WHITEPAPER

LITGENIE: LEVERAGING AI NLP IN PHARMACOVIGILANCE LITERATURE SEARCH & REVIEW

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Introduction

In our previous white paper[1], we discussed the 'Challenges and Solutions in Local/Regional Literature Monitoring in Pharmacovigilance'. This paper emphasizes on LitGenie: A platform that provides quick, affordable, fully traceable results for literature search and review to increase productivity through established workflows, interactive dashboards.

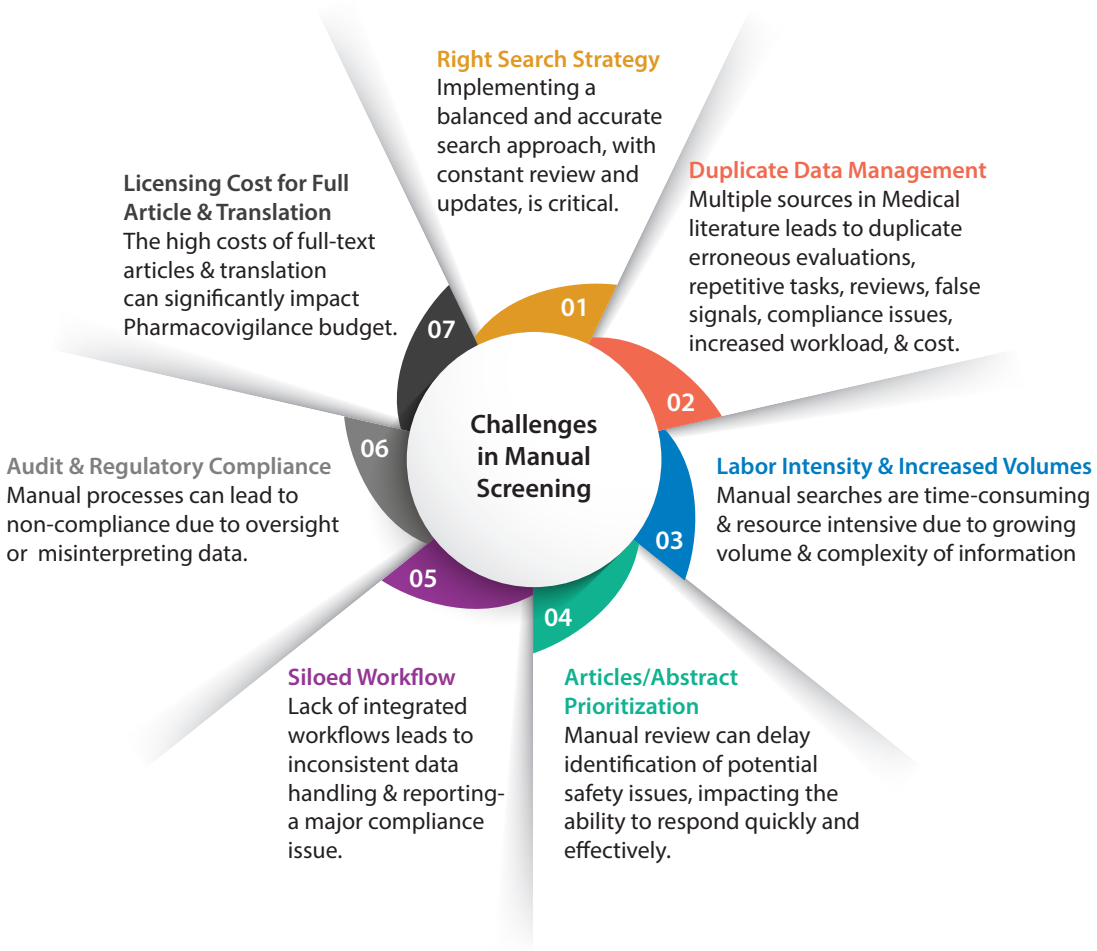
Industry challenges in Manual Screening of Literature Publications

