Study on Role and Importance of Pharmacovigilance Software in Pharma

By

Neelam Devi

Dissertation submitted for the partial fulfillment of the

MBA Pharmaceutical Management

Academic year, 2018-2020

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TO WHOMSOEVER MAY CONCERN

This is to certify that Neelam Devi , Student of MBA Pharmaceutical Management from The IIHMR University, Jaipur has undergone internship training atSarjen System from 17/02/2020 to 17/05/2020.

The Candidates has successfully carried out the study assigned to him during internship training and h is approach to the study has been sincere, scientific and analytical.

The Internship is in fulfilment of the course requirements.

I wish him all success in all his future endeavors.

Assit.Dean, Assoc. Professor
The IIHMR University, Jaipur

Dr Sandeep Narula
The IIHMR University, Jaipur

THE IIHMR UNIVERSITY, JAIPUR

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled "Study on role and importance of pharmacovigilance software in Pharma companies" and submitted by (Neelam Devi) IIHMR-U/02/2018-20/0142 under the supervision of Dr Sandeep Narula for the award of MBA in Pharmaceutical Management of the University carried out during the period from 17/02/2020 to 17/05/2020 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other institute or other similar institution of higher learning.

Signature

Content

Preface

Any information is incomplete while not first-
hand expertise regarding it.While the health sector particularly entering into rub of the items is very es sential as its issues square measure complicated and deep unmoving. To manage the issues within the health sector MBA student of pharmaceutical management need to grasp the functioning of the variou s organizations be it non-
public for this purpose thesis of three month is scheduled penned to second year.

For the aim of thesis, I am glad that I got a chance to figure below Sarjen system pvt. Limited as I assum ed, I might get to grasp the functioning of Business development department that equipped the promot ing team the way to tackle their customer.

In the Sarjen System complete dissertation was given to me to find out the Market of pharmacovigilan ce software and the number of Pharma Company using software i.e. moving toward digital ADR repo rting.

Acknowledgement

I would like to express my sincere gratitude towards Sarjen System for selecting me for my dissertation project and allowing me to work on this project and for providing a good working ambience for the successful completion of this project.

I would like to express my sincere gratitude towards my Mentor Dr. Sandeep Narula for his constant support. His guidance and teaching have been of great help during my project.

Finally, I would like to express a special word of gratitude towards Mr. Rohit Jain of Sarjen system Pvt. Ltd . Without his guidance, it wouldn't have been possible for me to look into niche opportunities in my project.

Last but not the least, I would like to express my sincere thanks to my institute IIHMR University for providing me with all kind of support in my dissertation project at Sarjen system.

Neelam Devi

MBA Pharmaceutical Management

IIHMR University, Jaipur

Abstract

From study start up to the study close out, software plays an important role in the clinical research. Sof tware is helpful in reducing the burden of administration and high workload by performing informatio n in a single location. It supports the trails by collaboration between all the research organizations. Co mbination of these software greatly increases the speed and efficiency in managing, maintain, plannin g, performing and reporting of the study data. For clinical trial management certain software, like Op en Clinica, Real-time-
CTMS were used for patient management and requirement, investigator management, regulatory co mpliance at the study site and CRO site. Whereas Pharmacovigilance software like Argus, Aris Globa l, PvEdge are the drug safety data base used during the study also used for reporting of ADR by an orga nization or through the different sources. The PvEdge software is
on demand software that are highly recommended by the pharma as well as CRO.PvEdge is now incre asing its visibility towards educational institute also. PvEdge having the additional module as pharma covigilance Academia module that helps the pharma professionals to understand the workflow of the software. Thus, as pharmaceuticals is moving fast toward the digital platform. The result obtained fro m this report is helpful and informative to understand the software media in pharma world.

Introduction

PV (Pharmacovigilance)is the technological know-how of amassing, tracking, studying, assessing, and evaluating records. The healthcare vendors and p atients at the harmful results of medicinal drugs, biological products, blood products, herbals, vaccine s, clinical gadgets, conventional and complementary medicines record the ADR to the pharma compa ny then it must be reported to the regulatory frame. Maximizing drug safety and retaining public self-assurance has emerge as a large venture increasingly more complex. Pharmaceutical and biotechnolo gy organizations should not most effective screen, but additionally proactively estimate and manipul ate drug threat while a product's lifecycle, from improvement to submit-marketplace. Pharmacovigilance is specially involved with ADRs, which can be drug responses whic h might be noxious and unintended, and which occur at doses normally used for the prophylaxis, diag nosis or remedy of disease, or for the modification of physiological feature. Continuous tracking of dr ug consequences, side results, contraindications, and outright harmful outcomes could result in an ex cessive degree of morbidity, and in some instances, even mortality is important to exploit advantages and reduce risks. No diploma of care and warning at the pre-medical and scientific testing levels can assure absolute safety, while a drug is advertised and prescrib ed to massive populations throughout the U. S. A. And out of doors. Because medical trials contain nu merous heaps of sufferers at maximum, less not unusual side results and ADRs are often unknown on the time a drug enters the market. Post advertising PV uses tools inclusive of facts mining and resea rch of case reviews to become aware of the relationships among tablets and ADRs. The drug regulator y companies have the duty of getting a well-hooked up Pharmacovigilance system to reveal ADRs throughout the drug development phase and lat er throughout the life of a marketed drug. A complex and vital relationship exists between extensive ra nges of partners in the practice of drug protection monitoring which includes authorities, industry, fitn ess care centers, hospitals, academia, scientific and pharmaceutical institutions, poisons records cent ers, health specialists, patients, clients, and media. Sustained collaboration and commitment are critic al if future demanding situations in Pharmacovigilance are to be met that allows you to broaden and fl ourish. Since only a few new drugs had been discovered in India and hardly ever any new drug became launched for the first time in India within the past, there has been no major compulsion to have a robust Pharmacovigilance device to discover ADRs of advertised merchandise. The revel in from the market s where the drug turned into in use for numerous years before its introduction in India, changed into us ed by the organizations and the regulatory groups to assess the protection parameters and take correcti ve movements, such as the withdrawal or banning of the drug in question. The evolution of a brand-new patent regime within the Indian pharmaceutical and biotechnology industries as a Trade-Related Intellectual Property Rights and Services (TRIPS) makes it incumbent upon India to not copy patented merchandise and marketplace them wit hout a license from the innovator business enterprise.

