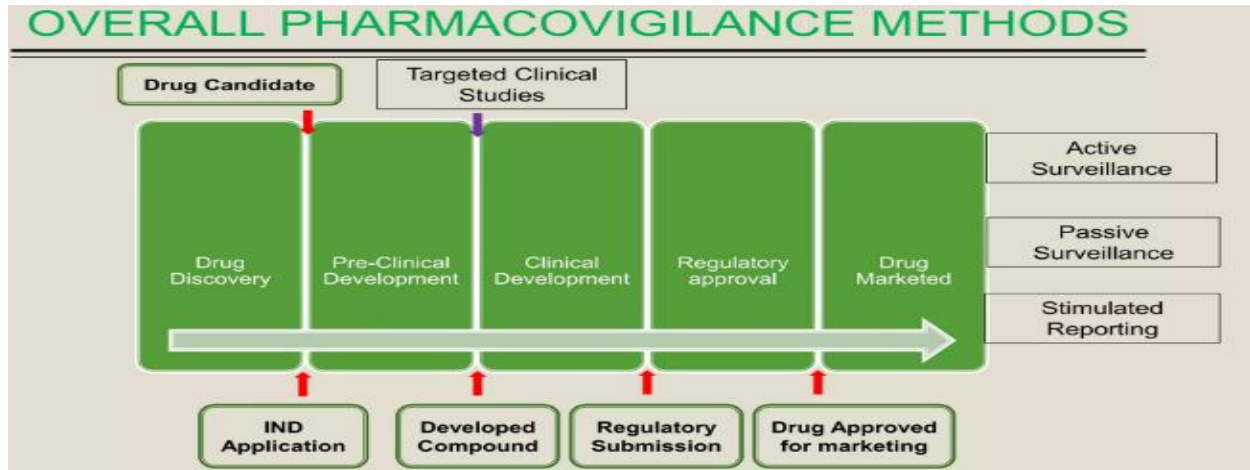


Targeted clinical investigation

- Targeted clinical investigation is the pharmacovigilance methods.

OVER-ALL PHARMACOVIGILANCE METHOD

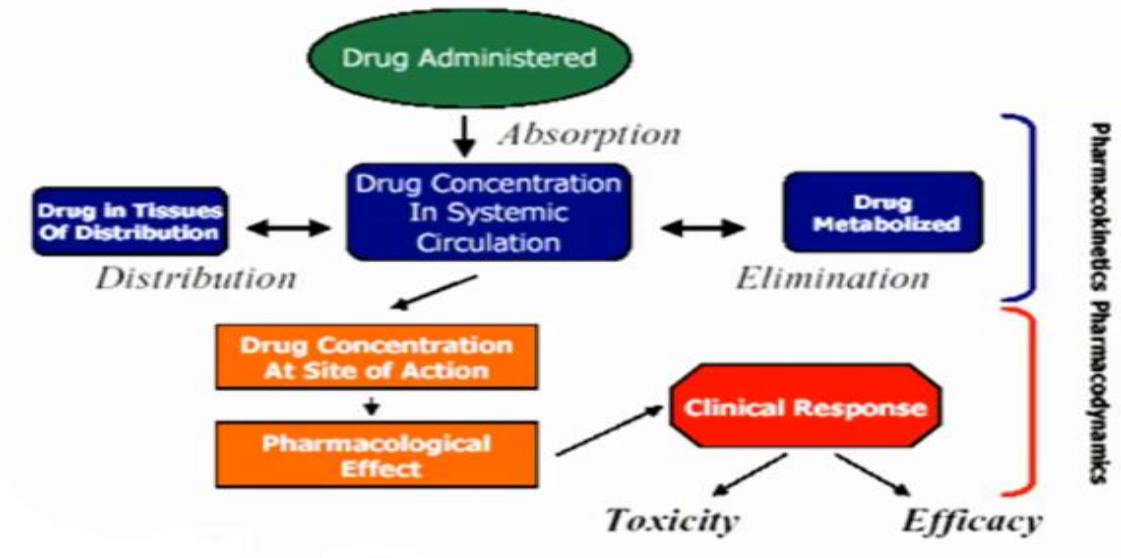


Targeted clinical investigation-

- When significant risks are identified from pre-approval clinical trials, further clinical studies might be called for to evaluate the mechanism of action for ADRs.
- This investigation includes-
 - > PK and PD studies
 - > Genetic testing
 - > Interaction studies
 - > Large simplified trial

PK and PD studies-

- Pharmacodynamics is the study of how a drug affects an organism, whereas pharmacokinetics is the study of how the organism affect the drug.
- Pharmacodynamic and pharmacokinetic studies are conducted to determine whether a particular dosing instruction can put patients at an increased risk of adverse events.










