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ON RESPONSIBLE AI  
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## Governing Responsible Artificial Intelligence and Data in the Middle East and North Africa (MENA)

The American  
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Onsi Sawiris  
School of Business  
Access to Knowledge  
for Development Center

IDRC · CRDI  
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# Navigating Patient Data Practices and Challenges in Tunisia: A Prelude to AI Adoption in Healthcare



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# **NAVIGATING PATIENT DATA PRACTICES AND CHALLENGES IN TUNISIA: A PRELUDE TO AI ADOPTION IN HEALTHCARE**

## ***Case Study***

Meriem ben Trajem  
Barr El Aman for Research and Media

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## INTRODUCTION

The global healthcare sector is undergoing a fundamental transformation driven by advances in medical data utilization. This evolution is reshaping health information standards, business models, and institutional structures across healthcare systems. In Tunisia, as in many MENA countries, healthcare data governance has become a critical challenge in modernizing the health system, particularly in leveraging emerging technologies and artificial intelligence (AI) for improved healthcare delivery.

Tunisia's healthcare system is in a transitional phase, shifting from paper-based medical records to digital formats. Public hospitals have begun implementing electronic medical records (EMR) or dossier médical informatisé (DMI) as part of a national digital health development program.

This initiative aims to modernize the Health Information System (HIS) and address institutional disparities in digitization. However, the implementation of this shift requires substantial organizational adaptation.

The COVID-19 pandemic accelerated digital transformation of healthcare, prompting the rapid adoption of technologies such as teleradiology, e-pharmacy, teleconsultations, and telemonitoring. These innovations have redefined medical data usage and sharing, highlighting the pressing need to rethink healthcare data ecosystems in the digital era. As Tunisia expands its digitization efforts, balancing patient privacy, data security, and the effective use of information for healthcare improvement becomes a pressing concern.

This study examines how healthcare institutions in Tunisia collect, process, and manage patient data, exploring the implications of digital transformation on data governance, security, and patient confidentiality.

## I. BACKGROUND RESEARCH

### 1. General overview of the legal framework applied to health data in Tunisia

Tunisian legislation on personal data protection, particularly regarding health-related data, is pri-

marily based on **Organic Law No. 2004-63**, adopted on **July 27, 2004**.<sup>1</sup> To enhance and clarify the legal framework surrounding personal data protection in this sector, the **National Authority for Protection of Personal Data (INPDP)** adopted **Deliberation No. 4** on **September 5, 2018**.<sup>2</sup> Under this legislation, health data is classified as sensitive information, which grants it enhanced protection to ensure privacy, safeguard personal health information, and maintain confidentiality.

### Conditions for processing health data

The collection, transfer, processing, and storage of health data are permitted only under the following conditions:

- **Explicit consent:** processing requires the explicit and informed consent of the patient or their legal representative.
- **Legal obligations:** processing may be conducted to fulfill legal or regulatory requirements.
- **Public interest:** processing is allowed for purposes related to public health objectives.
- **Medical follow-up:** processing is authorized to ensure individualized medical follow-up for patients.
- **Scientific research:** data may be processed within the framework of validated research protocols.

### Authorization requirements

Any processing of health data must include:

- Prior authorization from the INPDP.
- A detailed declaration specifying the purposes and methods of processing.

### Key provisions of Deliberation No. 4

#### ► PURPOSE LIMITATION

- Clear and predefined objectives must be established.
- Any further processing that is incompatible with the original purpose is prohibited.

#### ► RIGHTS OF DATA SUBJECTS

- Respect for fundamental rights and freedoms.
- Right of access: individuals can review their data and obtain a readable copy.
- Data portability: patients can request that

<sup>1</sup> *Loi organique n° 2004-63 du 27 juillet 2004, portant sur la protection des données à caractère personnel [Organic Law n° 2004-63 of 27 July 2004 on the protection of personal data]*. (2004). Retrieved from DCAF - Tunisie Legal Database: <https://legislation-securite.tn/latest-laws/loi-organique-n-2004-63-du-27-juillet-2004-portant-sur-la-protection-des-donnees-a-caractere-personnel/>

<sup>2</sup> National Authority for Protection of Personal Data. (2021, October). Recueil de la protection des données personnelles [Compendium of personal-data protection]. Tunis. Retrieved from [https://inpdp.tn/Receuil\\_INPDP.pdf](https://inpdp.tn/Receuil_INPDP.pdf)

their healthcare provider transfer their data to another provider.

- Right to rectification: individuals can correct inaccurate data.
- Right to erasure: under specific conditions, individuals can request data deletion.
- Right to restrict processing: processing may be limited in certain circumstances.
- Right to objection: individuals may object to data processing for legitimate reasons.

#### ► **SECURITY MEASURES**

The framework mandates robust measures to protect data against unauthorized access, alteration, deletion, or transfer. These measures include:

- Restricted access: data access is limited strictly to what is necessary for the exercise of professional duties.
- Compliance with professional secrecy: all processing must respect confidentiality obligations.
- Anonymization: data must be anonymized for research and study purposes.
- Secure backup: data integrity must be ensured through secure backup copies.

#### ► **DATA RETENTION AND HOSTING**

- Retention period: data retention is subject to strict time limits based on its intended purpose.
- Hosting restrictions: hosting data outside Tunisian territory is prohibited without prior authorization, and processing is restricted to approved hosts.
- Anonymization is required for long-term retention.
- Documentation of procedures: archiving and deletion processes must be documented.

#### ► **DATA TRANSFERS**

- Prohibited transfers: data transfer outside Tunisia is strictly prohibited without prior authorization.
- Adequate protection: any transfer must ensure an adequate level of data protection.

#### ► **OBLIGATIONS OF DATA CONTROLLERS**

To ensure compliance, data controllers are required to:

- Appoint data protection officers (DPOs).
- Maintain processing-activity records.
- Conduct regular compliance audits.
- Provide continuous staff training on data protection.
- Document all compliance measures.

Pending updates to the law, Deliberation No. 4 aims to align Tunisian legislation with international standards, particularly the European GDPR, while maintaining specific provisions tailored to Tunisia's legal and cultural context.

## **2. Digital healthcare in Tunisia**

Tunisia adopted the Digital Health<sup>3</sup> strategic development plan (2017–2025) with the aim of modernizing the country's health information system. Despite the significant amount of information that comes out of the various administrative entities and production sites reporting to the Health Ministry, users of the health information system express concern about obtaining up-to-date and reliable data, which is essential for informed decisions and evaluations to be made. It is often the case that epidemiological data, including those related to mortality, morbidity, disability and epidemiological surveillance, are incomplete and lacking in credibility. Similar problems arise when it comes to information regarding social determinants of health, as well as territorial and social disparities. The main reason for this situation is the fragmentation, compartmentalization and lack of integration of subsystems within the health information system. Furthermore, data sharing and the adoption of new technologies remain insufficient.

To address these issues, the government has initiated several efforts to enhance the healthcare information system. A central element of this transformation is the implementation of electronic medical records (EMR)<sup>4</sup> across public health facilities. In recent years, the rollout of EMR has begun in several public hospitals, with Habib Thameur University Hospital leading the charge, followed by other university hospitals. This initiative is steadily expanding to additional healthcare facilities, including six regional polyclinics, with the aim of establishing a unified pa-

3 Tunisian Ministry of Health. (n.d.). Programme de Développement de La «Santé Numérique» En Tunisie [Digital health development program in Tunisia]. Tunis. Retrieved from <http://www.santetunisie.rns.tn/fr/prestations/programme-de-d%C3%A9veloppement-de-la-%C2%ABsant%C3%A9-num%C3%A9rique%C2%BB-en-tunisie>

4 Ministry of Health Tunisia. *Digital Health Development Program in Tunisia*. <http://www.santetunisie.rns.tn/fr/prestations/programme-de-d%C3%A9veloppement-de-la-%C2%ABsant%C3%A9-num%C3%A9rique%C2%BB-en-tunisie?start=3>

tient file system. Pilot projects<sup>5</sup> have also been launched in a district hospital and two primary health centers in the Hammamet region as part of the Essaha Aziza<sup>6</sup> program, which focuses on digitalizing primary healthcare services. Most recently, Jebiniana Regional Hospital<sup>7</sup> in Sfax has adopted the EMR system.

At the heart of these efforts is the Ministry of Health's information technology center (CIMS),<sup>8</sup> which plays a pivotal role in advancing eHealth in Tunisia. The center actively supports public health institutions in their digital transition while ensuring compliance with current security standards.

### 3. An overview of data related to women's health

Numerous organizations and stakeholders in Tunisia are involved, regularly or ad hoc, in the collection of health data and the production of statistical indicators<sup>9</sup> related to the gender dimension of healthcare. These indicators, derived from surveys or studies, come from a variety of sources, such as the Institut National de la Statistique;<sup>10</sup> various organizations under the Health Ministry, such as the National Office of Family and Population, the National Institute of Public Health, and the Directorate of Basic Health Care; international non-governmental organizations, such as the WHO and UNAIDS; and national organizations, such as the AMC.

The indicators include the rate of access to prenatal care, life expectancy at birth by gender, maternal mortality rate, birth rate, rate of contraceptive use among women in couples, proportion of births attended by qualified health professionals, adolescent fertility rate, female infant mortality rate, cesarean section rate, abortion rate, complaints from women denied medical abortion in public facilities, number of family-planning beneficiaries, and number of reproductive health procedures.

