ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4

Journal of Coastal Life Medicine

Regulatory Innovation in Artificial Intelligence for Accelerated Medication

Received: 19 October 2022, **Revised:** 16 November 2022, **Accepted:** 26 December 2022

Sushma J. Kamble1*, Prathmesh S. Pawar1, Pooja B. Kolse1, Girish A. Kashid1, Ravindra C. Sutar1, Gowtham Menon1

1Sanjivani College of Pharmaceutical Education and Research Kopargoan, Maharashtra, India-423603

***Corresponding Author: Sushma J. Kamble**

Sanjivani College of Pharmaceutical Education and Research Kopargoan, Maharashtra, India-423603
sushmakamble328@gmail.com

Keywords:

Artificial intelligence, regulatory innovation, Accelerated Medication, Medicinal Product, Natural language Processing.

Abstract

This review provides information on the use of artificial intelligence in regulatory innovation for accelerated pharmaceutical marketing. This article contains information on the legal obstacles to pharmaceutical innovation.

In this section, we'll discuss how innovation can reduce this burden while maintaining compliance and safety. There are barriers to innovation in the pharmaceutical sector, despite the fact that it is gaining headway in other regulatory areas. This article demonstrates how innovative and disruptive automation and AI can be used to remove these barriers and handle regulatory difficulties in the pharmaceutical business. A few case studies were also included in the review.

Although expensive and prone to delay, regulatory procedures in the pharmaceutical industry are essential to the safe and effective use of medication. Here, the discuss various regulatory difficulties and provide concrete instances of how artificial intelligence (AI) might improve and expedite these procedures.

1. Introduction:

The word "AI" has been heavily misused in recent years by marketing teams all around the world. The phrase has evolved into a useful abbreviation for any consumer-facing technology that exhibits automation-like traits but little intelligence across a wide range of industries. This casual usage of the term AI created some misunderstanding, weakened its significance, and kept people in the dark about the current state of AI's most significant advancements.

The advancements in artificial intelligence and machine learning have resulted in nothing short of astounding innovation. Artificial intelligence-based solutions are being used in a wide range of aspects of our world. The recent benefactor of the trend is the pharmaceutical business.

Pharmaceutical artificial intelligence is rapidly expanding. Pharmaceutical businesses are increasingly investigating - or utilising - AI-based solutions in their research, discovery, and production operations. It would be a fantastic idea to provide an overview and evaluation of the pharmaceutical industry's present AI solutions, though, given the knowledge about the state of knowledge and benefits.AI delivers to the pharmaceutical business is currently quite restricted [9].

Many people experience hope and optimism on New Year's Eve. On December 31, 2019, however, hopes for the upcoming year were dashed when Wuhan, China, announced the first epidemic of viral pneumonia cases of unknown aetiology. More than 108 million COVID-19 cases and 4,306,398 fatalities had been recorded as of August 10, 2021, throughout more than 192 nations and territories.

The on-going need for humanity to create secure and efficient remedies for a variety of illnesses, including viral infections, has been brought into stark relief by COVID-19.

Over the course of history, researchers in the pharmaceutical industry have created and discovered a

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

variety of miracle drugs, from penicillin to AZT1 Scientific innovation.

However, as previous experiences have demonstrated, the development of novel medicines can be dangerous. Governmental organisations all around the world have as a result established numerous rules that must be properly followed to ensure the creation of safe and efficient treatments.

Such rules are extremely necessary, but they can have the unintended consequence of delaying the release of 1. novel therapies while driving up costs.

The regulatory process often begins during the R&D and pre-clinical development phases, when regulatory teams decide whether a submission to the appropriate regulatory authorities is necessary as well as the format, deadlines, and information that must be included in the submission. Dedicated teams concentrate on staying current with the continuously changing requirements of the health authorities.

The regulatory teams obtain the necessary paperwork from the research teams during the clinical development phase. These documents are examined for submission readiness, and problems with missing elements, page ordering, structure, and content are noted. The regulatory teams' job is to ensure that the clinical trial application and the data that follows meet the requirements of the health authorities and that there are on-going conversations with the health authorities to communicate any changes to safety, protocols, and investigators. This is a complicated and manual process.

The marketing application phase, where regulatory teams construct a drug application in the form of a submission dossier, is perhaps one of the most important stages in the medication approval process [1].

