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Saudi clinical trials registered on Clinicaltrials.gov, and the role of national health institutions in supporting clinical studies in Saudi Arabia: An exploratory and analytical study

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Abstract:

Clinical trials are among the most important research studies in which researchers test new ways to prevent, detect, or treat diseases according to a detailed protocol. Clinical trials aim to evaluate the need for medical, surgical, or behavioral intervention primarily to treat a particular health problem. They are often used to see if a new treatment is more effective and/or has less harmful side effects than a common treatment. Each trial aims to improve survival rates or reduce side or late effects of treatment, through which diseases can be detected early before symptoms appear. Clinical trials are also looking into testing methods to prevent health problems that threaten people at risk of developing genetic or chronic diseases. In light of the continuous research development in the field of storing, retrieving and analyzing medical data in what is known as health informatics, which is the multidisciplinary field that integrates information science with health care to organize and analyze medical data, improve patient outcomes, the current study aims to explore the reality of Saudi research studies and clinical trials available in the Clinicaltrials.gov. It is considered one of the most important global databases in this field. Today, it is necessary to explore the advantages of this type of research study, which is considered one of the most important references in the field of medical sciences and related fields. The study also addressed the approach taken by the competent health authorities in the Kingdom of Saudi Arabia towards registering clinical trials. The study includs (1465) Saudi clinical trials available on Clinicaltrials.gov, which it dates back to the period from 2002 to May 2025 at the time of the current study. The study relied on the descriptive analytical methodology based on bibliomterics method aims to identify the reality of Saudi clinical trials and analyzing the objective and numerical trends of these trials. The study reached a set

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of results, most notably that the number of Saudi clinical trials reached 1465 trials during the study period extending from 2002, the start date of the first clinical trial registered on the clinicaltrials.gov website, until mid-2025. Furthermore, the number of topics covered by the clinical trials reached 1135 topics, most notably the topic of type 2 diabetes with 28 clinical trials, followed by the topic of cerebral palsy with 20 studies, then the topic of knee pain with 17 trials, breast cancer with 16 trials, then Covid-19 with 10 trials, and 1103 of the Saudi clinical trials included in the study relied on the interventional method to conduct clinical trials, which represents 75.2% of the number of experiments under study. Saudi healthcare institutions and universities were the main funders of clinical trials, funding 60% of all trials registered in Saudi Arabia. King Saud University in Riyadh ranked first, sponsoring 115 clinical trials registered on Clinicaltrials.gov.

Keywords: Clinicaltrials.gov, Clinical trials, Clinical studies, Health informatics, Clinical Trials Data Management, National Health Institutions, Saudi Arabia.

Firstly, the methodological framework

1/Introduction

Clinical studies involve research that tests or observes the success of proposed medical methods when applied to humans. Some clinical studies, also called clinical trials, test new treatments, such as new drugs or other therapies. These studies help researchers find out whether a new treatment is effective or less harmful than standard treatments. Clinical studies usually include human participants or volunteers and may also include human samples such as blood or tissue, with the aim of developing medical knowledge. Clinical trials help find new methods better for detecting, diagnosing, treating, and preventing diseases. Types of clinical research include clinical trials, which test new treatments for a disease and natural history studies, which collect health information to understand how the disease develops and progresses over time (National Cancer Institute, 2025).

Clinical studies are divided into two main types: clinical studies, also known as interventional studies, and observational studies that do not involve testing new treatments but are designed to collect information about the disease, understand it better, and improve patient outcomes and may include medical examinations, tests, and questionnaires. The primary method researchers use to determine the safety and effectiveness of a new treatment is through clinical trials. For a drug to become approved for circulation, it must first be tested in a series of clinical trials, known as

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Phase 1, Phase 2 and Phase 3. After a phase 3 clinical trial, data from the trial is sent to a regulatory agency, which determines whether the drug should be approved for use. Clinical trials may compare the treatment method already in use with the therapeutic alternatives proposed in the clinical trial (Browning, 2019)

There are different types of clinical trials (Cancer Research UK, 2021):

- Treatment Trials: Treatment trials make up the vast majority of clinical studies and involve individuals with certain health conditions. These trials aim to evaluate new treatments or innovative approaches to using currently available treatments.
- Prevention trials: Prevention trials are concerned with studying possible means of reducing the risk of developing certain diseases. These trials often involve people who are not infected but have a high risk of infection or who have been infected before and are at risk of recurrence.
- Screening trials: Screening trials aim to explore mechanisms for early detection of diseases before clinical symptoms appear, increasing the chances of effective therapeutic intervention in the early stages.
- Supportive care/palliative Care Trials: These trials seek to improve the quality of life of individuals, especially those with chronic symptoms or side effects resulting from treatment, by evaluating effective supportive interventions (National Cancer Institute).

2/The importance of the study and its justifications

The importance of the study stems from the scientific significance of clinical trials in the field of health informatics and related fields, given the spread of numerous epidemics, their causes, and physical and psychological illnesses for which effective treatments have yet to be found, such as cancer, dementia, major depression, and immune diseases such as AIDS, among others, and its role in reducing the serious side effects of other treatments. This type of research study has received increasing global attention with the development of modern technical means, which has prompted international bodies and organizations to pay attention to this important aspect of exploratory and analytical research studies and seek to introduce this production, record it, and publish its data and results, which give scientific and material excellence to these bodies and institutions. Since 2005, members of the Committee of Editors of International Medical Journals (ICMJE) have stated that registration of clinical trials in specialized clinical trial databases is a prerequisite for consideration of publication acceptance. The Kingdom of Saudi Arabia is one of the

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countries keen on this type of clinical research study and registering its clinical trials on Clinicaltrials.gov in order to ensure and comply with the global approach to registering clinical research studies and the Kingdom's vision. The Saudi Health Council launched its national initiative in 2019 (Clinical Trials and Laboratory Development) within the National Program for Industrial Development and Logistics Services, as this initiative is part of the initiatives of the Ministry of Energy and Industry. In partnership with industrial clusters in supporting the localization of the pharmaceutical industry in the Kingdom, within the framework of the Kingdom's Vision 2030. Despite the significance of this type of exploratory and analytical study, it has not received the attention of researchers to introduce it, and developing international standards for its registration, the importance of publishing its data and results, and the reality of the contributions of our Arab countries to this important aspect of research studies.

3/Objectives of the study

The study aims to achieve a main objective, which is:

Exploring the reality of Saudi clinical trials registered on Clinicaltrials.gov and provide a descriptive analysis of the objective, categorical, and qualitative characteristics of these trials. Also, discovering the criteria for registering clinical trials and the role of Saudi healthcare institutions in supporting Saudi clinical studies.

4/The problem of the study and its questions

The main problem of the study revolves around the growing interest in registering clinical trials and the global interest in this type of research studies and the magnitude and dispersion of research production in this field, with the scarcity of Arab studies interested in this type of research studies and thus, the necessity of working to explore this category of studies and analyze their numerical and qualitative trends in Saudi Arabia. Accordingly, a set of questions are raised that the current study attempts to answer, as follows:

- 1. What is the significance, purpose, and types of clinical trials? And what is the purpose of ClinicalTrials.gov?
- 2. Which Saudi health institutions are actively involved in the support and regulation of clinical trials within the Kingdom?
- 3. What is the reality of Saudi clinical trials registered with Clinicaltrials.gov and what is their objective distribution?



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- 4. What types of Saudi clinical trials are registered on Clinicaltrials.gov, what is their status, and what are their results?
- 5. What is the age distribution of participants in Saudi Clinical Trials?
- 6. What is the distribution of participants in Saudi clinical trials according to gender?
- 7. What is the distribution of Saudi clinical trials according to their phases?
- 8. What is the distribution of Saudi clinical trials according to their funders?
- 9. What is the distribution of Saudi institutions and universities sponsoring Saudi Clinical trials?
- 10. What is the time distribution of Saudi clinical trials registered on Clinicaltrials.gov according to the year of start and the year of completion?
- 11. What is the distribution of Saudi clinical trials based on the duration of each trial?

5/Field of study and its limitations

The current study was based on exploring the reality of Saudi clinical trials and their objectives, categorical, numerical and qualitative characteristics:

Objective limits: Saudi clinical trials registered on the Clinicaltrials.gov in all its fields and topics.

Categorical limits: The treatment method used in clinical trials, whether through treatment with medications, radiation, diet, or other treatment methods.

Time limits: The study monitored Saudi clinical trials registered on the Clinicaltrials.gov from the date of the first Saudi clinical trial registered at the base until May 2025. Data was collected in the period from January to May 2025.

6/Study methodology

The current study relied on exploring the reality of Saudi clinical trials and their objective and categorical fields, in addition to identifying international standards for registering clinical trials and the extent of application of those standards by Saudi health authorities. The descriptive analytical methodology based bibliomterics method and its technics and procedures was used to suit this study and its objectives in describing and analyzing the results, formulating the study's questions and answers, and analyzing the results, The study used the bibliometric approach to determine the numerical and qualitative trends of the clinical trials under study.

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7/Terminology of the study

7/1 Clinical Trials

Clinical trials are the most important means of identifying the causes of diseases, reducing their risks, predicting them, and developing hypotheses for their treatment. Many international institutions, such as the World Health Organization (WHO), the European Medicines Agency (EMA), and the FDA Food and Drug Administration, have sought to establish standards for registering clinical trials and making their data known. It may extend to introducing its results and approving them with the health authorities responsible for this.

7/2 Clinicaltrials.gov

The Clinicaltrials.gov is one of the most important databases for clinical research studies and their data. It primarily seeks to provide information about clinical trials for researchers, health professionals, and beneficiaries in general. The base includes clinical trials for the United States of America and 200 other countries around the world (Clinicaltrials.gov).

7/3 Health informatics

Health informatics is an interdisciplinary field that integrates information technology, and clinical expertise to manage and analyze health data for improving the quality, efficiency, and accessibility of healthcare, Benefits of health informatics include reducing errors, expanding access to care, providing real-time feedback, and enhancing communication between healthcare teams and patients to support better decision-making (Petersen et.al, 2020).