Objective

To identify the role and use of pharmacovigilance software by pharmaceutical company.

Research Methodology

Mode of data collection:

- Study Type –Descriptive Study.
- Type of data – Primary and Secondary data.
- Technique – Online survey of company using the pharma software.
- Data collection-
  Secondary data is collected through company and primary data collected through the calling s urvey technique.
- Sample size – Indian company 500.
- Study Timeline – Three month (Feb2020-May2020).
- Data Analysis tool – MS Excel

Literature Review

- An open search for relevant articles was undertaken in MEDLINE (the PubMed database) and ninety google search using key words like "pharmacovigilance", "spontaneous reporting", "ADR reporting",92"adverse drug reaction reporting", "under reporting of ADRs", "spontaneous A DR reporting system"93and "India"; with their corresponding MeSH terms if any, joined by OR or AND op erators where94applicable.The articles obtained from the reference list of the preliminary search wer e used tofurther gather relevant articles using what is referred to as the snow ball technique. No search filters were96used but the articles were limited to the ones published in English Language. Themes emerging from97the literature search for both obstacles as well as possible solutions were characterized into distinct nighty eight categories. We did not use any predetermined categories for analysis and allowed incorporati on of99relevant themes and issues emerging from the search to provide a more comprehensive understanding100of the context and processes linked to the problem.
- The articles published from 2003 to 2011was included with the subject of the establishment of accepting ADR reports submitted by patients directly to NCAs. Articles published prior to 2003 were not included, because at that time any of the European countries actively supported the collection of ADR submitted by patients. To meet the inclusion criteria, the articles had to be prospective or retrospective studies, which investigated ADR reports submitted by HPs an d patients to NCAs established in the European MSs. Detected articles should compare one of

the following criteria: reporter age and gender, most frequently reported ADRs and/or drugs, and the seriousness of the ADRs.

- The articles based on the analysis of reports from PVPI or patients were excluded, to achieve the most uniform data dedicated to the comparison of reports from both sources. Reviews or meta-analyses were not included, as the main objective is to provide an overview of the studies concerned with the direct comparison of ADR reports from Healthcare professionals and patients.

Data Analysis and Interpretation:

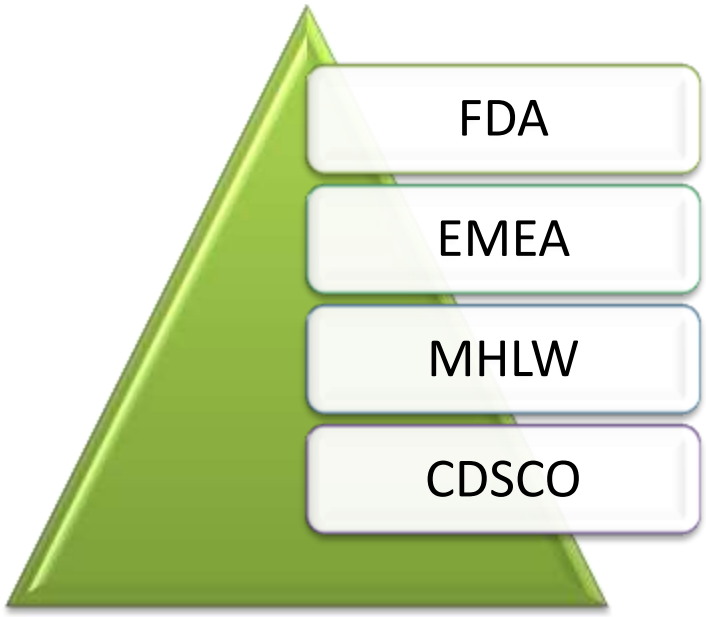
Analysis and interpretation of data has been carried out to deduce the conclusion with the aid of appropriate statistical tools.

Clinical Trials in India:

Global pharmaceutical corporations has discovered India to be a preferred vacation spot for clinical trials due to the fact India's scientific research area and opportunities.

As consistent with a latest document from the Federation of Indian Chambers of Commerce and Industry (FICCI), clinical visibility, scientificvisualisation , scientific trial revel in, rules, commercialisation ability, price competitive are a number of the rising drivers chargeable for the complete change of Indian medical research in pevious year. Indian-born settlement studies companies (CROs) had a ability to provide a blessings of know-how the Indian have a bettersituation, offer services at more competitive charges, and having a higher knowledge of Investigator sites within the us of a in comparison to the more modern entrants in the marketplace. India's favorable regulatory framework and policies withthe international requirements, increasing focus of top medical exercise pointers, and its implementation via clinicians are some of the primary motives propelling the increase of medical studies in India. The therapeutic area-sensible distribution of medical trials and the availability of various affected person population throughout predominant therapeuticarea India.

Agencies involves for clinical Research Regulation in India



FDA: Food and drug Administration.

EMEA: European Medicines Agency.

MHLW: Ministry of health, Labor and welfare JAPAN.

CDSCO: Central Drug Standard Control Organization.

