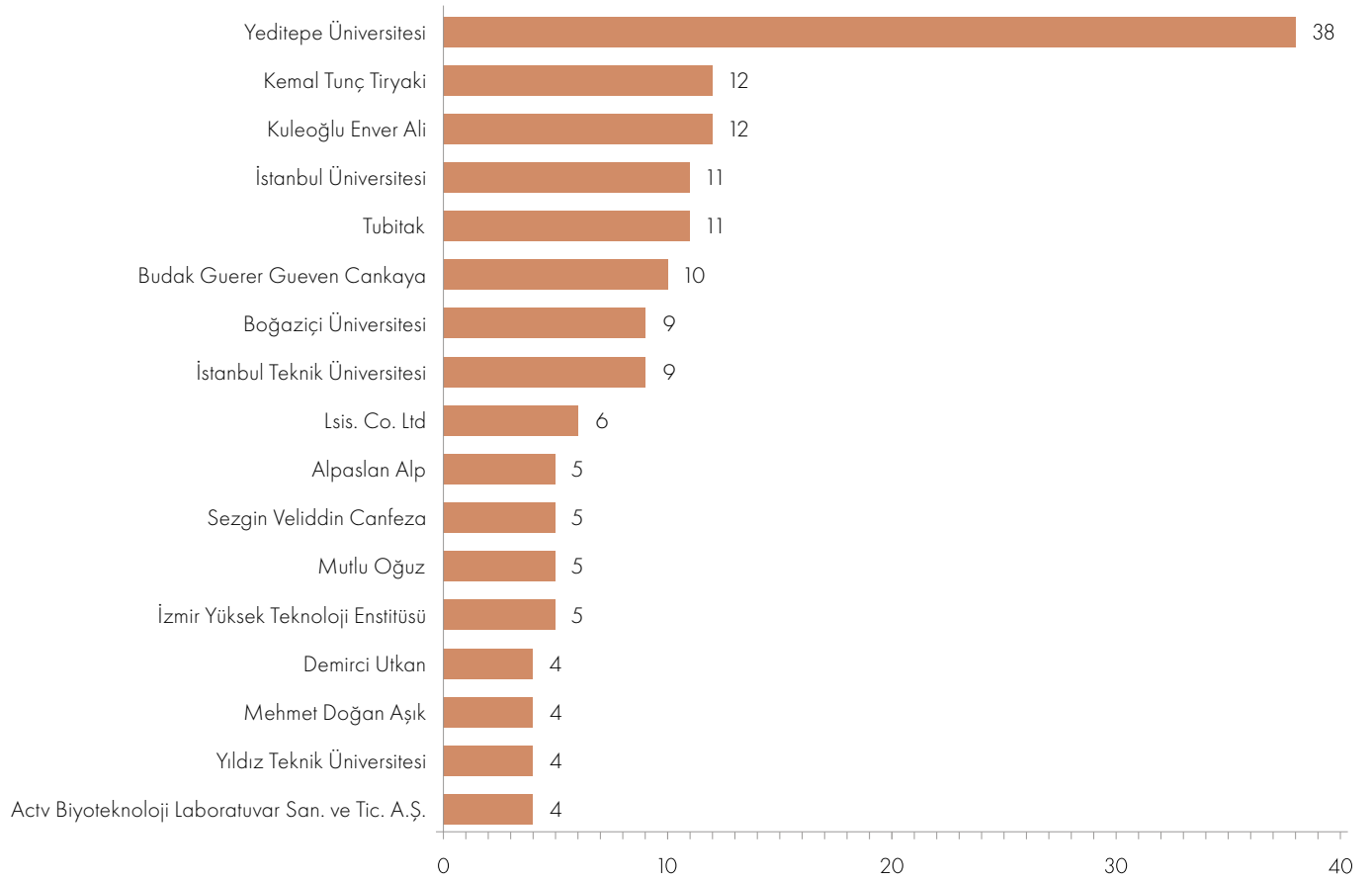


Figure 8. Institutions and Organizations with Patent Applications in the Field of Biotechnology

The yearly changes in the applications of top 20 owners of priority patent applications of Turkey in the field of biotechnology, the new entrants in the field and institutions which paused their studies in the field are shown in Figure 11.

Heat Map in the Field of Biotechnology in the Last 9 Years	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Yeditepe Üniversitesi			1	1	1	1	12	14	6	2
Kuleoglu Enver Ali							10	1		1
Kemal Tunç Tiryaki						1	5	6		
TÜBİTAK				1	10					
Budak Guerer Gueven Cankaya				9			1			
İstanbul Teknik Üniversitesi							2	7		
Boğaziçi Üniversitesi			9							
Hacettepe Üniversitesi								3	4	1
İstanbul Üniversitesi				3		3	5			
Lsis. Co. Ltd.							6			
İzmir Yüksek Teknoloji Enstitüsü							1	2	1	1
Mutlu Oğuz					1	4				
Sezgin Veliddin Canfeza					5					
Alpaslan Alp	5									
Actv Biyoteknoloji Laboratuvar San. ve Tic. A.Ş.							2		2	
Yıldız Teknik Üniversitesi							1	3		
Mehmet Doğan Aşık						1	3			
Demirci Utkan						1	3			

Figure 9. Heat Map of the Patent Applications in the Field of Biotechnology in the Last 9 Years

It is observed that Yeditepe University has been actively continuing its studies in the field of biotechnology since 2013. With the patent applications made in 2017 and 2018, Yeditepe University constitutes the hottest part of the map, ranking first in the field.

