Artificial Intelligence at the helm: Revolutionizing life sciences sector

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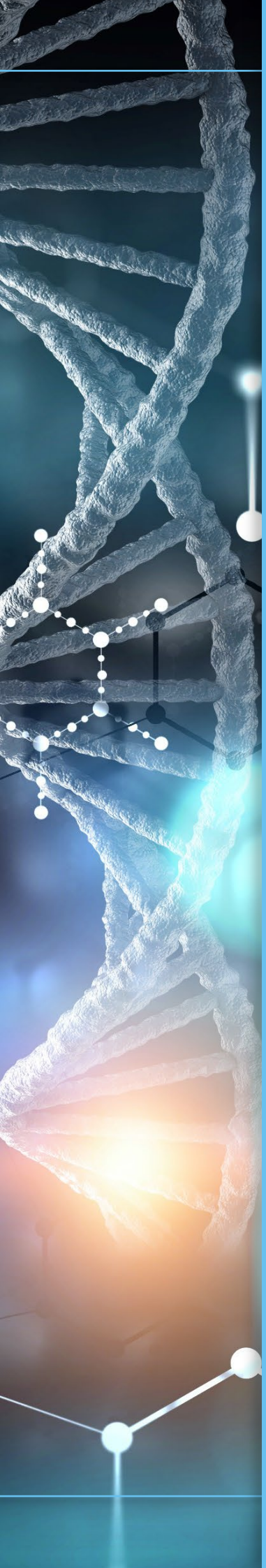
Foreword



Suresh Subramanian

Partner,
National Life Sciences Leader,
EY Parthenon

We at EY are delighted to present the report, "**Artificial Intelligence at the helm: Revolutionizing life sciences sector**", in partnership with Microsoft, unveiled at the BioAsia 2025 conference at Hyderabad. We extend our sincere congratulations to the leadership of BioAsia and the Government of Telangana for their exceptional efforts in orchestrating this globally recognized conference. With its 22nd edition, BioAsia continues to amplify its influence, and it is an honor for EY and its partner Microsoft to be a part of this extraordinary journey.

The AI revolution is reshaping every facet of the life sciences value chain, marking a transition from art of the possible to a tangible, influential reality. This publication delves into the vast potential and pioneering possibilities AI is unlocking, offering an in-depth examination of AI implementation strategies and best practices. Through real-world examples and case studies, we investigate AI's current applications and its boundless future prospects in life sciences. In research labs, AI is accelerating breakthroughs—identifying drug targets and predicting molecular interactions with unprecedented speed and accuracy. Clinical trials benefit from intelligent algorithms that enhance patient matching, streamline site selection, and optimize timelines. On the manufacturing floor, predictive analytics ensure predictive and preventive management, while resilient supply chains adapt in real-time to fluctuating market demands.

On the healthcare delivery side, AI-enabled diagnostics and wearable technology are democratizing health insights. Information, once exclusive to specialists, is now accessible to patients. Data-driven solutions are helping in diagnosing diseases early and enabling personalized treatment.

For a business-led AI transformation, it is critical to identify and prioritize high-impact areas that result in maximum impact. These areas should lay the groundwork for the AI journey, ensuring that investments in AI are in sync with opportunities that are crucial to the business and offer a high return on investment. Once businesses identify these high-impact areas, the next step is to advance up the value chain by strengthening capabilities in data management, analytical processing, and AI-driven decision-making. This progression ensures that AI investments translate into sustained competitive advantage and long-term impact.

The strategic application of GenAI is a potent catalyst in this journey, enhancing operational efficiencies and serving as an indispensable ally. With each step forward, the business not only strengthens its foundation but also strategically positions itself to harness the full potential of AI for continuous growth and innovation.

This report provides a strategic and actionable roadmap for enterprise-wide AI integration across business functions, offering insights and guidance to navigate the complexities of adoption and maximize AI's potential. It is a call to action for businesses to harness AI's capabilities and lead the charge in the new frontier of global healthcare. Let us move forward into a future where AI not only shapes but defines industry relevance and success!

Shakthi Nagappan
CEO,
Telangana Lifesciences

The life sciences sector stands on the cusp of an unprecedented transformation, with artificial intelligence emerging as the driving force behind innovation and progress. This convergence of AI with biological sciences transcends a mere technological enhancement—it marks a fundamental shift that is breaking down traditional barriers and accelerating the journey from research to real-world treatments and reshaping how healthcare is delivered.

Companies are now harnessing machine learning algorithms to predict protein structures, identify novel drug candidates, analyze complex biological data, and enhance diagnostic precision, including predictive analytics for early disease detection. This technological revolution is unlocking possibilities once thought unimaginable.

This synergy between AI and life sciences is only just beginning, with boundless potential for future innovation and improvement. From promoting preventive healthcare and developing personalized medicine to streamlining clinical trials and advancing surgical robotics, AI is proving to be an invaluable ally in transforming human health and well-being.

Recognizing AI's transformative potential, the Government of Telangana, in collaboration with EY, is hosting a panel discussion on, 'AI Transformation in Healthcare' at the 22nd edition of its flagship international convention – BioAsia – taking place from 25 February to 26 February 2025 under the theme 'Catalysts of Change: Expanding Global Healthcare Frontiers'. Over the years, BioAsia has been instrumental in shaping and building a vibrant life sciences ecosystem in Telangana, led by technology and innovation. Over the years, BioAsia has convened top leaders across healthcare, research, start-ups, pharma, and technology, cementing its place as oe of India's most insightful life sciences symposia.

Trupen Modi

Sr. Industry Executive,
Pharma and Life science
Microsoft

In today's rapidly evolving healthcare landscape, few forces hold as much transformative promise as Artificial Intelligence (AI). Once primarily the domain of computer scientists, AI has moved to the forefront of life sciences innovation, shaping everything from how we discover potential drug targets to how we optimize global supply chains and personalize patient care. It offers a future in which critical decisions — from diagnosing ailments to streamlining research — can be guided by powerful, data-driven insights capable of accelerating breakthroughs with unprecedented precision.

This report, **Artificial Intelligence at the helm: Revolutionizing the life sciences sector**, arrives at a pivotal moment. Around the world, pharmaceutical organizations are leveraging AI to more efficiently identify novel compounds and shorten clinical timelines. Medical technology companies are embedding intelligent algorithms into devices that proactively flag health anomalies. Academic medical centers are exploring the power of machine learning to advance research, refine educational programs, and personalize treatment protocols. Meanwhile, new regulatory frameworks are evolving to ensure patient safety, data protection, and ethical integrity in this new digital frontier.

The chapters that follow illuminate how AI is redefining every facet of the life sciences—encompassing discovery, development, manufacturing, and beyond. They also candidly address the attendant complexities: from algorithmic bias to ethical risks, from the necessity of advanced data infrastructure to the urgency of training a new generation of AI-savvy scientists, clinicians, and researchers.

My hope is that this report will spark ideas, ignite productive debate, and serve as a guide for stakeholders across the life sciences ecosystem—whether in large pharmaceutical companies, biotech start-ups, academic institutions, MedTech enterprises, or policy agencies. By embracing the insights herein, we stand better equipped to harness AI's potential and shape a future where patients benefit from more precise therapies, medical professionals leverage real-time intelligence, and organizations thrive through unprecedented operational efficiency and innovation.

Let us stand at this juncture with optimism, curiosity, and a commitment to responsible progress. The future of life sciences hinges not only on technological innovation but also on collaborative efforts. We must work together to ensure AI's promise becomes reality for all.


AI

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Executive summary

The life sciences sector is experiencing a transformative evolution driven by artificial intelligence (AI), with significant implications across pharmaceutical, biotechnology, medical technology (MedTech) sectors and academic medical centers (AMCs). The global AI market demonstrates substantial growth potential, with AI in pharmaceuticals sector expected to reach to US$16.49 billion by 2034, driven by AI's transformative impact on drug discovery, clinical trials and personalized healthcare. Similarly, AI in the medical devices segment is projected to reach US$97.1 billion by 2028, driven by the growing adoption of AI-powered diagnostic tools, smart medical devices, wearables and surgical robotics. This growth is further accelerated by cross-industry factors, including rapid technological advancements, declining AI costs, a focus on sustainable innovation, and supportive government policies all of which combine to impact healthcare access and outcomes at a much higher level.

AI's impact on the life sciences value chain

Across the pharmaceutical and biotechnology sectors, AI is revolutionizing R&D by accelerating target identification, molecular design and drug-target interaction predictions. It enables personalized medicine through the analysis of genetic profiles, clinical data and environmental factors. It also optimizes clinical trials by improving patient recruitment, site selection and trial management. In manufacturing and supply chain, AI enhances operational efficiency with intelligent automation and predictive maintenance. Additionally, AI-driven insights and automation are transforming regulatory submissions, marketing and sales strategies, allowing companies to better understand market demands and patient needs.

In the MedTech sector, AI is revolutionizing R&D by using real-world data to optimize device design and enabling creation of patient-specific devices through simulations and generative design. In commercial operations, predictive maintenance is ensuring device reliability, reducing downtime and extending equipment lifespan. Additionally, AI is driving significant business transformations and unlocking new revenue streams by enabling the development of smarter medical devices. AI is enhancing diagnostic capabilities through advanced imaging systems, connected devices and wearables. Surgical robotics are becoming more sophisticated with real-time data analysis and augmented reality guidance.

In AMCs, AI is transforming medical education through immersive training experiences, with mixed reality tools while also personalizing learning. AI is also revolutionizing data and knowledge management by efficiently collecting and analyzing patient data from medical registries, automating literature reviews and optimizing grant funding processes.

With rapid AI advancements, nations worldwide are implementing regulations to ensure responsible governance. These include legal frameworks for AI development, data protection measures, and guidelines for AI/ML-powered medical devices' safety and effectiveness. Additionally, protocols for leveraging AI in regulatory decision-making are being established. India too has adopted a forward-looking approach with initiatives like the 'National Strategy for Artificial Intelligence #AIforAll' and the 'IndiaAI' mission to strengthen its global AI leadership and democratize AI benefits across all societal levels.

With the profound applications of AI transforming life sciences, adoption is no longer optional– it has become a critical imperative for maintaining competitiveness. Delayed adoption can lead to loss of market share, reduced operational efficiency and limited access to breakthrough innovations.

Challenges and strategic implementation

There are several critical challenges that organizations may face when implementing AI, categorized into ethical, technical and operational challenges:

- **Ethical**: Concerns include algorithmic bias and the lack of transparency in AI decision-making.
- **Technical**: Issues revolve around data privacy, security and compliance with complex and evolving regulations across all countries.
- **Operational**: The industry faces a shortage of interdisciplinary talent. Additionally, effective change management is required to minimize resistance and ensure firm-wide AI integration.

These challenges should be viewed as opportunities for developing better implementation strategies in the life sciences sector.

AI maturity can be categorized into three levels—foundational, innovative and transformational — where each level represents increasing sophistication in AI capabilities and organizational readiness. Different organizations can exist at different maturity levels across various functions simultaneously. The key is to recognize current positioning, frame the desired strategic future state, and chart a clear path toward higher maturity levels through systematic capability building.

To navigate these challenges and advance along the AI maturity curve, organizations must focus on these five critical strategic pillars:

1. **Business and operating model transformation:** Requires a shift towards 'AI-first' strategy and the integration of AI-driven decision support systems across business operations.
2. **Technology stack enhancement**: Involves building a flexible infrastructure that enables AI development and deployment at scale while accommodating emerging advancements.
3. **Comprehensive data strategy for AI-ready data**: Demands Demands robust data governance to ensure accuracy, security and compliance, along with a scalable infrastructure for AI-ready data.
4. **Preparing the workforce for AI:** Bridges the gap between technological innovation and practical execution through effective change management, ensuring workforce adaptability.
5. **Confronting and managing AI-related risks:** Calls for strong risk and compliance frameworks, including real-time governance mechanisms for transparency, advanced data filtering techniques to improve AI system reliability and AI-powered security solutions to strengthen cyber defenses.

The future belongs to organizations that embrace AI today, preparing strategically to overcome its challenges and leverage its full potential for tomorrow's breakthroughs in healthcare and life sciences. As the landscape continues to evolve, those who can effectively navigate these changes while maintaining a focus on ethical implementation and practical value creation will be best positioned to lead the next wave of innovation.

01

Pioneering innovation and excellence:

The promise of artificial intelligence (AI)


Ai
Ai
Ai

> *This is the way all drugs will be designed in the future. In the next decade, AI technology will become ubiquitous.*
>
> Andrew Hopkins, Former CEO, Exscientia (2022)[1]

> *Every day, we are figuring out how to accelerate drug development, reduce costs, and improve chances of success with modern tech and AI. If we get this right, we will make someone's life better or save their life. It is incredibly motivating.*
>
> Dr Olga Kubassova, CEO and founder of Image Analysis Group[2,3]

> *AI will revolutionize the way we live, including our healthcare system.*
>
> Michelle Donelan, UK Secretary of State for Science, Innovation and Technology, on the allocation of 13 million pounds to support the advancement of AI in healthcare (2023)[4]

Indian life science sector: AI adoption and impact (EY survey)

~13%	~50%	~75%
improvement in labor efficiency driven by GenAI advancements in the healthcare sector.	of the surveyed Indian Life Sciences (LS) organizations are already exploring GenAI actively, with budgets allocated or already invested.	of CXOs from surveyed Indian LS organizations confirmed that AI has been instrumental in reducing costs and driving customer satisfaction.
Source: EY India jobs study: Transforming work with GenAI	*Source: EY India C-suite GenAI Survey 2024*	*Source: EY India C-suite GenAI Survey 2024*

Sources: 1. guardian.com, 2. IAG, 3. olgakubassova, 4. UCLA news

Artificial Intelligence (AI) has moved beyond speculative fiction to become a vital part of the scientific and industrial landscape. Its impact is particularly significant in the life sciences sector, which includes Pharmaceutical, Biotechnological, and Medical Technology (MedTech) sectors, and Academic Medical Centers (AMCs). AI acts as a catalyst for innovation, accelerating research, improving operational efficiencies, and significantly enhancing patient care with sophistication once thought impossible.

In drug development, intelligent AI algorithms predict molecular interactions with remarkable accuracy. In clinical development, these AI algorithms streamline patient recruitment and enable continuous monitoring of clinical trials, effectively compressing drug development timelines from decades to years.

The influence of AI extends beyond research labs and clinical settings, reshaping manufacturing and supply chain processes within the life sciences sector. AI brings operational efficiency by optimizing production schedules, reducing waste, and improving inventory management. Predictive maintenance algorithms decrease equipment downtime, and sophisticated AI logistics platforms streamline the global distribution of medical products.

On the commercial front, AI is revolutionizing the way patients and healthcare providers interact with personalized communication tools and predictive analytics that enhance engagement and care delivery. Sales representatives are now equipped with AI-powered insights, enabling them to tailor their interactions with healthcare professionals based on individual preferences and requirements. This digital evolution is not merely about improving efficiency, it is about cultivating a healthcare environment that places patients at the heart of every innovation.

AI's influence is equally transformative in the MedTech space, fostering the creation of intelligent medical devices, refining diagnostic procedures, and implementing predictive maintenance systems that anticipate and prevent equipment failures. These advancements extend to the management of medical inventories and the optimization of patient care pathways. In surgical suites, AI-driven robots are assisting surgeons in performing highly precise and

minimally invasive procedures, setting new standards for patient outcomes.

Concurrently, AMCs are employing AI to identify new therapies to improve patient health, develop precision medicines, maintain medical registries, and train medical doctors with modern technologies.

