CONNECTED REAL-WORLD DATA

LIGHTENING GREY ZONES IN HUMAN HEALTH

CONTENTS

Connected real-world data offers insights complementary to the information gathered in clinical settings, thus contributing to a holistic understanding of patients' conditions and pathways.

Data from mobile applications, wearables, and other connected objects, as well as self-reported patient data, can be used to augment and accelerate drug development and clinical practice by rendering them more patient-centric.

1 REAL-WORLD DATA: SOURCES AND USE ACROSS THE PHARMA VALUE CHAIN

REAL-WORLD DATA (RWD), INFORMATION ON PATIENT HEALTH STATUS OR HEALTHCARE DELIVERY ROUTINELY COLLECTED FROM A VARIETY OF SOURCES, IS CONSTANTLY GROWING IN VOLUME, DIVERSITY, AND QUALITY.

As per the US FDA definition, real-world data refers to data relating to patient health status and routinely collected from a variety of sources.[1] The digitalization of information treatment, as well as the adoption of technology-driven services in healthcare and wellness, are leading to the generation of an ever-increasing volume and accuracy of RWD.

EXAMPLES OF RWD SOURCES

- ELECTRONICS HEALTH RECORDS
- LAB VALUES & BIOMARKERS DATA
- MORTALITY DATA
- DRUG & DISEASE REGISTRIES
- PHARMACY DATA
- HOSPITALS DATA
- CLAIMS DATA
- SURVEY DATA
- DATA COLLECTED BY PHARMA (observational)
- SOCIAL MEDIA DATA
- CONSUMER DATA
- DATA FROM WEARABLES

The particularity of RWD is that it is empirical by nature, as opposed to clinical trial data collected in controlled settings and not reflecting real-life contexts. RWD is often unstructured, voluminous, dynamic, and heterogeneous in terms of patient conditions and journeys, which makes it prone to incompleteness.[2]

It is important to distinguish RWD and real-world evidence (RWE), which represents clinical evidence about the usage and potential benefits or risks of a medical product that is generated by analyzing RWD. [1] Until recently, RWE main applications were limited to satisfying post-launch regulatory requirements or conducting epidemiologic and observatory studies. However, the growing diversity, quality, and accessibility of RWD have encouraged pharma companies to leverage RWE more broadly across the value chain. While the reproducibility of RWE remains a key topic, it is crucial to integrate RWD in evidence-based decision-making. [3]

EXAMPLES OF RWE APPLICATIONS

1 RESEARCH

- Better understand diseases at molecular level
- Decipher unmet needs and outcomes that matter to patients
- Optimize the generation of research leads and define clinical development strategies

2 CLINICAL DEVELOPMENT

- Facilitate clinical trials design optimization and feasibility assessment
- Accelerate clinical trial execution and enhance its reliability
- Reduce costs and optimize resources allocation for new product development

3 REGULATORY SUBMISSIONS

- Support regulatory strategy and operations: approvals and label expansions
- Project the results of clinical trials in real-world settings to support submission
- Contribute to safety management and adverse event detection

4 MARKET ACCESS

- Support pricing and reimbursement strategy definition
- Refine medico-economic models
- Demonstrate value and facilitate outcome/ value-based contracts implementation

5 MEDICAL AFFAIRS

- Understand and identify the product use and positioning in the real world
- Understand prescription and treatment patterns to improve standards of care and ensure patient safety
- Support cross-functional evidence needs (e.g., answer arising clinical/scientific questions)

In addition, healthcare authorities are growing more receptive to the use of RWE for supporting and clarifying clinical results to inform the regulatory decision-making. Indeed, both the FDA and the EMA accept RWE to support the demonstration of medications safety and efficacy, even if case-by-case analysis is often required to ensure that the used data is fit for purpose. [4], [5], [6]

2 CONNECTED HEALTH IN A NUTSHELL

BOTH THE FOOTPRINT AND THE POTENTIAL OF CONNECTED HEALTH ARE CONSTANTLY EXPANDING WITH THE TREND HAVING ESPECIALLY ACCELERATED IN THE POST-COVID PERIOD.

