

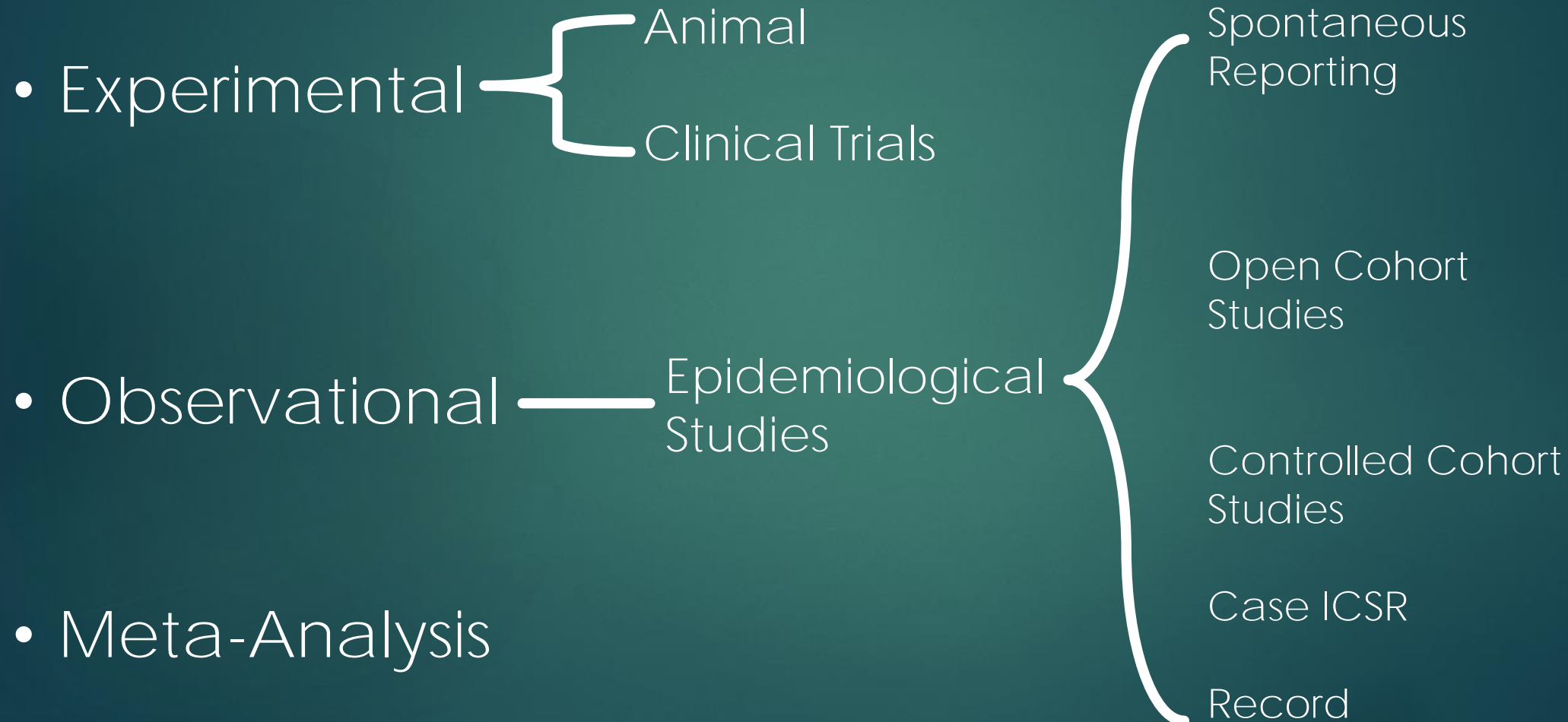


Spontaneous Reporting of Drug- Related Problems

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Methods used to study Drug Related Problems



Spontaneous Adverse Drug Reactions Reporting

Principle:

The alert patient/healthcare professional connects an undesirable medical event with drug exposure

A **SUSPICION** is created

Report suspicion to the national pharmacovigilance program



A large rectangular box with a thick red border contains a map of India. On the left side of the map, there is a black stick figure in a suit with a blue tie, standing with one hand on its hip and the other raised. Below the figure, the text "Mr. Babloo" is written in red. At the bottom left of the box, the word "Suspicion" is written in a large, stylized font. At the bottom right, the word "Signal" is written in a similar font, enclosed in a light grey rectangular box. A large red arrow curves from the bottom of the box towards the "Signal" box.