AUTHORITIES OF NCC PvPI

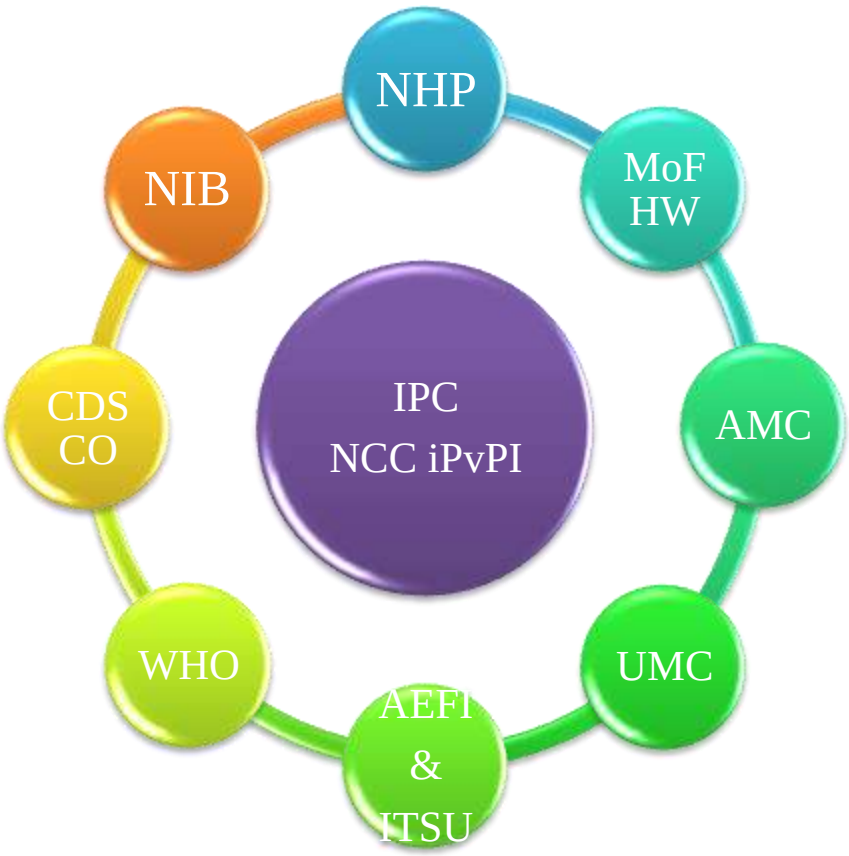


Fig: - Coordination of various authorities of NCC PvPI

Importance of pharmacovigilance

- Thalidomide tragedy (1961-sixty-two): the best of everydrugs disaster.
- Thalidomide has was introduced as a secure and powerful Hypnotic and Antiemetic. It hastily comes to be popular for the remedy of nausea and vomiting in early pregnancy.
- Through this the drugs proved to be an effective human affective antigen that brought about the fundamental delivery defects in estimated 10,000 kids.
- Phocomelia changed into characteristic capabilities.
- The Sulfanilamide tragedy:
- Elixir sulfanilamide was an improperly prepared sulfanilamide medicinal drug that p

urpose mass poisoning in the United States in
1937. It motives the dying of more than a hundred human beings.

- The thalidomide catastrophe led, to be harful in Europe
- These technique found and require that a new drug plan should be certified via well-reputated regulatory authorities earlier than brought in scientific uses.

Pharma company report all the ADR in their data base.

System of adverse drug reaction reporting.

Things to be Report – PvPI encourages all varieties of suspectes ADRs reporting whether they may be Unknown, Serious or Non-
serious rare no matter an established causal dating between drug and the reaction. ADRs related with t he use of allopathy drugs, vaccines, conventional drug treatments, clinical devices, contrast media, an d so forth. All this will be reported.

- Any Life-threatening occasions or death.
- Patient at a risk of hospitalization
- Congenital anomaly
- Medically considerable occasion (If the occasion is taken into consideration extreme with the aid of doctor)
- Lack of efficacy linked with the use of a medical device or drug product

At what time to Report -

- All suddencases have to be suggested within ten days.
- All existing ADR ought to be stated as soon as viable due to the fact over-reporting is usually better than under-reporting.
- The death event need to be pronounced as early as possible, whileevery other severe ADR/event needs to report inside seven days only.
- All non-critical cases should be suggested within thirty days.

Person that can report-The individuals working in healthcare team are theassingsource of information in PV.

- Medical Professional.
- Pharmacists
- Dentist.
- Midwives Along with HCPs patient, patient's relatives, the witness or any common person after medical confirmation can also report.

Regulatory to report-
All healthcare and patient/consumers can report ADRs to Authorized regulatory bodies. For IndiaiC DSCO.

Following are the services that enhancingPV Activity in India

The
helplinefacilityassistance of ADR reporting considering using telecommunication and speak to conn ect in India, PvPI-NCC released a helpline number in wide variety (one hundred eighty 3024) on eleven October
2014 that enables to increases the participation of the patients, stakeholders and publics in ADR repor ting. That created cognizance and stepped forward facts collected from all components of the united st ates of America, which was very tough formerly. After receiving the ADR records anacknowledgmen tandmessage use to drop to the sender. This messaging facility may creates a high-quality effect and builds self-
assurance in public which ensures honest and timely reporting of ADR for reinforcing drug safety.

The Android mobile application is also there for ADR reporting:Majorly in developing nations because of the loss of simple availability and smooth-
floating procedures effects in below-reporting of ADR which is an extreme subject.As we know India is developing at a quicker charge in the IT zone thatis an excellent opportunity to make use of pu blic health. India has 1.33 billion populations out of which approximately seventy-seven.58% of people are using mobile telephones and getting records
on a single click. Considering the large internet connectivity, it became greater suitable to introduce t he idea of reporting and verbal exchange of ADR with PvPI, stakeholders, and population via smartph ones. For smooth and quicker reporting of ADR, NCC PvPI had developed a cell app in association wi th Netaji Subhash Chandra Bose Medical College, Jabalpur, on 22 May
2015. This approach becomes a lot inspiring to several Clinical Research Organizations or groups to c reate and very own consumer-pleasant ADR reporting app and web sites.

