RXLOGIX,Noida
Associate Business Quality Analyst

Major Project report submitted in partial fulfilment of the requirement for the degree of Bachelor of Technology

in

Computer Science and Engineering

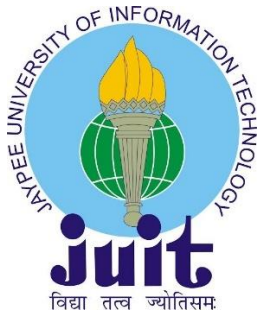
By

Pradyuman Sharma(181335)

UNDER THE SUPERVISION OF

Mr. Deepak Agarwal

To



Department of Computer Science & Engineering and Information Technology

Jaypee University of Information Technology Waknaghat, Solan-173234,

Himachal Pradesh, INDIA

CANDIDATE DECLARATION

I hereby declare that the work presented in this report entitled **"Pradyuman Sharma"** in partial fulfilment of the requirements for the award of the degree of **Bachelor of Technology** in **Computer Science and Engineering** submitted in the department of Computer Science & Engineering and Information Technology**,** Jaypee University of Information Technology Waknaghat is an authentic record of my own work carried out under the supervision of **(Mr. Deepak Agarwal)** (Associate Director, Professional Services).

The matter embodied in the report has not been submitted for the award of any other degree or diploma.

Pradyuman Sharma
181335

This is to certify that the above statement made by the candidate is true to the best of my knowledge.

Supervisor Name: Mr. Deepak Agarwal

Designation: Associate Director

Department: Professional Services

Dated: 28-05-2022

CERTIFICATE

This is to certify that the work which is being presented in the internship report titled **"Rxlogix,Noida "** in partial fulfilment of the requirements for the award of the degree of B.Tech in Computer Science And Engineering and submitted to the Department of Computer Science And Engineering, Jaypee University of Information Technology, Waknaghat, is an authentic record of work carried out by **Pradyuman Sharma** during the said period; February 2022 – till date, ensuring proper care towards the rules and regulations as specified by the Non-Disclosure Agreement signed between Pradyuman Sharma and Rxlogix, Noida, Uttar Pradesh dated 7th February, 2022.

Pradyuman Sharma (181335)

This is to certify that the above statement made by the candidate is true to the best of my knowledge.

REPORT UNDERTAKING

I, Pradyuman Sharma, 181335, (B.Tech- Computer Science and Engineering) currently pursuing my internship with Rxlogix from 07th February, 2022 to July, 2022.

As per procedure I must submit my internship report to the university, related to my work that I have done during this internship.

I have compiled my internship report, but due to COVID-19 situation procedure being followed, my mentor in the company is not able to sign this report and no digital signatures are allowed as part of the company's confidentiality policy.

So, I hereby declare that the internship report is fully designed/developed by me, and no part of the work is borrowed or purchased from any agency. And I'll produce a certificate/document of my internship completion with the company to the Training and Placement Cell whenever COVID-19 situation gets normal.

Pradyuman Sharma

181335

ACKNOWLEDGEMENT

Firstly, I am so gratefulness to Almighty God and thankful for his divine gracethat made it possible to successfully complete the project work in a smooth way.

I am grateful and wish my profound indebtedness to Supervisor Mr. Deepak Agarwal. Deep Knowledge & keen interest of my supervisors in their respective fields to carry out this project. Their endless patience, scholarly guidance, continual encouragement, constant and energetic supervision, constructive criticism, valuable advice, reading many inferior drafts and correcting them at all stages have made it possible to complete this project.

I would like to express my heartiest gratitude and thankful to **Mr. Deepak Agarwal**

I would also generously thank each of the individuals who have helped me continuously and straightforwardly or in a roundabout way to make this project a success. In this odd and strange situation, I also want to thank thevarious staff individuals, both educating and non-educating, which have developed their convenient help and facilitated my undertaking.

Pradyuman Sharma

181335

Table of Content

S. No.	Chapter	Page No.
1.	Introduction	5-10
2.	Literature Survey	11-12
3.	System Development	12-39
4.	Performance Analysis	40-44
5.	Conclusions	45
6.	References	46

INDEX

Figure(i)	Github code search
Figure(ii)	Notepad++
Figure(iii)	SQL Loader
Figure(iv)	SQL Developer
Figure(v)	Company Products
Figure(vi)	PV Report Template
Figure(vii)	PV Publisher Template
Figure(viii)	PV Signal Template
Figure(ix)	PV Risk Manager Template
Figure(x)	PV Central Template
Figure(xi)	PV Quality Template
Figure(xii)	Framework of PVD
Figure(xiii)	Flow of Data
Figure(xiv)	PL/SQL
Figure(xv)	PL/SQL Datatypes
Figure(xvi)	PL/SQL Architecture
Figure(xvii)	PL/SQL Body
Figure(xviii)	Cases Process in ETL
Figure(xix)	Steps to INCR ETL
Figure(xx)	Steps to INIT ETL
Figure(xxi)	Table master
Figure(xxii)	Column master
Figure(xxiii)	Column mapping
Figure(xxiv)	Field Group
Figure(xxv)	Terminology in Source

Chapter-1 INTRODUCTION

1.1 Introduction

The speed and volume of clinical research to discover effective drug against novel corona virus has been remarkable. To address the unmet medical need, the regulations are made flexible and convenient without any relaxation in drug safety reporting. The pharmacovigilance activities, especially adverse event reporting regardless of clinical trials or clinical practice should continue as usual because patient safety is the priority. The exposure to experimental drugs with limited evidence of risk - benefit makes it more crucial to adapt robust safety monitoring, accuracy in adverse event reporting, and timely assessment. With the current restriction on physical contact, travel and free movements, isolation, quarantine, and huge clinical workload during pandemic, causality assessment will be more challenging. It may not be possible to capture details of all adverse events, thereby affecting completeness and quality of safety reports. A substantial number of COVID 19 patients will receive investigational drugs along with multiple other medications for clinical manifestations and drug therapy for lifestyle diseases. Causality assessment will be a challenge due to overlapping toxicities, multiple confounding, contributory factors, and insufficient data on safety and risk profile of combining drugs. Assessment will be unable to precisely determine the causality as certain or unlikely, although, it will be valuable in categorizing the causal association as “possible” adverse drug reactions and their scientific basis. Several of these detailed reports, when collated, can identify risk factors for possibilities of prevention or avoid harm. In the current situation of pandemic and uncertainty of experimental new and old repurposed drugs, causation needs to be viewed for the study drug with a public health perspective. After all, this is the best time-tested approach to generate evidence and drug evaluation to prevent damage to prospective patients.

1.2 Problem Statement

Not a single event over the last century has had such an impact on human life, such as the COVID-19 pandemic. It is a devastating serious public health risk, hard and at times scary. Unfortunately, there is not a single drug treatment with proven efficacy, and almost all drugs being tested are repurposed and used on compassionate ground.

The world is desperate to find ways to slow the spread of the novel coronavirus and discover game changer. Interestingly, a web search term COVID 19 clinical trials revealed the ever-increasing number of clinical trials registered across the globe. To address this unmet medical need, the central regulatory authorities in India immediately announced fast track review and approval process for all clinical trial applications for COVID 19 drugs and vaccine. Moreover, the new norms of social distancing and lockdown during pandemic may not facilitate the conventional methods of data collection. Recognizing the impact on various clinical trials related activities, the central regulatory authorities allowed sponsors, investigators, and ethics committee to modify the conduct of trial, considering the participants' safety, decide mutually on case-to-case basis and emphasized the use of the electronic system. These notifications made the clinical trial process flexible and convenient in this extraordinary vulnerable situation.

Although the regulators acknowledge the challenges involved, there is no relaxation in drug safety reporting. The pharmacovigilance activities, especially clinical safety reports, should continue as usual because patient safety is the priority. This indicates that the show must go on without any compromise on patient safety, compliance with good clinical practice, and trial integrity.

About pharmaceutical Industries

Develops, produces, and markets drugs or pharmaceuticals licensed for use as medications
• What makes this industry unique is:
– *Research*
• Drug discovery is the process by which potential drugs are discovered or designed
– *Regulations*
• Laws and regulations regarding the patenting, testing and ensuring safety and efficacy and marketing of drugs
– *Ethics*
• Healthcare is in a unique position balancing profit and the public good
– *Economics*

• **Largest of any industry**
• in 2014, global spending on prescription drugs topped $1 Trillion and seen at 1.5 trillion in 2021.
• US is the Largest market – 1/3rd of global pharmaceutical market ($374 billion in annual sales)

• **Why we need drugs:**
– Treatment of disease
– Diagnosis of a disease
– Prevention of a disease
– Enhance body function
• A disease is a particular abnormal condition, a disorder of a structure or function, that affects part or all of an organism. Disease is often construed as a medical condition associated with specific symptoms and signs. It can be
– Pathogenic (infection)
– Hereditary (genetic disorder)
– Deficiency (malnourishment)
– Physiological (asthma, stress)

1.3 Objectives

In view of the enthusiasm, urgency, and rush to find out effective drug treatment and vaccine for COVID 19, the question is, how do we ensure the safety? Several new and old drugs ranging from anti-malaria to anti-viral and immune modulators with the potential effect on novel coronavirus are being deployed, tested for clinical care and research. The use of drugs on compassionate grounds, exposing the participants to the investigational product with limited evidence of risk-benefit makes it more vital to adapt robust safety monitoring, adverse event reporting, and assessment. However, majority of the trials during pandemic are primarily designed to define clinical benefits and outcomes with less attention to adverse events and safety aspects. On the other hand, there is no acceptable gold standard study design to determine a true drug safety issue. Hence, various heterogeneous sources such as randomized controlled clinical trials, real-time observational studies or spontaneous adverse event reports are used for safety assessment. This will help the policymakers to decide to continue or discontinue the use of the proposed drug(s) in clinical care and research. Therefore, it becomes the collective responsibility to ensure and support the collection of drug safety data for timely review, causality assessment and real-time signal detection. Although this will be an opportunity for pharmacovigilance experts, clinicians, and regulators to collaborate, assessment of suspected adverse event reports, especially causality appraisal, will be a difficult task.

The basic essence of the pharmacovigilance and suspected adverse event reports is to detect the risk profile of the drug at the earliest and identify the population at risk. The assessment of safety reports comprises evaluation of probability (causal association or link) of the relationship between exposure to medicine and the occurrence of adverse events. The essential primary step is to suspect an adverse drug event (a causal link) and then "prove or disprove it." Conventionally, the enthusiasm for the assessment depends on the seriousness of the adverse event, the need of subsequent actions to either patient(s), modify prescribing information (regulatory) and undertake further confirmatory studies. Formal algorithms and statistical methods are available for causality assessment, although, WHO-UMC and Naranjo Probability scale are widely used and internationally accepted for an objective assessment. The assessment criteria are based upon some specific features of the event of interest including time relationship between drug administration and appearance of the event, pharmacological characteristics of the suspected drug (pharmacokinetic and pharmacodynamic actions), medical plausibility (clinical presentation and supporting investigations), likelihood or exclusion of other causes, de-challenge information and re-challenge, if done. Besides these, clinical judgment by experts is also essential. Conventionally, causation is done with respect to the patient treated; however, in the current situation of pandemic and uncertainty of experimental new and old repurposed drugs, it needs to be viewed for the study drug with a public health perspective. In fact, causality assessment during pandemic is more crucial as the causation results will help in early identification of drug-related harm and prevent at–risk patients from exposure.

1.4 Methodology

However, causality assessment in pharmacovigilance is a challenging and time-consuming task. The complex nature of adverse events, wide variations in clinical manifestations, background frequency of the adverse event, characteristic of the disease process, and use of multiple drugs with the same temporal sequence, etc., are some of the factors that may not facilitate the analysis. With the current restriction on physical contact, travel and free movements, isolation, and quarantine during pandemic, it will be even more challenging. It may not be possible to capture details of all events, thereby affecting completeness and quality of safety reports. Possibly, these reports may lack the essential data with missing mandatory items like full description such as onset, characteristics, and time course of the adverse event. Second, the suspicion is usually retrospective and desired baseline laboratory investigations are often not available. In case the patient is treated on outdoor basis, the de-challenge and outcome details are missing. Application of algorithms and assessment of these incomplete drug safety reports will be practically impossible.

The adverse reactions due to the drug may vary from mild symptoms to serious life-threatening or significant medical event and can be rare or common. The time relationship between intervention and appearance of adverse event is vital criterion. An adverse event immediately after the drug therapy establishes a strong causal association while an AE after a long latent period can be missed, requires long-term follow-up, adequate resources, and expertise for safety evaluation. Adverse events with high background frequency, especially fever, cough, pneumonia at times of crisis also poses a challenge. In addition, there can be multiple contributing factors for drug-induced adverse events. The use of concomitant drugs with overlapping toxicities, pre-existing medical conditions/co-morbidities, elderly patients, alcoholics, are possibly either contributory or confounding factors. This requires a careful evaluation to what extent each of these factors contributes to the occurrence of adverse events. Baseline laboratory tests and investigations along with monitoring at regular intervals will certainly facilitate assessment by excluding the potential alternative causes. In light of the huge clinical workload and lack of systematic monitoring during the pandemic, only a team of proactive professionals strictly following the treatment protocols will capture the details. The hue and cry for the use of hydroxychloroquine for COVID 19 patients have been the best example. The effect of hydroxychloroquine on QTc interval is also shared by concomitant drugs (antimicrobials, antiviral, antifungal, diuretics, etc.,) and electrolyte disturbances. Nonavailability of specific diagnostic tests and critical details will make the causal assessment inconspicuous. Conversely, simultaneous withdrawals of all the suspected drugs with overlapping toxicities in case of an adverse event, de-challenge criteria become irrelevant. While re-challenge is unethical and never attempted to prove causality. Unique drug-induced effect also known as phenomenological reaction (S. J. Syndrome or acute dystonia) are rare; therefore, it becomes imperative to look for alternative causes for considering causal relationships. Further, a substantial number of COVID 19 patients treated for lifestyle diseases will be taking long-term medications along with an experimental drug. Possibly these patients may also receive multiple other medications for associated clinical manifestations. Currently, the data is not sufficient for evaluating the safety and risk profile of combining drugs in such a situation. Furthermore, the proposed COVID 19 drugs (antivirals) are metabolized through cytochrome 3A4 pathway; either substrate or inhibitor may result in significant drug – drug interactions. To better understand these complexities, the specific patient population should be

monitored with prespecified clear questions and objectives using appropriate data collection tools and analytical plan.