Regarding severe diseases affecting women, notably breast and gynecological cancer,<sup>11</sup> various studies have attempted to estimate incidence and mortality rates<sup>12</sup> despite insufficient statistics and the lack of precise, updated data.<sup>13</sup> Indicators relating to sexually transmitted diseases include the percentage of women with knowledge of HIV/AIDS transmission, the prevalence of HIV/AIDS, the rate of access to antiretrovirals for pregnant women and the rate of access to antiretrovirals.

Recently, the African Modeling and Analytics Academy for Women project (AMAX),<sup>14</sup> which is led by the Institut Pasteur de Tunis, has focused on mathematical modeling and data analysis related to infections affecting women in Africa, including human papillomavirus (HPV), hepatitis B virus, COVID-19, and antibiotic resistance. It established a learning and research network in Africa to build capacity for modeling and analysis of women's health. The project also aims to develop a platform to standardize data collection and guarantee information security, thus helping to improve understanding of women's health issues in Africa and guide public health policies.

### 4. AI-driven healthcare innovation ecosystem in Tunisia: startups and research initiatives

The integration of AI into Tunisia's healthcare system, while still in its early stages, shows promising signs of rapid development and transformation. Currently, there are no precise statistics on the use of AI in this sector. However, indicators related to digital health more broadly, including those utilizing AI, are available. The digital health market is experiencing significant growth,<sup>15</sup> with forecasts predicting a growth rate of 6.07% between 2024 and 2029, reaching a market size of €91.52 million by 2029. This development is driven by several key factors, including the increasing adoption of smartphones, improved internet connectivity, and enhanced telecommunications infrastructure.

5 African Manager. (2023, July 12). Le ministre de la santé prend connaissance de la numérisation du système d'information sanitaire à l'hôpital local de Hammamet [Health minister takes stock of information-systems digitalization at Hammamet regional hospital]. Retrieved from <https://africanmanager.com/le-ministre-de-la-sante-prend-connaissance-de-la-numerisation-du-systeme-dinformation-sanitaire-a-lhopital-local-de-hammamet/>

6 Essaha Aziza. (2022). Numérisation des services de soins de première ligne : réunion d'information des partenaires [Digitization of front-line care services]. Retrieved from <https://www.essaha-aziza.org/post/numerisation-sspl-info>

7 La Presse. (2024, December 14). Lancement du dossier médical électronique à Jebiniana [EMR launch in Jebiniana]. Retrieved from <https://lapresse.tn/2024/12/14/tunisie-sante-lancement-du-dossier-medical-electronique-a-jebiniana/>

8 Tunisian Ministry of Health information center. <http://www.cims.tn/>

9 National Institute of Statistics, Tunisia. (2015). Rapport national genre Tunisie [National report on gender]. (pp. 50-53). Retrieved from [https://www.ins.tn/sites/default/files/publication/pdf/rapport%20national%20genre%20Site%20\\_0.pdf](https://www.ins.tn/sites/default/files/publication/pdf/rapport%20national%20genre%20Site%20_0.pdf)

10 National Institute of Statistics, Tunisia. (2022). Statistiques. Retrieved from <https://www.ins.tn/statistiques/124>

11 Dhaouadi, S. et al. (2021). Burden of Breast and Gynecological Cancers in Tunisia between 1990 and 2030: Trend and Projection. *La Tunisie Médicale*, 99(4), 390-398.

12 UNFPA, and Institut National de la Santé. Statistiques nationales sur les causes de décès en Tunisie 2020 [National statistics on causes of death, 2020]. Retrieved from <http://www.santetunisie.rns.tn/images/statistiques-deces2021.pdf>

13 National Institute of Statistics, Tunisia. Causes Médicales de Décès [Medical causes of death]. (p. 36). Retrieved from [http://www.insp.rns.tn/index.php?option=com\\_content&view=section&id=26&Itemid=224](http://www.insp.rns.tn/index.php?option=com_content&view=section&id=26&Itemid=224)

14 African Modeling and Analytics Academy for Women (AMAX). (n.d.). Retrieved from Bill and Melinda Gates Foundation: <https://acgh.grandchallenges.org/grant/african-modeling-and-analytics-academy-women-amaax>

15 Digital Health - Tunisia. (n.d.). Retrieved from Statista: <https://fr.statista.com/outlook/hmo/digital-health/tunisia?currency=eur>

The Tunisian government is actively supporting this digital transformation through strategic initiatives, such as the planned launch of a **national AI strategy in 2025**<sup>16</sup> and a comprehensive healthcare digitalization program.

The **2021 annual report by Startup Tunisia**<sup>17</sup> also provides valuable insights into the digital health sector. Healthtech startups represent **9.4% of all startups**, totaling 61 companies, 2.3% of which integrate biotechnology into their product development. The digital health sector has experienced consistent growth in the number of startups, marked by a **30% increase between 2019 and 2020**, followed by a remarkable **50% increase between 2020 and 2021**. This trend can be partly attributed to the impact of the **COVID-19 pandemic**, which spurred entrepreneurs to develop various solutions, including ventilators, sterilization methods, and early disease detection systems—all leveraging AI.

#### Notable examples of AI research and development projects in Tunisia's healthcare sector

**InnoDeep**<sup>18,19</sup> is a noteworthy platform that combines teleradiology with AI to provide timely responses to diagnostic and therapeutic needs. This solution was adopted during the COVID-19 pandemic and is currently focused on developing new detection methods for breast cancer.

**Neurologs**<sup>20</sup> stands out as one of the few startups offering a comprehensive cloud-based platform. It provides healthcare professionals with convenient access to various AI-assisted diagnostic solutions, integrates personalized treatment recommendation systems, and equips practitioners with tools for both basic and clinical research into brain disorders.

AI is significantly impacting medical research, particularly in drug discovery and in understanding microorganisms like SARS-CoV-2 and its variants. **MajestEYE**<sup>21</sup> has developed solutions addressing these challenges. Additionally,

**InstaDeep**<sup>22</sup> formed a strategic alliance with BioNTech in 2020 to develop innovative immunotherapies using the DeepChain technology platform, targeting various cancers and infectious diseases. In 2021, an AI program was established to predict new high-risk COVID variants.

**AI-Powered Medical Imaging - QUNIE and DeepTek**,<sup>23</sup> a proof-of-concept project initiated on November 28, 2022 at **Abderrahmen Mami Hospital**, focuses on AI-powered medical imaging to assist in diagnosing lung diseases such as tuberculosis. This collaboration aims to enhance the efficiency of radiology departments and address the doctor shortage in Africa through improved diagnostic capabilities.

**Institut Pasteur de Tunis (IPT)** is a leading public research center for infectious diseases whose **Laboratory of Molecular Epidemiology and Experimental Pathology**,<sup>24</sup> led by researcher **Emna Harigua**, is focused on developing computational approaches that combine AI with bioinformatics. This research aims to improve understanding and management of infectious diseases through advanced analytical techniques.

The **INTERACT Project**<sup>25</sup> is a pioneering initiative that integrates responsible AI with wastewater quality surveillance to monitor waterborne pathogens. By analyzing extensive wastewater data, this project employs AI to generate actionable recommendations aimed at controlling the spread of pathogens. An AI-powered dashboard has been developed by the project to track trends in pathogens and antibiotic resistance, enhancing public health responses.

#### Predictive healthcare models<sup>26</sup>

Several Tunisian doctors and engineers are engaged in constructing and validating AI models for critical areas such as intensive care and anesthesia. These models aim to predict septic shock, non-invasive ventilation failure, and mortality rates, showcasing the potential of AI to enhance patient outcomes.

16 Njaya, S. (2024, November 13). Tunisia Announces New Digital Transformation and AI Strategy. *We Are Tech Africa*. Retrieved from <https://www.wearotech.africa/en/fils-uk/tech-stars/tunisia-announces-new-digital-transformation-and-ai-strategy>

17 Startup Tunisia. (2021). Rapport Annuel 2021 [Annual report 2021]. Retrieved from [https://startup.gov.tn/sites/default/files/2022-10/Rapport\\_annuel\\_2021\\_VERSIONWEB\\_opt\\_1.pdf](https://startup.gov.tn/sites/default/files/2022-10/Rapport_annuel_2021_VERSIONWEB_opt_1.pdf)

18 InnoDeep – Augmented Intelligence platform. Homepage at <https://www.innodeep.net/>

19 Docteur Imago. (2022, 05 31). La téléimagerie combinée à l'IA permet de gagner du temps sur le diagnostic [Tele-imagery combined with AI saves time in diagnosis]. *Docteur Imago*. Retrieved from <https://docteurimago.fr/actualite/produits/la-teleimagerie-combinee-a-lia-permet-de-gagner-du-temps-sur-le-diagnostic/>

20 Neurologs – AI for brain health. Homepage at <https://neurologs.org/>

21 MajestEYE – to See and Foresee. Homepage at <https://www.majesteye.com/>

22 Blaise, L. (2022, February 10). InstaDeep, la start-up tunisienne qui a séduit BioNTech et Google. *Le Monde*. Retrieved from [https://www.lemonde.fr/afrique/article/2022/02/10/instadeep-la-start-up-tunisienne-qui-a-seduit-biontech-et-google\\_6113114\\_3212.html](https://www.lemonde.fr/afrique/article/2022/02/10/instadeep-la-start-up-tunisienne-qui-a-seduit-biontech-et-google_6113114_3212.html)

23 Quine Corporation. (2022). News release - AI powered medical imaging demonstration begins in Tunisia. *Quine*. Tokyo. Retrieved from <https://www.quine.com/en/newsrelease/20221129/>

24 Institut Pasteur de Tunis. (n.d.). Emna Harigua, intègre un Comité scientifique international pour la découverte de médicaments assistée par l'intelligence artificielle [Emna Harigua, member of international committee for AI-assisted drug discovery]. Retrieved from [http://www.pasteur.tn/index.php?option=com\\_content&view=article&id=909:emna-harigua-integre-un-comite-scientifique-international-pour-la-decouverte-de-medicaments-assistee-par-lintelligence-artificielle-&catid=41:actualites&Itemid=147](http://www.pasteur.tn/index.php?option=com_content&view=article&id=909:emna-harigua-integre-un-comite-scientifique-international-pour-la-decouverte-de-medicaments-assistee-par-lintelligence-artificielle-&catid=41:actualites&Itemid=147)

25 Tunisia - A responsible AI-driven Initiative for Tackling Waterborne Pathogen (re)Emergence in Tunisia. (n.d.). Retrieved from AI4PEP: <https://ai4pep.org/tunisia/>

26 Elhechm, Y. Z. (2022). Medicine at the dawn of Artificial Intelligence. *La Tunisie Médicale*, 100(5), 354–355. Retrieved from <https://latunisiemedicale.com/pdf/MAI2022-02.pdf> Elhechm, Y. Z. (2022).

