PHARMACOVIGILANCE IN INDIA AND EMERGING MARKETS: *AN INDUSTRY PERSPECTIVE*



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Disclaimer

The content expressed in this presentation is solely my experience and practice in Pharmacovigilance. This presentation and views stated are not necessarily that of Wockhardt Limited.

Contents



Why?



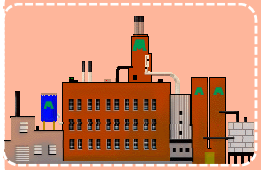
Emerging markets



Role of Pharmaceutical Industry



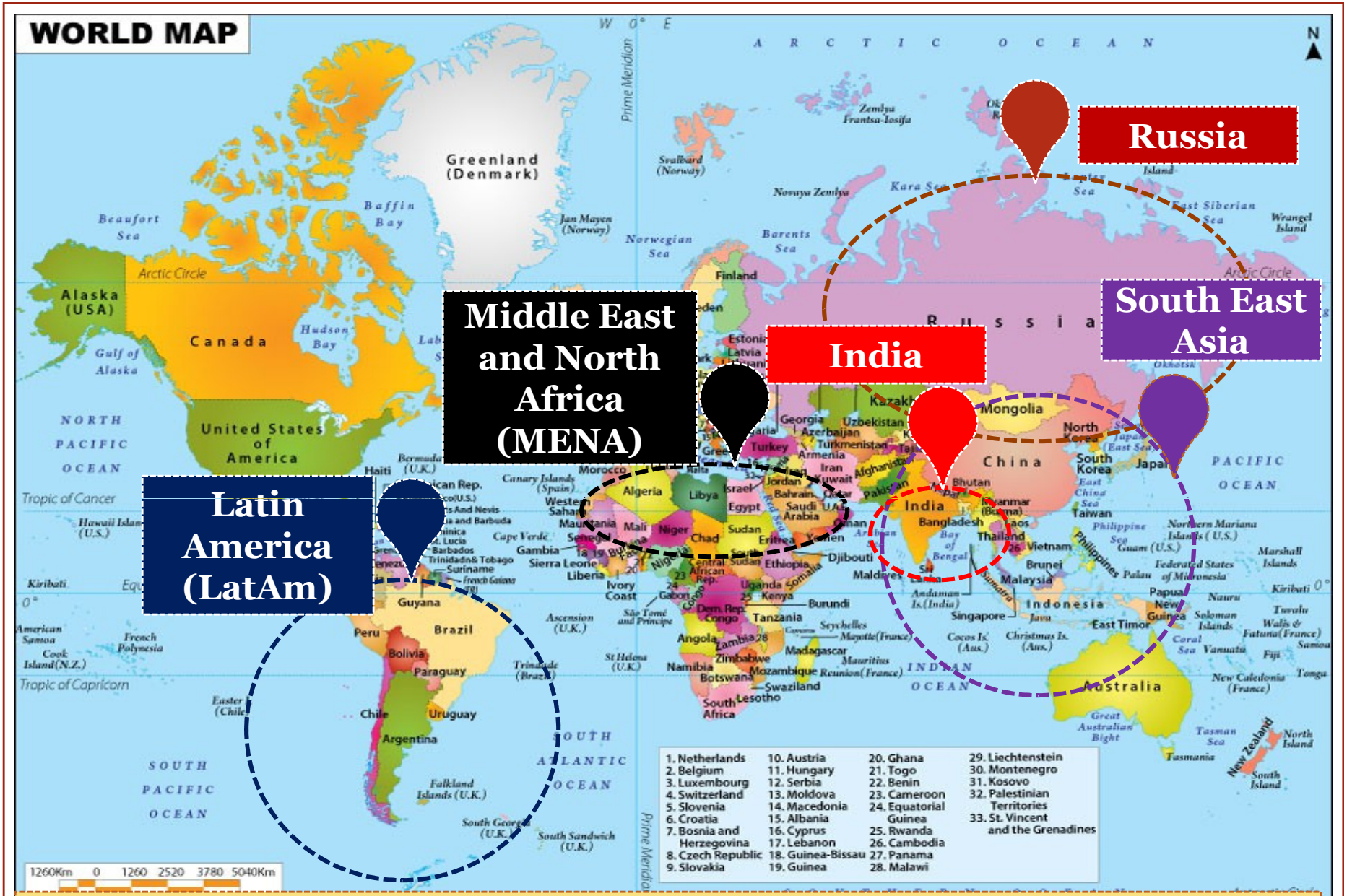
Stake holders



Pharmacovigilance Models

- **In recognizing the drug adverse effects at the earliest possible stage so that the risk never becomes disproportionate to benefit.**