F. ACADEMY

The number of academics engaged in studies on biotechnology increases every year in our country and has reached 1,968 according to current data (2019).

It would be beneficial to mention some scientists who have conducted very important studies in the field of biotechnology in Turkey in this section.

Prof. Dr. Fazilet Vardar, is one of the pioneers of bioengineering in Turkey, and won the TÜBİTAK Incentive Award in the “Field of Bioengineering” in 1989. He is a member of the European Patent Office EPO Academic Advisory Board, AUTM International Committee, EuKTS Board of Directors and ASTP-PROTON NAAC. He has about 200 scientific publications, 15 of which are about R&D and Innovation Policies, 6 books and 23 book chapters 13 of which are about R&D and Innovation policies, as well as numerous scientific papers and 3 patent applications. He has been peer reviewing many scientific journals. He has been involved in 67 national and international projects, 29 of which are in the field of bioengineering. 21 of these were supported by different international sources, primarily the EU Framework Programs.

Prof. Dr. Fikretin Şahin conducts scientific studies on the molecular diagnosis and characterization of microorganisms of clinical, food, environmental and plant origin and the development of biological formulations for industrial use, as well as the development and production of antimicrobial materials, stem cells, gene therapy and cancer. He has been granted various awards by national and international institutions due to the scientific studies he carried out throughout his academic life. Prof. Dr. Şahin has most recently won the grand award for scientific dissemination and stated that he is working on next generation cancer drugs in the areas where gene therapy and biotechnology are joined, and that a significant part of them has reached the stage of patenting, while some of them have reached the clinical stage.

Prof. Dr. İsmet Deliloğlu Gürhan conducted scientific studies on monoclonal antibody production, biocompatibility of biomaterials, wound healing, 3D cell cultures, scale-up in cell cultures, mesenchymal stem cells, viral vaccines and recombinant protein production. He wrote 97 papers presented at national meetings and 108 papers presented at international meetings. He has 8 books, 56 completed projects and 14 awards.

Prof. Dr. Işıl Kurnaz carries out scientific studies on molecular neurobiology, gene regulation, ETS proteins, neuronal survival, neuroprotection, neurodegeneration, and brain tumors. Important outputs have been presented to the international scientific community by the researches performed on extensions of the nerves called axons, through which nerves connect with each other, in the Molecular Neurobiology Laboratory directed by her. As a result of their findings, it was announced that damaged nerve cells could be regenerated for the treatment of Alzheimer's and Parkinson's. These scientific findings were published in the PLoS One Journal in USA.

Assoc. Dr. Özgür Urartu Şeker works on synthetic biology, genome engineering and nanobiotechnology. Assoc. Dr. Şeker and his team have developed a new system for the diagnosis of Covid-19. This project was financially supported by Bilkent University UNAM and TÜBİTAK. "Synthetic key systems for coronavirus detection" were developed using synthetic biology and advanced genetic engineering methods in the project. The diagnostic system developed with synthetic biology was transformed into a device using 3D technology.

Dr. Devrim Demir Dora is interested in the research areas of recombinant protein production, production and licensing of biotechnological and biosimilar drugs, development of biopharmaceuticals, nanotechnology, medicinal products for advance therapy, medicinal products for gene therapy, development of non-viral nucleic acid delivery systems for gene therapy, cancer treatment, bacterial transformation, quorum sensing mechanism and genetic competence. The 'Bacterial Transformation Kit' is patented.

05

Clinical Studies

Report on R&D and Engineering Capabilities
in the Healthcare Sector in Turkey

CLINICAL STUDIES

In terms of the number of clinical studies carried out, Turkey globally ranks 26th with 521 clinical studies (2019). Turkey already has a significant infrastructure in terms of clinical researches and has the potential to triple its capacity in the medium term. The total economic value of the clinical researches carried out in Turkey is estimated as 327.7 million USD annually as of June 2019.

The value of the employment created in Turkey thanks to the clinical researches is approximately 44.5 million USD.

The total economic value of the clinical researches carried out in Turkey is estimated as 327.7 million USD annually as of June 2019. The total economic value includes both the clinical research investments in Turkey estimated at 139.0 million USD (788.8 million TL) and the added value of the innovative pharmaceuticals provided to clinical study volunteers, which is estimated at 188.7 million USD. Since the industry-backed clinical researches are primarily carried out by multinational pharmaceutical companies in Turkey, a large portion of the money spent for clinical researches is considered as foreign direct investment. This means that the clinical research investment of 139.0 million USD (788.8 million TL) made in Turkey directly contributes to the macroeconomic balance, which is one of the main objectives of the New Economy Program.

