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Data Management in Pharmacovigilance

Ajay Francis Christopher

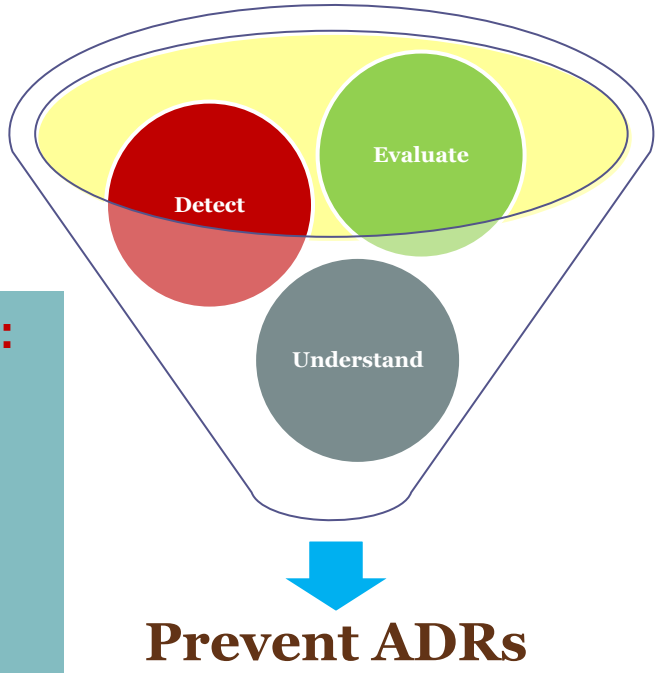
Demonstrator (Clinical Research)

University Center of Excellence in Research,

Baba Farid University of Health Sciences,

Faridkot, India.

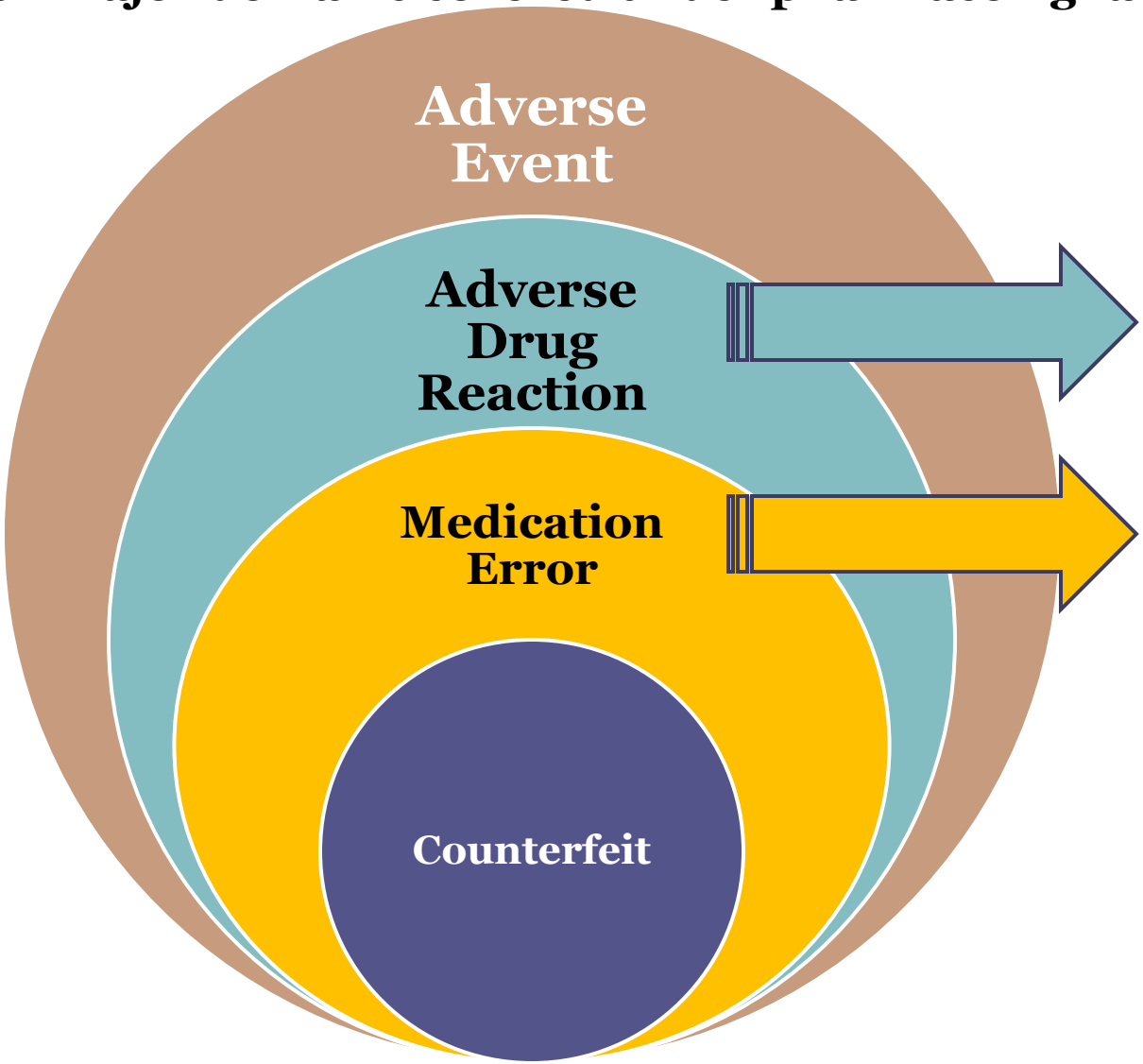
- The World Health Organization (WHO) defines pharmacovigilance as the **science and activities** relating to the *detection*, *evaluation*, *understanding*, *and prevention of adverse reactions* to **medicines or any other medicine-related problems**.



