

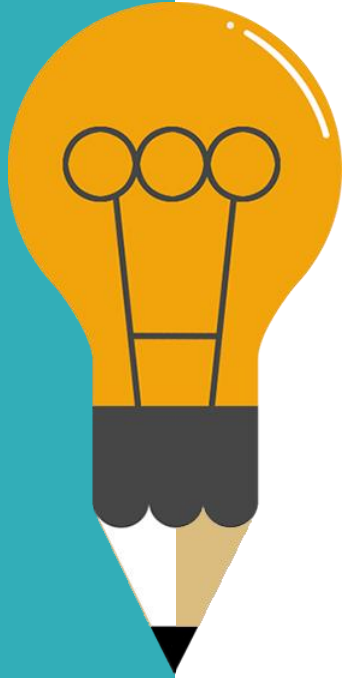
# Pharmaco- epidemiology

Prepared by: Esraa Boamoud

Presented by:  
Esraa Boamoud  
Salsabil Ghazali



# Objectives



01

Definition of Pharmacoepidemiology.

02

History of pharmacoepidemiology.

03

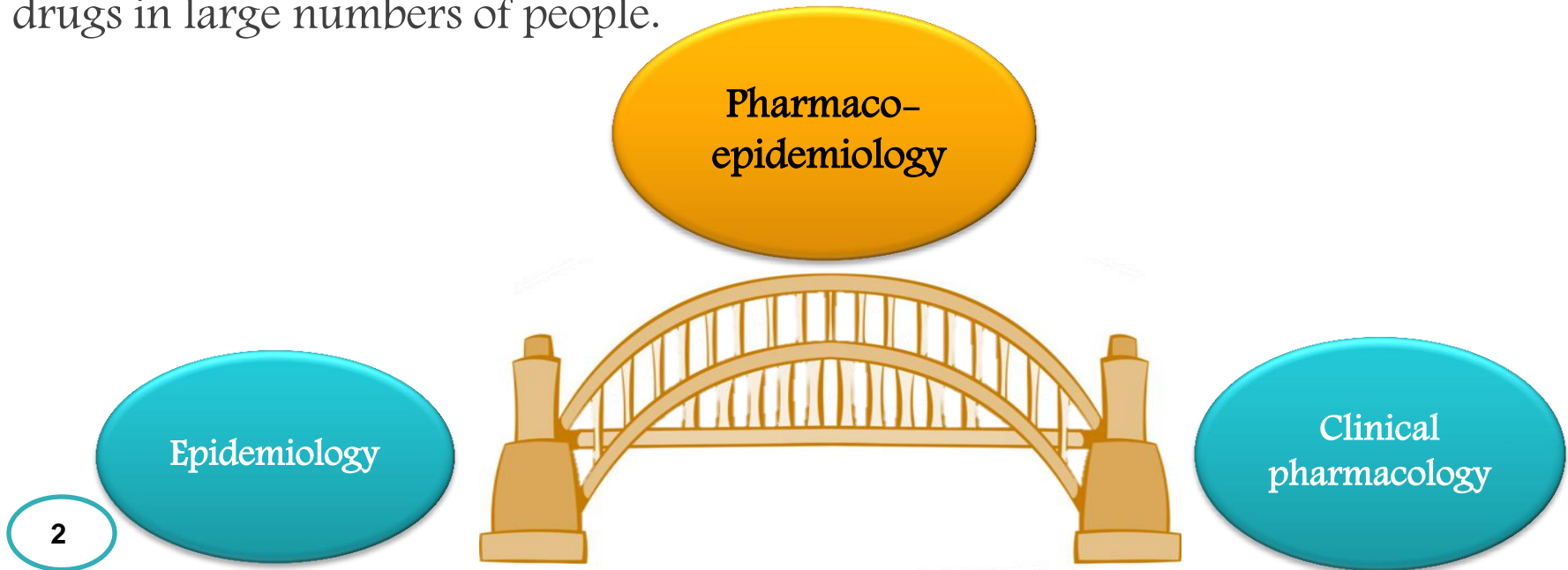
Importance of Pharmacoepidemiology

04

Reasons to perform  
Pharmacoepidemiological studies

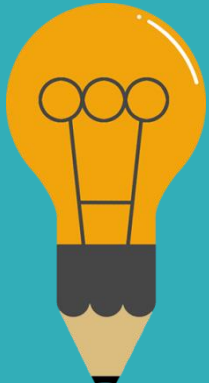
# Pharmaco-epidemiology

**Pharmacoepidemiology** is defined as the study of the utilization and effects of drugs in large numbers of people.



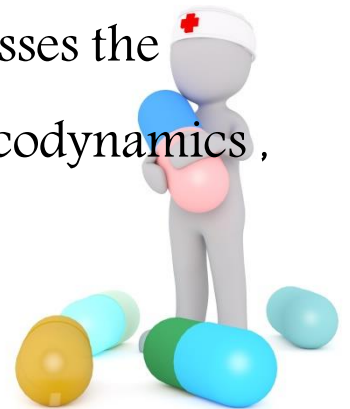
# Epidemiology

- ❑ Epidemiology is the study of the distribution and determinants of health-related states or events (i.e., diseases).
- ❑ It is divided into two basic areas:
  - ❑ The study of infectious diseases, i.e., epidemics.
  - ❑ The study of chronic diseases.
- ❑ Pharmacoepidemiology uses the techniques of chronic disease epidemiology to study the use and effects of drugs.



# Clinical Pharmacology

- ❑ Clinical pharmacology is the study of drugs in humans, and is divided mainly into pharmacokinetics and pharmacodynamics.
- ❑ Pharmacoepidemiology can be considered to fall within clinical pharmacology, because it encompasses the elements of pharmacokinetics and pharmacodynamics, to explore the effects of drug regimen.



# History of pharmacoepidemiology

Little attention was paid to adverse drug reactions, until the Chloramphenicol began to cause aplastic anemia

after the thalidomide disaster, changes were made in implementation While in the past only preclinical toxicity of drugs was being monitored

