

# AI in Healthcare Regulatory Affairs Market Valued at USD 1.2 Billion in 2024, Set to Reach USD 6.5 Billion by 2035 - TMR

*Global AI in Healthcare Regulatory Affairs Market to Hit USD 6.5 Billion by 2035 at 16.7% CAGR amid Rising Demand for Regulatory Efficiency and AI Solutions-TMR*

WILMINGTON, DE, UNITED STATES, February 23, 2026 /EINPresswire.com/ -- AI in Healthcare Regulatory Affairs Market Outlook 2035

The [global AI in healthcare regulatory affairs market](#) was valued at US\$ 1.2 Bn in 2024 and is projected to reach US\$ 6.5 Bn by 2035, expanding at a robust CAGR of 16.7% from 2025 to 2035. Market growth is driven by the increasing adoption of AI-powered compliance tools, rising complexity of regulatory requirements, and the need for faster drug approvals and clinical trial submissions.



AI in Healthcare Regulatory Affairs Market Outlook 2035

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## Market Overview

AI in healthcare regulatory affairs involves the use of advanced algorithms, machine learning, and natural language processing to automate and optimize regulatory compliance processes. These solutions help

pharmaceutical and biotech companies manage submissions, monitor regulatory changes,

ensure adherence to global standards, and reduce the risk of non-compliance.

With growing digitalization of healthcare data, increasing regulatory scrutiny, and expansion of global clinical trials, AI-driven solutions are becoming critical for regulatory affairs teams. Applications include document automation, regulatory intelligence, risk assessment, and post-market surveillance.

### Analysts' Viewpoint on the Global AI in Healthcare Regulatory Affairs Market

Analysts observe strong demand due to the dual need for efficiency and accuracy in regulatory submissions. AI helps reduce manual work, accelerate review processes, and ensure timely compliance with evolving regulations such as FDA, EMA, and PMDA standards.

North America dominates the market owing to advanced healthcare infrastructure and early adoption of AI technologies. Europe is driven by stringent regulatory frameworks, while Asia Pacific is expected to witness the fastest growth due to expanding pharmaceutical manufacturing and increasing clinical trial activities.

### Analysis of Key Players in the AI in Healthcare Regulatory Affairs Market

The competitive landscape is defined by technology providers, software companies, and consulting firms offering AI-driven compliance solutions.

Leading companies operating in the market include:

- Clarivate
- IQVIA Inc.
- Wipro
- Freyr
- Innoplexus
- Zenovel
- Indegene
- RegDesk, Inc.
- CELEGENCE
- Rimsys
- DDi.
- DXC Technology Company
- Ketryx Corporation

These companies are focusing on AI software development, cloud-based platforms, strategic partnerships with pharma firms, and expansion of regulatory compliance solutions across global regions.

## Recent Developments in AI in Healthcare Regulatory Affairs

- September 2025: Elsevier launched PharmaPendium AI, a generative AI assistant that helps regulatory affairs professionals and researchers efficiently access FDA and EMA publications for drug development intelligence.
- August 2025: Clarivate Plc introduced the AI-driven Regulatory Assistant in Cortellis Regulatory Intelligence to simplify and accelerate compliance with evolving global regulations for regulatory professionals in biopharma, medtech, and research institutions.

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## Key Developments in the AI in Healthcare Regulatory Affairs Market

- Integration of AI-powered analytics to predict regulatory changes and impact assessment.
- Automation of submission dossiers, labeling, and regulatory reporting.
- Cloud-based platforms enabling collaboration across global teams.
- Expansion of regulatory intelligence solutions for post-market surveillance.
- Adoption of machine learning to improve review timelines and reduce errors.

## Key Player Strategies

□ Technological Innovation

Focus on AI, ML, and NLP for automated regulatory compliance.

□ Pharma Collaboration

Partnering with healthcare organizations for tailored regulatory solutions.

□ Regional Expansion

Deployment of AI platforms across North America, Europe, and Asia Pacific.

□ Process Optimization

Reducing time and cost for regulatory submissions and monitoring.

□ Comprehensive Service Offerings

Combining regulatory intelligence, submissions management, and compliance monitoring.

## Challenges

- High implementation costs for AI-based regulatory platforms
- Integration with legacy systems in pharmaceutical companies
- Data privacy and cybersecurity concerns
- Limited AI expertise in regulatory teams

## Opportunities

□ Rising Pharmaceutical & Biotech Activities

Increasing clinical trials and drug approvals drive demand for AI compliance tools.

□ Global Regulatory Complexity

Growing need for harmonized, automated regulatory intelligence.

□ Digital Transformation in Healthcare

Adoption of AI-powered platforms for end-to-end regulatory operations.

□ Emerging Markets Expansion

Pharma companies expanding in Asia Pacific and Latin America require AI regulatory support.

□ Data-Driven Decision Making

AI insights enhance accuracy, speed, and efficiency of compliance processes.

## Market Segmentation

□ By Application

- Regulatory Submissions & Documentation
- Compliance Management
- Labeling & Post-Market Surveillance
- Regulatory Intelligence

□ By End User

- Pharmaceutical Companies
- Biotechnology Firms
- Medical Device Manufacturers
- CROs (Contract Research Organizations)

□ By Region

- North America - Dominant market with advanced AI adoption
- Europe - Strong regulatory frameworks and compliance requirements
- Asia Pacific - Fastest-growing region due to expanding pharma sector
- Latin America
- Middle East & Africa

## Why Invest in the AI in Healthcare Regulatory Affairs Market Report?

□ Long-term forecasts through 2035 with detailed market analysis

□ Competitive landscape and strategic profiling of leading AI solution providers

□ Insights into regulatory intelligence, automation trends, and digital compliance solutions

□ Regional demand analysis tied to pharmaceutical and biotech growth

□ Identification of high-growth opportunities in clinical, medical device, and post-market segments

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## FAQs

1. What is the projected AI in healthcare regulatory affairs market size by 2035?

The market is expected to reach US\$ 6.5 Bn by 2035.

2. What is the CAGR from 2025–2035?

The market is projected to grow at a CAGR of 16.7%.

3. Which application segment dominates the market?

Regulatory submissions and compliance management hold a significant share due to widespread adoption by pharma and biotech companies.

4. Which region leads the market?

North America leads due to advanced healthcare infrastructure and early AI adoption.

5. What are key market trends?

Automation of regulatory workflows, AI-driven compliance intelligence, cloud-based platforms, and integration with digital health solutions are shaping the market.

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