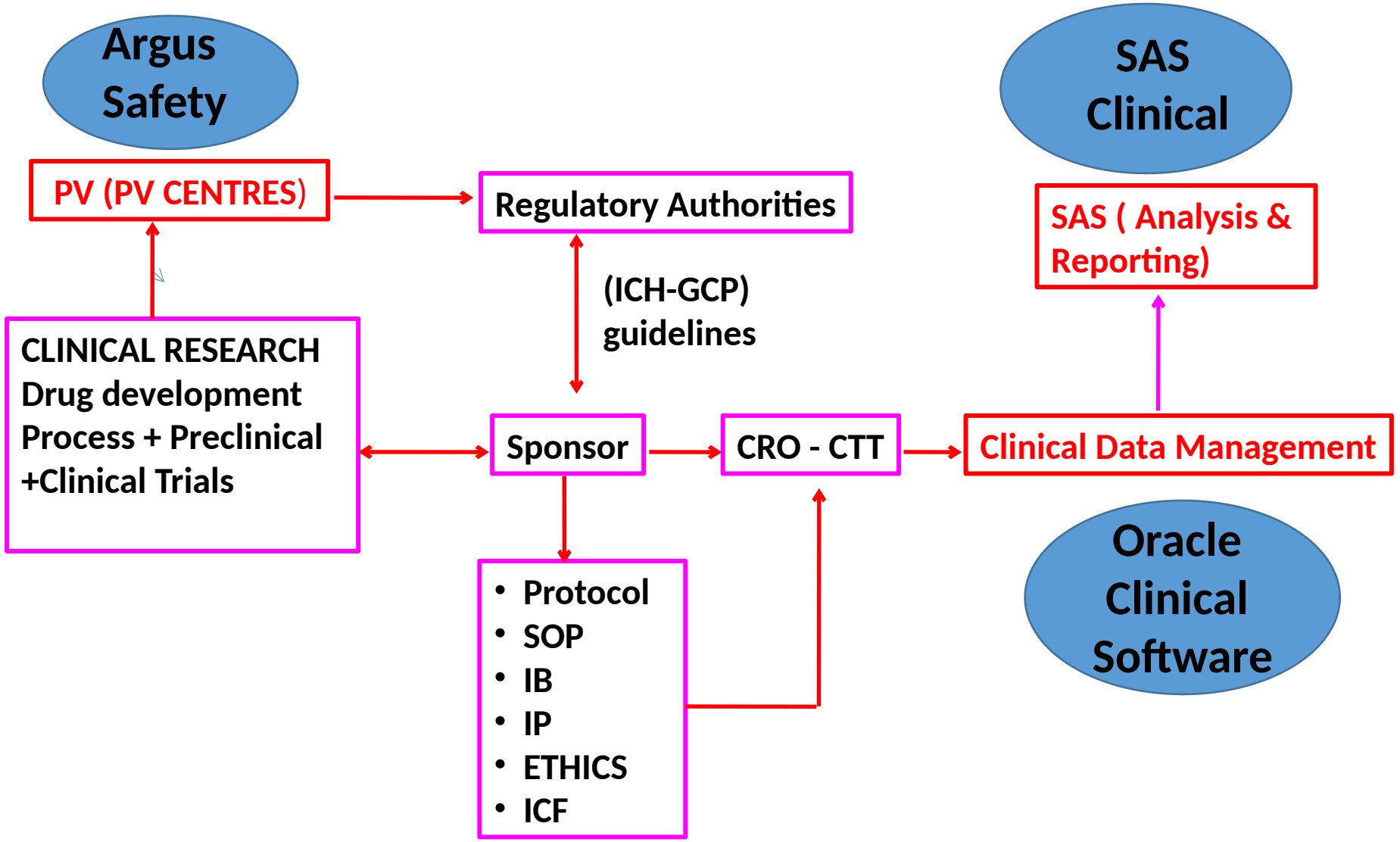
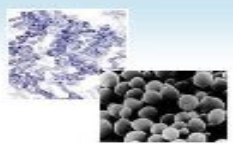
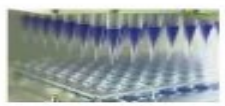
Clinical Data-Managing, Analyzing, Submitting Using Softwares (Oracle Clinical, Argus Safety & SAS)



