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American Chamber of Commerce in Hungary

EFFICIENT HEALTHCARE, INNOVATIVE HEALTH INDUSTRY

Recommendations by AmCham Hungary's Healthcare Committee for the Further Development of the Hungarian Healthcare Data Ecosystem

2024

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Comments and Recommendations

Opportunities in Health Data

1. Any data that holds **informational value regarding an individual's health** is health data. It can be **a significant asset** if it is of good quality, available in large quantities, and structured. These parameters have well-defined technical criteria. The more data there is available, the better the results that can be achieved.

2. The primary use of data refers to goals directly related to the individual patient's care, the planning, organization, or funding of their treatment. Resulting in **better health outcomes** and more satisfied patients, primary use also **improves financial efficiency**.

3. The secondary use of data refers to derived goals. Secondary data use **facilitates data-driven decision-making, increases system efficiency, improves planning capabilities, and enhances R&D outputs**. In Hungary, health expenditures amount to about 4.5 trillion HUF, and it is in our common interest that this amount be used as efficiently as possible.

4. Public health is an interdisciplinary field, where − besides medical goals −, epidemiological, economic, sociological, sustainability, and many other aspects must also be considered. **Effective, data-driven, and measurable public health programs can significantly impact the population's health and, thereby, national economic development**. A healthier workforce has tangible economic advantages. According to international reference values, an increase in the average expected lifespan by 1 year contributes to the economy's performance by approximately 4%.

5. In **clinical trials, companies rely heavily on available health data**, as during the planning phase, patient populations required by the trial parameters need to be clearly identifiable in the given country. Clinical trials contribute **tens of billions of forints to the Hungarian national economy** and provide the most modern therapies free of charge to tens of thousands of Hungarian patients. Due to the intense international competition for these trials, the quick finding of potential patient groups offers a competitive advantage.

The Hungarian Health Data Ecosystem

6. **The Hungarian health data ecosystem ranks well even in international comparison**, enjoying numerous technological and infrastructural advantages over other countries. With strategic prioritization and sufficient resource investment, this can **translate into a competitive advantage for the country**. However, it is also crucial to emphasize that no technological advantage in digitalization can be taken for granted very long, making the time factor critically important.

7. The Electronic Health Service Space (EESZT) is the **central and most vital element of the Hungarian health data ecosystem**, as it integrates data from other systems and enables the operation of numerous supplementary functions. Despite its advantages, the EESZT currently **does not reach its maximum potential**, as it lacks some crucial IT architectural and infrastructural features. One of the most pressing issues is that a vast quantity of the historical data stored in the system is in unstructured, hard-to-analyze (PDF) files.

The European Health Data Space (EHDS)

8. The **European Union is at a severe competitive disadvantage compared to the United States and China regarding data use and related digital innovation**. The European Data Strategy aims to improve this situation by extending the "common market" principle to several public data systems. The **European Health Data Space** is the first step in this process, and **its implementation would mark a significant step forward from the current status-quo for both patients and European innovation potential**.

9. The **implementation of the EHDS is still in an early stage**, offering significant leeway in defining standards and protocols. Countries whose standards are adopted by the shared data space will gain a competitive advantage. This incentivizes intense lobbying by member states. Due to the advanced technological state of the EESZT and its supporting systems, **Hungary can have an advantage in this process by serving as a best practice**.

Further Development of the Health Data Ecosystem

10. **Developing the health data ecosystem is a highly complex task** that requires integrating strategic, health-economic, medical, technological, and economic-competitiveness perspectives into a unified concept. **We propose the government establish a Health Digital Methodological Center to coordinate professional and operational tasks**. Since the center's activities are primarily related to health strategy, we recommend it be established within the framework of the healthcare administration.

11. We recommend **rapidly expanding and structuring health data assets to improve the quality of primary and secondary use and to enable complex analyses**. Three areas can be significantly enhanced: structuring PDF files, integrating telemedicine data, and interconnecting public data systems (EESZT, NEAK, NNGYK, KSH). We believe these developments represent an investment into the future which will bring definite returns in the coming years.

12. Even **relatively small-scale developments could significantly improve the field of clinical trials** as excellent human capacities and established avenues of professional collaboration are already available in Hungary. **Domestic and international innovative pharmaceutical companies and their representative professional associations possess significant knowledge** that could help with identifying the most efficient implementation of digital solutions.

13. **Secondary data use can significantly improve economic competitiveness and innovation outcomes**, therefore we recommend establishing the legal and institutional framework for this as soon as possible. The most crucial element of the framework should be an **agency dedicated to coordinating the secondary use of health data**. The agency's primary task would be to develop a business model based on actual use cases, which should be operated transparently and accessibly. We believe the organization should work directly under the National Data Asset Agency (Nemzeti Adatvagyon Ügynökség - NAVÜ) or another high-level organization providing horizontal oversight.

14. **The human element must be considered when developing the health data ecosystem**. Even the most well-designed systems cannot fulfill their function if end-users (healthcare professionals or patients) misuse or overlook them. The three main reasons for failure are typically system designs that do not fit into everyday practice, lack of end-user skills, and lack of trust. These must be adequately addressed in every planning process.

Introduction

The American Chamber of Commerce (AmCham) is a politically and financially independent business advocacy organization. AmCham has represented the interests of its Hungarian and international member companies since its establishment in 1989. Our activities aim to contribute to improving Hungary's global competitiveness and maintaining dialogue and cooperation between the private sector and the government in order to work towards common goals.

The AmCham Healthcare Committee has over 40 innovative life science member companies. These pharmaceutical and MedTech businesses through their breakthrough technologies, investments, and scientific research, significantly contribute to making Hungarian healthcare modern, sustainable, and value-based. The impact of their activities is well demonstrated by the fact that more than 40% of clinical trials registered by the Hungarian National Center for Public Health and Pharmacy (NNGYK) in 2023 were initiated by AmCham member companies.

As part of our advocacy work in the past years, we have prepared several position briefs and recommendation packages covering various areas of healthcare (e.g., *Cooperation for a Sustainable and Value-Based Healthcare*, and *Healthy Nation, Competitive Country*). Our current recommendation package is part of this activity. This document aims to highlight the opportunities in health data assets and initiate a dialogue on their use in a manner that not only benefits all stakeholders of the healthcare ecosystem but also serves as a breakout point for Hungary's European competitiveness.

Digitalization transforms all areas of the economy and society and healthcare is not exempt. Taking advantage of the possibilities in the process can:

- Improve the quality of care;
- Facilitate policy planning and professional management;
- Ensure more efficient resource use;
- Strengthen the domestic R&D ecosystem;
- Introduce new activities in Hungary that increase economic value.

However, we must also take note of significant risks: the time factor, intense competition, and the negative consequences of missing out on trends. The implementation process of the European Health Data Space gives the topic particular relevance and a cross-border dimension, giving urgency to the creation of favorable conditions that can help accelerate the development and integration of systems that contain high-quality, structured health data.

We firmly believe that if the good usage and development of the health data ecosystem received an appropriately strategic focus and were supported with sufficient human and financial resources, Hungary would be able to leverage many of its situational and technological advantages it currently holds in this area. The Hungarian EU presidency can also assist in this endeavor.

I. Opportunities in Health Data

An often-cited argument in favor of increased healthcare spending is that “every forint spent on healthcare increases the GDP by approximately two.”[1] Although the concrete relationship is more complex, increased healthcare expenditures are shown to have a multiplier effect on the GDP. However, the precise extent of the increase is contingent upon the efficiency of resource utilization. This chapter provides an overview of basic health data concepts and related criteria. We also aim to highlight how health data use can improve the efficiency of the healthcare system, thus indirectly promoting economic growth. Given the complexity of the area, it is essential to define and use a unified terminology that facilitates dialogue between various stakeholders.