Response form for HCPs: A comments shape from the HCPs is gathered at the PvPI to make sure the easy jogging of PV activities. HCPs may write their views, issues, and tips to the PV authority by using filling a prescribed shape possibility at the legit internet site.

Response form for consumer: Some non-public companies have the shape of the comment
on their legit websites for customers. Consumers can at once document ADR, guidelines, and some ot her problems associated with the product via filling the shape of a respective remark, through email, o r put up.

Drug Safety data reporting of marketed product: Periodic protection update reviews purveying is a provision to test the safety of advertised products. In India, it's miles compulsory for Marketing A uthorization Holders (MAHs) to submit PSUR to CDSCO two times a year for two
years.In December 2015 the representatives from MAHs, CDSCO, and NCC-PvPI.Thesee authority participated in an interactive session
on Review of PSURs/Post Marketing Surveillance records and PV Planning of Marketed Products he ld at New Delhi. The aim of this assembly turned into to beautify the participation of MAHs in PPI.

ADR reporting form in multi languages:InIndia multi-linguistic masses oflanguages isspoken in India. Due to this reason, flexibility in the language is needed to ease the method of ADR r eporting. The final purpose of the PV gadget is to make sure the safety of medicine some of the populat ion. By considering population boom and range, patients or the majority can post ADRs spontaneousl y by way of filling the ideal shape to be had of their handy language. This vernacular language facility became started out on 1 Aug. 2014, at NCC-PvPI. The affected person or his/her consultant/family is promoted to fill the form (Medicines Side Ef fect Reporting form for Consumers" i.e. blue form) or E-mail at pvpi.Compat@gmail.Com. This form is to be had in Hindi, Marathi, Bengali, Kannada, Assamese, O diya, Telugu, Tamil, Malayalam and Gujarati languages and may be downloaded from the legit websi te of IPC www. Ipc.GovIn

Educational courses and training program on PV: For the enhancement of the PV hobby, right schooling, and schooling related to PV pastime du ring the united states is vital. To fulfill these criteria the NCC has recognized nine clinical institutes tha t may offer PV training that's located at the nearby degree particularly in most important cities like Mu mbai, Mysore, Chandigarh, Kolkata, Bhopal, Ahmedabad, Rishikesh, Hyderabad. In addition, a few I ndian universities have adopted PV as a B. Pharmacy situation for you to boost the PV expertise, creat e consciousness, and construct new personnel to beautify drug safety.

Thecollaborationsof Pharma with CDSCO: PvPI is working closely with CDSCO zonal offices and other health authority of India. It takes opinion of NCC before making regulatory decisions. The NCC in collaboration with other nati onal and international organizations promotes safety of medicines.

Collaboration with WHO-Uppsala Monitoring Centre (UMC) and other health authorities: Upsala provides technical support to greater than 130 countries in the world.The final goal of PvPI is to develop excellent PV center in India.This is to find the global scenario and building of good PV system in India, PvPI-NCC is working in association with the WHO-UMC based in Sweden.

PvPI-NCC work in association with following authorities: Drug Controller General of India (DCGI), CDSCO, Department of Biotechnology (DBT), Ministry of Environment and Forests (MOEF), Indian Council of Medical Research (ICMR), Central Bureau of Narcotics (CBN), Ministry of Health and Family Welfare (MHoFW), National Pharmacovigilance Advisory Committee (NPAC), AEFI (An Adverse Event Following Immunization), Immunization Technical Support Unit (ITSU)

PV software

The market for pharmacovigilance software in 2020 and beyond is one that is attempting to catch up to other verticals that have long been disrupted b

y the "death of software". The barriers that were in place such as regulations with a moving target, dru g safety's role as a cost center only, and the difficulty of accessing data are breaking down. The result i s that there are now choices in the pharmacovigilance software market that weren't available just a fe w years ago with potential clients that are more willing than ever to look past the systems of record and focus resources
on building a system of intelligence that will drive pharmacovigilance workflow for years to come.

Vendors focused
on data and analytics can shift the paradigm of pharmacovigilance software and allow the science of p harmacovigilance to advance at a rapid pace. Innovation will come with end users empowered to take advantage of disparate data sources through a modern user experience. New signal detection algorith ms and new, more efficient workflow built
on the cloud and infinitely scalable, will allow drug safety departments to provide actionable contribu tions to all areas of an organization.

Evolution of PV software

The concept of the evolution of software from a "system of record", to a "system of engagement", to a "system of intelligence", is important and has far reaching implications for pharmacovigilance softw are.

A system of engagement evolves beyond handling case processing and storage to providing the capab ility for end-users to engage with those data and engage with other end-
users around those data. Signal management software allows for aggregate signal detection and the ab ility for users to take those data and organize them as they deem appropriate. Systems of engagement c reate efficiencies that lead to cost reductions.

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A system of intelligence connects with other systems and data sources to produce actionable intellige nce. This not only creates efficiency, but also revenue potential. The concept of PV generating revenu e may seem foreign but can occur when the function serves not only its regulatory purpose, but contrib utes to commercial decisions. PV Analytics are a system of intelligence where end users take advanta ge of disparate data sources through a modern user experience.

Licensed data are those data assets that an organization licenses from different vendors. Examples of t hese data include multi-
payer claims, EHR, and social listening. These sources vary widely in structure and use case and can o ften sit in different areas of the organization.

All of these data have different structures, different ontologies and different data dictionaries. These d ifferences make forming linkages and relationships within the data difficult without an extensive data

science effort and an intimate knowledge of all of the data. Even for those companies that could dedica te the budget and resources to this problem, those data would remain powerless without an equally lar ge effort in developing an actionable user-interface.

Modern pharmacovigilance departments are demanding seamless connections between all of their di sparate data corralled in next generation, commercial off-the-shelf platforms with an easy to use front end. And most importantly, they require the analyses of these drug safety data to be agile and flexible, while still maintaining analytical rigor.

