Research Policy of the Investigational Drugs in the Clinical Trial

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ABSTRACT

Objectives: This study aims to explore the research policy of investigational drugs in the clinical trial as a new initiative in Saudi Arabia. **Methods:** This article is a narrative review of pharmacy research. Litterateur researched specific research policies and procedures in pharmacy practice using a variety of databases, including PubMed, Medline, and Google Scholar. The period covered for the search is from the 1960s to October 2021. The terms used are in the English language and encompasses narrative reviews, systemic reviews, meta-analyses, and guidelines. The search term encompasses all hospital and community pharmacy-related services. Besides, there are national and international guidelines for conducting general research in hospital practice. The pharmacy research committee was formed and comprised numerous expert members, including clinical pharmacists, pharmacists specializing in drug information, and clinical research specialists. A member drafted the policy's guidelines, which were then reviewed and corrected by another member. The research specialist made the third revision. The subject emphasizes the research policy for investigational drugs in the clinical trial. **Results:** A general policy was established for investigational drugs in clinical trials, which included defining clinical trials and addressing related issues. Clinical trial approval policy, the role of the Institutional Review Board, the clinical responsibilities of the research team, and patient informed consent. Apart from that, clinical trials require patient records and auditing. **Conclusion:** The research policy for investigational drugs in a clinical trial is a novel initiative within pharmaceutical care research and development. The research policy for investigational drug in clinical trials protects patient rights and safety. Additionally, encourage pharmacy services to implement and conduct clinical trials in pharmacy practice at healthcare institutions of Saudi Arabia.

Key words: Research, Policy, Clinical trial, Drug, Investigational, Saudi Arabia.

INTRODUCTION

There are numerous research designs, including case reports, case series, case-control studies, and cohort studies apart from randomized clinical trials, systematic reviews, and meta-analyses.[1,2] The design strength ranged from a low of one such case report to a high of meta-analysis.[1,2] In the pharmacy practice, each design should have policies and procedures. The clinical trial had the most complex design with numerous and extensive procedures. Clinical trial performance standards were established nearly a century ago.[3] However, the entire picture was not clear until the International Council for Harmonisation released the first guideline in the 1970s and then regularly updated it. It is now referred to as good clinical practice guidelines.[3] Several studies discussed the guidelines in great detail.[4-10] However, detailed reviews of practical policy and procedures are rare or not found in biomedical publications. The majority of healthcare organizations kept their policies and procedures as their copyright throughout the institutions. Thus, the authors are unfamiliar with comprehensive publications on practice policy and procedures for conducting medication clinical trials.[11,12] However, there are reporting guidelines for clinical trials.[13-15] The current topic's goal is to declare the research policy and procedures, focusing on medication clinical trials.

MATERIALS AND METHODS

It's a narrative review of pharmacy research. Litterateur searched for specific topics related to research in pharmacy practice in a variety of databases, including PubMed, Medline, and Google Scholar. The time frame for the search is from the 1960s to October 2021. The terms used were in English and included narrative review, systemic review, Meta-analysis, and guidelines. The policies were limited for the previous ten years. In a search term, all hospital or community pharmacy services are included. Inpatient pharmacy, outpatient or ambulatory care pharmacy, satellite pharmacy, extemporaneous preparation, repackaging units, pharmacy store, drug information center, and clinical pharmacy services were among the pharmacy services available. Furthermore, the National and international guidelines for general research in hospital practice.[3-10,16-21] The Saudi Food and Drug Authority (SFDA),[5,16] the European Medicine Agency,[9] the American Society of Health-System Pharmacists (ASHP),[10] and the World Health Organization (WHO),[7] and other literature.[11,12,22,23] Aside from that, the Equator Network is a library of health research guidelines based on observational studies. This includes the Consolidated Standards of Reporting Trials (CONSORT); the Guidelines for Reporting Parallel Group Randomized Trials, which are

guided by writing policy and procedures[13-15] which a committee of pharmacy researchers developed. Clinical pharmacists, drug information pharmacists, and clinical research specialists are among those who work in this field. One member's policy draft guidelines were reviewed and corrected by a second member, and the research specialist completed the third revision. Pharmacy research practice, research and ethical committee, data collection and organizations, quality of pharmacy research services, competency of pharmacy research services, and pharmacy research education and training were among the topics covered. The current reviews were reported in accordance with the adopted international Appraisal of Guidelines, Research, and Evaluation (AGREE).[24]

The search term methodology was done as follows:

Search: research policy[Title/Abstract] Filters: Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, Humans, English