Reasons to have a Pharmacovigilance system:

1) **Patient safety at risk (loss of life, injury).**
2) **Loss of money.**
3) **Loss of trust in healthcare system.**
4) **Has a huge effect on healthcare.**
5) **Regulatory requirement.**

Four major domains covered under pharmacovigilance



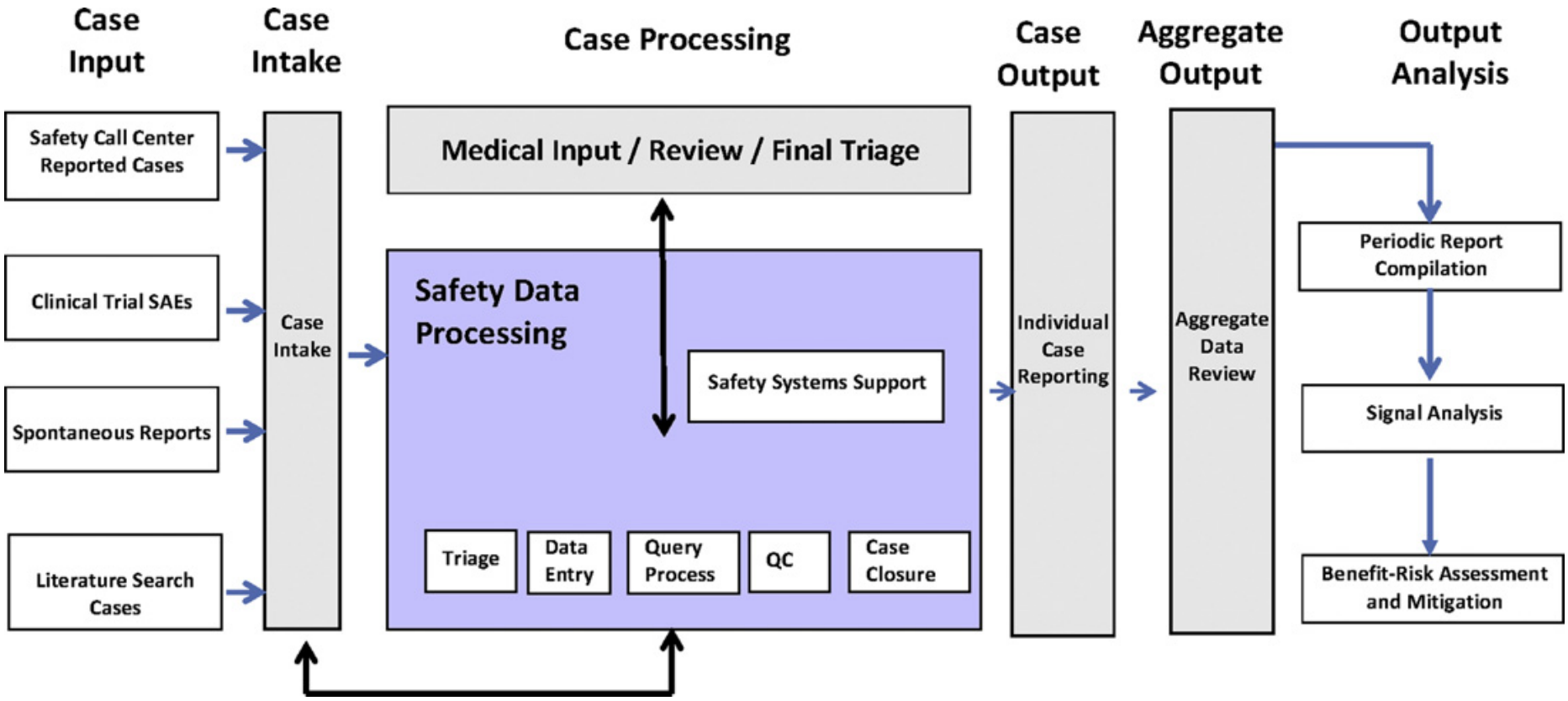
Loss of life:
about 7000 or more people die.

