Research Policy of the Research Data Management in Pharmacy Practice

Yousef Ahmed Alomi*, BSc. Pharm, MSc. Clin Pharm, BCPS, BCNSP, DiBA, CDE
Critical Care Clinical Pharmacists, TPN Clinical Pharmacist, Freelancer Business Planner, Content Editor, and Data Analyst, Riyadh, SAUDI ARABIA.
Amal Hassan Al-Najjar, BSc, MSc, Drug and Poison Information Center, Security Forces Hospitals, Riyadh, SAUDI ARABIA.
Hamidah Qasim Ali Abushomi, BSc, MSc. Clin Pharm
Dammam Medical Complex, Dammam, SAUDI ARABIA.
Maha Hussein Almadany, BSc, Pharm
Health Care Quality Management Professional Diploma (HCQM), Pharmacy Quality Department, King Salman bin Abdulaziz Medical City, Al Madina Al Monwarah, SAUDI ARABIA.
Abeer Hussin Almasoudi, BSc. Pharm,
Director, Administration of Research and Studies, Ministry of Health, Tabuk, SAUDI ARABIA.

Correspondence:
Dr. Yousef Ahmed Alomi, Bsc. Pharm, msc. Clin pharm, bcps, bCNSP, DiBA, CDE
Critical Care Clinical Pharmacists, TPN Clinical Pharmacist, Freelancer Business Planner, Content Editor and Data Analyst, P.O.BOX 100, Riyadh 11392, Riyadh, SAUDI ARABIA.

Phone no: +966 504417712
E-mail: yalomi@gmail.com

Received: 17-08-2021;
Accepted: 19-11-2021;

Access this article online
www.ijpcs.net
DOI: 10.5530/ijpcs.2022.11.5

ABSTRACT

Objectives: This study aims to declare the research policy of Data management in pharmaceutical care services 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 includes 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 of Data management in pharmaceutical care services. **Results:** The data management policy for research at pharmaceutical care services was established. That includes the design of the data collection, the data resources, and the data collector. Additionally, the data preparation for analysis, the data's reliability and validity, and storage data. **Conclusion:** The Data management policy for research in pharmacy practice is a new initiative as part of pharmacy departments' research and development efforts. Data management in pharmacy care services may increase the documentation of pharmacist research and activities. The basic foundation of pharmacy analytics is the new vision of pharmacy career professionals.

Key words: Research, Policy, Data management, Pharmaceutical care, Services, Saudi Arabia.

INTRODUCTION

There are numerous research designs, which include selecting a research topic or problem, formulating the problem, conducting a literature search on the topic, and selecting an appropriate research methodology and data collection.[1-3] Besides, data analysis using appropriate biostatistics tools elucidates the significance of the results, their interpretation, and subsequent discussion and conclusion with author recommendations.[1-3] Each step required specific criteria and abilities to complete. The data collection stages were one of the most time-consuming aspects of the research. Numerous guidelines discussed data collection and the abilities required for data collection.[4-6] Each methodological approach used a unique set of data collection tools. Qualitative research techniques include cross-sectional surveys and data collection via standard questionnaires or online surveys.[6,7] The clinical trial used various forms to collect data via standard computerized forms.[8] Certain types of research rely on interviews to collect data. The interview was recorded regularly or via an online survey that included a recording. Thus, each investigation methodology required a unique set of skills and tools. Numerous studies have been conducted on the data collection practices used in healthcare services.[9-16] To manage clinical research data effectively, policies and procedures are required.[9-16] Few or infrequently found data collection in pharmacy research practice.[17] The authors were unaware of any studies focusing on data collection steps in pharmacy research. This review aims to disclose the data collection methods used in pharmacy practice research.

