Role of Risk Management in Pharmacovigilance

DR MANJUNATH H

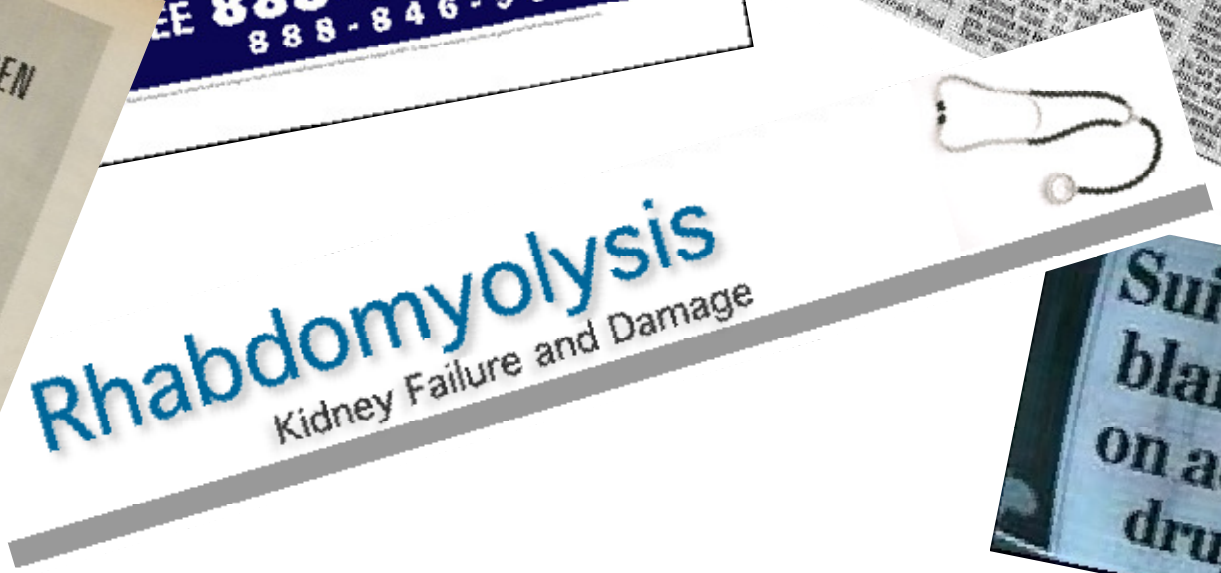
JJM MEDICAL COLLEGE




VIOXX®
STROKE ~ HEART ATTACK ~ DEATH
BLOOD CLOTS ~ PULMONARY EMBOLISM

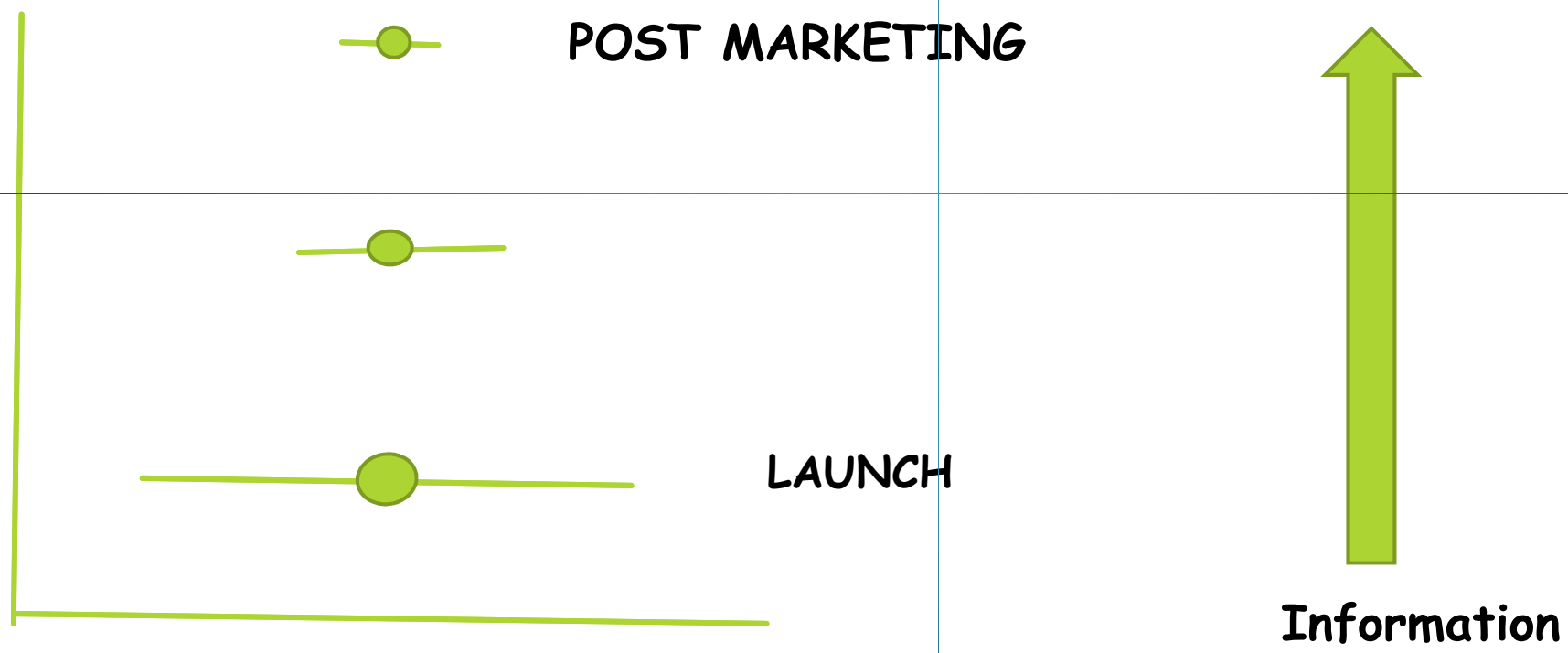

DARVON
LIFTS THE BURDEN
OF
PAIN
A non-narcotic analgesic with the potency of codeine
POLIO VACCINE


Viagra blindness a
Britons 'lost sight after
taking impotence drug'