Injury:
1.5 million Americans

Loss of money:
- 17 billion USD (Med. error)
- 29 billion USD (ADRs)

- Institute of Medicine of the National Academies, 2000. To Err Is Human: Building a safer Health System, L. T. Kohn, J. M. Corrigan, M. S. Donaldson, eds. Washington, D.C.: National Academy Press.
- IOM Committee on Identifying and Preventing Medication Errors. 2006. Preventing Medication Errors, P. Aspden, J. A. Wolcott, J. L. Bootman, and L. R. Cronenwett, eds. Washington, D.C.: National Academy Press.

Major activities associated with Pharmacovigilance





TYPES OF REPORTS RECEIVED AT THE PV CENTER:

- **Spontaneous Serious/ Non-serious case reports or SAE from clinical trials**:
  - Death
  - Lack of Effect (LOE)
  - Drug exposure during Pregnancy
  - Drug Counterfeit
  - Drug Interaction
  - Drug Dependence
  - Drug Overdose
  - Suicide
  - Drug Abuse
  - Medication Error (storage, prescribing, dispensing, administering)

Step 1: Case Input or AE collection

- It involves collection of adverse experience information from multiple sources.

- Traditional sources are **clinical trials** and **spontaneous reports**

- Other sources of information include:
  - Internet reports
  - Solicited reports from patient support programs
  - Surveys
  - Epidemiological studies
  - Disease registries
  - Regulatory and other database
  - Licensor



Step 2: Case Triage or Case assessment

- Complaint is receive at the PV department and is classified for processing.

- **Activity 1:**
  Reports is **date stamped** when received (generally should be done within 24 hours of receipt).

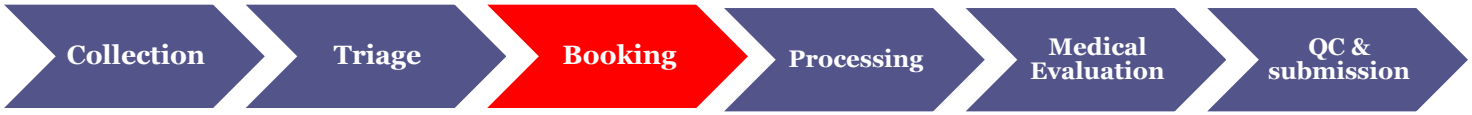
- **Activity 2:**
  Initial triage is performed by DSAs to determine whether the report needs **urgent processing** (SUSARs, high priority reports).

- **Activity 3:**
  Triage also covers **validation of case report** **for accuracy, completeness and bonafied information** as per regulatory requirements i.e:
  - Identifiable patient
  - Identifiable reporter
  - Suspected drug
  - Adverse drug reaction/Product quality complaint.



Step 3: Case booking and processing

- Following triage, the **case information is entered into a computerized safety database**.
- Drug safety database (Aris G, Argus, etc) is designed to collect safety data in an organized manner.
- Various **mandatory fields** are filled by the data entry personnel e.g. date of receipt of ADR, patient, reporter, AE, suspected drug, seriousness criteria and reporter causality assessment.
- Other required information as per local regulations include: type of source (spontaneous, literature, clinical trial) and **duplicate check**.
- Once minimum information is entered for reporting, the case is saved and assigned a **manufacturer control number** (MCN).



