

# AN UPDATE OF CLINICAL TRIALS LANDSCAPE IN TÜRKİYE TÜRKİYE'DEKİ KLİNİK ARAŞTIRMA MANZARASININ GÜNCELLEMESİ

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## ABSTRACT

**Objective:** Clinical research is essential to enhance scientific knowledge and provide better patient outcomes. This work evaluated clinical trials in Türkiye between 2019-2023 and compared them with previous research.

**Material and Method:** Clinical trials in Türkiye registered in the ClinicalTrials.gov database between 01.01.2019 and 30.09.2023 were examined and evaluated. Trials were filtered by study type, study phase, recruitment status, funder type, location, condition, or disease. Comparative analyses were executed for different cities and countries.

**Results:** The total number of registered clinical trials in Türkiye was 12,563. The number of trials registered between 2019 and 2023 was 8,851. Of these, 68.21% were interventional and 9.3% were industry-sponsored. The majority of trials (61.13%) were completed, while 18.78% were still recruiting patients. Leading cities in Türkiye were İstanbul and Ankara with the highest trial numbers. Despite a remarkable increase in the total number of clinical trials in Türkiye, no considerable change was detected in the number of industry-sponsored trials. The majority of trials with unknown status (85%) were non-industry-sponsored in all countries in the comparative analysis. The highest numbers of trials were found in respiratory, pain/pain management and oncology in Türkiye among the evaluated fields including cardiovascular disease, genetic disorders, diabetes, and obesity.

**Conclusion:** The total number of clinical trials in Türkiye showed a considerable increase when compared with developed countries including Germany, France, and the United Kingdom, however, the reasons behind the lower number and stability in the yearly increase rate of industry-sponsored trials should be revisited by all stakeholders.

**Keywords:** Clinical trials, Türkiye, research

## Öz

**Amaç:** Klinik araştırmalar bilimsel bilgiyi geliştirmek ve hastalar için daha iyi sonuçlar elde etmek adına gerekli araçlardır. Bu çalışma Türkiye'de 2019-2023 yılları arasında yapılmış olan klinik çalışmaları değerlendirmek ve önceki analizle karşılaştırma yapmayı amaçlamaktadır.

**Gereç ve Yöntem:** Türkiye'de yapılmış olan klinik araştırmaları değerlendirmek için ClinicalTrials.gov veri tabanına 01.01.2019 ve 30.09.2023 tarihleri arasında kaydedilen klinik araştırmalar incelenmiştir. Araştırmalar çalışma türü, çalışma fazı, çalışmanın durumu, destekleyici türü, lokasyon, hastalık durumuna göre filtrelenmiştir. Türkiye'deki farklı şehirler ve farklı ülkeler için karşılaştırmalı analiz yapılmıştır.

**Bulgular:** ClinicalTrials.gov veritabanında Türkiye'de kayıtlı olan klinik araştırma toplam sayısı 12563'tür. 2019-2023 yılları arasında kaydedilmiş olan çalışma sayısı ise 8851'dir. Bu çalışmaların %68,21'si girişimsel, %9,3'ü endüstri tarafından desteklenen çalışmalardır. Çalışmaların çoğunluğu olan %61,13'ü tamamlanmıştır, %18,78'i ise hala hasta alımı yapmaktadır. En fazla klinik çalışma kayıtlı olan iller İstanbul ve Ankara'dır. Türkiye'de toplam klinik çalışma sayısında belirgin bir artış olmasına rağmen endüstri tarafından desteklenen çalışma sayısında anlamlı bir değişiklik saptanmamıştır. Karşılaştırmalı analize dahil edilen ülkelerin tamamında durumu bilinmeyen çalışmaların çoğunluğu (%85) endüstri tarafından desteklenmeyen çalışmalardır. Kardiyovasküler hastalık, genetik hastalıklar, diyabet ve obezitenin de dahil olduğu farklı tıbbi alanlar değerlendirildiğinde Türkiye'de klinik çalışma sayısının en fazla olduğu alanlar solunum hastalıkları, ağrı/ağrı yönetimi ve onkoloji olmuştur.

**Sonuç:** Türkiye'de klinik çalışma sayısı artmış ve Almanya, Fransa, Birleşik Krallık gibi gelişmiş ülkelerle karşılaştırıldığında benzer bir sayıya ulaşmıştır. Bununla birlikte, endüstri tarafından desteklenen çalışmaların sayısının daha düşük olması ve yıllık artışlarının sabit olmasının nedenleri tüm paydaşlar tarafından tekrar gözden geçirilmelidir.

