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Digital Health and Real-World Data in Greece:

The transformation of the health ecosystem and the structural effects on the economy

Executive Summary

The increasing use of Information and Communication Technologies (ICTs) alongside the introduction of novel digital devices, applications, and platforms, have paved the way for the digital transformation of the health ecosystem, and are bound to disrupt the means by which healthcare services are provided to individuals. This digital transition will revolutionize the entire healthcare system with significant benefits to the society and the scientific and research community. At the core of this process is the proper utilization of real-world data (RWD), which is a common practice in multiple countries around the world, but is still at very early stages in Greece. This process is evolving alongside the relevant technological advancements and the systematic collection and digitization of large quantities of health-related data and is expected to have a horizontal impact in the digital transformation of modern healthcare systems.

While Real-world data (RWD) is in fact a subset falling under the umbrella term of Big Data, they have significant conceptual and operational differences. These mainly relate to their structured form, as they include specific data-models with corresponding coding standards, which are stored in tailor-made RWD repositories. Their main goal is to verify the safety and effectiveness of various treatment methods, and novel pharmaceutical and medical products, providing different and more generalizable results than those that stem from Randomized Clinical Trials (RCTs). In addition, they can provide robust documentation of a patient's actual treatment during hospitalization, diverse data-driven documentation of multiple treatments/diseases simultaneously, and they can aid in updating and optimizing clinical standards and critical information. This documentation supports medical practice and covers diverse groups of individuals, that may not be covered by the strict participation criteria usually present in RCTs.

Another potential source of RWD is the healthcare business sector that provides patient, prescription and hospitalization data from various clinical registries, insurance carriers and

public/private healthcare institutions. These types of data can be collected on-site, at the same time with the medical case-study at hand or retrospectively from experimental studies or general clinical observations. Additional sources include electronic health records, databases from pharmacies, patient-based research networks and databases or even social-media platforms and healthcare smartphone applications.

However, RWD is not the only source of digital information in the healthcare sector. Another equally important source is real-world evidence (RWE), which derive from the appropriate scientific processing of RWD. RWE also include strict data validation and standardization procedures that facilitate their utilization as proper research evidence regarding the potential benefits and risks of a medical/healthcare product.

The profound contribution of RWD and RWE to medical science and clinical practice is interrelated with their unprecedented size and reach, as they unlock a vast range of possible applications that were previously unexplored due to various limitations. From the recording of large datasets to the validation of complex bioindicators and the feasibility study of a clinical trials, RWD and RWE applications are constantly expanding in different subjects, including clinical trial design, pharmaceutical products and healthcare services safety and quality control, epidemiological research, disease classification, quantitative applications in medicine science (such as Quantitative Systems Pharmacology - QSP), precision medicine, social network analysis, cybersecurity and digital governance, and of course as a quantitative tool to support regulatory interventions and frameworks.

The various benefits linked with the utilization and applications of RWD and RWE have brought them in the spotlight of different digital health national agendas worldwide. After all, digital health and RWD/RWE are critically intertwined, as radical technological innovations in the health sector have a significant impact in several stages of the RWD and RWE value chain. On the other hand, increasing use of health-related digital data further stimulates the ongoing digital transformation of the overall healthcare ecosystem.

However, their merits are also accompanied by several challenges that mostly relate with interoperability problems between different data sources and repositories. Another critical set of challenges relates with confidentiality and privacy issues regarding data-sharing among the various stakeholders of the healthcare ecosystem and, of course, the encompassing issue of patient personal data protection. The roots of these problems can be traced to the lack of relevant regulatory frameworks that provide proper guidelines regarding data collection, validation, standardization, protection, sharing and utilization. These types of regulatory frameworks are still absent or at an infant stage in most national and international digital health strategies.

To tackle some of these shortcomings, several countries have undertaken national initiatives towards the creation of RWD repositories. Such initiatives are usually integrated under the umbrella of operations of a dedicated public or private (or in several cases a public-private sector

research collaboration) research institution or excellence center, which utilizes these data to advance medical research, innovation, and clinical practice. Notable examples include the Maccabitech Institute in Israel and the Karolinska Institute in Sweden.

Focusing on the case of Greece, the state-of-the-art on RWD collection is quite promising as 11 million users-patients, 60 thousand physicians (from both the public and the private sector) and 11 thousand healthcare service providers (including pharmacists) are already interconnected in an extensive network of information systems and data repositories. Furthermore, Greece's overall digital strategy has prioritized the digital transformation of the healthcare ecosystem, which is also strengthened by the National Recovery and Resilience Plan "Greece 2.0". Within this context, several actions that include the interoperability among the different actors of the ecosystem are already well under way. However, the wealth of digital information deriving from the extensive catalogue of digital repositories and sources still remains unutilized, as a functional and regulatory gap can be traced in the stages that follow data collection in the overall RWD/RWE value chain, which relates to the secondary RWD processing for the production of RWE and other types of clinical evidence.

A possible remedy to fill this gap, would be the creation of an excellence center with a dedicated mission to advance research and innovation on medical science and clinical practice through the proper collection and utilization of RWD. This initiative is well-placed in the epicenter of the RWD collection ecosystem in Greece and can contribute to the overall upgrade of healthcare and medical services, while also creating positive externalities to both the society and the national economy. Focusing on the latter dimension, the large-scale investment plan required for this endeavor can provide significant structural benefits for the economy. In this line, a quantitative approach based on the basic principles of input-output analysis indicates that each 1mil. € of investment in the project directly contributes 496k € in the national GDP, while the overall structural benefit in terms of GDP – which includes the indirect effects from the stimulation of economic activities – is approximately 959k €. Another line of structural benefits relates to employment, as the direct contribution of 1mil. € investment for the creation and operation of an RWD excellence center directly supports 13 job positions and has a multiplying effect in the rest of the economy as well, which sums up in a contribution of 24 job positions in total.

The establishment of a center of excellence based on the collection, management and processing of RWD could be the link between RWD collection databases and the stakeholders that can use them to produce health products and services. Such an endeavour could serve as the core of an entire digital ecosystem for RWD, receiving primary data from existing stakeholders and supplying them with RWE and other critical clinical information, thus, enhancing research and innovation in the health sciences and substantially upgrading the services provided. The economic effects of such an investment can also stimulate GDP and be a source of new, highly specialized job positions for the country, providing a countermeasure to "brain-drain" both directly (through job creation) and indirectly (through the structural effects of RWD-related investments on other sectors of the economy, thus, stimulating overall economic activity in the country). At the same time, it may

enhance “brain-gain” (i.e. the attraction of specialized scientific staff from abroad), attracting international scientific excellence, which in turn can attract significant investments from both the domestic pharmaceutical industry as well as from abroad. At the same time, it can offer significant benefits to society and the economy, as well as alternative sources of direct and indirect revenue for the health system.

Therefore, the potential benefits of integrating the utilization of digital data into the country's digital health ecosystem are multidimensional. However, the regulatory gap that has been identified in the country's strategic planning for their utilization need to be addressed. To overcome this, a key step is to build a regulatory framework that will ensure the opportunities and prospects for the collection and use of RWD, while at the same time ensuring quality and reliability in the data collection process and their subsequent utilization and protecting the patients' privacy and confidentiality. This framework could be the basis for the development of significant economic activity around the processing and utilization of RWD, creating the appropriate collaborative structures that will mobilize the ecosystem's stakeholders towards investments in research and development, thus, solidifying the utilization of RWD as an important growth enabler for the economy.

Research team

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