

Clinical Pharmacokinetics: A Rising Field of Study in Health Sciences

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Given the industry-level demand and career opportunities, clinical pharmacokinetics has already been a preferred course among students



In the last few years, we have seen a rise in mutations and variations of several viruses. Take, for example, the coronavirus, which has evolved significantly since 2020. Variants occur when there is a change or mutation to the virus's genes. All viruses change over time. Some more than others, and some faster than others. As we continue to face newer diseases, it has also led to the development of important medical advances. Newer drugs are being patented more frequently, and while clinical trials are key to the process of making these drugs, market-ready; the study of pharmacokinetics plays a crucial role.

Simply speaking, 'pharmacokinetics' (PK) is the study of how the body interacts with a drug or any administered substance for the entire duration of exposure. It is the relationship between the quantity of the administered substance and the concentration obtained at the desired site depending on absorption, distribution, metabolism, and excretion (ADME). 'Clinical pharmacokinetics', however, is a slightly different concept. It is a process that applies the principles of pharmacokinetics to determine the appropriate dosage of a drug in order to maximise its benefits and minimise toxicity, of any kind. The parameters of clinical pharmacokinetics are essential to investigate the bioavailability and bioequivalence of existing drugs in order to launch generic versions.

Objective, Importance and Challenges

Clinical pharmacokinetics plays a critical role in patient care services, enabling safe, effective, and efficient delivery of medicines. The goal of studying clinical pharmacokinetics is to be able to evaluate dosages and ensure the therapeutic concentration at the site of action.

The key parameters of pharmacokinetics—which play a significant role in the process of clinical trials—include absorption, distribution, metabolism, and excretion. These parameters are also critical in the discovery and development of new therapeutic entities and preclinical studies. They help analyse the safety, efficacy, and toxicity levels in a drug; with a focus on the dose-response relationship, of the potential patient. The study of clinical pharmacokinetics also explains the inter-individual variations in drug response among a large group of the population.

Regulatory guidelines also emphasise the importance of clinical pharmacokinetics, especially for new drugs under development and post-marketing clinical trials of already existing drugs. Given the significant investments in research & development (R&D) made by pharma companies and biotechnology firms, the demand for clinical pharmacokinetics in the present and future is inevitable.

Importance and role of a Clinical Pharmacokineticist

The development of the bioanalytical method is key to properly investigating new drugs and creating generic versions of already-existing drugs. In order to validate the bioanalytical method, there is a need to establish the accuracy, precision, sensitivity, specificity, and quantity limitations of a drug. A clinical pharmacokineticist is an expert in this respect and plays an important role in the development and validation of bioanalytical methods. Additionally, a pharmacokineticist also needs to be aware of the regulatory requirements of “The Ministry of Health and Welfare” in order to conduct preclinical and clinical pharmacokinetic studies.

Challenges

The primary challenge faced by healthcare practitioners is the variability of drug concentration in the body. The pharmacokinetics of a drug depends upon an individual's physiological conditions (such as age, gender, race, and pregnancy) and pathological conditions (such as renal impairment, hepatic impairment, obesity, cardiac dysfunction, etc.).

Further, considerations of pharmacokinetic analysis, bioavailability, possible complications of active metabolites, and studies in special populations, all present challenges in this space. The current trends in clinical pharmacokinetics have increased their significance in the industry.

There is an evident need for integration with existing divisions of medicine and pharmacy which will lead to a strong demand for clinical pharmacokinetics professionals to bridge any industry gap. Therefore, making clinical pharmacokinetics a promising career option for individuals wishing to excel in the healthcare sector.

Roles offered for clinical pharmacokinetics include but are not limited to coordinating & collaborating with the product development teams, medical affairs, clinical and regulatory affairs, PMO, NPI, or any other cross-functional team, as required for new product ideation, bio-strategy & bio-studies.

Lucrative Career Prospects

With respect to the job opportunities available in the market, a student can pursue a path to become a principal scientist, research scientist, pharmacokineticist, clinical development associate, clinical research, pharmacovigilance, clinical data management, bio-analytics, and biostatistician after studying clinical pharmacokinetics. The students also have the option to pursue higher education in clinical pharmacokinetics, biopharmaceutics, and other related fields and explore these fields to build a better world.

Given the industry-level demand and career opportunities, clinical pharmacokinetics has already been a preferred course among students. Many students at national and international levels have started exploring clinical pharmacokinetics as a

profession and with the advent of technology, clinical pharmacokinetics surely offers lucrative career paths to young minds.

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