1906

1950s

1961

1962

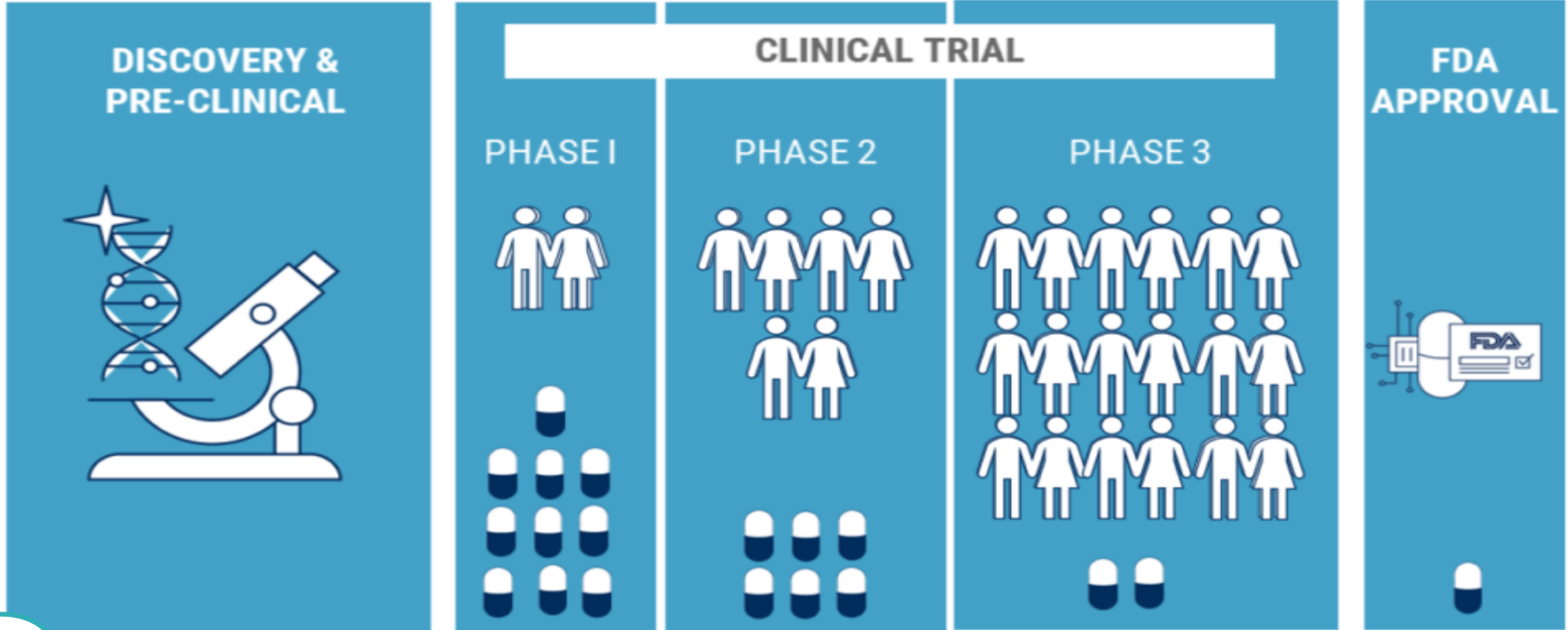
1960s

The Pure Food and Drug Act, was designed to prevent food and drug frauds and wrong labeling

The thalidomide disaster

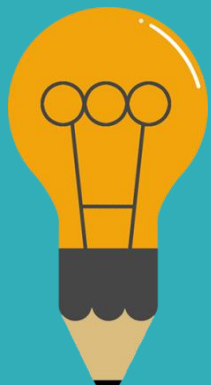
is the beginning of the discipline of **pharmaco-epidemiology**.

# Clinical Trials



# Importance of PE studies

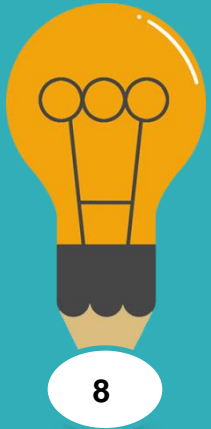
- ❑ Pharmacoepidemiology (PE) is an important area that evaluates the effects of drug use in large populations.
- ❑ Data obtained from pharmacoepidemiological studies may highlight ways to reduce certain drug-related problems and provide reliable information on the safety profile of a drug.





# Importance of PE studies

- ❑ It helps determining the frequency of adverse drug reactions by compiling data all the way from pre-marketing to post-marketing phases.



# Importance of PE studies

- The importance of pharmacoepidemiology is highlighted by variety of outstanding drug withdrawals in recent years. Each of these withdrawals was preceded by severe or fatal adverse effects that had been unrecognized or underappreciated at the time of approval



