Digital Health Uptake

Project acronym: DigitalHealthUptake
Grant Agreement Number: 101083929
Project full title: Uptake of Digital Solutions in Health and Care
Website: digitalhealthuptake.eu

Romania-Turkiye Regulatory Comparison in the Frame of Interoperability

Smart Hospital

Funded by the European Union

EKSPOTURK

Digital Innovation Zone

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1. Introduction

This informational document has been developed for the Smart Hospital Project, funded under the Digital Health Uptake, Call for Twinnings within the Digital Europe Program. The twinning initiative involves two principal entities: Smart Hospital by Ekspoturk, representing Turkiye as the originator, and Digital Innovation Zone, representing Romania as the adopter. Beyond geographical proximity, both parties share cultural practices, facilitating the planned transfer of knowledge and experience to enhance regional prosperity.

The Smart Hospital Project aims to address challenges related to interoperability within the digitalization processes of healthcare systems. It seeks to convene stakeholders to explore emerging technologies, exchange insights, transfer expertise, and provide interconnected feedback.

A foundational understanding of the regulatory landscapes of both countries is anticipated to provide healthcare stakeholders with essential background knowledge. The subsequent sections of this document will delve into the regulatory frameworks of each party, detailing their current status and implementation processes. The final segment will analyze these regulations, facilitating a comparative assessment between Türkiye and Romania.

2.
Brief Evaluations of Regulations of Twinning Parts' Authoritative Administrative Units Regarding Interoperable Health Systems

In the evolving landscape of healthcare technology, interoperability plays a crucial role in ensuring seamless communication and functionality across diverse medical devices and systems. This comparative analysis explores the approaches of Romania and Turkiye towards interoperability within their respective healthcare frameworks. Romania, aligning with EU directives, emphasizes stringent regulatory frameworks and the establishment of a National Interoperability Platform to enhance data exchange and streamline administrative processes. In contrast, Turkiye focuses on digital transformation initiatives and integrated healthcare portals to facilitate secure access to health data, showcasing distinct yet complementary efforts in advancing interoperability standards. This analysis delves into the regulatory landscapes of both nations to highlight their strategies in fostering effective interoperability within healthcare systems.

2.1. A Brief Evaluation of Romanian MDR Regarding the Interoperability

Medical Device Regulation (MDR)

2.1.1. How it is Emphasized:

In Romania, as in other EU countries, the emphasis on interoperability under the MDR is significant due to the growing need for medical devices to work seamlessly across various healthcare systems and platforms. The MDR stresses interoperability to ensure that devices can communicate and function effectively within the broader digital infrastructure of healthcare systems. This is crucial for enhancing patient safety, device effectiveness, and facilitating innovation in medical technology.

2.1.2. How it is Defined

Interoperability within the context of the MDR, generally refers to the ability of different medical devices, software, and health systems to exchange and make use of information efficiently and accurately. This includes both technical and semantic interoperability:

Technical interoperability involves the hardware and software components, systems, and platforms that enable devices to connect and operate.

Semantic interoperability ensures that the information exchanged between systems is understandable and retains its meaning across various platforms.

2.1.3. Government Promotion

The Romanian government, along with the European Union, promotes the interoperability of medical devices through several mechanisms:

Regulatory Frameworks: Implementing the EU's MDR guidelines, which include specific requirements for the design and manufacture of medical devices to ensure they meet interoperability standards.

Funding and Grants: Providing financial support for research and development projects that focus on the innovation of interoperable medical devices.

Collaboration with Technology Companies: Encouraging partnerships between healthcare providers and tech companies to develop solutions that enhance the interoperability of medical devices.

Educational and Training Programs: Offering training for manufacturers and healthcare providers on the importance of interoperability and how to implement it effectively.

*Information translated from official ADR website

Interoperability is the foundation of Romania's digital infrastructure and the cornerstone of public administration at the European level.

On June 9, the Romanian Parliament adopted Law 242/2022 on the exchange of data between information systems and the creation of the National Interoperability Platform, and the legal act was published in the Official Gazette on July 20, 2022.

