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AI Assisted Scientific Review: A future Scope

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ABSTRACT

The incorporation of Artificial Intelligence (AI) in the scientific and regulatory review procedure poses a transformational change in the evaluation of the pharmaceutical, biotechnology, and medical device products in terms of safety, efficacy and quality. Based on manual review of documents and human based judgment, regulators are increasingly applying AI tools, including machine learning, natural language processing and predicative analytics. The present paper discusses the way international regulators, such as the U.S. FDA, UK NICE, Health Canada, and others, embrace AI-based technologies as a better means of data screening, risk identification, and decision-making. It presents some concrete projects such as the ELSA tool developed by the FDA highlighting significant decreases in the time take to review and more safety issues revealed. There is also the comparison, in the paper, of the manual and the AI-assisted review procedures, as well as the challenges posed by the quality of the data and the transparency of the algorithm as it is experienced today, and the prospective path of the AI in regulatory science, such as the real-time decision support, global harmonization, and the post-market surveillance. The application of AI will shift, as it moves towards becoming an essential instrument within regulatory work processes by facilitating rapid, consistent, and patient-friendly scientific review.

INTRODUCTION

The regulatory affairs set of functions starts with a scientific review, the thorough regulation agency review of the scientific, clinical and technical data which have been presented by the pharmaceutical, biotechnology and medical device industry. During this rigorous review check, it is established that drugs, biologics, medical devices, or any other products, which may harm patients, are safe, effective, and meet the quality standards to be used in the market. Marketing authorization is based on scientific review in order to protect the health of the public. (USFDA,2017)

The procedure usually implies the examination of the variety of potentially critical documents, including non-clinical study data, clinical trial outcomes, chemistry, manufacture and controls (CMC) data, product labeling, packaging, and risk management plans. These documents need to include regulatory requirements and they are typically included in application documents like the New Drugs Application (NDA), the Biologics License Application (BLA), or the Marketing Authorization Application (MAA), depending on which regional regulations are used. (USFDA,2022)

An important control point is scientific review so that only products that have passed stringent tests of safety, efficacy and quality may appear in the market. It safeguards the patients against hazardous or under-performing products and maintains integrity, openness, and responsibility of regulatory judgement. (USFDA,2023)

As the volume of data is growing, as new therapies (including gene and cell therapies) are becoming more complex and because of the pressure to approve new therapies faster without compromising their safety, the role of scientific review assisted by AI is becoming more significant. Technological application Artificial intelligence tools such as machine learning and natural language processing are finding their way into regulatory processes to drive efficiency, reduce errors by humans, and provide further data-driven decision-making. (USFDA,2025)

2. List of countries implementing AI in Scientific Review

- **United States:** The FDA implemented a science-based AI system named Elsa to make scientific review, check labels and perform inspection. (USFDA,2025)

- **United Kingdom**: United Kingdom: NICE uses the NICE AI Framework to evaluate the AI tools that aim to be used in the NHS. (NICE,2025)
- **Canada**: Regulatory Hub In Canada, the Regulatory Hub uses AI to identify drug safety signals through Health Canada.(HEALTH CANADA,2025)
- **Singapore**: The Health Sciences Authority and A*STAR together operate AI4Health which is an AI platform to oversee clinical trials and make predictive analysis. (A*STAR,2025)
- **European Union**: The EU shares the real-world evidence with the EMA to use in DARWIN EU and other AI technologies.(DARWIN EU 2020)
- **China**: NMPA is using an AI-based system, called Tianyan, to monitor and detect clinical fraud. (NMPA,2023)
- **Japan**: The AI-Pilot program initiated by the PMDA aims at the post-market surveillance and the detection of safety signals. (SaMD,2023)
- **Australia**: The TGA employs a nameless AI technology, natural language processing to process safety reports of medicines. (TGA,2024)

2.1 Implementation and Success

1) United States – FDA's ELSA Tool Pilot Success

Since 2023, the U.S. Food and Drug Administration (FDA) has conducted a pilot program with an AI tool named ELSA (Evaluation and Labeling Support with AI). It was utilized in aid of scientific evidence of labeling documents on the new drug applications (NDAs).

Success:

• Cut down time of review by more than 40 percent in a few pilot case.

• Helped reviewers to give more attention to risk-benefit judgments than clerical work.

Following successful pilot, FDA was determined to implement it in full scale by 2025. (USFDA,2025)

2) United Kingdom – NICE AI Framework Implementation

As an example, the National Institute for Health and Care Excellence (NICE) of the United Kingdom has adopted an AI Evaluation Framework, which focuses on testing the effectiveness and hazards of AI-driven health technologies, notably condensed on diagnostics and imaging.

