White paper

FSP solutions

PPD FSP Pharmacovigilance solutions

AI-driven case intake benefits and key implementation considerations

Introduction

Pharmacovigilance (PV) case intake is critical in adverse event (AE) reporting, ensuring compliance with global regulatory requirements and maintaining patient safety. However, for many years, the increasing complexity and volume of individual case safety reports (ICSRs) have presented challenges for organizations using manual workflows. Traditional case intake methods, which include receiving, transcribing and validating reports, were becoming increasingly unsustainable as regulatory expectations evolved and the volume of cases increased. Despite the optimism shown by some technology vendors that the use of artificial intelligence (AI), there was scant evidence of significant deployment of AI in real functioning pharmacovigilance systems over the years. Barriers to adaptation were attributed to significant costs of the system configuration and datasets needs for both implementation and ongoing maintenance. In this white paper, PPD™ Functional Service Partnership (FSP) Pharmacovigilance solutions experts:

- Re-examine the benefits of AI-assisted case intake and processing.
- Discuss barriers to adoption of earlier systems and two key factors which have significantly reduced these barriers over the past four years.
- Share five key implementation considerations.

Advantages of AI-assisted case processing

In most PV systems, case processing is the most labor-intensive activity. Large pharmaceutical companies and FSP PV solution providers deploy hundreds of individuals to process (or often re-process) data from a variety of formats into a global safety database. The potential benefits of AI-assisted case processing are both of a “good practice” (GXP) or non-GXP nature.

- GXP benefits:
  - Reduces overall case cycle times.
  - Lessens impact of case volume fluctuations.
  - Increases processing consistency.
  - Enables earlier duplicate detection.
  - Facilitates faster identification of problematic cases (e.g. containing conflicting information or missing key details required for processing, such as protocol number or reporter causality for study cases).
  - Improves filing consistency.
  - De-risks black swan case volume surges, e.g.:
    - Case boluses originating from regulators, class action lawsuits, upstream compliance projects or third party (non-partner) studies.
    - Stimulated reporting resulting from publicity of a particular product safety issue.
- Non-GXP benefits:
  - Reduces case processing workforce, thereby reducing costs once the labor savings exceed the additional technology-related costs.
  - Eases scalability of the PV system to accommodate new products and increasing case volume trends.
  - Enables surfacing real-time performance metrics with minimal effort.

Barriers to adoption of earlier systems

Manual case intake systems that link local affiliate PV functions (who receive cases from reporters) with the global PV department (who process cases into the safety database) have been around for several decades. It is within these tools that some of the earlier attempts at automation were made.

The high implementation and ongoing costs of these tools meant that they were usually only cost-effective and deployed for (or by), larger pharmaceutical companies whose PV systems handled tens of thousands of cases per year. Even then these tools may not have been consistently used across all local safety offices, particularly local offices receiving low volumes of cases.

As automation (first robotic process automation (RPA) and later AI) was introduced into some of these tools, new challenges emerged which maintained a high barrier to adoption for smaller pharmaceutical companies and FSP providers:

- **Configuration:** Some systems require several weeks of programming and testing effort to configure each new intake format (e.g. an AE intake form for a given study). Maintenance demands then require ongoing access to specialized resources and are both disruptive and costly, particularly for companies with lower case volumes combined with an array of intake formats. Smaller companies may also have less influence on the format in which cases are received from larger partners.
- **Training datasets:** Earlier AI systems initially needed to be trained with very large datasets (e.g. thousands of cases that previously were manually processed). This was an obstacle for companies with smaller total volumes of historical cases in their safety databases.

PPD FSP Pharmacovigilance solutions experts highlight an additional unspoken barrier to AI adoption was anxiety over the potential response from regulatory authorities, in particular inspectorates. PV is a highly conservative discipline, and many companies closely follow both regulatory publications and industry trends in inspection findings. The lack of specific regulatory authority guidance and industry inspection experience around AI technologies used in PV contributed to hesitation.

Two recent game-changing factors

As noted above, significant barriers to adoption of AI-assisted case processing included anxiety around the potential response of regulatory authorities, and challenges in configuration and training datasets. The beginnings of resolution to both came from two external events:

- Covid-19 vaccines: In 2021, following the commercial launch of the Covid-19 vaccines amidst the global pandemic, the volume of AEs received by vaccine manufacturers and regulatory authorities was so enormous that some of the organizations had no option but to urgently accelerate the deployment of AI. There simply weren't enough available human pharmacovigilance case processors in the global labor market to support legacy manual processes. To get a sense of the unbelievable scale of this challenge, during 2021 alone the European Medicines Agency (EMA) received 1.68 million reports concerning Covid-19 vaccines, almost as much as the combined volume of all other medicinal products authorized in the European Economic Area (EEA) over the same time period[1].
- Widespread access to large language models (LLMs): The public launch of ChatGPT in November 2022 was followed by a variety of other similar generative AI tools built off LLM methodologies. Many organizations have since procured access to private versions of these tools, so they can benefit from the tool learning from a combination of proprietary and public data (e.g. internet), while their proprietary data remains fully firewalled within their organization.

Together these two aspects have reduced some of the anxiety around regulatory response to introduction of AI (now that marketing authorization holders (MAHs) and regulatory authorities who implemented this technology are sharing lessons learned) and substantially reduced some of the configuration and training dataset challenges of the past. However, the direct and indirect costs associated with many current commercial systems are better suited to the needs of large companies than medium and small companies.