**Anahtar Kelimeler:** Klinik araştırmalar, Türkiye, araştırma

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## INTRODUCTION

Clinical trials in Türkiye between 2009 and 2018 were investigated in an earlier report and published in 2020. It included the evaluation of the number of clinical trials, study type, study phase, and funder type by using ClinicalTrials.gov database as the global source (1, 2). Previous work has shown that the number of clinical trials in Türkiye was not as high as expected. According to the findings the total number of registered trials in Türkiye was 3,880, of which 42% were industry-sponsored trials, and 74.9% were interventional trials. The total number of clinical trials in Türkiye was reported to be less than developed countries with a comparable population (1).

Türkiye is a country with a growing population of over 80 million, so contributions to clinical research are essential to improve scientific knowledge in different disease areas and to achieve improvements in public health (1). In addition to the direct impact on scientific improvement and economic growth, clinical trials may offer patients the best access and treatment to new promising treatment options, especially in the management of serious conditions, such as rare diseases and oncology (3). The latest regulations and legislation for clinical trials in Türkiye are given on the website of the Turkish Medicine and Medical Devices Agency (4). Türkiye strives to improve the approval and permission process and keep clinical trials procedures updated in line with new developments in clinical research and technology.

In this work, we investigated and evaluated the current setting for clinical trials in Türkiye between 2019 and 2023. All registered clinical trials were evaluated according to study type, study phase, recruitment status, funder type, location, condition, or disease. Additionally, the main results were compared with selected countries.

## MATERIAL and METHODS

The clinical trials posted between 01.01.2019 and 30.09.2023 in the ClinicalTrials.gov database were analyzed to determine the current setting in Türkiye (2). The detailed evaluation was executed according to study type, recruitment status, study phase, funder type, gender, age, and location including different cities in Türkiye and other countries.

For the comparative analysis Germany (83.31 million), France (67.93 million) and the United Kingdom (67.73 million) were selected as the leading countries in the field of clinical research in Europe due to their comparable populations. Other countries including the United States of America (333.28 million), China (1.4 billion), the Russian Federation (143.55 million), South Africa (59.89 million), Egypt (109.3 million), Argentina (46.23 million), Thailand (71.69 million) were selected based on their location on different continents. The United States and China were selected as leading countries in the field of clinical trials globally. The database of the Worldbank was used for the population analysis of different countries selected for the comparative analysis (5).

For an analysis of different disease areas, specific terms were used for the condition or disease. The search in the database of

ClinicalTrials.gov was executed for respiratory diseases by using the keywords "respiratory disease", "respiratory failure", "asthma", "pneumonia", "chronic obstructive disease", "respiratory tract disease", "respiration disorder" or "respiratory insufficiency". The search for pain and pain management was executed by using the keywords "postoperative pain", "chronic pain", "acute pain", "back pain", "neck pain", "headache", "migraine", "analgesia", "pain management", "cervical pain" or "pain control". The search for oncology was executed by using the keywords "oncology", "cancer" or "tumor". The search for genetic diseases was executed by using the keywords "genetic disorder", "genetic disease", "genetic syndrome" or "chromosomal syndrome". The search for cardiovascular diseases was executed by using the keywords "cardiovascular disease", "coronary artery disease", "coronary syndrome", "heart failure", "arrhythmia", "hypertension", "cardiomyopathy", "valvular heart disease", "endocarditis" or "congenital heart disease". The search for diabetes was executed by using the keywords "diabetes mellitus", "diabetes" or "diabetic". The search for obesity was executed by using the keyword "obesity".

## Statistical analysis

The present work was designed as a descriptive study; therefore, a specific analytical statistical test was not conducted. The findings are given as numbers and percentages.

## RESULTS

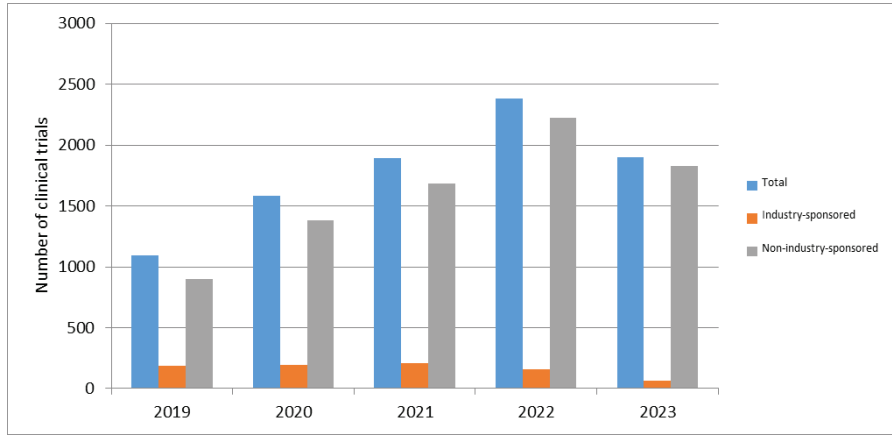
The total number of registered studies in Türkiye accessible on ClinicalTrials.gov was 12,563 while the total number of registered studies between 2019 and 30 September 2023 was 8,851 which were evaluated in this analysis (2). The majority (68.21%) were interventional studies. Observational studies comprised the remaining 31.75% and there were four expanded access studies (0.04%). Among observational studies, there were 617 patient registries.

