Benefits of a clinical research strategy for Turkey

A roadmap for innovation-driven growth

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KEY FINDINGS

MESSAGE 1: CLINICAL RESEARCH IS A KEY TOOL TO ACHIEVE TURKEY'S ECONOMIC POLICY OBJECTIVES

Innovation and R&D are crucial for economic growth, fostering innovation, creating more healthcare resilience, and improving global competitiveness, including clinical trials; recognized in the government's core strategy documents. A clinical trial strategy would allow the government to achieve greater economic development, create more value-added, foster innovation and R&D, reduce the trade deficit, and support a healthier and health-resilient society.

MESSAGE 2: CLINICAL RESEARCH BENEFITS TURKEY'S ECONOMY, HEALTHCARE AND PATIENTS

The current value of clinical research in Turkey is estimated at USD 327.7 million (TRL 1,860.1 million) annually, with direct economic and broader societal effects (healthcare system and patients). Clinical research leads to lower medical costs for research subjects, lower financial burden for the Social Security Institution, additional income and more resilience for the healthcare system and State, and generates employment.

MESSAGE 3: TURKEY HAS A LARGE UNTAPPED CLINICAL RESEARCH POTENTIAL

Turkey ranks 26th globally in terms of the number of clinical trials conducted annually (521 clinical trials in 2019) but when ranked relative to population, GDP and the size of the pharmaceutical industry, Turkey drops in the rankings. This suggests that Turkey has ample opportunity for growth to increase its share of the global clinical research investments.

MESSAGE 4: TURKEY COULD IMPROVE IN KEY FACTORS TO INCREASE CLINICAL RESEARCH ATTRACTIVENESS

While Turkey is doing relatively well on six indicators, there are immediate opportunities to improve in eight other indicators: patient recruitment and easy access to patients, patient awareness, process simplicity, new investigator development, physician incentives, dedicated clinical research staff, foreseeable clinical research costs, and sponsor incentives.

MESSAGE 5: ANALYSIS SHOWS A STRONG CLINICAL RESEARCH STRATEGY POTENTIAL FOR TURKEY

Addressing all improvement opportunities and involving all stakeholders, Turkey could become a regional leader in the Middle East region in 3 to 8 years measured by the number of clinical trials. By adapting to global trends as well, Turkey can further improve and become a leader in the broader region of the Middle East and Central and Eastern Europe, becoming a global top 10 clinical research country in 8 years.

MESSAGE 6: BEING A TOP 10 CLINICAL RESEARCH COUNTRY WOULD MEAN NEARLY TRIPLING ITS NUMBER OF CLINICAL TRIALS

This would lead to annual total clinical research value of USD 1,130.1 million (TRL 9,675.4 million), and approximately 70,000 patients enrolled in clinical trials annually by 2027. Up to 12,700 investigators would be involved in more than 1,600 clinical trials. The annual value of innovative medicines provided to Turkish patients would reach USD 650.9 million (TRL 5,572.4 million).

KEY POLICY RECOMMENDATIONS

1. **Establish a central patient database:** Establish an anonymous patient database which lays out numbers of patients by region and/or healthcare institution and by detailed health information.

2. **Design a patient referral system:** Establish a patient referral system across healthcare institutions. Ensure that this system is accessible for physicians and other relevant healthcare staff.

3. **Raise public awareness:**
   - » Run public awareness campaigns to raise awareness of the patient and public benefits of clinical research.
   - » Publish information on upcoming and ongoing clinical trials on a publicly accessible website and communicate new clinical research to related patient associations.

4. **Streamline and centralize documentation and ethics committee submission:**
   - » Standardize documentation required by institutions, ethics committees and other authorities in the submission phase.
   - » Streamline document submission through an online system which related parties can access so that submissions are made online with one set of standard documents.

5. **Reinforce implementation of ethical review standards:** Ensure the implementation of high standards in ethical review across all ethics committees.

6. **Build an investigator network:** Establish a database which lays out the network of physicians trained and experienced in clinical research and interested in primary investigator roles.

7. **Increase capacity in a wider range of institutions:** Build and increase clinical research capacity in all the relevant institutions with access to patients.

8. **Provide formal education, academic incentives, and career advancement opportunities:**
   - » Train healthcare staff in clinical research through courses and graduate degrees on clinical research.
   - » Revise regulations to include clinical research for academic and career advancement.
   - » Amend regulations to include clinical research in physician performance evaluation.

