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A Retrospective Descriptive Analysis of the Saudi Clinical Trials Registry from 2010 to 2021

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Keywords
Clinical research · Clinical trials · Drugs · Clinical trial registries · Database · Saudi Arabia

Abstract

Introduction: To date, the number and type of drug trials undertaken in Saudi Arabia have yet to be assessed comprehensively. This study aims to give a holistic view and describe the patterns of drug clinical studies registered and conducted in Saudi Arabia from 2010 to 2021, including the most common study phases, study site distribution, most commonly studied diseases, study sponsorship, and statistics about contract research organization (CRO) use. ***Methods:*** A descriptive cross-sectional study of all completed drug clinical study applications submitted to the Saudi Clinical Trials Registry at the Saudi Food and Drug Authority (SCTR-SFDA) database from February 2010 to December 2021. ***Results:*** The SCTR received 477 drug clinical trial applications from February 2010 to December 2021. Of these, 151 (31.7%) were accepted and completed their studies, while 214 (44.9%) were accepted but had ongoing studies. Most submitted trials (62.7%) were international multicenter studies, while 37.3% were conducted only in Saudi Arabia. Phase 3 and 4 trials were the most submitted study phases, followed by phase 2 and phase 1. The most studied therapeutic areas were oncology, endocrinology/metabolism, cardiology, and infectious diseases. Pharmaceutical companies sponsored most studies (62.7%) compared to local investigator (non-pharmaceutical) studies (37.3%). The Riyadh region had the most clinical study sites, followed by the Makkah region and the Eastern Province region. Of the 151 completed studies, 46.4% were published, with multinational studies being more likely to be published than local studies. Pharmaceutical companies were more likely to sponsor multinational studies, while studies conducted in Saudi Arabia only were more likely to be sponsored by local investigators. Only 33.3% of the studies employed CRO services, with 6.5% of studies conducted locally in Saudi Arabia using CROs and 26.8% of studies delegated CROs for multinational studies. ***Conclusions:*** SCTR has shown an increase in evaluated applications over time. The number of completed trial reviews in Saudi Arabia had increased from 18 in 2010 to 55 in 2021. This indicates the SFDA's ability to monitor and regulate more studies in the future, with the majority of submitted trials being international multicenter studies. The most studied therapeutic areas were oncology, endocrinology/metabolism, cardiology, and infectious diseases, with pharmaceutical companies

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sponsoring most studies. The Riyadh region had the most clinical study sites, and only a third of the studies employed CRO services.

Introduction

Clinical trial (CT) is a type of research that is conducted on humans in clinical settings, which plays a significant role in providing a scientific foundation for discovering and using new treatments for diseases [1]. CT is considered the gold standard to provide evidence for medical product safety and efficacy for registration by regulatory authorities [2, 3].

In recent years, the number of clinical trials globally has been increasing due to the demand increase in research and development for new medicine, generalizing trial results for the global population, regulatory requirements for registering a medical product, and other reasons [4]. For instance, the US ClinicalTrials.gov had 100,208 registered studies in 2010, which increased to 362,545 registered studies in 2020 [5]. The number of clinical trials registering at the International Clinical Trials Registry Platform (ICTRP) had significantly increased from 19,287 registered studies in 2005 increased to 25,544 registered studies in 2010 and 8,192,470 registered studies in 2020 [6].

Due to the increasing number of CTs, there is a need to control and govern them. Clinical trials registry platform is a regulatory database containing all information about clinical trials involving humans while being governed and managed within a specific framework. It is important to make the database available to the public to improve transparency on clinical trials, ensure that the study is conducted according to ethical agreement by the Institutional Review Boards, ensure researcher is following the study application, prevent selective reporting, prevent duplicate research, help patients know what trials are ongoing to enroll in, and guide investigators to research the topics that need to be further explored [1, 7–9].

In 2005, the World Health Organization (WHO) established an international registry called the ICTRP. It collects information from 17 primary registries and other registries [9, 10]. As a result, the International Committee of Medical Journal Editors (ICMJE) announced in 2007 that "all clinical trials involving human subjects should be prospectively registered before they will be considered for publication" [11]. In 2008, the Declaration of Helsinki stated, "every clinical trial must be registered in a publicly accessible database before recruitment of the first subject" [12]. Today, there are several clinical trial registries. For example, ClinicalTrials.gov in the USA, the EU Clinical Trials Register, the Australian New Zealand Clinical Trials Registry (ANZCTR), the Brazilian Clinical Trials Registry (ReBEC), the Chinese Clinical Trial Registry (ChiCTR), and many others.

