Nishith Desai Associates

LEGAL AND TAX COUNSELING WORLDWIDE

MUMBAI SILICON VALLEY BENGALURU SINGAPORE NEW DELHI NEW YORK GIFT CITY

Research

Artificial Intelligence in Healthcare

Navigating Regulatory Frontiers in India

March 2025

Research

Artificial Intelligence in Healthcare

Navigating Regulatory Frontiers in India

March 2025

DMS Code: 119795.2

FT INNOVATIVE LAWYERS 2019
FINANCIAL TIMES
ASIA-PACIFIC WINNER

Ranked as the 'Most Innovative Indian Law Firm' in the prestigious FT Innovative Lawyers Asia Pacific Awards for multiple years. Also ranked amongst the 'Most Innovative Asia Pacific Law Firm' in these elite Financial Times Innovation rankings.

Chambers AND PARTNERS

IFLR1000

The LEGAL 500

BENCHMARK LITIGATION

asialaw

WWL

ASIAN LEGAL BUSINESS

INDIA BUSINESS LAW JOURNAL

INDIA BUSINESS LAW JOURNAL THE A LIST 2023 2024 LAW ASIA

INDIA BUSINESS LAW JOURNAL DEALMAKER 2023 LAW ASIA

Mergermarket An Acuris company

ITR WORLD TAX

iel ELITE

BUSINESS TODAY

THE NATIONAL LAW REVIEW

equalFi

IDEX LEGAL AWARDS

LEGAL ERA BY THE PEOPLE. FOR THE PEOPLE. OF THE PEOPLE

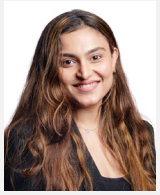
LawWiser .com

Disclaimer

Contact

For any help or assistance please email us on **concierge@nishithdesai.com**
or visit us at **www.nishithdesai.com**.

Acknowledgements



Uttara Jhaveri

uttara.jhaveri@nishithdesai.com

Uttara is a member of the Pharmaceutical, Healthcare, Medical Device, and Digital Health Team at Nishith Desai Associates. She holds an LLM (National and Global Health) from Georgetown University Law Center. She has advised pharmaceutical companies, medical professionals, and medical device companies on regulatory and compliance matters and has experience in litigation.

Tanya Kukade

tanya.kukade@nishithdesai.com

Tanya is a senior member in the Pharmaceutical, Healthcare, Medical Device and Digital Health Team at Nishith Desai Associates. Additionally, she is also an integral part of the Make-in-India practice at Nishith Desai Associates.

She has advised numerous multinational pharmaceutical and medical device companies on regulatory aspects oof licensing, price regulation, import, compliances, as well as intellectual property matters. She also has experience in commercial documentation and litigation matters for pharmaceutical companies, matters relating to technology and media laws, and public procurement.

Eshika Phadke

eshika.phadke@nishithdesai.com

Eshika is a Leader in the Pharmaceutical, Healthcare, Medical Device and Digital Health Team at Nishith Desai Associates. She has extensive experience advising multinational companies on regulatory issues, compliances, marketing and promotional activities, product labelling and claims, anti-trust risks, public procurement, interactions with government, and commercial documentation. In her previous role, Eshika worked closely with early-stage startups to enable them to bring their product to market, as a result of which she has practical experience dealing with the challenges that industry players at varying stages face across the product lifecycle. She also has experience working with hospitals and doctors to defend medical negligence suits.

Dr. Milind Antani

milind.antani@nishithdesai.com

Dr. Milind Antani, a renowned surgeon turned lawyer, heads the Pharmaceutical, Healthcare, Medical Device and Digital Health practice as well as the Food & Beverages practice at multi-skilled, research-based international law firm, Nishith Desai Associates where he represents high net-worth clients in matters allied to Regulatory advice, JVs, M&As, VC and Private Equity investments, Collaborations, Licensing and Commercialization. He also leads Social Sector Practice and represents various global and national foundations in India.

Dr. Antani continues as an active participant in helping frame national policies on key impact areas, within the medical field.

Contents

Glossary of Terms 1

Introduction 2

Applications of AI in Healthcare and Life Sciences 3

A. Diagnostics 3

B. Automation of Laboratory Testing 3

C. Clinical Imaging 4

D. Clinical Decision Support 4

E. Precision Medicine 4

F. Predictive Modelling 4

G. Robotic Surgery 4

H. Virtual Health Assistants 5

I. Electronic Health Records 5

J. Remote Monitoring 5

K. Mental Healthcare 5

L. Research & Development 6

M. Drug Discovery 6

N. Clinical Trial Recruitment 6

O. Genome Editing 6

P. Bioinformatics 6

Approach to Regulating AI in Healthcare: Global Perspective 8

A. United States of America 8

B. United Kingdom 9

C. European Union 10

Regulation of AI for Healthcare in India 11

A. Regulatory Bodies 11

B. Approaches to Regulation of AI 12

C. Other Applicable Laws 14

Challenges to Regulation of AI in India 19

I. Licensing Requirements 19

II. Clinical Investigations 19

III. Post-Approval Changes 19

IV. Labelling 20

V. Pricing 20

VI. Advertising and Claims 20

VII. Promotion to Healthcare Practitioners 21

Risks and Ethical Challenges 22

I. Bias and Discrimination 22

II. Quality of Data 22

III. Doctor-Patient Relationship 22

IV. Privacy and Confidentiality 22

V. Physician Preparedness 23

VI. Cybersecurity 23

VII. Environmental Impact 23

Conclusion 24

Beyond AI 25

A. Virtual Reality and Augmented Reality in Medical Training and Education 25

B. Robotics in Healthcare 25

C. Nanotechnology in Diagnostic Imaging and Drug Delivery 26

D. 3D Printed Organs 27

E. Predictive Analytics in Healthcare 28

F. Personalized Medicine 29

Glossary of Terms

Abbreviation	Full Form
AAEC	Appreciable Adverse Effect on Competition
AI	Artificial Intelligence
AR	Augmented reality
CCI	Competition Commission of India
CCPA	Central Consumer Protection Authority
CDSCO	Central Drugs Standard Control Organization
CERT-In	Indian Computer Emergency Response Team
Contract Act	Indian Contract Act, 1872
CPA	Consumer Protection Act, 2019
Data Protection Rules	Information Technology Act, 2000, the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or information) Rules, 2011
DCA	Drugs and Cosmetics Act, 1940
Digital Competition Law	Digital Competition Bill, 2024
DMRA	Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954
DPCO	Drugs (Price Control) Order, 2013
DPDPA	Digital Personal Data Protection Act, 2023
EHRs	Electronic Health Records
EU	European Union
GED	Genome Editing
ICMR	Indian Council of Medical Research
IP	Intellectual Property
LM PCR	Legal Metrology (Packaged Commodities) Rules, 2011
MDR	Medical Device Rules, 2017
MeitY	Ministry of Electronics and Information Technology
MHRA	Medicines and Healthcare Products Regulatory Agency
ML	Machine Learning
MoHFW	Ministry of Health and Family Welfare
NHA	National Health Authority
NMC	National Medical Commission
RMP	Registered Medical Practitioner
SaMD	Software-as-a-Medical-Device
SPDI	Sensitive Personal Data or Information
Telemedicine Guidelines	Telemedicine Practice Guidelines, 2020
Trade Secrets Bill	Protection of Trade Secrets Bill, 2024
UCMPMD	Uniform Code for Marketing Practices in Medical Devices
USA	United States of America
US FDA	US Food and Drug Administration
VR	Virtual reality

Introduction

Artificial Intelligence (**"AI"**) is transforming healthcare globally, and India is emerging as one of the most dynamic regions adopting this cutting-edge technology. The advancements in AI have the potential to optimize patient care, streamline administrative processes and improve disease identification and mitigation.

With its vast and diverse population, India faces unique challenges in healthcare delivery, including access to quality care, a shortage of skilled healthcare providers, and the rising burden of chronic diseases. AI has the potential to address these challenges by improving the accuracy of diagnoses, enhancing treatment plans, streamlining administrative tasks, and making healthcare services more accessible to remote and underserved populations.

The challenges posed by an ageing population, the increasing prevalence of chronic diseases, and the escalating costs of healthcare are prompting governments, healthcare providers and consumers to seek innovative solutions and transform healthcare delivery models. The Covid-19 pandemic has forced the healthcare industry to implement large-scale transformations by integrating data-driven insights into patient care. The pandemic has also underscored the existing shortages in the healthcare workforce and disparities in access to care. The growing availability of diverse data types, such as genomics, economic, demographic, clinical, and phenotypic data, combined with advancements in mobile technology, computing capabilities, and data security has the potential to fundamentally reshape healthcare delivery models through AI-enhanced systems.[1]

In India, AI has started to revolutionize various aspects of healthcare, ranging from diagnostics to drug discovery and patient care. The country is witnessing a surge in AI-based startups, research, and collaborations between healthcare providers, technology companies, and government institutions, paving the way for AI-driven innovation. He government's push for National Health Stack, Ayushman Bharat, and Pradhan Mantri Jan Arogya Yojana are helping create the necessary ecosystem for AI-powered healthcare innovations.