The number of registered studies increased each year between 2019 and 2022. The evaluation according to study type showed that 824 studies out of the total 8,851 were industry-sponsored, and that number increased between the years 2019 and 2021 but decreased between 2022 and 2023 (Figure 1).

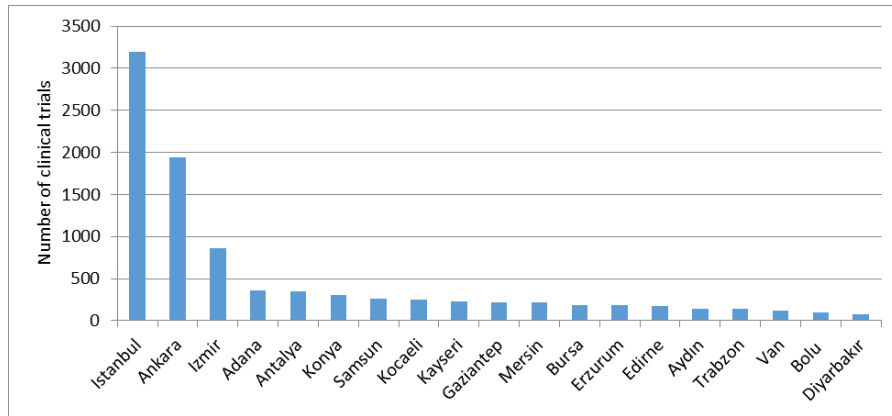
Female participants were included in 8,560 studies, while male participants were included in 7,373. Five thousand six-hundred and eleven (5,611) studies included older adults. Older adults were described as participants over 65 years of age. The pediatric population was included in 1,928 studies which was defined by the ages between 0 to 17 years.

The cities with the highest number of studies were Istanbul and Ankara. Three thousand one-hundred and ninety-four (3,194) studies were conducted in Istanbul and 1,939 studies were conducted in Ankara. There was a decrease in the number of studies starting in Izmir and 865 studies across other parts of the country (Figure 2).

The studies were evaluated according to the study phase. Out of the total of 74 studies in Early phase 1/Phase 1, 53 studies

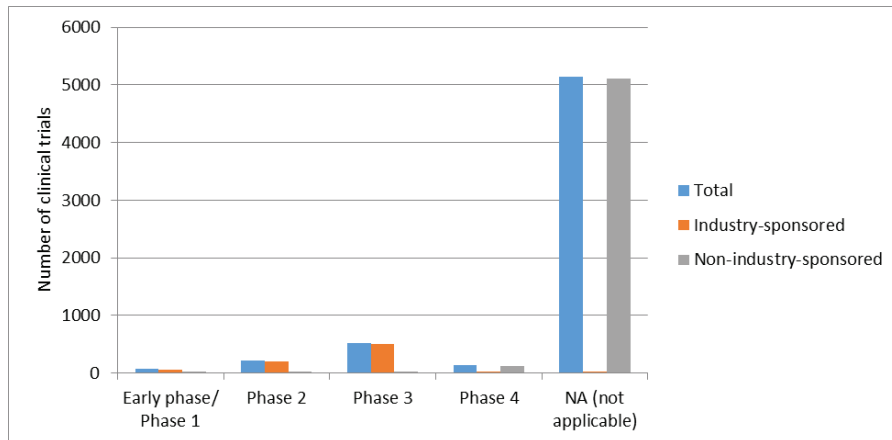


**Figure 1:** Number of registered clinical trials between 2019 and 2023 on ClinicalTrials.gov in Türkiye and their distribution according to funder type



**Figure 2:** Location of clinical trials in Türkiye\*

\*Multicenter clinical trials are in multiple locations which may lead to an excess in the total number of trials registered (8,851) in Türkiye.



