WHITE PAPER

AUTOMATION IN PHARMACOVIGILANCE

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Introduction

Pharmacovigilance (PV) is a complex process of identifying, tracking, and reporting of adverse events of therapies including, drugs and medical devices. Further adds the convolution of very stringent reporting timeline and requirement of skilled human resources for submitting the Adverse Drug Reactions (ADR's) reported by the patients, Health Care Professionals (HCP) and Regulatory Authorities.

Background

The volume of Adverse events being reported continues to increase since a decade due to factors including evolving regulations of drug safety, therapeutic inclination towards personalized medicine, ageing global population and increased burden of chronic diseases. Over time, sources of reporting have also evolved. New age sources like social media and latest technologies as mobile chatbot are now integral part of established sources for spontaneous and solicited cases. The effort required for processing larger case volumes has posed a challenge for pharmaceutical companies. Adopting automation of simple tasks will reduce the human dependency as manual entering of the data can be significantly eliminated resulting in quick turnaround time (TAT) and better quality.

Technology as an ambit

While automation technology like- Robotic Process Automation (RPA) has been increasingly used by several product developers, Natural Language Processing (NLP), Data Annotation, and Machine Learning (ML) can be further leveraged to increase efficiency and quality in case processing structured-content authoring and signal detection.

Pharmacovigilance Lifecycle

High-level pharmacovigilance lifecycle is depicted in figure 1

Individual Case safety reporting process represented in Fig.2 and Timelines for submission in Fig.3.

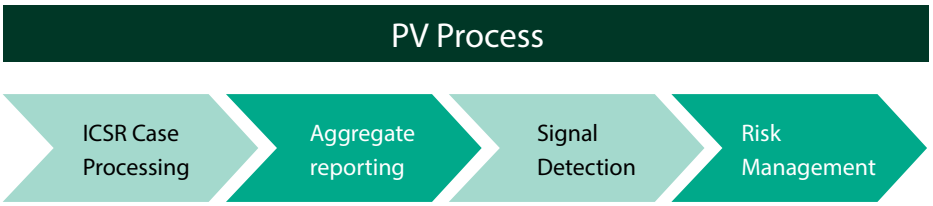


Fig.1 Pharmacovigilance Process

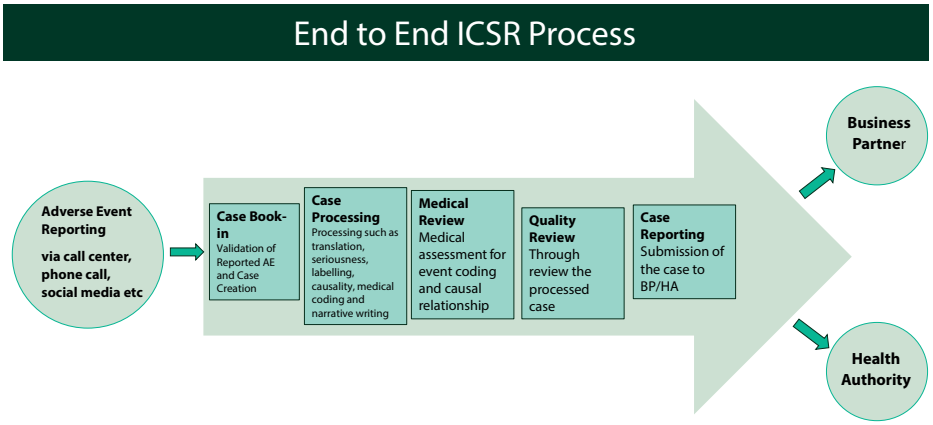


Fig.2 End to End ICSR Process

Case Submission

Fatal/ Life Threatening	**7 Calendar days**
Serious Case	15 Calendar days
Non-Serious	90 Calendar days

Fig.3 Case Submission Timelines

Automation for ICSR Case Processing

Due to ease of reporting methods and increased awareness of reporting ADR's, the volume of reporting adverse events has amplified causing a resource burden to pharmaceutical organizations in processing ICSRs.