The Saudi Food and Drug Authority (SFDA) ensure safety of food, drug for human and animal, safety of biological and chemical substance as well as electronic devices that are related to human health in Saudi Arabia [13]. As a part of the SFDA's responsibility, the SFDA established the Clinical Trial administration department in 2009 and initiated the Saudi Clinical Trials Registry (SCTR), which has similar responsibilities as ICTRP. In the beginning, it was a paper submission platform in 2010. Then, it launched an online system in 2013. SCTR archives formal records for all clinical drug trials conducted in Saudi Arabia. The main goals of SCTR are to improve the transparency of drug clinical trials conducted in Saudi Arabia by implementing international standards for information completion and precision of the study application and that a formal record of an internationally agreed minimum amount of information is publicly available. Additionally, clinical trial administration ensures the study adheres to the protocol in its application and follows good clinical practice guidelines [14–17]. A typical application file contains essential information such as the study protocol, informed consent form, clinical trial agreements, and other information necessary for the approval process [18].

To date, the number and type of drug trials undertaken in Saudi Arabia have yet to be studied accurately. Such information will be important to enable researchers to direct their future research better, enable pharmaceutical companies and contract research organizations (CROs) to better understand the specific needs of the Saudi Arabian regulatory requirements.

To our knowledge, one study describes the characteristics of drug clinical trials in Saudi Arabia [19]. The study got its data from the publicly available drug clinical trials list, which has an incomplete listing of studies registered before 2013 because the system was paper based. Also, CRO services and publication status are not mentioned. In addition, the time period is different.

This current study will demonstrate the SCTR's 11 years' experience comprehensively by describing the characteristics of drug clinical studies registered and conducted in Saudi Arabia from 2010 to 2021. All data from the SCTR database were used for the analysis. This study would enable a better understanding of the Saudi clinical trial landscape.