## Examples of drugs removed from the US Market due to safety concerns

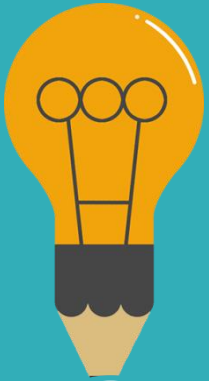
Terfenadine (1998) Arrhythmia

Astemizole (1999) Arrhythmia

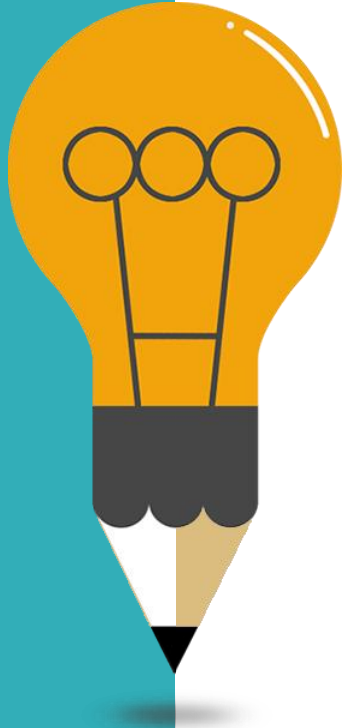
Triglitazone (2000) Liver toxicity

Cerivastatin (2001) Rhabdomyolysis

Rofecoxib (2004) Heart attack & stroke



# Reasons to perform PE studies

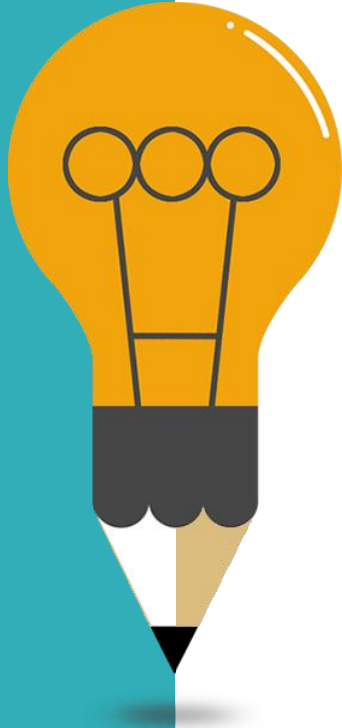


## 1. Regulatory

- To obtain earlier approval for marketing.
- As a response to a question by the regulatory agency.
- To assist application for marketing elsewhere .



# Reasons to perform PE studies

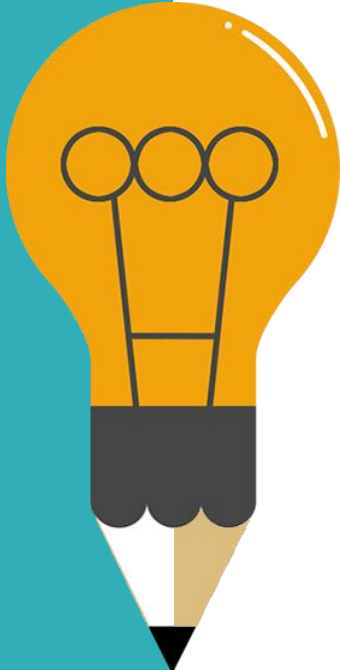


## 2. Marketing

- To assist market penetration by documenting the safety of the drug.
- To increase name recognition.
- To find new drug indications.



# Reasons to perform PE studies



## 3. Legal

- ❑ In anticipation of future product liability litigation.



# Reasons to perform PE studies

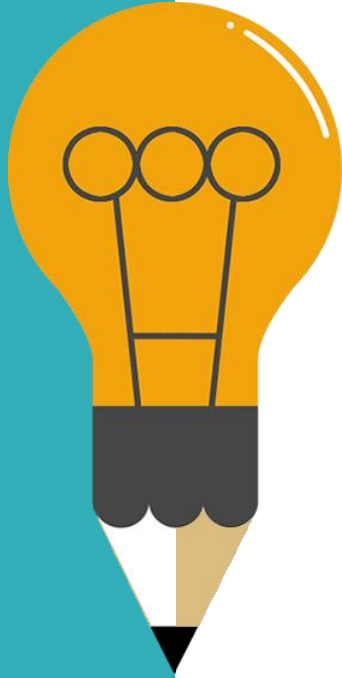
## 4. Clinical

### A. Hypothesis testing

- Problem hypothesized on the basis of drug structure.
- Problem suspected on the basis of preclinical or premarketing human data.
- Problem suspected on the basis of spontaneous reports .



# Reasons to perform PE studies



## 4. Clinical

**B. Hypothesis generating** : the need depends on:

- whether it is a new chemical entity.
- the safety profile of the class.





# Conclusion



To conclude, Pharmacoepidemiology is a new field that is considered to have an important role in increasing individual life quality by improving drug use across societies. As seen, recently this discipline is gain more attention worldwide, which should be applied nationally, too.

Thank you  
Any question