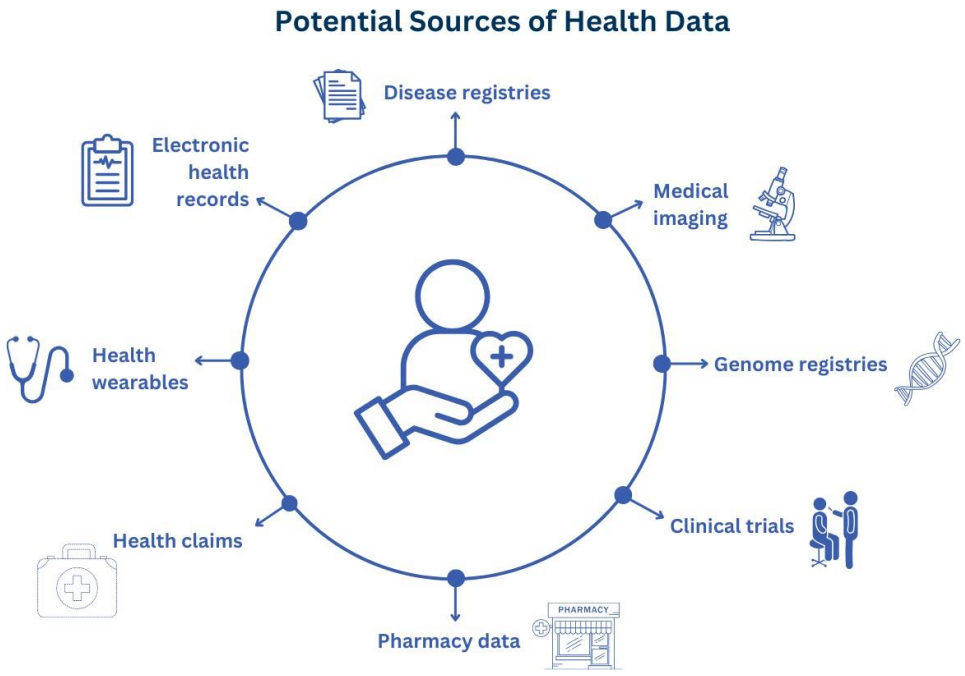
Conceptual Definitions, Data Sources

According to the General Data Protection Regulation (GDPR), health data refers to “*all data pertaining to the health status of a data subject which reveal information relating to the past, current or future physical or mental health status of the data subject*.”

The definition highlights the indirect nature of the concept, classifying any derived data that holds informational value regarding an individual’s health as health data. This designation extends to medical history, test results, pharmacovigilance and clinical research protocols, data collected by remote monitoring devices, patient satisfaction surveys, prescription records, social security data, and much more. Clinical data represent a much narrower range of health data, typically concerning specific health indicators of an individual, such as values in a laboratory diagnostic report. In this paper, we wish to consistently use the term health data in its broadest sense. A by-country conceptual and regulatory comparison of health data is included in *Appendix 1*.

Health data may originate from many different sources. In Hungary, these primarily include institutions of the public healthcare system, as well as private healthcare providers, and laboratory and imaging diagnostic networks. Also significant sources are the systems of the National Health Insurance Fund of Hungary (NEAK), the Hungarian National Center for Public Health and Pharmacy (NNGYK), the Hungarian Central Statistical Office (KSH), and some other institutions and public data systems.

[1] Századvég (2024): Az innovatív gyógyszeripar magyarországi fenntarthatósága [Sustainability of the innovative pharmaceutical industry in Hungary]



Source: Ortega, M., Sanky, M., & Kermany, A. (2021, July 19). Unlocking the Power of Health Data with a Modern Data Lakehouse. Engineering Blog

Quality Indicators, Structure

Health data only hold adequate informational value if they are of good quality. According to the widely known *Garbage In, Garbage Out (GIGO)* principle from data science, inaccurate or incorrect input data will lead to erroneous conclusions even if the processing itself is perfect. Data are considered of good quality if they meet the following five criteria:

1. **Completeness**
   Data are available in sufficient quantity and cover all necessary and expected parameters, without leaving “gaps” in the dataset.

2. **Accuracy**
   The numerical data values represent actual values and do not contain excessive rounding or generalization that could hinder intended use.

3. **Consistency**
   The data’s format, structure, and reliability are uniform, even across different sources.

4. **Timeliness**
   Data are sufficiently up-to-date for the intended use.

5. **Validity**
   Data accurately represent actual conditions and relationships and do not distort them in any particular direction.

Naturally, no data system is perfect, and faults always occur, even with the best of intentions. However, if the number of errors in the set is low, they can be filtered out and corrected by using appropriate analytical mechanisms.

The concept of *structure* is also often mentioned, which data meet if they are:

1. **Semantically uniform**
   Similar data appear in a consistent manner regardless of source (e.g., a particular abbreviation always denotes the same concept, or a specific physiological value is always provided in the same unit of measurement).

2. **Easily processable digitally**
   Data and other logically related information are organized into tables rather than being scattered in flowing text.

Good quality, structured data are essential for running analyses on large datasets (Big Data) and for developing and training Artificial Intelligence (AI) solutions.

Primary and Secondary Use

A good quality and well-structured data asset can be widely used for both direct and indirect purposes. *Primary use* refers to goals directly related to a particular patient's care, or the planning, organization, and funding of their treatment. *Secondary use* is much broader and typically does not concern a single individual but rather facilitates system-level overview. It simplifies strategic, budgetary, and operational planning, fuels innovation and R&D, highlights necessary focus areas in professional education and training, etc.

Below, we examine some usage areas where significant success can be achieved through systematic statistical data analysis, which can be further enhanced by using AI.

Faster and Better Patient Care, Efficient Patient Pathways

Healthcare professionals having more relevant information about their patients, facilitates quicker and more accurate diagnosing and improvement in clinical decision making. This is particularly true for diseases with complex and hard-to-identify symptom clusters (e.g., multiple sclerosis) or rare diseases. If patient data from Electronic Health Records (EHR) can be easily collated with molecular or imaging diagnostic datasets, exposed correlations can lead to swift and more accurate results.

Quick and accurate diagnosing also enables the early or even preventive identification of diseases and the fast-tracking of patients to the appropriate progressivity level of care required by their condition. This creates more predictable and personalized patient pathways (meaning that patients receive the most appropriate and timely sequence of care). This efficiency may be life-saving, especially in the case of high-risk diseases.

Well-organized patient pathways not only result in better outcomes for the individuals, but are also more economical. Inappropriate therapies yield less health gain, and are either poorly utilized or futile expenses. Similarly, treating patients at a higher than necessary progressivity level is an inefficient use of limited human and material resources and treatment capacities.

Monitoring care processes and patient pathways allows for reliable quality assurance, and the reviewing of ineffective protocols, and identification of redundancies and other obstacles in the healthcare system. Thus, beyond the immediate clinical use, health data also supports systemic-level professional and management decision-making.

Efficient R&D, More and Better Clinical Trials

Connecting health data systems increases data mass and diversity. It allows for discovering previously hidden correlations or causal relationships, which provide fertile ground for drug and active ingredient research, development of medical and diagnostic devices, and decision-assisting AI solutions. These factors significantly contribute to the potential of the innovation ecosystem.

Companies heavily rely on available health data during the clinical trials of various drugs. This is particularly true in the planning phase, where a crucial factor in selecting a country is whether patients can be identified along the targeted parameters and recruited in sufficient numbers. Furthermore, industry trends show that new drugs are becoming increasingly specialized to maximize efficacy, which also calls for an increasingly targeted patient recruitment process during the trials' feasibility studies. Due to the intense international competition for clinical trials, the ability to quickly find potential patient groups provides a significant competitive advantage.

With the advancement of clinical research methodology, the so-called *Real World Data (RWD)* approach is also gaining importance. This is based on the premise that standardized environment studies do not accurately show the real effectiveness of therapies, unlike those that are designed around circumstances that are present in patients' "everyday" lives. RWD studies require synthesizing information from many different data sources (e.g., EHR, diagnostic systems, remote monitoring devices, social security registers), which is only possible with adequate system connectivity. The RWD approach also significantly aids the long-term monitoring of the safety and efficacy of already marketed drugs, therapies, and medical devices, which can affect their reimbursement by the payer.

Targeted Public Health Programs, Faster Emergency Response

Public Health is a truly interdisciplinary field, where in addition to medical considerations, epidemiological, economic, sociological, sustainability, and many other aspects must also be taken into account. Consequently, public health can benefit significantly from the integration of data systems.

Data-driven analysis and planning can help identify vulnerable social groups, and aid the design of targeted screening and health promotion programs with increased reach and effectiveness. Optimized campaigns can significantly improve the population's health, thereby also enhancing national economic development. According to international reference values, a 1-year increase in the average life expectancy contributes by approximately 4% to the economy's performance.[2]

Quick response and high efficiency are crucial in epidemiological crises, when the best possible decisions must be made in the shortest possible time. Analyses, reports, and decision-assisting analytical dashboards can be quickly prepared if high-quality health data assets are available for use.

More Comprehensive Strategic Planning, Efficient Financing

The efficiency of strategic, operational, and controlling processes can be significantly improved if decisions are based on data. Public expenditure on healthcare is a significant item in national budgets. This applies to Hungary as well, with 4.43 trillion HUF spent in 2022[3] – a sum which is in every stakeholder's interest to be spent as efficiently as possible.

