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Pharmacology's Historical, Contemporary, and Future Traces in Turkey

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Abstract

Preclinical and clinical drug development is a protracted and difficult procedure. The Kingdom of Saudi Arabia (KSA) is showing an increased interest in promoting indigenous content, research, and innovation, including clinical trials (Phase I-IV). Saudi Arabia now has more than 650 registered clinical trials, and this number is anticipated to rise. Making sure that medications are used safely and effectively is a crucial component of drug research and clinical trials. Because it focuses on the effects of medications in humans, clinical pharmacology is essential for helping decision makers make well-informed choices during the drug development process. Clinical pharmacology includes areas of study include pharmacokinetics, pharmacodynamics, and pharmacogenomics. It is a developing field with numerous applications in all stages of Choosing the best dosages for Phase I, II, and III investigations, assessing bioequivalence and biosimilarity tests, and planning clinical studies are all part of drug development. Clinical pharmacology will be incorporated into research as well as regulatory bodies' requirements, which will enhance the drug development process and speed up the pipeline. Additionally, clinical pharmacology is used in hands-on patient care with the aim of individualised treatment. To optimise dosing for patients on an individual basis, techniques including therapeutic drug monitoring, pharmacogenomics, and model guided precision dosing are applied. Clinical pharmacology is a subject that is underutilised in KSA, so we think it's crucial to educate the scientific community and healthcare professionals about its potential and uses. In this review article, we give a summary of on the usage and applications of clinical pharmacology in medical treatment as well as drug development.

Keywords: Leonurus japonicas, Systems pharmacology, Menstrual disorders, Target prediction, Molecular docking

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Introduction

Drug development is a protracted, intricate, and expensive process that begins with drug discovery and ends with structured clinical trials. The promotion of innovation, research, and locally produced material is becoming increasingly popular in the Kingdom of Saudi Arabia (KSA) [1-2]. Getting pharmaceutical firms and contract research organisations (CROs) to perform clinical trials in KSA is a top priority. In KSA, there are currently around 650 registered clinical studies. This figure is regarded as being quite low. In contrast, Poland, which has a comparable GDP and population, has more than 6400 registered clinical studies. Increased attempts are being made in KSA to perform more clinical trials, thus it is anticipated that this number will rise soon. Clinical trials were not governed by any government agency in KSA prior to 2009 [3-5]. Instead, local Institutional Review Boards (IRBs) self-regulated clinical studies carried out at respective locations. In 2009, the Clinical Trials Administration was formed by the Saudi Food and Drug Authority (SFDA). Since 2013, early-phase clinical studies (Phase I, II, and III) must be registered with the Saudi Clinical Trials Registry and get SFDA permission before study beginning. An important principle of drug development and clinical trials, and its regulation is to ensure the safe and effective use of drugs. This is where clinical pharmacology, playing a vital role in informed decision making during the drug

development stage [6-8]. Clinical pharmacology studies the effect of drugs on humans and includes fields such as pharmacokinetics (PK), pharmacodynamics (PD) and pharmacogenomics (PGx). The fields have grown exponentially over the past two decades and are used throughout the whole preclinical and clinical drug development process. Particularly in positions such as choosing the best dose for Phase II and III studies, dosing in particular populations, assessing bioequivalence and biosimilarity studies, medication and food interaction research, as well as planning and carrying out clinical trials. Approximately half of the information provided in the package insert is related to clinical pharmacology .It is the responsibility of the clinical pharmacologists to evaluate investigational new drugs. Since mathematical modelling and simulation are now widely employed in drug development and are referred to as pharmacometrics or Model Informed Drug Development, many elements of clinical pharmacology have become more quantitative. Since mathematical modelling and simulation are now widely employed in drug development and are referred to as pharmacometrics or Model Informed Drug Development, many elements of clinical pharmacology have become more quantitative. Model-informed drug development uses information from a variety of sources, including real-world data, clinical research, and preclinical research, to inform decision-making during the drug development process. The Prescription Drug User Fee Amendments of 2017 set goals for the US FDA that include model-informed drug development. By individualised medicine, clinical pharmacology can also be used in front-line patient care . To improve patient dosing on an individual basis, techniques like therapeutic drug monitoring (TDM), PGx, and Model Informed Precision Dosing can be utilised. When seen from a regulatory, scientific, and industrial point of view, these areas of clinical pharmacology act as a potent instrumentfor improving drug safety and effectiveness in clinical trials throughout drug development and patient care [9-10]. The goal is to promote and inform medical professionals and the scientific community about the potential and uses of the science of clinical pharmacology, which is still neglected in KSA. In this review article, we discuss the uses of clinical pharmacology in both clinical drug development and direct clinical treatment, as well as give an update on Saudi Arabia's policies and practises for drug development.

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