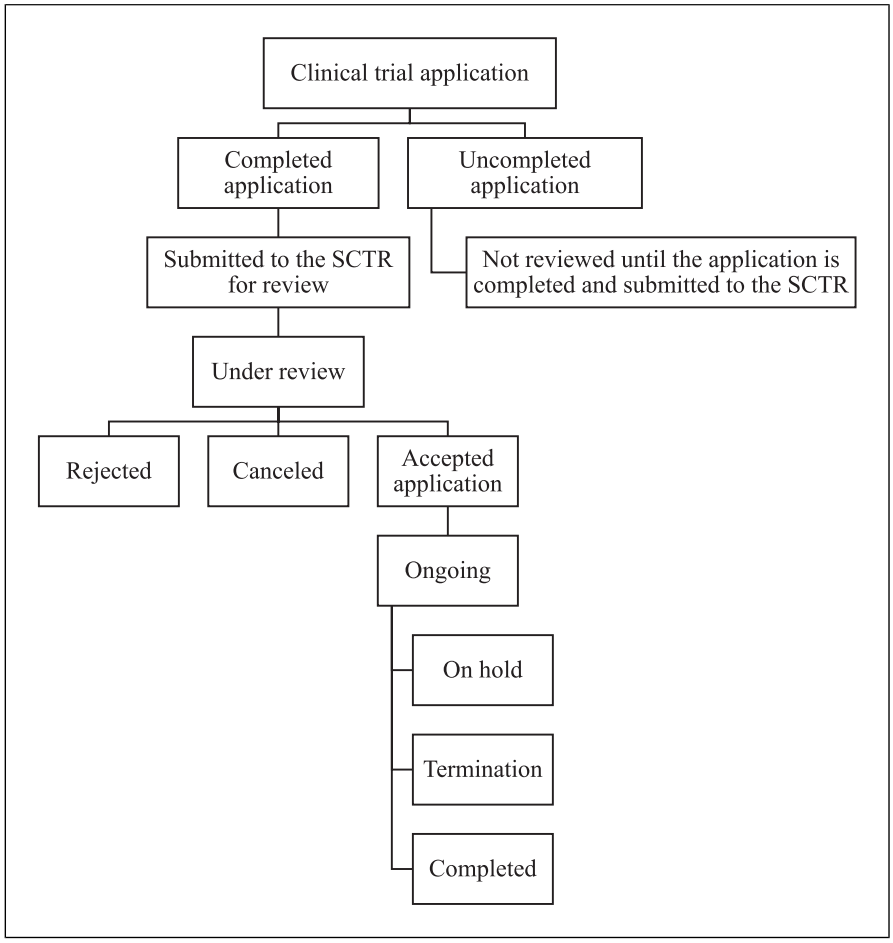

Fig. 1. SCTR application review process. Definitions: Under review – study application is under review by the SCTR. Rejection – SCTR rejected the study application. Canceled – the study application was canceled by request from the applicant before SCTR could take a final decision. Ongoing – study application was accepted and its clinical study is ongoing. On hold – study application was accepted. However, the applicant requested to place the study on hold. Termination – study application was accepted. However, the clinical study was terminated due to recruitment issues, safety, or other reasons. Completed – clinical study is completed.

Methods

A retrospective descriptive analysis study was performed to analyze all completed drug clinical study application submissions to SCTR from February 2010 to December 2021. Incomplete study applications were excluded from our study analysis as they were not submitted to be evaluated by SCTR reviews. An extraction sheet was used for the SCTR electronic archiving system of the paper submissions (2010–2013), and electronically extracted the SCTR online system submissions (2014–2021). The primary investigator extracted the required information manually, and a SCTR clinical reviewer revised the extracted information. Figure 1 shows the SCTR application review process. The following variables were included in the extraction sheet: trial phase, submission date by years, application status at the end of 2021 (canceled, completed, on hold, ongoing, rejected, termination, under review), application sponsor (pharmaceutical companies or non-pharmaceutical), therapeutic area, number of study sites per Saudi Arabia regions, study location (Saudi Arabia only, Saudi Arabia and other countries), and CRO.

To investigate the publication status, the authors searched the published studies in scientific literature search engines, including PubMed and Google Scholar, using the SCTR number, protocol number, and registered English study title without any limitation including language, dates, or location. The study must have a completed status at SCTR and have a full-length published article to be considered as a published study; interim analysis publication was not included because the study might be ongoing or did not start in Saudi Arabia. Data were analyzed using SPSS and Microsoft Excel to describe the data's basic features in a study and the descriptive statistics.

Results

The SCTR received a total of 477 drug clinical trial application submissions from February 2010 to December 2021. Of these applications, 151 (31.7%) of the applications were accepted and completed their study. In comparison, 214 (44.9%) applications were accepted and had ongoing studies, one (0.2%) application was accepted and had an on-hold study, 15 (3.1%) were accepted but terminated their study, 13 (2.7%) were canceled, 42 (8.8%) were under review, and 41 (8.6%) got rejected. The number of

