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Swasth Bharat, Viksit Bharat

Expanding the Reach of Diagnostics: The Digital Advantage

TABLE OF CONTENTS

02 FOREWORD BY FICCI

03 FOREWORD BY BDO INDIA

04 EXECUTIVE SUMMARY

05 INTRODUCTION

07 THE LANDSCAPE OF DIAGNOSTICS IN INDIA

15 EVOLUTION OF DIAGNOSTICS

24 REMOTE DIAGNOSTICS REVOLUTIONIZING DIAGNOSIS BEYOND LOCATION

32 BEYOND REMOTE DIAGNOSTICS: INNOVATIONS IN DIAGNOSTICS

43 REGULATORY DUE DILIGENCE

48 THE ROLE OF ABHA ID IN DIGITAL DIAGNOSTICS

54 RECOMMENDATIONS

58 CONCLUSION AND KEY TAKEAWAYS

59 ACKNOWLEDGEMENTS

60 REFERENCES

61 ABOUT BDO AND FICCI

FOREWORD BY FICCI



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The landscape of healthcare is undergoing a profound transformation and at the heart of it is the diagnostic industry. Diagnostics is an integral part of the healthcare continuum right from early detection to the effective management of diseases. Technology integration and adoption along with patient centricity are the driving forces of this transformation. Digital innovations are creating novel pathways to provide timely, accurate, and affordable diagnostic services to millions who have been left out of the service loop.

India has long grappled with the issue of access to quality healthcare and diagnostic services predominantly for rural and distant regions. Despite various initiatives and collective efforts to make healthcare services far more accessible, significant progress is yet to emerge in ensuring equitable access to quality diagnostic services.

The unprecedented COVID-19 pandemic significantly impacted the acceptance and adoption of these technological innovations and cemented the need for comprehensive, technology and data driven responses focused on people's safety and well-being. Moreover, changing consumer needs and preferences have also contributed to the widespread adoption of innovations, particularly providing a significant growth impetus for consumer-facing innovations.

At the core of this digital transformation is the push towards Universal Health Coverage (UHC). The key to providing high-quality healthcare in underprivileged areas lies on increased acceptance and enabling regulation for remote diagnostics such as teleradiology, and telepathology, along with other prominent innovations powered by artificial intelligence and machine learning. These technologies make the diagnostic process more efficient, and offer vital expertise over great distances, enhancing healthcare's equity and inclusivity. By harnessing the power of technology, we can get a step closer to a future where everyone, regardless of geographic location, can access world-class diagnostic services.

FICCI recognises this rapidly changing landscape of the diagnostic industry, the need for technology-driven and patient-centric innovations and the necessity to harness these to ensure enhanced access to quality and affordable diagnostic services across the length and breadth of the nation. Through this paper titled 'Expanding the Reach of Diagnostics: The Digital Advantage', we aim to provide not only the current landscape of the diagnostic industry in India, but also comprehensively map the role of technology in shaping its way forward and outline its role in achieving Universal Health Coverage.

This paper explores the emerging trends and challenges within India's diagnostic sector while highlighting the vast array of opportunities that digital innovations present. It outlines the numerous technological advancements, their use-case and associated challenges and regulatory hurdles to their large-scale adoption in the Indian healthcare system. We hope this paper will be a valuable resource for the health care professional, industry executive, and policymaker who share our vision of enhancing patient care through technology and innovation.

We also hope this paper, released during the 18th edition of FICCI's annual health conference -FICCI HEAL 2024 with the central theme 'Swasth Bharat, Viksit Bharat', opens doors for further discussion and deliberations in combining healthcare, digital advancements and innovations, and regulatory and commercial growth engines to contribute to the vision of universal health coverage for the citizen of India.

FOREWORD BY BDO INDIA





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The Indian diagnostic industry is undergoing a significant transformation driven by rapid advancements in digital technologies. Digital diagnostics have enormous potential to revolutionise the way diseases are identified, diagnosed, and treated in the future. These technologies also hold immense promise for enhancing healthcare quality and accessibility across India.

This knowledge paper offers a comprehensive overview of the current diagnostic landscape in India. It examines the key trends, challenges, and opportunities presented by digital innovations. It also provides an assessment of the evolution of digital diagnostics, highlighting the major technological advancements in the preanalytical, analytical and post-analytical phases, which are fundamentally improving the speed and precision of disease identification, diagnosis and management — ultimately improving patient outcomes and healthcare efficiency.

The paper emphasises the critical role of remote diagnostics in advancing universal health coverage (UHC), particularly in bridging the healthcare gap between urban and rural areas. By leveraging advancements in telemedicine and remote diagnostics, India could increase access to diagnostic services, improve efficiency and accuracy, reduce costs, and make healthcare more affordable. In the future, remote diagnostics will be indispensable in specialised medical treatments, enabling the sharing of medical images and expertise across geographical distances. However, the successful implementation of remote diagnostics depends on addressing several key challenges including internet connectivity, data protection, and regulatory frameworks. Investment in infrastructure, development of enabling policies, and fostering trust between patients and healthcare providers are crucial to reap the benefits of remote diagnostics.

By understanding the transformative potential of these technologies, policymakers, healthcare providers, and industry stakeholders can collaborate to maximise their benefits and improve health outcomes for India's population. Furthermore, this knowledge paper identifies high-priority areas for policy development that will accelerate the adoption of digital diagnostics solutions contributing to the realisation of UHC in India.

BDO India and FICCI are proud to present this comprehensive knowledge paper on the development and revolution of digital diagnostics in India. We are confident that this document will serve as an invaluable resource for understanding the current state of the diagnostic industry and the emerging trends that will shape its future. As a leading professional services firm, we are committed to promoting innovative solutions that improve health outcomes and help in advancing the healthcare industry. We hope this paper will inspire innovation, drive inclusive and progressive decision-making, and ultimately contribute to the well-being of the Indian people.

EXECUTIVE SUMMARY

In the rapidly evolving healthcare landscape, the Indian diagnostic industry finds itself at a pivotal juncture, propelled by the ongoing digital revolution. This knowledge paper, titled **"Expanding the Reach of Diagnostics: The Digital Advantage",** examines the current state of diagnostics in the country, underscoring the progressive impact of technological advancements and the urgent need for systemic reforms.

Diagnostics form the bedrock of effective healthcare delivery and the industry's projected growth reflects its important role. Reports estimate the sector will soar from USD 13bn in FY23 to a staggering USD 25bn by FY28. However, its growth has been uneven, with significant disparities between urban and rural areas. A large segment of the population still lacks access to quality diagnostic services, emphasising the necessity for innovative approaches to close this divide.

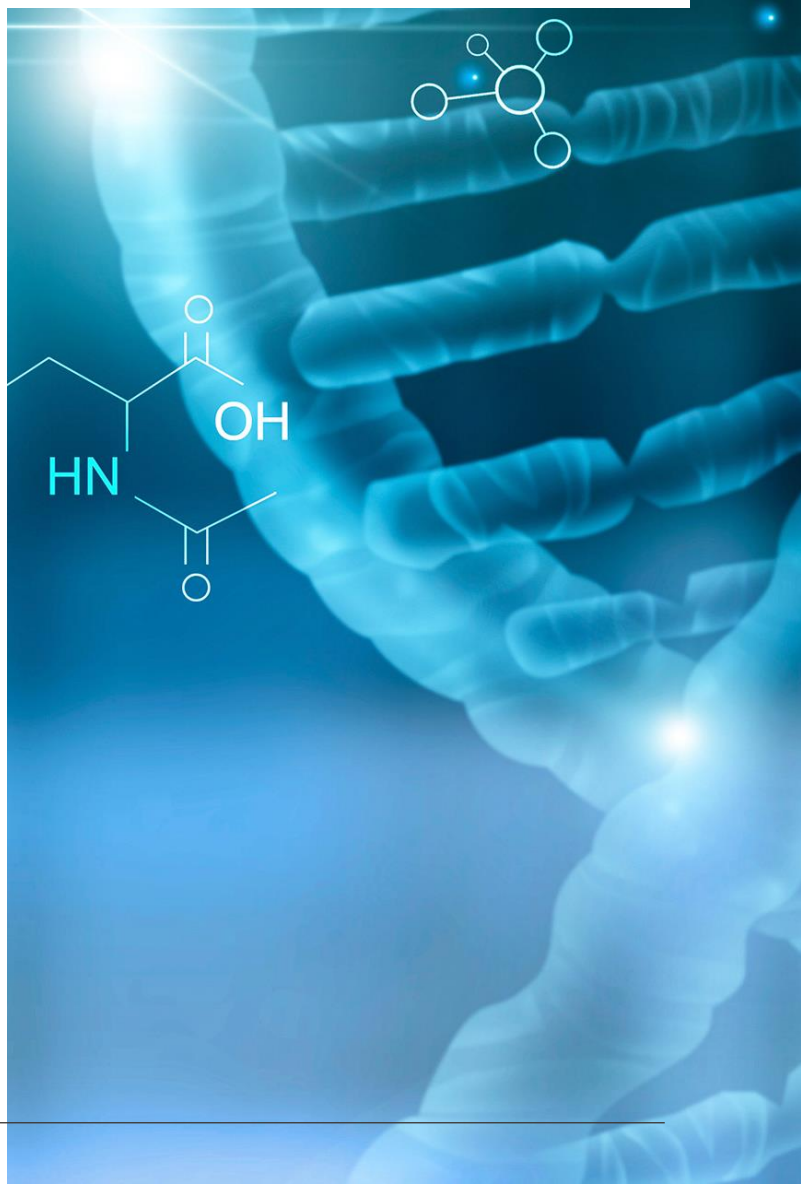
The COVID-19 pandemic was a watershed moment, accelerating the adoption of remote diagnostic technologies such as teleradiology and telepathology. These innovations have empowered healthcare providers to deliver timely services across geographical barriers, ensuring that even the most underserved populations benefit from advanced diagnostic tools.

Artificial intelligence (AI) and machine learning (ML) are poised to become integral components of diagnostic processes, enhancing both accuracy and efficiency in disease detection. These technologies facilitate early diagnosis and enable a more personalised approach to treatment planning, shifting the focus toward proactive health management.

Despite these advancements, the regulatory framework governing diagnostics in India also needs to evolve, as it is complex and outdated in its current state, hindering the seamless integration of digital solutions. Initiatives such as the Ayushman Bharat Digital Mission (ABDM) have made notable progress toward a unified digital health ecosystem, promoting interoperability and safeguarding data privacy. However, comprehensive regulatory reforms are necessary to ensure patient safety, data security and continued innovation in the sector.

The future of diagnostics in India is both promising and challenging. The rise of AI-driven and remote diagnostic technologies has unlocked limitless capabilities towards improving healthcare outcomes. An impetus for personalised medicine and proactive health management will be important in addressing persistent gaps in the system.

The integration of digital diagnostics offers a unique opportunity to enhance access, quality, and efficiency in healthcare delivery in India. To realise its true potential, regulatory hurdles must be addressed and stronger collaboration among stakeholders is essential. As innovations unfold, they will bring the nation closer to achieving universal health coverage and a more equitable, effective healthcare system for the future.



1 INTRODUCTION

Diagnostics is a critical pillar in the healthcare journey, serving as the foundation for accurate disease detection, timely treatment, and effective disease management. Early and precise diagnosis enables healthcare providers to make informed decisions, guiding interventions that can improve patient outcomes, reduce healthcare costs, and prevent complications.

Modern healthcare is at a tipping point of revolutionary transformation in the diagnostic industry. Promising new technologies and innovative methods reveal a new frontier in medical diagnostics that can transform the way we identify, manage and treat diseases. Whether AI-powered image analysis; telepathology; or point-of-care diagnostics, digital innovations are revolutionising the detection, diagnosis, and treatment of disease. Digitalisation has emerged as a powerful catalyst for change as India tries to make healthcare more accessible and of better quality.

Remote diagnostics empower healthcare professionals to conduct tests and evaluations from a distance. It also enables patients in remote areas to access timely diagnostic services without the need for extensive travel. Telepathology and teleradiology concentrate on the remote examination and interpretation of pathology slides and radiological images, respectively. This is especially useful in areas where specialised diagnostic professionals are limited, as experts can view cases from around the world, review and provide insights. By harnessing these technologies, healthcare systems can deliver more accurate diagnoses and timely interventions, even in geographically isolated areas.

Artificial intelligence (AI) and machine learning (ML) are no longer futuristic concepts but are now being integrated into existing diagnostic processes to enhance precision and efficiency. AI algorithms can analyse vast amounts of medical data, including imaging studies and genetic information, to identify patterns and make predictions with high accuracy. This capability not only aids in early disease detection but also supports personalised treatment plans, leading to improved overall patient care.

The COVID-19 pandemic acted as a significant catalyst in accelerating the development and acceptance of these diagnostic innovations. The urgency of the pandemic underscored the need for rapid, scalable diagnostic solutions and highlighted the limitations of existing healthcare infrastructures.



BRIDGING THE URBAN-RURAL DIVIDE

In India, with its vast geographical expanse and diverse healthcare landscape, digital diagnostics are playing a crucial role in bridging the urban-rural divide. Remote diagnostics and point-of-care devices are empowering individuals in remote villages to access quality diagnostic services that were previously out of reach. Telepathology and teleradiology are enhancing diagnostic capabilities in secondary and tertiary care settings. By connecting healthcare providers with experts from leading institutions, these technologies enable more accurate diagnoses and informed treatment decisions.

Digital diagnostics offer solutions to infrastructure challenges in rural areas, such as the limited availability of specialists and diagnostic equipment. By leveraging telemedicine and AI-powered tools, healthcare providers can deliver high-quality care even in resource-constrained settings.



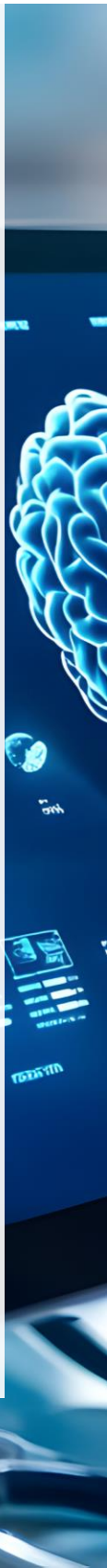
BETTER PATIENT CARE

The integration of digital diagnostics is leading to improved patient outcomes in several ways:

Early Disease Detection: AI-powered tools can analyse medical images and data to detect diseases at an earlier stage, enabling timely intervention.

Personalized Treatment: Digital diagnostics can support personalised treatment plans by providing valuable insights into a patient's unique medical profile.

Reduced Travel Burden: Remote diagnostics eliminate the need for patients to travel long distances for specialised care, improving accessibility and reducing financial burdens.





Despite these promising developments, fully realising the benefits of digital diagnostics in India requires addressing several key challenges. The regulatory environment must evolve to support the integration of these technologies while ensuring data privacy and patient safety. Clear guidelines for digital health tools, remote diagnostics, and data security are essential. Moreover, Government support is crucial in creating an infrastructure that accommodates these advancements.

The Ayushman Bharat Digital Mission (ABDM) is playing a pivotal role in establishing a unified digital health ecosystem. By promoting interoperability, data sharing, and standardisation, ABDM can facilitate the integration of digital diagnostics into the broader healthcare landscape, making them more accessible and affordable for all. Also, investments in technology, training healthcare professionals, and developing supportive policies vital to fostering an environment conducive to innovation will be paramount to harnessing the full potential of these technological advancements. By addressing these challenges and seizing the opportunities presented by digital diagnostics, India can significantly improve healthcare access, quality, and outcomes for its citizens.

The diagnostic industry in India stands at a pivotal moment, poised to undergo a profound transformation driven by digital innovations. As the country strives to enhance healthcare accessibility and quality, understanding the implications and potential of these technologies is imperative. This knowledge paper offers a comprehensive overview of the current state of the diagnostic landscape, exploring the transformative impact of digital innovations.

By examining key technological advancements, assessing their implications for healthcare delivery, and discussing necessary regulatory and policy measures, this paper aims to provide valuable insights for policymakers, healthcare providers, and industry stakeholders. Through a deeper understanding of the digital revolution in diagnostics, we can collectively navigate this evolving terrain and work towards a future where healthcare is more accessible, affordable, and effective for all citizens.

2 THE LANDSCAPE OF DIAGNOSTICS IN INDIA

The diagnostic landscape in India is highly fragmented and characterised by inequalities. Nevertheless, it is on the verge of change. Given its very high burden of communicable and non-communicable diseases, access to appropriate but affordable diagnostics has become very crucial. While progress has been made, access remains far from equitable, especially in rural and underserved settings.

Historically, the diagnostic services in India have been concentrated in urban centres. Infrastructure gaps, workforce shortages, and high costs have restricted access to quality diagnostics in rural populations. However, the recent advances in technology and government initiatives are gradually filling these gaps.

The introduction of the National Essential Diagnostics List by the WHO and ICMR marks a significant step towards prioritising diagnostics in India's healthcare system. By recognising critical role of diagnostics in improving health outcomes, these initiatives aim to ensure that essential diagnostic tools are available and accessible to all.

As the digital revolution unfolds, innovative technologies are reshaping the diagnostic landscape. From remote diagnostics and point-of-care devices to AI-powered image analysis, these advancements offer the potential to bridge the diagnostic gap, improve accuracy, and enhance accessibility, ultimately contributing to better healthcare outcomes for all Indians.

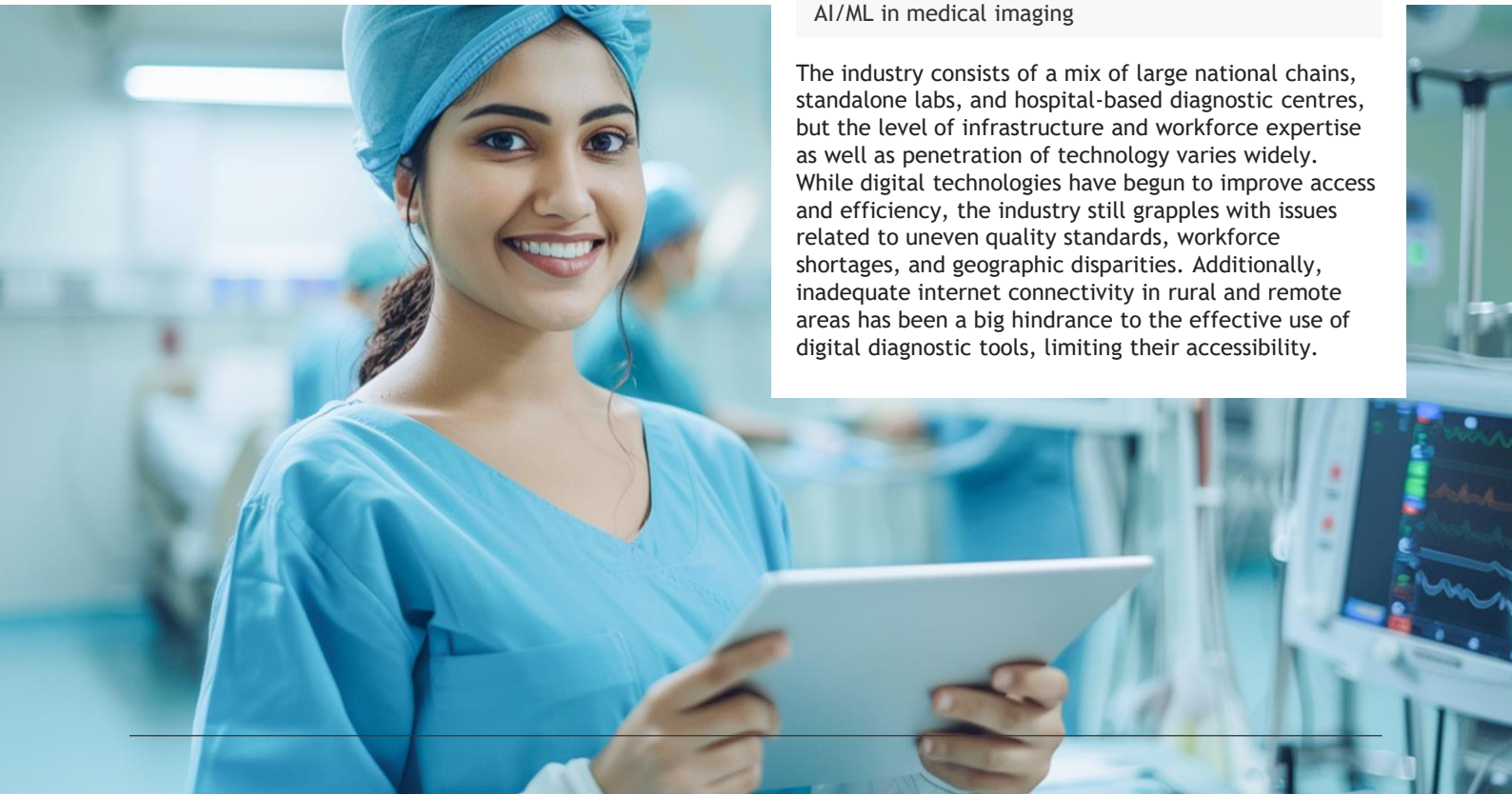
A SNAPSHOT OF THE INDIAN DIAGNOSTIC LANDSCAPE

The Indian diagnostic industry has witnessed significant growth in recent years, driven by factors such as increasing healthcare awareness, rising prevalence of chronic diseases, and government initiatives. It is also a highly fragmented sector, with significant variations in infrastructure, accessibility, and quality across different regions.

The Indian diagnostics industry is projected to reach USD 25bn by FY28, up from USD 13bn in FY23, backed by attractive margins and immense growth potential in the two main segments of the sector, pathology and radiology. The pathology market size is about USD 7.5bn or 58% of the diagnostics market, while radiology accounts for the rest, with soft radiology commanding a 55% share compared to advanced radiology[1]

The growth of the Indian diagnostic market can be attributed to two major categories:
Major investments from private healthcare firms and global investors along with increased public-private partnerships with government funding for improved access and quality of care
Technological upgrades and innovations such as point-of-care testing, real-time diagnostics, and AI/ML in medical imaging

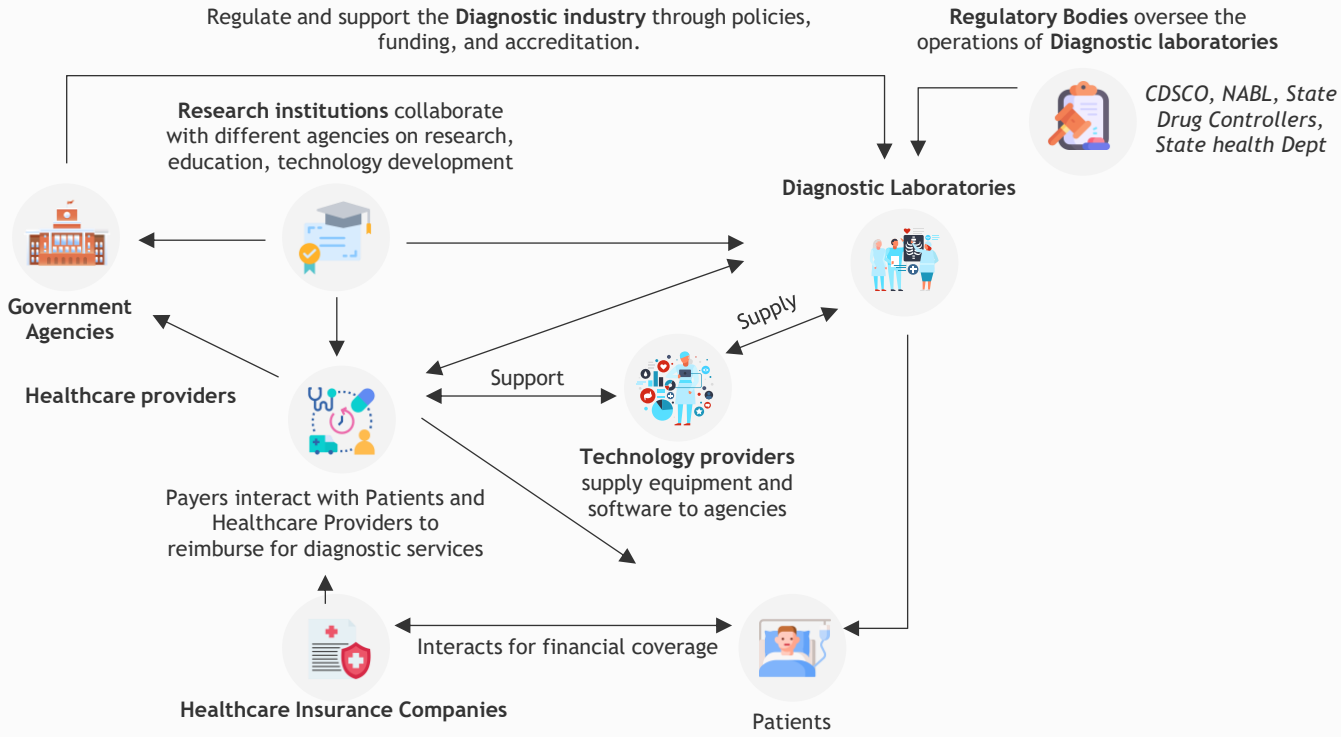
The industry consists of a mix of large national chains, standalone labs, and hospital-based diagnostic centres, but the level of infrastructure and workforce expertise as well as penetration of technology varies widely. While digital technologies have begun to improve access and efficiency, the industry still grapples with issues related to uneven quality standards, workforce shortages, and geographic disparities. Additionally, inadequate internet connectivity in rural and remote areas has been a big hindrance to the effective use of digital diagnostic tools, limiting their accessibility.