2. Barriers to Regulatory

Technology innovation in pharmaceuticals:

Although there are substantial fundamental differences between the pharmaceutical and financial services industries, they share similar drivers in terms of efficacy and efficiency and encounter various challenges when implementing new technologies. The management of virtual assets is mostly the emphasis of the financial sector, but the pharmaceutical industry must contend with physical limits and would be more adversely affected by production interruptions. Some of the difficulties encountered by people striving to innovate the pharmaceutical sector include the ones listed below:

1. Complexity
2. Resistance
3. Risk
4. Scarcity

Complexity: Pharmaceuticals are recognised for their intricate timetables and procedures. Any regulated industry faces considerable challenges in implementing change due to internal complexity and procedural specificity. It is challenging to develop completely integrated, data-driven solutions since businesses have fragmented data due to feed storage in the pharmaceutical industry [2].
However, these issues are now starting to be affected by the development of integration technologies. For systems integration, this is regarded as the best in the world (SI). To ensure a seamless user experience, The Dock works directly with its clients to incorporate new solutions into their existing business processes and IT infrastructure.

Resistance to change: In any corporate setting, change management is risky and expensive. The pharmaceutical sector is faced with a perplexing paradox of visionary executives operating in a setting with antiquated systems and procedures. Additionally, the pharmaceutical sector has recently seen several difficulties, and workers are tired of change.

Budget constraints, complex stakeholder contexts, increased market access challenges, patent expirations, increased regulatory scrutiny, evolving communication channels, and a significant amount of M&A activity have all affected the sector over the past few years. Therefore, it should come as no surprise that workers occasionally experience "change fatigue." People develop a sense of direction lessens and change fatigue as a result of being overly exposed to it.

As a result, gradual, low-impact modifications are frequently favoured to drastic, systemic ones.

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

As a result, when change ushers in new technology, this should be done in a way that involves all stakeholders. In the Dock, there is involve all stakeholders who will be impacted by new technologies at an early stage of ideation and development, recognising their unique pain points so that new technologies may address those pain points.

2. **Risk:** Pharmaceutical executives worry that adopting new, occasionally unproven technologies could result in more consumer safety and compliance problems than with legacy systems. This covers the price of corrective action, product recalls, and the chance of losing fresh approvals. These expenses taken as a whole could potentially exceed $100 million [4]. The ensuing audits and controls, where the examination of batch records, control reviews, and certifications might easily result in an additional $100 million in expenses, are another significant aspect of non-compliance. Regulators have the power to impose fines of up to $500 million and a cost of $15,000 per day for noncompliance [3].

Another non-compliance risk is litigation, where expenses can reach $1 billion [4] if a typical flaw is found in a newly automated operation. A backlash from the public would also be seriously detrimental to sales and brand recognition [3].

Any automation or AI project should aim to reduce and eliminate such risk by carefully strengthening current procedures to safeguard customer safety.

3. **Talent Scarcity:** New personnel are required to adapt and sustain regulatory systems as the industry innovates. This is true not only for conventional pharmaceutical professions but also for modern capabilities like cloud computing, artificial intelligence, machine learning, and data analytics. In addition to employee change weariness, the pharmaceutical sector is experiencing a talent shortage in both its traditional and emerging markets.

Simply put, there aren't enough skilled workers out there to cover this talent gap. Pharmaceutical companies struggle to attract workers with cutting-edge technology abilities since they must compete with other industries for their talent.
Additionally, the information that is lost when excellent people leave a complex and compartmentalised industry like pharmaceuticals makes losing them utterly heart breaking. Many of the sophisticated operations in the pharmaceutical sector can only be fully understood by those who have worked there for a long time due to a lack of comprehensive operating procedures and historical documentation.

However, these issues can be remedied by utilising technologies like knowledge management and information retrieval systems powered by artificial intelligence, where current and future knowledge can be safely stored. For instance, it deploy cutting-edge AI in chemistry, manufacturing, and controls (CMC) to enable regulatory relations teams to mine CMC knowledge to quickly respond to regulators' questions.

3. The Forces of Changes:

Since the 2008 financial crisis, regulators in that industry have implemented more complicated restrictions. The quickest and easiest method to comply with all the laws in the years following the financial crisis was to add more personnel to it. Automation and digitalization are the only practical ways to automate regulatory operations, nevertheless, given the current skills deficit. The regulatory constraints placed on the financial industry as a result of the 2008 financial crisis have motivated them to innovate. Due to these factors, the financial services sector has improved its regulatory systems more than the pharmaceutical sector.