The law regulates the adoption of measures regarding technologies, equipment, software programs, and the data used by them to contribute to increasing the degree of interconnection between the information systems of authorities and public institutions and to facilitate data exchange between them, based on the principles and objectives of the European Interoperability Framework.

The legal act applies equally to public institutions from both central and local administration, so that,

together, the integrated architecture of digital services and the legislative framework so necessary for regulating data exchange between information systems ensure that public services are centered around the citizen as the end user.

The law provides for the creation of the national interoperability platform, which will be implemented based on the implementation norms that the referred entities will use for connecting and integrating public services at the national level.

Increasing the degree of interconnection of the information systems of institutions and public authorities, facilitating the exchange of data between public institutions, and simplifying administrative processes will lead to increased effectiveness of the administrative act, by implementing the "only once" principle.

The interoperability law aims to improve the quality of public services by facilitating the exchange of data between information systems, reducing the bureaucratic and administrative burdens of individuals and legal entities, and increasing the transparency of data use by authorities and public institutions.

The law assigns the regulatory function in the field of implementing the National Interoperability Platform to the Ministry of Research, Innovation, and Digitization (MCID), while the monitoring, control, and evaluation function belongs to the Authority for the Digitalization of Romania.

According to Article 11 of the Interoperability Law:

(1) Authorities and public institutions are required to use the National Interoperability Platform for accessing data contained in the registers managed by other authorities and public institutions, necessary for providing public services.

(2) Authorities and public institutions are required to provide services without requesting additional documents containing exclusively information available through the National Interoperability Platform or for the purpose of obtaining data that can be provided through the National Interoperability Platform.

(3) Authorities and public institutions providing public services do not have the right to request individuals and legal entities for proofs or certifications of data already collected or created by the respective authorities and institutions. The data used in providing public services must be taken exclusively from the basic registers available through the National Interoperability Platform.

(6) Authorities and public institutions are required to change their work procedures, respectively to propose changes regarding current legislation, to provide public services under their responsibility, exclusively based on data that can be obtained through the National Interoperability Platform.

Increasing the degree of interconnection of the information systems of institutions and public authorities, facilitating the exchange of data between public institutions, and simplifying administrative processes will lead to increased efficiency and effectiveness of the administrative act by implementing the "only once" principle.

The interoperability law aims to improve the quality of public services by facilitating the exchange of data between information systems, reducing the bureaucratic and administrative burdens of individuals and legal entities, and increasing the transparency of data use by authorities and public institutions.

According to Article 17 of the Interoperability Law:

(1), lit. b) central and local public authorities and institutions that hold a basic register are required to integrate with the National Interoperability Platform within 18 months from the platform's operation and to provide access to this data through the National Interoperability Platform;

(1), lit. c) within 5 years from the date of entry into force of this law, public authorities and institutions will provide public services also electronically, through their own portals, when this is possible

(2) From the date of implementation of the National Interoperability Platform, public authorities and institutions will no longer have the right to request from private individuals or legal entities information that can be obtained through querying the National Interoperability Platform.

According to Article 18 of the Interoperability Law:

(1) All private legal entities that provide services or IT solutions to public authorities and institutions are required within 90 days from the entry into force of this law to continuously provide access to their beneficiaries and authorized providers, through standardized REST API software communication interfaces and the corresponding documentation for their use, to the databases used by the applications managed by them.

(2) Legal entities mentioned in paragraph (1) are required to connect their information systems managed on behalf of or for public authorities and institutions to the National Interoperability Platform.

2.2. A Brief Evaluation of Turkish MDR Regarding the Interoperability

The term interoperability (birlikte çalışabilirlik) has had almost 20 years of recognition in the Turkish public policy agenda. Even though the first step was taken in 2005, the most recent general interoperability information can be derived from the Turkish Interoperability Principles Guide (2012, Former Ministry of Development). This guide provides a framework for institutions and defines ten standards for public institutions to model their fields of interoperable systems.