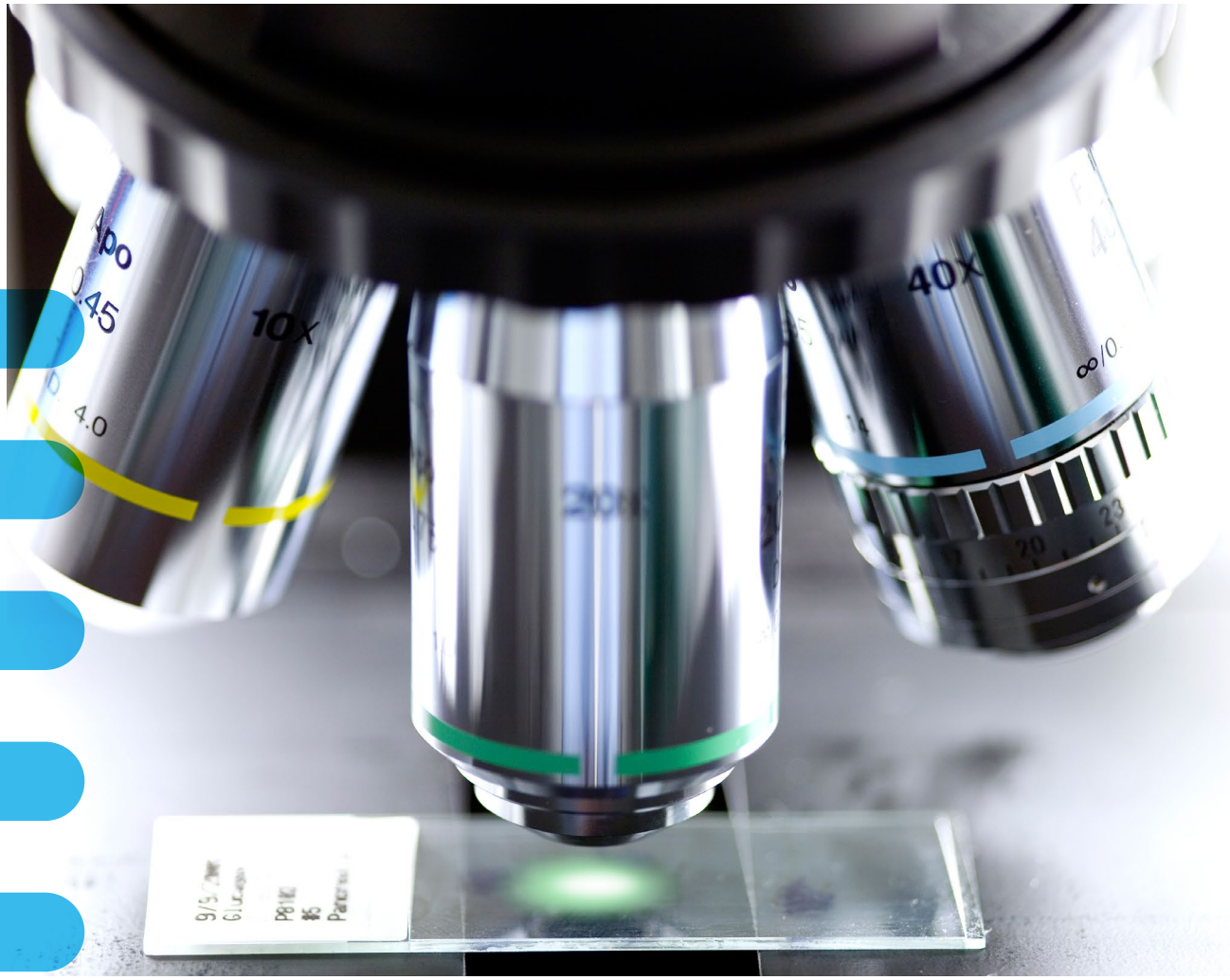
9. **Revise R&D regulations:**
   - » Ensure that a pre-approval clinical study is considered R&D even if only one phase is conducted in Turkey.
   - » Ensure that not only investigators employed as permanent hospital staff but also co-investigators working under temporary contracts are eligible for R&D incentives.

10. **Establish clinical research centers with dedicated staff:** Establish new or revamp existing clinical research centers to employ full-time healthcare and administrative staff dedicated to clinical research.

11. **Improve accounting systems in healthcare institutions:** Revamp healthcare institutions' accounting systems ensuring the correct itemization and invoicing of clinical research costs.

12. **Increase incentives for companies to run clinical research in Turkey:**
   - » Increase direct incentives for sponsors and contract research organizations that run clinical research in Turkey.
   - » Increase direct funding for startups or other companies that have limited or no capacity to fund their clinical research.
   - » Streamline the regulatory review submission of drugs of which Phase III clinical research has been done in Turkey.
   - » Provide strong sponsor incentives and intellectual property protection for clinical research to improve Turkey's relative attractiveness.

EXECUTIVE SUMMARY



POLICY CONTEXT

The vision of the Turkish government is to make Turkey a stronger and more prosperous country which produces greater value and shares welfare more equitably. Building a strong and stable economy is considered as one of the key dimensions of this vision. To achieve it, the government has laid down its key policy objectives and tools in several core policy documents. In particular, the 11th Development Plan (the Plan) details the components of the ultimate goal of economic growth and development and lays out a detailed policy plan to achieve this goal. Policy priorities established in these strategic documents include fostering innovation and increasing global competitiveness, productivity, exports, inward investments, production and employment, while reducing the current account deficit and improve financial stability. The 2020-2022 New Economic Program (Midterm Plan) and the 2020 Annual Program of the Presidency of the Republic set out specific actions to realize the policy objectives of the Plan. In particular, the Annual Program asks: "*How can the national R&D environment be promoted to help foster innovation and increase Turkey's competitiveness in the international arena?" and "How can Turkey become an economic leader in the region, linking the EU with the Middle East?*".

Figure A: Key policy documents of the Turkish government

POLICY DOCUMENT	TIMELINE	
11th Development Plan	2019-2023	Medium-term
2020-2022 New Economic Program	2020-2022	Medium-term
2020 Annual Program of the Presidency of the Republic	2020	Short-term

The specific target for Pharmaceuticals in the Plan is to increase the country's competitiveness and move it higher up in the global value chain. Innovation and R&D are considered crucial for this purpose and several policy targets are presented to promote innovation in the industry. Recognizing the critical role of clinical research in the pharmaceutical R&D process, the Plan puts forward a specific policy target to address this area: making Turkey a regional leader in clinical research.

STUDY OBJECTIVES

With this policy context as a driver, this study looks at the potential benefits for Turkey of a clinical research strategy and makes recommendations on how to implement such a strategy successfully.

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Against the backdrop of consensus reached by the public and private sectors in the strategic importance of pharmaceuticals, especially with respect to the R&D link into global value chains, this report is timely and instrumental in making a strong case that focusing on clinical research is the best strategy. Turkey already has a considerable base in conducting clinical research with the potential to triple its size in the medium term. Turkey does not have to wait for one or two decades to climb up to the Top-10 of the global rankings in pharmaceutical R&D. Concentrating on clinical research and getting the policies right, the country is well positioned to make considerable progress in the next 3 to 8 years.