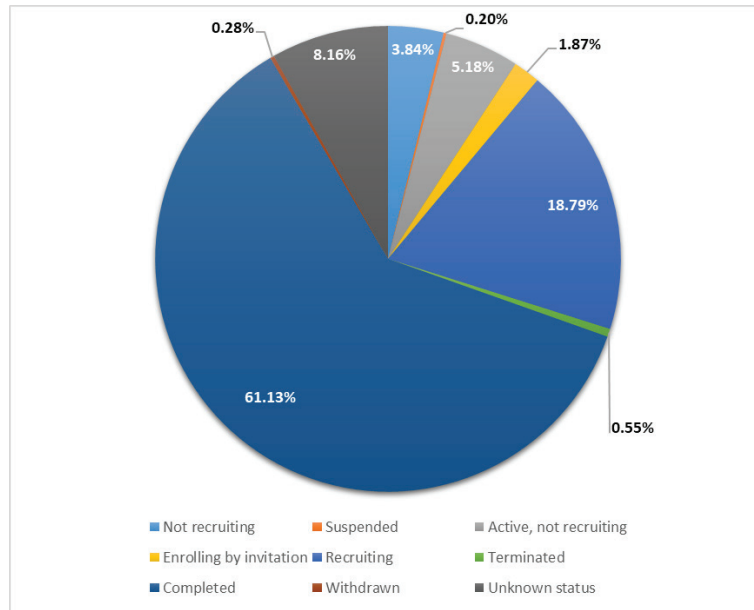
**Figure 3:** Distribution of clinical phase studies in Türkiye \*

\*“NA (not applicable)” studies did not have a phase definition registered in the database.

were industry-sponsored. The number of Phase 2 studies was 225, and Phase 3 studies were 525 with a high proportion of industry-sponsored trials (87% and 96%). The number of Phase 4 studies was 136 (14% industry-sponsored) and the number of studies without defined phases (“NA” studies; not applicable

studies) was 5,140 of which only 31 were industry-sponsored. The majority were non-industry-sponsored (99.4%) (Figure 3).

The percentage of industry-sponsored clinical trials conducted with drugs/pharmaceuticals and medical devices were 86.94%



**Figure 4:** Clinical trials in Türkiye according to recruitment status

and 4.19%, respectively. The rest (8.87%) consisted of trials with other interventions such as psychotherapy, surgery, diet, etc., and other types of clinical studies such as patient registries, development of biomarkers and diagnostic tests.

The evaluation according to recruitment status (including 8,847 studies and excluding 4 expanded access studies) showed that most of the trials (61.13%) were “completed” (n=5408). One thousand six-hundred and sixty-two (1,662) studies were still “recruiting patients” and 340 studies were “not recruiting” as of the last update on ClinicalTrials.gov (14.10.2023). The number of “withdrawn” studies was 25 (0.28%), 49 studies were “terminated” (0.55%) and 18 studies were “suspended” (0.20%) According to recruitment status 458 studies were “active but not recruiting”. There were 722 studies with unknown recruitment status (Figure 4).

The recruitment status is defined in the database as follows ; “Not yet recruiting”: The study has not started recruiting participants; “Recruiting”: The study is currently recruiting participants; “Enrolling by invitation”: The study is selecting its participants from a population, or group of people, decided on by the researchers in advance. These studies are not open to everyone who meets the eligibility criteria but only to people in that particular population, who are specifically invited to participate; “Active, not recruiting”: The study is ongoing, and participants are receiving an intervention or being examined, but potential participants are not currently being recruited or enrolled; “Suspended”: The study stopped early but may start again; “Terminated”: The study stopped early and will not start again. Participants are no longer being examined or treated; “Completed”: The study ended normally, and participants are no longer being examined or treated (that is, the last participant’s last visit occurred); “Withdrawn”: The study stopped early, before enrolling its first participant; “Unknown”:

A study on ClinicalTrials.gov whose last known status was recruiting; not yet recruiting; or active, not recruiting but has passed its completion date, and the status has not been verified within the past 2 years.

The United States (US), China, France, United Kingdom (UK), Germany, the Russian Federation, Egypt, Argentina, and Thailand were included in the comparative analysis of registered clinical trials. The total registered number of studies between 2019-2023 was highest in the United States (n=47,329) and China (n=18,406). The number of clinical studies in France (n=12,725) was higher than in Türkiye. The number of non-industry-sponsored trials were higher than industry-sponsored trials in all the countries except Germany, the Russian Federation and Argentina (Figure 5).

The comparative evaluation of France, Germany, the United Kingdom, and Türkiye demonstrated that there was a decrease in the number of clinical trials in Germany and the United Kingdom between 2020 and 2023. The number of clinical trials in France decreased starting from 2020 as well whereas the number in Türkiye increased between 2019 and 2022. Despite the decrease in registered trials in Türkiye in the first three quarters of 2023, the number of registered trials in Türkiye is higher than the numbers in France as of 2023 (Figure 6).