Five key AI-driven case intake solution considerations

Large mature organizations may benefit from rigid automation, emerging and evolving pharma and biotech companies are likely to need more flexible solutions. While there is no one-size-fits-all solution, here are five key considerations necessary to choose sustainable, long-lasting solutions with a healthy return on investment (ROI).

1. **Balancing automation with human input**
   With oversight, AI can efficiently support data intake, extraction and transformation to the point where it can be readily imported into a safety database. Later process stages such as case assessment and medical review require more nuanced input by PV professionals to ensure data integrity, clinical accuracy and regulatory compliance. We recommend a balanced approach between machines and humans, ensuring that automated aspects remain human-readable for oversight purposes (i.e., an interface design which factors in the needs of the human reviewers and avoids a black box approach).
2. **Handling variability in reporting formats**
   Adverse event data is received by PV departments in many different formats. These range from structured formats E2B extensible markup language (XML) files and clinical database outputs), to semi-structured formats (including various adverse event reporting forms), and unstructured formats (like emails, literature articles and website screenshots). Since extraction accuracy is important for data integrity and compliance purposes, and new formats are difficult to foresee, PPD FSP PV solutions experts recommend using approaches that provide flexibility.
3. **Selecting data extraction methods**
   Structured data extraction methods have higher accuracy rates but are more rigid, whereas unstructured data extraction methods may have lower accuracy rates (requiring more subsequent human intervention) but offer greater flexibility. For a given PV system, consideration should be given to the most common data formats received and whether it is possible to influence a change from unstructured to structured. Ultimately, given that most PV departments receive a range of structured and unstructured data, we recommend a hybrid approach: a configuration and validation of structured extraction for those formats received in higher volumes (e.g. Council for International Organizations of Medical Sciences (CIOMS-I) from a business partner or standard AE forms received from an internal department), and use of LLM-supported unstructured data extraction for the remainder.
4. **Assessing technology costs vs. return on investment (ROI)**
   Implementing AI automation inevitably involves initial set-up (e.g. configuration, dataset training, validation and process integration) and ongoing related costs which can be substantial. As well as the direct costs paid to the technology vendor, organizations may also need access to specialized resources, such as programmers. This potentially offset the cost-efficiencies gained from reducing headcount. It is essential to fully evaluate and balance costs vs. efficiencies as it relates to a given PV system (e.g. factoring in typical case sources, case volumes, case complexity and ability to integrate with remaining systems). We recommend that organizations model in detail both the immediate and long-term returns related to their specific operational needs and consider less tangible GXP benefits outlined.

5. **Balancing technology Integration with team engagement**
   Successful integration of technologies into a PV system requires that teams embrace and engage with the new systems. This involves not only team member training and support but also fostering a culture that values innovation and continuous improvement. By striking the right balance between AI providing efficiency and human intervention ensuring complexity and accuracy, companies can reduce cost while maintaining or even enhancing consistency and regulatory compliance. We recommend thoughtful design of teams around new technologies, ensuring positive promotion and efficient technological investigation and problem resolution to avoid manual workarounds.

Conclusion

Though the promise of AI-assisted case intake and processing has been around for some time, it is only within the past four years that this became a reality following lessons learned from the emergence of Covid-19 vaccines and publicly available LLMs.

As companies assess integrating AI-driven platforms, they need to consider balancing automation with human input, handling reporting formats' variability, the right data extraction methods, cost assessments against ROI and ways to successfully integrate and balance technologies with team engagement. As barriers to implementation and ROI thresholds decrease, use of this technology will increasingly become an option for small and mid-size pharmaceutical and biotechnology companies as a way of decreasing both costs and risks within their PV systems.

PPD FSP Pharmacovigilance solutions enable biotech, biopharmaceutical and medical device companies to meet their timelines by delivering the best of the best: hard-to-find, top-tier staff who bring a customer-first problem-solving mindset to a range of clinical development services, including PV.

Where a drug or device developer can't always predict — or find and retain — the staff and services it needs, our experts deliver a breadth and depth of therapeutic and functional expertise unmatched in the industry, uniquely positioning PPD FSP Pharmacovigilance solutions to deliver the right experience and knowledge to fill immediate resource gaps. To ensure projects launch on time and stay on budget, we have dedicated roles focused on rapidly ramping up engagements, keeping clients informed with high-touch communications, and applying on-demand staff and services as needed.

We know what it takes to reliably solve the full range of PV challenges. Whether filling small gaps in services, outsourcing multiple functions across a portfolio, or providing expert PV technology guidance and solutions, PPD FSP Pharmacovigilance solutions are tailored to each developer's individual requirements to provide much-needed resource flexibility, reliability and continuity.

Our PPD FSP Pharmacovigilance solutions specialists support more than 250 clients and maintain PV compliance for medicinal products and medical devices across almost 100 countries. Our commitment to PV ensures that companies everywhere can count on us to deliver value-added capabilities, high levels of efficiency and cost savings to ensure on-time, on-budget delivery, every time.

Ready to leverage AI-driven solutions for your case intake process?

Partner with **PPD FSP Pharmacovigilance solutions** today.

References

1. C.03_2021 Annual Report on EudraVigilance for the European Parliament the Council and the Commission

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