

**Exchange of Knowledge Across  
the Lifecycle of Digital Health Initiatives**

# **A COOPERATIVE KNOWLEDGE TRANSFER BETWEEN INDIA AND THE EU**

*Research Paper*

*November 2023*



Funded by  
the European Union

# EXCHANGE OF KNOWLEDGE ACROSS THE LIFECYCLE OF DIGITAL HEALTH INITIATIVES

A COOPERATIVE KNOWLEDGE TRANSFER BETWEEN INDIA AND THE EU

**Research Paper**

**November 2023**

**Authors:**

**Vaishnavi Sharmam** Research Associate, The Dialogue  
**Kamesh Shekar**, Senior Programme Manager, The Dialogue  
**Kazim Rizvi**, Founding Director, The Dialogue  
**Pavan Ananth** Founder & CEO, Pravesh Global  
**Deepshika Chhetri**, Consultant, Pravesh Global  
**Mujaheed Shaikh**, Professor of Health Governance, Hertie

*This paper is written in the framework of the EU-India Think Tanks Twinning Initiative 2022-23 – a public diplomacy project aimed at connecting research institutions in Europe and India, funded by the European Union*

*The contents of this publication are the sole responsibility of the authors and can in no way be taken to reflect the views of the European Union.*

# Table of Contents

<b>1. Introduction</b>	<b>2</b>
1.1. Enhanced Data-driven Decision-making	2
1.2. Strengthening Public Health Monitoring and Disease Management	3
<b>2. Scope and Methodology of Our Study</b>	<b>5</b>
2.1. Research Methodology	5
2.1.1. Secondary Research	5
2.1.2. Primary Research	5
<b>3. Scope of Digital Health Initiatives in India &amp; the EU - A Comparative Analysis</b>	<b>6</b>
3.1. Interoperable Health System	6
3.2. Identification & Targeting	14
<b>4. Policy Landscape of Jurisdictions for Digital Health Ecosystem</b>	<b>17</b>
4.1. Guiding Principles of Digital Health	17
4.2. Digital Rights	20
<b>5. Constraints Faced by EU and India Within the Digital Health Ecosystem</b>	<b>23</b>
5.1. Regulations and Policies Governing Digital Health Data (DHD)	23
5.1.1. Constraints in India's DHD Protection Landscape	23
5.1.1.1. Absence of a Legislative Mandate	23
5.1.1.2. Lack of Higher Degree Protection to Health Data	24
5.1.1.3. Compliance Constraints	24
5.1.1.4. State Exemptions & Deemed Consent	25
5.1.1.5. Rights and Duties of Data Principals	25
5.1.2. Constraints in the EU's DHD Protection Landscape	25
5.1.2.1. Premises of Data Protection Regulation	26
5.1.2.2. Over-reliance on Consent Artefact	26
5.1.2.3. Privacy Vs. Value of Data/Digitalisation	26
5.2. Scalability of the Digital Health Ecosystem	27
5.2.1. Scalability Challenges in India's Digital Health Ecosystem	27
5.2.2. Scalability Challenges in the European Union's Digital Health Ecosystem	27
5.3. Interoperability of the Digital Health Ecosystem	28
5.3.1. Interoperability Concerns in India	28
5.3.1.1. Lack of Vertical Regulatory Interoperability	29
5.3.1.2. Lack of Centre-State Interoperability	29
5.3.2. Interoperability Concerns in the European Union	30
5.3.2.1. Lack of Foundational and Semantic Interoperability: Private level	30
5.3.2.2. Lack of Foundational and Semantic Interoperability: National level	30
<b>6. Exchange of Knowledge to Enhance Regulations and Policies Governing Electronic Health Records - Recommendations for India</b>	<b>31</b>
6.1. Extending Additional Protection to Health Data	31
6.1.1. Resilient Rule-making	31
6.1.2. Advisory Role	32
6.2. Regulatory Interoperability to Enhancing the Ecosystem	32
6.2.1. Legal Regulatory Interoperability Among Digital Health Laws	33
6.2.2. Horizontal Administrative Interoperability Among Sectoral Regulators	34
6.2.3. Vertical Administrative Interoperability Between the Centre and States	34
6.3. Evaluating the Performance of the Data Protection Regulations	35
<b>7. Exchange of Knowledge to Enhance Interoperability and Scalability - Recommendations for the EU</b>	<b>37</b>
7.1. Laying the Roadmap through Digital Public Infrastructure	37
7.1.1. ABDM Ecosystem	37
7.1.2. Repurposing Aarogya Setu and CoWIN	38
7.2. Importance of the Digital Identification System	40
7.3. Enhancing Scalability Using the Ecosystem Approach	41
7.3.1. Public Sector Involvement: State level	42
7.3.2. Private Sector Involvement	42
7.3.2.1. Sandbox Mechanism	42
7.3.2.2. Private-Public Interface	43
7.3.2.3. Assisted Model of e-Sanjeevini	43

7.4. Principle-based Interoperability	43
7.5. Balancing Data Protection and Value Creation	45
7.5.1. Federated Architecture	45
7.5.2. Consent Managers	45
<b>8. Enabling Digital Health Interactions between the EU and India</b>	<b>47</b>
8.1. Opportunities for EU-India Coordination and Harmonising Digital Health Initiatives	47
8.2. Implementational Roadmap for a Principle-based Data Transfer Framework	48
<b>9. Conclusion</b>	<b>50</b>

## **Abstract**

The European Union (“EU”) and India, two of the most significant jurisdictions in the world, are in the process of introducing transformative legal and policy instruments that seek to leverage digital technologies for health. On 15 August 2020, India unveiled its National Digital Health Mission policy - later rolled out as the Ayushman Bharat Digital Mission (“ABDM”) - that seeks to create an open, interoperable digital health ecosystem in the country, enabling various digital health systems to engage with each other and empower individuals to be in control of their health data. On the other hand, on 3rd May 2022, the EU released a proposal for a regulation for a European Health Data Space (“EHDS”) to address health-specific challenges to electronic health data access and sharing and create a common space where natural persons can easily control their electronic health data.

However, considering these jurisdictions’ geographical, cultural, and historical dispositions, various concerns emerge that may cause hindrance to these projects. While the EU has demonstrated its highly-advanced approach towards policy-making in data-relevant domains, including health, India has showcased its efficiency and experience in scaling data systems and making them interoperable. Accordingly, this research paper highlights certain specific policy- and implementation-level concerns that both jurisdictions need to pay heed to while going ahead with their respective projects. Additionally, after studying the various digital healthcare ecosystems in these jurisdictions, the paper makes certain recommendations to work towards a seamless design, development, deployment, and operation of the frameworks.

## 1. Introduction

Definitions of “digital health” across the globe differ. However, it is generally agreed upon that it relates to the delivery of healthcare services to the public at large using information and communication technology (“ICT”) as the primary medium.<sup>7</sup> It encompasses various technologies and concepts such as eHealth, wearable devices, telehealth and telemedicine, health information technologies, etc., with an emphasis on the access and delivery of healthcare services.<sup>8</sup>

Even though the effects of COVID-19 have been materially reduced, the pandemic provided an opportunity for jurisdictions across the globe to reassess and reevaluate their extant healthcare systems, along with exploring the opportunities and affordances effective digitisation has to offer in terms of access. Even when jurisdictions across the globe attempt to reap the affordances that healthcare technology may offer, significant obstacles need to be overcome. While the influx and complexity of newer healthcare solutions have changed drastically, impacting and aiming for better outcomes for patients and medical practitioners,<sup>9</sup> the role of the executive and policymakers is not only actively regulating the market but also creating a nurturing ecosystem that enables a seamless growth for digital healthcare solutions, mitigating any potential negative consequences. As noted by the WHO, incorporating quality healthcare service requires collaborative efforts by the government, industry, and civil society and requires policy and implementation processes to be transparent, people-centric, measuring and generating information, and investing in the workforce.<sup>10</sup>

With the advent of ICT and emerging technologies in the healthcare sector, it is imperative to re-conceptualise access - actual access and perceived access - to healthcare services accordingly, inter alia, keeping in mind geographical (ease of travel and distance of travel), temporal (time convenience and appointment scheduling), financial (eligibility, complexity, affordability, and out-of-pocket costs), cultural (language, trust, stigma, understandability), and digital (connectivity, usability, and privacy) factors that materially affect access to healthcare.<sup>11</sup> As both the EU and Indian jurisdictions move towards formulating and implementing their digital health laws, the accessibility of quality healthcare services would be a critical factor to pay heed to, considering the relevant socioeconomic factors and context.

### 1.1. Enhanced Data-driven Decision-making

Data-driven decision-making is critical to leverage the affordances of data that is collected, stored, and analysed to understand the intricacies of current healthcare challenges better and, accordingly, develop effective solutions. The most effective utilisation of data for healthcare solutions entails the efficient use of data that is already being collected and stored, especially linking these data across different organisations and devices that collect it, including medical hospitals and clinics, pharmacies, laboratories, medical devices, and applications, etc.<sup>12</sup>

One of the most critical mechanisms for enabling data-driven decision-making is Electronic Health Records (“EHR”). These are real-time records of an individual's entire personal health information, including medical details like history, physical exams, diagnoses, lab results, allergies, information on immunisations, etc., in a digital format. EHR computer systems employ information management tools to create automated processes by linking, analysing, and categorising the data for healthcare decision

---

<sup>7</sup> Fatehi F, Samadbeik M, Kazemi. (2020, November). What is Digital Health? Review of definitions. Studies in health technology and informatics, U.S. National Library of Medicine. <https://pubmed.ncbi.nlm.nih.gov/33227742/>.

<sup>8</sup> Id.

<sup>9</sup> Why the evolving healthcare services and technology market matters. (2018, May 3). McKinsey & Company. Retrieved November 30, 2023, from <https://www.mckinsey.com/industries/healthcare/our-insights/why-the-evolving-healthcare-services-and-technology-market-matters>

<sup>10</sup> WHO, OECD, International Bank for Reconstruction and Development/The World Bank. (2018). Delivering quality health services - A global imperative for universal health coverage. <https://apps.who.int/iris/bitstream/handle/10665/272465/9789241513906-eng.pdf>.

<sup>11</sup> John C. Fortney, James F. Burgess, Jr., Hayden B. Bosworth, Brenda M. Booth, Peter J. Kaboli. (2011, November). A re-conceptualization of access for 21st Century healthcare. Journal of general internal medicine, U.S. National Library of Medicine. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3191218/>.

<sup>12</sup> Vera Ehrenstein, Hadi Kharrazi, Harold Lehmann, Casey Overby Taylor. (2019, October). Obtaining data from Electronic Health Records. National Library of Medicine. <https://www.ncbi.nlm.nih.gov/books/NBK551878/>.

support, care management, and medical research.<sup>13</sup> Another critical mechanism is the Personal Health Record (PHR) pioneered by India, where health information is stored, maintained, and controlled by individuals. Such innovations go beyond the affordances allowed by Electronic Medical Records (“EMR”), which are digital versions of medical paper charts produced by the practitioner in one practice, and go towards providing a more comprehensive and holistic look at an individual’s medical history.

Data-driven processes are not only important for overall healthcare delivery and accessibility but also have applied usages in certain specific and emerging technological sectors, such as AI and ML, which materially aid in automation, prediction, and decision support for practitioners and researchers.<sup>14</sup>

There is an urgent need to realise the importance of health data in decision-making, its correlation with exacerbating exclusionary practices, and its potential for producing a holistic global sense of health. The current policy and legal framework for health data collection and sharing are insufficient and prevent medical researchers and innovators from utilising their maximum potential in both India and the EU.<sup>15</sup> Furthermore, poor health management systems may only further exacerbate inequalities and result in avoidable harm and risks.<sup>16</sup>

This requires active participation from all stakeholders, including the industry and government, in creating datasets for data-driven decision-making that adequately represent the populations and consider the contextual differences between landscapes. To facilitate the required participation and investment, to share learning, and to work toward similar goals and standards for addressing data-driven decision-making in health, it is critical to collaborate and cooperate with other jurisdictions and international stakeholders.

## 1.2. Strengthening Public Health Monitoring and Disease Management

As is evident from the COVID-19 experience, digital health initiatives play an important role in monitoring public health and disease management. The acceptance and development of digital technology have made numerous public health issues easier to monitor and manage, including epidemiological monitoring, contact tracing, case identification, mass vaccination service delivery, and public communication. Such initiatives can create accurate, prompt data feedback loops required to reinforce and constantly improve programme delivery, monitoring, and management and aid the executive in informed decision-making.<sup>17</sup>

As evidenced, such initiatives have greatly aided policymakers in creating appropriate policy and legal instruments for developing and enhancing containment strategies by enabling a real-time assessment of the efficacies of policy measures.<sup>18</sup> While recent ICT interventions and innovations have significantly sped up the proliferation of digital health initiatives, there is a need for a more global network in the real

---

<sup>13</sup> Menachemi, N., & Collum. (2011, May). Benefits and drawbacks of electronic health record systems. *Risk Management and Healthcare Policy*, 47. <https://doi.org/10.2147/rmhp.s12985>; Tang, P.C., McDonald, C.J. (2006). Electronic Health Record Systems. In: Shortliffe, E.H., Cimino, J.J. (eds) *Biomedical Informatics*. Health Informatics. Springer, New York, NY. [https://doi.org/10.1007/0-387-36278-9\\_12](https://doi.org/10.1007/0-387-36278-9_12).

<sup>14</sup> Nir Menachemi, Taleah H Collum. (2011). Benefits and drawbacks of Electronic Health Record Systems. *Risk management and healthcare policy*, U.S. National Library of Medicine. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3270933/>.

<sup>15</sup> Why the evolving healthcare services and technology market matters. (2018, May 3). McKinsey & Company. Retrieved November 30, 2023, from <https://www.mckinsey.com/industries/healthcare/our-insights/why-the-evolving-healthcare-services-and-technology-market-matters>

<sup>16</sup> Isabelle Rose I Alberto, Nicole Rose I Alberto, Arnab K Ghosh, Bhav Jain, Shruti Jayakumar, Nicole Martinez-Martin, Ned McCague, Dana Moukheiber, Lama Moukheiber, Mira Moukheiber, Sulaiman Moukheiber, Antonio Yaghy, Andrew Zhang, Leo Anthony Celi. (2023, May). The impact of commercial health datasets on medical research and health-care algorithms. *The Lancet*. <https://www.thelancet.com/action/showPdf?pii=S2589-7500%2823%2900025-0>.

<sup>16</sup> Sue Bowman. (2013, October). Impact of electronic health record systems on Information Integrity: Quality and Safety Implications. *Perspectives in health information management*, U.S. National Library of Medicine. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3797550/>.

<sup>17</sup> Drew DA, Nguyen LH, Steves CJ, Menni C, Freydin M;Varsavsky T, Sudre CH, Cardoso MJ, Ourselin S, Wolf J, Spector TD, Chan AT. (2020, May). Rapid implementation of mobile technology for real-time epidemiology of covid-19. *Science* (New York, N.Y.), U.S. National Library of Medicine. <https://pubmed.ncbi.nlm.nih.gov/32371477/>.

<sup>18</sup> Aziz Sheikh, Michael Anderson, Sarah Albala, Barbara Casadei, Bryony Dean Franklin, Mike Richards, David Taylor, Holly Tibble, Elias Mossialos. (2021, June). Health information technology and digital innovation for national learning health and care systems. *The Lancet*. [https://www.thelancet.com/pdfs/journals/landig/PIIS2589-7500\(21\)00005-4.pdf](https://www.thelancet.com/pdfs/journals/landig/PIIS2589-7500(21)00005-4.pdf)

world to effectively support governments and policymakers in monitoring public health and to accordingly take proactive measures to mitigate any potential negative consequences of health-related disasters.<sup>19</sup> At the same time, it is equally important for policymakers and executives to pay heed to rising concerns over its impact on individuals' privacy, security, and civil liberties.<sup>20</sup> As indicated by the WHO, these ethical concerns have to be paid due heed when establishing and operationalising public health monitoring systems - <sup>21</sup> an appropriate balancing approach has to be taken into account.<sup>22</sup>

In line with the WHO's objectives towards promoting and scaling up digital health and innovation,<sup>23</sup> this paper is a timely intervention that, inter alia, aims to first open a channel of communication and knowledge between the EU and India for promoting standards of interoperability and scalability for informed data-driven decision-making; second, evaluate the extant legal and policy landscapes to understand the value of digital health and how it can cater to regional needs, specifically related to privacy and data protection; third, consult key stakeholders to develop standards and best practices.

Chapter 2 of the paper discusses the scope of the paper in terms of what the key objective of the paper is, the limitations within the larger ambit of digital health, key research questions that we are trying to address and the methodology to be used. To understand how digital health operates in India and the EU, it is first important to understand both countries' approaches towards data protection, EHR, Electronic Media Records, infrastructure policies, etc. To this end, chapter 3 discusses the key principles and rights each jurisdiction provides within the data protection landscape.

Chapter 4 discusses the key constraints within the digital health ecosystem within India and the EU that the paper will concentrate on. This chapter also elaborates on the research questions. Chapter 5 discusses key recommendations for India synthesised from the EU's experience with data protection regulations. Here, we believe that India can learn from the EU about the organisation and scope of data protection as it attempts to promote digital health services in the country in a secure and outcomes-driven manner. Chapter 6 discusses key recommendations for the EU synthesised from India's experience with making interoperability at scale. Here, we believe the EU can learn from India's experience in implementing the ABDM system for digitising healthcare records and achieving interoperability at scale. Finally, chapter 7 discusses how to enable seamless interaction between digital health initiatives in India and its counterparts in the European Union, where individuals and healthcare service providers can utilise innovations from both jurisdictions.



## 2. Scope and Methodology of Our Study

As the world has increasingly rely on digital technologies in recent years, the healthcare industry has significantly transformed. EHRs represent the next step in healthcare innovation, providing a comprehensive and secure digital platform for storing and accessing patient information. Although both India and the EU are taking steps to implement and promote the use of EHRs to improve healthcare delivery for patients and facilitate population health management, research, and public health reporting, both face challenges and opportunities that are distinct yet related.

A key challenge for both is interoperability and data sharing within what can be considered a decentralised operational structure, which includes different levels of power, languages, health systems standards, payment mechanisms for providers, etc. Concurrently, both jurisdictions grapple with data security and privacy issues. While the EU is highly advanced in determining the scope of regulation concerning data security, India is ideally positioned in terms of scale concerning interoperability.

Therefore, through this study, we produced a timely paper laying out the procedures, parameters, and processes these two jurisdictions could heed while imagining and implementing their healthcare policies. The study aims to aid cooperative learning and knowledge transfer between the EU and India by understanding how knowledge and experiences regarding formulating and implementing digital health policies from these jurisdictions can enable a secure, efficient, and accessible digital healthcare ecosystem.

### 2.1. Research Methodology

We adopted PESTEL analysis (Political, Economic, Sociological, Technological, Legal and Environmental) to develop the list of boundary conditions and requisites for achieving the scale and scope of a mutually-profitable collaboration.

The study adopted a two-pronged approach in terms of methodology, involving both secondary and primary research. This section will discuss the details of the methodology in terms of research design, data collection methods, sampling methods, and analysis techniques adopted for this study.

#### 2.1.1. Secondary Research

The study undertook a detailed meta-analytic literature review to understand the data protection regulation landscape and mechanisms followed by India and the EU to outline the direction for a bilateral exchange between both jurisdictions. Our literature review covered an analysis of the data protection regulation landscape in India and the EU to ascertain and analyse the crucial similarities and differences between their data regimes. It analysed the implementation, scalability, and interoperability of the National Health Stack in India and compared it to the current situation in the EU, i.e., European Health Data Space regulations. Also, we systematically reviewed the literature on digital health ecosystems and scalability, including EU and Indian contexts. Finally, we also reviewed relevant literature through multiple databases and other sources and analysed the data to identify key factors that are essential for achieving the scale and scope of digital health.

#### 2.1.2. Primary Research

The study conducted primary research by engaging with industry experts, data governance experts, international relations experts, members of civil society, prominent European/Indian digital healthcare facilities, and other recipient stakeholders from India and the EU to understand multiple viewpoints and concerns around the interoperability and privacy of the digital health ecosystem. Below are some key details about our primary research methodology, from the research design to the analysis technique adopted for this study.

- **Research type:** The study took an interpretive lens by adopting a qualitative approach to understanding how India and the EU can exchange knowledge to enhance their digital health ecosystem. The research conducted for this study was also deductive in nature, where we

analysed the gaps within the digital health ecosystem of India and Europe using secondary research and moved towards building upon those inferences with data collected through primary research.

- **Time horizon:** In the span of the last four months (April 2023 - August 2023), we collected data for this study in a cross-sectional time horizon manner where all the needed input from the respondents was collected at one point in time with occasional follow-ups.
- **Sampling strategy:** The study adopted a non-probability sampling by selecting respondents for input in a non-randomised manner. Also, we adopted snowballing sampling, where some of our respondents put us in touch with other potential respondents. For the study, we contacted industry experts, data governance experts, digital health experts, members of civil society, prominent European/Indian businesses operating in and out of India/European Union, and other recipient stakeholders from India and European Union. We received 16 inputs from stakeholders from both India and Europe, predominantly from ecosystem players, digital health experts, academicians, civil society, etc.

Representatives	Numbers
India	11
European Union	5
<b>Total</b>	<b>16</b>

- **Data collection method:** We adopted a semi-structured interview design to seek input from the stakeholders, where all our stakeholder interviews were predominantly conducted virtually.
- **Data analysis method:** Our engagement with stakeholders provided a rich source of information to understand the EU and India's digital health landscape. We adopted the thematic analysis technique, where we analysed the themes within the dataset to identify meaning. The identified themes focus on the key aspects that relate to our research questions.

### 3. Scope of Digital Health Initiatives in India & the EU - A Comparative Analysis

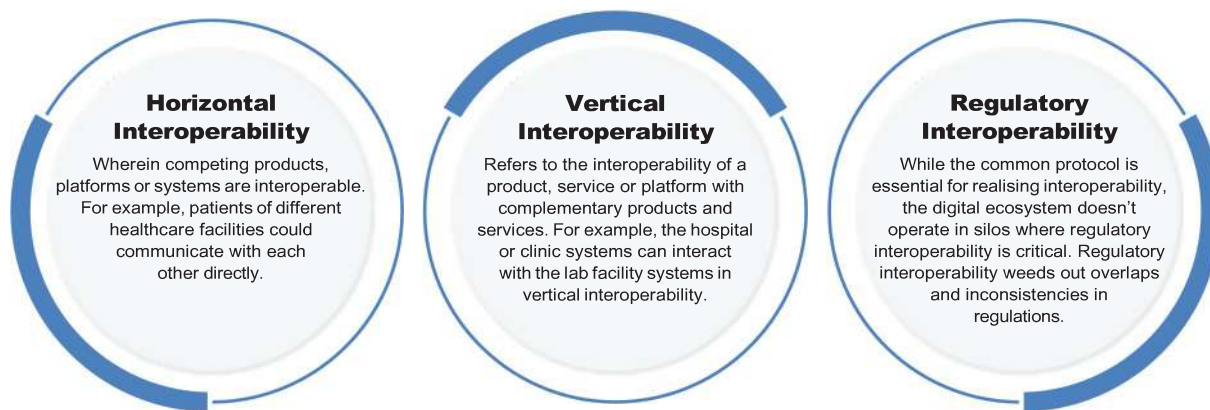
Both India and the European Union have extensive digital health ecosystems with similar objectives of securely achieving an interoperable system. However, both jurisdictions adopt different paths and approaches towards achieving the objective in terms of constituting an interoperable system, identification system, telemedicine, etc. Against this backdrop, in this chapter, we discuss the digital health ecosystem of India and the EU by analysing interoperable health systems, identification mechanisms, etc.

