Magna Scientia Advanced Biology and Pharmacy
eISSN: 2582-8363
Cross Ref DOI: 10.30574/msabp
Journal homepage: https://magnascientiapub.com/journals/msabp/

(REVIEW ARTICLE)

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Emerging Frontiers in Approval Process, Challenges, Future Perspectives and Recommendations for New drug Application (NDA)

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Magna Scientia Advanced Biology and Pharmacy, 2026, 18(01), 055-065

Publication history: Received on 21 April 2026; revised on 04 June 2026; accepted on 06 June 2026

Article DOI: https://doi.org/10.30574/msabp.2026.18.1.0037

Abstract

A new pharmaceutical product must submit the New Drug Application (NDA) in order to be approved for marketing. The Central Drugs Standard Control Organization, which is overseen by the Drug Controller General of India (DCGI), regulates the drug approval procedure in India. Comprehensive data about the drug product's quality, safety, efficacy, preclinical research, clinical trials, manufacturing procedure, and post-marketing surveillance is included in the NDA filing. To increase worldwide harmonization and standardize regulatory filings, the Common Technical Document (CTD) format has gained widespread acceptance. However, there are a number of obstacles that the NDA submission process must overcome, such as intricate legal requirements, problems with data management, protracted approval processes, worries about efficacy and safety, and political and economic considerations. New developments including artificial intelligence, electronic submissions, and enhanced. The modernization of NDA documentation is being aided by recent developments like artificial intelligence, electronic submissions, enhanced data security methods, and standardized international criteria. The regulatory requirements for drug approval in India, the format of NDA documentation, the main obstacles to the submission process, and future prospects for enhancing regulatory effectiveness and international harmonization in pharmaceutical submissions are all covered in this review.

Keywords: ICH M4Q; E; CTD; SUGAM; New Drug Application; Artificial Intelligence; Machine Learning; Real-World Evidence (RWE).

1. Introduction

A formal proposal filed to a regulatory body for permission to market a novel pharmaceutical product is known as a novel Drug Application (NDA). Since 1938, the NDA system has served as the foundation for the regulation and control of new medications in the US, requiring approval prior to commercialization.[1] The NDA is a thorough document that drug sponsors use to give specific information about the pharmacology, toxicology, safety, efficacy, quality, manufacturing process, and labeling of the drug product. The NDA for regulatory assessment contains the data produced during preclinical research and clinical trials carried out under an Investigational New Drug (IND) application.[13]

An NDA's main goal is to give regulatory bodies enough scientific proof to decide whether a drug is safe and effective for the intended use, whether the benefits outweigh the risks, whether the suggested labeling is appropriate, and whether the manufacturing processes and quality control procedures are sufficient to guarantee the product's identity, strength, purity, and quality. [2] As a result, the NDA includes all of the drug's developmental history, including animal study results, clinical research, pharmacokinetic data, manufacturing and chemical information, packaging specifics, and product specifications.[14] [17]

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The US Food and Drug Administration, in particular the Center for Drug Evaluation and Research (CDER), reviews and approves NDAs in the US [3]. Under the direction of the Drug Controller General of India, the Central Drugs Standard Control Organization oversees the submission and approval of NDAs in India. Before new pharmaceutical goods are put on the market, the Indian regulatory system makes sure they adhere to the necessary safety, efficacy, and quality criteria. [6] Therefore, by guaranteeing the availability of safe and effective medications, the NDA filing procedure is a crucial stage in the drug development process and plays a significant role in safeguarding public health.[18]

2. Regulatory requirements for drug approval in India

- Central drug standard control organization (CDSCO)
- Drug controller general of India (DCGI)

2.1. Central drug standard control organization (CDSCO)

The primary regulatory authority for pharmaceutical medication regulation in India is the Central medication Standard Control Organization (CDSCO). The Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, is in charge of CDSCO's main headquarters, which is situated in New Delhi.[5] It is essential to the approval of new capsules, clinical trial regulation, bioequivalence research evaluation, prescription medicine import licensing, and post-advertising and marketing surveillance through pharmacovigilance applications. [6] [15] It has implemented a number of measures to enhance the drug approval process's accountability, efficiency, and transparency.