These emerging markets have their own PV systems

FDA U.S Food and Drug Administration	emea	CDSCO
AERS	Eudravigilance	Manual/Vigiflow via PVPI (ADR monitoring centre)
Med watch Program (voluntary and Mandatory)/ electronic reporting	Mandatory electronic reporting	Manual reporting
Consumer reporting	Yellow card system	HCP reporting/Consumer reporting
PSUR Requirement: 1) Quarterly during the first 3 years 2) Annual reports thereafter.	PSUR Requirement: 1) Every 6 months for 2 years 2) Annually for the 3 years 3) Every 5 years	PSUR Requirement: 1) Every 6 months for 2 years 2) Annually for the 2 following years 3) Every 5 years.

Role of Pharmaceutical Industry

- **Collection of adverse events**
- **Monitoring drug safety trends**
- **PSUR (periodic safety update report)**
- **Adequate training and communication**
- **Creating awareness about drug safety**
- **Reporting system for all type of cases (ex: serious ADR,SUSARs etc)**
- **Synchronization between Pharmaceutical company and regulatory authorities**

Pharmacovigilance model: *Stake holders*



Patients



Physician and medical associations



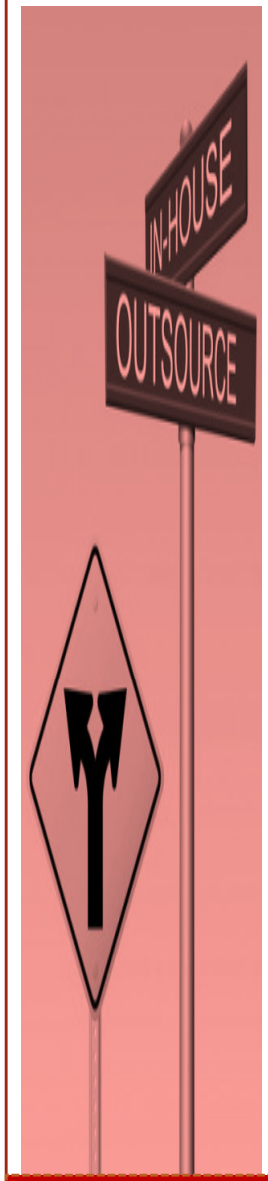
Media



Pharma Industry and associations



Regulatory authorities



PV model:
Part In- house –Part Outsourced

PV model:
Fully Outsourced end to end

PV model:
Fully In- house end to end



OUTSOURCED

OUTSOURCED

PHARMACOVIGILANCE MODEL

Pharmacovigilance model: *An industry perspective*



DATA DISTRIBUTION SYSTEM

MEDICAL REVIEW

DATA PROCESSING SYSTEM

DATA ANALYSIS SYSTEM

DATA COLLECTION SYSTEM

Pharmacovigilance model: *An industry perspective*



DATA DISTRIBUTION SYSTEM

MEDICAL REVIEW

DATA PROCESSING SYSTEM

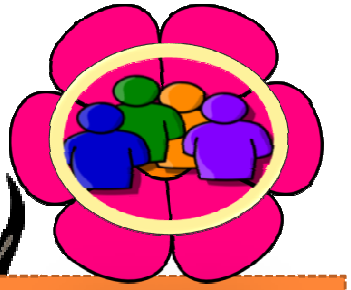
DATA ANALYSIS SYSTEM

DATA COLLECTION SYSTEM

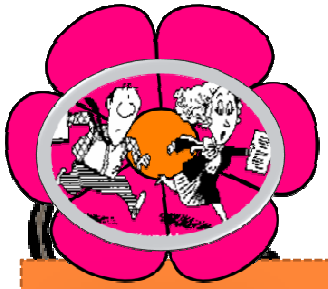
DATA COLLECTION SYSTEM



Health care professionals

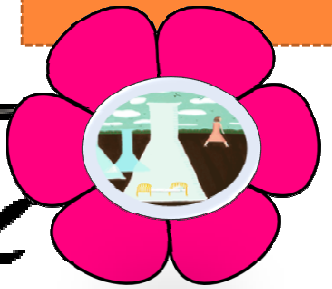


Non- Health care professionals



Spontaneous reporting

Clinical trials





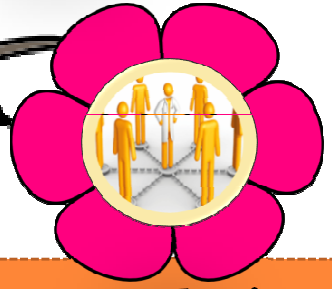
CMS



Literature searches



Electronic medical records



Post marketing surveillance

CIOMS FORM

CIOMS FORM
SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1.PATIENT INITIALS (first, last)	1a COUNTRY	2. DATE OF BIRTH			2a.AGE Years	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTANCE OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING ☐ CONGENITAL ABNORMALITIES ☐ OTHER MEDICALLY IMPORTANT
7+13 DESCRIBE REACTION(S) (including relevant tests/laboratory data)										