### Educational initiatives for autism<sup>27</sup>

A Tunisian team won first prize at an AI competition in Addis Ababa for developing an educational platform that uses AI to help autistic children better understand and manage their stress. The project highlights the application of AI in specialized education.

### Enova Robotics<sup>28</sup>

Specializing in robotics and AI, **Enova Robotics** develops intelligent robotic solutions for various applications, including healthcare.

### SimCo project - Université Centrale<sup>29</sup>

This project focuses on developing an intelligent decision-support system using AI and machine learning. It assists neurologists in confirming diagnoses for patients with neurological disorders (e.g., Alzheimer's, stroke) by simulating driving behavior in a 3D environment. The project also contributes to patient rehabilitation and assesses driving capabilities for individuals over 65.

### Initiatives at Université Tunis El Manar (UTM)<sup>30</sup>

UTM has launched several scientific research projects aimed at utilizing AI in healthcare and education. This includes establishing a chair in AI to develop applications that address national health priorities.

### Training and development initiatives

Given these advancements, there is an increasing demand for healthcare professionals who are skilled in the latest information-processing technologies. Various training programs have been established:

The **Institut Supérieur des Technologies Médicales** in Tunis offers engineering courses focused on the intersection of AI and health, including innovative health-data processing technologies.

Recent offerings from medical faculties include certificates of complementary studies in AI or technological innovation for doctors.

In 2021, the **Higher Institute of Biotechnology of Sidi Thabet**, the **National School of Informatics Sciences**, and the **Institut Pasteur de Tunis** jointly opened a research master's degree program in bioinformatics.

**atics Sciences**, and the **Institut Pasteur de Tunis** jointly opened a research master's degree program in bioinformatics.

**The Bio & Tech – e-Health Incubation Program<sup>31</sup>** was launched to foster the e-health sector in Tunisia, bringing together medical and technological stakeholders. It supports innovative healthcare projects from ideation to market testing, bridging the gap between scientific research and practical applications in healthcare technology.

## II. METHODOLOGY

### 1. Theoretical framework: choice of method

This study aims to provide an overview of patient-data governance in various healthcare institutions in Tunisia, focusing on the associated opportunities and challenges. To do this, we draw on the Health Data Governance Principles,<sup>32</sup> a set of principles intended to provide guidelines for health data management in health systems and public policy. They have been adopted by a number of international organizations, including the World Bank,<sup>33</sup> and can be used as a framework for designing and implementing national health-data governance systems. Developing these principles is an essential step toward ensuring equitable governance of health data around the world.

There are three interconnected objectives:

#### **Protect people**

The governance of health data must balance the need to protect individuals, groups, and communities with the importance of using health data for societal benefit. In order to identify and mitigate possible harm, rigorous evaluation and risk analysis are essential at all stages of the data lifecycle. Special measures should be taken within health data governance to prevent various harms, including harassment, discrimination, surveillance, and data-driven exploitation, which would result in a breach of privacy and data protection laws.

<sup>27</sup> Generative AI for Africa Hackathon Finalists Project Underway in Addis Ababa. (2023, November 11). *ENA*. Retrieved from [https://www.ena.et/web/eng/w/eng\\_3571495](https://www.ena.et/web/eng/w/eng_3571495)

<sup>28</sup> Enova Robotics: Tunisian Robots, Global Demand. (2019, December 15). *EmTech MENA*. Retrieved from <https://emtechmena.com/enova-robotics-tunisian-robots-global-demand/>

<sup>29</sup> *Projet SimCo : L'IA Pour La Santé [Project SimCo: AI for health]*. (n.d.). Retrieved from Université Centrale: <https://www.universitecentrale.net/fr/244/projet-simco-l-ia-pour-la-santem>

<sup>30</sup> African Manager. (2024, February 24). L'UTM lance des projets de recherche scientifique en IA pour la santé et l'éducation [UTM launches AI research projects for health, education]. *African Manager*. Retrieved from <https://africanmanager.com/lutm-lance-des-projets-de-recherche-scientifique-visant-a-utiliser-lintelligence-artificielle-dans-les-domaines-de-la-sante-et-de-education/>

<sup>31</sup> Digital Africa. (2023, November 28). Bio & Tech, an e-health incubation program in Tunisia. *Digital Africa*. Retrieved from <https://resilient.digital-africa.co/en/blog/2023/11/28/bio-tech-an-e-health-incubation-program-in-tunisia/>

<sup>32</sup> The Global Health Data Governance Principles. *Principles*. Health Data Principles. <https://healthdataprinciples.org/principles>

<sup>33</sup> *Data governance in health*. Retrieved from World Bank: <https://openknowledge.worldbank.org/server/api/core/bitstreams/2dad9719-f398-4414-ae58-e4f3eca16f26/content>

### Promote health value

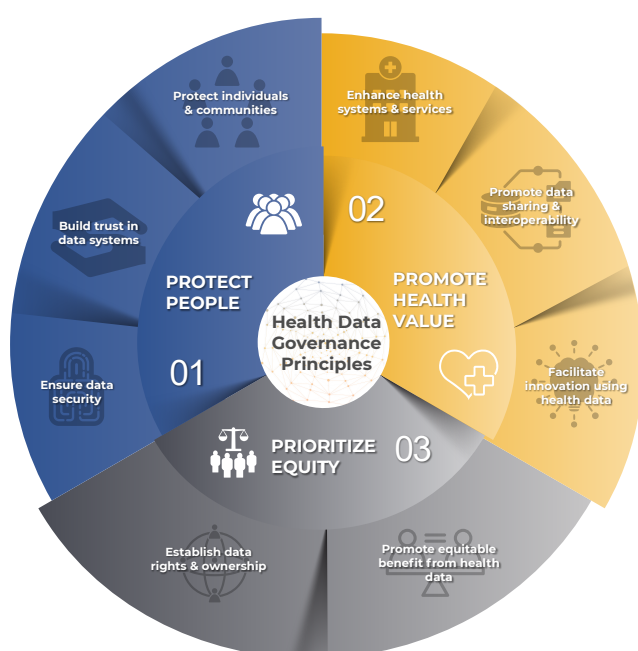
The efficiencies and resilience of health systems can be improved by maximizing the value derived from data utilization and analysis. Additionally, this objective involves the secure exchange of high-quality data to gain a deeper understanding of healthcare challenges and needs. It is also essential that the governance of health data be forward-looking and anticipate the integration of emerging technologies such as AI.

### Prioritize equity

Equity in the governance of health data requires the representation of all individuals, segments, and categories of society, regardless of their social or economic standing. A further component of equity is the inclusion of human rights in data-related laws, thus reducing inequalities and ensuring data contributors' protection.

In order to assess the degree of convergence between these principles and the reality of patient data governance in Tunisia, this case study examines various aspects of patient data collection, processing, sharing, storage, and protection.

The case study is presented within a comparative regional approach. To accomplish this, we developed a questionnaire based on the structure of the data catalog developed by A2K4D. Thus, we aim to ensure that our Tunisian case study is methodologically consistent with other case studies from the MENA region.



**Figure 1:** The Health Data Governance Principles framework.<sup>34</sup>

The questionnaire was presented to a variety of healthcare professionals and complemented by semi-open interviews. With these interviews, it is possible to gain further understanding of Tunisian patient data governance.

## 2. Selection of participants: identifying study participants

Tunisia's digitization of data highlights a significant disparity among healthcare institutions. To illustrate the range of states of patient-data governance in each context, we selected five types of hospitals (polyclinic, private hospital, regional hospital, specialized hospital, and university hospital). The institutions were categorized based on the phase of patient-data digitization:

### 1) Full digitization of the medical record:

- One private hospital located in Tunis
- One public university hospital (Habib Thameur Hospital)
- Radiology services at the regional hospital in Ben Arous.

### 2) Advanced transition toward implementation of an electronic medical record:

- Six polyclinics of the National Social Security Fund (CNSS), which are medium-sized public hospitals affiliated with the Ministry of Social Affairs that provide general outpatient care, specialized care, and diagnostic services to social security beneficiaries.

### 3) Paper-based systems:

- One public oncology hospital (Salah Azeiz Hospital)
- One regional hospital in Ben Arous providing emergency, internal medicine, and gynecology services.