In this research paper, we have explored the key areas of AI application in healthcare in the country, the manner of regulation of AI tools and models in the healthcare sector in other jurisdictions followed by the assessment of regulatory framework surrounding AI in India at present. We have also discussed the legal challenges faced by the healthcare industry in adopting and applying AI.

1 Accessible at: https://pubmed.ncbi.nlm.nih.gov/34286183/.

Applications of AI in Healthcare and Life Sciences

AI is rapidly reshaping the landscape of healthcare and life sciences industry in India, offering transformative solutions to address some of the country's most pressing healthcare challenges and is unlocking new frontiers in research, innovation, and healthcare delivery. By leveraging AI's capabilities, India can move closer to achieving universal health coverage, improving patient outcomes, and creating a more efficient, cost-effective healthcare system.

In this chapter we explore the diverse applications of AI across various sectors of healthcare and life sciences in India, including diagnostics, telemedicine, personalized medicine, accelerating drug development, improving diagnostic tools, administrative efficiency, and drug discovery.

A. Diagnostics

The evolution of AI has long been linked to the diagnosis and treatment of diseases, with significant milestones dating back to the 1970s. Early rule-based AI systems were designed to diagnose blood-borne bacterial infections and demonstrated potential for accurate disease diagnosis and treatment, they struggled to gain widespread adoption in clinical settings due to their inability to match the accuracy and clinical judgment of human healthcare providers.[1]

In the realm of disease diagnosis, a major area of AI research focuses on analysing diverse data sources, including diagnostic imaging, genetic testing, electro-diagnostic procedures, clinical laboratory results, and physical examination notes.

B. Automation of Laboratory Testing

AI's impact on clinical laboratories is also notable, especially in enhancing efficiency and precision. Automated methods, such as those used in blood cultures, susceptibility testing, and molecular platforms, have already become standard practice in many laboratories, significantly improving efficiency. The integration of AI into clinical microbiology labs could further optimize processes, such as selecting the most appropriate antibiotic treatments, which could improve cure rates for infectious diseases. Moreover, AI has the potential to shorten clinical trial durations, increase productivity, and improve clinical development outcomes. One major challenge in drug development is non-clinical toxicity, which contributes to high rates of drug failures in clinical trials. Advances in computational modelling, however, are improving the prediction of drug toxicity, refining the drug development process.[2]

1 Accessible at: https://pmc.ncbi.nlm.nih.gov/articles/PMC2464549/.

2 Accessible at: https://www.researchgate.net/publication/355069925_Applications_of_Artificial_Intelligence_AI_in_healthcare_A_review.

C. Clinical Imaging

Another promising application of AI is the automated classification of clinical imaging, particularly in radiology. A recent analysis of AI-based medical devices approved in the U.S. and Europe between 2015 and 2020 revealed that more than half were approved for radiological applications. This trend is driven by the limitations of human vision in clinical imaging. The development of deep learning algorithms to detect tumours in mammograms at earlier stages, leading to improved diagnostic accuracy and better treatment outcomes for breast cancer patients are a solution to such human limitations. Similarly, AI has shown promise in detecting aneurysms linked to diabetic retinopathy, using deep learning-based unsupervised learning techniques. Research has demonstrated that such AI models can achieve strong diagnostic accuracy and cost-effectiveness.

D. Clinical Decision Support

AI assists healthcare providers in diagnosing and treating patients by analyzing medical records, clinical guidelines, and the latest research. AI-powered decision support systems can suggest personalized treatment plans, predict patient outcomes, and highlight potential risks, helping to reduce errors and improve care.

E. Precision Medicine

Precision medicine involves tailoring medical treatments and interventions to the individual characteristics of each patient, such as their genetic makeup, lifestyle, and environment. The integration of AI into precision medicine holds the promise of improving diagnostic accuracy, treatment efficacy, and patient outcomes.

AI plays a pivotal role in this field by analyzing vast amounts of data, such as genomics, electronic health records, and medical imaging, to identify patterns that may not be apparent to human clinicians. AI-powered systems provide clinicians with evidence-based recommendations tailored to the individual patient's needs, helping to optimize treatment strategies, reduce medical errors, and enhance patient outcomes.

F. Predictive Modelling

AI models can predict disease risk, progression, and treatment outcomes based on patient-specific data. By learning from historical patient data, these models assist clinicians in making informed decisions about prevention and treatment plans.

G. Robotic Surgery

AI is used in robotic surgical systems to assist surgeons in performing precise and minimally invasive procedures. Robots can enhance the surgeon's precision, reduce human error, and shorten recovery times. AI systems can also provide real-time feedback, making surgery more efficient and safer.

H. Virtual Health Assistants

AI-driven virtual assistants, such as chatbots and voice-based systems, provide patients with medical information, answer questions, and offer guidance on symptoms and medications. These assistants can also schedule appointments, remind patients about medications, and monitor chronic conditions remotely, improving patient engagement and compliance.

I. Electronic Health Records

In parallel, healthcare organizations are increasingly adopting AI to automate labour-intensive, high-volume repetitive tasks. AI startups and companies are addressing the need for tools that can handle these demanding activities. One such adaptation is the analysis of large datasets from Electronic Health Records (**"EHRs"**), which contain both structured data (i.e. laboratory tests and procedures) and unstructured data (i.e. radiology reports and discharge summaries). The complexity and variety of data within EHRs make them difficult to analyse manually, but AI techniques enable the processing of this information to enhance understanding of the medical history, genetic markers, and family health risks of the patient.[3]

J. Remote Monitoring

AI enables remote monitoring of patients through wearable devices and sensors that track vital signs, physical activity, and other health metrics in real-time. AI algorithms analyze this data to detect early signs of deterioration or disease progression, allowing for early intervention and reducing hospital readmissions.

K. Mental Healthcare

Traditionally, mental healthcare practitioners rely on direct interactions and behavioural observations to diagnose and treat mental health conditions. However, AI-powered tools can enhance these capabilities by assisting in early detection and diagnosis.These tools can generate customized treatment plans and provide continuous support, bridging resource gaps, promoting a stigma-free environment, and complementing professional expertise. In this way, AI holds promise in addressing the evolving challenges of mental health care.[4]

Recent advancements have also enabled AI to develop personalized treatment plans using intelligent algorithms. These algorithms analyse patient data, incorporating genetic, lifestyle, and environmental factors to recommend the most effective and cost-efficient treatments tailored to individuals. Furthermore, AI-powered digital tools, such as virtual therapists and chatbots, have significantly increased the scalability and accessibility of therapeutic interventions.[5]

3 Accessible at: https://pmc.ncbi.nlm.nih.gov/articles/PMC11141850/.

4 Accessible at: https://www.tandfonline.com/doi/epdf/10.2147/RMHP.S461562?needAccess=true.

5 Accessible at: https://www.sciencedirect.com/science/article/pii/S2949916X24000525.

L. Research & Development

The biotechnology sector generates vast datasets that require sophisticated methods for storage, filtering, and analysis. The integration of AI-driven technologies, particular Machine Learning (**"ML"**) and Deep Learning, is transforming the efficiency, accuracy, and speed of research and development in medical biotechnology. AI can analyse data from diverse sources, uncovering insights that would be difficult for human researchers to identify.[6] By harnessing the power of AI, the biotechnology industry is poised to make significant strides in improving patient care, optimizing treatment outcomes, and boosting the overall efficiency of healthcare systems.

M. Drug Discovery

AI accelerates the drug discovery process by predicting the interactions between molecules and biological targets, identifying new drug candidates, and optimizing clinical trial designs. It can also assist in repurposing existing drugs for new diseases, speeding up the development of treatments and reducing costs.

N. Clinical Trial Recruitment

AI can streamline the clinical trial process by identifying suitable candidates for trials based on patient data, improving the recruitment process. It can also monitor trial data in real-time, making it easier to detect problems or adjust protocols quickly.

O. Genome Editing

Genome Editing (**"GED"**) allows for genetic engineering by inserting, deleting, modifying, or replacing the DNA of a living organism.[7] GED technologies have been employed to address disease-causing mutations, such as those in tumour suppressor genes or cardiovascular diseases, insert new genes into cells and tackle genetic diseases such as sickle cell anaemia.[8] The application of AI-based editing technologies allows for precise and targeted editing of the genetic code of organisms. AI models can identify patterns and correlations within genomic data, facilitating breakthroughs in personalized medicine.

P. Bioinformatics

Bioinformatics acts as an intermediary between biological research and the computational analysis of complex datasets. It provides critical tools and methodologies to analyse, interpret, and derive meaningful insights from large and complex datasets. Traditional bioinformatics relies on rule-based algorithms, statistical models, and manual data interpretation.

6 Accessible at: https://cdn.fortunejournals.com/articles/ai-and-machine-learning-in-biotechnology-a-paradigm.pdf.

7 Accessible at: https://pmc.ncbi.nlm.nih.gov/articles/PMC10800897/.

8 Accessible at: https://www.researchgate.net/publication/379113749_Applications_and_Challenges_of_Artificial_Intelligence_in_Life_Sciences.