The Medical Device Rules, 2017, simplified clinical trial rules, and established the SUGAM online platform for regulatory applications are important initiatives.[19] These programs mark important advancements in India's regulatory framework's modernization and fortification.[6]

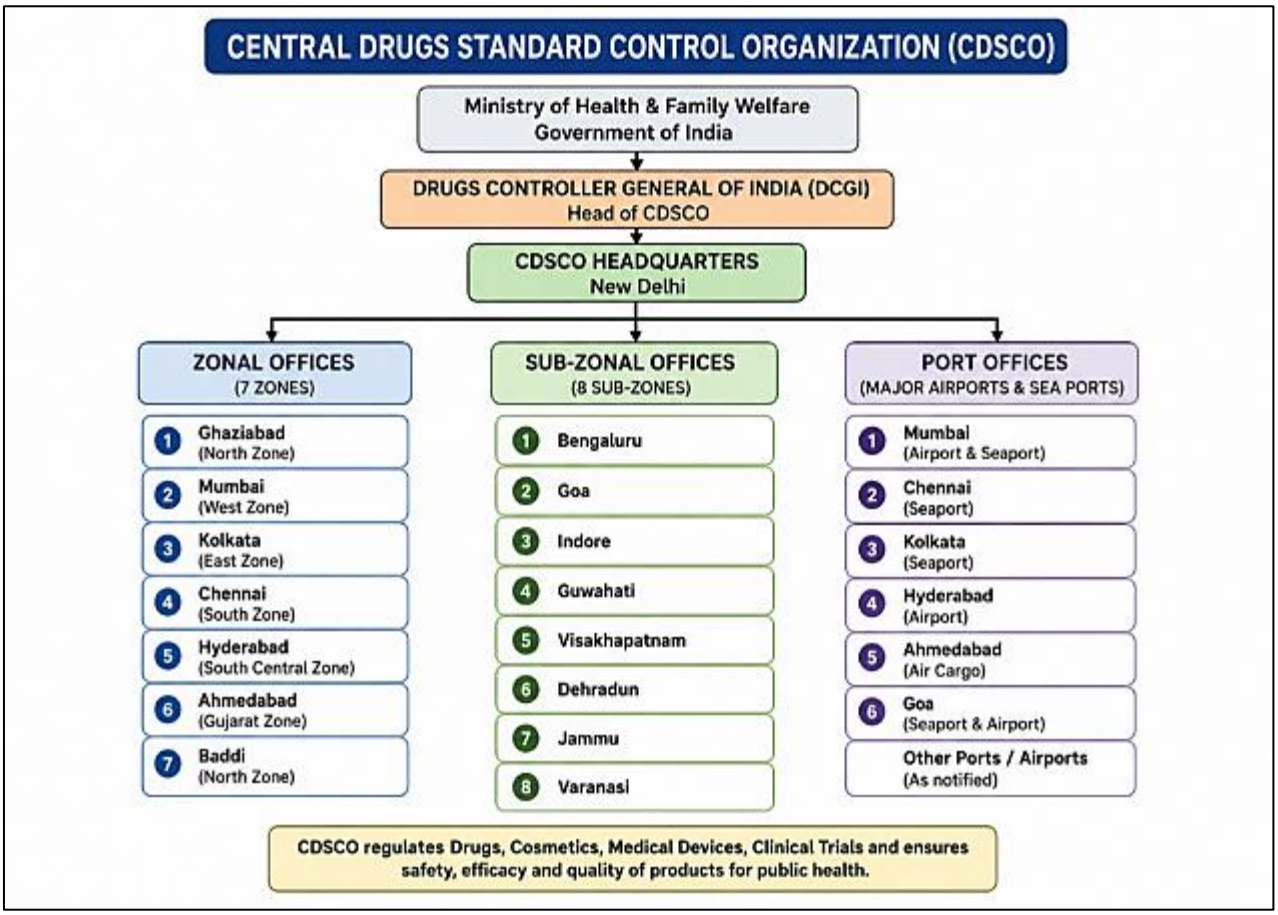

Figure 1 CDSCO framework

2.1.1. Function Of CDSCO

- Establishing guidelines for medications, cosmetics, equipment, and diagnostics.
- Establishing regulations and amending laws and regulations.
- To approve new medications for sale and oversee clinical trials in India.
- To grant licenses for the production of specific drug categories as Central License Approving Authority, such as blood banks, medical devices, r-DNA medications, large volume parenteral, vaccines, and serum.
- To control the requirements for imported medications and work pertaining to the Drugs Consultative Committee (DCC) and Drugs Technical Advisory Board (DTAB).
- Organizing the State Drugs Control Organisations' efforts to ensure the Act is administered consistently and offering policy recommendations. [7]