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.[18-31] The Saudi Food and Drug Authority (SFDA),[19,20] the European Medicine Agency,[30] the American Society of Health-System Pharmacists (ASHP),[31] and the World Health Organization (WHO),[28] and other literature.[32,33] Additionally, there is literature on the management of data in healthcare services.[9-16] The pharmacy research committee was formed and comprised of numerous expert members. That includes clinical pharmacists, pharmacists specializing in drug information, and clinical research specialists. One member drafted the policy guidelines, another member reviewed and corrected them, and a research specialist revised them three times. The topic covered various areas, including pharmacy research practice, research and ethical committees, data collection and organization in pharmacy practice, the quality of pharmacy research services, pharmacy research competency, and pharmacy research education and training. The current reviews were reported following the internationally adopted Appraisal of Guidelines, Research, and Evaluation (AGREE) standard.[34]

Search: pharmacy research policy[Title/Abstract] Filters: Full text, Humans, English

(("pharmacie"[All Fields] OR "pharmacies"[MeSH Terms] OR "pharmacies"[All Fields] OR "pharmacy"[MeSH Terms] OR "pharmacy"[All Fields] OR "pharmacy s"[All Fields]) AND "research policy"[Title/Abstract]) AND ((fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Translations

pharmacy: "pharmacie"[All Fields] OR "pharmacies"[MeSH Terms] OR "pharmacies"[All Fields] OR "pharmacy"[MeSH Terms] OR "pharmacy"[All Fields] OR "pharmacy's"[All Fields]

Search: pharmaceutical research policy[Title/Abstract] Filters: Full text, Humans, English

(("biopharmaceutics"[MeSH Terms] OR "biopharmaceutics"[All Fields] OR "pharmaceutic"[All Fields] OR "pharmaceutics"[All Fields] OR "pharmaceutical preparations"[MeSH Terms] OR ("pharmaceutical"[All Fields] AND "preparations"[All Fields]) OR "pharmaceutical preparations"[All Fields] OR "pharmaceutical"[All Fields] OR "pharmaceuticals"[All Fields] OR "pharmaceutical s"[All Fields] OR "pharmaceutically"[All Fields]) AND "research policy"[Title/Abstract]) AND ((fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Translations

pharmaceutical: "biopharmaceutics"[MeSH Terms] OR "biopharmaceutics"[All Fields] OR "pharmaceutic"[All Fields] OR "pharmaceutics"[All Fields] OR "pharmaceutical preparations"[MeSH Terms] OR ("pharmaceutical"[All Fields] AND "preparations"[All Fields]) OR "pharmaceutical preparations"[All Fields] OR "pharmaceutical"[AllFields] OR "pharmaceuticals"[All Fields] OR "pharmaceutical's"[All Fields] OR "pharmaceutically"[All Fields]

Search: investigational drug policy[Title/Abstract] Filters: Full text, Humans, English

("investigational"[All Fields] AND "drug policy"[Title/Abstract]) AND ((fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

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: data management[Title] Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, in the last 10 years, Humans, English

("data management"[Title]) 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]))

Search: data management[Title] Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, in the last 10 years, Humans, English

("data management"[Title]) 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]))

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

("data management"[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

data management[MeSH Terms]: "data management"[MeSH Terms]

Search: pharmacy data management[Title/Abstract] Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, in the last 10 years, Humans, English

(("pharmacie"[All Fields] OR "pharmacies"[MeSH Terms] OR "pharmacies"[All Fields] OR "pharmacy"[MeSH Terms] OR "pharmacy"[All Fields] OR "pharmacy s"[All Fields]) AND "data management"[Title/Abstract]) 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

search: pharmacy data management[MeSH Terms] Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, in the last 10 years, Humans, English

(("pharmacie"[All Fields] OR "pharmacies"[MeSH Terms] OR "pharmacies"[All Fields] OR "pharmacy"[MeSH Terms] OR "pharmacy"[All Fields] OR "pharmacy s"[All Fields]) AND "data management"[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

pharmacy: "pharmacie"[All Fields] OR "pharmacies"[MeSH Terms] OR "pharmacies"[All Fields] OR "pharmacy"[MeSH Terms] OR "pharmacy"[All Fields] OR "pharmacy's"[All Fields]

data management[MeSH Terms]: "data management"[MeSH Terms]

armacy: "pharmacie"[All Fields] OR "pharmacies"[MeSH Terms] OR "pharmacies"[All Fields] OR "pharmacy"[MeSH Terms] OR "pharmacy"[All Fields] OR "pharmacy's"[All Fields]

Search: pharmaceutical data management [Title/Abstract] Filters: Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, in the last 10 years, Humans, English

