# SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES

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

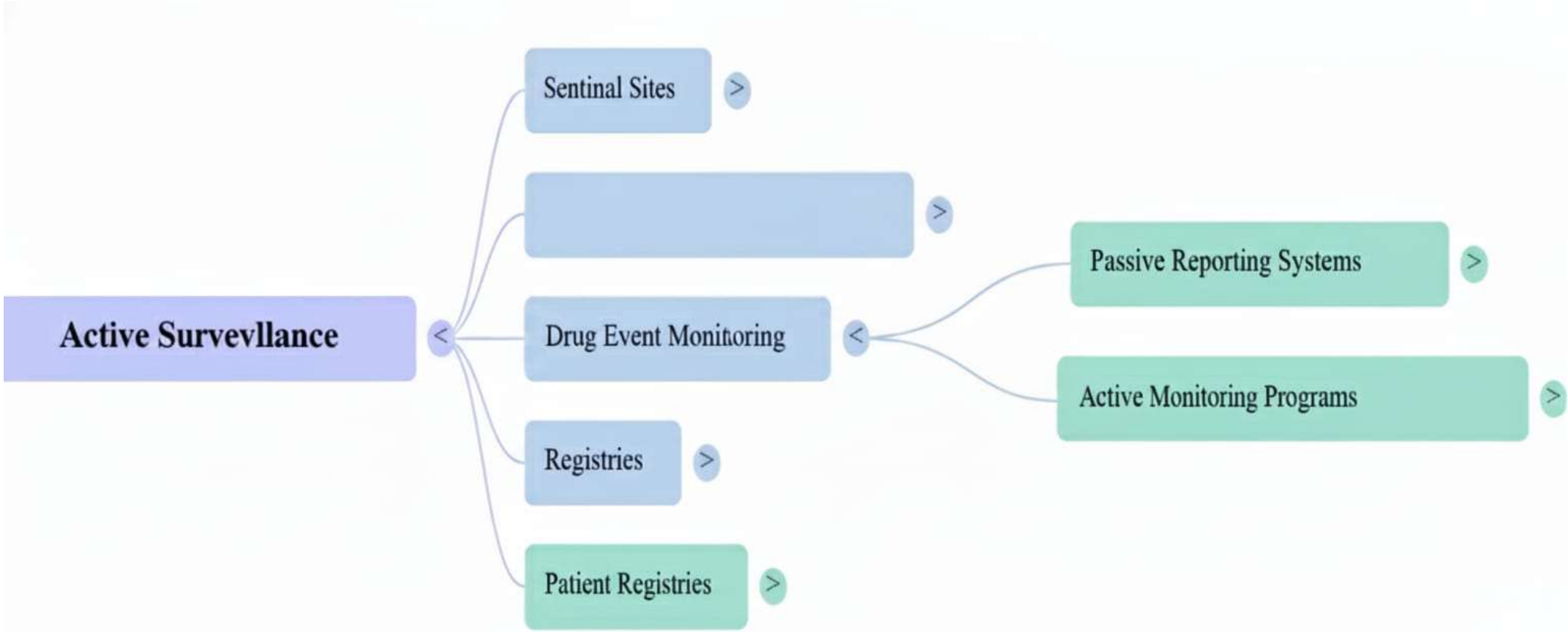
***Approved by Pharmacy Council of India, New Delhi.***

**Coimbatore -641035**

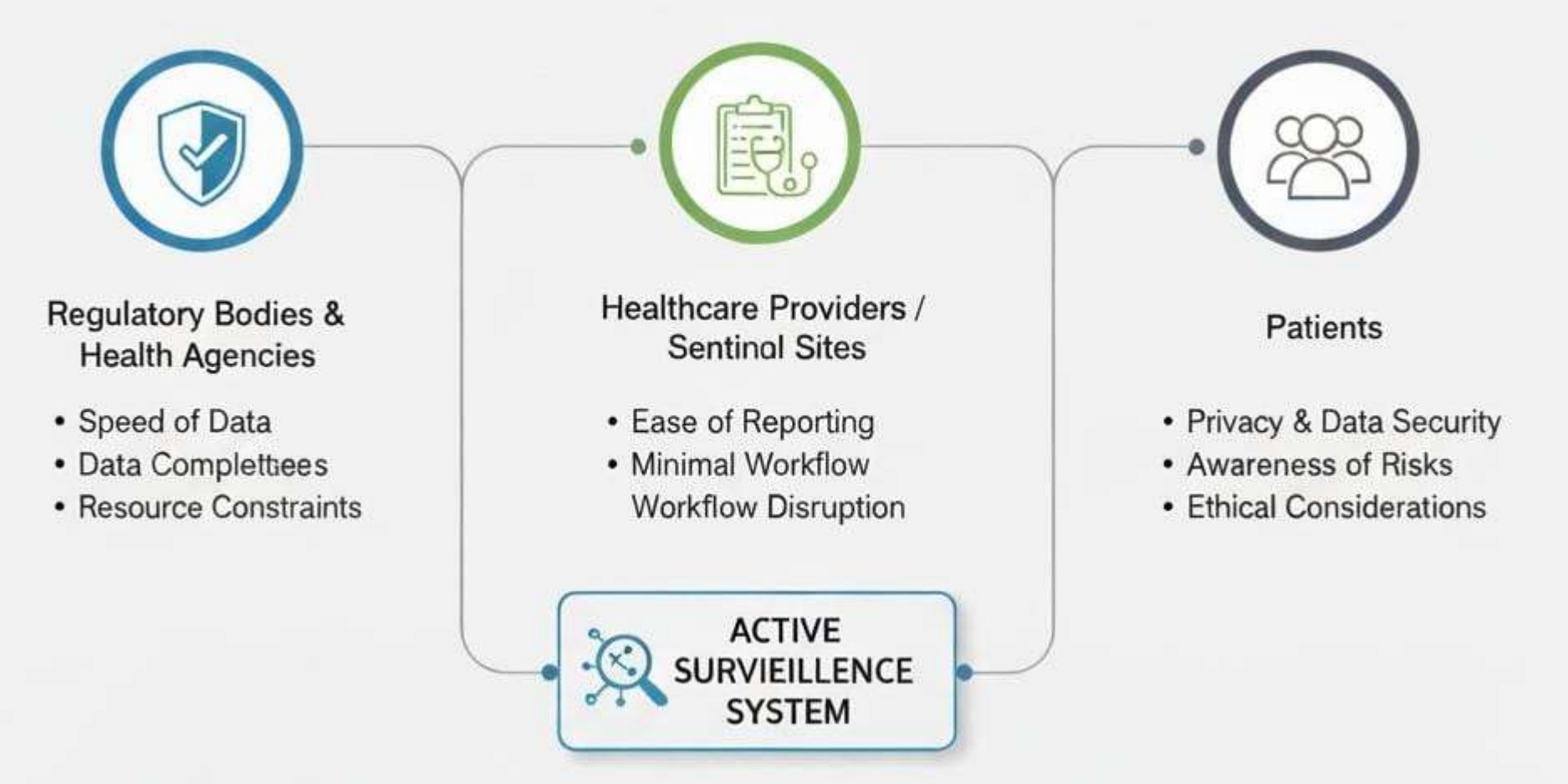
COURSE NAME : PHARMACOVIGILANCE (BP805ET)

