Dissertation Project

Organization – Sarjen Systems Pvt.Ltd .

IIHMR University.

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MBA PM 10

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Company Profile

- Company Name- Sarjen Systems Pvt.Ltd.
- Business Type – Business Technology.
- Founder – Nikur Mody.
- Key strengths, Focus Areas- Business applications, Data Analytics, Enterprise Mobility, Cloud Computing, Machine Learning
  - Software Consulting Company since
  - Team of 200+ members
  - Global delivery model with active customers in 50+ countries - ISO 9001:2015 certified
  - Microsoft Gold/Azure Certified Partner
  - SAP Practices and implementation
  - Proficient in web technologies
  - Native and hybrid mobility solutions on Android, iOS, Windows platforms
  - Software for Industry niche: Pharmaceuticals, Life sciences, clinical research, FMCG
- Address- Office No. 601, 6th Floor, Arista-The Business Hub Near Rahul Tower Cross, Anand Nagar Road, Satellite Ahmedabad GJ 380015 IN

Title:

To study the roles and importance of Pharmacovigilance software in Pharma and Healthcare industry.

Project Summary

- Starting from study start up to study close out, software plays an important role in clinical research. Software helps in reducing the burden of administration and high workload by performing information in a single location. It supports the trails by facilitating the collaboration between all the research organizations. Integration of these software greatly enhances the speed and efficiency in managing, maintain, planning, performing and reporting of the study data. For clinical trial management certain software, like,, were used for patient management and recuirement, investigator management, regulatory compliance at the study site and CRO site. Whereas Pharmacovigilance software like Argus, ArisGlobal, PvEdge are the drug safety data base used during the study also used for reporting of ADR by an organization 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 increasing its visibility towards educational institute also. PvEdge having the additional module as pharmacovigilance 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 from this report is helpful and informative to understand the software media in pharma world.

Introduction?

What is Pharmacovigilance ?

The World Health Organization (WHO) describes pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. This includes:

- ❑ – Collection and Evaluation of spontaneous case reports of suspected adverse events
- ❑ – Pharmacoepidemiology studies (ICH 2004).

Terminology in Pharmacovigilance

Adverse drug Reaction (ADR)

A response to a medicine which is noxious and unintended, and which occurs at doses normally used in man

Adverse drug Event (ADE)

Any untoward medical occurrence that may present during treatment with a medicine but which does not necessarily have a casual relationship with this treatment.

Side effects (SE)

Any unintended effect of pharmaceutical product occurring at doses normally used by patients which is related to pharmacological properties of drug.

Unexpected Adverse Drug Reaction

An adverse, the nature or severity of which is not consistent with domestic labelling or market authorization or expected from characteristics of the drug

Serious Adverse Drug/Reaction

- Untoward medical occurrence that at any dose:
- Result in death
- Require inpatients hospitalization of existing hospitalization
- Result in persistent or significant disability.
- Is life-threatening

Pharmacovigilance Process

1. Detecting and Response an ADR

- ADR form is filled out with the patient and reaction details in the prescribed format

❑Spontaneous reporting

❑Mandatory reporting

Spontaneous Reporting

- Most common form for ADR reporting
- Healthcare professional identify and report any suspected adverse drug reaction to their National Pharmacovigilance Centers

Mandatory reporting

- Manufacturing are required to submit reports they receive from healthcare providers to the National Authority, in the form of a **PSUR(Periodic Safety Update Report)**
- A regulatory document prepared by Marketing authority holder and submitted to the Agency

Who can report ADR

Pharmacist

Doctors

Manufacturer

Dentist

Nurse

Others

PvEdge

PvEdge drug safety database provides comprehensive analyses of adverse events arising from the use of pharmaceutical products (Drug, Medical Device or Therapy, Vaccine). It is an advanced Pharmacovigilance solution that helps combat the complexity of the safety data and comprehensively caters to all risk management requirements 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 context of cumulative information.

Research methodology

- SECONDARY RESEARCH
- Secondary Research Information is collected from a number of publicly available as well as paid databases. Public sources involve publications by different associations and governments, annual reports and statements of companies, white papers and research publications by recognized industry experts and renowned academia etc. Paid data sources include third party authentic industry databases.

- PRIMARY RESEARCH
- Once data collection is done through secondary research, primary interviews are conducted with different stakeholders across the value chain like manufacturers, distributors, ingredient/input suppliers, end customers and other key opinion leaders of the industry. Primary research is used both to validate the data points obtained from secondary research and to fill in the data gaps after secondary research.