Rhabdomyolysis
Kidney Failure and Damage


Suicides
blamed
on acne
drug

onfidence about the safety



RISK MANAGEMENT

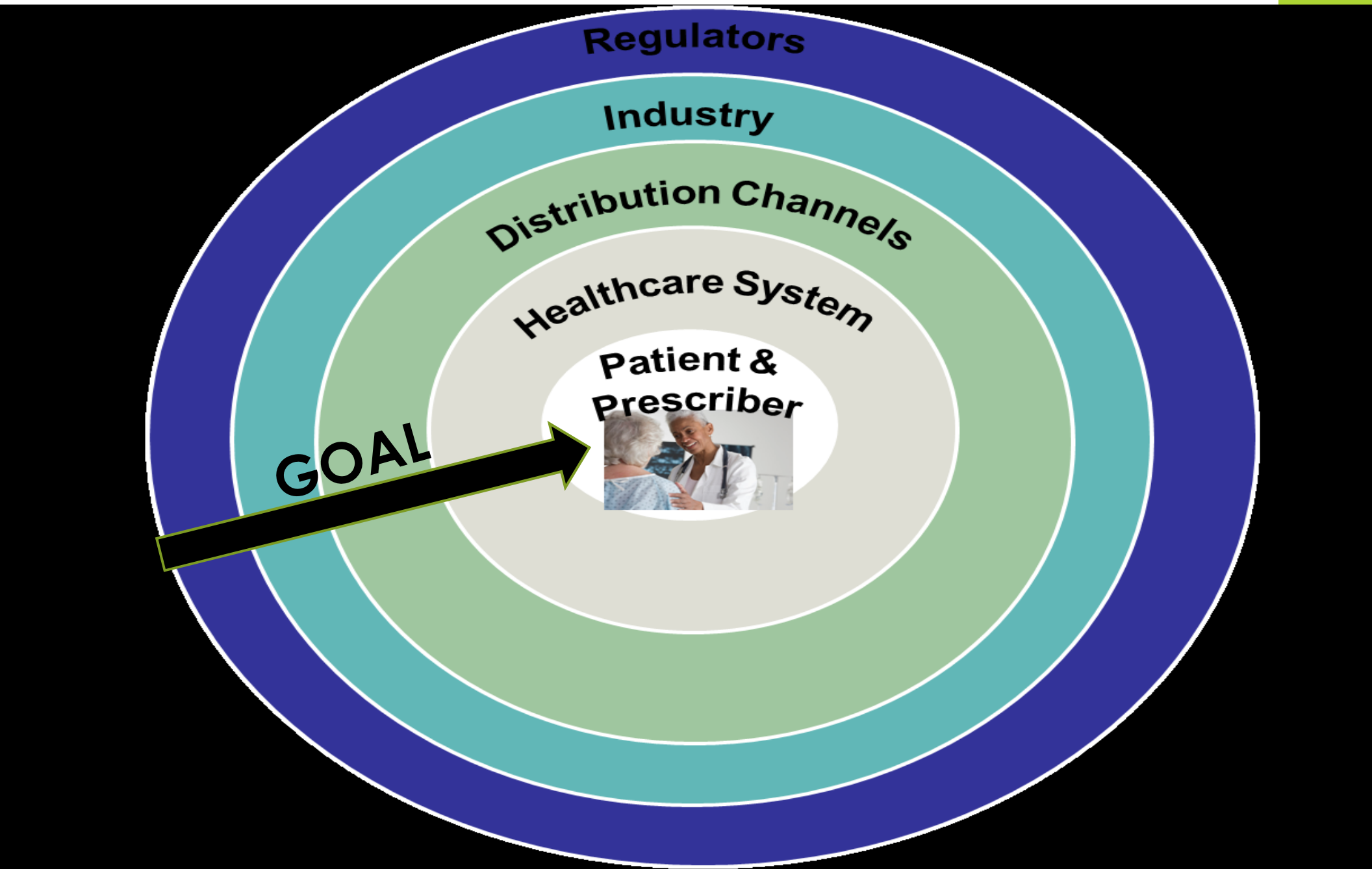
- RISK MANAGEMENT is a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to medicinal products, including the assessment of the effectiveness of those interventions .

- Risk Management = Risk Assessment + Risk Minimization

Aim of Risk management



- To ensure that the benefits of a particular medicine (or a series of medicines) exceed the risks by the greatest achievable margin for the individual patient and for the target population as a whole.


Regulators
Industry
Distribution Channels
Healthcare System
Patient &
Prescriber
GOAL

Purpose ???

- To **identify the risks** associated with a medicinal product
- **Develop methods** to clarify further the safety profile of a product
- **Plan ways** to minimise risk to individual patients in clinical use.



Which products ???