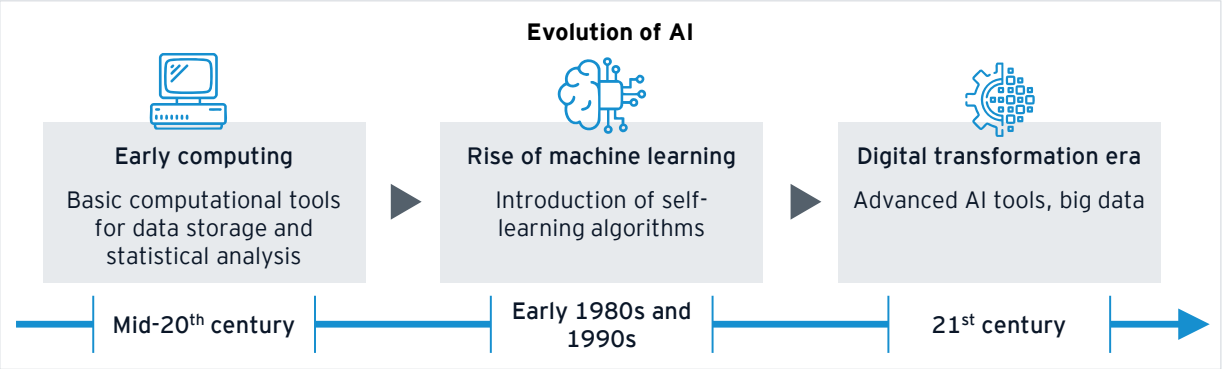
Additionally, AI is revolutionizing the regulatory landscape in the life science industry. It is automating the analysis of regulatory documents, streamlining the submission process for regulatory approval of new drugs and medical devices, and monitoring regulatory changes to ensure ongoing compliance. This reduces time to market and improves accuracy in meeting regulatory requirements.

This end-to-end transformation of the life sciences value chain is creating unprecedented efficiencies, reducing costs, and most importantly, accelerating the delivery of life-saving therapies to patients. In the next chapter of this report, we will delve deeper into AI use cases, exploring its potential and showcasing how companies around the world are reaping the benefits.

> As pharmaceutical giants, biotech innovators, medical technology (MedTech) pioneers, and AMCs harness AI's potential, we are witnessing a revolution that is redefining the boundaries of what is possible across the value chain of a drug from discovery to delivery to the patient. The question is no longer, 'Will AI change life sciences?' but rather, 'How far can this symbiosis of human intellect and artificial intelligence take us?'

Evolution of AI in life sciences

The journey of AI in the Life sciences sector has been nothing short of revolutionary. This section delves into the historical trajectory of AI, charting its ascent from rudimentary computational tools to the sophisticated systems that now underpin a dynamic and innovative industry.



Foundation years: Early computing to machine learning

The genesis of AI in the biomedical sciences can be traced back to the mid-20th century, with the advent of basic computational tools. These early systems were primarily employed for data storage and rudimentary statistical analysis. In pharmaceutical research, early computers managed chemical compound libraries and assisted in formulating potential drug candidates.

As we progressed into the 1980s and 1990s, the field witnessed a quantum leap with the emergence of machine learning (ML), a pivotal branch of AI that crafts algorithms capable of learning from data to make informed decisions. ML heralded the introduction of more intricate algorithms, such as those used in quantitative structure-activity relationship (QSAR) modeling, that could predict the effects of chemical compounds with greater accuracy.

These early applications laid the groundwork for more sophisticated AI-driven methodologies and self-learning algorithms.

Digital transformation era

The turn of the millennium marked the onset of the big data era, characterized by an exponential growth in the volume of information generated from high-throughput technologies. Innovations such as next-generation sequencing (NGS) and other advanced analytical tools produced an unprecedented wealth of genomic and proteomic data. This data explosion necessitated more sophisticated AI tools for analysis and interpretation, which in turn catalyzed significant breakthroughs in the comprehension of genetic markers, disease pathways and complex biological interactions.

This period also saw a digital metamorphosis that transcended industry boundaries, heralding a new age of advanced automation, intelligent manufacturing processes and optimized supply chain management. AI-driven customer engagement platforms began to reshape the very fabric of business operations and technological interactions.

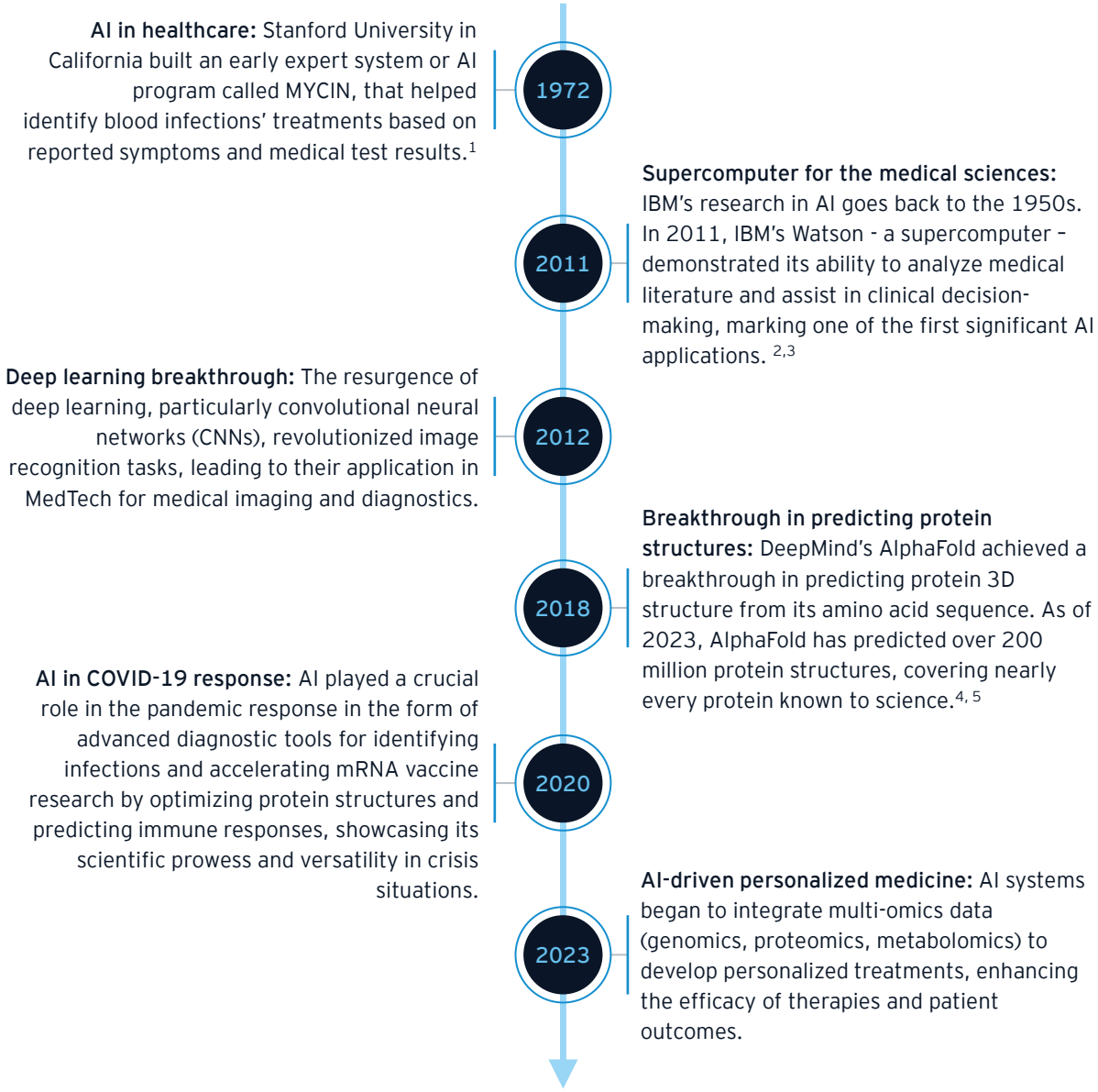
Early challenges

The early integration of AI into the pharma and biotech sectors was met with significant challenges. Issues such as the scarcity of high-quality data and the lack of standardized protocols for AI implementation were substantial hurdles. The computational power necessary for advanced AI algorithms was limited, constraining their practical use. The intricacy of biological systems presented obstacles for precise modeling and prediction.

The MedTech sector encountered regulatory barriers in the adoption of AI-powered devices, ensuring their safety and efficacy remained paramount. In the broader field of life sciences, researchers faced challenges in assimilating AI into established experimental workflows and ensuring the reproducibility of AI-influenced results.

Despite these initial obstacles, relentless progress in computing infrastructure, data management practices, and algorithmic development has steadily eroded these barriers over time, setting the stage for the widespread adoption of AI that we witness today. The subsequent chapter of this report will delve into the contemporary utilization of AI across various sectors and explore the visionary prospects that lie ahead.

AI milestones: Transforming drug discovery and development, diagnosis and patient care



Sources: 1. MYCIN, 2. IBM Watson, 3. IBM Watson healthcare, 4. AlphaFold database, 5. AlphaFold

Regulatory evolution: Safeguarding AI innovation in life sciences

As AI continues to revolutionize the life sciences sector, a parallel transformation has been unfolding in the regulatory landscape. The rapid advancement of AI applications and the immense potential that lies ahead, coupled with growing concerns about ethical implications and patient safety, have catalyzed an unprecedented evolution in global regulatory frameworks. This shift aims to balance the fervor of AI innovation with the imperative of safeguarding public health and data privacy.

In the **European Union**, a trailblazing approach has materialized through comprehensive regulations such as the proposed 'EU AI Act', which seeks to establish a harmonized legal framework for AI development and deployment. Other regulations across the EU include 'General Data Protection Regulation' (GDPR, 2018) and the 'Data Governance Act', supported by frameworks such as the 'European Medicines Agency (EMA) AI workplan'.

The **United States** has also taken significant steps, with the Food and Drug Administration (FDA) issuing focused guidelines on AI-powered medical devices (Software as a Medical Device and Good Machine Learning practice), emphasizing the importance of transparency, accountability, and ongoing monitoring. In addition, the FDA has also issued guidelines on leveraging AI in regulatory decision-making related to drugs and biological products. These guidelines provide recommendations on the use of AI to produce information intended to support regulatory decision-making regarding safety, effectiveness and the quality of drugs. Moreover, the US has bills and acts such as the 'National AI Initiative Act (NAIIA)' and 'Data Care Act' to promote AI usage and govern the responsible use of AI in the US, respectively.

In the APAC region, **Japan** has created regulatory frameworks such as the 'ML quality management guidelines' and 'Implementation of AI principles'.

India, too, has embraced a proactive, forward-thinking approach to AI governance, recognizing both its transformative potential and the need for responsible deployment. India's AI policy landscape includes a mix of strategic initiatives, regulations, and advisories designed to harness AI for economic growth and societal benefits. Notable strategic frameworks and policies include: [1]

- **2018: National Strategy for Artificial Intelligence #AIforAll:**[2] Released by NITI Aayog, this comprehensive strategy document outlines the vision to position India as a leader in AI for economic growth and social inclusion. It provides recommendations for AI adoption across industries, including healthcare, education, agriculture, smart cities and transportation.
- **2021: "Principles for responsible AI":** Launched by NITI Aayog, these principles are a continuation of the National Strategy for Artificial Intelligence. The principles examine ethical considerations surrounding the implementation of AI solutions in India.[3]
- **2023:** Legal frameworks such as the **'Digital Personal Data Protection Act (DPDP Act)** of 2023 provides a foundation for data privacy in the digital age.
- **2024: The IndiaAI Mission is a flagship program** intended to bolster India's global leadership in AI and democratize the benefits of AI across all strata of society.
- **2024: Policy advisories from the Ministry of Electronics and Information Technology (MeiTY)** continue to guide beyond NITI Aayog's recommendations, emphasizing the dual goals of nurturing innovation and mitigating associated risks.[4]

[1] The AIdea of India 2025 : How much productivity can GenAI unlock in India
[2] National Strategy for Artificial Intelligence
[3] Responsible-AI-22022021.pdf
[4] Regulation of AI and Large Language Models in India

Evolving regulations and guidelines to govern AI usage*

Europe

2018: General Data Protection Regulation (GDPR)

GDPR legislation updated and unified all the previous data privacy laws across EU, setting rules for protection of individuals' data, and its responsible collection and usage by companies

2022: Data Governance Act

Seeks to increase trust in data sharing, with strengthened mechanisms to increase data availability and overcome technical obstacles to data reuse. It also supports the setup and development of Common European Data Spaces in strategic domains

2023: The EU AI Act

The Act emphasizes human oversight, transparency, and robust security measures to mitigate risks

★ **2023: European Medicines Agency (EMA) AI workplan for 2023-2028**

Aim to embrace AI for internal regulatory use

- Provide support in development and evaluation of AI within the medicine lifecycle
- Use of AI tools and technology in internal and external regulatory protocols and developments

United States

2021: The NAIIA

- Supports and promotes AI research, education, and collaboration initiatives
- Bolsters AI infrastructure, AI use for national security and defense
- Emphasizes the importance of AI in maintaining economic competitiveness
- Encourages the development of standards and guidelines for AI systems

★ **2021: USFDA's AI/ML-based SaMD Action Plan**

Outlines a tailored approach for reasonable assurance of safety and effectiveness throughout the lifecycle of AI/ML-based SaMD

★ **2021: GMLP for medical devices**

Guiding principals on safe and effective design, development, clinical validation, and use of AI/ML- based medical devices

2023: Data Care Act of 2023

The bill establishes duties for online service providers on secure handling of individual-identifying data/ personal data

★ **2025: AI use in regulatory decision-making for drugs and biological products**

USFDA is expected to provide further guidance on AI usage to support regulatory decisions regarding the safety, effectiveness, and quality of drugs and biological products. This guidance will likely address the evaluation of AI-generated evidence in regulatory submissions, the validation of AI tools used in drug development, and the ongoing monitoring of AI systems in the post-market phase

Asia-Pacific

India

2022: Draft - National Data Governance Framework Policy

Launched 'India Datasets' program to ensure that non-personal and anonymized data from both government and private entities are safely accessible by research and innovation ecosystem

2023: The Digital Personal Data Protection (DPDP) Act

The law governing and protecting digital personal data processing. It emphasizes the importance of responsible AI practices in sensitive sectors, including life sciences.

2025: Draft - Digital Personal Data Protection Rules

Rules to operationalize the DPDP Act, aiming to safeguard citizens' rights for the protection of their personal data

Japan

2021: Implementation of AI principles

Guidance focused on human-centric AI use, education, privacy, security, transparency and fairness

2022: ML quality management guidelines

Guiding framework for ensuring the quality of ML-based products and services

*non-exhaustive

SaMD: Software as a Medical Device; GMLP: Good Machine Learning Practice; EMA: European Medicines Agency; NAIIA: National AI Initiative Act

★ Regulation/ guidelines specific to life sciences industry

Sources: European Parliament, EMA AI Workplan, EU GDPR, EU Data Governance, NAIIA, AI in SaMD, GMLP, AI Model Framework, Data Care Act, DPDP Act, Draft NDGF, 2025Draft DPDP rule, ML Quality Management, AI Principles

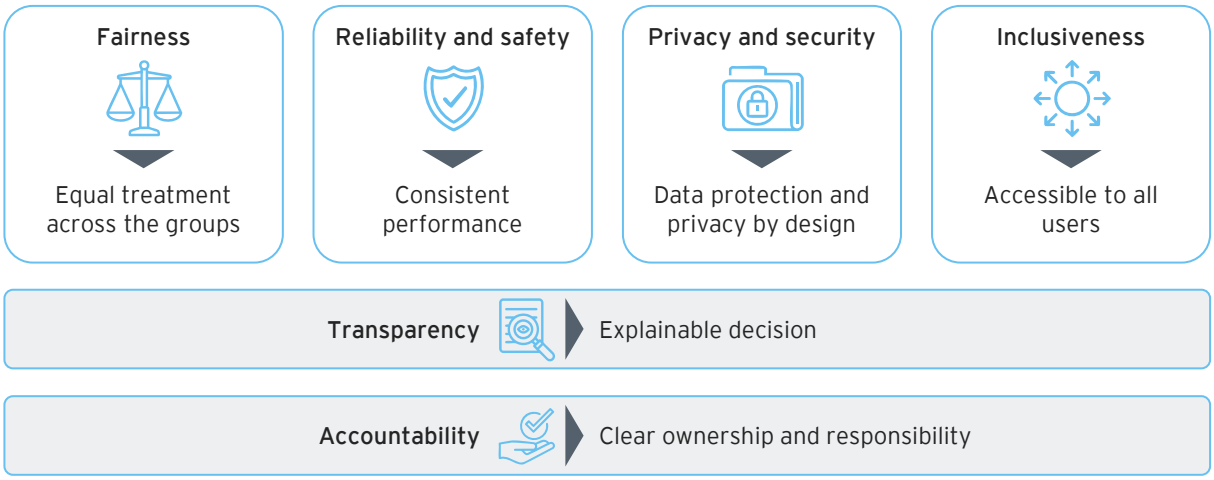
India's pivotal role in the global AI domain is underscored by its substantial investment of approximately INR 10,300 crore in March 2024 in the **IndiaAI Mission**.[5] The mission encompasses seven pillars with initiatives across digital health improvement. These include creating scalable AI computing ecosystems, deploying indigenous Large Multimodal Models (LMMs), building unified data platforms, promoting AI applications in critical sectors, increasing AI educational courses, providing funding to AI-based start-ups, and deploying AI responsibly with guiding frameworks.

