Chapter– 10

"CLOUD HOSTING AND BIP REPORTING"– NEXTROVE

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Nextrove is a global professional services firm focused exclusively on serving Pharmaceutical and Biotech organizations. We take pride in being the only consulting firm to assist clients with PV, EQMS, RIM, Regulatory and Clinical Affairs, Salesforce, and Integration services. Our mission is to deliver preeminent and innovative solutions that enable the global Health Science industry to improve public and patient safety.

With a team present globally in the US, Canada, Israel and India that has an average experience of 12+ years in PV, Regulatory, QA, EQMS and MDM, we have helped our clients meet project timelines, effectiveness and cost targets in a variety of engagements. The combination of our business knowledge and technical skill-set allows us to bridge the gap between business needs and technology to meet and exceed the expectations of our clients.

Pharmacovigilance Expertise

Extensive experience implementing Argus Suite (Argus Safety 8.1.x/ 8.2, Argus Japan, Insight, Argus MART, Argus Analytics), support AB Cube's SafetyEasy PV, Ennov's PV Works and Sarjen's PVEdge

Reporting & Analytics

Implemented Business Objects, Cognos, Tableau, and OBIEE for periodic and ad-hoc reporting. Developed analytic solutions like Argus Analytics or Spotfire.

Data Migration

Expertise to lead and perform high volume data migrations with varied level of complexity between multiple safety systems including Argus, ARISg, Empirica Trace and other home grown systems

Customization & Integration

Extreme proficiency in customizing Argus as well as integrating with external interfaces including clinical (e.g. Rave Safety Gateway), Axway, Sales Force, and ERP systems

Hosting Expertise

Implementation of multiple hosting platforms including Oracle, Rackspace, Amazon and Azure

Veeva, Salesforce SMEs

Veeva and Salesforce professionals, including certified Veeva CRM, Veeva Vault and Salesforce administrators and developers.

Services Provided

Nextrove offers end-to-end PV services with a business-centric and problem-solving focus to ensure regulatory compliance, best practices and maximum efficiency.

Servcies:

1. Pharmacovigilance
2. Japan Practice
3. Integration
4. Trackwise
5. Salesforce
6. Veeva Practice
7. Regulatory And Clinical
8. Cloud Hosting
9. Managed Services

Pharmacovigilance Overview

At Nextrove, we have performed over 200 safety system implementations, upgrades and data migrations and also help organizations manage their drug safety applications more accurately and confidently. We take pride in not only providing services to meet current regulatory compliance requirements but also positioning our clients to be prepared for future developments. Furthermore, by applying our proven methodology we minimize the impact of system implementations, upgrades and migrations both from the cost perspective as well as the impact on your team's resources all while ensuring strict compliance to operational and regulatory requirements.

Safety Implementation & Upgrade

We have an average of over 200 combined Argus implementation, database upgrade and data migration project experience involving Argus, Argus Japan, ARISg and E2B Pilots with regulators.

Data Migration:

We have proven data migration methodologies and accelerators including DM mappings, code, and DM scripts to help our clients execute projects at a low cost and risk all with no compromise in quality.

E2B R2 & R3 Offerings:

We have lead E2B(R2,R3) regulatory pilots with FDA, EMA, Health Canada, PMDA and China. We support planning, test registration and formal testing process for both CROs and Pharma clients.

Compliance, SOP, Work Instructions:

In order to ensure compliance with 21 CFR Part 11, EMA, PMDA and ICH guidelines, we support with full system and process audits. We also develop SOPs for data management, reporting and other processes

1.3 Why Choose nextrove

Nextrove provides a set of services which includes Pharmacovigilance, Trackwise and Case Processing. We bring a business-centric, problem-solving focus to ensure regulatory compliance.

Innovative, Long-term Solutions

We provide solutions that can grow and adapt with your business for long-term success

Global Team

Through our global team of experts, we are able to provide comprehensive 24/7 Tier 2 and Tier 3 support.