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name and batch no.)		20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA
17. INDICATION(S) FOR USE		
18. THERAPY DATES (from/to)	19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.)

IV. MARKETING AUTHORIZATION HOLDER/MANUFACTERER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER/MARKETING AUTHORIZATION HOLDER (MAH)		26. REPORTER'S DETAILS
24b. ORIGINAL REPORT NO.	24c. MAH CONTROL NO.	
24d. DATE RECEIVED BY MAH	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ COMPETENT AUTHORITIES	
25a. DATE OF THIS REPORT	25b. REPORT TYPE ☐ INITIAL ☐ FOLLOW UP	

Confidential

Page 1 of 1

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by healthcare professionals

CDSCO
Central Drugs Standard Control Organization
Directorate General of Health Services,
Ministry of Health & Family Welfare, Government of India,
FDA Bhavan, ITO, Kotla Road, New Delhi
www.cdsco.nic.in

(AMC/ NCC Use only
AMC Report No.
Worldwide Unique no.

A. Patient Information

1.Patient Initials _____

2.Age at time of Event or date of birth _____

3. Sex ☐M ☐ F

4. Weight ____Kgs

12. Relevant tests / laboratory data with dates

B .Suspected Adverse Reaction

5. Date of reaction stated (dd/mm/yyyy)
6. Date of recovery (dd/mm/yyyy)
7. Describe reaction or problem

13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)

14. Seriousness of the reaction

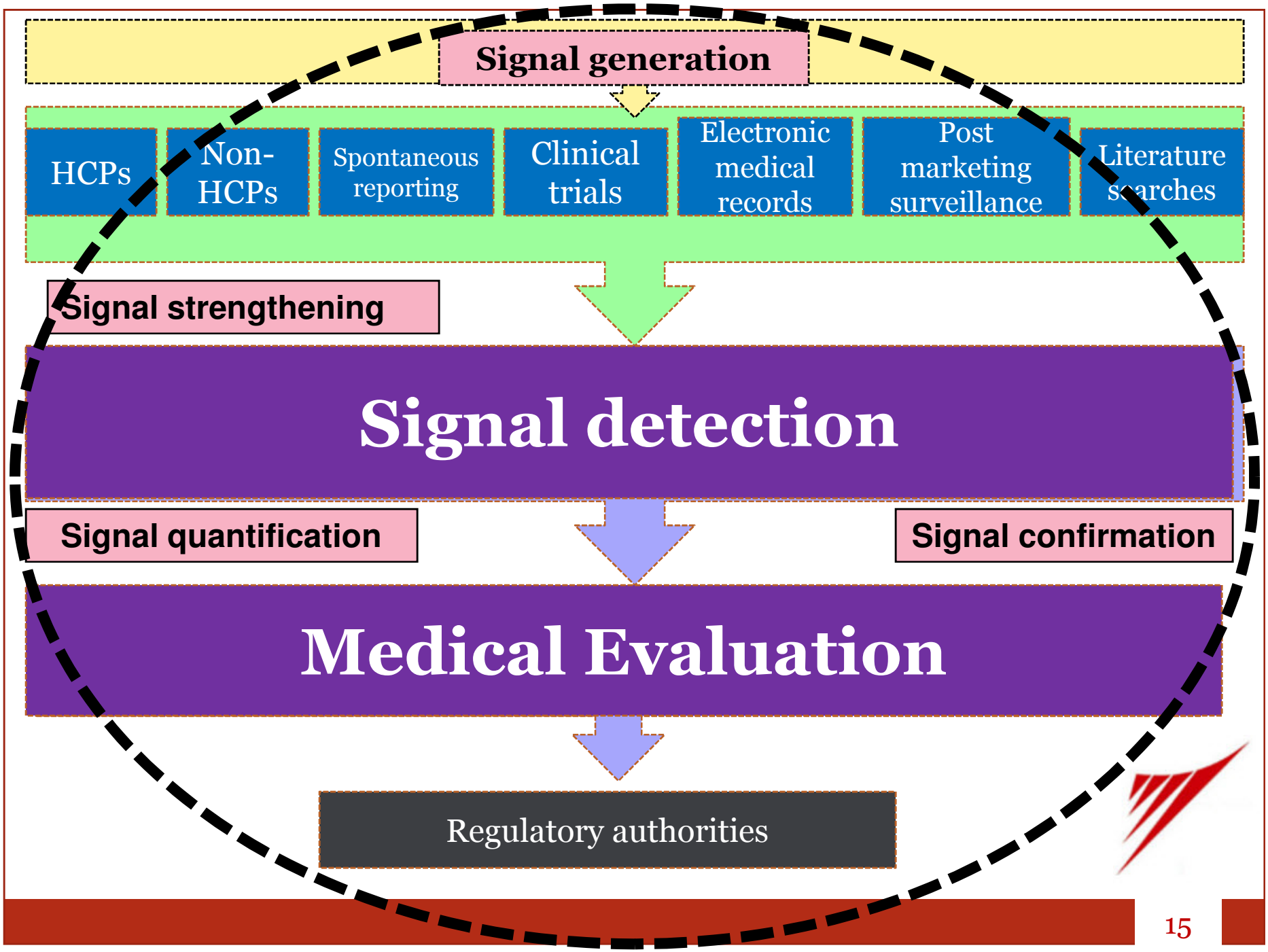
- ☐ Death (dd/mm/yyy)_____
- ☐ Life threatening
- ☐ Hospitalization-initial or prolonged
- ☐ Disability
- ☐ Congenitial anomaly
- ☐ Required intervention to prevent permanent impairment / damage
- ☐ Other (specify)