However, the emergence of high-throughput screening and AI-driven technologies has rendered these traditional approaches less effective, as they are time-consuming and struggle to handle intricate and complex data. AI-based technologies can efficiently handle large datasets and enable a detailed modelling of the biological processes.

Additionally, ML methods are being used to design novel drug molecules with specific properties, accelerating the drug discovery process. Moreover, ML and Deep Learning algorithms assist researchers in analysing large and complex datasets, deepening our understanding of biological processes, and enabling the development of personalized therapies. As a result, AI-based technologies hold significant potential to enhance data analysis and expedite research and development in the life sciences sector.[9]

9 Accessible at: https://pmc.ncbi.nlm.nih.gov/articles/PMC11413381/.

Approach to Regulating AI in Healthcare: Global Perspective

Regulators across the world are taking strides towards regulating AI-based medical technologies to ensure patient safety, address ethical concerns, and protect data privacy. With the growing use of AI in healthcare, regulations aim to minimize risks, ensure fairness, and promote transparency. These efforts help standardize practices, maintain high-quality care, and establish clear accountability in the event of errors.

While the specifics of the regulations may vary, at present, most national regulatory authorities are regulating AI-based medical technologies as medical devices — more specifically, as a software-as-a-medical-device (**"SaMD"**).

SaMD refers to software applications - not being part of a hardware medical device — intended for medical purposes, these applications are designed to diagnose, treat, or monitor diseases, conditions, or specific medical functions, and can range from diagnostic tools and treatment planning systems to wellness apps. SaMD can function independently or interact with other devices, but does not require hardware to fulfil its intended purpose. Given its role in patient care, SaMD is subject to regulation to ensure it is safe, effective, and meets necessary standards for healthcare use. The regulatory framework for SaMD typically involves assessing the risk, clinical validation, and ensuring that the software meets quality, safety, and performance standards.

A. United States of America

The US Food and Drug Administration (**"US FDA"**) has been actively working towards developing guidelines for both the use of AI in the drug development process, as well as for AI-driven SaMD in United States of America (**"USA"**).

Similar to other jurisdictions, the US FDA regulates AI-driven medical technologies as SaMD. However, recognising the limitations of the existing framework, it has since released numerous guidance for the industry that cater to the specific requirements of AI-driven technologies. These include: "Good Machine Learning Practice for Medical Device Development: Guiding Principles",[1] "AI/ML SaMD Action Plan",[2] "Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles",[3] "Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles"[4] and "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions".[5]

1 Available at: https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles.

2 Available at: https://www.fda.gov/media/145022/download?attachment.

3 Available at: https://www.fda.gov/medical-devices/software-medical-device-samd/predetermined-change-control-plans-machine-learning-enabled-medical-devices-guiding-principles.

4 Available at: https://www.fda.gov/medical-devices/software-medical-device-samd/transparency-machine-learning-enabled-medical-devices-guiding-principles.

5 Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence.

In 2024, the US FDA published a report titled "Artificial Intelligence and Medical Products: How CBER, CDER, CDRH, and OCP are Working Together"[6] which outlines how the various centers within the US FDA plan to align their efforts to advance the responsible use of AI for medicinal products.

In January 2025, the US FDA published a draft guidance document titled "Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products"[7] which provides recommendations to industry on the use of AI to produce information or data intended to support regulatory decision-making regarding safety, effectiveness, or quality for drugs.

The US FDA had demonstrated that it is bullish on the potential impact that AI-driven medical technologies can have on the industry. However, recognising the gaps in the existing legal framework, it has developed guidances to enable the industry and promote innovation, whilst ensuring transparency, product safety and effectiveness.

B. United Kingdom

In 2019, the UK's National Institute for Health and Care Excellence, in collaboration with the National Health Service, introduced the *"Evidence Standards Framework for Digital Health Technologies."* This document outlines the rules for digital health products, including apps, software, and online platforms, whether they are standalone or used in conjunction with other health tools.

Further regulatory efforts were initiated in 2021 by the Medicines and Healthcare Products Regulatory Agency (**"MHRA"**) through the *"Software and AI as a Medical Device Change Programme."* This initiative aims to establish clear rules for AI medical devices, focusing on the entire lifecycle of these devices, including aspects like cybersecurity, data privacy, and post-market monitoring. The program also addresses challenges such as algorithmic changes, potential bias, and the interpretation of AI-driven decisions.[8] Building on these efforts, in 2022, the UK's Regulatory Horizons Council released a report titled *The Regulation of AI as a Medical Device*, which emphasizes improving communication and encouraging patient and public involvement throughout the lifecycle of AI medical devices.

6 Available at: https://www.fda.gov/media/177030/download?attachment.

7 Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological.

8 Accessible at: https://www.gov.uk/government/news/mhras-ai-regulatory-strategy-ensures-patient-safety-and-industry-innovation-into-2030 and https://pmc.ncbi.nlm.nih.gov/articles/PMC10930608/#sec4-healthcare-12-00562.

C. European Union

The European Union (**"EU"**) also introduced the *"European Medical Device Regulation,"* which defines a "medical device" to include software as a medical device when specifically intended for "one or more of the medical purposes" outlined in the definition of a medical device. Consequently, an AI system developed for use in a healthcare setting may be classified as a SaMD if its intended usage falls within the scope defined under the Regulation.[9]

In April 2021, the EU proposed the AI Act, establishing a unified legal framework for AI products and services, spanning from development to deployment. The AI Act outlines key provisions related to risk management, data governance, technical documentation, transparency, human oversight, accuracy, robustness, and cyber-security under Articles 9 to 15. It also defines the responsibilities of AI providers, importers and deployers towards users under Articles 16 to 28. The AI Act adopts a risk-based approach to regulation and classifies AI systems based on their potential risks. 10 In healthcare, high-risk AI systems include applications such as biometric identification, patient sorting based on medical history, and the management of public health services and EHRs. These high-risk systems are subject to strict requirements for data governance and risk management. For low- and minimal-risk systems, such as chatbots used in healthcare, a voluntary code of conduct is in place to ensure safety and reliability. However, some critics argue that the AI Act is too rigid, as it does not provide a mechanism to add new AI applications to the "high-risk" category if they unexpectedly emerge in sectors with significant risks.[11]

9 Article 2 defines 'medical device' as any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: — diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, — diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, — investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, — providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. The following products shall also be deemed to be medical devices: — devices for the control or support of conception; — products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

10 Accessible at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202401689.

11 Accessible at: https://pmc.ncbi.nlm.nih.gov/articles/PMC10930608/#sec4-healthcare-12-00562.

Regulation of AI for Healthcare in India

At present, a web of laws become applicable to healthcare and AI technology independently, several of which get triggered in regulating AI application in healthcare in India. AI based applications in healthcare may be subjected to a combination of the existing laws, regulations and guidelines which can be adapted to AI use cases in the absence of a specific law. The Indian regulatory framework for AI-based medical devices and healthcare technologies - which may incorporate AI - is evolving, with a focus on ensuring safety, efficacy, and ethical considerations.

A. Regulatory Bodies

In India, the regulation of AI in healthcare would involve several regulatory bodies, each addressing different aspects of AI technology, healthcare, medical devices, data privacy, and ethical considerations. The key regulatory bodies that play a significant role in regulating AI in healthcare are:

I. Central Drugs Standard Control Organization

The Central Drugs Standard Control Organization (**"CDSCO"**) is the primary regulatory authority for medical devices and drugs in India. Since many AI applications in healthcare are integrated into medical devices (e.g., diagnostic tools, imaging systems, decision support systems), CDSCO will play a central role in regulating AI-based medical devices.

II. National Health Authority

The National Health Authority (**"NHA"**) is responsible for overseeing and implementing Ayushman Bharat Digital Health Mission, which aims to create a digital health ecosystem. AI plays a significant role in this ecosystem for tasks like diagnostics, telemedicine, and digital health records. NHA coordinates the implementation of national health programs, including those that may use AI technology in healthcare delivery.

III. Indian Council of Medical Research

The Indian Council of Medical Research (**"ICMR"**) is the apex body for the formulation, coordination, and promotion of biomedical research, and will play a significant role in regulating the clinical validation and ethics of AI-based healthcare tools.

IV. Ministry of Health and Family Welfare

The Ministry of Health and Family Welfare (**"MoHFW"**) plays a crucial role in driving the adoption, regulation and integration of AI technologies into the country's public health systems.

V. Ministry of Electronics and Information Technology

The Ministry of Electronics and Information Technology (**"MeitY"**) is involved in the broader governance of information technology and AI and will play a significant role in regulating digital health technologies, including AI applications in healthcare.

VI. Central Consumer Protection Authority

As AI-based healthcare tools become more consumer-facing, the Central Consumer Protetion Authority (**"CCPA"**) will play a role in regulating and protecting consumers from unsafe or misleading AI healthcare products.

VII. Indian Computer Emergency Response Team

Indian Computer Emergency Response Team (**"CERT-In"**) is responsible for cybersecurity in India, and it will play a role in regulating the cybersecurity of AI-driven healthcare applications.