Unrivaled Domain and Technical Expertise

With 12+ years of average experience and over 200 completed projects, our consulting teams are proven in battle.

What is Pharmacovigilance?

The World Health Organization defines pharmacovigilance (PV) as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem."

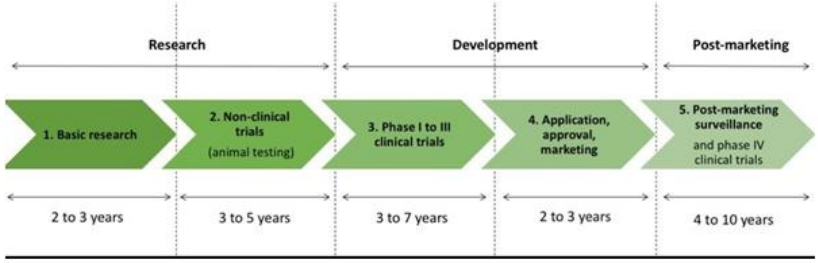
Oracle Argus is a comprehensive pharmacovigilance platform which enables pharmaceutical companies and clinical trial organizations to make faster and better safety decisions, optimize global compliance, and easily integrate risk management. There are a number of commercial off the shelf pharmacovigilance safety database solutions available and all can present significant savings in cost, resource and time to the alternative of the development of in-house solutions, not to mention the obvious advantages of taking a system that has been 'tried and tested' but many other companies in the industry.

Drug Development Phases

1. Phase I -- Healthy volunteers
    - Pharmacodynamics/pharmacokinetics.
    - Estimation of initial safety and tolerability.
    - Small group of subjects (20-80).
2. Phase II -- Healthy volunteers and/or patients
    - Dosing requirements and therapeutic efficacy.

- Continue Phase I safety assessment.
- Large group of subjects (up to 300).

3. Phase III -- Patients
   - Confirm therapeutic efficacy, safety and comparisons with other medications.
   - Larger groups of subjects (up to 3000)/multicenter trials.
4. Phase IV/V – Post-marketing studies
   - Delineate additional risks, benefits, and optimal use.



Scope of Pharmacoviglance

CLINICAL STUDIES

- Limited number of exposed patients
- Blinded or open studies
- Well-defined daily dose
- Limited number of prescribers (investigators)
- Well-defined indication
- Well-defined inclusion and non-inclusion criteria to be enrolled in the study
- Controlled co-medications
- Strict clinical and/or biological monitoring

MARKETED DRUGS

- Large number of exposed patients
- "Uncontrolled" co-medications (self-medication)
- Variable compliance
- Off label use

- Limited monitoring
- Difficult evaluation of the number of exposed patients

Steps includes in Pharmacovigilance Activities

Pharmacovigilance

- Collate information received from various sources.
- Investigate and assess data.

Report ICSRs to Regulatory Authorities.

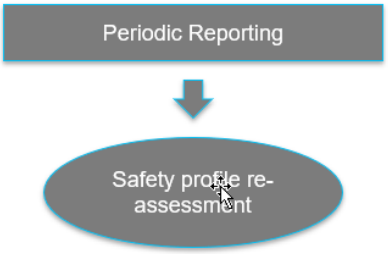
Aggregate data facilitates the creation of:

- Local Summary of Product Characteristics.

Perform Signal Detection

Reporting to Health Authorities

- Immediate reporting
- Only if serious (and related)



Regular reporting

- Well-defined periods
- Health Authorities assessment reports

Drug Safety –Who Must Report

Every Drug, Biotech and Device Company is required to report,Company includes manufacturers, distributors, local offices, subsidiaries, licensees,Evaluate and report product safety information to worldwide regulatory agencies, Companies have "safety departments" - Oracle Argus/AERS users,Individual healthcare professionals are encouraged to report. After reporting to the company the comapnay should make an valid report and send it to the desired regulatory authority within the time frame.

How to Handle an AE from Start to Finish

Intake

- AEs arrive via phone, E2B, mail, FAX, email, website, sales rep, legal, health authorities, clinical studies, literature, business partners, social media, etc.

