“Overview of Pharmacovigilance”

By

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Was born in Egypt in 1995. Student in the level 4 in the faculty of pharmacy Ahram-Canadian University . Will be graduated in 2018 . Have an experience in the pharmacy field through :

Training in a community pharmacy in Egypt in the summer of 2014 ,Attending many courses in 2015 and 2016 about the first aid ,marketing and sales .

Have a good experience in the field of pharmaceutical industrial , marketing and sales through of 6 weeks internship in Eva -pharma one of the biggest companies in Egypt and middle east . Attended many online courses on Ashp elearning and received the certificates about hospital pharmacy and many fields of pharmacology . Have many interests as : attending pharmaceutical conferences , events , courses and internships also interested in pharmaceutical researches and development , biotechnology , OTC and learning other languages.

Overview of pharmacovigilance

The topic will illustrate some important points about pharmacovigilance which can make the subject more clear , simple and understandable that is Through of **“overview of pharmacovigilance”** . The contents of the topic will discuss the definition , introduction , methods of pharmacovigilance , adverse drug reactions , limitation of clinical study , necessity of the topic , who is responsible for pharmacovigilance ,what are the responsibilities of the pharmacovigilance , the importance of reporting adverse drug reaction and examples of some drugs were withdrawn thanks to pharmacovigilance studies . All of that contents and the more will be discussed through the presentation . the subject will discuss also the future of the pharmacovigilance and some suggestions to promote and develop this field .