B. Approaches to Regulation of AI

I. AI as a Medical Device

In India, the regulation of AI as a medical device is emerging in response to the increasing use of AI technologies in healthcare. Given the complexities of AI systems — especially those used in diagnostics, treatment decision-making, and patient monitoring — the Indian regulatory framework is working towards ensuring safety, efficacy, and accountability while promoting innovation in the sector.

AI-based healthcare solutions like diagnostic tools, medical devices, or software used in treatment would generally be classified as a medical device, and would be required comply with the Medical Device Rules, 2017 (**"MDR"**) notified under the Drugs and Cosmetics Act, 1940 (**"DCA"**).

Medical devices in India are regulated according to their intended use and risk to the patient. Devices are typically classified into one of the following categories:

- Class A: Low risk
- Class B: Moderate risk
- Class C: High risk
- Class D: Very high risk

AI-powered medical devices (such as diagnostic tools, imaging systems, and decision support systems) would undergo a similar approval process based on their intended use and the risk they pose to patients and may fall under moderate risk categories (Class B or C) depending on their application.

Where an AI-based application falls within the definition of a medical device under the applicable laws, such devices would be required to undergo regulatory evaluation by the CDSCO, including clinical investigations, risk assessments, compliance with standards applicable to the device, certification of quality management systems, etc. as per the MDR before being marketed or used in healthcare settings.

Moreover, AI applications in diagnostic software must comply with clinical validation standards to ensure their accuracy, safety, and effectiveness. This is especially important for healthcare providers, as patient safety depends on the reliability of these tools. However, AI-specific issues, such as continuous learning, dynamic updates, explainability, and ethical considerations, are not yet fully addressed under the current framework.

Under the current regulatory framework in India, software that can perform medical functions independently without the need for a hardware component (e.g., diagnostic algorithms, monitoring software, etc.), is considered Software as a Medical Device. SaMD falls under the existing medical device regulatory framework, meaning it needs to meet the safety and efficacy standards prescribed under the MDR.

II. Restriction on use of AI

The application and adoption of AI in the healthcare sector in India is increasing significantly. In India, only a registered medical practitioner[1] (**"RMP"**) is permitted to practise medicine upon obtaining a license from the National Medical Commission (**"NMC"**) in compliance with the applicable laws. Where the AI tools are not being regulated as a medical device as discussed above, and AI is being applied to perform functions which include patient evaluation, diagnosis or management, etc. directly for the patient, the functions are likely to constitute practice of medicine, which would trigger licensing requirements prescribed by the NMC. At present, the applicable laws in India do not cater to the possibility of AI holding the license to practise medicine in India.

The Telemedicine Practice Guidelines, 2020 (**"Telemedicine Guidelines"**)[2] issued under the Indian Medical Council (Professional Conduct, Etiquette and Ethics Regulation, 2002 by the NMC, provides a framework for the legal and ethical use of telemedicine, including AI-based technologies. The guidelines allow for remote consultations between doctors and patients through digital platforms. However, the role of AI tools in these consultations is still primarily supportive. The guidelines provide that AI can be used as an assistive tool but must always operate under the supervision of a licensed medical professional. The final responsibility for the diagnosis, treatment plan, and patient outcomes lies with the healthcare provider, not the AI. AI tools are not allowed to counsel patients or prescribe any medicine to a patient.

The regulatory framework continues to evolve to keep up with technological advancements, and AI in telemedicine will likely become more tightly regulated as it becomes a more integral part of healthcare delivery.

1 A registered medical practitioner is an individual duly registered with the National or State Medical Council to obtain a license to practise medicine in India.

2 Accessible at: https://esanjeevani.mohfw.gov.in/assets/guidelines/Telemedicine_Practice_Guidelines.pdf.

C. Other Applicable Laws

A. Biomedical Research

In an effort to provide guidance for the ethical application of AI in the healthcare sector, the ICMR has released the Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare.[3] These guidelines apply to AI-based tools used in all biomedical and health research and applications involving human participants and/or their biological data. The guidelines emphasize the need to use AI in research ethically and stress the importance of maintaining data privacy, obtaining informed consent from individuals, and ensuring the integrity and quality of data used in AI applications.

B. Data Protection and Privacy

At present, the Information Technology Act, 2000, the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or information) Rules, 2011 (together the **"Data Protection Rules"**) constitute the data protection framework in India.

The data protection framework is in the process of transformation given that the Digital Personal Data Protection Act, 2023 (**"DPDPA"**) was passed by the legislature in August 2023 and is in the process of being brought into force in a phased manner. The Draft Digital Personal Data Protection Rules, 2025 for the purpose of implementation of the DPDPA are also in the process of being finalized. Once the provisions under the DPDPA are brought in force, it will replace the Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011.

AI systems in healthcare often process sensitive personal data, such as medical histories, diagnoses, and genetic information. At present, the patient's personal information, such as medical history and physiological conditions, are considered Sensitive Personal Data or Information (**"SPDI"**) under the Data Protection Rules. However, the DPDPA covers all personal data (and not just SPDI as under the current data protection framework), digital health businesses would be required to comply with enhanced requirements for the collection, processing and storage of personal data collected from users/patients. These include higher notice and consent requirements; data subject rights and duties; duties for data fiduciaries and processors, compliances for children's data; compliances for cross-border transfers of data, etc.

While there is no comprehensive law specifically targeting AI in healthcare, data privacy laws play a critical role in regulating AI applications and data processors would be required to ensure compliance with specific requirements including:

i. **Consent:** AI-based healthcare tools must obtain explicit consent from individuals before processing health data.

ii. **Data Security:** AI systems must ensure high standards of data security to prevent data breaches.

iii. **Accountability:** Entities involved in processing health data, including AI developers, will be held accountable for any misuse or security failures.

3 Accessible at: https://www.icmr.gov.in/ethical-guidelines-for-application-of-artificial-intelligence-in-biomedical-research-and-healthcare.

However, AI-specific privacy concerns, like the handling of large datasets and data used for model training, are not yet fully addressed under the existing framework.

C. Intellectual Property

With AI pushing the boundaries of the healthcare arena, there is also a rising need to protect years of research and technologies developed. The application of AI in healthcare introduces complex issues related to Intellectual Property (**"IP"**), as AI-driven technologies often involve a mix of software, algorithms, data, and innovative healthcare solutions. In India, several IP laws govern the protection of AI technologies, including those applied in the healthcare sector. These laws are designed to protect various aspects of AI systems and their innovations, such as algorithms, data, software, and inventions.

IP law offers protection to inventions, creative work, and ideas which generally form a large pool of intangible markets. It is wise to patent innovations and inventions in the healthcare sector to ensure they reach the right people and will be put to proper use to save lives. Given that at present, AI is not considered as a self-determinant entity for the purposes of the IP laws, companies are exploring ways to protect the inventions through the existing opportunities available within the current framework

i) Patents

The Patent Act, 1970 is the primary law governing the protection of inventions in India. A patent grants the inventor exclusive rights to their invention for a specified period (usually 20 years), provided the invention is novel, non-obvious, and industrially applicable.

Patents can be granted for innovative AI algorithms, medical devices, and AI-driven software applications if they meet the basic criteria of novelty, non-obviousness, and industrial application. However, there is an ongoing debate about whether AI algorithms themselves are patentable or if the underlying mathematical methods and abstract ideas fall under exceptions to patentability. However, applications of AI that solve technical challenges will have the most chance of being patented.

ii) Copyrights

The Copyright Act, 1957 protects original literary, dramatic, musical, and artistic works, including software code and database structures. Copyright protection arises automatically once the work is created and does not require registration, though registration provides legal advantages.

AI innovations such as applications, software, and algorithms must obtain appropriate protection as they have broad-scale usage. Usually, copyright serves as the simplest form of protection for algorithms given that the source code, algorithm, and specific implementation of AI systems used in healthcare applications can be protected under copyright as literary works.

The datasets used to train AI models, especially in healthcare (e.g., medical records, diagnostic images, genomic data), may also be eligible for copyright protection if they are original and involve creative selection, arrangement, or presentation.

iii) **Trademarks**

The Trade Marks Act, 1999 governs the registration and protection of trademarks in India. Trademarks protect the brand identity of a product or service, such as names, logos, slogans, or other identifiers that distinguish a business in the marketplace.

Companies developing AI-driven medical devices or healthcare solutions, such as diagnostic platforms or telemedicine apps, can protect their brand names, logos, and taglines associated with the product or service.

iv) **Trade Secrets**

India currently lacks a specific law protecting trade secrets, relying instead on principles of equity, common law, and statutes like the Indian Contract Act, 1872 (**"Contract Act"**), and the Information Technology Act, 2000. However, the Protection of Trade Secrets Bill, 2024 (**"Trade Secrets Bill"**) proposed by the 22nd Law Commission of India outlines specific rights and responsibilities for holders of trade secrets, and aims to establish a dedicated legal framework for trade secret protection in India, addressing the current reliance on common law and contract law.