Fortunately, off-the-shelf next generation technology is now available for pharmacovigilance departments. Scalable, flexible, and agile platform solutions can make key processes like signal detection, validation and management acc essible and equally scalable to pharmacovigilance departments and services vendors of all sizes.

Many legacy software providers are trying to combat this problem by adding data and analytics suites on top of traditional workflow tools. This is a classic square-peg-in-a-round-hole solution - a band-aide approach that has been insufficient and fails to address the core issue of expanded safety science t asks and responsibilities.

This development isn't surprising. Traditional software providers have products that require months-long implementation processes and multi-million-dollar investments. And with a highly regulated and workflow-dependent industry like pharmacovigilance, there are troves of standard operating procedures in plac e. With competing priorities and strained resources, the seemingly logical (read: easier) approach has been one of quick fixes. Analytic jammed in SOP here... new dataset jam med into an SOP there...

But it's quickly become clear to many drug safety professionals that "quick fixes" aren't working any more. And, even worse, those supposedly quick fixes may actually be stifling true innovation in the in dustry. With modern software-as-a-service and agile approaches to development, it doesn't have to be this way. Forward thinking pharma covigilance departments are realizing this and taking steps today to adapt and move their processes fo rward.

Complex data integrations and modern analytics can't sit on top of traditional workflow tools. In a data-first world, those workflow tools need to be built in and around the data and analytics that drive decisio n making. And, yes, those workflow tools still need to comply with GVP best practice and regulatory r equirements, but they must also allow for the flexibility to continue to expand in the future.

Top PV software in India

- PvEdge
- Oracle Argus Safety
- ArisG
- Oracle Adverse Event Reporting System (AERS)
- ClinTrace
- repClinical
- Vigilanz Dynamic Monitoring System
- AB Cube
- PV works

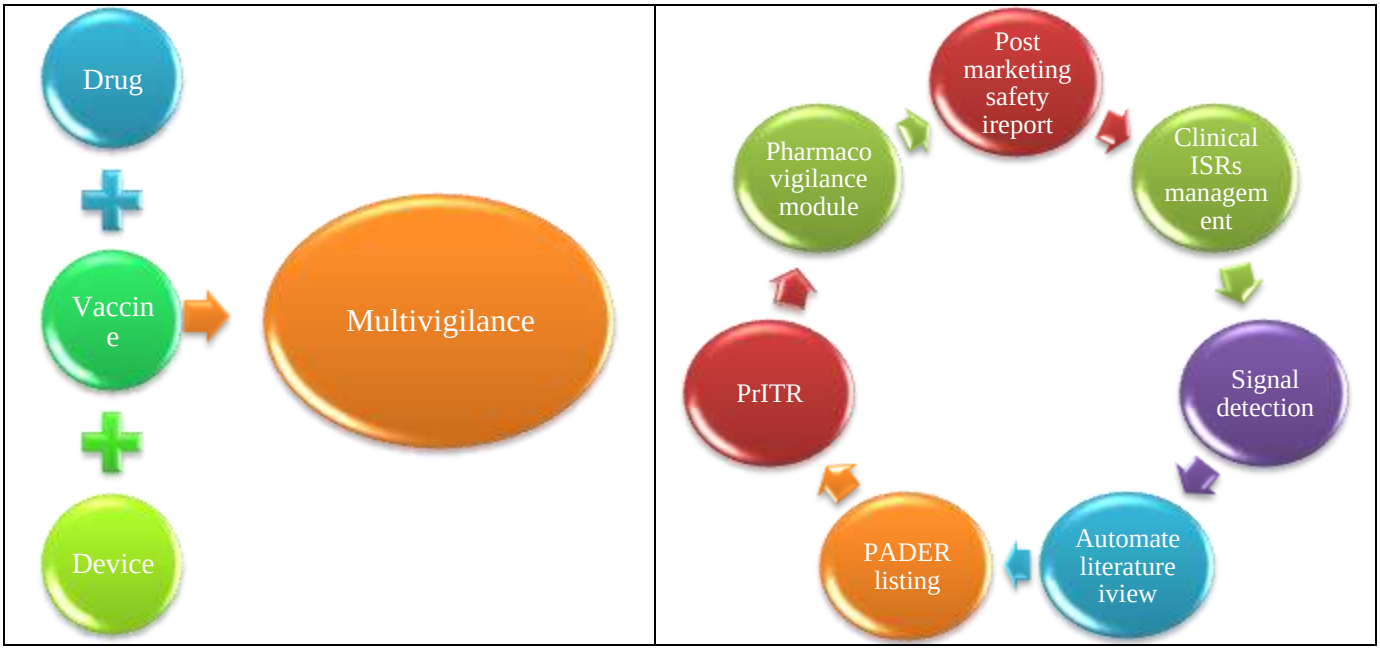
PvEdge

PvEdge drug safety database
which provides comprehensive analyses of adverse events arising from the use of pharmaceutical pro ducts
(Drug, Medical Device or Therapy, Vaccine). It is an advanced Pharmacovigilance solution that help s combat the complexity of the safety data and comprehensively caters to all risk management require ments
on a single platform, ensuring global regulatory compliance. The drug safety database allows the risk -
benefit analysis of medicinal products taking into account new and emerging information, in the cont ext of cumulative information.
Pharmacovigilance since the beginning has been a compliance-
driven activity, wherein your regulatory compliance determines your company's risk assessment sco res. Global regulations are harmonizing towards ICH and PvEdge drug safety database is compliant w ith those ICH E2B R3 and GDPR regulations.
At present, the focus of pharmacovigilance has shifted from passive data collation and reporting to pr oactive pharmacovigilance with greater emphasis on Risk-
Benefit assessments and Signal Detection. PvEdge drug safety database offers complex data analysis and querying of safety data sets, allowing quantitative and qualitative signal detection, resulting in bet ter risk-benefit profiling of drugs.
The extensive features of PvEdge include:

- Workflow which supports to segregate Data Entry, QC and scientific assessment/medical review.
- Extensive data validation and cross-field validation checks – validate case files for E2B compliance.
- Global Dictionary support and Dictionary management (MedDRA version management)

- Audit records for safety data management activities
- Management Dashboard: Delivers dashboard with the ability to focus on relevant domain providing users with the information to draw attention to anomalies and outliers, making it possible for them to take actions quickly.
- Serious Adverse event automated narrative writing & multi lingual text support
- Duplicate case checking
- Centralized triage prior to full case processing
  PvEdge also has add on modules through which additional features can be added to it.
  PvEdge has been developed not only to record the adverse events but also analyze and generate variou s regulatory reports, such as:
- E2B.
- CIOMS.
- MedWatch.
- ICH approved periodic reports including PSURs, bridging reports and other annual report.

Solution



PrITR:

(Product Inquiry Trial Response System)

An efficient module to get hold of technique, evaluate, and document all product-precise inquiries, Medical records inquiry, and product fine criticism along with adverse occasion because of PCQ about worldwide compliance.

Amidst the complexities of the sort of product statistics received, it's miles certainly a challenge to preserve song history of the info touching on distinctive product inquiries, including the sort of product inquiry and in which location should it's appropriately categorized. In the modern-day, corporations want to track all the product relevant records, which we may term as Pro-pharmacovigilance in aid of pharmacovigilance and cope with all kinds of the purchaser and health care professional problems which have widely been segregated as inquiries. This includes, but isn't limited to:

•Product inquiry inclusive of inquiry on categorized data, a well-known query from the customer, Lack of efficacy facts e.g.: Probable emergence of a resistant strain to an anti-microbial, allergic reaction of any nature, Misuse/abuse of the product.

•Medical information inquiry: Question of healthcare professionals on drug usage method, question on drug package deal leaflet, and many others.

•Product complaints.

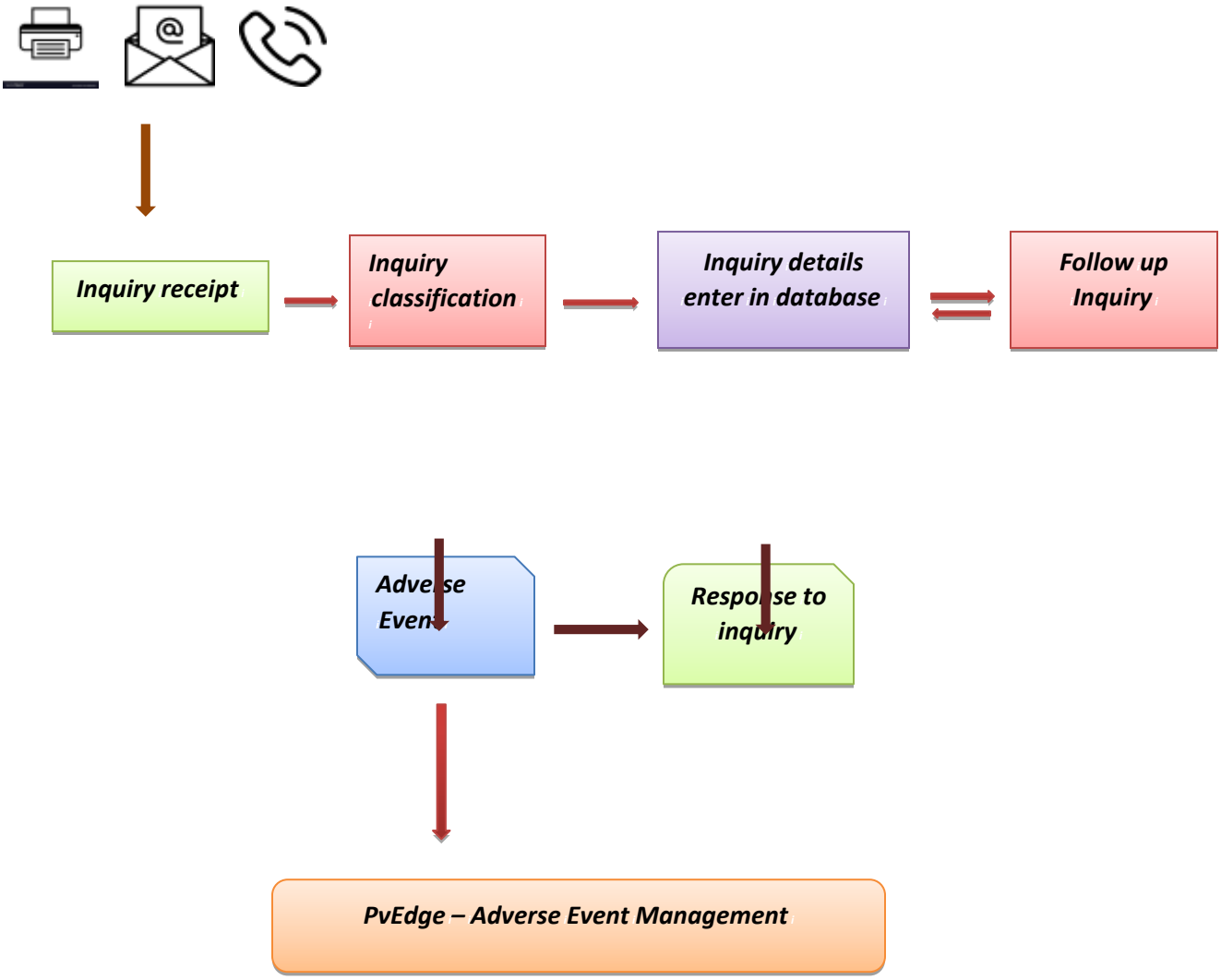
•Adverse occasions after drug consumption/administration together with medication blunders, overdose, off label use or loss of efficacy.