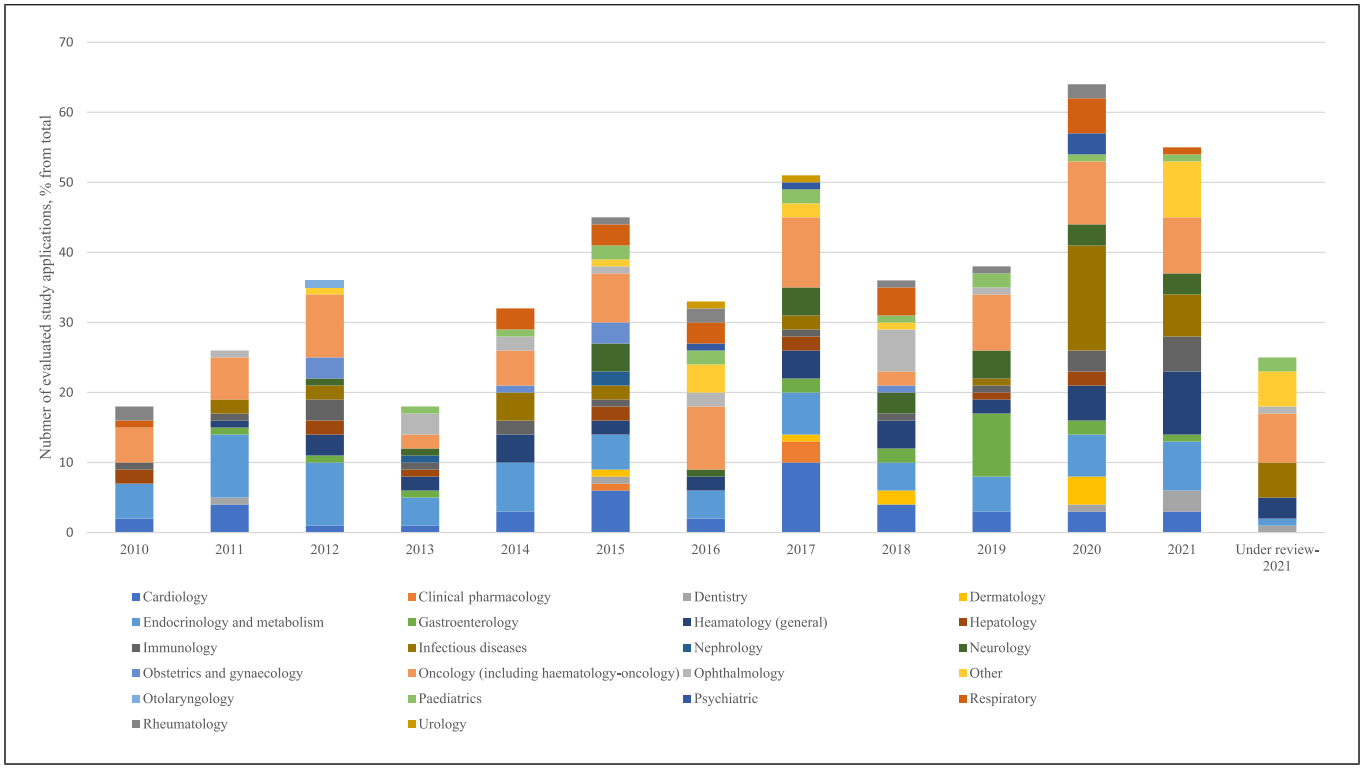

Fig. 2. Number of yearly evaluated study applications by SCTR between 2010 and 2021, by therapeutic group.

evaluated applications increased over time, with a sharp decline of 3.8% in 2013 and reaching its peak of 13.42% in 2020 (Fig. 2). Table 1 presents the characteristics of all submitted applications in SCTR.

The majority of submitted trial applications (299 [62.7%]) were international multicenter studies (i.e., Saudi Arabia is one of the international study sites), whereas 178 (37.3%) were conducted only in Saudi Arabia. Phases 3 and 4 were the most submitted study phases with 205 (43%) and 196 (41.1%) trials, respectively, followed by phase 2 with 56 studies (11.7%), and phase 1 with 20 studies (4.2%). Most phase 1 studies were bioequivalence studies (15 out of 20 studies). Figure 3 shows the number of trial phases per therapeutic area, which shows that most of phase 1 was for cardiology, phases 2 and 3 for oncology, and phase 4 for endocrinology/metabolism. Pharmaceutical companies sponsored most studies (299 studies, 62.7%) compared to local investigator (non-pharmaceutical) studies (178 studies, 37.3%) (Table 1).

Clinical study sites were mainly located in the Riyadh region, with 449 (49.61%) sites, followed by the Makkah region, with 277 (30.61%) sites, and the Eastern Province region, with 137 (15.14%) sites (Table 2). Each study could be conducted at multiple sites inside one region or in multiple regions in Saudi Arabia. The most studied therapeutic area was oncology (87 studies, 18.2%), followed by endocrinology/metabolism (72 studies, 15.1%), cardiology (42 studies, 8.8%), and infectious diseases (39 studies, 8.2%) (Table 3).

We compared the therapeutic area to the application sponsor (Table 3) and found that pharmaceutical companies were more likely to sponsor endocrinology/metabolism studies than oncology or cardiology studies. On the other hand, local investigator (non-pharmaceutical) applicants sponsored infectious disease studies, followed by oncology and endocrinology/metabolism.

Out of 151 completed studies, 70 (46.4%) were published. Of these studies, 63 (41.72%) were multinational studies, and 7 (4.63%) were local studies (Table 4). Pharmaceutical companies are more likely to sponsor multinational studies (257 studies, 79.3%), while studies conducted in Saudi Arabia only were more likely to be sponsored by local investigators, 111 (72.5%) (Table 5). Out of 477, only 159 (33.3%) studies employed CRO services, with 31 (6.5%) studies conducted locally in Saudi Arabia using CROs, and 128 (26.8%) delegated CROs for studies conducted in Saudi Arabia and other countries (international multicenter studies) (Table 6).