AE Triage

- Date stamp (if not electronic), confirm clock start date, identify suspect products, case type, seriousness, causality, expectedness, minimum criteria, identify 7-day, 15-day, pregnancy, complaint, etc.
- Prioritize based on type of case.
- Death/LT, Expedited 15-day, Other serious non-expedited, expedited in one country, but not another; non-serious cases

Data Entry

- Check duplicates, determine if initial or follow-up, enter case into database, assign Case ID, code products/AEs (Coder may do this piece), create narrative/auto-narrative, send follow-up queries

Quality Review

- Review of assess seriousness, entered data and review data from source received.

Medical Review

- Review of medical content, assess seriousness, expectedness and relatedness

Case Closure/Completion

- After case is triaged, assessed data entered, coded, and medically reviewed, case can be considered closed or completed.
- If follow-up is received, case can be re-opened and processed.

Distribution/Submission

- Case meeting reporting requirements can be submitted/distributed to health authorities, affiliates, internal depts, other companies, etc.
- Reports are typically sent with a cover letter in the local language.
- Literature reports are sent with a copy of the article.

After the submission we have to do the signal detection using the data collected in the database using the oracle databse.

TOOLS AND TECHNOLOGIES USED

SQL: SQL (Structured Query Language) is used to perform operations on the records stored in the database, such as updating records, inserting records, deleting records, creating and modifying database tables, views, etc. SQL is not a database system, but it is a query language. SQL is a short-form of the structured query language, and it is pronounced as S-Q-L or sometimes as See- Quell.

Oracle Database: An Oracle database is a collection of data treated as a unit. The purpose of a database is to store and retrieve related information. A database server is the key to solving the problems of information management. In general, a server reliably manages a large amount of data in a multiuser environment so that many users can concurrently access the same data. All this is accomplished while delivering high performance. A database server also prevents unauthorized access and provides efficient solutions for failure recovery.

EXCEL: Excel is a spreadsheet program from Microsoft and a component of its Office product group for business applications. Microsoft Excel enables users to format, organize and calculate data in a spreadsheet.

Argus Safety Database

Key features of Argus include

- Integrated, highly scalable end-to-end safety platform
- Single global database
- Common code base
- Regular release schedule
- Automated global case processing
- Periodic reporting
- E2B exchange
- Scientific querying
- Detailed analytics
- Out-of-the-box integration with Oracle Health Sciences InForm EDC Suite

Safety Case Management

- Compliance with global regulations and standards
- Lower cost and complexity through SaaS deployment
- Efficient case processing via automations and ease of use
- Powerful, extensible, and user-friendly analytics and reports

- Single global database that includes Japan cases and user interface
- Configurability avoids customization and lowers total cost of ownership

METHADOLOGY

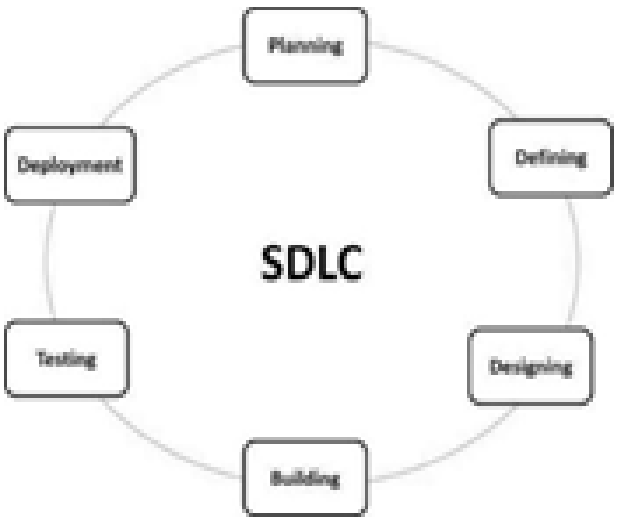
We have many pharmaceuticals clients all over the world we are providing the best solution for their reporting and products to make their business grow.