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- ***References***

1. Introduction



1. Introduction

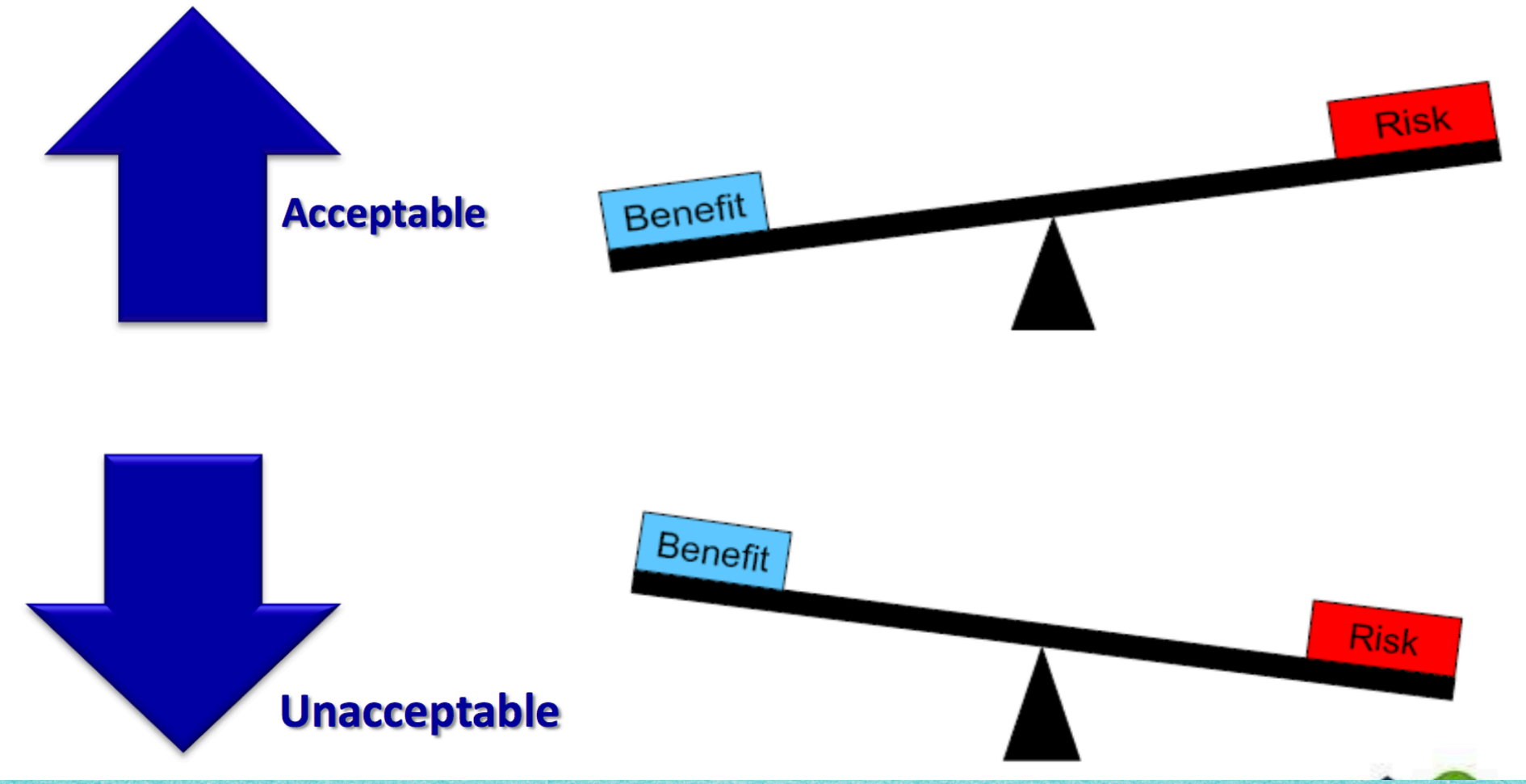


1.Introduction

- All medicines (pharmaceutical and vaccines) have side effect some are known many are still unknown even this medicine has been in clinical use. The important to monitor both known and unknown side effects of medicines in order to determine any new information in relation to their safety profile .
- Pharmacovigilance looks at all available information to assess the safety profile of a drug
- Spontaneous reporting depends on the health professional – YOU.
- Pharmacovigilance should also take the benefit of the drug in account

1.Introduction

Risk/Benefit Balance of medications




Next...

What is Pharmacovigilance?



2.Definition

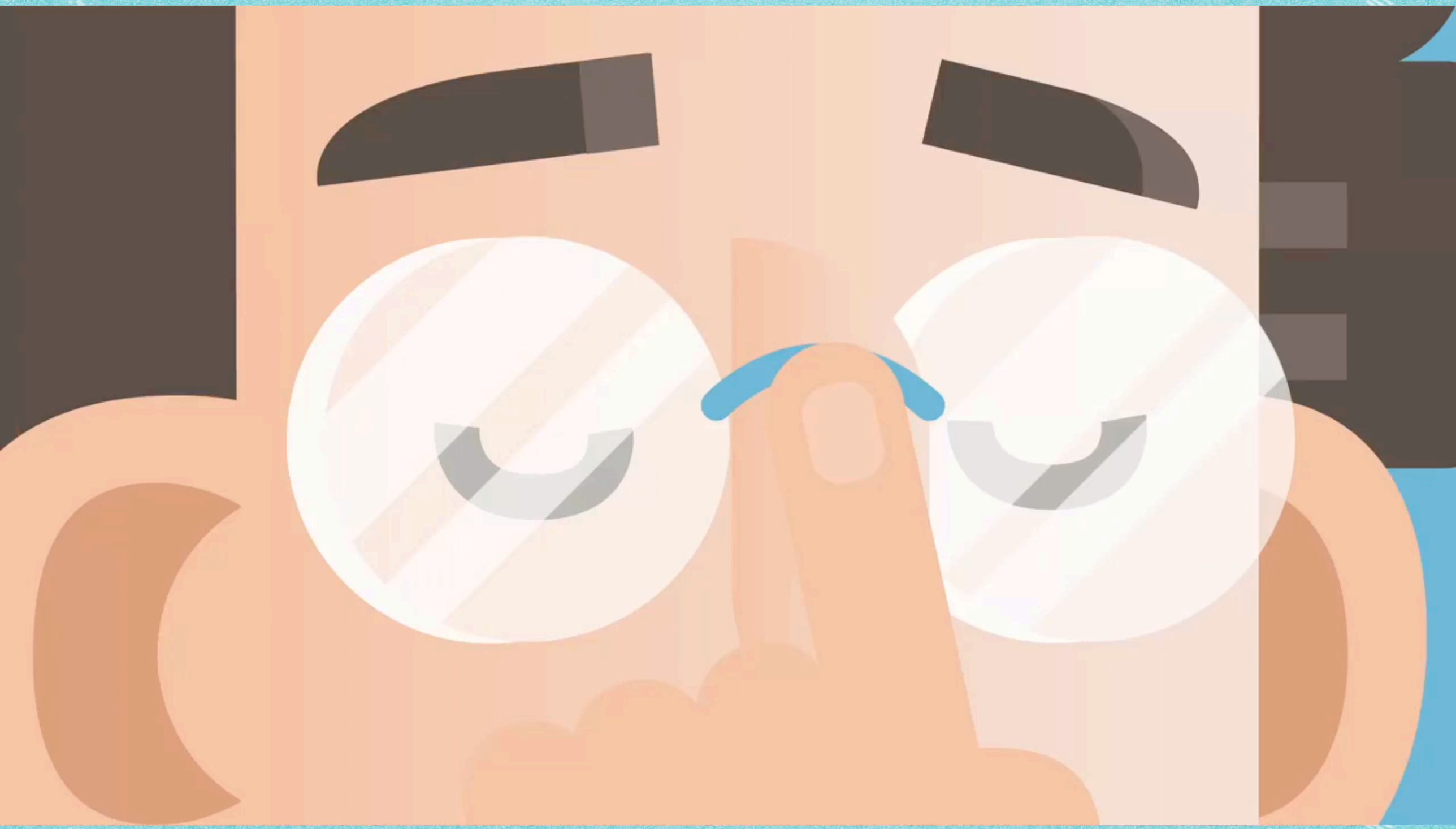
Pharmacovigilance(PV) also called as (drug safety)