Trade secret is defined under the Trade Secrets Bill as information that (i) is a secret regarding precise configuration and assembly of components that is not widely known or accessible to persons, (ii) that derives commercial value on account of being a secret, (iii) has been kept a secret through deployment of reasonable steps, and (iv) if disclosed, may cause damage to the holder of such information. The Trade Secrets Bill provides various rights to the holders of trade secrets, i.e., the right to (i) use or disclose, including licensing, of trade secrets, (ii) enter into an agreement in order to protect trade secrets through restricting access and prevention of disclosure, wherein such an agreement will be subject to the Contract Act (iii) institute proceedings in case of misappropriation of trade secrets and/or to prevent further misappropriation/ disclosure of trade secrets in public domain.

D. Consumer Protection

The Consumer Protection Act, 2019 (**"CPA"**) provides for protection of consumer's interest and establishes a redressal mechanism. It imposes multiple responsibilities upon sellers and service providers including prohibition of unfair trade practices, misleading advertisements and establishes product liability regime. CCPA is the regulatory body under the CPA which presides over the administration of CPA and issues penalties.

AI systems can pose risks, especially if they malfunction or cause harm to users or third parties. Depending on the harm caused by defective AI systems the company may be held liable under the CPA. Product liability provision under CPA would be triggered in case of harm caused due to defective design, implementation, or data breaches.

i) **Product Liability**

Product liability refers to the responsibility of a product manufacturer or product seller, of any product or service, to compensate for any harm caused to a consumer by such defective product manufactured or sold or by deficiency in services relating thereto. In the context of an AI-based healthcare product or service, it means that the company could be held legally responsible if defects in the AI system, software, or device it provides, leads to harm, injury, or loss to a user, such as a patient or healthcare provider.

ii) **Types of Defects Leading to Product Liability**

There are generally three types of defects that can lead to product liability:

1. **Design Defects:** These occur when the AI system, algorithm, or healthcare product is inherently dangerous or flawed due to its design. For example, if an AI diagnostic tool is designed in a way that consistently leads to inaccurate diagnoses, which causes patient harm, the company could be liable for the design defect.
2. **Manufacturing Defects:** These are defects that occur during the production or assembly of the AI product or service. For example, if the AI system is incorrectly programmed or the software is not properly tested before being deployed, leading to errors that harm a patient, the company could be held liable for the manufacturing defect.
3. **Marketing Defects (Failure to Warn):** These occur when the company fails to provide adequate instructions, warnings, or disclaimers about the risks associated with the AI product. For instance, if the AI-based diagnostic tool doesn't come with proper user guidelines, or if the risks are not clearly communicated to the end-users (doctors, patients, etc.), the company could be held liable if the AI product causes harm due to these deficiencies.

iii) **Specific Considerations for AI in Healthcare Products**

Given the nature of AI in healthcare, product liability risks can be more complex. Some additional factors to consider are:

4. **Accuracy of the AI System:** AI products, particularly those used in healthcare (like diagnostic tools or decision-making systems), rely on data and algorithms. If the AI system is faulty and provides inaccurate results (e.g., misdiagnosis, improper treatment suggestions), and this leads to patient harm, the company may face liability for the harm caused by inaccurate or faulty predictions.
5. **Clinical Validation and Testing:** If the AI product is used in clinical settings or makes medical recommendations, it must be rigorously tested and clinically validated to ensure that it works as intended. If the product has not been properly tested or validated in real-world healthcare environments, and it causes harm, the company could be liable for failing to meet safety standards.
6. **Data Quality and Security:** AI in healthcare relies heavily on data. If the data used to train the AI model is inaccurate, incomplete, or biased, the AI may make poor decisions that could lead to harm. If the product relies on personal data of individuals, the company would also be required to comply with data protection and cybersecurity laws to ensure data security and prevent breaches.

AI systems, especially autonomous ones, are increasingly being integrated into healthcare decision-making. This creates a challenge in determining responsibility if something goes wrong. Clear guidelines and disclaimers are crucial to managing this risk and are awaited from the regulatory authorities.

E. Anti-Trust

The Indian anti-trust law - the Competition Act, 2002 - aims to protect consumer interest by preventing practices that hamper fair and healthy competition in India. The Competition Act broadly deals with anti-competitive behaviours and potentially anti-competitive combinations. The Competition Commission of India (**"CCI"**) serves as the regulator under the Competition Act.

The Competition Act follows an ex-post approach, where the CCI examines whether an agreement or action has had an appreciable adverse effect on competition (**"AAEC"**) either after receiving a complaint or where it has reason to believe that suo moto action should be initiated. However, in an attempt to more effectively regulate competition in digital markets, a draft of the Digital Competition Bill, 2024 ("Digital Competition Law") was released in 2024. The Digital Competition Law adopts an ex-ante approach i.e. it prescribes certain guardrails within which companies must function, in order to deter anti-competitive behaviours. The Digital Competition Law is still to be finalised and brought into effect. Once enacted, it could have far-reaching implications for AI-driven medical technologies as well.

Under the competition framework, an AI-based medical technology company could, deliberately or inadvertently, engage in several potentially anti-competitive behaviors that may violate antitrust or competition laws. We have briefly discussed examples of some behaviours:

- Tying arrangements may be used to force customers to purchase additional services or products, stifling competition from other providers. For example, a company offering a hospital software package that requires customers to also purchase AI-powered diagnostic tools, thereby limiting the ability of competitors to enter the market.
- Predatory pricing could occur if the company deliberately sets prices below cost to drive competitors out of the market, with the intent of later increasing prices once competition has been reduced. For example, a company may offer its AI-powered healthcare solutions free of cost initially in an attempt to eliminate competition, only to raise prices once the competition is gone.
- Data hoarding is another anti-competitive behavior, where a company controls access to crucial health data that competitors need to improve their AI models. For example, a company using proprietary patient data that is difficult for new entrants to access, creating an unfair barrier to entry. These practices can reduce competition, limit innovation, increase costs, and ultimately harm consumers, potentially triggering regulatory scrutiny and legal action.
- Imposing unfair or discriminatory terms in contracts with healthcare providers, requiring them to exclusively use their product while prohibiting the use of competitors' products. These contracts could include penalties or conditions that make it financially impractical for healthcare providers to switch to other solutions, thus locking them into a single supplier.

Challenges to Regulation of AI in India

The regulation of AI as a medical device in India presents a number of challenges for healthcare-based AI companies. AI technologies are inherently dynamic and distinct from traditional medical devices which are typically physical, static product. The existing regulatory framework has been modelled around the latter, and fails to address the distinct characteristics of AI systems, such as their capacity for learning, adaptation, and evolution over time through machine learning, as well as the manner in which they are placed on the market.

I. Licensing Requirements

The CDSCO has specifically recognised AI-driven SaMD, and has released guidance on the risk classification of SaMD devices. However, in the absence of specific relaxations or guidance for AI-driven SaMD, such devices do not strictly align with current legal framework complying with the requirements thereunder becomes especially challenging.

A medical device that is being placed on the market must either be covered under an import license or a manufacturing license, as the case may be. In order to obtain such a license, the developer would have to satisfy certain requirements, including in terms of quality management standards. It could prove challenging for a company dealing in AI-driven SaMD to demonstrate compliance with the quality management standards prescribed for products and the manufacturing site, which could result in undue delays in receiving a license.[1]

Additionally, the requirement that a medical device only be sold at a licensed premises could also prove impractical, since AI-driven SaMD's are often freely available to download from the website or through an app store. Such channels would not, realistically, be able to procure a license to sell medical devices [2] under the MDR.

II. Clinical Investigations

In order to establish the safety, performance and effectiveness of a medical device, the MDR requires that a clinical investigation be conducted in or on human participants before a medical device which does not have a predicate may be placed on the market. In certain cases, a waiver may be granted. This requirement would apply to novel AI-driven SaMDs as well. Presently, the CDSCO has not issued any guidance on the manner in which clinical investigations are to be conducted for SaMD.

III. Post-Approval Changes

Under the MDR, post approval changes are categorised into major changes and minor changes. The former requires prior approval from the licensing authority, while the latter must be notified to them in writing.

1 Fifth Schedule to the MDR.

2 A license in Form 21 of the Drugs Rules or registration certificate in Form MD-42 is required to sell, stock, exhibit or offer medical devices for sale or distribution.

However, the post-approval changes have been based on devices which are static and predictable by their nature. Given the dynamic nature of AI-driven SaMD, this could result in frequent notifications having to be made.

IV. Labelling

The labelling of medical devices is stringently governed in India. Labelling requirements are laid down under the MDR and the Legal Metrology (Packaged Commodities) Rules, 2011 (**"LM PCR"**). Certain declarations must mandatorily appear on the label of every medical device. For an AI-driven SaMD, it could prove challenging to determine the manner in which the labelling ought to be done, since there is no label *per se*.

V. Pricing

In India, all medical devices are subject to the pricing restrictions under the Drugs (Price Control) Order, 2013 (**"DPCO"**). The DPCO restricts device manufacturers from raising the price of a device by more than 10% in a twelve-month period.[3] Additionally, the manufacturer is required to submit an annual price list to the National Pharmaceutical Pricing Authority in a stipulated format. This could prove superfluous and onerous for developers of AI-devices.