Turkey's Strengths in Clinical Studies in terms of the Country's Attraction Factors	
Patient Pool	
Process Time Planning	
HRA and Quality Standards	
Reimbursement of Standard Treatment	
Patient Recruitment and Easy Access to Patients	
Easy Access to Treatments	
Ease of Processes	
Increasing the Number of Researches	
Doctor Incentives	
Physical Facilities	
Supporting Incentives	

Kaynak: IQVIA

A. PUBLIC SECTOR

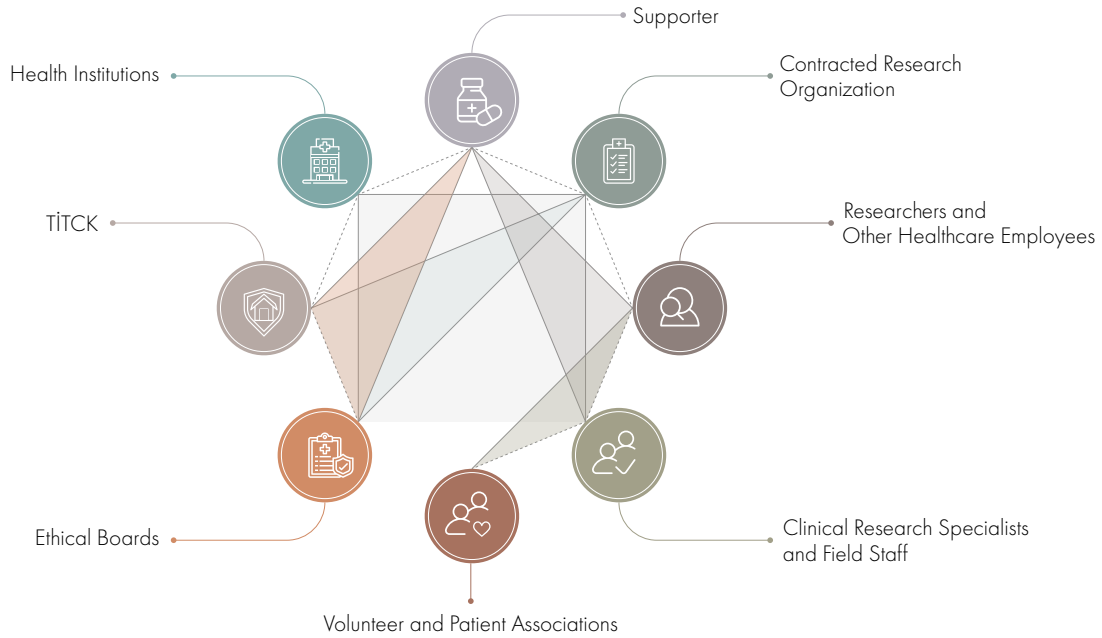
The 11th Development Plan

The aim to “become a leader in clinical researches” is emphasized in the 11th Development Plan. The 11th Development Plan underlines that clinical researches are R&D activities, in order to support pharmaceutical R&D activities and increase the scientific contribution of clinical researches.

According to the Plan, all clinical researches conducted before licensing the product shall be considered within the scope of R&D, without any prerequisite (The 11th Development Plan, 366.1). Furthermore, according to the Plan, information programs regarding incentives and intellectual property rights will be presented to pharmaceutical developers, primarily the researchers at universities, in order to accelerate the commercialization process. (The 11th Development Plan, 363.5)

It is estimated that the studies to be carried out in the field of public sector will ensure an average yearly growth of 10.3% in the first 8 years and 1,142 clinical researches in 2027, under the moderate growth scenario. Under the rapid growth scenario, it is estimated that 1,656 clinical researches, which is more than three times the current figure, will be reached in 2027.

Figure B. Clinical research stakeholders in Turkey



2020-2022 New Economy Program and 2020 Presidential Annual Program

2020-2022 New Economy Program (Medium Term Program) and 2020 Presidential Annual Program have laid down the actions required to reach the Plan's political goals. The Annual Program poses the following questions in particular: "How can the national R&D environment be supported to assist the development of innovation and boost Turkey's competitiveness in the international arena?" and "how can Turkey become the economic leader of the region by building a bridge between the EU and the Middle East?". The specific goal set for the pharmaceutical sector in the plan is to increase the country's competitive power and bring it to a higher position in the global value chain in pharmaceuticals. To this end, it is believed that innovation and R&D are critically important and numerous policy targets have been presented to support innovation in the sector. Acknowledging the critical importance of clinical researches in the pharmaceutical R&D process, the Plan sets a specific policy goal regarding the field: Making Turkey the regional leader in the field of clinical researches.

Turkey already has a significant infrastructure in terms of clinical researches and has the potential to triple its capacity in the medium term. Turkey does not have to wait for 10 or 20 years to become one of the top 10 countries in the global ranking for pharmaceutical R&D. Turkey is well positioned to make significant progress in 3 to 8 years, by focusing on clinical researches and implementing correct policies.

In addition to these strategic policy documents, the strategic plans of the Ministry of Industry and Technology, TITCK and Presidency of Health Institutes of Turkey (TÜSEB) also support innovation and R&D in the pharmaceutical and medical devices sector, with specific policy goals and action plans in the fields of activity.

2019-2023 Ministry of Health Strategic Plan

The purpose is to encourage R&D and innovation and increase domestic production and exportation in healthcare services by creating an attractive environment for clinical researches. TÜSEB has been given the responsibility for the actions planned within this context. Furthermore, it is aimed to support R&D activities for priority health products such as drugs, vaccines, diagnostic kits and biomedical equipment and to cooperate with other organizations such as TÜBİTAK and the Ministry of Industry and Technology in order to ensure that the healthcare sector derives more benefit from R&D and technology supports provided by these institutions. In line with the policy goals specified in the strategic documents, TÜSEB describes its strategy as encouraging and supporting R&D activities in the field of healthcare in the 2019-2023 Strategic Plan, presenting a detailed action plan and setting the performance indicators in this regard.