Case processing by DSA/ PV scientist

- DSA add all the information reported in the ADR Reporting form (CIOMS form/ MedWatch Form)

- Other activities include
  - Narrative writing
  - Findings of laboratory investigation
  - Company causality assessment
  - and labeling of ADR (USPI, CDS, IB, Local document)
  - Query for more information or if any discrepancy
  - Data reviewed/validated



Medical evaluation

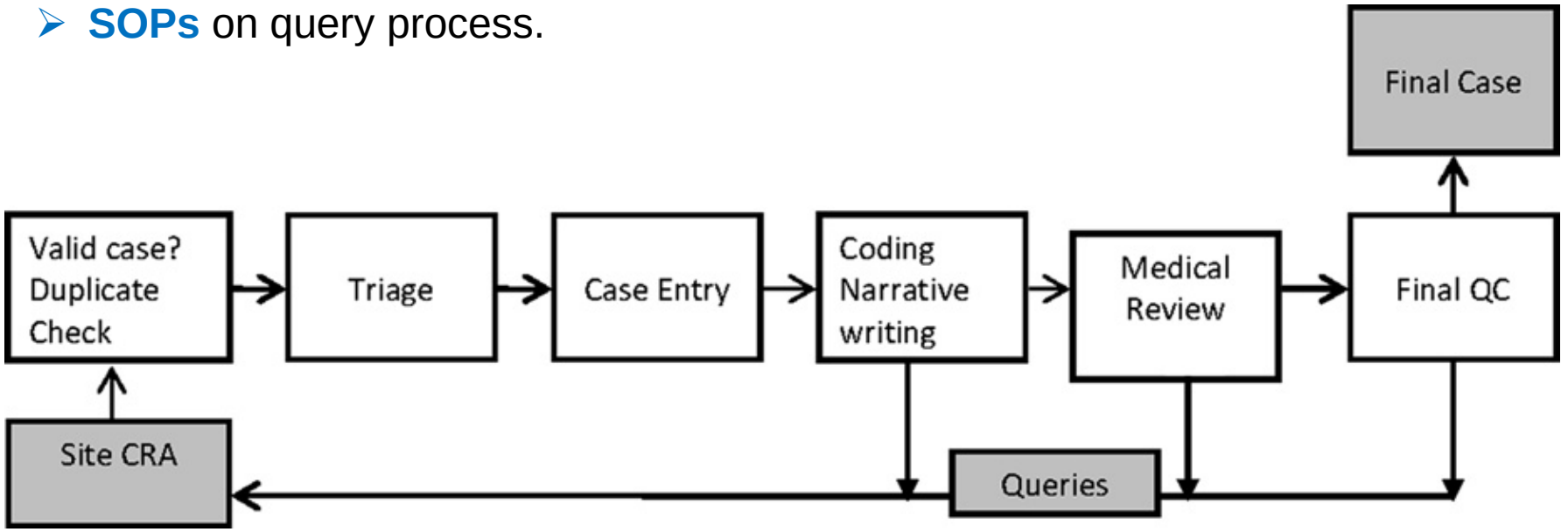
In medical evaluation, the HCP or DSP checks the:

- ❑ Appropriate **linkage of reporter AE** with the preferred term.
- ❑ The **labeling of the AE** against the reported events in the company labeling documents.
- ❑ **Seriousness and causality** assessment.
- ❑ **Alternative cause** of the ADR and CIOMS comments (if any).
- ❑ Medical history and additional information needed.
- ❑ Narrative (completeness, chronology and medical relevance).



Query or Additional Information

- Additional information is requested from the **affiliate** or **the investigator** for any discrepancy or support case information.
- Query can be sent during **case processing and medical review** (i.e ideally when the case is open)
- **SOPs** on query process.





Quality Check

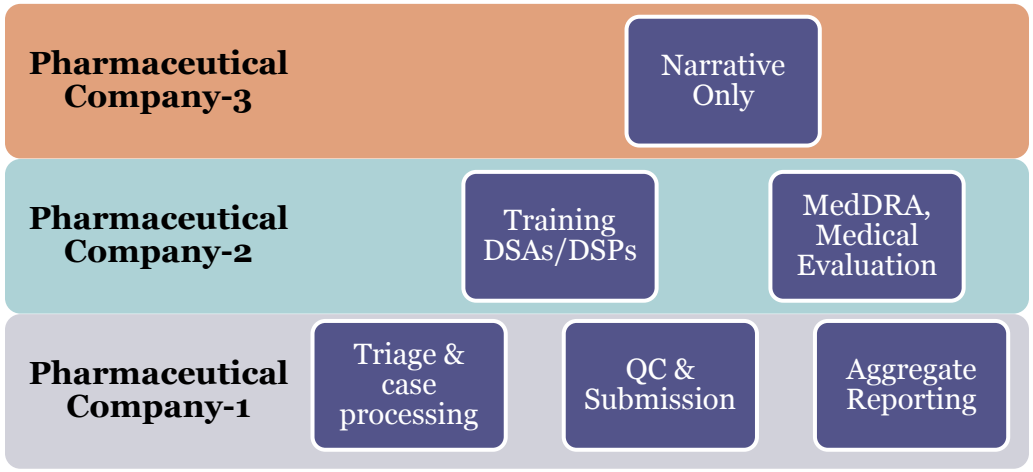
- ICSRs are **randomly selected** for quality check.
- Ideally when the ICSR/SAE report is ready for submission to the regulatory authority.
- Only important fields (which could leads to substantive correction) are checked against the source documents.
- Case after satisfactory QC is locked/closed and submitted to regulatory department and to licensee.