•Other inquiries: Any other preferred inquiry that doesn't fall inside the above standards.

Examples include:

- Equipment that is damaged or broken.
- Physical defect in packaged form of the product.
- Broken needles.
- If the labels are missing.
- If the customeris inableto administer the product.
- Products with totally different color, appearance, or particles.
- Any user error.

Workflow and Functionality of PrITR



PrITR: Product inquiry Trial and Response system

Progression in Pharmacovigilance departments

Progression 1:

The use of new data sources have been constrained by limitations on how to implement novel methods without disrupting traditional signal detection, validation, and management work flow. Analyzing these data in siloes creates a "can't see the forest for the trees" scenario where the isolated insights that may be generated only make it to a departmental slide deck, a conference abstract, or, at best, a journal publication rather than to a place of real operational benefit.

In order to properly operationalize these data in for pharmacovigilance workflow, the silos need to be broken down. To do this the data must be:

1) Characterized and the limitations understood;

2) Linked together.

3) Presented in a way that makes them actionable.

Safety data can be categorized into three buckets: company owned, curated, and licensed data. Company owned data include those captured in a clinical safety database or the data that are received from spontaneous post-marketing reporting and are stored in internal databases.

Vendor curated data include FDA Adverse Event Reporting System (FAERS), WHO's Vigibase, and the various unstructured data that exist, such as clinical study results that are published in government registries like clinicaltrials.gov or found in publications, abstracts, and poster presentations.

Licensed data are those data assets that an organization licenses from different vendors. Examples of these data include multi-payer claims, EHR, and social listening. These sources vary widely in structure and use case and can often sit in different areas of the organization.

All of these data have different structures, different ontologies and different data dictionaries. These differences make forming linkages and relationships within the data difficult without an extensive data science effort and an intimate knowledge of all of the data. Even for those companies that could dedicate the budget and resources to this problem, those data would remain powerless without an equally large effort in developing an actionable user-interface.

Modern pharmacovigilance departments are demanding seamless connections between all of their disparate data corralled in next generation, commercial off-the-shelf platforms with an easy to use front end. And most importantly, they require the analyses of these drug safety data to be agile and flexible, while still maintaining analytical rigor.

Progression 2:

In a resource constrained,environment,pharmacovigilancedepartments are trying to leverage technology to work smarter and act bigger.

Most pharmacovigilance departments are resource constrained. Whether its human capital, budget, or bot h, drug safety specialists within pharmaceutical companies are being asked to do a lot more with very little .

In a resource constricted environment, organizations must work smarter to achieve near and long-term goals.

With little, new off-the-shelf technology being introduced for pharmacovigilance departments, "working smarter" has meant cre ating in-house solutions using spreadsheets or outsourcing key processes.
Maintaining an audit ready process with spreadsheets is not scalable and outsourcing has limitations. Wh en outsourced contractors use large legacy software solutions, the restrictions on types of reports and limitations on how data can be viewed and manipulated can severely restrict how a pharmacovigilance department op erates and supports the organization.

When the weight of these restrictions become too much, the only choice has been for the pharmacovigilan ce department to turn to large legacy software solutions. But this choice has significant cost and implemen tation consequences that can more than offset the advantages.

Fortunately, off-the-shelf next generation technology is now available for pharmacovigilance departments. Scalable, flexible, and agile platform solutions can make key processes like signal detection, validation and management acc essible and equally scalable to pharmacovigilance departments and services vendors of all sizes.

Progression 3:

In response to new data sources agile, flexible approaches todata, ana lytics, and workflow are in high demand.

Modern pharmacovigilance departments today do more than process and review ICSRs. They are inv olved in the entire lifecycle of a drug, providing vital data points and analysis that inform everything fr om clinical trial design to commercial planning to post-market safety surveillance. In order to perform well, pharmacovigilance and safety science teams req uire access to an array of data and the analytics to make sense of those data. The insights gained from u nique combinations of clinical and real-world data can drive signal detection, epidemiological research, and evidence generation, all of whic h support organization-wide decisions.

However, achieving that goal is not easy.
With multiple platforms and tools contracted into various departments, simply knowing who holds th e access for one of the numerous available data sources is hard to discover. When the data are finally o btained, complex and outdated user interfaces make the analysis tasks much more difficult than they s hould be.

Many legacy software providers are trying to combat this problem by adding data and analytics suites on top of traditional workflow tools. This is a classic square-peg-in-a-round-hole solution - a band-aide approach that has been insufficient and fails to address the core issue of expanded safety science t asks and responsibilities.

This development isn't surprising. Traditional software providers have products that require months-long implementation processes and multi-million-dollar investments. And with a highly regulated and workflow-dependent industry like pharmacovigilance, there are troves of standard operating procedures in plac e. With competing priorities and strained resources, the seemingly logical (read: easier) approach has been one of quick fixes. Analytic jammed in SOP here... new dataset jammed into an SOP there...

But it's quickly become clear to many drug safety professionals that "quick fixes" aren't working any more. And, even worse, those supposedly quick fixes may actually be stifling true innovation in the in dustry. With modern software-as-a-service and agile approaches to development, it doesn't have to be this way. Forward thinking pharma covigilance departments are realizing this and taking steps today to adapt and move their processes fo rward.

Complex data integrations and modern analytics can't sit on top of traditional workflow tools. In a data-first world, those workflow tools need to be built in and around the data and analytics that drive decisio n making. And, yes, those workflow tools still need to comply with GVP best practice and regulatory r equirements, but they must also allow for the flexibility to continue to expand in the future.