MAPPING KEY STAKEHOLDERS IN INDIAN DIAGNOSTIC INDUSTRY

The Indian diagnostic landscape is made up of seven major stakeholders-

1. Healthcare providers which include public hospitals, private hospitals, diagnostic centres, general practitioners, specialists;
2. Patients which include individuals and health insurance companies;
3. Government Agencies which include Ministry of Health and Family Welfare, State Health Departments, National Health Mission among other bodies;
4. Diagnostic laboratories which include government laboratories, private laboratories, national chains, stand-alone labs;
5. Technology Providers which include medical device manufacturers, health startups software developers, IT service providers;
6. Regulatory bodies such as CDSCO and NABL
7. Payers such as health insurance companies and government health insurance schemes and finally Research Institutions and Universities.



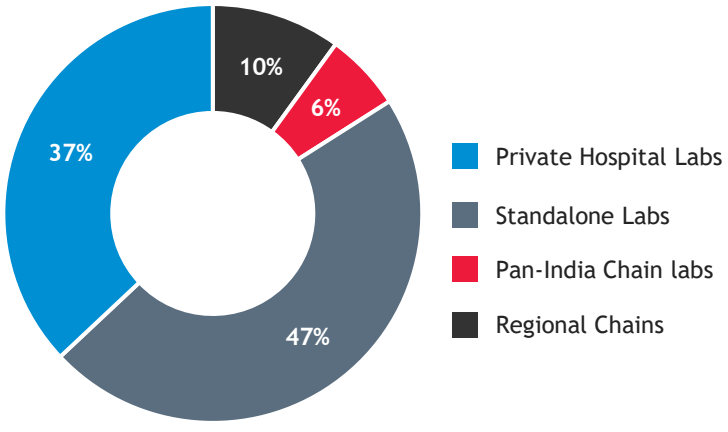


Figure 1: India Diagnostics Laboratory Market by Provider Type

The providers include a wide range of service providers such as standalone laboratories, regional chains, national chains, small and medium private hospitals, large private hospitals, and Government hospitals and institutions. Out of approximately 55,000 radiology labs, over 80% are standalone labs. The market showcases a fragmented picture with standalone centres at 47%, private hospital labs at 37%, Pan-India chain labs at 6% and the rest covered by regional chains[2].

Additionally, Urban Diagnostics captures a major chunk of the market with most diagnostic tests (by volume) being concentrated in metro and tier 1 cities such as Delhi, Mumbai, Bangalore, Hyderabad, Pune, Chennai, etc.; in contrast, rural diagnostics accounts for 22% market share[3].

The Indian Government is a major stakeholder through policy initiatives like Ayushman Bharat and the National Digital Health Mission, which aim to improve access and affordability in diagnostics. The flagship initiative of the Government, Ayushman Bharat seeks to comprehensively strengthen the health system from the primary level to tertiary care, thereby signalling a marked shift in focus from the implementation of vertical health programmes. Its first dimension is focused on building the next-generation primary healthcare system through a network of HWCs to promote good health as well as detect diseases early. Through its plans for a United Health Interface (UHI), digital registries, and electronic health records (EHR), the Ayushman Bharat Digital Mission (ABDM) could provide an impetus to digitisation of health. The Ayushman Bharat PM-JAY scheme has a high potential to increase healthcare expenditure per capita in India.

Emerging healthcare startups are playing a transformative role in driving innovation within the Indian diagnostic industry. These startups are leveraging technology to bridge gaps existing in the industry. This has led to a surge in tech-enabled diagnostic solutions in the market which concentrate on various aspects, including point-of-care testing, real-time diagnostics, clinical decision support systems, data-driven lab optimisation solutions, and AI in medical imaging. Through digital health platforms, services such as online consultations, home-based testing, and remote diagnostic services, have contributed to improving issues surrounding access, availability and affordability of diagnostic services. The agility and focus on technological disruption make them key stakeholders in shaping the future of diagnostics in India, promoting a more inclusive and efficient healthcare ecosystem.

India's approach towards diagnostics has been dictated by a long history of vertical, disease-specific programmes which contributed immensely to the control of infectious diseases such as human immunodeficiency virus (HIV), tuberculosis and malaria. While vertical programmes were successful in improving access to treatment and diagnostics for specific diseases, the availability of diagnostics for conditions other than the ones covered in the vertical programmes continues to remain inadequate across the health systems. Moreover, this traditional system has introduced major barriers within the market with issues such as low penetration to tier 2 and tier 3 cities, out-of-pocket costs for diagnostic tests, and health insurance providers not covering the cost of diagnosis and testing[4].



CHALLENGES FACED BY THE TRADITIONAL DIAGNOSTICS SYSTEM

Despite the combined efforts of the Government and the private sector to provide sufficient diagnostic services, challenges such as insufficient healthcare infrastructure, a shortage of trained professionals, financial constraints, governance and regulatory challenges, and innovation challenges persist. These challenges collectively impact the awareness, access, and affordability of these services among the population[5].

INFRASTRUCTURAL CHALLENGES

The presence of adequate infrastructure for diagnostic services impacts the patient experience, provider interactions, service delivery and outcomes.



Limited Availability of Diagnostic Facilities and Tests: Limited Availability of Diagnostic Facilities and Tests: At present there are around 1,00,000 labs across India and despite joint efforts by the government and private players to provide quality diagnostic services, gaps persist. There are only 5200 NABL accredited labs in India[6]. 42% of diagnostic labs are concentrated in metro and tier 1 cities with tier 2-3 cities lagging at 7% each[7]. Despite being home to over 70% of Indians, rural and non-metro areas face a significant shortage of high-quality diagnostic services. A shortage of readily available diagnostic facilities, especially in rural and remote areas can lead to long waiting times and limited access to tests and specialized consultations.

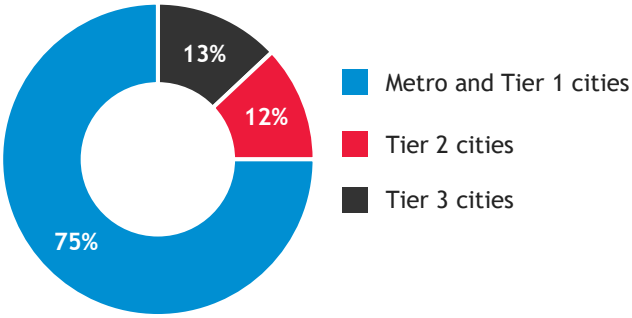


Figure 2: Distribution of Diagnostic Labs in Cities

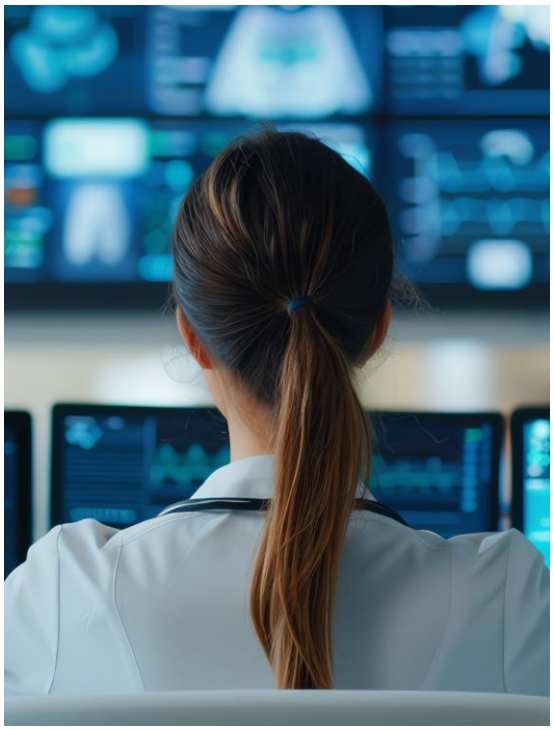
Indian Public Health Standards (IPHS) notes that adequate infrastructure that is required to provide quality diagnostic services includes functional healthcare facilities, functional spaces for lab and diagnostic services, adequate and appropriate technology, and digital infrastructure. Key factors to establish adequate infrastructure include considerations regarding geographical accessibility, availability of land/ spaces for establishment, financial constraints, to name a few.

Inadequate Supply of Essential Resources: There are limited diagnostic facilities and services available, wherein, many diagnostic facilities lack the necessary equipment, reagents, and trained personnel to provide comprehensive services.

Connectivity Issues: NSSO (National Sample Survey Office) data reveals a staggering disparity: only 24% of rural households have internet access, compared to 66% in cities[8]. While urban areas generally have access to fast and reliable internet, rural and remote regions often suffer from slow speeds or inconsistent connections, impeding the use of digital diagnostic tools and telemedicine services.

Power Supply Issues: Rural areas still face challenges with electricity supply including lack of access to reliable power due to geographical isolation and high capital costs, insufficient supply, power theft, and high infrastructure costs[9]. Unreliable power supply can disrupt the operation of diagnostic equipment and lead to data loss.

Long Travel Distances: Sparse and limited availability of diagnostic testing facilities forces patients in rural areas to travel long distances for basic tests, incurring additional costs and inconvenience. Long distances also impact report collection, diagnosis and follow-up for patients, thereby affecting the overall treatment journey.



HUMAN RESOURCES FOR HEALTH (HRH)



Shortage of Skilled Professionals: India faces a shortage of skilled and qualified medical professionals and healthcare providers. The condition is only exasperated with the increase in demand of medical services. With over 1,00,000 labs[10] and limited workforce there is a shortage of qualified laboratory technicians, pathologists, and radiologists, and doctors who sign off on the reports. Industry discussions noted a total of 80,000 doctors and approved pathologists who can verify reports. The resource crunch adds to the burden and volume of work undertaken by a singular technician and practioners.

Unequal Distribution: While urban diagnostic centres are generally well-staffed with qualified professionals, rural and semi-urban areas struggle to attract and retain trained personnel. The uneven distribution of the workforce impacts the quality and reliability of diagnostic services, with rural centres often relying on underqualified or insufficient staff. Although rural India constituted approximately 71% of the total population in 2016, only 36% of all health workers are in rural areas[11]. This shortage contributes to inefficiencies in diagnostic processes and limits the number of services that can be offered in underserved areas.

Retention Challenges: The retention of the workforce also depends on reasonable production capacity, a conducive environment, job stability of contractually hired staff, systematic-cum-responsive training systems and efficient financial disbursement practices. Lack of connectivity and unstable work conditions create difficulty in retaining qualified staff, especially in rural areas and smaller diagnostic facilities.

Inadequate Training and Development: Limited opportunities for continuing education and professional development for diagnostic staff.

CHALLENGES POSED BY MARKET DYNAMICS



Fragmentation: The market is highly fragmented with several players ranging from standalone centres at 47%, private hospital labs at 37%, Pan-India chain labs at 6% and the rest covered by regional chains[12]. This fragmentation can lead to price competition and challenges in standardisation.

Price Sensitivity: Based on NSS 75th round, approximately 12.6% of out-of-pocket expenditure (OOPE) and outpatient treatment is on diagnostic tests. Increasing average prices and overall high out-of-pocket expenditure make Indian patients generally price-sensitive. An increase in pricing leads to patients moving to alternative service providers. This can put pressure on diagnostic laboratories to offer competitive pricing.

Government Price Controls: The Government has implemented price controls for certain diagnostic tests, limiting the pricing power of laboratories. Moreover, through initiatives such as the Free Diagnostic Service Initiative (FDSI), a broader range of diagnostic and imaging services are being delivered free of cost. This was further strengthened through Comprehensive Primary Health Care (CPHC) rolled out through Ayushman Bharat- Health and Wellness Centres (2018) to provide an expanded range of free diagnostic services at primary healthcare facilities.

Negotiation Power of Large Hospitals: Large hospitals often have significant bargaining power with diagnostic laboratories, leading to price pressures and contractual challenges.

Technological Advancements: The rapid pace of technological advancements such as AI systems, automated processes and image processing across radiology and pathology require continuous investment in new equipment and training, upkeep and maintenance, software and data security updates etc., leading to an increase in operational costs.

Changing Consumer Preferences: Evolving consumer preferences, such as a growing demand for personalised healthcare, home-based diagnostics, home collection, use of apps and online bookings, digital reports etc. present new opportunities and challenges for the industry to accommodate.

While India's diagnostic industry has made considerable progress in urban areas, disparities in infrastructure, workforce availability, accessibility, and quality highlight the need for continued investment and reform, particularly in underserved regions. Addressing these gaps is critical to improving healthcare outcomes and ensuring equitable access to diagnostic services across the country.

REGULATORY LANDSCAPE OF DIAGNOSTICS IN INDIA

The existing policy and regulatory framework for the diagnostic sector in India focuses on outlining the legislation, guidelines for standards, basic minimum requirements and enforceable rules for medical equipment and devices, laboratories, manufacturing and distribution of diagnostic kits and medical devices.

To provide standardised quality of care, there are certain regulatory bodies that overlook key quality considerations for diagnostics in India.

THE CENTRAL DRUGS STANDARD CONTROL ORGANIZATION (CDSCO)

CDSCO under the Ministry of Health & Family Welfare is the National Regulatory Authority (NRA) of India. CDSCO is primarily responsible for the approval of new drugs and medical devices, establishing standards for drugs, and clinical trials, providing quality control regarding imported drugs, coordination of State Drug Control Organisations, providing oversight and bringing uniformity in the enforcement of the Drugs and Cosmetics Act, and granting licenses of certain specialised categories of critical drugs and medical devices as the Central License Approving Authority.

NATIONAL ACCREDITATION BOARD FOR TESTING AND CALIBRATION LABORATORIES (NABL)

NABL is an autonomous institution that is a part of the Quality Council of India. The main aim of NABL is to provide an impartial assessment of the quality standards for institutions, government bodies, and primary institutions regarding diagnostic standards. This voluntary accreditation assists in reinstating trust regarding quality and standardised services to consumers, as well as the Government. It is to be noted that the norms prescribed by NABL primarily focus on the quality of equipment, infrastructure, and quality certifications, more than other aspects of diagnostics.

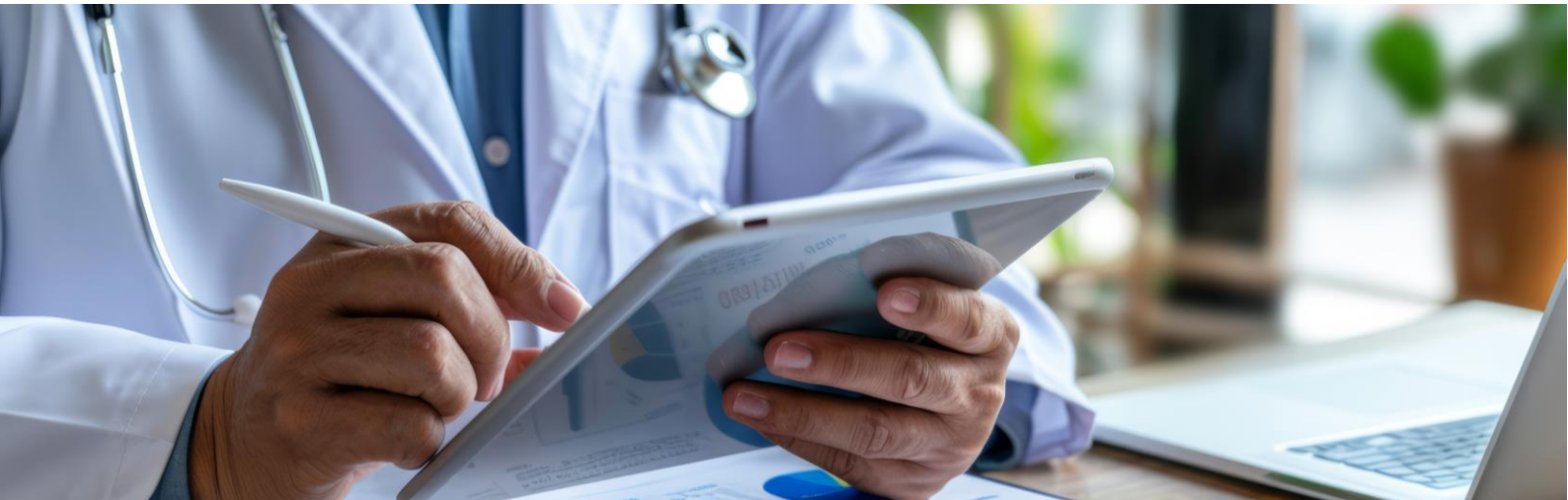
STATE DRUG CONTROLLERS

State Drug Controllers are a part of the State Drugs Standard Control Organisation, a body that oversees the implementation of drug and cosmetic laws at the state level. They overlook regulatory control over the manufacture, distribution and sales of drugs, medical devices, and cosmetics to maintain standards and ensure availability at a reasonable price.

STATE HEALTH DEPARTMENTS

State Health Departments look after regulating healthcare facilities, including diagnostic laboratories, within their respective jurisdictions in the State along with guiding and supervising the Health and Family Welfare Programmes.

India has a comprehensive, yet complex policy and regulatory framework geared towards the diagnostic and medical sector within the country. The current regulatory and policy framework for medical devices and diagnostics is spread across several legislations, guidelines and policies.



The key legislation and rules are outlined below:

The Drugs and Cosmetics Act, 1940

Regulation of drug import, production, distribution in India is governed by Drugs and Cosmetics Act. These rules classify medications, detailing storage, sale, and prescription guidelines. The primary objective is to ensure quality and reliability of drugs and cosmetics, prevent adulteration, hold pharmaceutical companies accountable for negligence and substandard practices.

Information Technology Act, 2000

The Information Technology Act, 2000 provides a legal framework and recognition for transactions carried out by means of electronic data interchange and other means of electronic communication, and data protection, relevant for the digitalization of diagnostics.

The Indian Public Health Standards, 2007

IPHS for healthcare facilities, published in 2007 under the NRHM, establish uniform standards to enhance healthcare quality. They serve as benchmarks for assessing functionality of health facilities and guide infrastructure planning and upgrades in states & union territories. IPHS documents have been revised to reflect updated protocols & new programs, particularly for non-communicable diseases.

The Clinical Establishments Act, 2010

The CE Act sets minimum standards for diagnosis and treatment, mandating registration for all healthcare facilities. While states can voluntarily adopt the Act, many have their own regulations due to health being a state subject. Currently, 12 states and 6 union territories have implemented the CE Act in their jurisdictions.

The Free Diagnostic Service Initiative, 2015

Launched in 2015 under the National Health Mission, the FDSI aims to provide accessible and affordable diagnostic and imaging services, including pathological and radiological tests, at no cost. It ensures essential diagnostic tests are available at public health facilities, further strengthened by the Comprehensive Primary Health Care program to enhance services at various healthcare levels, ultimately reducing out-of- pocket expenditure.

Biomedical Waste Management Rules, 2016

BMW Rules, under the Environment (Protection) Act of 1986 and overseen by the Ministry of Environment and Forest (MOEF), regulate biomedical waste management. They outline guidelines for characterization, segregation, storage, transport, and treatment, and specify infrastructure and disposal requirements for hospitals and diagnostic labs.

Medical Devices Rules, 2017

These regulations prioritize quality and safety in the manufacturing, import, sale, and distribution of medical devices, distinguishing them from drugs. For the first time, they align with international standards, offering a risk-based categorization, establishing product standards, and outlining timelines for licensing processes.

National Essential Diagnostics List (NEDL),2019

In 2018, WHO established its 1st Essential Diagnostics List (EDL) of 113 recommended tests for global access. India adopted the National Essential Diagnostics List (NEDL) in 2019, tailored to its healthcare priorities, featuring 117 general tests, 29 disease-specific tests, 24 imaging tests. The NEDL supports the Free Diagnostic Service Initiative and aligns with Sustainable Development Goal 3.8, promoting universal health coverage.

Telemedicine Practice Guidelines, 2020

In 2020, the Government of India issued Telemedicine Practice guidelines, establishing norms for medical records, physician-patient relationships, privacy, informed consent, and continuity of care. These guidelines define eligibility for telemedicine practice and apply to the MoHFW's telemedicine application, 'eSanjeevani'.

New Drugs, Medical Devices and Cosmetics Bill, 2022

MOHFW released the draft New Drugs, Medical Devices, and Cosmetics Bill 2022 to update 1940 Drugs and Cosmetics Act. The bill proposes new definitions for clinical trials, over-the-counter drugs, and medical devices, aiming to ensure that medical products sold in India are safe, effective, and of high quality. It defines medical devices, including diagnostic equipment and software.

The National Medical Devices Policy, 2023

It proposes a 'Single Window Clearance System' to streamline licensing, reduce compliance burdens, and enhance the role of Indian Standards, aligning them with international norms. Additionally, it aims to establish consistent pricing regulations to ensure affordability and protect patients.

Digital Personal Data Protection Act, 2023

This act regulates the governance of personal data collected by organisations and aims at protecting the individual's privacy by empowering them with rights over the manner in which their data is processed.



Alongside the legal framework, there are two driving missions of government of India that act as the cornerstone and anchor the diagnostic landscape within the country

National Health Mission (NHM)

The NHM envisages achievement of universal access to equitable, affordable & quality health care services that are accountable and responsive to people's needs. Through various guidelines and initiatives that promote the use of digital health technologies in healthcare delivery across its key focus areas, the mission is central towards meeting Sustainable Development Goal 3- Ensure healthy lives and promote well-being for all at all ages, including Universal Health Coverage.

Ayushman Bharat Digital Mission (ABDM):

The Ayushman Bharat Digital Mission (ABDM) aims to develop the digital infrastructure necessary to support the integrated health infrastructure of the country. It aims to bridge the existing gap amongst different stakeholders of healthcare ecosystem through digital highways through a unified digital health ecosystem, including provisions for electronic health records and data sharing.

The regulatory landscape in India, while evolving, needs to accommodate the ever-expanding range of diagnostic services and the technologies introduced. A major issue with regulations is the long-standing systemic delay in the translation of policies to implementation, which affects the population coverage, range of services, cost-efficiency, and quality of care. There are concerns regarding the new technology, AI/ ML, data privacy and security.