2.2. Drug Controller General of India

The Central Drugs Standard Control Organization, which oversees pharmaceuticals and medical devices in India, is led by the Drug Controller General of India. In India, the DCGI is in charge of authorizing new medications, clinical trials, and medical equipment. Under the Drugs and Cosmetics Act, the Central Government appoints the DCGI. [8] For efficient drug regulation, the organization collaborates with state drug control authorities. The Drug Consultative Committee (DCC) and the Drug Technical Advisory Board (DTAB) also provide guidance to the DCGI.[15] In order to achieve regulatory convergence to worldwide norms like as ICH, WHO, and USFDA standards, this DCGI is also crucial. India's reputation as a center for clinical research would improve as a result.[9]

2.2.1. Responsibilities

- The DCGI sets standards for the production, distribution, and sale of pharmaceuticals in India.
- Serving as an appellate authority in the event of a drug quality dispute.
- The creation and upkeep of a national reference standard.
- To provide uniformity in the Drugs and Cosmetics Act's enforcement.
- Drug analyst training provided by State Drug Control Laboratories and other organizations.
- Examination of cosmetics obtained as survey samples from CDSCO (Central Drug Standard Control Organization).[5] [15]

3. New drug application

A novel Drug Application (NDA) is a request for authorization to market a novel medication that is made to the appropriate regulatory body.

A sponsor must provide preclinical and clinical test results for analysis of drug information and a description of manufacturing processes in order to be granted this approval. [9]

A sponsor provides preclinical and clinical test data to the NDA for analysis of drug information and a description of manufacturing processes in order to receive this authorization. Once the agency receives the NDA, it goes through a technical screening. This assessment makes sure that enough information has been provided in every field to support "filing" the application for formal FDA review.[10]