Pharmakon-------in greek----drug

Vigilare ----------in latin------to keep watch

Def : Pharmacovigilance is the science &activities relating to the detection , assessment, understanding and prevention of adverse effects (WHO collaborating centre for international drug monitoring*)*

2.Definition



3. Necessity of PV

Is PV a necessity or not ?

3. Necessity of PV



Patient Care

- To improve patient care & safety in relation to medicines & all medical & para-medical interventions



Public Health

- To improve public health & safety in relation to the use of medicines

Risk Benefit Assessment

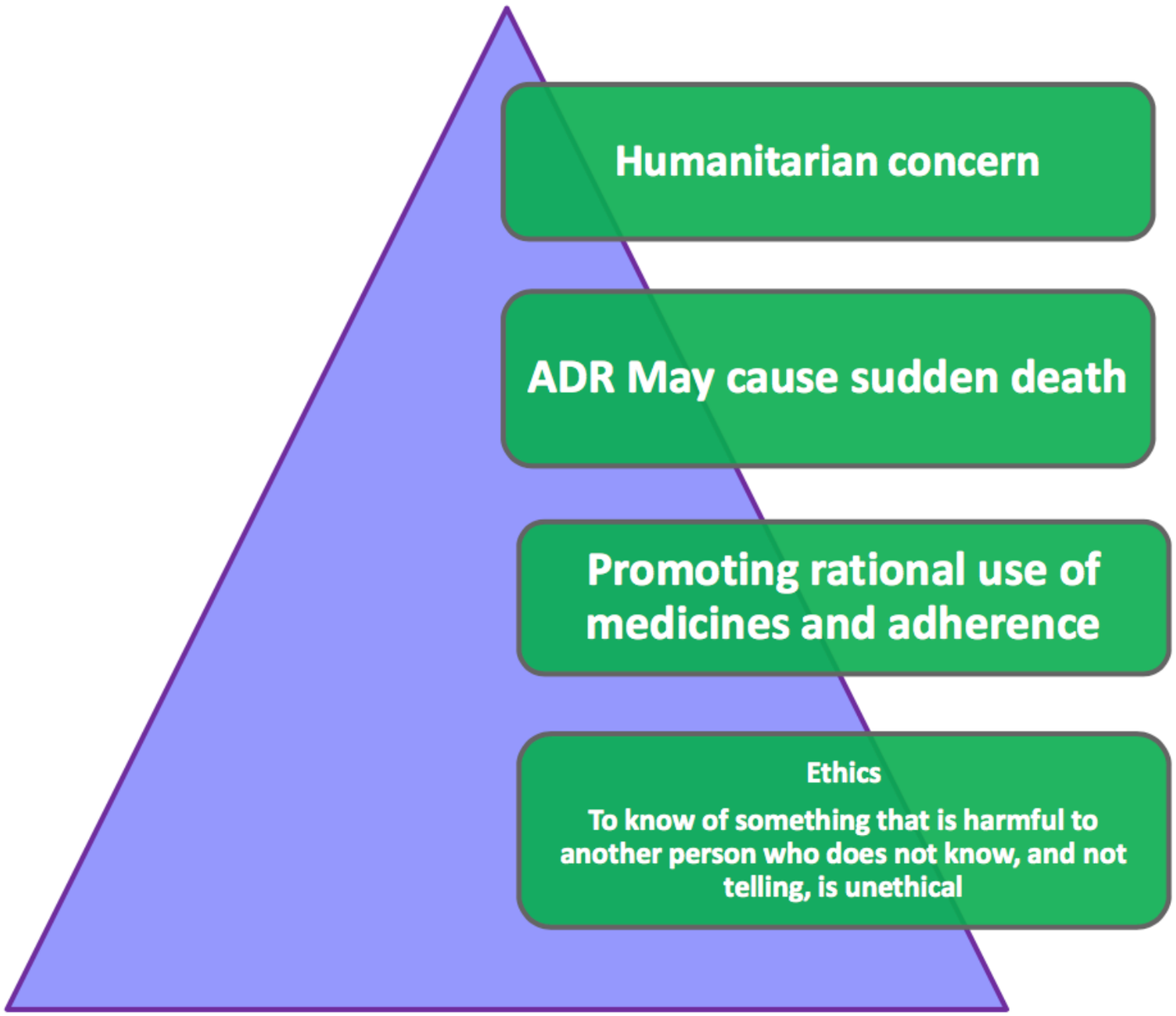
- To contribute to the assessment of benefit, harm, effectiveness and risk of medicines

