

SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES



Affiliated To The Tamil Nadu Dr. MGR Medical University, Chennai

Approved by Pharmacy Council of India, New Delhi.

Coimbatore -641035

COURSE NAME : PHARMACY PRACTICE (BP703T)

VII SEM / IV YEAR

TOPIC 5 : SPONTANEOUS CASE REPORTS AND RECORD LINKAGE STUDIES

DESIGN THINKING IN SPONTANEOUS CASE REPORTS AND RECORD LINKAGE STUDIES

DESIGN THINKING OF DRUG INTERACTION



EMPATHIZE

Understand
the users

DEFINE

Frame
the
problem

IDEATE

Brainstorm
creative
solutions

PROTOTYPE

Build a
simple
version

TEST

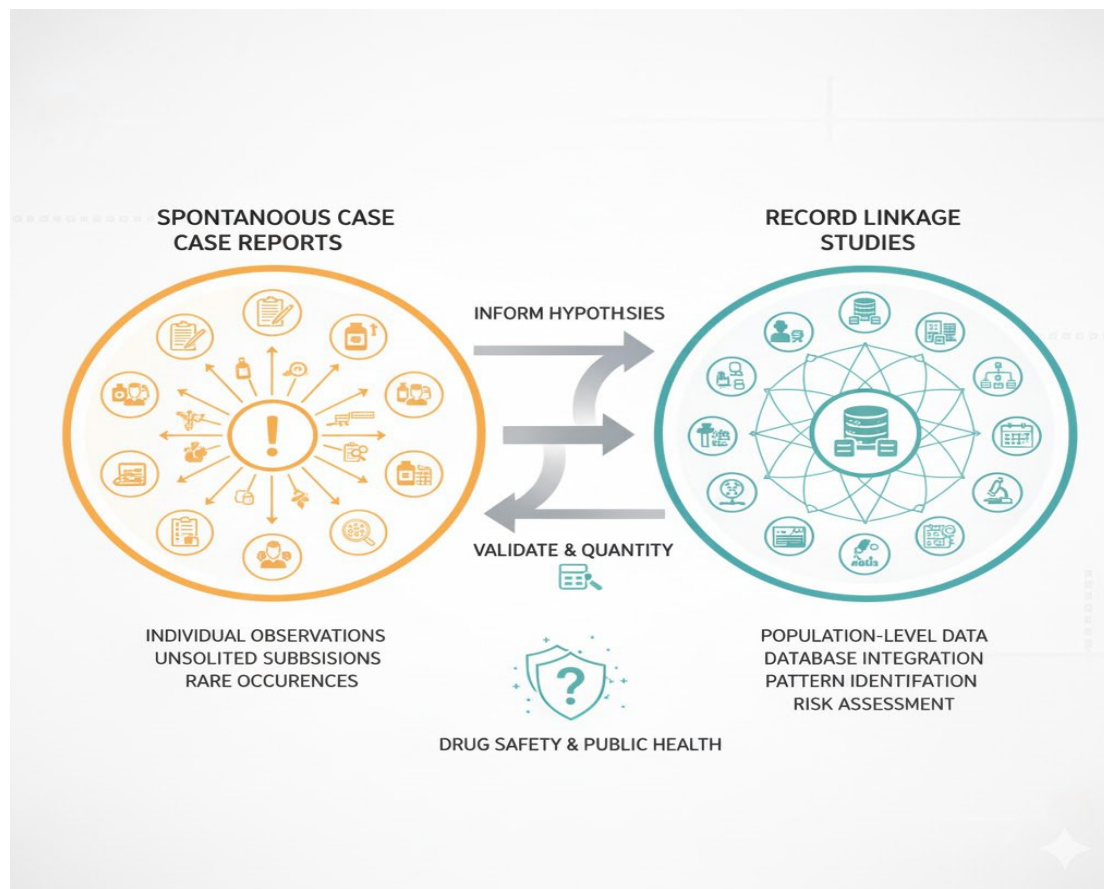
Gather
feedback

MINDMAP



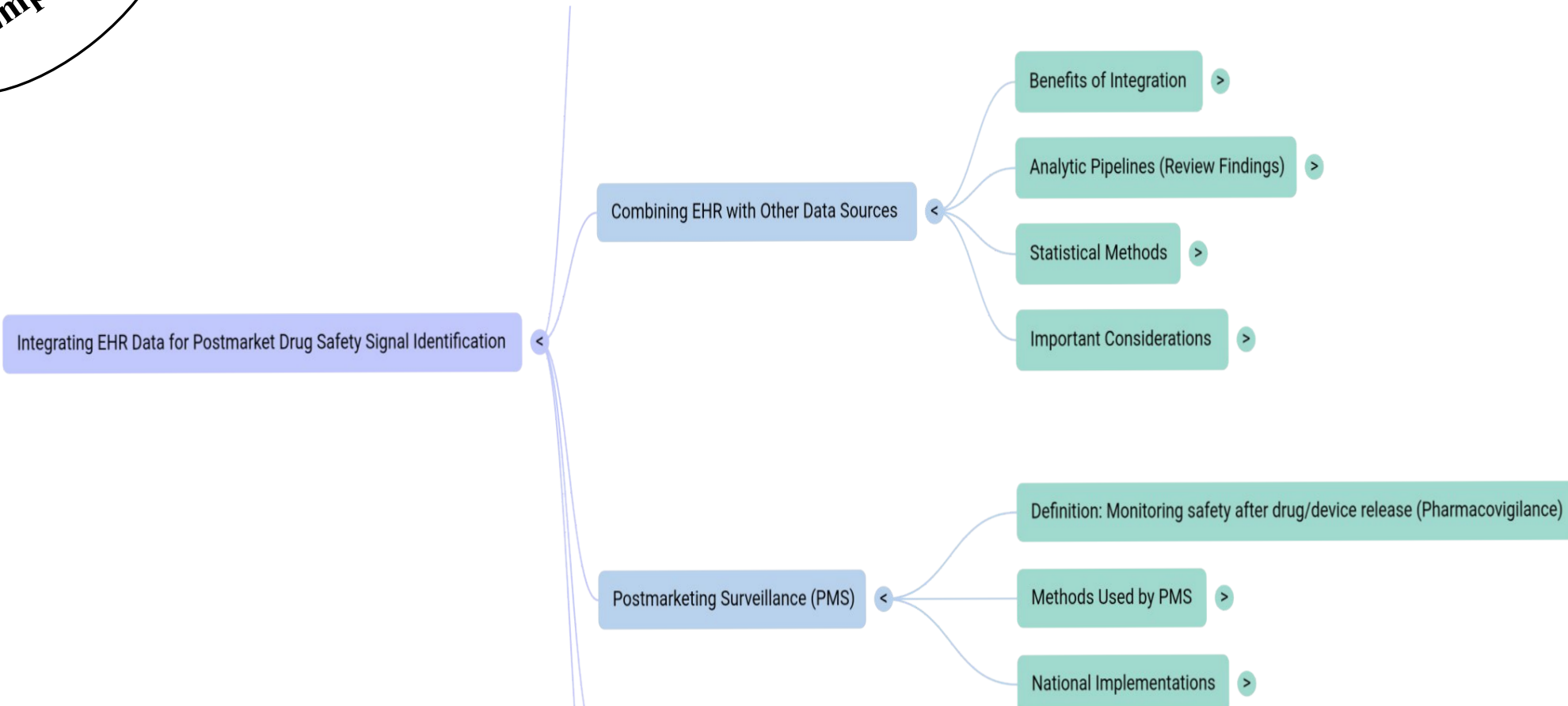
Empathize

INTRODUCTION



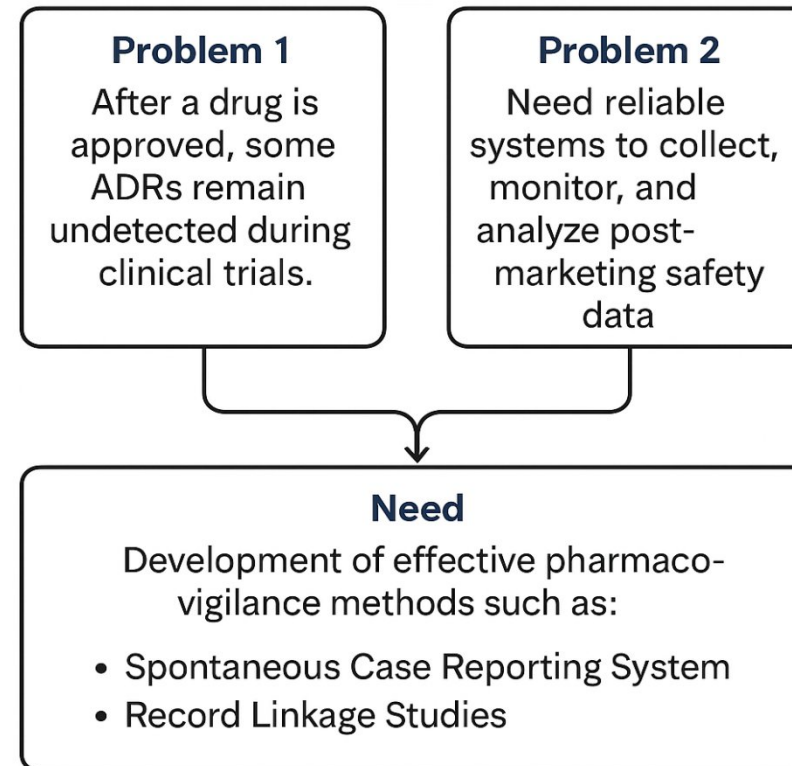
Empathize

SPONTANEOUS CASE REPORTS



Empathize

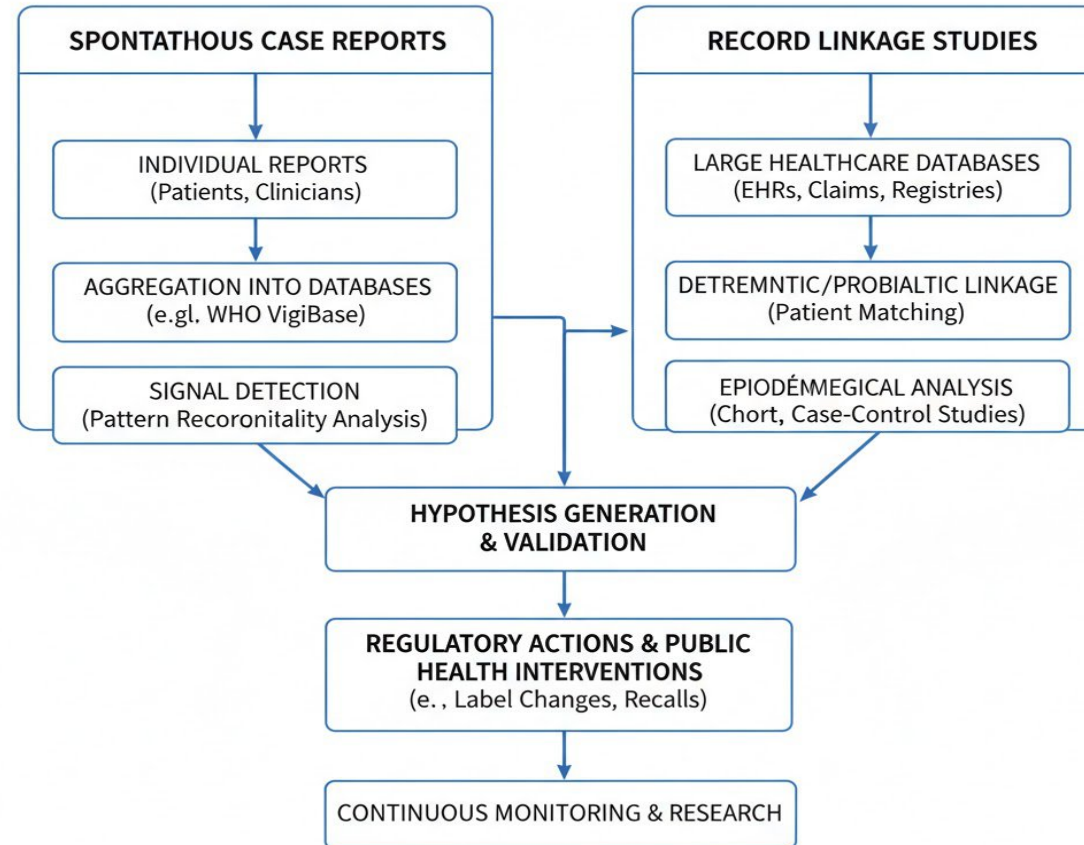
REPORTS AND LINKAGE



Empathize

SCR AND RLS

PHARMACOVIGILANCE: ADVERSE DRUG EVENT DETECTION



Define

REPORT DATABASE PORTAL



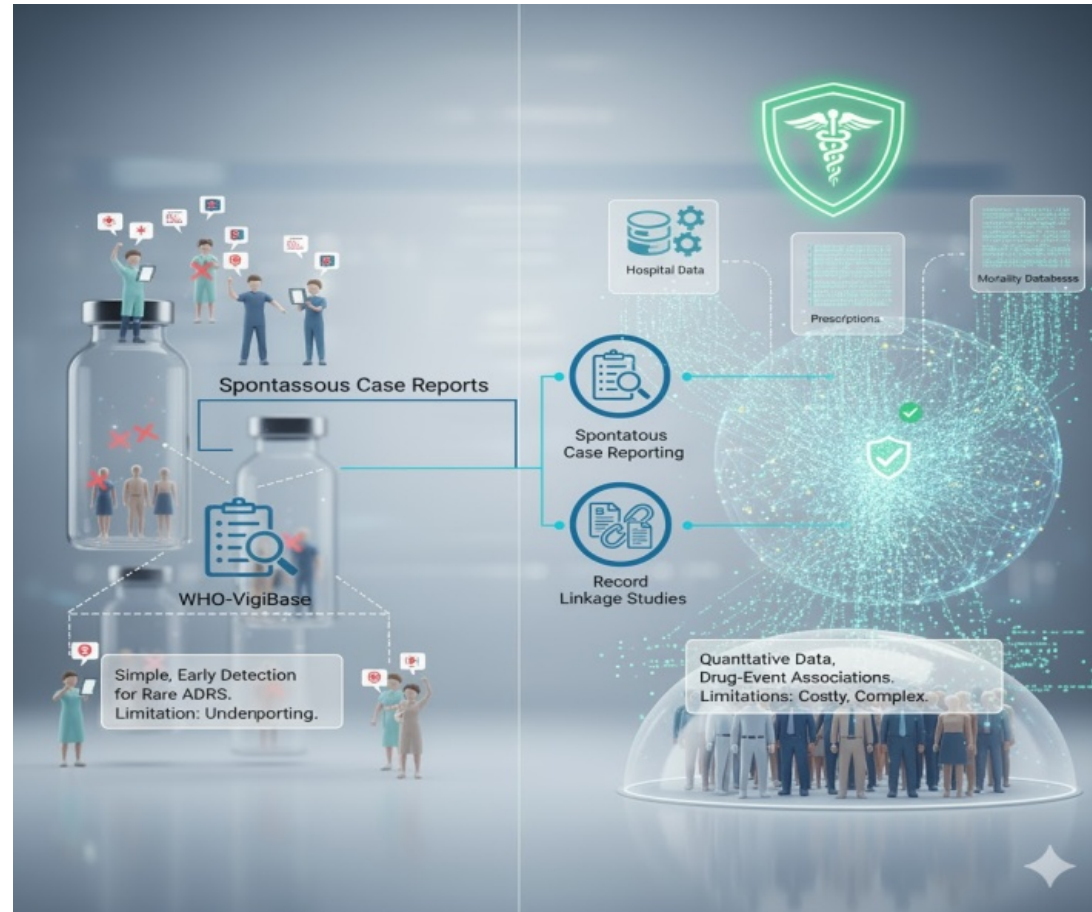
Define

DETECTING ADVERSE EFFECTS



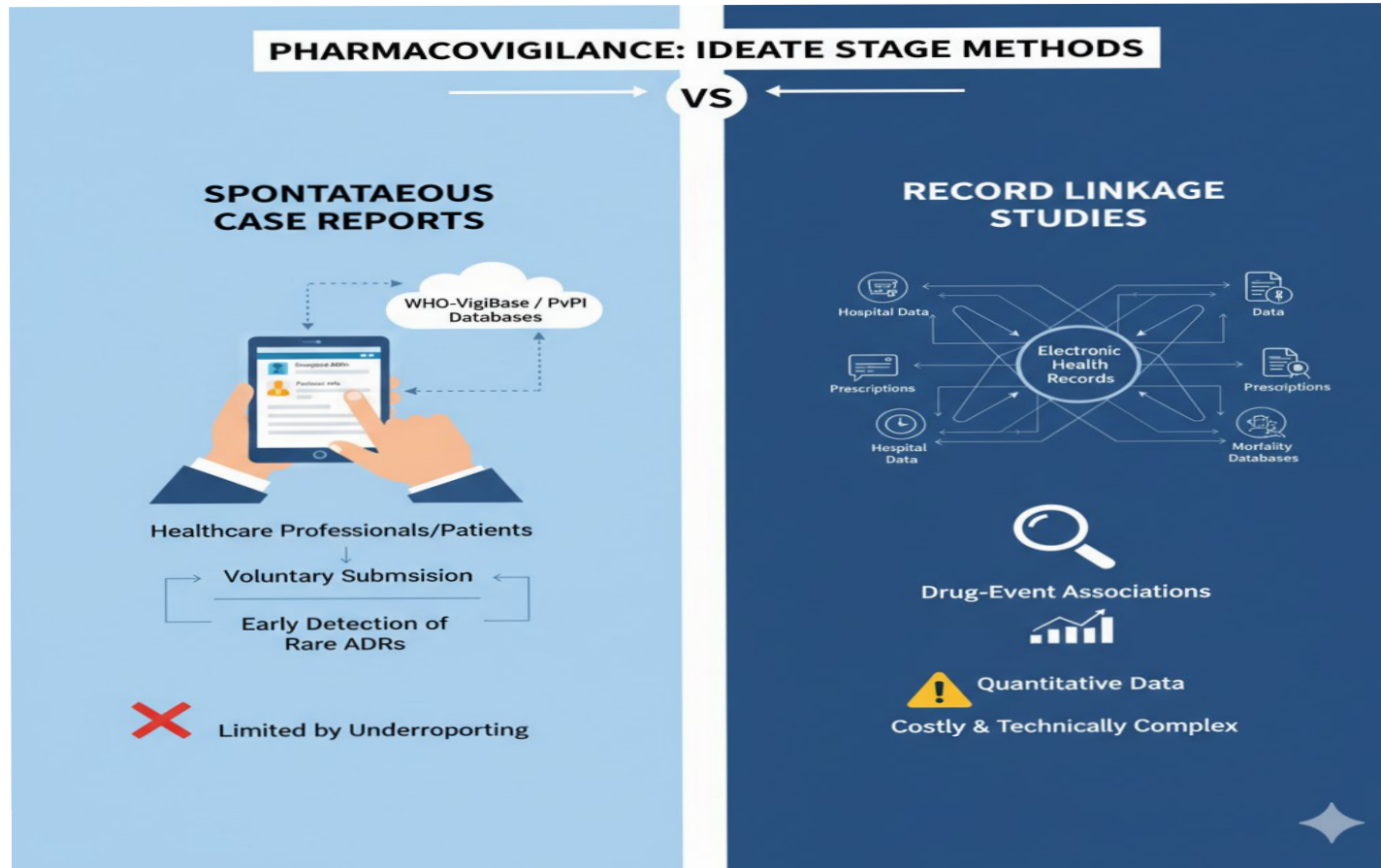
Ideate

METHODS OF REPORTING