These standards are: Alignment with European Commission studies, Use of the internet and WWW as the main communication mechanism, Right to equal access, Security, Protection of personal data, Use of open standards and international standards, Use of common standards to ensure semantic integrity, Scalability, Preservation of information over time, and Principle of participation.

As the Turkish administrative system changed in 2018, some authorities were nullified, such as the Ministry of Development and the Ministry of European Union, and their responsibilities were transferred to other institutions such as the Presidency of Strategy and Budget and the Ministry of Foreign Affairs' General Directorate of Relations with the European Union. Additionally, the regulatory process changed due to institutional changes, requiring the MoH to build relationships and cooperate with other institutions. Therefore, there are multiple sources of information for the interoperability processes of the healthcare system.

As the Turkish Ministry of Health is the main and only authority to form and implement regulations regarding medical devices and healthcare technologies, this report will follow the announcements, statutes, regulations, and circular letters of the MoH's related institutions: Turkish Medicines and Medical Devices Agency, General Directorate of Health Information Systems, and the Presidency of Strategy and Budget. Even though the word interoperability (birlikte çalışabilirlik) is not commonly used in texts, there are many clues implying the policies regarding it.

It should be noted that the Turkish administrative system's digital transformation started with the 10/08/2006 Circular Letter of Establishment, Operation, and Management of the e-Government Gateway by the Prime Ministry. The healthcare system gateways connected to the e-Government are MHRS (Central Physician Appointment System) and e-Pulse (e-Nabız). The MHRS e-portal was opened in 2013, enabling citizens to get appointments from 81 cities.

The regulation on Personal Health Data dated 21.06.2019 mentions e-Nabız as a system established by the Ministry of Health that allows individuals, their physicians, or authorized third parties to access their health data. Here are the key points regarding e-Nabız:

Access to Health Data: Individuals with an e-Nabız account can access their health data according to their privacy preferences. They can also set these preferences and are informed in detail about the implications of their privacy settings.

Health Data by Healthcare Professionals: For those without an e-Nabız account, healthcare professionals can access their health data under specific conditions, such as:

Family physicians can access data without time limitations.

Physicians who have an appointment with the patient can access the data on the day of the appointment and during the related healthcare process.

Physicians at the healthcare facility where the patient is admitted can access the data for 24 hours.

Physicians at the healthcare facility where the patient is hospitalized can access the data until the patient is discharged.

Privacy and Security: The system allows individuals to set privacy preferences to prevent unauthorized access to their past health data. If someone does not want their past health data to be accessed by anyone, this can be specified in their e-Nabız settings.

Consultation Feature: The system facilitates consultations by enabling radiologists to access radiological images from authorized healthcare facilities and share these images for second opinions or consultations with other radiologists through live consultations.

In June 2019, the Ministry of Health announced that the telehealth system was integrated into interoperability standards. The Picture Archiving and Communication Systems (PACS) have been integrated into 1,855 healthcare facilities, allowing nationwide access to medical images and reports via central software. This integration enables citizens to view their medical records through e-Nabız accounts and allows healthcare providers to access patient records, including images from other facilities. As of July 2019, the system contains 184 million radiological images and 80 million reports. Radiologists can access and report images remotely and seek second opinions through live consultations.

The system has achieved international certification for interoperability, passing tests in the “Information Technology and Radiology” frameworks at the IHE Connectathon. This recognition highlights its ability to work seamlessly with other systems. Additionally, a duplicate examination prevention service was

implemented nationwide from April 1, 2019, reducing unnecessary tests and radiation exposure while saving time and costs for patients. This service has improved access to previous medical images and reports for both patients and healthcare providers.

As mentioned in the 2019-2023 Development Plan:

585. Data of quality and detail that can be used as input for data and evidence-based policy-making, suitable for use in scientific research and analyses, and enabling international comparisons will be produced.

585.1. Health data sets will be restructured, data quality will be increased, and an infrastructure that allows for international comparison will be established.