Appropriate data analysis can identify where resources can be optimally allocated within the healthcare system to achieve the biggest impact. These can be compared with underperforming areas to analyze differences and identify breakout points, and examine and evaluate new operation models. These include technology assessments and financing models that are based on the long-term health outcomes of procedures, therapies, and devices.

II. The Hungarian Health Data Ecosystem

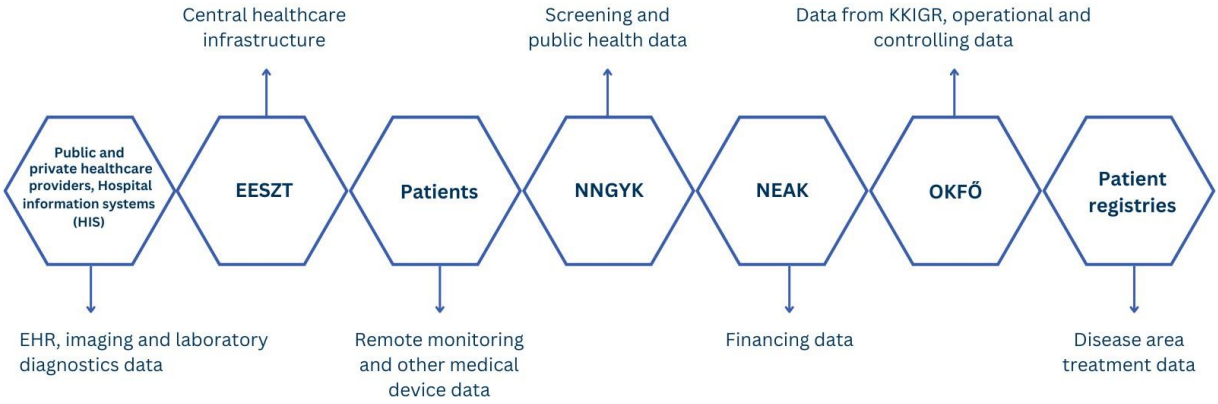
Various hospital-management, patient registry, diagnostic, and other IT systems have been used in the Hungarian healthcare system for decades, but for much of this time these systems operated in isolation without any connectivity features.

The turning point came in December 2015, when Parliament passed *Act CCXXIV of 2015* on the *Amendment of Certain Health and Health Insurance-related Laws*, paving the way for the development of the Electronic Health Service Space (EESZT), which has since become the

[2] Bloom, Canning & Sevilla (2003). The Effect of Health on Economic Growth: A Production Function Approach. World Development Vol. 32, No. 1, pp. 1–13, 2004.
[3] Source: Hungarian Central Statistical Office

central system of digital healthcare. The *National Digitalization Strategy (2022-2030)* contains numerous objectives concerning the further development of the EESZT and other health data assets. These goals include increased data structuring, the linking of new data sources and collection channels (e.g., through telemedicine devices or patient satisfaction surveys), and establishment of auxiliary systems.

Current and Planned Data Sources in the Hungarian Health Data Ecosystem



Source: Dr. Magdolna Kádár, Head of the Development Policy Department of the Ministry of the Interior; based on her presentation delivered at the conference of the Hungarian Healthcare Management Association (MEMT) on April 25, 2024.

The Electronic Health Service Space (EESZT)

The EESZT system is the central component of the current health data ecosystem, which:

- Integrates data from other IT systems and databases providing “single-gate” user access.
- Designates the fundamental alignment points for future digital developments, providing a framework for the incorporation of new potential data sources.
- Offers a platform for developing new internal functions and user interfaces (e.g., patient pathway management system, Outpatient Directional System, Health Window application).

The implementation of the EESZT can be considered a success, even by international standards, as there are few examples of comparable, integrated and high-functioning health data systems with similar development potential. We therefore welcome the government’s plans to further enhance and expand the system’s functions. Below, we examine some related considerations and opportunities.

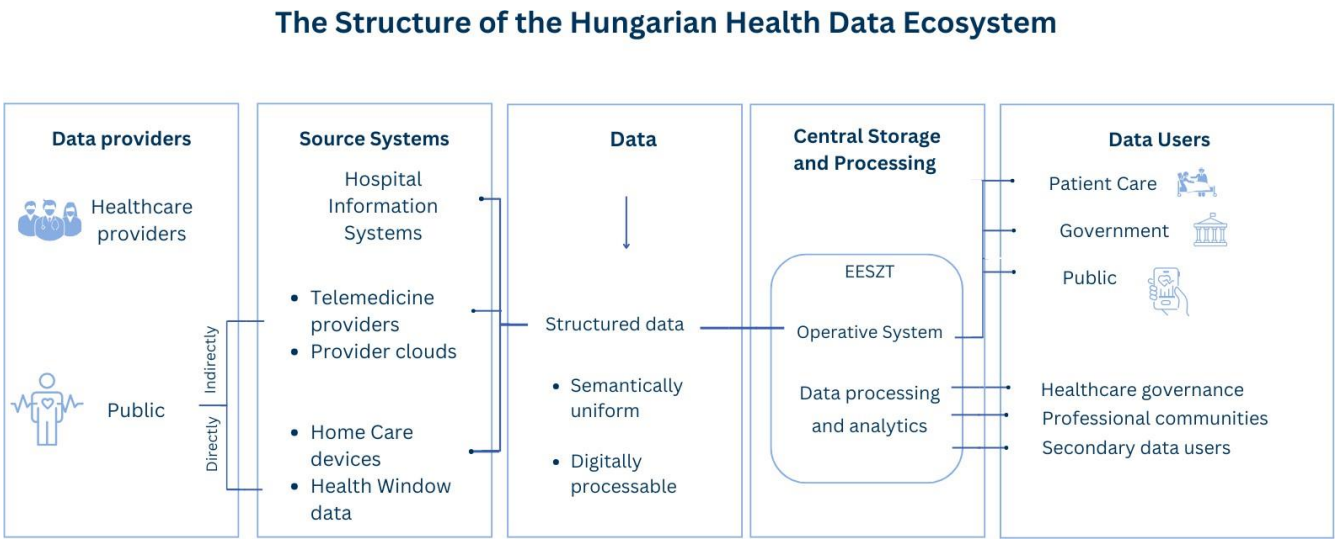
Data Structure, Data Warehouse

The EESZT currently presents a mixed picture regarding the state of stored data. Most outpatient records, discharge documents, and test results are uploaded in PDF files (practically separate documents often containing flowing text in varied formatting). Although these files can be quickly and reliably retrieved in a “catalog-like” fashion, they are not sufficiently structured. Auspiciously, forms that allow for structured data input are increasingly being introduced across specific medical and therapeutic areas (e.g., laboratory diagnostics, GP records, obstetric records)., however, there is a need to expand and expedite the process.

Creating structured forms for specific medical fields would pave the way for the proper conversion of the historical PDF data mass with the help of currently available AI solutions. This process would significantly increase the volume of data assets available for analysis, and the EESZT would become fully capable of servicing complex analytical demands. Structuring historical data is a necessary precondition for achieving the goals outlined in the first chapter, by opening up the Hungarian health data asset for both primary and secondary data use.

Developments that affect data structuring also have IT architectural and infrastructural aspects. The most important architectural development goal is the creation of a central data warehouse. The data warehouse could service higher-level search and query needs and enable the implementation of specialized functions supporting primary and secondary data use through specifically designed, partitioned segments (data marketplaces). When creating the data warehouse, it is essential to develop capabilities for storing imaging diagnostics data which currently the EESZT is not capable of. Since preserving the images themselves would require considerably larger storage capacities, it is instead advisable not to store the image files themselves, but rather their appropriately labeled data fingerprints. There are available technological solutions for such digital fingerprinting.

In addition, appropriate infrastructural improvements are needed to ensure the system’s overall reliability and stability. This primarily translates to increased computing and storage capacities, which can be achieved through either physically installed servers or by utilizing cloud-based services.



Source: Based on the presentation delivered by Miklós Mázi, Leading Expert at ESZFK Nonprofit Ltd., at the conference of the Hungarian Healthcare Management Association on April 25, 2024.

EESZT Complementary Systems

The primary function of the EESZT is to support treatment and care activities, a task it performs with the help of complementary systems (so-called service packages) built on the existing IT framework.

Patient Management Systems

Patient care is a highly complex medical and organizing process that can be influenced by numerous external and internal factors. No two patients are in the same situation, therefore the optimal patient pathway should always be determined on a case-by-case basis. Finding this is crucial for achieving the best health outcomes paired with the most efficient use of time and resources of all involved patries (patients, caregivers, healthcare professionals).