VIII SEM / IV YEAR

TOPIC 2 : ACTIVE SURVEILLANCE

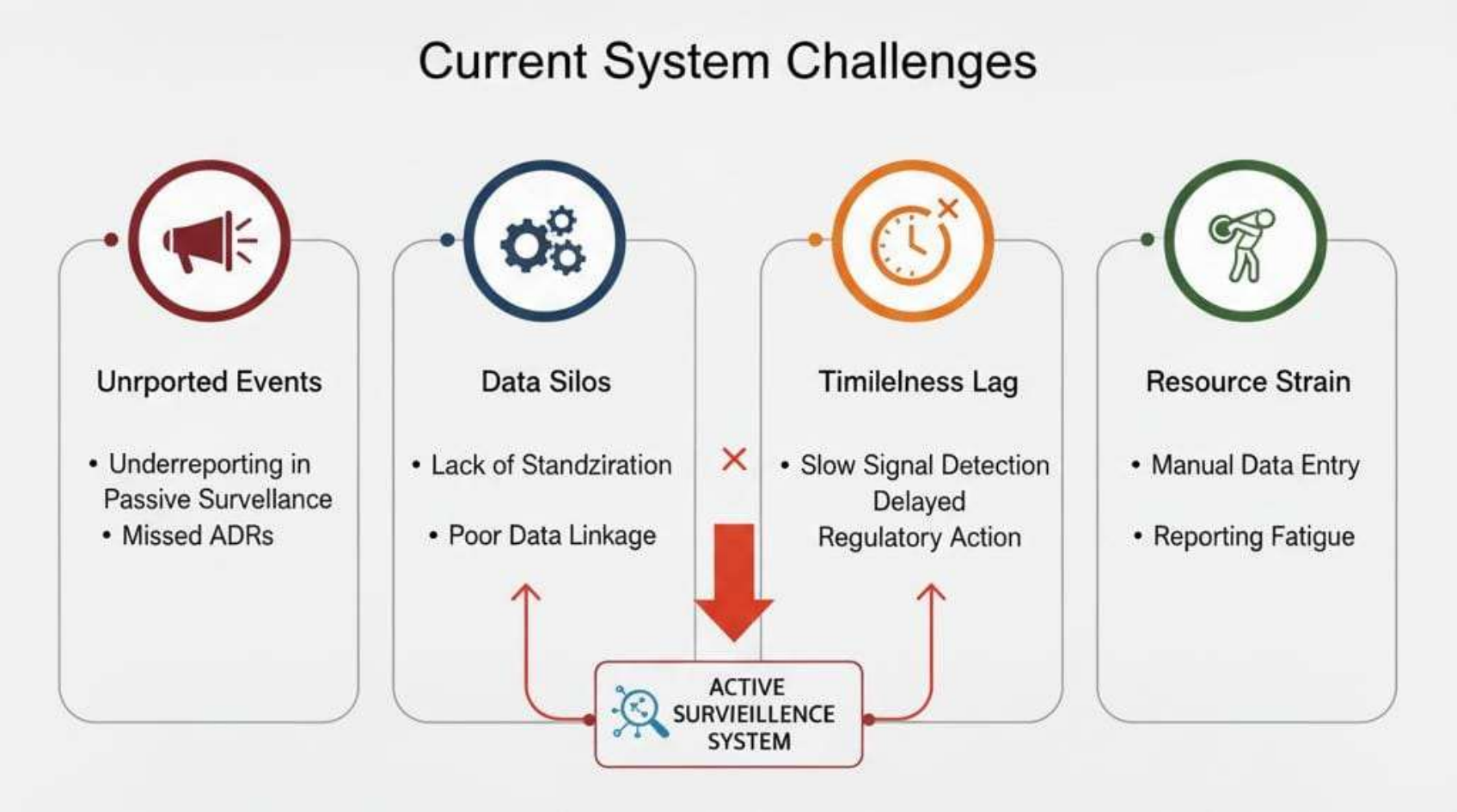

Active Surveyllance
Sentinal Sites
Drug Event Monitoring
Passive Reporting Systems
Active Monitoring Programs
Registries
Patient Registries