#### 3.1. Interoperable Health System

Interoperability plays a critical role in the digital ecosystem. Benefits from data are maximised when it is Findable, Accessible, Interoperable and Reusable.<sup>24</sup> In its Digital Agenda, the European Commission has identified a lack of interoperability as one of the seven “most significant obstacles” to the “virtuous cycle” of digitalisation.<sup>25</sup> However, while placing importance on interoperability in the digital ecosystem, one must remain aware of how interoperability is a means to achieving better system efficiency, and it both incurs costs and reaps benefits. Interoperability can be understood in the following three forms:

<sup>24</sup>. SSRN. Urs Gasse. Interoperability in the Digital Ecosystem. 2015, July.  
[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2639210](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2639210)

<sup>25</sup>. European Commission. Communication From The Commission To The European Parliament, The Council, The European Economic And Social Committee And The Committee Of The Regions. 2010, August.  
[https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52010DC0245R\(01\)&from=DA](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52010DC0245R(01)&from=DA).



Interoperability in these manifestations helps to enhance the effectiveness of data by presenting it or storing it in standardised models, coupled with easy data transfer protocols to enable knowledge and insight sharing.<sup>26</sup> This ultimately enhances connectivity, enabling individuals across the state (Indian case) and national borders (European Union case) to transfer their health data seamlessly. In this context, India and the European Union recognise the importance of having an interoperable healthcare ecosystem through their recent initiatives, enabling the free flow of health information across the healthcare ecosystem. While various initiatives may indicate interoperability in healthcare systems, in this section, we will discuss two key initiatives from India and the European Union, which try to enable interoperable systems for the free flow of health information.



### India's Ayushman Bharat Digital Mission

India's journey toward pioneering and transforming governance using technological innovations like Digital Public Infrastructure, has evolved significantly. India has also transformed from being an adopter of technology to creating scalable technology that complements the ecosystem. The two main consortia of Digital Public Infrastructures (DPIs) built using Digital Public Goods (DPGs) are India Stack and Ayushman Bharat Digital Mission (ABDM), which have various layers and components.



### European Health Data Space

European Health Data Space tries to create a health-specific ecosystem based on common standards, practices, rules, infrastructure, etc., to enable individuals to have digital access and control of their electronic health personal data nationwide and EU-wide. This is proposed to be realised by creating a single market of electronic health record systems relevant to medical devices. Besides, the European Health Data Space is considered as integral and central component which may enhance the strength of the European Health Union.

<sup>26</sup> Flynn, S. (2022, February). Allowing Solutions to Speak to One Another – The Importance of Interoperability. IEE Computer Society. <https://www.computer.org/publications/tech-news/trends/importance-of-interoperability>

India and the European Union take a similar approach towards empowering individuals, by allowing access and control of their health information and working backwards towards establishing an appropriate infrastructure, mechanisms, incentive systems, etc., within their jurisdictions. However, a similar objective of enabling interoperability as a means to enable the free flow of health information has been approached differently, as discussed in the table below.

Parameters	India	European Union
Mission/ Background	<p>As envisioned under the National Health Policy 2017,<sup>27</sup> the Ministry of Health and Family Welfare set up the National Digital Health Mission (NDHM) - a federated structure. In this policy, NDHM outlined a plan to issue a health ID to data principals and procedures for enabling the transfer of health information between the health information provider<sup>28</sup> to health information user<sup>29</sup> through the NDHM network, amongst other arrangements within the National Digital Health Ecosystem (NDHE).</p> <p>Following the successful pilot,<sup>30</sup> on September 27, 2021, the Prime Minister of India launched the Ayushman Bharat Digital Mission ('ABDM'), previously known as the 'National Digital Health Mission'. The ABDM's stated objectives include 'strengthening the accessibility and equity of health services' as part of a citizen-centric approach.<sup>31</sup></p>	<p>Like India, adding to the building blocks of the European Union's Digital Health Policy,<sup>32</sup> the European Health Data Space (EHDS)<sup>33</sup> has been established to provide control and access to health information in the hands of individuals. Through this initiative, the EU outlines how health information can be transferred cross-border for primary (personal use by the patients) and secondary purposes (data aggregation for finding health patterns) using interoperable systems.</p> <p>Through EHDS, health data access bodies, namely health facilities, healthcare professionals, etc., will be connected to the decentralised EU infrastructure, i.e., HealthData@EU.<sup>34</sup> This infrastructure ensures that Europeans can access healthcare wherever they travel and reside within the European Union.</p>

<sup>27</sup>. GOI, Ministry of Health and Family Welfare. National Health Policy. 2017.

<https://main.mohfw.gov.in/sites/default/files/9147562941489753121.pdf>

<sup>28</sup>. GOI, Ministry of Health and Family Welfare. Draft Health Data Management Policy: Version 2. 2022. Clause 4 (r).

[https://abdm.gov.in:8081/uploads/Draft\\_HDM\\_Policy\\_April2022\\_e38c82eee5.pdf](https://abdm.gov.in:8081/uploads/Draft_HDM_Policy_April2022_e38c82eee5.pdf) ["Draft HDMP"]

<sup>29</sup>. Draft HDMP, Clause 4 (s).

<sup>30</sup>. Ministry of Health and Family Welfare. (2020). A brief guide on Ayushman Bharat Digital Mission (ABDM) and its various building blocks. National Health Authority, GOI.

[https://abdm.gov.in:8081/uploads/ABDM\\_Building\\_Blocks\\_v8\\_3\\_External\\_Version\\_eabbc5c0f3\\_4\\_a96f40c645.pdf](https://abdm.gov.in:8081/uploads/ABDM_Building_Blocks_v8_3_External_Version_eabbc5c0f3_4_a96f40c645.pdf). ["ABDM Brief Guide"]

<sup>31</sup>. Id.

<sup>32</sup>. European Commission. eHealth.

<https://digital-strategy.ec.europa.eu/en/policies/ehealth#:~:text=The%20European%20Commission%20is%20working,services%20in%20health%20and%20care.&text=The%20European%20Commission%20published%20a,to%20build%20a%20healthier%20society>

<sup>33</sup>. The European Health Data Space (EHDS). (2022, May).

<https://www.european-health-data-space.com/#:~:text=The%20European%20Health%20Data%20Space%20sets%20out%20a%20common%20EU,regulatory%20activities%20and%20personalised%20medicine.> ["EHDS Proposal"]

<sup>34</sup>. EHDS. Health Data @ EU Pilot. <https://ehds2pilot.eu/>.

Parameters	India	European Union
<b>Objective</b>	<p>Two key objectives of India's ABDM are firstly, to build an ecosystem, where personal health records of individuals are easily accessible to themselves and to healthcare professionals and facilities based on their informed consent.</p> <p>Secondly, it promotes better management of the health sector by leveraging health data analytics and medical research.</p>	<p>The EHDS also has similar goals to India's ABDM. The primary objective of the EHDS is to empower individuals through increased digital access to and control of their electronic personal health data, both EU-wide and nationwide.</p> <p>The secondary goal is to enhance research, innovation, policy-making and regulatory activities using health data.</p>
<b>Stakeholders Involved</b>	The key stakeholders within ABDM are patients, healthcare professionals, healthcare facilities, central government, and state governments.	The key stakeholders within EHDS are patients, healthcare professionals, healthcare facilities, European Union and member states' national governments.
<b>Components/ Infrastructure</b>	<p>The ABDM has various key components and infrastructure, as discussed below, to realise the above-mentioned objectives.</p> <p><b>ABHA Number:</b> Through this component, the mission establishes a standardised mechanism for digitally identifying individuals across healthcare providers. Also, the mission has developed a consumer-facing ABHA mobile app that allows individuals to control and access their health records, spread out across the system, using their ABHA number.<sup>35</sup></p> <p><b>Healthcare Professionals Registry (HPR):</b> Through this registry, the mission is to create a repository of healthcare professionals involved in the delivery of healthcare services across both modern and traditional systems of medicine.<sup>36</sup></p>	<p>One of the key existing infrastructures, which would be leveraged under EHDS, is the eHealth Digital Service Infrastructure (eHDSI), which is built upon electronic, cross-border health services. eHDSI consists of two parts as discussed below:</p> <p><b>ePrescription and eDispensation/ Patient Summary:</b> The infrastructure provides a means for European citizens to access continued healthcare while they are travelling across other EU nations by enabling the seamless, cross-border transfer of data, including electronic prescriptions, electronic dispensation, and patient health summary.<sup>39</sup></p> <p><b>IT Tools for the European Reference Networks (ERN):</b> This is a virtual network of healthcare providers across the European Union. The</p>

<sup>35</sup>. GOI, National Health Authority. ABDM Components. <https://abdm.gov.in/abdm-components>.

<sup>36</sup>. GOI, National Health Authority. ABDM: Healthcare Professionals Registry. <https://hpr.abdm.gov.in/en>

<sup>39</sup>. European Commission. (n.d.-b). Electronic cross-border health services. Public Health.

[https://health.ec.europa.eu/ehealth-digital-health-and-care/electronic-cross-border-health-services\\_en](https://health.ec.europa.eu/ehealth-digital-health-and-care/electronic-cross-border-health-services_en)

Parameters	India	European Union
	<p><b>Health Facility Registry (HFR):</b> Similar to the HPR, the HFR has been formed to create a repository of health facilities (both public and private) in India across different systems of medicine.<sup>37</sup></p> <p><b>Unified Health Interface (UHI):</b> While other components of ABDM are implemented, UHI is currently in the process of design and operationalisation. UHI will be a digital public infrastructure, integrating various open networks of End Users Applications (EUAs) and participating Health Service Provider (HSP) applications. Using UHI as a base layer (open source), various private and public sector innovations can bring patients closer to healthcare facilities that were previously inaccessible. For instance, similar to the Unified Payments Interface (in the financial sector), through which individuals can make transactions, regardless of which UPI platform or bank they use, patients may book appointments, teleconsultation and other healthcare-related services through UHI platforms across the ecosystem, irrespective of which EUAs or HSPs they have enrolled in.<sup>38</sup></p>	<p>network is used to discuss complex or rare diseases and conditions requiring specialised treatment. Operationally, for reviewing patients' diagnoses and treatment in special cases, the ERN convener constitutes an advisory board empanelling doctors across disciplines using a dedicated IT platform and telemedicine tools.<sup>40</sup></p>
<b>Health Information</b>	<p>Moving beyond Electronic Medical Records (EMR), which are managed by the hospitals, and EHR, which are maintained by the state governments, the ABDM discusses Personal Health Records, which enable</p>	<p>The two key forms of health information, which is the predominant focus of the EHDS, are EMR and EHR, especially information such as electronic prescriptions, electronic dispensation, and patient health summary.</p>

<sup>37</sup>. GOI, National Health Authority. ABDM: Overviews and Pathways for HFR Registration. [https://abdm.gov.in:8081/uploads/HFR\\_Pathways\\_cbd50f5183.pdf](https://abdm.gov.in:8081/uploads/HFR_Pathways_cbd50f5183.pdf)

<sup>38</sup>. GOI, National Health Authority. NHA launches the Unified Health Interface initiative. <https://abdm.gov.in/collaborative-development>

<sup>40</sup>. European Commission. (n.d.) European Reference Networks: Overview. [https://health.ec.europa.eu/european-reference-networks/overview\\_en#:~:text=European%20Reference%20Networks%20\(ERNs\)%20are,and%20concentrated%20knowledge%20and%20resources..](https://health.ec.europa.eu/european-reference-networks/overview_en#:~:text=European%20Reference%20Networks%20(ERNs)%20are,and%20concentrated%20knowledge%20and%20resources..)

Parameters	India	European Union
	<p>patients to compile, update and keep a copy of their own records, which can help them better manage their care and are person-focussed.<sup>41</sup></p>	
<p><b>Horizontal Interoperability</b></p>	<p>In India, the ABDM is trying to achieve horizontal interoperability between health professionals and health facilities in India. For instance, ABDM's Health Professional Registry and Health Facility Registry try to bring health professionals and facilities that are currently not digital and those who already use digital systems to follow a single digital system to manage Electronic Medical Records voluntarily.</p>	<p>In the European Union, the EHDS is trying to achieve horizontal interoperability at the level of digital health systems operated and provisioned by different nationals by bringing uniform standards, principles, rules, governance, etc., to electronic health record systems.<sup>42</sup></p> <p>The EU already has electronic, cross-border health services, i.e., HealthData@EU, for Europeans to access healthcare wherever they travel and reside within the Union. However, there is less interaction between the nations within the European Union regarding secondary purposes, i.e., the use of health data for research, innovation, policy-making, and regulatory activities. Therefore, besides enhancing horizontal interoperability at scale for primary purposes, the EHDS also highlights the importance of electronic, cross-border health services for secondary purposes.</p>
<p><b>Vertical Interoperability</b></p>	<p>There is less clarity on how both India and the European Union would tackle the issue of vertical interoperability. During our stakeholder engagement, some stakeholders pointed out that it would be more practical to have an interoperable digital health ecosystem to address issues with vertical interoperability at the technical level. A stakeholder had hinted that there is an apparent disparity in the supply chain, where many new digital tech solutions only cater to one specific aspect of treatment. They pointed out the many demands across the various stakeholders in the entire ecosystem, when the different data types may have to be interrupted. For instance, there are many formats in which lab results can be delivered, which are read by different healthcare systems; however, when discussing vertical interoperability, a trade-off has to be made in order to choose a uniform format.</p>	

<sup>41</sup>. GOI, Ministry of Health and Family Welfare. EHR Standards for India. <https://main.mohfw.gov.in/sites/default/files/17739294021483341357.pdf>

<sup>42</sup>. European Parliament. (2022). Interoperable Europe Act . EU. [https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/745711/EPRS\\_BRI\(2023\)745711\\_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/745711/EPRS_BRI(2023)745711_EN.pdf)

Parameters	India	European Union
<b>Regulatory Interoperability</b>	<p>In the context of data protection, regulatory interoperability is a precondition for nationwide health data's interconnectedness and free flow. After a long process, India recently passed the Digital Personal Data Protection Act 2023, which applies to both public and private sectors. However, in the meantime, state governments have also constituted various data policies to govern state functions like public health initiatives. Therefore, there is currently less clarity regarding regulatory interoperability between state policies and central legislation. (For more details, refer to section 5.3.)</p> <p>As health falls within the state function of schedule 7 of the Indian Constitution, while ABDM tries to provide the prerequisite, its implementation and adoption is within the purview of the state governments. So far, only some states have shown an interest in adopting ABDM, though many may follow in the future.</p>	<p>Like India, the European Community Treaty allows member states to run their own healthcare systems. However, it is unclear how the upcoming European Health Data Space Regulation, a legal act that applies automatically to member states as soon as it enters into force, will operate without depriving the member states of their regulatory rights to govern health. (For more details, refer to section 5.3)</p> <p>On the topic of data protection, the EHDS clarifies that it builds further upon the EU General Data Protection Regulation (GDPR), proposed Data Governance Act, draft Data Act and Network and Information Systems Directive.</p>
<b>Incentives</b>	<p>While the incentive structure is well defined for both patients (to enhance their access and control) and the government (enhancing universal health coverage), the incentive structure for healthcare professionals and healthcare facilities is less clear, excluding the ABDM Sandbox Mechanism.<sup>43</sup></p>	<p>During our stakeholder engagement, experts from the European Union highlighted the fact that the incentive structure for EHDS is unclear.</p>
<b>Oversight</b>	<p>The ABDM has hierarchical oversight, starting from the Mission Steering Group, to oversee and guide the mission, the Empowered</p>	<p>Under EHDS regulation, there is the suggestion of constituting a European Health Data Space Board, comprising of the representatives of digital health</p>

<sup>43</sup>. GOI, Ministry of Health and Family Welfare. EHR Standards for India. <https://main.mohfw.gov.in/sites/default/files/17739294021483341357.pdf>



Parameters	India	European Union
	<p>Committee to make policy-level decisions, the Ministry of Electronics and Information Technology, and the Ministry of Health and Family Welfare to constitute regulations and legal frameworks. Finally, the National Health Authority would implement the mission by coordinating with respective ministries, state governments, etc.</p>	<p>authorities and new health data access bodies from all the member states, the Commission, and observers to govern the system.</p>
<b>Legislation and Implementation</b>	<p>The National Health Authority and ABDM were formed using subordinate legislation. While the government had expressed interest towards passing legislation to buttress these systems, they never saw the light.</p> <p>Moreover, as health, as a function, falls within the state's list of businesses, ultimately, the state governments implement the ABDM in their respective states.<sup>44</sup></p>	<p>The European Union is taking a regulatory route to establish EHDS, which would ultimately obligate the governments of member states to adopt and implement it.<sup>45</sup></p>
<b>Status-quo and the Way Forward</b>	<p>The ABDM is currently in the process of establishing its various components and the reach of the components already established amongst the key stakeholders.</p>	<p>While electronic, cross-border health services exist voluntarily, the European Parliament is deliberating about the EHDS regulations.</p>

This section showcases that both India and the European Union, under respective digital health initiatives, are trying to achieve similar objectives and goals. However, the pathways both jurisdictions are taking to reach and realise the charted goals differ. Therefore, exchanging experiences faced by both jurisdictions towards reaching a common goal through different pathways holds great value in collectively weighing up mistakes and enhancing the digital health ecosystem.

<sup>44</sup>. Constitution of India, 1950, Seventh Schedule.


<sup>45</sup>. The European Health Data Space (EHDS). (2022, May).

<https://www.european-health-data-space.com/#:~:text=The%20European%20Health%20Data%20Space%20sets%20out%20a%20common%20EU,regulatory%20activities%20and%20personalised%20medicine>

## 3.2. Identification & Targeting


Digital identification, when studied from a design perspective, has been dubbed as ‘the reimagination of the citizen-state relationship that is centred on a technology platform’.<sup>46</sup> Digital IDs serve a dual purpose, i.e., enhancing convenience for individuals and reducing administrative costs and efficiency in public service delivery for the government. The digital identification system requires deeper analysis as it tries to redefine various forms of citizen-state relationships, especially in terms of (a) how the government creates a social contract<sup>47</sup> with the citizens, in terms of providing them with proof of identity through verification, (b) how foundational digital IDs help de-duplicate functional ID systems<sup>48</sup>, (c) how databases, created through these digital identities, are used for targeting welfare and social protection, and (d) how these digital IDs are used for authenticating and delivering welfare to the targeted population. The Sustainable Development Goals (SDGs) also discuss the need for digital identification.

Therefore, to fulfil the SDGs target, the European Union and India are implementing various digital identification systems to aid in targeting various healthcare services and benefits. Here we discuss how India’s functional ID, i.e., ABHA number, and the European Digital Identity (eID) systems work to target healthcare services.



### India’s ABHA ID

One of the key layers/components of ABDM is the ABHA (Ayushman Bharat Health Account) ID/ Number, used for identification, authentication and threading health records of patient with the informed consent of the patient across multiple systems and stakeholders. The ABHA ID has been introduced to ensure continuity of care within healthcare in India. Complementing the creation of longitudinal healthcare records, the ABHA ID is meant to provide seamless access to healthcare services across the country.



### European Digital Identity (eID)

Under the Regulation of Electronic Identification and Trust Services, the EU is establishing a European Digital Identity (eID) system to ensure that people and businesses can use their own national electronic identification schemes (eIDs) to access services in other EU member states through the digital wallet system (EUDI). The objective is to aid business, citizens and public authorities to perform secure and seamless electronic transactions EU-wide.

While both India and the European Union have forms of digital identification systems, how they are operationalised, implemented, and utilised is different, especially in the context of digital healthcare delivery, as discussed below.

<sup>46</sup>. Dreze, J. (2017, May 8). Dissent and Aadhaar. The Indian Express.

<https://indianexpress.com/article/opinion/columns/dissent-and-aadhaar-4645231/>.

<sup>47</sup>. Markus Loewe, Tina Zintl, Annabelle Houdret, The social contract as a tool of analysis: Introduction to the special issue on “Framing the evolution of new social contracts in Middle Eastern and North African countries”, World Development, Volume 145, 2021, 104982, ISSN 0305-750X, <https://doi.org/10.1016/j.worlddev.2020.104982>.

<sup>48</sup>. Types of ID systems | Identification for Development. (n.d.). ID4D. Retrieved May 15, 2023, from <https://id4d.worldbank.org/guide/types-id-systems>.

Parameters	India	European Union
<b>Background</b>	The initiative of issuing ABHA ID finds its genesis in ABDM, which finds its roots in National Health Policy 2017, as discussed in section 3.1. <sup>49</sup> The COVID-19 pandemic only increased the strain on healthcare services nationwide, which paved the way for the rapid introduction and scaling up of Digital Health Initiatives.	The Regulation on Electronic Identification and Trust Services tries to create regulatory stability across European Union member states regarding electronic transactions. As an extension of this regulation, the EU established the eID system within the purview of member states' governments to promote the widespread use and availability of services using these identification technologies.
<b>Objective</b>	The ABHA ID was introduced to ensure the continuity of care within healthcare in India. Complementing the creation of longitudinal healthcare records, the ID is meant to provide access and control to individuals over the health information held by healthcare services nationwide.	The objective is to aid businesses, citizens, and public authorities to perform secure and seamless electronic transactions across the EU.  At the member state level, the eID system helps establish a centralised eGovernment gateway, introduce the first national eID card, enhance security, etc. <sup>50</sup>
<b>Applicability to Healthcare Services</b>	The ABHA ID is a functional ID, which only serves its intended purpose, i.e., to provide access to and control healthcare. Besides, ABHA ID will extend individual access to UHI in future.	The eIDs are not specifically designed to cater to healthcare services; they facilitate all electronic transactions across borders. But in some countries like Denmark, Sweden, Estonia, etc., they provide unique IDs, like ABHA. However, the architecture is different from ABDM.
<b>Legal Framework and Requirement</b>	Functional digital IDs like ABHA ID are constituted without a legal framework. Hence, they are not considered legal IDs unless they are specifically recognised as serving such a purpose.	eIDs, as discussed earlier, are statutorily backed under the Regulation on Electronic Identification and Trust Services.  Some countries, like Estonia, Belgium, etc., have made eIDs to be mandatorily linked with their mandatory national IDs. <sup>51</sup> Countries like Poland, Malta,

<sup>49</sup>. GOI, Ministry of Health and Family Welfare. National Health Policy. 2017.

<https://main.mohfw.gov.in/sites/default/files/9147562941489753121.pdf>

<sup>50</sup>. European Commission. Overview of Member states' eID strategies.