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This report is comprehensive, comparative and inclusive in its nature, based on a very extensive literature review, analysis of quantitative data, while making extensive use of insights and knowledge garnered through in-depth interviews, first-hand conducted surveys, and broad stakeholder inputs. A clinical research strategy can only be implemented successfully if all stakeholders needed for different elements of the approach engage and

cooperate. Believing in the importance of ownership of the issue by all stakeholders, this study was designed from start to end as an inclusive one to reflect multiple aspects of the clinical research domain by consulting with major actors in the field: government officials, industry, regulators, as well as think tanks and academics. To this end, 60 people in- and outside of Turkey – from among the different actors – were interviewed to better understand the reality of clinical research in practice. A comprehensive workshop with the participation of 55 people representing the diverse nature of stakeholders was held in October 2019, providing important inputs into developing recommendations for reaching the objectives set out in government policy papers through a clinical research strategy.

Figure B: Clinical Research stakeholders in Turkey

CLINICAL RESEARCH IN FIGURES

The pharmaceutical industry in Turkey, put forward in the referred strategy documents as one of Turkey's key strategic industries, is worth USD 7.7 billion (TRL 43.8 billion), with locally produced drugs making up 49.4% of the total market value. A third of the local production value belongs to the products of international pharmaceutical companies and the rest to national companies. Turkey exports USD 1.2 billion worth of pharmaceutical products to more than 160 countries around the world. It is estimated that nearly 37,000 people are employed in the pharmaceutical industry – approximately a third employed by international companies and the rest by national companies – with additional employment in the surrounding industries. [1,2,3,4,5]

R&D investment in the Turkish pharmaceutical industry reached USD 86.0 million in 2017, growing at a compound annual growth rate (CAGR) of 4.7% between 2009 and 2017. The number of accredited R&D centers grew from 1 in 2008 to 33 in 2019. As of 2017, the number of people employed in these centers was 1,399. Despite the growth in local R&D investments, however, the estimated ratio of Turkish pharmaceutical industry R&D spending to the total pharmaceutical market size in 2018 remains below 1.5%, well behind the global estimated ratio of 14.9%. [4,6]

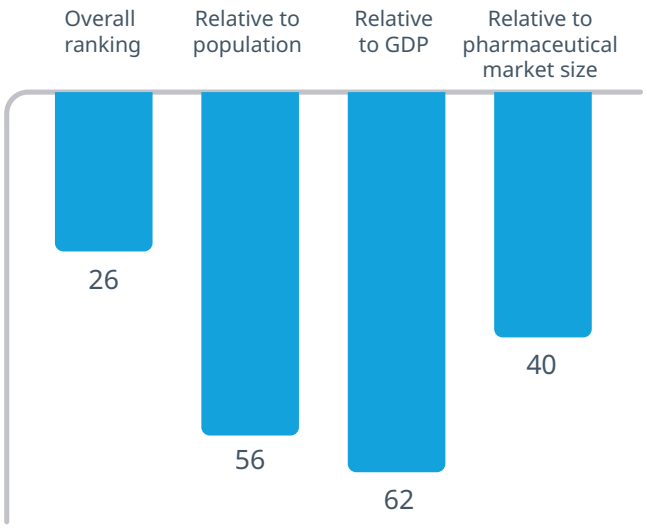
Total annual R&D expenditures of pharmaceutical and biotechnology companies worldwide reached USD 178.9 billion in 2018 – growing by 4.2% annually between 2010 and 2018, which corresponds to 21.6% of total worldwide and 23.8% of non-generic worldwide prescription sales revenues.

The pharmaceutical industry differs in key aspects from other industries: it is the most R&D intensive sector globally, and pharmaceutical R&D is long-term, expensive and high-risk. Developing a new drug lasts 10 to 15 years, costs USD 2.6 billion (including the cost of failures) on average, and only 1 or 2 out of 10,000 potentially successful compounds ultimately become a medicine. Clinical trials hold the largest share in pharmaceutical R&D investments. Phases I, II and III trials (which take place prior to the regulatory review submission of the drug candidate) make up 50.2% of the total R&D investment. When Phase IV trials (i.e. clinical research that takes place after marketing authorization) are included, the total investment in clinical research corresponds to 61.6% of the overall pharmaceutical R&D investment. [7,8,9,10,11,12,13]

Pharmaceutical R&D is long-term, expensive and high-risk.

As of June 2019, 16,720 industry-sponsored clinical trials (Phase I through IV) were ongoing worldwide. With 521 active trials, a number that has been stable since 2013, Turkey holds the 26th place globally. When correcting for the size of the country, however, Turkey drops in the rankings: to 56th place when corrected for the size of the population; to 62nd place when corrected for the size of gross domestic product (GDP), and to 40th place when corrected for the size of the pharmaceutical market.

Figure C: Turkey's global ranking in the number of active clinical trials

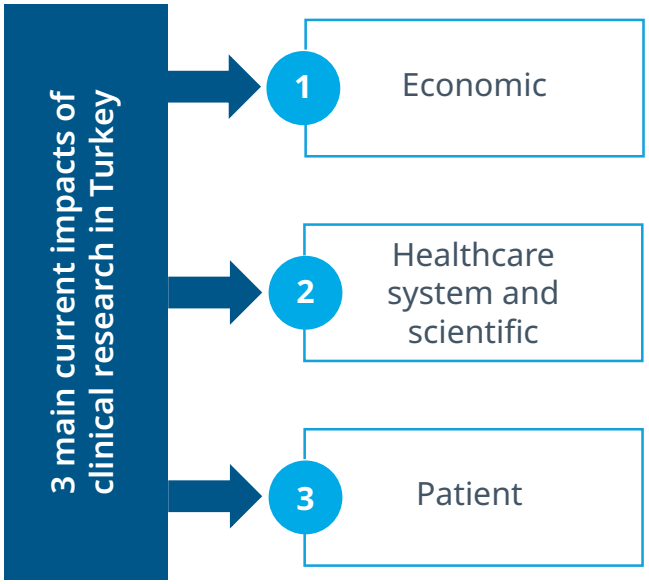


This points to an important opportunity for Turkey to increase the number of clinical trials conducted in the country and gain a greater share globally. To realize the 11th Development Plan target of becoming a regional leader in clinical research, Turkey would need to double its total number of clinical trials to lead the Middle East region, or nearly triple it to lead in the broader region of the Middle East and Central and Eastern Europe. The latter would also place Turkey among the Top-10 of global leaders in clinical research.