Success:

• The accuracy of lung cancer detection tools was tested in terms of the machine learning algorithms via AI.

• Made evaluation process 30 per cent shorter, helping NHS to adopt it quicker. (NICE,2025)

3) Canada – Health Canada's Regulatory AI Hub

Health Canada established an AI-enhanced Regulatory Review Hub, which finds direct safety signals in real-world data (RWD) such as electronic health records and adverse event reports.

Success:

• Identified a safety signal in a form of a pediatric cough syrup using automated signal detection early on.

• Allowed the implementation of corrective measures and labeling of products within a shorter time.

• Incorporated into the multi-agency work of CADTH and CIHR. (HEALTH CANADA,2025)

4) Singapore – AI4Health Project

In Singapore, the Health Sciences Authority (HSA) and the ASTAR joined efforts and announced the AI4Health project, in which AI will be used in clinical trial monitoring and predictive analytics.

Success:

• Real-time tracking of trial participants by using AI powered dashboards.

• Marked off any data anomaly that potentially indicated protocol exceptions.

• Cut the total time needed to audit trials by half enhancing compliance and safety assurance. (A*STAR)

5) China – NMPA's Tianyan System

The National Medical Products Administration (NMPA) in China has created Tianyan, an AI system capable of identifying clinical trial fraud and the discrepancies in submissions.

Success:

• Identified duplication in clinical data of various anti-diabetic drugs trials.

• resulted in the abandonment or disallowance of frauds.

• Strengthened accountability in its regulatory process through AI-supported audit.(NMPA,2023)

Table.No.1: Regulatory Review Timelines & Expected AI Assisted Review Timelines

Application Type	Initial Review	Technical/Scientific Review	Final Review / Decision	Overall Target Duration	Expected AI-Assisted Duration
IND	Around 30 days (safety evaluation)	Ongoing with protocol submissions	Duration matches clinical trial phases	Varies (begins with trial initiation)	Initial: 10–15 days
NDA	About 2 months (filing assessment)	6–8 months (standard); 4–6 months (priority review)	1–2 months (labeling and approval)	10 months (standard); 6 months (priority)	6–8 months (standard); 3–4 months (priority)
ANDA	Approximately 2 months (filing review)	6–8 months (technical equivalence evaluation)	1–2 months (final decision)	Roughly 10 months total	5–6 months total
BLA	Around 2 months (filing review)	6–8 months (standard); 4–6 months (priority)	1–2 months (labeling and finalization)	10 months (standard); 6 months (priority)	6–8 months (standard); 3–4 months (priority)
510(k)	About 15 days (acceptance review)	60–90 days (detailed technical review)	15–30 days (final decision)	Typically 90 days in total	45–60 days total
PMA	Around 45 days (filing review)	180–220 days (in-depth technical review)	30–60 days (final decision, including panel review)	9–12 months overall	6–9 months overall

Table.No.2: Drawbacks of manual Review

Aspect	Manual Review (Drawbacks)	AI-Assisted Review (Benefits)
Time Efficiency	Manual reviews are slow, requiring significant human effort and causing delays.	AI accelerates data processing, delivering faster results and approvals.
Data Volume Handling	Managing complex datasets is challenging and inefficient manually.	AI can efficiently process and analyze large, diverse datasets.
Error Risk	Human reviewers are more prone to mistakes, inconsistencies, or oversights.	AI offers consistent analysis and systematically flags anomalies.

Aspect	Manual Review (Drawbacks)	AI-Assisted Review (Benefits)
Knowledge Retention	Institutional knowledge may be lost with staff changes or turnover.	AI systems retain and consistently apply historical review logic.
Scalability	Scaling manual review requires more staff and resources, increasing costs.	AI scales easily to handle more data without major increases in cost.
Document Navigation	Manually reviewing vast numbers of documents is inefficient and slow.	AI enables quick search, summarization, and keyword extraction.