7/4 Clinical Trials Data Management

Clinical Data Management (CDM) is a vital component of any clinical trial. It involves the systematic collection and management of participant data in accordance with regulatory requirements (Krishnan Kutty, B, 2012). Most researchers engage in CDM activities as part of their research efforts. The core aim of CDM is to ensure the generation of high-quality, reliable data by minimizing errors and missing information while maximizing the completeness and accuracy of the data available for analysis (Lu, Z., & Su, J., 2010).



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8/ Review of Literature

Research was conducted to access studies relevant to the current study using the keywords "clinical studies Saudi Arabia", "clinical trials Saudi Arabia", "Clinical Trials Data Management Saudi Arabia" in the following data bases:

- Clinicaltrials.gov
- Ovid; Wiley online library; Oxford journals; Evidence Based Medicine Reviews, Medline DATE 1946
- pubmed.ncbi.nlm.nih.gov
- In addition to the Dar al- Al-Mandumah,2025 database and the unified catalogue
- Egyptian University's online libraries, 2025).

The researcher found no studies on the subject of searching for Saudi clinical trials in the ClinicalTrials.gov database and their support by Saudi healthcare institutions. The researcher found no previous studies that dealt with the same topic, but there are some related studies that will be presented below.

8/1 Studies that dealt with clinical trials in Saudi Arabia:

- 1. (Alsaywid, Basim et al, 2024): This research project aimed to understand and address the challenges faced in conducting clinical trials in Saudi Arabia by gathering insights from clinical trial professionals from different disciplines and research scientists, and developing strategies that will improve the clinical trial process in Saudi Arabia.
- 2. (Aloudah, N. M., & Shaman, A. M, 2024): An exploratory qualitative study aimed to identify the challenges facing clinical trials in the Kingdom of Saudi Arabia. Semi-structured interviews were conducted with nine key stakeholders from pharmaceutical companies and Contract Research Organizations (CROs). The thematic analysis revealed three main themes: operational challenges, difficulties in regulatory procedures for obtaining approvals, and the competitive advantages that position the Kingdom as a promising and attractive environment for conducting clinical trials.

The current study is completely different from the methodology of the two previous studies, as the two studies differ in the nature of objective treatment from the current study, as the two studies focused on the challenges and obstacles facing conducting

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such experiments in the Kingdom of Saudi Arabia and did not address the same clinical trials registered in Clinicaltrials.gov and their various analyses.

8/2 Studies that dealt with clinical trials in a specific country:

- 1. (EL-Masry, Ayman, 2024): The study analyzed the whole trials going in Egypt; to reflect the patterns and elements of these medical trials, the study used the quantitative analysis method to analyze all patterns of Egyptian clinical trials, the study concluded that the most rated subject is "Postoperative Pain" as this is the most condition/subject studied in clinical trials ran in Egypt, the majority of clinical trials in Egypt, started 1/1/2019. The number of these trials were 129 clinical trials, and the majority of "primary completed date" was December the first, 2023.
- 2. (Taruno, Hiroyuki ,2022) the study extracted information on clinical intervention studies registered between 1 April 2018 and 30 September 2020 in the conventional University Hospital Medical Information Network Clinical Trials Registry (UMIN- CTR) and the new Japan Registry of Clinical Trials (JRCT). The study collected and analyzed information on registration dates, intervention types, funding, secondary sponsors and use of designated administration, data staff in multidisciplinary roles (research planning support, research management, statistical analysis, monitoring and auditing).
- 3. Wilson, P., & Huser, V. (2024): The objective of this study was to evaluate the discoverability of supporting research materials, including supporting documents, individual participant data (IPD), and associated publications, in US federally funded COVID-19 clinical study records in Clinicaltrials.gov (CTG).

The first study had a similar nature and methodology to the current one, but it differed from it in the method of presentation, analysis, and geographical affiliation to clinical trials. The second study dealt with the subject of clinical trials in Japan registered in the information network of university hospitals, which is close to the subject of the current study, but the nature of implementation and the study sample are completely different, as is the research methodology. The third study dealt with the subject of the materials supporting the clinical research and the documents associated with it in Clinicaltrials.gov, which is completely different from the subject of our current study and the nature of its methodology.

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8/3 Studies that addressed the role of blockchain technology in managing clinical trial data:

- 1. (Zhuang, Yan, et al ,2022): This study proposed a comprehensive blockchain-based Clinical Trial Management System (CTMS) that covers all stages of the clinical trial process. The proposed system showed an overall better performance. The system design, implementation, and case studies demonstrated the potential of blockchain technology as a potential solution to CTMS challenges and its ability to perform more health care tasks.
- 2. (Hirano, Tomonobu et al, 2020): The study aimed to develop a data management system based on blockchain technology for clinical trials and test the system through breast cancer clinical trial. The project was conducted to demonstrate clinical data management using blockchain technology.

The previous two studies focused on the importance and usefulness of blockchain technology in managing clinical trial records, which differs from the nature and methodology of the current study.

Comments on previous studies:

Through the previous presentation of previous studies, it became clear that there are two studies that address the issue of the challenges of conducting Saudi clinical trials. The two studies did not address the comprehensive survey of the Saudi trials themselves or their different distributions and orientations, so they differ completely from the nature of the current study. Ayman Al-Masry's study and Taruno's study, Hiroyuki, dealt with Egyptian and Japanese clinical trials, the two studies differ completely from the current study in methodology and application. Wilson, P., & Hauser v. study examined funding for US clinical trials under covid-19 is completely different from the current study. The remaining studies focused on approaches to applying blockchain technology in the management of clinical trial data, which differ in subject matter, methodology, and application from the present research. Nevertheless, this study has drawn upon prior works in several respects, particularly with regard to their findings.

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Secondly, the theoretical framework

Saudi Health Institutions Supporting Clinical Trials:

Saudi Arabia is one of the most important countries in the Islamic world, one of the largest Arab countries, and known for its diverse population. It receives frequent visitors of different nationalities who come to perform Umrah and Hajj. Moreover, the Kingdom hosts residents from different backgrounds, which increases its social and cultural richness and increases the need for health care and attention in this diverse community of citizens, residents or visitors. Saudi Arabia possesses strong foundations for advancing its clinical trials system by streamlining regulatory frameworks and enhancing operational efficiency. The extensive hospital network and consolidated patient databases, alongside national initiatives such as registries and biobanks, position the Kingdom of Saudi Arabia as an attractive environment for global pharmaceutical companies. While significant progress has been made academically, commercialization and patent development remain limited. This highlights the need to integrate entrepreneurial and commercial dimensions from the early stages of clinical trials to ensure market viability and align funding with implementation.

The World Health Organization report indicates the Kingdom's clear interest in improving medical care and launching health and environmental initiatives. The Kingdom is a major participant in international health diplomacy, as it is one of the first countries interested in providing financial support and contributing to finding solutions to respiratory diseases, bacterial infections, and Covid-19. Saudi Arabia is considered one of the first three countries contributing to provide aid to support the operations of the World Health Organization in Yemen, Iraq, Pakistan, Bangladesh and others, equivalent to 300 million US dollars, which reflects the Kingdom's keenness and orientations to support the health sector and medical research locally and globally (World Health Organization, 2024).

Given the significant genetic diversity among Saudi citizens and foreign residents in the Kingdom, Saudi Arabia has placed great emphasis on the healthcare sector. The country has prioritized the establishment of medical institutions that play a vital role in the ongoing efforts to enhance healthcare services, reduce disease incidence, and lower mortality rates. Saudi Arabia's healthcare sector has made notable progress in scientific research, driven by increased government funding and international collaboration. However, clinical research has not advanced at the same pace, underscoring the need to examine the current status of Saudi-registered clinical trials

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in Clinicaltrials.gov, and the contributions of Saudi healthcare institutions, and the extent of their compliance with international standards in this field.

The following provides an overview of the main Saudi healthcare institutions involved in clinical trials, outlining their foundations, core objectives, and strategic policies dedicated to advancing this vital area of medical research:

- King Saud university (KSU): King Saud University (KSU), established in 1957 (1377 AH), is Saudi Arabia's first and one of its most prestigious academic institutions. KSU comprises numerous specialized faculties and institutes, alongside state-of-the-art research centers that significantly contribute to scientific progress and knowledge dissemination. Aligning with healthcare advancements and Vision 2030, King Saud University's Medical City established a Clinical Trials Unit in 2017, officially launched in 2018, dedicated to applying high-quality research standards, supporting researchers, and positioning the city as a leading platform for clinical trials nationally and regionally (King Saud University, 2024). In alignment with the university's strategic research plan, a specialized health research center was established to provide essential infrastructure for advanced health research in basic medical and clinical sciences. This center, Prince Naif Health Research Center, stands as one of Saudi Arabia's distinguished institutions dedicated to impactful healthcare research, particularly emphasizing collaboration with Saudi hospitals through its dedicated Clinical Trials Unit (PNHRC, 2023). On May 23, 2023, King Saud University Medical City (KSUMC) organized a Clinical Trials Day at the College of Dentistry. The event aimed to raise awareness about the importance of clinical research in advancing dental and medical care, and to highlight the role of clinical trials in developing evidence-based treatments (Medical City King Saud University, n. d)
- King Faisal Specialist Hospital & Research Centre (KFSHRC): Clinical Research Department King Faisal Specialist Hospital and Research Centre.
- The Clinical Research Department at King Faisal Specialist Hospital and Research Centre was established in December 2020 with the objective of promoting and facilitating the implementation of future clinical trials. It aims to streamline the process of patient enrollment into cutting-edge clinical trials conducted both locally and internationally.
- Functioning as the central coordinating body for clinical research within the institution, the department oversees and manages trials initiated by in-house investigators as well as those sponsored by external entities. It plays a pivotal