CURRENT IMPACT OF CLINICAL RESEARCH

Clinical research provides several benefits to the country, which can be grouped under three main areas: economic, healthcare system and scientific, and patients.

Figure D: Current impact of Clinical Research in Turkey



At the moment, the total economic value of clinical research run in Turkey is estimated at USD 327.7 million (TRL 1,860.1 million) annually as of June 2019, corresponding to 0.3% of the total global clinical research economy. This total amount includes both the clinical research investment in Turkey, which is estimated as USD 139.0 million (TRL 788.8 million), and the added value of the innovative medicines provided to clinical trial subjects, which is estimated as USD 188.7 million (TRL 1,071.3 million). Since industry-sponsored clinical research in Turkey is largely conducted by multinational pharmaceutical companies, most of the money spent

on clinical research is considered as foreign direct investment. This means the clinical research investment of USD 139.0 million (TRL 788.8 million) made in Turkey directly contributes to a macro-economic equilibrium which is one of the key targets of the New Economic Program. This direct investment consists of five key components: reduced financial burden for the Social Security Institution (SSI) thanks to the medical costs of clinical research subjects undertaken by sponsoring companies totaling USD 46.4 million (TRL 263.5 million), additional income to the healthcare system amounting USD 23.4 million (TRL 133.0 million), direct income to the state of USD 6.2 million (TRL 34.9 million), value of the employment generated thanks to clinical research estimated as USD 44.4 million (TRL 251.8 million), and other direct economic contribution of nearly USD 18.6 million (TRL 105.7 million). In addition, clinical trial research could lead to a higher value of Turkish exports (not higher quantities) which would reduce the trade deficit, improving the current account equilibrium, a key target of the New Economic Program.

From a healthcare system and scientific perspective, clinical research impacts not only healthcare professionals and institutions, but also startups in the pharmaceutical industry. As indicated above, clinical research saves the SSI USD 46.4 million (TRL 263.5 million) per year. In addition, it has a positive effect on healthcare professionals as engagement in clinical research increases their state-of-the-art understanding of diseases and latest potential treatments because of exposure to novel scientific developments, allows them to link to wider (international) research networks, and know of better ways to treat patients with rare diseases. And, specifically from a scientific perspective, it impacts them through increased prestige, reputation and scientific publications, gaining experience in rigorous scientific discipline and practices, first-hand exposure to the novel scientific developments, career advancement opportunities and access to a wider scientific network. On the other hand, clinical research benefits startups through its contribution to the pharmaceutical R&D infrastructure and research capabilities. To support pharmaceutical R&D activities and elevate the scientific contribution of clinical research, the 11th Development Plan emphasizes clinical research as an R&D activity. According to the Plan, all clinical research conducted before product registration will be considered within the scope of R&D without any pre-condition (11th Development Plan, 366.1). The Plan also declares that pharmaceutical product developers, especially researchers at universities, will be provided with information programs on incentives and intellectual property rights to accelerate the commercialization process. (11th Development Plan, 363.5)

The 11th Development Plan emphasizes clinical research as an R&D activity.

From a patient perspective, it is estimated that approximately 21,700 subjects are currently enrolled in clinical research in Turkey. Participation in clinical research mainly provides patients receiving the investigational drug with the benefit of early access to innovative treatments and of potentially better health outcomes. In addition, with medical professionals engaging more in clinical research, working on state-of-the-art scientific medical developments, also for patients in Turkey that are not enrolled directly in clinical research, potential new treatments are more known and thus general access could be enhanced.

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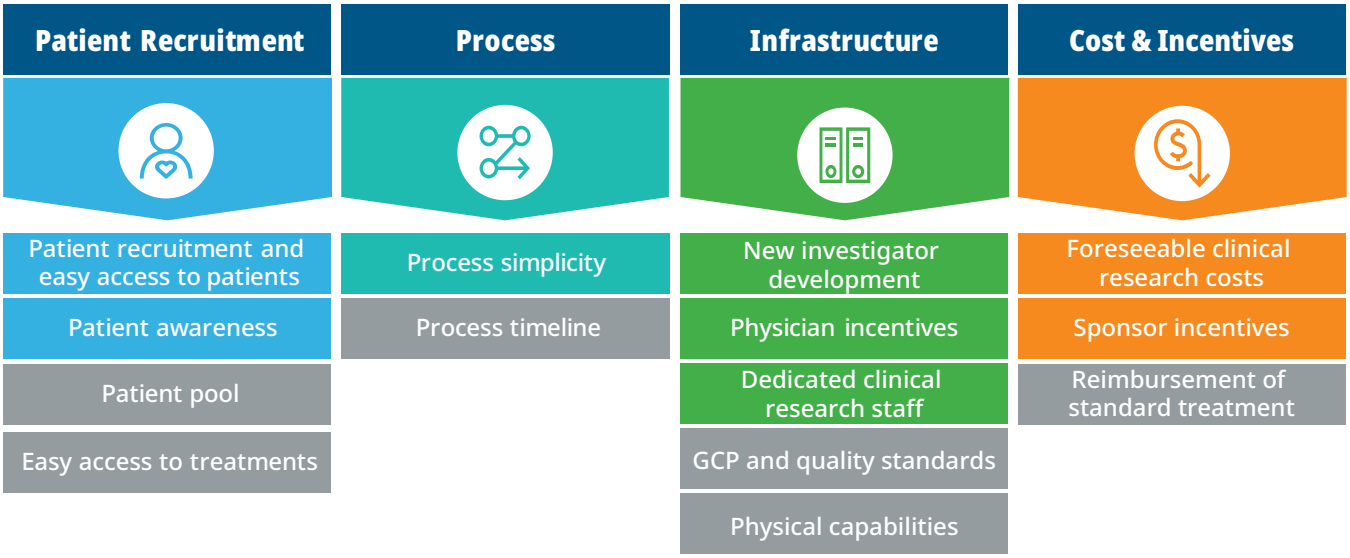
FACTORS FOR CLINICAL RESEARCH ATTRACTIVENESS