(("biopharmaceutics"[MeSH Terms] OR "biopharmaceutics"[All Fields] OR "pharmaceutic"[All Fields] OR "pharmaceutics"[All Fields] OR "pharmaceutical preparations"[MeSH Terms] OR ("pharmaceutical"[All Fields] AND "preparations"[All Fields]) OR "pharmaceutical preparations"[All Fields] OR "pharmaceutical"[All Fields] OR "pharmaceuticals"[All Fields] OR "pharmaceutical s"[All Fields] OR "pharmaceutically"[All Fields]) AND "data management"[Title/Abstract]) 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

pharmaceutical: "biopharmaceutics"[MeSH Terms] OR "biopharmaceutics"[All Fields] OR

"pharmaceutic"[All Fields] OR "pharmaceutics" [All Fields] OR "pharmaceutical preparations" [MeSH Terms] OR ("pharmaceutical"[All Fields] AND "preparations"[All Fields]) OR "pharmaceutical preparations"[All Fields] OR "pharmaceutical"[All Fields] OR "pharmaceuticals" [All Fields] OR "pharmaceutical's"[All Fields] OR "pharmaceutically"[All Fields]

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

(("biopharmaceutics"[MeSH Terms] OR "biopharmaceutics"[All Fields] OR "pharmaceutic" [All Fields] OR "pharmaceutics"[All Fields] OR "pharmaceutical preparations"[MeSH Terms] OR ("pharmaceutical"[All Fields] AND "preparations"[All Fields]) OR "pharmaceutical preparations"[All Fields] OR "pharmaceutical" [All Fields] OR "pharmaceuticals"[All Fields] OR "pharmaceutical s"[All Fields] OR "pharmaceutically"[All Fields]) AND "data management"[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

pharmaceutical: "biopharmaceutics"[MeSH Terms] OR "biopharmaceutics"[All Fields] OR "pharmaceutic"[All Fields] OR "pharmaceutics" [All Fields] OR "pharmaceutical preparations" [MeSH Terms] OR ("pharmaceutical"[All Fields] AND "preparations"[All Fields]) OR "pharmaceutical preparations"[All Fields] OR "pharmaceutical"[All Fields] OR "pharmaceuticals" [All Fields] OR "pharmaceutical's"[All Fields] OR "pharmaceutically"[All Fields]

data management[MeSH Terms]: "data management"[MeSH Terms]

RESULTS

The pharmacist should adhere to the following data management policies and procedures in pharmacy practice:[9-16]

Data collection design

- The researcher should develop a data collection strategy. First, the data set must contain several variables that will be analyzed further in the research. To begin, the data must include demographic information about the participants, such as their gender, age, qualifications, and experiences. In addition, some information, such as the number of beds, hospital specialties, accreditation, and health insurance coverage, may be included. The second data collection component is information necessary to address the research's objective.
- The researcher should be aware that many variables may increase the analysis workload.
- A variety of literature exemplified creating a survey or data collection template that the researcher can refer to for additional information.

Resources of data
Data generation

There are various ways to genera the data that's including but not limited to the following

Governmental or organizational reports.

The government or organization's information reports are among the wealthiest data sources. For example, it may include an annual statistical report on institutions' performance. This type of data requires the same data to be extracted without modification and is valuable in the introduction of research or requires additional analysis and interpretation to meet the research's objectives. Consequently, these data types are exempt from IRB review.[35,36]

Regulation reports

Some regulation organizations like SFDA generate the data about medications registration information and post-marketing surveillance about medications related problems and distribute regularly.

Scientific organizations or society's data

Some scientific societies might generate data by surveys about specific diseases or Heath management, such as the World Health Organization.

Universities reports and research

The majority of universities generate the data about various knowledge through a research project of faculties or post and undergraduate studies.

Pharmaceutical and medical companies

All manufacturers generate data by conducting scientific research about their products and distribute the data through reports or publications.

Research data

Various researchers make a research by collation data through surveys and summaries the data through scientific publications in the biomedical journals.

New project data

Some inviters or consultation offices generate the data for the new project. They make various studies like feasibility study and marketing research.

Business companies

Most businesses generate their data about selling products, incomes, expenses. They used for the market analysis of their products or services.