REPORT SCREEN	1	Report Origin
	2	Classification
	3	Local/External case ID
	4	Date received at company
	5	Medically confirmed
PATIENT SCREEN	6	Patient initials
	7	Patient gender
	8	Birth date / Age at time of Event
	9	Age Group
	10	Date of death if fatal outcome
REPORTER SCREEN	11	Last name/organisation
	12	Country
	13	Reg/Patient reference ID
	14	Reporter Type
SUSPECT ROCHE DRUG/COMPARATOR AND DRUG THERAPY	15	Drug selection/correct IND/NDA/formulation
	16	Dose, Frequency, Route and Therapy dates
	17	Lot number (if provided)
	18	Flags
CONCOMITANT MEDICATIONS	19	Drug names and therapy information
TEXT/NARRATIVE	20	Full narrative
ADVERSE EVENT SCREEN	21	Reported term
	22	Seriousness criteria
	23	Onset date
DRUG/EVENT SCREEN FOR SUSPECT AND COMPARATOR DRUGS	24	All relevant labels entered and correct
	25	Causality (Except for legal cases)

Case load at the Pharmacovigilance department and the need of PV management

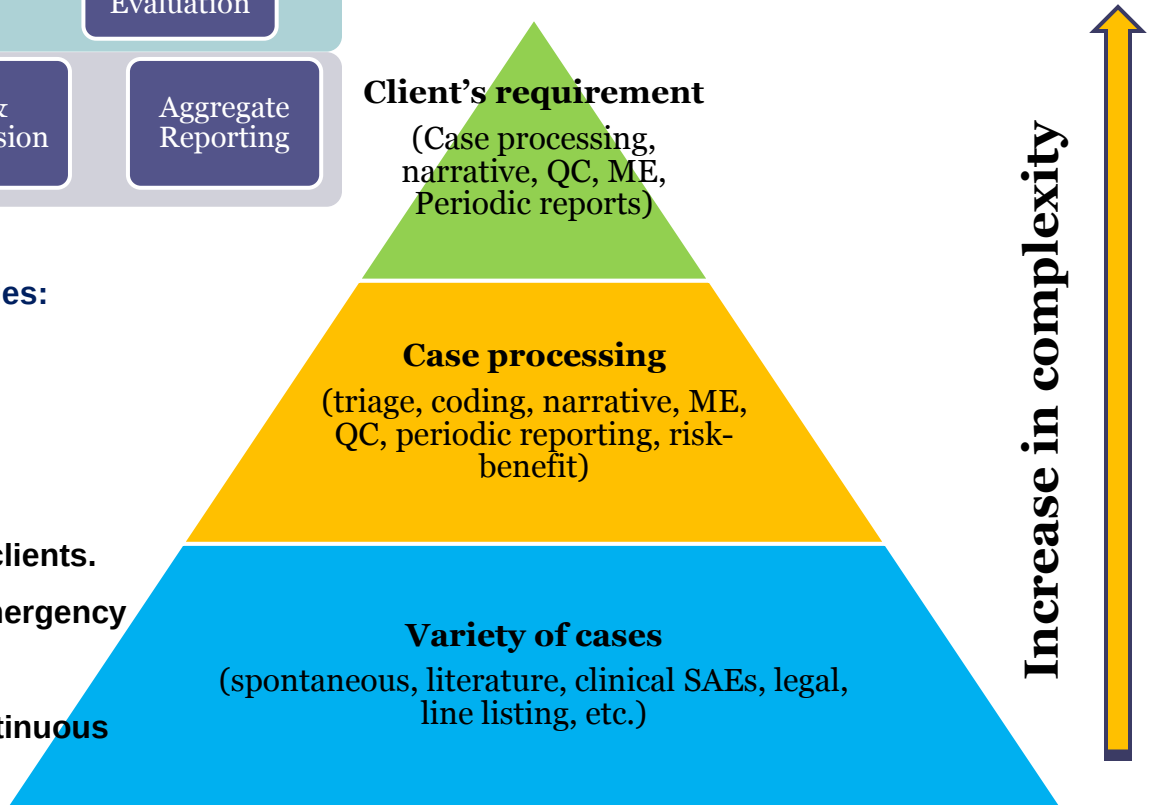
PV case varieties	Volume of cases (approx)
ICSRs	300-400 daily
SAE from clinical trials	80-100 daily
Legal cases	30-50 daily
Literature	20-50 daily
Narratives	250-300 daily
Line listing	Occasionally
PSUR	2-5 monthly
Small projects	2-3 monthly
QC report	Weekly
Compliance report	Weekly
DSA training records	Occasionally (new GCP SOPs)
Internal Audit	Quarterly