At each selected hospital, we collected responses from healthcare professionals, including administrative staff, physicians, nurses, midwives, floor supervisors, directors, managers, and engineers.

To highlight specific challenges related to data processing and the adoption of AI, we also sought input from biologists and data scientists working at the Institut Pasteur de Tunis (IPT). As a scientific research institution under the Ministry of Health, the IPT conducts investigations, missions, analyses, and scientific research related to human and animal public health. The institute also prepares biological products such as vaccines, serums, and antigens when their production is deemed necessary.

<sup>34</sup> The World Bank's Health Data Governance Principles (<https://healthdatagovernance.org/principles/>), revisualised

### 3. Data collection

Data collection was carried out using responses obtained from a structured questionnaire developed in line with the World Bank's 2022 Health Data Governance methodological framework. The questionnaire was specifically designed with the digitalization of Tunisia's healthcare sector in mind, with the specific aim of gaining a deeper understanding of current practices related to patient data.

The questionnaire included questions on five key aspects of data governance: data collection, processing, sharing, storage, and security.

To facilitate response collection, we divided the queries into three questionnaires according to interviewee profiles. The first questionnaire was intended for medical staff, including doctors, nurses, midwives, and floor supervisors. The second questionnaire was designed for directors, managers, and engineers. The third was designed for personnel involved in research initiatives, including biologists, physicians, and data scientists.

Before collecting their answers, we explained our study objectives to the participants during interviews.

To obtain a representative sample and a comprehensive view of each facility, interviews were conducted across different departments and services within each establishment.

## III. FIELDWORK FINDINGS: EXISTING HEALTH DATA PRACTICES

### 1. Data collection

#### *Protect people*

We will begin by addressing data collection through the prism of the first objective: protecting people. The first principle is to ensure that data collection is undertaken only when necessary, guaranteeing that the information collected is used accurately and appropriately. The second principle focuses on the quality, availability and accessibility of data to establish reliable and easily accessible datasets. In accordance with the third principle, it is necessary to ensure that the consent of individuals is informed and fully understood in order to protect their privacy and rights.

Data collected from patients can be divided into three categories: medico-administrative data, medical data, and clinical data.

#### *- Medico-administrative data*

This data is collected during the patient registration process and used for billing purposes. There are several types of information included in it, namely identification information (first and last name, date of birth, address, health insurance number), demographic information (gender, age, region, profession, and family situation), medical classification of the patient (disability status, presence of chronic illnesses), clinical profiles of clinicians who have provided care, invoicing of medical services, and private health insurance usage. In all healthcare establishments, this type of information is digitized.

Additionally, some of this data may be found in the patient's medical file, where it is taken into account when tailoring care to meet the patient's individual needs. It is important to note that medico-administrative databases are not intended for research purposes, but rather to facilitate the oversight of the administrative and financial management of medical institutions. However, some doctors may have access to this data and can verify and supplement it during research studies by reaching out to a specific group of patients who meet the relevant criteria for the intended research or evaluation.

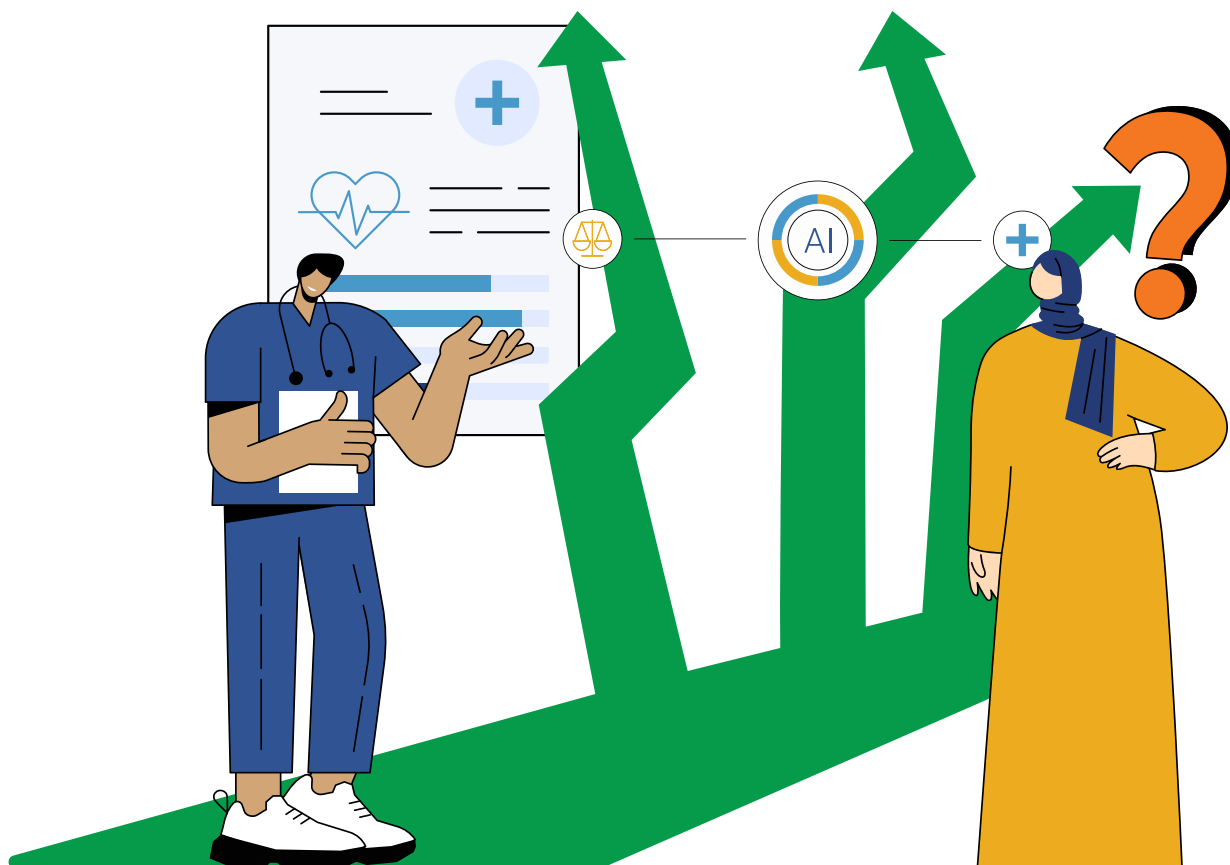
#### *- Medical and clinical data*

Clinical data is information collected, observed or generated specifically for a clinical study. On the other hand, medical data refers to health-related information provided by the patient to the physician for the purpose of receiving medical care. This data is recorded in the health record and represents the most significant component of patient data.

In order to provide the best possible care to patients, accurate medical information must be collected. The extent and level of detail of this information is carefully tailored to meet the specific needs of the medical intervention. It includes elements such as allergies, medical history, symptoms, clinical metrics (such as blood pressure, temperature and weight), and previous examinations.

In practice, the most detailed information is recorded in a patient's file during medical consultations. Certain services, such as radiology and biological laboratory analysis, may only require specific information that would be relevant to the analysis or procedure, such as allergies or the presence of a medical condition.

It is important to note that collection of this data is not dependent upon the level of digitalization of the healthcare establishment but on the nature of the services it provides. Each healthcare



service tailors its data collection to its specific requirements in order to ensure appropriate medical care. There is, however, a greater chance of human error when data is entered manually, resulting in reporting errors due to omissions, duplications, or inaccurate and incomplete data entries. Some establishments that have adopted EMR are less likely to experience these deficiencies inherent in paper records. An EMR system can significantly improve the quality and completeness of data due to its ergonomic design and ability to alert the user when information should be completed or verified.

When patient data is collected for research projects or studies, two distinct approaches are employed, each determined by the nature of the study:

Retrospective studies utilize pre-existing data extracted from patients' medical records. Current legislation permits the collection of patient medical information for purposes aligned with public health objectives and to ensure individualized medical follow-up. In these cases, explicit patient consent is not mandated.

Conversely, prospective studies involve the collection of new clinical data. This approach typically necessitates obtaining the patient's informed consent, both verbally and in writing. This process ensures that the patient is fully informed about the study and willingly agrees to participate.

Regardless of the study type, accessing medical data requires approval from department heads and the ethics committees of hospitals or the IPT. Furthermore, for research projects, it is imperative to secure prior authorization from the National Authority for Protection of Personal Data (INPDP). These multi-layered approval processes serve to safeguard patient privacy and ensure ethical conduct in medical research.

### **Promote health value**

In this section, we will take a closer look at the practice of data collection within the framework of the second objective: promoting health value. We will focus on the following key elements: improving the efficiency, effectiveness, and resilience of the healthcare system; promoting data sharing and interoperability; and the judicious utilization of data to enhance health services for both individuals and communities.

According to the doctors we interviewed across different types of hospitals, during repeat visits, they use existing data and conduct additional interviews and clinical examinations in order to fill in missing information and monitor a patient's progress. Patients' files are supplemented with laboratory and radiology results by doctors who are responsible for their follow-up.

Those working in establishments without EMR systems often face challenges related to the legibility of handwritten annotations and a lack of detail in manual notes. These issues are particularly problematic when transferring medi-

cal records between doctors, especially for patients with chronic illnesses, long-term follow-up needs, or hospitalization histories. In such cases, the risk of critical-data loss increases due to the size of the file and the frequency of handling. Feedback from doctors at the university hospital and the clinic highlights that these complications are less common in establishments that have adopted EMR.