The number of clinical trials with “unknown status” was also evaluated in these countries which was highest in China and lowest in Argentina. The vast majority of trials with “unknown status” were non-industry-sponsored (Table 1).

Among the registered clinical trials in Türkiye 866 were conducted in “respiratory”, 852 in “pain/pain management”, 811 in “oncology”, 645 in “cardiovascular”, 230 in “genetic disorders”, 219 in “diabetes” and 158 in “obesity” disease areas. The number of industry-sponsored trials was higher in oncology (37.6%) and genetic disorders (46.5%) when compared with other disease areas (Figure 7).

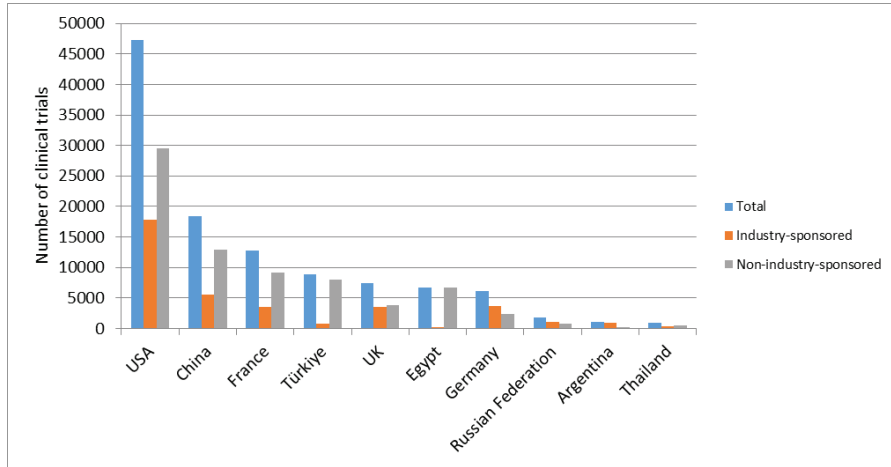


Figure 5: Comparison of clinical trial numbers between different countries (2019-2023)

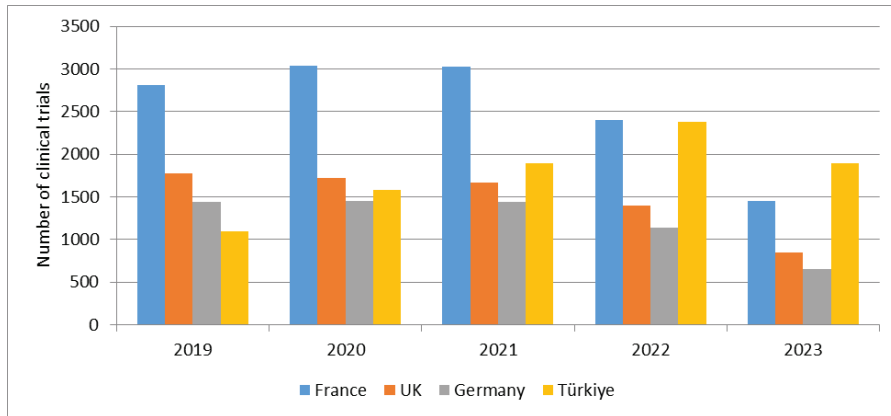


Figure 6: Comparison of numbers of clinical trials in different countries between 2019 and the first 3 quarters of 2023