Additionally, India's **Ayushman Bharat Digital Mission (ABDM),** launched in 2021, is transforming the digital health paradigm with the use of technologies, such as GenAI to enhance efficiency and efficacy in healthcare delivery. Through ABDM, patients can access healthcare services remotely via teleconsultation. Health professionals can access comprehensive patient histories and use clinical decision support tools for personalized treatments. This approach provides data access to policymakers, program managers and researchers, bolstering transparency and reliability in healthcare.

With robust IT infrastructure, a strong talent pool and pioneering health initiatives, India presents a big opportunity for growth in the life sciences sector. **Life sciences companies need to be prepared to effectively integrate and serve the needs of this increasingly digital healthcare ecosystem.**

Microsoft's responsible AI framework with six principals guiding AI development and use

Parallel to government regulations, tech companies have also introduced frameworks for ethical AI deployment. A prime example is Microsoft's Responsible AI framework. This framework takes a holistic approach to AI development and deployment. It is built on six fundamental principles: fairness, reliability and safety, privacy and security, inclusiveness, transparency, and accountability. These principles help in developing innovative AI systems that prioritize human values and societal benefits.



Source: Framework, AI practices

For pharmaceutical and healthcare organizations globally, active engagement with burgeoning AI ecosystems is imperative to maintain a competitive edge in the swiftly evolving domain of AI-driven healthcare innovation. As regulatory bodies worldwide continue to refine their approaches, the interplay between innovation and oversight will remain a critical factor in the responsible advancement of AI in life sciences.

[5] https://indiaai.gov.in/article/union-budget-2024-25-allocates-over-550-crores-to-the-indiaai-mission

Market opportunity and future trajectory: The expanding AI horizon in life sciences sector

Global market size and growth drivers

The integration of AI across the global life sciences sector represents a substantial market opportunity. The global AI market in medical devices is projected to grow from US$22.3 billion in 2024 to US$97.07 billion by 2028 at a CAGR of 44.4%, fueled by rising adoption of AI-powered diagnostic tools, smart medical devices, wearables and surgical robotics.[6]

Similarly, the global AI in pharmaceuticals market is forecasted to grow at a 27% CAGR from US$1.5 billion in 2024 to US$16.49 billion in 2034.[7,] This surge is attributed to AI's ability to accelerate drug discovery, interpret big data, and advance personalized medicine. Moreover, the growing need for precision and efficiency in clinical trials is also driving AI adoption. AI technologies can enhance the accuracy of matching patients to suitable trials, boost recruitment rates, ensure better patient engagement and retention throughout the trial period.

In the academic sphere, the market for AI datasets and licensing in academic research and publishing was estimated at US$381.8 million in 2024 and is projected to grow at a CAGR of 26.8% from 2025 to 2030. AI applications are expanding into various domains, including automated content review in academic publishing, citation analysis, metadata enrichment, research-driven simulations and predictive modeling in healthcare.[8]

Regionally, North America continues to dominate the market for AI in life sciences, attributed to the presence of large pharmaceutical companies, advanced healthcare infrastructure, and significant investments in AI research. Meanwhile, the Asia-Pacific region is emerging as a dynamic growth hub, fueled by swift technological progress, increased healthcare spending, and an expanding biotech and MedTech industry. This region is becoming a pivotal center for utilizing technology in the production of generic and biosimilar drugs, as well as advanced medical devices. The surge in Contract Research Development and Manufacturing Organizations (CRDMOs), along with an increasing focus on personalized medicines, is indicative of APAC's commitment to innovation and manufacturing excellence in the life sciences sector.

Cross-sector synergies and additional growth drivers

Beyond sector-specific growth drivers, several cross-sector synergies are fueling AI adoption:

- **Advancements in technology**: the increasing availability of big data, advancements in machine learning algorithms, and the proliferation of high-performance computing resources are making AI integration easier.
- **Falling cost of AI:** The plummeting cost of AI solutions, including accessible platforms, like OpenAI's GPT, and open-source models such as Meta's Llama, coupled with cloud service innovations and hardware optimization, is democratizing AI adoption.
- **Emphasis on personalized and efficient healthcare:** The demand for precision medicine, customized treatments and enhanced operational efficiencies is transforming healthcare delivery and improving patient outcomes.
- **Focus on sustainable innovations**: The push for eco-friendly and resource-efficient solutions is driving AI's role in optimizing processes, minimizing waste and advancing sustainable practices across the industry.
- **Policy support and strategic collaborations:** Favorable government policies, regulations providing clarity on AI usage, and collaborative efforts between industry, technology providers and academic institutions are creating a robust ecosystem for AI-driven advancements.

In conclusion, the market for AI in pharma and biotech, MedTech and AMCs is vast and poised for substantial growth. The integration of AI into these sectors is not only enhancing operational efficiencies and research capabilities, but also driving innovation and improving patient outcomes.

> As AI technologies continue to evolve and permeate deeper into biomedical fields, the market opportunities will expand, offering immense potential for companies to invest in and benefit from AI-driven advancements.

[6] Artificial Intelligence in Medical Devices Market Set for Unprecedented Growth

[7] AI in Pharmaceutical Market Size to Hit USD 16.49 Billion by 2034

[8] AI Datasets & Licensing for Academic Research And Publishing Market Report 2030

02

Harnessing AI now:

Current impact and future prospects


COR T2 STIR
TI 160.0
TR 4840.0
TE 44.0
Center
Avanto 6011190
RP
10cm
AI
MF 1.64
TI 160.0
TR 4840.0
TE 44.0

The convergence of AI and life sciences represents a crucial turning point in technological innovation. As computational capabilities expand and data become increasingly sophisticated, AI stands at the forefront, redefining the contours of pharmaceutical and biotechnological value chain, medical technology innovation, and the academic research landscape.

This chapter delves into the sweeping transformations that AI is catalyzing across these pivotal sectors.

Revolutionizing the pharma and biotech sector with data-driven agility and enhanced efficiency

In the pharma and biotech sector, AI is facilitating a shift towards more data-driven and agile business models across the business functions. The adoption of AI is resulting in higher efficiency and output at lower costs.

Transformative benefits of AI in Pharma and Biotech*

~90% reduction in time and money spent in drug development process Source: Forbes.com	**~30%** reduction in size of control arm in clinical trials; reliable clinical evidence in less time Source: clinicaltrialsarena.com	**~8 months** to discover candidate molecules after project launch Source: Evotec.com
~40% reduction in regulatory report writing at scale Source: outsourcing-pharma.com	**>90%** accuracy in predicting price of new drugs Source: okra.ai	**~1 second** per paper for medical literature review Source: kantify.com

*non-exhaustive

AI applications across pharma and biotech value chain

1. Research and development

a. Revolutionizing drug development

The traditional drug discovery process has long been characterized by extensive timelines, astronomical costs and high failure rates. AI is dramatically disrupting this landscape, introducing unprecedented efficiency and precision. This transformation touches every critical phase of drug discovery: from target identification, where AI extracts insights from complex omics and imaging datasets to understand disease mechanisms at an unprecedented resolution, to molecular design, where generative models create novel chemical structures and proteins with desired properties. In the drug development phase, predictive models simulate drug-target interactions, identify Absorption, Distribution, Metabolism, and Excretion (ADME) properties, assess toxicity, including insights into immune responses and drug immunogenicity, and identify biomarkers for treatment response. AI also accelerates drug repurposing by analyzing structure-activity relationships and identifying alternate indications for existing therapeutics.

Company examples: revolutionizing drug development

Companies such as Atomwise and Exscientia (now Recursion) are revolutionizing the drug discovery and development with their AI platforms that can design molecular structures, predict binding affinities, and significantly compress drug development timelines. What once took decade-long processes now potentially unfolds in months, with substantially reduced financial investments and higher probability of success.

AstraZeneca moved five targets in the discovery portfolio in less than three years with the use of BenevolentAI's proprietary AI-enabled drug discovery platform.

Roche is exploring 'Organoid-on-chip' platforms to gain better insights into mechanism of drug toxicities, improve predictability, reduce animal use in scientific testing.

India's contribution to this transformative wave is exemplified by CRDMO Aurigene's AI/ML-assisted drug discovery platform launched in 2024. This platform is anticipated to yield a 35% reduction in cycle time from chemical design to synthesis and testing, marking a significant leap forward in the efficiency of drug development.

Insilico Medicine is accelerating drug discovery with its fully integrated platform, Pharma.AI to identify novel therapeutic targets, design new molecules, and select ideal candidates for further testing.

Sources: Atomwise, Exscientia, AstraZeneca, Roche, Aurigene , Insilico

Pfizer leverages GenAI to drive patient-centric innovation

- Launched Pfizer-Amazon Collaboration Team (PACT) initiative in 2021 to optimize new medicine development through cloud-based solutions
- Pursued 14 projects under PACT using tools from AWS including: AI/ ML, compute, storage, security, cloud data warehousing, laboratory, clinical manufacturing, and clinical supply chain efforts

The problem: Need for PACT

- **Bandwidth for prototyping:** Company needed more resources to rapidly prototype and evaluate new technologies
- **Data discovery time:** Scientists spent excessive time manually searching for data, impacting productivity

The solution: How PACT helped

- **Prototyping support:** AWS's Prototyping and Cloud Engineering team, worked directly with Pfizer's business and IT teams, enabling rapid development cycles
- **Key GenAI and ML innovations:**
  - **Intelligent search platform,** enabling documents search by voice command and chatbot
  - **Manufacturing anomaly detection** by using ML-based tools to predict maintenance needs and reducing equipment downtime

Key impact

Faster prototype

Reduction in time from prototype to MVP (minimum viable product) stage from > three months to six weeks

Time saving

Scientists saved up to 16,000 hours annually in data search time

Cost reduction

Achieved a 55% reduction in I nfrastructure costs

Innovation culture

Fostered a culture of bold innovation within Pfizer, leading to multiple projects moving into production

> *We have changed our innovation culture and done a lot in a very short time. The most important benefit I have seen through the PACT program is that it has inspired people to think bolder.*
>
> Vijay Bulusu, Head of Data & Digital Innovation for Pharmaceutical Sciences Small Molecule (PSSM), Pfizer

Sources: Driving Patient-Centric Innovation in Life Sciences Using Generative AI with Pfizer | Case Study | AWS

b. Personalized medicine

The future of pharmaceutical research lies in personalization. AI enables an unprecedented granular analysis of genetic profiles, clinical measurements, lifestyle factors, and environmental conditions, allowing researchers to develop targeted therapies tailored to each individual. By interpreting complex genomic data, machine learning models can identify specific biomarkers associated with diseases, creating pathways for precision treatments that minimize adverse effects and maximize therapeutic effectiveness.

Company examples: Personalized medicine

Serna Bio, founded in 2021, develops small molecules that modulate RNA translation and splicing to treat challenging diseases. By combining synthetic biology, machine learning, and multiplex screening, they have created the world's largest database of functional RNA structures and specialized chemical libraries, supporting both internal programs and external collaborations in biologic and personalized medicine drug discoveries.

IIT Madras developed an AI-based tool, 'PIVOT', that can predict cancer-causing genes in an individual, a critical component in patient stratification/ selection for clinical trials. By leveraging an individual's genetic profile, PIVOT aids in determining the likelihood of response to treatment, thereby informing personalized cancer treatment strategies.

Tata Memorial Hospital (TMH) has introduced AI through a 'Bio-Imaging Bank' for early cancer detection. By analyzing vast data including radiology and pathology images, clinical details, outcome data, treatment specifics from ~60,000 patients, AI algorithms enable precise detection of cancers like head, neck, and lung, demonstrating a 98% accuracy rate and also reducing radiation exposure in pediatric patients undergoing CT scans.

Sources: Serna Bio, IIT Madras, Tata Memorial Center

c. Clinical trials optimization

The integration of AI is not confined to early-stage research; it is also transforming clinical trial design and execution across multiple dimensions. AI-driven platforms are revolutionizing protocol development by optimizing study designs and reducing study arm sizes. In patient recruitment, AI algorithms are automating initial screening processes, identifying ideal subjects and improving trial diversity. The technology is equally impactful in identifying site locations with the highest likelihood of success by predicting potential risks, such as protocol deviations or safety issues. Additionally, clinical trial control towers offer centralized, real-time oversight of multiple trial aspects.

AI-based smart management systems can help optimize, automate, and add intelligence into trial management, planning and costing. AI can also aid in the creation of synthetic data, providing valuable research insights when actual patient data is scarce. AI streamlines clinical trial submissions, resulting in faster regulatory approvals. AI also plays a pivotal role in facilitating decentralized trials, which promise enhanced efficiency and success rates.

Company examples: Clinical trial optimization

Image Analysis Group (IAG) is an imaging Clinical Research Organization (iCRO) that uses advanced imaging and AI to accelerate drug development. Their proprietary cloud-based platform, DYNAMIKA, streamlines imaging data management in clinical trials. It helps in optimizing clinical trial designs with imaging-based endpoints that can accelerate go/no-go efficacy decisions for emerging therapeutics and improve patient selection in clinical trials.

J&J, in partnership with ConcertAI, is deriving innovative insights from real-world clinical data that inform clinical strategies and support study designs at a pace not possible through legacy approaches.

AstraZeneca developed AIDA (Automatic Identification Detection Adjudication) in 2023, an AI solution that can support the automated detection, reporting and assessment of key outcome events in cardiovascular trials. AIDA identifies cardiovascular events much more rapidly than traditional reporting methods that rely on patients or family members to report.

Pfizer collaborates with Vysioneer by providing access to one of its oncology clinical trial datasets. Vysioneer leverages its advanced machine learning techniques to streamline the drug efficacy assessment process, enabling Pfizer to evaluate drug performance with enhanced precision while uncovering advanced biomarkers and novel endpoints.

TCS launched Connected Clinical Trials platform in 2022. This cloud-based, patient-centric interface streamlines operations by connecting patients, sites, and sponsors with features for tracking, digital labeling, adherence monitoring, electronic diaries, outcomes assessments, consent, and tele visits. It supports automated data collection and remote monitoring for handling large volumes of data efficiently.

Sources: IAG, J&J, Astrazeneca, Pfizer, TCS

Case study: GenAI for efficiency in regulatory submissions

Issue

- Regulatory process can often slow down drug development.
- Manual processing of regulatory documents and dossiers can introduce errors, resulting in delays or rejection of applications.
- Engaging in multiple global markets, handling the sheer volume of regulatory submissions and compliance tasks, is very difficult.

Solution

- GenAI integration can automate the creation of structured reports, summaries, and submissions required by regulatory authorities

Potential impact

- Improved efficiency and optimization of the process
- Significant reduction in time taken to respond to regulatory queries
- Improved regulatory intelligence
- Improved compliance levels by reducing likelihood of errors in dossier submissions

Case study: GenAI enabled R&D assistant for Route of Synthesis (ROS) generation

Issue

- R&D process in life sciences sector has traditionally been time and money intensive, marked by a high failure rate.

Solution

- GenAI can suggest optimized synthetic routes for producing target molecules.
- GenAI can be used to automatically generate ROS (Route of Synthesis) derived from credible internal and external sources of literature and study data.

Potential impact

- Automated route selection
- Intelligent automation of process and output
- Comprehensive analysis of synthesis and insights trends
- Reduced time and costs

Use case: GenAI-enabled clinical agent for R&D efficiency

Use case

- GenAI can assist clinical trial team to reduce the decision-making timeframe by study selection, identifying the CRO, collating and monitoring data and generate report from credible internal and external clinical trial databases

Potential impact

- Identification of study
- CRO selection basis capability, technology and past performance
- Efficient regulatory submission
- Faster report preparation
- Detailed protocol preparation basis study duration, patient pool and demographics, inclusion and exclusion criteria

2. Manufacturing and supply chain optimization

Beyond research, AI is transforming pharmaceutical manufacturing and logistics, extending from edge to cloud for comprehensive IT/OT (Information Technology / Operational Technology) data and analytics. In manufacturing, intelligent automation and robotics are reducing manual errors and enhancing operational efficiency. Predictive maintenance systems proactively monitor equipment, predicting failures and minimizing downtime. Quality control is bolstered by AI's real-time monitoring, which detects anomalies and predicts issues to fine-tune key performance indicators (KPIs). Yield optimization is another critical area where AI provides insights to maximize output and reduce waste by analyzing production data. Technology transfer processes are streamlined through AI, ensuring seamless transitions from development to manufacturing. Capacity modeling is refined with AI's predictive analytics, enabling better planning and utilization of manufacturing resources.