VI. Advertising and Claims

In India, advertising and promotional activities pertaining to medical devices are stringently regulated. The MDR does not expressly regulate these activities, but any misleading claims made on the label of a device would render it misbranded for the purpose of the Drugs and Cosmetics Act.

The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 (**"DMRA"**) contains stringent restrictions vis-à-vis the claims that may be made in relation to certain specified conditions. The DMRA prohibits advertisements about medical device in terms which suggest or are calculated to lead to the use of that device for (a) The procurement of miscarriage in women or prevention of conception in women; or (b) The maintenance or improvement of the capacity of human beings for sexual pleasure; or (c) The correction of menstrual disorder in women; or (d) The diagnosis, cure mitigation, treatment or prevention of any disease, disorder or condition specified in the schedule to the DMRA. The schedule to the DMRA contains a list of 54 disorders such as heart disease, cancer, diabetes, disorders of the menstrual flow, female diseases (in general), fevers (in general), obesity, and high or low blood pressure.

With the advent of medicine, several of these conditions are now treatable or manageable, if not entirely curable. A number of AI-driven medical technologies have been developed in relation to these scheduled disorders, which have been shown to have promising results. However, companies are restricted from making claims in relation to them, which affects their ability to effectively market them to HCPs and patients.

3 For devices which are specifically notified in the Schedule to the DPCO, the regulator stipulates a ceiling price that may be charged. However, no SaMDs are notified as on date.

VII. Promotion to Healthcare Practitioners

The Uniform Code for Marketing Practices in Medical Devices (**"UCMPMD"**), issued by the Department of Pharmaceutical in September 2024, is a set of guidelines which governs the promotional activities of medical devices companies, as well as their interactions with HCPs. Our detailed write-up on the UCMPMD may be accessed here.

The UCMPMD stipulates conditions for the textual and audio-visual promotions pertaining to devices, which must be adhered to. Additionally, the UCPMPD lays down restrictions in terms of the manner in which companies may interact with HCPs, including for educational purposes.

Given the complex and novel nature of AI-driven SaMD's, it would be necessary to provide training to HCPs prior to them deploying these technologies in their practice. Given the dynamic nature, it could also be necessary for these trainings to be periodically conducted. Potentially, this could result in scrutiny under the UCMPMD.

Risks and Ethical Challenges

I. Bias and Discrimination

AI models can inherit biases present in the data they are trained on. This can lead to discriminatory outcomes, such as unequal healthcare treatment for certain demographics, which may exacerbate health disparities and undermine trust in the system.

II. Quality of Data

The availability and quality of medical data is pertinent for the performance of AI systems as it relies on large, diverse datasets to generate reliable and accurate predictions.Without access to comprehensive data that represents the full spectrum of patient populations, AI models may produce skewed or incorrect results, leading to potential risks in diagnosis and treatment.[1]

Additionally, selecting the appropriate clinical metrics and methodologies is crucial. Defining relevant and actionable data in a clinical context can be challenging, and errors in this process may mislead the AI algorithms and systems. AI systems also face challenges when deployed in clinical settings, as they lack the clinical intuition that human healthcare providers possess. While AI can assist with pattern recognition and predictive analytics, it cannot apply common sense or adapt to the nuanced complexities of patient care. This gap highlights the importance of maintaining human oversight in AI-driven healthcare decisions.[2]

III. Doctor-Patient Relationship

The increasing reliance on AI could undermine the human aspects of healthcare, such as the doctor-patient relationship. There are concerns that patients may feel alienated or lose trust in their healthcare providers if AI systems take on a larger role in decision-making, potentially reducing human empathy and judgment.

IV. Privacy and Confidentiality

The integration of AI and big data into healthcare brings significant ethical, legal, and operational risks, particularly concerning patient data privacy.

Protecting patient data is essential not only from an ethical standpoint but also legally, as breaches can undermine trust in AI systems, compromise patient autonomy, and result in legal repercussions for health-care providers. The regulation of AI in the existing framework of data protection laws or the enactment of stringent data protection laws for AI is necessary to maintain patient confidentiality and prevent breaches, particularly as AI and big data become central to healthcare and precision medicine.[3]

1 Accessible at: https://pmc.ncbi.nlm.nih.gov/articles/PMC8285156/.

2 Accessible at: https://www.researchgate.net/publication/377091459_The_Integration_of_Artificial_Intelligence_into_Clinical_Practice.

3 Accessible at: https://www.researchgate.net/publication/378288596_AI_in_Data_Privacy_and_Security.

V. Physician Preparedness

Additionally, the widespread adoption of AI in healthcare will require significant training and awareness, as variations in technology and implementation across different healthcare settings could pose obstacles. In countries like India, where AI adoption may be more challenging in rural or smaller regions, the successful implementation of AI requires overcoming significant barriers, such as limited access to technology, language barriers, lack of training, and varying levels of expertise.

VI. Cybersecurity

With the growing use of AI in healthcare, cybersecurity becomes a critical concern. The increasing reliance on AI and big data makes healthcare systems more vulnerable to cyberattacks that could compromise sensitive patient data, disrupt operations, and jeopardize patient safety.

VII. Environmental Impact

While AI holds promise for addressing global challenges like climate change, its environmental impact is becoming more apparent. The computational power required to train complex AI models, particularly deep neural networks, results in substantial energy consumption, leading to an increased carbon footprint. The electricity used for training AI models, especially when sourced from non-renewable energy, contributes to higher carbon emissions. Additionally, the ongoing energy demands for deploying and fine-tuning these models further strain energy resources. The growth of data centres, which are essential for AI-driven applications, exacerbates environmental concerns.

Conclusion

The integration of AI into the healthcare industry has the potential to revolutionize patient care, improve efficiencies, and drive advancements in medical research. However, the legal and ethical implications of AI in healthcare present a complex landscape that requires careful consideration and robust regulatory frameworks.

From a legal perspective, the current landscape is evolving, with existing frameworks like data protection laws and medical device regulations needing to be adapted to account for the unique challenges posed by AI technologies. Issues such as liability, accountability, and intellectual property remain pivotal, as AI systems become more autonomous and integral to clinical decision-making. The challenge lies in determining who bears responsibility in cases of error or harm caused by AI systems, as well as ensuring that these systems are transparent, auditable, and maintain patient trust.

As AI continues to evolve and integrate further into healthcare, both legal frameworks and ethical guidelines must adapt in tandem. Policymakers, healthcare providers, and technologists must collaborate to create a balanced and adaptive approach that prioritizes patient safety, equitable outcomes, and transparency. Only through such a comprehensive approach can the potential benefits of AI be fully realized while mitigating the risks and ensuring that the core values of healthcare – patient well-being, autonomy, and justice – are upheld.

AI in Indian healthcare, if managed judiciously, is a boon. Despite regulatory frameworks being in early stages, India's commitment to ethical guidelines and AI standards positions it favorably. While legal challenges exist, addressing them with robust frameworks, stringent regulations, and ethical practices can allow India to harness AI's benefits. Collaborative efforts and visionary leadership are essential, shaping a healthcare landscape that meets diverse needs, setting a precedent for global AI adoption, and revolutionizing healthcare positively. Addressing legal challenges requires collaborative efforts. Investment in technological infrastructure, skill development, and defined regulatory standards are pivotal.

Beyond AI

A. Virtual Reality and Augmented Reality in Medical Training and Education

Virtual reality (**"VR"**) and augmented reality (**"AR"**) have become transformative tools in medical training and education. VR immerses users in a fully synthetic 3D environment, offering an experience that engages the visual and auditory senses, while AR overlays digital information onto the real world via electronic devices. Both technologies provide a unique opportunity to simulate real-world medical scenarios, making them useful in medical training and education. VR has the potential to allow medical students and trainees to practice complex procedures in a riskfree environment, simulating surgeries and other medical interventions with virtual patients. This helps trainees build skills, practice decision-making, and enhance muscle memory before engaging with real patients. AR, on the other hand, has been assisting healthcare providers in training and receiving critical information about patients to make medical decisions.

Therefore, VR proves particularly beneficial in neurosurgery and minimally invasive surgeries, offering simulations that help improve precision and reduce human error. Moreover, VR has shown promise in providing a distraction during acute pain episodes, and it is being explored for chronic pain management and rehabilitation for stroke victims. AR enhances the real-time learning experience by allowing medical trainees to interact with real patients while receiving information about patient history or medical conditions, improving both the quality and speed of training and education.

However, despite their promise, the integration of VR and AR into healthcare settings is fraught with challenges. The specialized hardware and infrastructure required to implement these technologies has high costs, which may limit their adoption especially in low-income countries. Furthermore, a pertinent challenge remains in ensuring that skills learned in virtual environments accurately translate to real-world clinical scenarios or during surgical procedures.

While VR and AR hold immense potential in revolutionizing medical education and training, addressing the challenges related to cost, accessibility, and translation of benefit to the clinical settings is essential.[1]

B. Robotics in Healthcare

The applications of robots in healthcare settings can be done across several domains including service, assistive, socially assistive, teleoperated, and interventional robots. Service robots assist in tasks such as medication dispensing, patient transport, and hospital logistics, streamlining hospital workflows. Assistive robots, help patients with daily living activities and enhance mobility, while socially assistive robots can interact with patients, providing companionship or emotional support. Teleoperated systems, such as telesurgery, enable healthcare providers to deliver medical care remotely, bridging gaps in access to healthcare. Interventional robots, particularly those used in minimally invasive surgeries, increase surgical precision, improving patient outcomes, reducing recovery times, and minimizing risks associated with traditional procedures.