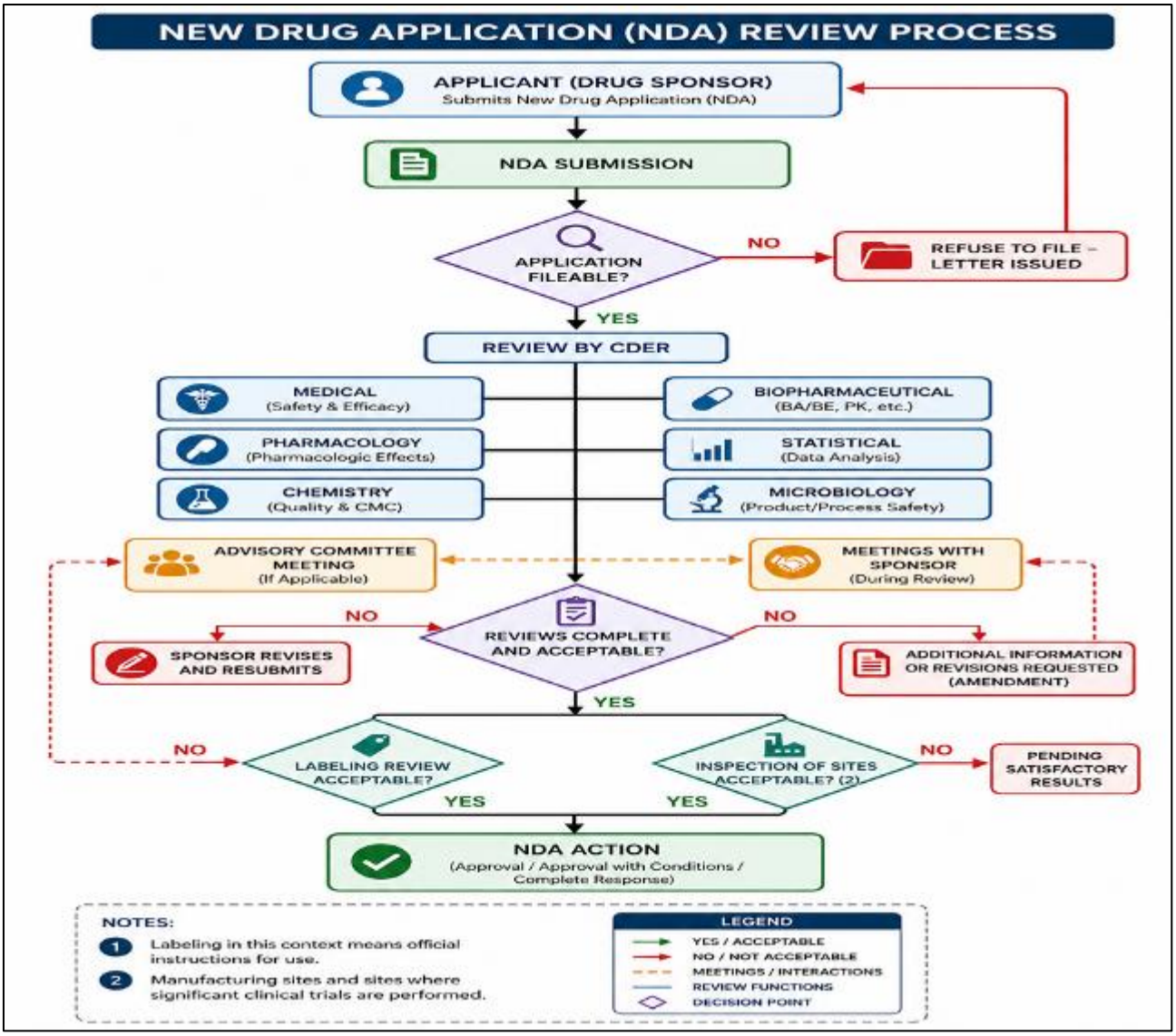

Figure 2 New drug application process

Following the FDA's assessment of an NDA, the sponsor may be sent one of three actions:

- Not Approvable: List the shortcomings in this letter and provide an explanation.
- Approvable: The term "approvable" refers to a medication that has minor flaws that can be fixed, such as labelling modifications and a potential promise to do post-approval research.
- Approval: It indicates that the medication is authorized. The FDA gives the applicant a chance to meet with the agency and explain the shortcomings if the activity is either approvable or not. [11][13]

The pharmaceutical business or sponsor gathers all relevant data, documentation, and information about the medicine before submitting an NDA in India. Preclinical research, clinical trials, chemistry, manufacturing, and quality control data are usually included in this. [9] Schedule Y of the Drugs and Cosmetics Rules specify the structure and content standards that the NDA submission must adhere to.[21]

3.1. Requirements for Permission of New Drug Approval

In accordance with the terms of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, the manufacturer or sponsor must submit an application in Form 44 to get permission for new drug approval. The Drug Controller General of India has the ability to submit the application to the Central Drugs Standard Control Organization.[21]

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use recommends that the documentation be developed in accordance with the widely recognized Common Technical Document (CTD) standard. [23] The administrative, quality, nonclinical, and clinical data needed for regulatory examination are contained in five modules that make up the CTD.