Digital health, the popularity and importance of which have been rising in recent years, encompasses a wide range of technologies. Thus, according to the FDA, it includes mobile health, health information technology, wearable devices, telehealth and telemedicine, and personalized medicine. [7]
One of the important branches of digital health is connected health – a large set of strategies, products, and services leveraging digital technologies (including software and connected objects) to improve or establish measurable health progress or outcomes. Connected health incorporates digital wellness products and clinically validated solutions. [8] The basis of connected health is formed by software-driven, sensor-based, and patient-focused technologies. [9] The term Internet of Medical Things is also sometimes used to describe the interconnected network of devices and systems used by patients, caregivers, and healthcare professionals. Data generated by such devices and systems is by essence the keystone for leveraging the connected health applications to improve patients' outcomes.

DIGITAL WELLNESS

Consumer solutions enhancing healthy lifestyle or serving health-related purposes

EXAMPLE A wearable delivering wellbeing advice

A Finnish startup Ōura developed a smart ring capturing vital signs and connected to a mobile app, which provides the users with a possibility to track and improve their activity, recovery, sleep, and menstruation cycle. [10]

DIGITAL COMPANIONS

Evidence-based solutions working in conjunction with traditional medical products and measuring or intervening in people's health

EXAMPLE A digital solution for patient support

Since 2022, Happify Health and Biogen are partnering to provide a digital solution for the education and well-being of people living with multiple sclerosis. The solution provides patients with relevant information, peer support, and access to healthcare professionals. [11]

DIGITAL THERAPEUTICS (DTX)

Outcome-based (clinically validated and regulated) digital therapeutic interventions for the prevention, management, or treatment of a medical condition

EXAMPLE Wearables for pain relief

Hinge Health, one of the most highly valued DTx startups, is specialized on joint and muscle pain relief. It combines the access to a clinical care team with motion tracking enhanced by wearable sensors and computer vision, as well as an FDA-cleared device delivering electrical impulses to provide pain relief. [12]

The global digital health market size, currently valued at over $200 billion, was largely boosted by the recent covid pandemic and is expected to reach $1.5 trillion by 2030.[13] For instance, the combined enterprise value of global DTx providers has grown eight times over the past five years, with venture capital funding on the rise, especially in Europe.[14]

To find out more about the ways life science organizations can build a strong connected health portfolio, refer to our recent point of view Transforming connected health.

3 CONNECTED REAL-WORLD DATA

CONNECTED RWD, COLLECTED WITH DIGITAL TECHNOLOGIES MOSTLY IN NON-CLINICAL CONTEXTS, OPENS AN OPPORTUNITY TO GET A 360-DEGREE UNDERSTANDING OF PATIENTS AND THEIR HEALTH PATHWAYS.

Most of the conventional RWD is collected during medical visits. It thus relies on the examinations by healthcare professionals, laboratory tests, or information reported by patients to their physicians. In a way, this means seeing a patient through the doctor's eye and at a specific time and place.

Connected health solutions, on the other hand, open a possibility of collecting health data outside the clinical environment, in the patients' daily life, often at his or her home. The connected RWD illuminates the "blind spots" in the patients' pathways by providing insights on their activity, behavior, attitudes, or treatment adherence. It is thus complementary to traditional RWD as it could help to contextualize the patients' outcomes, thanks to:

- measuring relevant parameters more frequently or better (for example, measuring vital signs every day or even all day and not only during the medical visit), and
- obtaining new data points (for example, obtaining an objective assessment of the quality of sleep, stress level, or cognitive decline).