Communication

- To promote understanding, clinical training & effective communication to health professionals & the public

3. Necessity of PV

Why do we need pharmacovigilance?



3. Necessity of PV

- build communication and relation between the patient and medical stuff
- Increase the trust between the patient and healthcare stuff

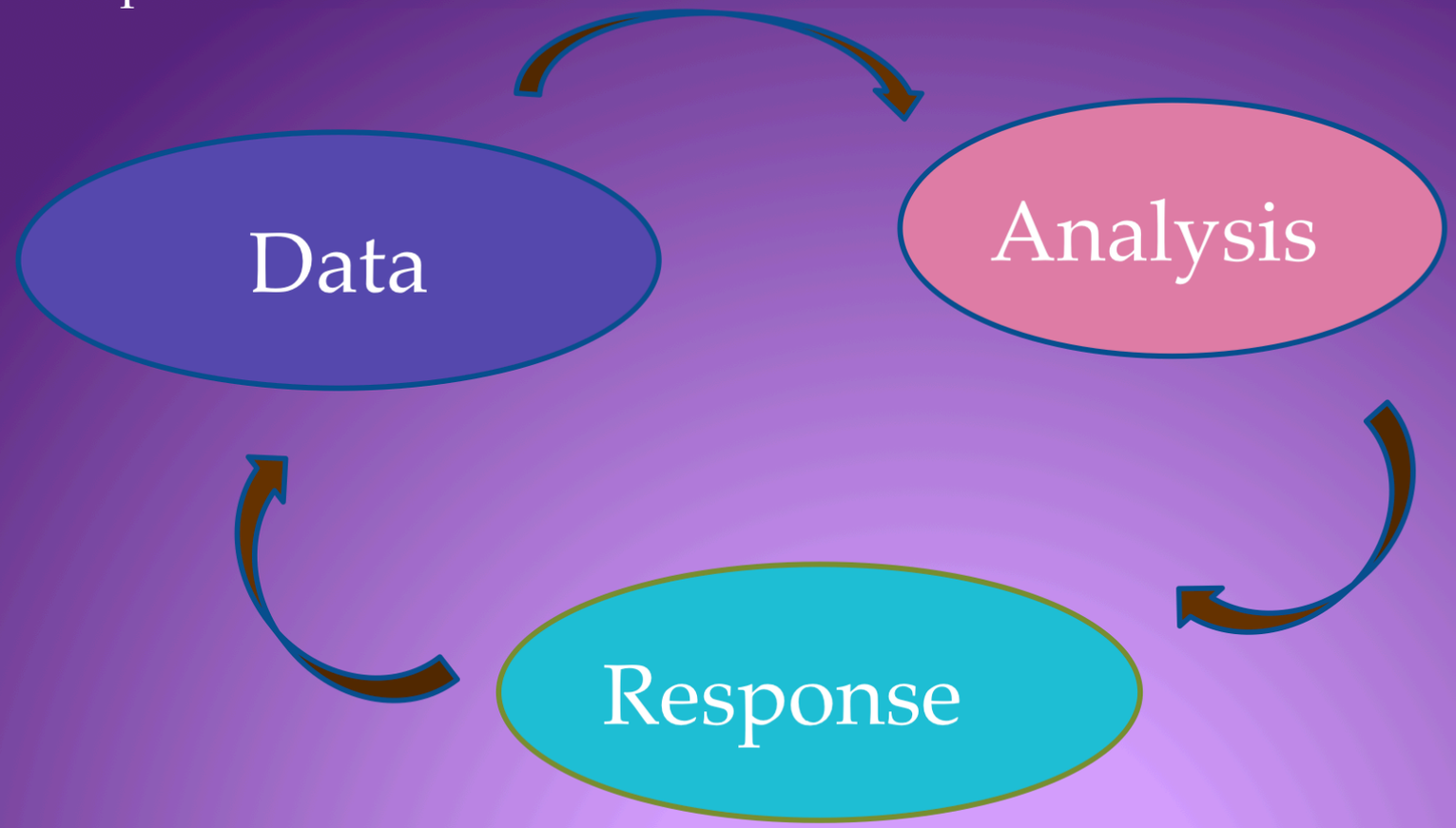
4. Adverse Drug Reaction (ADR)