585.2. Cooperation and coordination regarding data sharing between institutions will be improved.

The next development plan, which covers the time this report is written, expands the focus on interoperability. In the 2024-2028 Development Plan:

716. Data and evidence-based policy-making will be facilitated by the production of quality and detailed data that is suitable for use in scientific research and analyses, accessible, and enables international comparisons.

716.1. Detailed and high-quality data production will be ensured for international comparisons, standardization processes of health data will be conducted in accordance with national/international norms, data quality and reliability will be increased, and the cybersecurity of health data will be strengthened.

716.2. Cooperation and coordination for data sharing between institutions will be improved.

716.3. By anonymizing health data, the legal and administrative infrastructure necessary for its secondary use, particularly for R&D, and its transformation into economic value will be established.

The current regulation implemented gives two definitions for Data Standards and Integration, Imaging, Data Model, Data Delivery and Transfer, and Data Backup and Archiving:

Article 4:

t) MDM (Minimum Data Model): Developed by the General Directorate to ensure compliance of

tables and fields of data held in local databases by healthcare providers with national standards, to minimize data loss, to facilitate adaptation, to ease access to citizens' past data, and to ensure the seamless progress of the process. It is used by HIMS (Health Information Management System) service recipients during SBYS changes and other data transfer processes.

u) MDM View: The view of the Minimum Data Model prepared and updated by the HIMS service provider in accordance with the MDM, defining the minimum content of the HIMS.

Article 12:

(2) HIMSs comply with the integration-compatible devices and systems of healthcare providers and other systems developed by the Ministry.

In the fourth section, covering Standards and Integration, Imaging, Data Model, Data Delivery and Transfer, Data Backup, and Archiving, Article 12 specifies that the standards and guidelines for data transmission, as determined by the General Directorate, are published and updated on their website. HIMS must be compatible with healthcare providers' integration-capable devices and other systems developed by the Ministry. Integration details are defined in procurement documents, and integration costs are regulated. HIMS providers must follow set guidelines to ensure no disruption in healthcare services, and they must comply with access rules to healthcare provider devices and Ministry data centers. Article 13 mandates the use of DICOM worklists in PACS systems for accurate patient imaging, requires new addendums for changes to approved reports, and enforces integration with the Telemedicine System.

Article 14 focuses on the data model, delivery, and transfer, requiring adherence to the MDM Guide for creating MDM views and ensuring data consistency. SBYS providers must audit MDM views and facilitate data transfer between systems. PACS images must be delivered in original formats, and historical data must be accessible for transfers. Technical Competence Tests for data transfer proficiency are required, with successful providers receiving certification. Article 15 mandates regular backups of databases, including MDM views, with secure storage and regular restoration tests. The fifth section addresses Confidentiality, Audit Logs, Audits, and Enforcement. Article 16 ensures compliance with personal data protection regulations, with secure data storage. Article 17 requires audit logs maintenance, and Article 18 grants audit authority to the Ministry. Article 19 outlines sanctions for regulatory breaches.

3. Results

Legal Frameworks: Romania's approach is explicitly guided by EU regulations (MDR), influencing its interoperability laws directly.On the other hand, Turkiye's regulatory framework focuses on digital infrastructure development and data security within healthcare systems, indirectly supporting interoperability goals.

Government Initiatives: Both countries emphasize the importance of interoperability through legal and infrastructural developments. Romania's establishment of a National Interoperability Platform is a notable step towards unified data access across public services. Turkiye's approach focuses on integrating existing systems and improving data accessibility through national portals.

Technical Implementation: Romania's emphasis on technical and semantic interoperability aligns closely with EU directives, ensuring comprehensive device compatibility and data exchange. Turkiye's efforts are more decentralized but demonstrate significant achievements in healthcare data integration and accessibility.

In summary, while both countries prioritize interoperability within their healthcare systems, Romania's approach is more structured around EU directives and explicit legal frameworks, whereas Turkiyeemphasizes digital integration and access through national healthcare portals and infrastructure development.


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