



STRATEGIC REPORT

By  **TECHTOMED**

SECONDARY USE OF HEALTH DATA COMING FROM DIGITAL DEVICES

2025

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About the authors

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Methodology

DISCLAIMER: This strategic report presents the main collaborations but is not exhaustive due to the significant number of advances, new technologies, programs or partnerships in the field of digital health. Also, the collaborations presented are recent or ongoing. Other collaborations were excluded.

 **The methodology is based on desk research and selected experts interviews**

Desk research: websites from institutions and private companies, press releases, specialized journals and newsletters, books and publications

Used keywords: pseudonymization, anonymization, reuse of digital health data, confidentiality, real world evidence, IoT, GDPR

Key experts ITW from Academics, DataScience companies, Institutions, lawyers & legal, Private Medtech and Pharma, Tech companies, others Private sector as automotive / aviation industries

Research period: 2024 – 2025

Language: English

Number of pages: X

Interviewees



Editorial : Why a dedicated report?

In an era defined by technological advancements, the role of health data generated by digital devices has become a cornerstone of modern healthcare innovation. Beyond its primary use in patient care, the secondary utilization of this data offers transformative opportunities to improve public health, drive research, and optimize healthcare delivery.

Digital devices—ranging from wearable fitness trackers to sophisticated medical-grade tools—generate vast volumes of real-time data. When aggregated and analyzed, this information can illuminate patterns and trends that were previously inaccessible. For example, longitudinal data on heart rate variability or blood glucose levels can inform predictive analytics, leading to earlier interventions and reduced healthcare costs.

Secondary use also propels research forward. The integration of real-world evidence from digital devices into clinical trials enhances the diversity and scope of study populations, increasing the generalizability of findings. Furthermore, healthcare systems can leverage these insights to design population health strategies, addressing challenges such as chronic disease management and health equity.

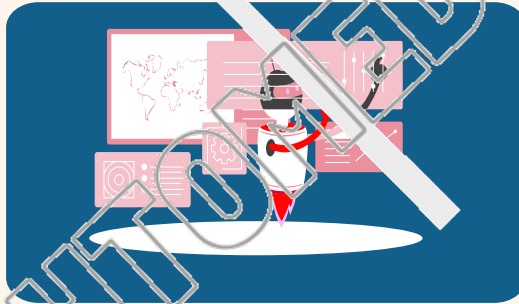
However, harnessing this potential is not without challenges. Privacy concerns, data interoperability, and regulatory compliance remain significant hurdles. Addressing these issues requires a balanced approach that prioritizes patient consent and data security while fostering collaboration among stakeholders.

In today's practice, the secondary use of digital health data is not just an opportunity—it is a necessity. It offers a path to more personalized, efficient, and equitable healthcare systems. As this domain evolves, it will be crucial to align technological innovation with ethical frameworks to ensure that the benefits of this data revolution are realized for all.

SUMMARY

DEFINITIONS

- Glossary of key terms
- Overview of health data acquisition technologies



SECONDARY USE OF HEALTH DATA

- Overview of digital devices
- Examples of consortium, partnerships and initiatives



LEGAL, ETHICAL AND REGULATORY ISSUES

- A legislation in favor
- Regulation basics
- Anonymization and pseudonymization

USE CASES

- Opportunities for industries
- Real-world examples

How to read this report : SCORE CARD example

Principal category

Sub category

Infography

Source with the direct link to the document

These stakeholders have developed different business models related to the secondary use of health data

MODELS BASED ON DATA ACCESS

The most direct model is charging for the access to the databases. This model has two options :

- A subscription model with clients paying a recurrent subscription for access to the database. The value is dependent on the quality and completeness of the datasets.
- A usage-based model in which clients pay a fee based on the use they make of the database (e.g.: number of requests, volume of data downloaded, etc.)

MODELS BASED ON DATA TRANSFORMATION

They players create value by transforming raw data into insights. They charge for their services on a project-basis :

- Structure and standardization services including transforming a non-structures database into a structured one, standardizing data to FHIR or OMOP international standards, etc.
- Data analysis and insights generation services such as applying machine learning models to conduct predictive analysis.

VALUE-BASED DATA MODELS

These business models tie their compensation to the value created for the client. For instance, they can be based on royalties on the discoveries facilitated by their services.

A similar model bases the compensation on the results generated, such as improve the efficacy of hospital management, reducing the number of readmissions, etc.

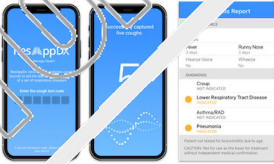
These models are less common and often used in complement with other business models.

INNOVATIVE MODELS

In recent years, new business models have been developed including :

- Platform models such as that of the 'DH.
- Consortium models, often used in research setting to pool together resources and share the benefits.