Unfortunately, causality assessment by algorithms methods is limited to ascertain causality precisely as “certain” or “unlikely” in the presence of multiple confounding variables. However, they are valuable in the evaluation of causal association as “possible” adverse drug reactions and their scientific basis. Often” possible” is viewed as a downgraded category. However, it means that there is evidence for “reasonable possibility” to suggest a causal relationship between the drug and the adverse event. Several of these detailed reports when collated can identify risk factors for possibilities of prevention or avoid harm. After all, this is the best way to prevent damage to the prospective end users.

1.5 Organization

• **WHO Definition:** Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem

– Together with the WHO Collaborating Centre for International Drug Monitoring, Uppsala WHO
promotes PV at the country level (WHO-UMC). At the end of 2010, 134 countries were part of
the WHO PV Programme.

• PV is undertaken to continuously monitor and evaluate product risk-benefit in an ongoing manner
• For early signal detection - quickly identify new medical risks to patients
• To provide optimal prescribing information and advice
• To comply with regulations, reporting timelines and regulator expectations. To avoid warnings, fines or penalties
• To avoid product liability and legal costs

• To avoid business interruption and product withdrawal

RxLogix is a one-stop-shop for all PV needs applying the most recent technology advances like machine learning, artificial intelligence, and best practice methodological approaches. After a thorough evaluation of commercially available signalling and analytical software vendors, the FDA selected RxLogix’s PV Surveillance Suite Platform, replacing their legacy FAERS signalling system. FDA has decided to implement RxLogix PV Surveillance Suite (Modules – PV Reports, PV Signal, PV Analytics, and PV Datahub) for advanced data analytics, signal detection, evaluation, signal management, and benefit-risk assessment. RxLogix experienced team of business and technology innovators work with Pharmacovigilance and Risk Management Professionals to help increase the compliance, productivity, and quality for the entire Drug Safety value chain thus ensuring patient safety. RxLogix highly values defiant bold thinkers entrenched in the world of science, medicine, and innovation. From a strategic perspective, RxLogix proactively seeks innovative solutions as pre-emptive strikes against second-rate thinking.

RxLogix is a global pharmacovigilance solutions company specializing in innovative software and expert consulting services and is headquartered in Princeton, New Jersey. It's talented team of business and technology innovators work with Pharmacovigilance and Risk Management Professionals to help increase the compliance, productivity, and quality for the entire Drug Safety value chain. It understands that ensuring patient safety while advancing medical and scientific research is vital to life sciences companies. It is defiant bold thinker entrenched in the world of science, medicine, and innovation. It is Digital. It is Health. It is Patient Safety. It proactively seeks innovative solutions as pre-emptive strikes against second rate thinking. RxLogix is your one stop shop for all the PV(Pharmacovigilance) needs.

It provides solutions to the ever-changing drug safety and Pharmacovigilance challenges with real business understanding, solid technical expertise, and an array of streamlining software solutions. It's team of experts has worked closely with the world's leading life sciences companies to deliver innovative solutions time after time.

The software solutions and consulting services assist your Pharmacovigilance and Risk Management departments in working more effectively and efficiently.

RxLogix has implemented and maintained safety and clinical systems in over 50 leading Pharmaceutical, CRO (Contract Research Organization), Biotechnology, and Medical Device Organizations, including Merck, Bayer, BMS, Servier, Outsuka, Quintiles and Oracle.

Chapter -2 LITERATURE SURVEY

Feasibility study is an important phase in the software development process. It enables us to have an assessment of the product being developed. It refers to the feasibility study of the product in terms of outcome of the product, operations required for implementing it. Feasibility study should be performed on the basis of various criterion and parameters. The various Feasibility Studies are:

Economic Feasibility
Operational Feasibility
Technical Feasibility

2.1 Economic Feasibility

It determines whether the required software is capable of generating financial gains for the company. In this, cost benefit analysis is done in which expected costs and benefits are evaluated.

2.2 Operational Feasibility

Operational feasibility assesses the extent to which the required software performs a series of steps to solve business problems and user requirements. This feasibility is dependent on human resources and involves visualizing whether the software will operate after it is developed and be operative once it is installed.

Thus, it is basically concerned with the issues like whether the software will be used effectively if it is developed and implemented.

2.3 Technical Feasibility

Technical feasibility assesses the current resources (hardware and software) and technology which are required to accomplish user requirements in the software within the allocated time and budget. The hardware and software requirements are apt and are available resources. Also, the grant access from the source side must be available so that the data is available on which further manipulations and testing are to be implemented.

Also, the basic values of the company's products are Commitment, Innovation, Expertise and Legacy. So, it truly follows all the values along with providing the best Quality to its clients.

Types of Regulatory Reporting

Expedited Reporting:

– This refers to ICSRs (individual case safety reports) that involve a serious and unlisted event (an event not described in the drug's labelling) that is considered related to the use of the drug.
– In most countries, the timeframe for reporting expedited cases is 7/15 calendar days from the time a drug company receives notification.

Aggregate reporting:

– also known as periodic reporting, plays a key role in the safety assessment of drugs. Aggregate reporting involves the compilation of safety data for a drug over a prolonged period (months or years), as opposed to single-case reporting
which, by definition, involves only individual AE reports.

– The advantage of aggregate reporting is that it provides a broader view of the safety profile of a drug. Worldwide, the most important aggregate report is the Periodic Safety Update Report (PSUR) and Development safety updated report (DSUR).

Chapter-3 SYSTEM DEVELOPMENT

The Pharmaceutical industry is working long before the computers and introduction of tools like Argus Safety. Even before existence of such tools, companies had to report to Regulatory Authorities. So, to report such ADRs Pharmaceutical companies used to send these reports via letters e.g., postcards. Then Fax came into picture, and it replaced the letter system. When computers and IT world was introduced to the pharmaceutical's companies, it completely changed the face of Pharmacovigilance. Now we have tools and electronic transmission of reports. Now even to report any Adverse Reaction electronic means are available. MedWatch 3500 A form can be filled and submitted to either the Companies or directly to the Regulatory Authorities.

Currently, PV System uses Argus Safety, provided by Oracle, and additional tools. New and improved areas of functionality required to meet emerging regulations are not present within the existing system.

The Pharmacovigilance system also needs to be able to receive and handle data from other sources which is emerging as a critical function.

3.1 PROPOSED SYSTEM

Multiple report letters/postcard for cases become unmanageable.
So, E2B reports started for electronic transmission and reduced the paperwork. It made analysing tons of case data easy by means of SQL queries.

The database is maintained which should also be able to determine potential risks and Adverse Reactions for drugs in clinical trials and post marketed products.

PV system can identify the risk and classify the drug as unsafe so that its clinical trials and research can halt before the company has to pay huge amounts of fine to regulatory authorities like US Food and Drug Administration and to protect patient's health.

3.2 REQUIREMENT ANALYSIS

A requirement is a feature of the system or a description of something the system can do in order to fulfil the system purpose. The Software Requirement Specification is a document that contains all the user requirements. The SRS document is used by the software developer, test engineers, project manager and customer.

- It states the functional capabilities that are to be fulfilled,
- Serves as the basis for the performance,
- Serves as a basis for future enhancement.

3.3 REQUIREMENT SPECIFICATION

Installation Qualification:

Installation qualification (IQ) activities consist of verification of the infrastructure and application software installation according to the vendor's requirements. This includes but is not limited to the registration of the hardware and/or software (as required), verification of "As Built Drawings" and review of any installation associated documentation. Successful completion of this section of the protocol will demonstrate that the system's installation is suitable for its intended use.
Installation qualification activities will be performed for both the test and production environments.

3.4 HARDWARE AND SOFTWARE REQUIREMENTS

 Hardware Requirements:
Processor – 1-2 GHz (P4) or onwards
RAM – 8 GB and above
System type – 64-bit Operating System

 Software Requirements:
Operating System - Windows 7 and above
Version Control System - GitHub/GitShell
Database - Oracle 11.2.0.1 Client32
PLSQL/SQL Development - TOAD for Oracle, SQL Developer, Notepad++
Test Management - JIRA

Multiple VPN Connections – Viscosity

GITHUB/GITSHELL

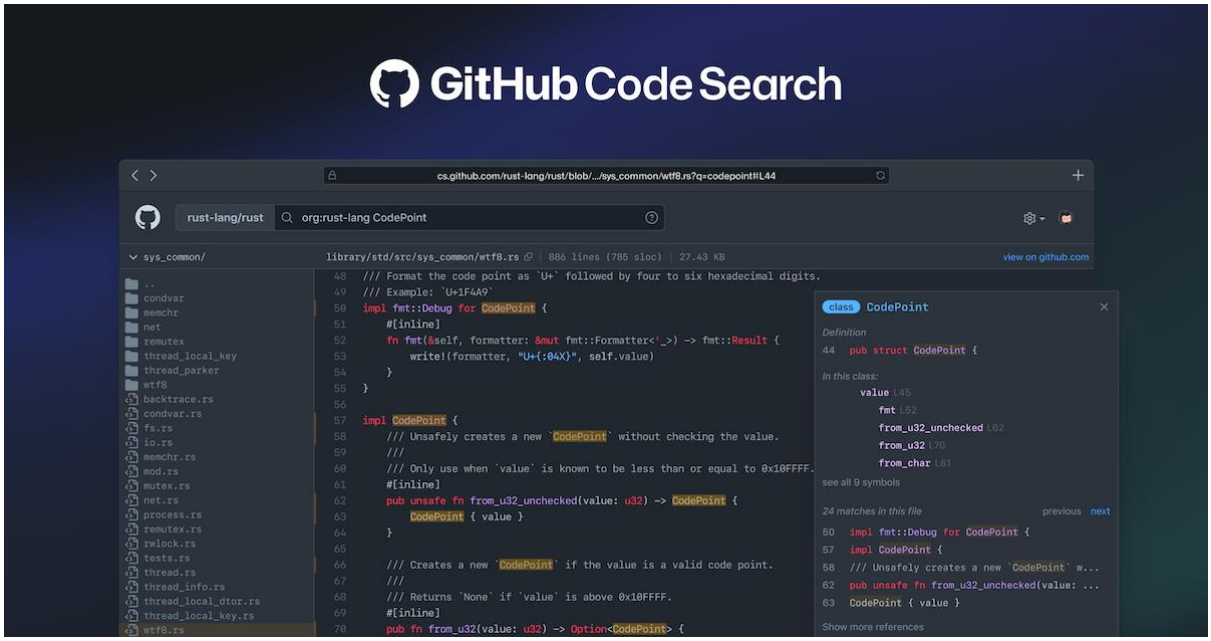


FIGURE (i)

NOTEPAD++

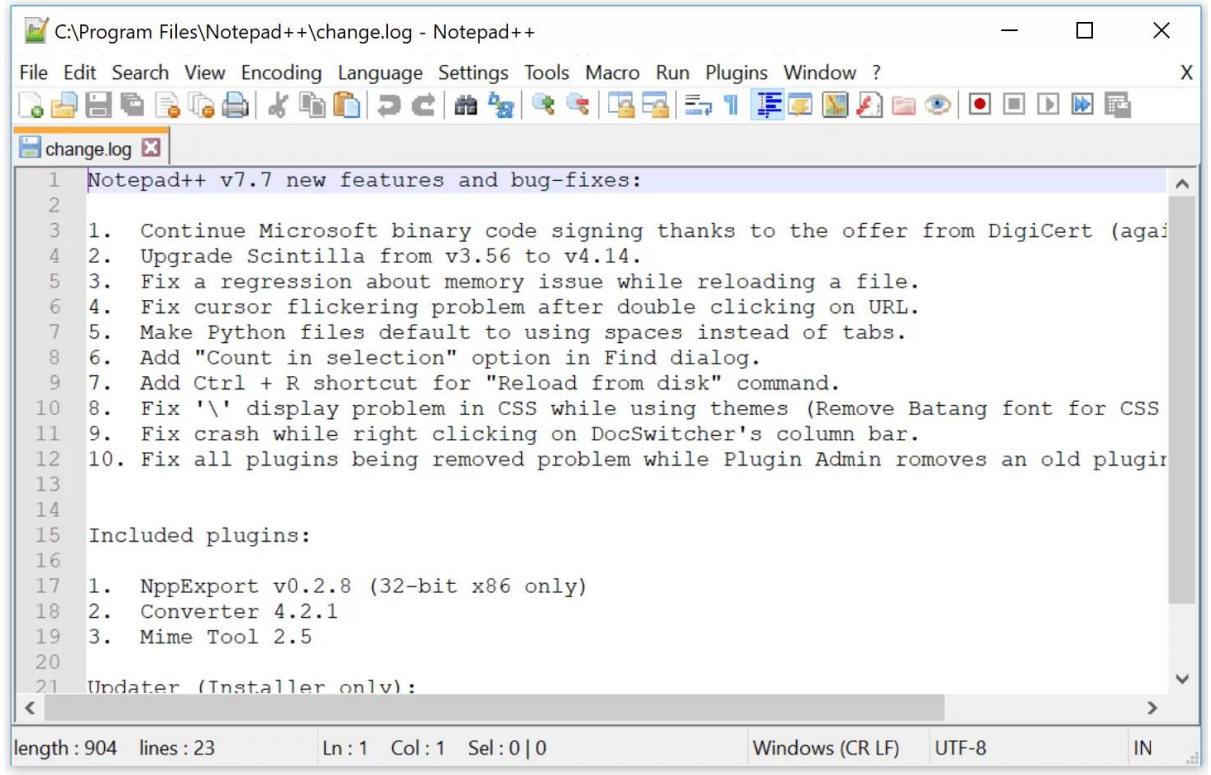


FIGURE (ii)