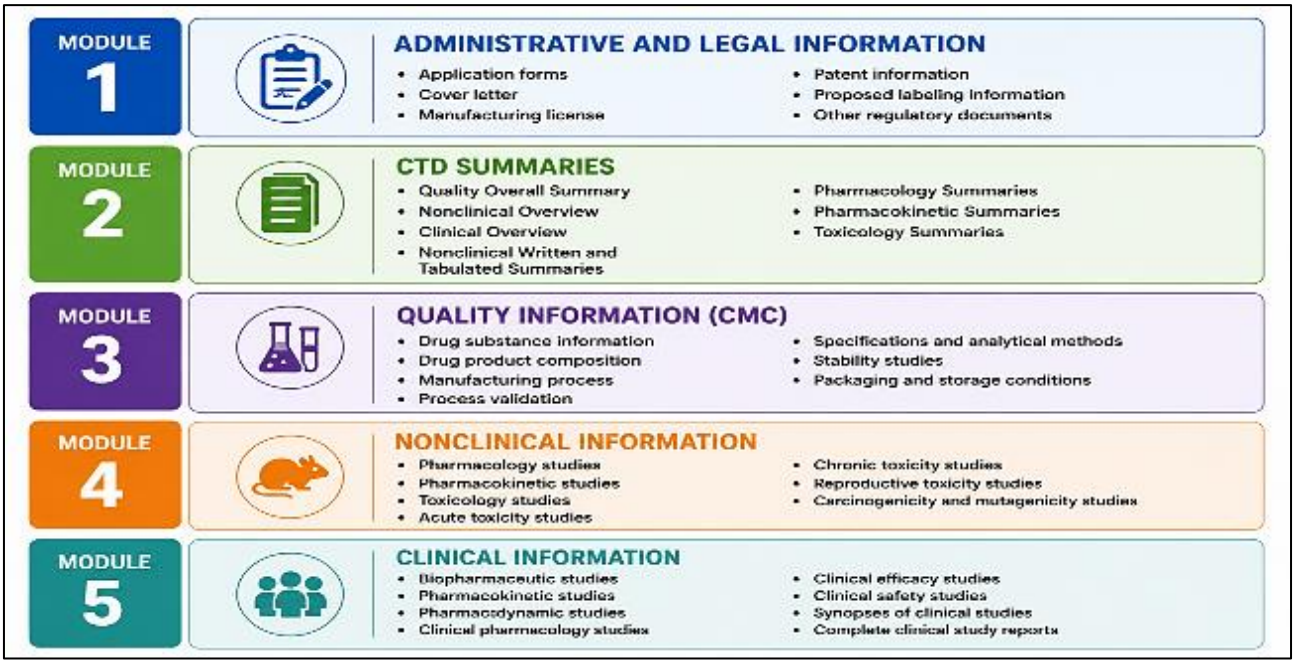

Figure 3 CTD modules

4. Main challenges in NDA submission process

4.1. Challenges in Drug Approval

Preclinical testing, clinical trial design, patient recruiting, data management, regulatory filings, manufacturing control, and post-marketing surveillance are only a few of the difficulties associated with the medication approval process. [13] These procedures are frequently costly, time-consuming, and intricate. Additionally, during the drug development process, meeting regulatory standards and guaranteeing drug safety and efficacy continue to be top priorities.[16]

4.2. Safety and Efficacy

A crucial stage in the approval of a medication is the assessment of safety and effectiveness. Significant scientific proof that the medication is both safe and effective for its intended usage is required by regulatory bodies. Even after marketing approval, negative effects could still happen, therefore ongoing observation and risk communication are crucial for patient safety.[23]

4.3. Post-Marketing Surveillance

Monitoring the long-term efficacy and safety of licensed medications requires post-marketing surveillance. Manufacturers are required by regulatory bodies to disclose safety-related concerns, product flaws, and adverse medication responses. Penalties, product recalls, or license suspension may follow noncompliance with these regulations.[12]

4.4. Political and Economic Aspects

4.4.1. Political Aspects

Public health concerns, political pressure, and media attention can all have an impact on drug clearance decisions. Public worry over approval delays, especially for life-saving drugs, can put more strain on regulatory bodies.

4.4.2. Drug Pricing and Economic Factors

A substantial financial commitment is required for both drug development and regulatory compliance. Long approval processes, numerous clinical trials, and complicated restrictions can raise the total cost of medications and impede patients' access to care.

4.4.3. Harmonisation Worldwide

To standardize pharmaceutical regulations across nations, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use was founded. Harmonisation lowers study duplication, increases regulatory standard consistency, and speeds up global access to safe and effective medications.[11][17]