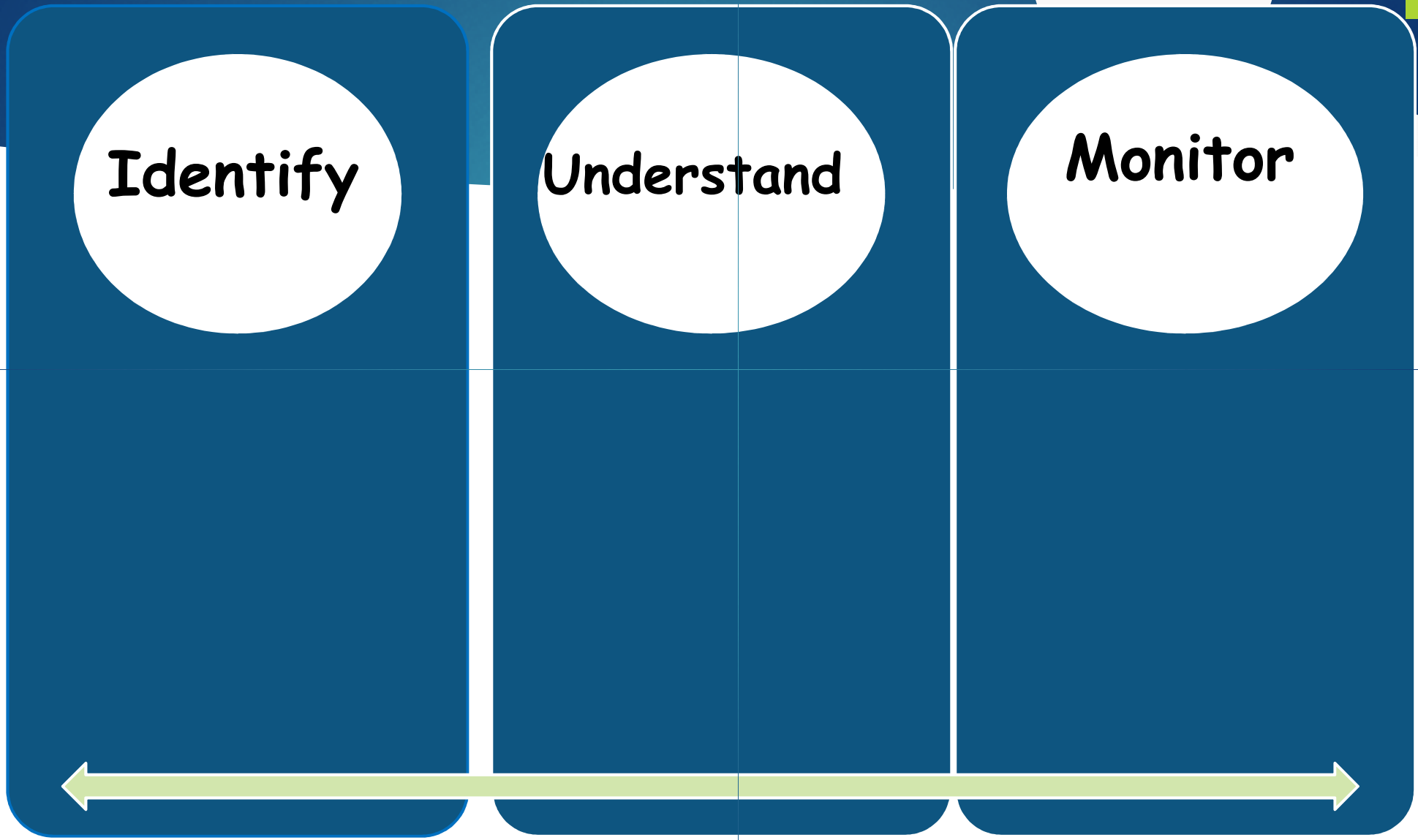
- **New active, biosimilar or generic** with risk minimisation for reference substance
- **New dosage form, route, indication**, manufacture process for biotech product
- **On request** of authorities
- If **Marketing Authorization Holder** (MAH) identifies a safety concern
- Other situations for **centrally authorised product**. e.g. fixed combination