In public university hospitals and polyclinics, doctors note that the EMR currently in use greatly enhances the management of drug prescriptions. This system allows proactive monitoring of medication usage based on predefined lists, alerting doctors to potential contraindications. On the other hand, the oncology hospital does not utilize EMR. Instead, it relies on a specialized system designed exclusively for managing pharmaceutical products. This system has proven highly effective in tracking the availability, distribution, and follow-up of cancer treatments. Its success could serve as an incentive for the hospital to consider digitizing its medical records in the future.

Despite the clear advantages of EMR in improving data collection and patient care, their implementation and effective use in public hospitals continue to face significant challenges.

Healthcare establishments transitioning to EMR, particularly in the CNSS polyclinics studied, are in a difficult phase, wherein data management is simultaneously electronic and paper-based. While healthcare professionals generally agree on the need to move away from paper records, some doctors report resistance from colleagues during this dual-system phase. This reluctance stems primarily from the dual tasking imposed on physicians, who must learn to use the EMR system effectively while also maintaining paper records. The resulting frustration and negative perception of the process's efficiency discourages full engagement with the EMR system. Adding to the resistance among staff members is the prospect of transforming long-established practices.

Interviews and surveys conducted at a regional hospital and an oncology hospital, neither of which have implemented EMR, highlight budgetary constraints as the primary barrier to adoption. Limited financial resources prevent these institutions from investing in essential information technology and modern equipment.

Adding to this challenge is a shortage of doctors and qualified personnel, which severely affects the quality of medical records. Many professionals are leaving the public sector for private practice or seeking opportunities abroad, attracted

by better working conditions and higher salaries. As a result, the remaining physicians face excessive workloads, often managing an unsustainable number of patients. In such demanding circumstances, maintaining detailed and accurate documentation becomes increasingly difficult. This frequently leads to incomplete medical records, critical omissions, and an elevated risk of errors, undermining the overall quality of patient care.

### **Prioritize equity**

Some of the doctors and researchers interviewed for this study address the importance of equity-focused data collection in medical research and practice. Their insights indicate that capturing a range of patient characteristics—such as gender, sex, age, socioeconomic status, regional background, and citizenship status—is essential for gaining a comprehensive understanding of the full spectrum of health experiences within the population.

The interviewees identify EMR as a transformative tool for collecting comprehensive data across diverse populations, addressing historical gaps in healthcare records. Physicians from various institutions highlight how implementing EMR could help overcome current data deficiencies. Many note that enhanced data collection would not only improve direct patient care but also advance targeted research initiatives.

A particular concern raised is the underreporting of health issues in inland regions, particularly regarding violence, sexually transmitted infections, and cancers such as breast cancer. These issues are often overlooked due to social stigma and limited health insurance coverage, creating significant blind spots in understanding women's health, especially in disadvantaged areas.

Another key theme from the interviews is the importance of effective patient communication during data collection. Clinicians and researchers shared their experiences in tailoring communication approaches to match patients' educational backgrounds and comprehension levels. This personalized approach, they note, fosters an environment where patients feel comfortable sharing sensitive health information, ultimately leading to more accurate and comprehensive data collection.

## 2. Data processing

### Protect people

In our examination of data processing practices, we will emphasize the importance of establishing a reliable digital environment that bolsters confidence in personal-information management.

The healthcare sector's data-processing activities primarily occur within the framework of research studies or specific projects. Researchers at the Institut Pasteur de Tunis (IPT), along with several interviewed physicians, report employing pseudonymization or anonymization techniques for personal health data whenever feasible. These methods are particularly crucial when combining or merging databases, as they help ensure that individuals cannot be easily identified from the processed data, thus safeguarding patient privacy.

Furthermore, data processing in this context is subject to strict regulations and requires prior authorization from the National Authority for Protection of Personal Data (INPDP). This authorization must clearly outline the objectives of the project, identify the individuals authorized to process the data, and specify the scope of the data, including its types and intended purposes. These measures are implemented to ensure compliance with data protection standards and to minimize the risk of misuse.

### Promote health value

The processing of health data plays a vital role in promoting health value through enhanced medical studies, improved healthcare services, and optimized utilization of health information. Our research has revealed several key challenges and opportunities in this domain, based on extensive interviews with healthcare professionals and researchers.

Medical data presents unique challenges in research contexts, largely due to its primary orientation toward clinical documentation rather than research applications. Healthcare professionals document patient information narratively, using inconsistent medical terminology and personalized shorthand that varies across practitioners and institutions. This unstructured approach, while effective for patient care, creates significant obstacles for systematic research analysis. Researchers frequently encounter ambiguous or incomplete records, requiring extensive cross-verification through multiple sources to ensure data accuracy. The situation is further complicated by healthcare institutions' use of multiple, often disconnected information systems, leading to data fragmentation, redundancies, and inconsistencies that demand careful resolution.

The adoption of EMR has emerged as a promising solution to these challenges. According to





engineering professionals we interviewed, EMR systems have demonstrated success in reducing treatment complications through automated checks and alerts regarding conflicting information, in addition to facilitating the integration of structured data fields with standardized vocabulary. The broader implementation of EMR systems is expected to enhance the overall data ecosystem, particularly in supporting advanced technological applications such as AI.

Researchers from the IPT's Laboratory of Molecular Epidemiology and Experimental Pathology provide concrete examples of AI's current applications. Their work in utilizing AI for lesion image analysis in diagnostics has yielded promising results. The lead research team notes that image-based AI applications have advanced particularly rapidly, thanks to the availability, relative reliability, and structured nature of imaging data compared to other forms of medical information.

Young doctors and researchers interviewed for this study consistently underscore two critical needs: enhanced interdisciplinary collaboration and increased recruitment of data specialists, including data managers, analysts, and statisticians. They view such expertise as essential for advancing medical research and improving healthcare outcomes through better data utilization.

### **Prioritize equity**

This section will address data processing in relation to the third objective, prioritizing equity. As part of this goal, it is essential to ensure that health data is used to provide equitable benefits by actively minimizing bias throughout the processing stages.

Physicians highlight how systematic approaches to data cleaning and preprocessing are essential, particularly when addressing missing-data patterns that might disproportionately affect certain demographic groups. Their experiences reveal that implementing regular bias audits and advanced statistical analyses enables research teams to identify and address systemic errors early in the research process, preventing downstream impacts on study outcomes.

### 3. Data sharing

#### **Protect people**

We will examine data sharing in the context of protecting individuals, emphasizing the importance of establishing trust through the regulation of access to data.

Access to medical data is tiered based on roles and responsibilities to maintain security and confidentiality. This hierarchical structure ensures that access to sensitive medical data is carefully managed to align with ethical considerations and operational needs while minimizing risks of data misuse.

Department supervisors in clinics using EMR have broader access to oversee patient management within their area and can manage systems remotely via dedicated applications.

Doctors are granted access solely for patient care, whether through paper records or EMR.

Paramedical staff, radiologists, and biologists have limited access, restricted to the information necessary for the care they provide.

Administrative staff are restricted to handling non-medical administrative data.

Data managers and engineers have comprehensive access to the clinic's data systems to ensure that information systems function optimally.

Data scientists work with curated and usually anonymized datasets tailored to the specific requirements of their studies.

#### **Promote health value**

The insights and elucidations provided by the healthcare professionals reveal how data-sharing practices and challenges are evolving in line with the objective of promoting health value. This includes a focus on the benefits of health data and the importance of interoperability between data systems.

In the context of research projects and evaluations, patient data may be shared with doctors across all public medical establishments, as well as with medical students conducting theses at public university hospitals. However, private hospitals typically do not participate in research or data-sharing initiatives.

Challenges persist in designing research projects that involve data sharing. Within the public sector, accessing and extracting information from medical records can be complex, and research databases created through various proj-



ects are rarely made available for further use by doctors or researchers.

Integrating data among professionals and institutions presents significant obstacles, particularly when merging legacy databases or reconciling different datasets. These challenges arise from inconsistent categorization and terminology, as well as inadequate documentation, which complicate efforts to understand the structure and context of the data.

An example of a rare data-sharing initiative among institutions is a significant project conducted at the IPT. In this case, data from two public hospitals is being utilized as part of a national collaboration to address epidemiological and clinical objectives related to the diagnosis of leishmaniasis. Additionally, another database was established through an international collaboration focused on developing diagnostic tools, which involved sharing patient data with data scientists and biologists.

In response to the need for standardized protocols in database design, a data-sharing platform was developed to serve as a model for future implementations. This platform has offered valuable insights and established key criteria for creating databases that are more shareable and interoperable.

To ensure the interoperability of patient data, the Ministry of Health aims to implement a unified EMR system that is linked to unique social identification numbers. This vision depends on the widespread adoption of the EMR across all public hospitals and basic health centers. However, achieving this goal presents challenges, including mobilizing the private sector and establishing seamless connections between disparate information systems within individual health facilities.

## 4. Data storage

### **Protect people**

Our focus in this section will be on data-storage practices, emphasizing the importance of implementing a secure storage mechanism that adheres to the strictest privacy protection standards, ensuring the integrity and security of data.

All of the establishments we surveyed use local servers for the storage of their data. In the case of the IPT, the cloud is used exclusively for collaborative purposes. In this context, data is anonymized and only stored with the approval of the national data protection authority. Moreover, access to the databases is restricted to those with specific profiles and roles within a given project.