# MINDMAP

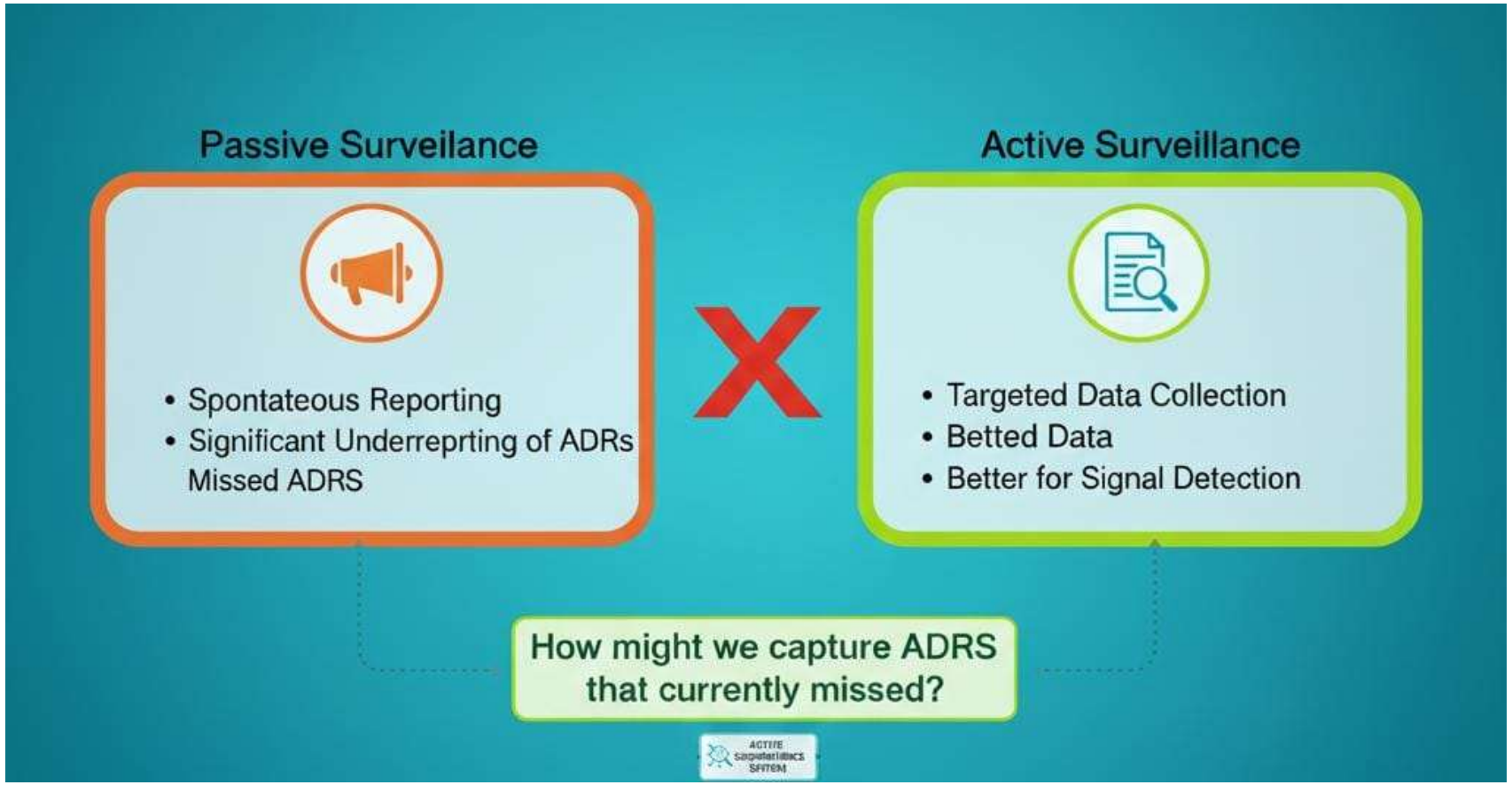

Regulatory Bodies & Health Agencies
• Speed of Data
• Data Completiees
• Resource Constraints
Healthcare Providers / Sentinal Sites
• Ease of Reporting
• Minimal Workflow Workflow Disruption
Patients
• Privacy & Data Security
• Awareness of Risks
• Ethical Considerations
ACTIVE SURVIEILLENCE SYSTEM