Voice-based technologies

Type of technology	Data source	Possible data types	Example
Voice-based technologies	Voice-Based Pathology Detection	Voice frequency patterns, vocal tremor measurements, speech rhythm analysis, pronunciation clarity, voice onset time, harmonic-to-noise ratio, jitter measurements, shimmer values, phonation time, vocal fatigue indicators, breathing patterns, voice quality metrics, speaking rate, vocal strain markers, acoustic biomarkers	Sonde Health Platform 
	Cognitive Disorder Analysis	Speech fluency metrics, vocabulary complexity, semantic coherence, word-finding difficulty, grammatical accuracy, response latency, verbal memory patterns, linguistic complexity, attention indicators, cognitive processing speed	Winterlight Labs Analyzer 
	Emotional State Monitoring	Voice stress indicators, emotional valence, arousal levels, mood patterns, prosodic features, speech energy, conversational engagement, emotional expressivity, voice modulation, social interaction patterns, anxiety markers, confidence levels, fatigue indicators, emotional stability metrics	Cogito Dialog 
	Early Respiratory Disease Detection	Cough sound analysis, breathing pattern recognition, respiratory rate, breath sound characteristics, wheeze detection, bronchi measurements, vocal cord function, air flow patterns, speech effort levels, respiratory fatigue indicators, upper airway sounds, bronchial sounds, voice quality changes, respiratory cycle timing	ResApp Health Diagnostic (acquired by Pfizer) 
	Speech Disorder Monitoring	Articulation accuracy, phonological patterns, speech rhythm metrics, stuttering frequency, prosody measurements, speech rate variation, pronunciation patterns, voice onset time, syllable duration, speech intelligibility scores, language development markers, therapeutic progress metrics, disfluency patterns, communication effectiveness	Verboso Analytics 

Report to unite ecosystem players to free up secondary use of healthcare data – dec 23



'The significant potential for re-using France's rich heritage of healthcare data is still under-exploited in a competitive international context.'
'Data reuse projects could be abandoned or significantly delayed by a lack of clarity on the rules governing the use of data, by the variability in pricing methods, and by long negotiation times.'



Cf slide 31

2.4 Creating the conditions for optimal secondary use of healthcare data

2.4.3.2 Establish a body of rules concerning the use of data

Two data pricing grids have been shared by two hospital health data warehouses (AP-HP and HUGO) to identify the main costs involved in providing data to a project developer in order to generate pricing based on these costs in line with the Data Government Act.

The calculation of costs is based on the measurement of the man-hours required for contracting at each stage of the project (examination of project feasibility and specifications, administrative and regulatory files, etc.), and on the application of man-day rates based on a common salary scale (varying according to the profiles of the resources concerned).

➔ Recommendations:

1. Establish a single fee schedule, adopted by the regulatory authority and enforceable against all data producers (e.g. in Finland's Findata with a public fee schedule adopted by decree that breaks down the fee into data access license, the cost of extractions and provision of data by the data producer, costs associated with the data pseudonymization and anonymization process (with the application of hourly flat-rate financing) and the cost of remote access to the secure environment. This single pricing scale incorporates rate adjustments based on the customer's profile (university, SME, ...).
2. Maintain the existence of several reference pricing grids (two to three), under the aegis of the strategic committee for health data, from which players could choose.

4.4.3. Consider the possibility of using data from My Health Space for secondary purposes

The current impossibility, in France, of using health data entered into the digital health space (ENS) and the shared medical record (DMP) - a component of the ENS - for purposes other than those for which they were collected, i.e. 'to promote prevention, coordination, quality and continuity of care' (article L 1111-14 du CSP)

➔ Recommendations:

1. The reuse of data entered in digital health spaces for research purposes is made possible with the **express consent** of the person concerned to enter it in his or her health space
2. Provide information to holders of digital health spaces on the benefits of reusing health data for research purposes.

The Data Governance Act seeks to increase trust in data sharing

The Data Governance Act seeks to increase trust in data sharing, strengthen mechanism to increase data availability and overcome technical obstacles to reuse data.