SQL-LOADER

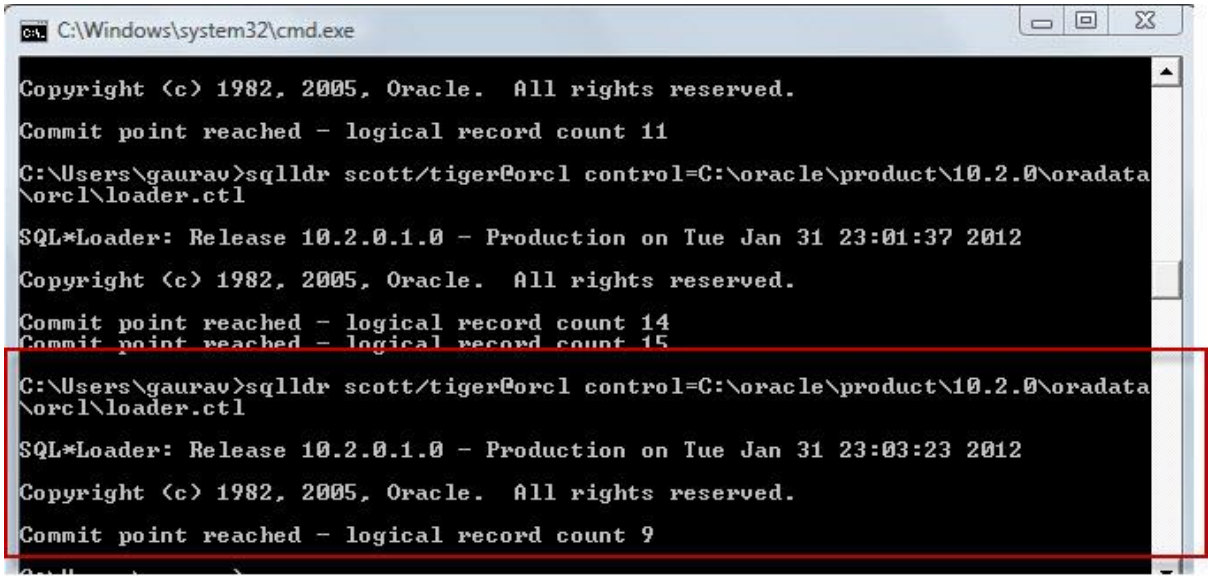


FIGURE (iii)

SQL-DEVELOPER

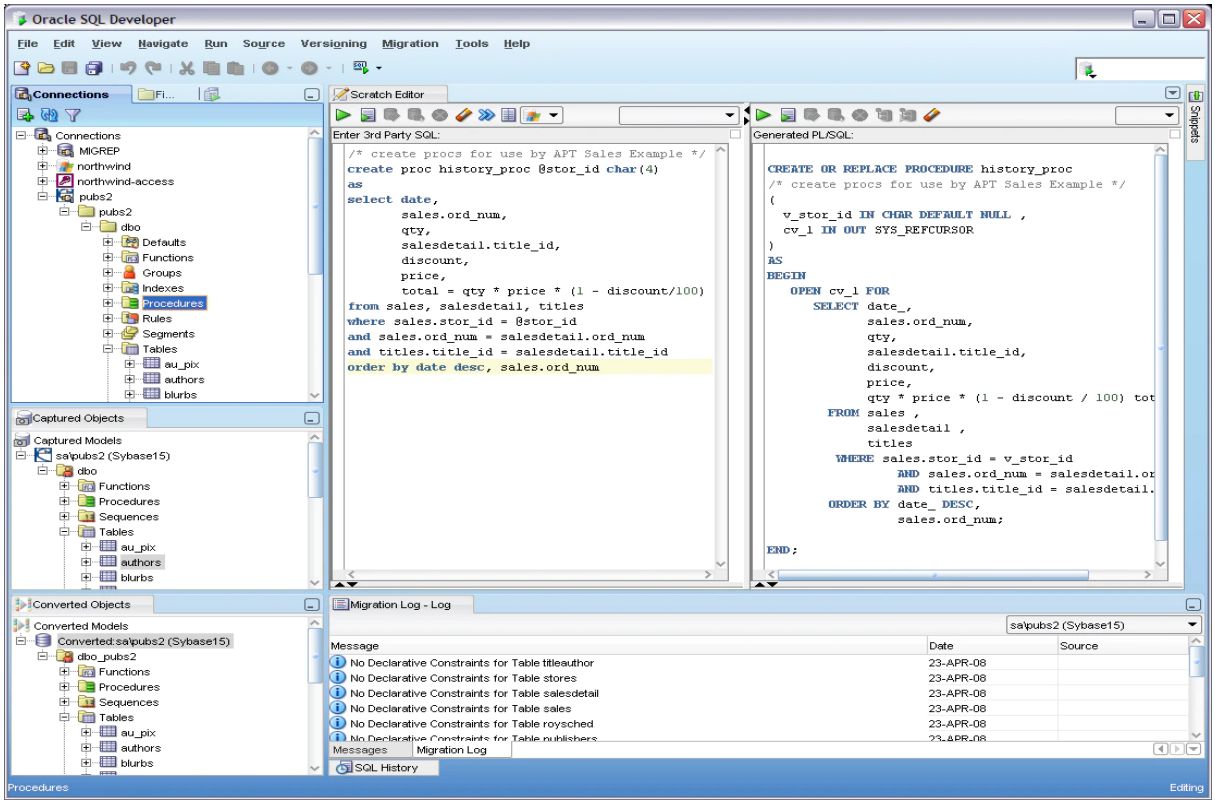


FIGURE (iv)

3.5 ABOUT SYSTEM

PV DATAHUB is an integrated, controlled environment for clinical data that enables life sciences organizations to make decisions based on accurate and timely information.

It is the backbone of all the Rxlogix products i.e., PV Reports, PV Intake, PV Signal, PV Central and many more.

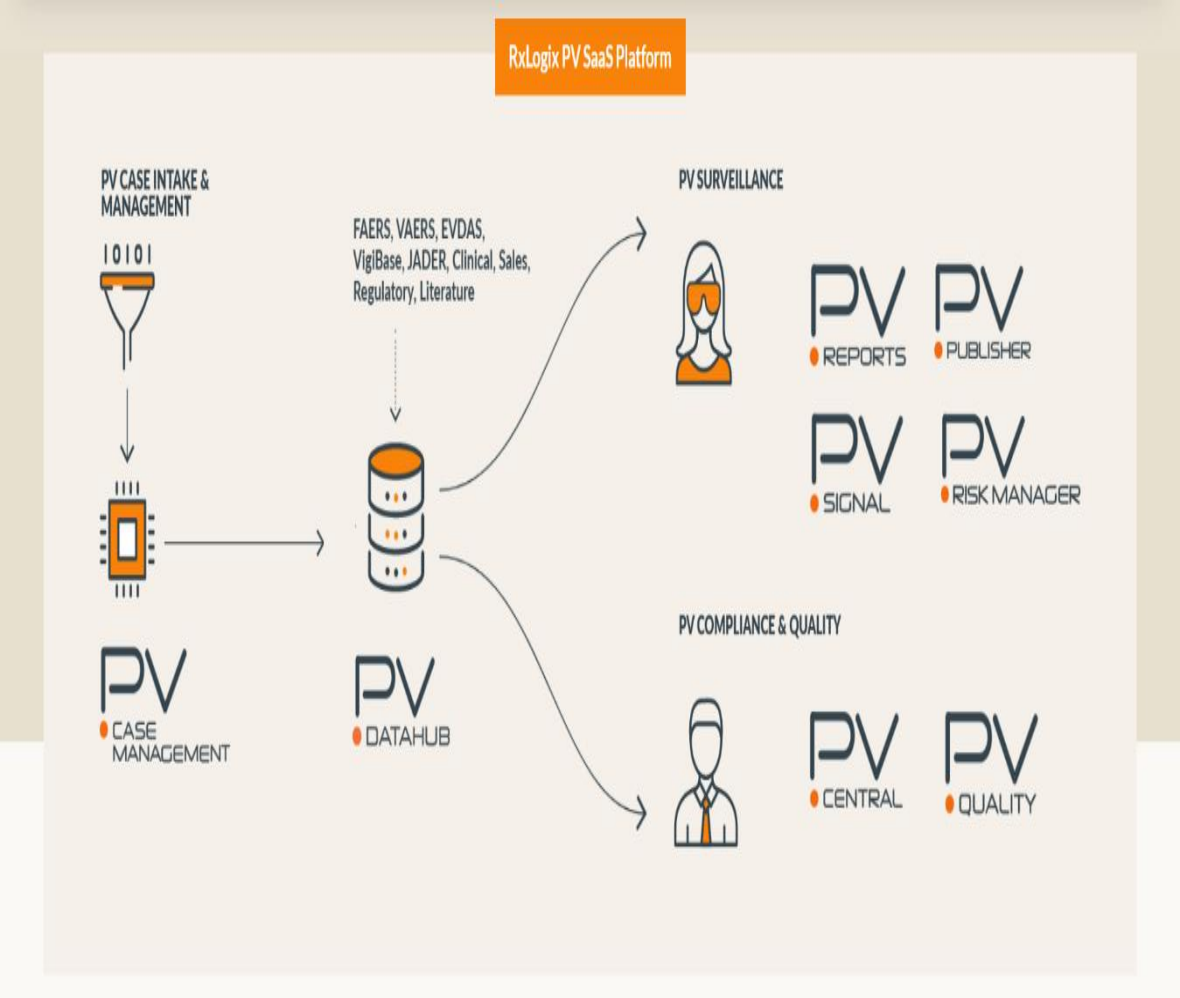


FIGURE (v)

PV Case Management

Automate your Case Intake and Processing activities using RxLogix PV Case Management (PVCM)
PVCM cognitive AI technology enables organizations to make their end-to-end case management processes significantly more automated and streamlined with increased efficiency and productivity at much lower cost. It aids better case quality and proactive identification, evaluation and minimization of risks.

- PVCM's AI based solutions are based on the observation of patterns in large volumes of past data using Machine Learning (ML) and Deep Learning (DL) and apply it learning on new safety information.
- It also leverages Natural Language Processing (NLP) and Computer Vision (CV) to intelligently interpret text and images to retrieve meaningful safety information automatically.

Key Features

- **All-in-one Case Intake solution:** Single application and business process to handle all kinds of structured and unstructured case types, sources, formats and intake mediums.
- **Automated Case Intake and Processing:** Multiple automated case intake and case processing functions powered by AI, ML and NLP technologies to take the workload off from the main safety system workflow cycles.
- **Follow-up holding area:** Hold and combine multiple follow-ups in parallel to avoid disruptions to the active workflow cycle in the main safety application.
- **External as well as Internal Usages:** Can be used by external users like HCP, Consumers, Sales Reps as well as internal users like Affiliates, Call Centers, etc. by leveraging its Configurable Intake form templates based on the case or user type.
- **Extensible Intake design:** Extensible by design to support additional or customer-specific intake sources and formats.
- **Multi-lingual, Multi-vigilant, multi-tenant by design:** Flexible and extensible application design to support multiple languages, multiple streams of vigilance and multiple tenants in the same application instance.

Key Benefits

- **Speed and Scalability:** Faster and scalable case intake and processing via automation powered by AI, ML and NLP technologies.
- **Efficient Case Intake and Processing:** Efficient case intake and processing through flexible, user-friendly and automation features.
- **Improved Case Quality:** Significantly enhanced case data quality by capturing the information directly from the source in the system. Automation of intake, data entry and transmission via E2B eliminates chances of human errors and duplicate data entry.
- **Excellent User Experience:** Significantly richer functionality and end user experience wherever manual case processing is required.

- **Extensible:** Flexible architecture and design to meet differing as well as future needs for clients.
- **Lower TCO:** Single COTS solution for all kinds of case intake needs.
- **GxP and 21 CFR Part 11 Compliance:** Provides full compliance with GxP and 21 CFR Part 11 requirements.

PV REPORTS

One-Stop Integrated PV Reporting and Analytics Solution (Including System in Japanese)

RxLogix PV Reports is the most advanced, user-friendly, and self-service tool for Regulatory Reports, Ad-hoc Reports, OOB Spotfire Integration and Visualizations.

Decrease overheads by more than 50% and insulate yourself against any regulatory findings. Request for a demo and find out "How?"

"All work and no play make Jack a dull boy" Strike the right balance with PV Reports. Take heed, act quick, increase productivity and compliance!

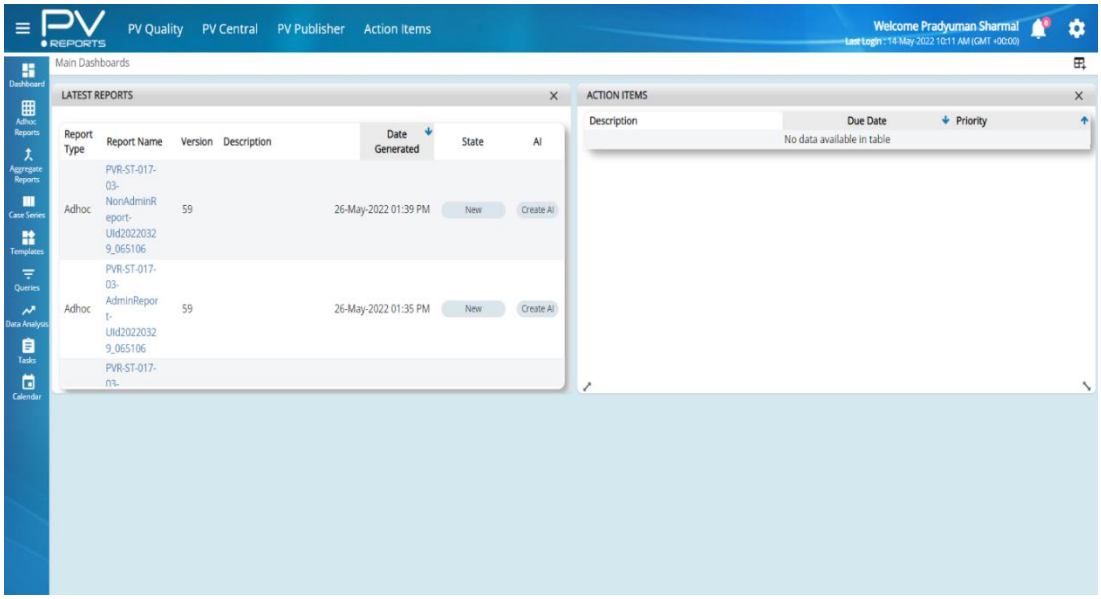


FIGURE (vi)

Key Features

- **OOB Regulatory Aggregate Reports** System provides out-of-the-box Regulatory Aggregate Reports such as PBRER, PADER, and DSUR with user-friendly ability to define supplemental reports.
- **Self-Service Reporting** – PV Reports provides the ability to the end users to generate reports with no need to wait for others to do it for them.
- **Smart Charts** Configure reports with rich-interactive charts by a few clicks.

- **Integrated Data Analysis** System provides integrated data analysis capabilities for dynamic slicing and dicing of data.
- **Rich System Functionality** System provides as-of-date reporting, report scheduling, report and query library, ad-hoc reporting, query building, my reports and many other sophisticated features.
- **Simplified Architecture** PV Reports uses PV DataHub as a centralized data warehouse designed for high-performance Reporting and Signaling capabilities.