The patient pathway management system module, created in the collaboration of the government and business actors, connects all participants of the patient pathway by simultaneously placing the patient and their care at the center. It helps doctors assemble treatment plans tailored to the individual's specific needs according to existing protocols and available care sites at the appropriate progressivity level. The system is currently being tested within pilot programs in several Hungarian hospitals and treatment centers. If these programs reach a positive conclusion, we recommend accelerating the development process and expanding coverage for other medical fields as soon as possible.

The functionality of the patient pathway management module is well complemented by the Outpatient Directional System (JIR), which was introduced with the aim of increasing the

efficiency of the outpatient specialist care system, facilitating cooperation between primary and specialist care, and improving patient satisfaction. The development of the JIR was prompted by population surveys that highlighted the most cumbersome aspects of patient interactions with the healthcare system – the initiating of contact with healthcare professionals and long waiting times. Thus, the JIR allows patients to directly book appointments with general practitioners and specialists. As a side benefit, the introduction of the JIR can show the actual length of waiting lists within the Hungarian healthcare system highlighting actual capacity needs while also serving as an "equalizer" of appointment bookings between overburdened and less frequented care sites. To ensure the system's seamless operation, we recommend creating appropriate end-user incentives (such as the recently suggested 1000 HUF booking fee) to motivate patients to show up for their appointments or cancel them within a reasonable timeframe. Patients failing to show up for appointments en masse could make current capacity issues even worse and may ultimately undermine the entire project's success.

Health Window, Public User Interface

The *Health Window (Egészségablak)* application serves as an end-user interface that provides direct public access to the EESZT's data content and to the services of its auxiliary systems. The public functions of the patient pathway management system and the JIR booking service are also expected to be accessible for patients on this platform. This could synergize well with the already available personal calendar management functions.

The Health Window application in its current version offers numerous services. Patients can access all their care documents, test results, and prescriptions – which they can redeem electronically through the ePrescription system. The patient information leaflets for medicines, which are continuously updated according to the NNGYK's database, can be accessed by all users. The *TB lamp* function allows quick verification of an individual's social security status at any time, which, as a secondary benefit, could soon entirely replace the fragile and unpopular Social Security (TAJ) card. The system's informational functions include simple but important HCP information (such as GPs' contact details and consultation hours) as well as scientifically validated articles on diseases, health conditions, and health concepts outlined under the *Health A-Z* menu option.

Overall, the Health Window is a very well-designed platform that is easy to understand and use. With additional development, it could become a single-gate solution for most, if not all administrative interactions between the population and the healthcare system. To achieve this end goal, the intuitive user experience must remain the guiding principle in the development process. Although download numbers for the application are dynamically increasing, we recommend launching a communication campaign with positive messaging to further popularize the application and encourage active use. This could be linked to a broader communication program promoting the *Digital Citizenship Program*.

Concerning the direction of future development, we recommend starting a social dialogue about the functions of the Health Window with the involvement of universities and patient

organizations. This should focus on the needs of an aging population, many of whom struggle with chronic diseases and comorbidities. Providing care to this broadening social cohort will require an increasingly significant share of healthcare resources, therefore achieving increased efficiency in the allocation of financial and human resources is paramount.

Institutional Management, Controlling, and Other Systems

In addition to those mentioned above, there are many other existing or in-development systems that supply data to the EESZT. The primary goal of these is to support capacity planning, resource management, and logistics. Such systems include Hospital Information Systems (HIS), their equivalents for general practitioners and private practices (miniHIS), the Inpatient Care Support System (ÁTR), the Central Hospital Integrated Management System (KKIGR), the Ambulance Rescue Management System (MIR), the Pathology Management System (PIR), and many more.

Giving a detailed review of each would far exceed the scope of this paper, still, we may conclude that, although they were created with the intention to support the work of medical workers, some of the finished products have not lived up to practical expectations and applicability to real-life scenarios. Identifying the exact reasons for these shortcomings would require a case-by-case analysis, but in general, we may conclude that in the future special attention should be given to the uniformity of technological standards and parameters, especially in terms of compatibility with the EESZT. In addition, involving future users in the development process and integrating their professional and practical insights can significantly increase the quality and acceptance of the final products. The success or failure of any digital platform will ultimately be determined by its users.

III. The European Health Data Space

Data is often said to be the new oil, by which speakers typically refer to its value and fundamental importance in the modern economy. While this analogy is true in a sense, it is nevertheless misleading as data and oil have very different characteristics. Unlike oil, data (if collected meticulously) is available in essentially infinite quantities and can be used repeatedly, without limitation. Some experts estimate that more than 1100 terabytes of health data can be collected from an average person during their lifetime[4]. Furthermore, the more data we use, the better the outputs will be – especially in AI development. For these reasons, the limiting factor on outputs are mostly due to the lack of sufficient exploitation capabilities.

In the ongoing social and economic transformation of the data revolution, the already heated global competition has become even more intense with the emergence of large language models (LLMs). The European Union is already at a disadvantage due to its fragmented nature compared to other global players like the United States or China. The *European Data Strategy*, issued by the Commission in 2020, aims to rectify this by extending the “common market”

[4] Source: IBM Health and Social Programs Summit, 2014.

principle to public data in healthcare, agriculture, manufacturing, energy, mobility, finance, public administration, and education. The first element of this initiative is the creation of the European Health Data Space (EHDS), launched by an agreement between the European Council and the European Parliament in April 2024, initiating the lengthy planning and implementation process with an end date of 2030.

Easier Primary and Secondary Use

The main goal of the EHDS project is to provide high-quality patient-centric care to EU citizens by creating a shared data space to facilitate the *free movement of patients* as inseparable from the free movement of labor. Connecting the primary patient population at the European level will allow patient pathways to be tracked across borders in order to provide optimized therapies instead of the typical ad hoc care provided today. As a result, patients will receive better diagnoses and more personalized care, and their treatments could continue across EU borders without interruption. Healthcare professionals would also have the option to conduct cross-country consultations with peers.

Equally important is to unburden the secondary data use at the European level for policy-making, public health analysis, R&D and innovation. These uses will significantly benefit from the larger data pool of the EHDS and will yield better outcomes. A particularly promising future use would be the possibility to compare the efficacy of particular policy measures, protocols, and financing models by collecting and connecting data from various countries, as well as the quicker investigation of epidemiological events for quicker deployment of emergency countermeasures.

Risks and Opportunities

At this initial stage in the creation of the shared data space, it is still difficult to predict the outcome, but we would like to offer some considerations.

The EHDS regulation underlines the need for EU citizens to retain complete control over their data in line with GDPR data governance principles. This includes whether they wish to appear in the system at all. Therefore, the project can only reach its full potential if each country successfully communicates to its citizens the benefits of participating in the common data space. This could be challenging in member states where people are more sensitive about data protection or distrust their government.

A future issue to be addressed is the R&D access of business actors to the EHDS. According to current plans, applications linked to specific projects would be approved by designated decision-making government bodies in each of the member countries. We believe that access criteria must not be overly restrictive, otherwise the EHDS may not significantly impact the European Union’s innovation potential. To ensure that the access framework is balanced, we recommend consulting with health industry stakeholders before implementing the relevant EU regulations in Hungary.

Hungary's Situational and Technological Advantage

There are still many open theoretical and practical questions that need to be decided and agreements to be reached on a number of technological standards, allowing for significant flexibility in the implementation phase. If Hungary can demonstrate a best practice for other member states, it could potentially influence the entire EHDS process. In our view, this provides real opportunity due to the technological and operational advantages of the EESZT and its complementary systems.

Since the EESZT integrates well with other systems, its standards could also be adopted in the EHDS. The Health Window app is a nice illustration to the system's capabilities, and aligns well with the patient-centric focus of the EHDS. During the implementation process, member states may voluntarily introduce specific local provisions related to the EHDS ahead of schedule. As an early adopter, Hungary can prove that its solutions are workable and is worth considering by other countries as well.

There is some concern that giving even partial access to the Hungarian health data asset in connection with the EHDS is a risk, as countries with greater analytical capacities could disproportionately benefit from the shared data space at the comparative detriment of others. Acknowledging the risk, we must also point out that these countries would benefit even more if they successfully lobbied for their technological solutions to become the standard. In this case, Hungary would not only suffer a disadvantage in exploiting the common data asset but would also have to make significant changes to its own systems, potentially requiring a near-complete redevelopment of the Hungarian health data ecosystem. Therefore, it is essential for Hungary to instead take the lead in the initiative. However, time is limited, and we encourage the government to act immediately in formulating a forward action plan, preferably during the European Union presidency.