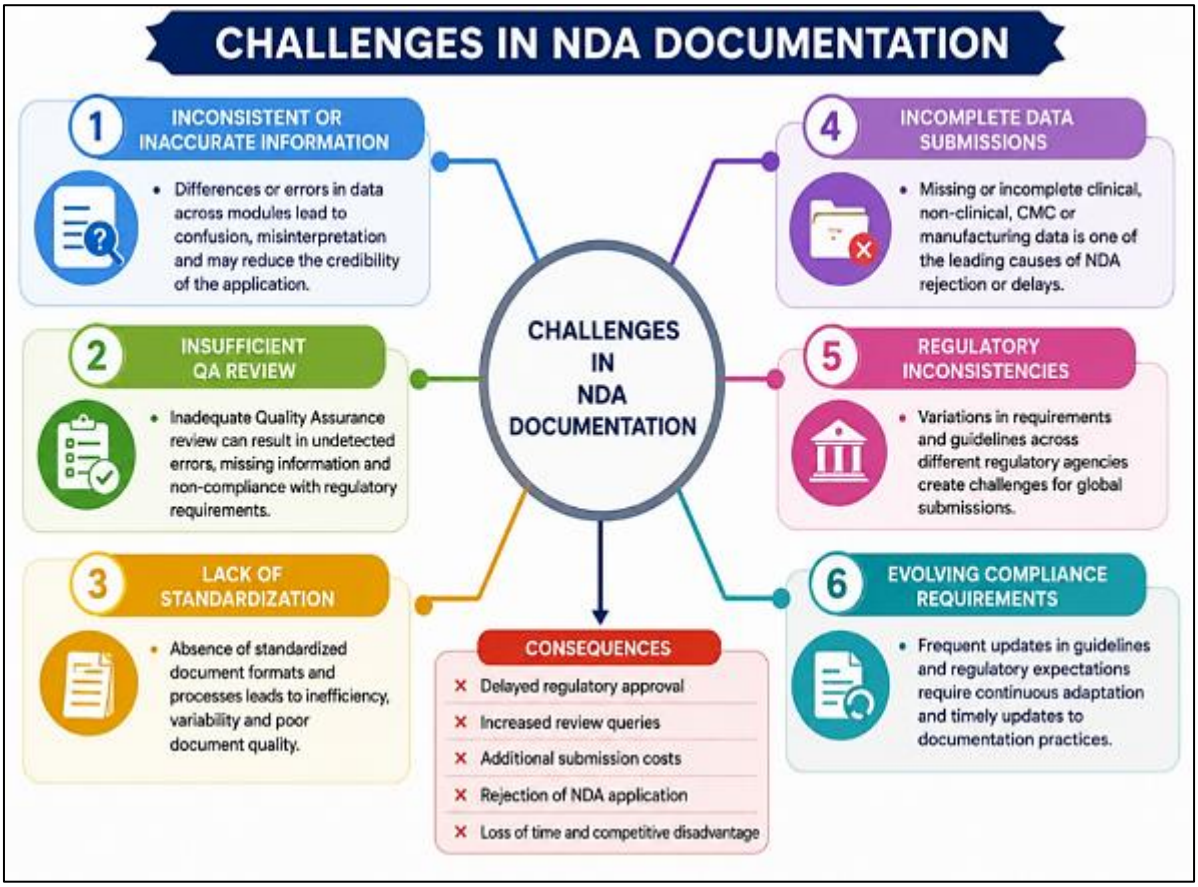

Figure 4 Challenges in NDA

5. Future perspectives and recommendations in NDA documentation

5.1. Future Developments in NDA Documentation

The New Drug Application (NDA) process is constantly changing due to developments in digital technologies and regulatory science. It is anticipated that a number of new improvements will enhance the effectiveness, precision, and international acceptance of regulatory submissions.

5.2. Emerging Trends in Regulatory Affairs: AI, Machine Learning, and Real-World Evidence

Modern regulatory issues are changing due to the combination of Artificial Intelligence (AI), Machine Learning (ML), and Real-World Evidence (RWE). These cutting-edge technologies enhance data analysis, submission management, automated document generation, and regulatory decision-making procedures. AI and ML-based tools speed up NDA documentation and review, improve efficiency, and lessen human mistake.

Furthermore, drug safety, efficacy, and post-marketing surveillance are supported by Real-World Evidence gathered from electronic health records, patient data, and clinical practice. The speed, precision, and calibre of pharmaceutical regulation procedures are all being enhanced by these advancements.