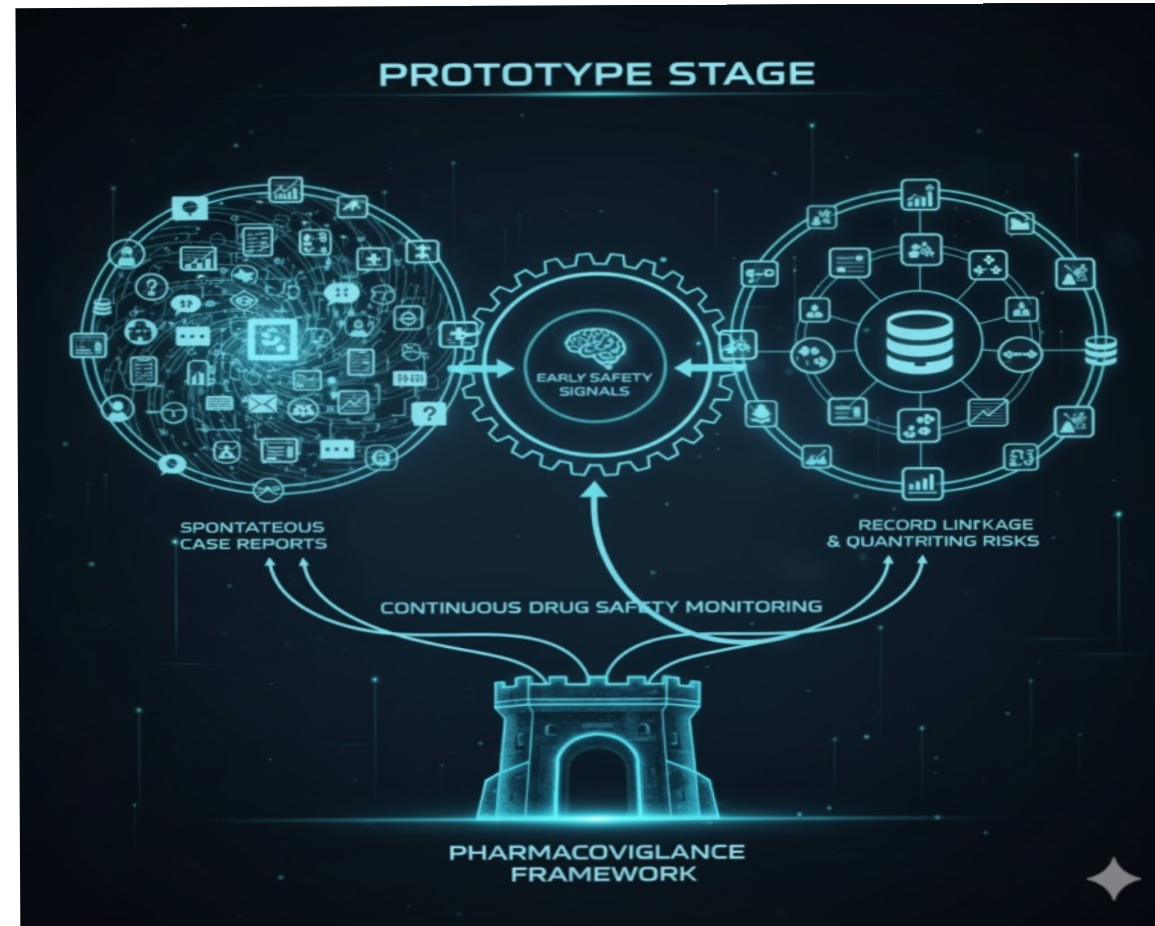


Prototype

IDEATE STAGE METHODS



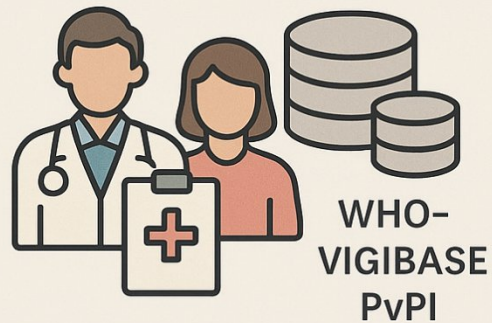
PROTOTYPE FRAMEWORK



PROTOTYPE SYSTEM ARCHITECTURE

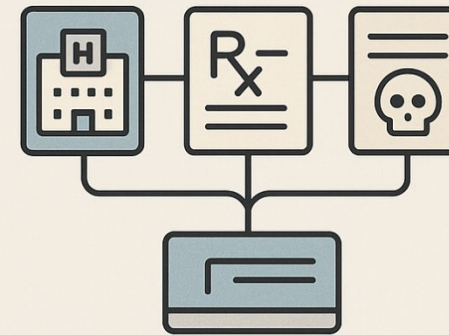


SPONTANEOUS CASE REPORTS



- Voluntary submission of suspected ADRs
- Simple and useful for early detection of rare or serious ADRs
- Limited by underreporting

RECORD LINKAGE STUDIES



- Linkage of electronic health records
- Provide quantitative data on drug-event associations
- Costly and technically complex



CLASS ASSESSMENTS