The premises currently dedicated to storing and archiving paper-based medical records do not always have the necessary safeguards to adequately restrict access and ensure optimum security. The risks to which medical document storage systems may be exposed are epitomized by incidents such as the fire at the Habib Thameur University Hospital archives, that took place on November 15, 2022. The fire broke out at approximately 10 p.m. in the archives of the hospital, resulting in the destruction of a significant portion of the hospital's records. The cause of the fire remains undetermined, and an investigation was launched by the Tunis prosecutor's office to determine the circumstances surrounding the incident. Currently, there is no publicly available information regarding the presence of fire mitigation measures, such as sprinkler systems, within the archive area. The extent of the damage to the records and the potential impact on hospital operations have not been comprehensively reported.<sup>35</sup>

The present situation underscores the need to reassess and improve security measures in order to address the existing vulnerabilities. Further investigation into fire prevention infrastructure within hospital facilities may be necessary to assess risk mitigation strategies for similar incidents in the future.

### **Promote health value**

Depending on the degree of digitalization within the institution, two data storage systems may coexist. Firstly, there is manual archiving, which refers to the storage and management of medical records in paper format. Alternatively, establishments that have partially or fully implemented EMR may use local servers.

In the case of polyclinics, a backup data-storage facility has been in place since 2022. The purpose of this initiative is to ensure the security and continuity of their operations. Due to the sensitive nature of the data, and to further enhance its security, the storage facility is located in Tunisia. During the transitional period before the new patient file data-collection software is used across the board, hospitals will also use paper files, which are then digitized, as in polyclinics.

In light of this, the digitization of archives is not only urgent, but essential for all public health institutions. It is worth noting that polyclinics will soon be embarking on a project to digitize patient records.

<sup>35</sup> Tunisienerique. (2022, November 16). *Tunisia – Prosecution opens investigation into the fire of archives of Habib Thameur Hospital*. News Tunisia. Retrieved from <https://news-tunisia.tunisienerique.com/tunisia-prosecution-opens-investigation-into-the-fire-of-archives-of-habib-thameur-hospital>

Furthermore, the digitization of medical records is proving to be a complex task, which can be hampered by issues relating to the legibility and clarity of paper documents, a challenge highlighted by doctors interviewed at the oncology hospital.

By successfully implementing electronic storage methods, medical data can be protected and managed more efficiently, with access to information facilitated and healthcare costs reduced.

## **5. Data security**

### ***Protect people***

In line with the objective of protecting individuals, we will explore the critical matter of data security, shedding light on the adequacy of the practices noted in our survey. They appear to align with key measures such as the use of de-identification and anonymization techniques, compliance with best practices in data protection and confidentiality in data storage. Still, there is a need to implement robust technical measures to ensure secure data processing.

There are a number of contexts in which anonymization is crucial. In retrospective studies, it is carried out prior to the sharing of specifically selected data. In national screening campaigns, such as those for STDs, breast cancer, or diabetes, anonymization is carried out before the results are sent to the Ministry of Health. Anonymization is also essential in the context of collaboration among establishments that require data to be shared. During our interviews, it was noted that the use of the cloud is conditioned on data anonymization and mandatory authorization from the national data protection authority.

Nevertheless, certain types of research require additional information from patients, which may involve collecting their contact details to obtain the missing data. In such cases, the entity responsible for safeguarding patient data may act as an intermediary, requesting patient consent before providing researchers with their contact information. Additionally, healthcare professionals responsible for monitoring patients have access to identifying patient information but are bound by medical confidentiality obligations, ensuring that data sharing adheres to ethical and legal standards.

### ***Promote health value***

The majority of healthcare professionals interviewed do not appear to be fully aware of the importance of patient data or the benefits gained from a reliable and robust data ecosystem. Greater awareness must be raised among them of the importance of observing the nation-

al data protection authority recommendations and procedures regarding the protection of personal data in the healthcare sector.

Based on our interviews, particularly with doctors, data security often appears to be associated with respect for medical confidentiality. The ethical imperative is reflected in the firm restrictions placed on access to patient files, which is limited to healthcare professionals responsible for the patient's care and may only be granted if a medical act is required.

More specifically, healthcare professionals who use EMR note that access to the software is secured with login procedures and passwords, restricting use for each user profile.

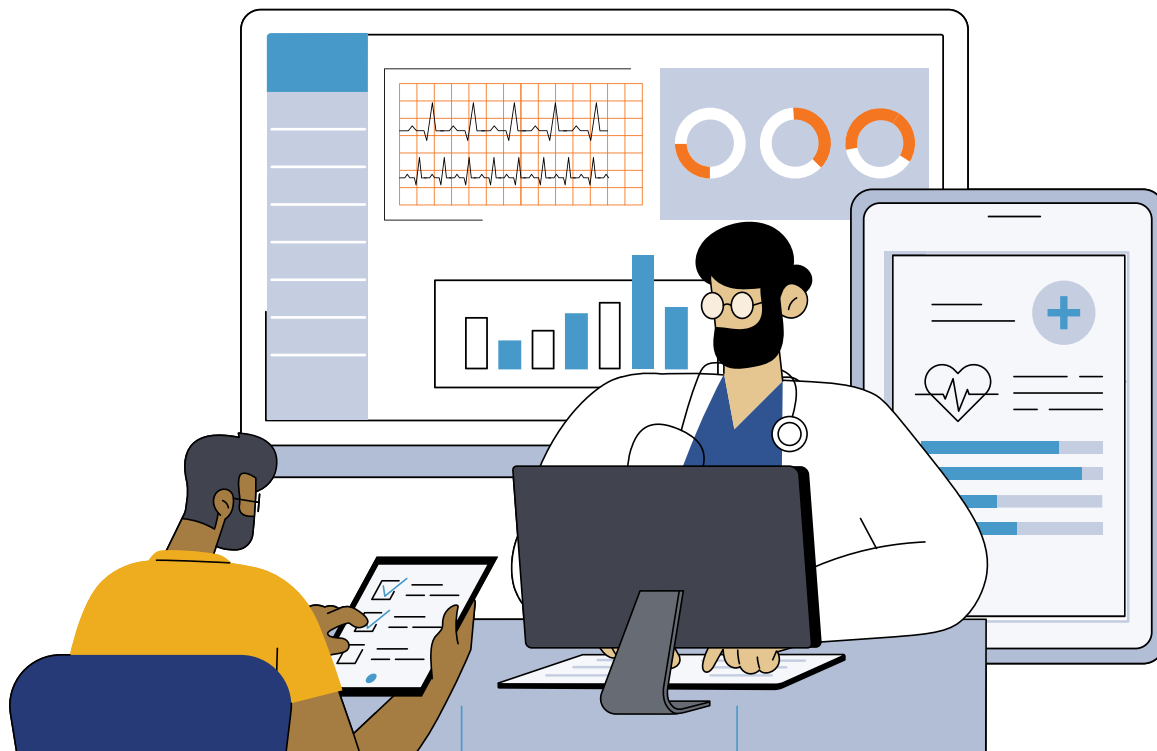
As a matter of fact, research projects requiring patient data generally employ an anonymization approach to maintain the confidentiality of patient information. It is imperative to ensure that datasets cannot be used to identify patients under any circumstances.

Furthermore, through the interviews conducted with various healthcare professionals regarding their perception of sensitive data, it is apparent that most do not distinguish between sensitive and non-sensitive data; they unanimously regard all data as confidential.

However, within the IPT, the sensitivity of the data is clearly and explicitly noted, given the intense data-processing activities carried out by the professionals interviewed. According to them, patient identification data, such as the national identity card number, exact address, passport number, first name, surname, and national insurance number are among the most sensitive because they permit direct identification of the patient. There is a strong understanding within the IPT of the need to protect this information rigorously due to the clarity surrounding the classification of this information.

When it comes to data governance regulations, most of the surveyed healthcare professionals underscore the importance of creating standards and guidelines that clearly outline best practices. Furthermore, they stress the importance of making various stakeholders in the healthcare sector aware of data protection concerns and the relevant directives issued by the competent authorities.

Nevertheless, many of those surveyed believe that it is not necessary to enact new laws in this regard at present, suggesting that the main focus be placed on improving the conditions that allow for better practices to take hold.



#### IV. ANALYSIS AND TAKEAWAYS: DATA CHALLENGES VERSUS OPPORTUNITIES

The electronic medical record (EMR) is intended to facilitate the coordination of care among healthcare professionals and to improve the traceability of treatments. The widespread implementation of this technology in all public health facilities is one of the key elements of the ambitious project to digitalize the health sector.

The widespread deployment of the EMR could be significantly delayed due to the difficulty involved in promptly and adequately meeting the technological infrastructure needs of all healthcare facilities. In addition, there is a major challenge in ensuring that all those involved, particularly doctors with heavy workloads, take ownership of this tool. For these practitioners, transition phases could be viewed as periods during which they have to invest both time and energy into updating their paper files and mastering the EMR. The dual task may be interpreted as a potential source of wasted time, which increases the risk of discouragement with respect to its adoption and optimal utilization.

In terms of the challenges associated with managing paper files, two major issues can be identified. There are security vulnerabilities and accessibility issues associated with the storage spaces currently in use. Moreover, digitization itself is proving to be a complex undertaking, due

to obstacles such as poor legibility and clarity of information in medical records.

In addressing the issue of patient data, it is important to consider the data produced by private entities. As institutions with substantial financial resources, they are distinct in their complete digitalization of all operations, including medical records. This approach optimizes the management of resources and the overall organization of the establishment. Although there are vast amounts of medical data generated in this process, private entities do not participate in research projects, limiting access to essential sources of information.

In an effort to centralize patient data and guarantee their interoperability, the government plans to introduce a single electronic medical record that corresponds to unique social identification numbers. The achievement of this objective has proven particularly challenging, given the difficulty in mobilizing the private sector and linking the various information systems used across all healthcare establishments.

