

Role of Industry in the improvement of Pharmacovigilance System

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Outline

- History
- Responsibilities
- Drivers of the System
- The Process
- Governance – Structure & Steps
- Changing Environment
- Process Implementation
- Conclusion

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Thalidomide Disaster

- Launched - 1957
- First reports of birth defects - 1959
- 10000 infants affected by Phocomelia.
- Withdrawn the market - Nov 1961



Outcome

1. Birth of Phamacovigilance
2. Drug development programs cannot provide full safety information
3. Brought industry and regulators closer –Guidelines/Policies framed.

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- “All things are poison, and nothing is without poison: the dose alone makes a thing not poison,”

Paracelsus (1493 - 1541)



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Pharmacovigilance - A Shared Responsibility

1. **Company**
   - legally and morally responsible for monitoring their product.
2. **Regulatory authorities**
   - Ensure safety of licensed drugs.
3. **Doctors**
   - Prescription of safe drugs & Educate patients.
4. **Pharmacist & Nurse**
   - Monitoring, Identification and reporting of ADRs.
5. **Consume**r
   - Reporting to Health Care Providers

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Drivers of the System…

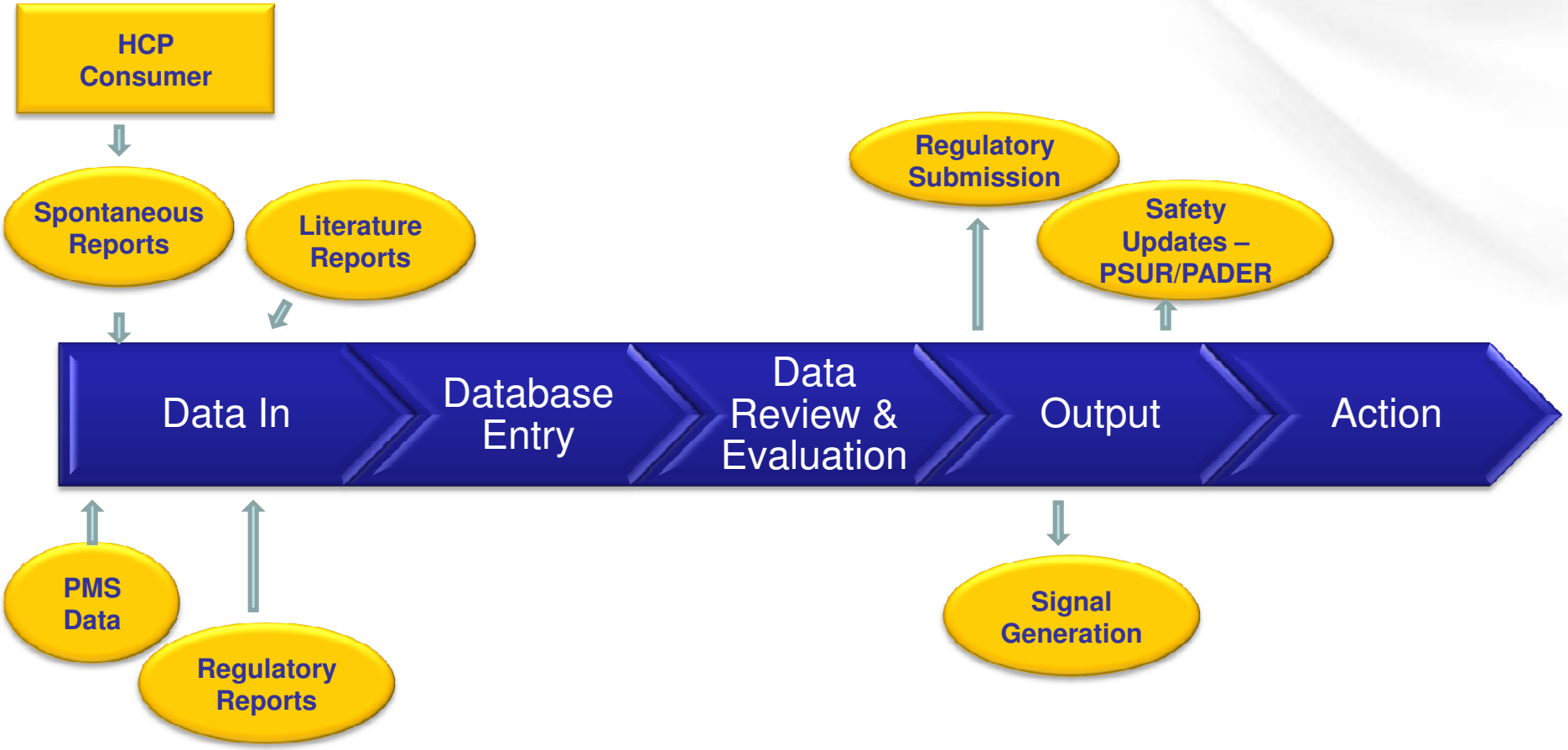
- Guidelines / Policies / Directives
- Ethics / Social Responsibility.
  - Updating Safety information / Black box warning / Withdrawal
- Audits / Inspections
- Rules / Fines / Compensation