Genetic Testing-

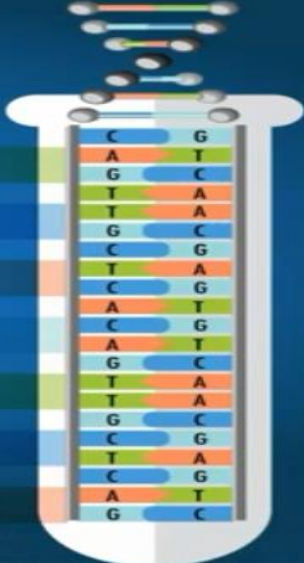
- It is the study of a person's DNA in order to identify genetic differences or susceptibility to particular diseases or abnormalities.
- Several methods can be used for genetic testing:
 - Molecular genetic tests
 - Chromosomal genetic tests
 - Biochemical genetic tests

Genetic test can Help to-

GENETIC TESTING
NHGRI FACT SHEETS
genome.gov

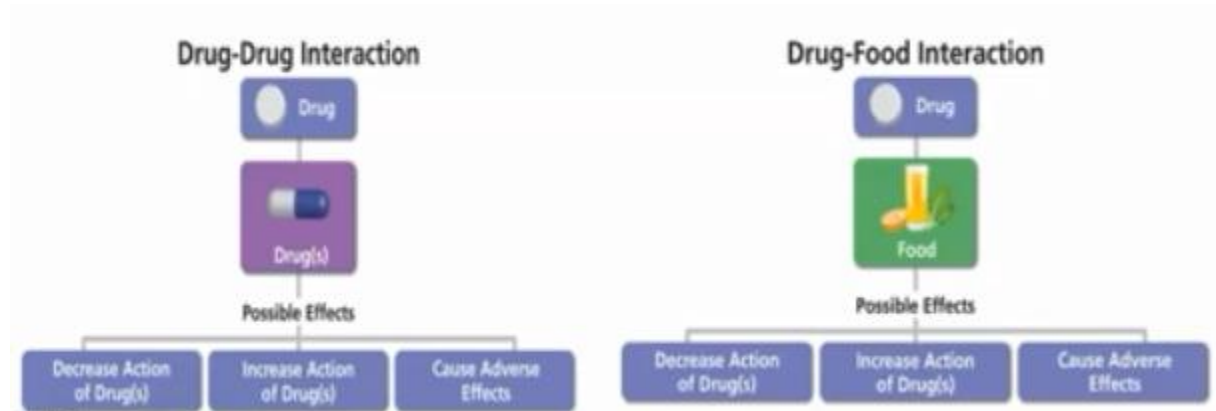
Genetic Tests Can Help to:

-  **Diagnose Your Disease**
-  **Pinpoint Genetic Factors That Caused Your Disease**
-  **Predict How Severe Your Disease Might Be**
-  **Choose the Best Medicine and Correct Dose**
-  **Discover Genetic Factors That Increase Your Disease Risk**
-  **Find Genetic Factors That Could Be Passed to Your Children**
-  **Screen Newborns for Certain Treatable Conditions**



Interaction studies-

Based on the pharmacological properties and the expected use of the drug in general practice, conducting specific studies to investigate potential drug-drug interaction and food-drug interaction might be called for



Drug- Drug interactions-

- Drug- drug interactions occur when a drug interacts , or interferes, with another drug. This can alter the way one or both of the drugs act in the body, or cause unexpected side effects.

Aspirin + Warfarin	Synergism (excessive bleeding)
Antibiotic + Blood thinner	Antagonism (less effect)
Codeine + Paracetamol	Addition (increased analgesic effect)
Clavulanic acid + Amoxicillin	Synergism (increased antibiotic effect)
NSAID+ Cox2 inhibitors	Synergism (increased bleeding)
SSRI,S + VITAMIN K	Synergism (increased bleeding)
Anti emetics + Tranquilizers	Unknown effect (Breathing problems)
H2 Blockers +PPI's	Alteration (increased ph of stomach)
Phenobarbitol + Warfarin	Antagonism (less effect)
Erythromycin + Warfarin	Synergism (increased bleeding)

Drug-food interactions-

- A drug-food interaction happens when the food you eat affects the ingredients in a medicine you are taking so the medicine cannot work the way it should.
- Bisphosphonates+ Any drug Reduced effectiveness of drug'
- Benzodiazepines + grapefruit Inhibit enzyme involved in drug metabolism
- Digoxin + Oatmeal Decreased adsorption of drug
- Aspirin + Milk Upset stomach
- Acetaminophen + Alcohol Liver damage
- MOA Inhibitors + Food (tyramine) Severe headache
- Tetracycline + calcium food Reduced absorption of drug
- Warfarin + Vitamin K Reduced effect of drug
- Celecoxib + milk Upset stomach
- Naproxen + Fatty food Upset stomach
- Oxycodon + Alcohol Coma, asthma
- Caffeine + Food Rapid heart beat

Large simplified trial-

- It is a type of randomized clinical trial ideally suited to answer many important clinical questions and because it typically answers only one or two questions in a broader patient population, is generally more efficient and less expensive than other large randomised clinical trials.
- It has a large sample size and statistical power to detect clinically relevant treatment effects, Providing unambiguous result and minimizing the effects of random errors.