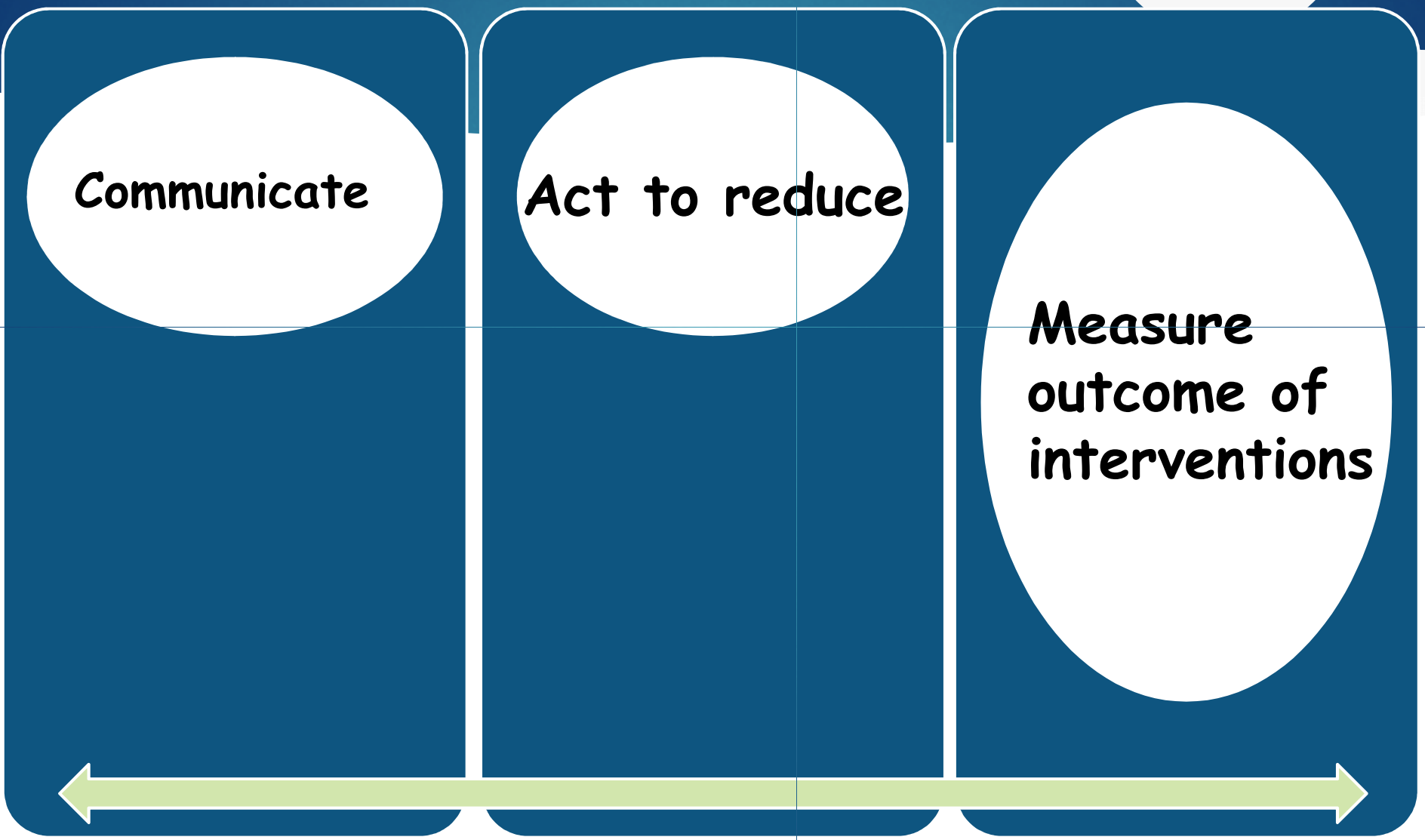
STEPS


Detection
Communication
Risk Management
Assessment
Minimization

RISK DETECTION AND ASSESSMENT

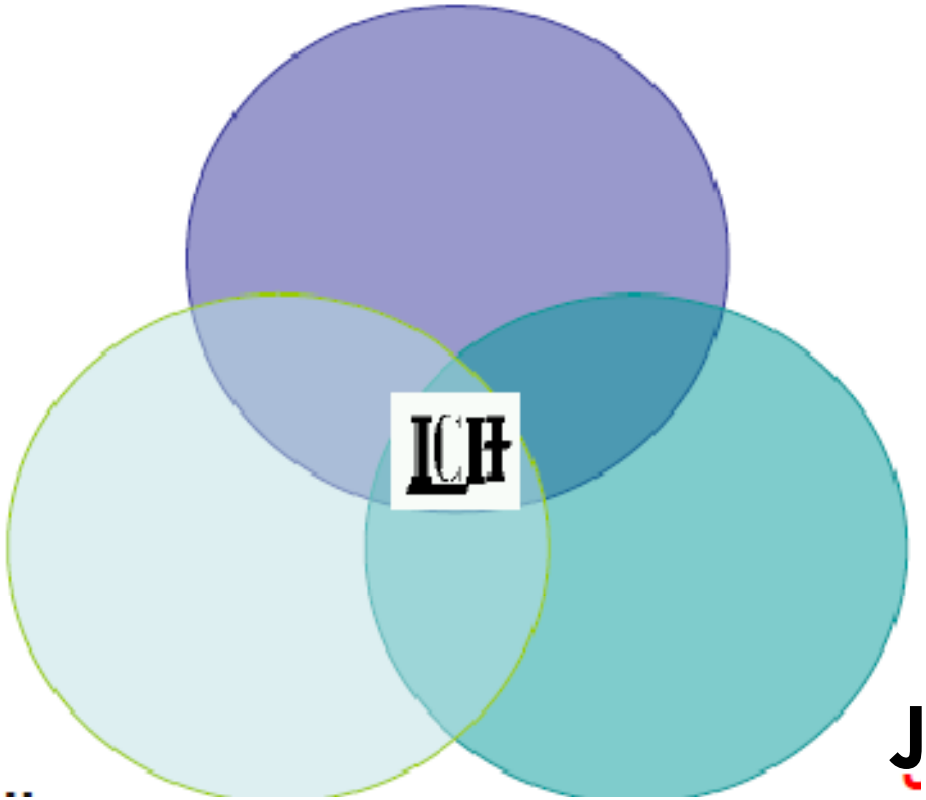


RISK MINIMISATION AND COMMUNICATION



Global Risk Management Planning

Europe



US

Japan

	ICH	EU	FDA	Japan
-	ICH E2E: Pharmacovigilance Planning	Eudravigilance Database Implemented	PDUFA III	EPPV Introdu