Study Type –Descriptive Study.

Type of data – Primary and Secondary data.

Technique– Online survey of company using the pharma software.

Sample size – Indian company 500.

Study Timeline – Three month (Feb2020-May2020).

Data Analysis tool – MS Excel

Data Analysis and Interpretation

PV software

- In recent years, the rapid development of “big data analytics” has created a surge within pharmaceutical companies to leverage data from the entire value chain to drive actionable insights. Although other departments within pharmaceutical companies have long been focused on utilizing data driven insights, modern pharmacovigilance departments are just starting to fully incorporate a data-and-analytics-first approach to signal detection, validation, and management.

Top software for PV

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

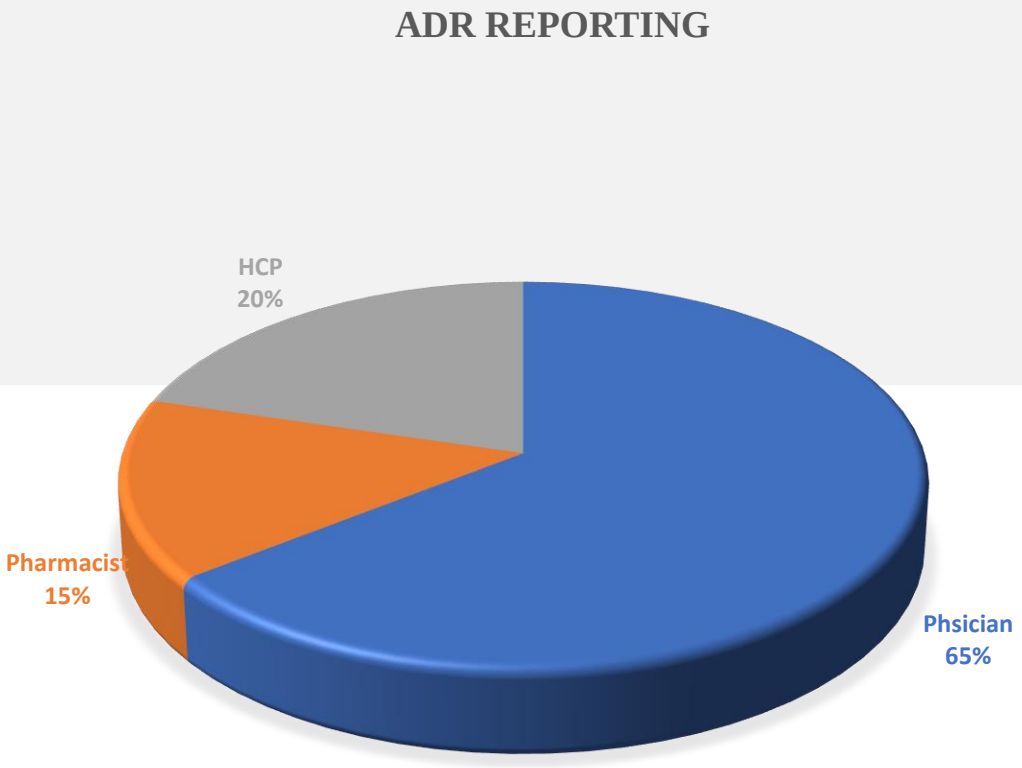
Trends in pharmacovigilance software

1.Pharmacovigilance departments want to use new data sources but are finding it hard to operationalize them all.

2.In a resource constrained environment pharmacovigilance departments are trying to leverage technology to work smarter and act bigger.