Empathize

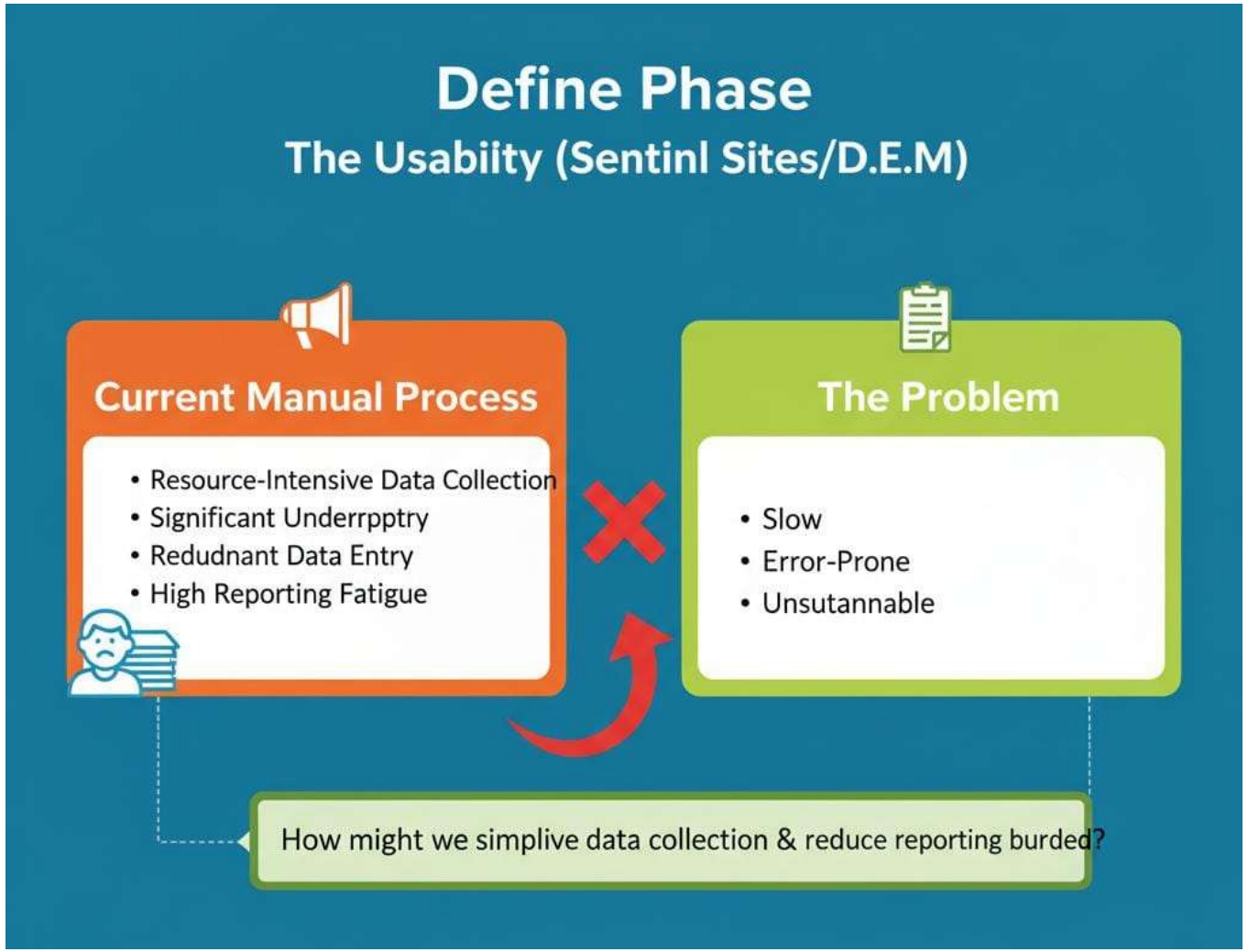
# INTRODUCTION



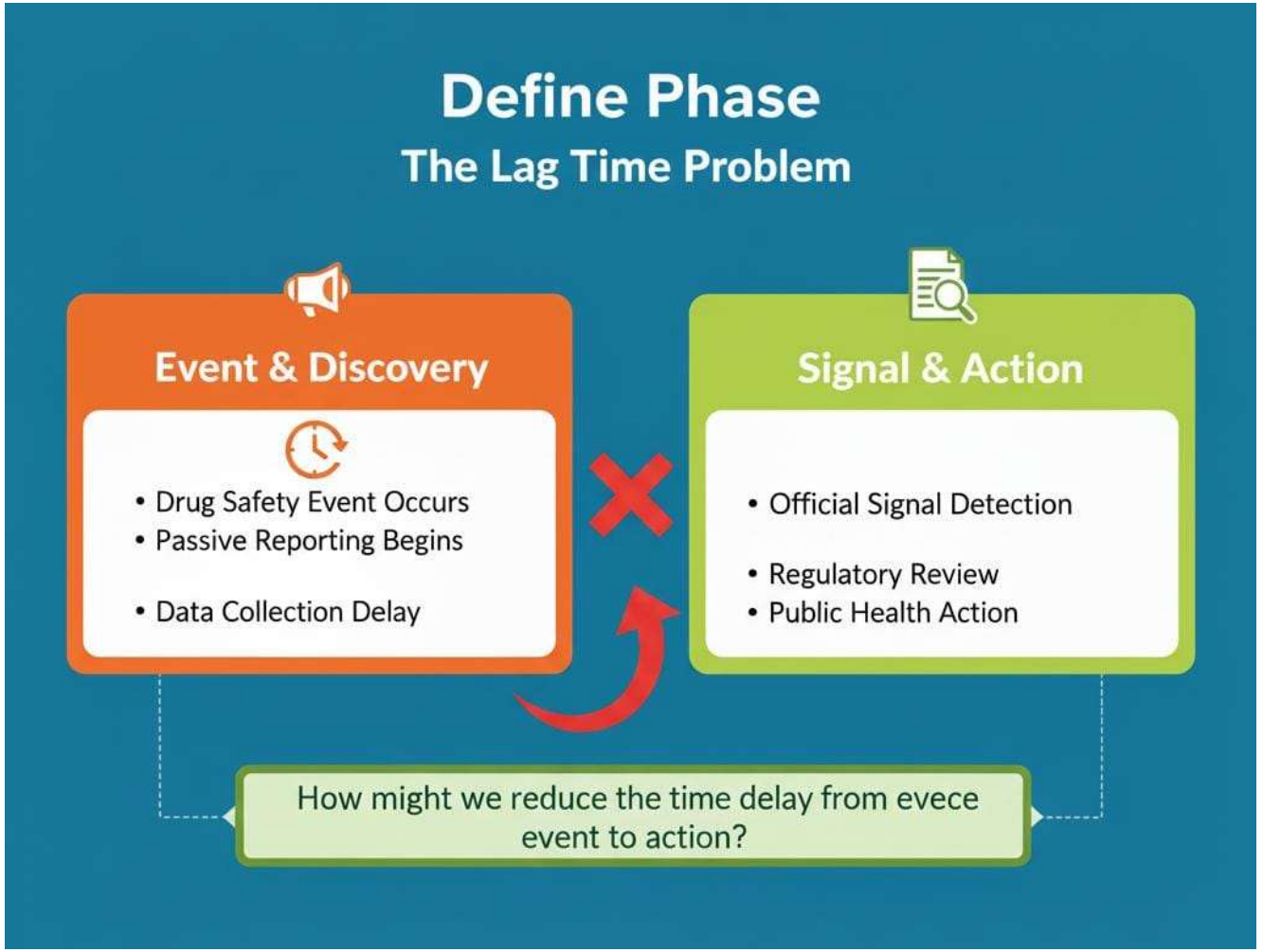
Empathize


Passive Surveilance
• Spontateous Reporting
• Significant Underreprting of ADRs
Missed ADRS
X
Active Surveillance
• Targeted Data Collection
• Betted Data
• Better for Signal Detection
How might we capture ADRS that currently missed?