4. Adverse Drug Reaction (ADR)

Adverse drug reaction(ADR)

a)Serious adverse reaction.

b) Unexpected adverse reaction.



4. Adverse Drug Reaction (ADR)

- **Adverse Event (AE):** Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment.

- **Adverse Drug Reaction (ADR):** Any noxious change which is suspected to be due to a drug, occurs at doses normally used in man, requires treatment or decrease in dose or indicates caution in future use of the same drug.

- Therefore, an adverse drug reaction is an adverse event with a causal link to a drug.

4. Adverse Drug Reaction (ADR)

- **Classification of (ADR) :**

-**A**ugmented (ADR)

-**B**izarre (ADR)

-**C**hemical (ADR)

-**D**elayed (ADR)

-**E**nd of treatment (ADR)

4. Adverse Drug Reaction (ADR)

Augmented (ADR)

- Reactions which can be predicted from the known pharmacology of the drug
- Dose dependent,
- Can be alleviated by a dose reduction

E.g.

- Anticoagulants → Bleeding,
- Beta blockers → Bradycardia,
- Nitrates → Headache,
- Prazosin → Postural hypotension.

4. Adverse Drug Reaction (ADR)

Bizarre (ADR)

- Cannot be predicted from the pharmacology of the drug
- Not dose dependent,
- Host dependent factors important in predisposition

E.g.

- Penicillin → Anaphylaxis,
- Anticonvulsant → Hypersensitivity

4. Adverse Drug Reaction (ADR)

- **C**hemical (ADR)
  - Biological characteristics can be predicted from the chemical structure of the drug/metabolite

E.g.

- Paracetamol → Hepatotoxicity

- **D**elayed (ADR)
  - Occur after many years of treatment.
  - Can be due to accumulation.

E.g.

- Chemotherapy → Secondary tumours
- Phenytoin during pregnancy → Teratogenic effects
- Analgesics → Nephropathy

4. Adverse Drug Reaction (ADR)

End of treatment (ADR)

- Occur on withdrawal especially when drug is stopped abruptly

<u>E.g.</u>

- Phenytoin withdrawal → Seizures,
- Steroid withdrawal → Adrenocortical insufficiency.