Key Benefits

- **User-Friendly Interface –** Intuitive and simple "Apple" like PV Reporting platform.
- **Periodic Reports Management –** Out of the box capabilities to generate and manage periodic reports within the system from report configuration to submission.
- **Japanese Reports –** System provides an integrated solution for Japanese reporting requirements.
- **Data Analysis –** Slice and dice the data on the fly with integrated data analysis.
- **Data Consistency –** Single database for all reporting, analytics, and signaling resulting in consistent results all across.
- **Rapid Deployment** Implementation in a manner of weeks including support for hosted deployments.
- **Excellent Performance** 70,000 cases CIOMS II Line Listing report in 1m 58s.
- **Significant Cost-Saving –** Rich report & query catalog supported by powerful self-service report capabilities to reduce your custom reporting costs by at least 60-80%.

PV PUBLISHER

PV Publisher tool provides end-to-end solution for aggregate reports processing and automation. It provides rich features for document co-authoring and review, and for delivery of high-quality documents.

Integration with content management solutions, auto-generation of submission ready reports based on templates, communication with regulatory authorities using E2B R3, eCTD format and an open architecture for plug and play with other applications makes it an easier choice for customers.

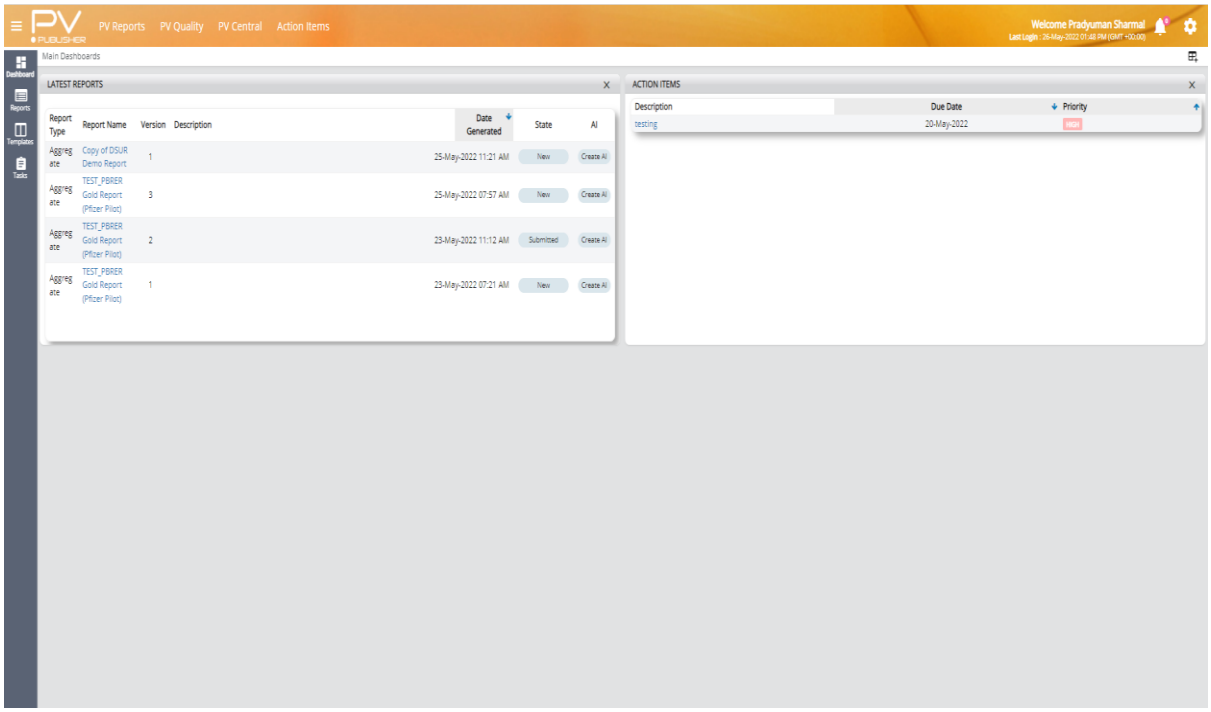


FIGURE (vii)

Key Features

- **One Stop Publishing Solution**: Works with both PV and Clinical groups for end-to-end processing of aggregate reports and automation.
- **Design**: Well-thought through design to take care of most of the pain points from the existing custom solutions used for aggregate reports processing
- **Template Based Reports** – Supports commonly used word templates for worldwide market authorization holders and provides submission ready dossiers in PDF format with bookmark capability.
- **Configurable Workflow** – Uses configurable workflow for managing the entire lifecycle of aggregate reports from planning, tracking report authoring, task distribution, submission, and generation of audit reports.
- **Rule-based output for different Countries** – Ability to generate multiple reports from the single template based on country of submission and other parameters.
- **Compliance**: Compliant with all Regulatory Guidelines
- **Use or Reference Previous Output**: Comparison with previous report outputs and content reuse makes authoring and review of future reports a lot easier
- **Plug and Play**: Plug and play by design to support data from standard PV systems and reporting sources

Key Benefits

- **End to End Reports Processing** – Provides ease of use for report output generation, report authoring and review, sharing and publishing of reports.
- **Process Simplification** – Streamlines & simplifies the document writing process for periodic report production.
- **Significant Cost and Time Saving with Automation** – Automated process steps to get submission ready reports significantly faster resulting in cost and time savings.

- **Quality Improvements** – Auto-population of contents and comparison with previous report outputs yield better quality submission ready reports.
- **Easy to Use –** Intuitive, simple to operate the system with almost no training required.
- **Rapid Deployment:** Leverage RxLogix implementation and validation package for faster implementation including support for hosted deployments

PV SIGNAL

Comprehensive, Compliant and User-Friendly Signal Detection and Management Solution

PV Signal is the industry's most complete signal detection and management solution. It is fully compliant with EU GPV Module IX regulations. It provides a dynamic data mining environment for detecting signals, uncovering patterns, and recognizing emerging trends in spontaneous adverse event report data. PV Signal supports seamless review across various data sources and provides advanced signal analysis using machine learning and AI based technologies.

Save Operational time by leveraging PV Signal and instead use your time to focus on patient safety, long-term sustainability, and public health.

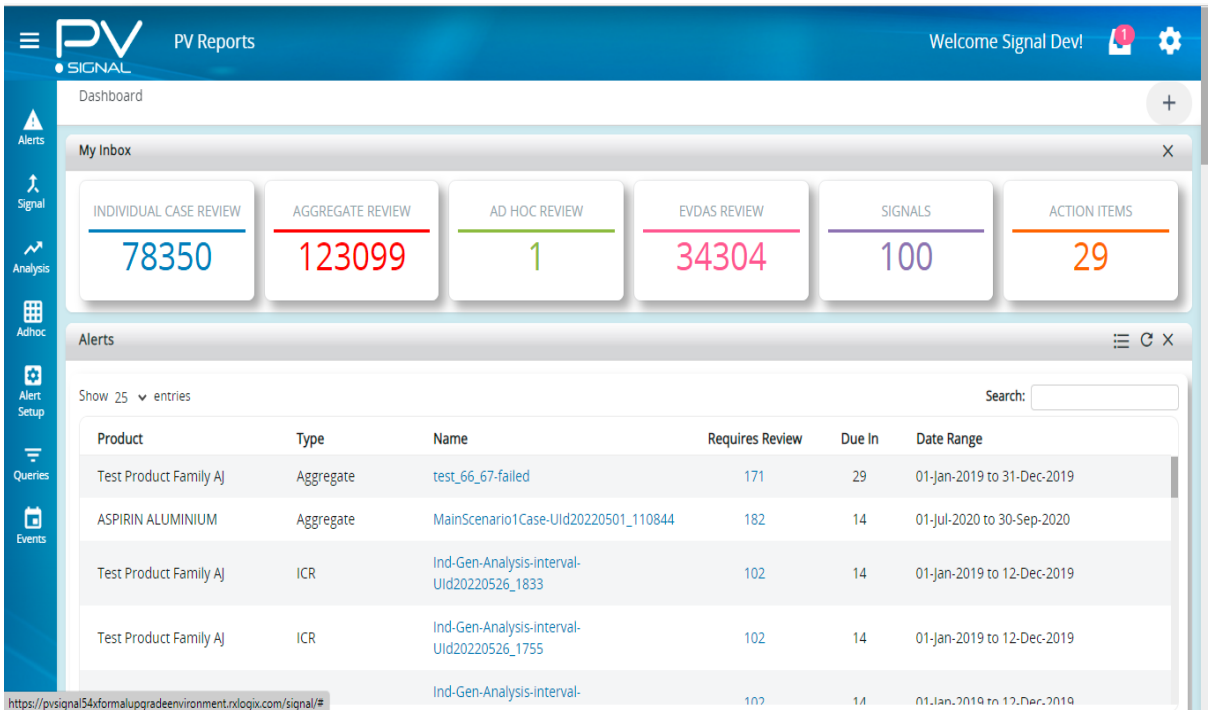


FIGURE (viii)

Key Features

- **Qualitative Signal Detection** Ability to configure qualitative signal detection criteria using flexible user interface for proactive monitoring.
- **Quantitative Signal Detection** Ability to perform quantitative signal detection on aggregate data using signaling algorithms.
- **Integrated Review Across Data Sources** Ability to perform review of aggregate data across different data sources from single user interface with an ability to compare data across sources
- **Literature Review** Integrated literature review using real-time search on most of the literature sources like PubMed and Embase
- **Signal Management** User-friendly yet powerful out of the box workflow engine for signal management all the way from detection to action & communication. Compliant with GPV Module IX – Signal Management Regulations.
- **Internal and External Data Sources** Ability to perform signal detection on internal and external data sources (FAERS, VAERS, EVDAS, VigiBase, JADER, Clinical Trials and Literature).
- **Advanced Trend Detection** Advanced trend detection using machine learning and historical data.
- **Integrated Reporting and Analytics** PV Signal is integrated with PV Reports module and Spotfire for integrated reporting and advanced data analysis.
- **Metrics and Dashboards** Out of the box dashboards for Signal monitoring and summaries.

Key Benefits

- **Signal Detection –** Provides ease of use in the configuration of signal detection rules-based alerts for qualitative and quantitative review.
- **Single Case Signal Detection and Management –** Provides ease of use in the configuration of signal detection rules based on DMEs, Events of Interest, SUSARs and user-defined conditions. Provides ability to view case data in ICSR and Temporal views for assessment for detected signals.
- **Auto Triaging –** Save time and cost by auto triaging the cases and drug-events pair, using built-in rule-based engine.
- **Single User Interface-** A one stop application for integrated review for Qualitative, Quantitative, EVDAS, Literature and management of identified signals.
- **Efficient Review of EVDAS Data-** Auto download, auto upload, triaging of eRMRs and case listings from EMA and adjudication of eRMRs.
- **Signal Management and Communication –** Signal management and role-based to-do lists to process the detected signals.
- **Multiple Data Sources –** Point in time capabilities and support for Argus, ARISg and other public databases.
- **Easy Scientific Analysis –** Provides ability to perform OLAP with Analytical tools for case series that triggers signal detection.
- **User-Friendly Interface –** Intuitive, simple to operate the system with almost no training required.

- **GxP and 21 CFR Part 11 Compliance** – Provides full compliance with GxP and 21 CFR Part 11 requirements.

PV RISK MANAGER

A robust Risk Management solution centralizing and tracking your Risk Management Plans integrated with our award-winning PV Signal and PV Reports products. Yet another Industry first solution from RxLogix

Key Features

- Holistic view of product safety profile, with emphasis on identified and potential risks and also on safety concerns which need to be managed proactively.
- Creation and management of risk management plans for all the topics associated with a product.
- Ability to configure templates based on pre-defined contents and auto-population of those template for the generation of risk plans.
- Configurable workflow for authoring, review and update of risk plans along with version control capability to compare multiple versions of risk plan.
- Integrated reporting for all kind of ad-hoc reporting on product safety profile and reports based on meta-data from the system.
- Capability to integrate with companies document management systems for managing access, links and interfacing systems to safety reference documents.
- User-defined checklist for finalizing risk plan and generation of submission ready contents for inclusion in aggregate reports.
- Auto notification for indicating progress and delays in managing the risk profile of products.
- Easy searching, sorting, task management and creation of user-based to-do lists for managing different view based on topics classification or risk categories.

Key Benefits

- **Flexible User-Friendly Interface –** Provides flexibility to have standard and configured fields to enter and maintain the product safety summary/planning/safety strategy, safety risk and commitments information.
- **End to end RMP/REMS Management –** Provides a user-friendly IT System environment to author, review and approve the RMP/REMS. No need to manage the contents in MS Word and SharePoint systems.

- **Product Profile –** Provides an integrated safety profile of the drug where all relevant information is available at one place.
- **Automated Emails Alerts and Notifications –** Provides ability to receive email alerts and online notifications, no need to actively monitor to-do lists.
- **Reporting and Metrics –** Provides standard reporting capability on all the available Risk Management data.
- **Role-based centralized work environment for Safety Scientists and Physicians –** Provides integrated and centralized environment linking all Risk Management-Signal Management-Aggregate Reporting-Data Analysis activities.
- **Workflow and To-Do Lists –** Provides a very user-friendly way to configure and manage workflow for RMPs, Safety Strategy Plans, and Safety Topics and the associated user and/or role-based to-do lists, internal and external commitments.
- **Integrated PV Publisher –** Provides authoring/publishing capabilities to create medical information contents.
- **Standard Interfaces –** Provides out of the box integration with Document Management System and the ability to integrate with other applications.
- **GxP and 21 CFR Part 11 Compliance** – Provides full compliance with GxP and 21 CFR Part 11 requirements.