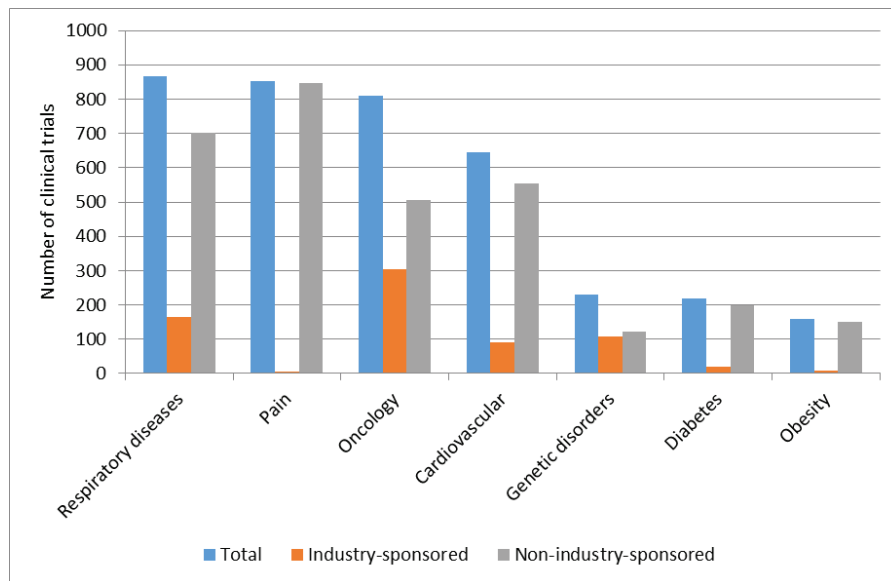


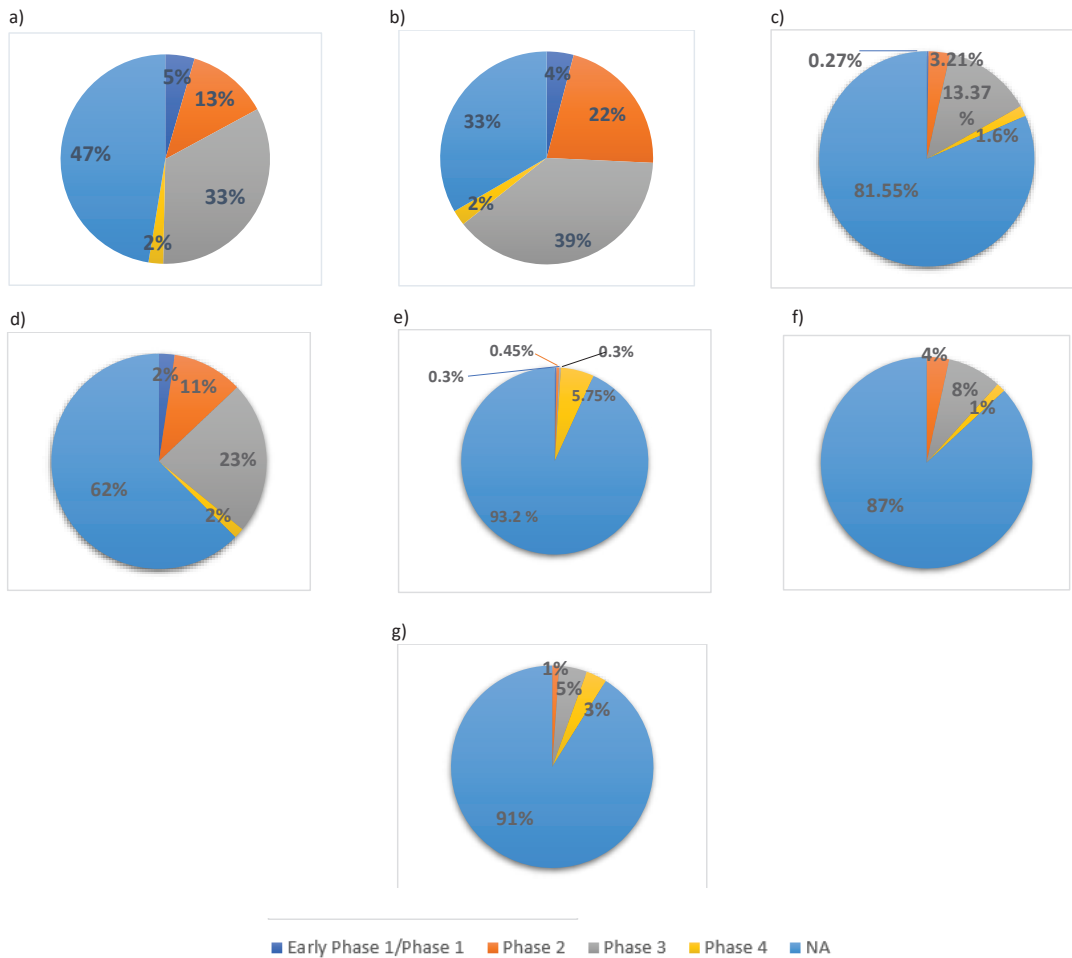
Figure 7: Clinical trials in different disease areas in Türkiye

**Table 1:** Number of clinical trials with “unknown status” and their distribution according to study funding type

	Total number	Industry-sponsored	Non-industry-sponsored
USA	1502	487	1015
China	3411	641	2770
France	1377	86	1291
Türkiye	722	19	703
United Kingdom	650	87	563
Egypt	1125	1	1124
Germany	347	53	294
Russian Federation	154	37	117
Argentina	49	9	40
Thailand	75	1	74

The number of clinical trials in oncology in Türkiye was 811 of which 74% were interventional and 26% were observational studies including 37 patient registries. Forty-seven percent (47%) of the interventional studies were “not applicable” which means that they did not have an applicable phase definition according

to the definition in the database. The vast majority of Early phase/Phase 1 (93%), Phase 2 (93.5%), Phase 3 (99.5%) and Phase 4 (35.7%) studies were industry-sponsored. Only one of the studies without a phase definition (NA; “not applicable” study) was industry-sponsored (Figure 8).