Figure 14. Distribution of phases and supporters of interventional clinical researches in Turkey

Source of the Support	Phase I - IV	Not Applicable	Total
Industry-backed Research	521	18	539
Research Supported by Other Institutions/Organizations	138	409	547
TOTAL	659	427	1086

Source: www.clinicaltrials.gov

To date, the Scientific and Technological Research Council of Turkey (TÜBİTAK) and TÜSEB have provided support for R&D activities for innovative drugs whose molecules are developed in Turkey, and medical devices whose prototypes are produced locally. Particularly TÜSEB called for cooperation with the developers to achieve this goal and has started to evaluate the project proposals received. TÜSEB published a total of 15 calls to support clinical researches in 2019 and 2020.

The Clinical Research Center, established under the Presidency of Health Institutes of Turkey (TÜSEB), coordinates clinical research conducted with the support of TÜSEB. In this context, it aims to dynamically develop the clinical research ecosystem in Turkey with groups including academics who are experienced in clinical research and who are registered on the TÜSEB Information Management System (TBYS). All academics, researchers, contracted research institutions (CRIs) and established clinical research centers that are registered on TBYS platform, that work for universities and research organizations and that are included in the eleventh development plan regarding clinical researches can be coordinated in cases where necessary.

B. PRIVATE SECTOR



Clinical research organizations that lead clinical researches in Turkey.

The research conducted by IQVIA demonstrates that the total size of the labor created through clinical researches is approximately 1,400 individuals. Approximately 720 clinical research specialists and managers, 470 field officers, 160 regulatory and center initiation managers and other staff, as well as 35 clinical research directors and senior management staff are employed by CRIs, central administration organizations and supporting companies in Turkey.

While investing in R&D centers, the sector players also establish partnerships with universities for the development of new drugs and medical technologies. The focus of R&D activities in the sector, which was formerly making additions to the existing molecules, changed over time and has now shifted to the development of biosimilar products, innovative application methods, new treatments, fixed dose combination drugs and new production methods.

Figure 18. Industry-backed active clinical researches in Turkey

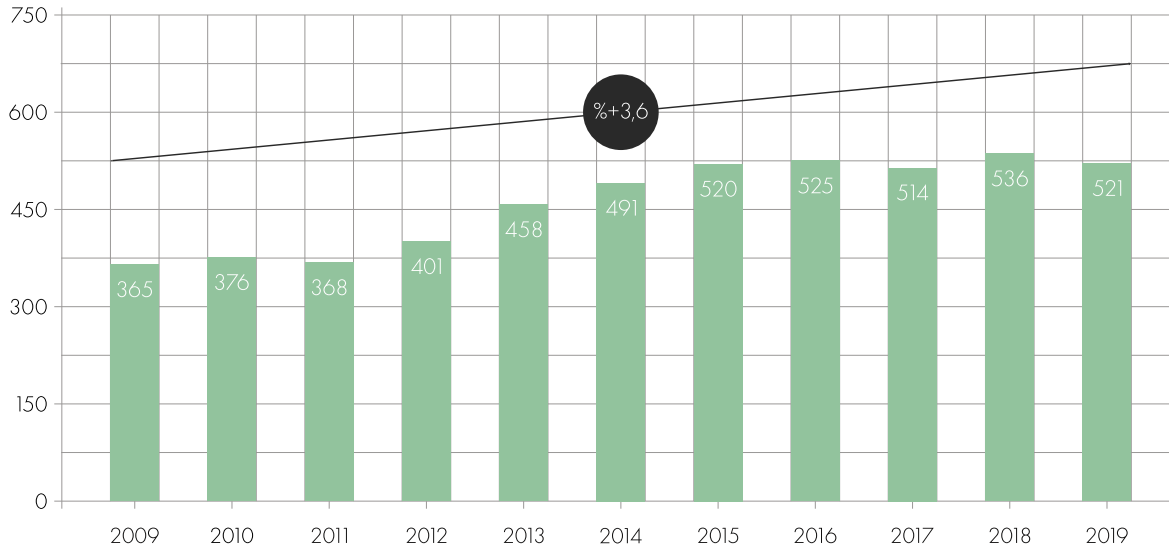


Figure 18: www.clinicaltrials.gov IQVIA Analizi

Example Case: RS Research

RS Research is a pharmaceutical company developing next-generation nanodrugs on innovative drug delivery platforms for targeted cancer therapy. Financed by venture capital, the company was founded by Prof. Dr. Rana Sanyal, a faculty member of Boğaziçi University Chemistry Department, and entrepreneur Sena Nomak in March 2015 in Istanbul. The Company's business model, which was developed by Boğaziçi University, Center for Life Sciences and Technologies (LifeSci), allows the company to benefit from the center's established infrastructure, while allowing the center to collect additional funds to support the platform's sustainability.

Using this infrastructure, RS Research developed a global, patented, new nanomedicine platform for drug delivery. The drug candidates in the company's portfolio, which target a range of cancer types, combine the efficacy of chemotherapy with the precision of tumor targeting.

The leading drug candidate in the Company's range of products received Investigational New Drug (IND) approval from TİTCK in 2017 and its R&D process is planned to be carried out the University of Health Sciences, Ankara Abdurrahman Yurtaslan Oncology Training and Research Hospital Phase 1 Center in Turkey from the initial stage.



C. Research Infrastructures

There are a total of 1,664 hospitals in Turkey, including public and private hospitals; however, clinical researches are mainly conducted in university hospitals (public or private) and training-research hospitals (including city hospitals containing training-research hospitals). The total number of these organizations in Turkey is 228 and 116 of them are university hospitals. The distribution of clinical studies by health organizations in 2019 shows that most of the studies are conducted in university hospitals.