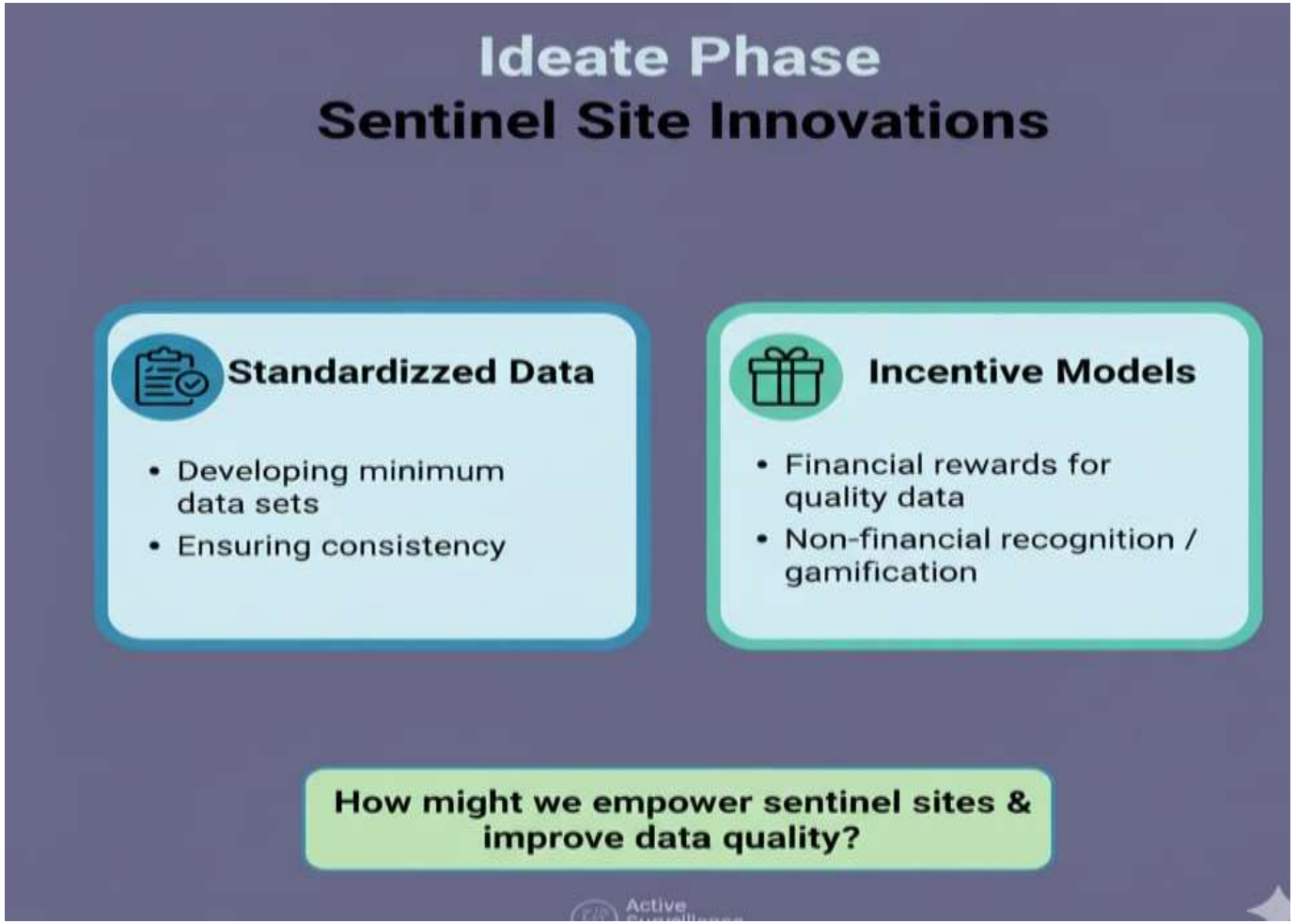
Empathize


Define Phase
The Usabiity (Sentinl Sites/D.E.M)
Current Manual Process
• Resource-Intensive Data Collection
• Significant Underrpptry
• Redudnant Data Entry
• High Reporting Fatigue
The Problem
• Slow
• Error-Prone
• Unsutannable
How might we simplive data collection & reduce reporting burded?

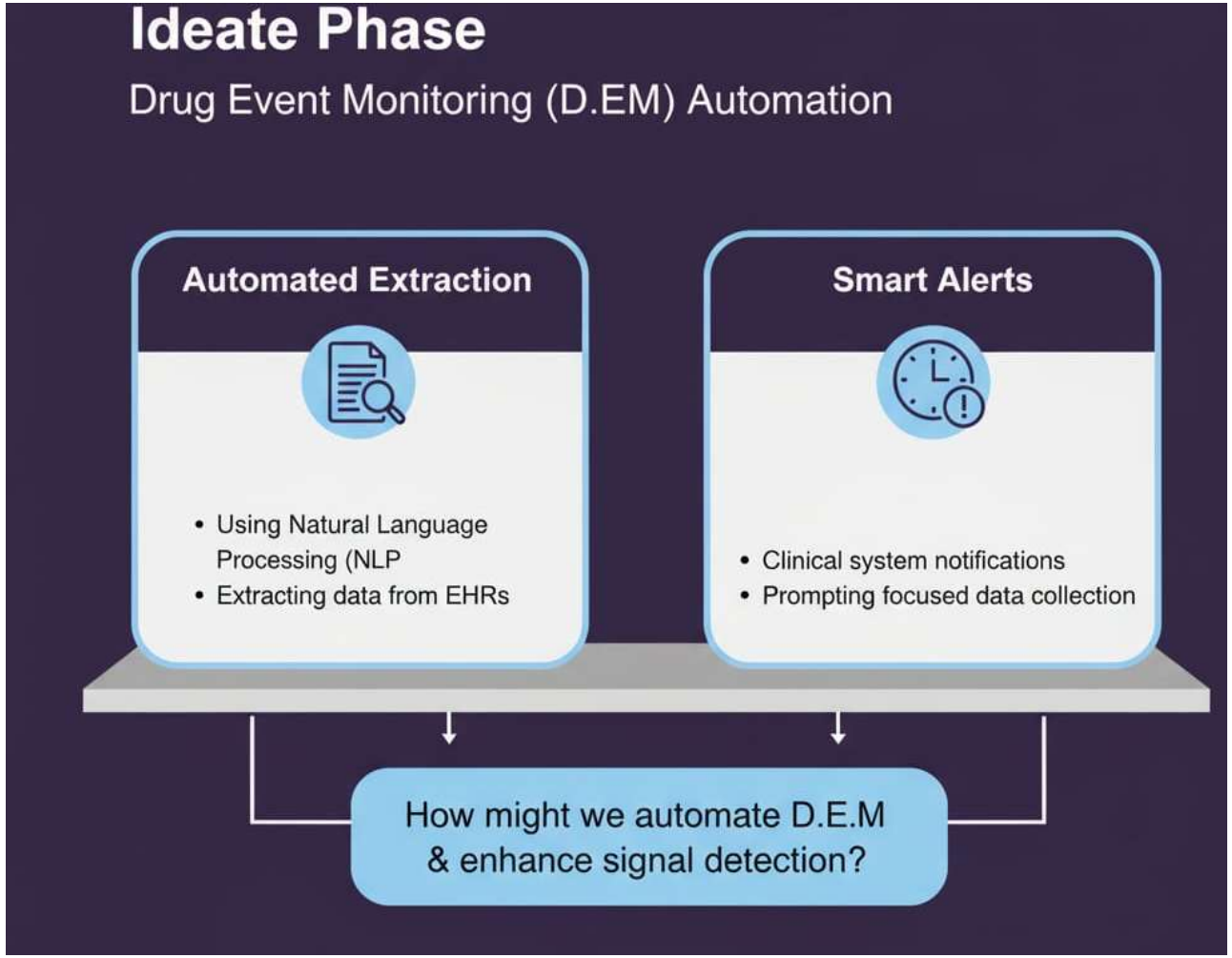
Empathize


Define Phase
The Lag Time Problem
Event & Discovery
• Drug Safety Event Occurs
• Passive Reporting Begins
• Data Collection Delay
Signal & Action
• Official Signal Detection
• Regulatory Review
• Public Health Action
How might we reduce the time delay from evece event to action?