3 EVOLUTION OF DIAGNOSTICS

With the innovation boom of the 2010s, there were various digital and technological advancements made within the diagnostic sector. From the early days of computerised tomography (CT) scans and magnetic resonance imaging (MRI) to the cutting-edge applications of artificial intelligence (AI) and telepathology, digital diagnostics has witnessed a rapid evolution. These innovations have not only enhanced the accuracy and efficiency of diagnostic procedures but have also expanded access to healthcare services, particularly in underserved areas. Innovations in laboratory information management systems (LIMS), data analytics, electronic health records, and digital connectivity benefited both technicians and patients, improving efficiency and accessibility.

While innovations like mHealth, digital pathology, telemedicine, health wearables, and AI/ ML were emerging in the Indian diagnostic space, the COVID-19 pandemic accelerated their adoption. The urgent need for rapid and accessible diagnostics spurred unprecedented acceptance of these technologies, transforming the landscape of the diagnostic industry. The pandemic served as a catalyst, revealing the vast potential for digital innovations to revolutionise healthcare delivery and improve patient outcomes.

IMPACT OF COVID-19

Trust on home collection

Home collection revenues (excluding COVID business) grew by **25-30%** for most of the national chains in FY21

Proliferation of molecular testing

Astronomical growth in the number of NABL accredited molecular testing labs- **40 in March CY20 to 1,690 in November CY21**

The additional capacity will remain in place as the pandemic subsides, which could potentially find multiple application for the RT-PCR assay as the dominant method for diagnosing viral infections in India.

Adoption of digital solutions for improving customer experience

Usage of apps (from aggregators as well as diagnostics chains) for booking tests increased as customers would continue to **book tests online** post COVID

Several diagnostics chain players have improved their online presence and invested in automating and expand for customer support team.

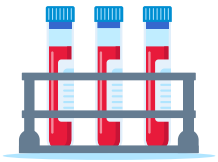
Usage of tele-diagnostics solutions

Multiple players have implemented technology to allow their technicians and pathologists to read images remotely to deliver better utilization of expert resources



IMPACT OF DIGITAL TECHNOLOGIES AND INNOVATION ON THE INDUSTRY

Over the past decade there have been major technological innovations within the diagnostic industry which have impacted the shape and nature of the sector. The innovations have brought in efficiencies in all three stages of the cycle of clinical laboratory testing – pre-analytical, analytical, and post-analytical stages - improved information access, streamlining the workflow as well as reducing the probability of error.



Pre-analytical stage

The diagnostic procedure begins with the pre-analytical stage, which includes all actions taken before the specimen is brought into laboratory.

Important actions include choosing an appropriate test, getting a patient's medical history and identifying information, gathering the specimen, making sure it is handled and transported properly, and then receiving and accessioning the specimen at the lab.



Analytical stage

Following specimen logging, comes the analytical phase, which includes the main testing and diagnostic processes.

Using the proper reagents, preparing samples for analysis, carrying out the testing procedure, maintaining and calibrating the instrument, putting quality control procedures in place, and taking part in proficiency testing programmes are all part of this step.



Post-analytical stage

The last stages of the diagnostic procedure, known as the post-analytical phase, are centered on quality control and result reporting.

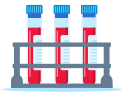
Reviewing and validating test results, determining critical values, interpreting data, delivering results to appropriate individuals, making sure test results are used appropriately, and putting quality assurance procedures in place for continual improvement are critical.

Phases	Consumer Facing	Operations Facing	Clinical Facing
Pre-analytical			
Personalized Testing Packages	✓		
Identifiers for archiving data		✓	
Barcoding		✓	
Realtime Geo-Tracking	✓	✓	
Healthcare focused GenAI chatbots	✓		
Analytical			
LMIS		✓	✓
Track System and Cobots		✓	✓
Teleradiology		✓	✓
Telepathology		✓	✓
AI-based Image Analysis		✓	✓
Biosensors / IoT		✓	✓
Post Analytical			
Customer Relationship Module	✓	✓	
Analysis of Longitudinal Data			✓
Omnichannel report delivery	✓	✓	
Digital Smart Reports	✓		✓
AI developed personalized videos	✓	✓	

Figure 3: List of technological innovations and their impact on service delivery

DIGITAL TECHNOLOGIES AND INNOVATION WITHIN THE INDUSTRY

The innovations within the diagnostic sector can be broadly categorized into addressing the three phases within the diagnostic journey-



PRE-ANALYTICAL STAGE

The pre-analytical phase consists of all steps from identification and selection of an appropriate test, preparing the patient for specimen collection and transport and processing of the specimen prior to the analytical step. Following are the key innovations in the pre-analytical stage:

PERSONALIZED TESTING PACKAGES

Individuals seeking insights into their health in two situations – either to test an illness or to monitor their wellness status. All innovations that inform which diagnostic package is relevant for both these situations fall under the category of personalised testing packages.

Diagnostic laboratories have started offering these personalised test packages in the form of packages and bundles to provide targeted diagnostic results. Customised packages make it convenient and flexible to assess core health parameters. It also helps to identify which tests should be done with limited medical knowledge and budget.

EXAMPLES:

Dr. Dang's Labs has launched a personalised package curator called 'Discover' which is a free-of-cost website that allows the customer to curate test packages based on a quiz regarding your health goals and concerns, medical history etc. to allow for targeted diagnostics.



https://discoverbydrdangs.com/

Max Healthcare offers comprehensive health packages called 'Wellwise' that can be tailored to meet individual health needs and preferences. These are categorised as essential, basic, advanced, exclusive, premium, and total packages.



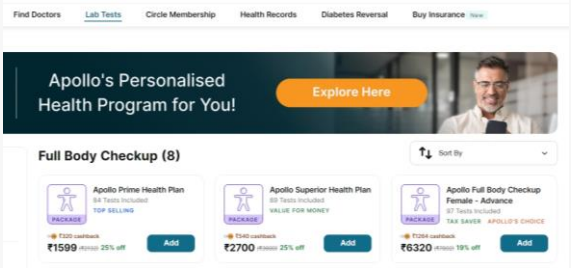
https://www.maxathome.in/sample-collection-lp/

Thyrocare Technologies Ltd. focuses on preventative healthcare with the aim of providing doorstep services. It is known for its extensive range of health packages, including personalised wellness and preventive health checkups. Test packages include 'Thyrocare Aarogyam' packages or packages as required by the consumer.



http://surl.li/wrjbiz

Apollo Healthcare offers 'ProHealth' - a personalised proactive health management programme that offers a physician-led evaluation, predictive health risk analysis and personalised wellness plans based on the test results.



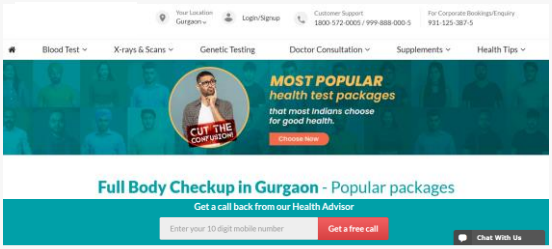
https://www.apollo247.com/lab-tests-category/full-body-checkup

Metropolis Healthcare offers 'TruHealth' - a range of comprehensive tests focused on monitoring the wellness of the patients. Within these packages, a variety of health checkup packages can be personalised according to individual health profiles.



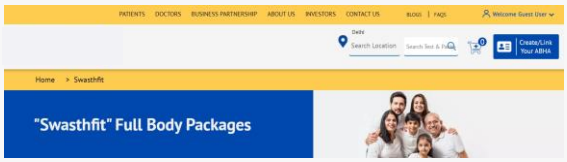
https://www.metropolisindia.com/health-checkup-packages/delhi?wpsrc=google+organic+search

Healthians focuses on home sample collection and offers personalised health packages that include a variety of tests based on individual health requirements. The test packages are categorised based on various parameters such as those that require fasting, monitoring illnesses such as thyroid and diabetes, and tests by unhealthy habits such as junk food, alcoholism etc.

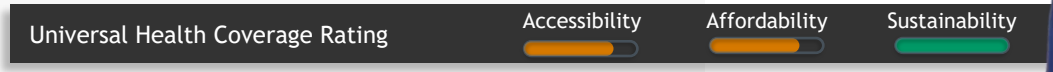


https://www.healthians.com/popular-package

Dr. Lal Pathlab offers 'SwasthFit' health packages which include a complete diagnostic profile of tests to get a comprehensive health evaluation of the body.



https://www.lalpathlabs.com/swasth-fit-packages-full-body-checkups





IDENTIFIERS FOR ARCHIVING DATA

Lab data archiving is the process of storing and preserving the raw and processed data generated by laboratory tests, and analyses. It is essential for ensuring the integrity, reproducibility, and accessibility of lab data, as well as complying with ethical and legal standards. Various chain labs in the country are utilising registered mobile numbers of patients to retain past reports and longitudinal records. This process allows the labs and the patients to access their records freely.

Universal Health Coverage Rating	Accessibility	Affordability	Sustainability

BARCODING

Sample barcoding in labs involves the use of a scanner with barcode labels to update, track and prevent errors in the labelled items at the time of sample collection. Barcode scanners assist in reducing errors during registration and handling samples, for improved accuracy, enhanced traceability, metadata and lineage data logging, efficient inventory management, loading samples swiftly and achieving accurate results with a quick scan.

Universal Health Coverage Rating	Accessibility	Affordability	Sustainability

APPS FOR REAL TIME TRACKING

In the past few years, the Indian diagnostic space has seen the introduction of a real-time sample tracking feature in the sample collection process. This has a two-pronged benefit - the lab can easily track the sample through the process journey and monitor its integrity; patients get visibility on the process and real-time updates regarding the progress of their testing journey. It also simplifies sample transfers between various locations through complete visibility across multiple labs using the real-time LIMS sample tracking feature, as they are collected and progress through the delivery cycle to their destination laboratories. Once securely received, the sample can continue to be monitored, allowing laboratories to maintain inventory and status accuracy along with providing process visibility to the patient.

EXAMPLES:

Healthians allows for diagnostic tests and live reporting of the sample four hours from the collection process. It also has features to track factors like phlebotomist tracking, qualification and experience level of technician, sample journey, etc. The goal is to provide transparency to the patients and personalise the entire sample collection process.

Thyrocare Technologies Ltd. provides real-time tracking of samples through their online portal, allowing both patients and technicians to monitor the status of tests.

Dr. Lal PathLabs offers a sample tracking system that enables patients to track their samples in real time via their website and mobile app.

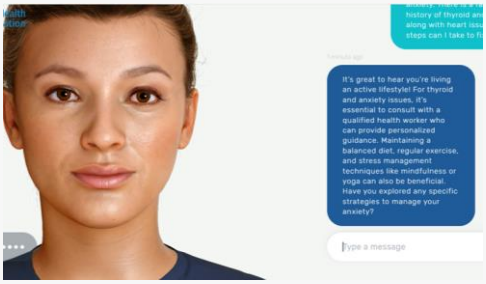
Universal Health Coverage Rating	Accessibility	Affordability	Sustainability

HEALTHCARE FOCUSED AI CHATBOTS

AI-powered Chatbots, by utilising technologies such as structured flows and Generative AI models, can handle a wide range of tasks, including symptom assessment, disease diagnosis, appointment scheduling, patient education and more. These chatbots can act as a preliminary round of screening to prevent randomised testing by adopting a healthcare-focused lens to help patients recognise which tests can be done based on their symptoms and concerns. These chatbots aren't foolproof yet and will require screening from a medical professional; however they can assist in reducing randomised and unrelated tests which may hinder accurate diagnosis.

EXAMPLES:

WHO launched S.A.R.A.H., a digital health promoter prototype powered by generative AI. It can provide information in eight languages across major health topics, including healthy habits and mental health, to help people optimise their health and well-being journey. The generative AI feature assists in providing accurate responses in real-time; engaging in dynamic personalised conversations that more accurately mirror human interactions and provide human-like, nuanced, empathetic responses to users.



https://www.who.int/campaigns/s-a-r-a-h

Universal Health Coverage Rating	Accessibility	Affordability	Sustainability

High Medium Low



ANALYTICAL STAGE

INNOVATIONS IN LIMS

A LIMS or Laboratory Information Management System is a software solution that is used to effectively manage laboratory samples and the associated data, thus standardising operations by maintaining and automating workflows, managing tests, and handling reporting procedures. Overall, a LIMS enhances the efficiency, accuracy, and reliability of laboratory operations, supporting better decision-making and improved outcomes.

01

Cloud based LMIS

Many LIMS solutions are now offered as cloud-based services, allowing for easier access, scalability, and reduced IT overhead.

02

Mobile Access

Mobile applications enable technicians and scientists to access LIMS data on-the-go, facilitating real-time updates and sample tracking

03

Bidirectional interfacing

A bidirectional lab interface allows a bidirectional flow of information electronically to the lab from the EHR and receive test results in EHR once results are available. It ensures real- time data exchange, enhancing efficiency and accuracy by preventing manual errors in workflows. It involves barcoding to relay information within LIS and machinery and eliminates the possibility of manual errors throughout the report generation process by directly feeding the results and values into LIS.

04

Automated Workflows

Innovations in workflow automation streamline laboratory processes, reducing manual errors and increasing throughput.

05

Enhanced Data Security

Mobile applications enable technicians and scientists to access LIMS data on-the-go, facilitating real-time updates and sample tracking

06

Customizable Dashboards

User-friendly interfaces with customizable dashboards provide labs with tailored views of their data and key performance indicators.

07

Interoperability

Improved interoperability with other systems (like Electronic Lab Notebooks and ERP systems) allows for seamless data sharing and enhanced collaboration.

08

Regulatory Compliance Features

Built-in tools for compliance with regulations such as GLP, ISO, and CLIA help labs maintain necessary standards and audits.

Universal Health Coverage Rating — Accessibility — Affordability — Sustainability

High — Medium — Low

TRACK SYSTEMS IN LIMS

Track Systems are integral to modern Laboratory Information Management Systems (LIMS), providing real-time tracking of samples, reagents, and equipment. Live reporting and geo-tracking of the sample offers optimisation for technician-facing processes such as tracking the stage of analytical testing, the status of the analyser, automating steps of the analysis process, etc. This opens the avenue to introduce further opportunities for streamlining the technical workflow.



Real-Time Sample Tracking

Enables laboratories to monitor the status and location of samples throughout the testing process.



Automated Notifications

Alerts technicians and lab managers about sample status changes or delays, enhancing workflow efficiency.



Integrated with barcode/ RFID technology

Uses barcodes or RFID tags for quick identification and tracking of samples, reducing manual errors.



Inventory Management

Tracks the usage and availability of reagents and consumables helping to prevent shortages.



Chain of Custody

Ensures that samples are securely tracked from collection to analysis, maintaining integrity and compliance.

Universal Health Coverage Rating	Accessibility	Affordability	Sustainability

COBOTS

Collaborative robots or Cobots are designed to reduce the physical workload on healthcare providers and technicians by automating repetitive logistical tasks. Within the diagnostics industry, they are placed inside the machine to avoid manual intervention to increase accuracy and efficiency.

Task Automation

Cobots can automate repetitive tasks such as sample handling, pipetting, and data entry, allowing lab personnel to focus on more complex activities.

Increased Precision

Cobots provide consistent and accurate results, minimising human error in laboratory processes.

Enhanced Safety

By taking over hazardous or physically demanding tasks, cobots help reduce the risk of injury to laboratory staff.

Flexible Integration

Cobots are designed to be easily integrated into existing laboratory workflows without significant changes to the infrastructure.

Real-Time Data Sharing

Many cobots can communicate with LIMS and other laboratory systems, ensuring seamless data transfer and real-time updates.

Universal Health Coverage Rating	Accessibility	Affordability	Sustainability

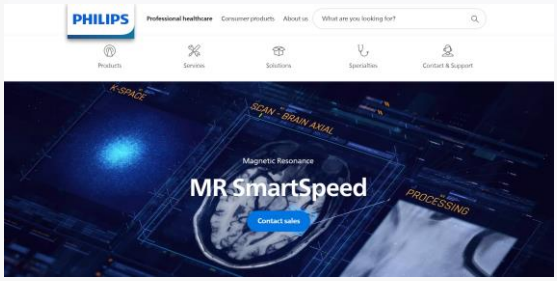
High Medium Low

AI/ ML ALGORITHMS

AI and machine learning (ML) can enhance the analytical phase of diagnostic laboratory work by automating data analysis, improving the accuracy of test results, and identifying patterns in complex datasets. These technologies enable faster processing of large volumes of diagnostic data, reducing human error and turnaround time and assisting in the early detection of diseases. Additionally, AI/ ML algorithms can predict potential anomalies, aiding pathologists in making more informed and precise diagnoses. These are also useful in remote analysis and reporting. AI has been particularly useful in processing biopsy and hysteroscopy samples.

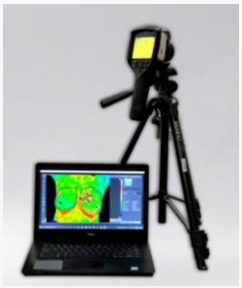
EXAMPLES:

Philip's SmartSpeed is an AI-based imaging technology that leverages a unique Compressed-SENSE-based deep learning AI algorithm to take speed and image quality to the next level for a large variety of patients. The inbuilt AI algorithm is applied directly at the source of the MR signal to enhance the ability to reconstruct a full image from under-sampled data while maintaining virtually equivalent image quality.



https://www.philips.co.in/healthcare/resources/landing/smartspeed

Niramai Health Analytix offers early-stage breast cancer screening solutions through a novel fusion of Artificial Intelligence and Breast Thermal Scans. This technology is a non-contact, non-invasive, portable, safe, automated solution that works for women of all ages. Incorporating AI and ML algorithms to analyse thermal image results with enhanced accuracy, automated methods of quantifying thermal scans and objective assessment of the thermal analysis.



https://www.niramai.com/about/thermalytix/

Universal Health Coverage Rating	Accessibility	Affordability	Sustainability

PoC TESTING

Point-of-care testing encompasses any tests performed at or near a patient and at the site where care or treatment is provided. Point-of-care tests can happen in a wide variety of locations by various people, including self-testing, given their portability. These tests become extremely vital in cases where there is limited availability of services.

EXAMPLES:

Rapid antigen point-of-care test is intended to detect antigens from the SARS CoV 2 virus in individuals suspected of contracting COVID 19. The rapid antigen tests can provide a result within 15-30 minutes. While there was a lot to be desired in terms of accuracy, these served as a first screening that could provide an indication if serious intervention and care were required.

Universal Health Coverage Rating	Accessibility	Affordability	Sustainability





POST-ANALYTICAL STAGE

CUSTOMER RELATIONSHIP MODULES (CRMS)

Customer Relationship Module (CRM) for healthcare assists in storing, managing, and utilising patient information and feedback, such that services can be improved by enhancing patient acquisition strategies. The data and feedback collected can assist in managing interactions, preferences, and purchase history successfully for every individual customer. With the help of customised CRMs, hospitals, laboratory chains and individual labs can have streamlined operations for in- and outpatients, especially for follow-ups and personalised services.

Universal Health Coverage Rating	Accessibility	Affordability	Sustainability

ANALYSIS OF LONGITUDINAL DATA

Longitudinal patient data provides full view of a patient's history with various aspects of healthcare-diagnostics, disease-susceptibility, primary care and treatment, emergency visits, prescriptions, medication adherence, and more. Through analysing the longitudinal data, patient journeys can be made more personalised by predicting potential health issues.

EXAMPLES:

Mesh Bio is a digital health startup that specialises in precision healthcare analytics. In partnership with Roche Diagnostics, they have developed a cardiac patient management digital solution that brings together Mesh Bio's predictive analytics and data generated from Roche Diagnostics' products, and provides clinicians with automated risk assessment and continuous longitudinal monitoring of key biomarkers. Such insights allow healthcare professionals to provide continuous care instead of "one-off" treatments, eventually leading to better outcomes and even disease prevention.

Niramai Health Analytix uses innovative technology for health monitoring, allowing for the collection and analysis of longitudinal health data.

Universal Health Coverage Rating	Accessibility	Affordability	Sustainability

OMNI-CHANEL REPORT DELIVERY

To cater to customer convenience and preference, diagnostics reports are now being delivered through various channels, formats and platforms such as email, WhatsApp, SMS etc. The traditional model had the patient collect reports at the physical lab, however, through digital reports, results can be accessed anywhere, on any platform, at any time.

Universal Health Coverage Rating	Accessibility	Affordability	Sustainability

DIGITAL SMART REPORTS

In contrast to the traditional diagnostic reports, which report the results against the scale, the reports are digitised, and each element of the results is broken down into easily understandable terms; Accompanying it are the explanations of the results and suggestions regarding net steps the patient can take.

Key features include:

- Visualisation of the results in easy-to-understand formats, graphical representations of data, and comparisons with standard values.
- Trend analysis through technical analysis that attempts to predict future disease susceptibility based on recently observed trends and historical data such as medical history, previous test results, family medical history, etc.
- Personalised insights based on the results and trends predicted to ensure tailor-made treatment plans and recommendations for the patient's needs.
- Mobile access of reports makes it convenient for patients and healthcare providers to access them anywhere at any time. Moreover, it takes away the need to carry physical copies and store them.
- Lifestyle recommendations

These features make it easy for the patient to understand their results.

Universal Health Coverage Rating	Accessibility	Affordability	Sustainability

High Medium Low

4 REMOTE DIAGNOSTICS REVOLUTIONIZING DIAGNOSIS BEYOND LOCATION

The COVID-19 pandemic accelerated the use of telehealth and remote diagnostics in India, with healthcare providers adopting telemedicine and remote diagnostics as a way to continue providing healthcare services while maintaining social distancing.

Remote diagnostics enable healthcare professionals to conduct tests and evaluations from a distance, breaking down geographical barriers and ensuring timely access to critical care. This innovative approach leverages advanced communication technologies and digital tools to provide timely and accurate diagnoses, regardless of the location. By integrating remote diagnostics into healthcare systems, practitioners can enhance patient access to specialised care, reduce wait times, and improve overall health outcomes.

Remote diagnostics bridge the gap between patients in remote or underserved areas and specialised medical centres. This democratisation of healthcare allows for more equitable access to diagnostic services, regardless of a patient's location.



TELERADIOLOGY EXPANDING DIAGNOSTIC REACH

Radiological investigations help with an accurate diagnosis, risk stratification, and prognostication of diseases. Teleradiology is a part of the larger telemedicine network which involves the use of telecommunication systems to transmit radiological images from one location to another. The primary source of digital imaging modalities includes digital X-ray [computed radiography (CR) or digital radiography (DR)], CT scanners, MRI scanners, ultrasound scanners, PET-CT scanners, gamma cameras, and angiographic data, etc.

Access to high-quality diagnostics and specialist opinion remains a cause of concern with 60% of Indian population living in rural areas. There is an inequitable distribution of radiology facilities in the country with most of the trained radiologists being concentrated mainly in larger cities and towns. Traditional radiology set-ups are resource-intensive and require substantial financial and human resource investment. Moreover, there is a severely imbalanced ratio of 1:100,000 with fewer than 10,000 radiologists for a billion people[13].

Teleradiology provides an effective solution for bridging the gaps between demand and supply. It has also become commonplace due to widespread availability of computers, high-bandwidth access to the internet, and communications standards in medicine.

TYPICAL WORKFLOW

The typical workflow of teleradiology involves the following steps:

Image acquisition at the imaging centre/ hospital:

During the radiological examination, the images are captured and sent to the DICOM router which standardises the format of images from various modalities such as X-ray, CT, MRI, ultrasound, etc. to ensure compatibility with different systems and devices.

Image Upload and Storage:

The captured images are then uploaded to the PACS server via the internet, where they are stored in a digital format in a secure, centralised repository, such that are easily retrievable.