("research policy"[Title/Abstract]) AND ((guideline[Filter] OR meta-analysis[Filter] OR practiceguideline[Filter] OR review[Filter] OR systematicreview[Filter]) AND (humans [Filter]) AND (english[Filter]))

Search: research policy[MeSH Terms] Filters: Full text, Guideline, Practice Guideline, in the last 10 years, Humans, English

((("research personnel"[MeSH Terms] OR ("research"[All Fields] AND "personnel"[All Fields]) OR "research personnel"[All Fields] OR "researcher"[All Fields] OR "researchers" [All Fields] OR "research"[MeSH Terms] OR "research"[All Fields] OR "research s"[All Fields] OR "researchable"[All Fields] OR "researche"[All Fields] OR "researched"[All Fields] OR "researcher s"[All Fields] OR "researches"[All Fields] OR "researching"[All Fields] OR "researchs"[All Fields]) AND "policy"[MeSH Terms]) AND ((y_10[Filter]) AND (guideline[Filter] OR practiceguideline [Filter]) AND (fft[Filter]) AND (humans [Filter]) AND (english[Filter]))

Translations

research: "research personnel"[MeSH Terms] OR ("research"[All Fields] AND "personnel"[All Fields]) OR "research personnel"[All Fields] OR "researcher"[All Fields] OR "researchers"[All Fields] OR "research"[MeSH Terms] OR "research"[All Fields] OR "research's"[All Fields] OR "researchable"[All Fields] OR "researche"[All Fields] OR "researched"[All Fields] OR "researcher's"[All Fields] OR "researches"[All Fields] OR "researching"[All Fields] OR "researchs"[All Fields]

policy[MeSH Terms]: "policy"[MeSH Terms]

Search: research procedures[Title/Abstract] Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, Humans, English

("research procedures"[Title/Abstract]) AND ((guideline[Filter] OR meta-analysis[Filter] OR practiceguideline[Filter] OR review[Filter] OR systematicreview[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Search: research procedures [MeSH Terms] Filters: Full text, Guideline, Practice Guideline, in the last 10 years, Humans, English

((("research personnel"[MeSH Terms] OR ("research"[All Fields] AND "personnel"[All Fields]) OR "research personnel"[All Fields] OR "researcher"[All Fields] OR "researchers"[All Fields] OR "research"[MeSH Terms] OR "research"[All Fields] OR "research s"[All Fields] OR "researchable"[All Fields] OR "researche"[All Fields] OR "researched"[All Fields] OR "researcher s"[All Fields] OR "researches"[All Fields] OR "researching"[All Fields] OR "researchs"[All Fields]) AND "methods"[MeSH Terms]) AND ((y_10[Filter]) AND (guideline[Filter] OR practiceguideline[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Translations

research: "research personnel"[MeSH Terms] OR ("research"[All Fields] AND "personnel"[All Fields]) OR "research personnel"[All Fields] OR "researcher"[All Fields] OR "researchers"[All Fields] OR "research"[MeSH Terms] OR "research"[All Fields] OR "research's"[All Fields] OR "researchable"[All Fields] OR "researche"[All Fields] OR "researched"[All Fields] OR "researcher's"[All Fields] OR "researches"[All Fields] OR "researching"[All Fields] OR "researchs"[All Fields]

procedures [MeSH Terms]: "methods"[MeSH Terms]

Search: research report[Title/Abstract] Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, Humans, English

("research report"[Title/Abstract]) AND ((guideline[Filter] OR meta-analysis[Filter] OR practiceguideline[Filter] OR review[Filter] OR systematicreview[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Search: research reporting[Title/Abstract] **Filters:** Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, Humans, English

("research reporting"[Title/Abstract]) AND ((guideline[Filter] OR meta-analysis[Filter] OR practiceguideline[Filter] OR review[Filter] OR systematicreview[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Search: research report[MeSH Terms] Filters: Full text, Guideline, Practice Guideline, in the last 10 years, Humans, English

("research report"[MeSH Terms]) AND ((y_10[Filter]) AND (guideline[Filter] OR practiceguideline[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Translations

research report[MeSH Terms]: "research report"[MeSH Terms]

Search: clinical trial policy[Title/Abstract] Filters: Full text, Humans, English

("clinical trial policy"[Title/Abstract]) AND ((fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Search: clinical trial policy[MeSH Terms] Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, in the last 10 years, Humans, English