We provide ***Migration*** solution for Oracle ***Argus*** Safety pharmaceutical document management ***migrations***; moving ***data*** from source to destination with 100% verification.

There are three type of Installation:

1. Fresh Installation
2. Upgrade Installation
3. Mapping Installation
   a) Direct mapping
   b) Code List mappin
   c) Business mapping

In this project me and my team has given has installed a fresh argus system in the cloud based and done the configurations as discussed with the client. We have used the SLDC approach to aims to produce a high-quality software that meets or exceeds customer expectations, reaches completion within times and cost estimates.



Steps Involved in our projects:

a) Interacting with client
   - Creating configuration specification documents.
   - As per the client requirements.
   - Taking follow up if there any change

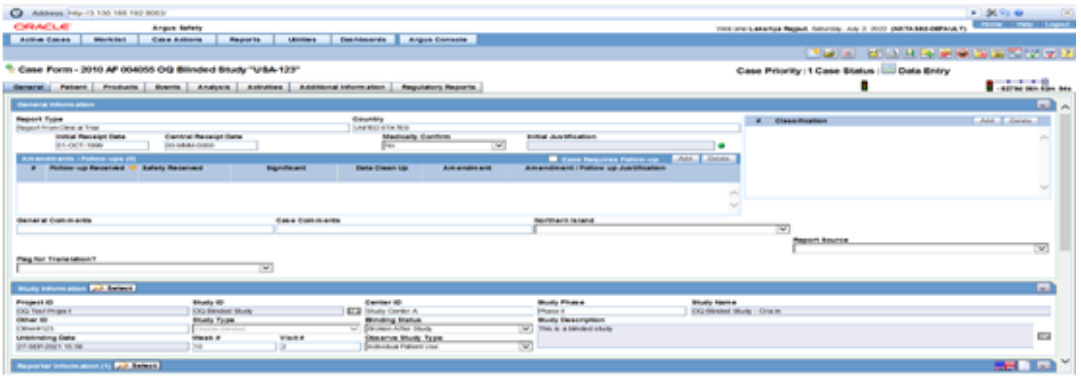
b) Establish different servers
   - Sandbox server
   - Validation server
   - Production server

c) Proving them software with the desired configurations
   - Argus web sever
   - Transaction server
   - Database server

d) Proving 24*7 support

Argus Web server

Argus is a systems and network monitoring application. It is designed to monitor the status of network services, servers, and other network hardware. It will send alerts when it detects problems.



Safety Database

Contains all serious clinical trial AEs (as well as all serious and non-serious post-marketing AEs)

– Does not typically contain non-serious clinical trial AEs.

– Captures all the data associated with adverse event reports in data-fields.

- Generates individual (e.g., MedWatch, CIOMS) and periodic reports.
- Tracks regulatory submissions.
- Supports ongoing surveillance of adverse event profiles.
- Tracks safety signals.

Location	Details
FDA	• AIMS – Project management system • MWPlus: e-system to review/process/ evaluate/analyze AE reports • FAERS database for medical review/evaluation • FOI site • Enterprise Search: Used to store /link image to appropriate cases • Esub - E2B submissions • SCOPUS – Internet search engines • SPL - Labeling database • Empirica – Emerging potential signals, as well as other system support to manage post-marketing commitments, risk evaluation/mitigation strategies, periodic reviews of new molecular entities, data mining, tracking product waivers, etc.
Uppsala Monitoring Committee (UMC)	• Maintains data on behalf of WHO • Data supplied by national health authorities • No review, just analyses/signaling
EMA Eudravigilance	• Stores clinical trial data thru post-marketing • Used for electronic exchange of SAEs among EMA, member states, health authorities, MA holders, clinical trial sponsors • Used for download of post-marketing serious and EU non-serious ICSRs to NCAs and MAHs; Access to the EV database through Access Policy • Safety signals, continuous monitoring/evaluation of potential safety issues • EVCTM (Clinical Trial module), EVPM (Post-marketed module)
Health Canada	• Drug safety database
MHRA	• UK database