Image Retrieval and Interpretation:

Radiologists or other authorised users can retrieve the images digitally from the picture archiving and communication systems (PACS) viewer on their DICOM-supported workstations for review, interpretation and diagnosis.

Report Generation:

Once the images are interpreted, radiologists generate a diagnostic report which is often integrated into the PACS system and uploaded to the PACS server along with the images.

Report and Image Archiving:

The images and reports are archived in the PACS server for long-term storage and future reference.

Report Distribution and Collaboration:

Doctors and healthcare providers at the healthcare facility can access the generated diagnostic report through the PACS server to hold consultations.

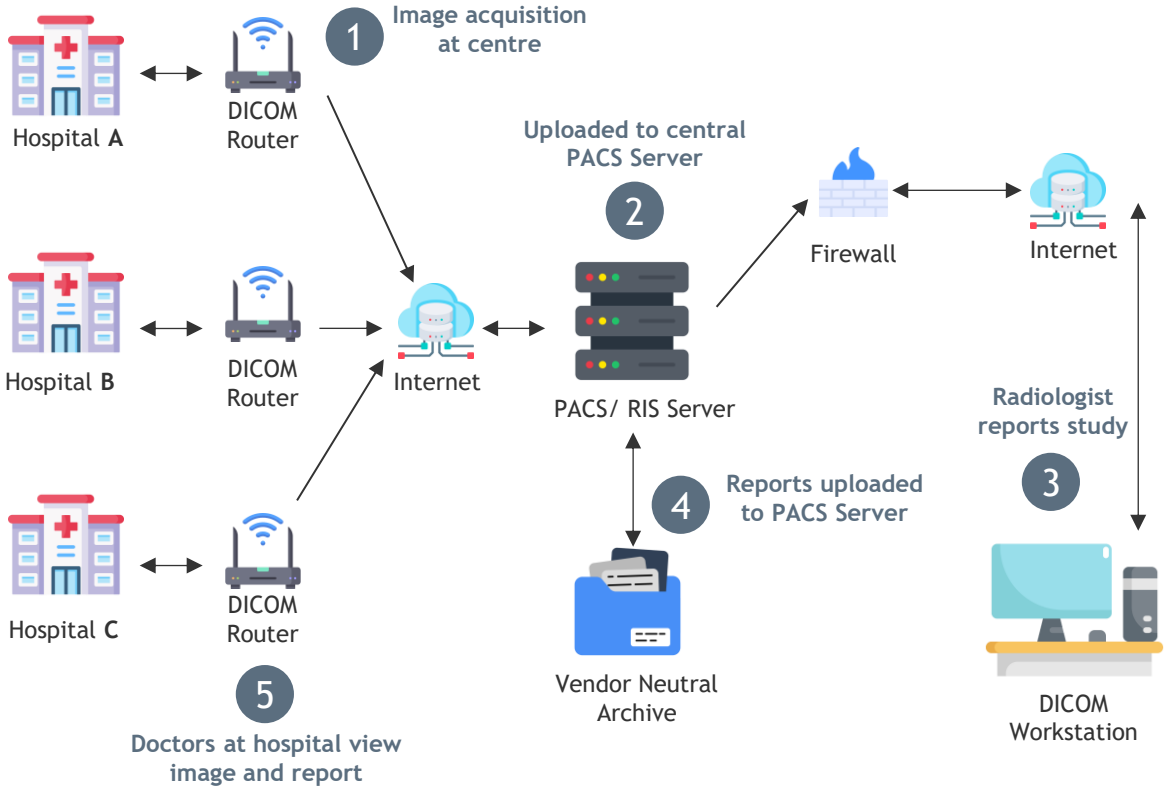
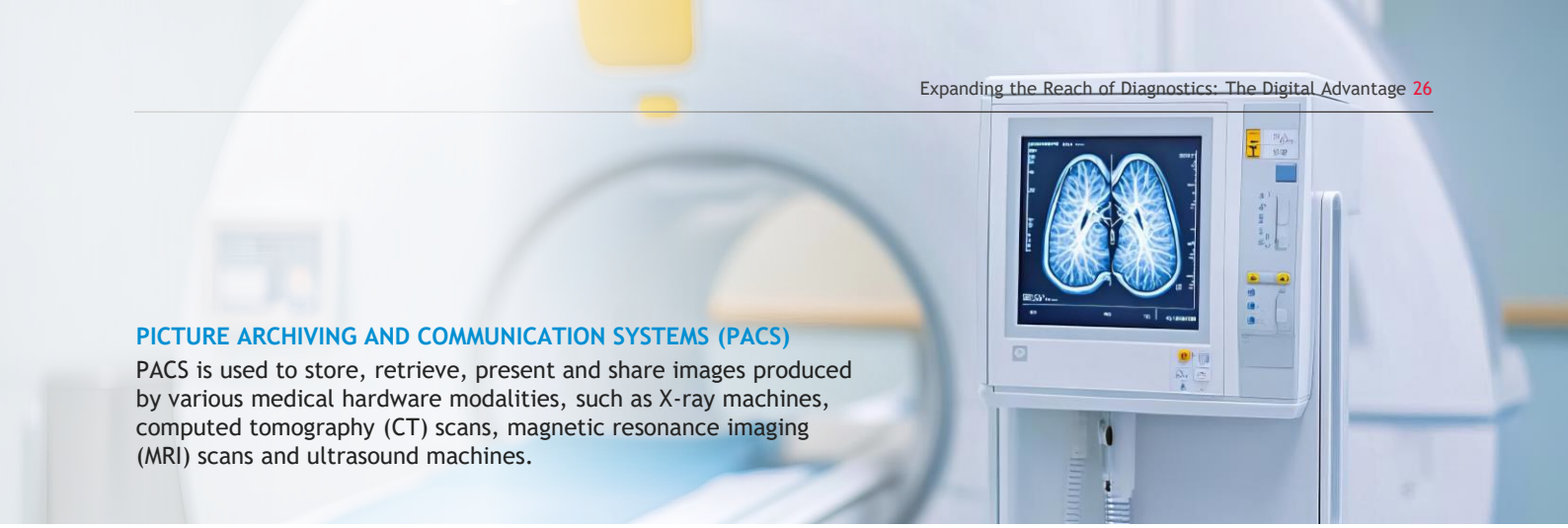


Figure 4: Modern teleradiology workflow
Source: Raster https://www.raster.in/teleradiology.php



PICTURE ARCHIVING AND COMMUNICATION SYSTEMS (PACS)

PACS is used to store, retrieve, present and share images produced by various medical hardware modalities, such as X-ray machines, computed tomography (CT) scans, magnetic resonance imaging (MRI) scans and ultrasound machines.

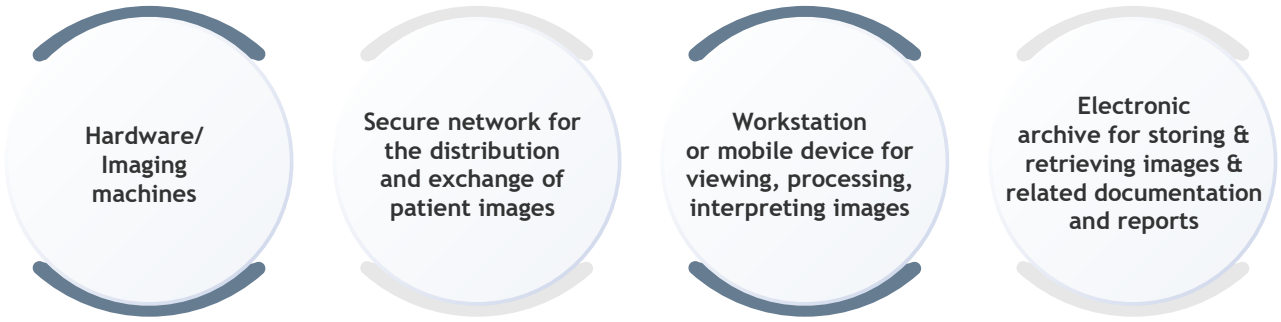


Figure 5: Components of PACS

The modern use of PACS can be attributed to DICOM (Digital Imaging and Communications in Medicine), a standard protocol for the management and transmission of medical images and related data. It enables imaging technologies to connect with and transfer health data to systems at other healthcare organisations. DICOM provides a standard file format and network protocol to enable the storage and retrieval of medical images in a PACS.

Integrating PACS software into existing systems can be expensive, costing approximately USD 40,000 (approximately INR 33,20,000)[14]. The prices can vary based on additional features, storage requirements, and the number of users or centres. While the initial investment in PACS can be significant, the long-term benefits in terms of improved efficiency, accuracy, and access to diagnostic services can outweigh the costs. Government initiatives and subsidies can also help reduce the financial burden for healthcare providers in India.

PACS have replaced conventional radiographic films, hard-copy films and reports; Instead, medical images and non-image data can be securely stored digitally on-premises. The storage media for PACS can be online (cloud storage) or offline (on-premises). It acts as the digital image-viewing hub and serves as the primary communication bridge between radiologists, radiologic technologists and referring providers by enabling all authorised clinicians to access medical images and reports quickly, easily and from virtually any location.

BENEFITS OF TELERADIOLOGY

Given the digital nature of radiologic imaging, which is transmittable, this technological innovation has become extremely valuable in bridging the gap between the demand for and supply of radiological expertise. Teleradiology addresses the issue of lack of availability of timely and accurate diagnostic services. Remote locations that do not have the required infrastructure benefit greatly from this system.

Improving Diagnostic Accuracy and Timeliness

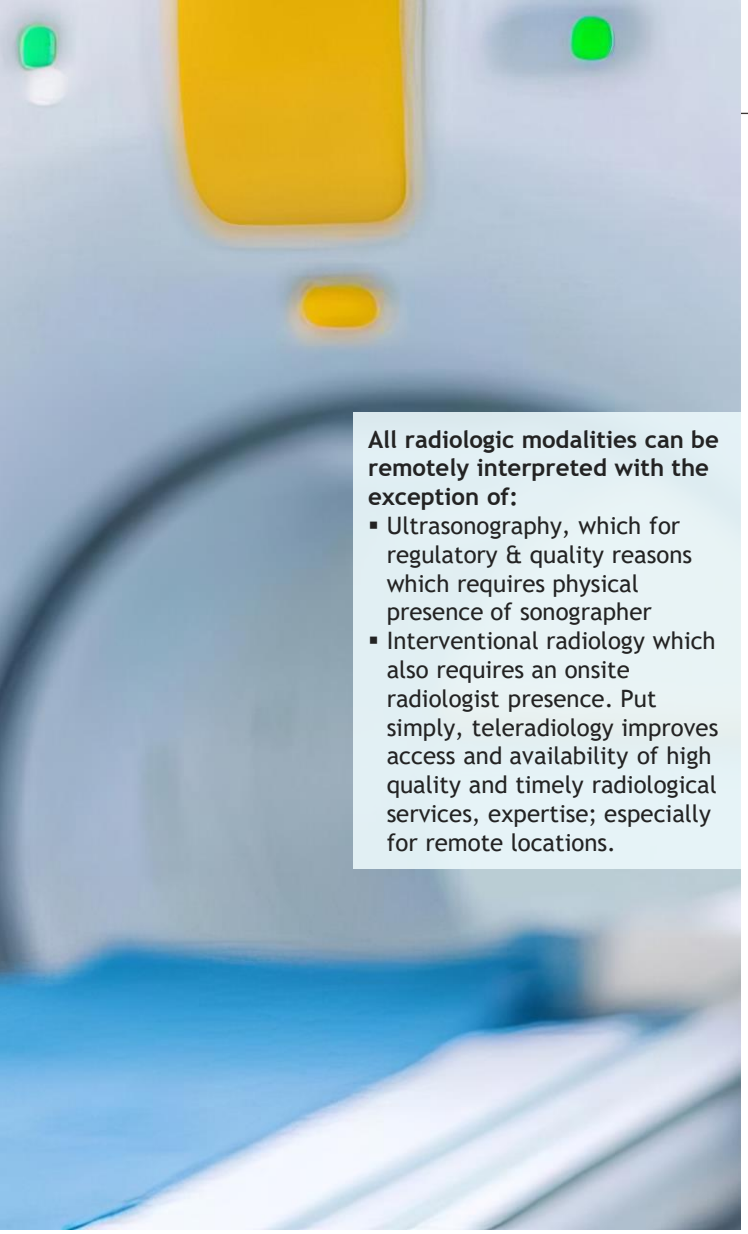
Digital Access to the most updated version of patient's medical images, clinical reports and history can assist in radiologists and other healthcare professionals to expedite and improve the accuracy of diagnosis and treatment, lessening the livelihood of treatment or prescription errors and preventing redundant testing.

- **Access to Medical History**: Digital access to patient medical records facilitates comprehensive reviews, leading to more accurate diagnoses.
- **Reduces Turnaround Times**: Teleradiology can significantly decrease the time it takes to generate diagnostic reports.
- **Emergency Support**: Teleradiology is particularly valuable in emergency settings, ensuring prompt diagnosis and treatment.

Enhancing Efficiency and Productivity

Teleradiology is geared towards enhancing efficiency in reporting given that is primary goal is to generate and deliver an accurate and comprehensive report in the shortest possible time. This includes significant decrease in report turnaround time. With its origins in emergency diagnosis, teleradiology ensures continued availability of services levels specifically in emergency setting by providing prompt diagnosis.

- **Streamlined Workflows**: Teleradiology can optimize workflows by reducing the need for physical transportation of images and reports.
- **Improved Communication**: Digital platforms enable efficient communication between radiologists, referring physicians, and patients.
- **Cost-Effectiveness**: Teleradiology can reduce the costs associated with maintaining on-site radiology departments and hiring additional staff.



All radiologic modalities can be remotely interpreted with the exception of:

- Ultrasonography, which for regulatory & quality reasons which requires physical presence of sonographer
- Interventional radiology which also requires an onsite radiologist presence. Put simply, teleradiology improves access and availability of high quality and timely radiological services, expertise; especially for remote locations.

Addressing the Shortage of Radiologists:

The global shortage of radiologists and skilled personnel has been an underlying issue in providing quality diagnostic services. There are around 20,500 radiologists registered with the India society of Radiology and imaging. This translates to only 1 radiologist per 100,000 population. Additionally, subspeciality radiologists are scarce and are mainly concentrated in large tertiary care hospitals and academic institutions.

- **Wide-scale access**: With teleradiology, accessing radiological expertise is no longer bound by space, time, or speciality expertise thereby making it readily accessible for patients in remote and underserved areas.
- **Global Collaboration**: Images can be shared across the globe for insights and interpretation from experienced personnel and subspecialty experts beyond the bounds of geography.
- **Efficient Utilization of Resources**: Teleradiology systems can be deployed to cater to remote and inaccessible locations equipped with imaging equipment, but no radiologists is available. By connecting radiologists with patients in need, teleradiology ensures mire efficient use of available expertise.

SPECIFIC CHALLENGES AND CONSIDERATIONS

Some of the specific challenges that must be noted:

Image Quality

Ensuring high-quality image transmission and display is crucial for accurate interpretation. Not all equipment have a digital output. Some images need to be converted to a modality-independent DICOM format. High-end digital scanners, specialised software, computed radiology efforts are utilised to ensure format compatibility and digitally available images, in case the images are retrospectively converted. Documentation such as prior reports, lab reports, prescriptions, can be digitised and converted to DICOM so they are available to radiologists along with images while reading. This would enhance the accuracy of the results.

Technical Challenges

Internet connectivity and technical issues can impact the effectiveness of teleradiology systems. Flow of images from source to servers and further to radiologists' workstation must be fast, secure, and reliable. Speedy transmission of images can be achieved through compression and use of specialised software. This ensures availability of images within seconds, if not minutes, which aids in reducing the turnaround time and increasing efficiency.

Regulatory Compliance

Adhering to data privacy and security regulations is essential to protect patient information. The images and data shared through teleradiology servers also contain a significant number of metadata related to patient, study, etc, apart from actual pixel data. Maintaining security and confidentiality of this data during transmission is essential. While many service providers take proactive measures, such as encryption of data, authorised access etc., there is a need for a robust legal and regulatory framework that governs these concerns and must be adhered to.

Availability and Integrity

Availability includes the availability of data when required by an authorised user and quick availability of teleradiology services for quick interpretation. With limited digital infrastructure and connectivity, digital literacy and reliance on traditional testing models, penetration and acceptance of teleradiology services remains a hurdle.

Data security is usually thought of as a triad of Confidentiality, Integrity, and Availability (CIA). Research and developments in data security are central to the development and expansions of teleradiology, Picture Archiving, and Communication Systems (PACS) and e-Health services within the country.



TELEPATHOLOGY:
Revolutionizing remote diagnosis

Traditionally, glass slides are physically transported through commercial courier services. However, there is the underlying risk that during shipping, slides may get lost or damaged; this risk is eliminated by employing telepathology. It is particularly helpful when limited slides are available for review or making recut sections is unfeasible. Telepathology is the practice of remotely interpreting pathology slides using digital imaging and telecommunication technologies. It involves the transmission of digitised tissue samples for examination by pathologists located in different geographical locations.



Figure 6: Use Cases of Telepathology

DIGITAL PATHOLOGY SYSTEM:
Role of digital pathology scanners, image management systems (IMS), and telepathology platforms

Digital pathology system requires an appropriate information system, an image management system, and slide scanners. An ideal digital pathology system would allow all these components to be interoperable and support an integrated digital workflow. Today, Digital Pathology has evolved from a process of scanning slides and viewing images digitally to supporting richer integration and data-exchanges between systems, while supporting extensive and complex workflows.



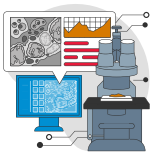
Information Systems

Enable interphase communication with the various enterprise information resources of DPS that include hospital information system (HIS), electronic medical records (EMR), laboratory information system (LIS), and radiology picture archiving and communication system (PACS).



Image Management System

Manages, stores and retrieves large volume of high-resolution digital images, including those generated by digital pathology scanners. Typically includes features such as image annotation, image analysis, and image sharing capabilities which combine viewing functionality with data management.



Digital Scanners

Specialized machines that convert glass slides of tissue specimens into high-resolution digital images. These scanners can image at varying magnifications and are mostly desktop applications installed at workstation, used for annotation and basic metadata management.

BENEFITS OF IMPLEMENTING TELEPATHOLOGY SYSTEMS AND PLATFORMS

Telepathology offers various benefits by enhancing efficiency and effectiveness of pathology services, making high-quality healthcare more accessible and affordable, ultimately improving patient outcomes.

Improved Access to Expertise

Telepathology helps to transcend geographical constraints. It allows healthcare providers to share and access digital pathology images remotely, and thus it is particularly beneficial for rural or under-served areas by opening up access to specialty pathology services and diminishing the requirement for patient travel. It takes care of availability-related concerns due to shortage of skilled technicians, difficulty in transport etc.

Fastest Turnover Time and Efficient Workflows

Telepathology streamlines a workflow by removing the need for physical transport of slides, reduces turnover time, which allows for faster consultation and collaboration, leading to diagnosis and treatment decisions being done more quickly and improving patient outcomes.

Educational Opportunity

Telepathology systems and images can be used by students, trainees, and researchers to gain access to a vast repository of images for educational knowledge and training. The images also offer scope for fine-tuning AL/ML algorithms. This allows and continuous sharing and up-to-date information.

Increased Coordination and Collaboration

Telepathology, being a modality, fosters coordination among health practitioners since numerous experts can image and discuss different pathology images simultaneously. With this in mind, the probability of multi-disciplinary and intraoperative consults, seeking second opinions, and peer review increases, hence enhanced accuracy and consensus in diagnosis



SPECIFIC CHALLENGES AND CONSIDERATIONS

While telepathology is instrumental in improving access, availability and affordability of pathology services, it also entails specific challenges.

Technical Challenges

For continuous uninterrupted telepathology services, robust IT infrastructure, high-speed internet connectivity, compatible software and hardware are necessary. The systems of telepathology are technically intensive to keep running with consistent technical support due to their resource intensity in dealing with issues that may arise.

Digital Image Quality

Digital pathology images have greatly improved with time, but there remains scope for variance in image quality as compared to standard glass slides. Scanner resolution, image compression and colour representation may influence image quality, in turn affecting the accuracy and interpretation of a pathology image, thus, it may lead to diagnostic disparity.

Cost and Investment

Implementing telepathology systems and platforms requires significant financial investment. Expenses include costs to establish digital imaging equipment and infrastructure, IT infrastructure upgrades, software licenses, maintenance costs, etc.

Legal and Regulatory Issues

Telepathology is involved with the transfer and storage of patient data and, as such, brings up issues of privacy and security along with regulatory compliance issues. Proper applicability of data protection measures, secure transmission protocols, and rules and regulations should then be taken into consideration.

Integration with Workflow

To be effective, the digital pathology systems must be seamlessly integrated with the existing systems and IT infrastructure in the laboratory. This includes electronic medical records, laboratory and/ or hospital information systems, image archiving and communication systems along with any other systems used by the laboratory. This needs strategic planning and coordination for integrating telepathology with the pathology workflows. Without proper integration, digital pathology systems can become a bottleneck in the pathology workflow, slowing down the process and increasing the risk of errors.

Limitation of Diagnostic

Although telepathology is proven to be effective for most applications, more complex diagnostic procedures like immunohistochemistry or molecular pathology might require physical examination of the slides or further tests. Thus, telepathology must be employed judiciously, considering the limitations due to remote imaging and the requirements of each case.



REMOTE DIAGNOSTICS: BRIDGING THE GAPS TO ACHIEVE UNIVERSAL HEALTH COVERAGE

Remote diagnostics, leveraging technology to connect patients and healthcare providers across distances, is crucial for bridging the universal health coverage (UHC) gap in India.

REMOTE DIAGNOSTICS: A STEP CLOSER TO UNIVERSAL HEALTH COVERAGE

One of India's top priorities for its healthcare system is Universal Health Coverage (UHC). The use of remote diagnostics present a viable way to overcome major obstacles and advance UHC.

Enhanced Accessibility and Availability: Access to healthcare services can be greatly enhanced via remote diagnostics, especially for underprivileged communities living in rural and isolated places. The Oxford Open Digital Health project highlights how digital health tools might help people get past geographical obstacles. Patients can obtain prompt diagnoses without having to travel large distances thanks to telemedicine consultations and remote diagnostics, which expedites treatment and enhances patient outcomes. In addition, home-based diagnostic services and mobile health platforms can facilitate greater accessibility to healthcare for individuals with impairments, women, young people, and the elderly, who may encounter barriers in conventional healthcare settings.

Improved Affordability: Remote diagnostics has the potential to drastically lower medical expenses. Remote consultations and POC devices reduce overhead costs for patients and clinicians by doing away with the requirement for physical infrastructure and in-person consultations that come with traditional diagnostics. Digital tools also enable healthcare providers to scale their services more effectively, which reduces overall costs and increases accessibility to diagnostics for populations with lower incomes.

Increased Diagnostic Accuracy: Technology is constantly advancing to increase the accuracy of remote diagnostics. AI-powered instruments and advanced imaging systems are better at analyzing data and spotting anomalies. This can result in earlier and more accurate diagnoses, which can eventually improve treatment results and cut down on needless medical expenses related to missed or delayed diagnoses.

Remote diagnostics offer a promising solution for improving healthcare access and affordability in India. However, challenges such as infrastructure, data security, and workforce training must be addressed to ensure their widespread adoption. By investing in these areas, India can harness the potential of remote diagnostics to achieve UHC and improve health outcomes for all citizens.

While remote diagnostics offer significant potential for improving healthcare access and efficiency, several challenges must be addressed to ensure their effective integration into the healthcare system and contribution to universal health coverage (UHC):

REGULATORY HURDLES AND THE NEED FOR CLEAR GUIDELINES

India is navigating a complicated regulatory landscape with gaps in established standards when it comes to remote evaluation. Although some monitoring is provided by current systems such as NABL accreditation, a more thorough approach is required to guarantee quality and consistency.