Drug Discovery Process - Style 5

Target Selection	Lead Discovery	Medicinal Chemistry	In Vitro Studies	In Vivo Studies	
Cellular & Genetic Targets	Synthesis & Isolation	Library Development	Drug Affinity & Selectivity	Animal Models of Disease States	Clinical Trials & Therapeutics
Genomics	Combinatorial Chemistry	Structure Activity Studies	Cellular Disease Models	Behavioural Studies	
Proteomics	Assay Development	In Silico Screening	Mechanism of Action	Functional Imaging	
Bioinformatics	High-throughput Screening	Chemical Synthesis	Lead Candidate Refinement	Ex Vivo Studies	

Your logo

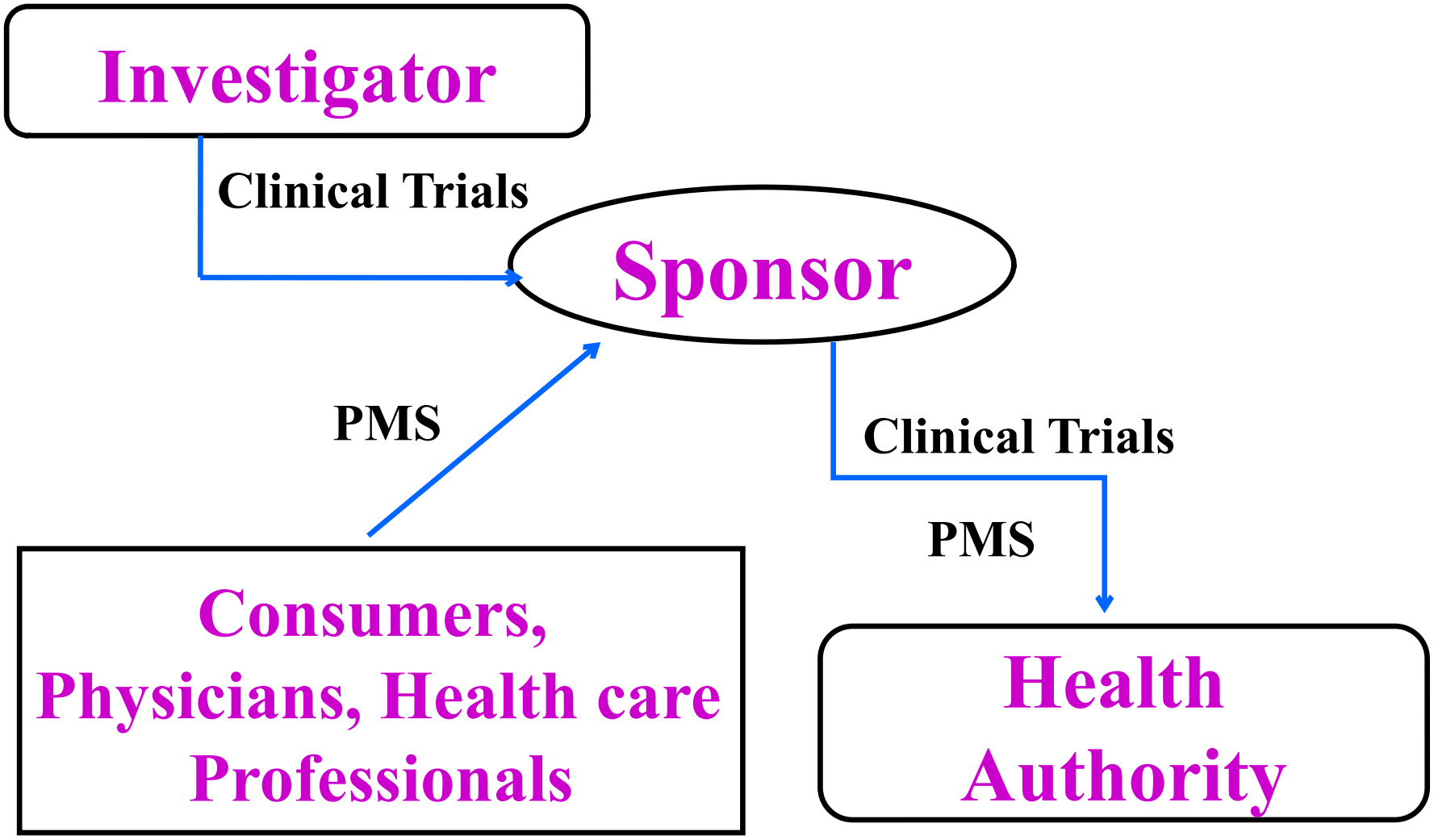
Drug research	Preclinical	Clinical trials	Evaluation/ Approval	Phase IV studies
 	Lab and animal experiments 	**Phase I:** 20-100 healthy volunteers **Phase II:** 100-500 patients → safety, dosing **Phase III:** 1,000-10,000 patients → efficacy, adverse events 	(up to 2 years)	(more than 2 years)