BENEFITS

- **Make more data available and facilitate data sharing across sectors and EU countries** in order to leverage the potential of data for the benefit of European citizens and businesses. *Example:* Good data management and data sharing will enable industries to develop innovative products and services, and will make many sectors of the economy more efficient and sustainable. It is also essential for training AI systems.
- **Data driven innovation will bring benefits for companies and individuals.** *Example in health data:* improving personalized treatments, providing better healthcare, and helping cure rare or chronic diseases, saving approximately €120 billion a year in the EU health sector

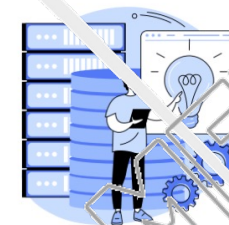
IN PRACTICE

The EU will boost the development of trustworthy data-sharing systems through 4 broad sets of measures:

- 1 **Mechanisms to facilitate the reuse of certain public sector data that cannot be made available as open data.** *Example:* the reuse of health data could advance research to find cures for rare or chronic diseases.
- 2 **Measures to ensure that data intermediaries will function as trustworthy organisers of data sharing or pooling within the Common European Data Spaces.**
- 3 **Measures to make it easier for citizens and businesses to make their data available for the benefit of society.**
- 4 **Measures to facilitate data sharing,** in particular to make it possible for data to be used across sectors and borders, and to enable the right data to be found for the right purpose.

IMPACT ACROSS THE EU

The Regulation will allow the EU to ensure that it is at the forefront of the second wave of innovation based on data.



Businesses will benefit from a reduction in costs for acquiring, integrating and processing data, and from lower barriers to enter markets.



Businesses will also see a reduction in time-to-market for novel products and services.

How to choose between anonymization and pseudonymization?

The choice between anonymization and pseudonymization results from a compromise between the following questions:

1. Is it necessary to preserve the fineness of the data at the level of the individuals making up the dataset?
2. Is it necessary to be able to share the dataset simply and widely?

When to opt for anonymization?

When the use does not justify identifying data, or when it is more important to enable data to be shared widely and easily (not related to GDPR).

Examples of use:

- Generic statistics (e.g. population statistics)
- Wide exploitation via data challenges
- Open data sharing to ensure reproducibility of research for example

Drug ID	Age group	Period	Patient count
A	20-30	Q1 2020	225
A	30-40	Q1 2020	137
B	20-30	Q2 2020	51

Example of an anonymized dataset

When to opt for pseudonymization?

When it is more important to preserve the acuteness of the individual information making up the dataset while limiting the risks associated with its processing

Examples of use:

- Studies requiring detailed data on an individual level (e.g. study of individual pathways)
- Matching of datasets using individual information (e.g. masked social security number)

Patient ID	Birth date	Drug ID	Date
E321004D	1993/07	A	2020/01/04
F121004D	1993/07	B	2020/05/23
FE1003O	1974/01	A	2020/01/05

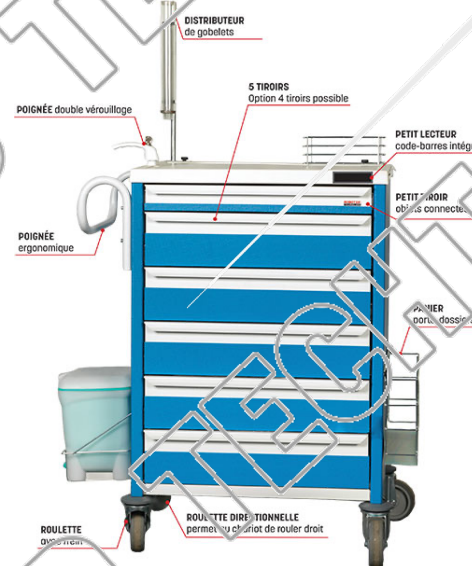
Example of a pseudonymized dataset

Healthcare application for connected objects: e-hospital

Video-conferencing telemedicine cart, with battery, with ECG, with stethoscope, with pulse oximeter, with ultrasound probe, with blood pressure monitor, height-adjustable, with drawer, safe



E-cart



Bluetooth medical sphygmomanometer, Bluetooth pulse oximeter
Automatic measurement of heart rate and arterial oxygen saturation

Calculation or rapid entry of other main emergency parameters: **temperature, blood glucose, respiratory rate, Glasgow score, visual analog scale**

- Automatically generates a summary of vital signs data
- Transmits and archives this information in the patient's file

→ **Direct measurement of vital parameters via Bluetooth-connected medical devices**

Connected MRI



Technology to guide and support the HCP

Data transfer

Positive distractions for the patient

Glucometer



Blood pressure monitor



Oximeter



Secondary use of health data for drug research and development

STRATEGIC VALUE PROPOSITION

Enhanced Disease Understanding

- Continuous real-world physiological data collection
- Multi-parameter correlation analysis
- Natural history of disease documentation
- Identification of novel biomarkers
- Better understanding of disease subtypes and progression

R&D Process Optimization

- More efficient patient stratification
- Enhanced endpoint measurement
- Reduced trial costs and duration
- Better protocol design
- Early efficacy signals detection