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- role in creating an enabling research environment through the support of a highly experienced, multidisciplinary team—ensuring that clinical studies are conducted efficiently and in accordance with the highest scientific and ethical standards. (King Faisal Specialist Hospital & Research Centre, 2024)
- The Ministry of Health (MOH): Saudi Arabia's Ministry of Health (MOH) was officially established by Royal Decree No. 5/11/8697 on 26-08-1370H / 1951, following earlier efforts by King Abdul Aziz to organize healthcare in the Kingdom. These began with the founding of the Public Health Department in Mecca in 1343H / 1925 and the public health and ambulance agency in 1344H/1925. These bodies laid the groundwork by building hospitals, regulating medical practice, and addressing public health needs—particularly during Hajj and Umrah seasons, MOH is the primary governmental body responsible for managing and delivering healthcare services across the Kingdom. It plays a leading role in formulating health policies, regulating medical practices, In the context of clinical research, the MOH contributes to the planning, approval, and supervision of clinical trials through its affiliated bodies and ethical review committees. It also collaborates with academic and research institutions to enhance the quality and scope of clinical studies conducted in the Kingdom. (Saudi Ministry of Health, 2024).
- King Abdullah International Medical Research Center (KAIMRC): King Abdullah International Medical Research Center (KAIMRC) established in 2006 under the Ministry of National Guard Health Affairs (MNGHA) is a leading institution in Saudi Arabia focused on advancing medical and biomedical research. In collaboration with King Saud bin Abdulaziz University for Health Sciences (KSAU-HS), KAIMRC integrates research, education, and clinical practice to promote innovation and improve healthcare outcomes.
- KAIMRC has been spearhead an initiative to develop clinical trials an effort that culminated in the official launch of the National Command Center for Clinical Trials (NCCCT), April 201. The center's mission is to advance the clinical trial ecosystem in the kingdom,
- KAIMRC specializes in key areas such as clinical research, genomics, cancer, biotechnology, AI, bioinformatics, and infectious diseases. It houses advanced laboratories, biobanks, and clinical trial units. At KAIMRC the Clinical Trials administration plays a central role in managing and supporting clinical research. Key units under this administration include the Feasibility Unit, Scientific Review Office, Clinical Trials Operations Investigational, Drug Unit, Quality Assurance, and Promotion and Engagement Office. The Center's Phase

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- 1 Clinical Trials Unit (CTU) is important because it is the only SFDA-accredited facility in Saudi Arabia for Phase 1 trials, the King Abdullah International Medical Research Center (KAIMRC) was organized World Clinical Trials Day 2025 on Tuesday, May 20, at King Abdulaziz Medical City in Riyadh. This special event highlights the pivotal role of clinical trials in driving scientific discoveries, developing innovative therapies, and enhancing the efficiency and quality of healthcare (MNGHA, 2025).
- King Abdulaziz City for Science and Technolog: King Abdulaziz City for Science and Technology (KACST) plays a pivotal role in enriching the research, development and innovation system in the Kingdom, as it is a national laboratory and oasis for innovation, and the technical reference body for the government and private sectors. It also contributes to supporting innovation by conducting scientific and applied research, accelerating technical development, localizing emerging technologies, and building national capabilities, with the aim of achieving technical progress and promoting sustainable development in the Kingdom (KACST, 2022). recommended strengthening the Kingdom's global position in clinical research and enabling innovation. It also recommended evaluating emerging companies within the Sandbox incubator environment for health innovations, and enabling data sharing. The KACST pavilion presented the experience of Nano Palm, which provides low-cost biorobots to treat sickle cell diseases, and contributes to raising the success rate of clinical trials and significantly reducing development costs.
- Saudi Food and Drug Authority (SFDA): The Saudi Food and Drug Authority (SFDA), established by Royal Decree No. (A/13) on 3/3/1423 AH, is the national regulatory body responsible for ensuring the safety, efficacy, and quality of food, pharmaceuticals, biological and chemical products, cosmetics, pesticides, and medical devices. It also oversees the safety of electronic products that may impact public health.

The SFDA is tasked with formulating national food and drug policies, conducting scientific clinical research to address health-related challenges, and building a robust knowledge base to support education, consultation, and implementation programs.

The SFDA is the regulatory body responsible for the approval, oversight, and ethical governance of clinical trials in the Kingdom of Saudi Arabia. Its core responsibilities include evaluating clinical trial protocols for safety and

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- compliance, issuing the necessary licenses to conduct trials, and managing the Saudi Clinical Trials Registry (SCTR). (Saudi Food and Drug Authority, 2025).
- The Saudi Health Council (SHC): The SHC was established under the name of 'the Health Services Coordination Council' in accordance with Article (16) of the Health Law issued by Royal Decree No. (M/11) dated (23/03/1423 AH). The Saudi Health Council plays a central role in shaping the healthcare system in the Kingdom through a broad range of strategic responsibilities and authorities. These include formulating the national healthcare strategy, developing hospital operational systems in accordance with efficiency and quality standards. Furthermore, the council is responsible for conducting health-related studies and research, including clinical trials (Saudi Health In 2019 the Saudi Health Council launched a national Council, 2025). initiative on clinical trials and laboratory development as part of the National Industrial Development and Logistics Program (NIDLP) under the umbrella of Vision 2030. This initiative, in collaboration with the Ministry of Energy and Industry and industrial clusters, supports the localization of the pharmaceutical industry in the Kingdom. It aims to establish a National Leadership Center to coordinate and promote high-quality, internationally compliant clinical trials across Saudi healthcare sectors, and encourage local and international companies to shift clinical trial activities to the Kingdom. Furthermore, it promotes innovation among healthcare professionals by stimulating clinical research and reducing the cost of conducting trials abroad (Saudi Health Council, 2024).

Based on the overview of the most prominent Saudi centers and institutions supporting clinical trials in the Kingdom, it is evident that Saudi Arabia is strongly committed to advancing this critical area of research, this reflects the nation's strategic focus on improving healthcare outcomes and fostering scientific innovation. Despite this progress, various studies (Alsaywid, Basim et al, 2024), (Aloudah, N. M., & Shaman, A. M, 2024) have identified certain challenges that may hinder the full potential of clinical research development. These challenges could be attributed to factors such as regulatory complexities, limited public awareness, insufficient specialized training, or gaps in coordination among stakeholders. Addressing these barriers is essential to further strengthen the clinical research in the Kingdom.

The WHO Country Cooperation Strategy –Saudi Arabia (2024–2026) was signed, reaffirming the shared commitment to strengthening public health priorities in line with Vision 2030 and the Health Transformation Programme. This programme is

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fully aligned with the 13th global plan of action, the upcoming 14th global plan of action, and the WHO eastern mediterranean strategy (2020–2023), and emphasizes enhanced collaboration across all levels of the organization and the Kingdom. Saudi Arabia's active role in health diplomacy through financial support and cross border cooperation has contributed to addressing major challenges, including COVID-19, antimicrobial resistance, and humanitarian relief efforts.

The Saudi Health Council issued a clinical practice guidelines booklet; this booklet contains tools and templates for:

Adapt/adopt clinical practice guidelines (CPGs). Taking into account the best available evidence from many international sources to facilitate the following:

- Producing clinical practice guidelines for all health institutions
- Activating the role of healthcare practitioners in the Kingdom of Saudi Arabia (Saudi Health Council. Saudi health council national center for evidence-based health practice clinical practice guidelines booklet, 2025.)

As shown in the following figure, the Saudi Health Council has presented the clinical practice guidelines adaptation process in the form of a flowchart:



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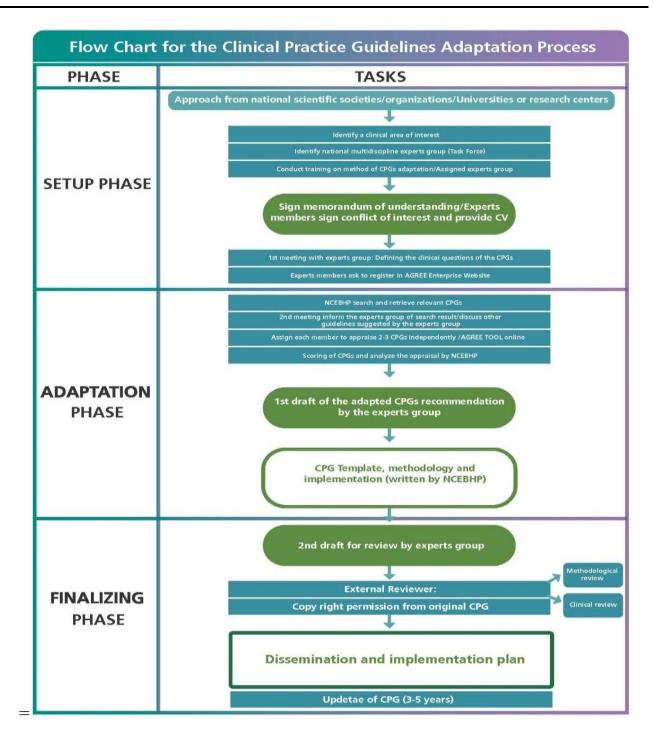


Figure (1). The clinical practice guidelines adaptation process Source. Saudi Health Council (2025)



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Thirdly, Analyze the study results

First collect data

3/1 Subjects / Conditions of Saudi clinical trials:

During the study period and through data analysis, Saudi clinical trials registered with Clinicaltrials.gov included a total of 1135 research topics and conditions. The researcher will present the most studied topics and conditions.