1 Accessible at: https://www.jmir.org/2021/2/e25499/.

One of the applications of assistive robotics is wearable robots, including prosthetic limbs and arms, orthotic devices, and exoskeleton. The robotic prosthetics aim to closely replicate the limb or arm by mimicking the joints and segments while providing sensory feedback and intuitive control to the user. On the other hand, orthotic devices and exoskeletons assist individuals with fully intact limbs but limited mobility or control. Orthoses are used to protect, support, or enhance the function of various body parts like the ankles, knees, and spine. The robotic orthoses take the form of an exoskeleton that surrounds the affected area, allowing for natural movement while offering support to the area. While the latest robotic exoskeletons are still costly and have limited battery life for regular use, they are mostly confined to rehabilitation centres. However, the progress in sensor technologies, design, and control systems has significantly propelled the creation of increasingly advanced and sophisticated prosthetic robots. This evolution reflects a shift from basic prosthetic devices, such as artificial limbs, to more intricate technologies like prosthetic hands and bionic limbs, which can be controlled directly by the muscles or nerves of the user.

Despite the promising applications, certain challenges hinder the implementation of robotics in healthcare. The high cost of robotic systems may pose a barrier, particularly in smaller or resource-constrained countries. The integration of robotic technologies into existing healthcare infrastructure, is another obstacle. Furthermore, the adoption of robotics is often met with resistance from healthcare providers due to concerns about job displacement and from patients who may be hesitant to trust machines in healthcare settings. To overcome these barriers, there is a need for transparency, effective training programs, and continuous education and awareness to ensure that both healthcare providers and patients understand the complementary role of robots in healthcare settings and the potential benefits to access and quality of healthcare.

The potential of robotics in healthcare is vast, realizing its full benefits will require addressing the technological, financial, and social challenges. Through ongoing innovation, research, and the development robotics has the capacity to revolutionize medical care, improving efficiency, patient outcomes, access to healthcare, and the overall quality of healthcare.[2]

C. Nanotechnology in Diagnostic Imaging and Drug Delivery

Nanotechnology has made significant strides in healthcare, particularly in diagnostic imaging and drug delivery. Nanomedicine, a specialized field of nanotechnology, focuses on utilizing nanoscale technologies for disease prevention, diagnosis, monitoring, and treatment. The application of nanotechnologies has led to significant advancements in medical imaging and drug delivery, enhancing the accuracy, precision, and effectiveness of treatments. Nanotechnology enables highly targeted and efficient drug delivery systems that minimize side effects by ensuring drugs are delivered directly to diseased cells while sparing healthy tissues.

Nanotechnology in drug delivery systems has revolutionized the treatment of diseases such as cancer, diabetes, and cardiovascular disorders. Nanoparticles can be engineered to encapsulate drugs and control their release, ensuring that they remain active for extended periods and reduce adverse side effects. A prime example of this is the use of liposomes to deliver chemotherapy agents directly to cancer cells, minimizing the toxic impact on other organs. However, despite the promising applications of nanomedicine, challenges related to the safety and toxicity of nanomaterials must be addressed. Research has shown that some nanoparticles may cause cellular damage or toxicity, raising concerns about their long-term effects within the body.

2 Accessible at: https://link.springer.com/article/10.1007/s42979-023-02551-0.

In diagnostic imaging, nanotechnology has introduced novel contrast agents that improve the resolution and specificity of imaging techniques such as X-rays, CT scans, MRI, and ultrasound. Traditional contrast agents often distribute non-specifically and metabolize quickly, leading to potential side effects. Nanoparticles, due to their size and ability to be engineered for specific targeting, offer a more controlled and localized distribution within the body. For instance, gold nanoshells, known for their biocompatibility, are being explored for cancer diagnostics through optical imaging, providing high-resolution visuals and early disease detection. The use of nanoparticles has also expanded the ability to perform non-invasive diagnostic tests, providing more accurate results with fewer risks to patients.

The technology offers significant promise in revolutionizing medical diagnostics and drug delivery, leading to more targeted, effective, and personalized treatments. However, its successful application in healthcare will depend on rigorous research to ensure the safety of nanomaterials, along with the establishment of regulatory frameworks to guide their use in healthcare settings. With continued innovation and comprehensive safety evaluations, nanotechnology holds the promise of improving healthcare outcomes and transforming the landscape of medical diagnostics and drug delivery.[3]

D. 3D Printed Organs

The present approach to repairing organ defects primarily relies on transplanting tissues and organs from human donors to patients. However, the limited regenerative capacity of these tissues presents a significant challenge in meeting the growing clinical demand. The demand for organ transplants continues to outpace the supply worldwide and is creating significant pressure on healthcare systems. This persistent disparity highlights the urgent need to address the shortage of available organs.

Recent advances in tissue engineering have introduced promising technologies, such as microfluidics, organ-on-chip models, and 3D printing, which are paving the way for new solutions. Microfluidic technologies precisely characterize the microenvironment that supports cellular survival, factoring in fluid flow, growth factor gradients, and biomaterial mechanical properties. Organ-on-chip systems, based on micro-processing technologies, replicate complex human organ microstructures, environments, and physiological functions. These systems enable the controlled simulation of extracellular matrix properties, gradient dilution, cell culture, and morphology detection within a single device, overcoming the limitations of traditional cell culture and animal models. Among these innovations, 3D printing holds promise for creating artificial tissues and organs with intricate vascular structures based on detailed digital models. The process involves capturing images with advanced imaging technologies, converting them into 2D patterns through computer-aided design, and using layer-by-layer deposition techniques to precisely place biomaterials and cells. This approach offers high control, reproducibility, and potential for large-scale production, positioning 3D printing as a leading technology for producing tissues and organs that closely resemble human anatomy.

Researchers have successfully printed biomimetic vascularized structures, such as hearts, livers, lungs, kidneys, and even parts of the human reproductive system. However, most constructs are limited to thin tissues or functional units. The creation of a full organ requires sufficient cell numbers and a vascular network that can sustain the activity of large tissue masses. While progress is being made, challenges remain in replicating the complexity of fully functional, large organs. The advancements so far lay a solid foundation for future developments in tissue production suitable for transplantation. The challenges include the development

3 Accessible at: https://pmc.ncbi.nlm.nih.gov/articles/PMC7953199/.

of tissue-specific bioinks that support tissue integrity and cell survival, the need for advanced printing techniques such as single-cell printing and multi-material printing, and the creation of complex vascular networks with nerve innervation. Additionally, regulatory frameworks must evolve to establish safety standards for these printed tissues and organs.

Although clinical applications of 3D-printed, vascularized tissues are still in their early stages, the progress has the potential to address the shortage of organs, worldwide. With ongoing technological advancements, 3D printing is poised to revolutionize tissue engineering, offering the potential to create fully functional tissues and organs with intricate vascular systems, potentially used for transplantation in the future.[4]

E. Predictive Analytics in Healthcare

Predictive analytics is becoming an essential tool in healthcare, using extensive patient data to optimize clinical outcomes, enhance resource management, and promote proactive care. Advanced data modelling techniques enable healthcare providers to anticipate patient needs, streamlining care delivery and improving overall healthcare quality.

The application of predictive analytics spans both clinical and operational domains. In clinical settings, predictive models help in early disease identification, using machine learning algorithms to detect early signs of cancer or predict the progression of chronic conditions like diabetes and heart failure. These models also enable personalized treatment strategies by forecasting how patients will respond to specific therapies. In addition to clinical applications, predictive analytics plays a crucial role in operational efficiency, forecasting patient volume, optimizing staff allocation, and improving patient flow management. Moreover, predictive models help engage patients by offering tailored health risk assessments, preventive care reminders, and personalized lifestyle recommendations, promoting healthier behaviours and preventing chronic diseases.

Despite its promising potential, integrating predictive analytics into healthcare systems presents several challenges. Data privacy and security concerns are paramount, with healthcare organizations needing to comply with regulations to protect sensitive patient information. The complexity of some predictive models, especially those using deep learning, can hinder interpretability and transparency, which may impact trust and adoption by healthcare providers. Furthermore, seamless integration with existing clinical workflows is challenging, as predictive analytics must be compatible with EHR systems and be user-friendly for healthcare providers with varying technical expertise. There is also an ethical imperative to address biases in predictive models to ensure fairness and equity in patient outcomes.

However, predictive analytics in healthcare is expected to benefit from emerging technologies, particularly AI and real-time data analytics. AI-powered solutions are anticipated to enhance diagnostic accuracy, clinical decision-making, and patient engagement while reducing operational costs and improving health equity. Innovations like federated learning offer a promising solution for training predictive models across decentralized data sources, enabling collaboration while maintaining patient privacy. As predictive analytics continues to evolve, it will support population health management by identifying high-risk individuals and implementing targeted interventions to improve public health outcomes. To fully leverage predictive analytics, healthcare organizations must invest in robust data infrastructure, training of healthcare providers and foster a culture of responsible data-driven decision-making.