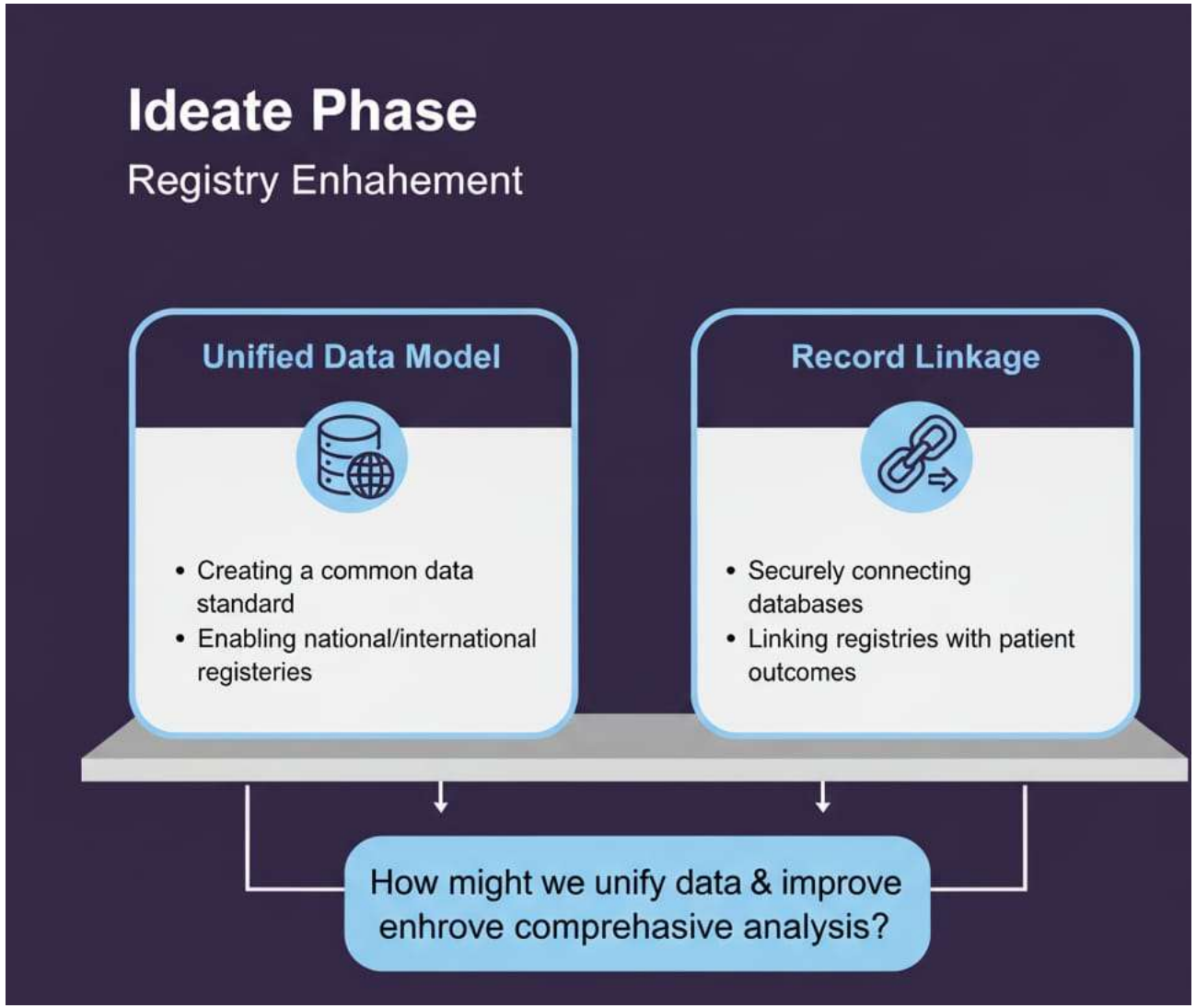
Define

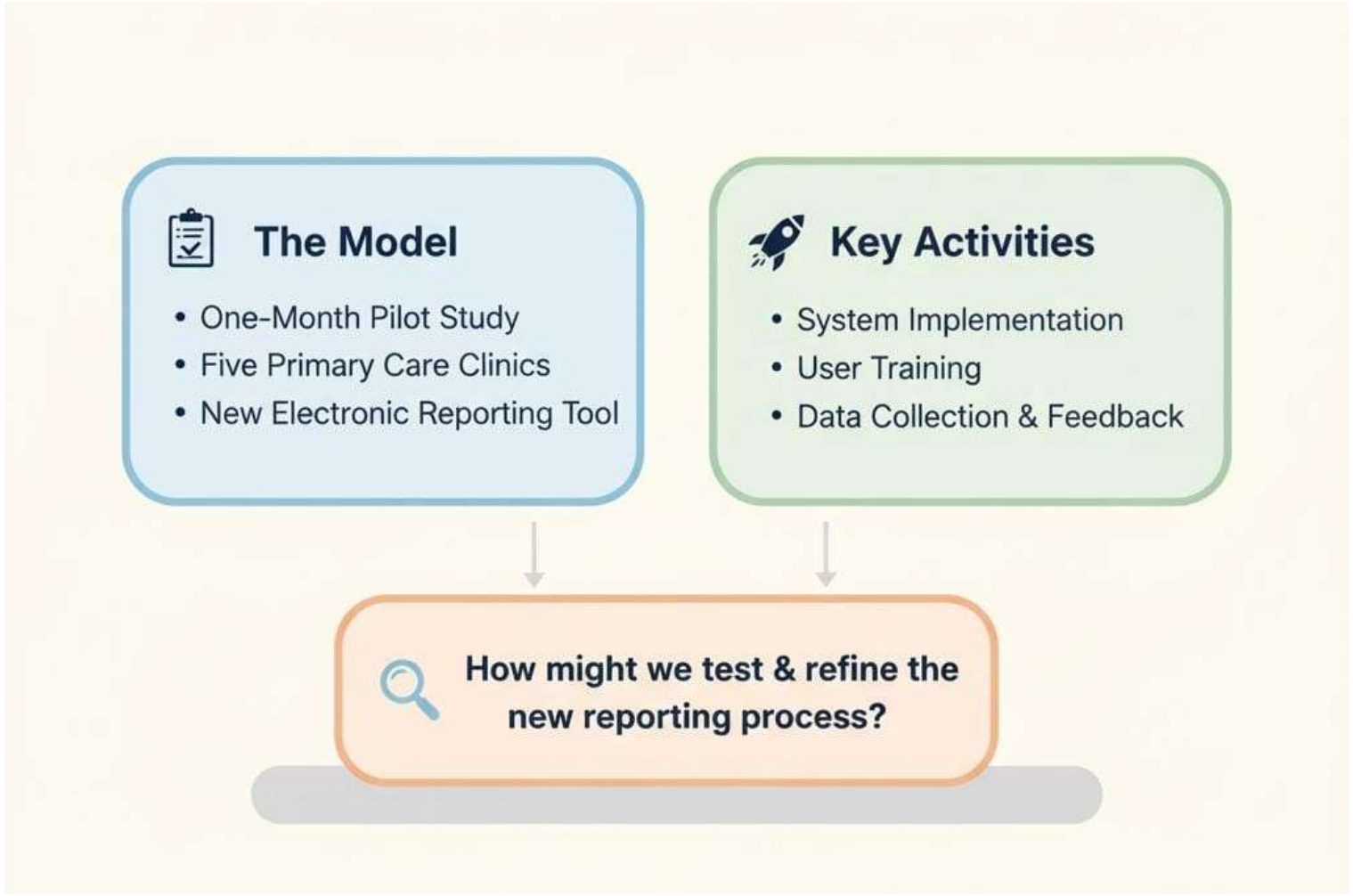

Ideate Phase
Sentinel Site Innovations
Standardizzed Data
• Developing minimum data sets
• Ensuring consistency
Incentive Models
• Financial rewards for quality data
• Non-financial recognition / gamification
How might we empower sentinel sites & improve data quality?

Define


Ideate Phase
Drug Event Monitoring (D.EM) Automation
Automated Extraction
• Using Natural Language Processing (NLP
• Extracting data from EHRs
Smart Alerts
• Clinical system notifications
• Prompting focused data collection
How might we automate D.E.M & enhance signal detection?

Ideate


Ideate Phase
Registry Enhahement
Unified Data Model
Creating a common data standard
Enabling national/international registeries
Record Linkage
Securely connecting databases
Linking registries with patient outcomes