Fortunately, there has been a change in how regulation and innovation interact in the pharmaceutical industry. New types of practise and new ways of thinking are helping to show the critical role regulators and regulation play in enabling socially, environmentally, and economically worthwhile innovation, when regulation and regulators were once considered as a barrier to innovation. By implementing regulatory interventions that support or even drive innovation, regulators are beginning to investigate how business-led innovation might help them accomplish their goals. The EMA and FDA are both innovative in how they oversee the pharmaceutical sector. The FDA acknowledged the need for internal change as a result of rising demands from the public, the pharmaceutical sector, and the 21st century.
In the European Union, the way clinical trials are conducted will undergo a major change when the Clinical Trial Regulation—Regulation (EU) No

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

536/2014—comes into application. This harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System (CTIS) [5].

4. AI Solution:

By developing fresh strategies that make use of cutting-edge technology like AI, one may be able to improve and streamline regulatory processes. According to recent studies, the usage of AI in the pharmaceutical business is growing, with a market size predicted to reach $10 billion by 2024.

5. AI Innovations:

Despite the numerous obstacles, genuine regulatory innovation is already taking place thanks to automation and artificial intelligence (AI).

Additional research has revealed regulatory intelligence to be a significant use of AI in the pharmaceutical sector [6]. Opportunities for the application of AI in the regulatory sector are highlighted in a 2018 paper by the Artificial Intelligence Consortium, which is made up of health authorities, NGOs, and industry regulatory specialists. They emphasise the use of artificial intelligence (AI) based on natural language processing (NLP) to extract intricate regulatory intelligence from unstructured material. AI can aid regulatory and a health authority in their decision-making processes for product characteristics, summaries, and CMC (chemical, manufacturing, and controls) documents, which would enable the pharmaceutical business to make submissions more quickly.

AI techniques have also been shown to have potential for processing and managing drug related information, including the extraction of terms related to adverse drug reactions (ADRs), which are unwanted effects caused by the administration of a drug [7]. ADRs are in the top 10 leading causes of death and cost approximately $75 billion annually in the United States [8].

5.1. AI in drug discovery and development:

The pharmaceutical industry's primary areas of activity are drug research and drug development. It has the highest concentration of more or less developed solutions. The following applications of AI show the most promising results:

- Data-driven target discovery (e.g., cancer drug targets)
- Next-generation sequencing
- Pre-clinical and early-stage drugs discovery
- Late-stage drug candidates
- Small molecule therapeutics
- Novel drug design
- Novel biological targets

While developing a functional drug requires a significant investment, drug development is a big industry with immense financial risks. Spending a lot of money on numerous candidate cures that ultimately fall short and get bogged down in testing or regulatory approval is not uncommon. The key to efficiently developing new medications is artificial intelligence. It improves the procedure for developing new medicines and further addresses the issue.

AI provides speedier, more affordable, and more effective drug discovery, which addresses many of the issues facing big pharma today [9].

5.2. AI in Pharmaceutical Manufacturing:

AI allows to streamlining production processes in pharma companies the improvements can span several areas such as:

- More consistent quality control, helping consistently meet Critical Quality Attributes (CQAs)
- Shorted design phase
- Improved waste management
- Supply chain management
- Inventory management
- Improve production reuse

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

- Predictive maintenance

Because AI has the potential to increase industrial efficiency, leading to faster output and fewer waste. Reduced human involvement and data processing are primarily responsible for making this possible. Production processes are greatly improved by machine learning algorithms, which ensure that some operations are carried out more accurately and help uncover areas that may be further optimised [9].

5.3. AI in Pharmacovigilance:

The science and practices of medication safety monitoring are known as Pharmacovigilance. These tasks include identifying, evaluating, comprehending, and avoiding negative drug effects or other potential drug-related issues.

Pharmacovigilance entails gathering and analysing vast volumes of data. Herbals, conventional and alternative medications, blood products, medical devices, herb vigilance, hemovigilance, and materiovigilance are now included in the program's list of concerns. It's a perfect area to use deep learning algorithms and AI for advanced analytics because there are so few data points to look at and draw conclusions from. PV offers options to address classification and prediction issues thanks to artificial intelligence. This promotes efficiency and the development of fresh thoughts.

