Optimizing Omni-channel Intake in Pharmacovigilance
A Cognitive Technology Approach

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Introduction

Digital technologies are being increasingly leveraged in the intake, reporting, processing, and handling of safety Adverse Event (AEs) and product quality complaint (PQC) cases due to the advancement of novel, intelligent and automated Pharmacovigilance (PV) platforms and PQC tools. Rapid development of such platforms has enabled processing of high volume of AEs/PQC reports within an extremely short period with reduced efforts, leading to improved safety analysis and regulatory compliance.

The adoption and shift from traditional PV intake model to a next-generation, automated and intelligent model presents technical challenges and organizational changes for the Life Sciences Industry. In an increasingly digital and connected environment, life sciences industry frequently finds itself facing opportunities that they cannot seize alone. "Ecosystem innovation" is one such opportunity for them and technology organizations to collaborate and develop new concepts, tools and techniques.

Life Sciences Industry is responsible for the safety surveillance of their medicinal products, and for the collection, case processing, and reporting of Adverse Events (AEs) and Product Quality Complaints throughout the product life cycle (from Clinical Development to Post-marketing phase) culminating with reporting to Regulatory Authorities. With the ever-increasing volume of safety reports from new and numerous structured and unstructured sources, multi-channel intake mechanisms and social listening, there has been an exponential increase in the workload and operational overheads for pharmacovigilance professionals. In addition, in recent years, data shared through social media, mobile apps, and other social media channels has increased manifold requiring data mining solutions and techniques.

There has also been an acute need to enhance interactions with patients, Health Care Providers (HCPs), and Key Opinion Leaders Incl. Regulatory Authorities. Timely consumer feedback on case tracking and reporting are the key mechanisms to maintaining the safety, quality, and compliance of any medicinal product. However, with the changing regulatory environment, evolving compliance standards and fragmented information channels, providing superior quality patient support and customer-centric 360 degree service is proving to be a big challenge.

Life Sciences PV contact centers too must innovate to provide optimal, accurate and timely information to patients and healthcare providers. These include outsourcing the PV activities, as well as expansion of manual PV workflows with technology solutions. However, these efforts are neither sustainable in the long term nor scalable in an unpredictable scenario of volume spikes.

Our document aims to provide a blueprint to demonstrate how advanced digital technologies can optimize the PV and Product Quality intake operations to efficiently collect AEs and PQCs from multiple channels and sources irrespective of volume, while maintaining a focus on patient safety.

Multi-channel intelligent intake solution

So, what does it take to build a robust, multi-channel safety intake solution? Key components that can be included while envisioning the solution architecture must include Data Sources, Data Ingestion Tools, a Data Lake, Data Transformation & Processing and Data QC & Submission. Let us now understand each of these architectural components in detail.