KEY DATA SOURCES AND THEIR APPLICATIONS

Therapeutic Area	Connected Data Sources	Strategic Applications
Oncology	• Wearable Devices: Smart patches (temperature, activity, sleep patterns), connected rings (heart rate variability, temperature) • Smart Home Technology: Connected mattresses (sleep quality, movement patterns), environmental monitoring (air quality, temperature), smart toilets (early detection markers) • Vehicle-Based Monitoring: Driver alertness systems (cognitive function), seat sensors (weight changes, posture)	• Early detection biomarker development • Treatment response monitoring • Side effect early warning systems • Patient quality of life assessment • Lifestyle impact analysis • Environmental exposure correlation • Treatment tolerance prediction
Rare Diseases	• Advanced Home Monitoring: Motion sensors (gait abnormalities, tremors), connected furniture (mobility changes), smart mirrors (physical manifestations) • Wearable Systems: Smart textiles (physiological parameters), connected insoles (gait analysis), smart glasses (visual symptoms) • Vehicle Integration: Driving behavior analysis (neurological symptoms), cabin sensors (physiological responses) • Voice Technology: Speech pattern analysis (disease progression), breathing pattern recognition	• Natural history documentation • Symptom pattern identification • Disease progression mapping • Novel biomarker discovery • Phenotype classification • Early diagnosis indicators • Treatment response patterns

Focus : Verily's Project Baseline

       	<table><tr><td>Partners</td><td>Project Baseline is a collaborative effort led by Verily Life Sciences (formerly Google Life Sciences), in partnership with Duke University School of Medicine, Stanford Medicine, and the California Health and Longevity Institute. In 2019, Novartis, Otsuka, Pfizer, and Sanofi joined Project Baseline.</td></tr><tr><td>Timeline & Scope</td><td>Launched in 2017, the Project Baseline Health Study is a multi-year longitudinal study designed to enroll approximately 10,000 participants across the United States over a four-year period.</td></tr><tr><td>Primary Goals & Objectives</td><td>Map human health through longitudinal, multi-modal data Deep phenotyping for cardiovascular, metabolic, neurological, and other diseases</td></tr><tr><td>Data Sources & Technologies</td><td>Classical: The study collects data from electronic health records (EHRs) of partner health systems, laboratory measurements, and imaging data. Connected Devices: Participants utilize the Verily Study Watch, equipped with ECG and inertial sensors, as well as other devices and a Baseline Platform for data integration and analysis</td></tr><tr><td>Therapeutic Focus / Use Case</td><td>Broad coverage (cardiovascular, metabolic, neuro) Discovery of digital biomarkers and disease progression insights</td></tr><tr><td>Implementation Approach & Model</td><td>Participants wear the Study Watch while also sharing clinical records + personal logs Continuous physiologic signals layered atop historically captured lab/imaging data, enabling robust analytics</td></tr><tr><td>Key Takeaways & Relevance</td><td>Demonstrates integrated approach (EHR + advanced wearables + environmental) Enables deep phenotyping and RWE generation for multiple disease states Fosters a collaborative ecosystem among academia, healthcare providers, and tech innovators</td></tr></table>	Partners	Project Baseline is a collaborative effort led by Verily Life Sciences (formerly Google Life Sciences), in partnership with Duke University School of Medicine, Stanford Medicine, and the California Health and Longevity Institute. In 2019, Novartis, Otsuka, Pfizer, and Sanofi joined Project Baseline.	Timeline & Scope	Launched in 2017, the Project Baseline Health Study is a multi-year longitudinal study designed to enroll approximately 10,000 participants across the United States over a four-year period.	Primary Goals & Objectives	Map human health through longitudinal, multi-modal data Deep phenotyping for cardiovascular, metabolic, neurological, and other diseases	Data Sources & Technologies	Classical: The study collects data from electronic health records (EHRs) of partner health systems, laboratory measurements, and imaging data. Connected Devices: Participants utilize the Verily Study Watch, equipped with ECG and inertial sensors, as well as other devices and a Baseline Platform for data integration and analysis	Therapeutic Focus / Use Case	Broad coverage (cardiovascular, metabolic, neuro) Discovery of digital biomarkers and disease progression insights	Implementation Approach & Model	Participants wear the Study Watch while also sharing clinical records + personal logs Continuous physiologic signals layered atop historically captured lab/imaging data, enabling robust analytics	Key Takeaways & Relevance	Demonstrates integrated approach (EHR + advanced wearables + environmental) Enables deep phenotyping and RWE generation for multiple disease states Fosters a collaborative ecosystem among academia, healthcare providers, and tech innovators
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IDENTIFIED USE CASES

DOs & DON'Ts for industrials

Regarding the complexity of the subject, we interviewed several experts to understand at a deeper level the challenges of secondary use of health data



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