Layers of complexity at a Pharmacovigilance Department

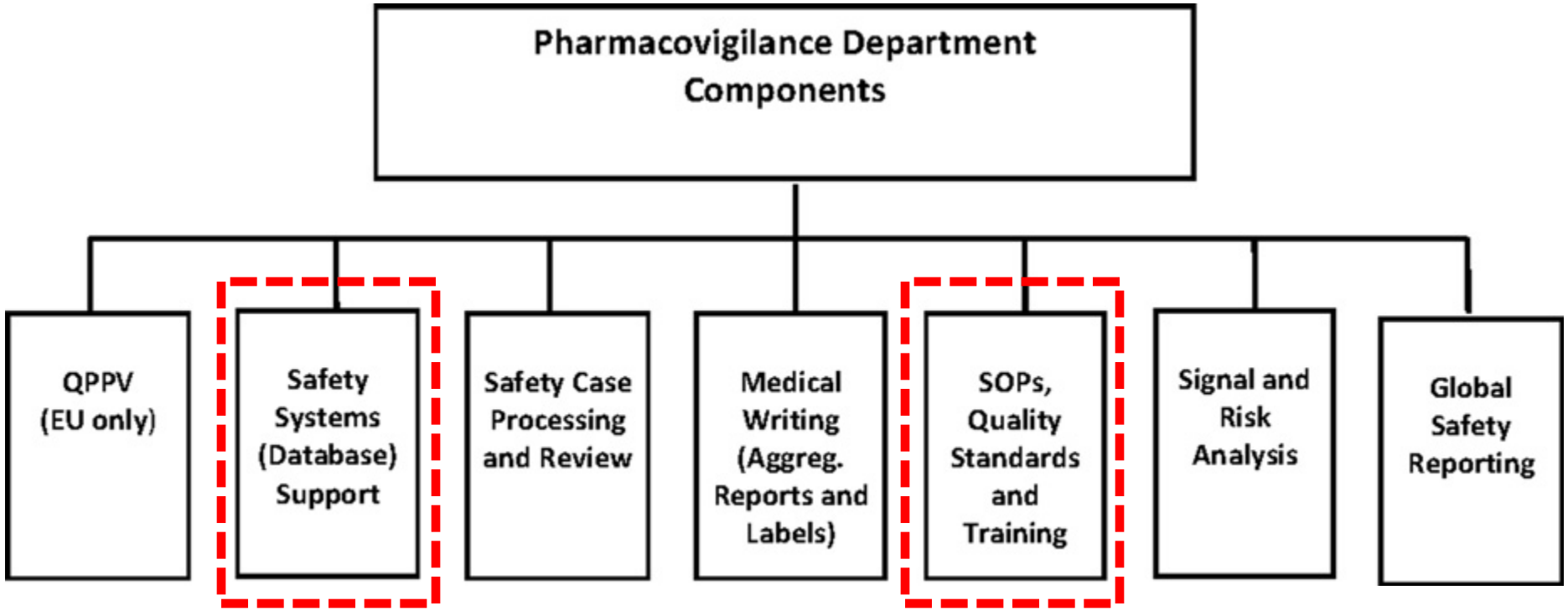


How to keep a track on various PV activities:

1. **More than one client.**
2. **Varied requirements.**
3. **Meet stringent timelines.**
4. **Real time status and WIP across all clients.**
5. **Flexible and competent to handle emergency workload.**
6. **Quality assurance (CAPA, audit, continuous improvement).**



Other important activities at the pharmacovigilance department



Enterprise resource planning (ERP) is the solution

- Dynamics NAV 2009 (formerly Navision) is business management software and part of Microsoft's enterprise resource planning (ERP) software portfolio.