[https://ec.europa.eu/cefdigital/wiki/download/attachments/364643428/eID\\_Strategies\\_v4.0.pdf](https://ec.europa.eu/cefdigital/wiki/download/attachments/364643428/eID_Strategies_v4.0.pdf)

<sup>51</sup>. Electronic Frontier Foundation. Mandatory National IDs and Biometric Databases. <https://www EFF.org/issues/national-ids>

Parameters	India	European Union
		<p>etc., have eID systems and have also made it mandatory to sync new national IDs.<sup>52</sup> On the other end of the spectrum, countries like France, Italy, etc., have eID systems, but they are not mandatory.<sup>53</sup> Also, countries like Bulgaria don't have an eID system.<sup>54</sup></p>
<p><b>Role of Government</b></p>	<p>Governments traditionally provide functional IDs to serve some sector-specific needs and usage. Therefore, the government issues ABHA IDs to individuals to simplify accessing and controlling their health information.</p>	<p>In the case of eID, the role of the national government differs depending on the member state. In Finland, the government acts as a regulator and supervisor for eID schemes, including the supervision of private identity brokers for the public sector. In countries like Austria, Estonia, etc., the government acts as the sole identity provider, like India. On the other hand, some countries like Belgium, Italy, etc., follow a mix of both roles, i.e., regulatory and identity provider.</p>

Within the healthcare sector, both jurisdictions have different approaches when it comes to digital identification. While India has a specific health ID, the EU has a foundational digital identification system, which may or may not be extended to healthcare service delivery based on the discretion of the governments of the member states. Therefore, exchanging ideas on the experience of India in developing a functional ID linked to the foundational ID would be of great value for the EU in terms of establishing a system that only caters to identification, targeting, and healthcare service delivery.

---

<sup>52.</sup> *Id.*  
<sup>53.</sup> *Id.*  
<sup>54.</sup> *Id.*

## 4. Policy Landscape of Jurisdictions for Digital Health Ecosystem

To understand how digital health operates in India and the EU, it is first important to understand both countries' approaches towards data protection, EHR, Electronic Media Records, infrastructure policies, etc. To this end, this chapter discusses the key principles and rights each jurisdiction provides within the data protection landscape.

Notably, the provisions of the DPDP Act 2023, do not apply to foreign personal data processed in India. Furthermore, the GDPR restricts the transfer of personal data outside the EU, unless the recipient jurisdiction proves that there is an adequate level of protection for personal data.<sup>55</sup> Consequently, any sharing of personal data between the two jurisdictions is difficult under the legal and policy landscape.

Additionally, it is important to note that the rules and regulations under the recently enacted Digital Personal Data Protection Act, 2023, are yet to be notified by the policymakers, and so there is a certain degree of legal and regulatory uncertainty as to its implementation. When the corresponding rules and regulations are notified, the legal and policy landscape on how the EU and India could cooperate on digital health will become clearer.

### 4.1. Guiding Principles of Digital Health

The ABDM and the European Health Data Space (EHDS) have similar goals and objectives, as relayed above. The table below will briefly discuss some of the key guiding principles of these ecosystems, including the essential components in their design, and the guiding principles for their overall development. As is evident, both jurisdictions essentially employ similar approaches towards designing and developing their frameworks, however, certain divergences occur in their policies, which will be discussed in detail in the subsequent chapters.

Parameters	India	European Union
<b>Design</b>	<p>At the design stage, the ABDM considers the following principles:</p> <p><b>(i) Interoperability:</b> The building blocks and components of ABDM (for instance, ABHA number, HPR, HFR, PHR) will conform to open standards, be interoperable, and be based on open source software products and open source development.<sup>56</sup> The interoperability and connectivity aspect of the system envisages a network between hundreds of different, disparate, existing digital health systems, allowing public and private providers to create software/applications to provide various innovative</p>	<p>At the design stage, the EHDS considers the following principles:</p> <p><b>(i) Interoperability:</b> One of the key pillars of the EHDS is an interoperable network of technical and semantic interoperability, especially with reference to EHR. It builds on extant regulations to allow natural persons to control their health data effectively at national, regional, and local levels. The proposal seeks to mandate the interoperability requirements that otherwise lacked widescale and effective implementation under soft law instruments.<sup>57</sup></p>

<sup>55</sup>. GDPR, Article 44.

<sup>56</sup>. Ministry of Health and Family Welfare. (2019, October). National Digital Health Blueprint. Page 11. GOI. [https://abdm.gov.in:8081/uploads/ndhb\\_1\\_56ec695bc8.pdf](https://abdm.gov.in:8081/uploads/ndhb_1_56ec695bc8.pdf).

<sup>57</sup>. EHDS Proposal.

Parameters	India	European Union
	<p>means to access healthcare and health records.</p>	
	<p><b>(ii) Inclusivity:</b></p> <ul style="list-style-type: none"> <li>• The operation of ABDM will not exclude patients who do not have an ABHA number, or healthcare providers who are not registered with the system.</li> <li>• The system will be designed to be accessible even without internet connectivity.</li> <li>• Registration within the ABDM ecosystem will be free of charge, and entirely voluntary.<sup>58</sup></li> <li>• The Grievance Redressal Mechanism is operational in six Indian languages, including English.<sup>59</sup></li> </ul>	<p><b>(ii) Inclusivity:</b></p> <ul style="list-style-type: none"> <li>• The EHDS will enable the accessibility of health data across borders in and across member states.</li> <li>• The regulation, if enacted, will mandate member states to adhere to common technical standards and provide access to data in national languages.</li> <li>• Accessing the health data will be free of charge for individuals.</li> </ul>
	<p><b>(iii) Security &amp; privacy:</b> The ecosystem is designed to ensure the security and privacy of the data of citizens, healthcare professionals, and healthcare facilities through a federated architecture and an encrypted transmission of information, which will be built into the design of the ABDM infrastructure. The NHA is tasked with providing the appropriate technological and operational guidelines for ensuring the security and privacy of the personal data of data principals and for the maintenance of EMRs and EHRs.<sup>60</sup></p>	<p><b>(iii) Security &amp; privacy:</b> The ecosystem is designed to ensure the security and privacy of the data of citizens, healthcare professionals, and healthcare facilities, primarily by employing techniques for the pseudonymisation, anonymisation, generalisation, suppression, and randomisation of personal data.<sup>61</sup> The NIS Directive is undergoing a revision to raise the EU common level of ambition of the cybersecurity regulatory framework, through a wider scope, clearer rules, and stronger supervision tools. The Commission’s proposal addresses these issues across three pillars: (1) member state capabilities, (2) risk management, (3) cooperation and information exchange.<sup>62</sup> Further, manufacturers must declare their conformity with the EHDS proposal.<sup>63</sup></p>

<sup>58</sup>. ABDM Brief Guide, Pages 14-15.  
<sup>59</sup>. ABDM Brief Guide, Page 50.  
<sup>60</sup>. Draft HDMP, Clause 26.3.  
<sup>61</sup>. EHDS Proposal, Page 35.  
<sup>62</sup>. EHDS Proposal, Article 17.  
<sup>63</sup>. EHDS Proposal, Articles 14-27.

Parameters	India	European Union
	<p><b>(iv) Consent:</b> The ABDM will establish Health Information Exchange - Consent Managers, who will ensure the identity of individuals intending to share information is first verified, the consent of the person/patient is taken and logged in, and only after that will the health records be shared.<sup>64</sup> The DPDP Act 2023 will regulate these Consent Managers; the DPDP Act 2023 will provide the minimum responsibility, function, and liabilities of such managers and must be registered with the Data Protection Board of India.<sup>65</sup></p>	<p><b>(iv) Consent:</b> The EHDS will be in full compliance with the GDPR. The consent requirements will accordingly be freely given, specific, informed, and unambiguous.<sup>66</sup></p>
	<p><b>(v) Research access:</b> The ecosystem will enable the leveraging of health data analytics and medical research. However, consent for specific purposes will be taken while utilising it for research or analysis.<sup>67</sup></p>	<p><b>(v) Research access:</b> The ecosystem will provide a robust legal framework for the use of health data for research, innovation, public health, policy-making, and regulatory purposes. Further, under certain conditions, researchers, innovators, public institutions, or the industry will have access to large amounts of high-quality health data for research and innovation. Such access will require a permit by health data access bodies that are to be set up by member states in a manner that does not compromise the identity of the individual.<sup>68</sup></p>
<p><b>Development</b></p>	<p>At the development stage, the ABDM will consider the following principles:</p> <p><b>(i) Participatory approach:</b> The policymakers are conducting public consultations with key stakeholders, a practice which</p>	<p>At the development stage, the EHDS will consider the following principles:</p> <p><b>(i) Participatory approach:</b> The policymakers have conducted public and expert-level consultations with key stakeholders, alongside impact</p>

<sup>64</sup>. Draft HDMP.

<sup>65</sup>. DPDP Act 2023, sections 2(g) and 5.

<sup>66</sup>. GDPR, Article 4(11).

<sup>67</sup>. ABDM Brief Guide, Page 43.

<sup>68</sup>. EHDS Proposal, Article 37.

Parameters	India	European Union
	is ongoing for a variety of specific policies. <sup>69</sup>	assessments. <sup>70</sup>
	<b>(ii) Navigating technical uniformity:</b> The NHA has investigated and established common standards and languages for the ABDM. <sup>71</sup>	<b>(ii) Navigating technical uniformity:</b> The policymakers have investigated and established common specifications and standards for the EHDS. <sup>72</sup>
	<b>(iii) Governance framework:</b> The NHA will establish and investigate the possibility of enabling cooperation and communication mechanisms between the centre and the states. <sup>73</sup>	<b>(iii) Governance framework:</b> The proposal has leveraged extant legal and policy mechanisms to enable seamless cooperation and communication between the EU and the member states. <sup>74</sup>
	<b>(iv) Ecosystem approach:</b> The ABDM framework will cover all public and private actors, including individuals, healthcare providers, industry, researchers, and regulators.	<b>(iv) Ecosystem approach:</b> The EHDS framework will cover all public and private actors, including individuals, healthcare providers, industry, researchers, and regulators. It further delineates the health data into two types - primary and secondary - based on their usage, and specifically approaches the regulation of these types of data.
	<b>(v) Nature of adoption:</b> The ABDM framework enables voluntary participation in the ecosystem and does not mandate the key stakeholders to adopt the framework.	<b>(v) Nature of adoption:</b> The EHDS framework, by virtue of being a 'regulation', will be binding for member states, and these states will have to implement it.

## 4.2. Digital Rights

The table below briefly relays some of the key rights a data principal/subject has against the data fiduciary/controller. Note, that the EHDS is designed to be in full compliance with the GDPR, and so the available digital rights for the EHDS are discussed as enumerated under the GDPR. Additionally, in India, the available digital rights for the ABDM will be discussed by reading the DPDP Act 2023, along with the draft HDMP.

<sup>69</sup>. See ABDM - Publications, <https://abdm.gov.in/publications>

<sup>70</sup>. EHDS Proposal, Pages 9-12.

<sup>71</sup>. ABDM Brief Guide, Page 7.

<sup>72</sup>. EHDS Proposal, Page 28.

<sup>73</sup>. ABDM Brief Guide, Pages 7-8.

<sup>74</sup>. EHDS Proposal.



Rights	India (DPDP Act 2023 r/w Draft HDMP)	EU (GDPR)
Regarding consent processes	<p>Consent is to be freely given, specific, informed, and clear.<sup>75</sup> The consent of the data principal may be electronically or physically obtained, either via the data principals themselves or HIE-CM. Physically received consent will later be digitised.<sup>76</sup> These HIE-CM will act as the nodal point for consent withdrawal, modification, and updating. These managers shall not access, process, or store the data, and shall maintain records of all consent activities.</p>	<p>The GDPR requires consent to be freely given, specific, informed, and unambiguous.<sup>77</sup> It is an affirmative action by the subject, whereby they clearly state that they agree to the processing of personal data relating to them and shall accordingly have the right to withdraw such consent.</p>
Right to confirmation and access	<p>The data principals shall, inter alia, have the right to confirmation and access from the data fiduciaries as to (i) whether data has been processed, (ii) the data that is processed or a summary of it, (iii) a summary of processing activities on such data, (iv) information regarding privacy notices, including the purpose of processing and data retention. All such information has to be provided in a clear and concise manner. Further, the data principal shall have the right to access in one place all the identities of data fiduciaries with whom the data has been shared, alongside the categories of data shared.<sup>78</sup></p>	<p>The data subjects shall, inter alia, have the right to confirmation and access from the controllers as to (i) whether data has been processed, (ii) the purposes of processing, (iii) categories of personal data, (iv) recipients or categories of recipient, (v) the period of data retention, (vi) existence of the right to request from the controller rectification or erasure of personal data or restriction of processing of personal data, (vii) where the personal data are not collected from the data subject, any available information as to their source, (viii) the existence of automated decision-making, including profiling. Further, the subjects can request a copy of the personal data undergoing processing.<sup>79</sup></p>
Right to restrict or object	<p>The data principal can restrict or object to the disclosure of his/her personal data by the data fiduciary.<sup>80</sup></p>	<p>The data subject can restrict or object to the processing of their personal data by the controller.<sup>81</sup></p>

<sup>75</sup>. Draft HDMP, Clause 9.2.

<sup>76</sup>. Draft HDMP, Clauses 8 and 11.

<sup>77</sup>. GDPR, Article 4(11).

<sup>78</sup>. Draft HDMP, Clause 14.1 (a).

<sup>79</sup>. GDPR, Article 15.

<sup>80</sup>. Draft HDMP, Clause 14.1 (b).

<sup>81</sup>. GDPR, Articles 18 and 21.

Rights	India (DPDP Act 2023 r/w Draft HDMP)	EU (GDPR)
<b>Right to correction and erasure</b>	The data principal shall have the right to correct, complete, update, or erase their personal data. The data fiduciary is obliged to erase data unless its retention is necessary for compliance with any law. <sup>82</sup>	The data subject shall have the right to rectify inaccurately listed personal data. <sup>83</sup> Further, the data subject shall have the right of erasure on certain specific grounds including when data are no longer necessary in relation to the purposes; withdrawn consent; unlawfully processed data; under obligation with the law. <sup>84</sup>
<b>Right to data portability</b>	The data principal can request that their data be transferred to another data fiduciary, where technically feasible, including the data provided to the fiduciary, and data that has been generated in the course of the provision of services by the data fiduciary. <sup>85</sup>	The data subject can request that their data be transferred to another data controller, where technically feasible, including the data that is processed pursuant to contract or consent, and data that is processed via automated means. <sup>86</sup>
<b>Right of grievance redressal</b>	The data principal may approach a Data Protection Officer (“DPO”) for inquiries and questions, the details of whom are published on the website. Where feasible, the fiduciary may designate a DPO or someone else as the Grievance Officer, who will be responsible for grievance redressal. In a case where there is no response or resolution, the principal may write to the ABDM authorities via their website portal. <sup>87</sup>	The data subject has the right to lodge a complaint with a supervisory authority [primarily, Data Protection Authority (“DPA”)], who is supposed to keep the complainant informed of the progress and the outcome of the complaint including the possibility of a judicial remedy. <sup>88</sup> In the case of lack of action, lack of information about the outcome or progress of their complaint, or against the decision of the DPAs, the complainant may pursue a judicial remedy. <sup>89</sup>

<sup>82</sup>. DPDP Act 2023, Section 12.

<sup>83</sup>. GDPR, Article 16.

<sup>84</sup>. GDPR, Article 17.

<sup>85</sup>. Draft HDMP, Clause 14.2 (c).

<sup>86</sup>. GDPR, Article 20.

<sup>87</sup>. Draft HDMP, Clause 32.

<sup>88</sup>. GDPR, Article 77.

<sup>89</sup>. GDPR, Article 78.

## 5. Constraints Faced by EU and India Within the Digital Health Ecosystem

The previous chapter provides the background of the digital health ecosystem of India and the European Union. In this chapter, we will discuss what the key constraints within the digital health ecosystem are that the paper will be concentrating on. This chapter will elaborate on the research questions.

### 5.1. Regulations and Policies Governing Digital Health Data (DHD)

To understand the constraints related to the policies and regulations governing the EHR of both India and the EU, it is first important to understand how both countries approach the subject of data protection, specifically related to EHR. India's data protection landscape has recently got an overarching data protection regime, while ABDM has constituted a Health Data Management Policy (draft 2 is being deliberated) to protect health data within the ecosystem. In addition, there are also EHR Standards 2016, SNOMED CT, Telemedicine Practice Guidelines (2020), etc., which also suggest privacy and data protection-related provisions to safeguard DHD.

On the other hand, the European Union's General Data Protection Regulation has been adopted and benchmarked globally as a golden standard of data protection regulation. In parallel, the European Union is also in the process of enacting European Health Data Space regulations<sup>90</sup>, Data Governance Act, Data Act, etc., which may also have a say over safeguarding EHR, as discussed in chapter 4. Some national-level regulations, standards, and guidelines also apply to EHR. For instance, in Belgium, in addition to GDPR, the Belgian Law on the Protection of Natural Persons applies to DHD and overarches the digital health ecosystem.<sup>91</sup>

As both countries approach the governance of EHRs differently, there are definite merits in the systems followed by both India and the European Union; however, both jurisdictions also face constraints, as discussed below.

#### 5.1.1. Constraints in India's DHD Protection Landscape

India's data protection landscape has evolved significantly over the past couple of years with the recent enactment of the Digital Personal Data Protection Act 2023.<sup>92</sup> This act indicates an important step towards establishing privacy and enacting data protection in India. In parallel, the draft Health Data Management Policy 2.0 ('HDMP') grants the National Health Authority the authority to formulate subordinate rules and guidelines within the ABDM. For instance, the NHA is now granted the authority to 'specify the procedure for permitting different classes of entities, such as data fiduciaries, data processors, Health Information Providers, Health Information Users, and repositories, to operate in the National Digital Health Ecosystem (NDHE)'.<sup>93</sup> However, while India's data protection landscape has evolved, it is also anticipated that there will be constraints in extending the protection to specific data forms, like DHDs, for the following reasons.

##### 5.1.1.1. Absence of a Legislative Mandate

The HDMP states that the NHA can specify the purposes for the collection or processing of personal data within the digital health ecosystem.<sup>94</sup> But both the NHA (as a nodal body) and the ABDM (the digital health ecosystem) are backed by cabinet decisions, i.e., an executive mandate without any statutory

---

<sup>90</sup> It is suggested that EHDS builds further on the General Data Protection Regulation (GDPR), proposed Data Governance Act, draft Data Act, and Network and Information Systems Directive.

<sup>91</sup> ICLG. Digital Health Laws and Regulations: Belgium 2023.  
<https://iclg.com/practice-areas/digital-health-laws-and-regulations/belgium>

<sup>92</sup> MeitY. The Digital Personal Data Protection Act 2023.  
<https://www.meity.gov.in/writereaddata/files/Digital%20Personal%20Data%20Protection%20Act%202023.pdf>

<sup>93</sup> Ministry of Health and Family Welfare. (2019, October). National Digital Health Blueprint. GOI.  
[https://abdm.gov.in:8081/uploads/ndhb\\_1\\_56ec695bc8.pdf](https://abdm.gov.in:8081/uploads/ndhb_1_56ec695bc8.pdf)

<sup>94</sup> Ministry of Health and Family Welfare. (2022, April). Health Data Management Policy. National Health Authority, GOI.  
[https://abdm.gov.in:8081/uploads/Draft\\_HDM\\_Policy\\_April2022\\_e38c82eee5.pdf](https://abdm.gov.in:8081/uploads/Draft_HDM_Policy_April2022_e38c82eee5.pdf)

backing.

Without a comprehensive regulatory framework, the implementation process and infrastructure act as regulations, substituting or displacing parliamentary law.<sup>95</sup> Implementation processes can create path dependencies, foster cooperation, or structure conflict resolution.<sup>96</sup> In the case of India's public-interest technology, such as the ABDM, the plumbing of the digital health ecosystem functions as a regulation instead of the system being developed on the foundation of an ex-ante regulatory framework. Legislation with built-in accountability and transparency measures is an important step towards building a citizen-centric framework to produce the desired outcomes. However, a framework restricted to responsiveness, evaluation, and accountability may not have the same flexibility as one with a legal mandate to establish rights, delineate responsibilities, and provide remedies. Remedies and iterative stakeholder participation are essential elements of effective accountability practices.<sup>97</sup> As the enrolment of healthcare professionals and facilities within the ABDM ecosystem is voluntary, the HDMP only applies to the enrolled entities. Therefore, HDMP is a prerequisite/condition to be part of ABDM rather than protecting the digital health ecosystem. While the intention to draft legislation to support these systems was expressed in 2019, it has yet to come to fruition. Therefore, as a non-statutory body performing a crucial public function, it is important to clarify the scope of NHA's mandate and the checks on powers that they are required to wield.

### 5.1.1.2. Lack of Higher Degree Protection to Health Data

The Digital Personal Data Protection Act 2023 ("DPDP Act 2023") will apply to healthcare professionals, providers, and facilities. However, the demarcation between personal and sensitive personal data, as suggested in the bill's previous version, is absent in India's Digital Personal Data Protection Act. This means there is no higher degree of protection for a breach of certain categories of personal data, such as financial data, biometric data, health data, data related to sexual orientation, etc., which is highly likely to cause greater harm to an individual.

Having said that, the DPDP Act 2023 is not India's first effort to regulate personal data. Various laws and regulations directly or indirectly apply to handling personal data in India, specifically sensitive personal data. The Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules 2011 (SPDI Rules), under the Information Technology Act 2000, set certain security standards for the body corporates to follow. It specifies that the collection of medical records and history should only be done for a lawful purpose connected to the function of the organisation.<sup>98</sup> It incorporates privacy principles, such as use limitation,<sup>99</sup> purpose specification, etc., and even gives individuals the right to correct their information.<sup>100</sup> SPDI Rules and the IT Act also prohibit body corporates from transferring data across borders until the third party has adequate safeguards. However, the applicability of SPDI Rules and whether they would be observed within the DPDP Act 2023 is unclear.

### 5.1.1.3. Compliance Constraints

India's DPDP Act 2023 does not contain a provision for establishing a Data Protection Authority (a separate regulatory body). However, the Act has provisions for establishing a Data Protection Board, whose functions are significantly diluted, for instance protecting the interest of the data principal and promoting awareness about data protection is removed while emphasis is made on determining non-compliance with provisions of this act and imposing penalties. One of the key functions that are lacking is promoting awareness and understanding of the risks, rules, safeguards, and rights concerning personal data protection amongst data fiduciaries and data principals.

---

<sup>95</sup> GOI, National Health Authority. Response to DRAFT HEALTH DATA MANAGEMENT POLICY. [https://abdm.gov.in:8081/uploads/Kazim\\_Rizvi\\_The\\_Dialogue\\_35dbacfb8d.docx](https://abdm.gov.in:8081/uploads/Kazim_Rizvi_The_Dialogue_35dbacfb8d.docx)

<sup>96</sup> Id.

<sup>97</sup> Id.

<sup>98</sup> The Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 ["SPDI Rules"] Rule 5(2).

<sup>99</sup> SPDI Rules, Rule 5(4).

<sup>100</sup> SPDI Rules, Rule 5(6).

Realising that people's understanding of privacy is detached from reality,<sup>101</sup> it is important for the regulatory body to equip them with proper knowledge of digital rights to begin the conversation and momentum. In addition, in emerging economies like India, there are various healthcare start-ups and small-scale businesses still in the process of understanding compliance with data protection norms, as this is a new concept for them.

#### 5.1.1.4. State Exemptions & Deemed Consent

The DPDP Act 2023 empowers the central government to exempt any government agency from the act on various grounds, including the sovereignty and integrity of India, security of the state, friendly relations with foreign states, maintenance of public order or preventing incitement to any cognisable offence relating to any of these. Government exemptions are not just required but necessary for the national security of the state, and their inclusion in the bill is certainly a legitimate requirement. However, certain aspects of these exemptions do not fit well with the principles of necessity and proportionality as enshrined in the Puttaswamy Judgement<sup>102</sup> that recognised the right to informational privacy as a fundamental right and laid down certain requirements to be fulfilled if this right is to be restricted. Deemed consent applies to the performance of activities by state actors, like providing subsidies, benefits, services, licenses, certification, etc.