Connected RWD includes, among else, digital biomarkers – the physiologic, pathologic, or anatomic characteristics of a patient continuously measured via hardware and software – which can serve as objective indicators of normal or pathologic biologic processes or biological responses to a treatment. [15], [16]

DATA FROM MOBILE APPLICATIONS

Data collected from patient's mobile phone

EXAMPLE Everyday activity monitoring for identifying disease symptoms

There is a growing interest in identifying early clinical manifestations of Alzheimer's disease using the sensors of the patient's mobile phone. For example, patients can be asked to perform a fixed distance walking test or to tap a button as fast and as regularly as possible to assess, respectively, their gross motor function or fine motor control. The information on the patient's location and a meta-analysis of his text messages can help to identify depression or anxiety. [17]

Another example in neurodegenerative disorders is Floodlight MS, a science-based smartphone app designed to inform clinical conversations and healthcare provider decisions in multiple sclerosis by collecting objective data on patient function between medical visits. [18]

DATA FROM WEARABLES

Data on patient's behavior and health status generated by a wearable technology

EXAMPLE Data from a wearable for predicting disease course

To improve the understanding of Duchenne muscular dystrophy, researchers collected a digital readout of patients' whole-body movement behavior during daily activities using a bodysuit with sensors. Machine learning algorithms were then applied to predict disease progression. [19]

In another study, wrist- or ankle-worn activity monitors in conjunction with an app for collecting patient-reported outcomes proved relevant for collecting data on amyotrophic lateral sclerosis progression. [20]

DATA FROM OTHER CONNECTED OBJECTS

The readings of connected health and wellness devices

EXAMPLE Data from a connected device for facilitating diagnosis

The French startup Withings is already leveraging the vital signs collected by a connected mattress to identify individuals at risk of sleep apnea, and is currently working on a hands-free connected home urine lab that can be used for multiple biomarker analyses. [21]

Another startup based in Ireland, Head diagnostics, has developed a handheld medical device for the rapid assessment and evaluation of brain impairment and diagnosis of neurological diseases including Parkinson's disease or traumatic brain injuries (concussions). [22]

SELF-REPORTED PATIENT DATA

Data from patients' interactions with conversational agents, peers, or healthcare professionals

EXAMPLE Conversations in patients' communities for drug usage monitoring

Conversations in patient forums and social networks can be analyzed using text mining or natural language processing in order to identify the drugs with which people with terminal disease are experimenting. [23]

Kap code analyzes the patients' conversations about their disease, treatment, and life on social media, thus creating a rich source of RWD. [24]

4 LEVERAGING CONNECTED RWD

CONNECTED RWD IS AN IMPORTANT LEVER FOR DEMONSTRATING THE VALUE OF BOTH TRADITIONAL THERAPIES AND DTX.

As mentioned above, the regulators are growing more receptive to the use of RWE. Thus, the EMA is leading multiple initiatives around RWD quality, discoverability, governance, and proper use, including Data Analysis and the Real-World Interrogation Network (DARWIN EU). [25] [26]

The data from digital companions and DTx can be used for RWE generation post-market authorization.

In late 2019, Germany adopted the Digital Healthcare Act, which defines market access and reimbursement rules for digital health applications. Since then, over 40 digital health applications have been approved. [27] According to experts, leveraging the data generated by such applications in the real world represents a great opportunity for an efficient, agile, and patient-oriented approach to evidence generation. [28]

MORE GENERALLY SPEAKING, BETTER UNDERSTANDING THE PATIENT THROUGH CONNECTED RWD COULD FACILITATE THE SWITCH TO PERSONALIZED MEDICINE.

For several decades, a shift towards patient-centricity has been observed across the patient pathway. Indeed, the characteristics of an individual patient are more and more extensively used to select the right preventive, diagnostic, or therapeutic option.