The topics and conditions of Saudi clinical trials have varied considerably, branching into numerous studies aimed at discovering new treatments or approaches for a wide range of diseases, including, for example:

- 1- Diabetes Mellitus, Type 2
- 2- Cerebral Palsy
- 3- Knee Osteoarthritis
- 4- Breast Cancer
- 5- Covid-19

The following table presents examples of the most prominent topics addressed in Saudi clinical trials, based on the most frequently recurring subjects

Table (1). Subjects/ Conditions of Saudi clinical trials Registered on Clinicaltrials.gov

Highest Subjects/ Conditions researched	Count Of Subjects/ Conditions
Diabetes Mellitus, Type 2	28
Cerebral Palsy	20
Knee Osteoarthritis	17
Breast Cancer	16
Hypertension	10
Covid-19	10
Asthma	10
Obesity	9
Sickle Cell Disease	8
Hemophilia A	7
Stroke	7
Postoperative Pain	7
Atrial Fibrillation	6
Heart Failure	6
Hepatocellular Carcinoma	6

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Highest Subjects/ Conditions researched	Count Of Subjects/ Conditions	
Multiple Sclerosis	6	
Low Back Pain	6	
Dental Caries	5	

From the previous table we can see the following:

- Diabetes type 2 was the most tried and tested topic.
- According to data from Clinicaltrials.gov, diabetes mellitus type 2 represents the most frequently investigated topic among Saudi clinical trials, with a total of 28 registered studies addressing this condition. According to the World Health Organization, Saudi Arabia ranks second in the Middle East and seventh globally in diabetes prevalence, with over 7 million individuals diagnosed with diabetes and an additional 3 million affected by pre-diabetes. This represents a significant public health concern. The country faces numerous challenges in diabetes management, including the rising incidence among youth, associated vascular complications, sedentary lifestyles, delayed diagnoses, limited public awareness, and the high cost of treatment. Notably, healthcare expenditures related to diabetes have increased by over 500% in the past two decades, placing substantial strain on the national healthcare system (Robert, A., Al Dawish et al, 2016). This explains the trends of Saudi researchers and Saudi clinical trials towards paying attention to this disease and the fact that it comes in first place among Saudi clinical trials registered on Clinicaltrials.gov.
- The topic of Cerebral Palsy was the second most important topic addressed by Saudi clinical trials, with 20 clinical trials on this disease.
- Cerebral palsy (CP) is among the most prevalent developmental disabilities affecting children globally. A study conducted in Saudi Arabia, reported a CP prevalence of approximately 1.6 per 1000 live births, consistent with international figures as a permanent neurological disorder. CP impacts multiple developmental domains, particularly motor function, cognition, and communication. In Saudi Arabia, it is recognized as one of the most common pediatric neurological conditions (Gmmash, A., Aljuhani, T., & Albesher, R. A., 2025). This disease is spread as a result of consanguineous marriage, which is considered a well-known Saudi custom and tradition. Hence, there is a lot of interest in this topic and Saudi clinical trials are focused on it with the aim of providing new treatments or methods to prevent and limit its spread.



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- Several studies have highlighted the prevalence and impact of cerebral palsy in Saudi Arabia, where neurological disorders affect approximately 6.9 per 1000 children. Among these, intellectual disability and cerebral palsy present elevated prevalence rates of 2.7 and 2.3 per 1000, respectively. Additionally, epilepsy affects 6.5 per 1000 children. (Mushta, S. M., at all, 2024).
- In alignment with Saudi Arabia's national efforts to reduce the prevalence of cerebral palsy and mitigate its risk factors and underlying causes, local clinical trials have increasingly concentrated on the development and evaluation of effective therapeutic and management strategies.
- The analysis of Saudi clinical trials reveals a clear pattern in research focus areas, with certain medical conditions receiving higher attention due to their prevalence and public health impact. Knee osteoarthritis emerged as the third most commonly studied medical condition, which corresponds with its high global prevalence, particularly among women (Ouyang, Y., & Dai, M., 2025). This alignment between research priorities and disease burden underscores the responsiveness of Saudi clinical research to both national and international health challenges.
- Breast cancer ranked fourth among Saudi clinical trials registered on Clinicaltrials.gov, according to international and Saudi studies. In the world, breast cancer (BC) is the second leading cause of cancer-related death and is the most prevalent malignant tumor among women. In Saudi Arabia, this is the ninth leading cause of death (Ashareef et al., 2020). There is a high prevalence of breast cancer mortality among Saudi Arabian women, with the highest prevalence among divorced women. Though the prevalence of breast cancer mortality among men is lower than that of women, men had a higher risk of death (Alotaibi et al., 2018). From the above, it is clear the logic of Saudi clinical trials' interest in breast cancer and its presence among the most important clinical trials, given that it is one of the most important causes of death in the Kingdom.

3/2 Study Type of Saudi clinical Trials:

Clinical trials are generally classified into two main types: Interventional and Observational studies as follows:

Interventional trials involve assigning participants to receive specific interventions (such as a drug, device, or behavioral therapy) in order to evaluate their effects on health outcomes.



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• Observational studies do not assign interventions; instead, they follow participants in their natural settings to observe health outcomes and associations without experimental manipulation (NIH.gov, 2025).

Types of clinical trials include the following:

- Prevention trials: test ways to prevent diseases or their recurrence (e.g., medicines, vaccines, lifestyle changes).
- Screening trials: evaluate new methods for detecting diseases or conditions.
- Diagnostic trials: study or compare tests and procedures for diagnosis.
- Treatment trials: test new treatments, drug combinations, or surgical/radiation approaches.
- Behavioral trials: assess strategies to promote healthy behavior changes.
- Quality of life (supportive care) trials: explore ways to improve comfort and well-being in patients with illnesses.

From the next table and figure we can discover the following:

- Interventional trials constitute the predominant type of Saudi clinical research, accounting for approximately 1103 studies, or about 75% of all Saudi clinical trials registered on Clinicaltrials.gov. These trials involve the application of treatments such as drugs, radiation, medical devices, and other interventions to evaluate their effectiveness in achieving the intended outcomes.
- The number of Saudi clinical trials that relied on observational experiments reached 359 studies, which represents about 24.5% of all Saudi clinical trials. Observational trials are the second major type of clinical research that does not involve any interventions; rather, researchers collect information directly from participants or analyze previously collected data about them, which may include health status, lifestyle habits, or environmental factors.
- The predominance of interventional trials may be attributed to their use of diverse methods and human participants, which often yield more direct and impactful outcomes compared to relying solely on data and information, as is the case with observational studies. Notably, two trials employed direct rapid interventions through radiation, while the methodological approach in one trial was not clearly specified.



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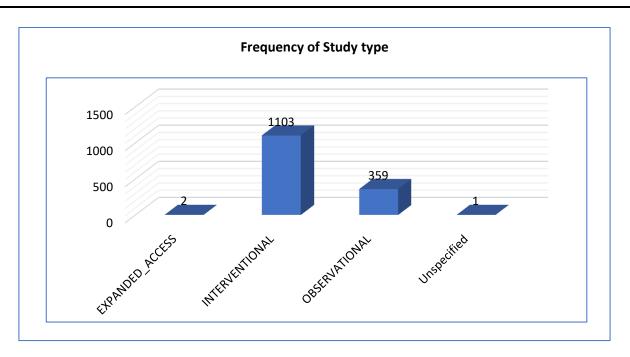


Figure (2). Frequency of types of Saudi clinical trials

Table (2). Percentages pf types of Saudi clinical trials

Study type	percentage
Interventional	75.3%
Observational	24.5%
Expanded Access	0.14%
Unspecified	0.07%
Totals	100%

3/3 Status of Saudi clinical trials:

The status of a clinical trial refers to its current condition, as defined in Clinicaltrials.gov, and may include: Recruiting, active (not recruiting), completed, terminated, suspended, withdrawn, unknown status, or no longer available. The next table presents the distribution of Saudi clinical trials according to their current status, including completion, termination, marketing, and other relevant categories. From the next table and figure we can discover the following:

Analysis of Saudi clinical trial data available on Clinicaltrials.gov showed that 916 trials were completed, accounting for 62.5% of all Saudi trials. A total of



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- 215 trials had an indefinite completion period, while 143 trials (9.8%) were actively recruiting. In addition, 24 trials had not yet begun recruitment, 8 submitted trials were withdrawn, 7 were suspended, 1 trial had received marketing approval, and 1 trial was no longer available in the database.
- After completing a clinical trial, researchers analyze the collected data to determine its scientific significance and decide whether to proceed to the next phase or discontinue the study if the intervention proves unsafe or ineffective. Results are often published in peer-reviewed journals to ensure reliability and may also be presented at conferences or highlighted in the media if of particular importance. Once a treatment is proven safe and effective, it may become a new standard of medical practice. Published results can be accessed by searching the study's official name or protocol ID in the National Library of Medicine (NIH.gov, 2025).
- Although most of the Saudi experiments have already been completed, there is no evidence of what these experiments have achieved and whether they have actually been invested in serving the goal for which they were prepared, which requires an individual study to investigate this aspect.

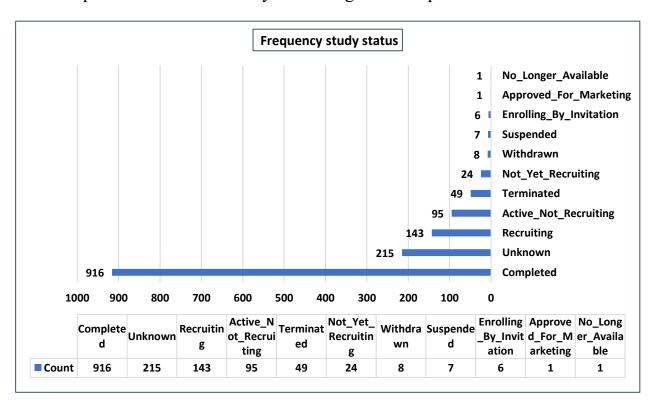


Figure (3). Frequency of status of Saudi clinical trials registered on Clinicaltrials.gov



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Table (3). Percentages of status of Saudi clinical trials registered on Clinicaltrials.gov

Study Status	percentages
Completed	62.5%
Unknown	14.7%
Recruiting	9.8%
Active_Not_Recruiting	6.5%
Terminated	3.3%
Not_Yet_Recruiting	1.6%
Withdrawn	0.55%
Suspended	0.48%
Enrolling_By_Invitation	0.41%
Approved_For_Marketing	0.07%
No_Longer_Available	0.07%
Total	100%

3/4 Results of Saudi clinical Trials:

Clinical trial results indicate whether a study has produced specific findings, remains ongoing without reported outcomes, or has failed to achieve its intended objectives. The following table and figure illustrate the number of clinical trials that have reported study results and those that have not yet yielded outcomes.