-		Guideline on Risk Management Systems for Medicinal Products for Human Use Template Volume 9A	FDA Risk Management Guidance Documents FDA Amendments Act (FDAAA) FDA REMS Guidance	•Committee B on Drug Disas •Safety Work Teams (ICHE PI and AE Management, Electonic databases
-	•ICH E2F: Developmental Safety Update Report •ICH E2C (R2): Periodic Benefit-Risk Evaluation Report- Step 2	Guideline on Good Vigilance Practices	•FDAAA Guidance- Safety Labeling and Post-Marketing Studies •PDUFA V	

GRMP

RA

RM

Risk Management Plan

Safety Specification

Pharmacovigilance Plan

Global Risk Minimization Strategy

Regional Risk Minimization Activities



Safety Specification

Clinical

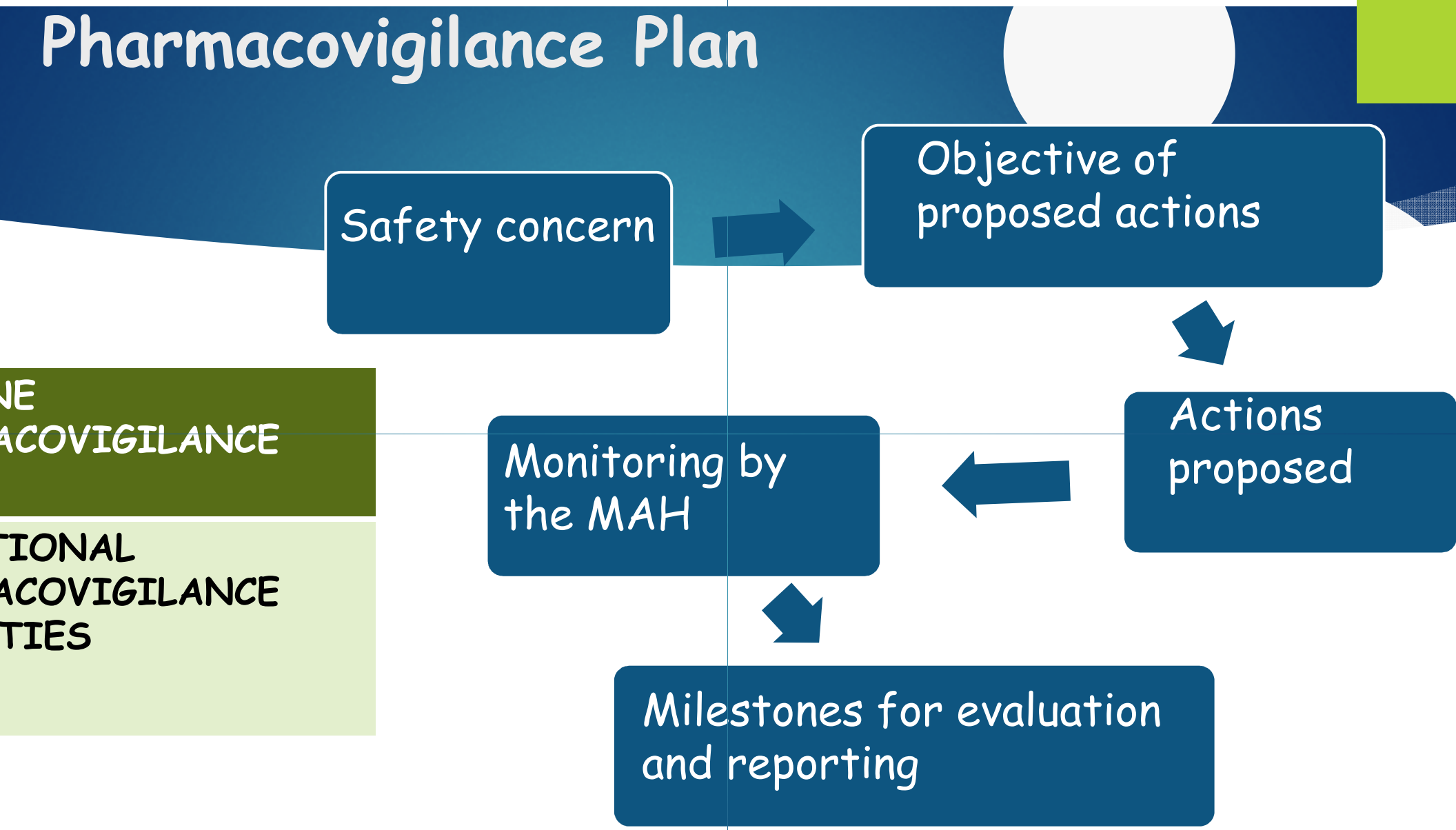
- Limitations of the human safety database
- Populations not studied in the PAP
- AE/ AR
- Identified and potential
- Epidemiology