- Typically a suite of integrated applications—that a company can use to
  - ✓ collect
  - ✓ store
  - ✓ manage
  - ✓ and interpret data from many business activities

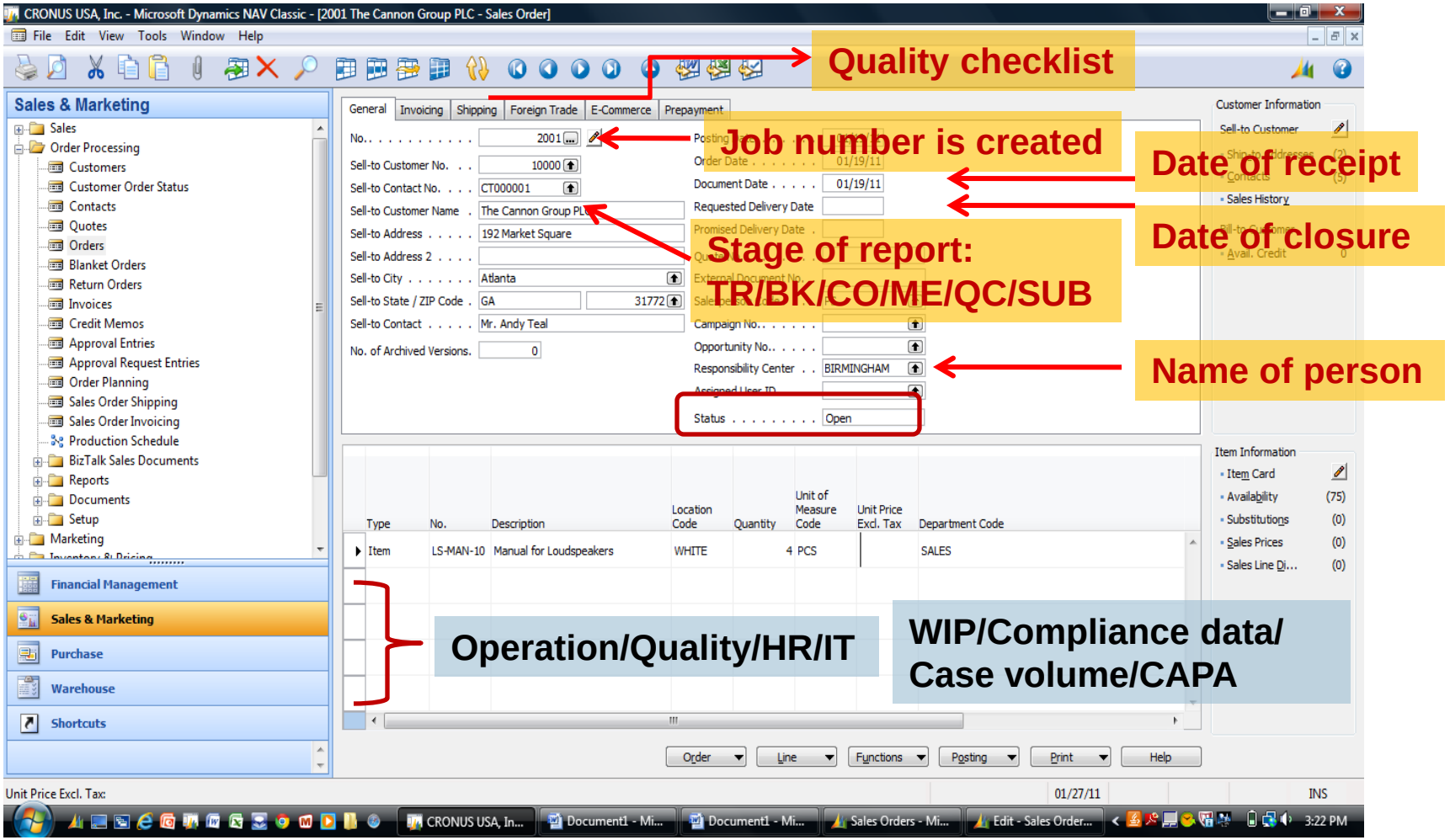
- ERP provides an integrated view of core business processes, often in **real-time**, using common database.