IV. Further Development of the Healthcare Data Ecosystem

In the previous chapters we outlined why we believe Hungary is in a good position to address the challenges besetting its healthcare system, and can gain substantial competitive advantage by further developing its health data and digital management systems. However, it is important to emphasize that no technological advantage in digitalization can be held for long. In this chapter, we present several proposals for consideration.

Establishing a Healthcare Digital Methodological Center

Developing the healthcare data ecosystem is a highly complex task, requiring the consideration of strategic, health-economic, medical, technological, and competitiveness perspectives in addition to patient needs, all integrated into a unified

concept which is then implemented into practice. Experience shows that without the active involvement of a professional coordinating body, even resources allocated for centrally managed top-down projects are not utilized efficiently. This sometimes leads to incompatible systems or duplicate functions that do not fit into a comprehensive structure. The situation may become even more complicated if unmet needs for digital solutions are fulfilled by *ad-hoc, locally implemented* solutions. Such (often AI) tools may help the everyday work of its users but will not fit into a coherent system-compatible framework. Therefore, choosing and implementing solutions that are adaptable in a synergistic way is vital for the long-term.

By these considerations, we propose that the government establish a Healthcare Digital Methodological Center to professionally perform operative and coordination tasks for the fulfilment of the following responsibilities:

- Mapping the systems, databases, and licenses used within the healthcare ecosystem.
- Establishing frameworks to achieve strategic goals.
- Coordinating the development of plans to ensure system-compatibility of concepts, with particular attention to AI solutions.
- Controlling the quality of completed digital systems from the aspect of professional usability and technological interoperability.
- Properly designing and verifying IT infrastructure, standardize technical specifications.
- Harmonizing the semantic terminology of different medical fields.
- Preparing for EHDS connectivity, coordinate related tasks and consultations, and promote Hungarian standards in Europe.
- Serving as the EHDS liaison agency regarding primary data use, supervise EHDS data channels.
- Coordinating professional dialogue among all actors in the healthcare ecosystem.
- Facilitating cooperation between the government and the private sector.

As evidenced by the list, the Healthcare Digital Methodological Center would perform an important, complex, and interdisciplinary task, and must operate with sufficient financial resources and a staff with appropriate skills and capabilities. Additionally, since the methodological center's activities are inextricably linked to the broader framework of health strategy, it would be advisable to separate its operation from the broader administrative digitalization apparatus and have it remain under the framework of the healthcare administration.

Expanding the Health Data Asset

In the previous chapters, we thoroughly discussed the sources of health data, the opportunities provided by the data asset, and how it can be expanded by integrating various systems. Although many promising projects are currently underway, we would like to highlight three areas of paramount importance that we believe should be prioritized.

Transforming PDF Files into Structured Data

The transformation of difficult-to-analyze PDF files into structured data has been on the agenda, for many years, but progress has been limited due to the complexity of the task. However, with the recent explosive advances in LLM development, many technical obstacles have been removed, opening the way for rapid progress. Numerous technological solutions from domestic research institutes as well as businesses are now available for use. We recommend strategically prioritizing this process and to assess the requirements to launch a coordinated data transformation project.

Connecting Public Data Systems

Most health data is divided among the EESZT and the systems of NEAK, NNGYK, and KSH, which are currently not interconnected. This poses a significant barrier to comprehensive data analysis. Given that some IT infrastructure prerequisites are still required for this connectivity, we recommend that the government provide extraordinary funding for expediting the integration process.

Telemedicine Data

We welcome the government's intention that all systems and technological platforms connected to the EESZT must be capable of structured data transfer, including remote monitoring and telemedicine devices. In addition, we also propose that data quality should be a significant consideration in the technology evaluation process. It is important to note that the term *medical device* is extremely broad, and lacks well-defined classification criteria, with a wide variation in quality and reliability.

We believe that for medical devices as well as for software designated as medical devices, a set of minimum criteria requirements should be introduced to clearly define the parameters by which they can be integrated into the Hungarian digital healthcare infrastructure. We recommend only allowing EESZT integration for solutions that are quality assured by the manufacturer.

Developments Related to Clinical Trials

In the global competition for hosting clinical trials, Europe has found itself in an increasingly unfavorable position due to over-regulation, and fragmented and complicated data access policies. Maintaining or improving the position of Hungary in the clinical trial rankings requires special attention.

Given the excellent network of professionals and established channels of cooperation, even relatively small improvements (e.g., in remote monitoring devices, patient selection criteria, HIS clinical trial modules) could have a significant impact. Domestic and international innovative pharmaceutical companies and their professional associations can provide concrete and easy-to-implement suggestions for development. Prioritizing this field is justified from both short and long-term perspectives.

Data Security

The health data asset represents significant value and should be protected with multi-faceted (physical, content, quality) security measures. As part of establishing an appropriate cybersecurity architecture, developing access rights and a legal framework is critical. We recommend that all systems and devices that input data into the EESZT adhere to the principle of data minimization and have built-in, NIS2 accredited information security measures. User groups should only access data they justifiably need and the appropriate application of pseudonymization and anonymization within the systems should also be considered. The retention period and storage conditions of various data types should also be defined. Consequently, further expansion of the *Act on the Processing and Protection of Health and Related Personal Data (1997, Act XLVII)* with appropriate concepts and criteria also seems appropriate.

Implementing the necessary data security considerations along with clear and transparent communication is crucial for fostering citizen trust and willingness to provide accurate personal data. We must underline that health data ultimately serves the patient's own interest, as it allows them to receive better care and services. In secondary use – often perceived as carrying more risk – individuals need not be identifiable. Data anonymization does not impair the outcomes of statistical analyses or AI training.

Data security also extends to concerns about the way data are stored. According to the global experience of our member companies decentralized cloud-based solutions offer higher protection than locally installed systems, which are vulnerable to on-site data theft or physical harm (e.g., sabotage, military attacks).

Secondary Data Use

There is ongoing work within the government to finalize the concept of an institutional framework for secondary data use and the development of policy guidelines. Given that this issue directly affects the operations of our member companies, we consider it essential that domestic and international life science companies be consulted from the outset to ensure the outcomes are compatible with industry standards and applicable to business realities.

We believe that an established and accessible framework for secondary health data use would bring significant economic benefits, particularly due to the facilitation of clinical trials conducted by domestic and international pharmaceutical companies where access to health data is crucial. Clinical trials annually contribute by tens of billions of HUF to the Hungarian national economy, and provide tens of thousands of patients with the newest therapies free of charge.[5]

[5] According to the Association of Innovative Pharmaceutical Manufacturers (AIPM) based on the IQVIA (2024) Economic Footprint of the Pharmaceutical Industry in Hungary study.

Dedicated Healthcare Data Asset Management Agency

Throughout the entire value chain of life science products, from initial development to post-market follow-up, AI is gaining increased importance. AmCham welcomes the amendment to the *Act (1997, XLVII)*, which from 2026, will allow EESZT data to be accessed in a dedicated training environment for AI algorithms with prior project approval from the Health and Science Council and an authorization from the Ministry of Interior. However, having a transparent and equal access framework that comprehensively regulates the secondary use of health data is essential. One of the most critical requests of the industry is the ability to directly purchase anonymized data. The framework must also include a data register from which the availability of specific types of data can be quickly and precisely determined.

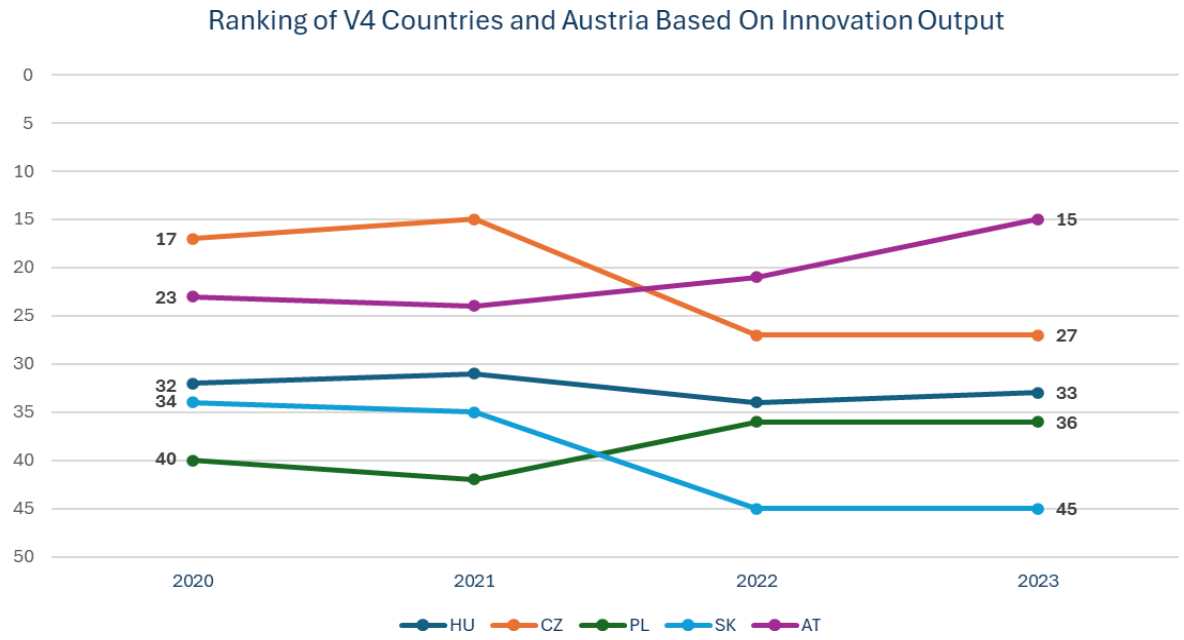
To operate the health data asset framework and to practically manage the health data asset, we recommend establishing a dedicated agency to fulfil the following responsibilities:

- Developing and operating the business model, access criteria and technical parameters for secondary data use.
- Maintaining administrative and practical contact with clients requesting data use.
- Compiling, updating, and operating the health data register.
- Acting as the EHDS liaison for secondary data use, evaluating and processing EHDS-related project applications, and facilitating connection to the system.

We believe this organization should either be directly under the National Data Asset Agency (NAVÜ) or a similarly high-level organization providing horizontal oversight.

Research and Development, University-Business Partnership

Although the European Union as a whole needs to significantly improve its competitiveness in R&D, the Global Innovation Index rankings of CEE member states in terms of innovation outputs lag behind even the EU average – primarily due to the economic realities of limited financial resources.



Source: Based on the Global Innovation Index editions of 2020, 2021, 2022, and 2023, published by WIPO.

In our opinion, the competitiveness of the Hungarian research-innovation ecosystem can be improved in three main ways:

1. Ensuring the availability of sufficient and high-quality data assets,
2. Providing broad access to the data asset,
3. Providing an environment that supports partnerships between universities, startups, and multinational and large domestic companies.

The government's strategic goal of fostering cooperation between multinational and large companies, universities, SMEs, and startups has been on the agenda for a long time. In connection to these efforts, our chamber summarized some of our members' practical experiences and formulated some recommendations in *Appendix 2*.

We must note that the R&D activities of multinational innovative life science companies are highly centralized, even on a global scale. Therefore, the areas of cooperation with local partners are usually limited around specific projects. A good example of such a partnership is the AI-based research of various, high public-health burden diseases (e.g., COPD) conducted at Semmelweis University's Faculty of Health and Public Administration aimed at early diagnosis and the identifying of factors and patterns that cause deterioration in patient health.

An appropriate framework and conditions for facilitating secondary data use could create an environment for research conducted along similar lines and may also foster an environment in which health technology startups can grow. A startup that emerges from a supportive ecosystem is more likely to partner with international companies, which then helps them enter into the global market.

A General Approach to Digital Systems Development

A frequently recurring question within the Hungarian health data ecosystem is whether digital solutions are better delivered via specifically developed systems or the adoption of market-available, customizable, EU-referenced software solutions.

Proponents of custom software development argue that although the initial development costs are often higher, in the long-term savings catch up, because ultimately the finished product will become state property. On the other hand, marketplace solutions require the continuous payment of license fees with ownership remaining with the service provider. However, this approach does not consider that license fees typically include support services (e.g. bug fixes, version control, system maintenance), which also have significant cost implications and must always be performed on proprietary systems. We do not wish to advocate for either approach, but instead recommend examining and weighing options on a case-by-case basis.

Training and Education

The capacity to exploit health data assets is not only affected by policy and technological conditions but also the availability of personnel that possess the appropriate skills. To train such professionals, new, targeted university programs and the revision of current curricula are needed. Data experts are in short supply worldwide, and the fact that data scientists who specialize in healthcare need to be proficient in both healthcare systems and medical IT further narrows the pool. Dedicated education programs have only recently been launched even at the most prominent global universities, so starting similar programs in Hungary could not only meet local needs, but also serve as a breakout point for Hungarian higher education. In this regard, the health data science program at the Semmelweis University Healthcare Management Instruction Centre in 2024 is an outstanding example.

With the spreading of digital technology, new fields in medicine are emerging, and healthcare as a whole is being transformed. Emerging technologies will not replace but rather complement the work of doctors and healthcare workers, and this requires a new mindset, and skills. In addition to the training of health data scientists, the technological proficiency of healthcare professionals must also be enhanced, including basic IT and data science skills, a fact that should be reflected in the university curricula. For working professionals, targeted courses can help raise general digital literacy and open the ability to apply new digital solutions to their work. We recommend developing training programs tailored to specific medical professions which should also be integrated into the accredited credit system. Change management can be significantly facilitated by a positive message highlighting that the new skills will help HCPs excel professionally, in addition to making their daily work easier.

Appendix 1.

Comparison of the Conceptual and Regulatory Characteristics of Healthcare Data by Country

	Definition of health and medical data		Secondary use of health data		Regulation of data sharing for clinical trials and R&D		Protection of data sovereignty	
HU	Health data in Hungary fall under the category of "special data", which is regulated by Act XLVII of 1997 (Eüak.) and the GDPR. Health data is handled according to strict data protection and professional confidentiality rules. The relevant legislation defines "health data" as any information relating to a person's health, health care or use of health services. The concept of 'medical data' is not defined in the relevant legislation, but the scope of such data is mainly limited to data relating to medical care and activities carried out by health professionals.		The secondary use of health data in Hungary is strictly regulated, in particular for research purposes and statistical analysis. The Electronic Health Service Space (EESZT) provides centralised storage and access to health data, allowing secondary uses such as statistical use. **Proposal / Conclusion:** **Developing the necessary legislative framework to regulate areas for improvement in the context of secondary data management (such as making the process of data sharing more efficient, ensuring more innovative data flows between recipients of secondary use and data controllers).**		Access to health data for the purpose of scientific research requires authorisation from the head of the institution or a data protection officer under the provisions of the Health and Safety at Work Act. During scientific research, no copies of the data stored may be made that include personal identification data. The use of data and the authorisation procedure for medical research on human subjects are governed by the stricter provisions laid down in Act CLIV of 1997 (the Act on the Protection of Human Subjects). **Proposal / Conclusion:** **Developing a data sharing infrastructure, the process of data extraction and sharing, and the regulation of patient consent for research purposes, balancing business and health promotion and prevention interests.**	The rules on the treatment of and access to health data as sensitive data in Hungary strictly limit access to and transmission of the data, ensuring a high level of data protection. The regulation is based on the GDPR and the Infotv. and sectoral regulations (Eüak., Eütv.). **Proposal / Conclusion:** **Areas of legislation to be developed to protect data sovereignty include the transfer and management of health data abroad, the development of the information and consent process, and the role of ethics committees.**	
BG	Diff.: Yes ☐ No ■	In Bulgaria, "health information" is a category of personal data that includes information about a person's health, similar to the definition in the GDPR. The term "medical information" does not have a legal definition.	Diff.: Yes ■ No ☐	General data protection legislation applies, including the principles of purpose limitation and lawfulness. The provisions of the Personal Data Protection Act apply, which allow for the secondary use of personal data for scientific research, statistical purposes or the National Archives.	Diff.: Yes ☐ No ■	The national legislation on clinical trials (Medicinal Products in Human Medicine Act and Ordinance No. 31) defines the actors and responsibilities for data sharing, but there is no specific provision for data sharing in the field of R&D.	Diff.: Yes ☐ No ■	There is no data localisation requirement in Bulgaria. The general GDPR rules on data storage and processing apply, and data transfers must take into account the requirements for data transfers to third countries.
CH	Diff.: Yes ☐ No ■	In Swiss law, the term "personal health data" is used to include any information that may indicate the physical or mental health of an individual, including the results of medical examinations and genetic data. The Human Research Act (HRA) gives a similar definition of health data, but also covers genetic data. There is no legal definition of 'medical data', but health data should be understood in a broader sense than 'medical data'.	Diff.: Yes ☐ No ■	It is important to distinguish between the secondary use of health data for research purposes and the general use of data in Swiss law. Data protection laws, such as the FADP, contain specific provisions on data processing for research purposes, which facilitate research if certain conditions are met. The Human Research Act (HRA) applies to such research and requires consent of individuals to the use of their data, in some cases no objection is sufficient, provided it is approved by an ethics committee.	Diff.: Yes ☐ No ■	For data sharing for research purposes, the relevant articles of the Human Research Act (HRA) apply. Anonymisation or encryption is usually required for further use of the data. Data sharing for other purposes is only possible if there is a legal basis or informed consent.	Diff.: Yes ☐ No ■	The Human Research Act (HRA) requires individuals to give consent to the transfer of biological material or genetic data abroad. The transfer of non-genetic health data abroad for research purposes is permitted if the relevant requirements of the Data Protection Act (FDPA) are met, for example, by ensuring an adequate level of data protection or by obtaining the consent of the individual.
CZ	Diff.: Yes ■ No ☐	In the Czech Republic, the term "medical condition information" is used, which is regulated, for example, by Act 372/2011. The processing of medical data is regulated by the GDPR and Act 110/2019 on the protection of personal data.	Diff.: Yes ☐ No ■	In July 2023, the Czech Ministry of Health approved the project "Secondary Use of Health Data", which aims to develop a legal and organisational framework and is expected to be completed by the end of 2025. The project aims to develop a legal framework for secondary data use.	Diff.: Yes ☐ No ■	Data processing in clinical trials is governed by the GDPR and EU Regulation 536/2014, as well as the Czech Ministry of Health Regulation 463/2021, which requires the subject of the clinical trial to be informed about the processing and to sign a consent form.	Diff.: Yes ☐ No ■	No specific data localisation requirements are mentioned, but the processing of personal data is strictly regulated under GDPR and Czech law.