University hospitals have the largest share in Phase II, III and IV clinical researches. In terms of their share in the overall clinical research burden, all of the top 15 clinical research centers are affiliated to a public or private university hospital.

Figure 22. Distribution of hospitals in Turkey

ALL HOSPITALS • 1.664				
All State Hospitals • 1.064			All Private Hospitals • 1.064	
State • 868	Education and Research • 112	University • 868	University • 32	Private • 32
Health Organizations where Clinical Researches can be Carried Out				

Source: IQVIA Analizi OneKey Veri Tabanı

Figure 23. Top 15 clinical research centers in Turkey

Top 15 Centers (By Estimated Share In General Clinical Research Burden)	Estimated Share In The Total Clinical Research Burden (%)
Hacettepe University Faculty of Medicine	10-15
Ege University Faculty of Medicine	10-15
Ankara University Faculty of Medicine	8-13
Kocaeli University Faculty of Medicine	8-13
İstanbul University Cerrahpaşa Faculty of Medicine	8-13
Gazi University Faculty of Medicine	7-12
Akdeniz University Faculty of Medicine	5-10
Karadeniz Teknik University Faculty of Medicine	4-9
Acibadem Adana Hospital (Acibadem University)	4-9
Mersin University Faculty of Medicine	4-9
Ondokuz Mayıs University Faculty of Medicine	4-9
Dokuz Eylül University Faculty of Medicine	3-8
Trakya University Faculty of Medicine	3-8
İstanbul Medeniyet University Göztepe Education & Research Hospital	3-8
Marmara University Pendik Education & Research Hospital	3-8

Source: IQVIA Analizi

Figure 24. Phase I clinical research centers in Turkey

Phase I Clinical Research Centers
Ege University Research and Application Center of Drug Development and Pharmacokinetics (ARGEFAR)
Dokuz Eylül University Phase 1 Clinical Trial Center
Ege University Faculty of Medicine Pediatrics Hospital- The Clinic of Pediatric Hematology
Erciyes University Hakan Çetinsaya Good Clinical Practices & Research Center
Gazi University Hospital, Department of Pediatric Metabolism
Koç University Phase 1 Clinical Trial Center
Health Sciences University Oncology Education & Research Hospital Phase 1 Center
Health Sciences University Chest, Vein and Cardiac Surgery Education & Research Hospital

Source: [TİTCK](#)

It is estimated that the number of specialist doctors participating in clinical researches as researcher is approximately 4,000, and 10 to 15% of these doctors assume the role of head researcher.

Recently, a Clinical Research Center has been established within TÜSEB. One of the purposes of the center is to ensure that researchers who would like to conduct clinical researches are directed to the institutions where the studies will be carried out and the studies are followed up and supported within TÜSEB, which is a public organization.

D. Other

The Clinical Research Association was established in 2006 to ensure the development of clinical researches in Turkey in accordance with universal standards and regulations. It supports the conduct of clinical researches at universal standards in Turkey and engages in educational activities for this purpose. The Association cooperates with international organizations and brings together representatives of academia, industry and national authorities to ensure excellence in clinical research in our country. By undertaking activities which can set examples for Turkey and the surrounding countries as well, the Association reached almost 300 members. The Clinical Research Association organizes scientific congresses, seminars, training programs and issues publications in the field of clinical research. In addition, it cooperates with national and international ministries, universities and other relevant organizations, World Health Organization (WHO), European Medicines Agency (EMA), The United States Food and Drug Administration (FDA), National Institutes of Health (NIH) and Drug Information Association (DIA) about clinical researches.

Association of Contract Research Organizations (SAKDER) aims to ensure professional solidarity of Contract Research Organizations in Turkey, to solve possible problems by negotiating with the relevant parties on behalf of its members, to represent its members on relevant platforms, to improve and increase the quality of the services of its members for the pharmaceutical/health sectors, to solve the problems arising from the pharmaceutical/health researches, to ensure that the related private and legal persons are informed about and execute international applications, and to establish and develop the related legislative and professional ethical norms.

06

Incentive and Support Mechanisms

Report on R&D and Engineering Capabilities
in the Healthcare Sector in Turkey

Technopark Incentives

Under the Law no. 4691 on Technology Development Zones, the following incentives are available for organizations operating in technology development zones:

- 22% Income and Corporate Tax exemptions based on earnings
- Exemptions regarding wages
- 18% Value Added Tax Exemption
- Customs Duty Exemption

R&D Center Tax Incentives

Under the Law no. 5746 on Supporting Research and Development Activities, R&D Centers certified by the Ministry of Industry and Technology of Turkey are entitled to benefit from the following incentives:

- R&D Allowance 100%
- Income Tax Exemption 80-95%
- SSI Employer's Share Support %50
- Stamp Duty Exemption 100%
- Customs Duty Exemption 100%

Investment Incentive System

Support Elements	General Incentive Applications	Regional Incentive Practices	Incentivization of Primary Investments	Incentivization of Strategic Investments
VAT Exemption	✓	✓	✓	✓
Customs Duty Exemption	✓	✓	✓	✓
Tax Reduction		✓	✓	✓
Social Security Premiums Employer's Share Support		✓	✓	✓
Income Tax Withholding Support	✓	✓	✓	✓
Social Security Premium Employee's Share Support		✓	✓	✓
Interest and Dividend Support		✓	✓	✓
Investment Area Allocation		✓	✓	✓
VAT Return				✓