Merck Vioxx settlement cost - $4.85 billion *

* http://www.drugwatch.com/vioxx/lawsuit/

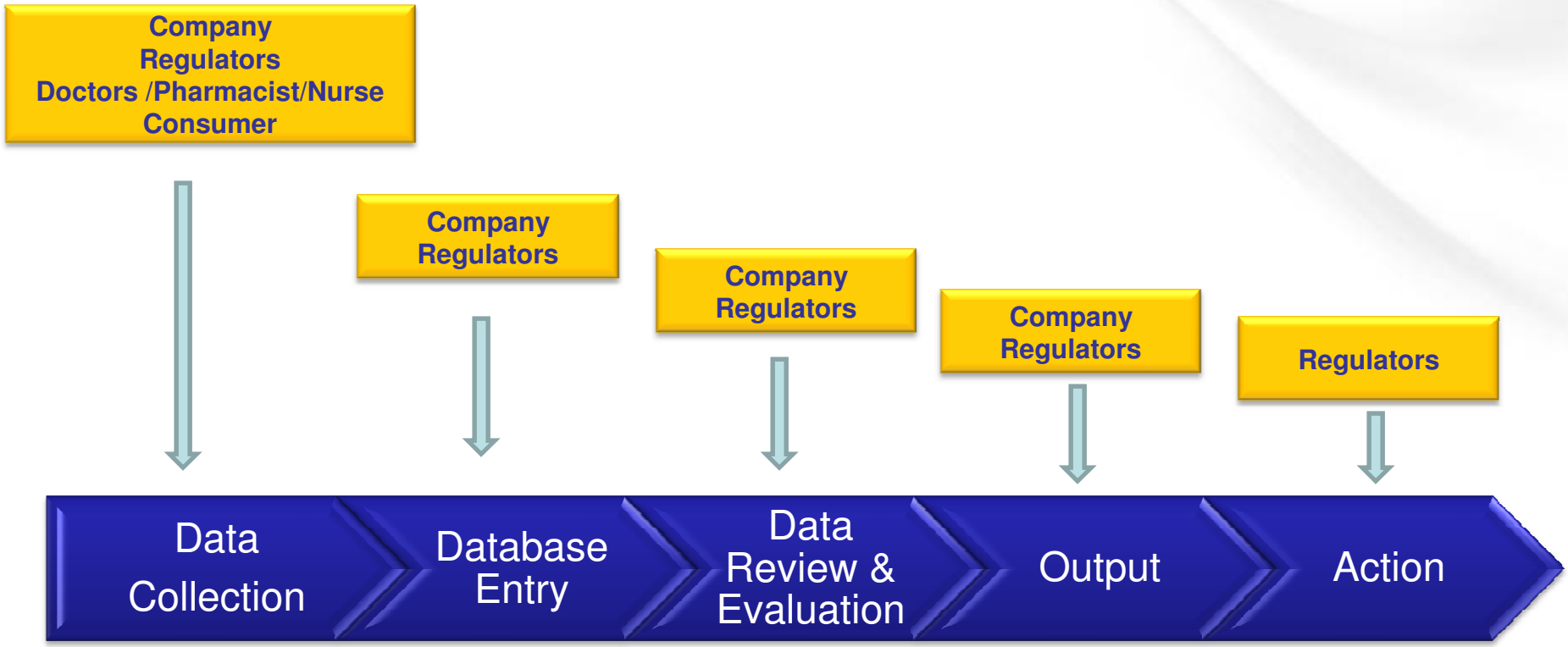
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Pharmacovigilance Process