Healthcare organizations

All healthcare organizations generate their data about the type of patients, types of diseases, utilization of medications or resources, and productivity of the institutions.

Individual data

- The data were collected from respondents via a survey. Personal contact with respondents or distribution of surveys via social media is used to collect data. Also, distribute the survey to members of the general public or health care providers.
- Additionally, the responders may be located or employed by the same organization. Hence, the researcher must obtain permission to distribute the survey in the organization. However, this type of data collection is exempted from IRB approval.[35,36]

Previous studies

These data were used to write the letter to the editor or editorial topic and review articles, systematic reviews, and meta-analyses. For instance, the research appropriately utilized this type when writing the research introduction or comparing the data to current research. Occasionally, the researcher summarises their findings and data for publication in a review article, systematic review, or meta-analysis. Therefore, this type of data is exempt from the Institutional Review Board.[35,36]

Patient profile

The researcher or data collector may collect data on a patient's profile through case studies, case-control studies, cohort studies, or clinical trials. These types of data require IRB approval.[35,36]

Data collector[37]

A data collector is someone who collects data for researchers on their behalf. They could be compensated or uncompensated data

collectors. The data collector should adhere to the instructions below when collecting data.

- The data collector should familiarise themselves with the type of data collected.
- The data collector must be aware of when the data was collected.
- The data collector should collect accurate information from patient profiles or distribute surveys to a targeted group.
- The data collector should securely maintain data without disclosing it to anyone.
- The researcher should educate or train the data collector about the data collection process, the data resources, and the duration of the data collection period.
- The data collector may be identical, mainly if the research is conducted on healthcare providers or other healthcare professionals, such as students, residents, or recent graduates.
- The data collector should collect data on a timely basis. The survey responders should contact or distribute the survey to the appropriate individuals to encourage participation.
- The data collector should solicit and respond to any comments, suggestions, or inquiries from respondents or consult with the researcher.
- The data collector should notify the researcher if incorrect information is accidentally collected.
- The data collector should contact survey respondents more frequently, for example, every 3-4 days.
- The data collector should entice respondents to complete the survey.
- The data collector considers thanking respondents for taking the time to complete the survey.
- The researcher should not provide the data collector with any research proposal or IRB approval, as this is the researcher's responsibility. The data collector is performing the researcher's duties for them.
- The data collector may volunteer to collect data or compensate the researcher. For example, he may receive a thank-you letter or certificate from the data collector, money, or a gift, or he may associate his name with the research after completing the data collection by contributing to the writing of a research manuscript or reviewing the article or analysis.

Data preparation for analysis

- Before preparation, the researcher should review all data and delete anyone who does not meet the research criteria.
- The researcher should verify the accuracy of their data. Specific automated data collection should eliminate the need for manual forms; google Docs or survey monkeys, or any electronic data collection companies can filter data based on completeness. The system will delete any data or surveys that are not completed.

Data reliability and validity

When the researcher reaches more than 30 samples, they should conduct a reliability test, such as McDonald's ω, Cronbach alpha, Gutmann's λ2, and Gutmann's λ6, to revise the data if there are any problems. Additionally, when the sample size exceeds 100, the researcher should conduct validity tests using factorial analysis with regression to determine whether their questions should be changed or deleted from the data.

Data storing

- For case study design or case series, case-control, surveys, and clinical trials, the researcher should store their data and all documentation papers in a secure location for at least five years after publication. However, specific research designs do not require data retention, for example, review articles, systematic reviews, and meta-analysis studies.
- Certain electronic websites, for example, survey monkey and google docs, can store data.

CONCLUSION

Data management policies and procedures are critical in pharmacy research and investigational medications. It needs to avoid discrepancies in the outcome and research results by providing accurate information in various types of studies. Additionally, it will enhance the pharmacist's data management skills. As a result, data management procedures are strongly recommended for all healthcare organizations in Saudi Arabia.