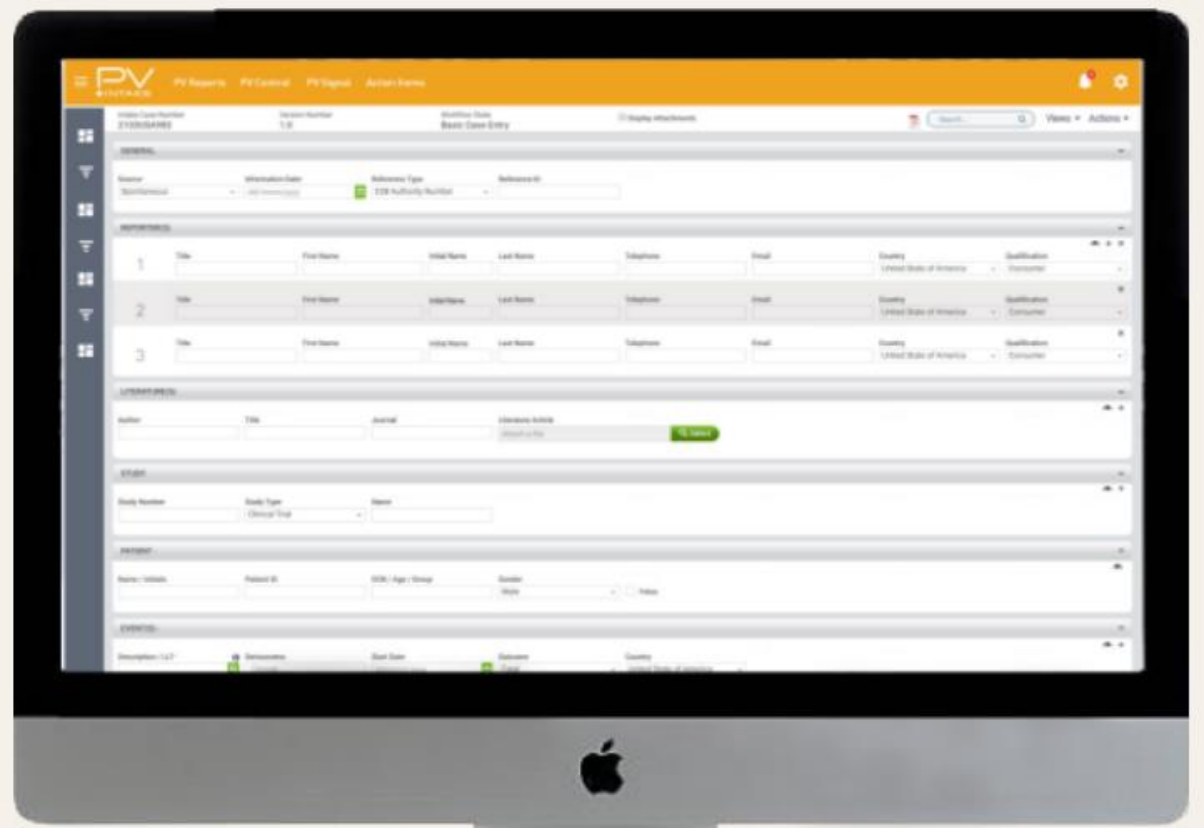


FIGURE (ix)

PV CENTRAL

Global Compliance and Productivity Monitoring
PV Central is a global compliance and productivity monitoring tool. In addition, it provides late case assessment for both inbound and outbound case data exchanges.

With PV Central, managers can spend more time working “on the business” as opposed to “in the business”. Management time can be spent on strategy and other department aspects. This sophisticated fine-tuned product will help you run PV Operations effectively and assures you better outcomes.
Take charge. Always have relevant metrics on your fingertips in real-time.

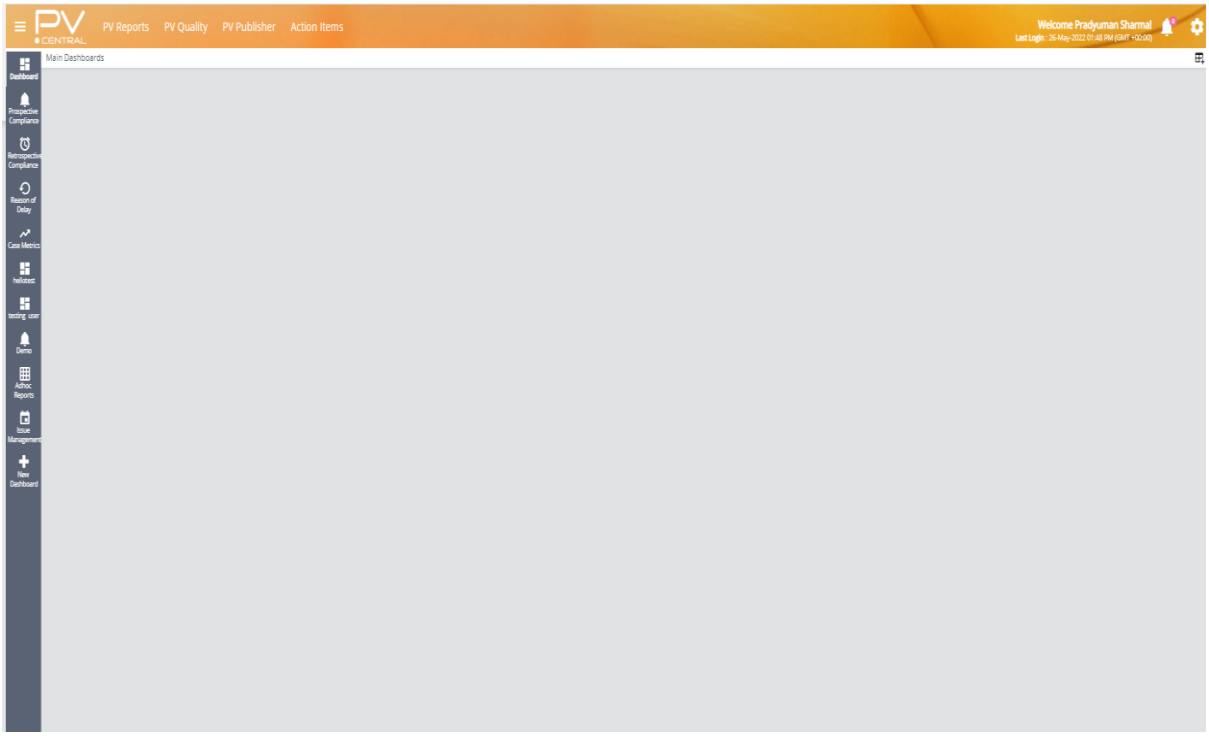


FIGURE (x)

Key Features

- **Safety databases are good at case processing and producing data for regulatory reports.** But it is not a project management tool. RxLogix PV Central is developed specifically for Safety Leaders and their teams to easily manage the entire case and project load.
- Existing safety solutions present only limited management reporting, RxLogix PV Central has a **sophisticated dashboarding system that provides inbound/outbound compliance, productivity and workload metrics.**
- **Existing solutions** do not facilitate proactive monitoring, visibility and transparency. RxLogix PV Central provides this as a basic feature.

- Safety Executives do not usually login and have access to the Safety or Signal Detection databases. **RxLogix PV Central solution aggregates** all of this information in an easy, user-friendly interface.
- Manual assembly and presentation of meaningful information for Safety Management are time-consuming and expensive. **RxLogix PV Central extracts** the data you need most and presents this information in the visual formats you need most.
- Data presented by most systems are usually not directly actionable. **RxLogix PV Central allows you to easily view, forecast, report, and action based on the information extracted**.

Key Benefits

- **Actionable Intelligence –** Enables Safety Management to identify issues and act on them within the same system e.g. innovative late case analysis, action item assignment and tracking.
- **Early Warning Signals –** Early alerts allow you to run your business smoothly without surprises.
- **Cost Savings –** PV Central removes the need to manually assemble data and provides quick and easy presentations of meaningful Safety Management information. RxLogix PV Central aids in the reduction of delays.
- **Inspection Readiness –** Centrally manage your readiness for global inspections, including support for the PV System Master File (PSMF).
- **Management Reporting Solution –** Portal solution with role-based metrics including support for drill down and filtering that fills functionality gaps in transactional case management systems such as Oracle Argus Safety and ARISg.
- **Mobile Ready –** Intuitive, simple operating system that requires almost no training. The system is available on mobile devices and includes support for popular mobile platforms including Android and iOS.
- **Rapid Deployment –** RxLogix works closely with your team for rapid implementation (weeks) and ensures support for hosted or on-site deployments.

PV QUALITY

Do you want high-quality data in your safety database that support conclusions and interpretations without any compromise?

PV Quality is a safety data quality management solution that enables safety operations managers to detect case processing quality issues and implement corrective and preventative actions.

PV Quality is designed for companies to improve data quality and drive consistency across their case processing operation in general whether it is in the outsourced or in-house processing model. In particular, CRO organizations can derive significant operational efficiencies and synergies with this solution which will benefit our clients overall.

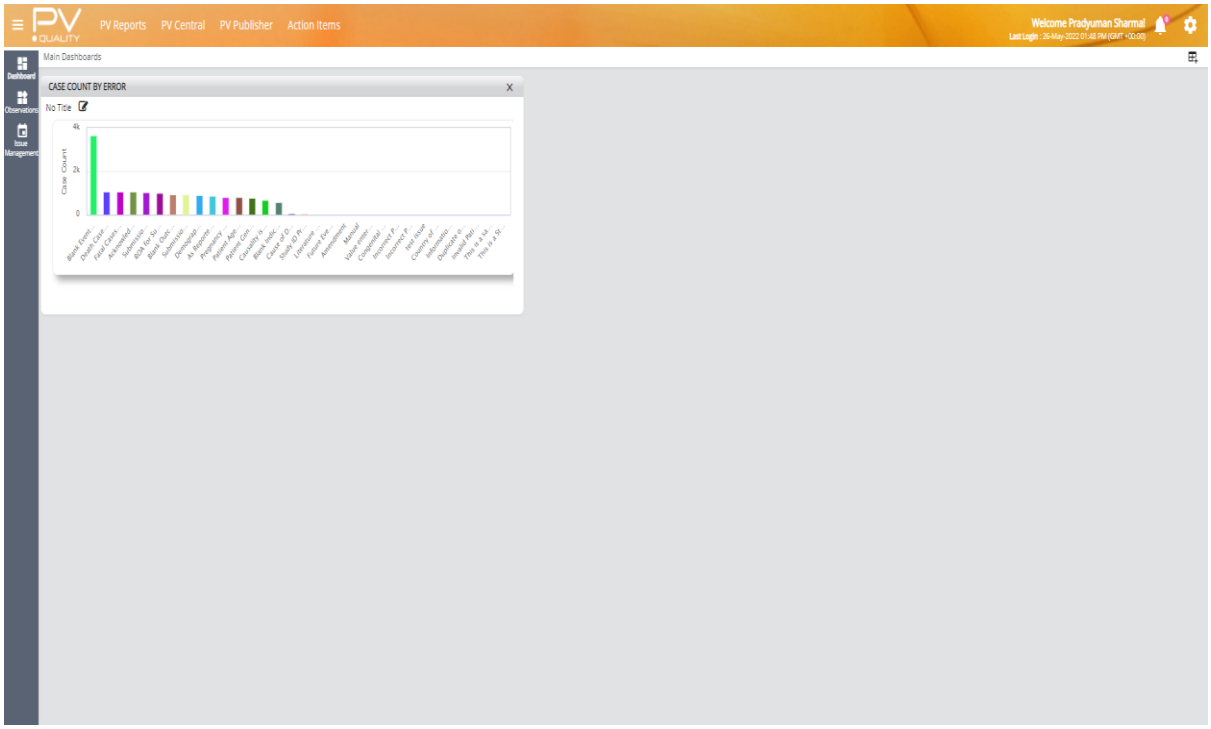


FIGURE (xi)

Key Features

- **Proactive Monitoring:** Monitor and get alerted with key indicators to address potential compliance issues before it's too late.
- **Expedited and Aggregate Reporting Compliance:** Real-time Monitoring of Global Compliance Rate by Destination, Site, Region, and other attributes etc.
- **Intake Compliance (Business Partners and Affiliates):** Configure and automatically track Business Partner and Affiliate compliance as per configured SLAs.
- **Reason of Delay Assessment:** Late case assessment, root cause analysis and trending for tracking and inspection support.
- **Automated Assessment:** Automated identification of reason of delays, root cause and preventive actions.
- **Productivity, Workload and Cost per Case Assessment:** Monitoring productivity, cost per case and workload by various attributes such as site, user type, case type, workflow state etc.
- **Configurable Dashboard:** Set up multiple focused dashboards for different business functions and user groups e.g., QPPV Dashboard, Site Leads Dashboard, Vendor Dashboard.
- **Dynamic Outputs:** Interactive operational metrics to instantly slice and dice the data.

Key Benefits

- **Actionable Intelligence –** Enables Safety Management to identify issues and act on them within the same system e.g., innovative late case analysis, action item assignment and tracking.
- **Early Warning Signals –** Early alerts allow you to run your business smoothly without surprises.
- **Productivity-** Significant productivity increase with the use of automation and latest technology such as automated identification of potential delay reasons, auto-assignment, automated recurring compliance monitoring report etc.
- **Cost Savings –** PV Central removes the need to manually assemble data and provides quick and easy presentations of meaningful Safety Management information. RxLogix PV Central aids in the reduction of delays.
- **Inspection Readiness –** Centrally manage your readiness for global inspections, including support for the PV System Master File (PSMF).
- **Mobile Ready –** Intuitive, simple operating system that requires almost no training. The system is available from mobile devices and includes support for popular mobile platforms including the iPhone, iPad.
- **Rapid Deployment –** RxLogix works closely with your team for rapid implementation (weeks) and ensures support for hosted or on-site deployments.
- **User-Friendly Interface –**Intuitive and simple "Apple" like Operational Reporting platform.