DE	Diff.: Yes ☐ No ■	There is no German-specific definition of "health data", the definition in Article 4(15) GDPR applies. "Medical data" is not a defined concept in German law. If "medical data" relates to an individual, it is considered "health data" as defined above.	Diff.: Yes ■ No ☐	The National Health Data Usage Act (GDND), which entered into force in March 2024, regulates the secondary use of health data, allowing healthcare institutions to process it for quality assurance, patient safety, medical, rehabilitation, nursing research and statistical purposes. In addition, Section 27 of the Federal Data Protection Act (BDSG) allows the processing of special categories of personal data for research purposes without consent if the interests of the controller significantly outweigh those of the data subject.	Diff.: Yes ☐ No ■	The legal basis for the processing of data in clinical trials is usually explicit consent under Article 9(2)(a) of the GDPR. Sponsors and trial sites are usually joint controllers (Article 26 GDPR), but in exceptional cases trial sites may also be considered as data processors (Article 28 GDPR), and their role is defined by their involvement in the design and implementation of the trial protocol.	Diff.: Yes ☐ No ■	As regards data sovereignty, the general principles of the GDPR apply.
ES	Diff.: Yes ☐ No ■	In Spain, the definition of "health data" is equivalent to the definition of "data concerning health" in Article 4(15) of the GDPR. The term "medical data" does not have a legal definition, but there is a concept of "health record", which contains data on the patient's condition and clinical evolution.	Diff.: Yes ☐ No ■	A supplementary provision of the Spanish Organic Law 3/2018 (LOPDGDD) regulates the secondary use of health data, which is defined as further processing. Secondary use is possible under various conditions, for example for health research purposes.	Diff.: Yes ☐ No ■	The rules on data sharing for clinical trials and R&D are set out in the LOPDGDD. Data processing is usually based on the consent of the data subject, but there are specific situations where data can be processed without consent, for example in public health emergencies or where data are pseudonymised.	Diff.: Yes ■ No ☐	There is no specific concept of data sovereignty, but the Spanish Data Protection Agency recommends the use of advanced techniques such as federative learning to protect data, as well as the use of design and default protection to ensure data sovereignty.
FR	Diff.: Yes ☐ No ■	The concept of health data in French legislation refers to a set of personal data relating to a person's physical or mental health, including health services and information about the person's state of health. The term "medical data" is not defined in French law.	Diff.: Yes ■ No ☐	The French national legislation on the use of secondary health data requires compliance with the rules on the processing of personal data. Patients must be informed, there must be a legal basis, and the exceptions in Article 9 of the GDPR must be applied, unless the data are anonymised. The secondary purposes must be compatible with the original, primary data processing purposes. In France, data from the SNDS database may be used for research purposes if it is not possible to identify the data subjects.	Diff.: Yes ☐ No ■	Article L. 1124-1 of the French Public Health Code regulates the sharing of data on clinical trials. The processing of clinical trial data relating to medicinal products is subject to authorisation by the CNIL, pursuant to Article 76 of Law No 78-17 of 6 January 1978, as amended. In addition, the sharing of clinical trial data is also subject to the provisions of the GDPR.	Diff.: Yes ■ No ☐	Data sovereignty is primarily guaranteed by the GDPR. The Law of 21 May 2024 No. 2024-449 on the "Provision and Regulation of the Digital Space" contains several provisions on data sovereignty, such as obligations to protect public administrations, economic operators and public interest groups, including the Health Data Centre, against extra-territorial legislation.
GB	Diff.: Yes ☐ No ■	There is no specific legal definition of "medical data" in the United Kingdom. Under the GDPR, "health data" is considered a special category of data, referring to personal data related to the physical or mental health of individuals.	Diff: Yes ☐ No ■	The Data Protection Act 2018 and the UK GDPR are the primary laws regulating the secondary use of health data in the United Kingdom.	Diff: Yes ■ No ☐	Data sharing is regulated by several organizations, such as the MHRA (Medicines and Healthcare products Regulatory Agency) and the HRA (Health Research Authority). The Caldicott Principles and the National Data Guardian also play important roles in safeguarding data and ensuring its proper use.	Diff: Yes ■ No ☐	In 2023, NHS England assumed responsibility for digital technology, data management, and healthcare service delivery, which also includes the protection of data sovereignty.
IE	Diff: Yes ☐ No ■	"Health data" is defined under both the GDPR and the Irish Data Protection Act. There is no specific regulation, but the two terms have different meanings within the legislation.	Diff: Yes ■ No ☐	The secondary use of health data is regulated by the GDPR and the Irish Data Protection Act.	Diff: Yes ■ No ☐	"Health research," which includes clinical trials, is regulated by the Irish Data Protection Act and its implementing regulations.	Diff: Yes ☐ No ■	The Irish Data Protection Act protects data sovereignty in accordance with GDPR provisions.

IT	Diff: Yes ■ No ☐	Under Italian law, there is no distinction between "health" and "medical" data concerning personal data protection. Both fall under the category of personal data as defined by the GDPR, and the specific data processed depends on the purpose of the data processing.	Diff: Yes ■ No ☐	Previously, the Italian data protection law (Privacy Code) imposed strict requirements for the secondary use of health data, including the explicit consent of the individuals concerned and prior approval from the "Garante". However, a recent amendment has relaxed these requirements, allowing secondary use with the approval of the relevant ethics committee, without prior approval from the "Garante", except in high-risk cases.	Diff: Yes ■ No ☐	Data sharing depends on the contractual structure of clinical trials. Under Italian law, the sponsors of trials and the research hospitals are independent data controllers, and their rights and obligations are defined in the national standard clinical trial contract.	Diff: Yes ☐ No ■	Data sharing within the EU is generally not restricted. Transfers of data outside the EU are governed by Chapter V of the GDPR, and the Privacy Code stipulates that specific regulations may apply to data processing for national security and defence purposes.
LT	Diff: Yes ☐ No ■	The definition of 'health data' is based on the GDPR. The term 'medical data' is not specifically defined in Lithuanian law, but it is often used as a general category that includes, for example, medical histories and diagnoses.	Diff: Yes ☐ No ■	In Lithuania, the 'Law on the Secondary Use of Health Data,' which came into effect on July 1, 2022, regulates the conditions and framework for the secondary use of health data.	Diff: Yes ■ No ☐	The requirements for the processing of personal data in the case of biomedical research are regulated by the law titled 'Ethics in Biomedical Research.' The protection of health information, especially regarding data stored in biobanks, is also regulated, and data sharing can only occur with the appropriate permissions.	Diff: Yes ■ No ☐	Although there are no specific data localization requirements in Lithuania or the EU, permissions for the secondary use of health data can only be granted to legal or natural persons operating in Lithuania, which limits the opportunities for foreign entities.
LU	Diff: Yes ☐ No ■	The processing of health data is subject to the GDPR and local regulations, but there is no specific definition for the term "medical data."	Diff: Yes ☐ No ■	The legal basis for secondary use is provided by the GDPR and local data protection laws, with particular emphasis on purpose limitation and the consent of the data subject.	Diff: Yes ☐ No ■	A separate consent declaration is required for research projects related to secondary use, and the data must be anonymized whenever possible before transmission.	Diff: Yes ☐ No ■	Ensuring the security and confidentiality of data is mandatory by complying with data protection regulations, especially when the data is to be transmitted outside the EU.
PL	Diff: Yes ■ No ☐	In Poland, the fundamental concept is "medical documentation," which includes the patient's health records, including electronic health data. "Individual medical data" encompasses any data processed about the patient by medical institutions and pharmacies, containing information related to the patient's health status.	Diff: Yes ■ No ☐	The existing regulations allow for the scientific use of medical documentation in an anonymous manner and provide access to the data of medical records for scientific research and statistical purposes. EU regulations, such as the Data Governance Act (DGA) and the GDPR, are also applicable.	Diff: Yes ■ No ☐	General data protection regulations apply to data sharing, and the patient's consent is required for the use of data for research and R&D purposes.	Diff: Yes ☐ No ■	Medical documentation and data are subject to detailed national regulations that govern their processing and storage, and access to the data is strictly limited.
RO	Diff: Yes ☐ No ■	There is no explicit regulation in Romania that distinguishes between health data and medical data.	Diff: Yes ■ No ☐	There is no specific regulation; however, various laws, such as those related to clinical trials, scientific research, and education, may be relevant in this context.	Diff: Yes ☐ No ■	Data sharing in Romania is primarily governed by the GDPR and EU Regulation 536/2014, as well as national legislation (e.g., Law No. 95/2006, Law No. 46/2003, and GEO No. 29/2022).	Diff: Yes ■ No ☐	General data protection laws, such as those concerning the protection of personal data, are applicable in this case.