15. Outcomes

- ☐ Fatal
- ☐ Continuing
- ☐ Recovering
- ☐ Recovered
- ☐ Unknown
- ☐ Other (specify)_____

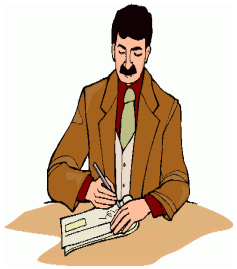
C.Suspected medication(s)

S.No	8. Name (brand and /or generic name)	Manufacturer (if known)	Batch No./ Lot No. (if known)	Exp. Date (if known)	Dose used	Route used	Frequency	Therapy dates (if known give duration)		Reason for use of prescribed for
								Date started	Date stopped	
i.										
ii.										
iii.										

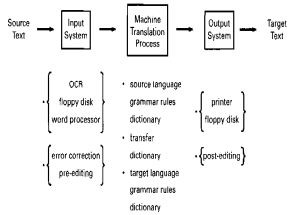

Signal generation
HCPs
Non-HCPs
Spontaneous reporting
Clinical trials
Electronic medical records
Post marketing surveillance
Literature searches
Signal strengthening
Signal detection
Signal quantification
Signal confirmation
Medical Evaluation
Regulatory authorities



Data in regional languages



Authorized vendor



In house translation system



Data in English language

Translation of data/ adverse event forms is a part of data collection system which is carried out to translate data from regional language to English language.

Safety data exchange agreements (SDEA)

License partners



Third party manufacturers



Safety data

Safety data exchange agreements (SDEA)

Khattri et al. Clin Res Reg Aff, 2012.

