

Research and Reviews: Journal of Medical and Health Sciences

Drug Development and Regulation

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Short Commentary

Received: 10/05/2015
Accepted: 21/05/2015
Published: 10/06/2015

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Keywords: Drug development
Drug discovery, Pivotal trials,
Preclinical research

INTRODUCTION

Drug development is the mission of pharmaceutical research companies to follow the path from understanding a disease and giving safe and effective treatment for patients. As we know for drug development minimum it is taking 10-15 years of time. For the development of drug at first there is a need to target the disease after that to develop the hypothesis for treatment mechanism and to determine the feasibility of producing the compound. The cost of developing a new drug is over €800 million.

Through drug discovery when a new lead compound is identified and a new pharmaceutical drug is introduced to the market that process is known as drug development [1]. Phase of drug development:

Drug discovery (It includes to target the disease, their symptoms and biochemical pathways after that to search target for drug. Target can be a molecule or a protein receptor that is specifically associated with pathology)



Preclinical research (pharmacology, toxicology) it includes laboratory and animal testing to know that the compound should be safe and biologically active



Preclinical development (This phase include precise testing and optimization of the selected compounds to identify the lead structure. Testing is done in vitro and in vivo to study pharmacodynamics and pharmacokinetics metabolism.)



Pivotal trials



Clinical research: Phase I Clinical trials (to determine safety and dosing usually in healthy persons)
Phase II Clinical trials (used to get the initial efficacy of drug in small number of patients to assess how drug is getting absorbed, distributed metabolized and excreted.)
Phase III Clinical trials (used to determine safety & efficacy in large number of patients)



FDA Drug approval (also known as post approval trails in which drug is submitted to FDA for allowing human exposure to the drug.)

- In-silico modeling is used for Drug Development for Inhalation Treatment [2].

Natural Products and Drug Development:

Natural products are an extremely useful source for new medicines to deliver a great variety of structural templates for drug discovery and development. A significant number of drugs have been obtained from plants and used by humans as medicine as in Ayurveda. To discover drug the chemical and pharmacologic investigation of ethno botanical information shows a significant developments in the field of medicine. Plants which are used by human being from long time are considered as most successful for ethno botanical uses. In studies it is found that related plants from different geographic regions are used to treat medical conditions in the same therapeutic areas.

Some natural products are also used for the development of drug.

For example:

Lauric Acid - Cardiovascular Disease [3]

lipstatin - antiobesity

Cephalosporin- antibacterial

Doxorubicin- oncology

pneumocandin B- antifungal

artemisinin 40- antimalarial

Examples of some drug development studies:

- Bioavailability Studies on the Developed Prochlorperazine Maleate Sustained Release Tablets by HPLC [4]
- HPLC method has been developed and validated for the quantification of metolazone in human plasma, after solid phase extraction (SPE) [5]
- Bioequivalence Study of Simvastatin [6]
- Simple Screening Method for Staurosporine in Bacterial Cultures using Liquid Chromatography-Tandem Mass Spectrometry [7]
- Various research on RNA having a good impact which done for medical genomics [8]
- Determination of Clobetasol in Rat Plasma and its Application to Skin Penetration through HPLC [9]

There are four new pharmacological targets developed for asthma treatment: proteinase inhibitors and flavonoids, arginase and iNOS inhibition, Rho-kinase inhibitors, cholinergic anti-inflammatory system and nicotinic receptors [10]. UV-Metric, pH-Metric and RP-HPLC Methods to Evaluate the Multiple pKa Values of a Polyprotic Basic Novel Antimalarial Drug Lead, Cyclen Bisquinoline [11].

As we know diabetes is one of the vital diseases in the world and its therapy is also not easy, thus there is a need for the drug development for diabetes [12]. Some medicinal plants are also used for the treatment of diabetes since they having ant diabetic property [13]. MicroRNA is used for the anticancer drug development and also used for some viral infection treatment [14]. Nanotechnology is also used in some pathological treatment of Alzheimer's disease [15]. It is found that replicate design is not applicable as an approach for showing the high inter/intra subject variability of highly variable drugs and there is a need for wider acceptance [16]. For HIV drug development there is need to inhibit Protease auto processing [17]. Neurodegeneration and Cancer Mitochondria Specific Antioxidants and their Derivatives are used for drug development [18]. Peptide drugs which is generally the short synthetic and long-acting drugs [19]. Plants based drug are used for anticancer drug development [20].

Positron Emission Tomography is used in Drug Development [21]. There is a need to follow an ethno pharmacological approach using traditional knowledge to increase success in drug discovery and development [22]. Single Nucleotide Polymorphic (SNP) plays an important role in Drug Development and Toxicity [23].

CONCLUSION

It is important to identify the areas in the development chain that needs to be improved or methods by which one can hasten the process. Biosimilar drugs are used for the drug development. There is need for novel initiatives to boost the development of drug which include be a partner of governmental organizations and industry.

ACKNOWLEDGMENT

This content of the article is scrutinized and approved by M. Murali and written by Neha Anand.

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