Suspicion

Signal

Advantages of Spontaneous Reporting

- ▶ Large Population
- ▶ All medicines included
- ▶ Can cover all facilities where care is provided
- ▶ Long term perspective
- ▶ Patient Analyses possible.
- ▶ Inexpensive

Requirements for Spontaneous Reporting

A form

&

Caring
Individuals

Limitations to Spontaneous reporting

Under-reporting

Factors affecting reporting volume:

Severity of the reaction

Time in the market

Promotional claims

Promotion of reporting system

Publicity of specific association

Which one would trigger you more to report ?



VS



Limitations to Spontaneous reporting

Under-reporting

Factors affecting reporting volume:

Severity of the reaction

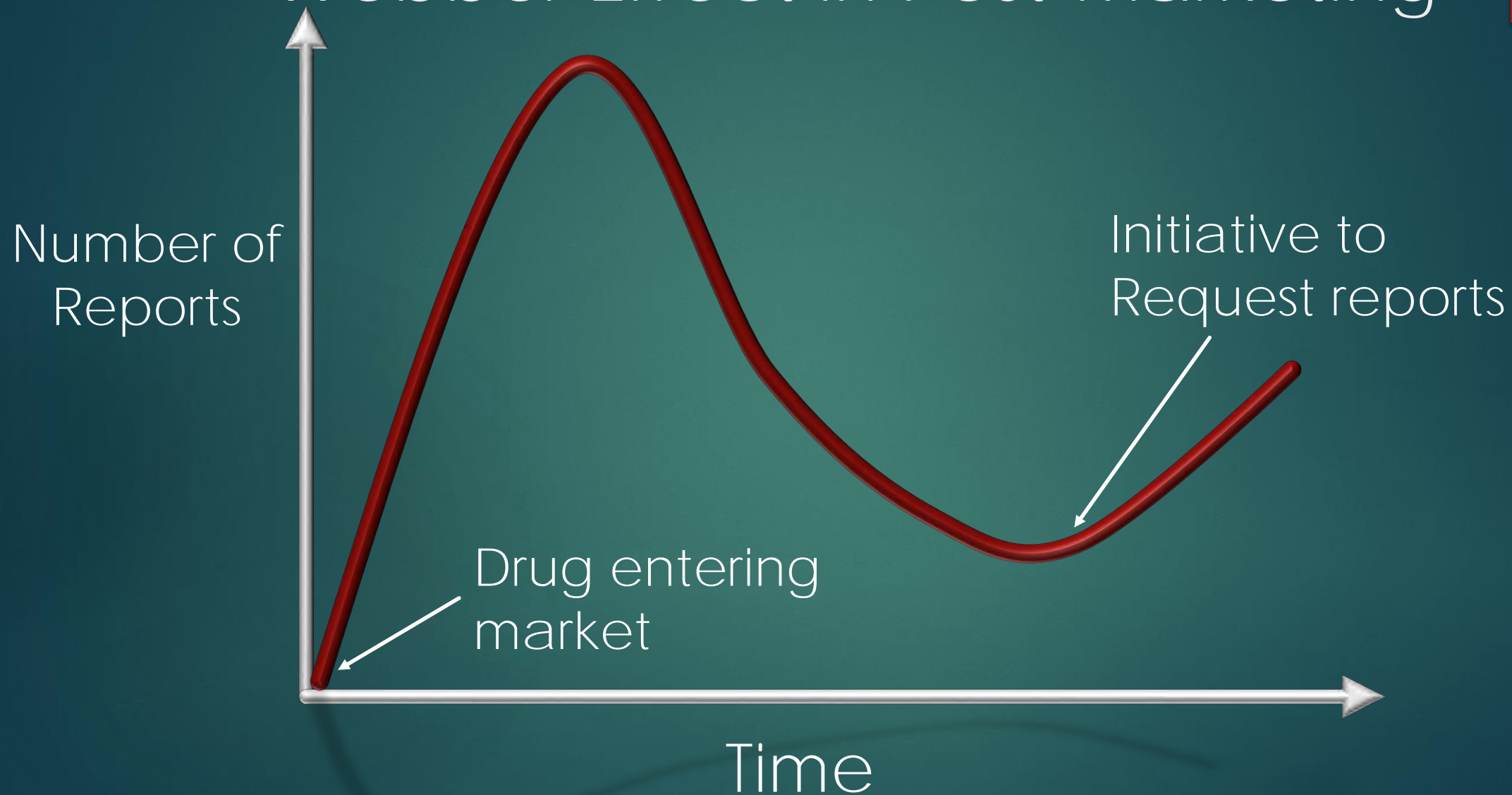
Time in the market

Promotional claims

Promotion of reporting system

Publicity of specific association

Webber Effect in Post-Marketing



Limitations to Spontaneous reporting

Under-reporting

Factors affecting reporting volume:

Severity of the reaction

Time in the market

Promotional claims

Promotion of reporting system

Publicity of specific association

Limitations to Spontaneous reporting

Under-reporting

Difficult to detect



Delayed reactions (Type D)
Reactions with high background incidence (Type C)