From the next table and figure we can discover the following:

- We explore that 176 (12%) of the 1465 Saudi clinical trials registered on the Clinicaltrials.gov, had reported results, whereas 1289 (88%) had not yet reported outcomes at the time of this study.
- Such findings are not unexpected, as numerous clinical trials may require extended durations and additional methodologies to yield outcomes, whereas others are discontinued due to the absence of conclusive results.



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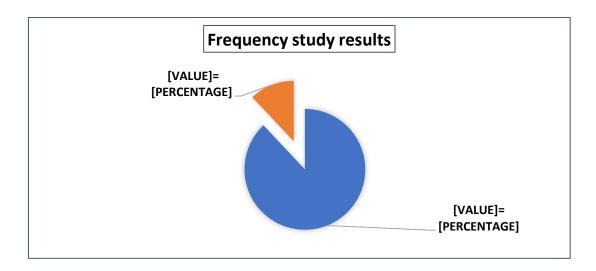


Figure (4). Frequency of results of Saudi clinical trials registered on Clinicaltrials.gov

Table. (4). Percentage of results of Saudi clinical trials Registered on Clinicaltrials.gov

Study Results	percentages	
NO	88%	
YES	12%	
Totals	100%	

3/5 Age Distribution of Participants in Saudi Clinical Trials:

Clinical research is the cornerstone for generating evidence on the safety and efficacy of medical treatments and procedures. Scientific advancements, both past and present, have been made possible through the participation of volunteers whether healthy or affected by illness in clinical studies. Such research involves rigorous and methodologically complex testing, often conducted in collaboration with communities impacted by disease. As clinical research paves the way for improved diagnosis, prevention, treatment, and potential cures, participation in clinical trials is fundamental to achieving meaningful outcomes. The contribution of volunteers is therefore indispensable, representing a critical component without which clinical research would not attain its intended impact.

One essential requirement of clinical trials and clinical research is ensuring diversity among volunteer participants. Depending on the nature and objectives of the study, participation may be limited to specific age groups or expanded to include a broader



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range of ages. Numerous studies highlight that insufficient representation of all age groups in clinical trials can compromise the validity and generalizability of the findings, thereby undermining the overall goals of clinical research (Schwartz, J. B. 2023).

From the next table and figure we can explore the following:

- The diversity of volunteers participating in Saudi clinical trials in general, as the trials included volunteers from adults, the elderly, and children Many clinical trials were conducted on volunteers of all age groups.
- Adults represent the largest percentage of participants in all Saudi clinical trials, in addition to participating with other age groups in the majority of trials. It is worth noting that 330 trials representing 22.5% of the total trials included in this study were limited exclusively to adult participants. The elderly showed minimal participation in Saudi clinical trials, with only 5 studies involving them, representing 0.34% of the trials examined. This limited involvement may be attributed to a lack of awareness regarding the significance of such trials, as well as reluctance or fear of participation findings that align with the conclusions of (Wei, L. S., 2024).

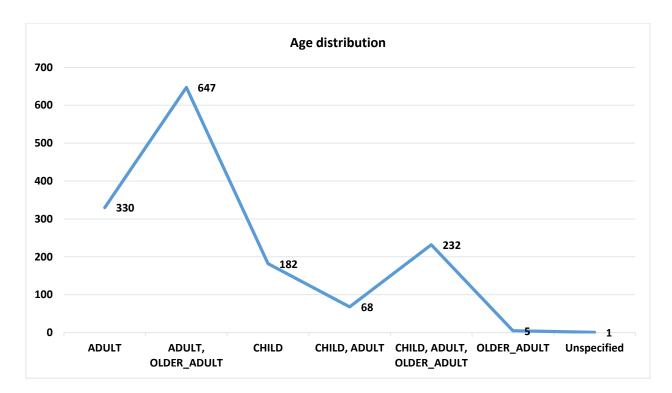


Figure (5). Frequency of age Distribution of Participants in Saudi Clinical Trials



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Table. (5). Percentage of age Distribution of Participants in Saudi Clinical Trials

Age	Percentages
Adult, Older Adult	44.2%
Adult	22.5%
Child, Adult, Older Adult	15.8%
Child	12.4%
Child, Adult	4.6%
Elderly	0.34%
Unspecified	0.07%
Totals	100%

3/6 Distribution of volunteers in Saudi clinical trials according to gender:

Clinical trials are conducted according to a pre-defined protocol designed to first ensure the safety of participants, reduce risks, and address specific research objectives. The protocol specifies the objectives of the study. The volunteers qualified to apply the experiment to risk avoidance, duration, and data to be collected. Each trial is supervised by a principal investigator, with the research team continuously monitoring the health of participants to evaluate safety and effectiveness.

From the next table and figure we can explore the following:

• The majority of clinical trials were conducted on both male and female volunteers, with a total of 1253 trials, representing 85.5% of all Saudi clinical trials. Some experiments were applied to women only, and their number reached 129 clinical trials, representing 8.8% of the number of clinical trials. The application of 81 experiments was limited to male volunteers only, representing 5.5% of the researches, while the gender of the volunteers was not clear in two Saudi clinical trials registered on Clinicaltrials.gov.



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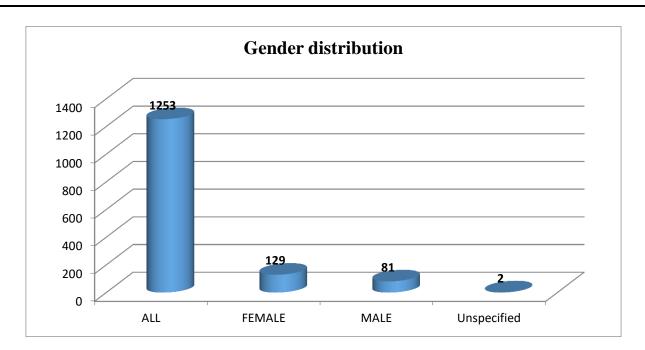


Figure (6). Frequency of distribution of volunteers in Saudi clinical trials according to gender

Table . (6). Percentages of distribution of volunteers in Saudi clinical trials according to gender

Gender	Percentages
All	85.5%
Female	8.8%
Male	5.5%
Unspecified	0.14%
Totals	100%

3/7 Distribution of registered Saudi clinical trials according to their Phases:

Clinical trials are conducted through sequential phases, each serving a distinct purpose in evaluating the safety and efficacy of new treatments.

- Phase I involves a small cohort (20–80 participants) and focuses on assessing safety, tolerability, and potential side effects.
- Phase II expands to a larger group (100–300 participants) to further evaluate safety and preliminarily determine efficacy.



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- **Phase III** includes a broader population (1,000–3,000 participants) to confirm effectiveness, monitor adverse reactions, compare the intervention with existing standards, and collect comprehensive data to support safe clinical application.
- **Phase IV** occurs post-approval, monitoring the intervention in the general population to gather additional evidence on long-term safety, effectiveness, and optimal usage. (National Institutes of Health, 2025).

From the next table and figure we can explore the following:

- The number of Saudi clinical trials in which the experimental phases were not specified reached 601 studies, representing approximately 41% of the total registered trials. In addition, 362 trials, accounting for more than 24% of the total, did not indicate the stage they had reached. Conversely, phase III clinical trials constituted more than 16% of the total, representing studies that are close to achieving their final outcomes, where the proposed treatment is administered to a large number of volunteers in order to confirm its efficacy, monitor potential side effects, and compare it with similar treatments.
- The early phase I of treatment ranked lowest, with only nine Saudi clinical trials registered on the Clinicaltrials.gov. This phase remains in its initial stages, during which the treatment's effects are evaluated on a very limited number of participants, typically not exceeding 80 volunteers.
- By analyzing the stages of the recorded Saudi experiments, it becomes clear that the status of most experiments is not specific and that other experiments are still in their early stages, which indicates the lack of seriousness of some studies or their failure to reach encouraging results in the early stages to complete the advanced stages of the experiment.



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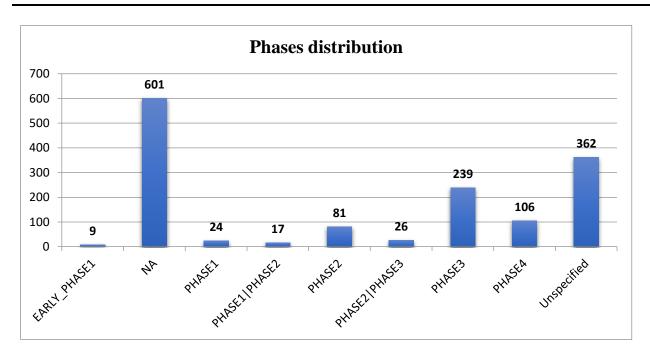


Figure. (7). Frequency of distribution of registered Saudi clinical trials according to their **Phases**

Table. (7). Percentages of distribution of registered Saudi clinical trials according to their Phases

1 mases		
Phases	Percentages	
NA	41.0%	
Unspecified	24.7%	
Phase3	16.3%	
Phase4	7.2%	
Phase2	5.5%	
Phase2 Phase3	1.8%	
Phase1	1.6%	
Phase1 Phase2	1.2%	
Early_Phase1	0.6%	
Totals	100%	

3/8 Distribution of registered Saudi clinical trials according to their Funders

By analyzing the data of Saudi clinical trials registered on the Clinicaltrials.gov, it was observed that a wide range of funders contributed to the development of Saudi



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clinical trials during the study period. These funders encompassed diverse categories, including governmental and industrial entities, academic institutions, Saudi health organizations, non-Saudi institutions, as well as health networks and alliances.