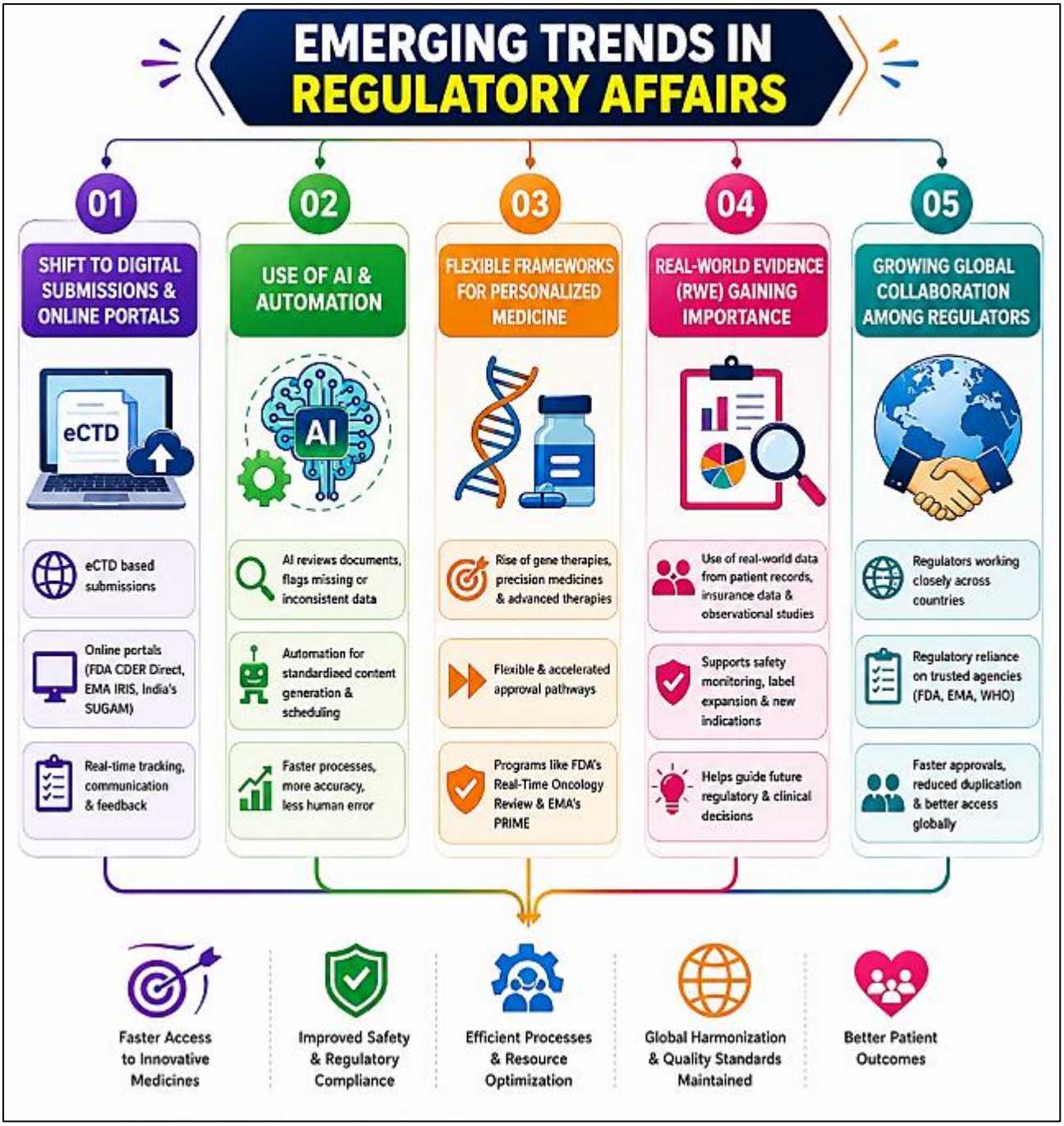

Figure 5 Emerging trends in regulatory affairs [27]

5.2.1. Benefits used in AI

- Automation: Artificial intelligence (AI) can automate routine processes, lowering the need for manual labour and freeing up human resources for more imaginative and strategic jobs.
- Effectiveness: AI algorithms are significantly faster and more accurate than humans at processing and analyzing vast amounts of data, which enables them to make decisions and solve problems more effectively.
- Precision: AI systems can carry out activities with a high degree of consistency and precision, which minimizes errors brought on by human variables like fatigue and distractions.

- Scalability: Systems driven by AI are easily scalable to manage heavy workloads and vast data volumes without disproportionately increasing human effort.
- 24/7 Availability: AI-driven apps are able to operate continuously, providing support and services whenever required. This is very helpful for global businesses and essential services.
- Personalization: By assessing user behavior and preferences to deliver pertinent recommendations and content, AI enables experiences to be tailored.
- Data analysis: AI can identify significant patterns and insights in massive datasets, allowing businesses to make well-informed predictions and decisions.
- Safety and Risk mitigation: AI can be used in hazardous environments or situations when people's safety is at risk, cutting down on the duration that individuals are in dangerous situations [28].

5.2.2. Drawbacks

AI-Based Software Validation

One of the biggest challenges still facing AI-driven systems is validation. It is difficult and still up for discussion to develop risk-based validation frameworks for AI applications in healthcare.