**Figure 8:** Evaluation of clinical trials in Türkiye in different disease areas according to study phase: a) Oncology, b) Genetic diseases, c) Cardiovascular disease, d) Respiratory diseases, e) Pain/Pain management, f) Diabetes, g) Obesity

The clinical trials in the genetic diseases area registered in Türkiye in the ClinicalTrials.gov database were mostly interventional trials (69%) most of which were Phase 3 trials (39%). There were 13 patient registries among observational trials. The majority of trials in Early phase/Phase 1 (85.7%), Phase 2 (94.5%), Phase 3 (95.45%), and Phase 4 (100%) were industry-sponsored. Only one of the "not applicable" studies (NA) was industry-sponsored (Figure 8).

The number of studies in the cardiovascular disease area in Türkiye between 2019-2023 was 645. Forty-two point five percent (42.5%) were observational trials including 67 patient registries. The majority of the Early phase/Phase 1 (100%), Phase 2 (92%) and Phase 3 studies (98%) were industry-sponsored. Eighty-one point fifty-five percent (81.55%) of the interventional trials were "not applicable" (NA) and most were non-industry-sponsored (97.4%) (Figure 8).

Our search in the respiratory diseases area comprised COVID-19 studies and lung cancer studies as well. There were 866 studies in respiratory diseases, 18.9% were industry-sponsored. Fifty-seven percent (57%) of the trials were interventional. Observational trials included 72 registries. The majority of the Early phase/Phase 1 studies (75%), Phase 2 studies (81%) and Phase 3 studies (95%) were industry-sponsored. Sixty-two percent (62%) of the interventional trials were "not applicable" when stratified according to phase definition (Figure 8).

The number of trials in pain and pain management was 852 of which five studies were industry-sponsored. There were 192 observational trials including 45 patient registries accessible in the database. Seventy-seven point four percent (77.4%) of the trials were interventional trials. The majority of the interventional trials (93.2%) were "not applicable" according to the phase definition from the database (Figure 8).

The number of studies in the diabetes area was 219. The percentage of industry-sponsored trials was 9.5%. Seventy-four (74) of the registered trials were observational including 12 patient registries. Of the 145 interventional trials there was no Early phase/Phase 1 study registered in the database. All the Phase 3 studies were industry-sponsored. There were only two Phase four trials of which one was industry-sponsored. The majority of the "not applicable" (NA) trials were non-industry-sponsored (Figure 8).

The trials in obesity in Türkiye comprised 90 interventional and 68 observational trials which included 15 patient registries. There was no Early phase/Phase 1 trial registered in the database. Ninety-one percent (91%) of the interventional studies were "not applicable" (NA) when stratified according to the phase description in the database. The percentage of Phase 4 trials was 3% (n=4), all of which were industry-sponsored (Figure 8).

## DISCUSSION

Like previous reports on clinical trials, the majority of clinical trials are being conducted in the United States and Europe. Clinical trials are vital tools of scientific advancement for all

stakeholders in the healthcare system. Patients, investigators, health authorities and funder bodies including both the pharmaceutical/medical device industry and public organizations/institutions benefit from clinical trials. In addition to scientific purposes, due to the economic impact of sponsored clinical trials on the healthcare system, all countries make improvements and increase awareness to get the maximum benefit.

In this work we analyzed the years 2019, 2020, 2021, 2022, and the first 3 quarters of 2023 and detected an increase in the number of clinical trials in Türkiye between 2019 - 2022 and a slight decrease in the first 3 quarters of 2023. When compared to the previous analysis, there was a considerable increase in the total number for the last five year period, however, the number of industry-sponsored trials (9.3%) was still lower than non-industry-sponsored trials throughout the period of our evaluation (1). Although it might not be the only factor, the registration of clinical research for publication requirement (6) asked by many scientific journals could have led to the high numbers of registered investigator-initiated studies in the ClinicalTrials.gov database (1). The influence of the increased awareness of researchers and the improvements in clinical trial regulations may also be other important factors. Although it was not possible to reach a definitive conclusion, the overall findings in our study show the enhancement and widespread research culture at the country level. As an expected result, in line with the population of cities, Istanbul, Ankara and Izmir are still the leading cities with the highest number of clinical trials.