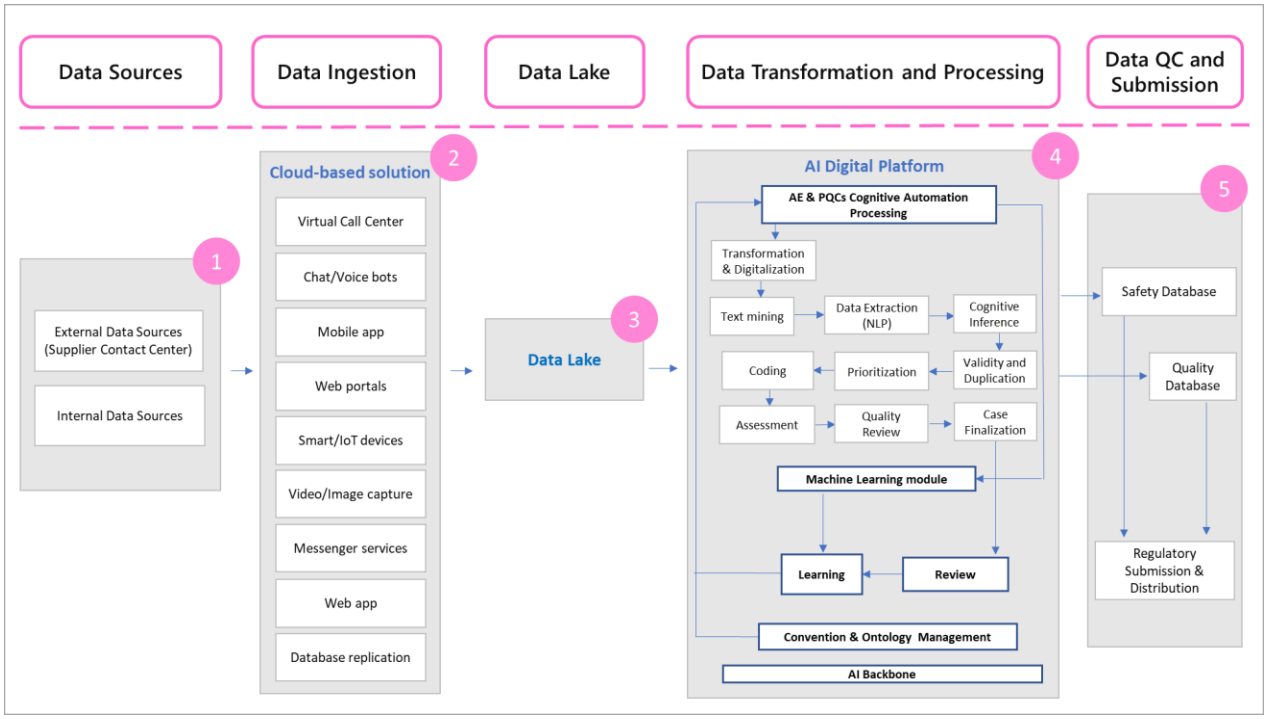

Fig 1. Architectural representation of Multi-channel Intelligent Intake

1. Data Sources

An effective safety information management system mines data from multiple channels, platforms, databases, medical literature, social networks, and other digital resources. These sources have a variety of different interfaces, ranging from direct database access, file transfer systems, API driven access, etc. All data sources play a key role in augmenting product safety and proactively ensuring patient safety through continuous evaluation of the benefit/risk profile of customers products. Few commonly referenced data sources include smart sensors and wearable devices, voice activated devices (such as Alexa), emails/telephone/fax, surveys, social media, patient forums, apps, messenger services, call recordings/transcripts, etc. In addition, Clinical Trial Management Systems, EHR, Literature and Medical Information, Regulatory Authorities and Sentinel systems, Third-party medical product information, PV & PQC capture portals too contribute to the ever-increasing gamut of data sources.

2. Multi-Channel Data Ingestion tools

Data ingestion needs to routinely deal with unstructured data sources such as x-rays, images, handwriting discharge notes, or call center notes that can significantly influence the outcome of an AE or PQC. Many data sources make use of different technologies to share and export data, thereby increasing the criticality of selecting the right ingestion tool.

Connecting these systems to a cloud-based PV platform provides actionable data. In addition, cloud-based platforms also offer a seamless and cost-effective mechanism to consume API-driven access to information, without the need to install and manage server clusters.

If case, ingestion involves legacy data, a data replication solution can be leveraged. Replication of databases allows data exchange between homogeneous as well as heterogeneous databases. To ingest audio, video, documents, semi-structured/unstructured data, etc., the solution should be able to connect directly to the network and storage lake and eliminate the need to modify applications.

To ingest real world data, a secure, reliable, scalable, and cost-efficient mobile application that suits different devices such as smart wearables, phones, and tablets should be considered. For other patient data ingestion channels including emails, SMS, etc., a flexible and scalable outbound and inbound communication tool may be considered.

Patients also utilize call centers, voice/chat bots, and voice activated devices. In such scenarios, the ingestion solution should be an omni-channel, intelligent cloud contact center, enabling machine learning, speech-to-text and natural language processing (NLP) techniques to automatically transcribe contact center calls and extract valuable customer insights embedded in voice.

A digitally advanced technology solution should be able to monitor and ingest specified channel using stream processing and leverage Machine Learning to translate and extract meaningful insights from that data (*Fig 2*).