((("clinical trial"[Publication Type] OR "clinical trials as topic"[MeSH Terms] OR "clinical trial"[All Fields]) AND "policy"[MeSH Terms]) AND ((y_10[Filter]) AND (guideline [Filter] OR meta-analysis[Filter] OR practiceguideline[Filter] OR review[Filter] OR systematicreview[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Translations

clinical trial: "clinical trial"[Publication Type] .or. "clinical trials as topic"[MeSH Terms] .or. "clinical trial"[All Fields]

policy[MeSH Terms]: "policy"[MeSH Terms]

Search: clinical trial reporting[Title/Abstract] Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, Humans, English

("clinical trial reporting"[Title/Abstract]) AND ((guideline[Filter] OR meta-analysis[Filter] OR practiceguideline[Filter] OR review[Filter] OR systematicreview[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Search: clinical trial report[MeSH Terms] Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, Humans, English

((("clinical trial"[Publication Type] OR "clinical trials as topic"[MeSH Terms] OR "clinical trial"[All Fields]) AND "research report"[MeSH Terms]) AND ((guideline[Filter] OR meta-analysis[Filter] OR practiceguideline[Filter] OR review[Filter] OR systematicreview[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Translations

clinical trial: "clinical trial"[Publication Type] .or. "clinical trials as topic"[MeSH Terms] .or. "clinical trial"[All Fields]

report[MeSH Terms]: "research report"[MeSH Terms]

RESULTS AND DISCUSSION

The clinical drug study is a type of interventional clinical trial in which "Any investigation in human subjects with the purpose of determining or verifying the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), identifying any adverse reactions to an investigational product(s), and/or studying the absorption, distribution, metabolism, and excretion of an investigational product(s) to establish its safety and/or efficacy. Therefore, the terms clinical trial and clinical study are interchangeable."[8,9,16] The clinical study's advantages included the following: Blinding is more likely, randomization facilitates statistical analysis, and the best experimental design is a Randomized Clinical Trial (RCT).[25,26] On the contrary, the disadvantages were prohibitively expensive, time-consuming, volunteer bias, occasionally ethically problematic, more difficult to conduct, and bias (selection/allocation/observer/attrition/measurement/compliance).[25,26]

To avoid bias, a clinical trial is "blinded," and the participants are unaware of whether they are in the experimental or control arm of the study.[16,27] The blinding could be single, double, or triple. Due to single blinding, the patient is oblivious to the treatment he is receiving. Due to the double-blinding, neither the subject nor the investigator knows which treatment is being planned. Thus, double-blinding ensures that all patient or therapy groups are treated and observed in the same manner. A method for maintaining blinding in a clinical trial in which the two treatments cannot be similar. Supplies are prepared for Treatment A (active and placebo) and Treatment B (active and placebo); patients are then randomly assigned to one of two treatment groups, either A (active) and B (placebo), or A (placebo) and B (active).[16,27]

A standard trial against which experimental observations can be evaluated can be used to control controlled trials.[28] As far in clinical trials, one group of participants is given an experimental drug. In contrast, another group (the control group) is given either a standard treatment for the disease or a placebo. Therefore, a control group serves as a standard against which experimental results are measured. For example, one group of subjects will be given experimental medications or treatment,[28] and the control group, on the other hand, is given either a standard treatment for the illness or a placebo, a therapy with no significant efficacy. The control group must be ethically justifiable and capable of answering the study's most critical questions. The term "historical control" refers to an individual or group for whom data were collected prior to the study set.[29,30] There is a substantial risk of bias in studies that use historical controls due to systematic differences in the comparison sets caused by changes in risk, prognosis, and health care over time.[30]

The suggested general policy for investigational drugs in the clinical trial is as follows[4,5,7-10,13-16,22,23,31]