ORCID ID

Yousef Ahmed Alomi https://orcid.org/0000-0003-1381-628X

ACKNOWLEDGEMENT

None.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

KSA: Kingdom of Saudi; **SFDA:** Saudi Food and Drug Authority (SFDA); **EMEA:** European Medicine Agency; **WHO:** World Health Organization; **ASHP:** American Society of Health-System Pharmacists; **AGREE:** Appraisal of Guidelines, Research, and Evaluation

REFERENCES

1. Von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. PLOS Med. 2007;4(10):1623-7. doi: 10.1371/journal.pmed.0040296.
2. Von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: Guidelines for reporting observational studies [internet]. Vol. 370; 2007. Available from: http://www.thelancet.com. Available from: http://www.plosmedicine.org [cited 25/2/2022].
3. Langan SM, Schmidt SA, Wing K, Ehrenstein V, Nicholls SG, Filion KB, *et al*. The reporting of studies conducted using observational routinely collected health data statement for pharmacoepidemiology (RECORD-PE). BMJ. 2018;363:k3532. doi: 10.1136/bmj.k3532, PMID 30429167.
4. Guidelines for responsible, data management in, scientific research, [Internet]. Available from: http://www.rcreducation.com [cited 25/2/2022].
5. Society for Clinical Data Management. Good clinical data management practices; 2013.
6. Krishnankutty B, Bellary S, Kumar NB, Moodahadu LS. Data management in clinical research: An overview. Indian J Pharmacol. 2012;44(2):168-72. doi: 10.4103/0253-7613.93842, PMID 22529469.
7. Van Den Broeck J, Cunningham SA, Eeckels R, Herbst K. Data cleaning: Detecting, diagnosing, and editing data abnormalities. PLOS Med. 2005;2(10):e267. doi: 10.1371/journal.pmed.0020267, PMID 16138788.
8. Borghi J, Abrams S, Lowenberg D, Simms S, Chodacki J, Borghi J, *et al*. A research data management guide for researchers. Res Ideas Outcomes. 2018 May 9;4:e26439. doi: 10.3897/rio.4.e26439.
9. Odigwe FN, Bassey BA, Owan VJ. Data management practices and educational research effectiveness of university lecturers in south–south Nigeria. JESR. 2020;10(3):24-34. doi: 10.36941/jesr-2020-0042.
10. Bardyn T, Patridge E, Moore M, Koh J. Health sciences libraries advancing collaborative clinical research data management in universities. J eScience Librariansh [internet]. Vol. 7(2). p. e1130; 2018 July 20. Available from: https://escholarship.umassmed.edu/jeslib/vol7/iss2/4/ [cited 25/2/2022].
11. Ashiq M, Usmani MH, Naeem M. A systematic literature review on research data management practices and services. GKMC. 2020. doi: 10.1108/GKMC-07-2020-0103.
12. Pavlenko E, Strech D, Langhof H. Implementation of data access and use procedures in clinical data warehouses. A systematic review of literature and publicly available policies. BMC Med Inform Decis Mak. 2020;20(1):157. doi: 10.1186/s12911-020-01177-z, PMID 32652989.