AI-powered apps can automate the tedious and laborious activities involved in processing clinical cases, which reduces processing time and lowers total Pharmacovigilance costs. Applying natural language processing (NLP) to a large set of data, such as white papers, articles, books, or electronic medical records, would be another use of AI that might offer value by identifying unanticipated impacts of a new therapeutic product[9].

6. Artificial Intelligence in Regulatory Affairs:

Another significant area of the pharmaceutical sector that can profit from adopting AI technology is regulatory affairs. Pharma firms must not only stay up to speed with the most recent national and international standards and laws, but also with the complicated discovery and research procedures. A regulatory team would normally collaborate with the pharmaceutical personnel to manage this extensive knowledge and ensure compliance. Even the most conscientious team, however, cannot ensure that the drug will reach the market.

AI can be used as a tool to centralize the information on important updates from regulatory bodies:

- FDA
- EMA
- TGA
- Health Canada
- CHMP
- PRAC

To ensure that a drug is approved, pharmaceutical companies need precise interpretation, application, and communication both inside and outside the organisation. Regulatory affairs specialists are accountable for following local regulations as well as global ones:

- Preparing medications for regulatory submission and overseeing the regulatory agencies' approval procedure,
- Negotiations to ensure drug approval,
- Finding solutions for limitations imposed by science and law.
- Gathering and analysing scientific information,
- Developing plans for the company's success and the sale of medicines

Ensuring that the drug's advertising and packaging correspond to local, national, and international regulations. Pharmaceutical regulatory affairs experts can receive alerts from AI about the most recent international, national, and state laws. The regulatory team may evaluate the drugs on the market and develop informed plans with the help of this dashboard[9].

6.1. AI in Regulatory Submissions:

Pharmaceutical firms will save time and money by avoiding capital-intensive investments in compliance and regulation by automating the regulatory filing

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

process with AI. By automating some of the monotonous and time-consuming operations that people must perform, AI can aid in this process. AI can be used, for

instance, to automatically create regulatory paperwork using templates or extract data from clinical studies.

Large amounts of data can be analysed using AI to find patterns and links that would be impossible for humans to find on their own. This demonstrates how AI is a major innovation-driver in the pharmaceutical industry.

AI will speed up the evaluation process for producing new drugs and hastening their introduction to the market in regulatory issues. The application of AI in medication regulatory matters is still in its early stages, but as more businesses use this technology, it is likely to become more prevalent [10].

7. Case Studies of AI innovation:

The expertise in using cutting-edge AI to solve regulatory problems. These concepts were created following extensive client discussions that resulted in workshops. Where a detailed examination of their regulatory practises took place. The C-suite, regulatory, business, and IT teams were just a few of the many client stakeholders participating in this. Among these are solutions for drug labelling, advertising, and CMC (chemistry, manufacturing and controls).

7.1. AI for drug labelling:

Teams of medical, legal, and regulatory experts monitor the most recent data on pharmaceutical products as part of the labelling process, which results in accurate information about the indications, directions, dosage, side effects, and other safety information being presented on consumer packaging and information leaflets. Consumers may experience major health difficulties if the information on drug labels is not accurate or up to date. Drug labels are the safety information linked with these leaflets and packaging.

A summary of the key scientific data required for the safe and effective use of a human prescription medicine or biological product must be included on drug labels, according to regulations enforced by regulators like the FDA.

Additionally, after a drug is on the market, it needs to go through ongoing clinical trials and be watched for potential negative drug responses. This may lead to many label modifications yearly across numerous markets, and these processes of designing, reviewing, approving, and implementing changes take time.

As a result, drug product labels frequently fall behind new medical understanding because it may have been years after the drug was initially made available on the market.

As an illustration, a review of 9,105 drug product labels revealed that a sizable portion of multi-manufacturer therapies and Due to incomplete, obsolete, and improperly formatted generic therapies' adverse drug reaction (ADR) sections, there were inconsistencies.

Studies have also found that drug product labels failed to keep up to date with the latest findings from scientific research and clinical trials. Issues included deficits in the pharmacokinetic data listed in product labels, omissions in age-related product label information in anti-depressants, quantitative information missing in 92% of 50 renal drug products and deficits in drug-drug interaction information in 15% of the product labels for treatments that interact with warfarin.