In the supply chain, AI-powered analytics enhance visibility, identifying bottlenecks and inefficiencies in real time and streamlining operations. AI assists in identifying sustainable sources for raw materials, aligning with environmental goals and reducing the carbon footprint of manufacturing processes. It also supports supplier performance management by assessing supplier data for compliance with quality standards and delivery timelines. AI optimizes routing and delivery schedules, reducing lead times and improving customer satisfaction by ensuring the timely delivery of pharmaceutical products. This digital transformation extends beyond cost reduction, enhancing demand sensing and forecasting accuracy, and facilitating a more synchronized orchestration of the supply chain.

Company examples: Manufacturing and supply chain optimization

Pfizer's integration of live process data into their maintenance systems exemplifies the shift from preventative to predictive maintenance. This proactive approach has curtailed downtime and provided teams with actionable data, culminating in heightened productivity and yield.

Merck KGaA, in collaboration with Aera Tech, used AI/ML algorithms to improve demand forecasting accuracy, optimize sourcing and capacity planning, limit inventories, and enable real-time decision-making based on external (e.g., natural disasters) and internal events. This use of AI led to improved forecast accuracy in 90% of products and increased customer service to hospitals from 97% to 99.9%.

Cipla adopted Manufacturing Execution Systems (MES) to achieve streamlined manufacturing. MES bolsters efficiency by automating material flow and offering real-time updates on changing requirements. This paperless operation minimizes waste and ensures precise cost tracking.

Sources: Pfizer, Merck KGaA, Cipla

Case study: 'Golden batch analytics' for manufacturing golden batches consistently

Issue

- Several challenges occur during the batch manufacturing of drugs, such as inadequate robust data collection methods, reliance on manual or paper-based systems without a centralized data management repository. This can result in inconsistent record-keeping and a vulnerability to human errors, hindering comprehensive data analysis. Consequently, processes often run sub-optimally, leading to inconsistency in outcomes, such as yield, cycle time, Right First Time, and adherence to quality specifications. Additionally, manual control of the process introduces further variability, affecting both yield and cycle time.

Solution

- By employing AI/ML models, available data can be leveraged to optimize the process and manufacture "golden batches" consistently.
- Golden Batch Analytics, an AI/ML product, identifies an optimal recipe - a specific blend of combination of critical process parameters and material attributes - that reliably yield golden batches.
- A golden batch is defined by achieving one or more of the following objectives:
  - Minimum cycle time
  - Maximum yield
  - Higher process capability on specified quality parameters/specifications

Potential impact

- Improved yield
- Improved cycle time/throughput
- Improved process capability/consistency to meet the product quality parameters

Case study: Intelligent Process Optimizer for Contract Development and Manufacturing Organizations (CDMOs)

Issue

- In CDMOs, the production of developmental batches, encompassing both early and late-phase clinical trial batches, tends to be inefficient due to the small quantities involved and the lack or scarcity of historical data needed to devise a golden batch recipe.

Solution

- GenAI can be harnessed to develop an "Intelligent Process Optimizer", capable of generating optimal recipes and identifying common failure modes for variables such as reaction conditions, temperature, mixing speeds, and duration.
- This ensures the achievement of Right First Time (minimal failures), highest yield and quality, and minimizes waste and cycle time.

Potential impact

- Increased achievement of Right First Time
- Reduced instances of out-of-specification results
- Shortened supply lead time/project timelines

AI adoption by Indian LS companies: Pioneering progress and future-proofing business

Case study: Computer System Validation (CSV) Co-pilot

Issue

- 21 CFR part 11 is a section of Code of Federal Regulations that outlines the US FDA guidelines and requirements on using electronic records and signatures.
- Organizations operating within FDA-regulated environments must ensure compliance with 21 CFR Part 11. This involves maintaining a documented process that upholds data integrity, assures quality, and conforms to GxP regulations.

Solution

- GenAI can create CSV related deliverables including 'User Requirement Specification (URS)', 'Functional Requirement Specification (FRS)', 'Fall Risk Assessment (FRA)', 'Test Scripts (TS)', and 'Validation Plans (VP)' from scratch based on user inputs and pre-defined formats and templates.

Potential impact

- Improved productivity due to reduction in repetitive tasks
- Increased accuracy
- 100% traceability
- Improved compliance levels with constantly evolving regulatory requirements
- Improved quality and robustness of quality management system

Use case: Optimizing procurement with AI-enabled 'Should Cost Modeling'

Use case

- 'Should Cost Modeling' is an analytical approach that scrutinizes data of all cost drivers and raw materials contributing to a product's cost. This method has become indispensable in product development and procurement strategies.
- GenAI-driven 'Should Cost Modeling' harnesses a significant amount of unstructured data and information available from research papers and various data sources. It then recommends the right "should cost" price for raw materials and packaging materials (RM/PM), providing a solid foundation for commercial negotiations.

Potential impact

- Significant reduction in base cost of direct materials
- Enhanced ability to drive cost savings in B and C class materials
- Establishment of a comprehensive price benchmarking database
- Improved negotiation power
- Enhanced ability to evaluate new product launches and investments

3. Commercial operations

AI is revolutionizing the pharmaceutical commercial operations landscape in three key areas: sales and marketing, regulatory affairs and market access. This technological evolution not only bolsters revenue streams but also promotes wider access to care and medications, fostering a healthcare delivery system that is both more efficient and centered around patient needs.

Within sales and marketing, AI solutions boost efficiency and improve engagement with customers. Medical Representatives (MRs) are equipped with sophisticated AI tools that reduce administrative burdens and enable data-driven, personalized interactions with healthcare providers. AI-powered 'virtual assistants' support MRs by scheduling appointments, providing product information and handling routine inquiries. Tools such as 'conversational AI' leverage information from Customer Relationship Management (CRM) systems and real-time market data to provide on-demand insights, empowering MRs with the right information at the right time needed for impactful discussions. AI can continuously scan regulatory changes, ensuring that marketing and sales activities remain compliant across jurisdictions. Workforce analysis through AI identifies training needs for the MRs to boost effectiveness.

In the realm of regulatory affairs, AI is streamlining data management, speeding up the journey to compliance and market approval. AI is also proving invaluable in pharmacovigilance by swiftly analyzing and reporting adverse events, thereby enhancing drug safety and patient care. AI is enhancing market access by designing outcome-based contracts and value-based models tailored to specific populations and needs. It enables product differentiation through data mining of historical trends and current market dynamics, crafting targeted value messages. AI is also transforming scientific exchange, providing healthcare professionals with instant access to the latest research updates and tailored medical advice. This fosters deeper engagement, informed decision-making, and collaborative synergy within the healthcare ecosystem.

Company examples: Commercial operations

Pharma companies such as Pfizer India and Sun Pharma are using conversational AI with multilingual capabilities, breaking down language barriers and enhancing communication with healthcare professionals across diverse regions.*

Novartis 'ACTalya', an AI-powered digital assistant for field-based associates, that provides insights into content optimization, timing, and method of communications, has provided millions of recommendations to more than five thousands associates across different markets.

Wörwag Pharma in collaboration with TheraLyze.ai submits its first AI-generated Individual Case Study Report (ICSR) to the European Medicine Agency (EMA), exemplifying AI's potential in efficient regulatory interactions.

Sources: *Based on an interview with a former Executive Vice President at GSK India, as reported by Citeline. Novartis, Wörwag Pharma

> *AI is transforming the commercial front for pharma, especially in sales enablement, omnichannel marketing, and patient engagement. While global adoption is robust, markets like India are steadily catching up. To maximize effectiveness, firms must overcome challenges like data silos, compliance complexities and adoption gaps.*
>
> Salil Kallianpur, former executive vice-president at GSK in India (2025)[1]

Sources: 1. Citeline

AI adoption by Indian LS companies: Pioneering progress and future-proofing business

Case study: GenAI-driven insights bolstering medical representatives' (MR) effectiveness and enhancing doctor engagement

Issue

- Sales force was struggling to get higher in-clinic face time with doctors.
- Data from various sources on doctors and micro-market was isolated in separate databases and static dashboards, hindering efficient decision-making and personalized engagement with healthcare professionals by area managers, sales reps, and marketing teams.
- Company wanted to analyze aggregated data on doctors and therapy areas from multiple sources, such as field sales rep visits, doctor online interactions, prescription trends, to tailor recommendations for brand promotion, practice development, patient outcomes, and doctors' research needs.

Solution

- Using GenAI, the company could automate the analysis of large data sets to provide insights on doctors, regions, and therapy areas:
  - recommending right actions to MRs suited to doctor's unique persona and overall segment strategy
  - enabling MRs to better address healthcare provider (HCP) queries on products, molecules, clinical trials, new launches, drug efficacy, etc., supporting a service-focused approach in sales interactions

Potential impact

- Enhanced capabilities, efficiency, and capacity of MRs to offer personalized experiences to doctors resulting in longer in-clinic time, and positioning MRs as trusted partners, especially in Tier 2 and 3 cities
- Doctors benefit from insights on disease trends, prescription patterns and regional initiatives to improve their practice and patient footfall
- Increase MR productivity and reduced attrition rates
- More nimble and effective sales planning
- Head office team can create more relevant marketing material, optimize the budget for patient support program (PSP) by reallocating resources basis emerging trends

Case study: GenAI for improved compliance and efficiency in pharmacovigilance (PV)

Issue

- Safety intake is crucial in PV as it involves gathering extensive data on adverse drug reactions from diverse sources, which is foundational for later submission of PV system master files (PSMF).

Solution

- GenAI leverages NLP to identify, evaluate, and automate the processing of adverse event (AE) data from unstructured sources, creating structured reports for regulatory submissions in line with regional guidelines, thereby reducing compliance risks. It can handle large volumes of data, including clinician notes, scientific literature, and social media, to detect safety signals.
- GenAI can automate and streamline the creation of post-market surveillance reports mandated by regulators, decreasing manual effort and guaranteeing prompt, data-informed surveillance essential for ongoing drug safety oversight.

Potential impact

- Significant reduction in the time needed to process, identify, categorize, and extract data from reported adverse events (AEs)
- Enhanced regulatory intelligence by staying current with evolving guidelines
- Increased compliance with regulatory requirements through accurate and timely AE reporting

Pharma and Biotech: Current AI applications and emerging trends*

Research and development

Target identification
- Novel molecular target and biomarker discovery
- Novel rare variants for complex diseases

Drug development
- Reduced Design-Make-Test-Analyze cycle
- Predict ADME, efficacy, safety, toxicity, immunogenicity
- Drug repurposing
- Organ-on-chip platforms (gain better insights into disease mechanisms, improve predictability, reduce animal use)

Personalized medicine approach
- Genetic profile analysis
- Health data study

Clinical trial (CT) design
- Creating study protocols
- Predictive analytics for patient outcomes

Patient recruitment
- Automating initial screening
- Identifying subpopulations

Site selection
- Predicting potential risks (protocol deviations, safety issues)

Trial management and monitoring
- CT control towers
- Automated trial planning and costing
- Data quality and integrity monitoring
- Patient adherence and engagement
- Regulatory submission preparation
- Synthetic data generation
- Conduct in-silico trials and decentralized clinical trials

Manufacturing and supply

Manufacturing
- Intelligent automation
- Predictive maintenance
- Quality control
- Regulatory compliance monitoring
- Yield optimization
- Technology transfer and capacity modeling
- Energy efficiency
- Simulation /process modeling (digital twins)

Supply chain (SC)
- Demand forecasting
- Inventory optimization
- Supplier risk management
- Efficient logistics management
- Protecting supply chain integrity
- Self-healing supply chains
- Networked supply chain

Commercial and marketing

Sales and marketing
- Optimized marketing strategies
- Streamlined promotional material review
- Salesforce effectiveness
- Improved customer experience
- Compliance/ process simplification

Regulatory
- Streamlined data management
- Automated pharmacovigilance processes

Market access
- Designing outcome-based contracts and value-based models
- Targeted value messages

Emerging trends*

AI-driven drug discovery	▪ AI algorithms to identify novel candidates with superior efficacy and safety ▪ Enhanced predictive modeling to enable drugs for previously untreatable diseases ▪ Generative models- Generative Adversarial Networks (GANs) / Variational Autoencoders (VAEs) to design custom molecules for specific therapy targets
Personalized multi-omic therapies	▪ Integration of multi-omics data (genomics, proteomics, metabolomics, etc.) to facilitate the creation of therapies that target multiple aspects of diseases, customized to individual genetic profiles, thereby revolutionizing personalized medicine
Continued manufacturing and supply chain innovations	▪ AI to further optimize manufacturing processes and supply chain management, creating autonomous systems capable of predictive maintenance and self-correction, responding dynamically to operational challenges
AI-powered regulatory compliance	▪ Next-gen pharmacovigilance using NLP and sentiment analysis to monitor social media and other data sources for real-time drug safety monitoring ▪ Explainable AI (XAI) to ensure transparent AI driven decision-making

*non-exhaustive

AI transforming MedTech with smarter, connected devices and personalized healthcare

In the MedTech industry, AI is driving significant business transformations by enabling the creation of smarter, more connected medical devices. MedTech companies are utilizing AI to engineer devices that transcend traditional functionalities, evolving into sophisticated tools capable of gathering, analyzing and leveraging health data to deliver real-time insights.

In the MedTech industry, AI is not only advancing the entire value chain—from R&D to manufacturing and commercial operations—similar to the pharma and biotech sectors, but it is also revolutionizing both products and services. Let us explore the details of these advancements:

Transformative impact of AI in MedTech*

~70%-80% of accuracy achieved by AI systems in predicting heart attack risk from eye scan Source: scitechdaily.com	**~99%** reduction in turnaround time to confirmed tuberculosis diagnosis (from three weeks to around two hours) Source: Qure.ai	**~50%** reduction in measurement time with AI-supported MRI image reconstruction Source: siemens-healthineers.com
~35% reduction in customer service requests with the use of predictive maintenance systems for MRI devices Source: GE HealthCare	**~30%** decrease in workflow steps with AI-powered surgery planning and navigation system Source: stryker.com	**Sub-millimeter** of accuracy achieved with AI-driven robotic surgery systems Source: accuray.com

*non-exhaustive

AI applications in MedTech sector across the value chain

In **research and development**, MedTech innovators are leveraging AI's transformative power to pioneer outcome-oriented device research and innovation. It plays a crucial role in various functions during the conception and feasibility analysis phase.

AI, driven by Natural Language Processing (NLP), analyzes historical patient data to design test cases and informs decisions on device design optimization. AI also uncovers real-world patient insights into unmet needs and product performance, driving more targeted device innovation. During **designing and prototyping**, AI simulations and generative design contribute to creating patient-specific devices. Real-time AI computations aid in conceptualizing devices and understanding performance dynamics, including safety predictions. AI-powered digital twins simulate and test hardware and software, assessing the impact of factors like light and moisture. AI-based analysis of molecular structures predicts interactions of device components with human tissues or fluids, aiding in the selection of the most suited materials. AI-powered 3D printing designs patient-specific implants using algorithms trained on surgeon- and radiologist-validated patient data, automating the design workflow and supporting clinical decision-making.

In clinical validation, as in the pharma and biotech sectors, AI facilitates in-silico trials and real-time trial monitoring. This AI-driven approach accelerates development and transforms medical device conception, design and validation, enhancing success rates and patient outcomes.

Within manufacturing and supply chain functions, AI's impact in the MedTech sector mirrors that in the pharma and biotech sectors, improving operational efficiencies by automating manufacturing processes and optimizing supply chain logistics. This leads to lower costs, better product quality, and the agility to adapt to market changes. AI-driven analytics also improve forecasting and inventory management, further streamlining production and distribution in the MedTech industry.

AI is also transforming MedTech **commercial operations** by boosting customer engagement. AI-driven chatbots and virtual assistants enhance customer support, while services such as predictive maintenance for hospital devices ensure reliability, minimize downtime and extend the life of medical equipment.