Medical research and innovation projects face a number of significant challenges, such as data availability, accessibility, quality, and quantity. Among these difficulties, the unstructured nature of medical data, often manifested in shorthand text and inconsistent terminology usage by healthcare professionals, makes it difficult to manage. Data entry errors, which are inevitable, add to the complexity of data processing. To reduce the rate of errors and the rate of miss-

ing data, multiple verification methods must be implemented. Additionally, the integration of data from disparate systems may result in duplication and inconsistency.

Research projects, particularly those seeking to leverage AI, require the collection of thousands of datasets from patients to establish correlations and provide predictions. Unfortunately, there are a number of obstacles that must be overcome in order to meet this need, including a persistent reluctance around the sharing of medical data, even among healthcare professionals. This lack of cooperation significantly hinders the development of innovative research projects that have the potential to benefit the entire scientific community. A lack of knowledge regarding best practices for sharing data further exacerbates this situation.

The electronic medical record yields considerable advantages by providing a structured and harmonized system for the collection of all patient-related information, including diagnoses, treatment plans, and outcomes. By using structured data fields, vocabulary is standardized in accordance with current clinical terminology standards, thereby reducing spelling and notation errors. Furthermore, optimizations in EMR systems enable automatic checks and alerts to be generated when contradictory information is detected, thereby improving data integrity. It is expected that the use of this tool will improve the consistency and shared understanding of medical information, thus contributing to an overall improvement in the quality of healthcare data management.

In addition, the development of innovative initiatives based on image processing for analysis and diagnosis, such as the detection of melanoma, have already demonstrated impressive success. Due to the availability of such types of data, AI systems that are primarily focused on image analysis can be deployed more easily. A concrete example of this innovative approach is the InnoDeep initiative, which successfully combines teleradiology and AI. This initiative, which was adopted by public health institutions during the COVID-19 pandemic, is also dedicated to adapting its tool to aid in the early detection of breast cancer.

In terms of collaboration and data sharing, several research projects have been launched, creating collaborative platforms for data sharing to facilitate collaboration between multiple partners. Through such platforms, various stakeholders are able to collaborate securely and efficiently while ensuring the integrity and security of the data being shared.

These initiatives do, however, encounter challenges, such as attracting and retaining qualified medical and technical personnel. As part of the digital transformation of the public health sector, more data managers and data scientists need to be recruited. In fact, there is a great number of qualified professionals who are turning to career opportunities abroad, attracted by more favorable working conditions and higher salaries.

Medical knowledge is rapidly evolving, highlighting the essential role of AI as a tool to increase efficiency, automate cognitive work, free up time for value-added tasks, and improve predictive capabilities for decision-making. With its capacity to process massive streams of data, AI can play a crucial role in the study and treatment of rare diseases, reducing bias and enabling a shift toward personalized and predictive medicine.

## V. POLICY RECOMMENDATIONS

### *Strengthening the ongoing process of digitizing patient records*

In view of the central role played by the EMR in modernizing the healthcare sector, and given the budgetary constraints affecting working conditions in public healthcare establishments, several actions can be considered to support the widespread adoption of the EMR.

Ideally, each hospital management team should produce an annual evaluation of current data practices, identifying obstacles to the implementation, adoption, and optimal use of the EMR, with the goal of developing urgent action plans for improvement.

Additionally, detailed rules and procedures for managing medical records and patient data should be developed and unified across the different facilities. These rules should be approved by all stakeholders, taking into account the unique constraints of their environment. This approach aims to gain the full support of medical staff, particularly physicians, and actively involve them in the adoption of this vital tool while adhering to a policy of protecting personal data.

Furthermore, public hospitals should establish a dedicated data governance department to monitor these matters.

### *Enhancing the skills of healthcare professionals*

With the increasing demand for skills around the use of digital technologies, it is essential to

develop educational programs tailored to the diverse profiles of professionals working within the patient-data ecosystem. Firstly, there is a need to design specific training courses for existing personnel. Additionally, it is worthwhile to incorporate one or more mandatory modules addressing both theoretical and practical aspects within university curricula aimed at future healthcare professionals.

Along with fostering a digital culture, staff must also be trained in regulatory compliance regarding sensitive data. As an example, conducting awareness-raising sessions is recommended to inform healthcare professionals about the health-data guidelines set by the National Authority for Protection of Personal Data.

### ***Establishing a dedicated health data institution for research and innovation***

The establishment of an institution dedicated to healthcare data would contribute to the advancement of healthcare research and innovation. Specifically, this entity should be responsible for overseeing and facilitating the sharing of data from various medical information systems, including those linked to the EMR, as well as data collected for research purposes, such as through specialized registries or patient surveys. One objective of the initiative would be to organize and promote the creation of a platform for the collaborative sharing of data from multiple sources.

The data would be standardized to enable reuse for monitoring, research, or healthcare purposes while adhering to ethical and regulatory imperatives. With this initiative, AI would receive a substantial boost in the healthcare sector. This institution would be open to anyone interested in undertaking a study, research, or evaluation in the field of healthcare in the public interest.

### ***Adherence to best practices and ethical considerations in healthcare data governance***

Detailed guides on appropriate health data governance practices should be developed and tailored to the type of data and sector of activity, covering aspects such as collection, processing, sharing, and storage, taking into account the particularities of each type of data (economic, clinical, biological, demographic, etc.) and each sector of activity (insurance, hospitals, public and private laboratories, private companies providing analytical services and technological innovations). This approach ensures strict compliance with current standards and health data governance principles while clarifying the imple-

mentation of specific procedures tailored to the unique nature and activities of each entity.

There is also a need to initiate a debate in Tunisia and conduct a national reflection based on international initiatives relating to ethical and regulatory aspects of AI in healthcare. These should be adapted to the Tunisian context. The objective is to contribute to the development and implementation of appropriate policy and regulatory frameworks for the responsible use of AI and big data in healthcare, in order to realize the benefits promised by these technologies.

Data analysis in healthcare, via AI in particular, has the potential to transform the sector in significant ways. However, to achieve these benefits equitably and ethically, proactive collaboration between policy makers, researchers, civil society groups, and industry is essential. In fact, one measure that could be taken to address the problems of bias associated with data and algorithms is to create a dedicated ethics committee. The committee would be responsible for resolving ethical issues related to AI, including the quality of data used in AI processes. Among the committee's responsibilities would be the development of government recommendations designed to identify and minimize the potential harms associated with these biases.

## **CONCLUSION**

The purpose of our study was to shed light on existing practices regarding patient data, taking into account the progress made in the deployment of the electronic medical record and the challenges to be addressed in order to establish a data ecosystem conducive to research and innovation and favorable to the adoption and application of AI.

Guided by the World Bank's Health Data Governance Principles, we evaluated the degree of convergence between these principles and patient-data practices in Tunisia. Several aspects of data collection, processing, sharing, storage, and security were examined. To gain these insights, we sought to survey the experience and perspective of a variety of professionals working in various healthcare establishments. Although our sample size was limited, employing this methodology allowed us to collect information that significantly enriched our study.

The Tunisian national digital health strategy recognizes the development of an electronic medical record as a key priority. This initiative has proven to be a valuable tool for facilitating patient-data collection and access more effectively and comprehensively, as well as simplifying co-

ordination among healthcare professionals and ensuring continuity of care between providers. These features contribute to healthcare facilities' improvement, making the electronic medical record a vital component of healthcare systems.

Nevertheless, the ultimate function of an electronic medical record, and the most challenging, is patient-data interoperability. This will enable access to a larger and more diverse range of datasets, overcoming the challenge of utilizing fragmented data from multiple sources. It will result in a valuable, structured database. It may, however, prove challenging to integrate diverse information systems, potentially delaying the attainment of interoperability.

Utilizing this unified system to its full potential will facilitate the creation of a data ecosystem that will contribute to the development of a collaborative approach, thereby reducing medical overconsumption and improving healthcare policy evaluation. Furthermore, the expanded datasets will provide valuable resources for the development of AI algorithms geared toward research and innovation, enabling rapid and in-depth data analysis and improving healthcare services.

The development and deployment of these technologies will, however, raise significant ethical, legal, and organizational concerns. Therefore, Tunisia should develop appropriate regulatory strategies to ensure the responsible use and governance of its data. It should also develop an environment conducive to the adoption and integration of AI in healthcare.

## LIMITATIONS

Our study has the following limitations:

- The small size of our sample resulted from the challenges encountered in obtaining sufficient responses within the study's specified time constraints.
- It would have been beneficial to enrich our study by conducting more interviews with various stakeholders involved in patient data governance. This would have provided a more comprehensive perspective.
- An avenue for improvement could involve conducting in-depth analyses using a reference institution for each type of healthcare facility, as well as for each level of digitalization. These analyses would lead to a better understanding of patient data governance practices and the specific challenges faced by each type of facility.