We identified fourteen key factors that contribute to a country's attractiveness for clinical trial inclusion, as shown in Figure E. We have grouped them under four pillars – patient recruitment, process, infrastructure, and cost and incentives. These factors impact the country's attractiveness through fast and flawless study set-up and execution. When Turkey is assessed in terms of each of the fourteen factors, eight major improvement opportunities stand out to have the potential to support the growth of clinical research in Turkey.

Figure E: Factors determining country attractiveness for clinical research*



Source: In-depth interviews; IQVIA Survey; IQVIA Analysis

* Factors shaded in grey have been identified as well-performing areas where no immediate action is recommended.

- The Patient Recruitment pillar consists of the attractiveness factors concerning the speed and ease of patient enrollment in clinical trials. Of the four factors under this pillar, Turkey has improvement opportunities in "*patient recruitment and easy access to patients*" and in "patient awareness" to speed up patient enrollment in clinical trials.
- Under the Process pillar are "*process simplicity" and "process timeline*", concerning the processes of regulatory and ethics committee submission and review processes. Building on Turkish Medicines and Medical Devices Agency's (TİTCK) major improvements in this regard, there is further opportunity to simplify the ethics committee submission and review processes.
- The Infrastructure pillar captures the factors concerning all critical dimensions of clinical research infrastructure in a country. To increase clinical research capacity, Turkey has opportunities in "*new investigator development*", improving "physician incentives" and employing "*dedicated clinical research staff*" in healthcare institutions.
- The Cost & Incentives pillar includes three factors concerning not only the cost of conducting clinical research but also its accounting and budget planning as well as the incentives that encourage innovative pharmaceutical companies to conduct more clinical research in Turkey. In this regard, Turkey has the opportunity to improve on clinical research costs and incentives, including regulatory data protection (RDP).

GLOBAL TRENDS IN CLINICAL RESEARCH

Beside these improvement opportunities, emerging clinical research trends around the globe pose further possibilities for growth in this area. These are important if Turkey aims to become a global Top-10 leader in clinical research. The use of digital health data, patient-reported outcomes (PRO), real world evidence (RWE) and predictive analytics as well as artificial intelligence, and access to pre-screened pools shape the present and near future of the global clinical research environment. Combined with the development of innovative drugs targeting complex diseases and conditions and with the availability of biomarker tests, the use of these new developments is changing the regulatory landscape globally. [28]

Turkey has already picked up and gained traction in some of these global trends (e.g. the use of digital health and mobile technologies, PROs), while it has the opportunity to improve its infrastructure to adapt

to other trends. By adapting to the shift into new types of drugs and complex treatments relatively quickly, Turkey has started to build the fundamental clinical research experience to support the New Economic Program policy target of realizing projects for the development of value-added precision and transformational drugs targeting cancer, chronic and rare diseases. On the other hand, there is still ample room to improve efficiency and productivity in clinical research processes in Turkey to gain a competitive edge globally – in part to be addressed via Turkey's digital transformation (a critical tool in the 11th Development Plan) and in part by providing sufficient R&D-supporting incentives.