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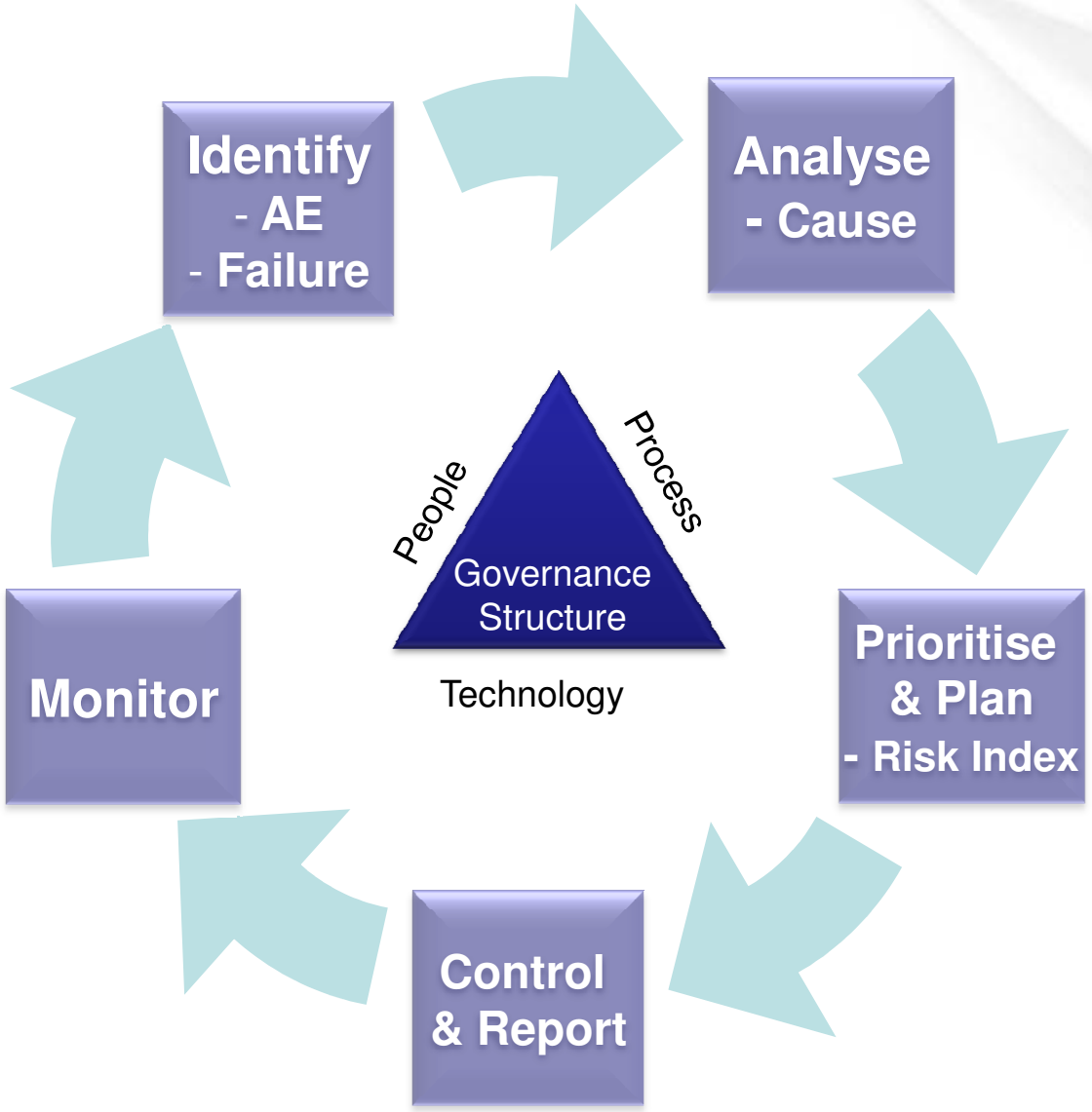
Pharmacovigilance Process – Who is doing what



Company/Industry plays a very vital role in the process

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Governance – Structure & Steps



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Changing Environment –Expectations from Industry

- Compliance to Proactive Safety

- Constantly evolving regulatory environment demands
  - Updation of systems and processes
  - Continuous training and development programs