From the next table and figure we can discover:

Non-industrial Saudi entities, including universities, governmental agencies, and ministries, financed 879 Saudi clinical trials, accounting for 60% of all Saudi clinical studies conducted during the study period. This substantial contribution reflects the Kingdom's commitment and the active role of its institutions in fostering and supporting the development of such research endeavors. The industrial sector contributed to the support of 406 Saudi clinical trials, representing approximately 27% of the total studies. In comparison, non-Saudi universities and institutions funded 137 clinical trials, accounting for nearly 9% of Saudi clinical research. Furthermore, health networks and alliances supported 39 clinical trials, representing 2.7% of the total Saudi clinical studies conducted during the study period. The National Institutes of Health (NIH) contributed to the funding of four Saudi clinical trials, while one trial did not specify the nature or type of its funders.

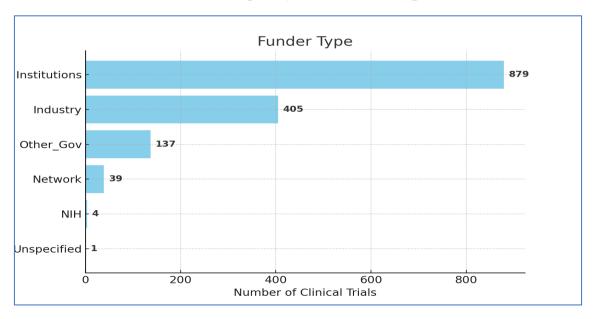


Figure. (8). Frequency of distribution of registered Saudi clinical trials according to their Funder



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Table. (8). Distribution of registered Saudi clinical trials according to their Funder

Funder Type	Percentages	
Saudi Universities and Health Institutions	60.0%	
Industry	27.6%	
Other_Gov	9.4%	
Network	2.7%	
NIH The National Institutes of Health	0.27%	
Unspecified	0.07%	
Totals	100%	

3/ 9 Saudi Health Institutions sponsoring Saudi clinical trials registered on Clinicaltrials.gov

Saudi clinical trials registered on Clinicaltrials.gov have been sponsored and funded by many Saudi health institutions, health centers, hospitals, and universities. From the next table we can see:

Saudi health institutions sponsoring Saudi clinical trials have diversified. According to data from Clinicaltrials.gov. King Faisal Specialist Hospital and Research Center came in first place, sponsoring 62 Saudi clinical trials, followed by King Abdullah International Medical Research Center with 35 clinical trials. As we presented in the theoretical aspect of this study, the two centers are among the most important Saudi health institutions, despite their limited participation in Saudi clinical trials from the researcher's point of view. This may be due to the presence of international organizations such as the World Health Organization and others in which Saudi clinical trials are registered, which requires further survey in future studies.

The Saudi Ministry of Health contributed to sponsoring only 10 Saudi clinical trials out of the trials registered on Clinicaltrials.gov. According to the observed data from Clinicaltrials.gov, neither Saudi Food and Drug Authority (SFDA) nor the Saudi Health Council (SHC) participated in sponsoring any Saudi clinical trial during the study period, despite them being among the most important Saudi bodies responsible in this field (Appendix 2). The researcher believes the limited participation of Saudi health institutions in clinical trials registered on Clinicaltrials.gov. This may be due to the lack of keenness to register all Saudi clinical trials. The researcher also see the need to review the goals and directions of these institutions and the budgets allocated to support this type of trials, while Saudi universities are the most keen and



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productive in this regard due to the presence of many hospitals, institutions and health centers that belong to these universities.

Table. (9). Distribution of Saudi Health Institutions Sponsoring Saudi Clinical Trials

Sponsor	Count	%
King Faisal Specialist Hospital & Research Center	62	32.1%
King Abdullah International Medical Research Center	35	18.1%
King Fahad Medical City	14	7.3%
National Guard Health Affairs	14	7.3%
King Abdul Aziz Specialist Hospital	10	5.2%
King Khaled Eye Specialist Hospital	10	5.2%
Ministry of Health, Saudi Arabia	10	5.2%
King Abdulaziz Medical City	8	4.1%
Procare Riaya Hospital	8	4.1%
King Saud Medical City	6	31%
Saud Al Babtain Cardiac Center	6	3.1%
King Abdullah Medical City	5	2.6%
King Khalid University Hospital	5	2.6%
Total	193	100%

3/10 Saudi Universities Sponsoring Saudi Clinical Trials Registered on Clinicaltrials.gov

The number of clinical trials sponsored by Saudi academic institutions and universities reached 502 trials out of the total Saudi clinical trials registered on Clinicaltrials.gov during the study period, representing approximately 34% of the total Saudi clinical trials, which numbered 1465 trials.

From the next table we can see:

The number of Saudi universities sponsoring clinical trials registered on clinicaltrials.gov reached 21 universities. King Saud University in Riyadh came as the first Saudi university to sponsor Saudi clinical trials with 115 clinical studies representing approximately 23% of the total research sponsored by Saudi universities which registered on clinicaltrials.gov, followed by Imam Abdulrahman bin Faisal University in Dammam in second place to sponsor 62 Saudi clinical studies, followed by King Abdulaziz University in Jeddah with 59 clinical studies, then Umm Al-Qura University in Mecca with 39 clinical



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studies. The least contributions came from Dar Al Uloom University in Riyadh, which sponsored only two experiments, and finally Jeddah University, with one clinical study. The previous results are logical, as King Saud University in Riyadh has a large number of research centers and initiatives, which is natural given that it is the oldest and most prestigious Saudi university and occupies an international position in light of its Arab leadership in all international university rankings, on which scientific research is one of the main points on which these rankings depend to rank universities globally (KSU, 2025).

Table . (10). Distribution of Saudi Universities Sponsoring Saudi Clinical Trials

Sponsor	Count	%
King Saud University	115	22.91%
Imam Abdulrahman Bin Faisal University	62	12.35%
King Abdulaziz University	59	11.75%
Umm Al-Qura University	39	7.77%
Qassim University	34	6.77%
University Of Jazan	25	4.98%
Riyadh Colleges Of Dentistry And Pharmacy	25	4.98%
Prince Sattam Bin Abdulaziz University	23	4.58%
University Of Hail	16	3.19%
Princess Nourah Bint Abdulrahman University	15	2.99%
Majmaah University	14	2.79%
Taibah University	14	2.79%
Riyadh Elm University	17	2.39%
King Khalid University	11	2.19%
Taif University	11	2.19%
King Faisal University	9	1.79%
University Of Tabuk	6	1.20%
Jouf University	5	1.00%
Prince Sultan Military College of Health Sciences	4	0.80%
Dar Al Uloom University	2	0.40%
University Of Jeddah	1	0.20%
Total	502	100%



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3/11 Temporal Distribution of Saudi Clinical Trials Registered on Clinicaltrials.gov by start year

From the next figure we can see:

- The chronological distribution of Saudi clinical trials registered with Clinicaltrials.gov by trial start year extended for 23 years from 2002 to mid-2025, the date of preparation of this study. The year 2002 witnessed the beginning of one Saudi clinical trials registered on Clinicaltrials.gov, while mid-2025 witnessed the registration of 53 clinical trials.
- The years 2020, 2021, 2022 and 2023 recorded the largest number of clinical trials initiated in the Kingdom of Saudi Arabia, with 155, 147, 142 and 140 trials, respectively. This focus of activity can be attributed to the impact of the covid-19 pandemic, including the emergence of respiratory diseases and their associated complications, the development of various vaccines, as well as increased attention and care directed at chronic and incurable diseases. Together, these factors contributed to the significant increase in Saudi clinical trials registered on Clinicaltrials.gov during this period.

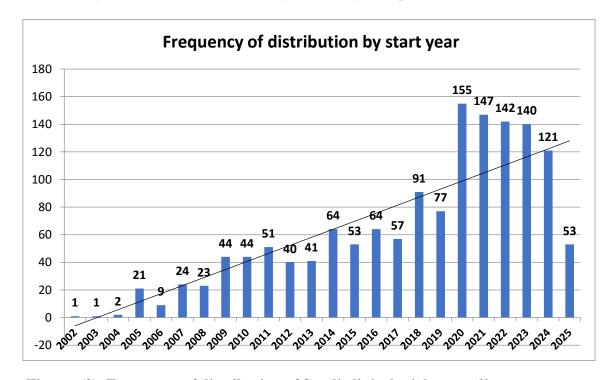


Figure. (9). Frequency of distribution of Saudi clinical trials according to start year



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3/12 Temporal Distribution of Saudi Clinical Trials Registered on Clinicaltrials.gov by completion Date

From the next figure we can see:

By 2024, the number of Saudi clinical trials classified as completed, recruiting, unknown, or terminated reached 1173, accounting for approximately 80% of all Saudi clinical trials registered on Clinicaltrials.gov. This finding aligns with the data presented in Table 3, which summarizes the status of clinical trials in the study. The years 2021 and 2023 recorded the highest rates of trial completion, with 149 clinical trials completed in 2021, followed closely by 148 trials in 2023, according to Clinicaltrials.gov, the remaining trials are scheduled to conclude between 2025 and mid-2050.

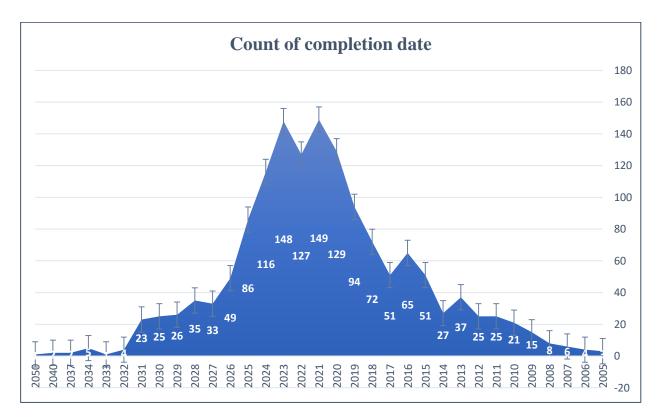


Figure. (10). Distribution of Saudi clinical trials according to completion Date



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3/13 Distribution of the registered Saudi clinical trials according to the duration of the trial

From the next table and figure we can see:

The majority of trials (438), accounting for 30% of Saudi clinical trials registered on Clinicaltrials.gov, required more than three years to complete their stages. This was followed by 332 trials (23%) that lasted more than one year but less than two years. In contrast, only 5 trials (0.3%) were completed within a single day. Additionally, the duration of 27 trials (2%) was not specified. The variation in trial durations may be attributed to the specific nature of each study, the design adopted, and the medical condition under investigation.