How might we unify data & improve enhrove comprehasive analysis?


The Model
• One-Month Pilot Study
• Five Primary Care Clinics
• New Electronic Reporting Tool
Key Activities
• System Implementation
• User Training
• Data Collection & Feedback
How might we test & refine the new reporting process?

Prototype

## Sentinul Sites

- Doctors
- Nurses
- Pharmacists
- Reporting

## Drug Event Monitoring (DEM)

- Data Analysts
- Informaticits
- PV Specialists
- Signal Detection

Active Surveillance System

## Registries

- Researchers
- Biotastisistins
- Data Curators
- Long-term Tracking

REVALIDATION WILL REQUIRE
EXTRA MONITORING

1

## 🤯 When there's "too much data, too little clarity"...

What objective should we focus on?

A) 🎨 Enhance Clarity

B) ⚡ Ensure Timeliness

2

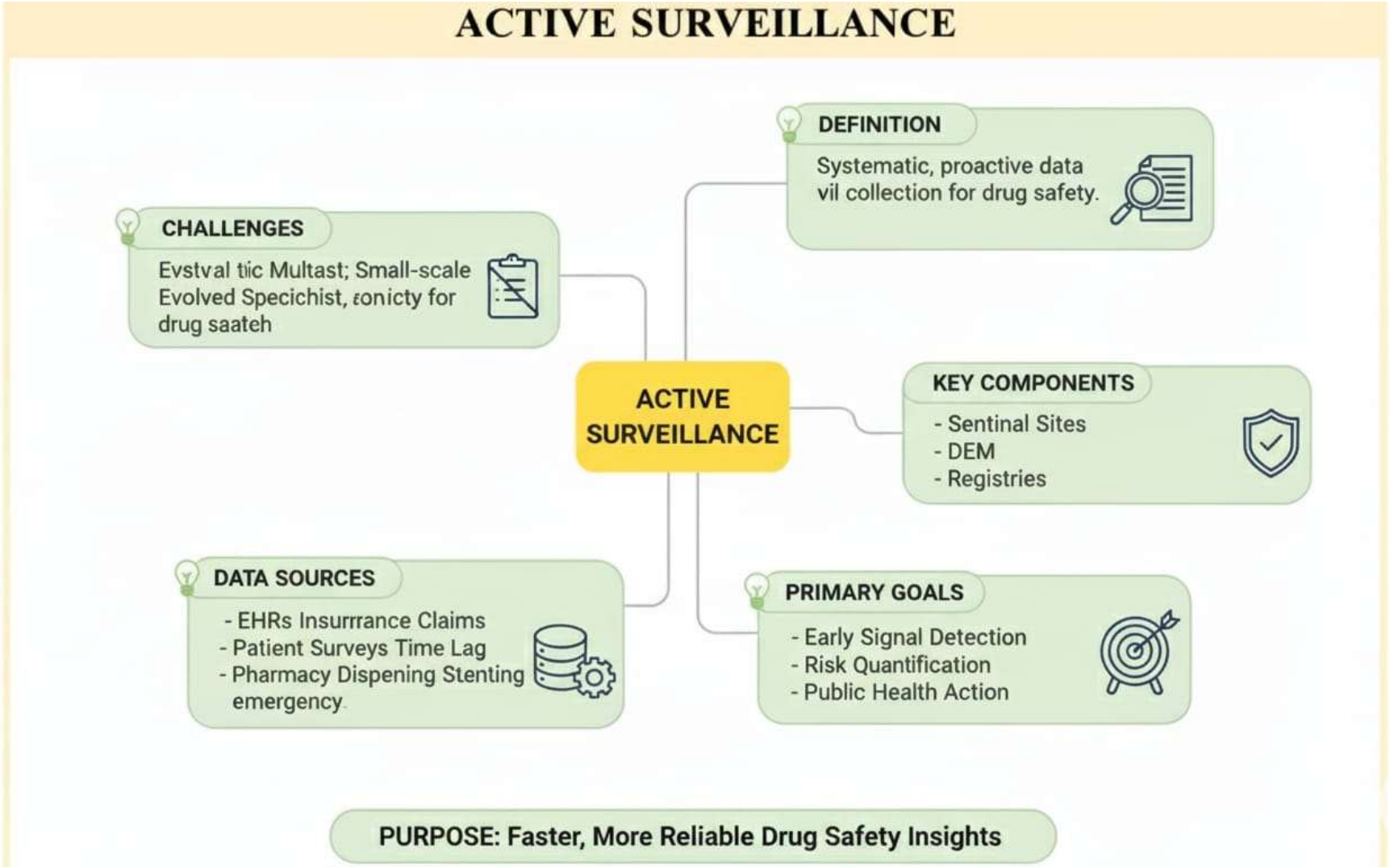
## 🐌 Safety alerts are moving slower than a snail!