TÜBİTAK Supports

	Big Company		SME		Individual Entrepreneur		Goal-oriented
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1. 1501 • Industrial R&D
2. 1503 • Project Markets
3. 1507 • SME R&D
4. 1505 • University - Industry Cooperation and SanTez
5. 1509 • International Industry R&D Support
6. 1511 • Priority Fields R&D
7. 1512 • Techno - Initiative Individual Young Entrepreneurs (BİGG)
8. 1513 • TTO Support
9. 1514 • Venture Capital Investment Fund
10. 1515 • Pioneering R&D Laboratory
11. 1601 • Innovation and Entrepreneurship Capacity Building
12. 1602 • Patent Support

1501 Industry R&D Program	
Grant Support Rate	75%
Maximum Project Duration	36 Months
Maximum Project Budget	Varies depending on the call.
Payment Period	In 6-month periods
Project Idea Owner Award	7,500 TL
Call Periods	2 calls a year, in 6-month periods, and 2-month application periods 1st Call: January-March 2nd Call: July-September

TÜBİTAK 2020-2021 / Health (Private Sector)

Priority Technology Areas	Planned Total	Priority R&D and Innovation Subjects			
Digital Technologies in Healthcare	4	E-Health Applications	ICT Based Innovative Medical Devices	Big Data and Data Analytics in Healthcare	Artificial Intelligence Technologies in Healthcare
Pharmaceutical*	4	Blood and Blood Products	New Molecule Discovery for Innovative Reference Drugs	Controlled/Targeted Drug Delivery systems for Cancer and Autoimmune Diseases	Biotechnological and Biosimilar Drugs
Biomedical Equipment Technologies	4	Innovative Implants	New Generation Prosthesis and Orthotics	Innovative Medical Imaging Systems	Robotic Surgery Technologies
Bionanotechnology and Biomaterials	3	Personalized Medicine: Diagnosis & Monitoring Technologies	Innovative Medical Consumable	Regenerative Medicine and Artificial Tissues/Organs	
Vaccines	1	Diagnostic and Monitoring Technologies			
Diagnostics/ Diagnostic Kits	1	Domestic Diagnostic Kits			

Source: TÜBİTAK 1501 and 1507 Programs Priority Areas

07

Good Practices and Investment Examples

Report on R&D and Engineering Capabilities in
the Healthcare Sector in Turkey



Güldem BERKMAN

General Manager - Amgen Turkey & Gensenta



1. Gensenta is one of the most important and established companies of our country's pharmaceutical industry. We observe that Amgen has also invested in the company's future, with its investments made in 2012 and subsequent years. What is your opinion of Gensenta's current situation and its position in the sector?

After the first 2 years we spent in the Turkish market, which we had entered in 2010 as Amgen, we acquired Mustafa Nevzat İlaç, which was established in 1923 and is one of the first biosimilar producers of Turkey with a well-established background, and Gensenta with its renewed image, for an amount of 700 million USD. This investment placed us among the top 10 global companies which directly invest in Turkey across all sectors in the last 10 years. In this respect, we operate in the field of biotechnology with Amgen and in the field of generics and biosimilars with Gensenta in Turkey. We have two production facilities producing finished products and active ingredients under the organization of Gensenta in Turkey. We invested an additional 125 million USD in these facilities in the last 8 years and are now at world standards in terms of biotechnological drug production.

As Amgen Turkey and Gensenta, we are honored by the impact we have on our country with a total of over 1000 employees in our two companies, our high value-added exports, and our contributions to science and human health.

2. With your recent investments, you also stand out as a center where biopharmaceuticals are offered to the surrounding markets. What can you share with us about Gensenta's position in markets outside of Turkey, as a pharmaceutical development, production and export base?

In addition to our efforts to export the first and only biosimilar product in Turkey, we are one of the companies with highest R&D expenditures of our country, with the additional investments we make in our facilities in Turkey for production and export of biotechnological pharmaceuticals. We aim to export to the 5 biggest regions that cater to 70% of the world's pharmaceutical market, by developing innovative products with high added value in Turkey. We have made additional investments worth 35 million USD for the production and export of biotechnological pharmaceuticals and 40 million USD to bring the Gensenta production facilities to Amgen's standards, and we continue our investments. One of our goals is increasing the number of products whose raw materials are also developed and produced by us within Gensenta's finished product portfolio.

3. What do you think of the progress made by the Turkish pharmaceutical industry in the fields of R&D, innovation and biotechnology in recent years? Could you briefly talk about your company's R&D activities and cooperation efforts?

Gensenta owns the only penicillin production facility in Turkey and became the first Turkish pharmaceutical manufacturer to receive FDA approval for a finished product, after its raw material and finished product facilities were approved by the FDA in 2006. As Gensenta, we produce active ingredients of penicillin group, active ingredients of macrolide group and active ingredients of other drugs, while meeting a significant part of the lyophilized vial capacity in Turkey. We have undertaken the mission to contribute to the priorities set in the Pharmaceutical Strategy Report of Turkey, such as export, domestic production and R&D. Gensenta has approximately 300 licensed products in total and approximately 30 products whose applications are in progress.

4. We know that your Company's R&D center is accredited by the Ministry of Industry and Technology. What can you tell us about the contribution of public supports to research activities?

We believe that public supports have made invaluable contributions particularly to development activities to date. It is important that such projects reach more global scales and are capable of guiding research activities as well. In our opinion, it would be critical for the future to increase the number of and diversify the cooperation-oriented programs, considering the needs of the patients and stakeholders in countries' healthcare systems.