1. The main purpose of spontaneous case reporting systems is:





CLASS ASSESSMENTS

A. Spontanouss Caportes



Are active, database-driven studies that quantifcare prorsity risk in large populations

C. Advantages



Are passive, unlisted reports from ide or large patients



B. Record Linkage Studies



Are passive, unlisted from healthcare professionals or or patients

D. Record Linkage Studies



Are excellent for detecting early, sar gnals but suffer from under-reporting bias



Choose the correct option



CLASS ASSESSMENTS

2. Spontaneous reporting systems primarily depend on:





CLASS ASSESSMENTS

A. Under-reporting Bias



Many ADRs, especially mild ones, are never reported to authorities

B. Lack Denomitor Data



Unable to calculate incidence rates as the total number of exposed patients is unknown

C. Difficulty in Causality Assessment



Challenging to definitively link to drug drug to reaction without to controlled comparison group

D. High Cost & Time-AsConsuming



Typically much cheaper and faster to collect than conducting database studies



Choose the correct option



CLASS ASSESSMENTS



3. Which of the following is a major limitation of spontaneous case reporting?





CLASS ASSESSMENTS

A. Quantify Risk & Incidence



Calculate population-based incidence rates and relative risk (IR/RR) in large cohorts

B. Study Rare ADRs



Feasible to investigate very rare adverse reactions in large, pre-existing datasets

C. Real-World Data



Reflects drug use patterns and outcomes in diverse, in general, general patient populations

D. Provide Detailed Causality



Excellent for establishing definitive cause-and-effect-relationships due detailed clinical narratives.



Choose the correct option

REFERENCES

1. Merchant S.H. and Dr. J.S.Quadry. A textbook of hospital pharmacy, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. A textbook of Clinical Pharmacy Practice-essential concepts and skills, 1st ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. Hospital pharmacy, 5th ed. Philadelphia: Lea & Febiger; 1986.
4. Tipnis Bajaj. Hospital Pharmacy, 1st ed. Maharashtra: Career Publications; 2008.
5. Scott LT. Basic skills in interpreting laboratory data, 4thed. American Society of Health System Pharmacists Inc; 2009.

Thank
you!