4. Adverse Drug Reaction (ADR)

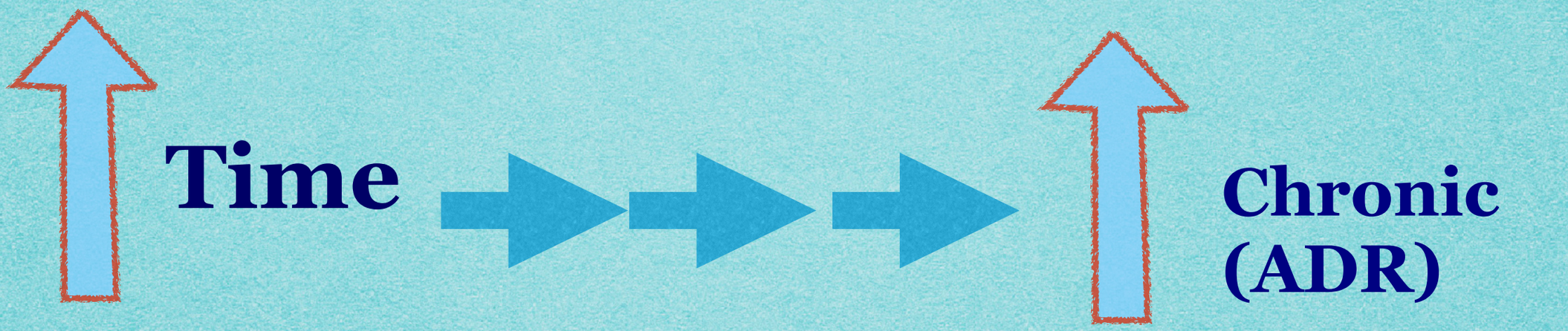
- **A**ugmented (ADR)

Dose → → → **ADR**

- **B**izarre (ADR)

Drug sensitivity → → → **ADR**

- **C**hemical (ADR)
  - **Some chemical structure** have predictable and known → **ADR**
- **D**elayed (ADR)



- **E**nd of treatment (ADR)