-Clinical

- xicity
- neral
- armacology
- ug
- eractions

tant identified risks | Important potential risks | Important missing information

Pharmacovigilance Plan



NE
ACOVIGILANCE

TIONAL
ACOVIGILANCE
TIES

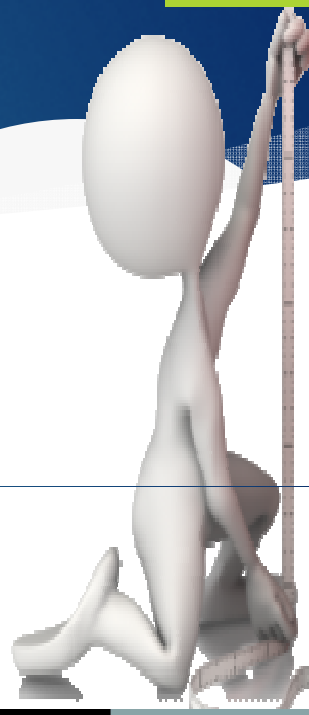
Pharmacovigilance

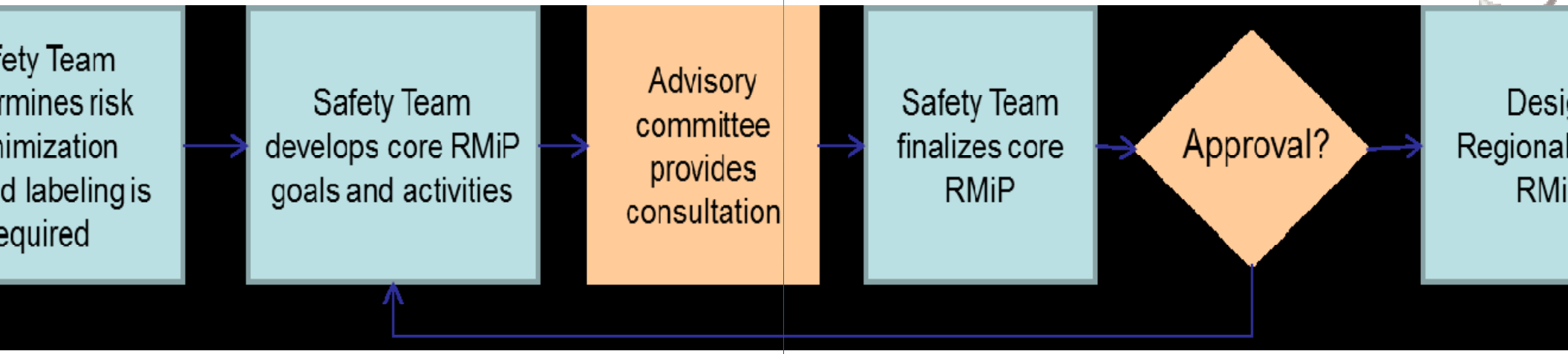


- Post marketing Pharmacovigilance
- Targeted safety studies
- Observational/Epidemiological studies
- Descriptive studies
- Active surveillance
- Drug utilization studies
- Additional educational material about the medicine and its use
- Training programs