Evaluation of AI-Based Clinical Endpoints for Safety

AI systems that provide new clinical outcomes need to go through a thorough safety assessment. Before being approved by regulators, potential safety alerts found using AI-generated data must be carefully evaluated.

AI-Based Medical Technology Regulatory Review

Regulatory bodies have challenges due to the growing complexity of AI-enabled medical equipment. To properly assess and keep an eye on advanced AI technology, regulators need to acquire specialized knowledge.

Insufficient Technical Knowledge

A lot of pharmaceutical companies don't have enough expertise or understanding of AI technologies, which makes it difficult to successfully use and use them.

Insufficient Infrastructure for Information Technology

A strong IT infrastructure is necessary for the effective implementation of AI. To enable AI applications, pharmaceutical businesses frequently need to make significant expenditures in digital platforms, computer resources, and data management systems.

Electronic Data Management's Complexity

High-quality, well-organized datasets are essential to AI systems. Large-scale electronic data collection, standardization, and management continue to be major organizational challenges.

Poor Training Data Quality and Accuracy

The quality of training datasets has a significant impact on the performance of AI models. Despite sophisticated algorithms, inconsistent, partial, or biased data might produce incorrect results and erroneous predictions.

Data Security and Privacy Issues

Concerns about patient privacy, data security, and regulatory compliance are brought up by the usage of huge healthcare databases.[31]

5.3. Enhancements in Data Security and Integrity

Maintaining data security and integrity has grown crucial as electronic submissions proliferate. Secure data management platforms, electronic validation tools, and sophisticated cybersecurity systems all aid in preventing illegal access to and data loss of private and sensitive pharmaceutical information.

5.4. Global Harmonization of NDA Requirements

Through groups like the International Council for Harmonization of Technical criteria for Pharmaceuticals for Human Use, efforts to harmonize regulatory criteria globally are still growing. Harmonized rules promote quicker worldwide drug approval, enhance uniformity in regulatory expectations, and decrease duplication in multi-regional submissions.

5.5. Use of Templates and Checklists

The organization, uniformity, and completeness of NDA submissions are enhanced by the adoption of standardized templates and regulatory checklists. While checklists help guarantee that all necessary information and supporting documents are included before submission, templates help maintain a consistent document structure.

5.6. Standardization of Document Formats

Consistent font style, spacing, headers, numbering, and margins are examples of standard formatting techniques that enhance document readability and make regulatory scrutiny easier. Additionally, standardization reduces formatting-related errors and improves submission quality.

5.7. Use of Clear and Concise Language

NDA documentation must be written in a clear, succinct, and scientifically accurate manner. Writing that is clear and organized enhances communication with regulatory bodies and lowers the possibility of miscommunication or further review questions.

5.8. Inclusion of Supporting Data

To prove a drug product's safety, effectiveness, and quality, comprehensive supporting data such as clinical research reports, non-clinical data, stability studies, and manufacturing information is essential. The entire NDA submission is strengthened by the appropriate arrangement and inclusion of supporting documentation.[27]

6. Conclusion

A crucial step in the development and regulatory approval of pharmaceutical drugs is the New Drug Application (NDA) procedure. It guarantees the safety, efficacy, and acceptable quality of newly released medications. Before approving, regulatory bodies like the Central Drugs Standard Control Organization and the US Food and Drug Administration thoroughly assess preclinical, clinical, and manufacturing data. Global regulatory filings are now more organized and standardized thanks to the Common Technical Document (CTD) format. Additionally, the NDA procedure is crucial to preserving patient safety and public health. However, the regulatory process is still impacted by issues including protracted approval processes, complicated paperwork, expensive development, and post-marketing safety monitoring.

The efficiency and correctness of regulations are being enhanced by developments in digital technology, electronic submissions, and artificial intelligence. The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use is spearheading global harmonization activities that are supporting consistent regulatory standards across many nations. All things considered, the NDA procedure continues to be an essential regulatory tool for guaranteeing that the general public has access to high-quality, safe medications.

Compliance with ethical standards

Acknowledgments

The authors would like to thank Dean, Madurai Medical College, Principal, College of Pharmacy, Madurai Medical College and all other lab studies.

Disclosure of conflict of interest

The authors have no conflicts of interest regarding this investigation.

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