Important details often missing

Number of exposed unknown

Bias

Types of Adverse Drug Reactions

Type A:
 related to dose and pharmacologic effect 
 Unwanted
 Exaggerated

Type B
 Uncommon and unpredictable 
 Immune
 Idiosyncratic

Type C
 chronic- increased risk level

Type D
 delayed

Type E
 end of therapy

What to report !

First: Creation of reporting culture

Report as soon as you suspect a drug therapy has resulted in negative, unintended effect.



Everything that raises
your suspicion.

- Severe effects
- Unexpected effects – not on pamphlet
- Serious effects – definitions available
- Related to a new drug

What to report !

Unwanted effects: { Type A
Type B

Unexpected lack of efficacy: { Substandard or counterfeit
Resistance
Interaction

Quality problem

Dependence or abuse

Medication errors

Poisoning

What to report !

Allopathic medicines:  Rx
OTC

Traditional medicines

Biologics (including vaccines)



Devices

Veterinary medicines

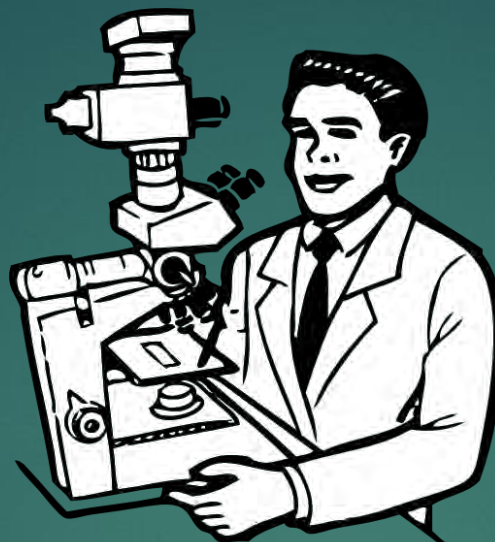
Cosmetics

Areas for
Exploration

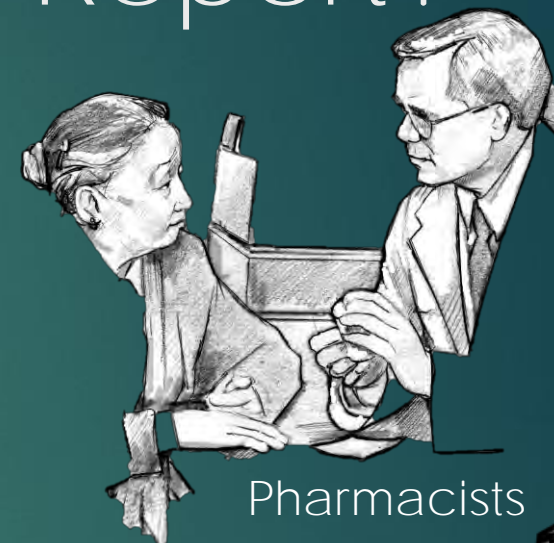
Who should Report?



Physicians and Nurses



Medicines manufacturers



Pharmacists



Healthcare Administrators



Dentists



Patients



TV Commercial in Neighboring Country