Pharmacovigilance model: *An industry perspective*



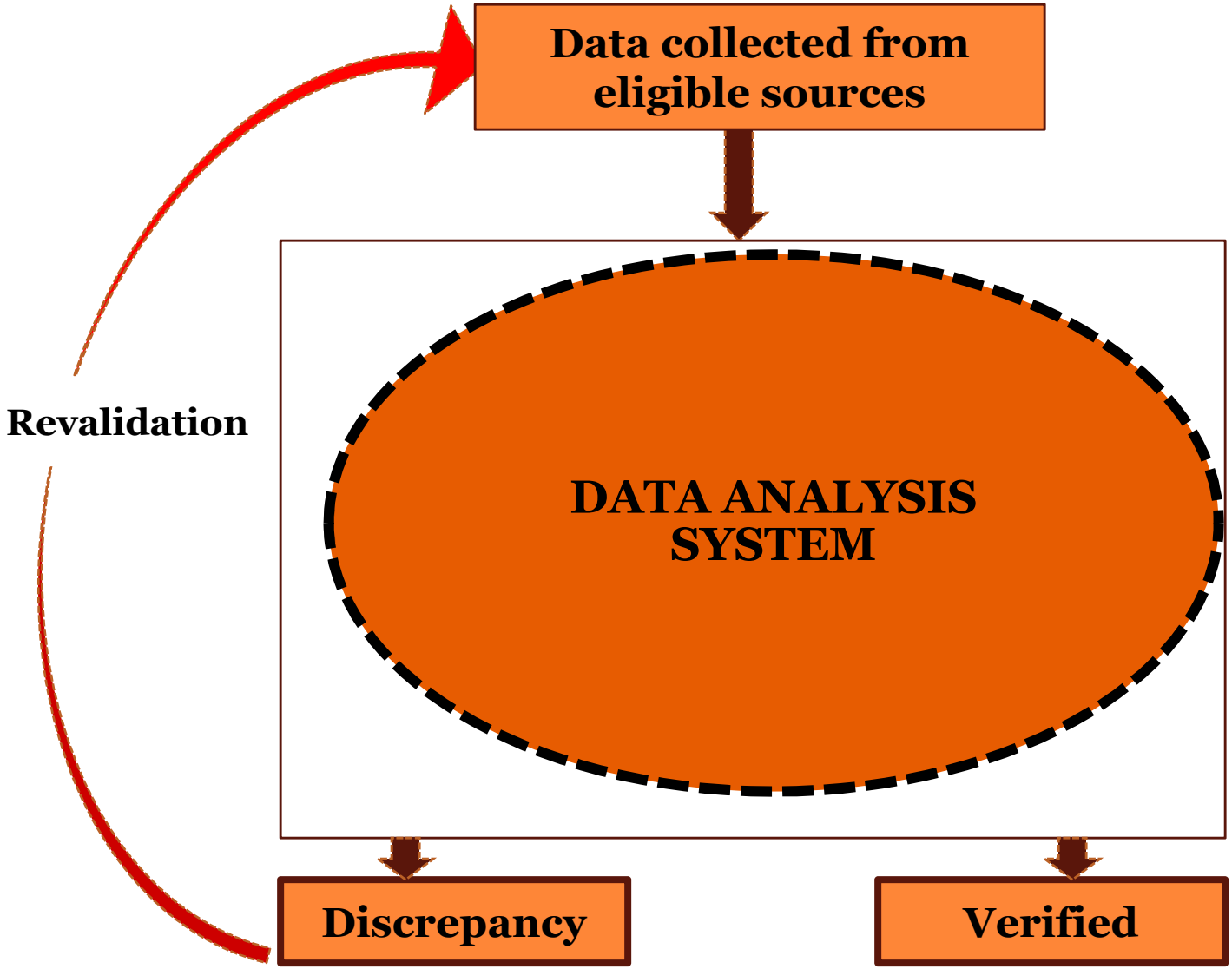
DATA DISTRIBUTION SYSTEM

MEDICAL REVIEW

DATA PROCESSING SYSTEM

DATA ANALYSIS SYSTEM

DATA COLLECTION SYSTEM


Data collected from eligible sources
Revalidation
DATA ANALYSIS SYSTEM
Discrepancy
Verified

Pharmacovigilance model: *An industry perspective*



DATA DISTRIBUTION SYSTEM

MEDICAL REVIEW

DATA PROCESSING SYSTEM

DATA ANALYSIS SYSTEM

DATA COLLECTION SYSTEM

Pharmacovigilance model: *Data processing system*



ARGUS



MedDRA



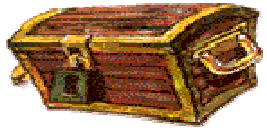
ARISG



WHO drug dictionary



Local regulatory AE form



Company drug repository

Pharmacovigilance Model: *An industry perspective*



DATA DISTRIBUTION SYSTEM

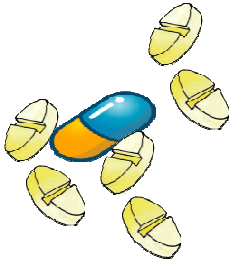
MEDICAL REVIEW

DATA PROCESSING SYSTEM

DATA ANALYSIS SYSTEM

DATA COLLECTION SYSTEM

Pharmacovigilance Model: *Medical review*



Medicinal product

Causal relationship



Adverse drug reaction

Medical review is carried out to determine the causal relationship between medicinal product and ADR.