<u>About pharmaceutical Industries</u>

Develops, produces, and markets drugs or pharmaceuticals licensed for use as medications
• What makes this industry unique is:
– *Research*
• Drug discovery is the process by which potential drugs are discovered or designed
– *Regulations*
• Laws and regulations regarding the patenting, testing and ensuring safety and efficacy and marketing of drugs
– *Ethics*
• Healthcare is in a unique position balancing profit and the public good
– *Economics*
• **Largest of any industry**
• in 2014, global spending on prescription drugs topped $1 Trillion and seen at 1.5 trillion in 2021.
• US is the Largest market – 1/3rd of global pharmaceutical market($374 billion in annual sales)

• **<u>Why we need drugs:</u>**
– Treatment of disease
– Diagnosis of a disease
– Prevention of a disease
– Enhance body function

• A disease is a particular abnormal condition, a disorder of a structure or function, that affects part or all of an organism. Disease is often
construed as a medical condition associated with specific symptoms
and signs. It can be
– Pathogenic (infection)
– Hereditary (genetic disorder)
– Deficiency (malnourishment)
– Physiological (asthma, stress)

FRAMEWORK OF PVD

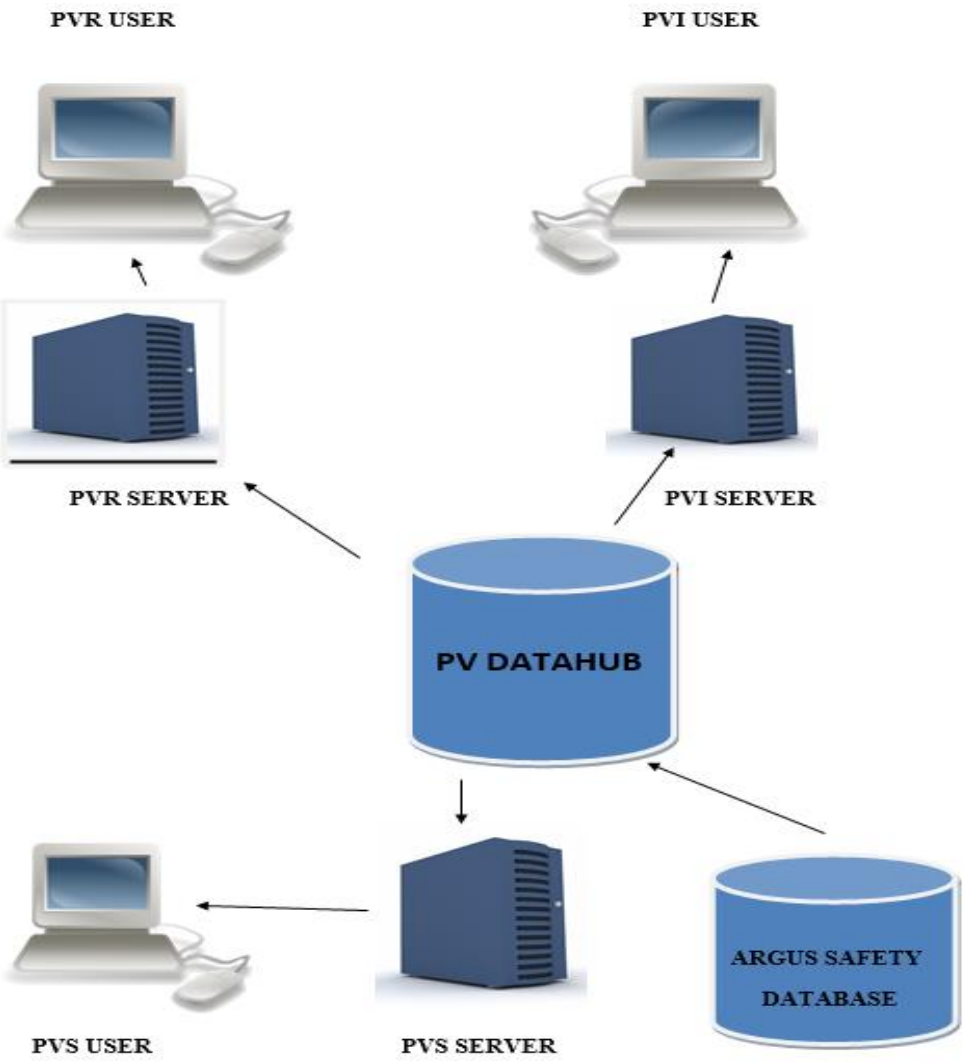


FIGURE (xii)

FLOW OF DATA

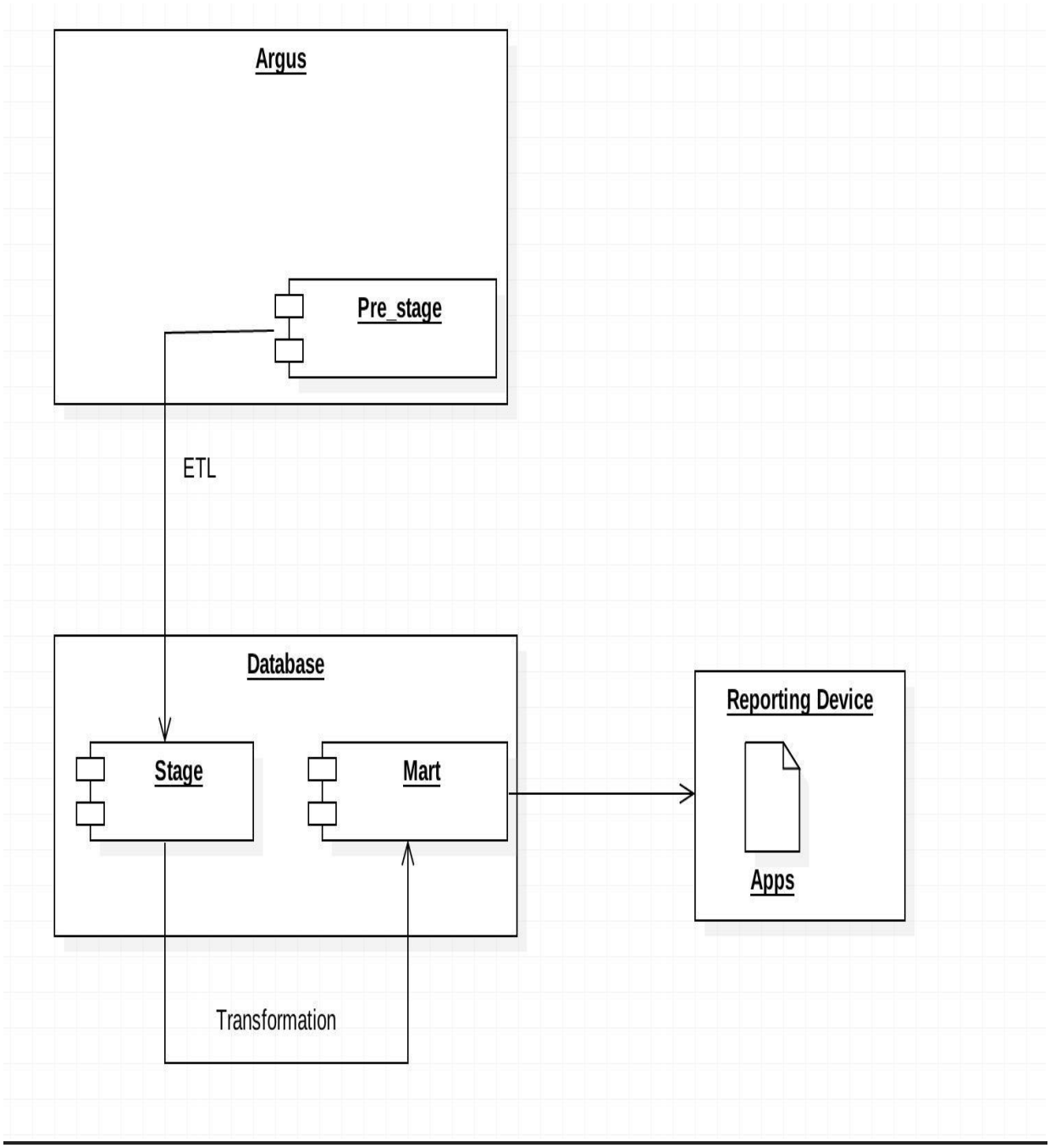


FIGURE (xiii)

PL/SQL

What is PL/SQL?

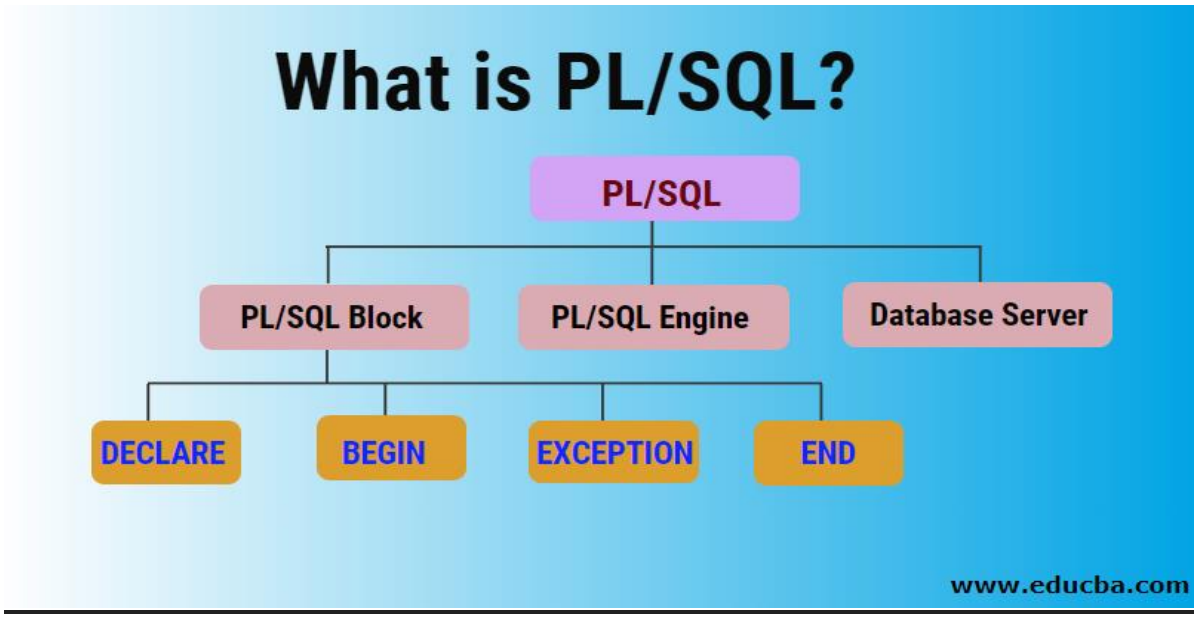


FIGURE (xiv)

PL/SQL DATATYPES

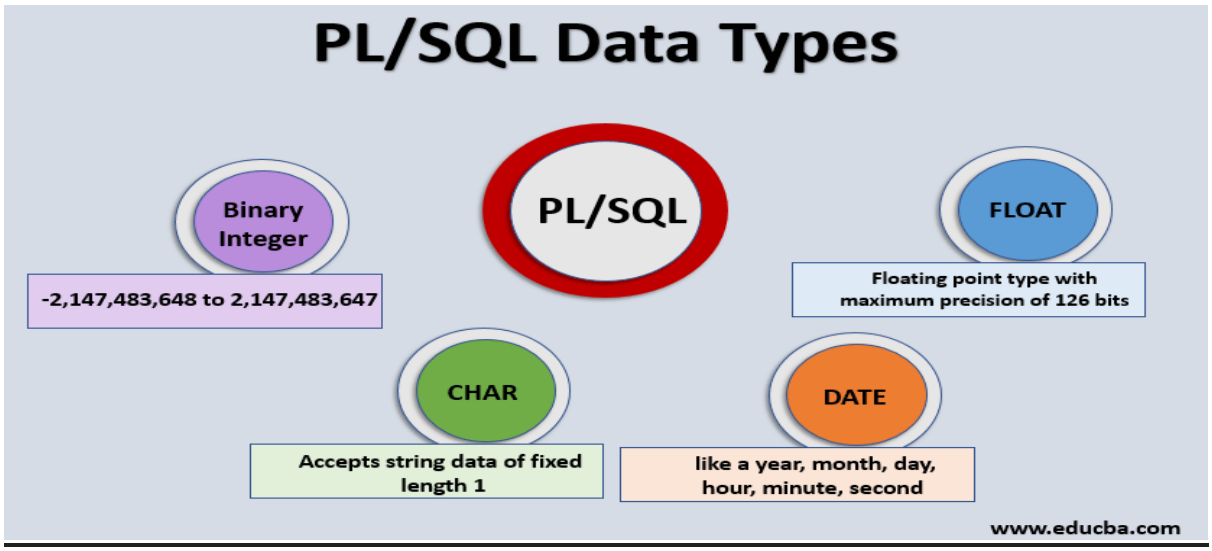


FIGURE (xv)

PL/SQL ARCHITECTURE

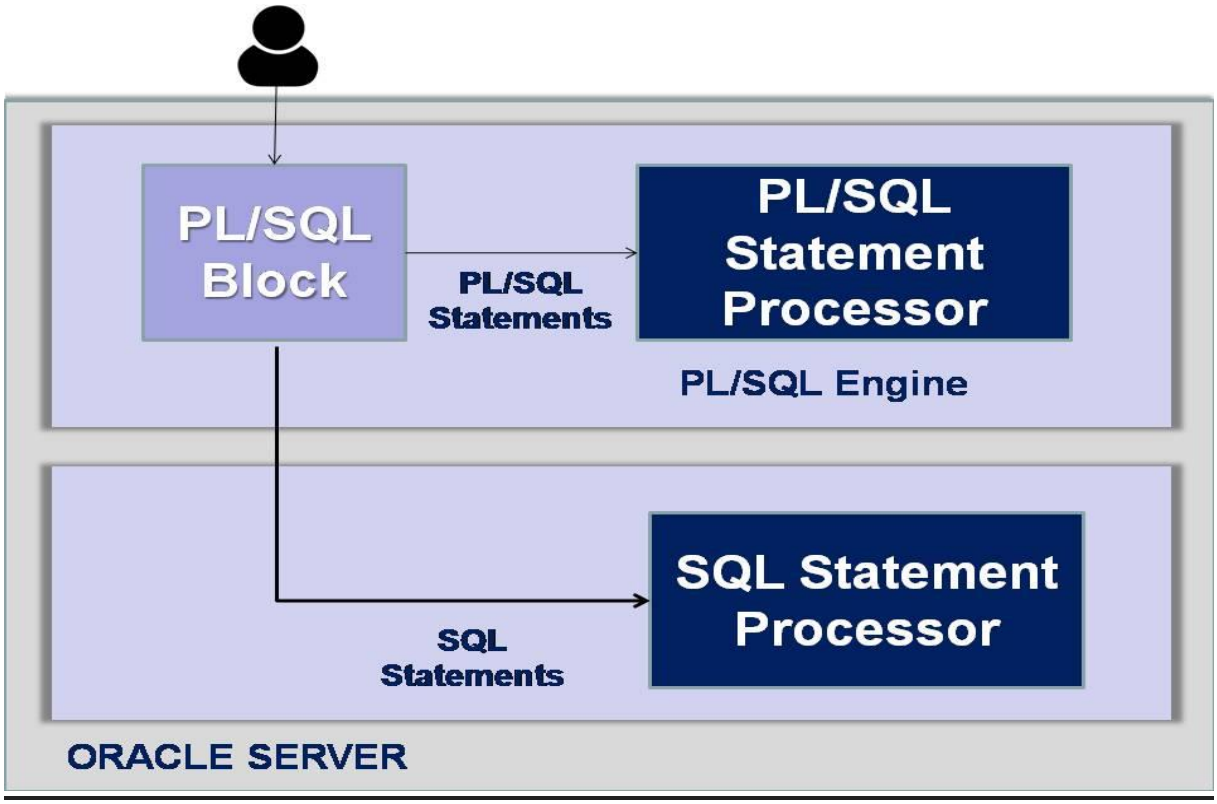


FIGURE (xvi)