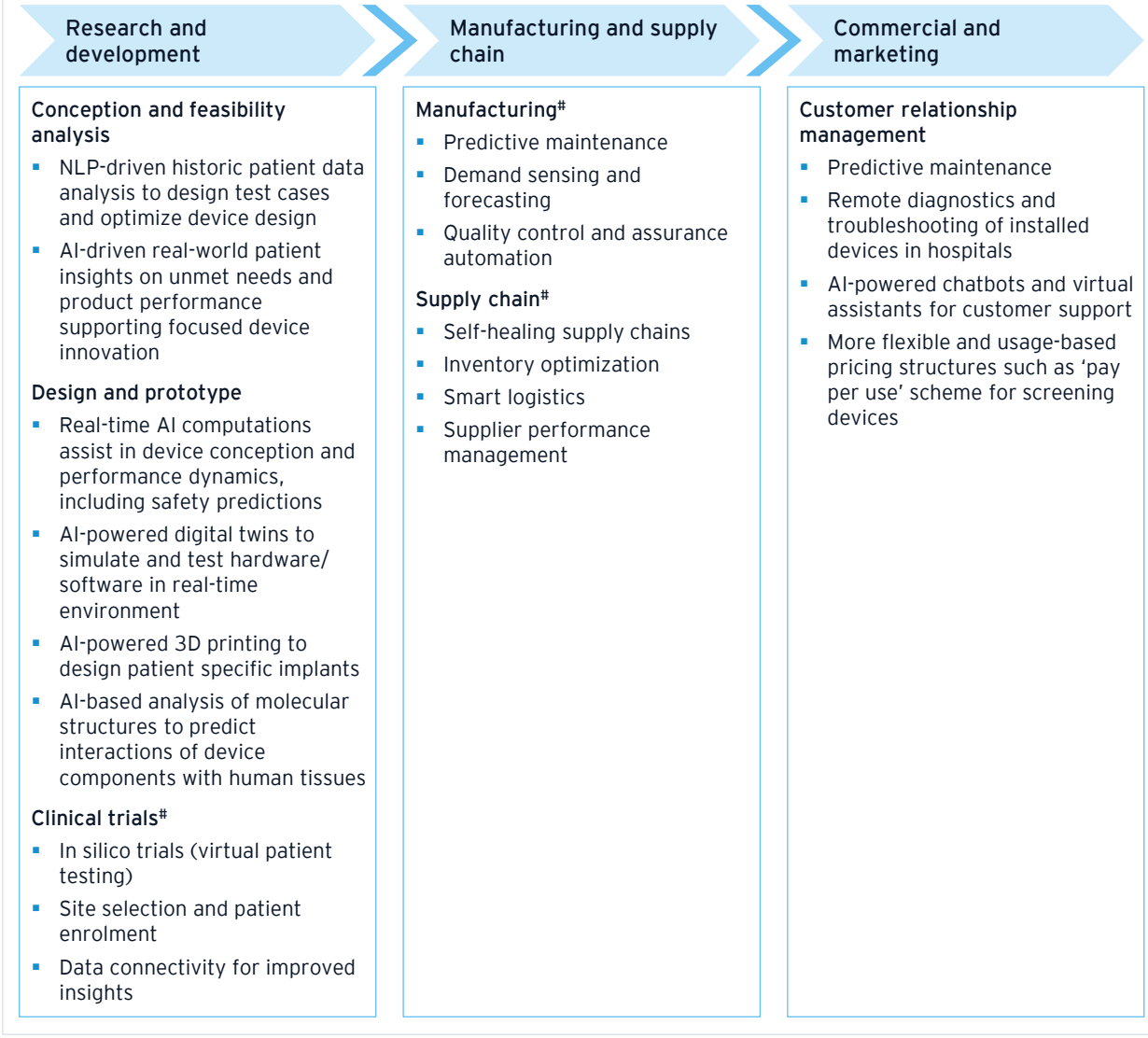
Company examples: Research and development

GE Healthcare's 'OnWatch Predict' for MRI uses a digital twin of MRI machines to monitor critical components and detect any potential issues quickly. In 2020, this system results in an average increase in MRI uptime of 4.5 days per year, and reduction in customer service requests by up to 35%.

Sources: GE healthcare

The integration of AI into MedTech is opening up new revenue streams with data-centric services and advanced diagnostics, broadening the scope of offerings. Additionally, more flexible, usage-based innovative pricing models are emerging, such as pay-per-use scheme, monthly rentals and subscription models. These advancements empower MedTech companies to provide more holistic, value-driven solutions to healthcare providers and patients, positioning them at the forefront of healthcare innovation.

AI applications across MedTech value chain*



*Non-exhaustive

#AI applications similar to Pharma and Biotech sector

AI applications in MedTech sector: Revolutionizing products and services

1. Advanced diagnostic capabilities

Medical technology is at the forefront of a diagnostic revolution, propelled by the integration of AI. AI-powered imaging systems are setting new benchmarks in diagnostic accuracy, complementing human capabilities. Machine learning algorithms can analyze radiological images to identify potential cancerous developments, cardiovascular risks and neurological anomalies with unprecedented precision. On-edge diagnostic devices, equipped with AI-powered real-time analytics, further accelerate this shift by enabling instant disease detection and decision-making at the point of care.

AI-enhanced digital stethoscopes analyze heart and lung sounds, assisting in the early detection of cardiac and respiratory conditions. AI-powered wearables continuously monitor vital signs and detect anomalies, providing early warnings for conditions such as arrhythmias or sleep apnea. AI enhances endoscopic procedures by identifying abnormal tissue and lesions in real-time, improving the detection of gastrointestinal diseases.

These AI applications span various diagnostic modalities, including ultrasound image analysis for obstetric and gynecological health, dermatological evaluations for skin cancer detection, and speech and language processing for neurological disorders diagnosis. AI is also transforming ophthalmology by analyzing retinal images to detect eye diseases. Each of these use cases underscores AI's pivotal role in advancing medical diagnostics and patient care.

This AI-driven shift is reshaping MedTech business models from being purely product-based to also service-oriented models that offer continuous patient monitoring and personalized healthcare solutions.

Company examples: Advanced diagnostic capabilities

PathAI is revolutionizing the field of pathology with AI algorithms that bolster the accuracy of diagnoses. By meticulously analyzing histopathological images, PathAI's models identify cancerous cells with a degree of precision that outstrips conventional methodologies, thereby curtailing diagnostic errors and enhancing patient care.

Qure.ai leverages deep learning algorithms to automate the interpretation of radiology exams and streamline the diagnostic process.

Niramai is revolutionizing breast cancer screening globally with its novel, radiation-free, AI-assisted thermal imaging technology. This breakthrough approach facilitates early and precise detection of breast cancer, underscoring the potential of AI in improving health outcome.

OncoStem Diagnostics' proprietary AI-based test, 'CanAssist Breast' uses a statistical model to identify the patient's risk of breast cancer recurrence over five years. The prognostic test analyzes the critical biomarkers in the tumor and classifies the patients into "low- risk" or "high-risk" based on which the oncologists can frame an informed and personalized treatment plan avoiding chemotherapy for many.

Sources: PathAI, Qure.ai, NIRAMAI health analytics, Oncostem

Qure.ai: Transforming radiology imaging interpretations

Quick facts

2016	24 patents	~13	90+
founded	as of Mar'23	FDA approved AI-enabled solutions	countries reached

Innovative AI-powered products* enabling more accurate and faster diagnoses

qXR: AI-based solution for Chest X-Ray automation and interpretation	**40% turnaround time (TAT)** reduction Available in **90+ countries**, 3,100+ sites
qTrack: AI-based platform for end-to-end Tuberculosis (TB) screening and case management	**99%** reduction in TAT to confirmed diagnosis (from 3 weeks to around 2 hrs) Available in **55+ countries** and 1,900+ sites
qMSK: AI-based trauma related musculoskeletal (MSK) X-Rays interpretation	**<20 sec** processing time >0.9 sensitivity to detect signs of fracture
qER: AI solution for faster head CT interpretation	**179%** increase in proportion of stroke patients receiving early intervention in golden hour

*Selected examples, non-exhaustive

Sources: Qure AI | AI assistance for Accelerated Healthcare, Qure.ai/news, Qure.ai FY22-23 impact report

2. Robotics and automation

The landscape of surgical interventions is undergoing a profound transformation with the advent of intelligent robotic systems. Pioneering platforms, such as Intuitive Surgical's da Vinci, integrate real-time data analysis with augmented reality guidance and mechanical precision. These technologies enable minimally invasive procedures with greater accuracy and shorter patient recovery times.

AI-driven robotic systems are revolutionizing post-operative care by delivering personalized rehabilitation exercises that adapt to patient progress, thereby streamlining the path to recovery. Furthermore, AI is enhancing robotic prosthetics and orthotics, providing users with greater control and a more natural range of movement, ultimately improving the quality of life for individuals reliant on these assistive devices.

Company examples : Robotics and automation

Meril's recently unveiled robotic surgery system, MISSO, exemplifies the integration of AI in surgical applications. Designed for knee replacement surgeries, MISSO harnesses AI to slash pre-operative planning time by 83% and increases personalization of the procedure.

Sources: Meril

3. Remote monitoring and preventive healthcare

AI-powered wearables represent a paradigm shift in healthcare monitoring. Devices from Apple, Fitbit, and others now provide continuous health tracking, offering real-time insights into physiological parameters and potential health risks. AI-powered virtual assistants provide round-the-clock monitoring and support for patients, reducing the burden on healthcare staff and improving patient care.

Integrating AI with diagnostic devices enables data analysis from various sources to predict potential health issues, enabling timely interventions. For example, machine learning models can analyze ECG data to detect atrial fibrillation, facilitating prompt medical intervention.

AI-driven applications are redefining the concept of personal health coaching, catering to both healthy individuals and patients. These intelligent systems deliver personalized recommendations for diet, exercise and overall wellness, drawing from a rich pool of user data. Furthermore, AI's integration with home systems and sensors offers vigilant health monitoring, ensuring the well-being of residents, especially the elderly and those with special healthcare requirements – within the comfort and security of their own homes.

Several preventive programs and solutions leveraging AI to enhance patient health and outcomes are emerging in India as well. Apollo's ProHealth program, informed by data from over 22 million health checks, exemplifies this trend. Similarly, iiV Health's FootPlus utilizes AI for the early screening and detection of Peripheral Arterial Disease, showcasing the potential of AI in preventive healthcare initiatives.

AI is revolutionizing preventive healthcare through data-driven insights and personalized intervention

Apollo's ProHealth

India's first AI-driven personalized, predictive, and preventive health check program

Based on data from 22 million health checks

The 24/7 platform allows integration of patient data from several sources into one digital health record to provide:

- Personalized health risk assessments (HRA)
- AI-powered predictive risk scores (cardiac, pre-diabetes, chronic obstructive pulmonary disease)
- Personalized guidance and care continuum

iiV Health Solutions

Preventive HealthTech start-up in India developing AI/ML-based screening devices

Developed FootPlus, an AI/ML-based smart, non-invasive device that early screens and monitors peripheral artery diseases

- Detects capillary/peripheral blood flow using thermal exchange technology in under nine minutes
- Portable and Bluetooth-enabled remote diagnostics
- Does not require trained medical personnel

Sources: Apollo247.com, iivhealth.com

In addition to enhancing patient outcomes, the MedTech companies benefit from AI applications across the value chain similar to those in pharma/biotech, spanning R&D, manufacturing, supply chain and commercialization. AI streamlines medical device design, expedites prototyping, and ensures products meet safety and efficacy standards. In manufacturing, AI-driven systems optimize production lines, manage inventory accurately, and forecast demand to prevent shortages or overproduction.

In the supply chain, AI offers real-time tracking and logistics management for timely and efficient distribution of medical devices. In commercial operations, AI tailors marketing strategies, enhances customer relationship management and uncovers new market insights, driving growth and innovation. Integrating AI across these functions boosts efficiency, reduces costs, and fosters a more agile and responsive MedTech sector to meet evolving healthcare demands.

Current AI applications across MedTech products and services*

Advanced diagnostic capabilities

- AI-powered imaging systems (e.g., MRI system, CT scan, ultrasound, X-Rays) analyzing images with high precision
- On-edge diagnostic devices (e.g., POC and portable screening devices) providing instant disease detection and decision-making
- Use of AI across multiple diagnostic areas:
  - AI-augmented endoscopic techniques
  - digital stethoscopes
  - advanced speech and language processing
  - predictive hypotension analytics
  - retinal and dental images analysis
  - histopathological images analysis

Remote monitoring and preventive healthcare

- AI-powered wearables to continuously monitor vital signs, detect anomalies and provide early warnings
- AI-based devices for remote monitoring (smart inhalers, continuous glucose monitoring systems, home dialysis system)
- AI-based solutions enabling postoperative care by continuous progress tracking of various metrics
- AI-based apps providing personalized health insights, recovery exercises, trends, and reminders

Robotics and automation

- Robotic-assisted devices for improved surgical precision
- Real-time data analysis to adjust movements and provide augmented reality overlays to guide complex surgical procedures
- AI-enhanced advanced surgical planning and navigation platforms providing real-time feedback during operation

Emerging trends*

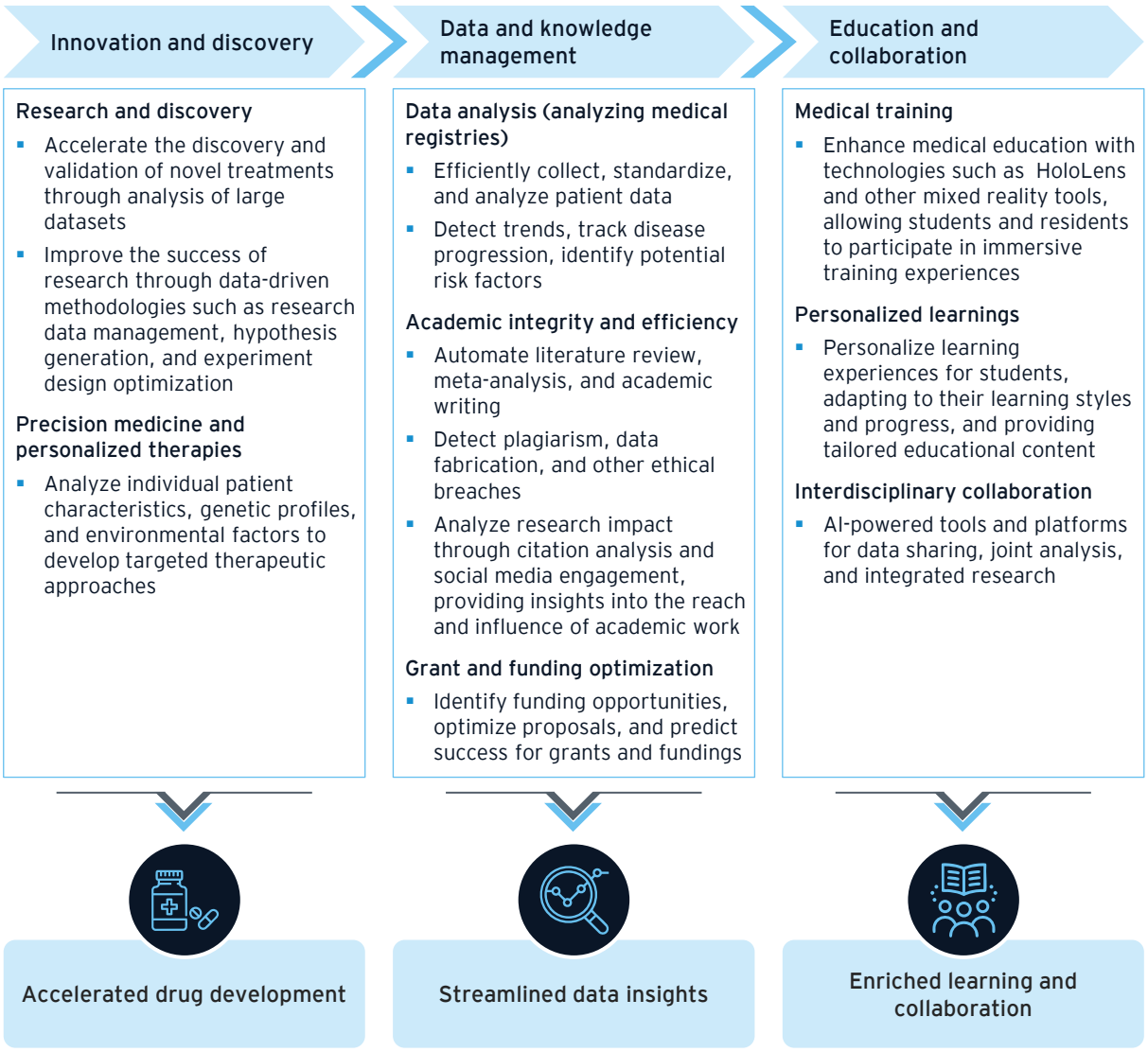
Enhanced diagnostic intelligence	▪ AI will refine predictive diagnostic capabilities, advancing beyond current models to offer more comprehensive health assessments by seamlessly combining multi-dimensional patient data—including genetic, environmental, and lifestyle factors.
Surgical technological optimization	▪ Robotic surgical platforms will evolve, incorporating advanced machine learning to further improve real-time decision-making during the procedures. ▪ Sophisticated augmented reality applications will enable surgeons to provide customized patient-specific interventions, leading to better outcomes and reduced surgical risks.
Intelligent health management systems	▪ Next-generation wearable and implantable technologies will transcend current health monitoring and management capabilities, developing more sophisticated predictive and preventive functionalities that dynamically adapt to individual physiological changes in real time with unprecedented personalization.
Customized drug delivery systems	▪ AI will personalize drug delivery systems, such as smart pills and targeted nanotechnology, to release medications at optimal times and dosages based on real-time patient data.
Expanding digital therapeutics	▪ AI will enhance digital therapeutics, offering behavior modification programs and therapeutic interventions for a range of conditions, from mental health to chronic disease management.