Clearer Guidelines: Creating regulations specifically addressing PACS and CRM usage, liability, licensing, and quality assurance in relation to remote diagnostics.

Data Security Concerns: Safeguarding private patient information sent and stored during remote diagnostics, and implement robust data security measures in practice.

Mandatory Physician Presence: In distant locations where access to specialists may be restricted, the need for a physician to sign diagnostic reports in person may act as a deterrent to the widespread use of remote diagnostics.

ENSURING DATA SECURITY AND PATIENT PRIVACY DURING IMAGE/SLIDE TRANSMISSION AND STORAGE

Data security and patient privacy are critical concerns in remote diagnostics, where sensitive medical information is transmitted and stored digitally. There is a risk of data breaches, hacking, or unauthorised access.

Absence of Specific Healthcare Regulations: Advocating the development of specific laws and regulations, such as the Digital Information Security in Healthcare Act (DISHA), that regulate data security and privacy in the healthcare sector.

ABDM Compliance: There is a need for diagnostic facilities to become and remain ABDM compliant. Integration with ABHA IDs will set up the foundation and flow for electronic health records in India.

Standardized Security Measures: Encouraging the adoption of standard cybersecurity practices among all healthcare providers, such as safe data storage, encryption, and adherence to global norms such as Health Insurance Portability and Accountability Act (HIPAA).

Regulatory Oversight: Implementation of commonly used security measures varies across healthcare providers in the country, particularly in smaller or rural diagnostic centres. Particularly, for smaller or more remote diagnostic facilities, increased regulatory control is needed to guarantee adherence to data privacy and security laws.

Digital Health Infrastructure: Promoting data exchange and interoperability across various healthcare systems, and investing in creating a standardised digital health infrastructure.

Awareness and Education: Informing patients and healthcare professionals about the value of data security and privacy, and offering training on safe patient information handling procedures.

IMPORTANCE OF HEALTHCARE PROFESSIONAL TRAINING AND COMPETENCY IN REMOTE DIAGNOSTIC WORKFLOWS

The success of remote diagnostics, including teleradiology and telepathology, relies heavily on the competency and training of healthcare professionals operating these systems. Additionally, using sophisticated tools like AI-driven diagnostic systems or handling PACS requires technical proficiency, which is often limited in smaller clinics or rural areas. The lack of formalized training programs on these emerging technologies presents a significant barrier to scaling remote diagnostic services

While the adoption of telemedicine technologies is still evolving, many professionals lack the specific skills required for effectively using digital diagnostic platforms. Radiologists, pathologists, and lab technicians need specialised training to navigate digital workflows, interpret images transmitted remotely, and maintain accuracy in diagnoses. AI-driven diagnostic systems or handling PACS requires technical proficiency, which is often limited in smaller clinics or rural areas. The lack of formalised training programmes on these emerging technologies presents a significant barrier to scaling remote diagnostic services.

Specialized Training: Establishing competency-based training programmes, workshops, and certification courses for healthcare professionals, as well as integrating these skills into medical education, is crucial to ensuring high-quality remote diagnostics in India.

Integration with Medical Education: To guarantee that aspiring professionals are ready, the inclusion of remote diagnostics training in medical curricula is essential.

Certification Programs: It is important to create certification programmes to acknowledge healthcare providers' proficiency with remote diagnostics.

ADDRESSING POTENTIAL DISPARITIES IN INTERNET CONNECTIVITY ACROSS DIFFERENT REGIONS

A major challenge for remote diagnostics in India is the disparity in internet connectivity and digital literacy between urban and rural regions. High-speed internet is essential for transmitting large diagnostic images, such as high-resolution CT scans or pathology slides, which can take significant bandwidth. While urban areas generally have access to fast and reliable internet, rural and remote regions often suffer from slow speeds or inconsistent connections, impeding the timely transmission and analysis of diagnostic data. This digital divide limits the effectiveness of teleradiology and telepathology services in rural healthcare settings, where they could provide critical access to diagnostic expertise.

Infrastructure Investment: To guarantee dependable access for remote diagnostics, improvements to the internet infrastructure, particularly in rural areas, must be prioritised. As the Government pushes for digital health expansion through initiatives like the National Digital Health Mission (NDHM), improving internet infrastructure in underserved areas becomes a key priority.

Public-Private Partnerships: Working with telecom firms would lower costs for patients and healthcare providers while increasing broadband access.

Alternative Connectivity Choices: To close the digital divide, alternative connectivity choices must be explored, including wireless technologies or satellite internet.

Simply put, the legislation to regulate medical laboratories in many Indian states is either outdated or non-existent; some states recently updating or enacting their laws. Universal adoption of external and inter-laboratory quality control mechanisms will help in standardisation and ensuring quality. Clarity and consensus on who can operate medical laboratories and the responsibility of different cadres of technical staff are required.

By addressing these key factors, remote diagnostics can play a vital role in democratising healthcare, moving India closer to achieving UHC by making diagnostic services accessible, affordable, and reliable for all.



5 BEYOND REMOTE DIAGNOSTICS: INNOVATIONS IN DIAGNOSTICS

Innovations such as point-of-care devices, AI-powered diagnostics etc. have enhanced the efficiency of consultations and also aid in swift and accurate decision-making regarding treatment plans. Collectively, this progress is moving the focus from solely diagnosing diseases remotely, to a more holistic approach in healthcare that fosters ongoing engagement and improves overall health outcomes.

These innovations are transforming healthcare by providing greater and timely accuracy, and accessible solutions. Such developments shift from the traditional notion of remote diagnosis as merely a monitoring modality, enabling proactive and personalised healthcare interventions, ultimately improving patient outcomes and reducing healthcare costs.



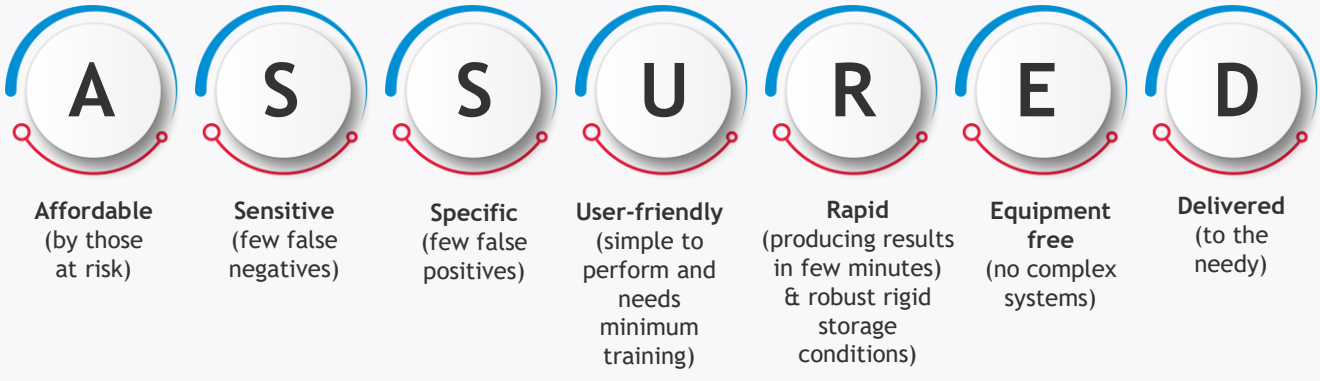
POINT-OF-CARE (POC) DIAGNOSTICS

India has a huge resource gap in delivering and maintaining diagnostic and healthcare facilities in resource-limited rural areas. There are approximately 4 million health workers in India-nearly 60% of which practice in urban areas whereas 70% of the Indian population lives in rural areas[15]. Given the scarcity of medical professionals and a skewed distribution ratio, healthcare providers experience tremendous burden that can cause inefficiency and underperformance. Moreover, complex diagnostic machinery requires regular maintenance by skilled professionals, which adds up to the overall cost of diagnosis.

Existing diagnostic equipment and tools usually require sophisticated infrastructure and space, stable electricity, highly trained technicians and experts, long durations of run time, among other requirements, which are often unavailable in limited resource settings.

Point-of-care (POC) testing refers to obtaining clinical data and parameters at the location of examination. In cases where physically accessing diagnostic facilities is difficult, POC devices offer the opportunity to conduct rapid testing at, or near, the site of patient care.

Taking note of the aforementioned discrepancies, World Health Organization (WHO) has outlined 'ASSURED' criteria for POC tests in resource-limited settings. Any POC devices must be:



Limitations in Indian Healthcare Systems

- Less manpower
- Regulatory issues
- Inadequate infrastructure
- Communication gap between doctors and patients

Implications of Using POC Devices in India

- Low turnaround time
- Personalized diagnostics
- Early detection and proper planning of treatment

Figure 7: Implications of using POC devices

BENEFITS OF POC DEVICES

Cost Effective	POC diagnostic devices offer testing at a low cost which is a major advantage for the Indian population as a large part cannot afford the cost conventional diagnostic.
Faster Turnaround Times and Results in a Single Visit	POC tests reduce the turnaround time drastically, which allows accurate and reliable results to be generated rapidly and can be effective in managing critical cases such as heart disease. Early detection is useful in implementing a treatment plan for proper illness management. Reduced time and rapid results are also beneficial for those travelling from distant locations as the diagnosis is completed in a single visit. Single visit diagnosis also limits the chance of spread of infection to the community, in cases of infection diseases.
Integration with Electronic Health Records (HER)	Integrating with EHR and digital health ecosystem will allow for data storage in central medical database. Data could be shared easily and securely with healthcare providers which optimises patient outcomes and benefits the providers.
Improved Decision-Making	POC devices empower healthcare providers to make informed decisions at the point of care, leading to more effective treatment plans, Faster access to information regarding health parameters can lead to improved patient outcomes by allowing for earlier intervention and reducing complications

CASE STUDY:

COVID 19 RAPID ANTIGEN TEST (RAT)

Numerous innovations in both diagnosis and treatment were anticipated during the COVID-19 pandemic - one such advancement: the utilization of rapid antigen tests (RAT). RATs were innovation, expeditiously implemented, required minimal training to perform, were much more affordable to manufacture than other modes of testing, and typically yielded results within the span of 5 - 30 minutes. Their reduced need for personnel, ease of use and efficiency contributed to COVID-19 management.

RATs can be used for self-testing, in which an individual "collects their own specimen and interprets their test result themselves".



The current trend in POC device innovation is inclined towards smart devices equipped with mobile healthcare provisions. This has the potential to revolutionize personalized healthcare monitoring and management. Several mobile-based devices and applications have been scaled up and commercialized for the monitoring and management of basic health parameters, such as blood glucose, blood pressure, weight, body analysis, pulse rate, electrocardiogram, and physical activity. This also reduces the burden on frontline healthcare providers.

CASE STUDY:

GLUCOSE MONITORING

POC diagnostic devices including glucose monitoring kits have been instrumental in changing the landscape of diagnosis in India. The machine is quite simple and requires a one-step process to obtain the results.

There are a range of devices from simple to complex that provide varying level of detail in glucose monitoring. There are handheld machines such as those manufactured by AccuCheck which provides instant monitoring of glucose levels with a tiny sample of blood, on the spot. On the other end there are complex machines such as Roche Diagnostics India Pvt. Ltd.'s benchtop POC device called 'Cobas b 221 system' which undertakes electrochemical detection of glucose levels.





AI-POWERED DIAGNOSTIC TO IMPROVE EFFICIENCY

In recent years, the healthcare landscape has borne witness to rapid proliferation of AI technologies, ranging from machine learning algorithms to sophisticated deep learning models. The surge in adoption of AI-based models is due to its potential in supporting remote diagnostics, enhancing accuracy, reducing turnaround time, augmenting human capabilities, interpreting complex datasets, and its potential for holistic analysis of various data sources.

IMAGE ANALYSIS AND INTERPRETATION

Enhanced Image Analysis: AI's ability to identify subtle pattern and anomalies in medical images.

Reducing Human Error: Maintaining consistent accuracy in image interpretation, reducing errors due to human fatigue or oversight.

OPERATIONAL EFFICIENCY

Efficiency and Speed: Speeding up the process of reading and interpreting of images

Cost Effectiveness: Reducing healthcare costs associated with diagnostic improves efficiency and accuracy.

PREDICTIVE AND PERSONALISED HEALTHCARE

Assistance in Complex Procedure: Providing precise imaging to aid doctors in complex medical procedures.

Integration with Other Technologies: Combining AI with Technologies like electronic health records for comprehensive health insights.

CLINICAL SUPPORT DECISION

Predictive Analytics: Using historical data for predicting potential health issues for early diagnosis.

Personalized Medicine: Analysing patient-specific characteristics for tailored diagnostic approaches.

Figure 8: The AI domains and functions in diagnostic imaging[16]
Source: AI in diagnostic imaging: Revolutionizing accuracy and efficiency.

The introduction of AI-powered diagnostics has revolutionised data analysis, decision-making, and automation within the diagnostic process. It integrates sophisticated algorithms, predictive models, machine learning and natural language processing to analyse vast amounts of patient data. This in turn enables early disease detection, personalised treatment recommendations, and improved patient management.

Enhanced Diagnostic Accuracy	The integration of AI in medical imaging analysis improves diagnostic accuracy which underscores the potential of AI to augment human capabilities, errors and fatigue to improve outcomes.
Robust Disease Detection	AI-driven predictive models increase accuracy of analysis thereby showcasing potential as an effective screening tool for early disease detection, timely intervention and treatment initiation.
Personalized Treatment Plans	AI-powered treatment recommendation systems can tailor treatment plans, provide personalised interventions and improving overall patient outcomes.
Insights from Unstructured Data	Electronic Health Records (EHRs) can be analysed to extract clinically relevant insights which demonstrates the potential of AI in unearthing valuable information from complex data sources.

Figure 9: Benefits of AI-powered diagnostic services

CASE STUDY:

SIGTUPLE

Diagnosis of several diseases still employs the microscopic testing model. However, microscopy is an entirely manual process, suffering from common pitfalls of inconsistency and inefficiency. Additionally, with limited pathologists, only 1 per million population, the burden increases.

SigTuple is a medtech company that automates microscopy through advanced AI and robotics. AI-assisted digital microscopy, enabled through the cloud for analysis, automates the manual microscopic review of biological samples.

Their product, named 'AI100', is an in-vitro diagnostic device designed to employ robotics and AI to digitise any biological sample on a glass slide to automate manual microscopy (automated cell identification backed with visual evidence and image analysis) and enable AI-aided remote review. Integrating AI with the diagnostics process promotes remote collaboration, takes the drudgery out of the current process, reduces the volume of work for pathologists, reduces turnaround time for patients, among other benefits, ultimately improving patient outcomes.



AI-powered diagnostics can streamline the entire diagnostic experience right from patient-facing services to analysis and results of the test. The cost-effective implications of AI-based algorithms must be noted. Given the proficiency in processing and analysing large volume of data rapidly and accurately, it reduces the need for repeat scans and minimises misdiagnosis risks, thereby reducing overall healthcare expenditure.

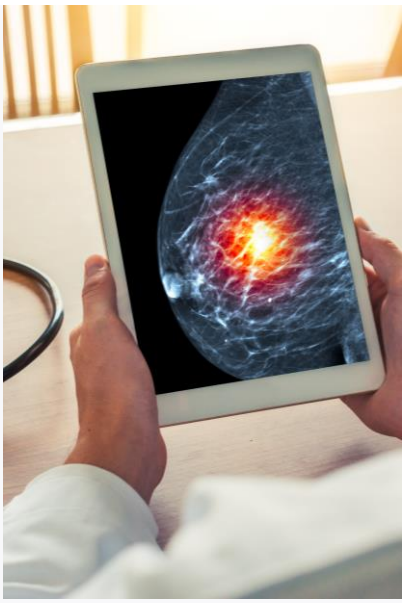
CASE STUDY:

NIRAMAI HEALTH ANALYTIX

Breast cancer is the most commonly occurring cancer for women in India, with one woman in twenty-eight likely to have the disease. Ministry of Health and Family Welfare notes that India ranks highest globally in the number of estimated breast cancer deaths (98,337) for the year 2022 among females. While mammography is the commonly used diagnosis method for early-stage breast cancer, it is radiation-based, hence limited in the frequency of usage. Moreover, mammography is more effective for women over 45 years and is cost-intensive.

The other method, thermography is prone to inaccuracies as interpreting a thermal image involves about 4,00,000 colour points for every person. To encourage frequent screenings and make the process as painless and non-invasive as possible, there is a need to have accurate diagnosis.

NIRAMAI Health Analytix is delivering a machine learning and artificial-intelligence-based breast cancer detection service. Through their 'Thermalytics' technology, a computer-aided AI and ML-based diagnostic engine, temperature variations on the chest are measured, converted into a cancer health report using 20 AI algorithms.

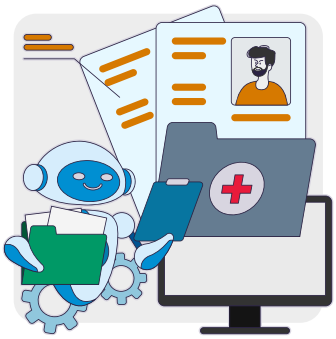


NIRAMAI screenings offer higher accuracy and increased effectiveness as noted in their trials.

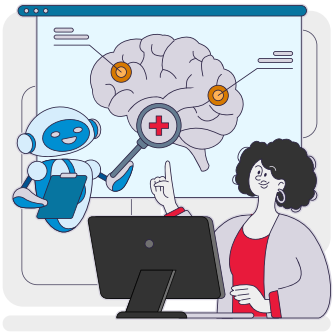
This technology is a non-contact, non-invasive, portable, safe, automated solution that works for women of all ages. By combining a high-resolution thermal sensing device with a cloud-hosted analytics solution, intelligent analysis of the thermal images can be facilitated.

HOW CAN AI-BASED INNOVATIONS BE INTEGRATED ACROSS ALL STAGES OF THE DIAGNOSTIC CYCLE

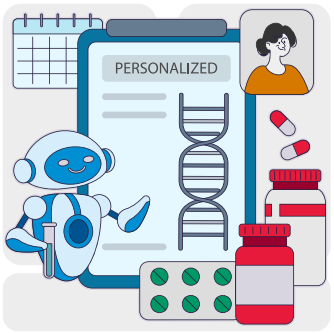
By integrating AI-based innovations across all stages of the diagnostic cycle, healthcare providers can improve the accuracy, efficiency, and personalisation of diagnostic services, leading to better patient outcomes and more effective healthcare delivery.



PRE-ANALYTICAL PHASE	
Patient Registration and Scheduling	AI-powered chatbots or virtual assistants can streamline the patient registration process, providing personalized recommendations and scheduling appointments.
Specimen Collection Optimization	AI algorithms can analyse historical data to optimize specimen collection protocols, reducing errors and improving efficiency.
Personalised Analytics	Improve customer satisfaction by AI chatbots addressing concerns around convenience, transparency and personalized treatment plans.
Predictive Analytics	AI can predict like likelihood of certain disease based on patient demographics, medical, history, and other factors, guiding the selection of appropriate diagnostic tests.



ANALYTICAL PHASE	
Image Analysis	AI-powered algorithms can analyze medical images, such as X-rays, CT scans, and MRIs, to identify abnormalities and support diagnosis, thus significantly reducing the time it takes to diagnose a patient.
Disease Classification	AI can assist in classifying disease based on their patterns and characteristics, improving diagnostic accuracy and consistency. This acceleration is critical as it facilitates convenience but can assist in potentially life-saving scenarios where rapid treatment decisions are needed.
Personalised Testing	AI can recommend personalized testing regimens based on a patient's individual risk factors and medical history.



POST-ANALYTICAL PHASE	
Result Integration	AI can support radiologists and pathologists in interpreting diagnostic results, improving accuracy and reducing turnaround times.
Decision Support	AI-powered tools can provide decision support by suggesting appropriate treatment plans based on diagnostic findings and patient characteristics.
Predictive Modelling	AI ca be used to predict disease progression and outcomes, enabling proactive management and early intervention.

Figure 10: Use case of AI integration in diagnostics cycle

REAL-TIME DIAGNOSTICS USING BIOSENSORS

The advent and proliferation of wearable technology in healthcare have opened a plethora of opportunities for continuous health monitoring, early disease detection, and personalised care delivery.1 Devices such as smartwatches, fitness trackers, tracking apps, sensors, continuously monitor vital signs, physical activity, and even sleep patterns. These devices are designed to be unobtrusive and user-friendly, making it possible to monitor a range of health parameters, including vital signs, physical activity, and sleep patterns in real time.

Today, the range of wearable systems includes micro-sensors, which enable continuous monitoring of various parameters such as heart rate, steps walked, sleep cycles, etc. Through uninterrupted contact with an individual's body, real-time monitoring and timely insights into various health parameters can be achieved.

Based on the Internet of Things (IoT) framework, wearables facilitate data communication both internally within the device system and externally with other devices and software, providing the possibility of healthcare monitoring using wearable devices.

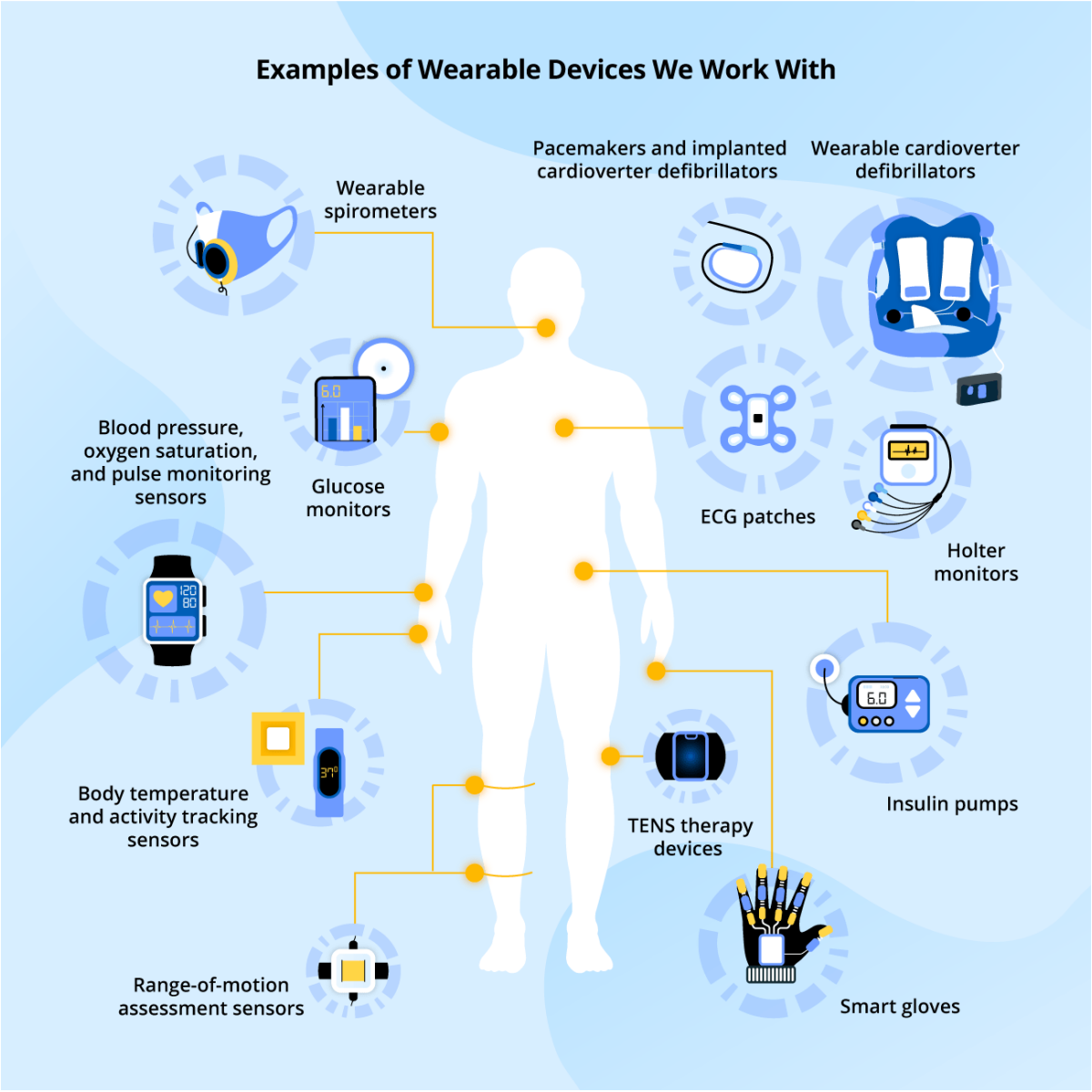


Figure 11: Examples of wearable devices for remote diagnostics and monitoring[17]
Source: Recharge Co (https://rechargeco.com.au/embracing-wearable-technology-for-health-and-wellbeing/)

These data-rich wearables provide valuable insights into overall health parameters and enable early intervention of risks and diseases. Moreover, data from these devices can be integrated to mobile applications and cloud-based platforms to store longitudinal data. Patients and healthcare providers alike can access data, tools, and workflows remotely, through secure, scalable, and user-friendly interfaces that run on smartphones, tablets, or other portable devices. Such wealth of data can enable healthcare providers to make data-driven treatment plans, personalised regimes and move towards preventative medicine.