5. One of the most important values for both research and production is human resources. What can you tell us about the ease of accessibility and quality of the qualified labor in our country?

Our country has a rich source of qualified labor. The world-class education received and the projects undertaken by the candidates at universities, as well as the increasing number of university-industry cooperation programs, add value to the quality and enrichment of the qualified workforce.

To encourage the young generation to join our company, first of all, we maintain a presence on the right platforms particularly on the social media channels they follow, on new career platforms and cooperations, by keeping close track of technology.

We reach out to hundreds of teachers and thousands of students through the projects of Amgen Foundation, in order to contribute to the education of future scientists in Turkey. Within the scope of Amgen Scholars, which is one of these projects, a total of 48 students from Turkey added exciting experience to their career journey with the projects they worked on for 8 weeks in European universities within the last 10 years.

The trainings delivered to primary and secondary school science teachers under the "Amgen Teach Hand in Hand for Science" project, which we have been implementing since 2014, ensure that teachers understand, love and question science. In this context, we have reached more than 400 teachers and almost 60,000 students through the cooperation of the Development Workshop, Koç Schools and ODTU BILTEMM in Turkey.



Prof. Dr. Cengizhan ÖZTÜRK

Coordinator - ISEK

Board Member - LifeSci



1. We are looking at a story that starts with the foundation LifeSci-Boğaziçi University Center for Life Sciences and Technologies in 2009 and continues with the Inovita-Health Technologies Incubation Center and Istanbul Health Industry Cluster afterwards. Could you tell us about these structures, laboratories and research opportunities and their effects on the healthcare entrepreneurship and technology ecosystem?

Boğaziçi University Center for Life Sciences and Technologies-LifeSci, which was established in 2009, still continues its establishment studies starting with the contribution of more than 50 million TL provided by the Ministry of Development, with additional development projects and different resources/supports. Researchers and scientific expertise in various academic units have come together in an interdisciplinary work spirit at the center. Together with the academics from Boğaziçi University who support the center and their students, more than 100 scientific research projects (micro and nano devices, molecular level imaging methods and analyses, robotic devices, materials for biosensing platforms, smart drug delivery systems, vaccine delivery technologies, algae food supplements, etc.) supported by national and international funds such as the Ministry of Development, Development Agency of Istanbul, TÜBİTAK and European Union are carried out constantly at the center and its affiliated laboratories. According to the LifeSci Wonders-2018 study, around 560 publications were issued and more than 2,600 citations were received, while consultation was provided for approximately 360 postgraduate theses and 13 patents related to these researches were obtained as part of the center's efforts. The center contains Medical Device Development, Vivarium and Test-Analysis Departments. Some of these departments are accredited, while the accreditation processes of some are ongoing, and they can provide academic and industrial services that complement each other. Infrastructure is provided for large projects that aim to contribute to Turkey's economy and increase the quality of human life, by creating innovative approaches and products in cooperation with other academic and industrial organizations.

The Center launched the Inovita Life Sciences and Technologies Istanbul Cooperation Platform in 2010 with the support of ISTKA, with the aim of creating an interface between the university and the industry for the commercialization of scientific researches conducted and new technologies developed in the field of life sciences and technologies. To support the innovative ideas in the field, Inovita Health Technologies Incubation Center, the first thematic incubation of Turkey, was established with the support of ISTKA in 2012. Through these projects, trainings and workshops attended by 905 entrepreneurs were organized, 29 thematic seminars were held and it was decided to support 23 of the 40 projects which participated in the jury evaluations.

As a result of these efforts, Istanbul Health Industry Cluster-ISEK was established in 2015 and became eligible for receiving support within the scope of the Cluster Support Program of the Ministry of Industry and Technology, under the coordination of Teknopark İstanbul A.Ş., a co-founder of the cluster, as of 2017. ISEK is a thematic regional project, which started out with the aim of becoming a regional development project in the healthcare sector in Istanbul Region and which currently continues its activities with more than 180 companies, research centers affiliated to 22 different universities, 14 related NGOs and 3 public organization members.

While setting up the main business packages of the cluster, it was aimed to increase the sector's export capacity and support the production of products with high added value in our country. In this respect, the business packages were created to provide support in the basic matters where a deficiency is perceived in the current ecosystem, taking into account a product's development process and the expectations/needs of the sector.

Business packages involving the conduct of prototype and pilot production, testing of products in accredited laboratories and creation of common marketing and sales strategies, starting from the first emergence of a right entrepreneurial idea and its maturation in all aspects within a systematic process were set up. These are 1. Medical Device Pilot Production Facilities, 2. Accreditation of Medical Device Test Laboratories, 3. Medical Sector Analyses, 4. Bioentrepreneurship and Innovation Program, 5. Innovative University-Industry Cooperation Activities, 6. Institutional and Organizational Structure and Strategic Development.

With these studies continued in collaboration with the sector since 2010, a number of firsts were implemented vertically in the health technologies in Turkey; investments were made/encouraged for enhancing the ecosystem by bringing together the sector stakeholders and a bridge was built between the policy makers and producers by raising awareness. The university-industry-public cooperation projects led by the center aim to ensure the provision of sectoral services at international standards, to enhance the ecosystem and consequently increase value-added production. The center and its related departments are open to cooperation to increase the impact of the studies carried out as needed within this framework.

2. We are actually talking about the most popular centers in the university-industry-entrepreneurship triangle for health technologies in our country. What are the fields on which your activities are focused?