Software integration and structured document authoring plays a role in addressing these issues by maintaining the integrity of information across the labelling process; however, there is still an enormous level of manual effort involved. Therefore, human and system failures can still lead to inaccurate safety information.

The natural language processing techniques offer a solution for processing and managing drug-related information, including the extraction of relevant clinical terms. For example, regulators, such as the FDA, mandate that label information for approved treatments should include observed and predicted, clinically significant drug-drug interactions (DDIs).

This platform can analyse and extract DDIs from unstructured drug label text, identifying treatments and detecting the relationships between them—

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

essentially putting meaningful structure on unstructured text then use this structured output to build a knowledge graph of interacting substances using Ampligraph, a machine learning tool developed by Accenture's Tech Labs that creates deep learning graphs. These graphs aggregate related drug label knowledge into a data structure that serves as a basis for detecting missing drug information and recommending suitable drug interactions [1].

7.2. AI in Chemistry,

Manufacturing and Controls:

Additionally, documentation pertaining to a novel drug's chemistry, manufacture, and controls must be submitted in order to bring it to market (CMC). However, pharmaceutical producers must constantly diversify their operations and deal with increased levels of complexity and speed in R&D. Their transformation of their CMC knowledge processes into digitally empowered, globally networked powerhouses capable of ground-breaking innovation at scale is a top goal for them.

Between research and manufacturing groups, divisional disconnects can be caused by legacy procedures. This leads to antiquated knowledge-sharing procedures and time-consuming working methods for scientists throughout the drug development process.

A primary example exists in the regulatory authoring process, where challenges with knowledge sharing can limit the ability to get a product to market as quickly as possible and in the hands of patients that need them. Regulatory documentation is based on diverse information sources across a wide range of development process information sources across a wide range of development process in repetitive cycles of review, feedback and response between pharmaceutical companies and regulators.

Enablers such structured content management systems are being created to collect, distribute, and evaluate regulatory information in order to improve the efficiency of this process. However, a large portion of the data that CMC currently processes includes semi-structured data from a variety of sources and unstructured text. Leveraging AI to innovate in this field by structuring and querying such data.

To address these challenges in CMC, the global innovation team at The Dock engaged closely with our pharmaceutical stakeholders who are working on the frontline of regulatory compliance, through a series of innovation workshop sessions.

The Dock team worked with experts from regulatory, research and manufacturing to understand CMC regulatory work processes and uncover key pain points and root causes. Then they co-created with the client on a prioritized set of future state features that can address pain points and create new value. Semantic search across databases, the ability to match past response to queries (RTQs) with suggested relevant documents were among the key features prioritized [1].

7.3. AI for promotional materials:

Additionally, regulators work to protect public safety by guaranteeing the accuracy of medication marketing materials through extensive surveillance and compliance operations. Additionally, pharmaceutical corporations guard their reputation and brand fiercely.

Patient safety issues, expensive fines, product recalls, and permanent reputational harm are just a few of the harms that can result from false information on promotional materials. Industry and health authority regulatory experts put a lot of work into intricate, labour-intensive processes to protect against these threats. Additionally, the amount of information that needs to be processed and the speed at which drug research is moving forward mean that both industry and regulators are dealing with growing workloads.

In the case of "blockbuster" medications, which have received authorisation to enter the market but are still technically in development. This is currently the case with cutting-edge medications like immunotherapies and is expected to be the case with any very effective therapies like a COVID-19 vaccination. Pre-approval is likely in such circumstances because stakeholders want to get these therapies on the market fast and successfully.

This calls for the continuation of follow-up clinical trials and the prompt dissemination of new information to drug labels and marketing collateral. Now that compliance for drug labels and advertising materials is so difficult to achieve, AI can help. This is assisting clients in streamlining their operations by

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

utilising AI to automatically compare promotional content to drug product basic data sheets and brand guidelines.

For instance, the screen capture from our promotion programme (bottom left) shows how marketing promotional content may be automatically compared to fundamental product safety facts, showing any disparities that might be unreliable or deceptive. A ground-truth database containing essential product attributes and safety information is utilised to extract and analyse text from PDF marketing brochures using natural language processing, and the accuracy of this unstructured content is then verified. Users are supplied with thorough feedback on any potential violations so they can address and repair any errors in the language using the links provided with the primary product information.