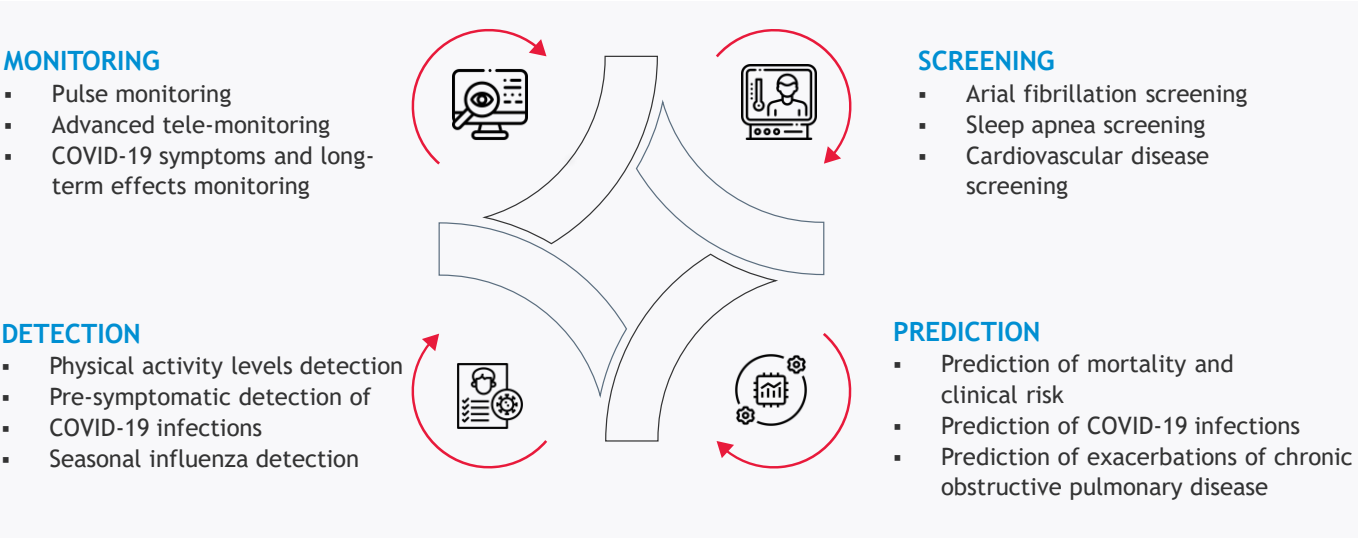


Figure 12: Main functions served by wearables for health

It is essential to note the distinction between consumer-grade and medical-grade wearable devices. Consumer-grade wearables provide users with insights into their daily activities and overall well-being by tracking parameters such as sleep patterns, heart rate, steps walked, etc. These include products such as Fitbit, Apple watch, mobile-based sensors etc.

On the other hand, medical-grade wearables are specifically designed for medical use, undergo rigorous testing and certification processes to ensure accuracy, reliability and regulatory compliance. They also are often used under the supervision of medical professionals. These include products such as insulin therapy pumps, respiratory rate monitors, seizure detection devices, cardiac monitoring and rehabilitation devices etc.

As technology advances, wearables are becoming essential tools for managing chronic conditions and promoting proactive health management. Moreover, they offer various benefits that empower the patient and allow for improved quality of care.

CASE STUDY

INSULIN PUMP SYSTEM

Wearable insulin therapy devices such as continuous glucose monitors and insulin pumps, are emerging as promising effective tools for management of diabetes. Glucose monitors provide continuous tracking of glucose levels through a sensor offering real-time data and alerts for significant fluctuations. Insulin pumps administer insulin through a subcutaneous catheter, allowing for tailored dosing as per current needs based on data from continuous glucose monitors.

Medtronic in India offers a complete set of wearable devices including reservoir, insulin pump, continuous glucose monitoring and a tracking platform automating insulin delivery by creating an artificial pancreas system. Research highlights their effectiveness in improving glycaemic control and reducing risks associated with glucose level fluctuations.



LIQUID BIOPSY

Liquid biopsy has been gaining widespread acceptance for diagnosis across medical fields, particularly in oncology. Unlike traditional biopsy procedures that require obtaining tissue from surgical procedures that may require aesthetic and risk complications, the liquid biopsy testing approach involves testing blood, urine or cerebrospinal fluid for circulating tumor cells (CTCs), cell-free DNA (cfDNA), exosomes and other biomarkers.

Through analysis of sample of blood, urine, or other body fluid, which circumvents the need for an invasive surgical procedure, we are able to detect minimal residual disease thus leading to early detection, to predict progression, monitor treatment progress, identify mechanisms of resistance, allowing to re-orient treatment strategies in a timelier manner. Moreover, it also complements surveillance strategies to monitor disease evolution and treatment response in real-time, thereby improving overall health outcomes for patients.

Non- Invasive

The big differentiator of the liquid biopsy is that is not considered invasive. To undergo a biopsy procedure, you will need to undergo a surgical procedure (or some variation) which increases the patient's discomfort, risk of complications and recovery time.

Early Detection

Liquid biopsy can detect mutations that cause cancer and other genetic changes in early stages, sometimes before the patient has signs of symptoms, or the tumor can be seen on imaging, which allows for the earlier treatment and better outcomes.

Real-Time Monitoring

Patients may undergo liquid biopsy testing repeatedly because it is simple to perform, as a result, the patient may have the opportunity for real-time monitoring of their disease and/ or their response to treatment. Clinicians can monitor or observe changes in tumor genetics or earlier signs of replace.

Robust Genetic Information

Liquid biopsy provides a fuller profile of the tumor genetics by detecting multiple mutations, and is a powerful diagnostic tool used for personalized medicine because it identifies about specific mutation or biomarker that guides target therapies.

Accessible for Tumors

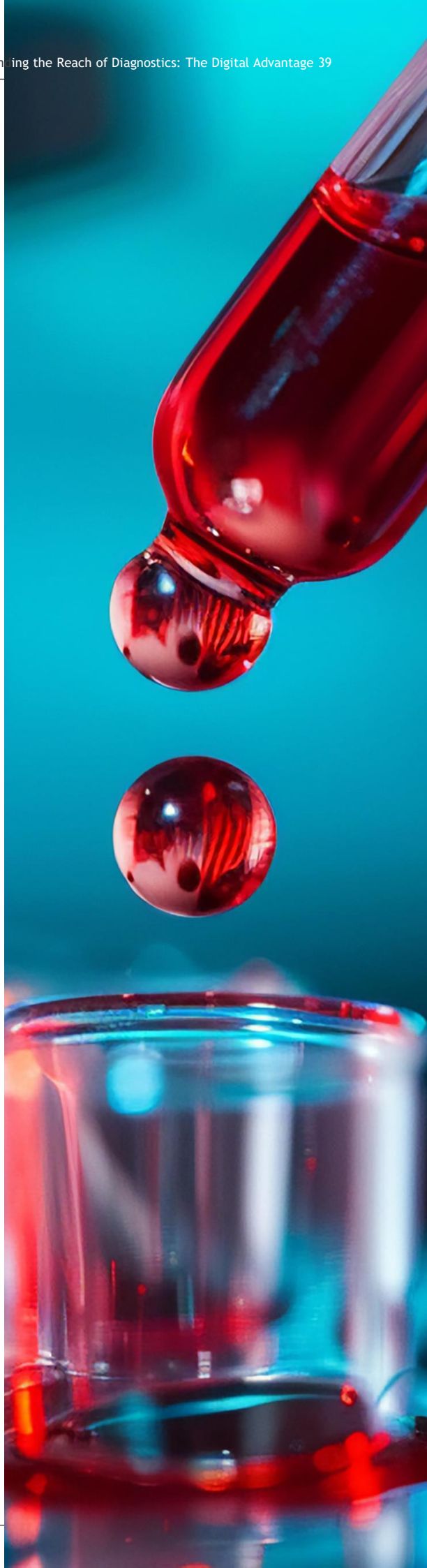
In tumor that resides in difficult and dangerous locations to access (ex. in brain or lungs), obtaining important diagnostic information on the tumor through liquid biopsy is now an accessible alternative.

Cost-Effective

Liquid biopsy is more effective as it avoids complex surgical biopsies, especially for patients who have to have testing repeatedly.

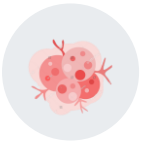
Minimal Recovery Time

Unlike tissue biopsies which can require some recovery (or significant recovery) and have virtually no recovery time that will allow patients to facilitate health.





While liquid biopsy is most widely used within oncology, it can provide diagnostic support across a variety of medical fields, offering fundamental information that aids in diagnostics, treatment planning, and monitoring of diseases.



Cancer
- Early Cancer Detection (MRD)
- Mutation Profiling for Targeted Therapies
- Monitoring Treatment Response
- Detecting Recurrence or Metastasis



Prenatal Testing
- Fetal Genetic Screening
- Early Sex Determination



Transplant Medicine
- Monitoring Organ Rejection
- Monitoring Graft Health



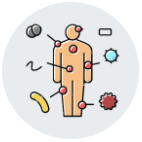
Infectious Disease
- Detecting Pathogen DNA/RNA
- Viral Load Monitoring



Neurological Disorders
- Detect biomarkers of Alzheimer's and Parkinson's Disease
- Detect Tumor DNA



Cardiovascular Disease
- Identifying Genetics Risk Factors
- Monitoring Heart Transplant Rejection



Autoimmune Disease
- Tracking Disease Activity

GENOMICS AND MOLECULAR DIAGNOSTICS

Technological advancements within genomics and molecular testing have revolutionised the field of diagnostics by facilitating greater accuracy, personalisation, and earlier disease detection. These advancements bring together genomics, molecular biology, bioinformatics, and digital technologies to provide better detection and interpretation of genetic and molecular markers of disease. Molecular testing is evolving rapidly, with an increasing number of tests available. In general, molecular testing falls into two broad categories with many different subtypes.

Genome sequencing and testing		Genetic markers	
Analyse the genetic material of a cell, either in whole or in part, to look for specific genes or gene changes.	**Examples** Test for pregnancy, predicting a person's response to certain medications.	Examine specimens for the presence of embedded genetic signals that strongly correlate with suspected disease	**Examples** COVID-19 PCR testing, testing on certain types of cancer tumors

Figure 13: Types of Molecular Testing

Genetic testing which used to be a niche speciality for rare disorders has transformed with a broad scope of applications for complex disease and personal use. Clinical genetic testing's applications span across medical disciplines such as newborn screening for highly penetrant disorders, testing for inherited disorders, predictive and pre-symptomatic testing for adult-onset and complex disorders; pharmacogenetic testing to guide individual drug dosage, selection, treatment.

Test	Description	Example
Newborn screening	Targeted tests for recessive genetic disorders	Phenylketonuria, cystic fibrosis, sickle-cell anaemia
Diagnostic testing	Confirmatory test or differential diagnosis testing for a symptomatic individua	Skeletal dysplasia, thalassaemia, craniosynostoses
Carrier testing	Targeted testing for asymptomatic individuals potentially carrying one or more recessive mutation	Cystic fibrosis, thalassaemia, Tay-Sachs disease
Predictive testing	Tests for variants causing or associated with diseases or disorders with a hereditary component, usually with adult-onset symptoms	Most cancers, cardiovascular disease, diabetes
Pre-symptomatic testing	Tests for variants causing or associated with diseases or disorders known to be inherited in the family, often with adult-onset symptoms	Huntington's disease, haemo- chromatosis, Alzheimer's disease
Pharmacogenetics	Targeted tests for variants associated with pharmaceutical dosage choice or adverse reactions	DNA tests for abacavir, warfarin, carbamazepine

Table 1: Examples of Genetic Testing[18]
Source: Molecular genetic testing and the future of clinical genomics

Recent breakthroughs in genomics, molecular biology, and next-generation sequencing (NGS) have made liquid biopsy more accurate, sensitive, and accessible.

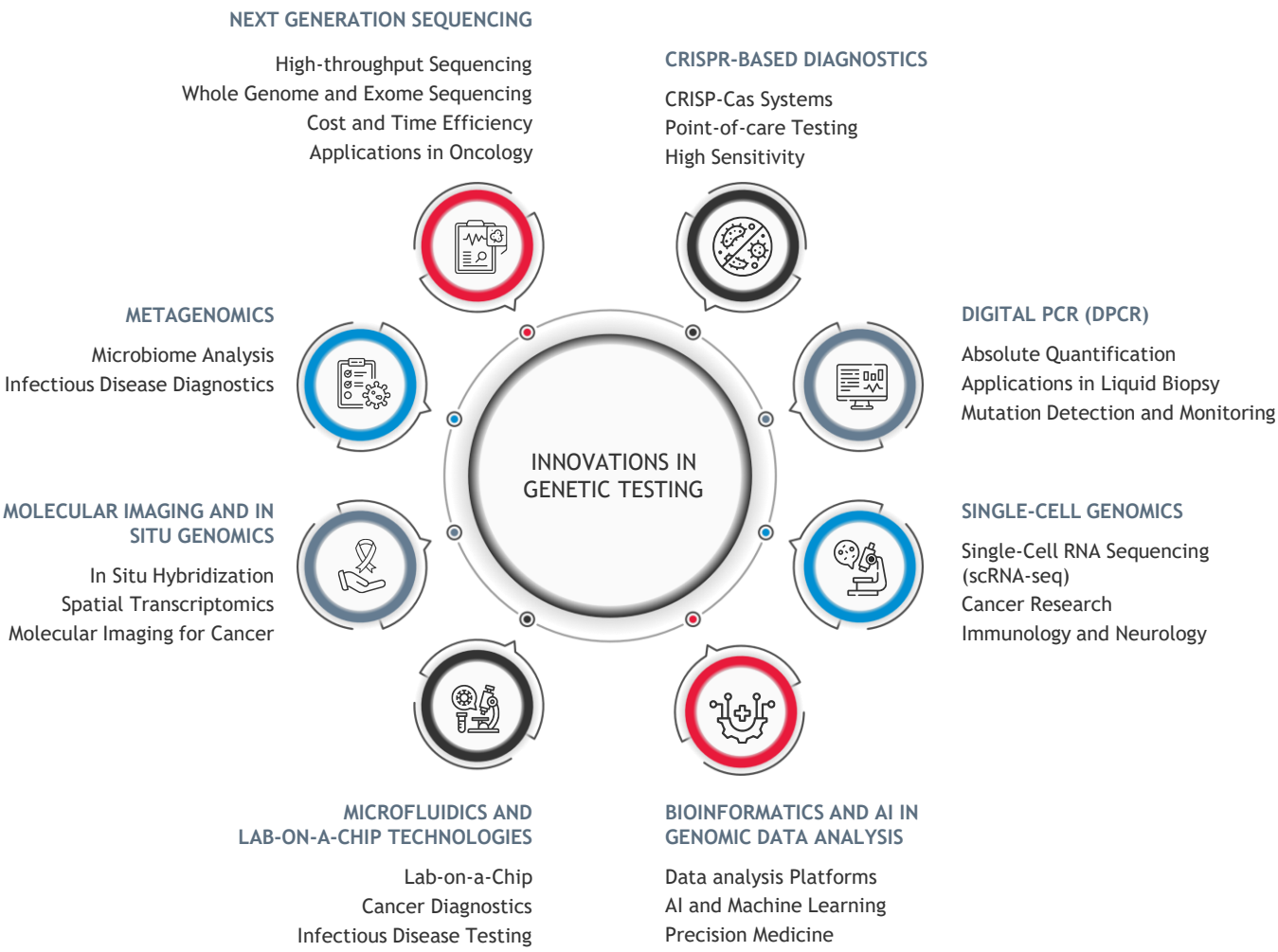


Figure 14: Innovations in Genetic and Molecular Testing

Progress in genomic and molecular diagnostic science is ushering in a new era for precision medicine and personalised healthcare. Emerging platforms such as NGS, CRISPR-based diagnostics, single-cell genomics, AI-enabled analysis, liquid biopsy will enable detection, monitoring, treatment of disease with unprecedented accuracy & greatly increase the speed and efficiency of these processes. Innovations in diagnostics will enable earlier disease detection, increasingly personalised treatment strategies, better patient outcomes in fields of medicine such as oncology, infectious disease, and genetic disorders.



6 REGULATORY DUE DILIGENCE

Digital transformations have been accepted and adopted within the healthcare and diagnostic space as a fact of the information age. M-Health, digital pathology, digital radiology, telemedicine, health wearables, digital and social connectivity, big data analytics, AI-based diagnostics, and electronic medical records are some of the key emerging digital health technologies.

While these technological advancements have been pivotal in revolutionising access to diagnostic services by providing value to customers, there are ethical, legal and security concerns that surround these technologies.

Data security, data quality, interoperability, patient privacy and confidentiality are big concerns that must be addressed within the regulatory landscape to ensure that the adoption of the technological advancements does not flout the awareness, trust, accountability and responsibility that accompanies the use of these innovations. Currently, the regulatory landscape for data protection includes a few monumental laws and regulations that attempt to address security and privacy concerns.

IT ACT

The IT Act, the SPDI Rules of 2011 and the intermediary guidelines comprise India's general framework for data protection. The IT Act's enhanced security safeguards make online transaction and electronic data transfers safe. It governs various internet activities, including the legal status of electronic records and the authentication of digital signatures, a wide range of cybercrimes- including hacking and denial-of-service attacks.

DISHA ACT

The DISHA concept, developed by the MoHFW, aims to safeguard healthcare data in India, ensuring patients retain ownership of their health information. It protects data during its flow in the healthcare system, establishing a national and state digital health authority, implementing privacy and security measures, and regulating the storage and exchange of electronic health information.

DPDP Act

This act governs how personal data is handled in India. It aims to protect people's privacy while establishing a framework for data accountability and governance. Its key purpose is to increase accountability and responsibility for enterprises that operate in India, such as mobile app developers, Internet services providers, and companies that collect, store and handle personal data on Indian citizens. The DPDP Act, is focused on digital personal data, does not cover non-personal data.

NATIONAL DIGITAL HEALTH AUTHORITY

The MoHFM aims to establish a statutory National Digital Health Authority (Neha) to promote e-health standards, enforce privacy safeguards, and govern electronic health record storage and sharing. NeHA will develop India's integrated Health Information System (IHIS), acting as a regulatory and standard-setting body. The DISHA seeks to legally establish NeHA and facilitate online patient data exchange, reducing duplication of efforts.

CONSUMER PROTECTION ACT (CPA)

The Consumer Protection Act (CPA) sets a structure for resolving consumer disputes and safeguards consumer interests. The CPA was developed to provide clients with a mechanism to settle grievance without having to go through the time-consuming and expensive process of filing a civil lawsuit.

Regardless of the significant advancements in digital health and diagnostics in India, the sector faces a critical challenge in the form of inadequate regulatory frameworks for data protection, security, and privacy.

The rapid adoption of telemedicine, remote diagnostics, and digital health platforms has led to an unprecedented volume of sensitive patient data being collected, transmitted, and stored online. However, there is no comprehensive legislation in place to govern the secure handling of this data.

The absence of a robust regulatory framework leaves critical gaps in ensuring that patient data is protected from breaches, unauthorised access, or misuse. Current laws, like the Information Technology (IT) Act, are insufficient for the specific needs of the healthcare sector, which demands stringent privacy safeguards and clear guidelines for the secure use of health data.

Without well-defined regulations, the growing reliance on digital health technologies risks compromising patient trust, undermining the potential of innovations that could revolutionise healthcare delivery in India. To ensure sustainable growth, the government must prioritise data security regulations that can support the digital evolution of the healthcare and diagnostics industries while protecting patient privacy.

India has a comprehensive, yet complex policy and regulatory framework geared towards the diagnostic and medical sector within the country. The current regulatory and policy framework for medical devices and diagnostics is spread across several legislations, guidelines and policies. The Drugs and Cosmetics Act, The Clinical Establishments Act and Medical Devices Act are the cornerstones of this framework.

These are governed by a host of regulators including the Central Drugs Standard Control Organisation, National Pharmaceutical Pricing Authority and State Licensing Authorities. Additionally, some specialty devices like radiological equipment are also under the purview of authorities such as the Atomic Energy Regulatory Board.

CHALLENGES AND CONSIDERATIONS IN DIGITAL DIAGNOSTICS REGULATIONS

Despite remarkable progress in designing and constructing the framework for digitisation of healthcare ecosystem, the complex and rudimentary nature of the policyscape introduces various complexities and hindrances to business and innovation within the industry. A significant revision of the country's legal and regulatory framework is required to ensure that it can adequately address concerns that accompany the technological innovations and digitisation such as compatibility, cybersecurity, and technical readiness.

Need to Revise and Interpret the Regulations to Accommodate New Technologies and Models of Data Collection and Distribution

Regulations for remote diagnostics remain, for the moment, very outdated. The standards, criteria and rules prescribed by regulatory bodies remain archaic in that there is no provision for accommodating the technological advancements and innovations within the diagnostic laboratory systems and devices such as data repository, POC and wearable devices, AI/ML usage within medical devices and diagnostics. As the industry continues to evolve, so will the regulations that ensure patients receive high-quality, accurate results. Until then, labs will have to operate from outdated rules and regulations while they continue to innovate.



Striking a Balance Between Security and Innovation

There is a significant gap in the regulations and guidelines that fails to acknowledge concerns regarding data security, data collection, archiving and hosting. The lack of clear guidelines regarding the nature, duration and use of data within the diagnostics space also hinders innovation and adoption of technological advancements given the murky nature of the policy and regulation landscape. For instance, the emerging technologies focusing on infection screening and detection require image archiving. These are also crucial for AI/ML enhancements yet there is a dearth of regulatory evolution regarding these issues.

Standardization and Interoperability

The present regulations, guidelines and policies are fragmented in nature, i.e., while the landscape attempts to cover all bases related to diagnostic and medical devices there is no uniform body or rules that comprehensively lay out everything in one place. There are different iterations and nuances laid out in various policies, acts and regulations that make it difficult to enter, navigate and innovate within the diagnostic space. There is a need for standardisation and an easy-to-understand set of rules and regulatory authorities. Moreover, while there are ambitious initiatives such as ABHA ID and EHRs that are guiding the public sector's vision for healthcare, the regulations do not yet accommodate issues of interoperability at a larger scale. For instance, the eSanjeevani platform's data is integrated with ABHA IDs, yet the provision and clearly laid out rules are lacking across the industry, with the diagnostics space especially left out. While attempts to undertake this have been made with objectives laid out in the National Medical Devices Policy 2023, there is a long way to go in its actualisation and implementation.