Table 1. Characteristics of clinical studies at SCTR, January 2010–December 2021

	Frequency, *n*	Percent
Trial phase		
Phase 1*	20	4.2
Phase 2	56	11.7
Phase 3	205	43
Phase 4	196	41.1
Total	477	100
Study location		
KSA only	178	37.3
KSA/international	299	62.7
Total	477	100
Type of sponsorship		
Pharmaceutical companies	324	67.9
Local investigator (non-pharmaceutical)	153	32.1
Total	477	100
Status		
Rejected	41	8.6
Canceled	13	2.7
Under review	42	8.8
Completed[$]	151	31.7
Ongoing[$]	214	44.9
On hold[$]	1	0.2
Termination[$]	15	3.1
Total	477	100

KSA, Kingdom of Saudi Arabia. Phase 1*, 15 of them bioequivalence studies. [$] The study application was approved; this is the study status by the end of 2021.

Discussion

This is the first study that comprehensively describes the experience of the SCTR from 2010 to 2021. The total number of submitted drug clinical study applications over the last 11 years was 477. Figure 2 shows that the number of yearly evaluated study applications increased over time, with a steep decline in 2013. This might be due to SCTR conversion from paper submissions to online submissions. The applicant needed to familiarize themselves with the online system and requirements before submitting their application, resulting in a low number of submissions. The years 2017 and 2020 were distinct from the rest as they are the most years with evaluated study applications. We noticed that most of 2017 submitted trial applications were for oncology. This might be because in 2017, there was an increase in newly approved cancer medication, and pharmaceutical companies want to study their newly approved medicine on Saudi population or submit a post-market monitoring study [20, 21]. On the other hand, the year 2020 showed an high number of evaluated applications (64 applications), and the most submitted therapeutic class study application was for infectious diseases; this might be due to coronavirus disease (COVID-19). COVID-19 started to spread worldwide in 2020. As it is a new infection, the scientific community needed more information about this infection. Therefore, the Saudi Minister of Education coordinated with many universities, Saudi research centers, researchers, and academics to study COVID-19 infection and funded their research [22]. In addition, many Saudi universities sponsored COVID-19 infection studies [23, 24]. It should be taken into consideration that 2021 SCTR had a considerable number of under review applications, where the applicant did not complete their initial registration requirement.

The submitted study applications during this time period did not address the most prevalent diseases in Saudi Arabia. Cardiovascular disease is the most prevalent disease in Saudi Arabia during the specified time frame [25, 26]. The most studied therapeutic group was oncology. This might be because of new disease-modifying innovations in oncology treatment [20, 27], although cardiovascular diseases had a high rate of mortality in Saudi Arabia in 2017 and 2018 (e.g., ischemic heart disease and stroke) [26, 28]. If we compare the therapeutic area of most submitted applications to SCTR, cardiovascular disease is the third