*Non- exhaustive

AI empowering academia: From research labs to lecture halls

In the dynamic environment of Academic Medical Centers (AMCs), artificial intelligence is becoming an indispensable ally, driving advancements across research, education and data management, and setting the stage for a new era of medical innovation and collaboration.

AI application across academic medical centers*



> *Artificial intelligence is not a substitute for human intelligence; it is a tool to amplify human creativity and ingenuity.*
>
> Dr. Fei-Fei Li, Co-Director, Stanford's Human-Centered AI Institute

*Non-exhaustive

AI applications in AMCs

1. Innovation and discovery

By leveraging the power of machine learning and advanced analytics, researchers can now sift through vast datasets such as patient outcomes, genomic information and clinical trials to drive groundbreaking insights that accelerate the discovery of medical breakthroughs. In the sphere of precision medicine and personalized therapies, AI analyzes individual patient characteristics, genetic profiles and environmental factors, paving the way for highly targeted therapeutic approaches. This tailored treatment paradigm promises to improve patient outcomes by focusing on unique aspects of each individual's disease.

Company examples: Innovation and discovery

The Robert Bosch Centre for Data Science and AI (RBCDSAI) at IIT Madras exemplifies the integration of AI in academic research:

- *uses AI-driven experimental design tools to optimize research processes*
- *leverages data science to provide actionable insights across diverse fields such as engineering, finance, and healthcare*
- *excels in interdisciplinary research in areas including network analytics, deep reinforcement learning, natural language processing*

Sources: Robert Bosch Center

2. Education and collaboration

Education and collaboration are at the heart of AMCs, and AI is playing a key role in transforming these domains. Medical training is being redefined through cutting-edge technologies like HoloLens and other mixed reality tools. These technologies provide students and residents with immersive training experiences that enhance their understanding and skills in ways traditional methods cannot match. By simulating real-life scenarios, learners can practice and refine their techniques in a safe and controlled environment.

Additionally, AI is personalizing the learning journey for each student. It adapts to their individual learning styles and progress, offering customized educational content that maximizes their learning potential.

AI-powered tools and platforms are enabling seamless collaboration by allowing data sharing, joint analysis and integrated research across disciplines. This promotes interdisciplinary research and accelerates scientific discoveries.

Company examples: Education and collaboration

The Homer Stryker M.D. School of Medicine at Western Michigan University has built a simulation center. The medical school is testing a tool that simulates patient meetings using chat robots to help students practice clinical skills. In addition, users can communicate with the robot to replicate a patient visit, such as inquiring why the robot needs medical attention and learning about the symptoms and medical history of the robot.

AI-driven platforms, like R Discovery and Scite, use machine learning algorithms to analyze vast amounts of academic content. These platforms assist researchers with personalized recommendations on relevant articles based on their interests, identifying potential collaborators to work with, and enhance literature review and manuscripts.

Sources: ncbi.nlm, R Discovery and Site

3. Data and knowledge management

In the data and knowledge management space, AI systems efficiently collect, standardize, and analyze patient data from medical registries. This capability allows for the detection of disease progression trends and the identification of potential risk factors, which are essential for improving patient care and outcomes. It not only aids in research but also informs clinical practice and public health policies.

Moreover, AI contributes to academic integrity and efficiency by automating the literature review process, performing meta-analysis and assisting with academic writing. It plays a crucial role in maintaining ethical standards by detecting plagiarism, data fabrication and other breaches. In terms of measuring research impact, AI tools analyze citation patterns and social media engagement, offering valuable insights into the reach and influence of academic work.

Lastly, AI is revolutionizing the process of grant and funding optimization. By identifying funding opportunities, optimizing proposals, and predicting the success of grants and funding applications, AI is ensuring that valuable research receives the support it needs to flourish.

Company examples: Data and knowledge management

'MedAware' technology developed by Harvard University analyze large-scale electronic medical records (EMRs) data using big data analytics and machine learning algorithms to understand how physicians manage patients in real-life circumstances.

Launched on 1 October 2024, BharatGen is India's first government-supported initiative to develop a multimodal large language model (LLM) with the aim of enhancing public service delivery and citizen engagement. Among its features, BharatGen's open-source framework bolsters the national AI ecosystem, benefiting government, private, educational, and research institutions by fostering a collaborative GenAI research environment.

Sources: ncbi.nlm, BharatGen

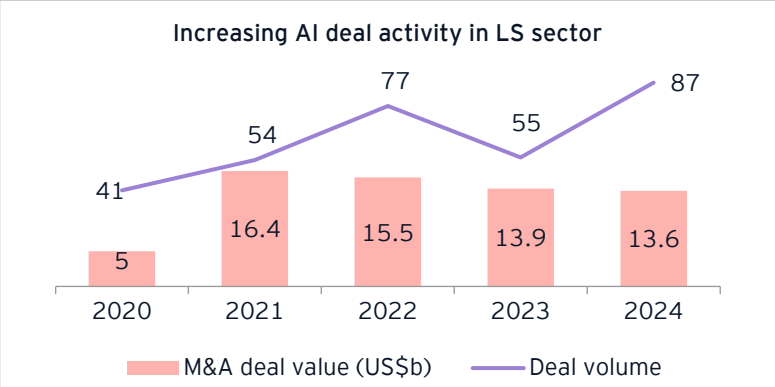
The time is now: Embracing AI for transformative growth

Rising AI-focused M&A and alliance deals in life sciences

The strategic importance of AI across the life sciences sector is further evidenced by the robust deal-making landscape.

Globally, life science companies are actively forging partnerships to harness AI capabilities across their value chains. From 2020 to 2024, there were over 300 AI-focused M&A and alliance deals in the life sciences sector, with deal volumes continuing to rise. The deal distribution reflects the industry's strategic priorities, with ~80% concentrated on R&D activities, underscoring the critical role of AI in accelerating drug discovery and development. Disease diagnosis and management account for 7% of these deals, while the remaining deals span operations, commercial activities and academic research collaborations. [9] This momentum has carried into 2025, with several significant AI partnerships already announced in the first month, signaling sustained trust and enthusiasm in AI's transformative potential across the life sciences sector.

Strategic alliances driving AI transformation across the life sciences' value chain



>300 AI deals (M&A and alliance) in 2020-2024, valuing **~US$65b**

US$712m paid by Recursion Pharma to acquire Exscientia (Aug'24 - largest LS AI M&A deal to date)

Recent AI deals announced in January 2025*

Company	Partner	Sector	Purpose
Mayo Clinic	NVIDIA	Pharma and Biotech (personalized medicine)	Deploy NVIDIA DGX™ Blackwell, for acceleration the development of next-generation pathology foundation models, instrumental in advancing personalized treatment strategies
Tempus	GSK	Pharma and Biotech (personalized medicine)	Combines real-world clinical data with molecular insights, equips oncologists with actionable intelligence, enabling the selection of personalized cancer treatments
The Arc Institute	NVIDIA	Academic medical centers (innovation and discovery)	Accelerate scientific research through computational models and tools that advance biomedical discovery, including engineering living systems and enhance understanding of complex diseases
Illumina	NVIDIA	Pharma and Biotech (Drug development)	Develop biological foundational models by interpreting multiomic data, accelerating progress in clinical research, genomics AI development, and drug discovery
Recursion pharma	Faro Health	Pharma and Biotech (Clinical trials)	Leverage Faro's AI platform for data-driven clinical trial design

Sources: EY Firepower report, EY analysis , GE Healthcare, Mayo Clinic, Tempus The Arc Institute, Illumina, Recursion pharma

[9] EY 2025 Firepower report

Note: EY firepower report methodology for deal analysis - Life sciences dealmaking activities were analyzed from January 1, 2014 to December 31, 2024 using data from Capital IQ, Biomedtracker and PitchBook. M&A deals with disclosed values greater than US$100 million were categorized according to the target's subsector (e.g., biopharma or MedTech). This does not include cross-border transactions that are part of larger, transformative transactions. For more detailed methodology, refer to EY 2025 Firepower report.

Surging investments and expanding regulatory approvals

The time is now: Embracing AI for transformative growth

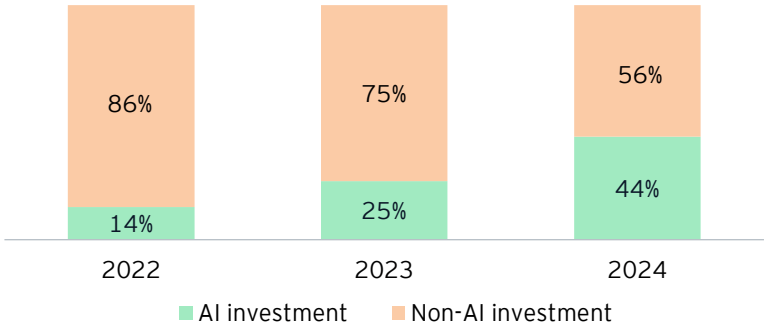
~50%
of approved drugs will involve AI in development and/or manufacturing within the next decade

Sources: CPHI report, 2023

~43%
Y-o-y increase in AI-based medical device approvals by FDA in 2023

Sources: EY pulse-of-medtech-industry, 2024

Investment into US-based and VC-backed companies



44%
of VC fundraising in 2024 across industries was in AI

Sources: EY- Large AI deals boost investment in 2024 VC market

> *AI is perhaps the most transformational technology of our times, and healthcare is perhaps AI's most pressing application.*[1]
>
> Satya Nadella, chief executive officer, Microsoft (2019)

> *We think that AI is poised to transform medicine, delivering new, assistive technologies that will empower doctors to better serve their patients. Machine learning has dozens of possible application areas, but healthcare stands out as a remarkable opportunity to benefit people.*[1]
>
> Google Health (2019)

Sources: 1. Medical Buyer

The trajectory of AI in life sciences is rapidly rising. Investor confidence in AI has surged, with Venture Capital (VC) funding across industries increasing from 14% in 2022 to 44% in 2024. This upward trend highlights the increasing recognition of AI's potential to drive efficiency and innovation. Regulatory approvals further demonstrate AI's rapid adoption in medical technology. The number of FDA-approved AI-enabled medical devices has grown by 176%, from 80 in 2019 to 221 in 2023.

The message is clear: organizations that delay AI adoption risk falling behind in this rapidly evolving landscape. The future belongs to those who embrace AI today, preparing strategically to overcome its challenges head-on and leverage its full potential for tomorrow's breakthroughs.

03

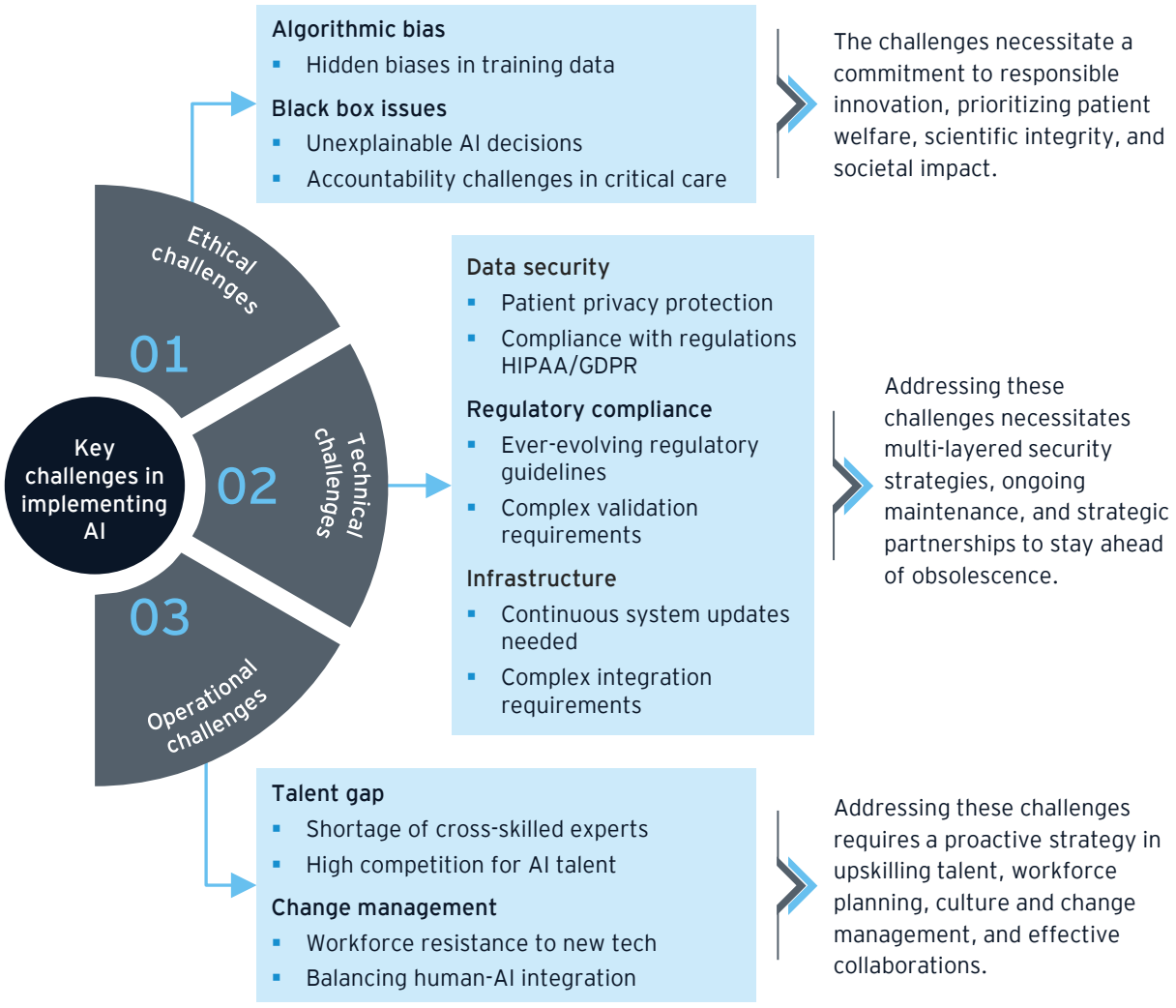
Confronting AI's complexities

Ethical, technical and operational considerations

As discussed in the earlier chapter, AI holds the potential to revolutionize the fields of pharmaceuticals, medical technology and academic research, offering groundbreaking advancements and efficiencies. This potential comes with a complex array of challenges that span ethical, technical and operational hurdles. While AI's potential is immense, these challenges require careful navigation to ensure ethical and responsible innovation.

Addressing issues such as algorithmic bias, the opaque nature of AI decision-making, the scarcity of skilled professionals, workforce transformation, investment balance, data security, and the need for advanced infrastructure are essential steps toward harnessing AI's full potential for the greater good.