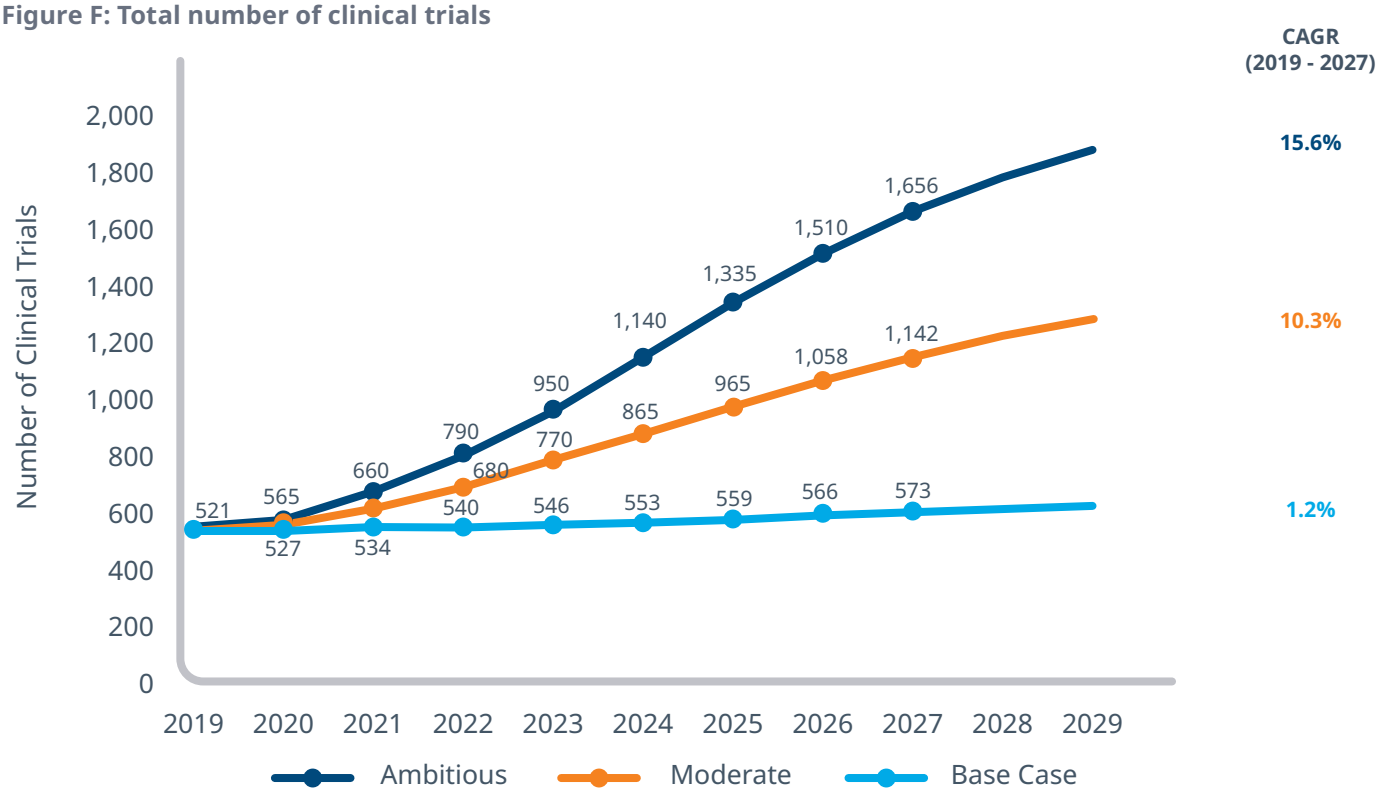
GROWTH SCENARIOS FOR CLINICAL RESEARCH IN TURKEY

The Turkish government has made a clear commitment to increase Turkey's competitiveness in the international arena and innovation has been elevated as an important means to achieve this goal. When its current global position and its growth potential in clinical research are considered, Turkey has ample room for growth in this area to meet its potential. In order to become a prominent country in clinical research, it needs to strengthen its infrastructure and deliver on the basic requirements that impact Turkey's attractiveness in this field. The potential impact of taking necessary steps in this regard have been evaluated in three different scenarios:

- **Scenario 1 –** Base Case Scenario: No major actions are taken. The total number of clinical trials grows at the same CAGR of the last 5 years. In this scenario Turkey does not improve its clinical research standing globally or regionally.
- **Scenario 2 –** Actions are taken in all identified improvement areas. The total number of clinical trials doubles after 8 years (which is the time needed to implement all the actioned improvements and see their full impact on the total number of trials). In this scenario Turkey becomes a regional leader in the Middle East in clinical research
- **Scenario 3 –** Ambitious Growth Scenario: Not only all fundamental actions are taken in all the improvement areas, but also extra steps are taken to incorporate and anticipate global clinical research trends effectively, and incentives are strengthened. The total number of clinical trials triples after 8 years. In this scenario, Turkey just enters the global Top-10 of most important clinical research countries, making it the leader in the broader region of the Middle East and Central and Eastern Europe.

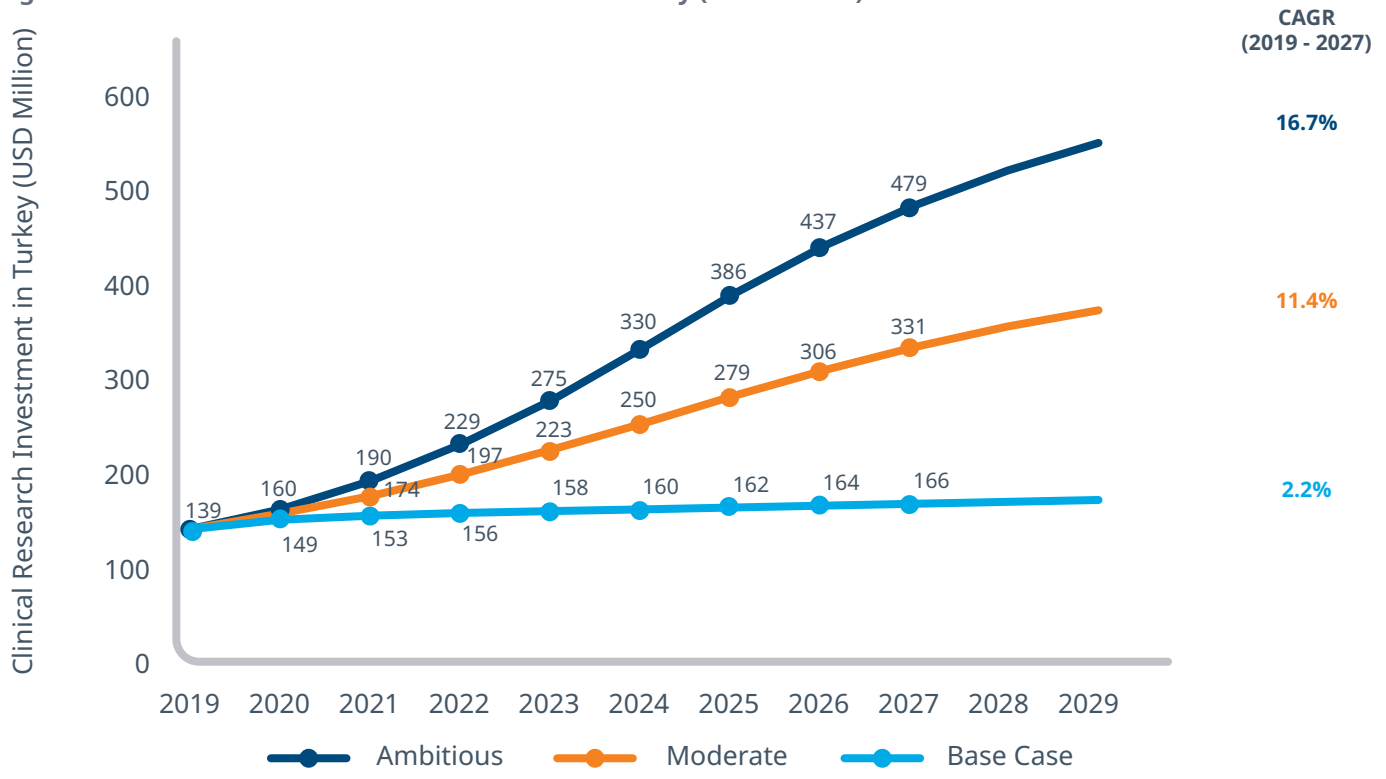
In the baseline scenario, as shown in Figure F, the annual growth rate in the number of clinical trials is 1.2%, increasing the number from 521 in 2019 to 573 in 2027. Turkey will – in this scenario – fall behind its global and regional competitors. In the moderate and ambitious growth scenarios, growth is expected to arrive at a steady state in 8 years and then level off to match global clinical trial growth over time. In the moderate growth scenario, the average annual growth rate in the first 8 years is 10.3% leading to 1,142 clinical trials in 2027. The largest growth in clinical trials is in the ambitious growth scenario, leading to 1,656 clinical trials, more than triple the current number.