3.0 AI Scientific review

Incorporation of advanced artificial intelligence (AI) technologies (machine learning ML, natural language processing NLP, and data mining) into the regulatory review process, aimed at optimizing routine work, accelerating analysis, and enhancing the accuracy and consistency with which a scientific literature review is conducted, may be also referred to as scientific review supported by artificial intelligence (AI). Reading of bulky, structured, and unstructured data containing regulatory entries and identifying trends in them and reporting inconsistencies is facilitated by such technologies. Increased size, scope, and complexity of applications to be submitted to regulatory agencies have necessitated the use of AI tools which are becoming an important component to streamline the review processes, reduce the likelihood of errors by an individual reviewer, and enable decisions based on data to be made at a faster pace. Therefore, there are a multitude of global regulatory bodies in different parts of the world including the U.S FDA, EMA, Health Canada, and many others, which are in the process of considering or experimenting with AI system to make way into the scientific review process as a contemporary participant. (USFDA,2025)

Table.No.3: AI in Regulatory & Scientific Review

Area	AI Contribution	Impact
Data Screening	Automates extraction from clinical trial reports, regulatory documents	Saves time; ensures comprehensive review
Risk Detection	Flags safety signals, adverse events from large datasets	Supports early safety assessments
Document Comparison	Detects inconsistencies or duplications across submissions	Enhances data integrity and compliance
Natural Language Processing (NLP)	Interprets unstructured text in submissions	Makes reviewer work faster and more accurate
Predictive Modelling	Forecasts trial outcomes or risk-benefit profiles	Supports decision-making
Workflow Optimization	Prioritizes high-risk submissions	Improves overall review efficiency

Example: The ELSA AI tool of the FDA can assist the reviewer in defining gaps, inconsistencies, and trends in regulatory applications, and lower the manual workload (FDA, 2024). (USFDA,2025)

Table.No.4: AI Contribution in Patientcare

Area	AI Contribution	Impact
Faster Approvals	Speeds up the drug/device review process	Patients get quicker access to therapies
Safety Monitoring	Tracks real-world evidence and adverse events using AI	Improves post-market safety
Personalized Medicine	AI analyzes patient data to tailor treatments	Leads to better clinical outcomes
Health Literacy	AI chatbots and tools explain complex data to patients	Empowers patients with knowledge
Drug Development	AI accelerates molecule discovery and trial design	Brings better therapies to market sooner

Example: Pharmacovigilance artificial intelligence (such as IBM Watson for Drug Safety) can be used to enable medications to stay safe after approval, which indirectly protects patients. (12)

Table.No.5: Evolution of the Scientific and Regulatory Review Process: Past, Present, and Future (AI)

Stage	Past (Traditional Review)	Present (Semi-Digital Review)	Future (AI-Assisted Review)
Data Submission	Paper-based dossiers; couriered documents	eCTD (Electronic Common Technical Document) submissions via online portals	AI auto-checks data quality, flags errors at submission stage
Document Screening	Manual reading and indexing; prone to human error	Keyword search and document tagging tools	NLP-based AI reads and classifies unstructured text, extracts key data
Clinical Trial Review	Line-by-line evaluation of trial protocols and results	Use of digital dashboards to view trial data	AI models predict trial outcomes, suggest flaws, and highlight safety issues
Comparative Analysis	Done manually by comparing legacy documents and data sets	Some automated versioning or cross-document linking	AI identifies inconsistencies across documents, flags recycled or duplicated content
Reviewer Time Load	Months per submission; backlog issues	Shorter due to digital access	Significantly reduced — AI handles routine checks; human reviewers focus on judgment calls
Decision-Making	Heavily reliant on individual expertise	Supported by structured templates and group reviews	AI provides evidence-based suggestions, trend analysis, and risk predictions

Post-Market Surveillance	Passive reporting systems (e.g., MedWatch)	Adverse event databases with analytics	AI monitors real-world data (EHRs, social media, wearables) for faster detection of safety risks
Transparency	Limited audit trails; time-consuming	PDF audit logs; basic traceability	Full audit logs with AI explain ability layers (XAI)
Speed	6–12+ months (NDA, BLA); 90-180 days (510(k), PMA)	Slightly improved due to eCTD	Faster turnaround; potentially cut timelines by 25–50% with validated AI systems