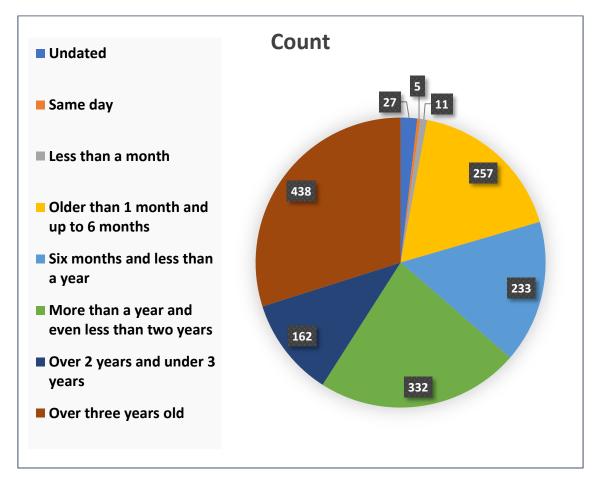


Figure. (11). Frequency of percentages of distribution of Saudi clinical trials according to their duration



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Table. (11). Percentages of distribution of Saudi clinical trials according to their duration

Duration	Percentages
Undated	1.84%
Same day	0.34%
Less than a month	0.75%
Older than 1 month and up to 6 months	17.54%
Six months and less than a year	15.90%
More than a year and even less than two years	22.66%
Over 2 years and under 3 years	11.06%
Over three years old	29.90%
Total	100%

Conclusions

The study monitored 1465 Saudi clinical trials registered on Clinicaltrials.gov. Diabetes type 2 is the most extensively researched topic for Saudi clinical trials, with 28 clinical studies conducted on it. Most types of clinical trials (1103) adopted the "interventional" method of conducting experiments. By mid-2025, Clinicaltrials.gov reported that 916 Saudi clinical trials were completed. The majority of participants in the experiments were adults', while the least participants were elderly. The majority of experiments involved male and female participants, while specific experiments were conducted on women more frequently than men. The majority of Saudi clinical trial funders were from Saudi health institutions and universities, King Saud University came at the forefront of funding Saudi clinical trials with 115 trials. The majority of Saudi clinical trials began in 2020. The number of these trials was 155 clinical trials. The majority of Saudi clinical trials were completed in 2021. The number of these trials reached 149 clinical trials. The majority of Saudi clinical trials took more than three years to complete, with a total of 438 trials.



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Recommendations

From the results of the current study, we can point to some recommendations as following:

- 1. Focusing on the fields of health informatics because of its great importance and related topics.
- 2. Creating a Saudi government data observatory to monitor Saudi clinical trials, their outcomes, and their applications.
- 3. Focusing on establishing data observatories to publish clinical trial results and findings, as Clinicaltrials.gov does not allow the publication of these results.
- 4. Preparing more studies on international institutions and organizations concerned with registering clinical trials globally.
- 5. Creating a unified Arab policy supporting clinical trials and increasing Arab cooperation in this vital field.
- 6. Preparing similar studies in the Arab world to determine the Arab medical contribution to this important aspect of medical scientific research.
- 7. Preparing studies on the most important institutions supporting this type of research and clinical studies in the Arab world.
- 8. Encouraging collaborations between Arab institutions to develop more efficient meta analysis.



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Appendix No. (1)

List of topics of Saudi clinical trials

Conditions	Count
Diabetes Mellitus, Type 2	28
Cerebral Palsy	20
Knee Osteoarthritis	17
Breast Cancer	16
Hypertension	10
Covid-19	10
Asthma	10
Obesity	9
Sickle Cell Disease	8
Hemophilia A	7
Stroke	7
Postoperative Pain	7
Atrial Fibrillation	6
Heart Failure	6
Hepatocellular Carcinoma	6
Multiple Sclerosis	6
Low Back Pain	6
Dental Caries	5
Non-small Cell Lung Cancer	5
Coronary Artery Disease	5
Cancer	4
Erectile Dysfunction	4
Crohn Disease	4
Metastatic Breast Cancer	4
Oral Hygiene	4
Healthy	4
Dental Caries in Children	4
Rheumatoid Arthritis	4
Vitamin D Deficiency	4
ASPIRATION	3
Schizophrenia	3
Diabetic Polyneuropathy	3
Acute Respiratory Distress Syndrome	3
Head and Neck Cancer	3
Multiple Myeloma	3
Down Syndrome	3
Scoliosis Idiopathic	3



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Mark Dain	1 2
Neck Pain	3
Anesthesia Pain	3
	3
Muscular Atrophy, Spinal	
Sepsis Colon Consen	3
Colon Cancer	3
Dentin Hypersensitivity	3
ARDS Septic Shock	3
Muscle Strength	3
Juvenile Idiopathic Arthritis	3
Chronic Low-back Pain	3
Dermatitis Atopic	3
Hemiplegic Cerebral Palsy	3
Pulmonary Arterial Hypertension	3
Crohn's Disease	3
Hemophilia B	3
Cervicogenic Headache	3
Patellofemoral Pain Syndrome	3
Diabetes Diabetes Mellitus, Type 1 Diabetes Mellitus, Type 2	3
Bronchial Asthma	3
Covid19	3
Hypertension, Pulmonary	3
Relapsing Multiple Sclerosis	3
Prostate Cancer	3
Diabetes Mellitus	3
Breast Neoplasms	3
Chronic Lymphocytic Leukemia	2
Myeloid Leukemia, Chronic	2
Colorectal Cancer	2
Symptomatic Irreversible Pulpitis	2
Chronic Kidney Disease and Hypertension	2
Labor Pain	2
Septic Shock	2
Flexible Flatfoot	2
Severe Asthma	2
Low Back Pain, Mechanical	2
Bradycardia	2
Chronic Stroke	2
Myelodysplastic Syndromes Leukemia, Myelomonocytic, Chronic	2
Smoking Cessation	2
Chronic Myelogenous Leukemia	2
Lung Diseases	2



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Chronic Ankle Instability	2
Burns	2
Football Players	2
Biliary Tract Cancer	2
Non-small Cell Lung Cancer Metastatic	2
Lung Cancer	2
Laparoscopic Cholecystectomy	2
Hemophilia A Hemophilia B	2
Type 1 Diabetes	2
Post Operative Pain	2
Osteoarthritis, Knee	2
Invasive Candidiasis	2
Metastatic Colorectal Cancer	2
Relapsing Remitting Multiple Sclerosis (RRMS)	2
Metastatic Renal Cell Carcinoma	2
COVID 19	2
Renal Cell Carcinoma	2
Uveitis	2
Sarcopenia	2
Ventilator Associated Pneumonia	2
Cardiac Surgery Cardiopulmonary Bypass	2
Dyslipidemia	2
Acute Lymphoblastic Leukemia	2
Educational Problems	2
Hepatitis C, Chronic	2
Vitiligo	2
Paroxysmal Nocturnal Hemoglobinuria	2
Pain Management	2
White Spot Lesion	2
Hodgkin Disease Lymphoma, Non-Hodgkin	2
Pain, Postoperative	2
Acute Myocardial Infarction	2
Multiple Sclerosis, Relapsing-Remitting	2
Obesity Overweight	2
Anxiety	2
Keratoconus	2
Tuberculosis	2
Thyroid Neoplasms	2
Chronic Low Back Pain	2
Plaque Induced Gingivitis	2
Iron Overload Sickle Cell Disease Other Anemias	2
Haemophilia A Haemophilia A With Inhibitors	2

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Hallux Valgus	2
Injection Site Irritation	2
Schizophrenia Psychotic Disorders	2
Physical Activity	2
Gingivitis	2
Carcinoma, Non-Small-Cell Lung	2
1005 Individual Repetitions	1
Total	1465



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Appendix No. (2)

Institutions sponsoring Saudi clinical trials

Sponcor	Count
King Saud University	115
King Faisal Specialist Hospital & Research Center	62
Imam Abdulrahman Bin Faisal University	61
King Abdulaziz University	58
Novartis Pharmaceuticals	41
Umm Al-Qura University	37
AstraZeneca	36
King Abdullah International Medical Research Center	44
Qassim University	33
Novo Nordisk A/S	32
Cairo University	31
Bayer	27
Hoffmann-La Roche	26
University of Jazan	25
Riyadh Colleges of Dentistry and Pharmacy	25
Prince Sattam Bin Abdulaziz University	22
Pfizer	18
University of Hail	16
Princess Nourah Bint Abdulrahman University	15
Medtronic Cardiac Rhythm and Heart Failure	14
King Fahad Medical City	14
Sanofi	14
Taibah University	14
National Guard Health Affairs	14
Children's Oncology Group	13
Majmaah University	13
Boehringer Ingelheim	12
Riyadh Elm University	12
King Khalid University	11
Eli Lilly and Company	11
King Abdul Aziz Specialist Hospital	11
King Khaled Eye Specialist Hospital	10



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Security Forces Hospital	10
Ministry of Health, Saudi Arabia	10
Taif University	10
Batterjee Medical College	10
Tanta University	9
King Faisal University	9
King Abdulaziz Medical City	8
Zagazig University	8
الخبر Procare Riaya Hospital	8
Abbott Medical Devices	7
Australian and New Zealand Intensive Care Research Centre	7
McMaster University	7
Boston Scientific Corporation	7
AbbVie	7
University of Tabuk	6
King Saud Medical City	6
Saud Al Babtain Cardiac Center	6
Pfizer's Upjohn has merged with Mylan to form Viatris Inc.	6
Benha University	6
Biogen	6
GlaxoSmithKline	6
King Abdullah Medical City	5
King Khalid University Hospital	5
Medtronic	5
Ain Shams University	5
Celgene	5
Najran University	5
The Eye Center and The Eye Foundation for Research in Ophthalmology	5
Jouf University	5
Princess Al-Johara Al-Ibrahim Cancer Research Center	4
Prince Sultan Military College of Health Sciences	4
Population Health Research Institute	4
Bristol-Myers Squibb	4
Beni-Suef University	4
NRG Oncology	4
National Cancer Institute (NCI)	4