Need for Involved Regulation and Monitoring of Labs

As much as voluntary accreditation and self-regulation efforts have been recognised as legitimate by the Government, there is a glaring absence of an over-arching, all-comprehensive framework, which specifically regulates diagnostic labs and devices in India. Given the voluntary nature and unsupervised implementation of the accreditation rules, there is a lack of uniformity in certified labs and medical devices. For instance, there are 1.1 lakh medical labs within the country but only 8633 labs are NABL accredited. Similarly, there are only 18 CDSCO-certified medical testing labs within the country. There is a lack of clearly defined penalties and fines around malpractices, fake certifications and manufacturing of subpar quality medical devices which do not provide a strong deterrent.

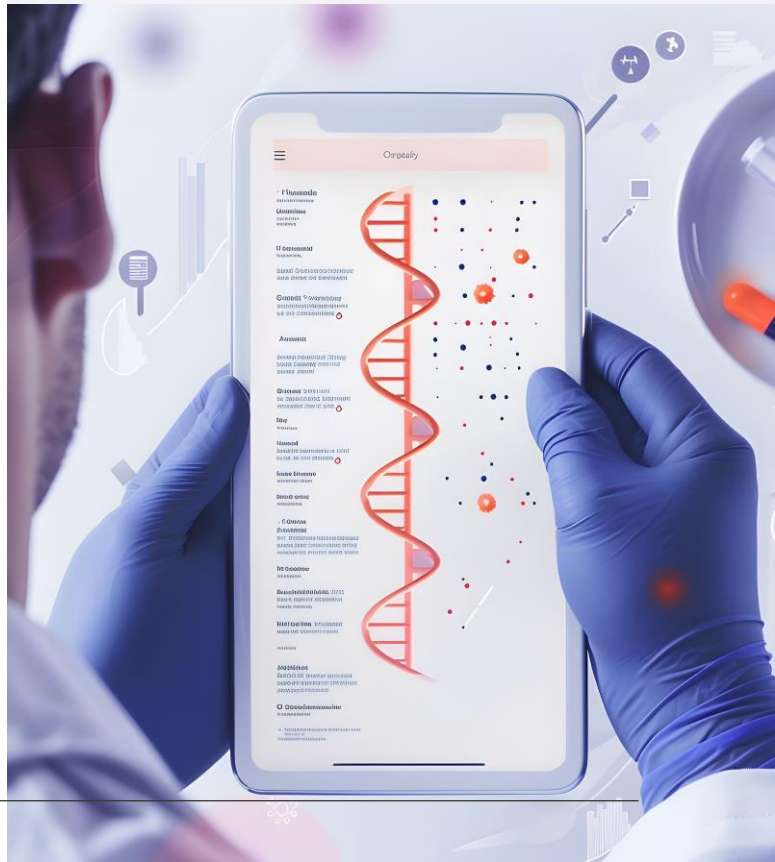
There is an urgent need to adapt to the evolving diagnostic landscape, given the rate of acceptance and adoption of the digital innovations. If we wish to provide universal access to healthcare and diagnostic services within the country, explicit and clearly demarcated rules and regulations are necessary, given the sheer volume of legal, structural, and ethical concerns around digital health.

NAVIGATING THE LANDSCAPE: A COLLABORATIVE APPROACH

Currently, there are little to no statutory regulations or official guidelines specific to telehealth practice within the country. While the legal and regulatory framework for telehealth in India is still underway, there have been increasing attempts to bring in comprehensive regulation and promotion of telehealth in the country.

The pandemic provided an impetus to address the concerns regarding the lack of regulatory support for technological innovations within the diagnostic sphere. With the speed at which the virus was spreading throughout the country, healthcare providers and technology companies recognised there was an urgent need for scalable, efficient diagnostic solutions. Additionally, lockdown and restrictions highlighted the importance of using telemedicine and remote diagnostics when delivering health services, thus pushing digital health solutions to gain higher acceptance and adoption to enable patients to access diagnostics without leaving their homes.

This urgency and realisation kindled a shared sense of purpose that sparked collaboration among stakeholders previously disparate in their focus. For instance, the pandemic forced agencies of the Government, healthcare providers, and the technology sector to collaborate in the creation and implementation of digital test kits: quick antigen tests as well as RT-PCR test kits. This collaboration was necessary to ensure that, in a matter of months, innovative technologies were adopted faster than ever before, and the diagnosis process became easier and faster and led to prompt identification and isolation of infected persons.



Similarly, during the pandemic, the Government mandated all players - public and private - in the diagnostic space to load any data captured to a common portal. This assisted in ease of viewing the status of incidence. This exercise was the impetus to bringing ABHA IDs into the ABDM ecosystem for the creation of EHRs for every patient irrespective of location and nature of the diagnostic facilities.

GUIDELINES FOR TELEMEDICINE

In March 2020, as a joint effort, the Medical Council of India (MCI) and NITI Aayog released the guidelines which provide a framework for telemedicine practice. It covers topics such as patient consent, privacy & confidentiality, prescribing medication, documentation &prescribes adherence to existing data protection laws.

NATIONAL DIGITAL HEALTH AUTHORITY (NeHA)

The Ministry of Health and Family Welfare (MoHFW) has suggested establishing NeHA, it would support, monitor, establish policies to lead India's transition to digital health system and be responsible for developing India's transition to digital health system & be responsible for developing India's integrated Health Information System

DIGITAL PERSONAL DATA PROTECTION ACT, 2023

Outlines laws governing handling of personal data within the country, it aims to protect people's privacy, establish framework for data accountability and governance. Upon DPDP Act's implementation, the information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data of Information) Rule, 2011 (SPDI Rules) and Section 43A of the IT Act will be superseded. Currently theses legislation address the legal and ethical challenges in digital health.

DIGITAL INFORMATION SECURITY IN HEALTHCARE ACT

Government introduced the act with of protecting privacy and maintaining the confidentiality of the patient's information.

AYUSHMAN BHARAT DIGITAL MISSION

In 20201, under National Digital Mission, ABDM was introduced with an aim to build comprehensive digital health infrastructure across the country. The ecosystem aims to leverage data, information and infrastructure services to facilitate interoperable, secure, confidential, private and standards-based digital systems to utilise health-related personal information to provide efficient, accessible, inclusive, affordable healthcare serbices. The objective is to bridge the existing gap amongst different stakeholders of healthcare ecosystem through integrated digital solutions and pathways.

Figure 15: Government Initiatives to Include Latest Innovative Developments

Further, the Government bodies also collaborated and brought in various initiatives and regulatory attempts to address the gaps.

The public-private partnerships that emerged during the pandemic proved that true and promising collaboration can drive innovation and better health outcomes. This was a bringing-together of Government agency expertise, healthcare providers, and tech companies to develop and deliver effective diagnostic solutions at speed.

The Government of India launched the Ayushman Bharat Digital Mission in 2021, under the National Digital Health Mission with the aim to build comprehensive digital health infrastructure across the country. It is a collaborative effort by the Government to address the challenges in the digital landscape. The objective is to bridge the existing gap among different stakeholders of healthcare ecosystems through integrated digital solutions and pathways. The ecosystem aims to leverage the data, information, and infrastructure services to facilitate interoperable, secure, confidential, private, and standards-based digital systems to utilise health-related personal information to provide efficient, accessible, inclusive, and affordable healthcare services.

While there is some progress in addressing the gaps as the Government introduces various initiatives and programmes to address the concerns surrounding technological innovations within the diagnostic space, there is a need for collaboration with the private sector to ensure that the efficacy of these programmes and initiatives is not limited.

The current regulatory and policy landscape continues to address the concerns of patient privacy, consent, storage and sharing of personal data etc. being addressed in a piecemeal fashion. To actualise the digital health vision that has been the defining feature of this decade, there is an urgent need to have a comprehensive legal and regulatory framework in place that can encourage more innovation in the field while ensuring trust, transparency and accountability for the stakeholders.





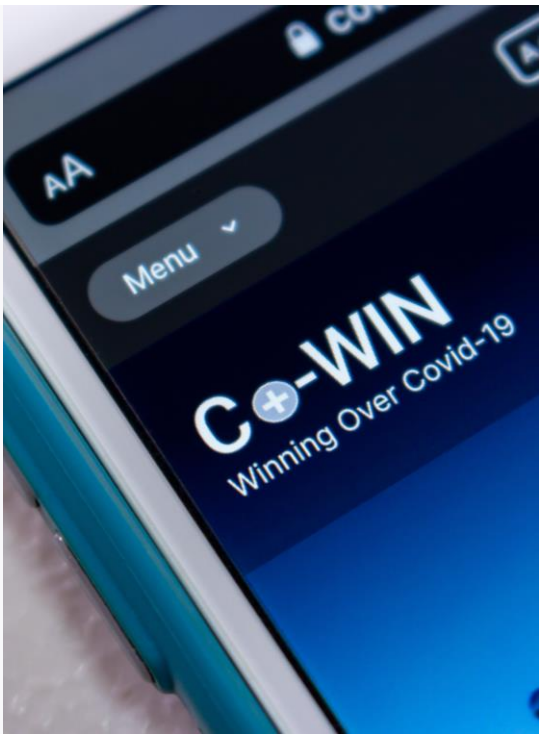
CASE STUDY:

CoWIN

The Covid Vaccine Intelligence Network (CoWIN) is a pan-India digital platform developed by the Government of India to manage the vast COVID-19 vaccination campaign. Launched on January 16, 2021, it revolutionised the rollout of the vaccination programme by orchestrating one of the world's largest vaccination drives. The Government provided the foundational digital infrastructure and regulatory framework, while private entities contributed technological expertise, resources, and innovation.

The development and maintenance of the CoWIN platform involved collaboration with private tech companies, which ensured the system was robust, scalable, and user-friendly. This technology-backed public-private initiative enabled smooth and effortless registration for vaccines, appointment-scheduling at neighbourhood centres, and certification processes, thereby ensuring efficient and transparent vaccine distribution.

Private healthcare providers and hospitals were integrated in enabling real-time tracking of vaccine stocks, thus ensuring wider reach and more efficient vaccine distribution. Moreover, CoWIN collaborated with other digital assets like DigiLocker, Aarogya Setu and UMANG apps to improve access and user experience.



CASE STUDY:

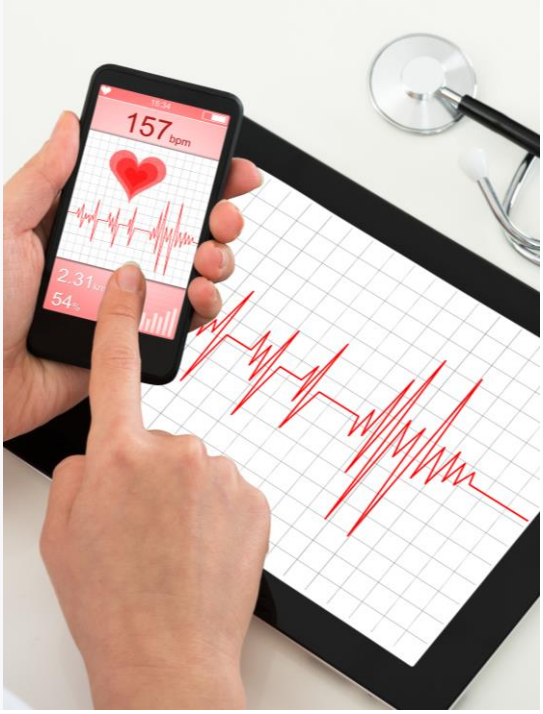
ADMI's Advocacy for Digital Transformation in Diagnostics

Association of Diagnostics Manufacturers of India is working closely with regulatory bodies like CDSCO, Department of Pharmaceuticals, and the Ministry of Health to establish clear, consistent guidelines for digital health applications used in diagnostics.

ADMI pushes for risk-based approaches and flexibility in regulations, ensuring innovations like AI-driven diagnostics or genomic testing are regulated based on the potential impact on patient safety, not merely traditional criteria. This aims to accelerate approvals while establishing clearer guidelines on data security and privacy. This ensures that safety is maintained while fostering faster implementation of cutting-edge diagnostic technologies.

They advocate for balancing innovation with patient safety, promoting a framework that defines the validation, efficacy, and security of these technologies. By collaborating with Government agencies, ADMI aims to expedite approvals while ensuring robust oversight, helping integrate digital health solutions such as AI-based diagnostic tools safely into mainstream healthcare practices.

This would promote safe and rapid integration of new diagnostic technologies into the healthcare ecosystem.



7 THE ROLE OF ABHA ID IN DIGITAL DIAGNOSTICS

Ayushman Bharat Digital Mission (ABDM) is the basis of the vision of the digital health ecosystem of the Government of India. It is the structural base of the core digital infrastructure for health systems rather than a solution. The aim remains to facilitate a unified network that links all major stakeholders of the healthcare system - citizens, healthcare providers and healthcare facilities and institutions.

ABDM has four key components that will be the backbone of the integrated digital ecosystem. Under ABDM, three distinct registries - ABHA IDs, HPR, HFR and three gateways - health information exchange and consent manager, unified health interface, health claims exchange, have been created to ensure interoperability. These registries and pathways are the foundational framework of the digital health ecosystem which will lay grounds for secure data management, patient empowerment and improved continuity of care.



Figure 16: Four key components of ABDM

REGISTERIES

PHR and ABHA IDs:
Personal Health Records (PHRs) enable individuals to manage and share their health data with healthcare providers. The Ayushman Bharat Digital Mission (ABDM) uses ABHA IDs as unique identifiers for PHRs. These 14-digit numbers allow users to store and share their health records securely and control who has access to their data.

Healthcare Professionals Registry (HPR):
A database of all healthcare professionals in India, providing a unique identifier for each professional. This allows patients to verify the credentials and qualifications of their healthcare providers.

Health Facility Registry (HFR):
A database of all healthcare facilities in India, providing information on hospitals, clinics, diagnostic centers, pharmacies, and more. This helps patients discover facilities that meet their needs, regardless of the system of medicine they prefer.

PATHWAYS

Health Information Exchange and Consent Manager:
A digital platform that enables secure and efficient exchange of health records between different healthcare providers. It allows patients to manage their data sharing preferences and ensures the privacy and security of their health information. This decentralised network reduces the risk of data breaches and facilitates the creation of longitudinal health records for personalised and continuous care.

Unified Health Interface (UHI):
A foundational component of the ABHA scheme, UHI aims to bridge the fragmented healthcare landscape in India. By integrating disparate health systems, UHI enables secure data sharing and communication between stakeholders, facilitating better coordination and care delivery.

Health Claims Exchange:
A platform for exchanging health claim information between insurers, healthcare providers, and other stakeholders. It streamlines claim processing, improves efficiency, and introduces transparency into the insurance industry by ensuring interoperability, machine-readability, and verifiability of data.

Figure 17: Registries and Pathways within ABDM



ABHA ID AND ITS POTENTIAL FOR SECURE DATA MANAGEMENT

The Ayushman Bharat Health Account (ABHA) health ID is a 14-digit unique identification number which is a part of the Ayushman Bharat scheme under the Ayushman Bharat Digital Health Mission. It is a unique identification number that identifies each citizen as a participant in the country's digital health ecosystem. With the unique identification number, citizens can create an exclusive identity which is consistent across healthcare providers and platforms to access all information conveniently in a unified system. The ID facilitates access to digital health records, public health programs and other healthcare benefits through a centralised digital repository.

ABHA ID provides various benefits to the patients which smoothen the access to healthcare services irrespective of the location.

- **Electronic Health Records**: Through the ABHA ID electronic health records including medical history, prescriptions, hospital records, diagnosis reports, test results, health insurance claims etc. can be centralised into a single comprehensive electronic record stored in a digital locker. The ID facilitates the storage and retrieval of patient information easily such that it can be shared with healthcare providers without the need of a paper trail. It prevents loss of health data over time as medical records are maintained digitally thus streamlining healthcare delivery. Moreover, it eliminates the requirement to maintain hard copies of reports while visiting a health care provider.
- **Seamless Document Sharing and Interoperability**: While all records and data linked to a particular ABHA ID are private and confidential, the accounts are portable in nature such that data can be shared with healthcare providers and insurers empanelled under the Ayushman Bharat scheme, allowing beneficiaries to access services seamlessly, regardless of their location.
- **Transparent And Accountable Process**: Integration of electronic health records with digital transactions related to health through a unified network improves efficiency, transparency and accountability within the healthcare system as every step of the process can be traced, thereby improving patient outcomes. Moreover, ABDM is data-blind i.e. it acts as a pipeline to facilitate the flow of information; however, it does not read or analyse the data that is stored. Concerns regarding privacy, trust and security of information have been considered.
- **Evidence Driven Decision Making**: The stored electronic medical records generate valuable insights which bring accuracy to the treatment process as healthcare providers can access previous diagnosis anywhere regardless of the geography. This facilitates data-driven decision making thereby improving the overall quality of care.
- **Cashless Claims Approval**: The current process for insurance claim approval is lengthy and complicated to navigate. ABHA ID allows linking insurance policy to the electronic health records which allows the healthcare institution to access the necessary policy details quickly, thereby speeding the claim process and making the healthcare experience smoother.

ADOPTION OF ABHA IDS: ROLLOUT AND CHALLENGES

ABDM has come a long way in setting a foundational base for various digital health initiatives within the country. While more than 50,000 healthcare facilities have been registered in the system, patient uptake of ABHA IDs remains low. For healthcare facilities and providers to be ABDM-compliant, there would be substantial costs to tailor the existing software, internal systems, medical machines and devices, etc. This would usher in a complete overhaul of the healthcare ecosystem as we know it. In an effort to not overwhelm the system and the stakeholders, compliance with ABDM features and pathways is currently voluntary.

Phase-wise rollout planned and ongoing will first focus on creating pathways and repositories for patient records, healthcare facilities, and providers to ensure their participation in digital ecosystem. This involves onboarding individuals and institutions onto the ABHA platform and establishing necessary infrastructure for data management. In this next phase, semi-structured data obtained from medical devices and healthcare facilities is converted and stored as semi-structured data within the linked ABHA IDs. Activities of the first phase will continue simultaneously. The final stage would be where algorithms are built into medical devices and healthcare facilities generating and analysing structured data, providing valuable insights into patient health and facilitating data-driven decision-making.

Phase 1 **Enrollment of patients and institutions**	Create pathways and repositories of patient records, healthcare facilties and providers to ensure particpation in the digital ecosystem
Phase 2 **Semi-structured data**	Presently, semi-structured data obtained from medical devices and healthcare facilities is converted to EHR and stored within linked IDs. In this phase as-is data is recorded without any cleaning/ analysis of it. Focus is on developing a generous data base without identifiers
Phase 3 **Structured data**	The final stage would be structured data wherein algorithms would be built into softwares of medical devices and healthcare facilities such that longitudinal data is automatically generated and analysed in context of the health issue.

Figure 18: Phase-wise roll out of ABHA IDs

PROCESS FOR DIAGNOSTIC FACILITIES

To achieve healthcare digitisation, it is a necessity to create a system that brings different and disparate health systems together in one integrated system. The Ayushman Bharat Digital Mission (ABDM) incorporates diagnostic facilities through a multi-phase process designed to maximise platform benefits and guarantee a seamless transition[19].

Milestone 1: Creation and Verification of ABHA Numbers for Smooth Patient Registration

Milestone 2: Establishing Health Information Provider (HIP) Services for Sharing Digital Records through the ABHA Personal Health Records App

Milestone 3: Developing Health Information User (HIU) Services to Grant Authorised Healthcare Workers a Comprehensive View of Patients' Medical History with Consent

The Government outlines API Security as a pre-requisite for integration with ABHA IDs. This includes HID role in gateway, prefix Bearer token value, sensitive data encryption through RSA by a public certificate[20].

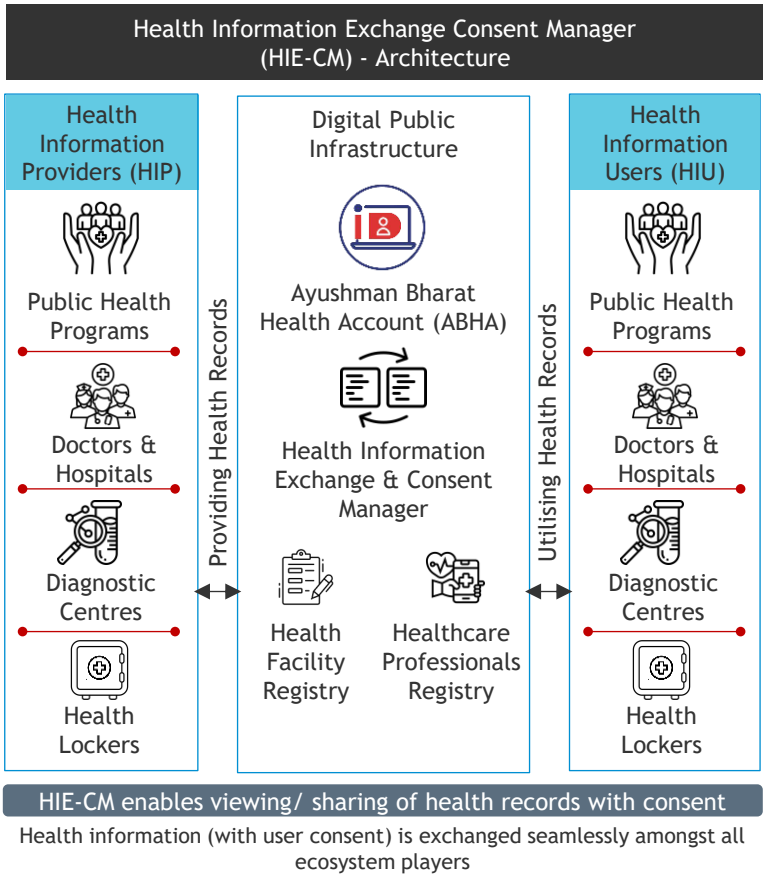
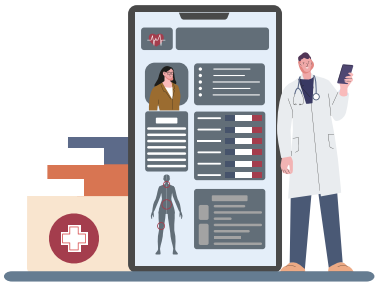


Figure 19: ABDM's Unified Health Interface usage
Source: NHA- Consultation Paper on Unified Health Interface







MILESTONE 1	MILESTONE 2	MILESTONE 3
ABHA NUMBER CREATION AND VERIFICATION	**BUILDING HEALTH INFORMATION PROVIDER (HIP) SERVICES**	**DEVELOPING HEALTH INFORMATION USER (HIU) SERVICES**
Acts as a unique identifier for individuals within the digital health ecosystem.	To share digital records via Personal Health Records (ABHA) app	To provide view if patient's medical history to authorized healthcare workers with complete consent.
▪ **ABHA Number Creation**: Users or Patients create their ABHA (Ayushman Bharat Health Account) Number using their aadhar umber. ▪ **ABHA Number Verification**: OTP is sent on aadhar link mobile number and verification is done. If the number is not linked, then by biometrics verification done.	▪ **Digital Health Records**: Secure storage and easy access to an individual's health records. ▪ **HIP Services Integration**: Integrate HIP services to ensure seamless access and sharing of health information.	▪ **Consent Requests**: Implement consent management to ensure that patients can control who accesses their health data. ▪ **Medical Data Access**: Ensure that health providers can access necessary medical data with patient consent.