PL/SQL BODY

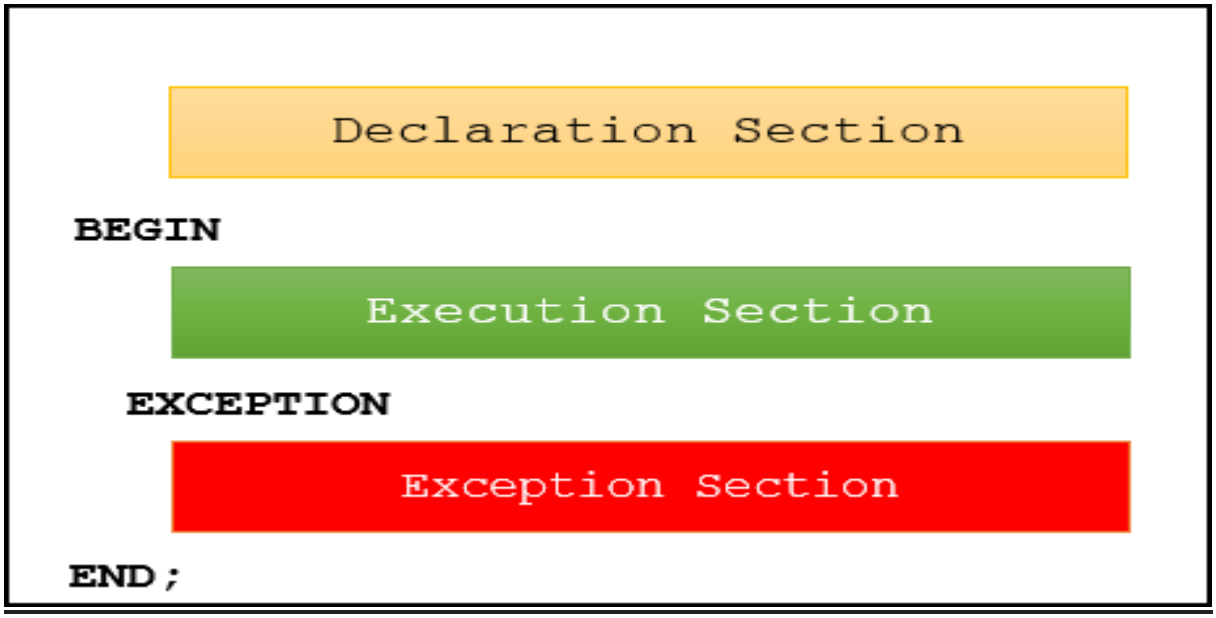


FIGURE (xvii)

STEPS IN WHICH CASE PROCESSES IN ETL

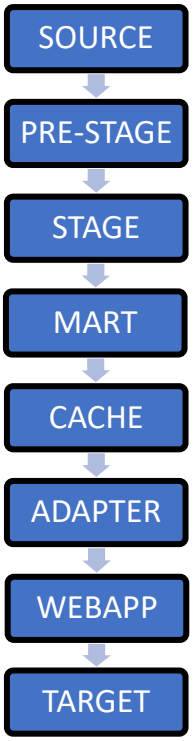


FIGURE (xviii)

1. The Source contains the data of client
2. The Data moves to pre-stage. This the point where data does not change
3. Then data transfers to stage where our company changes data and modify it into the needs of client
4. Then the data moves to cache where case level information's gets stored
5. This the part where data gets converted into JSON format
6. Then data transfers into target point where it reflects in Application
7. At this last point data gets stored into company database

STEPS TO FOLLOW FOR ETL

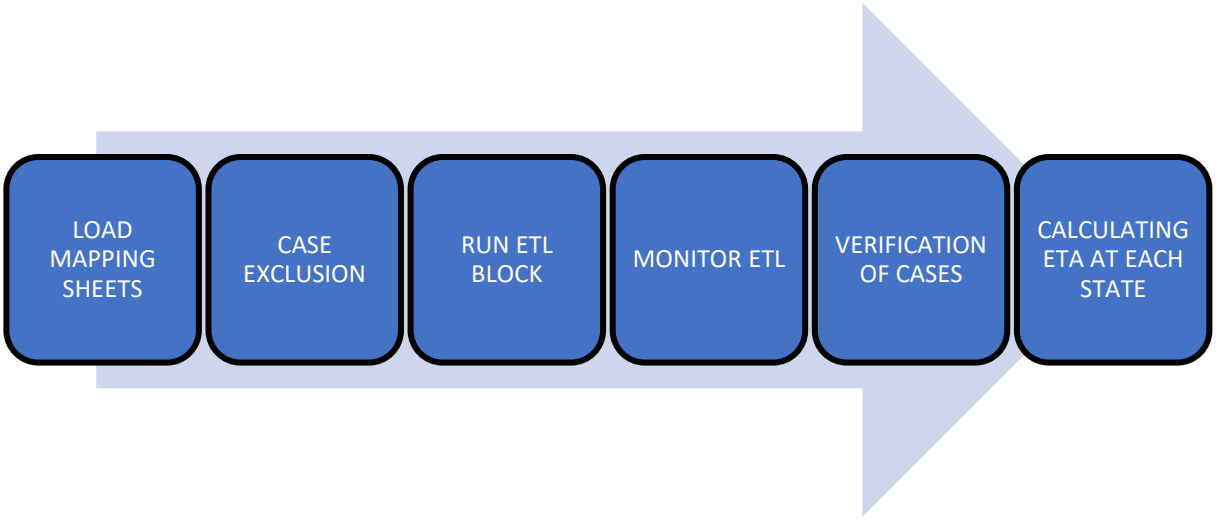


FIGURE (xix)

INIT ETL – This is defined as a process in which data transfers from source to target

1. Loading mapping Sheets: - Code level mapping from source to target gets loaded through sql developer
2. Case Exclusion: - In this stage we dry run the etl for restricted cases
3. Run ETL Block: - In this stage we dry run the ETL block for restricted cases
4. Monitor ETL: - In this stage we will monitor the block with certain queries
5. Verification of Cases: - In this stage we will verify that cases from source to target transferred correctly
6. Calculating ETA at each stage: - At this stage we will calculate the time taken at each stage to load the data

STEPS TO FOLLOW FOR INCREMENTAL ETL

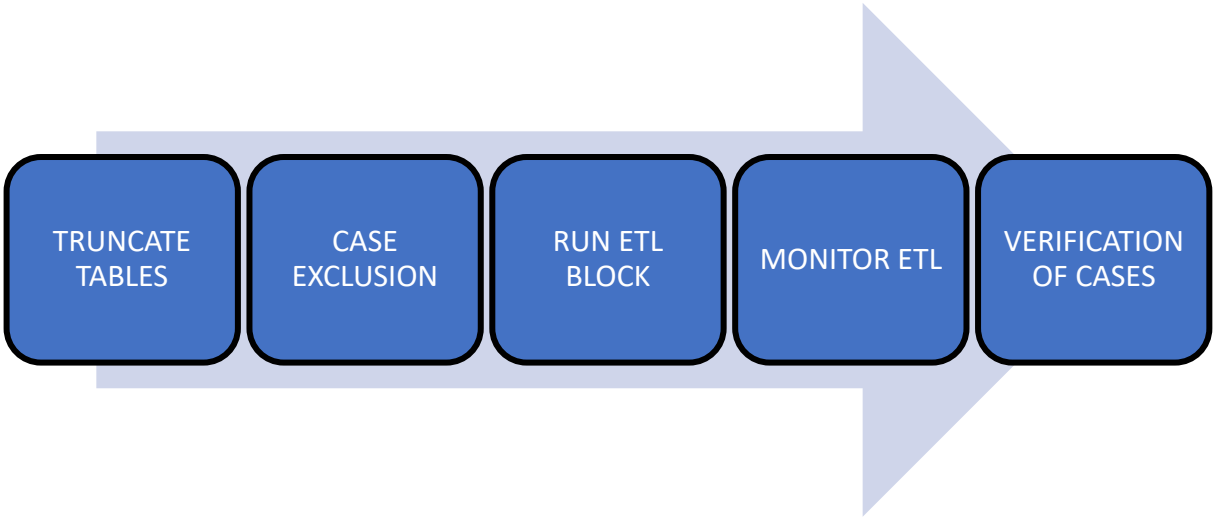


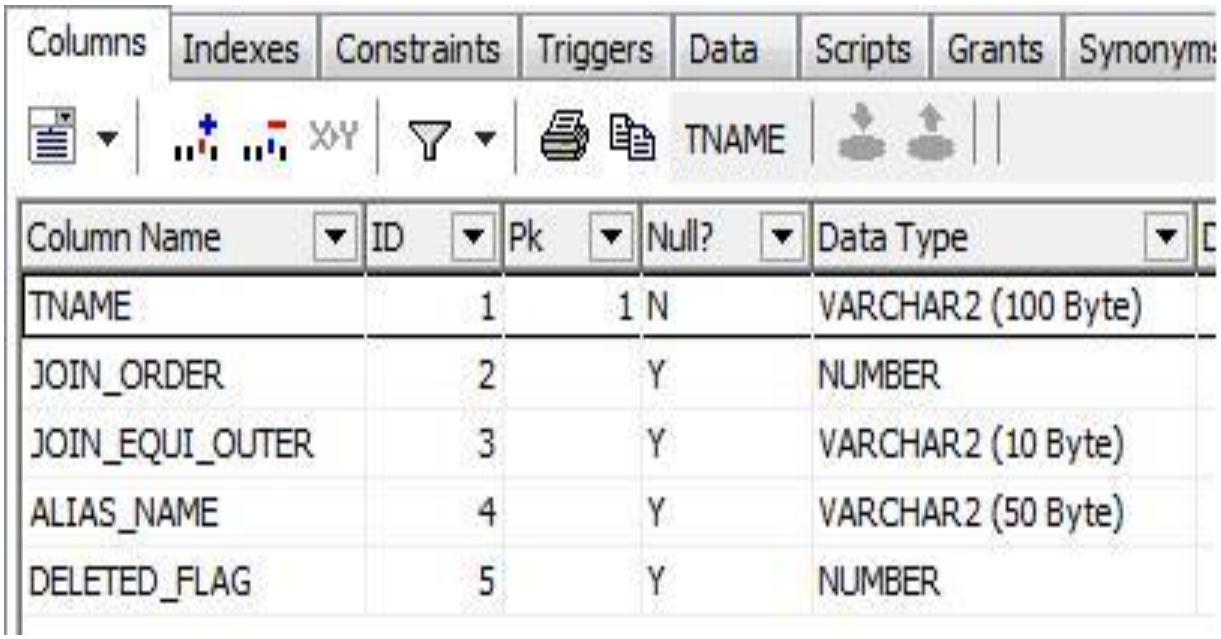
FIGURE (xx)

INCR ETL – This is defined as a process in which latest data transfers from source to target along INIT ETL

1. Truncate table: - At this stage we will truncate the tables and add the latest data
2. Case Exclusion: - In this stage we dry run the etl for restricted cases
3. Run ETL Block: - In this stage we dry run the ETL block for restricted cases
4. Monitor ETL: - In this stage we will monitor the block with certain queries
5. Verification of Cases: - In this stage we will verify that cases from source to target transferred correctly

MAIN TABLES FOR DATA EXTRACTION

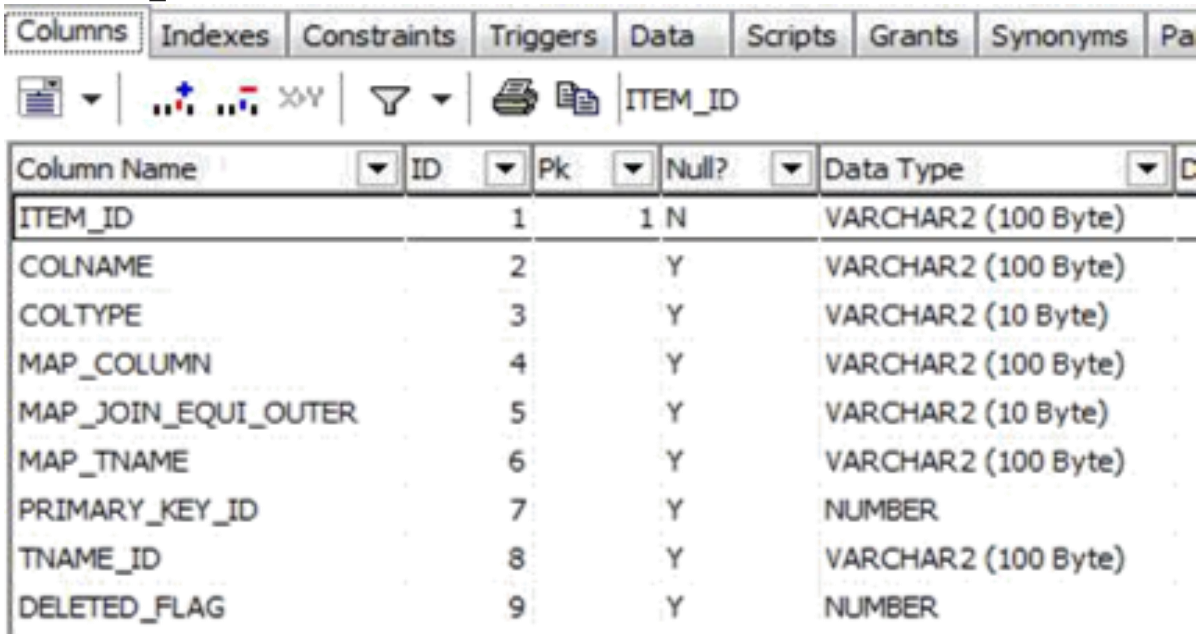
1.TABLE_MASTER



Column Name	ID	Pk	Null?	Data Type
TNAME	1	1	N	VARCHAR2 (100 Byte)
JOIN_ORDER	2		Y	NUMBER
JOIN_EQUI_OUTER	3		Y	VARCHAR2 (10 Byte)
ALIAS_NAME	4		Y	VARCHAR2 (50 Byte)
DELETED_FLAG	5		Y	NUMBER

FIGURE (xxi)