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- **ADR Reporting**

Fig.1

The study revealed that the reporting of ADRs is highly done by physician. Relatively lower reporting was done by pharmacist and other HCP also contribute in reporting of ADR. The reporting rate of pharmacists was low as compared to physicians because in India, the system of distribution does not leave much scope for the pharmacists to be a significant source of ADRs reporting. Similarly, even though nurses are in closer contact with the patients for a longer duration, in the event of ADRs observed by the nursing staff, it would be reported to the treating physician, who in turn if deemed appropriate, communicates the information to the relevant higher authorities.

- **Delivering Mode.**

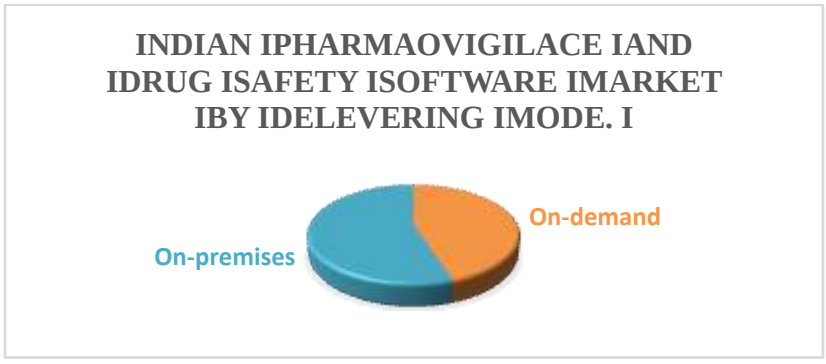

Fig.2

The software is working highly on On-demand and On-premises bases and showing positive response by the users. The data is fully secure by cloud bases storage.

- **Reporting Centre of ADR**

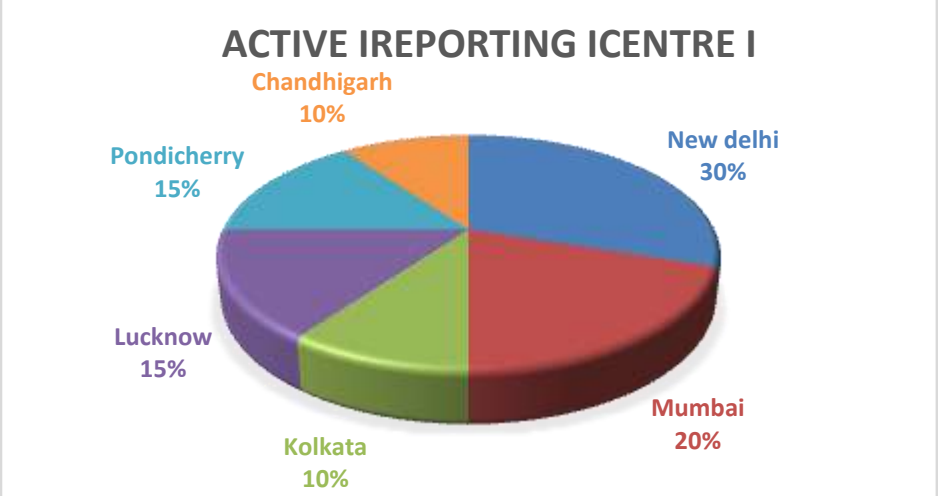

Fig.3

In India six regional center for reporting of ADR is set up. Of these six Centre New Delhi and Mumbai is highly active and reporting of ADR is high

- **Software having high demand**

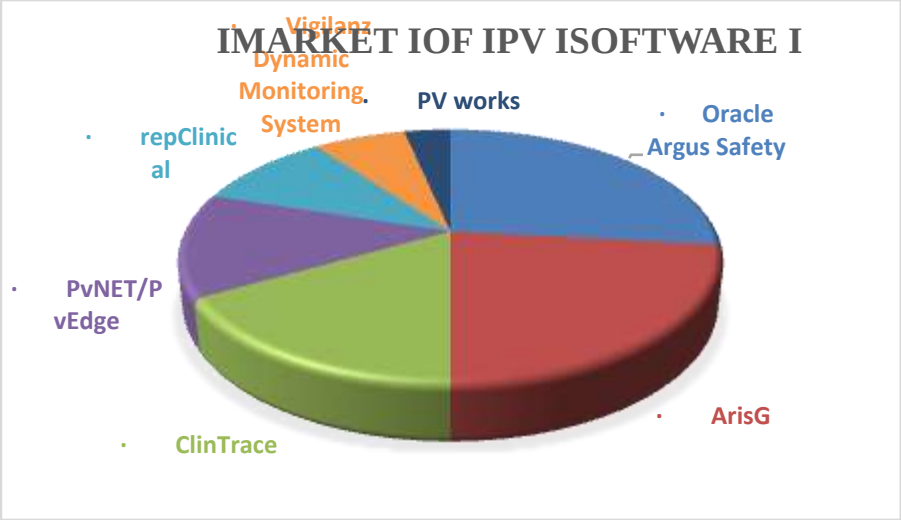

Fig.4

The study report find that Oracle Argus Safety is a high demand PV software and also recommended a nd used by most of the pharma as well as CROs.

Conclusion:

The study may conclude that the pharmaceutical company are using pharmacovigilance software at a high rate with moving year. The market growth of PV software is 6.4% i.e. from 2019 - 2020.The PV software. Currently
so many pharmacovigilance centers are working for drug safety monitor
on global level. The PV software reduces administrative burden and workload by consolidating infor mation at a single platform. Through PV software the data generated is of persistent quality and play a significant role in the outcome of the study. India is now consider to be a hub of clinical research. More and more clinical trials are being conducted in India now. The study may suggested that IT sector is w orking on large scale of delivery of software to Pharma company. The software PvEdge is on high demand as it is cost effective software
so company like Cadila, Intas pharma is currently using the software. The pharmacovigilance softwar e make the ease in reporting of reporting the ADR

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