The comparison with leading European countries in the field of clinical research demonstrated an increase in registered clinical trials in Türkiye. In the previous evaluation covering the years before 2019, the number of clinical trials in France, the United Kingdom and Germany was considerably higher than Türkiye. However, the present work covering the last five years demonstrated that the total number of trials in Türkiye was higher than Germany and the United Kingdom and even surpassed the numbers of France in the first 3 quarters of 2023. However, it should be taken into account that the number of industry-sponsored trials registered on ClinicalTrials.gov in France (27.5%), the United Kingdom (47.9%) and Germany (60.3%) were higher than in Türkiye (9.3%). There was also an unbalanced distribution of the number of industry-sponsored and non-industry-sponsored clinical trials among all countries. We also reviewed the number of trials with "unknown status" in different countries. Eighty-five percent (85%) of the trials with unknown status were non-industry-sponsored trials. The highest percentage was achieved in China where 18.5% of the clinical trials registered between 2019-2023 were unknown. The lowest percentage (4.4%) was obtained in Argentina where the vast majority of registered studies were industry-sponsored. This again may be evidence of tighter control and a higher quality of industry-sponsored studies.

Different disease areas were also evaluated such as oncology, respiratory diseases, genetic disorders, cardiovascular disease, diabetes, and obesity. The number of clinical trials in respiratory, pain/pain management, oncology and cardiovascular disease areas were prominently higher than in other disease areas with

a large number of industry-sponsored trials in oncology (37.6%). The search for respiratory disease trials in the database of ClinicalTrials.gov also included COVID-19 and lung cancer studies which may have contributed to the high number of trials in the respiratory disease area. Another fact and a possible limitation are that lung cancer trials are included in both respiratory disease and oncology trials which may have led to an overlap between respiratory and oncology trial evaluations. The high number of industry-sponsored trials in oncology could be an indication of an unmet need in this field.

In the evaluation according to different disease areas we detected an increase in the number of respiratory disease trials by 176% in 2020, but only 12% in 2021. Similarly, the number of trials increased by 79% in cardiovascular disease, 37% in oncology, 37% in diabetes and 21% in obesity in 2020 which may be related to the globally increased numbers of research activities during the COVID-19 pandemic. There was also an increase in the number of trials in the pain/pain management area by 9% in 2020, 38% in 2021 and 47% in 2022. There was no yearly increase in the number of trials in the field of genetic diseases.

The majority of the Early phase/Phase 1, Phase 2, and Phase 3 trials in oncology and genetic diseases area were industry-sponsored as well. We detected a remarkable number of trials in the pain/pain management area, most of which were investigator-initiated research activities. The number of Early phase/Phase 1 trials was highest in oncology (n=28) followed by respiratory diseases (n=12). Another interesting outcome was the low number of clinical trials in diabetes and obesity despite the prevalence of diabetes mellitus and obesity in our country (7, 8). There was no Early phase/Phase 1 trial in diabetes or the obesity disease areas either.

Regarding the intervention/treatment among industry-sponsored trials, it demonstrated that the vast majority (86.94%) of the trials were conducted with drugs/pharmaceuticals whereas only 4.19% of the trials were conducted with medical devices. The rest (8.87%) consisted of trials with other interventions such as psychotherapy, surgery, diet, etc., and other types of clinical studies including patient registries, development of biomarkers and diagnostic tests. By using the ClinicalTrials.gov database it was not possible to stratify if the clinical trials were supported by local or international pharmaceutical or device companies due to multinational collaborations in the field of clinical trials.

## CONCLUSION

Clinical trials that were registered on ClinicalTrials.gov between 2019 and the first three quarters of 2023 were included in this work. We provided an overview of the clinical trial setting in our country by filtering trials based on study types, recruitment status, study phases and evaluated different disease areas. To gain insights about our country's status on a global level we compared Türkiye with other countries. The total number of clinical trials in Türkiye increased and reached a high level when compared with developed countries including Germany, France, and the United Kingdom, however, the possible reasons for the lower number and the stability in the yearly increase rate of industry-sponsored trials should be revisited by all stakeholders of clinical trials.

**Ethics Committee Approval:** Information in the ClinicalTrials.gov database was used in the study.

**Peer Review:** Externally peer-reviewed.

**Author Contributions:** Conception/Design of Study- A.Ö., S.Ş.; Data Acquisition- A.Ö., S.Ş.; Data Analysis/Interpretation- A.Ö., S.Ş.; Drafting Manuscript- A.Ö., S.Ş.; Critical Revision of Manuscript- A.Ö., S.Ş.; Final Approval and Accountability- A.Ö., S.Ş.; Material and Technical Support- A.Ö., S.Ş.; Supervision- A.Ö., S.Ş.

**Conflict of Interest:** The authors have no conflict of interest to declare.

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