The government collects vital data from all citizens and is one of the biggest data fiduciaries, especially in the case of healthcare. The union government and some state governments increasingly use technology to extract data to enhance governance and welfare delivery. For instance, enrolment in flagship programmes like ABHA ID under Ayushman Bharat Digital Mission, eSanjeevani, etc.

#### 5.1.1.5. Rights and Duties of Data Principals

India takes a rights-based approach by vesting various rights in the hands of the data principal and mandating respective government authorities to safeguard those rights through regulation under various provisions within the act. However, the list of rights provided to individuals through the DPDP Act 2023 is limited compared to other data protection regulations present in different jurisdictions.

India's DPDP Act 2023 also introduces the duties of the data principal. The act states that the data principal shall not register a false or frivolous grievance or complaint with a data fiduciary or the board. Meanwhile, it also states that the data principal shall furnish only such information as is verifiably authentic, while exercising the right to correct or erase data under the provisions of this act. While a data principal is reasonably expected to follow these duties and exercise due diligence on its part while exercising such rights, it is important to note that India is just transitioning into digital rights; it is necessary that awareness and digital literacy around these rights are provided to the citizens. People in rural areas, women and the elderly need much guidance to understand and exercise rights under the data protection framework. Imposing a hefty penalty in case of non-compliance will affect the data principals negatively and might also deter them from filing genuine complaints where their rights have been compromised.

### 5.1.2. Constraints in the EU's DHD Protection Landscape

The EU's GDPR is considered the golden standard of data protection. However, the European Union faces constraints in balancing data protection with value creation. The impact on value creation emerges directly where some of the provisions may cause hindrance towards technological developments within critical sectors like healthcare, as they don't hold over time. Indirectly, keeping the conversation around data protection and value creation separate also hints that they work under two different tangents. Below are some of the direct and indirect constraints within the EU's DHD Protection Landscape.

---

<sup>101</sup> Grassroots Privacy Initiative – Engaging and informing citizens to exercise their fundamental right to privacy. (n.d.). The Dialogue. Retrieved November 26, 2022, from <https://grassrootsprivacy.in/>

<sup>102</sup> Justice K.S. Puttaswamy and Anr. vs. Union of India (UOI) and Ors., (2017) 10 SCC 1.

### 5.1.2.1. Premises of Data Protection Regulation

GDPR ensures everyone can enjoy their fundamental right to control their personal information and its processing. This shows the purpose and genesis of the GDPR is to protect the privacy of individuals. However, on the other side of the coin, the data can also benefit citizens, businesses, and communities, which is less realised in the European Union. For instance, while protecting health information is critical, health information can also unlock various innovations in solving rare diseases and medical conditions. Therefore, there is less realisation that data protection doesn't mean restricting data usage and processing, rather, it is to ensure data is shared and used appropriately.

### 5.1.2.2. Over-reliance on Consent Artefact

GDPR, being one of the key data protection regulations, has set various benchmarks across the globe regarding policy design for data protection. One such contribution has been the consent artefact, which is the bedrock of GDPR and has been adopted by other jurisdictions like India, Brazil, etc. However, being one of the oldest data protection regulations, GDPR has come full circle, where feedback on some of the mechanisms, like consent, has been mixed, and its legitimacy for processing data is debatable. Individuals may receive innumerable privacy notifications, causing consent fatigue.<sup>103</sup> It has been reported that data fiduciaries use dark patterns to manipulate data principals to obtain consent by playing with their cognitive abilities and bounded rationality.<sup>104</sup>

Moreover, the consent-based approach doesn't consider the complex data processing mechanism in the case of the healthcare ecosystem, where sometimes the individuals are not in the position to provide consent to process their health information or situations where AI is involved, it can become difficult. This could also cause data to fall through the cracks, as determining legitimacy of consent is nebulous in such situations. Adding to this, there are no other means through which individuals can exercise their agency over their personal data when their health information is transferred across borders, in the case of EHDS, or when using an AI-based health platform.

### 5.1.2.3. Privacy Vs. Value of Data/Digitalisation

With the rise of the Internet economy, technological developments have paved the way for the emergence of data-driven businesses and led to the digitisation of traditional businesses. This has led to improved product quality, reduced cost of operations, enhanced efficiency and service delivery, and developed allied industries, especially in critical sectors like healthcare.<sup>105</sup>

The European Union, to an extent, realises the value of data and is in the process of deliberating the Draft Data Act, which is trying to make the European Union ready to share the digital economy and innovation by facilitating the voluntary sharing of data by individuals and businesses, while also harmonising conditions for the use of certain public sector data. However, this draft is still being deliberated, and there is less clarity on how this would interact with the ePrivacy Directive and GDPR. Within the healthcare space, the EHDS is also trying to achieve an interoperable system, where health information EU-wide can be utilised for the secondary purpose of research, innovation, policy-making, and regulatory activities; however, this regulation is also in the deliberation stage.

On the other hand, European experts during our stakeholder engagement expressed a tussle in individuals' mindsets regarding data protection and digitalisation. Some experts highlighted how individuals consider sharing their digital footprints in return for digital health services may cause them to compromise their privacy. One of the European experts from Germany highlighted how the presence of GDPR and other historical reasons, specific to the nation, heavily influence the perception of individuals in terms of using digital health services, where the government may have access to sensitive data like health information. For instance, it was pointed out that a very small portion of the population had enrolled on an eHealth card in Germany, and now the government also provides an opt-out option, which makes the reach of the initiative minimal.

---

<sup>103</sup>. The Data Privacy Group. Peter Borner. Consent Fatigue. 2022, June. <https://thedataprivacygroup.com/blog/consent-fatigue/>

<sup>104</sup>. Id.

<sup>105</sup>. Shekar, K. (2022, September 30). Exploring a roadmap for digital trade. Times of India Blog. <https://timesofindia.indiatimes.com/blogs/voices/exploring-a-roadmap-for-digital-trade/>.

## 5.2. Scalability of the Digital Health Ecosystem

The digital transformation of healthcare systems has been a global imperative, aiming to improve patient care, enhance accessibility, and reduce costs. With technology playing an increasingly pivotal role in healthcare service delivery, both India and EU countries have embarked on ambitious journeys to integrate digital health solutions into their healthcare systems. These digital health initiatives hold the promise of enhancing healthcare accessibility, efficiency, and patient outcomes. However, as these nations strive to navigate the complexities of the digital health landscape, they face formidable scalability challenges that are impeding the realisation of the full potential of digital health.

### 5.2.1. Scalability Challenges in India's Digital Health Ecosystem<sup>106, 107, 108</sup>

India, a nation characterised by its vast population and a diverse array of healthcare needs, has been at the forefront of digital health adoption. While the potential benefits are undeniable, several pressing scalability challenges have emerged on this transformative journey.

**Infrastructure Disparities:** A critical challenge facing India is the inadequacy of digital infrastructure and connectivity in rural and remote areas. This glaring digital divide, perpetuated by socioeconomic disparities, severely hampers the widespread adoption of digital health solutions, particularly telemedicine and health information systems. The Indian experts also flagged this during our stakeholder engagement.

**Interoperability Issues:** The achievement of interoperability between various digital health platforms and systems remains a substantial challenge in India. The lack of standardized protocols and formats for healthcare data exchange hampers the seamless sharing of patient information among healthcare providers, negatively impacting the scalability of telemedicine and electronic health record (EHR) systems.

**Regulatory Framework:** Stringent regulatory processes and compliance requirements often slow down the introduction of new digital health technologies in India. The regulations governing telemedicine, health data, and medical devices are currently fragmented and often lack clarity. Startups and innovators encounter difficulties in navigating complex regulatory frameworks, impeding the rapid scalability of their solutions. This regulatory uncertainty has the potential to stifle innovation and deter investment in the sector.

**Healthcare Workforce Training:** Scaling digital health initiatives necessitates a workforce that is adequately equipped with the requisite digital skills. However, there is a glaring shortage of healthcare professionals trained in digital healthcare technologies, added to the deficiency in digital literacy among both healthcare workers and the general population.

**Financial Constraints:** While digital health offers the promise of long-term cost savings, the initial investment required can be daunting. Many healthcare providers, especially those in the public sector, face financial constraints that limit their ability to adapt and scale digital health solutions.

### 5.2.2. Scalability Challenges in the European Union's Digital Health Ecosystem<sup>109, 110</sup>

The different healthcare systems and regulatory environments in the member states of the European Union provide a number of unique scalability problems for the region's developing digital health

---

<sup>106</sup> Forbes. Hanu Tyagi. Digital Health Startups in India: the challenge of scale. 2019, March.

<https://www.forbesindia.com/article/isbinsight/digital-health-startups-in-india-the-challenge-of-scale/52799/1>.

<sup>107</sup> Rethinking Economics India Network. Digital Health in India: challenges and concerns. 2021, January.

<https://reindia.medium.com/digital-health-in-india-challenges-and-concerns-29de5040d565>.

<sup>108</sup> Jain, D. (2023, March 21). Regulation of Digital Healthcare in India: Ethical and Legal Challenges. *Healthcare*, 11(6), 911.

<https://doi.org/10.3390/healthcare11060911>.

<sup>109</sup> Reform Support. Balla D , Belani H, Berdun J, Boumpaki A, Crooks G, Kelepouris A, Merimaa K, Borej J , Hulek J, Matkun A , Ross P , Ricciardi W. Building Sustainable Digital Health Services in Europe: lessons learned from the COVID-19 Pandemic. 2021, March. [https://reform-support.ec.europa.eu/system/files/2021-06/Building%20\\_Survivable%20\\_eHealth\\_Strategies.pdf](https://reform-support.ec.europa.eu/system/files/2021-06/Building%20_Survivable%20_eHealth_Strategies.pdf)

<sup>110</sup> Țăran, A. M., Mustea, L., Vătavu, S., Lobonț, O. R., & Luca, M. M. (2022, April 19). Challenges and Drawbacks of the EU Medical System Generated by the COVID-19 Pandemic in the Field of Health Systems' Digitalization. *International Journal of Environmental Research and Public Health*, 19(9), 4950. <https://doi.org/10.3390/ijerph19094950>.

ecosystem.

**Fragmented Healthcare Systems:** The EU's digital health landscape is characterised by fragmentation, both in terms of technological solutions and regulatory frameworks. This underscores the lack of harmonisation among member states, making it challenging to establish a unified digital health infrastructure, that leads to compatibility issues and inefficiencies in cross-border healthcare.

**Data Privacy Regulations:** Data governance and sharing policies across EU member states represent a significant scalability hurdle. Achieving a balance between stringent data protection regulations, as exemplified by the European General Data Protection Regulation (GDPR), and interoperability requirements is a complex and nuanced task due to differing data protection regulations and cultural attitudes towards data sharing among EU countries. Complying with GDPR requirements can slow down the implementation and scalability of digital health solutions.

**Regulatory Complexity:** The EU's regulatory landscape for digital health is intricate, characterised by overlapping jurisdictions and regulations. This complexity can act as a deterrent to innovation and investment, making it challenging to scale digital health solutions uniformly across the EU.

**Limited Funding and Resources:** Many EU member states face budget constraints and resource limitations when it comes to digital health adoption. This lack of financial resources can hinder the deployment of digital health solutions and limit their scalability.

**Resistance to Change:** Resistance to change within the healthcare sector is a common challenge across the EU. Healthcare professionals and institutions may be hesitant to embrace new digital technologies, hindering their widespread adoption and scalability.

**Cybersecurity Concerns:** Just like India, the EU is not immune to cybersecurity threats. As digital health systems store sensitive patient information, they are attractive targets for cyberattacks. The need to ensure robust data protection measures can impose burdens on digital health startups and healthcare providers.

**Resource Allocation:** Both India and the EU must judiciously allocate resources to scale their digital health initiatives. In the context of the EU, the allocation of resources is complicated by budget constraints and competing priorities among member states.

While both India and the EU face scalability challenges in their digital health ecosystems, there are notable differences. India's challenges often stem from infrastructural and regulatory issues, while the EU's challenges are more related to the fragmentation of healthcare systems and stringent data privacy regulations. However, there are also common themes, such as interoperability concerns and cybersecurity challenges, that both regions need to address to enhance scalability.

## **5.3. Interoperability of the Digital Health Ecosystem**

To enhance the digital health ecosystem, it is important that health information is transferred and flows across the different technical systems (both in the case of the EU and India) of states (in the case of India) and member states (in the case of the EU). However, India and the EU respectively face interoperability concerns contextual to those jurisdictions. Similarly, as discussed in this section, the EU may face interoperability concerns at the level of digital health initiatives.

### **5.3.1. Interoperability Concerns in India**

As discussed in this section, the digital health ecosystem may face interoperability in India's regulations and centre-state relationships. The DPDPA 2023 sets obligations for data fiduciaries. Significant data



fiduciaries, safeguards for children's data, vested rights for individuals, allowing cross-border data transfers, outlining exemptions from the bill, contour for setting up a Data Protection Board (DPB), financial penalties, and grievance management system, etc. The definition of "Data Fiduciaries" incorporates the public and private sectors, which determine the purpose and means of processing personal data. While within India's quasi-federal system, public sector agencies and departments are at the central and state government levels, the adjudication and rule-making power in data protection matters is concentrated at the central level, which may cause friction within the digital health ecosystem.

### 5.3.1.1. Lack of Vertical Regulatory Interoperability

As health information is one of the sub-sets of personal data<sup>111</sup> under the Digital Personal Data Protection Act 2023, all the players within the ABDM, including the National Health Authority (unless exempt under clause 17), will come under the ambit of the central government and the Data Protection Board (DPB). This overlap of responsibility needs to be clarified.

The HDMP provides data principals the right to portability, access and confirmation, and disclosure. In addition to the rights discussed in HDMP, the DPDPA 2023 provides a set of digital rights to the data principals, including the right to correction and erasure, the right to nominate, the right to access information about personal data, and the right to grievance redressal. It is unclear whether crucial rights vested through the DPDPA 2023 will be enforced under HDMP. Besides, some rights provided under the HDMP do not find their place within DPDPA 2023. This has been iterated in the HDMP as well, where entities brought within the ambit of the HDMP must 'adhere to and comply with' laws, rules, regulations, and standards about data protection that are in force in India.

HDMP, the upcoming data governance framework, and DPDPA 2023 outline different grievance management systems for data fiduciaries (refer to the table below), creating overlaps and confusion for stakeholders. The timeline for resolution under the two frameworks may not be harmonised. Additionally, as the DPDPA 2023 states that the data principal can reach the DPB<sup>112</sup> with complaints, the functions of the ABDM-Grievance Redressal Officer are unclear.

### 5.3.1.2. Lack of Centre-State Interoperability

The Indian Constitution under the Seventh Schedule distributes the powers and responsibilities between the state government and central government under union, state, and concurrent list. There are 61 subjects under the state list within the constitution, where the state government can make laws for its own state. The report of the Srikrishna Committee acknowledged the interactions between the DPB (then Data Protection Authority of India) and state governments, where they mention the large amount of data collected by the state governments for delivering regulatory functions.<sup>113</sup>

For instance, maintaining "public order" is the subject of the state list (item 1) in the Seventh Schedule of the Indian Constitution. Similarly, another key subject that falls within the ambit of the state government is public health, which branches into various facets such as public health services like hospitals, healthcare services, insurance, pharmacies, medical labs, etc. For instance, during the COVID-19 pandemic, though we had the Aarogya Setu app, the state governments moved towards mechanising their own contact tracing app, like Innefu's Unmaze App in the Kasaragod district of Kerala. While private and public health services are subjected to DPDPB 2022, a centralised DPB, adjudicating this, might cause discord without proper coordination, as public health services fall within the state's regulatory functions.

Moreover, the state governments also acknowledge the value of data that government departments collect and try to make accessible in the larger ecosystem to drive economic and social benefits. The objective behind establishing an open public data ecosystem is to enhance the delivery of government services, have evidence-based policy-making, and have more innovation and economic developments, which is one of the key objectives of the ABDM, specifically within the healthcare space.

---

<sup>111</sup> DPDP Act 2023.

<sup>112</sup> Id.

<sup>113</sup> MeitY. (2017, July). Page 108. A Free and Fair Digital Economy Protecting Privacy, Empowering Indians Committee of Experts under the Chairmanship of Justice B.N. Srikrishna. GOI. [https://www.meity.gov.in/writereaddata/files/Data\\_Protection\\_Committee\\_Report.pdf](https://www.meity.gov.in/writereaddata/files/Data_Protection_Committee_Report.pdf)

For instance, Tamil Nadu Data Policy 2022 opens up the data (which may involve health-related information) held by the state departments to researchers and members of the public for research and non-commercial use with adequate safeguards. While the policy reiterates its adaptability with India's data protection regulation (but not HDMP), it also recognises the state government as the custodian of citizens' data.<sup>114</sup> As the circumstances occur, investigating the state government by the DPB will cause constitutional debates, as the central government will establish the DPB, whereas the state government doesn't have a say.

### **5.3.2. Interoperability Concerns in the European Union**

The European Union's digital health ecosystem is complex, filled with various EU-wide voluntary initiatives, national-level eHealth initiatives and private-sector innovations. While the envisaged EHDS tries to bring interoperability at different levels, the mission might face constraints at two levels, as discussed below.

#### **5.3.2.1. Lack of Foundational and Semantic Interoperability: Private level**

During our engagement with European experts, they highlighted the vastness of the digital health ecosystem in the EU, which operates differently based on the nation in terms of public initiatives and, in general, private innovations. For instance, France generates about 22 billion Euros per year through its digital health market, filled with start-ups trying to innovate solutions to intervene at the different stages of healthcare delivery. However, such innovations across the member states operate using different technical systems, which may bring out foundational interoperability concerns, i.e., lack of ability to send data from one IT system to another. Similarly, as these technologies try to plug solutions at different stages and levels of the healthcare ecosystem, using different technical systems might also bring out semantic interoperability concerns, i.e., the incompatibility of health IT systems to exchange and interpret information. This may cause roadblocks as EHDS tries to enhance the cross-border exchange of patient summary information.

#### **5.3.2.2. Lack of Foundational and Semantic Interoperability: National level**

Similar interoperability concerns may arise as member states at the national level follow different systems and initiatives because, as discussed earlier, health, as a function, falls within the ambit of the member states as per the European Community treaty. For instance, Germany has been in the process of establishing an elektronische Patientenakte – ePA (electronic patient record) system to provide access to health records to patients who have enrolled in the German statutory health insurance regime. The foundational and semantic interoperability will arise in this case when ePA centrally stores patient data in one virtual place, while an EU-wide parallel initiative, i.e., EHDS, tries to establish a decentralised system. This also creates a sense of confusion among the individuals between privacy-friendly and non-privacy-friendly options.

---

<sup>114</sup> Tamil Nadu date policy final.indd. (n.d.). Tamil Nadu e-Governance Agency. Retrieved March 4, 2023, from [https://tnega.tn.gov.in/assets/pdf/TN\\_DataPolicy\\_2022.pdf](https://tnega.tn.gov.in/assets/pdf/TN_DataPolicy_2022.pdf)

## 6. Exchange of Knowledge to Enhance Regulations and Policies Governing Electronic Health Records - Recommendations for India

This chapter discusses key recommendations for India synthesised from the EU's experience with data protection regulations. Here, we believe that India can learn from the EU on the organisation and scope of data protection as it attempts to promote digital health services in the country in a secure and outcomes-driven manner.

### 6.1. Extending Additional Protection to Health Data

The General Data Protection Regulations apply to all forms of personal data. However, over time, the European Union has come to recognise the importance of health data as a special class of data by defining it for data protection purposes. The provisions of GDPR obligate principles like purpose limitation, data minimisation, privacy-by-design, etc., to apply to processing health data. However, as the data protection jurisprudence evolved, the Data Protection Supervisor (European Data Protection Authority) realised the importance of having specific safeguards for personal health data and comprehensive protection by constituting rules under GDPR. Therefore, rules are designed under GDPR to ensure trust in emerging innovation, which tries to serve better-quality healthcare through clinical trials, eHealth services, etc.

India has recently passed a data protection regulation and is in the early stages of developing a jurisprudence on privacy and data protection aspects. Therefore, the EU's GDPR experience in tackling issues related to health data could provide some insights to India, as the data protection jurisprudence organically evolves to solve the issues related to health data through additional protection.

#### 6.1.1. Resilient Rule-making

The regulatory reflex in India regarding the technology sector is more ad-hoc and reactive than resilient. This ad-hoc nature illuminates the lack of technical expertise and agility. The DPDPA 2023 focuses on the responsibility of data fiduciaries. However, with the rapidly changing landscape of technology, data fiduciaries may not be the only data handlers in terms of the healthcare sector and, instead, will be increasingly replaced by new technologies and players, which may not currently fall under the definition of data brokers. This exclusion allows new technology and players to violate data protection laws and manipulate consumer data as they see fit. To remedy such exclusions, rule-making must keep pace with technological development; even though technology is advancing exponentially in geometric progression, according to Moore's Law, policy-making is barely scraping the trails of arithmetic progression.

One way to achieve this is through learning from the EU in terms of how it moves beyond data fiduciaries' obligations and tries to tackle the issue of health data by addressing different stakeholders using different mechanisms beyond liability. For instance, recently, the European Commission issued the Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast) and the Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for medicinal products, as well as an amendment to Regulation (EU) 2017/1001,<sup>115</sup> Regulation (EC) No 1901/2006,<sup>116</sup> and Regulation (EU) No 608/2013.<sup>117</sup> The suggested objective of these proposals was to simplify the EU's Supplementary Protection Certificates (SPCs) in line with national-level SPCs for medicinal products to improve transparency and efficiency.<sup>118</sup>

---

<sup>115</sup> EU. Regulation (EU) 2017/1001. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R1001>

<sup>116</sup> EU. Regulation (EU) 1901/2006.

<https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1901:20070126:EN:PDF#:~:text=This%20Regulation%20lays%20down%20rules,Directive%202001%2F20%2F2FEC.>

<sup>117</sup> EU. Regulation (EU) 608/2013. <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:181:0015:0034:en:PDF>

<sup>118</sup> European Data Protection Supervisor. Opinion 27/2023: on the Proposals for Regulations on supplementary protection certificates for plant protection products. June, 2023. [https://edps.europa.eu/system/files/2023-07/23-07-12\\_opinion\\_proposals\\_regulation\\_supplementary\\_protection\\_certificates\\_plant\\_protection\\_products\\_en.pdf](https://edps.europa.eu/system/files/2023-07/23-07-12_opinion_proposals_regulation_supplementary_protection_certificates_plant_protection_products_en.pdf)

A feedback mechanism, based on analysing the prevalence of complaints received by the Data Protection Board, is one way of identifying gaps in current regulations, as in the case of the European Union. For instance, the European Data Protection Board (EDPB) produces an annual report highlighting several cases the authority addresses.<sup>119</sup> The inferences from such reporting also made EDPB recognise the need for cooperation amongst Data Protection Authorities from the member states to apply GDPR consistently.