Since ICSR is an input to aggregate reporting, signal detection and risk management, each one of the subsequence PV processes have become data intensive.

This conundrum necessitates, a need for automation of tasks beyond RPA which are both value-add and non-value add in nature. This helps in managing the volume, reducing the cost and improves overall quality. Automation of ICSR processing can make the process leaner by eliminating redundant steps in the existing process and increase process efficiency.

ICSR Source and Case Types

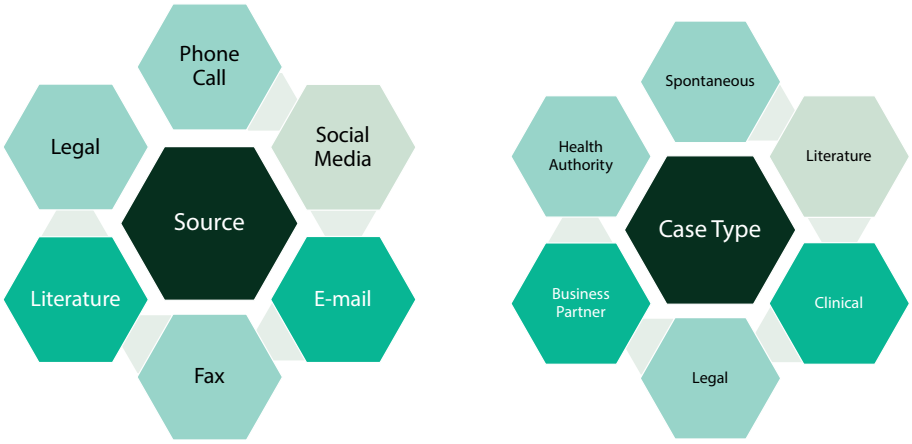


Fig. 4 Source for ICSR and Case Types

ICSR Case Flow

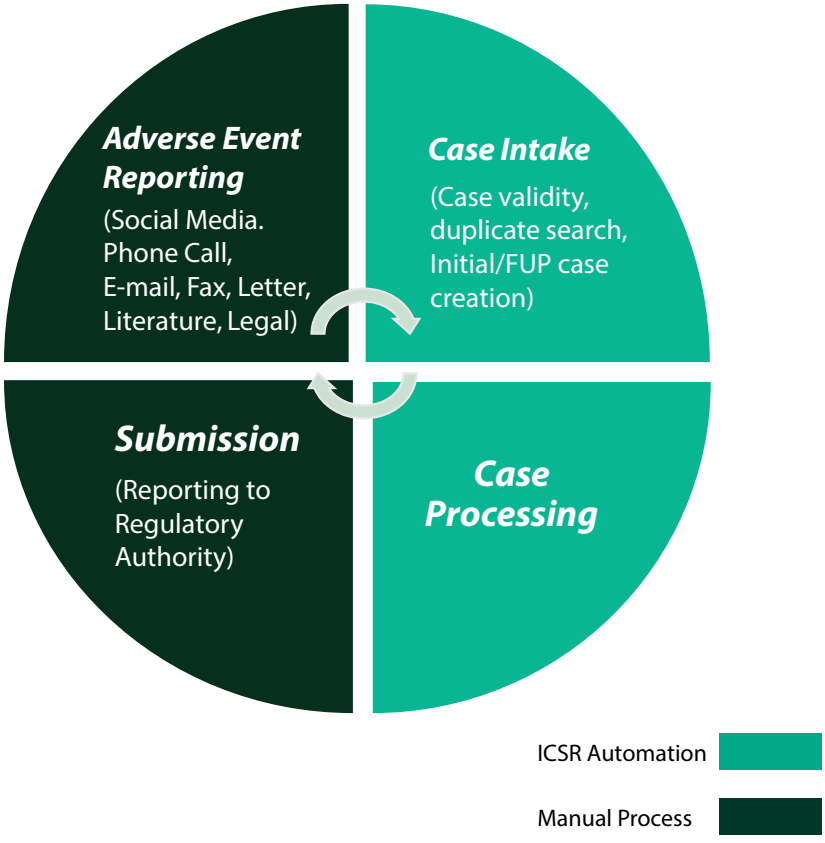


Fig.5 ICSR Case Flow

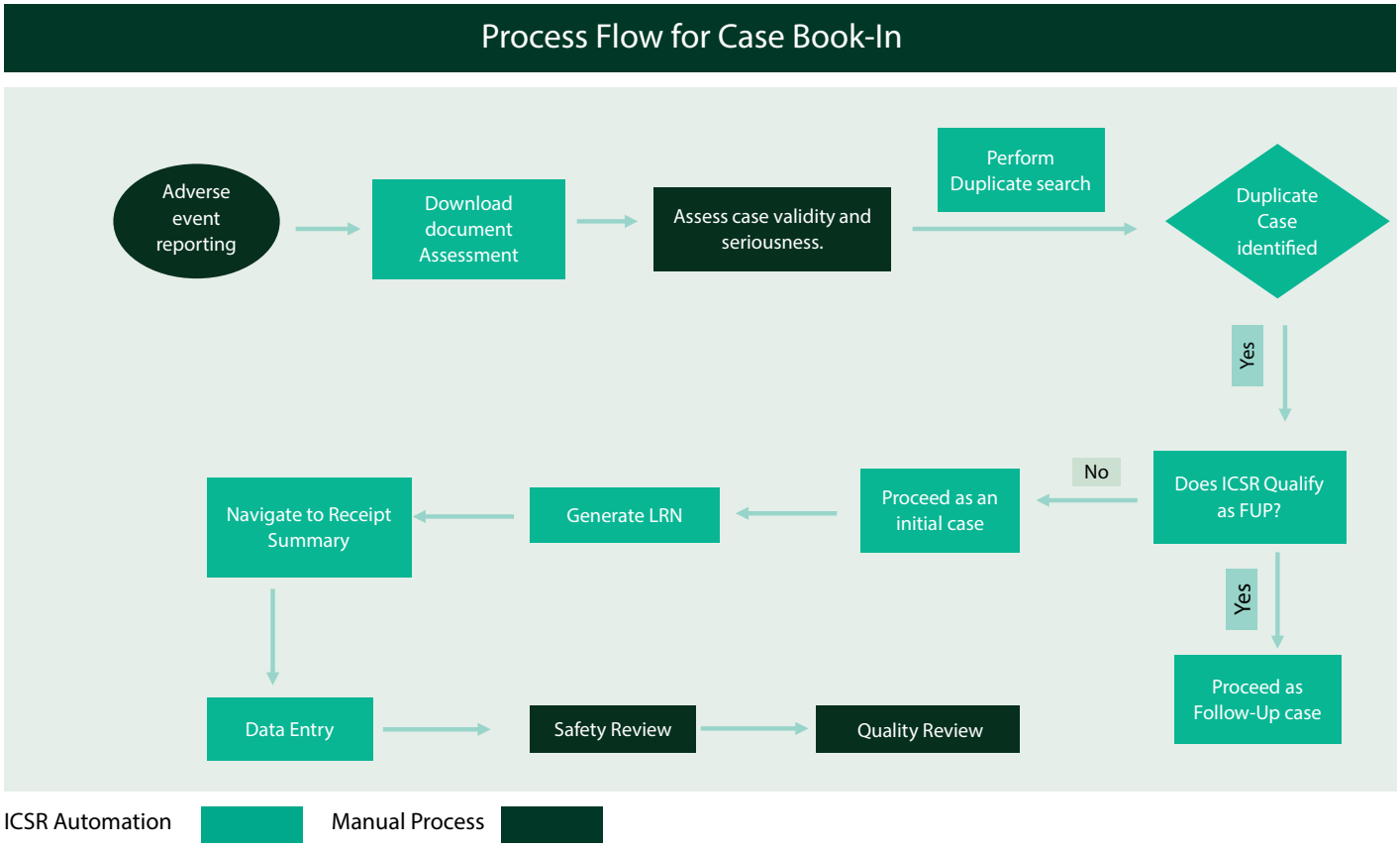


Fig.6 Process Flow for Case Book-In

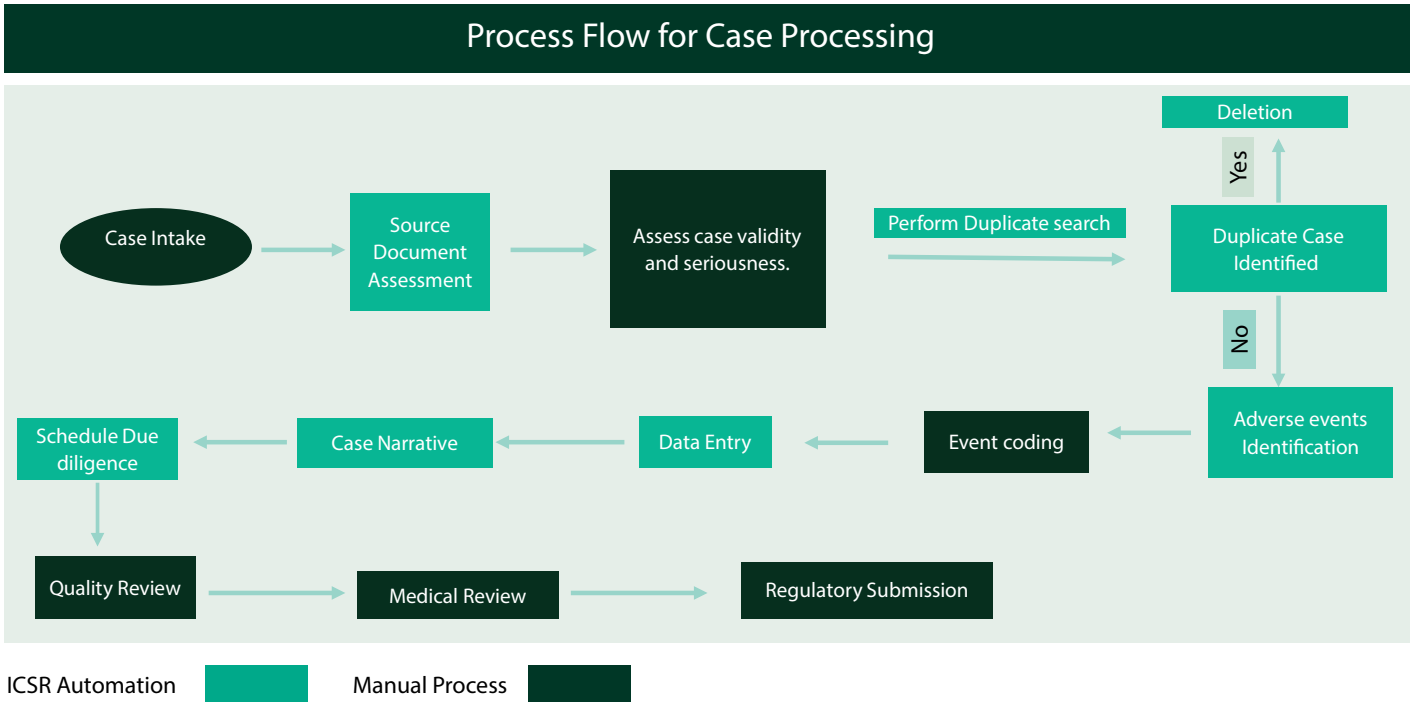


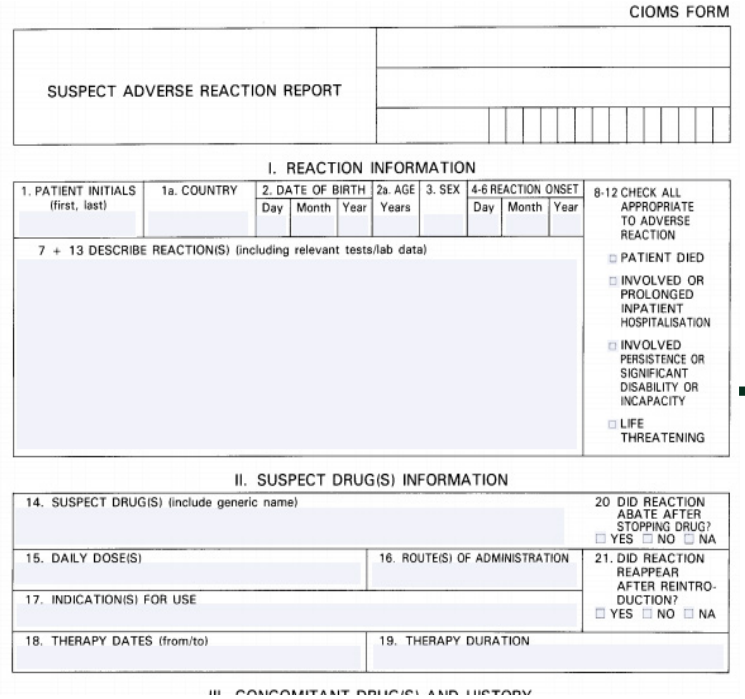
Fig. 7 Process Flow for Case Processing

Unstructured to Structured Content