As per European Medicines Agency (EMA) "Report on Pharmacovigilance Tasks"[2], medical literature monitoring produced 6495 unique cases (1.9%) from 355K literature articles in 2019 and by 2022 there are only 6161 unique cases (0.9%) with more than twice the screening volume of 2019 i.e., 718K. The current literature approach is labor- intensive, and the total time spent by PV professionals in literature review (end to end) is ~950 hours/month (100% capacity)[3], (with an estimation of 2 minutes to scan the abstract and 15 minutes to read full text article for ~6000 articles/per month by a top Pharma company) with a workload that can lead to missed timelines and missed important safety information.

However, our automation solution LitGenie, reduces manual labor to ~400 hours/month (42.1% capacity), saving ~ 60% of time spent by literature SMEs.

Hence, leading Pharma's and CROs are seeking AI-enabled solutions to streamline literature monitoring and review processes, enhancing drug safety management. Thus, offering a solution for successful digital transformation in literature review.

The figure highlights the challenges and its impact being faced by the pharmacovigilance industry in the current workflow:

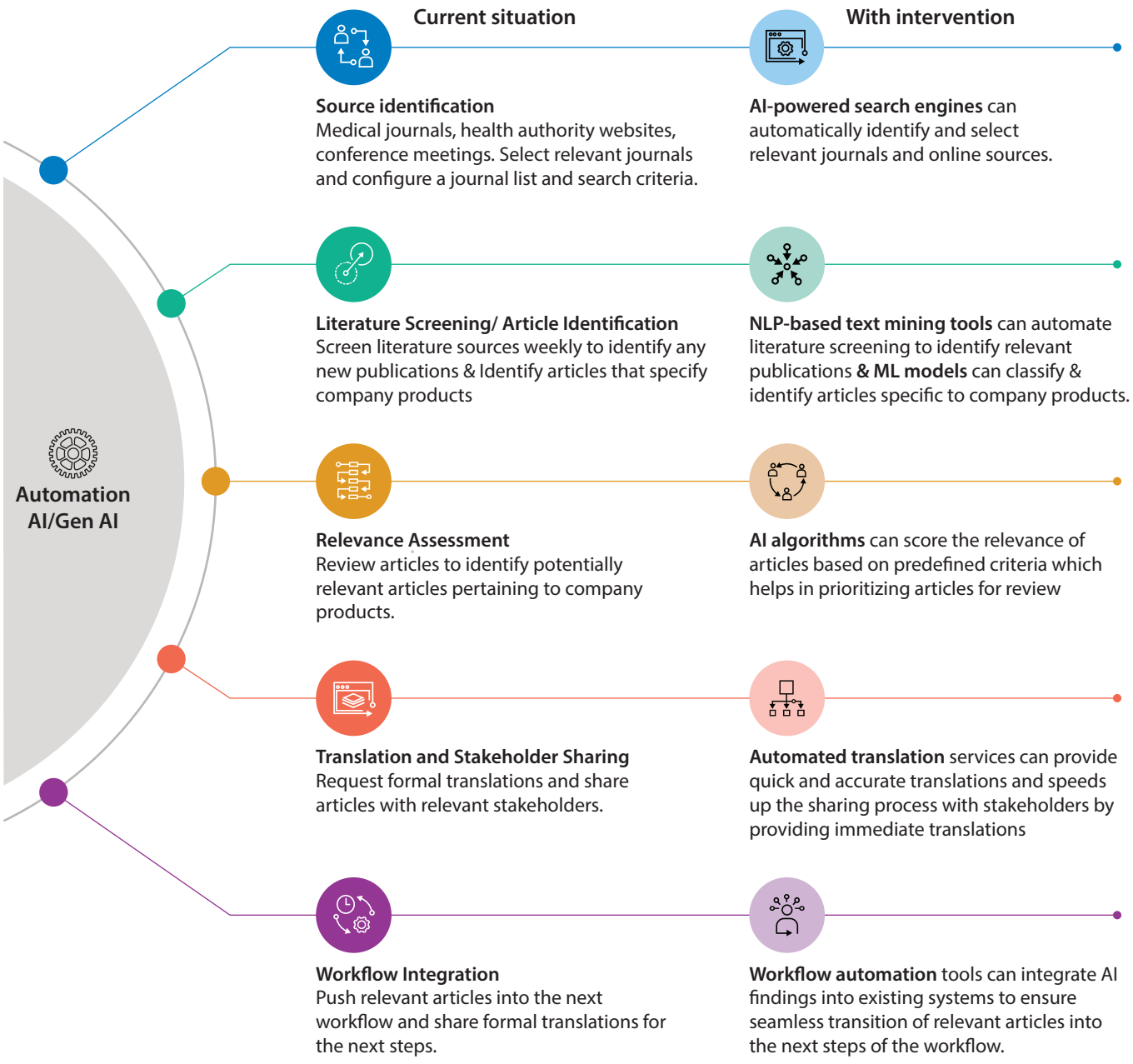


Current vs. Automated Process

Automation/AI/ML/NLP technologies could help us overcome the current challenges and complete the literature review efficiently.

Current situation vs AI/Automation interventions in Literature Workflow Process

Automation/AI/Gen AI will result in faster and more accurate Pharmacovigilance Decision-Making



LitGenie is an end-to-end medical literature monitoring platform for large to medium-sized pharmaceutical organizations and CRO's. With its exclusive AI-NLP productivity & prioritization capabilities, fully integrated workflow and interactive dashboards, the platform provides quick, affordable, and fully traceable results for medical literature search & review.

The platform help understand patterns, context and chronology of a case which helps in predicting & prioritizing the ICSR qualifiers.

Key Features of Solution

- Automated Search maintenance & management
- API enabled integration with Drug Safety Systems
- Rule based Automated Duplicate Check
- AI/NLP powered Literature screening and Prioritization for ICSR, Signal and Aggregate
- Integrated Workflows for Literature case lifecycle from Import to Re-import
- RPA enabled initial requests and follow-up for Full-text articles and Translations
- Process Alerts & Notifications alerts to avoid discrepancies and missed timelines.

Benefits of our Solution in Literature screening and review process

Automated solutions are now essential for ensuring both compliance and efficiency in PV. When implemented correctly, they offer several significant advantages:

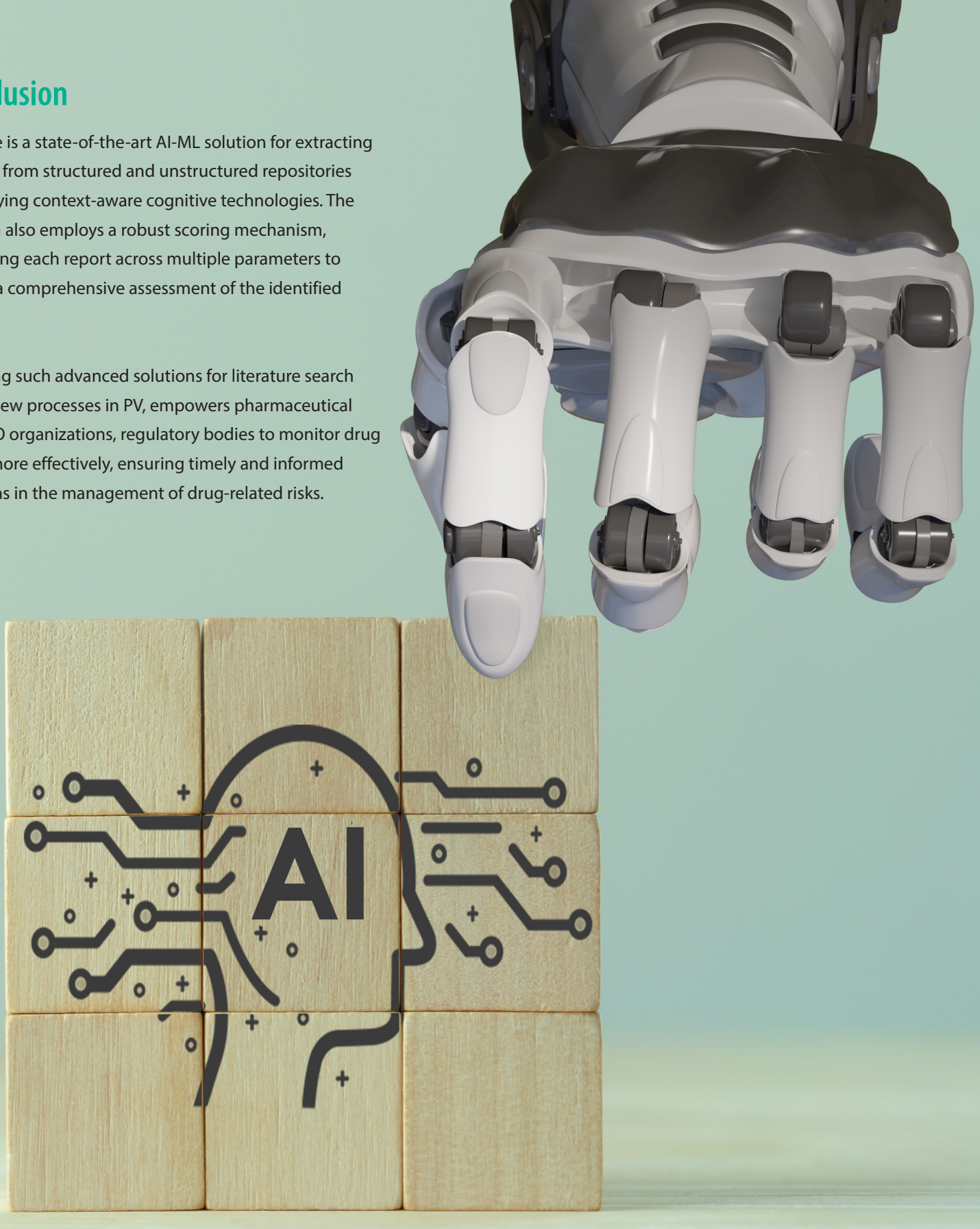
1. Maximizing Team Effectiveness: Automation enables PV specialists to focus on critical tasks that reduce risks and improve patient safety, freeing them from repetitive and time-consuming data processing duties.
2. Enhancing Compliance: Automated systems ensure consistent, auditable processes, minimize audit risks, and maintain regulatory compliance by capturing relevant safety information from literature.
3. Boosting Efficiency and Scalability: Advanced AI technology for PV can significantly reduce costs, enhance process efficiency, and enable organizations to efficiently scale their operations.
4. Configurable Workflow: The platform offers a fully customizable workflow, allowing users to tailor the process to meet specific regulatory needs.
5. Compliance and Validation: The platform is fully validated, audit-ready, and compliant, making it suitable for life sciences applications.
6. Significant Productivity Gains: Purpose-built AI technology enables up to 70% productivity gains, optimizing efficiency in regulatory literature monitoring.

These benefits underscore the transformative impact of automation on pharmacovigilance, driving both compliance and operational excellence.

Conclusion

LitGenie is a state-of-the-art AI-ML solution for extracting insights from structured and unstructured repositories by applying context-aware cognitive technologies. The solution also employs a robust scoring mechanism, evaluating each report across multiple parameters to deliver a comprehensive assessment of the identified ADEs.

Adopting such advanced solutions for literature search and review processes in PV, empowers pharmaceutical and CRO organizations, regulatory bodies to monitor drug safety more effectively, ensuring timely and informed decisions in the management of drug-related risks.



References

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Authors

Naveen Nirmal Kumar

Principal – ICLS

Ayushi Verma

Senior Consultant – ICLS

Kavitha Deekonda

Senior Consultant ICLS

For more information, contact askus@infosys.com