Learning from the European experience, if all the complaints received by India's Data Protection Board were to be analysed for prevalence, patterns would emerge to reflect where the mechanism has formed a void or lacks seamlessness. These complaints could flag the proportion of problems in legislation for pre-existing technologies and function as a signal for alerting any new technological trends that aren't covered by regulation yet. Once this audit of complaints is conducted and data patterns emerge, the problem areas become more apparent and easier to solve. Newer technologies can then be studied, understood, and regulated, recurring problems can be addressed with alternative solutions, and any blockages in redressal mechanisms can be eased.

### 6.1.2. Advisory Role

Another way through which GDPR has extended additional protection to health data is through expressing their opinion on EHDS. As soon as the EU published the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space Act, the Commission extended its request to the EDPB and European Data Protection Supervisor (EDPS) for advice, based on Article 42(2) of Regulation (EU) 2018/17253 ("EUDPR") on the Proposal.<sup>120</sup> This helped develop one of the key pillars of EHDS, i.e., protecting personal data, where EDPB and EDPS have claimed that EHDS is in full compliance with the GDPR and Regulation (EU) 2018/1725 (EU Data Protection Regulation).<sup>121</sup>

Therefore, it would be prudent to have an advisory function in India delegated to state-level and national-level data protection bodies or councils, similar to the Consumer Protection Councils formed under the Consumer Protection Act 2019. The objective would be to provide advice on promoting and protecting consumer rights under this act at the national, state and district levels, respectively.<sup>122</sup> Data protection bodies or councils could also consider setting up working groups of diverse members to advise on data protection practices related to health data.

Instituting an integrated knowledge management system for state-level data protection bodies or councils could enhance their capacity and consistency. The system must be integrated so that every state-level body and DPB can exchange knowledge through various means, like conferences, regular meetings, cloud databases, working groups, etc. For instance, Germany doesn't have a single, central Data Protection Authority; instead, it has several different authorities for each of the 16 German Länder (states), responsible for ensuring that data protection laws and regulations have been complied with. To ensure coordination and knowledge exchange between federal and state levels, Germany follows a similar system to the European Union, i.e., organising a Data Protection Conference twice a year with rotating chairmanship.<sup>123</sup> The key objective of these conferences is to achieve a uniform application of data protection law and to exchange knowledge by working together.

## 6.2. Regulatory Interoperability to Enhancing the Ecosystem

Regulatory interoperability - legal or administrative - is crucial for ensuring the effective and veritable implementation of laws and policies, especially those governing healthcare. The effective realisation and utilisation of the affordances that ICT has to offer are necessary to transcend territorial and linguistic

---

<sup>119</sup> EU. European Data Protection Boards: Annual Reports. [https://edpb.europa.eu/about-edpb/about-edpb/annual-reports\\_en](https://edpb.europa.eu/about-edpb/about-edpb/annual-reports_en)

<sup>120</sup> EU. Regulation (EU) 2018/17253. [https://edps.europa.eu/data-protection/our-work/subjects/regulation-20181725\\_en#:~:text=Regulation%20\(EU\)%202018%2F1725,adopts%20a%20principle%2Dbased%20approach.](https://edps.europa.eu/data-protection/our-work/subjects/regulation-20181725_en#:~:text=Regulation%20(EU)%202018%2F1725,adopts%20a%20principle%2Dbased%20approach.)

<sup>121</sup> Id.

<sup>122</sup> Refer to sections 6 and 7 of the Consumer Protection Act, 2019

<sup>123</sup> Data Protection Conference. (n.d.). BfDI. Retrieved November 2, 2022, from [https://www.bfdi.bund.de/EN/Fachthemen/Gremienarbeit/Datenschutzkonferenz/datenschutzkonferenz\\_node.html](https://www.bfdi.bund.de/EN/Fachthemen/Gremienarbeit/Datenschutzkonferenz/datenschutzkonferenz_node.html)

boundaries between states and regions, thereby preventing a fragmented approach towards regulating healthcare and, specifically, digital healthcare - a domain that is envisaged to be an interoperable global network of data.<sup>124</sup> The interoperability concerns in India and the EU are highlighted in the above chapters.

This section of the paper will premise itself mainly on the principles stated in the European Interoperability Framework (“EIF”), which is one of the primary policy instruments in the EU that seeks to bring legal, organisational, semantic, and technical interoperability and is cited as a common reference point in the EHDS proposal for its cross-border implementation.<sup>125</sup> The framework provides recommendations for national policies, strategies, and guidelines that encourage overall interoperability and recommends the way forward for designing the amending extant interoperability frameworks. The EIF encouraged public administrations to design and deliver services paying heed to 12 underlying principles, including digital accessibility; cross-border access in the EU; in-built privacy-in-design mechanisms; interoperability-by-design mechanisms; open data, specifications, and software; multilingualism; etc.<sup>126</sup> Notably, considering the non-binding nature of this policy instrument, the EU recently proposed a revamped regulation for the European Interoperability Framework (“New EIF”), which further builds on the principles set by the earlier framework.<sup>127</sup> The New EIF, if implemented, will be the central agency that will support and address cross-border interoperability of network and information systems for EHDS in the EU via establishing an ‘Interoperable Europe Board’.<sup>128</sup>

Accordingly, the sub-sections below will briefly discuss the different types of interoperability necessary in the healthcare ecosystem, paying heed to the mechanisms the EU employs in their policy-making and implementing processes.

### 6.2.1. Legal Regulatory Interoperability Among Digital Health Laws

Legal interoperability is foundational on having compatible legal and policy instruments that supplement and complement each other and do not contradict. Depending on the specific situations, it may be necessary to enact new laws, amend current ones, or reinterpret existing ones to accomplish this compatibility. Such legal interoperability is not only limited to apparent health-related legal and policy instruments but also extends to other sectoral regulations that may potentially impact the healthcare sector.

Legal interoperability forms a core principle of the EHDS, whereby it explicitly refers to and builds on binding (for example, the GDPR) and non-binding (for example, the EIF) legal and policy instruments to create a framework that leverages extant technologies and mechanisms. Further, the EHDS categorically deals with data protection and privacy concerns by frequently referring to the GDPR and does not expound in detail on these concerns.

However, the approach of the ABDM policy ecosystem stands starkly against that of the EU. Since the draft HDMP was formulated well before the DPDP Act 2023 was enacted, the draft HDMP provided its own rules concerning data protection and privacy. Consequently, as highlighted above, there are divergences in the draft HDMP and the DPDP Act 2023, especially in terms of the rights accorded to data principals and the overlap of the powers of the NHA and the DPB. This results in an unclear legal and regulatory landscape, leading to uncertainty and confusion. It would be necessary to resolve any potential conflicts in the law and clarify these before the executive effectively enforces the DPDP Act

---

<sup>124</sup> Angelina Kouroubali, Dimitrios G. Katehakis. (2019, April). The New European Interoperability Framework as a facilitator of digital transformation for citizen empowerment. *Journal of Biomedical Informatics*, Academic Press. <https://www.sciencedirect.com/science/article/pii/S153204641930084X>

<sup>125</sup> Page 44. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space. European Commission. (2022, May).

[https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC\\_1&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF)

<sup>126</sup> European Commission. (2017). New European Interoperability Framework: Promoting seamless services and data flows for European public administrations. EU. [https://ec.europa.eu/isa2/sites/default/files/eif\\_brochure\\_final.pdf](https://ec.europa.eu/isa2/sites/default/files/eif_brochure_final.pdf)

<sup>127</sup> European Parliament. (2022). Interoperable Europe Act. EU.

[https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/745711/EPRS\\_BRI\(2023\)745711\\_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/745711/EPRS_BRI(2023)745711_EN.pdf)

<sup>128</sup> European Commission. (2022, November). Page 20. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL: laying down measures for a high level of public sector interoperability across the Union [“Interoperable Europe Act”]. [https://commission.europa.eu/system/files/2022-11/com2022720\\_0.pdf](https://commission.europa.eu/system/files/2022-11/com2022720_0.pdf)

2023. Accordingly, it would be critical for Indian policymakers to build on extant laws and policies when designing the specific policies for ABDM, ensuring there is no conflict with existing laws and preventing avoidable uncertainty similar to that of the EU.

### **6.2.2. Horizontal Administrative Interoperability Among Sectoral Regulators**

As highlighted above, achieving interoperability among sectoral regulators is equally crucial to the effective implementation of the ABDM framework. Administrative bodies must maintain seamless and effective communication channels, especially in an age where administrative processes are automated and digital technologies are integrated into them. To this end, a robust system of legal obligations is a prerequisite, which is further supplemented with comprehensive procedures between various organisations that allow the transmission of the data and structured collaboration and cooperation.

Considering that the healthcare ecosystem is interlinked with various other industries, including the data protection and privacy domain, financial sector, education sector, etc., sectors which are specifically regulated via different laws and authorities and are currently undergoing digital transformation, it would be critical for NHA to develop a coordination and communication wing specifically designed to address inter-sectoral issues. For reference, the Interoperable Europe Board is, inter alia, tasked with supporting the implementation of national interoperability frameworks and other relevant policy instruments, ensuring policy frameworks and solutions are in consonance with each other.<sup>129</sup>

Since the ABDM is a policy framework and not a law, it becomes critical to address the extant legal framework for such sectors and investigate their consonance or contradiction with the ABDM policies.

### **6.2.3. Vertical Administrative Interoperability Between the Centre and States**

As explained above, vertical administrative interoperability is crucial to give effect to the ABDM, especially in India, which has an already complex administrative and federal structure. In India, the states enjoy wider latitude regarding subjects concerning health. Notably, while the EU has different legal and policy instruments it can select for law and policy-making, it is only in very select areas that binding instruments such as regulations are employed; in other cases, the member states have the latitude to implement or amend the law if they choose to implement non-binding instruments. For instance, the EU directives do not necessarily lay down specific provisions for the member states to follow, but instead, they lay down the objectives and expected outcomes that they can pay heed to while formulating their specific national legislations. Similarly, in India, where states are vested with the constitutional legislative competence for health, it would benefit the central government to lay down the bare minimum standards for issues the states can then legislate upon. One of the academics interviewed for the study, Joanna Bryson,<sup>130</sup> emphasised the need to accommodate diverse contexts and histories when contemplating binding policy instruments at the national/union level. This not only includes identifying common problems across states/jurisdictions and providing common standards and solutions for them but also the capacities and willingness of states/jurisdictions to implement these common standards and solutions.

Furthermore, the EIF implementation strategy addresses concerns regarding interoperability between the EU and member states; the focus areas highlighted concern: ensuring governance, coordination, and sharing interoperability initiatives; developing organisational interoperability solutions; developing, maintaining, and promoting supporting instruments for interoperability; etc.<sup>131</sup> It consequently lays down comprehensive mechanisms via which the EU and member states can communicate and coordinate with each other for their legislative and policy practices.

---

<sup>129</sup> Interoperable Europe Act, Article 15.

<sup>130</sup> Professor of Ethics and Technology at the Hertie School. She holds degrees in psychology and artificial intelligence from the University of Chicago (BA), the University of Edinburgh (MSc and MPhil), and Massachusetts Institute of Technology (PhD). Since July 2020, Prof. Bryson has been one of nine experts nominated by Germany to the Global Partnership for Artificial Intelligence. Note, that the researchers have received express consent from the interviewee to refer to their remarks/observations explicitly.

<sup>131</sup> European Commission. (2017, March). Communication - European Interoperability Framework – Implementation Strategy. [https://eur-lex.europa.eu/resource.html?uri=cellar:2c2f2554-0faf-11e7-8a35-01aa75ed71a1.0017.02/DOC\\_1&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:2c2f2554-0faf-11e7-8a35-01aa75ed71a1.0017.02/DOC_1&format=PDF); European Commission. (2017, March). Communication - European Interoperability Framework, Interoperability Action Plan. [https://eur-lex.europa.eu/resource.html?uri=cellar:2c2f2554-0faf-11e7-8a35-01aa75ed71a1.0017.02/DOC\\_2&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:2c2f2554-0faf-11e7-8a35-01aa75ed71a1.0017.02/DOC_2&format=PDF)

Accordingly, for state-specific institutions under the aegis of the ABDM framework, it would be critical for the executive to establish (i) clear codes of conduct at the centre and state levels, (ii) simple, clear, and uniform mandates for the institutions to follow in cases of crises and administrative conflicts, (iii) develop data specifications and tools to support an open source system of ABDM after consultation with the state, and (iv) provide ad hoc support and training to administrative bodies that are engaged in the healthcare sector in the states, clarifying the role and responsibilities of the ABDM.

### 6.3. Evaluating the Performance of the Data Protection Regulations

Since adopting the GDPR - considered a golden standard of data protection and regulation laws - there have been significant criticisms of its implementation and cooperation processes.<sup>132</sup> These criticisms are of major concern to the data protection authorities (DPAs), which are at the centre of the implementation processes envisaged by the GDPR, as having inadequate communications tools, incompatibility of various national procedures, differences in the lengths of the cooperating process, and administrative issues of identifying who is in charge of cases.<sup>133</sup> Further, the EU has acknowledged various other concerns regarding the governance and implementation by the citizens, including measures for promoting industry compliance, increasing citizens' control over data, and limiting the monitoring, profiling, and manipulation of citizens by private and public actors.<sup>134</sup>

To address these concerns, the EU has issued reformative measures, including a new regulation to streamline cooperation between DPAs when enforcing the GDPR and create processes for DPAs in different jurisdictions to cooperate better amongst themselves, reduce disagreements, and facilitate consensus among authorities. It will further include more clarificatory rules for businesses and individuals, intending to bring quicker remedies for individuals and more legal certainty for businesses. Furthermore, the new rules will provide comprehensive rules for harmonising the extant rules and procedures for cross-border data transfers and decrease discrepancy between DPAs.<sup>135</sup>

With the recent enactment of the DPDP Act 2023, comprehensive data protection and regulation are being established in India. Though the law will take months to be enforced by the executive,<sup>136</sup> it will be crucial for the executive and policymakers to pay heed to potential concerns that may arise in its implementation, especially after considering the issues faced in implementing the GDPR.

Accordingly, it would be critical to have comprehensive evaluation and assessment processes in place to check the implementation of the ABDM framework in consonance with the DPDP Act 2023. The EU, prior to the formulation of the EHDS, conducted an ex-post evaluation of the eHealth Network, an intensive impact assessment, and stakeholder consultations to gauge the necessity and nature of intervention required.<sup>137</sup> These considerations inevitably included the assessment of extant data protection regulations in the health sector, including the GDPR. While the ABDM ecosystem has already been introduced as a policy framework, it would be in the interests of the executive and policymakers to assess the impact of the DPDP Act 2023, especially on the health sector. Similar to the consultative practices in the EU, it would be greatly beneficial to assess performance by engaging in comprehensive stakeholder consultations, including direct consultation with citizens. Considering the diversity and the

---

<sup>132</sup> Ilse Heine. (2021, September). 3 years later: An analysis of GDPR enforcement. CSIS.

<https://www.csis.org/blogs/strategic-technologies-blog/3-years-later-analysis-gdpr-enforcement>; Brian Daigle, Mahnaz Khan. (2020, June). The EU General Data Protection Regulation: An Analysis of Enforcement Trends by EU Data Protection Authorities. United States International Trade Commission.

[https://www.usitc.gov/publications/332/journals/jice\\_gdpr\\_enforcement.pdf](https://www.usitc.gov/publications/332/journals/jice_gdpr_enforcement.pdf)

<sup>133</sup> Estelle Massé. (2021, May). Three Years under the EU GDPR: An Implementation Progress Report. Access Now.

<https://www.accessnow.org/wp-content/uploads/2021/05/Three-Years-Under-GDPR-report.pdf>

<sup>134</sup> Hendrik Mildebrath. (2022, April). The future of data protection and privacy: How the European Parliament is responding to citizens' expectations. European Parliament.

[https://www.europarl.europa.eu/RegData/etudes/BRIE/2022/729396/EPRS\\_BRI\(2022\)729396\\_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2022/729396/EPRS_BRI(2022)729396_EN.pdf)

<sup>135</sup> EU. (2016). Proposal for REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down additional procedural rules relating to the enforcement of Regulation (EU).

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0348>

<sup>136</sup> Aashish Aryan. (2023, September). Govt eyes graded timeline for Data Law Enforcement. The Economic Times.

<https://economictimes.indiatimes.com/tech/technology/govt-eyes-graded-timeline-for-data-law-enforcement/articleshow/103671956.cms?from=mdr>

<sup>137</sup> Page 8-16. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space. European Commission. (2022, May).

[https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC\\_1&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF)

digital divide in India, it would be critical for such grassroots engagement to be comprehensive and have a larger and more diverse sampling group. Further, as noted, the GDPR had a significant impact on the industry in the EU, especially the digital public health sector, whereby it had to make substantial and costly adjustments to satisfy the requirements of personal health data protection.<sup>138</sup> To prevent such a policy shock from occurring in India, where there is a visible upsurge in digital health technologies and solutions alongside the ABDM network, it would be critical for the Indian executive and policymakers to hold extensive consultations and enable a veritable feedback mechanism for the health industry to voice their concerns.

---

<sup>138</sup> Yuan, B., & Li, J. (2019, March 25). The Policy Effect of the General Data Protection Regulation (GDPR) on the Digital Public Health Sector in the European Union: An Empirical Investigation. *International Journal of Environmental Research and Public Health*, 16(6), 1070. <https://doi.org/10.3390/ijerph16061070>.



## 7. Exchange of Knowledge to Enhance Interoperability and Scalability - Recommendations for the EU

This chapter discusses key recommendations for the EU synthesised from India's experience of making interoperability at scale. Here, we believe the EU can learn from India's experience in implementing the ABDM system for digitising healthcare records and achieving interoperability at scale.

### 7.1. Laying the Roadmap through Digital Public Infrastructure

As the European Union is enacting EHDS regulations, there are key learnings from India's pioneering experiment of Digital Public Infrastructure, which might enhance the European infrastructure towards servicing interoperability at scale.

India's journey toward pioneering and transforming governance using technological innovations like Digital Public Infrastructure has evolved significantly. India has also transformed from being an adopter of technology to creating scalable technology that complements the ecosystem. The two main consortia of Digital Public Infrastructures (DPIs) built using Digital Public Goods (DPGs) are India Stack and Ayushman Bharat Digital Mission (ABDM<sup>139</sup>).

India Stack has revolutionised India's financial services ecosystem and set a global milestone by enabling presenceless, paperless, and cashless service delivery innovations in the form of digital public infrastructure.<sup>140</sup> One of the key outcomes of the India Stack is interoperability at scale, like India's Unified Payment Interface (UPI) systems, which pushed the needle on financial inclusion. Imbibing some key learnings from the India Stack experiment, some of the characteristics of the ABDM facilitate interoperability, harmonisation, principles of an open network, humane development, etc. These characteristics solve the key problems faced within the healthcare ecosystem, such as scaling, interoperability, last-mile penetration, cost efficiency, agility, etc.<sup>141</sup>

One of the key existing infrastructures that would be leveraged under EHDS is the eHealth Digital Service Infrastructure (eHDSI), built under electronic, cross-border health services. While eHDSI offers various salient components and features, the EU could adopt some of the key learnings from two of its key digital public infrastructures within the digital health space as follows.

#### 7.1.1. ABDM Ecosystem

The ABDM aims to have a national health information network and architecture in place by 2025, providing a safe and interoperable healthcare system and allowing access to and portability of health records between public and private sectors. It aims to use Digital Public Goods (DPGs) to improve healthcare's availability, accessibility, affordability, and acceptability. Citizens, public and private healthcare providers, digital innovations, and other stakeholders can work together to advance the fair digitisation of healthcare nationwide thanks to the interoperable frameworks, open protocols, and consent artefacts.<sup>142</sup> Some of the key aspects of the ABDM are promoting inclusivity, increasing accessibility irrespective of internet connectivity, free of-charge registration, voluntary participation, and having the option to opt-out; verified health registries will be the single source of truth; the privacy-by-design framework for protecting data.<sup>143</sup>

<sup>139</sup> Centre for Internet and Digital Economy, *Aadhaar: Platform or Infrastructure? Developing a taxonomy for India's Digital Public Ecosystem*, Policy Brief 3, February 2023.

<https://icrier.org/publications/aadhaar-platform-or-infrastructure-developing-a-taxonomy-for-indias-digital-public-ecosystem/>

<sup>140</sup> IMF. Yan Carrière-Swallow, Vikram Haksar, Manasa Patnam. *Stacking Up Financial Inclusion Gains In India*. 2021, July.

<https://www.imf.org/external/pubs/ft/fandd/2021/07/india-stack-financial-access-and-digital-inclusion.htm>

<sup>141</sup> Id.

<sup>142</sup> Sharma, R. S., Rohatgi, A., Jain, S., & Singh, D. (2023, March 31). *The Ayushman Bharat Digital Mission (ABDM): making of India's Digital Health Story*. *CSI Transactions on ICT*, 11(1), 3–9. <https://doi.org/10.1007/s40012-023-00375-0>.

<sup>143</sup> National Health Authority. (2021). *A brief guide on Ayushman Bharat Digital Mission (ABDM) and its various building blocks*.

In ABDM. Retrieved July 6, 2023, from

[https://abdm.gov.in:8081/uploads/ABDM\\_Building\\_Blocks\\_v8\\_3\\_External\\_Version\\_eabbc5c0f3\\_4\\_a96f40c645.pdf](https://abdm.gov.in:8081/uploads/ABDM_Building_Blocks_v8_3_External_Version_eabbc5c0f3_4_a96f40c645.pdf).

This envisaged national ecosystem contains several elements developed to make the various systems interoperable and efficient; these include health IDs, health records, health facility registries, health information providers, health information users, etc. Of these, the health ID - Ayushman Bharat Health Account ("ABHA")<sup>144</sup> - created under the ABDM and released in 2021, revolutionised the healthcare system in India and brought India closer to the realisation of the Sustainable Development Goals (discussed in detail in section 7.2). It enables beneficiaries to access all their medical records, access public health programmes and schemes, and share them with hospitals and other medical institutions, eliminating the need to stand in long queues or the fear of losing medical records.

Further, under the ABDM, the government has developed several policies and programmes that work towards achieving the stated objective: the draft Health Data Management Policy,<sup>145</sup> which lays down a data protection framework for any potential participant of the healthcare system, including healthcare provider, regulators, patients, healthcare professionals, etc.; ABDM Sandbox<sup>146</sup> (discussed in detail in section 7.4), which is a software testing environment that allows technologies or products to be tested in a contained environment in compliance with detailed guidelines;<sup>147</sup> Unified Health Interface Initiative,<sup>148</sup> which is an open protocol for various digital health services that will enable a variety of digital health services between patients and health service providers, including appointment booking, teleconsultation, service discovery, and others; Health Data Retention Policy<sup>149</sup> (refer to chapter 4), which is to ensure that every healthcare facility implements record retention and compliance with all applicable domestic laws.

The integrated digital health infrastructure for the nation is built on the shoulders of the ABDM.<sup>150</sup> A wealth of factors, including the general technological revolution in India, government policies and interventions in healthcare, the emergence of health-tech start-ups, the pandemic-induced impetus in digital healthcare, and the general awareness of health and wellness among the populace, all combine to create a profitable opportunity in healthcare.