Which challenge does this represent?

A) 📊 Information Overload

B) ⏰ Delayed Dissemination

# SUMMARY


ACTIVE SURVEILLANCE
DEFINITION
Systematic, proactive data vil collection for drug safety.
CHALLENGES
Evstval tiic Multast; Small-scale Evolved Specichist, ɛonicty for drug saateh
ACTIVE SURVEILLANCE
KEY COMPONENTS
- Sentinal Sites
- DEM
- Registries
DATA SOURCES
- EHRs Insurrrance Claims
- Patient Surveys Time Lag
- Pharmacy Dispening Stenting emergency
PRIMARY GOALS
- Early Signal Detection
- Risk Quantification
- Public Health Action
PURPOSE: Faster, More Reliable Drug Safety Insights

# CLASS ASSESMENTS

1. **Which of the following best describes sentinel surveillance in the context of active drug safety monitoring?**

**a.** Passive collection of adverse drug reactions from all healthcare facilities

b. Targeted data collection from selected healthcare sites to monitor specific drug events

c. Gathering data from patient self-reports without clinical validation

d. Random sampling of drug prescriptions across a country

# CLASS ASSESSMENTS

| A. PRE-CLINICAL | B. PHASE 1 TRIALS | C. PHASE 2 TRIALS | D. PHASE 3 TRIALS |
|---|---|---|---|
| | | | |
| LAB & ANIMAL STUDIES | SMALL GROUP SAFETY | EFFICACY & SIDE EFFECTS | LARGE POPULATION CONFIRMATION |
| A. Passive collection of adverse drug reactions from all healthcare facilities. | B. Targeted data collection from selected healthcare sites to monitor specific drug events. | C. Gathering data from patient self-reports without clinical validation. | D. Random sampling of drug prescriptions across a country. |

# CLASS ASSESSMENTS

**What is the primary purpose of drug event monitoring in active surveillance systems?**

a. To conduct clinical trials for new drugs

b. B. To systematically detect and evaluate adverse drug reactions during routine use

c. C. To register all patients prescribed with a particular drug for marketing purposes

d. D. To monitor only over-the-counter medication usage

# CLASS ASSESSMENTS

# CLASS ASSESSMENTS

**3. In the context of active surveillance, what role do patient registries primarily serve?**

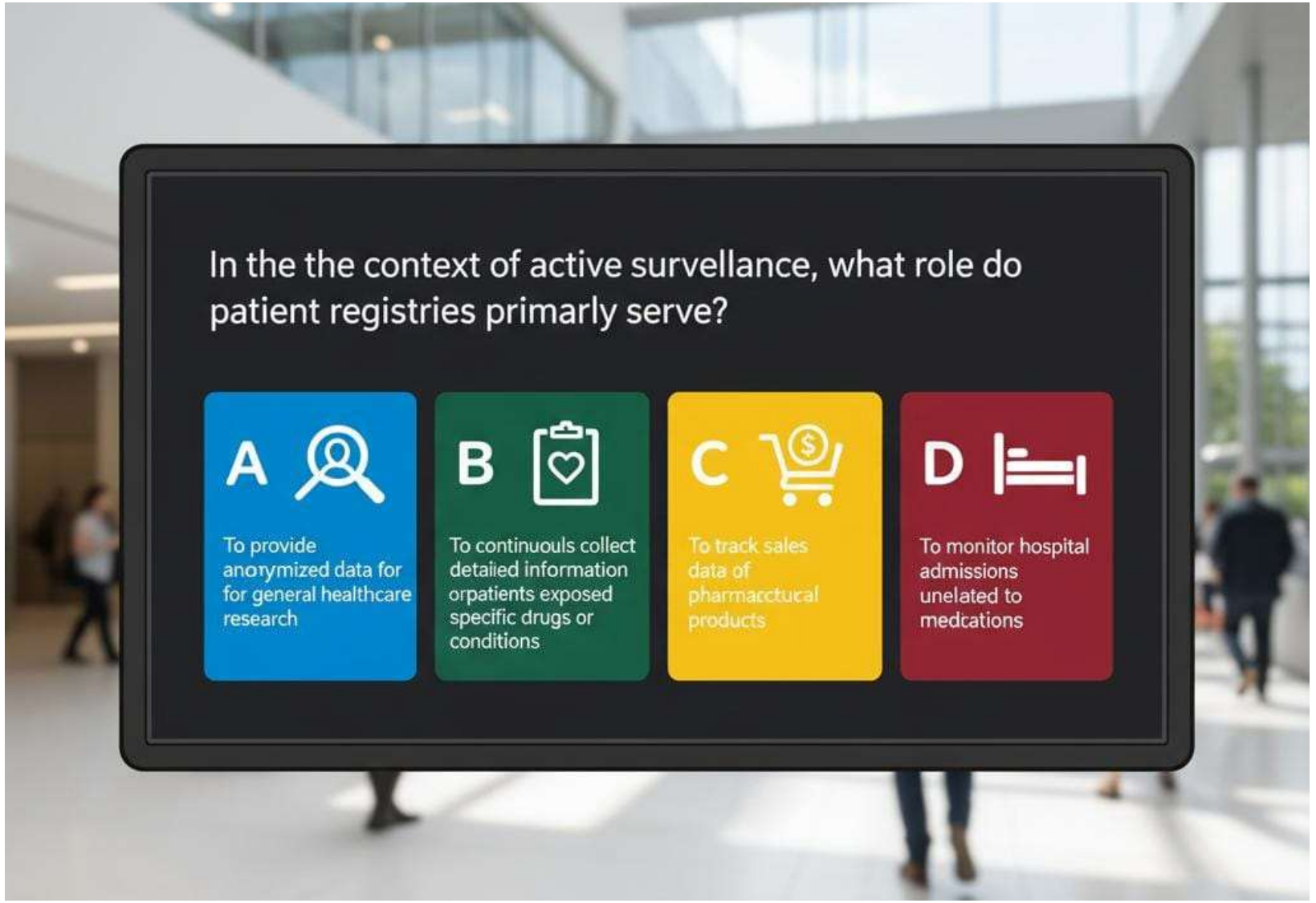
a. To provide anonymized data for general healthcare research

b. To continuously collect detailed information on patients exposed to specific drugs or conditions

c. To track sales data of pharmaceutical products

d. To monitor hospital admissions unrelated to medications

# CLASS ASSESSMENTS



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Thank
you!