1. All research teams members should be familiar with the Glossary of Clinical Research Terms as addressed in Table 1
2. Clinical trial regulation encompasses all phases and should adhere to SFDA guidelines.
3. Before conducting a clinical trial, all clinical trial research teams should obtain a certificate of good clinical practice.
4. Sponsors or manufacturers provide comprehensive education and training to all clinical trial participants about the clinical trial and drug protocol.
5. Before conducting any clinical trial, permission must be obtained from the SFDA.
6. All clinical trials should be conducted with an adequate number of investigators, a full complement of pharmacy services for research and clinical trials, and a full complement of nursing staff and facilities at healthcare organizations.
7. All clinical trials should utilize a computerized accounting program to record all associated material and equipment costs, as well as medication costs and payment issues.
8. All clinical trials should utilize an automated or software-based data collection form to record patient information, randomization procedures, and research follow-up following the conclusion of a clinical trial.
9. The sponsor or manufacturer submits a proposal to the institutional review board for new investigational drug research.
10. The IRB will conduct a thorough review of the document and approve the drug protocol according to regional and local regulations and laws.
11. All documentation and records on investigational medications used in clinical trials should adhere to the SFDA's clinical study regulations.
12. All phases of clinical trials should adhere to the regulations of the healthcare organization and the National Committee on Bioethics (NCBE).
13. Quality management should be incorporated into all clinical trial phases.
14. The IRB of the healthcare organization conducting the clinical trial should assess the trial's risks and benefits, as well as its cost-effectiveness.
15. The IRB evaluates the clinical trial proposal based on complete information about the research team, including their qualifications, experience, and anticipated duration of the trial, as well as the availability of appropriate staff and facilities. Additionally, all investigator groups should inform the sponsor or manufacturer of theirs. Additionally, compliance with applicable local laws and regulations.
16. Patients' integrity and welfare should be protected in accordance with the Helsinki declaration and throughout the clinical trial.
17. The IRB reviews and approves the clinical trial's financial aspects. That includes contractual agreements stipulating resource cost recovery, intellectual property agreements, insurance provisions, indemnification terms, and conflict-of-interest disclosures.
18. Informed consent should be obtained at all stages of clinical studies and should include the research's objective and associated risks and benefits. The principal investigator's name and telephone number and the name and phone number of anyone who receives patient inquiries. The alternative treatment was described in detail, including the risks and benefits. Apart from that, a general description of the study, the duration of drug therapy, and the patient's responsibilities are included. The generic and brand names of an investigational drug should be included in the informed consent.
19. Moreover, Patients may withdraw from the study at any time after signing a consent form. There will be no penalty or loss of benefits associated with refusing to participate in or withdrawing from the study. If circumstances warrant, the principal investigator may withdraw participants from the study. Additionally, the investigator should refrain from providing any new information that might influence a patient's decision to continue

Table 1: Glossary of Clinical Research Terms.[32-35]

Terms	Definition
A clinical trial	Human volunteers were used in a research study to answer particular health questions. Under controlled conditions, interventional studies establish whether experimental medicines or novel ways of employing existing therapies are safe and effective.
Control group	Participants are similar to the experimental group (for example, they are in the same age range) but are not given the experimental treatment. To compare the effect of the new drug, medical device, operation, changes are measured in both the treatment group and this group.
Experimental group	The group of individuals who got the new, well-researched treatment. This group is usually compared to a "control group," or individuals who don't seem to be given the treatment.
Institutional Review Board, "IRB"	A committee that has been officially assigned to safeguard individuals associated with research. This board should audit and approve each clinical study with the aim to ensure each person's safety, rights, privacy, and welfare.
Case Report Form (CRF)	A document records all protocol-required information on each trial subject for reporting to the sponsor.
Investigator Brochure	A collection of all known information about the test product to date includes chemistry and formulation data and preclinical and clinical data. It is at least once a year update. Once the product has been marketed, it's labeling (package insert) takes its position.
Informed Consent Form	A document outlines a study participant's rights and information on the study's objective, duration, needed procedures, and essential contacts. The informed consent statement explains the risks and potential benefits.
Placebo	A chemical with no therapeutic effect is given to a patient who believes it is medicine but isn't. Placebos are also known as 'dummy pills' or 'sugar pills.'
Investigational drug	The trial's drug; this meaning is interchangeable with "investigative novel drug" or "investigative medical product."
Medication number	Each experimental drug package has a unique number on the label used to dispense and track drugs in a trial. In addition, the number is used to ensure that the medicine is delivered in the correct quantity to various research facilities.
Adverse Event	Any negative experience associated with using a pharmaceutical in a patient is referred to as an adverse event, also known as a side effect. Adverse reactions can be moderate or severe. Serious adverse events can result in impairment, are life-threatening, require hospitalization or death, or result in birth abnormalities.
Serious adverse event	A life-threatening adverse event that necessitates hospitalization or an extended hospital stay causes continuous or substantial disability, causes congenital anomalies or congenital disabilities, or results in death.
Study completed date	The date of the last trial participant visited the research location for the final time (that is, "last partcipart, last visit") and the last samples or tests were gathered.
Sponsor	The Sponsor is the organization or person in charge of the clinical trial's many sites.
Principal Investigator	The person in charge of the clinical trials. He or she had scientific and technical guidance at a specific clinical site. Most of the time, the chief investigator will be a well-known physician in the field of research.
Study Coordinator	A crucial member of the research team; who works for the primary investigator or chief researcher. They are the individual who is generally in charge of the clinical study's daily operations.
Sub-Investigator	Any member of an investigational team other than the investigator.
Protocol	The clinical trial is based on a written study design. A protocol outlines subjects eligible to participate in the trial, the tests, procedures, medications, and dosages that will be administered, the outcome measures that will be analyzed, and the study's duration.
Subject	During a clinical study, an individual's reactions or responses to various therapies are assessed (either as a healthy volunteer or as a patient volunteer). A trial participant is another term for this person.
Double-blind research	A study in which neither the participant nor the researcher knows the treatment or control group is known as a double-blind study.
Double-blind, randomized, controlled clinical trial	A double-blind, randomized, controlled clinical trial is one in which study participants are evenly divided into two groups: one receiving the experimental intervention and the other receiving standard or no care. Neither group is aware of how they were assigned. This method decreases the risk of a "placebo effect," which occurs when a treatment that contains no active ingredient produces the same results as a treatment that includes an active component.
Blinding	A sort of clinical trial design in which one or more trial participants, such as the research team, are unaware of which treatments have been assigned to them.
Randomization	Refers to the technique of assigning clinical trial participants to treatment or control groups based on a chance factor to eliminate bias.
Recruitment Plan	The recruiting plan lays out how people will be recruited for the study and how the study will meet its enrollment objective.
Standard Operating Procedure (SOPs)	Detailed written instructions for ensuring consistency in the performance of a specific function among trials and patients at a single facility.