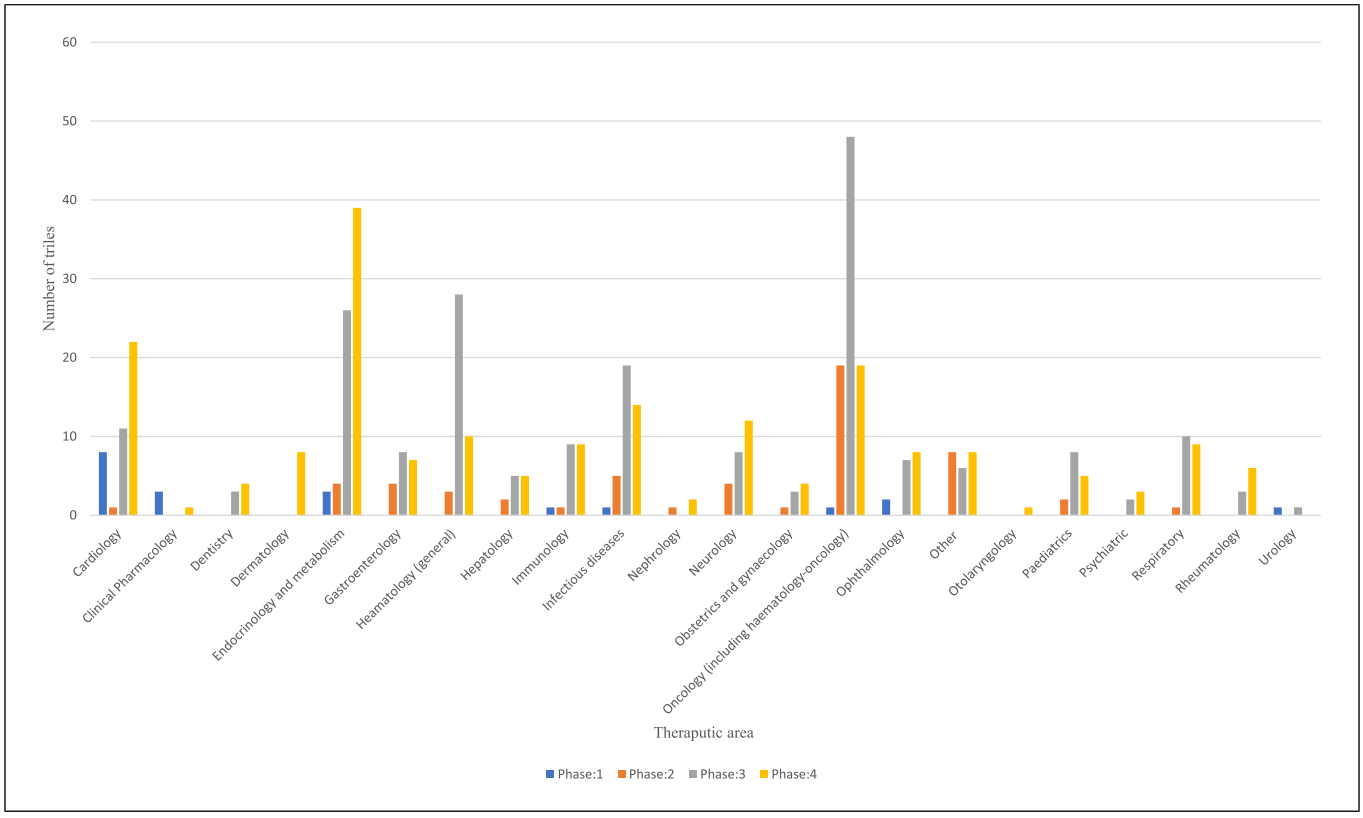

Fig. 3. Number of trial phases per therapeutic areas.

Table 2. Number of conducted study sites per region of Saudi Arabia

Name of region	Studies per region, *n*	Studies per region, %
Riyadh	449	49.61
Makkah	277	30.61
Eastern Province	137	15.14
Asir	15	1.66
Madinah	12	1.33
Najran	5	0.55
Tabuk	3	0.33
Qassim	2	0.22
Ha'il	1	0.11
Jazan	2	0.22
Al Jawf	2	0.22
Al Bahah	0	0.00
Northern borders	0	0.00
Total number of study sites conducted in Saudi Arabia	905	100

A single study could be conducted at multiple sites in multiple regions across Saudi Arabia. SCTR kept a record of how many sites a study had in the 13 Saudi Arabian Regions.

most studied disease in Saudi Arabia, with only 42 (8.8%) studies compared to 87 (18.2%) oncology studies; we could draw from this that researchers in Saudi Arabia are interested in conducting oncology research, and there is a need to investigate cardiovascular diseases in Saudi Arabia for better public health. A similar

Table 3. Therapeutic area studied compared to type of sponsorship

Therapeutic area	Total number of studies conducted in each therapeutic area, *n* (%)	Application sponsor	
		pharmaceutical companies, *n*	local investigator (non-pharmaceutical), *n*
Oncology (including hematology-oncology)	87 (18.2)	60	27
Endocrinology/metabolism	72 (15.1)	58	14
Cardiology	42 (8.8)	32	10
Infectious diseases	39 (8.2)	7	32
Hematology (general)	41 (8.6)	31	10
Neurology	24 (5)	15	9
Respiratory	20 (4.2)	17	3
Gastroenterology	19 (4)	14	5
Ophthalmology	17 (3.6)	14	3
Immunology	20 (4.2)	16	4
Hepatology	12 (2.5)	9	3
Pediatrics	15 (3.1)	7	8
Rheumatology	9 (1.9)	9	0
Other	22 (4.6)	10	12
Obstetrics and gynecology	8 (1.7)	5	3
Dermatology	8 (1.7)	8	0
Psychiatric	5 (1)	3	2
Clinical pharmacology	4 (0.9)	3	1
Dentistry	37 (1.5)	1	6
Nephrology	3 (0.6)	2	1
Urology	2 (0.4)	2	0
Otolaryngology	1 (0.2)	1	0
	477 (100)		

Table 4. Study location compared to publication status

Study location	Publication status*	
	no (%)	yes (%)
KSA only	30 (19.9)	7 (4.6)
KSA/international	51 (33.8)	63 (41.7)
Sub-total	81 (53.7)	70 (46.3)
Total	151 (100)	

KSA, Kingdom of Saudi Arabia. Publication status*: including completed studies only.