At BU LifeSci, some important sub-headings in the broad field of life sciences are gathered around three key infrastructures: 1) Intra-body device technologies within the Clean Room, which was established as part of the 'Department for Microsystem Based Medical Device Development', 2) Molecular biological and biotechnological studies based on the 'Experimental Animal Production and Care Department (Vivarium)', 3) the 'Test/Analysis Department' which consists of devices open to public use in various departments and which mainly hosts studies focused on smart drug binding/targeting technologies. Many projects are carried out in collaboration with the sector within the scope of these infrastructures.

Within the scope of implementation of the clean rooms, which is one of the main activities of ISEK and which will support the companies in the sector to enter R&D and cooperation projects in order to eliminate the foreign dependency in the field of healthcare, pilot production processes compliant with ISO 13485 and GMP requirements were set up within the cluster coordinator Teknopark Istanbul and provide services to companies. In addition, Teknopark Istanbul Incubation Center-CubelIncubation enables the implementation of important projects in the health technology ecosystem with the physical infrastructures and support mechanisms it provides. Studies to increase the capacities of these special infrastructures continue with specialized field setups and programs.

In addition to the funds provided by the Ministry of Industry and Technology, Ministry of Commerce and ISTKA, processes relating to applications for international funds focused on increasing the clustering capacity and supporting SMEs are carried out. In this context, a Cluster Go International project application was made in partnership with ISO-ISEK.

As part of development of health-oriented regional strategies, studies are carried out in cooperation with different institutions. The Healthtech Startup URGE program, implemented under the coordination of IKMIB-ISEK to increase the international activities of SMEs, has been launched with the participation of 20 member companies. Studies on Accredited Laboratories, which are critical for MDR compliance, are also ongoing. In this context, it is planned to launch a Quality Academy study in 2021.

ISEK took civil initiative and worked closely with public authorities also during the COVID process, which directly concerns and affects the sector. In this respect, the studies are shaped according to the needs of the sector as well.

3. How did the research and technology ecosystem of the life sciences develop in our country during this time?

It could be said that important developments took place in every subject in the field of life sciences and health technologies in the last 20 years. Technological infrastructures, human resources and the quality and quantity of projects have developed particularly upon the creation of many incentive and project support opportunities by the state, efforts to institutionalize the R&D culture at universities, and opening of technology transfer, project support and patent offices in addition to numerous new institutes and centers. Although these developments are quite important, they are not sufficient for our country. First of all, smarter investment/project supports and more patient planning activities fully coordinated among the relevant institutions are needed. Comprehensive cooperation activities focused on subjects which have priority for Turkey, but which are also relevant on a global level should be increased. By scheduling the plans as medium and long term and allocating resources accordingly, exports of value added products in the field could be increased to very high levels.

The most important 5 parameters which can bring Turkey to a competitive position on global scale in biotechnology and life sciences can be listed as follows.

- Establishing a clear national strategic roadmap on a local and global scale. (We need to have a national strategic roadmap which is supported by public policies but most importantly, which are predictable). Public involvement in the development of this strategy is necessary, but it should be essentially formulated by the value-creating stakeholders of the sector (universities, industry, NGO, entrepreneurs...).
- Allocation of sufficient resources focused on the health and life sciences sector by the public and private sectors. Focused, long-term and high-volume investment funds are necessary for this sector (the funding needs of entrepreneurs not only at research and early stages, but also those at different stages of development should be met)
- Enabling the bottom-up development of qualified and scalable ideas/projects
- Continuation of the support provided to establishment of all necessary infrastructures and interfaces (university research/service labs, accredited test labs, pilot production areas...)
- Ensuring a full integration of research, development and commercialization into the global system, propagating good examples and practices

4. Experienced human resources are among the most important assets in terms of technology and research. What do you think about our human resources in health researches as university-based initiatives? Do you think that Turkey is positively distinguished in terms of human resources in both research and entrepreneurship fields?

In addition to our current institutions that provide education at international standards, universities and focused programs whose number has been increasing in recent years are positive developments that support trained human resources. The trained manpower cannot meet the sector's needs in the processes relating to the implementation of innovative projects and conduct of technical researches in health technologies, which have become more important especially during the pandemic. Collaborative projects such as the industrial doctorate program can make a significant contribution to boosting the qualified workforce. University-industry collaborations are important for implementing advanced ideas put forward in scientific researches and for the transfer of knowledge to create a technology. The full maturation and institutionalization of these collaborations can ensure both the training of qualified manpower for the industry and the implementation of a series of successive projects that are based on basic sciences, but that can be commercialized. It is critical to support interface structures such as TTO, incubation center and cluster that accelerate and support this process.

5. What can you tell us about the role of public supports in the establishment and development of this capacity?

Thematic specialization should be increased and much more specific environments and support mechanisms should be set up in order to create economic value and support human resources in the field of healthcare. For researchers and entrepreneurs who develop technology, readiness of the ecosystem with the infrastructure and support at different levels, the general outlook and reliability of the country, and that the support provided for the sector with predictable processes particularly by public authorities with decision-making powers in healthcare are critical. It is important to approach the process with a collective perspective in order to implement approaches that create value and that are renowned globally. Training the human resources with an approach focused on basic sciences and technologies at a stage much earlier than university education and ensuring that trained and qualified manpower does not leave the country can be possible by maintaining an ecosystem which involves investors and systems that support the emerging ideas.

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