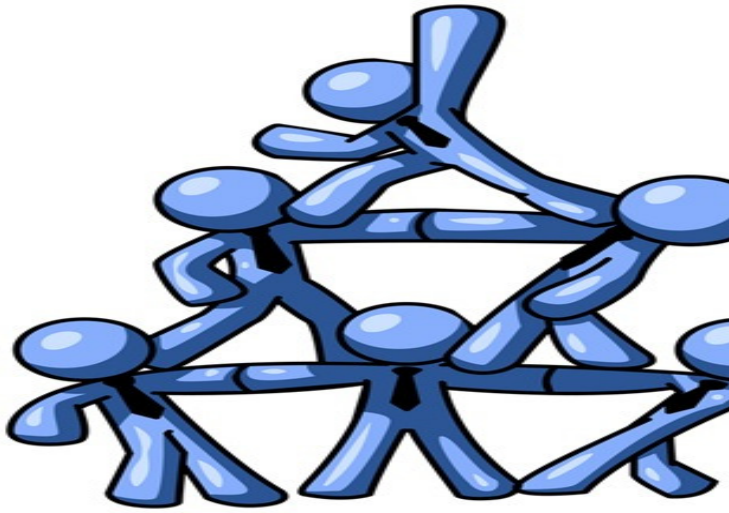
Risk minimization plan

- Routine risk minimization activities
- Additional risk minimization activity





Conclusion



- Pharmacovigilance and risk management are an essential part of pharmaceutical product development and commercialization.

Risk Management:

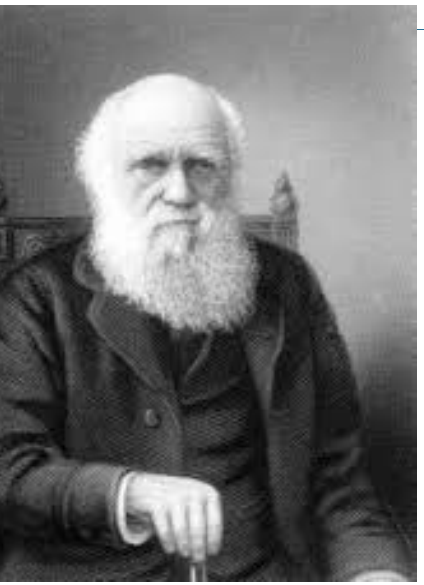
- Through life-cycle of products
- Involve all related stakeholders
- Transparency
- Utilization of existing data : Safer, more beneficial, and more optimal

- Epidemiological study :-General safety study , collect information in large sample , Specific safety study , determine frequency of ADR.
- A move away from reliance on spontaneous reporting towards more reliable evidence
- For building PV capacity requires a systemic approach to ensure that all safety aspects are monitored and addressed properly.

References

- Begoña Calvo and Leyre Zuñiga (2011). Risk Management Plan and Pharmacovigilanc System.Biopharmaceuticals: Biosimilars, Risk Management Trends, Prof. Giancarlo Nota (Ed.), ISBN: 978-953-307-314-9
- Suzanne Gagnon*, Peter Schueler**, James (Dachao) Fany. Pharmacovigilance and Risk Management; 151-159
- Kazuhiko Mori .Pharmacovigilance in Japan and Risk Management Plans（RMP）;Regulator Perspective[Internet] [cited 2012] available at http/:www.diahome.org
- The-importance-and-need-for-developing-robust-pharmacovigilance-training programmes in India [internet][cited December 2012] available at http://pharma.financialexpress.com/specials/ipc/1467--in-…

"It is not the strongest of the species that survive, nor the most intelligent, but the one most responsive to change."



Charles Darwin, 1859

THANK YOU