4.0 Challenges and Limitations:

- **Dependence on Data Quality:** The artificial systems require large volumes of data, which is clean, accurate, and well organized. There is a tendency that the review may include erroneous activities, and moreover, it might fail to identify any safety signal because of incomplete, inconsistent, and biased data, which makes the integrity of the review a complicated concept.
- **No Interpretability:** In general, most advanced machine learning algorithms or at least deep learning, are called front doors, i.e., their decision-making algorithm has no way of interpretation. This can pose certain challenges to regulatory circumstances that entail explainer ability and justification of decisions as aspects that are required to stimulate the sense of trust and responsibility among the populace.
- **Data Privacy and Security Concerns:** This kind of application of clinical trials uses sensitive, patient-level data and proprietary information with privacy and security concerns. The close focus on data privacy aspects (e.g. the HIPAA or GDPR) and security of these systems to cyber-attacks are some of the ongoing challenges in the expansion of the scope of AI application within the regulatory framework.
- **Regulatory Validation Requirements:** In order to be able to apply the AI tools fully in regulatory decisions making, agencies would be required to check the performance of the tools, accuracy of the tools, implementation and fairness of such tools. This requires well identified guidelines, benchmarks, monitoring-auditing among others many of which are yet to be evolved.
- **Human Oversight Need:** Human professionals will continue to be required to ethical, clinical judgment despite the abduction of engines towards semi-autonomy. When it comes to examining the new, risky, or ethically controversial fields, AI does not replace the expertise review; however, it can be added to it.

5.0 Future Scope

The opportunities that AI in scientific review will present to regulatory agencies will fundamentally change the ways in which medical products, drugs, biologics, and devices should be reviewed. It is expected that AI will move beyond an auxiliary tool and become an important subject of regulation operations as scientific submissions increase in volume and complexity. The description of this change is as follows:

- **Full Integration into Regulatory Workflows:** AI will be smoothly immersed into the process of scientific reviewing, beginning with pre-submission evaluation up to the follow-up surveillance of post-market. Inspectors and judiciary organs, including FDA, are already implementing AI in all centers, successfully piloting the technologies that reduced time spent on reviews by 73 percent and increased efficiency by eliminating manual repetitive and time-consuming work (USFDA2025) (MDDI Qmed, 2025) (Nielsen JPS et al., 2024) .The tendency is predicted to become recognized as a routine as the regulatory world is modernized
- **Smart Document Understanding:** AI will be capable of extracting, interpreting, and cross-referencing information contained in large volumes of scientific documentation to the extent that it will rely on advanced versions of natural language processing (NLP). Such ability minimally decreases human effort and increases review regularity and precision (Hartung et al., 2025) (Nielsen JPS et al., 2024) .
- **Real-Time Decision Support:** AI will provide reviewers with real-time analysis such as concise summaries, identification of safety issues, detection of inconsistencies, and even predictive analysis of how an application will be approved that are informed by a historical analysis. This enables the human experts to give special consideration on crucial issues and better decisions making. (USFDA,2025) (Hartung et al., 2025) (Nielsen JPS et al., 2024) .
- **Global Regulatory Harmonization:** As the AI systems evolve, international organizations will tend to embrace common validation models, which will enable them to conduct reviews collectively, creating mutual recognition agreements. This simplification will make the approval process of global products much easier and bring cross-border cooperation. (Fu L et al., 2024) (Fahimeh mirakhori et al., 2025)
- **Automated Post-Market Surveillance:** Radio giant will engage AI to constantly analyze real-world data in the form of electronic health records, social media, and pharmacovigilance databases. This enhances quick identification of adverse events and new safety signals that are faster and accurate as compared to the conventional surveillance systems (USFDA,2025) (Hartung et al., 2025) (Nielsen JPS et al., 2024) .
- **Enhanced Transparency and Trust:** Future AI systems will include explorable AI (XAI) functionality to help deal with the apparent anxieties about opaque and black-box decision-making. These will ensure rational explanations to AI-based conclusions, thus encouraging faithfulness among the regulators, industry stakeholders, and among the populace (USFDA,2025) (Fahimeh mirakholi et al., 2025)
- **Augmenting Human Expertise:** The AI cannot be used instead of humans, but only as a brainy assistant. AI enables regulatory professionals to get off the treadmill of routine assessment activities and allows professionals to work through the complex and value-added activities that involve expert judgment, thus maximizing efficiency and homogenization (USFDA,2025) (Hartung et al., 2025) (Nielsen JPS et al., 2024) .

CONCLUSION

The adoption of Artificial Intelligence in scientific and regulatory review mechanisms constitutes a paradigm change of evaluation of drugs, biologics, and medical devices in terms of their safety, efficacy, and quality. Through top regulatory agencies in the world, including the FDA ELSA instrument and the Singapore AI4Health, AI has already proven its ability to enable efficiency, shortened review times and superior safety signal detection. As the data complexity and data volume increases, the role of AI is estimated to change and become an essential part of regulator workflows rather than support. The AI future of scientific review is bright despite such issues as data quality, algorithm transparency, and the necessity of human supervision. AI will lead to not only more efficient regulation decision making but also trust, consistency, and overall patient safety in the global healthcare environment with continuous innovation, international harmonization with AI, and ethical AI models.

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