During our stakeholder engagement, experts from India flagged the following as the key learnings that the EU could adopt from India's ABDM Ecosystem. Firstly, stakeholders flagged how ABDM tries to unite various stakeholders, whether in the public or private sector. For instance, a stakeholder mentioned how the ecosystem had brought diverse private sectors like insurtech companies to the Core Data Center at IIT Bombay, which works closely with the ecosystem. Furthermore, the stakeholder, mentioned how foundations Bill & Melinda Gates Foundation (BMGF) are working on the ground to ensure that ABDM gets off the ground. Secondly, the stakeholders had mentioned that the EU could learn how India's success stories of the ABDM Sandbox, where that component has seamlessly picked up pace in addition to enabling digital innovations in healthcare, also paves the way for such innovations to seamlessly integrate themselves within the ABDM Ecosystem.

### 7.1.2. Repurposing Aarogya Setu and CoWIN

In addition to suggesting the discussed learnings from India, experts, during our stakeholder engagement, also mentioned how the EU could learn from the repurposing that India did with technologies, which were developed to serve during the COVID-19 pandemic. Under the ABDM scheme, the government repurposed its two applications - Aarogya Setu and CoWIN - that were of tremendous importance in monitoring and managing the pandemic.<sup>151</sup> Aarogya Setu was initially developed as a COVID-19 "contact tracing, syndromic mapping, and self-assessment" digital tool in the form of a smartphone app developed by the National Informatics Centre under the Ministry of Electronics and Information Technology.

---

<sup>144</sup> Abha number: ABDM. ABHA number | ABDM. (n.d.). <https://healthid.ndhm.gov.in/>.

<sup>145</sup> Ayushman Bharat Digital Mission - ABDM. (n.d.-b). [https://abdm.gov.in:8081/uploads/Draft\\_HDM\\_Policy\\_April2022\\_e38c82eee5.pdf](https://abdm.gov.in:8081/uploads/Draft_HDM_Policy_April2022_e38c82eee5.pdf).

<sup>146</sup> Sandbox.abdm.gov.in. (n.d.). <https://sandbox.abdm.gov.in/>.

<sup>147</sup> NDHM sandbox - ABDM. (n.d.-f). [https://www.abdm.gov.in:8081/uploads/sandbox\\_guidelines\\_b39bcce23e.pdf](https://www.abdm.gov.in:8081/uploads/sandbox_guidelines_b39bcce23e.pdf).

<sup>148</sup> NHA: Official website ayushman Bharat Digital mission. NHA | Official website Ayushman Bharat Digital Mission. (n.d.-a). <https://abdm.gov.in/collaborative-development>.

<sup>149</sup> Consultation Paper on proposed Health Data Retention Policy - ABDM. (n.d.).

[https://abdm.gov.in:8081/uploads/Consultation\\_Paper\\_on\\_Health\\_Data\\_Retention\\_Policy\\_21\\_28557f9a6a.pdf](https://abdm.gov.in:8081/uploads/Consultation_Paper_on_Health_Data_Retention_Policy_21_28557f9a6a.pdf).

<sup>150</sup> Sharma, R. S., Rohatgi, A., Jain, S., & Singh, D. (2023). The ayushman bharat digital mission (ABDM): Making of India's Digital Health Story. CSI Transactions on ICT. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10064942/>.

<sup>151</sup> Mukhopadhyay, S. (2022, September 26). Aarogya Setu, Cowin to be used for health issues other than covid as well. Mint. <https://www.livemint.com/news/india/aarogya-setu-cowin-to-be-used-for-health-issues-other-than-covid-as-well-11664156906037.html>.

It employed technology for contact tracing, whereby the user would be informed of COVID-19-positive contacts they may have made while going about their daily activities. The programme would notify the user if any contacts test positive. Additionally, the application also provided medical recommendations to prevent the spread of the pandemic.<sup>152</sup> It had upwards of 240 mn downloads as of September 2022.<sup>153</sup>

On the other hand, CoWIN, released in 2021, was developed as an end-to-end solution for tracking the registration, appointment, identity verification, vaccination, and certification of the COVID-19 vaccination. As noted, it performs several jobs concurrently alongside the vaccination delivery chain; these include helping with administrative management (via the Orchestration Module), supply chain monitoring for vaccines (Vaccine Cold Chain Module), enrolling citizens as vaccine recipients (Citizen Module), updating their vaccination status (Vaccinator Module), and issuing certificates following vaccination (Certificate, Feedback, and AEFI Module).<sup>154</sup> The application has a citizen-centric design with a user-friendly interface that makes it easy and convenient to register, choose a facility, and select the type of vaccine. Post-vaccination, the user would get access to a digital vaccination certificate with a QR code that could be printed and carried in person.

Both of these applications were instrumental in monitoring, controlling, and preventing the spread of the pandemic and demonstrating empirical evidence as to the potential, efficiency, and convenience of tech-enabled health services. The application has enabled around 2 bn vaccination doses, with around 1.1 bn beneficiaries to date at a formidable speed, a feat unparalleled by any other country with a similar demography and geography.<sup>155</sup>

The former CEO of the National Health Authority, Mr R.S. Sharma, announced last year that Aarogya Setu would be repurposed as India's health and wellness application and CoWIN as a health management information system for small doctors' clinics and nursing homes.<sup>156</sup>

Aarogya Setu is to be integrated within the ABDM, where the health ID, ABHA, will enable individuals to access other digital health services while maintaining a common pool of medical history by using the ABHA number to link their old and new medical records, including prescriptions from doctors, lab results, hospital records, etc. They can also share these records with registered health professionals and service providers.<sup>157</sup>

Further, with the integration of the Universal Immunisation Programme into the CoWIN platform, finding vaccination clinics and camps has become easier, where the application now sends immunisation reminders and provides digitally-verified certificates. The platform is further to be developed to include new areas, such as blood and organ donation, and it will also be repurposed as a Health Management Information System (HMIS) for healthcare professionals.<sup>158</sup>

Through these two Ayushman Bharat pillars, the National Health Authority has built an infrastructure that is reliable and interoperable, where people can use these technologies and get an Outpatient Department ("OPD") card instead of standing in a queue for a long time to check in at a hospital. Therefore, in this experiment of India repurposing some of its critical innovations into an infrastructure enabling interoperability, there are some key learnings for the EU regarding how foundational and semantic interoperability concerns (as discussed in section 4.3) can be tackled.

---

<sup>152</sup> Aarogya Setu. (n.d.). <https://www.aarogyasetu.gov.in/>.

<sup>153</sup> Mukhopadhyay, S. (2022, September 26). Aarogya Setu, Cowin to be used for health issues other than covid as well. Mint. <https://www.livemint.com/news/india/aarogya-setu-cowin-to-be-used-for-health-issues-other-than-covid-as-well-11664156906037.htm>.

<sup>154</sup> The actors and operations of a Digital Delivery Platform: Cowin. Dvara Research Blog. (n.d.). <https://www.dvara.com/research/blog/2021/06/16/the-actors-and-operations-of-a-digital-delivery-platform-cowin/>.

<sup>155</sup> Cowin Dashboard. CoWIN Dashboard. (n.d.). <https://dashboard.cowin.gov.in/>.

<sup>156</sup> Ians. (2022, September 26). Cowin, Aarogya Setu to be repurposed into India's health apps. Deccan Herald. <https://www.deccanherald.com/national/cowin-aarogya-setu-to-be-repurposed-into-indias-health-apps-1148386.htm>.

<sup>157</sup> Aarogya Setu. (n.d.-a). <https://www.aarogyasetu.gov.in/>.

<sup>158</sup> Perappadan, B. S. (2022, August 1). Cowin to gird universal immunization. The Hindu. <https://www.thehindu.com/sci-tech/health/cowin-technology-to-be-repurposed-for-healthcare-operations/article65706052.ece>; Suggest a tagline for repurposed Cowin. MyGov.in. (2023, February 13). <https://www.mygov.in/task/suggest-tagline-repurposed-cowin/>.

## 7.2. Importance of the Digital Identification System

The two main consortia of Digital Public Infrastructures (DPIs), built using Digital Public Goods (DPGs), are India Stack and Ayushman Bharat Digital Mission (ABDM), which have various layers and components. One of the key layers/components of both the consortia is the digital identity element to recognise individuals within the digital realm (similar to the physical public sphere), so that online transactions, interactions, identifications, etc., are smooth and consistent over time.

Within the paperless layer of India Stack, Aadhaar has been formed as a foundational biometric digital identity for enabling various products and innovations, utilising it as proof of an individual's legal identity. Various functional digital identities have been formed using Aadhaar as a foundational identification system or other KYC systems, including the Ayushman Bharat Health Account (ABHA) Number, for recognising individuals within the digital health realm under ABDM. These two digital identity systems within India form the bedrock for utilising various digital public infrastructures.

Therefore, India's digital identification system could advise the EU in the context of health and eIDs (electronic identification systems). The Indian government issues various IDs to individuals to simplify the process of accessing their rights, services, protections, etc. Fundamentally, the government extends two forms of IDs to individuals, i.e., foundational and functional IDs, which differ based on the target population, size, functions, uses, technicalities, etc., as follows:

**Foundational Identity:** The foundational ID as a proof of legal identity is issued to a wide population for identification purposes (answering the question of “Who are we?”) and for carrying out various transactions. Traditionally, the foundational ID comprises of national IDs, population registries, etc., like a birth certificate extended to everyone. The trust quotient and the value of the foundational ID as a legitimate identification verification and authentication tool increased in India with its endeavour towards issuing one of its pioneering Digital IDs - Aadhaar - to individuals as a unique<sup>159</sup>, verified, and duplication-free proof of legal identity.

Aadhaar, as a foundational identifier, has had a generational impact across India's development cycle while also being a source of inspiration for several other countries in the Global South to undertake identification projects.<sup>160</sup> The Aadhaar follows a centralised model, where we have The Unique Identification Authority of India (UIDAI) as a single authoritative and trusted source which dispatches digital ID.

**Functional Identity:** While foundational identity acts as the universal proof of an individual's identification, governments traditionally provide a variety of functional IDs to serve some sector-specific needs and uses. This involves, for instance, voter ID cards, ration cards, driving licenses, etc. These proofs of identity target a specific group of individuals to dispatch welfare, benefits, and access to a service; however, technically, functional IDs are not considered legal until they are specifically recognised to serve such a purpose. While functional IDs could serve only a small target population, they can sometimes have as broad a coverage as their intended service delivery, such as social protection, health, catering to universal populations, etc.<sup>161, 162</sup>. One such universal functional ID in India is the ABHA number introduced under ABDM.

In the digital landscape, the foundational and functional ID complement each other. Firstly, the uniqueness of the foundational ID, like Aadhaar, which acts as a single source of truth and can't be claimed by individuals multiple times, complements the process of issuing functional IDs and the

---

<sup>159</sup> Umar Bashir Mir, Arpan K. Kar, Yogesh K. Dwivedi, M.P. Gupta, R.S. Sharma, Realising digital identity in government: Prioritising design and implementation objectives for Aadhaar in India, *Government Information Quarterly*, Volume 37, Issue 2, 2020, 101442, ISSN 0740-624X, <https://doi.org/10.1016/j.giq.2019.101442>

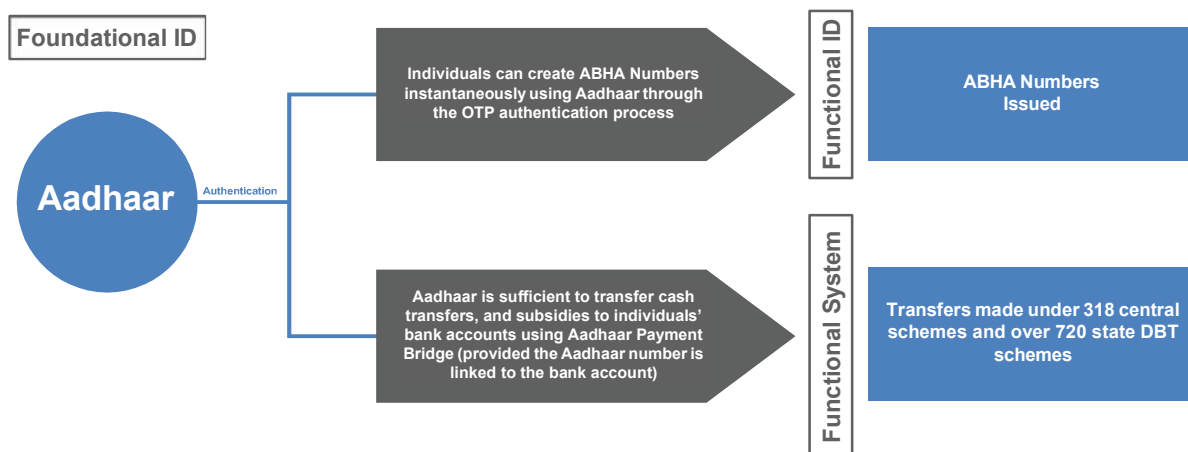
<sup>160</sup> Chakravorti, B. (2018, January 23). India's Aadhaar: A Unique Opportunity for Innovating in Digital Trust, But an Opportunity Easy to Squander. The OECD Forum Network. Retrieved May 15, 2023. <https://www.oecd-forum.org/posts/29531-india-s-aadhaar-a-unique-opportunity-for-innovating-in-digital-trust-but-an-opportunity-easy-to-squander>

<sup>161</sup> Vrinda Bhandari. (2020, July). Digital identities: Design and Uses. Centre for Internet and Society. <https://digitalid.design/evaluation-framework-case-studies/welfare.html>.

<sup>162</sup> Digital ID in Driving Social Protection – learning from India. Events Development Asia. (2017, September). <https://events.development.asia/system/files/materials/2016/09/201609-digital-id-driving-social-protection-learning-india.pdf>.

functional process by reducing deduplication rates, fraud, etc. However, there are also studies<sup>163</sup> which show that using Aadhaar as a single source of truth causes exclusionary concerns. Secondly, the coexistence of sector-specific functional IDs and foundational IDs, like Aadhaar, weeds out jurisdictional overlap and creates an environment for complementarianism.

**Figure: Symbiosis between Identification Systems**



Therefore, while the eID system provides set services for a mutual recognition of national electronic identification schemes (eID) across borders, vaguely similar to the Aadhaar system, the eID ecosystem is heterogeneous regarding maturity and regulatory factors at the member state levels. For instance, in some member states, the government only supervises the process of issuing eID; in some places, the government is the primary identity provider, while some member states follow mixed methods.<sup>164</sup> This heterogeneity in how digital identification is issued and subsequently used may cause issues in terms of interoperability.

Therefore, we believe some of the key learnings from India, regarding having one foundational ID, may aid the EU's endeavour towards interoperability. Besides, it is also essential to have a universal functional ID at the member state level for health purposes. Here, India's experience of how the same foundational ID (which may be at the EU level) is seamlessly used to authenticate a universal functional ID (which may be at the member state level) for the purpose of health could bring uniformity in issuance and streamline cross-border operations.

### 7.3. Enhancing Scalability Using the Ecosystem Approach

Implementing scalable digital health solutions has become an imperative in India's healthcare landscape, aiming to improve access, quality, and efficiency in healthcare delivery. India's journey toward scalable digital health solutions is complex, involving crucial stakeholders across the ecosystem. This ecosystem approach involves the active contribution of the public sector, private sector, and other third parties, pushing the needle towards last-mile delivery of digital health solutions. However, how India tries to bring the stakeholders together to solve scalability issues provides a key learning for the EU as follows.

<sup>163</sup> Falling through the Cracks: Case Studies in Exclusion from Social Protection - Dvara Research. (2021, May 3). Dvara Research. <https://www.dvara.com/research/social-protection-initiative/falling-through-the-cracks-case-studies-in-exclusion-from-social-protection/>.

<sup>164</sup> European Parliament. (2023). Electronic identification. Shaping Europe's digital future. <https://digital-strategy.ec.europa.eu/en/policies/electronic-identification>

### 7.3.1. Public Sector Involvement: State level

As discussed in previous chapters, as per the Indian constitution, health falls within the purgatory of the state governments, hence the implementation of the ABDM also falls within the discretion of the state government. Therefore, to ensure an uptake at the state level, the ABDM offers a federated architecture to adopt the best principles of cooperative federalism, while working with the states and union territories to realise the vision. The federated architecture offers that only some of the key building blocks are developed and maintained centrally, whereas all the other building blocks of the ABDM will be designed and modelled at the regional, state level, etc., to function independently in an interoperable manner.

The data collected by the state governments will stay within the state to keep it near the point of generation, ensuring that the state government will have their say over the data. The ABDM also encourages the state government digital health initiatives to blend within ABDM to enhance the capability of the health delivery infrastructure. For instance, the Tamil Nadu government's Population Health Registry has seamlessly integrated with the ABDM.<sup>165</sup> Therefore, as the EU member states will be implementing the EHDS, key learnings from India could be (a) keeping federalism intact using federated architecture and implementation and (b) encouraging member states to blend with the health space to be implemented.

### 7.3.2. Private Sector Involvement

The realisation of digital health initiatives and their scalability depends upon the uptake of the architecture by health service providers and professionals who directly interface with the users. On this aspect, India's ABDM offers some key learnings to the EU, beyond technical standards and regulations, where the mission tries to push for adoption through soft nudges by providing various incentives.

#### 7.3.2.1. Sandbox Mechanism

The government of India opted for a sandbox approach for ABDM to serve dual purposes: (a) to enable real-world interoperability testing, privacy safeguards, and compliance and (b) to integrate and innovate on components of ABDM. The sandbox is an adaptable, risk-managed environment to validate technological solutions in line with national health policies and regulations. It aims to build trust among stakeholders and evolve dynamically with the fast-paced health tech landscape. This structure allows both public and private players to experiment, ensuring the system's flexibility and scalability.<sup>166</sup> Besides, as the sandbox encourages innovations on the components of the ABDM, some of the innovations solve the scalability problem. For example, 'A.M.R.I.T' by Piramal Swasthya Management and Research Institute, an ABDM-integrated HMIS system,<sup>167</sup> is premised on providing health services that are scalable and accessible.<sup>168</sup>

The ABDM Sandbox enables "learning by doing," providing empirical evidence on the risks and benefits of emerging technologies to inform balanced innovation support. It allows stakeholders, from healthcare providers to tech companies, to test product viability without a costly large-scale rollout, making adjustments as needed. The sandbox also accelerates technology adoption and inclusion in healthcare, improving overall healthcare outreach. Finally, it leads to consumer benefits, such as a wider range of healthcare products and services, reduced costs, and better accessibility. The sandbox also provides hands-on experience with the NDHM's building blocks for the technical community, fostering more precise and efficient innovation.

The European Institute of Innovation and Technology (EIT) health accelerator launched a sandbox in 2020 to support SMEs to tap into that data to create healthcare innovations.<sup>169</sup> However, as we move

---

<sup>165</sup> Times of India. (2021, December 24). Government to start work on Tamil Nadu population health registry. The Times of India. <https://timesofindia.indiatimes.com/city/chennai/govt-to-start-work-on-tn-population-health-registry/articleshow/88463352.cms>.

<sup>166</sup> GOI, ABDHM. NDHM Sandbox: Enabling Framework. 2020, August.

[https://abdm.gov.in:8081/uploads/sandbox\\_guidelines\\_b39bcce23e.pdf](https://abdm.gov.in:8081/uploads/sandbox_guidelines_b39bcce23e.pdf).

<sup>167</sup> More than 50 digital health services/ applications integrated with Ayushman Bharat Digital Mission (ABDM). (n.d.).

<https://pib.gov.in/PressReleaseSelfFramePage.aspx?PRID=1845845>.

<sup>168</sup> Building Sustainability Framework - Piramal Swasthya. (2020, February 26). Piramal Swasthya.

<https://www.piramalswasthya.org/building-sustainability-framework/>.

<sup>169</sup> European Institute of Innovation and Technology. The Digital Sandbox Accelerator. 2020, May.

<https://eit.europa.eu/our-activities/opportunities/digital-sandbox-accelerator#:~:text=This%20programme%20supports%20SMEs%20to,new%20treatments%20and%20medical%20innovations.>

forward, extending such a sandbox under the EHDS ecosystem should be considered in a way that some of the key learnings from the ABDM Sandbox can be imbibed for the scalability of EHDS.

### 7.3.2.2. Private-Public Interface

The ABDM has clearly established its commitment towards interoperability, open APIs, a sandbox, and other means that enable private innovation. For example, the UHI consultation paper draws repeated attention to the role of private parties in the ecosystem, both as stakeholders and as developers of end-user-facing applications, such as consent managers, eHealth applications, private locker applications, and others.<sup>170</sup>

Some models of public-private interfaces have worked in the past within India. Learnings from those projects, which have been effective in the healthcare sector, can be migrated to the European context. For example, under the National AIDS Control Organisation ('NACO'), the Integrated Counselling and Testing Centres ('ICTC') were established in large maternity homes and missionary and charitable hospitals as a result of a public-private partnership ('PPP'). Similarly, PPP approach was adopted to implement the National Dialysis Services Programme in district hospitals.

### 7.3.2.3. Assisted Model of e-Sanjeevini

To further aid in India's scalability efforts, the e-Sanjeevini portal was integrated with the ABDM in June 2022, allowing users of e-Sanjeevini to create their ABHA numbers and link and manage their existing health records like e-prescriptions, medical records, etc.<sup>171</sup> The assisted model of e-Sanjeevini, whereby individuals who live even in the remotest places - who may not have access or knowledge of the possibilities digital health technology offers - can access e-healthcare services at secondary or tertiary healthcare facilities with the help of Community Health Officers. e-Sanjeevini's assisted model is not only noteworthy for increasing accessibility to e-healthcare but also implicitly increases awareness of such government initiatives and willingness to use digital health technologies.

This integration of the ABDM ecosystem does not approach scaling the technology as a separate activity, rather, it aids in creating scalability that is sustainable and reliable by leveraging extant healthcare initiatives that are already operationalised. This approach allows the government to avoid any double or duplicate efforts towards strengthening the public healthcare system and investing in parallel healthcare systems, whilst avoiding confusion among the public that implementing disparate healthcare initiatives that do not speak to each other would introduce.

## 7.4. Principle-based Interoperability

Foundational and semantic interoperability is one of the critical concerns European experts flagged through our stakeholder engagement towards achieving an interoperable system, which we discuss in detail in section 4.3. While India is also partially facing a similar issue, a step towards mending this has been suggested through ABDM, where the National Digital Health Blueprint sets a few minimal core, technical, and business principles such that, collectively, the ecosystem can reap the benefits of interoperability.

While eHealth Digital Service Infrastructure (eHDSI) comes with prescriptions, a principle-based approach (as suggested in India), where every player within the ecosystem is free to innovate while following the principles, may mend the foundational and semantic interoperability concerns in a gentler way with buy-ins from ecosystem players. Some key principles suggested through the National Digital Health Blueprint under different buckets are as follows.

---

<sup>170</sup> National Health Authority, Ministry of Health and Family Welfare. Consultation Paper on Unified Health Interface. 2021, March. [https://abdm.gov.in:8081/uploads/UHI\\_Consultation\\_Paper\\_60a9201c1d.pdf](https://abdm.gov.in:8081/uploads/UHI_Consultation_Paper_60a9201c1d.pdf)

<sup>171</sup> 'eSanjeevani', Govt. of India's free Telemedicine service integrated with NHA's Ayushman Bharat Digital Mission (ABDM). (n.d.). <https://pib.gov.in/PressReleasePage.aspx?PRID=1830743>.