5. Importance of reporting ADR

- ***Is reporting (ADR) an important ?***
- ***Why reporting ?***



4. Adverse Drug Reaction (ADR)

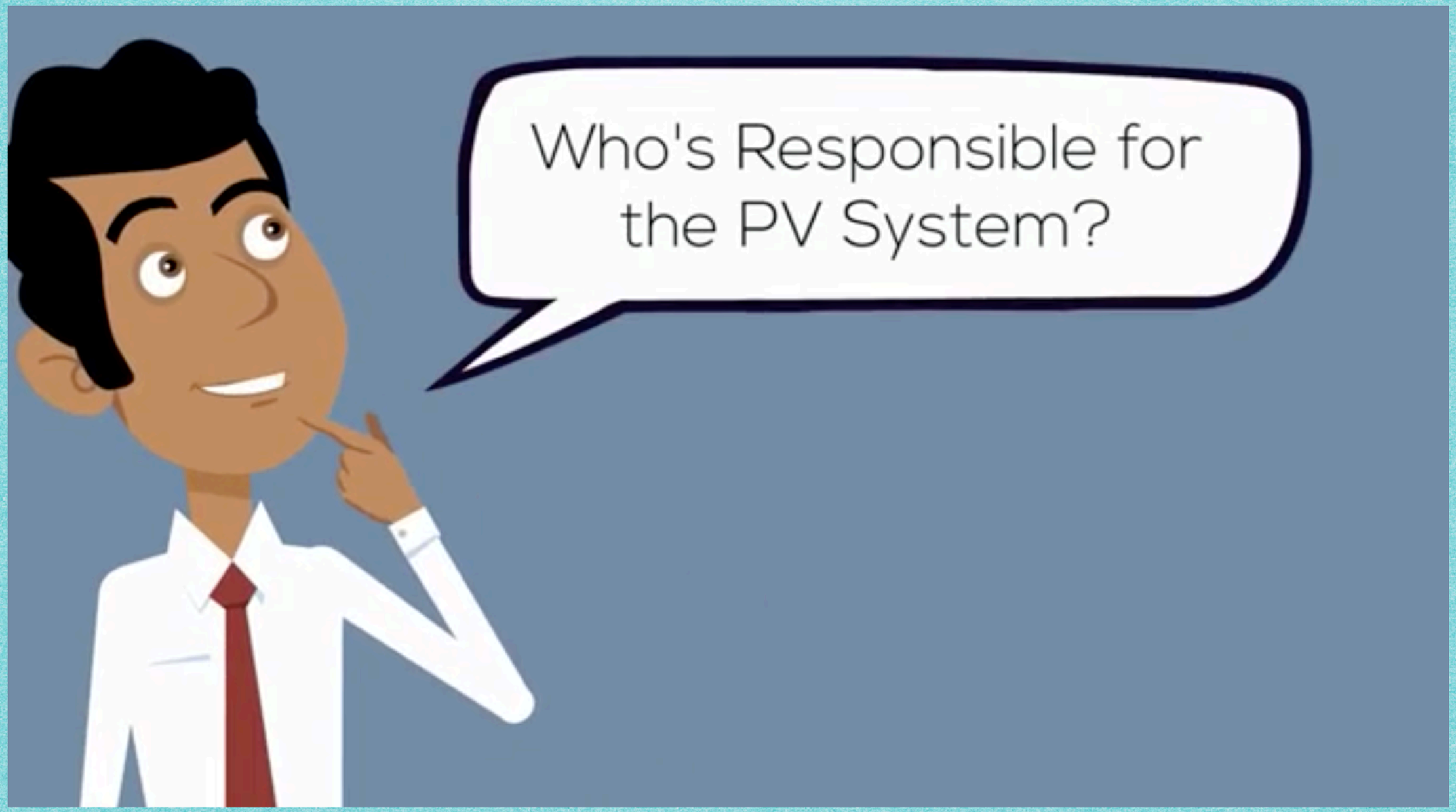
- Reporting vs Not reporting

6. How PV works ?

1. ADR suspicion → 2. ADR reporting

3. ADR analysis → 4. Sharing of findings

7. Who is responsible for PV





MAH is responsible for creation and maintenance of PV system. Due to the responsibility, MAH shall have permanently and continuously at its disposal an appropriately qualified person responsible for pharmacovigilance in EU (EU QPPV).



MAH

Marketing Authorization Holder

8. Clinical trials Study

Clinical development of medicines

Phase I
20 – 50 healthy volunteers to gather preliminary data

Animal experiments for acute toxicity, organ damage, dose dependence, metabolism, kinetics, carcinogenicity, mutagenicity/teratogenicity

Phase II
150 – 350 subjects with disease - to determine safety and dosage recommendations

Phase III
250 – 4000 more varied patient groups – to determine short-term safety and efficacy

Phase IV
Post-approval studies to determine specific safety issues

Preclinical Animal Experiments | Phase I | Phase II | Phase III | Registration | Phase IV Post-approval | Spontaneous Reporting

← Development → | ← Post Registration →

8. Clinical trials Study

Limitations of Clinical Study Data

	Clinical trials	Clinical Practice
Number of patients	Hundreds (rarely thousands)	Thousands to millions
Duration	Weeks	Years
Population	Pregnant, children, elderly excluded	All
Concomitant medication and illness	Avoided	Usually present
Dose	Fixed	Variable (compliance)
Conditions	Rigorous; more information	Flexible; less information

9. Examples of some drugs which have been withdrawn

Why Pharmacovigilance??

WHO established its Programme for International Drug Monitoring in response to the thalidomide disaster detected in 1961.

9. Examples of some drugs which have been withdrawn

Thalidomide disaster

thalidomide was used for insomnia However the drug was also found to cure morning sickness in pregnant women but the drug was not trialled or tested for this use on pregnant women and thus led to catastrophic deformations of the baby- best seen as limb abnormalities.

9. Examples of some drugs which have been withdrawn

Drug	Year	Reason
Lumiracoxib	2008	Hepatotoxicity
Aprotinin	2008	Kidney and cardiovascular toxicity
Tegaserod	2007	Cardiovascular ischemic events
Ximelagatran	2006	Hepatotoxicity
Valdecoxib	2005	Dermatology adverse events
Pemoline	2005	Hepatotoxicity
Rofecoxib	2004	Thrombotic cardiovascular events
Levomethadyl	2003	Fatal Arrhytmia
Rapacuronium	2001	Risk of fatal bronchospasm
Cerivastatin	2001	Rhabdomyolosis
Trovafloxacin	2001	Hepatotoxicity
Amineptine	2000	Hepatotoxicity, dermatological side effects, abuse potential
Cisapride	2000	Cardiac arrhythmias
Troglitazone	2000	Hepatotoxicity

10. Suggestions to promote the Future of PV



10. Suggestions to promote the Future of PV

Questions for the future!

How to improve
•Risk management
•Prevention
•Management of harmed/at risk patients incl. decisions on alternative treatment

How to decide what is an 'actionable' signal?
How to provide the best knowledge?

How to find signals from all available data?
What constitutes a signal?

How to access and manage new data, from new sources?
How to make the most of existing data: influen
of drug combinations, diseases, situations

How to ensure impact?
How to measure impact?
How to communicate?
How to promote PV?
How to get funding?

Marie Lindquist, Uppsala Monitoring Centre

the UPPSALA MONITORING CENTRE