Where business rules for each product and marketing channel are kept, the screen capture (below right) shows how marketing materials may also be checked against brand guidelines [1].

7.4. AI for IDMP Compliance: The art of the conceivable:

The Identification of Medicinal Product (IDMP) is a new legislation that is a crucial component of the European Medicines Agency's (EMA) telematics plan to enable the reliable transmission of medicinal product information in a strong and uniform manner through data standards.

The fact that data is frequently kept in a variety of disjointed, antiquated systems with inconsistent file formats and low integrity is a major problem. The data may also be available in unstructured formats, where extracting it has proven to be a laborious, time-consuming, and manual operation.

At Accenture, they think AI innovations like natural language processing (NLP), virtual agents, and robotic process automation (RPA) have the potential to enhance data transformation, data purification, and the use of data standards like IDMP [13]. We are creating a platform that uses intelligent automation to assist firms in their journey toward IDMP compliance by fusing our in-depth subject experience with technology and the regulatory landscape. The three main areas that the solution is designed to serve clients with are data analysis, data extraction, and data enrichment.

For instance, IDMP data may be kept in a manufacturing system or a regulatory information management (RIM) system. Organizations must make sure that the particular IDMP data piece is present in that system in addition to determining where the data is kept.

8. Conclusion:

AI-based pharmaceutical solutions are expanding, and many businesses are using them as their new field of competition. To effectively process enormous amounts of health data, the pharmaceutical business sorely requires digital transformation and new technology. It pinpoints important connections between them, reducing the time it takes for drugs to reach the market.

Healthcare has been altered by the pharmaceutical business, but in order to guarantee patient safety and successful treatment, strict regulatory requirements must be followed. This puts a strain on the industry because regulatory teams now have to make sure that data is accurately kept during the development of new drugs and after they are put on the market. It is difficult to improve the regulatory process through innovation; it must be done in a way that reduces costs while minimising the danger of non-compliance. They have demonstrated several instances where cutting-edge AI technologies may improve procedures in an environment with strict regulations by working directly with the pharmaceutical business.

Conflict of Interest:

No conflict of Interest

References:

[1] https://www.accenture.com/_acnmedia/PDF-165/Accenture-Innovation-in-Regulatory.pdf
[2] "Top 5 Challenges Faced by Analytics Start-ups," [Online]. Available: https://health.economictimes.indiatimes.com/news/health-it/top-5-challeng- es-faced-by-data-analytics-start-ups/69521596.
[3] "The Business Case for Quality,". Available: https://www.fda.gov/media/82992/download.

ISSN: 2309-5288 (Print)
ISSN: 2309-6152 (Online)
CODEN: JCLMC4
Journal of Coastal Life Medicine

[4] "Managing the Cost of Non-Compliance," [Online]. Available: https://www.pharmtech.com/view/managing-cost-non-compliance.

[5] "Regtech 101: What It Is, Why Now, & Why It Matters," [Online]. Available: https://www.cbinsights.com/research/regtech-trends-fintech/.

[6] Lamberti et al, "A study on the application and use of artificial intelligence to support drug development," Clinical Therapeutics, vol. 41, no. 8, pp. 1414-1426, 2019.

[7] Combi et al, "From narrative descriptions to MedDRA: automatically encoding adverse drug reactions," Journal of Biomedical Informatics, vol. 84, pp. 184-199, 2018.

[8] S. R. Ahmad, "Adverse drug event monitoring at the Food and Drug Administration,"[Online].Available: https://pubmed.ncbi.nlm.nih.gov/12534765.

[9] https://nexocode.com/blog/posts/ai-in-pharma/#artificial-intelligence-and-machine-learning-in-pharma

[10] https://www.regulatoryaffairsnews.com/post/artificial-intelligence-in-regulatory-affairs

[11] "The Challenge of IDMP Compliance," [Online]. Available: https://www.pharmtech.com/view/challenge-idmp-compliance.

[12] "The Challenge of IDMP Compliance," [Online]. Available: https://www.pharmtech.com/view/challenge-idmp-compliance.

[13] "Redefining Regulatory through Intelligent Automation," [Online]. Available: https://www.accenture.com/cn-en/services/life-sciences/regulatory