## APPENDIX

### Interview questions and their corresponding health data governance principles

HEALTH DATA GOVERNANCE PRINCIPLES BY WORLD BANK 2022		DATA COLLECTION	
HEALTH DATA GOVERNANCE PRINCIPLES		AIM AND OBJECTIVES QUESTIONS	QUESTIONS
P.1. Protect People	P.1.1 Protect Individuals & Communities	Collect data with defined purposes.	What types of clinical data do you collect during the interview? (e.g., medical history, medications, disease history, symptoms, previous examinations, allergies, clinical signs such as blood pressure, temperature, weight).
			What types of data is recorded on paper and what types are recorded on a computerized tool? (Administrative data, interview data, allergies, medical history, etc.).
		Collect personal/sensitive data with informed consent.	In the case of research studies, how do you obtain patient consent when collecting personal health data?
		Secured data collection mechanism: Data collection methods with robust data collection functionality.	What administrative data do you collect: consultation date, admission and discharge date, identity, registration number, date of birth, gender, address, social coverage and healthcare plan, chronic illness, disability, other.
	Are the paper-based data digitized afterward? If YES, for what purposes? (1. Administrative 2. Care and follow-up 3. Research and studies, e.g., theses, projects, registries).		
	P.1.2 Build Trust in Data Systems	Inclusive data collection mechanisms.	During repeated visits, do you rely on existing data or conduct the interview and clinical examination each time?
			Do you complement existing patient data from other sources? (e.g., do doctors outside your facility, other departments, archives, laboratories, radiology centers, etc.).
		Ensure consent is informed.	In the case of remote methods, how do you obtain patient consent when collecting personal health data?

		High-quality & accurate data collection processes.	What practices are implemented to improve data quality? // In your opinion, what is the best way to address these challenges?
			What improvements could be made in regulations to address digitization challenges?
			What problems have you identified? (1. Collection issues (e.g., incomplete data) 2. Incorrect filing and error rates 3. Human resources/skills 4. Other).
	P.1.3 Ensure Data Security	Ensure data security in data collection practices.	
P.2. Promote Health Value	P.2.1 Enhance Health Systems Services	Increase community engagement during data collection.	What problems have you identified? (1. Collection issues (e.g., incomplete data) 2. Incorrect filing and error rates 3. Human resources/skills 4. Other).
		Empower frontline health workers: Continual skill development.	
	P.2.2 Promote Data Sharing & Interoperability	Use previously collected data to reduce the need for new data collection.	During repeated visits, do you rely on existing data or conduct the interview and clinical examination each time?
			Do you complement existing patient data from other sources? (e.g. doctors outside your facility, other departments, archives, laboratories, radiology centers, etc.
			Patient data can be shared with 1/Other doctors 2/PhD students and researchers 3/Regional health authorities 4/Ministry of Health 5/Other. // For what purpose: 1/Care 2/Research and studies.
		Data collection systems to be designed for integration.	
		Define common data structures (e.g specific fields for data collection)	
	P.2.3 Facilitate Innovation using Health Data	New types of policies are needed for innovative collection of health data.	What constraints do you face when integrating different databases between professionals, institutions, and old/new databases on different datasets?
			In your opinion, does the government's initiative of digitizing data have an impact on data collection? (1. If YES, how?).

P.3. Prioritise Equity	P.3.1 Promote Equitable Benefits from Health Data	Inclusive data collection methodologies that	What administrative data do you collect? (e.g., consultation date, admission and discharge date, identity, registration number, date of birth, gender, address, social coverage, and healthcare plan, chronic illness, disability, other).
		Cross-cutting data collection methodologies that include gender, sex, age, socio-economic status, abilities, citizenship status, class, race, and ethnicity.	
		Mitigate data bias in health data collection.	
	P.3.2 Establish Data Rights & Ownerships	Develop health data trusts and health data cooperatives to define rules of data collection.	

HEALTH DATA GOVERNANCE PRINCIPLES BY WORLD BANK 2022		DATA PROCESSING	
HEALTH DATA GOVERNANCE PRINCIPLES		AIM AND OBJECTIVES QUESTIONS	QUESTIONS
P.1. Protect People	P.1.3 Ensure Data Security	Strong technical security measures for data processing (e.g., data security audits). Consider federated data processing across the system.	What practices are implemented to improve data quality? If, in your opinion, what is the best way to address these challenges?
		Consider federated data processing across	
P.2. Promote Health Value	P.2.3 Facilitate Innovation using Health Data	New types of policies are needed for innovative processing of health data.	Do you use technologies/software to process the data? If yes, which ones?
			Do you have a data analyst or similar role in your team?
			Are you trying to adopt artificial intelligence (AI) and machine learning (ML) technologies?
			How can these technologies specifically help (e.g., value in innovative data processing)?
			What is the biggest challenge facing the use of AI in the healthcare field, given the state of available datasets?

			In your opinion, what are the needs of the healthcare data ecosystem for the adoption of AI?
			What improvements could be made in regulations to address digitization challenges?
P.3. Prioritize Equity	P.3.1 Promote Equitable Benefits from Health Data	Mitigate data bias in health data processing.	
	P.3.2 Establish Data Rights & Ownerships	Develop health data trusts and health data cooperatives to define rules of data processing.	

HEALTH DATA GOVERNANCE PRINCIPLES BY WORLD BANK 2022			DATA SHARING
HEALTH DATA GOVERNANCE PRINCIPLES	AIM AND OBJECTIVES QUESTIONS	QUESTIONS	
P.1. Protect People	P.1.2 Build Trust in Data Systems	Data subjects may accept or decline further sharing of their data for purposes other than its initial intended use.	Is there a person/role responsible in your organization for defining data sharing rules?
	P.1.3 Ensure Data Security	Consider federated data systems across the health system for cross-system sharing and learning.	Are there multiple levels of data access (e.g., based on professional category, department, or management)? Do you complement existing patient data from other sources? (e.g. doctors outside your facility, other departments, archives, laboratories, radiology centers, etc.)
P.2. Promote Health Value	P.2.1 Enhance Health Systems Services	Enhance data sharing between health facilities and health providers for improved health services.	Do you complement existing patient data from other sources? (e.g. doctors outside your facility, other departments, archives, laboratories, radiology centers, etc.)
			Is patient data shared with: 1) Other doctors 2) PhD students and researchers 3) Regional health authorities health authorities 4) Ministry of health 5) Other

	P.2.2 Promote Data Sharing & Interoperability	Establish data sharing rules and guidelines.	Are your data sharing practices influenced by external factors (e.g. regulatory issues)?
			What are the problems related to data sharing in your organization?
			How do you think/suggest overcoming these challenges?
			What improvements could be made in regulations to address digitization challenges?
			Is there a person/entity to whom the request for necessary data for research/analysis should be addressed? Who?
		Validate informed consent before sharing data.	How is the request for data sharing made? 1) Oral 2) Written
		Promote interoperability (through recognized standards, e.g. basic data fields and open system design) of data systems for simpler and more secure data sharing between systems (especially during manual data transfers).	Do you consider specific standards when constructing databases to facilitate their sharing?
		Define common data structures (underlying architecture of data systems) across health systems to support data sharing	
		Define multiple levels of data access to minimise the risk of exposure with maximising sharing	Are there multiple levels of data access (e.g., based on professional category, department, or management)?
Use common definitions and global standards.	Who has access to raw data, items of individuals, and entities?		
	Support multi-sector partnerships.		
P.3. Prioritize Equity	P.3.2 Establish Data Rights & Ownerships	Develop health data trusts and health data cooperatives to define rules of data sharing.	

HEALTH DATA GOVERNANCE PRINCIPLES BY WORLD BANK 2022			DATA SECURITY
HEALTH DATA GOVERNANCE PRINCIPLES		AIM AND OBJECTIVES QUESTIONS	QUESTIONS
P.1. Protect People	P.1.1 Protect Individuals & Communities	Use secure data storage mechanisms (e.g., encryption, cloud servers).	Is the anonymization of the patient's profile done during a data-sharing request?
			What security standards are applied to data storage and extraction?
			Do you have a data manager or similar function?
	P.1.2 Build Trust in Data Systems	Align with best data protection and privacy practices for storage of data (e.g., two-factor authentication, encryption, de-identification).	How do you secure patient data during collection, processing, and sharing?
	P.1.3 Ensure Data Security	Require strong technical security measures for data processing (e.g., data security audits).  Mitigate risks related to security threats. Enhance data security through federated data.  Apply a human rights lens to health data governance (both traditional rights, e.g., security, health, and new rights associated with data, e.g., privacy).	Are you trained and informed about the modalities of personal data protection in the healthcare sector as established by the national authority for personal data protection? (Yes/No)
			What data do you consider sensitive?
Is there a person/entity to whom the request for necessary data for research/analysis should be addressed? Who?			

HEALTH DATA GOVERNANCE PRINCIPLES BY WORLD BANK 2022			DATA STORAGE
HEALTH DATA GOVERNANCE PRINCIPLES		AIM AND OBJECTIVES QUESTIONS	QUESTIONS
P.1. Protect People	P.1.1 Protect Individuals & Communities	Use secure data storage mechanisms (e.g., encryption, cloud servers).	How do you store your data? (local or cloud)?
			What security standards are applied to data storage and extraction?
			Who has access to raw data, items of individuals and entities?

	P.1.2 Build Trust in Data Systems	Align with best data protection and privacy practices for storage of data (e.g., two-factor authentication, encryption, de-identification).	How do you secure patient data during collection, processing, and sharing?
	P.1.3 Ensure Data Security	Mitigate risks related to security threats through data storage guidelines for confidential data.	
		Consider federated data systems (federated storage) across the health system.	
P.2. Promote Health Value	P.2.2 Promote Data Sharing & Interoperability	Support multi-sector partnerships.	
P.3. Prioritize Equity	P.3.2 Establish Data Rights & Ownerships	Develop health data trusts and health data cooperatives to define rules of data storage.	



MENA OBSERVATORY  
ON RESPONSIBLE AI  
مركز الشرق الأوسط وشمال أفريقيا للذكاء الاصطناعي المسؤول

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