AI implementation: Key challenges and considerations



Ethical and regulatory challenges: The moral compass

1. Algorithmic bias

At the core of AI's ethical challenges is the issue of algorithmic bias — a concern that is both subtle and profound, rooted in the foundational stages of AI systems development. Majority of today's AI applications are self-learning, deriving knowledge from the data and examples they are provided. These systems are not intrinsically impartial; biases present in the input data or the design of the algorithm can inadvertently lead to skewed outcomes that may exacerbate existing healthcare disparities. In the realm of pharmaceutical development, such biases could result in treatment protocols that are more suitable for certain demographic groups over others, thereby compromising the ideal of truly personalized medicine. For instance, in 2019, a healthcare algorithm serving 200 million US patients showed significant racial bias. By using healthcare cost history as a decision factor, the system inadvertently discriminated against black patients who historically spent less on healthcare than white patients with identical conditions. [10]

2. The 'black box' dilemma

The lack of transparency and interpretability in deep learning systems, known as the 'black box' problem, poses a significant challenge in healthcare. Understanding the rationale behind AI decisions is crucial, especially in life-critical applications, such as surgical robotics and diagnostic technologies.

Technical challenges: The digital foundation

1. Data privacy and security

In the life sciences sector, where patient information, clinical data and proprietary research are paramount, robust data protection becomes critical. Companies must implement sophisticated security measures, including strong encryption and stringent access controls, and compliance with country specific regulations such as EU's GDPR (The General Data Protection Regulation) and US's HIPAA (Health Insurance Portability and Accountability Act). According to the HIPPA journal in 2023, an average of 364,571 healthcare records in the US were breached every day[11].

2. Regulatory and compliance landscape

As discussed in Chapter 2, regulatory agencies worldwide are actively developing and updating regulations and guidelines concerning the use of AI within the life sciences domain. These measures are critical to safeguard patient well-being and to guarantee the dependability of AI-driven technologies. The evolving nature of these regulatory frameworks demands a strategic and informed approach to regulatory adherence, making it a complex yet essential aspect of AI integration in the life sciences sector.

3. Infrastructure and innovation

Establishing and maintaining a robust infrastructure for AI development is resource intensive but crucial for sustained advancement. Companies must commit to infrastructure excellence to avoid obsolescence and continue making progressive AI advancements.

[10] Racial Bias Found in a Major Health Care Risk Algorithm | Scientific American

[11] Healthcare Data Breach Statistics

Operational challenges: The human element

1. Interdisciplinary talent gap

A foundational challenge across all life sciences sectors is the acute shortage of interdisciplinary talent. Professionals who bridge domain expertise with advanced AI capabilities remain rare, creating a significant bottleneck in technological adoption and innovation. For instance, demand for such qualified AI professionals in India is projected to more than double by 2027, rising from ~600,000–650,000 to >1.25 million during 2022–27[12].

Simultaneously, AI is automating repetitive tasks and bringing operational efficiencies across all roles. This shift necessitates forward-thinking measures to reorient professionals towards more creative and strategic roles that are complemented by AI tools.

2. Change management for AI adoption

Implementing AI is not just about setting up new technology; it requires a fundamental change in the way an organization operates. Organizational readiness for effective AI adoption involves reshaping company culture, processes and employee mindsets to embrace AI-driven workflows. Effective change management is critical to ensure that employees are prepared and engaged in the transition towards an AI-integrated future.

As we look toward solutions, these challenges serve not as roadblocks, but as guideposts for developing robust implementation strategies. In the next chapter, we will explore strategies to navigate these complexities, turning challenges into opportunities for innovation and growth in the life sciences sector.

[12] How India can address the AI-Skills Gap for the Future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04

Shaping tomorrow

Strategic directions for AI in life sciences

Building on the challenges outlined in the previous chapter, this section shifts the focus from understanding challenges to seizing opportunities. As the life sciences sector navigates the complexities of AI integration, it becomes imperative to adopt forward-thinking strategies that translate potential into a tangible impact. This chapter delves into the strategic imperatives and practical frameworks necessary to harness AI's transformative power and secure the requisite return on investment (ROI).

The chapter lays out a comprehensive roadmap for navigating the technological, regulatory, ethical, operational, and other strategic requirements, guiding stakeholders toward a future where AI is a catalyst for efficiencies, an enhancer of equitable healthcare, and an accelerator of scientific breakthroughs. By addressing these multifaceted dimensions, we chart a course for realizing AI's full promise in the life sciences domain, ensuring that its integration is both successful and sustainable.

The risk of not adopting AI

For any organization, failing to adopt AI poses significant risks that can hinder growth, efficiency and long-term sustainability. These risks manifest across several critical areas:

- **Competitive disadvantage**: Organizations may risk losing their edge in the market as competitors leveraging AI outpace them in innovation and efficiency, attracting top talent and investor confidence
- **Operational inefficiencies**: Without AI, processes remain slower and less optimized, leading to avoidable productivity losses and inefficient use of resources, which can hinder scalability and growth
- **Customer trust erosion**: The inability to deliver personalized and innovative solutions fosters a perception of being outdated, potentially undermining trust in the organization's ability to meet evolving customer needs
- **Innovation stagnation**: Resistance to AI adoption limits access to transformative breakthroughs, increases research costs, and hampers the ability to provide cutting-edge, patient-focused care

The hidden costs of AI resistance*

Competitive disadvantage
- Market share erosion
- Talent drain to AI-driven firms
- Reduced investor confidence

Operational inefficiencies
- Quantified productivity loss
- Exponential resource wastage
- Slower process optimization

Customer trust erosion
- Inadequate customer experience
- Failing to deliver personalized solutions
- Potential disease management and treatment efficacy concerns

Innovation stagnation
- Increased research cost
- Missed breakthrough potential
- Reduced patient care (less personalized treatments, restricted predictive healthcare)

AI transformation is not optional, it is a strategic imperative for survival in the evolving ecosystem and future growth.

*Non-exhaustive

To avoid these risks, organizations must embark on their journey toward AI adoption and excellence. This begins with assessing their current AI maturity level and identifying strategic steps to advance along the curve, ensuring they stay ahead and mitigate the risks of delaying AI implementation.

Understanding AI maturity in life sciences

Organizations typically progress through three distinct maturity levels: foundational, innovative and transformational. Each level represents increasing sophistication in AI capabilities and organizational readiness.

Organizations can exist at different maturity levels across various functions simultaneously. The key is to recognize current positioning, frame the desired strategic future state, and chart a clear path toward higher maturity levels through systematic capability building.

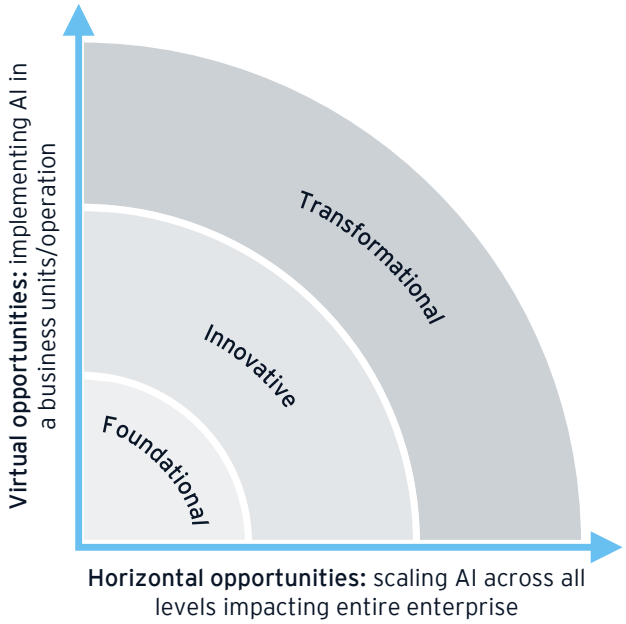
Maturity framework for AI implementation

Maturity levels

- Cultural transformation toward AI-first mindset
- Harnessing AI-driven decision-making across all levels and business units
- Continuous innovation and adaptation
- Advanced predictive and prescriptive analytics

- Advanced AI applications in specific business units/processes
- Scaled deployment of successful AI initiatives
- Cross-functional AI projects
- Enhanced data analytics capabilities
- Established AI Centres of Excellence

- Focus on building foundational AI capabilities
- Establishment of core data practices and governance
- Initial pilot projects in non-critical areas
- Building basic AI literacy across the organization



Key implementation strategies for AI success

Successful integration of AI and moving up the AI adoption maturity curve requires a comprehensive approach that addresses ethical, technological and organizational challenges. Here are the five critical strategic pillars, along with key components of success that companies should implement for a balanced and effective AI transformation.

1. Reimagining the business and operating model

The rapid evolution of AI technologies demands a fundamental rethinking of how life sciences organizations operate and deliver value. The traditional linear approach to drug development, clinical trials and healthcare delivery is increasingly insufficient in today's dynamic environment. Organizations need adaptive, intelligent systems that can respond to real-time insights and changing market conditions. The emergence of precision medicine, personalized therapeutics and digital health solutions requires a more agile and data-driven, future ready operating model.

As organizations embrace this paradigm shift and prepare to embed AI, they must look beyond surface-level changes to achieve meaningful transformation. This transformation extends far beyond mere process automation and a few pilot projects. Organizations must fundamentally reimagine their operational architecture by adopting AI-first strategy, i.e., integrating and deploying AI technologies across business functions and operations, and create systems that continuously learn, adapt and improve. This includes integrating AI-driven decision support systems across the value chain, implementing automated workflow optimization, and establishing real-time performance monitoring capabilities.

Reimagining the business and operating model | Move to an AI-first strategy by automating workflows, optimizing value chains, and introducing new interfaces for enhanced efficiency and value creation.

Key drivers for successful execution

- *Executive and senior **leadership sponsorship and commitment** to the organization's AI strategy.*
- *A strategic roadmap that identifies and **prioritizes high-impact AI initiatives across** the value chain. (e.g., drug discovery acceleration, clinical trial optimization, manufacturing efficiency, supply chain agility, commercial excellence, etc.)*
- ***Assessing current AI skills** and talent gaps and an approach to bridge them (e.g., whether to upskill, recruit, or partner with external experts)*
- ***Developing AI proof-of-concept (PoC) projects** to mitigate risks and validate potential value.*
- ***Defining clear accountability** through defined roles and responsibilities within AI governance structure.*
- ***Fostering collaboration** between scientific teams, data scientists, and business units to ensure AI solutions address real-world challenges.*
- ***Tracking** both short-term efficiency gains and long-term value creation by implementing appropriate KPIs.*

Key drivers for successful execution

To navigate this transformation successfully, organizations must establish robust leadership and governance frameworks. Success in this transformation requires more than just technical expertise – it demands unwavering leadership commitment and strategic alignment across the organization.

First and foremost, an organization needs an executive **leadership commitment**, as this serves as the driving force behind AI initiatives, providing the necessary resources and organizational support for success. A well-defined strategic **roadmap with prioritized AI activities** is essential to focus on the most impactful initiatives, optimize resource allocation and ensure maximum return on investment. For each AI use case, an organization should **define a responsible AI strategy** that ensures AI solutions remain trustworthy and beneficial for all users.

Organization must also **assess their current AI skills** and identify talent gaps**.** Once gaps are identified, they must determine the best approach to bridge

them—whether to upskill, recruit or partner with external experts.

To mitigate risks and validate potential value, organizations should **develop AI proof-of-concept (PoC) projects**. These pilot initiatives help refine priorities, address challenges early, and build confidence before scaling AI solutions organization-wide.

This commitment must be paired with the **implementation of well-defined Key Performance Indicators (KPIs)** to measure both immediate outcomes and long-term value creation. Additionally, **cross-functional collaboration** is vital, as several AI initiatives span multiple business units. Defining **clear roles and responsibilities** within the AI governance framework fosters accountability and facilitates seamless collaboration between technical and business teams.

Company examples: Reimagining the business and operating model

About 40% of Novartis CEO's annual incentive is based on the progress on the company's strategic pillars. In 2020, one of the strategic pillars was 'Data and Digital', which focuses on new initiatives and progress in cybersecurity, AI, and technology.

GSK has built a large in-house function dedicated to AI/ML with >160 experts based at key GSK R&D sites globally. This team works in partnership with external leading companies in the fields of data aggregation, AI technology, etc.

Sources: Novartis annual reports 2020, GSK annual report 2022

AI potential

AI represents more than just an incremental improvement — it is a transformative force. By enabling operational efficiencies and fostering customer-centric innovation, AI will fundamentally reshape industries, creating new competitive benchmarks, business models, and revenue opportunities.

Current state of adoption

*>50% of the enterprises have a GenAI strategy, only some have a fully integrated one with clear execution plans.**

Organizations must bridge the gap between AI strategy and execution to achieve tangible business value and sustainable competitive advantage in the growing AI market; moving beyond planning to comprehensive implementation is key.

*Source: EY India C-suite GenAI survey across industries, 2024

2. Rethinking the tech stack

The evolution of AI capabilities necessitates a fundamental reimagining of the technology infrastructure that supports life sciences organizations. Legacy systems and siloed technologies cannot support the computational demands and integration requirements of modern AI applications. Organizations need a flexible, scalable infrastructure that can handle complex AI workloads while maintaining compliance with stringent regulatory requirements. This technological transformation becomes even more critical as organizations face increasing pressure to accelerate drug discovery, improve patient outcomes and optimize operational efficiency.

Modern AI-powered technology stacks increasingly combine foundational models with specialized tools, creating hybrid architectures that optimize performance and efficiency. For example, traditional Robotic Process Automation (RPA) is evolving into intelligent automation by integrating GenAI, enabling systems to adapt dynamically to changes without manual intervention. In line with this requirement, major enterprise software providers are embedding AI capabilities directly into their platforms, providing ready-to-deploy AI tools that accelerate adoption and value realization.

To support this technological evolution, organizations must implement robust infrastructure that enables seamless integration and scalability, while maintaining strong security frameworks and compliance controls.

Rethinking the tech stack

AI industrialization to enable development and deployment at scale, and accommodate emerging AI advancements through enhanced automation and integration.

Key drivers for successful execution

- *Focus on developing **end-to-end platforms and infrastructure** for data science, data engineering, and applications development for AI activities.*
- ***Regularly updating technology** to incorporate advances in AI capabilities while maintaining regulatory compliance.*
- ***Developing a diverse portfolio of AI models** specifically tuned to life science applications, from molecule design to patient stratification.*
- *Establishing **standardized protocols** for AI model validation and deployment at scale.*
- *Proven mechanisms to identify and establish **strategic technology focussed partnerships (e.g., with technology providers** who understand life science regulatory requirements, start-ups, academia, other LS firms).*

Key drivers for successful execution

Success in this transformation requires a comprehensive approach that spans the entire AI lifecycle—from data preparation to model deployment and continuous monitoring. Organizations must **invest in a robust, end-to-end platform and infrastructure** that supports data science, data engineering, and application development for AI activities. These systems must be adaptable, **regularly updated** to keep pace with rapid AI advancements, and fully compliant with evolving regulatory requirements.

To scale AI solutions efficiently, **implementing standardized protocols** for automation and delivery is essential. A well-structured framework ensures consistency, accelerates deployment, and enhances operational efficiency.

Organizations should **maintain a diverse portfolio of AI models**, each tailored to specific business needs, enabling flexibility and resilience in AI-driven decision-making. Additionally, fostering **strategic technology partnerships**—with leading technology firms, start-ups, academic institutions, and other life sciences companies—is critical for augmenting internal capabilities. Establishing proven mechanisms to identify the right partners for each capability ensures that collaborations deliver maximum value.

This strategic alignment not only harnesses best-in-class expertise but also safeguards organizational control over core competencies, ensuring sustainable AI-driven innovation and competitive advantage.

Company examples: Rethinking the tech stack

Amgen partnered with NVIDIA to leverage its end-to-end BioNeMo Cloud service platform for training and fine-tuning protein LLMs, enabling advanced protein design and property prediction to accelerate drug discovery.

Pfizer invested in an incubation arm to attract and collaborate with start-ups to solve its business challenges related to AI and ML solutions. This helped Pfizer quickly partner with Saama Technologies during COVID-19 vaccine development to create an AI-powered tool to quickly clean clinical data. Saama was the winner in the 'incubation sandbox' inaugural competition, and hence Pfizer avoided months of negotiations and technical assessment time that would have been required to partner with an outside company.