Figure 20: Milestones for Diagnostic Services for ABDM integration

COVID-19 brought to the forefront the benefits of having a digital health record on a unified platform for seamless and secure access and sharing of data. Majority of ABHA IDs were linked as individuals underwent COVID tests at hospitals, and traced their journey on the Aarogya Setu App.

It was noted that most account owners fall within the ages between 19 and 45 years old—accounting for about 55.66% of all users - which is to say that young adults are more appreciative of ABHA's digital-based medical system given its convenience.

However, to garner a diverse and inclusive user base, ABHA needs to cater to all ages, especially seniors who require a significantly higher amount of medical attention due to their age-related health issues or chronic ailments like cardiovascular disorders, arthritis, cognitive decline, and cancer.



BENEFITS OF ABDM INTEGRATION

While India still has significant ground to cover, if implemented to its full scope, ABDM can yield tremendous direct and indirect benefits. If scaled up, the digital public health infrastructure can be the turning point of the Indian healthcare landscape by affecting millions of people and bringing the nation close to achieving universal health coverage.

Personalized Medicine and Treatment:

Longitudinal analysis of a patient's health records can provide insights into their pre-disposition to certain conditions and diseases, trends in medical history and risk of potential conditions. By analyzing substantial amounts of data treatment plans can be tailored to the patient based on their medical needs. Moreover, it can

Longitudinal analysis of a patient's health records can provide insights into their pre-disposition to certain conditions and diseases, trends in medical history and risk of potential conditions. By analysing substantial amounts of data, treatment plans can be tailored to the patient based on their medical needs. Moreover, it can reduce unnecessary treatment, and risk of adverse reactions, and improve the effectiveness of the treatment and quality of care. Shared health records will also allow various healthcare providers to collaborate effectively, especially in cases of a patient consulting multiple specialty centers.

Remote Monitoring:

Patients with chronic conditions such as diabetes, heart disease, thyroid and other lifestyle issues can be monitored remotely by analysing data from wearable devices and other remote monitoring tools to detect changes in a patient's health status in real-time. Remote monitoring can provide patients with greater autonomy and convenience as they can receive healthcare from the convenience of their home, allow for early intervention and prevention of complications by early intervention.

Predictive Analytics:

Analysis of a centralised health data repository could assist in identifying broader trends in the population and predict the risk of developing certain conditions or diseases. Through this insight, healthcare providers can take preventative measures which could lead to better health outcomes and a reduction in overall disease burden and healthcare costs.

Public Health Surveillance:

By analysing data from a centralised repository, disease outbreaks can be monitored at a macro level, spread of infectious diseases can be tracked in real-time, potential public health threats and emerging health crises can be identified. Public health surveillance has the potential to greatly improve the efficiency and effectiveness of disease monitoring and response, ultimately leading to better public health outcomes. For instance, COVID-19 management witnessed real-time data tracking which facilitated the implementation of targeted interventions to prevent the further spread of the disease.

Resource Optimization:

Aggregated health data analysis can assist in developing data-backed strategies for resource allocation and streamlining the delivery of care. Demand for medical services and equipment can be predicted. Moreover, the efficiency and effectiveness of medical equipment, such as ventilators and infusion pumps can be monitored to ensure optimal utilisation, thereby reducing equipment downtime and preventing shortages.

Frameworks for Data Exchange:

Through the digital infrastructure being built under the mandate of ABDM, data storage formats are envisioned to be standardised to enable data sharing and storage across the country and sectors. Health information exchanges and other interoperability platforms aim to standardise the data exchange frameworks for the country. For instance, UHI and EHRs (Electronic Health Records) systems like Epic, Cerner, Athenahealth require FHIR (Fast Healthcare Interoperability Resources) interfaces which offer standardised APIs for clinical data exchange between disparate healthcare systems and cross-platform data interoperability. IHE (Integrating Healthcare Enterprise) profiles outline precise implementation of standards such as HL7 and DICOM for specific clinical purposes like e-prescribing.

Introducing Digitally Signed Health Records:

Data entries made by healthcare providers will be digitally signed and tamper-proof, increasing accountability and transparency. Patients can securely access medical history from any location and share digitally signed e-records instantly with professionals. Crucial in medical emergencies.

The main purpose of ABHA IDs is the creation of EHRs in India for individuals seeking diagnostics, which would be visible to any practitioner in any locale in India to access health records of patient individuals and its trends thereby making diagnosis more specific; interventions can thereafter be planned in a specific manner as well.

Its role in streamlining processes, improving cost-efficiency, and facilitating innovations like AI-driven diagnostics positions acts as a catalyst for the widespread adoption of digital diagnostics. This will not only improve individual health outcomes but also enhance public health infrastructure, making diagnostics more accessible and affordable across the country.

ABHA IDs can be a transformative tool for scaling up the uptake of diagnostic services in the country by offering a unified, secure, and interoperable platform for managing health records. By simplifying access to diagnostic data, promoting transparency, and enabling remote and telemedicine-based diagnostics, ABHA IDs reduce barriers to healthcare access.

CHALLENGES IN ABDM INTEGRATION

There are significant challenges that are unique to the populace that must be accounted while tweaking the strategy to mainstream the concept of ABHA IDs.

Access To Digital Means

The National Sample Survey Office (NSSO) reports that 24% of rural Indian households have access to the internet, compared to a 66% penetration in cities. Additionally, only 14% of rural citizens actively use the Internet, in contrast to 59% of urban adoption. These statistics are important as 65% of the country's population resides in rural areas, which includes over 900 million people. There are various reasons for the disparity such as patchy network coverage, affordability, lack of vernacular language-based applications etc. As a result, the urban-rural divide continues to underline digital adoption and penetration rates despite various Government initiatives such as Digital India, BharatNet project, Common Service Centre networks etc. that have attempted to lay the groundwork.

Digital Literacy

A 2023 report published by Internet and Mobile Association of India (IAMAI) notes that urban areas have an internet penetration rate of 67%, while rural areas lag at 31%. While there are multiple reasons that can be attributed to this divide, digital literacy, socio-economic conditions and technological readiness can be highlighted as the major drivers. There is an urgent need to build digital skills, provide education and awareness to ensure continued access to essential services such as healthcare, education, employment etc., especially in times of unusual circumstances such as the COVID-19 pandemic.

Difference In Rural and Urban Priorities

There is a noticeable difference in the infrastructural and population priorities between the rural and urban parts of the country. Most of the urban parts of the country such as metro cities do not have infrastructure problems that include access to digital devices, stable internet connection and digital literacy. As a result, people in the urban setting prioritise issues surrounding authenticity and transparency of the process. Contrastingly rural areas of the country face barriers such as distance, physical access, access to digital devices, uninterrupted internet connection and digital literacy. There is a need for tailored strategies for implementing ABHA in different parts of the country. This is reinforced by the varying uptake of ABHA IDs across states wherein the highest numbers are concentrated mainly within Madhya Pradesh, Andhra Pradesh and Uttar Pradesh - areas that may have larger populations. Smaller states such as Lakshadweep or Arunachal Pradesh have relatively fewer enrolment (Paliwal, 2023). Analysing the readiness level of each state based on rural and urban level analysis might provide better results with targeted healthcare digitalisation efforts.

Voluntary Integration

Currently, integration of healthcare facilities with ABDM is voluntary which has been one of the major causes for lack of ABHA ID adoption. Private players across the industry work in silos on matters concerning digital innovations and infrastructure. Various hospitals, labs and other healthcare facilities are hesitant to share their data, make changes to their internal HMIS and LMIS to ensure integration with ABDM and are thus delaying the process of ensuring ABDM compliance until mandated. There is a need for a plan to engage private players given that they occupy a significant chunk of the market to actualise the vision of a unified digital health infrastructure.

Lack Of Clear Guidelines Around Data Sharing and Privacy

A centralised database poses risks surrounding privacy violations and data breaches. Centralised systems are often more vulnerable to security breaches and hacking attempts, given that sensitive data and infrastructure are located in one place. In 2019, it was reported that the personal information of over 130 million Indian citizens, including their Aadhaar number (a unique identification number), was leaked from a Government database (Orren, 2020). To mitigate these risks, it is crucial to have clear guidelines and rules surrounding data storage, encryption, sharing and robust security protocols to ensure that only authorised personnel have access to the database.

No Perceived Benefits to Users

Despite some proof of concept during the pandemic, a large chunk of the population does not perceive any obvious benefits to adopting ABHA IDs. While ease of access and sharing of records will ease the process of accessing healthcare services, currently there are no linkages with other schemes to attract the user base. The process is perceived to be extra work without any tangible benefits. There is a need to demonstrate to the masses the value-add that digital records contribute.

Despite remarkable progress in designing and constructing the framework for digitisation of the healthcare ecosystem, significant work still needs to be done on the country's digitalisation framework. Issues such as compatibility, cybersecurity, and technical readiness remain prevalent, especially in rural areas of the country. Moreover, as the legal and regulatory framework for digital health in India rapidly evolve, regulatory gaps persist that must be addressed.

8 RECOMMENDATIONS



The diagnostic landscape has witnessed a snail-like pace in uptake and adoption of digital and technological innovations. To drive the adoption and effective implementation of digital diagnostics in India, collaboration among government agencies, healthcare institutions, and technology companies is essential.

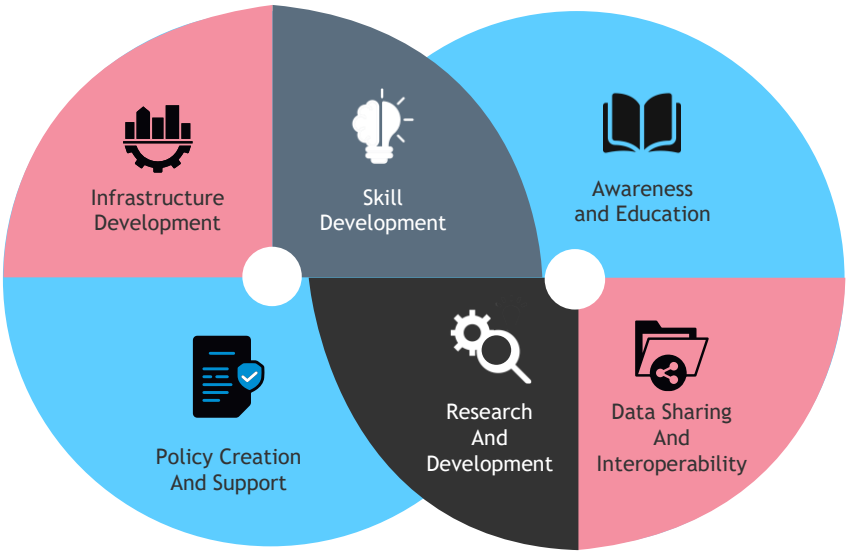
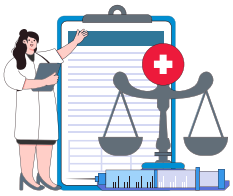


Figure 21: Areas of Collaboration

By fostering collaboration and addressing these key areas, India can create a conducive environment for the growth and adoption of digital diagnostics, leading to improved healthcare outcomes and greater access to quality care for its citizens.



Policy Creation and Support

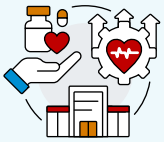
Favourable Regulatory Environment that fosters innovation and investment in digital diagnostics.

Financial Incentives such as tax credits or rebates, can spur the uptake of digital health technologies.

While there have been various technological advancements in the diagnostic sector in the last few years, the regulatory support from the government seems to lag behind. Concerns such as guidelines around technology-specific issues, standardisation on quality of the technology, data privacy and storage etc. are yet to catch up with market advancements such as use of remote diagnostics, POC devices, use of AI/ML etc. which are becoming commonplace in the market. There is an urgent need to bring in updated regulations and provide support for upscaling and adoption of these advancements. This includes updating guidelines in light of new technologies, improving the approval process for novel diagnostic instruments, regulatory support for upscaling, and ensuring established frameworks for quality control, ethical concerns and data demand privacy.

By providing financial incentives, the government can create a more favorable environment for the adoption of digital health technologies, driving innovation and improving healthcare outcomes such as:

- Offering tax credits to healthcare providers who invest in digital health technologies can encourage adoption and innovation.
- Providing rebates to patients who use digital health services can make these services more affordable and accessible to a wider population.
- Government subsidies can be used to support the development and deployment of digital health solutions, particularly in underserved areas.



Infrastructure Development

Broadband Connectivity: Investments in global broadband infrastructure for access to digital health services in all communities, especially in underserved areas.

IT Infrastructure: Support the development and rollout of IT systems, including HER and Data centers, to facilitate integrated digital diagnostics.

A robust and expansive digital health ecosystem will require round-the-clock and stable and quality IT infrastructure. This includes **broadband and internet connectivity till the last mile,** as emerging technologies such as remote diagnostics, telemedicine, and electronic health records will find success only when seamless connectivity is ensured between patients and healthcare personnel in the remotest areas. Until consistent, reliable, and affordable broadband connectivity can provide its equal benefits, the promise of digital health services in increasing access to diagnostics will remain unfulfilled. **Investment in and establishment of robust network infrastructure** is a necessary foundation for the same.

Moreover, digital systems require round -the-clock technical support, system maintenance, updated software, interoperability and compatibility with IT requirements of various systems such as laboratory information system, hospital information systems, electronic health records, telemedicine platforms, govt. database etc. that need to be integrated smoothly. There must be **clear guidelines that make the process of integration and interoperability easier** given that we have technologies and systems at various levels of maturity within the system.



Skill Development

Training and Education: Provide training and education initiatives for health professionals, ICT staff, and policymakers on using and the benefits of digital diagnostics.

Capacity Building: Investment in building capacity initiatives to develop skills and expertise in the workforce in the diagnostic sector.

The industry has always grappled with issues surrounding human resource such as shortage of trained, skilled and qualified resources which have become even more pressing as the healthcare landscape evolves with technological advancements. The current regulations are based on the traditional model of providing diagnostic services. A poignant issue remains that in order to be considered a valid test report, a doctor must physically sign the test results. This in turn introduces hurdles for digital test reports and results from other technological innovations. The **regulatory guidelines must be revised to take technological advancements and their validity into consideration.**

There is a need to **expand training programs and educational pathways.** The human resources must be routinely undergo capacity building and skill development at large scale to ensure that they are kept abreast the latest developments and their use in the sector. **Investment in specialized programs in diagnostic technology, laboratory sciences, and healthcare informatics** may be useful in ensuring that the human resource is updated.



Public-Private Partnerships

Public-Private Partnerships can test and leverage each party's strengths and resources.

Public System Support: Adoption of new advancements and procurement in the public sector will open up avenues for all stakeholders and players in the diagnostic landscape.

Public-private partnerships (PPPs) play a crucial role in driving innovation and accelerating the adoption of digital health technologies in India. By combining the strengths of government agencies, healthcare providers, technology companies, and research institutions, PPPs can foster collaboration, knowledge sharing, and resource mobilization.

Government agencies can provide policy support, regulatory frameworks, and financial incentives to encourage the development and deployment of digital health solutions. Healthcare providers can contribute their expertise in clinical practice and patient needs, while technology companies can leverage their innovation and technological capabilities. Research institutions can play a vital role in conducting research and development, generating evidence-based insights, and training healthcare professionals.

Additionally, **push from the public sector regarding uptake of new technological advancements at a large scale** will be beneficial for the entire industry. For instance, procurement of devices and machines at a large scale for use in public sector will provide a) Validity to device hence ushering in increased uptake across the industry b) Open up the market for all stakeholders thus ensuring affordability and accessibility to new technologies at a reasonable price for all players.



Data Sharing and Interoperability

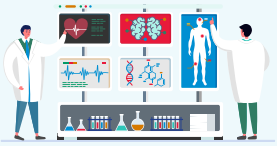
Developing Standards: Establishing standardized formats and protocols for data sharing and interoperability between discrete healthcare system.

Robust Data Privacy and Security: Implementation of robust data privacy and security measures to protect patient privacy and increase trust in digital health platforms.

As we move towards establishing an integrated digital health ecosystem, there is a need for legislations, regulations and guidelines with strict penalties in case of faltering surrounding data collection, processing, sharing and storage. Given the sensitive nature of personal identifying and health data, **there is a need for a dedicated health data privacy law, clear regulations and frameworks for data storage and sharing.** Additionally, **a central data security oversight body** must be established to ensure that there is a dedicated authority to oversee all matters related to data security.

Currently the private players ensure that their data storage and sharing practices meet the highest quality and are encrypted as it has a direct impact on their services and consumer perception. However, there is a need to ensure that all diagnostic facilities within the country operate with the highest consideration for data security. **Data security and encryption standards should be mandated at all levels.**

While there have been some efforts to bring in such legislations and regulations, there should also be **an incident reporting and resolution framework** in place to ensure that data breaches are reported to relevant authorities and a plan to effectively deal with them in place.



Research and Development

Funding Research Initiatives: Support R&D initiatives about advances in digital diagnostics.

Collaboration with Academia: Support and foster collaboration among government, health providers and academia in the research field to spur innovation.

As we adopt innovations and technological advancements for large-scale use within the industry, we must ensure that they have been modelled and tested in the Indian context to ensure optimum results. For **instance, mandating local clinical trials for AI/ML-based screening and diagnostic tools** to ensure that the algorithms respond to the special needs of the Indian population, which are different from the requirements in the West, probably related to the presentation of diseases, genetic factors, and environmental conditions that may impact the cases.

This introduces a need to **encourage the development of these innovations within the Indian landscape.** This includes **simplifying and standardising the approval and accreditation process along with clear guidelines around standards of software, technology, integration mechanism, data privacy etc.**

Establishing innovation hubs and incubators focused on healthcare technologies through collaboration with the government, private sector and academic institutions can provide a supportive environment for developing, testing, and scaling new solutions by new starters and innovators.

Moreover, to promote indigenous research and development **financial incentives and grants** can be provided with focus Indian entrepreneurs and developers on crafting solutions relevant to the Indian system of healthcare.



Awareness and Education

Public Awareness Campaigns: Public Awareness campaigns for patient access to and benefits of digital diagnostics with healthcare providers and public.

Understanding Concerns: Understanding concerns among participants about digital health technology which values patient privacy and trustworthiness.

Given the limited digital literacy and understanding of how a unified digital health ecosystem can be beneficial, there are concerns surrounding its use and data privacy among the public. Unless there are directly perceivable benefits visible to people the uptake of these services will remain slow. There is a need for **clear and transparent protocols in regard to the handling of health data within the digital health ecosystem. These should be accessible to the public, easy to understand and clearly communicate the steps taken to ensure data security.**

In order to overcome this, there must be efforts around addressing these concerns **through robust and strict legislations and regulations.** In case of violation of these **penalties should be enforced.**

Establishing an independent oversight body to be responsible for data protection security on health information platforms. This body can assist in ensuring that healthcare providers and tech companies do everything in their power to meet the highest standards of data protection.

Transparent, easy-to-understand consent mechanisms relating to the collection and sharing of data should be provided on digital health platforms to allow users to easily opt-in or opt-out when it comes to sharing data with healthcare providers, researchers, or third-party entities.

Additionally, **public awareness campaigns** would help in apprising the public about the benefits of a digital health ecosystem.

Category	Recommendation	Relevance	
		Government agencies	Industry
Policy Creation and Support	Favourable Regulatory Environment	●	
	Financial Incentives	●	
Infrastructure Development	Broadband Connectivity	●	
	IT Infrastructure	●	●
Skill Development	Training and Education	●	●
	Capacity Building	●	●
Public-Private Partnerships	Public-Private Partnerships	●	●
	Public System Support	●	
Data Sharing and Interoperability	Developing Standards	●	
	Robust Data Privacy and Security	●	●
Research and Development	Funding Research Initiatives	●	●
	Collaboration with Academia	●	●
Awareness and Education	Public Awareness Campaigns	●	●
	Understanding Concerns	●	●



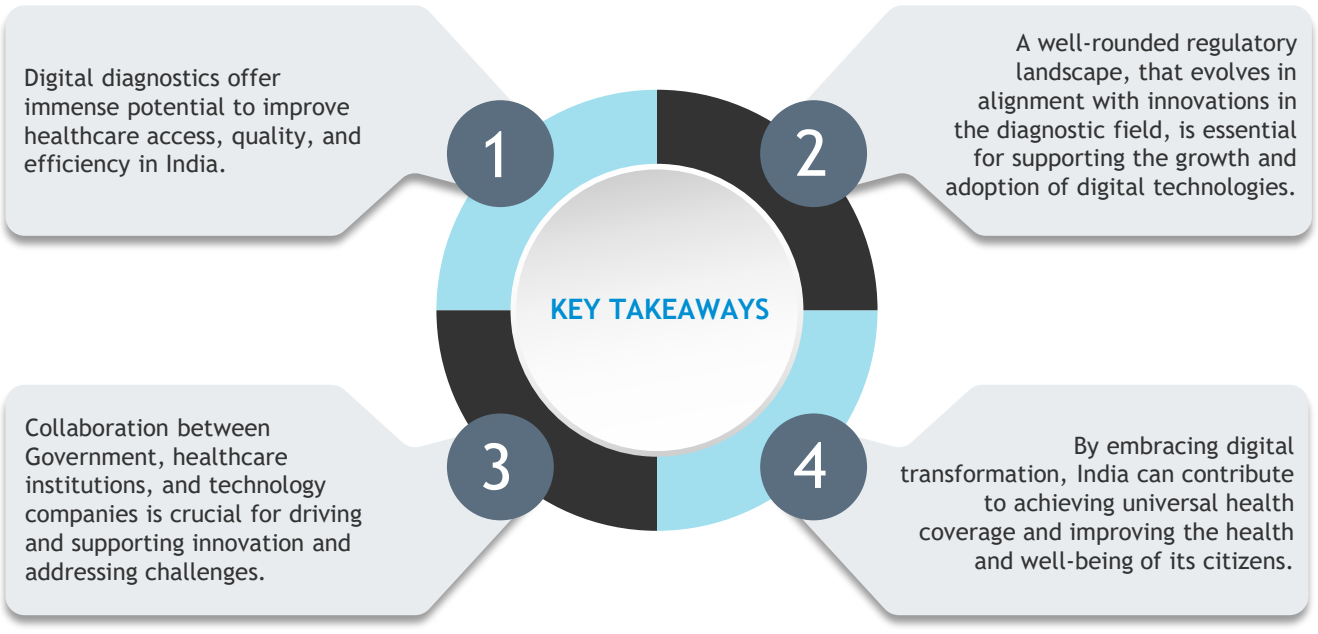
9 CONCLUSION AND KEY TAKEAWAYS

The diagnostic sphere in India is rapidly evolving and transforming due to advancements in digital technology. As India strives towards universal health coverage (UHC), digital and tele-diagnostics can enable improved access to diagnostic services, especially in rural and less well-served areas, reduce costs, and provide higher quality care. These enhancements will aid in improving health outcomes in India and reach the goal of reducing health inequities.

Nevertheless, to realise the full potential of digital diagnostics, a better regulatory framework is required that enables innovation whilst securing patient safety and data privacy. Governments and regulators must take an active role in developing an environment to support the adoption of digital solutions within a health system.

The Ayushman Bharat Digital Mission (ABDM) provides a centralised platform for facilitating the integration of digital diagnostics into the Indian healthcare system; storing and managing patient health records; ensuring data security & accessibility. ABDM is set to ensure interoperability between different healthcare systems and digital platforms is essential for effective data sharing and utilisation. Increasing awareness and adoption of ABDM among healthcare providers and patients is crucial for realising its full potential.

More critically, to integrate the use of digital and tele-diagnostics into the healthcare landscape, coordination with and between government agencies, health institutions, technology companies is essential. These stakeholders need to work together to resolve issues, lend expertise, and drive the successful integration of digital diagnostics into a healthcare system's fabric, thus enabling a seamless ecosystem.



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