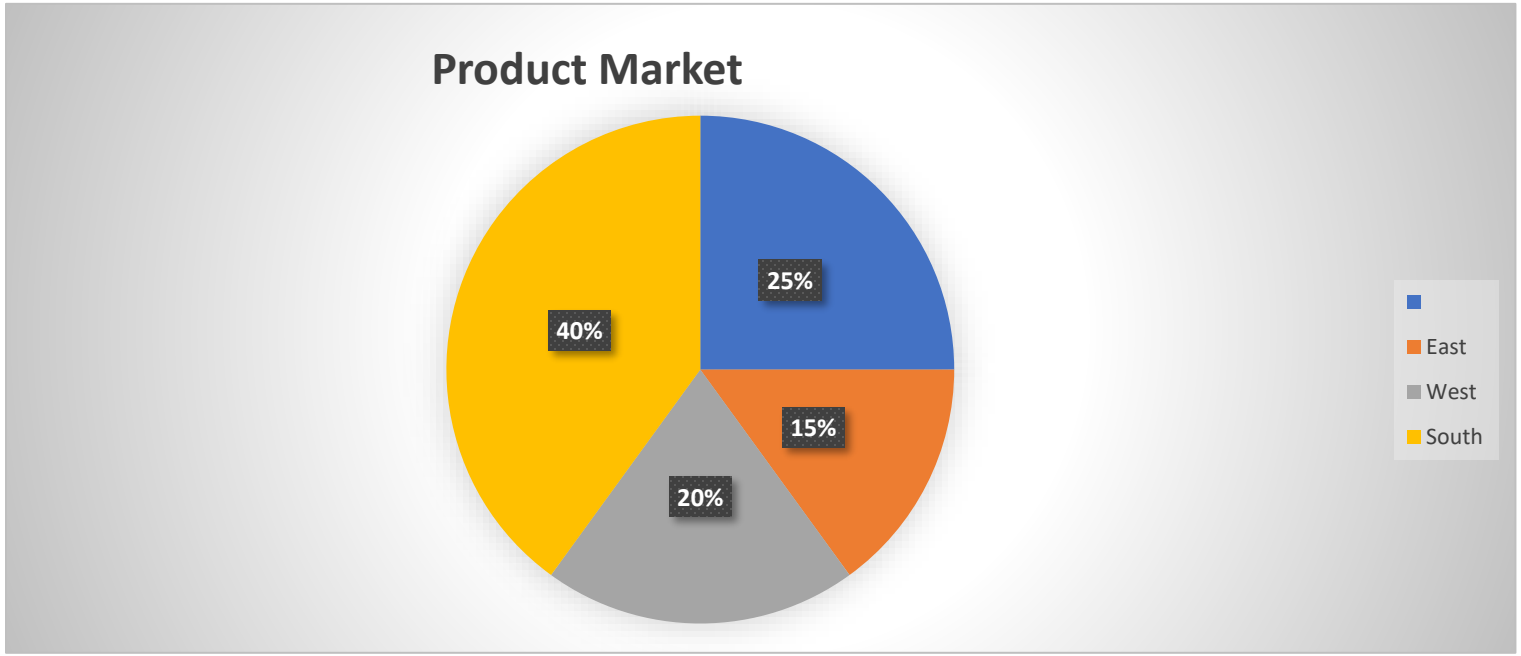
3.In response to new data sources agile, flexible approaches to data, analytics, and workflow are in high demand.

ADR reporting



- 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.

Product Market

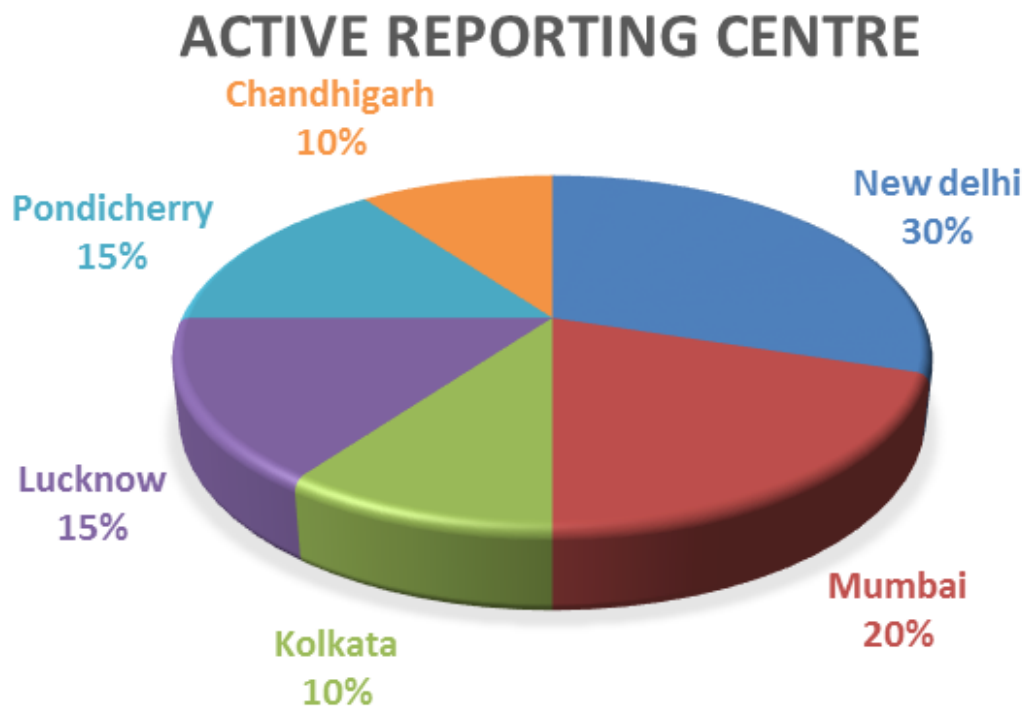


- The data may represent the market of PvEdge is 40% in South ,25 %in North, 15% in East and 20 % in west .
- The Product having a huge market in South region market. The data interpret that because of large number of Clinical research organization and pharmaceuticals organization is based in south region,this lead to provide high business in that area.