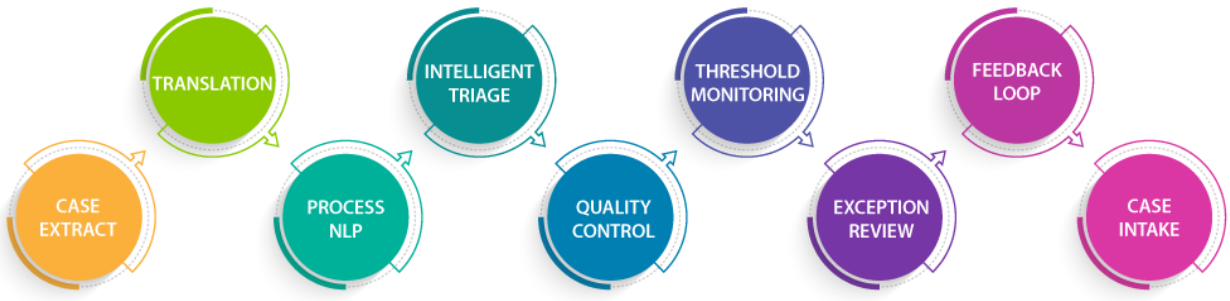

Fig 2. Safety case intake cognitive processing

3. Data Lake

More often than note, PV and PQC data is ingested from different sources, in structured, semi-structured, and unstructured formats, usually in large volumes and across different ingestion times. In such a scenario, incorporating a data lake can be useful. This data lake represents a centralized, single source-of-truth, secure data repository that is easily searchable, scalable, and audit ready. It provides a solution where all PV and PQC data can be stored. Processed data and meta data can be further ingested to downstream systems through push API services.

4. Data Transformation and Processing

It is imperative that a cognitive automation platform for end- to- end processing of safety cases covering activities such as Case Intake, Triage, Data Entry, Medical Coding, Causality Assessment and Narrative Writing for both E2B and Non-E2B fields is considered for effective Data Processing of structured, semi-structured & unstructured source documents. The platform must also support handwritten signatures and advanced Optical Character Recognition integration and leverage niche technologies such as AI, ML and NLP.

For structured documents, the platform may use template-based extraction linked to template configuration, digitize the document, extract the data, and apply business conventions to transform the data based on the business requirements. For semi-structured and unstructured documents, the platform may use a cognitive engine to extract case data from unstructured text/section using contextualization, AI models & NLP techniques.

5. Data Quality Control & Submission

Output generation and data transfer too is a critical step that requires attention. The output from the transformation and processing step should be a fully processed safety information as an E2B R3/R2 document. The platform must support a variety of integration/data transfer mechanisms with external services and/or systems to deliver the functionality.

Prior to moving to Safety database and Regulatory submission, the cognitive automation platform should perform first level quality review of the case information extracted, post which a second level level of human and/or machine Quality Control (QC) review. To further enhance this review process, an ideal platform should calculate confidence scores against each of the extracted fields, thus highlighting the fields (with relatively low confidence score) that would require focused manual intervention and facilitate the QC process.

To support and complete the regulatory submission, the system should be able to capture and track the case's complete journey from intake to distribution. This functionality allows for an aggregate, as well as granular level of analysis, and helps to create automated dashboards providing compliance information at each case stage and overall case level as well.

Key benefits

Transforming the existing contact center with an innovative and automated technology-based approach has multiple benefits. A few of them are listed below –

- Integration between different reporting channels
- Omni-channel patient 360-degree experience
- Streamlining of manual / labor intensive processes, leveraging AI
- Automation due to text mining, Natural Language Processing (NLP), and Machine Learning (ML) approaches
- Limited manual intervention to restricted set of decision points
- Drives efficiency while improving case quality
- Increased satisfaction by allowing more channels/modalities
- Technological advancements, automation, cognitive capture of events and innovation to increase capacity and decrease manual intake data entry & processing time
- Adherence to regulatory timelines for both AE & PQC intake regardless of the channel it comes from
- Avoids unpredictable cost resulting in volume fluctuations
- Future growth and cost efficiencies due to technology

Conclusion

Now, more than ever, Life Science Industry is facing a new era of transformation and must identify ways to reimagine the existing PV processes, reduce cycles times, bring greater transparency, quality, efficiencies, and agility to their organization. There are more potential data sources for AEs and PQCs than ever before, including Electronic Health Record (EHR) data, insurance claims and even social media.

These changes will require a visionary leadership and organizational change to drive Pharmacovigilance transformation. Cloud technologies combined with digital and cognitive automation act as key enablers to address the challenges and ensure patient safety.

About the Authors

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Dr. Alejandra Guerchicoff is a Ph.D. in Molecular Genetics with a Postdoctoral training in Molecular Cardiology and Genetics of Cardiac Arrythmias. She is working as an Industry Advisor for TCS ADD platform with the Life Sciences unit at Tata Consultancy Services (TCS). Dr. Guerchicoff possesses a rich experience of more than 20 years in the domain of clinical research and post-marketing pharmacovigilance for medical devices, drugs, combination products, gene and cell therapy, and software as medical device products. She has authored many prestigious journal publications and books on diverse subjects and different therapeutic areas. In her current role, Dr. Guerchicoff is working for the development of innovative technology solutions with the use of artificial intelligence and other modern technologies across various life sciences operations.

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