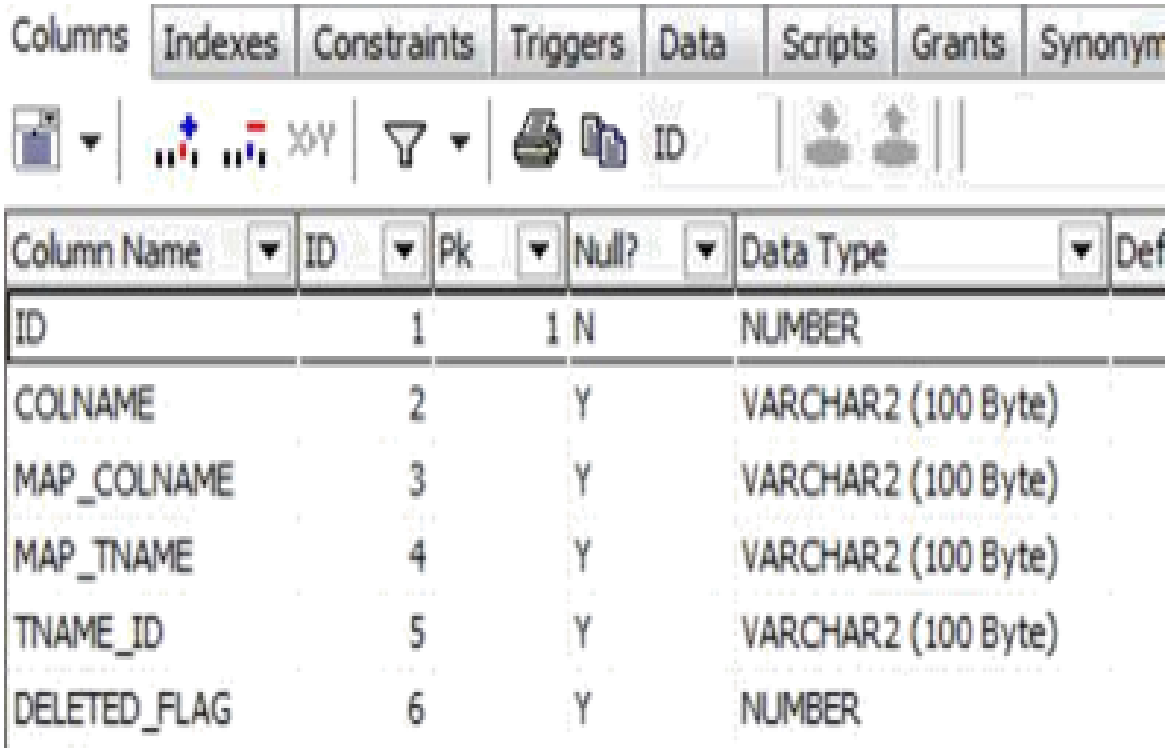
COLUMN_MASTER



Column Name	ID	Pk	Null?	Data Type
ITEM_ID	1	1	N	VARCHAR2 (100 Byte)
COLNAME	2		Y	VARCHAR2 (100 Byte)
COLTYPE	3		Y	VARCHAR2 (10 Byte)
MAP_COLUMN	4		Y	VARCHAR2 (100 Byte)
MAP_JOIN_EQUI_OUTER	5		Y	VARCHAR2 (10 Byte)
MAP_TNAME	6		Y	VARCHAR2 (100 Byte)
PRIMARY_KEY_ID	7		Y	NUMBER
TNAME_ID	8		Y	VARCHAR2 (100 Byte)
DELETED_FLAG	9		Y	NUMBER

FIGURE (xxii)

COLUMN_MAPPING

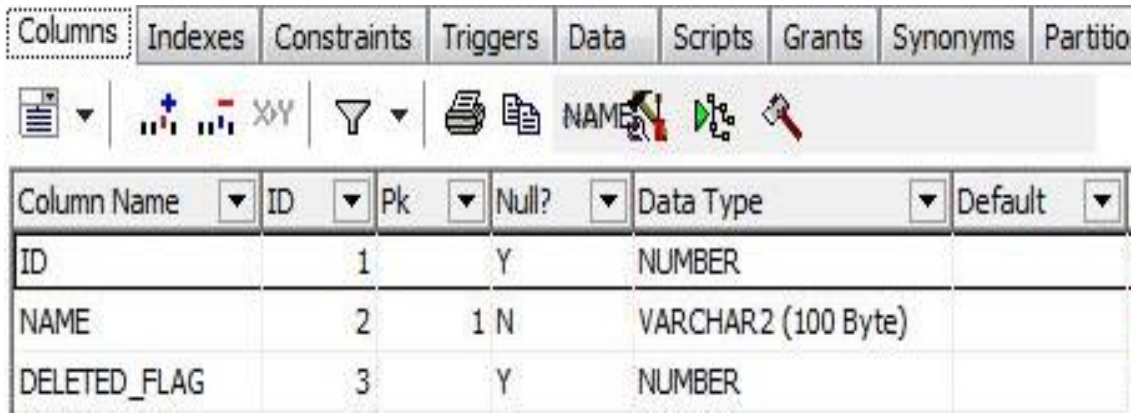


Columns | Indexes | Constraints | Triggers | Data | Scripts | Grants | Synonym

Column Name	ID	Pk	Null?	Data Type	Def
ID	1	1	N	NUMBER	
COLNAME	2		Y	VARCHAR2 (100 Byte)	
MAP_COLNAME	3		Y	VARCHAR2 (100 Byte)	
MAP_TNAME	4		Y	VARCHAR2 (100 Byte)	
TNAME_ID	5		Y	VARCHAR2 (100 Byte)	
DELETED_FLAG	6		Y	NUMBER	

FIGURE (xxiii)

FIELD_GROUP



Columns | Indexes | Constraints | Triggers | Data | Scripts | Grants | Synonyms | Partitio

Column Name	ID	Pk	Null?	Data Type	Default
ID	1		Y	NUMBER	
NAME	2	1	N	VARCHAR2 (100 Byte)	
DELETED_FLAG	3		Y	NUMBER	

FIGURE (xxiv)

Chapter 4- Performance analysis

AE - Adverse Event (or Adverse Experience)

– Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical
product and which does not necessarily have to have a causal relationship with this treatment.

• **ADR - Adverse Drug Reaction**

– All noxious and unintended responses to a medicinal product related to any dose should be considered
adverse drug reactions.

• **Unexpected Adverse Drug Reaction**

– An adverse reaction, the nature or severity of which is not consistent with the applicable product information
(e.g., Investigator's Brochure for an unapproved investigational medicinal product).

• **SAE - Serious adverse event or reaction** is any untoward medical occurrence that at any dose:
– results in death,
– is life-threatening
– requires inpatient hospitalisation or prolongation of existing hospitalisation
– results in persistent or significant disability/incapacity
– is a congenital anomaly/birth defect
– requires intervention to prevent permanent impairment or damage.

• **Signal** Reported information on a possible causal relationship between an adverse event and a drug, the
relationship being unknown or incompletely documented previously. Usually more than a single report is required
to generate a signal, depending upon the seriousness of the event and the quality of the information. (WHO, 1991;Delamothe 1992)

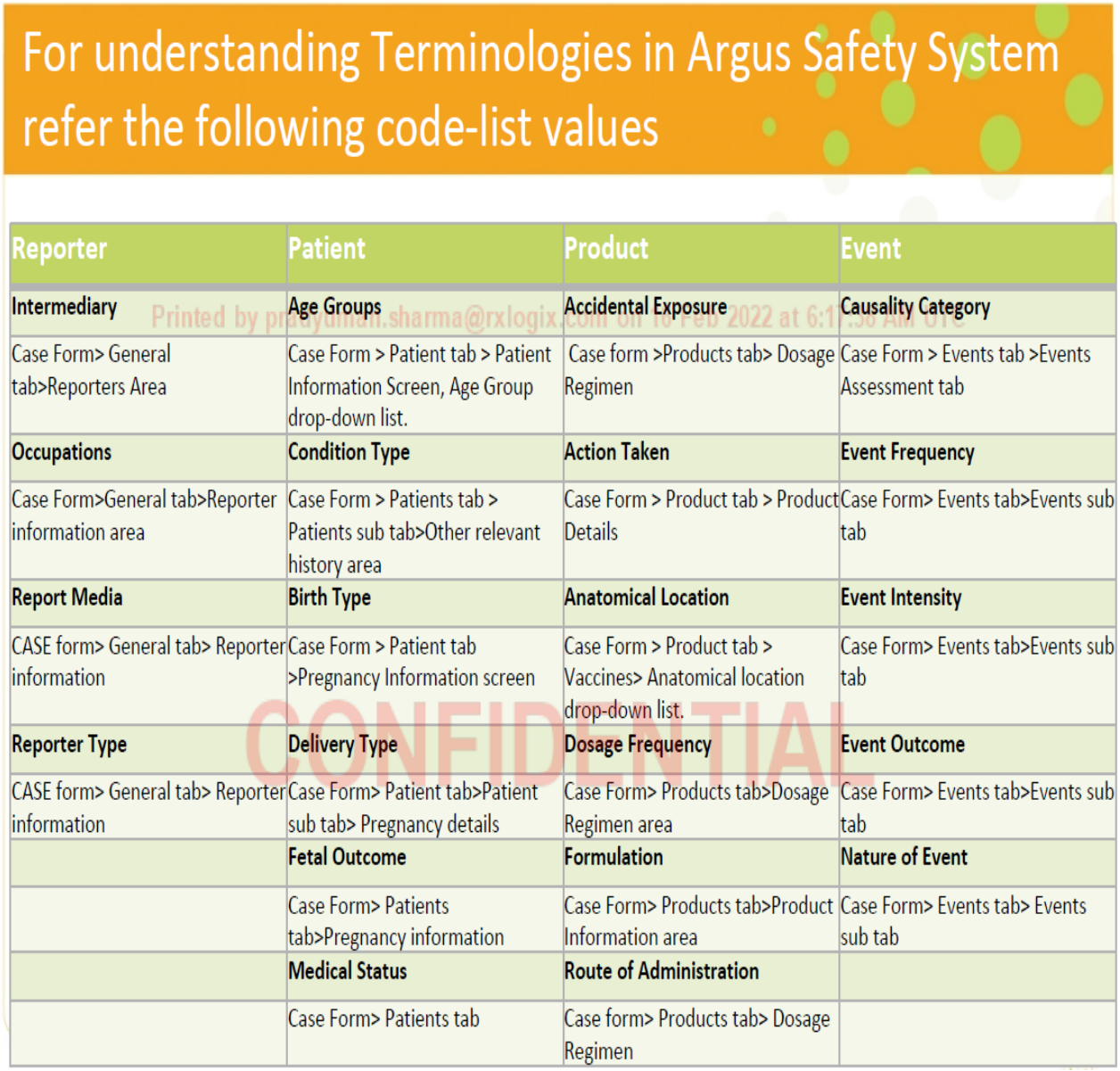


FIGURE (xxv)

SOURCE:

- **Unsolicited**

– Consumer reports: Should be regarded as spontaneous cases irrespective of medical confirmation.
– Literature: The MAH is expected to screen world-wide scientific literature for such reports. The reporting clock begins once the Company has identified the 4 minimum item reporting criteria.
– Internet: MAHs with websites should screen these regularly for ADRs and provide mechanisms of reporting e.g. ADR forms.
– Other sources: Any reports from non-medical sources should be regarded as Spontaneous

• **Solicited**

– These arise from organized data collection systems e.g. clinical trials; post approval named patient use programs, patient support and disease management programmes. Surveys of patients or healthcare providers or programmes of efficacy and patient compliance

• **Blinding**
– The process through which one or more test subjects in a clinical trial are unaware of the treatment they are receiving (the actual study drug, a competitor's marketed drug, or a placebo)
– In a single-blinded study, usually the subjects are unaware of the treatment
– In a double-blinded study, both the subjects and the investigators are unaware of the treatment assignments.
– Blinded studies are conducted to prevent the unintentional biases that can affect subject data when treatment assignments are known.
– When a Serious adverse reaction is judged reportable on an expedited basis, it is recommended to break the blind for that particular subject (ONLY that subject)

Causality Determination:

– This is done to see if the adverse event a patient is reporting is caused by the suspect drug in question or not.

• Causality categories (as described by the Uppsala Monitoring Centre):

Certain	Unlikely
Probable / Likely	Conditional / Unclassified
Possible	Un assessable / Unclassifiable

• Methods of Determination for Clinical Cases:

• De-Challenge (Stopping the use of a drug
– Disappearance of the AE is referred to as a Positive DE challenge and if the AE continues this is called a Negative DE challenge.

• Re-Challenge (Reintroducing the use of a drug)
– Reproduction of the AE is referred to as a Positive Rechallenge and if the AE does not reoccur this is called a Negative Rechallenge.

SAFETY INFORMATION CARRIERS

• **Investigator's Brochure**
– This is a document that would be created before a drug goes under clinical trials and may change
during a clinical trial.

• **CCDS - Company Core Data Sheet**
– This is a document prepared by the MAH (Marketing Authorization Holder) containing, in addition to safety information, material relating to indications, dosing, pharmacology, and other
information concerning the product used worldwide not just locally.

• **Package Insert / Label**
– The Document received with a Product containing information such as the Brand Name, Generic name of the product, Description, Clinical Pharmacology, Indications and Uses, Contraindications, Warnings (may include Drug Abuse and Dependence also), Precautions, Adverse Reactions, Over dosage, How Supplied, Dosage and Administration.

– A Package Insert may contain more side effects (adverse events) than are listed in the CCDS

– This is Local so different countries may have a different package insert

• A document providing the most complete information related to an individual case at a certain point in time
• Minimum Criteria for Reporting
– Identifiable patient
– Suspect medicinal product
– Identifiable reporting source
– In event or outcome (in clinical investigation cases, there is a reasonable suspected causal relationship)

• Initial Report
– The first set of information that the company
receives regarding a particular ICSR

• Follow-up Report
– Additional details that the company becomes aware of regarding an ICSR that is already in their database

Chapter -5 CONCLUSION

Eventually, the compassionate use of drugs may become a standard-of-care threatening collateral damage. What is required is more robust high-quality data for timely review and generate high-quality evidence. Systematic monitoring of all adverse outcomes, adverse events must be recorded and reported for a meaningful causality and risk-benefit assessment balancing individual safety and scientific necessities. It is likely that the number of safety reports may increase during the pandemic. To cope up, an efficient pharmacovigilance rapid response expert team to assess the drug safety reports on a weekly basis and respond to the concerns immediately will help in this regard.

- This project allowed me to work as a team.
- Therefore I could understand how it manages the flow of development by staying in sync with the requirements of the client.
- Undertaken to continuously monitor and evaluate product risk-benefit in an ongoing manner.

REFERENCES

- https://www.rxlogix.com
- https://verify.wiki/wiki/RxLogix
- http://www.dba-oracle.com
- https://en.wikipedia.org/wiki/Pharmacovigilance
- Sandya Krishna, Introduction to Oracle9i: PL/SQL, Student Guide, Vol. 1
- Sandya Krishna, Introduction to Oracle9i: PL/SQL, Student Guide, Vol. 2
- Navathe Shamkant B., Fundamentals of Database Systems, Fifth Edition, Pearson Publication