Delivering Mode.

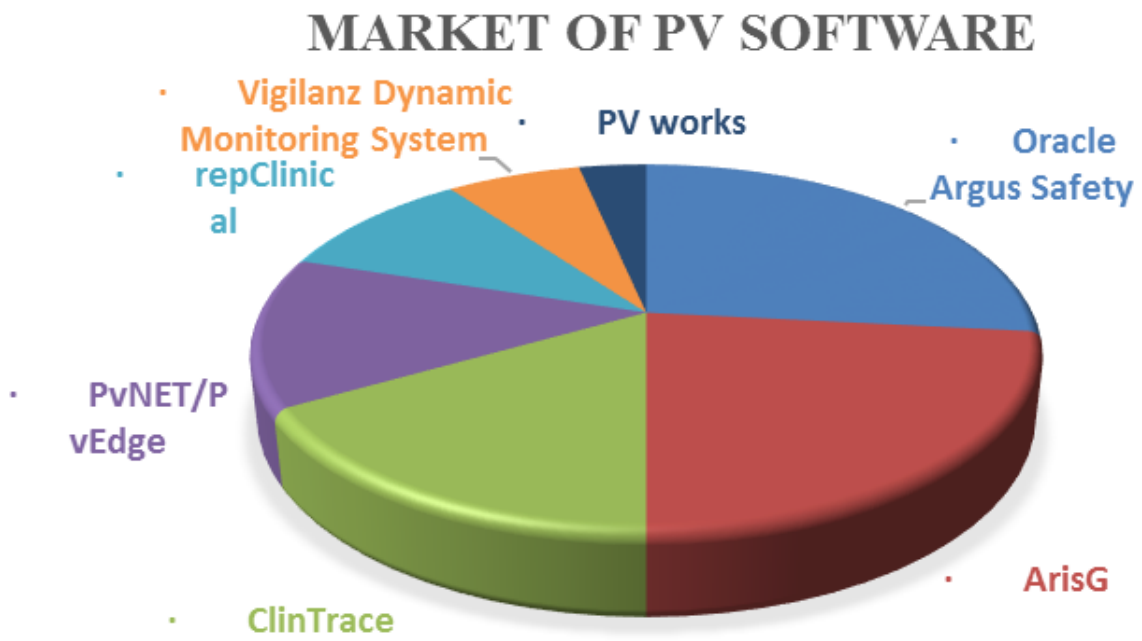
- The software is working highly on On-demand/cloud base and On-premises bases and showing positive response by the users. The data is fully secure by cloud bases storage

Reporting Centre of ADR



- 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.

Market driver



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SWOT Analysis

- **Strengths**
- Cost effective service – 1/7 of Labor cost.
- Rapidly growing and efficient talent pool of pharma, CRO.
- Efficient communication skill set.
- Automated literature report generated
- Readymade PSUR template with periodic data
- **Weakness**
- Brand awareness is low
- Brand loyalty is low
- Lack of pharma knowledge
- Team collaboration/communication
- **Opportunities**
- Exponential growth of pharmaceutical industry promoting necessity of an extensive PV systems
- Pandemic situation may create a demand of cost effective system .
- **Threat**
- High work load
- Limited understanding of global regulation
- Market drivers
- New emerging PV software market (Europe, china, South America, Eastern Europe)

Tactics and Plan

Executional Planning

- **Advertising and PR**

  Regular Update about the Product

  Newsletter Update

  PV website sharing

  High value content

  Short video of product

  Mass mailing

- **Target Audience**

  Pharma organization

  Clinical research Organization

  Pharma Institute

  Pharmacovigilance Institute

  FMCG

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.Currently so many pharmacovigilance centers are working for drug safety monitor on global level. The PV software reduces administrative burden and workload by consolidating information 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 working 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 software make the ease in reporting of reporting the ADR.

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- Thank you