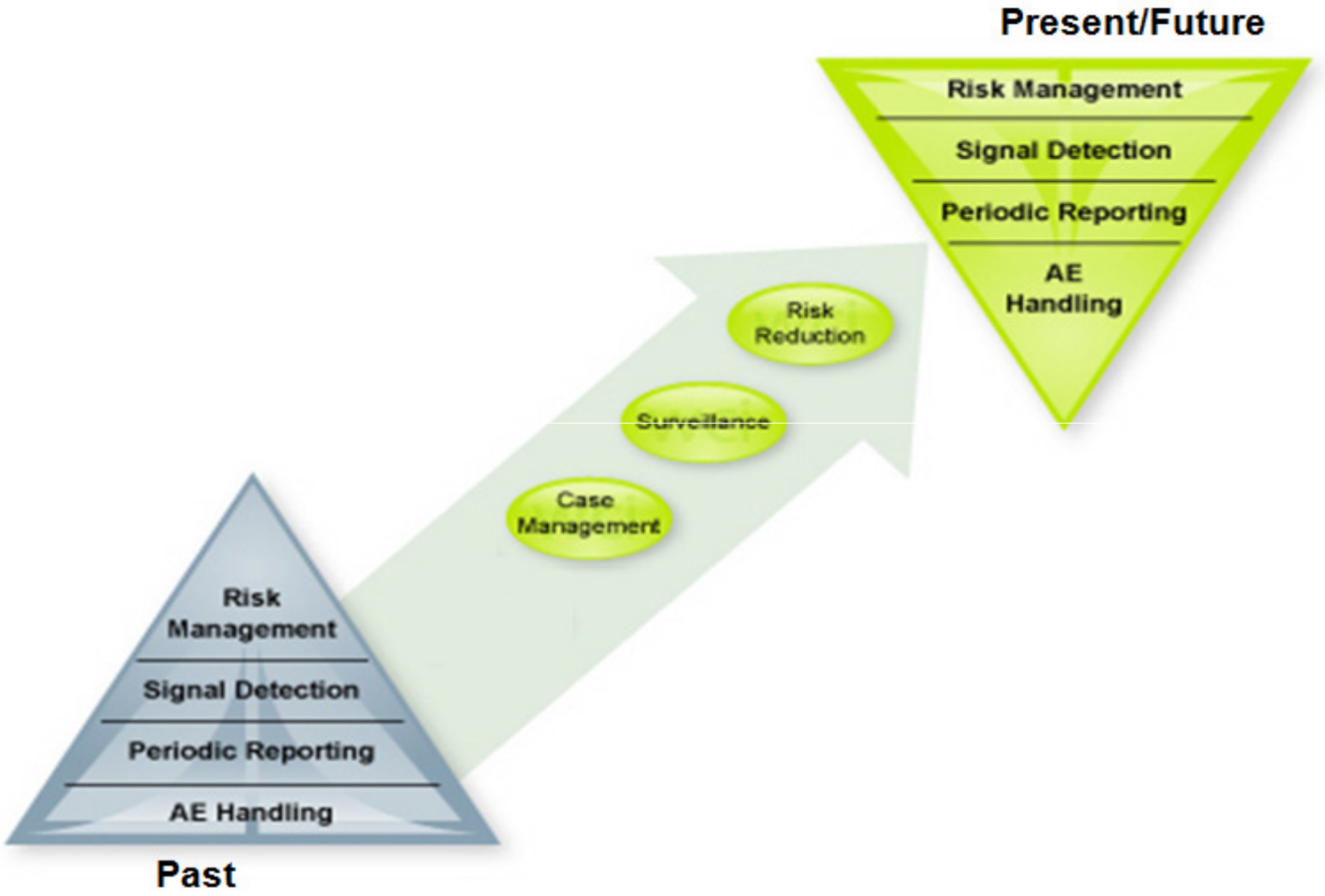
- Increased interest in drug safety by stakeholders

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Desire for more transparency

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Industry evolution to changing environment



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Implementation Steps

- Align and simplify SOPs across all operating companies
- Increase employee awareness of safety responsibilities
- Improved capability e.g. safety risk mgt, signal detection
- Defining global roles and responsibilities in partner agreements
- Improve automation