Pharmacovigilance Model: *An industry perspective*



DATA DISTRIBUTION SYSTEM

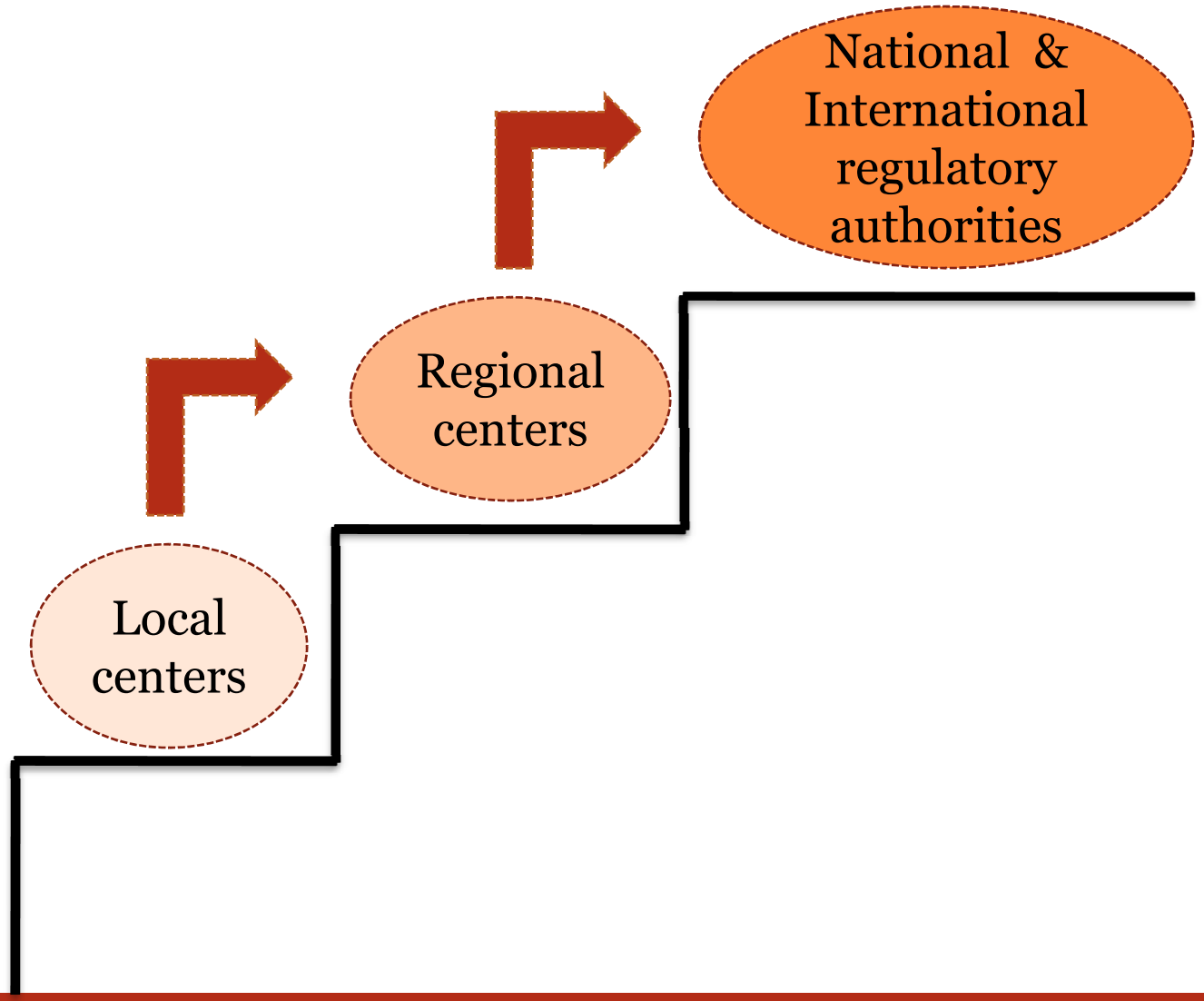
MEDICAL REVIEW

DATA PROCESSING SYSTEM

DATA ANALYSIS SYSTEM

DATA COLLECTION SYSTEM

Pharmacovigilance Model:
Data distribution system



Need of the hour in Pharmacovigilance in India and Emerging Markets

- Need for adequate data capturing systems
- Under and inaccurate reporting
- Need for training
- Collaboration with different Stake holders



•Biswas P. J Pharmacol Pharmacother, 2013.
•Kumar A. Sys Rev Pharm, 2011.
•Pan GJD. Drug Saf. 2014.

A robust approach to Pharmacovigilance