## Core Principles

**Identification:** Having unique and reliable identification of various players within the whole ecosystem.

**Trustworthiness:** Ensuring information created by the stakeholders within the ecosystem is trust-worthy.

**Creation of a longitudinal health record:** Capability for creating a longitudinal health record for every individual from information held in diverse systems.

**Consent:** Managing the consent for collection and/or use of personal/health data, to ensure privacy and confidentiality, in conformance to the laws of the land.

## Business Principles

**Wellness-centric and wellness-driven:** Enabling access to wellness centres, health, education, awareness, screening, early detection and AYUSH.

**Empowerment:** Mass awareness and education to avail of a wide range of health and wellness services.

**Inclusive by design:** Connecting the “unconnected”, digitally illiterate, remote, hilly and tribal areas through systems.

**Security/Privacy-by-design:** All the building blocks that require handling personal health records will be designed to comply with such policy ab-initio.

**Accountability:** Real-time dashboards, data analytics and visualization tools will support the performance management.

**Portability:** Personal Health Identifier with its supporting blocks, including adoption of Health Information Standards will play a pivotal role in the national portability.

**Principle-based:** Building based on the principle, “Think Big, Start Small, Scale Fast”

## Technical Principles

**Adopt IndEA:** The design of the building blocks of ABDM will adopt and conform to IndEA by default. Other national and international standards will be adopted in areas not covered by IndEA.

**Open Standards:** The policy of MeitY on open standards and open source software shall be adopted.

**Federated Architecture:** Only the identified core building blocks will be developed and maintained centrally. All other building blocks shall be designed to be operated in a federated model that factors regional, state-level platforms and systems to function independently but in an interoperable manner.



**Open API-based Ecosystem:** All the building blocks will be architected adopting the Open API Policy notified by MeitY.

**Accountability:** Compliance of legacy systems to the Blueprint principles and IndEA principles will be assessed through an appropriately designed assessment tool.

**Minimalistic Approach:** Easy, early and collective adoption of the Blueprint by majority shall be critical to its success.

**Single Source of Truth:** All the registries, data hubs and other master databases shall be built as Single Source of Truth and System of Record on different aspects and backed by strong data governance.

## 7.5. Balancing Data Protection and Value Creation

As discussed under section 4.1.2.3 during our stakeholder engagement, European experts expressed a tussle in individuals' mindsets regarding data protection and digitalisation. Some experts highlighted how individuals consider that sharing digital footprints in return for digital health services may cause them to compromise their privacy. Against this backdrop, the key learning from India's approach towards having privacy at the infrastructure level and mechanising techno-legal solutions would aid the EU in solving this concern. In this section, we will discuss two key aspects of the ABDM framework, which simultaneously aid in tackling the privacy concern and realising the value.

### 7.5.1. Federated Architecture

The EHDS will be connected to a decentralised infrastructure, i.e., eHealth Digital Service Infrastructure (eHDSI); however, this differs slightly from the federated architecture proposed under ABDM. The federated architecture is close to eHDSI, allowing interoperability and information sharing between semi-autonomous, decentrally organised entities, information technology systems, applications, etc. However, there is a principle-level difference between India and the EU.

The federation is at the national, state, and facility level in a decentralised fashion, where data protection principles of minimalism are imbibed at every level. The ecosystem creates an aura/sense of safety (though data security is agnostic) by promising that patient data is held at the point of care or the closest physical location. The ecosystem also creates a sense of control over the health data by discussing Personal Health Records, which enable patients to compile, update, and keep a copy of their own records that can help them better manage their care and are person-focussed.<sup>172</sup> Considering the public sector as a data fiduciary, the ecosystem ensures privacy by extending responsibility for the data protection obligations and compliances under the applicable laws to the public sector.

### 7.5.2. Consent Managers

Adding to the final layer of India Stack,<sup>173</sup> Niti Aayog's recent draft DEPA policy<sup>174</sup> proposes a "new class of business" titled consent manager. The consent manager will act as a conduit between (i) the data principal, (ii) data fiduciaries who hold the data, and (iii) data fiduciaries to whom the data principal seeks to transfer the data (refer to box 1 for a practical application). The concept of consent managers is also incorporated within the ABDM ecosystem, where each ABHA ID will be linked to a health data consent

<sup>172</sup> See Sarwal, D., & Gupta, V. (2022). Personal Health Record. In StatPearls. StatPearls Publishing. <https://pubmed.ncbi.nlm.nih.gov/32491689/>.

<sup>173</sup> IMF. Yan Carrière-Swallow, Vikram Haksar, Manasa Patnam. Stacking Up Financial Inclusion Gains In India. 2021, July. <https://www.imf.org/external/pubs/ft/fandd/2021/07/india-stack-financial-access-and-digital-inclusion.htm>

<sup>174</sup> NITI Aayog. Data Empowerment And Protection Architecture Policy. 2023, March. <https://www.niti.gov.in/sites/default/files/2023-03/Data-Empowerment-and-Protection-Architecture-A-Secure-Consent-Based.pdf>

manager so that when individuals want to transfer data, the consent manager aids the process by managing the consent. This highlights the privacy-centric approach taken at the ecosystem.

### **Box 1: Privacy-enhancing Technology: Account Aggregator System**

Similar to the Digital Personal Data Protection Bill 2022, NITI Aayog's draft Data Empowerment & Protection Architecture (DEPA) policy makes a case for a consent manager in the final layer of India Stack.

Following the draft DEPA policy, the Reserve Bank of India (RBI) notified the Master Direction for Non-Banking Financial Company - Account Aggregator in 2016. In September 2021, the Account Aggregator system was launched. Licensed under the category of NBFC, the Account Aggregator (NBFC-AA) will collect and share consumers' financial information with their consent from a financial information provider to a financial information user, acting as a consent manager for the transfer of financial information.

The technical aspects prescribed by RBI for NBFC-AA (NBFC - Account Aggregator (AA) API Specification 2019) are mostly in line with the privacy-by-design principle.

## 8. Enabling Digital Health Interactions between the EU and India

This chapter discusses how to enable seamless interaction between digital health initiatives in India and its counterparts in the European Union, where individuals and healthcare service providers can utilise innovations from both jurisdictions.

### 8.1. Opportunities for EU-India Coordination and Harmonising Digital Health Initiatives

Enabling opportunities for an EU-India coordination and harmonisation of digital health brings immense opportunity with respect to digital trade and collaboratively enhancing the well-being quotient. By enabling an exchange, India and the EU could unlock the comparative advantage of accessing innovative technological solutions from across both jurisdictions. Finding interoperability at different levels is critical for making this a reality, from technical (foundational and semantic) to regulatory. However, for the scope of this paper, we will discuss the means to enable regulatory interoperability, specifically in terms of data protection. India and the EU have domestic data protection regimes to protect individual privacy and introduce measures to enhance data security and minimise implications around national security. The harmonising of the digital health ecosystem would require mutually ensuring individual privacy by India and the EU.

Towards this end, the way to ensure the harmonisation of digital health while ensuring high-level privacy is to arrive at a bilateral/multilateral treaty based on certain principles that enhance consumer trust, protect user data, and ensure high-level security. The principle-based framework could be one of the best possible options India and the EU could consider, which can fulfil the objectives of deploying safeguards to ensure security, privacy, and data protection while allowing data to flow freely across borders, enabling interoperability between both digital health ecosystems. Various data protection and security principles can become prerequisites for any kind of business-to-business data transfer chains, i.e., health facility to health facility, health professional to health facility, labs to labs, etc.

Data protection is approached differently by India and other partner countries to cater to their respective domestic concerns and needs. However, our research on the cross-jurisdictional analysis of data protection regulations shows that there is potentially a principle-level congruence between India and other leading data protection regimes. We believe this similarity at the principle level could act as a means to initiate a conversation between India and other partner countries to enable data flow and digital health partnerships through consensus building.

The principles discussed below would aid India and the EU in collaboratively determining data protection levels. However, there could be friction points, as discussed in box 1 below, which need mending during the EU-India bilateral talks by policymakers to enable seamless data transfers. The framework maps principles to be followed at different stages of the data lifecycle by different ecosystem players. Collectively, respondents from our stakeholder consultation believe the mapped principles will enhance individuals' digital trust in such a way that they feel safe sharing data and using the digital health services from both jurisdictions, respectively.

#### Box 1: Friction Points Between India and the European Union

##### State Exemption

The DPDPA 2023 empowers the central government to exempt any government agency from the act on various grounds, including the sovereignty and integrity of India, security of the state, friendly relations with foreign states, maintenance of public order, or preventing incitement to any cognisable offence relating to any of these.

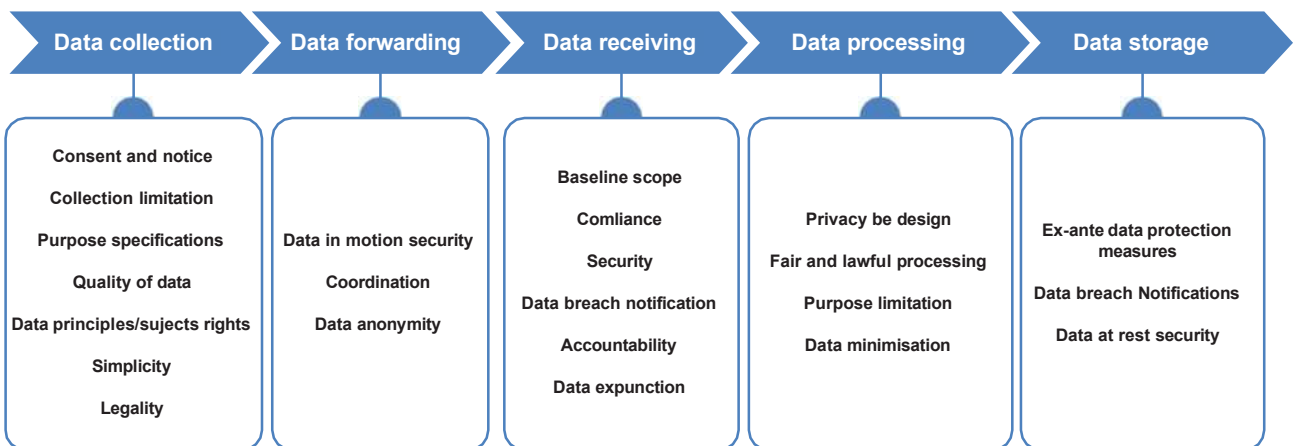
Government exemptions are not just required but necessary for the national security of the state, and their inclusion in the Act is certainly a legitimate requirement. However, certain aspects of these exemptions do not fit well with the principles of necessity and proportionality, which differ from the European Data Protection Standards. One of the key friction points would be clause 17 (1) (d), which denies the protections of the act to foreign data principals.

### Sectoral Data Localisation

In the case of India, there is less clarity on how sectoral data localisation operates in relation to trusted data flows to notified countries, suggested through the upcoming DPDPA 2023. This could cause contention due to inconsistency. For instance, as a quantum of financial data travels between India and the EU, the Reserve Bank of India's conditional data localisation mandate, where end-to-end data relating to payment systems must be stored in India, would be a point of contention. With these differences in regulations and guidance, it is technically impossible for data fiduciaries to process data by segregating it according to the mandates under different legislations. This would cause operational concerns for businesses, especially for the data processors and cloud service providers, as they must reprogramme their systems. However, the removal of provisions related to striking an MoU across regulators from DPDPA 2023 compared to previous iterations of the bill for establishing inter-regulatory coordination is concerning.

### Independent Authority

All the versions of India's Data Protection Bill consistently have a similar selection process for the Data Protection Board (DPB), which is dominated by either members of the executive themselves, or executive appointees. As DPB will be a supervisory authority for both the public and private entities, the absence of an independent board, distant from the executive wing, is a concern – especially from a cross-border data transfer perspective. Having an independent data regulator will be an important element for India to enter into bilateral data transfer treaties with other jurisdictions, including the EU. Member states of the EU have one individual regulator.



## 8.2. Implementational Roadmap for a Principle-based Data Transfer Framework

Coordination of various factors is essential for the seamless implementation of the principle-based data transfer mechanism. While there are various means, through which India and the EU can adopt a principle-based data transfer framework, this section will discuss the digital trade chapter as part of ongoing EU-India FTA negotiations as a means to enable this framework. During our engagement with academics, they suggested three layers of commitment through the digital trade chapter:

- (a) **Layer 1:** Clearly mentioning the economic interest between India and European Union by engaging in digital health,
- (b) **Layer 2:** Having provisions within the digital trade chapter where both India and European Union could come up with frameworks and mechanisms to enable cross-border data transfers through MoUs, etc., to harmonise the digital health ecosystem, and
- (c) **Layer 3:** Commitment from both India and European Union to aid ecosystem players by translating the frameworks into industry standards with the help of industry associations, experts, representatives, etc.

As layer 3 is out of the scope of this paper, we will just discuss layers 1 and 2 in detail. Both India and the EU must aid ecosystem players in implementing principles (irrespective of which mechanisms they choose) within their procedures and processes by forming various operational guidelines, standard operating procedures, awareness programmes, and private consultations. For seamless implementation, these aiding documents, prepared by the governments, must be tailored according to the domestic social, economic, and political contexts, within which the players in the ecosystem work. Moving forward, it is also crucial to identify one government agency with enforcement authority to supervise the ecosystem players' procedures and processes to see if they are aligned with the principles through mechanising various soft and hard enforcement measures. Also, the enforcement measures must be evaluated and implemented according to the nature and size of the non-compliance.

As both India and the EU are keen on having a digital trade chapter as part of the FTA,<sup>175</sup> it would be an ideal window for both India and the EU to negotiate on incorporating the principle-based data transfer framework as part of the negotiations. This negotiation should ensure a harmonised digital health ecosystem between India and the EU across borders using various mechanisms anchored in the principle-based framework.

India and the EU, through their digital trade chapter as part of the ongoing negotiations, can create an environment for economic growth, recognising the opportunities that the digital health ecosystem of both India and EU can unlock.

Both India and the EU must recognise the importance of the economic and social benefits of protecting the personal data of individuals who conduct or engage in electronic transactions to enhance consumer confidence in the digital health ecosystem. To this end, India and the EU must ensure they have at least minimum data protection policies and standards. Both India and EU must ensure transparency in their stand on privacy protection, where they publicly notify the remedies that individuals can pursue in case of a breach and the legal requirements for the players in the ecosystem. Besides, India and the EU must both cooperate to the maximum extent to protect personal information or data transferred from one party to another offshore.

---

<sup>175</sup> Jayaswal, R. H. L. A. R. (2022, July 18). India-EU FTA talks to focus on digital trade, data security, sustainability: Sources. Hindustan Times. <https://www.hindustantimes.com/india-news/indiaeu-fta-talks-to-focus-on-digital-trade-data-security-sustainability-sources-101658153156590.html#:~:text=Following%20the%20resumption%20of%20discussions,familiar%20with%20the%20matter%20said.>

## **9. Conclusion**

The evolution of EHR and their governance is pivotal in the digital age, with both India and the European Union (EU) striving to optimise their frameworks.

For India, it is imperative to extend robust protection to health data. A proactive, rather than reactive, approach to rule-making is required, emphasising the need for regulations that evolve with technological advancements. Drawing inspiration from the EU's advisory structures, India can establish a similar advisory entity to oversee EHR and ensure adherence to data protection norms. Additionally, legal congruence among digital health laws is crucial to ensure they are harmonious and mutually reinforcing. The intricate administrative fabric of India necessitates both horizontal interoperability among sectoral regulators and vertical interoperability between the central and state governments.

For the European Union, interoperability and scalability are critical. The EU can learn from the potential of the Digital Public Infrastructure, especially the transformative capabilities of the ABDM ecosystem and platforms like Aarogya Setu and CoWIN. Digital identification systems can also be emulated to ensure the streamlining of data exchange and to bolster the scalability of digital health initiatives.

In conclusion, India and the EU can derive much learning from each other's experiences. By fostering knowledge exchange and drawing from best practices, both regions can fortify their digital health ecosystems, ensuring they are resilient, interoperable, and primed for the future.

## Annexure 1. Solving Traditional Issues through Digital Health Initiatives in India & the EU - A Comparative Analysis

In this section, we will discuss how India and the EU solve the problem of disintermediation, out-of-pocket expenditure using a consumer-facing interface, health monitoring systems, telemedicine, e-Pharma network, etc.

### 1.1 Disintegration of Intermediation in Healthcare: The Impact of Digital Health Systems

A new era in healthcare has begun with the rising popularity of digital health systems, including EHRs, telemedicine, wearable health technology, and health information platforms. The healthcare ecosystem as a whole has been greatly impacted by these digital tools and systems, including patients and healthcare providers, insurers and health insurance platforms, as well as healthcare providers themselves. Due to the disruptive impact of digital health technology, traditional intermediaries, who historically played crucial roles in enabling healthcare exchanges, have been compelled to disintegrate.

For instance, the wide adoption of the EHRs has fundamentally changed the healthcare landscape. They have reduced the need for intermediaries such as physical medical record departments by enabling a direct connection between patients and healthcare providers.<sup>176</sup> As patients can access their health records, contact securely with clinicians, and take a more active part in managing their health, patient portals in EHRs have been proven to enhance patient-provider communication and engagement.<sup>177</sup>

Health insurance platforms, insurers, and patient-provider relationships have all seen significant change due to the advent of digital health systems, which have dismantled intermediary roles and eliminated them altogether. This change has given patients more authority over their health and encouraged cooperation among healthcare professionals. With the use of digital health systems, insurers can now communicate with policyholders directly and provide customised plans and incentives that are tailored to their needs.<sup>178</sup> In India, companies such as PolicyBazaar and Digit Insurance have used digital platforms to make health insurance more accessible, affordable, and customisable for consumers.<sup>179</sup> Further, initiatives like the European Health Insurance Card (EHIC) facilitate direct communication between individuals and their insurers in the European region. A government-issued card known as the EHIC gives EU citizens access to basic medical services while they are travelling throughout the EU and some other affiliated nations, reducing the need for intermediaries.<sup>180</sup>

Both India and the EU are starting their journeys towards healthcare disintermediation through digital health systems, but their journeys are distinguished by different tactics based on their unique healthcare environments, policies, and priorities. The global influence of digital health systems in India and the European Union shows their potential to revolutionise healthcare delivery and results, even though difficulties may still exist. While using digital health systems to disintermediate healthcare is a goal shared by India and the EU, their respective approaches are impacted by different healthcare

---

<sup>176</sup> See Adler-Milstein J;Holmgren AJ;Kralovec P;Worzala C;Searcy T;Patel V. (2017, November). Electronic health record adoption in US hospitals: The emergence of a digital “advanced use” divide. Journal of the American Medical Informatics Association : JAMIA, U.S. National Library of Medicine. <https://pubmed.ncbi.nlm.nih.gov/29016973/>

<sup>177</sup> Courtney R. Lyles, Eugene C. Nelson, Susan Frampton, Patricia C. Dykes, Anupama G. Cembali, Urmimala Sarkar. (2020, June). Using electronic health record portals to improve patient engagement: Research priorities and best practices. Annals of internal medicine, U.S. National Library of Medicine. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7800164/#:~:text=Electronic%20health%20records%20\(EHRs\)%20were,improving%20patient%20engagement%20\(1\).](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7800164/#:~:text=Electronic%20health%20records%20(EHRs)%20were,improving%20patient%20engagement%20(1).)

<sup>178</sup> Tanguy Catlin, Johannes-Tobias Lorenz. (2017, March). Digital Disruption in insurance: Cutting through the noise. McKinsey & Company. <https://www.mckinsey.com/~media/McKinsey/Industries/Financial%20Services/Our%20Insights/Time%20for%20insurance%20companies%20to%20face%20digital%20reality/Digital-disruption-in-Insurance.ashx>

<sup>179</sup> Deepanker Mahajan. (2023, April). Technology shifting online insurance buying process in healthcare industry from Hassle to Health. Times of India. <https://timesofindia.indiatimes.com/blogs/voices/207873/>

<sup>180</sup> Employment, Social Affairs & Inclusion. (2023, July). European Health Insurance Card. European Commission. <https://ec.europa.eu/social/main.jsp?catId=559>.

environments, policies, and aims. India's healthcare system, which is varied and resource-constrained, aims to eliminate gaps through technological innovation. While this happens, the EU is working to enhance patient outcomes and streamline healthcare systems with its standardised techniques. But, particularly in the European context, the requirement for standardised interoperability across many regions and nations offers a substantial issue. It is crucial to comprehend these geographical differences if digital health systems are to be adopted successfully.

## 1.2. Resolving Accessibility Issues Through Digital Health Initiatives

In terms of health equity, ICTs support fairness in healthcare access by reducing disparities in society. Populations that are underserved, such as those living in rural or economically underprivileged areas, may encounter disproportionate difficulties in getting access to healthcare. ICTs equalise differences by making virtual consultations, health monitoring, and health information dissemination available to everyone, regardless of socioeconomic status or geographic location.

Digital health initiatives include a variety of different models and mechanisms to deliver healthcare. A key model of digital health projects is virtual care, sometimes referred to as telehealth or telemedicine. Using digital communication capabilities, it enables healthcare providers to deliver medical treatments remotely. Virtual and telephone consultations (TCs) have now been widely utilised in response to COVID-19. There are various kinds of virtual consultations accessible, including synchronous TCs, video, text/image messaging, and asynchronous email consultations.<sup>181</sup> The utilisation of virtual COVID-19 care platforms is another example of a digital endeavour in virtual care. By enabling the remote monitoring and consultation with COVID-19 patients, these systems have given medical professionals the ability to lower the risk of viral transmission and provide timely advice on medical issues.<sup>182</sup>

Another important model of digital health initiatives is Remote Patient Monitoring (RPM). It draws upon non-invasive digital technologies to keep an eye on a patient's health, allowing for quick treatments and lowering the need for frequent in-person visits. Such technology has demonstrated considerable value in terms of treating chronic illnesses, improving patient outcomes, and saving money on medical expenses, thereby enabling quick modifications to treatment programmes.<sup>183</sup> It has also shown considerable benefits for the monitoring and management of patients during the COVID-19 pandemic, especially in terms of its ability to monitor vital signs and deliver timely interventions.<sup>184</sup>

### 1.2.1. Understanding Accessibility in India

With such a large and diversified population, India faces particular difficulties in ensuring that all of its residents have access to fair healthcare. The nation has now resorted to digital health initiatives to effectively address these accessibility challenges. Digital health initiatives are having an unprecedented impact in India, a country with a total population of more than 1.4 billion people. The goal of these initiatives is to deliver complete primary healthcare services at scale, ensuring that everyone may access healthcare regardless of where they live or their socioeconomic level.<sup>185</sup>

---

<sup>181</sup> Mold F, Cooke D, Ip A, Roy P, Denton S, Armes J. COVID-19 and beyond: virtual consultations in primary care-reflecting on the evidence base for implementation and ensuring reach: commentary article. *BMJ Health Care Inform*. 2021 January. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7804830/pdf/bmjhci-2020-100256.pdf>.

<sup>182</sup> Chung-Lee L, Catalo C. A new approach to digital health? Virtual COVID-19 care: A scoping review. *Digit Health*. 2023 February. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9926398/pdf/10.1177\\_20552076231152171.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9926398/pdf/10.1177_20552076231152171.pdf); Zammit, D.; Tomaselli, G.; Buttigieg, S.C.; Garg, L.; Macassa, G. Digital Virtual Consultations and Improved Stakeholders' Health and Wellbeing amongst Hospital Doctors. *Sustainability* 2023. <http://hig.diva-portal.org/smash/get/diva2:1743386/FULLTEXT01.pdf>.

