DRUG DISCOVERY AND CLINICAL TRIALS

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B-Pharm 4th Semester Pharmacology-I

DRUG DEVELOPMENT

During the development of new drugs molecules or compounds should have higher standard in the conduct, analysis and interpretation of preclinical and clinical studies for the smooth passes through the regulatory approval phase and eventually marketing.

SOME PATHWAYS OF DRUG DISCOVERY

- Target selection
- Lead discovery
- Medicinal chemistry
- In-vivo studies
- Preclinical studies
- Clinical studies

TARGET SELECTION

- It defined as the decision to focus on finding an agent with a particular biological action that is anticipated to have therapeutic utility.
- Target identification: to identify molecular targets that are involved in disease progression.
- Target validation: to prove that manipulating the molecular target can provide therapeutic benefit for patient.
- The technique used for the target identification is;
    - Cellular and genetic target
    - Genomics
    - Proteomics
    - Bio-informatics

Cellular and genetic target

- The drugs are usually act on either cellular or genetic chemicals in the body, known as target which are believed to be associated with disease.

Genomes

- The study of genes and their function, genomics aims to understand the structure of the genome, including the mapping genes and sequencing the DNA.

Proteomic

- It is the study of proteome, the complete set of proteins produced by a species, using the technologies of large scale protein separation and identification.

Bio-informatics

- Bio-informatics is a branch of molecular biology that involves extensive analysis of biological data using computer, for the purpose of enhancing biological research.

LEAD DISCOVERY

- A lead compound is an organic molecule that act as a prototype drug around which further optimization is centered and focused.

MEDICINAL CHEMISTRY

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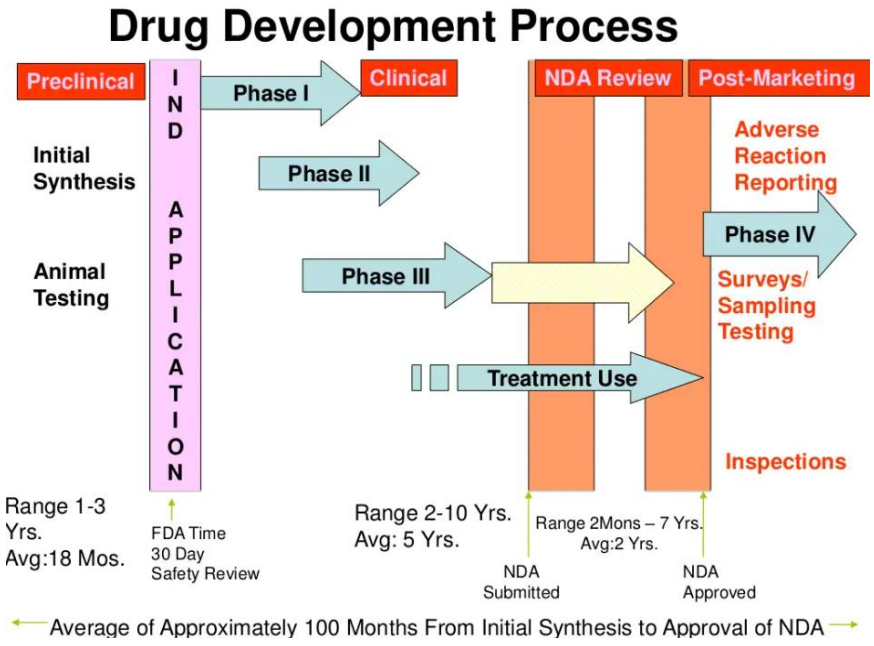
- It is a discipline at the intersection of synthetic organic chemistry and pharmacology.
- Focused on small organic molecules.



DRUGS REVIEW

- Before one can initiate testing in human being, extensive preclinical or laboratory research is required.
- Research usually involves years of experiments in animals and human cells.
- In this stage of testing is successful, the data are forwarded to FDA for requesting approval. This is called an Investigational New Drug Application (IND).
- If approved by the FDA, then next testing will be done in human beings.

PRECLINICAL STUDIES (ANIMAL STUDIES)

- Pharmacokinetic studies, absorption, distribution, elimination, in-vivo, in-vitro, acute, subacute, chronic toxicity studies and therapeutic index are determined.

CLINICAL TRIALS

- Set of procedures in medical research and drug development to study the safety and efficacy of new drug.
- Essential to get marketing approval from regulatory authorities.
- This stage may require upto 7 years.

PHASE I

- Clinical pharmacologic evaluation.
- First stage of testing in human subjects.
- 20-50 healthy volunteers.
- Concerned with:

- Human toxicity
- Tolerated dosage range
- Pharmacodynamics / pharmacology

PHASE II

- Controlled clinical evaluation
- 50-300 volunteers are required
- Controlled single blind technique
  - Patients unaware of the treatment, whether they receiving placebo or real drug.
  - Helps to avoid the Placebo effect.
- Concerned with;
  - Safety
  - Efficacy
  - Drug toxicity and Interaction

PHASE III

- Extended clinical trials.
- Most expensive and time consuming process.
- 250-1000 volunteers are required.
- Controlled blind technique (Double-blind study).
  - Randomized treatment study even the Doctors or Researchers are also not yet know which treatment is better.
- Concerned with;
  - Safety, efficacy
  - Comparison with other drugs
  - Packaging

PHASE IV

- Post marketing surveillance.
- Designed to detect any rare and long-term adverse effects.
- Adverse drug reaction monitoring.

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