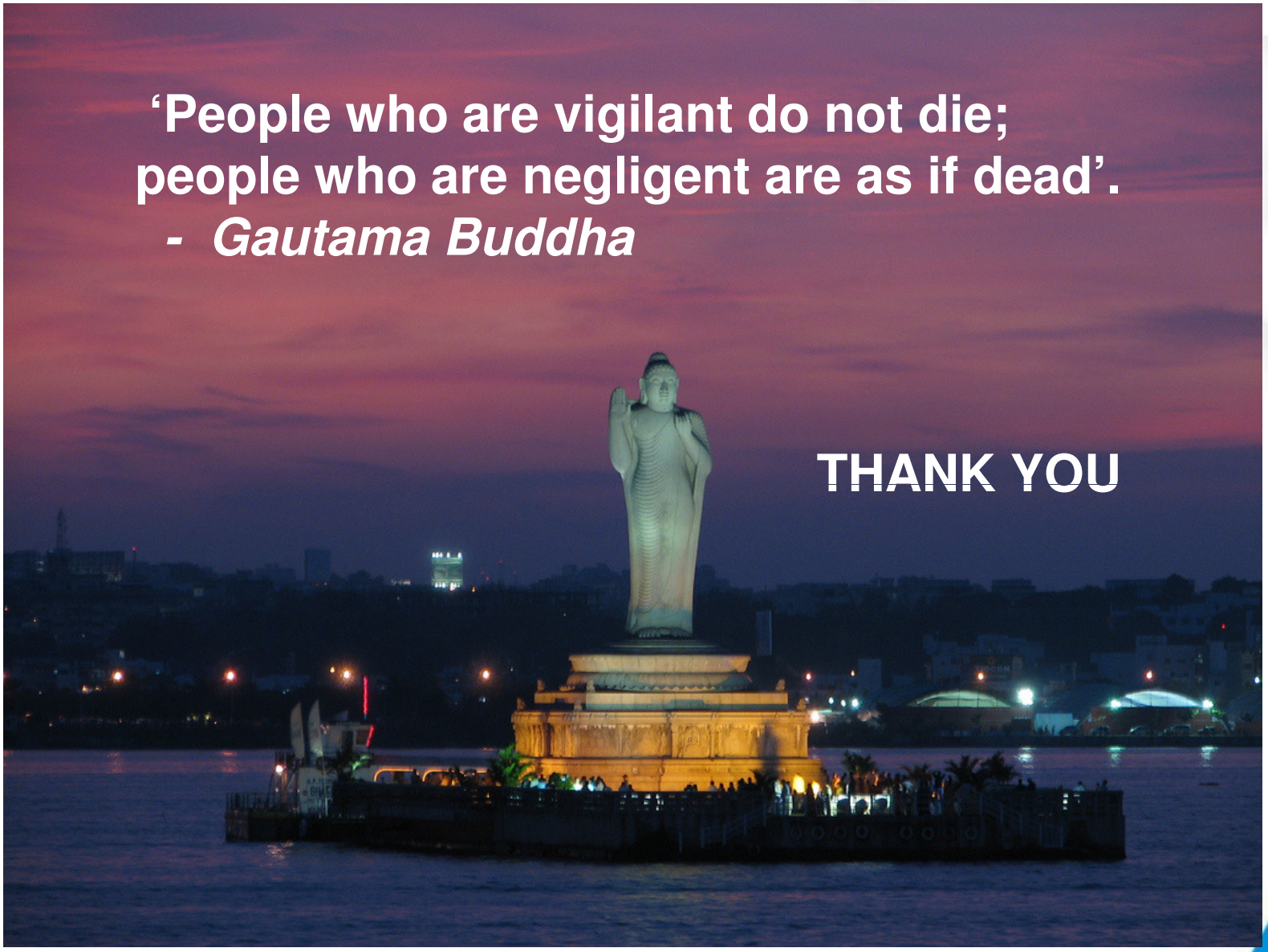
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Conclusion

- Pharmacovigilance
  - is a shared responsibility of all the stakeholders
  - is shifting from meeting compliance to a proactive safety approach
- Companies should have
  - Aligned approach to policies, Quality System for all partners
  - Global infrastructure (people, process & technology) in place

*Obsession to collect **each and every safety information** is the mantra for a successful Pharmacovigilance Program*

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‘People who are vigilant do not die;
people who are negligent are as if dead’.
- Gautama Buddha
THANK YOU

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Why it is difficult



- Identifying Rare (<1/10000 and >= 1/1000) and Very rare (>= 1/10000)* events
- At least 30,000 patients need to be exposed to detect a very rare ADR (1 in 10,000)
- Every event is a critical safety information

•http://who-umc.org/Graphics/24729.pdf
•Strom BL. Pharmacoepidemiology. 2nd ed. Chichester: John Wiley, 1994.

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