4 Accessible at: https://pdf.sciencedirectassets.com/320498/1-s2.0-S2590183424X00022/1-s2.0-S2590183424000127.

Predictive analytics is providing data-driven insights that improve patient care, optimize operational processes, and reduce costs.As predictive modelling becomes more embedded in clinical practice, it has the potential to reshape healthcare delivery, making it more proactive, personalized, and efficient. For this transformation to be realized, healthcare organizations must prioritize data security, model transparency, and equitable access to these technologies.[5]

F. Personalized Medicine

Personalized medicine is a healthcare approach that tailors medical treatment and prevention strategies based on the genetic, environmental, and lifestyle factors of the individual. While the definition of personalized medicine continues to evolve, its core principle remains the same: using individual characteristics to make informed, precise medical decisions. The applications of personalized medicine in healthcare are broad and transformative. They include early disease detection, where genetic and molecular diagnostics identify conditions in their early stages, enabling timely and more effective interventions. Personalized medicine also helps avoid preventable drug-related complications by moving away from the traditional approach, reducing adverse side effects and improving therapeutic outcomes. Additionally, genetic profiling ensures that the right drug is selected for the right patient, optimizing drug metabolism by tailoring dosages based on individual genetic variants.

One of the most significant applications of personalized medicine is in oncology, where treatments are customized based on the genetic makeup of both the patient and their tumour. Targeted therapies that focus on specific cancer cell mutations have dramatically improved patient outcomes by reducing tumour growth and metastasis while minimizing damage to healthy tissues and organs. Personalized medicine is also increasingly being used in cardiology to predict and prevent heart disease, utilizing genetic markers that influence cholesterol metabolism, blood pressure regulation, and inflammation. It also plays a crucial role in pharmacogenomics, where genetic testing determines how individuals will respond to various medications, ensuring that the correct drug and dosage are prescribed, thus improving both efficacy and safety.

By focusing on prevention, early diagnosis, and more effective treatments, personalized medicine can reduce healthcare costs by minimizing trial-and-error approaches and unnecessary hospitalizations. It also optimizes healthcare resource allocation by ensuring treatments are directed to individuals who will benefit most. However, challenges remain, including high costs, limited access to advanced diagnostic tools, and the need for healthcare providers to have specialized knowledge in genetics and genomics. Despite these obstacles, as technology advances and becomes more accessible, changes in regulatory frameworks, the widespread adoption of personalized medicine promises to revolutionize disease diagnosis, treatment, and prevention, ultimately leading to better patient outcomes and more efficient healthcare systems.

Personalized medicine represents a ground-breaking shift in healthcare, offering individualized treatment plans that are more effective and safer than traditional approaches. As genomic technologies continue to evolve, personalized medicine will become increasingly integrated into healthcare practices, allowing for early intervention, more targeted treatments, and better management of chronic conditions.[6]

5 Accessible at: https://www.researchgate.net/publication/384148771_Healthcare_Data_Analytics_and_Predictive_Modelling_Enhancing_Outcomes_in_Resource_Allocation_Disease_Prevalence_and_High-Risk_Populations.

6 Accessible at: https://www.researchgate.net/publication/354269399_Personalized_Medicine_A_Review.

About NDA

At Nishith Desai Associates, we have earned the reputation of being Asia's most Innovative Law Firm — and the go-to specialists for companies around the world, looking to conduct businesses in India and for Indian companies considering business expansion abroad. In fact, we have conceptualized and created a state-of-the-art Blue Sky Thinking and Research Campus, Imaginarium Aligunjan, an international institution dedicated to designing a premeditated future with an embedded strategic foresight capability.

We are a research and strategy driven international firm with offices in Mumbai, Palo Alto (Silicon Valley), Bengaluru, Singapore, New Delhi, Munich, and New York. Our team comprises of specialists who provide strategic advice on legal, regulatory, and tax related matters in an integrated manner basis key insights carefully culled from the allied industries.

As an active participant in shaping India's regulatory environment, we at NDA, have the expertise and more importantly — the VISION — to navigate its complexities. Our ongoing endeavors in conducting and facilitating original research in emerging areas of law has helped us develop unparalleled proficiency to anticipate legal obstacles, mitigate potential risks and identify new opportunities for our clients on a global scale. Simply put, for conglomerates looking to conduct business in the subcontinent, NDA takes the uncertainty out of new frontiers.

As a firm of doyens, we pride ourselves in working with select clients within select verticals on complex matters. Our forte lies in providing innovative and strategic advice in futuristic areas of law such as those relating to Blockchain and virtual currencies, Internet of Things (IOT), Aviation, Artificial Intelligence, Privatization of Outer Space, Drones, Robotics, Virtual Reality, Ed-Tech, Med-Tech and Medical Devices and Nanotechnology with our key clientele comprising of marquee Fortune 500 corporations.

The firm has been consistently ranked as one of the Most Innovative Law Firms, across the globe. In fact, NDA has been the proud recipient of the Financial Times – RSG award 4 times in a row, (2014-2017) as the Most Innovative Indian Law Firm.

We are a trust based, non-hierarchical, democratic organization that leverages research and knowledge to deliver extraordinary value to our clients. Datum, our unique employer proposition has been developed into a global case study, aptly titled 'Management by Trust in a Democratic Enterprise,' published by John Wiley & Sons, USA.

Research@NDA

Research is the DNA of NDA. In early 1980s, our firm emerged from an extensive, and then pioneering, research by Nishith M. Desai on the taxation of cross-border transactions. The research book written by him provided the foundation for our international tax practice. Since then, we have relied upon research to be the cornerstone of our practice development. Today, research is fully ingrained in the firm's culture.

Over the years, we have produced some outstanding research papers, reports and articles. Almost on a daily basis, we analyze and offer our perspective on latest legal developments through our "Hotlines". These Hotlines provide immediate awareness and quick reference, and have been eagerly received. We also provide expanded commentary on issues through detailed articles for publication in newspapers and periodicals for dissemination to wider audience. Our NDA Labs dissect and analyze a published, distinctive legal transaction using multiple lenses and offer various perspectives, including some even overlooked by the executors of the transaction. We regularly write extensive research papers and disseminate them through our website. Our ThinkTank discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged.

As we continue to grow through our research-based approach, we now have established an exclusive four-acre, state-of-the-art research center, just a 45-minute ferry ride from Mumbai but in the middle of verdant hills of reclusive Alibaug-Raigadh district. Imaginarium AliGunjan is a platform for creative thinking; an apolitical ecosystem that connects multi-disciplinary threads of ideas, innovation and imagination. Designed to inspire 'blue sky' thinking, research, exploration and synthesis, reflections and communication, it aims to bring in wholeness — that leads to answers to the biggest challenges of our time and beyond. It seeks to be a bridge that connects the futuristic advancements of diverse disciplines. It offers a space, both virtually and literally, for integration and synthesis of knowhow and innovation from various streams and serves as a dais to internationally renowned professionals to share their expertise and experience with our associates and select clients.

We would love to hear from you about any suggestions you may have on our research publications.
Please feel free to contact us at **research@nishithdesai.com**.

Recent Research Papers

Extensive knowledge gained through our original research is a source of our expertise.

February 2025

Taxing Offshore Indirect Transfers in India

February 2025

Clinical Trials and Biomedical Research in India

Legal and Regulatory Framework

February 2025

Telemedicine in India

The Future of Medical Practice

February 2025

The Indian Pharmaceutical Industry

Regulatory, Legal and Tax Overview

February 2025

Medical Device Industry in India)

Regulatory, Legal and Tax Issues

January 2025

Research Paper Compendium

Clickable Catalogue of Publications

For more research papers **click here**.

Nishith Desai Associates
LEGAL AND TAX COUNSELING WORLDWIDE

MUMBAI

93 B, Mittal Court, Nariman Point
Mumbai 400 021, India

Tel +91 22 6669 5000

SILICON VALLEY

220 S California Ave., Suite 201
Palo Alto, California 94306, USA

Tel +1 650 325 7100

BENGALURU

Prestige Loka, G01, 7/1 Brunton Rd
Bengaluru 560 025, India

Tel +91 80 6693 5000

SINGAPORE

Level 24, CapitaGreen
138 Market St
Singapore 048 946

Tel +65 6550 9855

MUMBAI BKC

3, North Avenue, Maker Maxity
Bandra–Kurla Complex
Mumbai 400 051, India

Tel +91 22 6159 5000

NEW DELHI

13-H, Hansalaya Building, 15
Barakhamba Road, Connaught Place
New Delhi 110 001, India

Tel +91 11 4906 5000

NEW YORK

1185 6th Avenue, Suite 326
New York, NY 10036, USA

Tel +1 212 464 7050

GIFT CITY

408, 4th Floor, Pragya Towers
GIFT City, Gandhinagar
Gujarat 382 355, India

Artificial Intelligence in Healthcare
Navigating Regulatory Frontiers in India

concierge@nishithdesai.com