13. Daniel C, Kalra D, Section Editors for the IMIA Yearbook Section on Clinical Research Informatics. Clinical research informatics. Yearb Med Inform. 2020;29(1):203-7. doi: 10.1055/s-0040-1702007, PMID 32823317.
14. Ismail L, Materwala H, Karduck AP, Adem A. Requirements of health data management systems for biomedical care and research: Scoping review. J Med Internet Res. 2020;22(7):e17508. doi: 10.2196/17508, PMID 32348265.
15. Wittig U, Rey M, Weidemann A, Müller W. Data management and data enrichment for systems biology projects. J Biotechnol. 2017;261(June):229-37. doi: 10.1016/j.jbiotec.2017.06.007, PMID 28606610.
16. Marcus DS, Erickson BJ, Pan T, CTSA Imaging Informatics Working Group. Imaging infrastructure for research. Part 2. Data management practices. J Digit Imaging. 2012;25(5):566-9. doi: 10.1007/s10278-012-9502-6, PMID 22710986.
17. Maguire A, Douglas I, Smeeth L, Thompson M. Determinants of cholesterol and triglycerides recording in patients treated with lipid-lowering therapy in UK primary care. Pharmacoepidemiol Drug Saf. 2007;16(July):228.
18. Bawazir S, Hashan H, Al Hatareshah A, Al Ghamdi A, Al Shahwan K. Regulating clinical trials in Saudi Arabia. ACCTRA. 2014;1(1):2-9. doi: 10.2174/2213476X01666140321182641.
19. Saudi Food and Drug Authority. Guideline for good clinical practice (GCP) E6. Vol. 6. (p. R1) [internet]; 2013. Available from: http://www.sfda.gov.sa/En/Drug [cited 25/2/2022].
20. Saudi Food and Drug Authority Drug Sector. Guideline for good clinical practice (GCP). 3rd version. Saudi Food and Drug Authority; 2020.
21. Wermeling DP. Clinical research: regulatory issues. Am J Health Syst Pharm. 1999;56(3):252-6. doi: 10.1093/ajhp/56.3.252, PMID 10030513.
22. Mahan VL. Clinical trial phases. Int J Clin Med. 2014;05(21):1374-83. doi: 10.4236/ijcm.2014.521175.
23. Berger VW, Antsygina O. A review of randomization methods in clinical trials. Clinical Investigation. 2015 December;5(12):847-53. doi: 10.4155/cli.15.53.
24. Baghbaninaghadehi F. Fundamentals of randomization in clinical trial. IJANHS. 2016;4(1):174-87. doi: 10.23953/cloud.ijanhs.143.
25. Davidson RA. Source of funding and outcome of clinical trials. J Gen Intern Med. 1986;1(3):155-8. doi: 10.1007/BF02602327, PMID 3772583.
26. Noorzurani MHR, Aziz NA, Abdul Aziz AF, Abd Hamid MZ, Mohamed M, Othman S, *et al*. The need for "good clinical practice" in health care research. S Afr Fam Pract. 2009;51(3):202-5. doi: 10.1080/20786204.2009.10873848.
27. Vijayananthan A, Nawawi O. The importance of Good Clinical Practice guidelines and its role in clinical trials. Biomed Imaging Interv J. 2008;4(1):e5. doi: 10.2349/biij.4.1.e5, PMID 21614316.
28. Handbook for good clinical research practice (GCP): Guidance for implementation. World Health Organization; 2002.
29. Earls F, Cook S. Integrated addendum to ICH. ICH harmonised guidelines. 2016;E6:(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE.
30. European Medicines Agency (EMA). Guideline good. Clin Pract. 2017;(December 2016);E6(R2):1-68.
31. Kay SC, Luke DG, Tamer HR. ASHP guidelines for the management of investigational drug products. Am J Health Syst Pharm. 2018;75(8):561-73. doi: 10.2146/ajhp170812, PMID 29626006.
32. Zenda S, Uchitomi Y, Morita T, Yamaguchi T, Inoue A. Establishment of a research policy for supportive and palliative care in Japan. Jpn J Clin Oncol. 2021;51(4):538-43. doi: 10.1093/jjco/hyab008, PMID 33561254.
33. Almarsdóttir AB, Kaae S, Traulsen JM. Opportunities and challenges in social pharmacy and pharmacy practice research. Res Soc Admin Pharm. 2014;10(1):252-5. doi: 10.1016/j.sapharm.2013.04.002.
34. Brouwers MC, Kerkvliet K, Spithoff K, AGREE Next Steps Consortium. The AGREE reporting checklist: A tool to improve reporting of clinical practice guidelines. BMJ. 2016;352:i1152. doi: 10.1136/bmj.i1152, PMID 26957104.
35. Phillips MS, Abdelghany O, Johnston S, Rarus R, Austin-Szwak J, Kirkwood C. Navigating the Institutional Review Board (IRB) Process for pharmacy-related Research. Hosp Pharm. 2017;52(2):105-16. doi: 10.1310/hpj5202-105, PMID 28321137.
36. THE RESEARCH ADVISORY COUNCIL. The research Ethics Committee (REC) guidance in the conduct of research at King Faisal Specialist Hospital and Research Centre; 2017.
37. Russell T, Marks J, Christal M, Teeter D, Sapp M, Korb R, *et al*. Best practices for data collectors and data providers [internet]; 1999. Available from: http://nces.ed.gov [cited 25/2/2022].