Unstructured Data and Language Translation

- Adverse event data received from patients or social media is very vague and in an unstructured format. To align this information, it is important to analyze the format of the data and convert them in a structured format which can further be easy to automate.
- Automating the data will require two steps:
  - Structure the data and translate the language
  - Automate the structured data set.

Data Structuring



CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

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

II. SUSPECT DRUG(S) INFORMATION

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

III. CONCOMITANT DRUG(S) AND HISTORY

ICH (reporting date)	1/22/2021	1/23/2021	1/24/2021	1/25/2021	Collated
Patient Name	Parvathi	Arshana	Arshana	Parvathi	Parvathi
first	P		A	P	P
last	S		M		S
Street address					
City	Bangalore	Pune	Bangalore	Bangalore	Bangalore
State	KA	MH	MH	KA	KA
Country	India	India	India	India	India
Zip code	12345	411033	411033	411033	411033
Phone	111	111	111	111	111

Fig. 8[1] Data Structuring

Benefits of Structuring the Data

The information received is in a very unstructured format. Case Processor must invest a very good amount of time to analyze this data. Scrolling to multiple documents at once may lead to miss on few information. Parsing/Structuring the data will be beneficial in both, manual as well as automated Case Processing. This will give the Case Processor view of the data in a single table view thus reducing the efforts. Pharmaceutical organizations can therefore be benefitted in reducing cost and gain efficiency leading with better-quality in processing cases which enables meet regulatory compliance.

Conclusion

Pharmaceutical organizations look forward in reducing manual efforts in the existing PV processes. Leveraging automation will optimize human effort and increase efficiency, thus taking the industry forward digitally.

Automation solution which includes Structuring the data (Fig. 8) Automating the manual processing steps in Intake and Case Processing (Fig. 6 & 7) and can then gradually move towards the Data Annotation, NLP, Machine learning and AI.

The average handling time of an ICSR is usually approximately 50 min manually for Solicitated reports. Adopting automation will help save approximately 25-30 minutes and increase case-processing volumes.

Subsequently, we will further discuss on the possible solutions to automate ICSR in our connected whitepapers.

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References

1. CIOMS Form: ICH Form
2. https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/good-pharmacovigilance-practices-Good pharmacovigilance practices | European Medicines Agency (europa.eu)

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