<sup>183</sup> See Vegesna, A., Tran, M., Angelaccio, M., & Arcona, S. (2017, January). Remote Patient Monitoring via Non-Invasive Digital Technologies: A Systematic Review. *Telemedicine and E-Health*, 23(1), 3–17. <https://doi.org/10.1089/tmj.2016.0051>.

<sup>184</sup> Mantena, S., & Keshavjee, S. (2021, July). Strengthening healthcare delivery with remote patient monitoring in the time of COVID-19. *BMJ Health & Care Informatics*, 28(1), e100302. <https://doi.org/10.1136/bmjhci-2020-100302>.

<sup>185</sup> See Balasubramanian, S. (2023, July 16). India Is Using Technology To Give 1.4+ Billion People Access To Healthcare. *Forbes*. <https://www.forbes.com/sites/saibala/2023/07/16/india-is-using-technology-to-give-14-billion-people-access-to-healthcare/?sh=655f4bce622a>.



India's healthcare environment has historically been plagued with accessibility difficulties, with discrepancies in healthcare delivery a major source of concern. The ABDM was designed as a ground-breaking step towards attaining universal access to healthcare by leveraging digital technologies to address these issues. India presents considerable problems in terms of healthcare access, including geographical inequities, poor healthcare infrastructure in rural areas, and unequal access to medical treatments. The mission of ABDM is to close these gaps by utilising the potential of digital health technologies.<sup>186</sup>

Digital health initiatives are crucial instruments for enhancing access to healthcare services. In India, this includes telemedicine services, which allow patients to consult with healthcare specialists remotely. This is especially helpful in a nation with sizable rural areas, where access to medical facilities is constrained. By removing the requirement for a physical visit, patients can receive medical advice and even prescriptions without travelling. The creation of thorough health information systems is another component of digital health projects. These technologies give healthcare professionals the ability to keep electronic health data current, monitor patient histories, and guarantee continuity of care—even in outlying locations.

Telemedicine emerged as an important healthcare delivery system during the COVID-19 pandemic. During the pandemic, telemedicine became a lifeline, allowing individuals to receive medical advice and medications from the comfort of their homes. Telemedicine apps' ease of use and accessibility have considerably lessened the pressure on overworked healthcare facilities, ensuring patients receive prompt medical care.<sup>187</sup> The e-Sanjeevani application - the Indian government's telemedicine application - serves as an exemplary template for not understanding the nuances of the accessibility issues plaguing India, but also the scalability potential for such systems.

In 2019, the Indian government released a national telemedicine service, eSanjeevani, which has two variants: (i) eSanjeevani Ayushman Bharat-Health and Wellness Centre, a provider-to-provider telemedicine platform which facilitates teleconsultation for patients who walk into these centres; and (ii) eSanjeevaniOPD, which is a patient-to-doctor telemedicine service to enable people to get outpatient services in the comfort of their homes.<sup>188</sup> Notably, post pandemic, the utility and reach of these services has increased manifold. Telemedicine has already served over 114 million patients at over 115,000 health & wellness centres through 15,700+ hubs, and over 1,100 online OPDs have been serviced by more than 225,000 medical practitioners as of April 2023.<sup>189</sup> The success of E-Sanjeevani is a result of its dedication to enabling universal access to healthcare. The platform is easy to use, making it available to those with different levels of digital literacy. This openness makes sure that everyone can take advantage of telemedicine services, even those who live in rural areas or have little experience with technology. This platform is being further revamped to provide multilingual support and includes artificial intelligence-based interventions.<sup>190</sup>

Further, in rural India, programmes like the Common Services Centres (CSCs) have already been introduced by the government to provide preventive and curative primary healthcare.<sup>191</sup> Furthermore, the Village Resource Centre (VRC) has emerged as a promising model for telemedicine and tele-education. These telemedicine-equipped VRCs act as primary healthcare facilities. Through video consultations, local healthcare professionals can also communicate with doctors and specialists, facilitating rapid diagnosis and treatment. Up until now, 500 VRCs have been established across India and, as a result of this, Indian Space Research Organisation endeavours to improve the standard of healthcare in rural areas.<sup>192</sup>

---

<sup>186</sup> Nadhamuni, S., John, O., Kulkarni, M., Nanda, E., Venkatraman, S., Varma, D., Balsari, S., Gudi, N., Samantaray, S., Reddy, H., & Sheel, V. (2021, July). Driving digital transformation of comprehensive primary health services at scale in India: an enterprise architecture framework. *BMJ Global Health*, 6(Suppl 5), e005242. <https://doi.org/10.1136/bmjgh-2021-005242>.

<sup>187</sup> Maraju, R. G., Choudhari, S. G., Shaikh, M. K., Borkar, S. K., & Mendhe, H. (2023, March 10). Role of Telemedicine and Digital Technology in Public Health in India: A Narrative Review. *Cureus*. <https://doi.org/10.7759/cureus.35986>; Rajkumar, E., Gopi, A., Joshi, A. et al. Applications, benefits and challenges of telehealth in India during COVID-19 pandemic and beyond: a systematic review. *BMC Health Serv Res* 23, 7 (2023). <https://doi.org/10.1186/s12913-022-08970-8>.

<sup>188</sup> E-sanjeevani. <https://esanjeevani.mohfw.gov.in/#/>.

<sup>189</sup> Id.

<sup>190</sup> Union Health Minister, Dr Mansukh Mandaviya hails the "eSanjeevani" landmark milestone of providing telemedicine services to more than 10 Crore patients. (n.d.). <https://pib.gov.in/PressReleaseDetailm.aspx?PRID=1899855>; Consolidated telemedicine implementation guide. Geneva: World Health Organization; 2022.

<sup>191</sup> CSC e-healthcare. <http://cschealth.in/>.

<sup>192</sup> Press Information Bureau (2014). Village Resource Centres. (n.d.). <https://pib.gov.in/newsite/PrintRelease.aspx?relid=103564>.

To support the overall ecosystem and ensure long-term stability, the government has implemented enabling guidelines, such as the "Telemedicine Practise Guidelines: Enabling Registered Medical Practitioners to Provide Healthcare Using Telemedicine," issued in March 2020. These guidelines establish norms and protocols governing all aspects of telemedicine practice, including physician/patient relationships, issues of liability and negligence, management and treatment procedures, patient consent, medical records maintenance, and patient records' privacy and security.

Despite the ambitious and positive goals for India's digital health accessibility, there are still a number of challenges to overcome before scaling and sustainability can be enabled. One of the most pressing concerns is ensuring that digital health solutions reach the most disadvantaged and marginalised communities. Reaching rural and neglected areas necessitates the development of novel techniques because of the complexity of India's diversified socio-economic landscape. To make digital health genuinely inclusive, it is crucial to address problems with connectivity, affordability, and digital literacy. Furthermore, ongoing monitoring and assessment, technical capacity development, and long-term funding are all necessary for digital health programmes to be successful.

## 1.2.2 Understanding Accessibility in the EU

In European Union, digital health projects have been a driving force in modernising healthcare delivery. These programmes have not only transformed patient care but have also been extremely important in addressing accessibility challenges, particularly in light of the COVID-19 epidemic. With the aid of recent study papers and publications, we will examine in this article how digital health technologies have impacted the accessibility of healthcare in European nations.

In the EU, though its adoption remains fragmented across regions, telemedicine has played a significant role as well. The COVID-19 pandemic boosted the EU-wide deployment of telemedicine. Telemedicine became an essential technique for conducting remote consultations, monitoring patients, and providing healthcare services while limiting physical interaction as healthcare systems confronted unprecedented challenges. A 2022 WHO study demonstrated the actual advantages that European patients have experienced due to the extensive use of telemedicine. The need for in-person visits to healthcare institutions has decreased due to telemedicine apps enabling users to meet with professionals, seek medical advice, and monitor their health problems remotely.<sup>193</sup>

From the EU, two members states have shown significant adoption and usage of telemedicine. The Estonian government rolled out the Estonian Health Insurance Fund (EHIF) in 2020 that has supported several telemedicine projects with the goal of enhancing patient engagement and accessibility to healthcare. The EHIF has provided secure telemedicine platforms allowing remote consultations between patients and medical professionals. Geographical restrictions can no longer prevent patients from seeking advice from experts, family doctors, or mental health professionals while relaxing in their own homes. To help patients with chronic diseases actively manage their health and cut down on the number of hospital visits, the EHIF also finances remote monitoring systems.<sup>194</sup>

Finland has also showcased its dedication towards digital health by rolling out telemedicine-oriented programmes. Finland's dedication to digital health is demonstrated by its thorough integration of telehealth services to increase access to healthcare. The healthcare system in Finland provides a variety of telehealth services, such as electronic prescriptions, digital health records, and virtual consultations with medical professionals. From primary care to specialised consultations, these services are available to meet various healthcare needs. This integrated strategy has improved patient convenience and healthcare coordination while also increasing access to healthcare services.<sup>195</sup>

In EU nations, there are a plethora of mobile health apps that provide a variety of healthcare services. These apps have developed to meet a variety of healthcare requirements, from managing chronic diseases to providing help for mental health. Through the provision of information, reminders, and

---

<sup>193</sup> WHO. Telemedicine has clear benefits for patients in European countries, new study shows. (2022, October 31). <https://www.who.int/europe/news/item/31-10-2022-telemedicine-has-clear-benefits-for-patients-in-european-countries--new-study-shows>.

<sup>194</sup> ICT&Health. Estonia's Roadmap To Telehealth: Identify Needs, Test And Update. 2022, May. <https://ictandhealth.com/estonias-roadmap-to-telehealth-identify-needs-test-and-update/news/>.

<sup>195</sup> Dashplus. Sofie Staelraeve. Finland is the ideal breeding ground for eHealth in Europe. 2022, January. <https://www.dashplus.be/blog/finland-is-the-ideal-breeding-ground-for-ehealth-in-europe/>.

real-time communication with healthcare providers, they have emerged as a crucial element of healthcare accessibility. The creation of safe and user-friendly user interfaces has also been facilitated by the advent of mobile health apps, guaranteeing accessibility for users of all ages.<sup>196</sup>

Among the EU member states leading the charge in harnessing digital prospects are Sweden, Finland, and Denmark. A notable example of utilising digital technology to improve healthcare accessibility is Kanta Services, a complete digital health platform servicing Finland's social and healthcare sectors as well as its citizens.<sup>197</sup> This service provides a Patient-Accessible Electronic Health Record (PAEHR), accessible through the My Kanta portal, enabling users to view their own medical records, medications, and test results. Strong authentication is used for access, including mobile identification, certificate cards, and online bank identities from Finland. Even when patients are not physically present in a healthcare centre, continuous monitoring through wearable technology feeds real-time health data into the Kanta system, enabling early intervention and personalised treatment regimens.<sup>198</sup>

### 1.3. Consumer-facing Interface

Consumer-facing digital health interfaces deliver multiple benefits. They give people more control over their lives by promoting active participation in their healthcare and establishing a sense of personal accountability for their health. Through symptom trackers and health risk assessments, these interfaces also enable an early diagnosis of health disorders, enabling prompt intervention and prevention. Additionally, they increase healthcare access by offering telemedicine and remote consultation services, particularly in impoverished areas. These user interfaces also provide tailored dietary and exercise advice, supporting more efficient and patient-centred care. Overall, they improve efficiency and convenience because consumers can quickly access healthcare services, track health data, and get medical advice while at home.

Consumer-facing interfaces in the digital health environment of both India and the European Union provide a wide range of tools and services that enable people to take control of their health. These user interfaces have been developed to include features that track physical health, encourage a balanced diet, track symptoms, and handle medical crises. Their advantages include raising public knowledge of health issues, enabling proactive healthcare management, and allowing quick reactions in urgent situations. However, a major problem with these technologies lies in their user interface, whereby individuals face issues in accessing, and meaningfully engaging with these technologies.<sup>199</sup>

The Digital Health and Care 2022 Communication of the EU emphasises the significant role of consumer-facing digital health interfaces. Such interfaces must be designed to offer a user-friendly experience that enables people to access and manage their health information efficiently. For example, applications like MyHealth@EU give EU residents instant access to their electronic health information, allowing them to evaluate test results, medications, and medical histories. This will promote patient engagement by allowing people to actively participate in the decision-making process regarding their healthcare. These user interfaces also include physical health tracking capabilities, allowing users to track fitness activities, check vital signs, and set personal health objectives.<sup>200</sup>

Furthermore, in India, one of the main components of the ABDM is the National Health Stack (NHS), which is envisioned to be an open protocol for digital health services that will allow interoperability between different, open, disparate end-user applications and health services provider applications.<sup>201</sup> Such a system would enable individuals to access multiple digital health services from any platform of

---

<sup>196</sup> Negreiro, M. (2021). The Rise of Digital Health Technologies During the Pandemic. EPRS | European Parliamentary Research Service. April 2021.

[https://www.europarl.europa.eu/RegData/etudes/BRIE/2021/690548/EPRS\\_BRI\(2021\)690548\\_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2021/690548/EPRS_BRI(2021)690548_EN.pdf).

<sup>197</sup> My Kanta. <https://www.kanta.fi/en/my-kanta-pages>.

<sup>198</sup> Eriksson-Backa, K., Hirvonen, N., Enwald, H., & Huvila, I. (2021, March 31). Enablers for and barriers to using My Kanta – A focus group study of older adults' perceptions of the National Electronic Health Record in Finland. *Informatics for Health and Social Care*, 46(4), 399–411. <https://doi.org/10.1080/17538157.2021.1902331>.

<sup>199</sup> The Digital Imperative The imperative for a consumer-centric, digitally enabled health ecosystem. (2018). In Deloitte . Retrieved September 26, 2023, from

<https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-the-digital-imperative.pdf>.

<sup>200</sup> Press corner - European Health Union: A European Health Data Space for people and science. European Commission. (2022b, May). [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_22\\_2711](https://ec.europa.eu/commission/presscorner/detail/en/ip_22_2711)

<sup>201</sup> Ministry of Health and Family Welfare, Consultation Paper on Unified Health Interface (2021). [https://abdm.gov.in:8081/uploads/UHI\\_Consultation\\_Paper\\_60a9201c1d.pdf](https://abdm.gov.in:8081/uploads/UHI_Consultation_Paper_60a9201c1d.pdf).

their choice, improving accessibility, quality, and efficiency. Individuals will also be able to electronically access their medical and health records, such as medical reports, lab results, clinical records, etc., and share them with their chosen healthcare providers.<sup>202</sup>

## 1.4. Out-of-Pocket Expenditure

Healthcare financing and expenditure are critical components of any healthcare system, and both the European Union (EU) and India are actively investigating new solutions to these problems. Both jurisdictions are currently going through dramatic changes brought on by health insurer seeding and digital health efforts, which have the potential to drastically lower out-of-pocket costs. Notably, despite differences amongst member states, the EU's expenditure on healthcare makes up a sizeable portion of GDP.<sup>203</sup> On the contrary, India's expenditure on healthcare constitutes around only 2% of its GDP.<sup>204</sup>

### 1.4.1 Scenario in India

For a long time, healthcare financing in India has been a difficult problem, with significant out-of-pocket costs that have strained people's finances.<sup>205</sup> In recent years, there has been a notable paradigm shift in India's digital health projects, which has the potential to completely change the way that healthcare is delivered, managed, and funded. These programmes use cutting-edge technologies to improve healthcare accessibility, value, and affordability, eventually enhancing patient care and improving the efficiency of the healthcare system. The ABDM and the PM-JAY scheme are two of the Indian government's most notable initiatives to solve this problem and advance healthcare reform. These programmes leverage the power of digital health technologies and improve health insurance coverage in an effort to lower out-of-pocket expenses.

The PM-JAY scheme offers health insurance coverage for secondary and tertiary care hospitalisations, including pre-existing conditions, in an effort to safeguard economically-vulnerable families financially.<sup>206</sup> To ensure that people can obtain high-quality healthcare services without facing financial challenges, it considerably reduces out-of-pocket healthcare costs. According to the most recent National Health Accounts Estimates for India (2019–20), out-of-pocket expenditure decreased from 62.6% in 2014–15 to 47.1% in 2019–20.<sup>207</sup>

The government programme Ayushman Bharat has been shown to be successful in raising awareness and enrolment among rural communities.<sup>208</sup> It has also been shown to have a significant impact on lowering out-of-pocket healthcare costs, especially for those who live below the poverty line. Beneficiaries of AB-PMJAY reported seeing a significant drop in out-of-pocket costs for hospital stays and medical care. The insurance coverage offered protection from exorbitant medical expenses. Additionally, AB-PMJAY promoted prompt medical attention, which decreased the amount of healthcare that was delayed because of financial restrictions. Moreover, the complete and successful implementation of the ABDM is anticipated to cut down on avoidable costs, both financial and social, lowering out-of-pocket expenditure.

---

<sup>202</sup> Id.

<sup>203</sup> Healthcare expenditure statistics. (2022). Eurostat Statistics Explained. Retrieved September 26, 2023, from [https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Healthcare\\_expenditure\\_statistics#Healthcare\\_expenditure\\_by\\_financing\\_scheme](https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Healthcare_expenditure_statistics#Healthcare_expenditure_by_financing_scheme).

<sup>204</sup> Live Mint (2023, January 31). Health expenditure at 2.1% of GDP in FY23: Economic Survey | Mint. Mint. <https://www.livemint.com/news/india/health-expenditure-at-2-1-of-gdp-in-fy23-economic-survey-11675160463795.html>.

<sup>205</sup> Nanda, M., & Sharma, R. (2023, July 6). A comprehensive examination of the economic impact of out-of-pocket health expenditures in India. *Health Policy and Planning*, 38(8), 926–938. <https://doi.org/10.1093/heapol/czad050>; Porecha, M. (2023, January 31). Economic Survey 2022-23 | Out-of-pocket health spending still high, despite hike in government expenditure. *The Hindu*.

<https://www.thehindu.com/sci-tech/health/economic-survey-2022-23-out-of-pocket-health-spending-still-high-despite-hike-in-government-expenditure/article66454817.ece>.

<sup>206</sup> GOI. Ayushman Bharat: National Health Protection Mission. 2018.

<https://www.india.gov.in/spotlight/ayushman-bharat-national-health-protection-mission>.

<sup>207</sup> Ministry of Health and Family Welfare. (2023b, April). National Health Accounts Estimates for India (2019-20) released. Press Information Bureau.

<https://pib.gov.in/PressReleaseframePage.aspx?PRID=1919582#:~:text=Another%20positive%20trend%20in%20the,out%2Dof%2Dpocket%20payments>

<sup>208</sup> Prasad, S. S. V., Singh, C., Naik, B. N., Pandey, S., & Rao, R. (2023, March 8). Awareness of the Ayushman Bharat-Pradhan Mantri Jan Arogya Yojana in the Rural Community: A Cross-Sectional Study in Eastern India. *Cureus*.

<https://doi.org/10.7759/cureus.35901>.

In India, operational mechanisms are altering the healthcare-funding landscape that is connected to digital health efforts and health insurer seeding; these mechanisms go beyond simple intellectual conceptions. The seamless integration and sharing of health data among different stakeholders, including insurers, is one of the key processes supporting the synergy between digital health activities and health insurer seeding. With the aid of this integration, insurers now have access to precise and current health data that is essential for processing claims, determining premiums, and assessing risk. As a result, health insurance becomes more data-driven and precise, significantly lowering the possibility of false claims and guaranteeing that people receive the best coverage possible.

Digital health efforts enable remote health monitoring and telemedicine, which insurers can use to provide cutting-edge insurance policies. Insurers can encourage policyholders to adopt healthier lifestyles and behaviours by giving them access to teleconsultations with healthcare professionals and wellness programmes. This proactive approach to healthcare lowers the likelihood of hospitalisation and the related out-of-pocket expenditure, ushering in a new era of preventive healthcare.<sup>209</sup>

## 1.4.2 Scenario in the EU

With an average annual growth rate of about 10.9%, healthcare spending in the EU accounts for a sizeable portion of its GDP. Notably, there are significant differences in healthcare spending among EU member states, with some them investing far more money in healthcare than others. The COVID-19 epidemic further strained healthcare spending across the EU, highlighting how urgent it is to optimise both the price and quality of care.<sup>210</sup>

In the area of healthcare, the EU is currently embarking on a transformational path, where the confluence of digital health initiatives and health insurers is reshaping the environment.<sup>211</sup> Within the EU, telemedicine services and remote monitoring technologies are rapidly expanding. Health insurance companies are increasingly working with telemedicine companies to provide policyholders with practical online consultations. This lessens the need for costly in-person appointments, supporting the EU's efforts to improve healthcare efficiency. The fusion of digital health data results in the exceptionally quick processing of claims means rapid reimbursements become the norm, relieving patients' financial burdens and improving the entire insurance experience.<sup>212</sup>

Endeavours to lower out-of-pocket expenditure on health have further been supported by concerted initiatives that are premised on a value-based healthcare ecosystem, whereby expenditures are focussed on (i) increasing interoperability, (ii) encouraging preventive healthcare initiatives, and (iii) investing in cross-border healthcare.<sup>213</sup> The complex interaction between health insurer seeding, digital health efforts, and the EU's overarching healthcare cost containment strategies promises a better, more effective future for EU healthcare. The EU is setting sail for a healthcare system that prioritises better patient outcomes and well-being while still being cost-effective as it increases its investments in regulatory frameworks and digital health infrastructure. These coordinated initiatives hold the key to ensuring that healthcare remains affordable and sustainable for every EU citizen even while healthcare prices continue to rise.

---

<sup>209</sup> Ganesan, D. Human Rights Implications of the Digital Revolution in Health Care in India. *Health Human Rights* 2022, 24, 5. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9212836/>.

<sup>210</sup> OECD. (2020). Health expenditure in relation to GDP. *Health at a Glance: Europe 2022 : State of Health in the EU Cycle* | OECD iLibrary.

<https://www.oecd-ilibrary.org/sites/788a13b4-en/index.html?itemId=%2Fcontent%2Fcomponent%2F788a13b4-en>.

<sup>211</sup> J. Scott MARCUS, Bertin MARTENS, Christophe CARUGATI, Anne BUCHER, Ilsa GODLOVITCH. (2022, December). Study: The European Health Data Space. European Parliament.

[https://www.europarl.europa.eu/RegData/etudes/STUD/2022/740054/IPOL\\_STU\(2022\)740054\\_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2022/740054/IPOL_STU(2022)740054_EN.pdf).

<sup>212</sup> Carola Brinkmann-Sass, Laura Richter, Tobias Silberzahn, Adam Somauroo. (2020, September). The European path to reimbursement for digital health solutions. McKinsey and Company.

<https://www.mckinsey.com/~media/McKinsey/Industries/Pharmaceuticals%20and%20Medical%20Products/Our%20Insights/The%20European%20path%20to%20reimbursement%20for%20digital%20health%20solutions/The-European-path-to-reimbursement-for-digital-health-solutions-v4.pdf>.

<sup>213</sup> EIT Health, *Implementing Value-Based Health Care in Europe: Handbook for Pioneers* (Director: Gregory Katz), 2020. <https://eithealth.eu/wp-content/uploads/2020/06/Implementing-Value-Based-Healthcare-In-Europe.pdf>; See Employment, Social Affairs & Inclusion. (2023, July). *European Health Insurance Card*. European Commission. <https://ec.europa.eu/social/main.jsp?catId=559>.