UA	Diff: Yes ■ No ☐	There is no clear distinction between "health data" and "medical data" in Ukrainian law.	Diff: Yes ■ No ☐	There is no specific regulation regarding the secondary use of health data. General data protection rules apply, including the necessity of processing data for specific and lawful purposes, as well as the explicit consent of the data subject.	Diff: Yes ■ No ☐	There is no specific regulation for R&D, but in the case of clinical trials, data sharing is based on the informed consent of the data subject, which includes the purpose of data processing and sharing data with third parties.	Diff: Yes ■ No ☐	General data protection rules and the data management requirements of the health electronic system are applicable, including information security regulations.
TR	Diff: Yes ☐ No ■	"Health data" refers to information concerning the physical and mental health of natural persons and is classified as special data under the regulation on the processing of personal health data. "Medical data" is not specifically defined but is generally considered a subset of health data that includes information specifically related to medical examinations, diagnoses, treatments, and medical records.	Diff: Yes ■ No ☐	Although there is no specific regulation for the secondary use of health data, the Personal Data Protection Law (KVKK) regulates the processing of health data, including secondary use. The secondary use of data requires that the data be processed anonymously, ensuring that the data cannot be identified.	Diff: Yes ☐ No ■	The processing of health data, as special data, is only permitted under certain conditions, such as with the explicit consent of the data subject or legal authorization. In clinical research and R&D, compliance with the provisions of the KVKK regarding data sharing is required, as well as obtaining permission from the Turkish Data Protection Board for cross-border data transfer.	Diff: Yes ■ No ☐	When processing the health data of Turkish citizens, the provisions of the KVKK and other relevant regulations must be observed, especially in the case of cross-border data transfer. Data controllers must register in the Data Controllers Registry System and adhere to additional security measures regarding the processing of special data.

Appendix 2.

AmCham Hungary's Position on the State of Collaboration Between Universities and the Private Sector

Introduction

The American Chamber of Commerce conducted a series of interviews involving medium, small, and startup companies, universities, and even representatives of the National Research, Development and Innovation Office (NKFIH) to assess the current level of collaboration between businesses and higher education institutions. These aimed to identify areas where there is potential for improvement.

Background

To ensure Hungary's long-term competitiveness, it is essential to establish a well-functioning, globally robust ecosystem comprising education, research, and innovation. In a modern economic environment higher education institutions play a key role as they are connected to our member companies on several levels. These include labor supply, collaboration on innovation projects, the marketing of innovation outcomes, and the possibility of financial and corporate venture investments in startup companies.

From the perspective of our members, the efficiency of the education system is primarily demonstrated by how well it prepares future employees for the challenges of the labor market (or challenges as an entrepreneur) and how much added value they can generate for their employers (or their investors). In order to increase – or even maintain – the economy's competitiveness, a highly educated workforce equipped with modern knowledge and skills is indispensable.

In 2021, the introduction of the new higher education operation model brought significant transformation to Hungarian universities. One of the primary goals of the process was to create a more favorable regulatory and economic environment for cooperation between higher education institutions and the business sector.

Observations & Recommendations

I. We welcome the government's long-term goal of creating a more flexible and predictable operational environment for higher education institutions by restructuring them into a foundation model. We understand that this was aimed at raising the quality of education and to make Hungarian higher education more competitive.

II. According to our general experience since the model change, higher education institutions are more open to collaborating with the business sector as well as to teaching Business 101 courses at non-business faculties. This practice-oriented knowledge can complement theory in other areas and make the knowledge of students more marketable. The disposition of the foundation over its own assets can give increased freedom in managing finances, and provides options for more flexible procedural and procurement rules – all of which are highly conducive to cooperation with the private sector.
However, the composition of the board of trustees often resulted in strong informal ties to the government, which has harmed the institutions' international network – as evidenced by the

multiple suspended international programs. To maintain societal credibility, it should be required for the boards to maintain a balance of members with sufficiently diverse backgrounds and experiences. Representation should extend to those who have practical knowledge about the institution (e.g. academics and researchers) as well as independent financial, business, legal, and other professionals.

III. One of the main barriers to innovation at universities is that educators and researchers simply do not earn enough solely by their regular work to ensure a comfortable living and therefore are forced to work second jobs or seek other paying activities. As a result, many are discouraged to rely only on their main profession for their income and are trying to monetize their innovations outside of the university. To counter this effect, we recommend making the remuneration for those working in higher education more competitive, irrespective of the university's operating model. Incentives for the practical, industry applicability of research outcomes must also be incorporated into the compensation system. It would also be prudent if university higher management were also evaluated based on the degree to which their institutions can operate independent of state-provided funding (e.g., through licensing fees or share dividends).

IV. It would be necessary to implement a program aimed at simplifying the administrative processes of universities and reducing administrative burdens, both in the day-to-day operation of universities and in cooperation between universities and companies.

V. Despite being evidently open to collaborate with businesses, the actual efficacy of joint initiatives vary widely from institution to institution. To improve the situation, we find it crucial to establish a unified, easily accessible framework that helps businesses map and utilize the services of higher education institutions. This may also speed up processes, helping with the meeting of market milestones and deadlines. We also recommended that a comprehensive university competency map be developed and continuously maintained, enabling business partners to easily find the research facilities and departments that align with their specific cooperation goals. In addition, the efficient marketing and promotion of institutional capacities (e.g. by publishing and promoting success stories) would also help greatly.

VI. To support a unified institutional framework, we also recommend employing dedicated project managers as well as fostering a project management mindset among university personnel working in the business coordination function. It would be beneficial for management to encourage a marketing and sales-based mindset and entrepreneurial spirit among staff.

VII. During the interviews, there were many mentions of cases where research outcomes (e.g. a new innovation) that was generated within a university were “smuggled outside” of the institution through alternative channels cutting its access to profits. This is despite the fact that the university provided the infrastructure that made the research possible. To prevent this abuse of the system, we propose implementing conflict of interest clauses for university educators and researchers in addition to the proposed income increase measures outlined in Section III. We also encourage

that promising research results be kept confidential until they can receive appropriate legal protection.

VIII. We have also observed that some universities fail to consider the practical value of potential research outcomes and select avenues that may not generate much interest from the private sector. This is due to a kind of "research imperative" to focus on areas most likely to receive domestic and EU grants. University management employs this strategy to complement the institution's income to meet a very tight institutional budget.

One possible solution is to have publicly financed research pre-approved by an advisory board comprising individuals with backgrounds in industry and civil society. This approach would require the consideration of the potential applicability of research outcomes rather than just the publication potential in scientific journals. We believe that aligning the career path of university educators and researchers with their peers working in private sector R&D, would significantly increase the number of marketable research outcomes from universities. This would also ensure that university researchers are aware of industry trends and the needs of business actors.

IX. Besides market-oriented research, it is essential to give room for basic research as well, since this is where the potential for "breakthrough" innovations lie. Basic research is also necessary to provide academic freedom, which is central to the attractiveness of the researcher career path for aspiring academics.