Figure F: Total number of clinical trials



When we look at the economic effects of these increases in clinical trials, the effects are very clear. Figure G shows the evolution of the investment value of focused clinical research strategies. The initial investment of USD 139.0 million (TRL 788.8 million) in 2019 increases to USD 165.8 million (TRL 1,419.1 million) in 2027 in the baseline scenario. But it increases much more to USD 330.5 million (TRL 2,829.6 million) in 2027 in the moderate growth scenario and to USD 479.2 million (TRL 4,103.0 million) in the ambitious growth scenario.[1]

Figure G: Size of clinical research investment in Turkey (USD million)



[1]See Appendix 2 of the full report for inflation and exchange rate asumptions.

Achieving the ambitious growth scenario would place Turkey among Top-10 countries in terms of the total number of clinical trials and among the Top-6 or -7 countries (right behind the United States, United Kingdom, Spain, Germany, Canada, France and Italy) in terms of the number of new trials in 2027. This would mean nearly 70,000 patients enrolled in clinical trials, reducing the financial burden of three times as many patients as in the base case scenario for the SSI. In the case of a moderate growth, Turkey would join the Top-15 countries in the number of total clinical trials and new clinical trial registrations in 2027. In both cases, the growth in clinical trials would come along with an increased capacity in the workforce, involving a greater number of physicians in trials as investigators and generating new job opportunities specifically in contract research organizations, site management organizations, and sponsor companies.

Achieving the ambitious growth scenario would place Turkey among Top-10 countries in terms of the total number of clinical trials.

Figure H does not include the potential impact of a stronger clinical research strategy for the resilience of the Turkish healthcare system and public health in times of health emergencies. More clinical trial activities would place Turkey more at the innovative frontline in the R&D process for finding new treatments and cures – e.g. in the coronavirus pandemic situation.

Figure H: Summary of impacts for each scenario in 2027 [2]

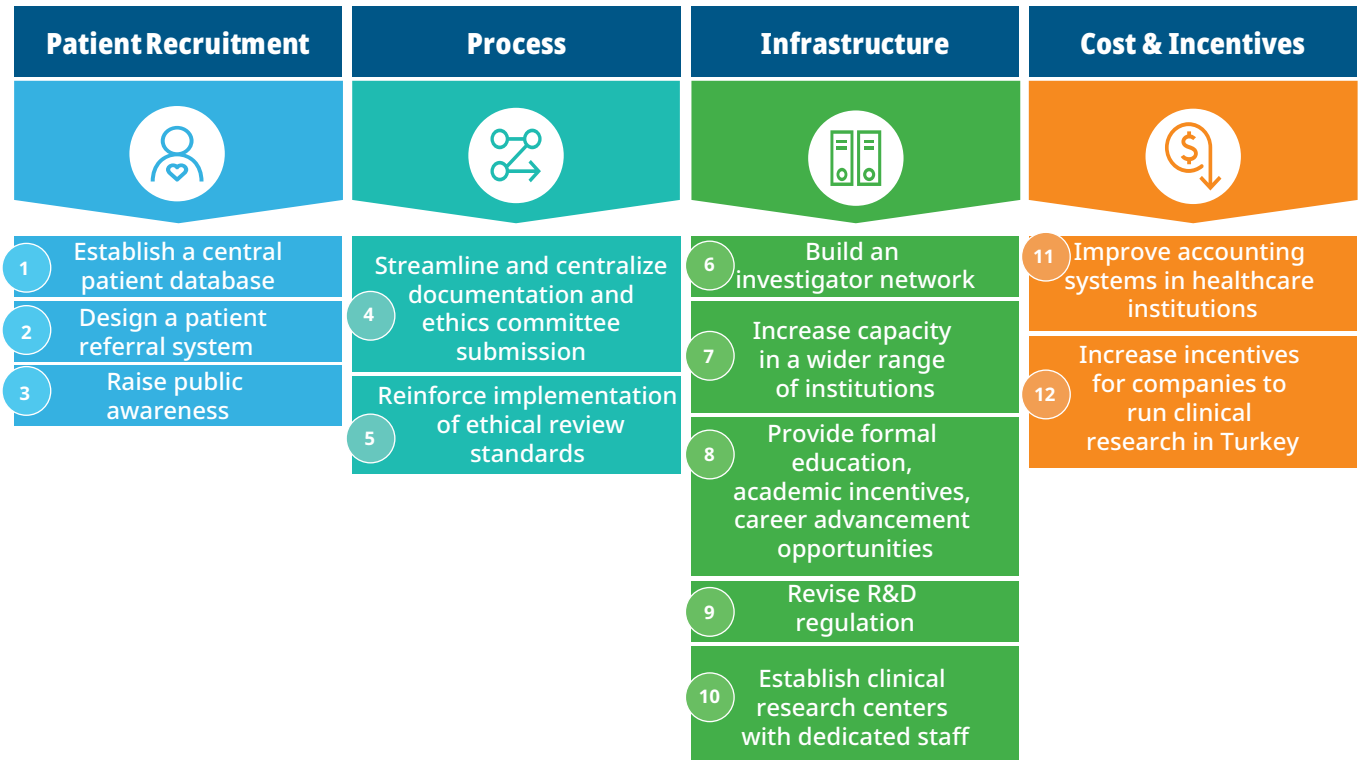
IMPACT	BASE CASE	MODERATE GROWTH	AMBITIOUS GROWTH
Economic impact (USD Million)			
Total investment in Turkey	165. 8	330.5	479.2
Reduced burden for SSI	55.4	110.4	160.1
Additional income to the healthcare system	27.9	55.7	80. 8
Value of generated employment	52.9	105.5	153.0
Other economic contribution	22.2	44.3	64.2
Total economic impact (USD million)	**390.3**	**779.4**	**1,130.1**
Healthcare system and scientific impact			
Number of trials	573	1,142	1,656
Annual number of new trials	120	296	448
Number of investigators	3,300-4,400	6,600-8,800	9,500-12,700
Patient impact			
Number of patients	23,903	47,661	69,109