- ERP systems track business resources and the status of business commitments.

- The applications that make up the system share data across the various departments that provide the data.

- ERP facilitates information flow between all business functions.
  - ✓ Inventory and order processing
  - ✓ Distribution and Supply Chain Management
  - ✓ Human resource management
  - ✓ Project Management
  - ✓ Analytics and reporting

Collection → Triage → Booking → Processing → Medical Evaluation → QC & submission



CAPA Report

Organization Name	CAPA Report
Job No.	XXX/CAPA/0008
Report Source	Org employee/Name
Report type	Solicited/Audit record
Problem definition	Med confirm error/ Users were unable to send/receive mail
Quantification of problem	Affect all user/ Dept. specific
Classification of Impact	Critical/moderate/low
Root cause analysis	Oversight by DSA/ No synchronization b/w servers
Acceptance of RCA	Yes/No
Alternative analysis by QA	
Date/time/signature	
Corrective action required	Yes/No
Proposed corrective action	Buddy check/ addition in QC checklist/Parallel exchange server
Alternative proposal	
Date/time (deadline)	
Follow-up/ Closure	
CAPA status	Open/closed
Date/time/signature	

Nonconformity Report

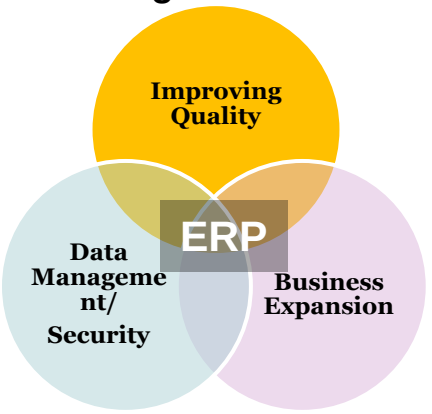
Sr. No	QMS AUDIT NONCONFORMITY REPORT
1.	**Company under Audit:** xxxxxx
2.	**AREA UNDER REVIEW:** a) Training/ Orientation b) Quality control c) IT
3.	**DOCUMENT REF:** i) SOP-T&M-014 ii) Quality Manual iii) XX-Record-No-003 iv) XX-Record-No-005
4.	**CATEGORY:** major/minor
5.	**REQUIREMENT:** a) Training/ Orientation to be completed within 30 days. b) QC sampling should be done randomly. c) Hard copy of IQ/OQ/PQ records should be available for 2 years.
6.	**NONCONFORMITY:** 1) Mr. XXX orientation conducted on DD/MM/YY which is 30 days after joining date. 2) Only particular category of case reviewed (serious) **OBJECTIVE EVIDENCE:** 1) Orientation training record. 2) QC data sheet.
7.	**Date of Audit:** DD/MM/YY **Signature**: Auditor/ Auditee.

Application of Microsoft Dynamics NAV 2009 in PV Data Management

1) Monitor **volume** of incoming cases.
2) **Uniform distribution** of case load in various teams.
3) Efficient **human resource management** during routine project allocation and during emergency situations (high incoming volume of cases, vacations and festivals).
4) Track **real time status of individual case** (at which level: triage, coding, ME, QC, submitted) to prevent late submission.
5) Monitor **WIP** status.
6) Imposing additional **checks and recording information** before case closure: Quality control checklist , query exchanged record to improve quality.
7) **Capacity building** for new projects and clients.
8) Record **CAPA** information.
9) Quick retrieval of information about discrepancies during **audits**.
10) **Automate various department** (Triage, Case booking, Case processing, Medical evaluation, Submission, QC, QA, Training, HR and IT) .
11) Save time, money and space (manual record).

Advantages gained with implementation of Microsoft Dynamics NAV

- Moderate level of training required
- Facilitated **error-free case processing** and **improve quality**.
- Facilitated efficiency of the business.
- Supported upper level management by providing information for **faster decision making with less chances of errors**.
- Created a **more agile company** that adapts better to change.
- Provided **improve data security**.
- Generated opportunities for additional business collaborations.



Drawbacks of Microsoft Dynamics NAV

- Requires **lot to time in customization** (6-9 months) for a small to medium size companies.
- **Harmonization** of ERP systems can be a mammoth task.
- Requires a **lot of planning and money**.
- Require highly **skilled professional** in Pharmacovigilance (for example SMEs) for process development.
- **Re-design PV processes** to fit the ERP system.
- Over reliance and **diverted focus from critical activities**.

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