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King Faisal Specialist Hospital & Research Centre, Jeddah	4
Alexion Pharmaceuticals, Inc.	4
Hikma Pharmaceuticals LLC	4
Genzyme, a Sanofi Company	4
Al-Azhar University	4
Wafaa Mahmoud Amin	4
Al Jedaani Hospital	4
Janssen Research & Development, LLC	4
Imam Mohammad ibn Saud Islamic University	3
Ahmed A. H. Abdellatif	3
Agios Pharmaceuticals, Inc.	3
Actelion	3
King Fahad Specialist Hospital Dammam	3
Wyeth is now a wholly owned subsidiary of Pfizer	3
Swedish Orphan Biovitrum	3
BioMarin Pharmaceutical	3
European Society for Blood and Marrow Transplantation	3
ApoPharma	3
Merck KGaA, Darmstadt, Germany	3
Sulaiman AlRajhi Colleges	3
Medtronic Bakken Research Center	3
Duke University	3
Al Hayat National Hospital	3
Société des Produits Nestlé (SPN)	3
Saudi German Hospital - Madinah	3
King Fahad Armed Forces Hospital	2
General Committee of Teaching Hospitals and Institutes, Egypt	2
Eagle Pharmaceuticals, Inc.	2
King's College London	2
London Health Sciences Centre Research Institute OR Lawson Research Institute of St. Joseph's	2
International Cancer Research Group, United Arab Emirates	2
Maged Basha	2
C. R. Bard	2
Johns Hopkins University	2
Janssen Pharmaceutica N.V., Belgium	2



Research and Studies Journal

Minia University	2
National Center for Complementary and Alternative Medicine, Saudi Arabia	2
Janssen-Cilag International NV	2
Janssen-Cilag Ltd.	2
Canadian Critical Care Trials Group	2
King Faisal Specialist Hospital and Research Centre Madinah	2
Kafrelsheikh University	2
St. Joseph's Healthcare Hamilton	2
The George Institute	2
The New Model of Care, Hail Health Cluster	2
The University of Queensland	2
Sanofi Pasteur, a Sanofi Company	2
SWOG Cancer Research Network	2
Alfarabi Colleges	2
Radiation Therapy Oncology Group	2
Amgen	2
Qassim Health Cluster	2
Novartis	2
Università Vita-Salute San Raffaele	2
Universiti Sains Malaysia	2
Prince Sultan Cardiac Center, Adult Cardiology Department.	2
University College, London	2
National Cancer Centre, Singapore	2
Ohio	2
Badr University	2
University of Nottingham	2
Al Mashfa Medical Center	2
Astellas Pharma Global Development, Inc.	2
Abbott	2
Elixir Medical Corporation	1
Ahmed Al Habash	1
AL Yousef	1
ECOG-ACRIN Cancer Research Group	1
Elaj medical centers	1
Egyptian Biomedical Research Network	1
Edwards Lifesciences	1



Research and Studies Journal

ECRI bv	1
Eastern Cooperative Oncology Group	1
Ahmad Abdullah Salawi	1
Exelixis	1
Ain Shams Maternity Hospital	1
Ahmed Aljomah	1
Fondazione Angelo Bianchi Bonomi	1
Hadir F. El-Dessouky	1
Guerbet	1
Gopal Nambi	1
GOG Foundation	1
Gilbert L. Raff, MD	1
Abdulaziz Abdulmunim Alabdulmunim	1
Abdulsalam Alqutub	1
European Organisation for Research and Treatment of Cancer - EORTC	1
Forma Therapeutics, Inc.	1
EMD Serono Research & Development Institute, Inc.	1
Fondation Hôpital Saint-Joseph	1
FluidAl Medical	1
Abha International Private Hospital	1
Fayoum University Hospital	1
Abrar Alzaher	1
Acerta Pharma BV	1
EST	1
GB002, Inc.	1
Ceric SÃ rl	1
Cook Group Incorporated	1
Asma Yahya	1
Comprehensive Rehabilitation Centre, Medina, Saudi Arabia	1
ClinTrio Ltd.	1
Clinical Urology and Epidemiology Working Group	1
Clinical Evaluation Research Unit at Kingston General Hospital	1
China Songjiang Hospital	1
Assiut University	1
Albireo, an Ipsen Company	1
Chair for Biomarkers of Chronic Diseases	1



Research and Studies Journal

Aseer Central Hospital	1
Association for Pediatric Pulmonary Hypertension	1
Centre Chirurgical Marie Lannelongue	1
Astellas Pharma Inc	1
Astellas Pharma International B.V.	1
Warszawa	1
Hakeam Abdulaziz Hakeam	1
Ausnutria Hyproca B.V.	1
Bassem Mohamed Sieda	1
Charlottesville	1
Dr. Anatoly Langer	1
Dr. Soliman Fakeeh Hospital	1
dr. Muhammad Abdelhafez Mahmoud, MD	1
Alexandria University	1
AlJohara M AlQuaiz, M.D.	1
Al-Zaytoonah University of Jordan	1
Dr. Mohammad Abu Shaphe	1
AMIR IQBAL	1
Amr kamel khalil Ahmed	1
Critical Care Pharmacotherapy Trials Network	1
Dr. Erfan and Bagedo General Hospital	1
CSL Behring	1
Ãngel Alberich Bayarri	1
Anwar Ali Ahmad Alameer	1
Dasman Diabetes Institute	1
Dar Al Uloom University	1
Armed Forces Hospitals, Southern Region, Saudi Arabia	1
Danisco	1
Cyclo Therapeutics, Inc.	1
Cyberjaya University College of Medical Sciences	1
Albireo	1
Amryt Pharma	1
University of L'Aquila	1
Niels Jørgen Secher	1
Rezolute	1
Retrotope, Inc.	1



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Resverlogix Corp	1
Rehab Werida	1
Reem Mohammad Alamoudi	1
Reem Alharthi	1
Rawan Alwafi	1
Queen's University, Belfast	1
University of Glasgow	1
Prof. Dirk Rades, MD	1
University of Jeddah	1
University of Chile	1
Prince Sultan Military Medical City	1
Royal Alexandra Hospital	1
Poland MEDYK Medical Center	1
Pharvaris Netherlands B.V.	1
peter metrakos	1
PepsiCo Global R&D	1
Orphalan	1
Origin Biosciences	1
OMER B ABDELBASIT	1
Octapharma	1
NYU Langone Health	1
University of Salford	1
University of Saskatchewan	1
KalVista Pharmaceuticals, Ltd.	1
Princess Maxima Center for Pediatric Oncology	1
St. Anna Kinderkrebsforschung	1
University Hospital, Antwerp	1
University Hospital Muenster	1
United Kingdom Airedale General Hospital; Oncology	1
University Hospital, Geneva	1
UMC Utrecht	1
Ultragenyx Pharmaceutical Inc	1
Turki Abualait	1
The Canadian Blood and Marrow Transplant Group	1
Thailand Research Site	1
Terumo Europe N.V.	1



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~	II
Technische Universität Dresden	1
Takeda	1
Rhode Island	1
Sunnybrook Health Sciences Centre	1
University of Sheffield	1
Sponsor	1
Spain Hospital de Basurto	1
Société Internationale d'Urologie	1
Shaimaa Mohamed Ahmed Elsayeh	1
Shaaban Elwan	1
Saudi Scientific Home Health Care Society	1
University of California, San Francisco	1
Samah Lutfy	1
Sajjad Rahman	1
Sahajanand Medical Technologies Limited	1
safia Darweesh halwsh	1
Russian Federation GBOU VPO Rostov State Medical University	1
University of Calgary	1
Inozyme Pharma	1
Nourah Mulfi Aljasser	1
Khalood Saeed Bahammam	1
khalid abd aziz mohamed	1
University Hospital, Basel, Switzerland	1
Karthick Balasubramanian	1
Juno Therapeutics, Inc., a Bristol-Myers Squibb Company	1
Jonathan Sinclair	1
Johns Hopkins Aramco Healthcare	1
Jerry Zimmerman	1
J. Fernando Arevalo, MD FACS	1
Ishrat Rahman	1
Ipsen	1
Vertex Pharmaceuticals Incorporated	1
Institut National de la Santé Et de la Recherche Médicale, France	1
Utah	1
Incyte Corporation	1
Incheon-gwangyeoksi [Incheon]	1



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Imperial College London	1
Imam Abdulrahman Al Faisal Hospital	1
Ibtihal Altalhi	1
Hungary Research Site	1
Hospital Universitario Getafe	1
Walid Mohamed Ragab Mohamed Badwi	1
Himayat Ullah	1
HemoShear Therapeutics	1
Hawra Al-Dandan	1
Hatan Mortada	1
lowa	1
Medical University of South Carolina	1
Monira Aldhahi	1
Mohamed Gaber Allam	1
Modus Therapeutics AB	1
Mirati Therapeutics Inc.	1
Middle East North Africa Stroke and Interventional Neurotherapies Organization	1
Meshalkin Research Institute of Pathology of Circulation	1
Merck Sharp & Dohme LLC	1
Merck Healthcare KGaA, Darmstadt, Germany, an affiliate of Merck KGaA,	1
Darmstadt, Germany	1
Medtronic Spinal and Biologics	1
Medtronic Italia	1
Medtronic Cardiovascular	1
University of Siena	1
King Abdul Aziz General Hospital	1
medina medical center	1
Hasan Al-Dorzi	1
MED-EL Elektromedizinische Geräte GesmbH	1
McGill University	1
Mayo Clinic	1
Mansoura University	1
Majed Aljeraisy	1
Maha A. Bahammam	1
LivaNova	1
Lebanese American University	1

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Zohaib Akram	1
University of Utah	1
04-730	1
Medtronic Cardiac Ablation Solutions	1
total	1465