[2] See Appendix 2 of the full report for inflation and exchange rate asumptions.

Recommendations for Turkey to enhance clinical research

To address the opportunities in all the improvement areas, a total of 12 recommendations for action steps have been developed. While grouped under specific improvement areas, most of the recommendations have the potential to impact multiple areas.

Figure I: Recommended actions



1. **Establish a central patient database:** Establish an anonymous patient database which lays out numbers of patients by region and/or healthcare institution and by detailed health information such as diagnosis, treatment, special conditions and genetic disorders.

2. **Design a patient referral system:** Establish a patient referral system across healthcare institutions. Ensure that this system is accessible for physicians and other relevant healthcare staff, includes information on upcoming and ongoing clinical trials and allows patient referrals between institutions.

3. **Raise public awareness:**
   - » Run public awareness campaigns to raise awareness of the patient and public benefits of clinical research and to overcome common prejudices.
   - » Publish information on upcoming and ongoing clinical trials on a website that is publicly accessible and communicate new clinical research to related patient associations, which can in turn relay such information to their members.

4. **Streamline and centralize documentation and ethics committee submissions:**
   - » Standardize documentation required by institutions, ethics committees and other authorities in the submission phase.
   - » Streamline document submission through an online system which related parties can access so that submissions are made online with one set of standard documents.

5. **Reinforce implementation of ethical review standards:** Ensure the implementation of high standards in ethical review across all ethics committees.

6. **Build an investigator network:** Establish a database which lays out the network of physicians trained and experienced in clinical research and interested in primary investigator roles.

7. **Increase capacity in a wider range of institutions:** Build and increase clinical research capacity not only in university hospitals but also in other institutions that have access to a large patient pool.

8. **Provide formal education, academic incentives, and career advancement opportunities:**
   - » Train healthcare staff in clinical research through courses and graduate degrees on clinical research in medical, dentistry and nursing schools.
   - » Revise regulations to include clinical research in academic and career advancement criteria.
   - » Amend regulations to include clinical research in physician performance evaluation.

9. **Revise R&D regulation:**
   - » Revisit the coverage of the R&D regulation for clinical research so that a pre-approval clinical study is considered within the scope of R&D even if only one phase is conducted in Turkey.
   - » Revisit the coverage of the R&D regulation for clinical research so that not only investigators employed as permanent hospital staff but also co-investigators working under temporary contracts are eligible for R&D incentives.

10. **Establish clinical research centers with dedicated staff:** In healthcare institutions where clinical research is conducted, establish clinical research centers or revamp the existing ones to employ full-time healthcare and administrative staff dedicated to clinical research.

11. **Improve accounting systems in healthcare institutions:** Revamp healthcare institutions' accounting systems ensuring the correct itemization and invoicing of clinical research costs.

12. **Increase incentives for companies to run clinical research in Turkey:**
   - » Increase direct incentives for sponsors and contract research organizations that run one or more phases of a drug's clinical research in Turkey.
   - » Increase direct funding for startups or other companies that have limited or no capacity to fund their clinical research.
   - » Speed up the regulatory review of drugs of which Phase III clinical research has been done in Turkey, by streamlining the submission process.
   - » Provide strong sponsor incentives and intellectual property protection for clinical research to improve Turkey's attractiveness in relative terms vis-à-vis Top-10 competitors.

FINAL COMMENT

Clinical research poses a major opportunity for Turkey in terms of enhancing economic development, attracting greater foreign direct investment, increasing domestic value-added, reducing the trade deficit, strengthening the resilience of the Turkish healthcare system in times of health emergencies, and creating a more innovation-focused economy, by means of only moderate domestic investment requirements aimed at improving or building new infrastructure, and creating strong framework policies.

Clinical research poses a major opportunity for Turkey in terms of enhancing economic development, attracting greater foreign direct investment, increasing domestic value-added, reducing the trade deficit, strengthening the resilience of the Turkish healthcare system in times of health emergencies, and creating a more innovation-focused economy.

When correcting for the size of Turkey's economy, population or pharmaceutical market, it is evident that Turkey has ample room for growth in the number of trials to take its fair share in global clinical research. Taking the recommended actions with the collaboration of all related stakeholders would help the country reach this goal and become a regional or even global leader in clinical research. What is needed to make the leap in clinical research is full engagement and collaboration of all stakeholders (i.e. government, industry, regulators). This will then be a huge step towards achieving the economic and industrial targets set in the government's policy documents.

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