in a study. Another statement could include the sponsor or registration audit gaining access to the patient's profile and other clinical trial-related information. Payment information for patients and treatment of an injury sustained during the study will be collected. If the child participant's parent or responsible person is not an English speaker, the consent form must include a translation in their language. Before signing, patients should have sufficient time to review all information contained in the informed consent. Additionally, the informed consent should include the patient's name and signature, as well as those of the principal investigator and present person. According to the IRB's guidelines, a copy of informed consent should be retained in the patient's profile, and a copy should be distributed to participants.

20. All information on Investigational Medications, including the drug sheet, drug procurement, storage, prescribing, preparation, administration, and monitoring, should be included in the pharmacy's research or investigational medication policy and procedure.
21. If the investigator's team conducts a clinical trial with randomization. They should follow the medication safety policy and follow blinding procedures when violating the code of blinding procedures.
22. All sponsors or manufacturers of clinical trials involving investigational drugs should adhere to the SFDA's good manufacturing practices guidelines.
23. All clinical trials should remain constant in terms of data and procedures. Any non-compliance with any information or steps that the clinical trial should have taken should have been abundant. Any update or modification to clinical information or procedures should be approved by the IRB.
24. All clinical trials should adhere to the drug protocol and have a plan in place to deviate from the protocol in the event of an adverse drug reaction or other drug-related problem, including emergency management.
25. The investigator team should regularly submit a clinical trial progress report or, as requested by the IRB. This includes a summary of the clinical trial and its compliance with the drug protocol, any risks or adverse events, and the initial clinical and economic outcome.
26. All clinical trials should be registered through the Saudi Clinical Trial Application System (SCTR) on the Saudi Food and Drug Administration's (SFDA) website, clinical trial.gov.
27. The IRB should monitor the clinical trial regularly via visit audit at each stage or information and ensure compliance with the clinical trial guidelines. If there are any discrepancies, the IRB has the authority to terminate the clinical trial at any time.
28. Clinical trial records should be retained for at least two years following approval of an indication by regulatory agencies. If the clinical study was conducted on an international scale, the documentation should be retained for a period of fifteen years.
29. The final report should be written in accordance with the Consolidated Standards of Reporting Trials (CONSORT); and the Guidelines for Reporting Parallel Group Randomized Trials.[13-15]

CONCLUSION

Clinical trial policies and procedures are essential in the practice of pharmacy. Patient safety is enhanced in any setting within a healthcare organization using this approach. Healthcare professionals, including pharmacists, review and update the entire policy and procedure regularly to ensure that it complies with new local regulations and international standards of good clinical practice. Clinical trial governance is strongly recommended for Saudi Arabia's new vision 2030.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

Funding

None

Consent for Publications

Informed consent was obtained from all the participants

Ethical Approval

This research was exempted from research and ethical committee or an institutional review board (IRB) approval.

https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html

ABBREVIATIONS

KSA: Kingdom of Saudi; **SFDA:** Saudi Food and Drug Authority (SFDA); **WHO:** World Health Organization; **ASHP:** American Society of Health-System Pharmacists; **STROBE:** Strengthening the reporting of observational studies in epidemiology; **RCT:** Randomized Clinical Trial; **SCTR:** Saudi Clinical Trial Application System.

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