Table 5. Study location compared to type of sponsorship

Study location	Application sponsor	
	pharmaceutical companies, *n* (%)	local investigator (non-pharmaceuticals), *n* (%)
KSA only	67 (20.7)	111 (72.5)
KSA/international	257 (79.3)	42 (27.5)
Total	324 (100)	153 (100)

KSA, Kingdom of Saudi Arabia.

finding was noticed for ongoing clinical trials in the USA in 2009. The number of cancer trials was much higher than cardiovascular disease trials, although ischemic heart disease was the most cause of death in the USA [29, 30]. In addition, majority of registered studies in the Iranian Clinical Trial Registry were for mental and behavioral disorders, despite the fact that Iranian greatest burden of diseases was cardiovascular disease [31]. Most of the studies were funded by pharmaceutical companies, 67.9% (Table 1). This result is almost similar to studies funded in the USA, where the number of studies funded by commercial sponsors reached 64.4% [32].

In the case of publication, it was found that the completed studies conducted in Saudi Arabia only had a lower rate of publication than the studies conducted in multinational centers. Several factors may have affected the publication rate of Saudi Arabian studies,

Table 6. Study location compared to CRO employment

Study location	CRO employment	
	no (%)	yes (%)
KSA only	147 (30.8)	31 (6.5)
KSA/international	171 (35.8)	128 (26.8)
Sub-total	318 (66.6)	159 (33.3)
Total	477 (100)	

KSA, Kingdom of Saudi Arabia; CRO, contract research organization.

such as the increase in the number of ongoing studies funded by the government in 2020, making it challenging to complete and publish them in less than a year, null findings, they might change the study title, or published in a journal not indexed in PubMed or Google Scholar.

The study has some limitations, such as missing information about therapeutic area, and whether it is a local or multinational study, especially in the early studies conducted in 2010–2013 before launching the online SCTR. To overcome this, we manually searched the SCTR paper submission electronic archiving system and gathered the missing information. Manually searching the data could affect the accuracy of the collected information. The publication status was not available in the SCTR. Therefore, we manually searched the publication using the protocol number or title of the study in PubMed or Google Scholar only. Therefore, we might miss some of the studies' publications because some of these studies might not be indexed at PubMed or Google Scholar, did not use the SCTR number, protocol number, or changed its title. In addition, study status might be mislabeled as ongoing because it depends on the researchers to submit the final report to change the study status.

The reasons for rejection, termination, cancellation, or on-hold study application status are not available at SCTR. A future study will be conducted on the study application review report to describe the reasons for such status.

Conclusion

This study sheds light on SCTR's experience in regulating drug studies over an 11-year period with an increasing number of trial applications during the time period and overcome the challenge of transforming from a paper registration to an online registration. This indicates the SCTR's ability to monitor and regulate future studies. However, the submitted study applications during this period did not adequately address the most prevalent disease in Saudi Arabia; this suggests a need for more research on cardiovascular diseases for better public health.

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Statement of Ethics

This study was exempt from the ethical approval by the Saudi Food and Drug Authority Ethics Committee.

Conflict of Interest Statement

The authors declare that there is no conflict of interest regarding the publication of this paper. The views expressed in this paper are those of the author(s) and not do not necessarily reflect those of the Saudi Food and Drug Authority or its stakeholders. Guaranteeing the accuracy and the validity of the data is the sole responsibility of the research team.

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Author Contributions

Abdullah Nasser Aljahmi and Radwan A Hafiz wrote the methodology. Abdullah Nasser Aljahmi, Haitham A. Al Hassan, and Radwan A Hafiz worked on data extraction. Abdullah Nasser Aljahmi and Bander Balkhi analyzed the data. Abdullah Nasser Aljahmi, Bander Balkhi, Haitham A. Al Hassan, and Radwan A Hafiz reviewed the analysis, writing, and editing. All the authors approved the final manuscript. All the authors approved the final manuscript.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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