Sources: Amgen+NVIDIA, Pfizer+Saama

Robust tech stack

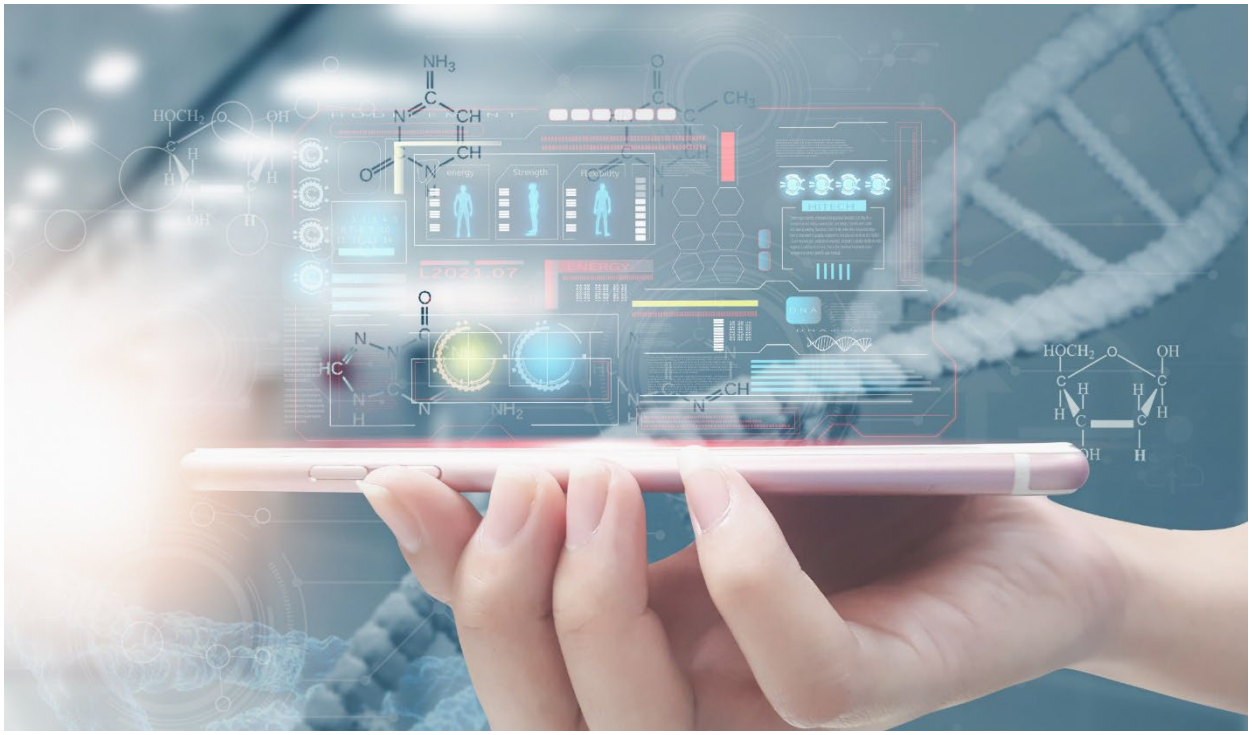
By rethinking their tech stack and embracing a more integrated and flexible approach, organizations can position themselves to harness the full potential of AI, driving innovation and achieving their strategic objectives in the ever-evolving life sciences landscape.

Current state of adoption

Only 16% *of the enterprises have a GenAI implementation approach (buy vs. build approach) clearly defined and consistently applied.**

This low percentage underscores the necessity for organizations not only to establish a clear AI strategy but also to regularly update and adapt their tech stack, ensuring it aligns with the latest AI advancements and industry best practices for a truly transformative impact.

*Source: EY India C-suite GenAI survey across industries, 2024



3. Comprehensive data strategy for AI-ready data

Data forms the foundation of successful AI initiatives, directly influencing model performance and business outcomes. The quality, diversity and volume of data assets fundamentally determine AI success, as even the most sophisticated algorithms falter without clean, structured and representative data. In the life sciences sector, the importance of data quality and governance cannot be overstated.

To achieve AI-ready data, organizations must undergo a fundamental shift in how they collect, store and utilize data. This journey involves addressing challenges related to data fragmentation, quality inconsistencies and regulatory compliance while establishing frameworks for effective data utilization. Implementing automated data quality management systems, real-time integration capabilities and advanced governance frameworks is essential to ensure data integrity and compliance. Additionally, the adoption of approaches such as federated learning and synthetic data generation techniques enables organizations to overcome privacy challenges while maintaining model performance.

Comprehensive data strategy for AI-ready data

Implement a robust data governance framework along with a scalable data infrastructure, ensuring data accuracy, security, and compliance.

Key drivers for successful execution

- *Using **FAIR principles** (Findable, Accessible, Interoperable, Reproducible) to ensure the data assets can be effectively leveraged for AI applications.*
- ***Plan the data lifecycle and governance framework:** Specify how you collect, store, process, and retire data for each AI use case. Include retention and disposal policies, and use version control to maintain accuracy during updates.*
- *Develop a flexible architectural framework that can **accommodate various internal and external data types**, e.g., from genomic data to clinical trial results.*
- *Creating secure **integration pathways for external data sources**, including real-world evidence and patient registries.*
- *Incorporate data management automation, and plan for **continuous monitoring and evaluation**.*

Key drivers for successful execution

Success in this transformation requires moving from siloed repositories to unified platforms capable of managing complex data landscapes, while meticulously establishing data governance frameworks tailored to each AI use case.

Organizations must **adhere to FAIR** (Findable, Accessible, Interoperable, Reproducible) principles to ensure data assets are effectively utilized for AI applications, incorporating data governance principles that address compliance with legal and ethical standards. This includes categorizing data based on sensitivity, controlling access, usage and storage, and **planning the data lifecycle** with clear policies on retention, disposal and version control.

To maintain data accuracy and consistency, it's essential to **set up AI fairness and bias controls**, utilizing tools to detect and mitigate bias, thereby ensuring equitable outcomes. Collaboration between AI and data teams is vital, aligning AI development with data engineering to build models on high-quality, well-managed data and establishing a unified pipeline for model training and data updates.

Organizations must also **prepare for data scalability**, forecasting the needs of AI workloads and opting for **flexible architectures**, possibly cloud-based, to efficiently manage resources, including external data sources. Automating data management tasks like tagging and cataloging through AI and machine learning can enhance accuracy and free up teams for strategic work.

Finally, **continuous monitoring and evaluation** are imperative, with regular audits of data and model outputs to ensure ongoing quality, performance and fairness. This proactive approach to data management, balancing the defensive need for data protection with the offensive drive for innovation, is key to leveraging AI technologies and maintaining regulatory compliance in a dynamic data environment.

Company examples: Moving to AI-ready data

Pfizer hired its first Chief Digital Officer (CDO) in 2019. In the first year, CDO prioritized building of a digital culture at Pfizer, e.g., using already available data more effectively for decision making, collecting more information digitally.

Novartis Oncology's AI-driven data platform, DROID, optimizes marketing by integrating data from 110 internal and external sources. It has also collaborated with the University of Oxford's Big Data Institute to draw data from multiple sources, including Novartis clinical trials, UK Biobank, Genomics England and China Kadoorie Biobank.

Sources: Pfizer, Novartis Annual report, 2019

AI-ready data

Those who master this data transformation journey, implementing proactive governance and quality assurance measures, will gain significant competitive advantages in the AI-driven future.

Current state of adoption

*Enterprises in India are at different stages of data readiness, with only a few 3% at a mature level.**

The importance of a robust data strategy cannot be overstated; it is the bedrock upon which AI systems are built. Those at the forefront will not only excel in their current markets but will also be well-positioned to lead in the creation of new ones, powered by the insights and capabilities that only a mature data ecosystem can provide.

*Source: EY India C-suite GenAI survey across industries, 2024

4. Getting people ready for AI

The human dimension of AI transformation represents a critical success factor that extends far beyond technical training and skill development. Organizations must develop comprehensive strategies for workforce development and change management that address both the technical and cultural aspects of AI adoption. This holistic approach becomes increasingly crucial as AI technologies become more deeply embedded in core business processes and decision-making frameworks.

Getting your people ready for AI: *Key implications for companies*

Bridge the gap between technological innovation and practical execution, along with effective change management, ensuring workforce adaptability.

Key drivers for successful execution

- *Fostering **a culture that embraces data-driven decision-making** while maintaining scientific rigor.*
- *Developing a **comprehensive talent strategy** that combines AI expertise with deep life sciences knowledge.*
- *Launching **AI democratization initiatives** that enable people to leverage AI tools effectively across roles and levels.*
- *Carefully **redesigning roles and responsibilities** to optimize the interaction between human expertise and AI capabilities.*
- *Execute **change management programs** that address the unique challenges of AI adoption in scientific environments.*

Key drivers for successful execution

Organizations must foster a culture that **embraces data-driven decision-making** and algorithmic thinking while prioritizing human creativity and insight. This cultural shift requires **comprehensive change management** programs that address both technical skills and mindset changes.

A multifaceted talent strategy is essential, combining strategic hiring of AI specialists, with **upskilling initiatives** for existing employees. **AI democratization** efforts are crucial for making AI tools accessible to a broader segment of the workforce, empowering them to integrate AI into their daily tasks. Additionally, organizations must consider how AI integration impacts job roles and team dynamics, **designing new job architectures** that optimize human-AI collaboration while ensuring employee engagement and satisfaction. By prioritizing these elements, organizations can effectively prepare their workforce for the AI revolution, driving innovation and achieving strategic goals.

Company examples: Getting people ready for AI

In 2021, Pfizer undertook many change management initiatives to deliver its digital strategy:

- *mini roadshows on presenting the vision of the future*
- *lunch-and-learns, agile sprint retrospectives, and ideation sessions with team members on projects*
- *sharing success stories and celebrating incremental wins*

Johnson & Johnson (J&J) has implemented an AI-powered talent development platform called 'J&J Learn' to upskill its workforce. This platform assesses employees' current skills, identifies gaps, and offers personalized learning opportunities, including mentorship programs and tailored educational content. By leveraging AI, J&J effectively aligns employee development with organizational goals, fostering a culture of continuous learning and adaptability.

Sources: Pfizer change management, Johnson & Johnson's matchmaking approach to upskilling employees

Skilled workforce

To truly harness the transformative power of AI, organizations must recognize that the greatest asset at their disposal is a well-prepared, agile workforce capable of navigating the complexities of an AI-enhanced landscape with creativity and insight.

Current state of adoption

~35% *of enterprises in India acknowledge the presence of some AI skills within their talent pool, but need significant investment.**

*Source: EY India C-suite GenAI survey across industries, 2024

5. Confronting the changing frontier of risk

As AI systems become more sophisticated and integral to operations, organizations face challenges that traditional risk management frameworks cannot adequately address. The unique characteristics of AI systems – including their complexity, opacity and potential for unintended consequences – create new categories of risk that require innovative approaches to management and mitigation. This evolution in the risk landscape can be effectively managed with a comprehensive approach that addresses technical, operational and ethical dimensions of AI deployment.

Organizations must implement real-time governance mechanisms, including automated compliance systems and robust threat detection. The development of explainable AI models is also essential to foster transparency and accountability within AI systems. Incorporating anomaly detection systems allows for immediate identification of irregularities and potential issues, reinforcing the reliability of AI systems. Furthermore, by employing better techniques and training for data filtering, organizations can significantly enhance the accuracy and trustworthiness of their AI applications. To bolster these efforts, AI-powered security solutions and cyber defense strategies are essential in safeguarding against evolving threats. They enable a proactive stance on security, ensuring that organizations' AI infrastructure remains resilient against cyber threats.

Confronting the changing frontier of risk

Ensure appropriate risk and compliance management with:

- real-time governance mechanisms ensuring transparency and accountability
- better techniques and training for data filtering to improve AI system reliability
- AI-powered security solutions and cyber defense strategies to minimize risk

Key drivers for successful execution

- *Integrating **compliance considerations from the earliest stages** of AI development.*
- ***Staying ahead of evolving regulatory** frameworks.*
- *Developing **ethical AI guidelines** that address the unique challenges of life science industry.*
- ***Conduct regular audits** of AI systems to ensure continued compliance and ethical operation.*
- *Ensuring **risk management frameworks** addressing the dynamic and probabilistic nature of AI models.*
- ***Inbuilt cybersecurity safeguards** to protect from any vulnerabilities.*

Key drivers for successful execution

To navigate the evolving landscape of AI risk successfully, organizations should integrate **compliance considerations from the earliest stages** of AI development, ensuring alignment with regulatory frameworks and ethical standards. This proactive approach requires the establishment of **robust risk management frameworks** that address the dynamic and probabilistic nature of AI models. **Regular audits** of AI systems are essential to maintain compliance and ethical operations, while **developing ethical AI guidelines** tailored to the unique challenges of the life sciences industry. Furthermore, **fostering cross-functional collaboration** among stakeholders will enhance accountability and facilitate the effective implementation of risk management strategies. By prioritizing these elements, organizations can ensure sustainable and responsible AI adoption while maximizing the value of their initiatives.

Company examples: Confronting the changing frontier of risk

Medtronic has developed 'AI Compass,' a framework of seven guiding principles for the ethical use of artificial intelligence in healthcare technology. It was created by a multidisciplinary team including IT, legal, regulatory with the aim to benefit users, including patients and healthcare providers.

Roche implemented data protection measures to ensure the protection of patient data through the use of advanced encryption technologies and secure data management systems. This includes the use of end-to-end encryption and regular security audits to ensure data integrity. Roche also implemented specific access controls and data sharing protocols to ensure that only authorized personnel have access to sensitive information.

In 2018, Takeda R&D created a data quality and governance playbook to support its overall data sciences' strategy and plan. The objective was to foster a data-driven culture, enable a common understanding of how R&D data supports business needs, establish clearly defined data governance policies, provide a scalable framework for future data needs.

As the digital landscape evolves, those who prioritize such robust risk mitigation practices will distinguish themselves, gaining a competitive edge and leading the way in the responsible adoption of AI technologies.

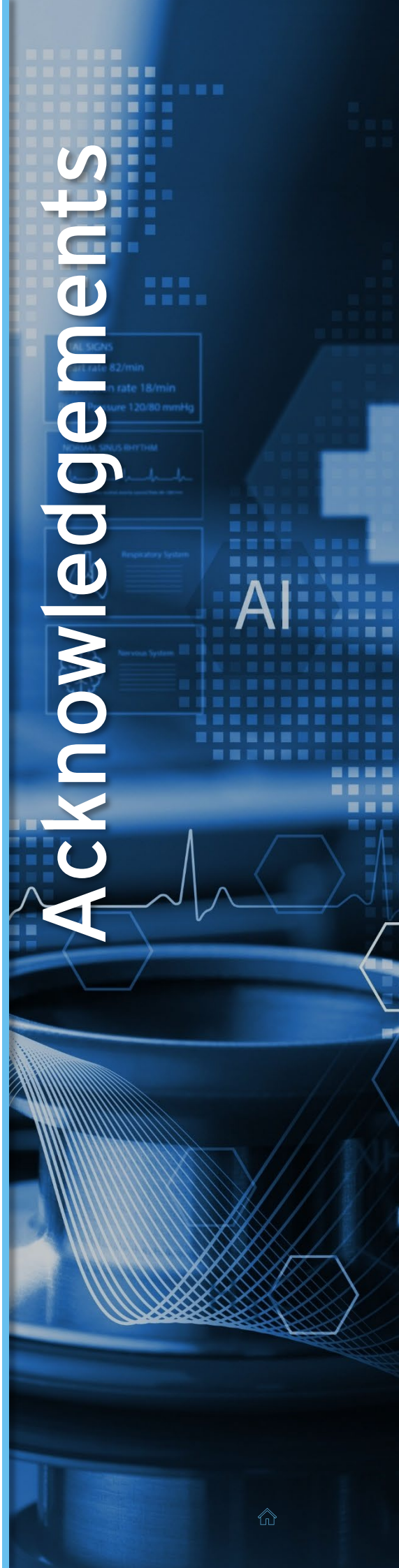
Sources: Medtronic AI Compass, Roche, Takeda

The journey toward AI excellence in life sciences is complex but achievable through the systematic implementation of these frameworks and strategies. Success requires careful attention to all five pillars while maintaining flexibility to adapt to changing circumstances.

Organizations must recognize that embracing AI is no longer optional; it is a critical imperative for maintaining relevance in an ever-evolving ecosystem...

...And achieving AI maturity is not a destination but an ongoing journey marked by constant enhancement and adaptation. As the landscape of technology shifts, so too must the strategies and approaches of those who seek to harness its power.

Acknowledgements



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