Source: based on PhRMA Profile Pharmaceutical Industry 2010

WHY PHARMACOVIGILANCE ?

 **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

Who reports about Adverse Events in Clinical trials and in PMS



Pharmacovigilance

Benefit Risk Analysis Skeleton...

Drug Effects

Good Benefit

Bad Risk - AE

Expected

Unexpected

Individual Case Data flow

Signal Detection

Risk Management

Case Intake

Unblinding

Case Lock

Case Triage

Medical Review

Reporting

Data Entry

Quality Review

Case Archive

ICSRs

Individual

Aggregate

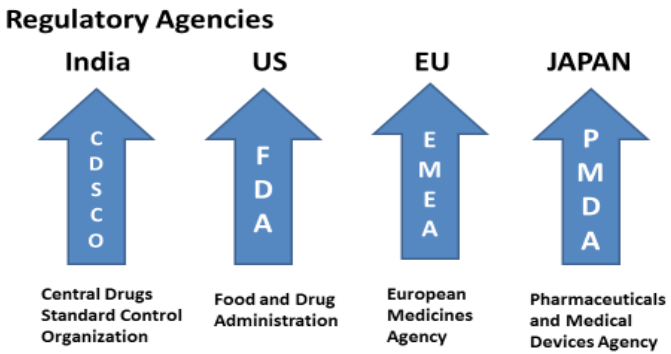
Expedited Reporting

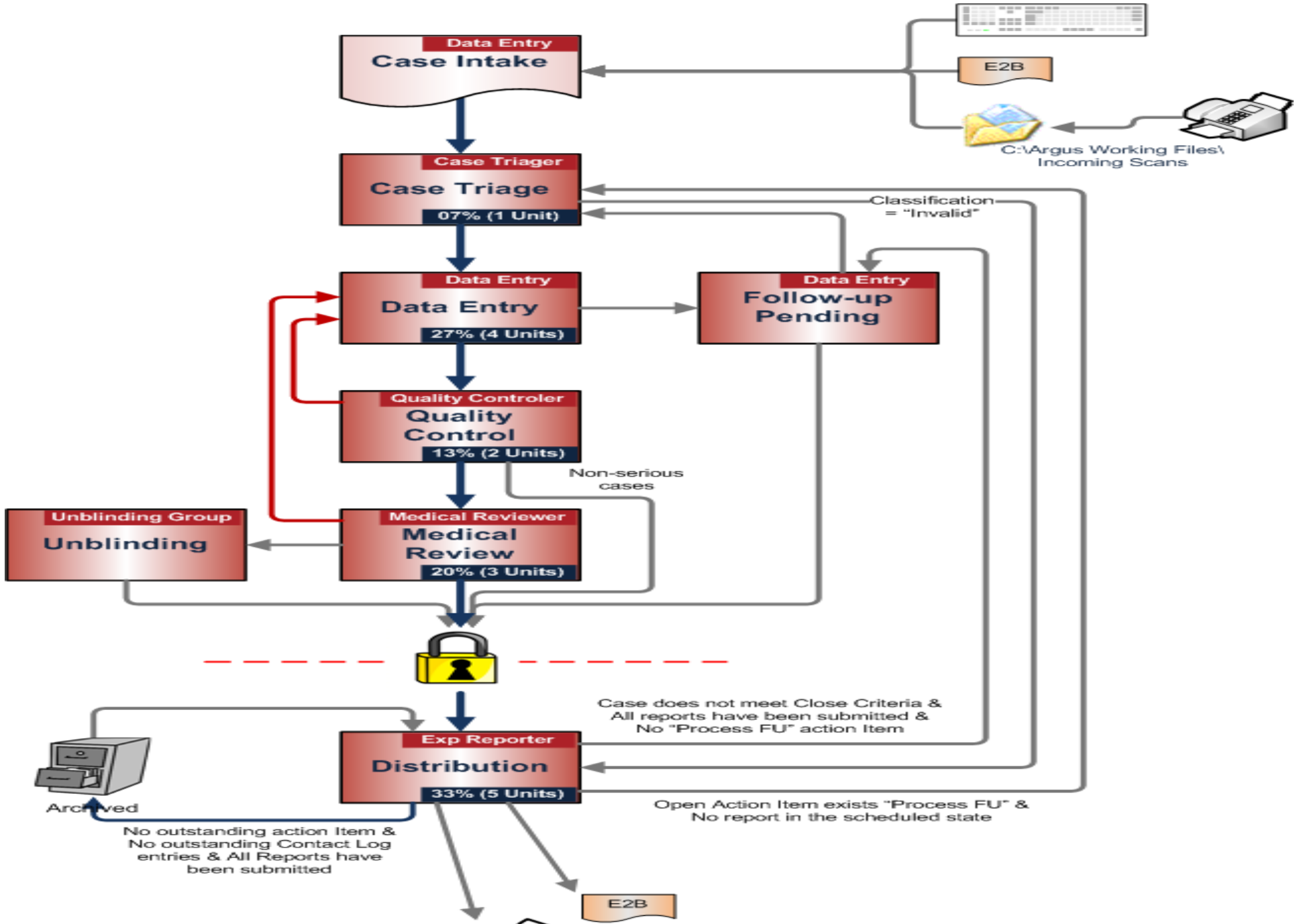
PSUR

No drug which is pharmacologically effective is without hazard

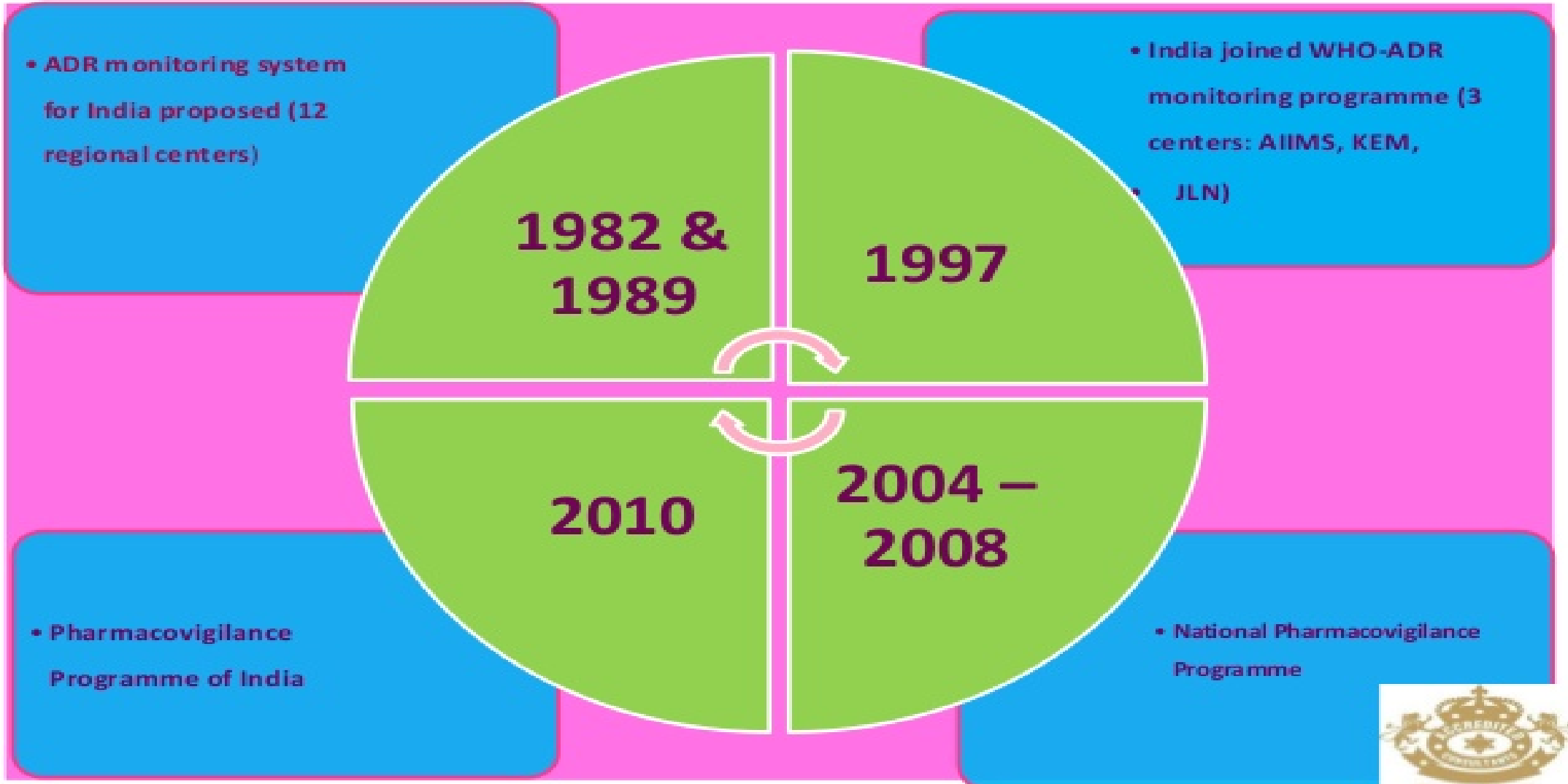
Suspected Adverse Reaction Forms:

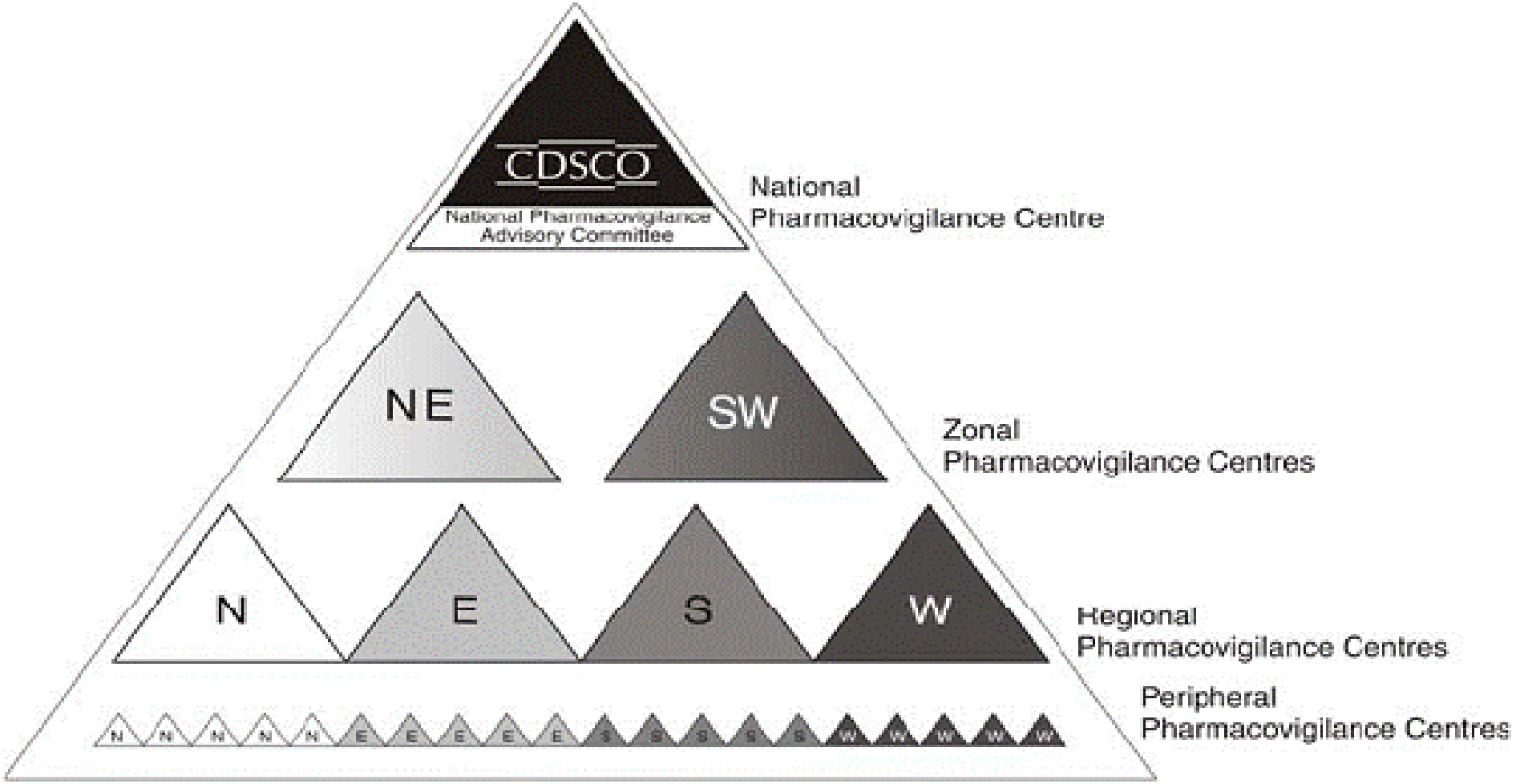
Blue Card - Australia
Yellow Card – UK
Canada Vigilance Reporting Form - Canada
CIOMS (Council for International Organizations of Medical Sciences) Form - WHO
FDA MedWatch Form 3500 - USA
Suspected Adverse Reaction Form – CDSCO – India
(Central Drugs Standard Control Organization)




Data Entry
Case Intake
E2B
C:\Argus Working Files\
Incoming Scans
Case Triager
Case Triage
07% (1 Unit)
Classification
= "Invalid"
Data Entry
Data Entry
27% (4 Units)
Data Entry
Follow-up
Pending
Quality Controler
Quality
Control
13% (2 Units)
Non-serious
cases
Unblinding Group
Unblinding
Medical Reviewer
Medical
Review
20% (3 Units)
Case does not meet Close Criteria &
All reports have been submitted &
No "Process FU" action Item
Exp Reporter
Distribution
33% (5 Units)
Archived
Open Action Item exists "Process FU" &
No report in the scheduled state
No outstanding action Item &
No outstanding Contact Log
entries & All Reports have
been submitted
E2B

Pharmacovigilance in India: A Brief History




CDSCO
National Pharmacovigilance Advisory Committee
National Pharmacovigilance Centre
NE
SW
Zonal Pharmacovigilance Centres
N
E
S
W
Regional Pharmacovigilance Centres
Peripheral Pharmacovigilance Centres
National Pharmacovigilance Programme