For instance, in oncology, the overall trend is toward considering the genomics, proteomics, transcriptomics, and molecular imaging in the choice of the treatment protocol to minimize the risks of adverse events while increasing the therapeutic impact. [29] One of the emerging approaches in cancer treatment is chronotherapy, which implies the understanding and use of circadian rhythms. Thus, in the case of chemo- or immunotherapies, the optimal timing of treatment could decrease drug toxicity and increase drug efficacy and tumor response. [30] In this context, the use of connected RWD can be beneficial in understanding the body's biological rhythms and better timing treatment administration. In addition, the analysis of connected RWD on the lifestyle and behaviors of people with cancer could help to identify the quality-of-life biomarkers. [31]

On the other hand, combining conventional health data with different elements of a patient's digital footprint might help to create his or her full health portrait. For example, integrating the data from wearables could help better describe clinically important subgroups in terms of heart rate, step count, and home blood pressure, [32] or better monitor and support patients after discharge post-surgery. [33]

Thus, the US-based startup Medable launched the Human Digitome project, a digital representation of human health based on the combination of data from connected objects and patient-reported data. [34] Even though the company has since specialized in facilitating decentralized clinical trials, [35] a platform like Digitome might have an interesting potential of being used across the healthcare value chain.

One of the possible uses of the accumulated RWD, both traditional and connected, is the development of patient digital twins. Indeed, modelling patients at the gene, cell, tissue, organ, or even behavioral level can help simulate the use of different available diagnostic or therapeutic interventions to select the optimal one.

Patient digital twins – virtual representations of patients based on multimodal data from multiple sources – can be used for in silico testing and the comparison of different therapeutic or preventive interventions to find out which option will work best for each individual. For instance, the avatars of patients can be developed based on the results of medical imaging and then modified using AI techniques to add or explore suspected or diagnosed diseases. Such simulations can help physicians identify the best-performing imaging resources for each individual patient. [36]

Digital twins can also serve for setting up closed-loop optimization schemes aimed at preventing, diagnosing, monitoring, and treating diseases. [37] Thus, a French startup Diabeloop combines continuous glucose monitoring and a connected insulin pump with a machine learning algorithm for optimal insulin dose calculation to create a closed-loop system. [38] Swedish researchers also worked on a proof-of-concept wireless closed-loop system for people with neurological disorders, including breath and gesticulation sensors, as well as an organic electronic ion pump for drug delivery. Of note, machine learning was performed on the data from sensors to better understand and predict events and trends. [39]

The use of digital models of patients based on RWD and existing in a virtual space can fall into the broader category of leveraging the metaverse in a healthcare context. To find out more on the topic, check out our point of view Will the metaverse be part of the future of healthcare?

IN ADDITION, LEVERAGING CONNECTED RWD COULD HELP TO IMPROVE MEDICATION ADHERENCE AND OUTCOMES.

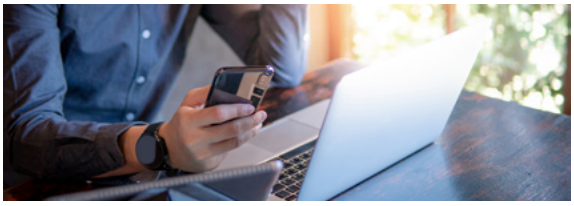
While the adherence to the prescribed treatment remains a grey zone and a significant pain point in the treatment pathways of many diseases, using connected RWD could help better understand and counter this phenomenon.

Indeed, attempts to improve and predict patient adherence using connected objects, such as connected sharp bins, have already been made. [40] At Capgemini, we have also worked to improve the use of medical devices, for instance with a connected inhalator for patients with chronic respiratory conditions, such as asthma or COPD, allowing patients to have the right dose regardless of the strength of the patient's intake of breath. It also minimizes patient error, training, and wasted doses.

5 CHALLENGES TO OVERCOME ON THE WAY TO CONNECTED RWD USE

THE PRACTICES FOR AGGREGATING AND USING CONNECTED RWD ARE STILL EVOLVING, AND THREE MAIN CHALLENGES NEED TO BE ADDRESSED.

DATA QUALITY AND INTEROPERABILITY



The quality of connected RWD might be jeopardized by selection bias (e.g., data describing only people owning a smartphone), inaccurate measurements, or missing data.

In addition, data from several sources might be difficult to combine due to differences in formats, which still exist despite the emerging standards (such as FHIR or OMOP).[41]

COMPLIANCE WITH LEGAL AND ETHICAL NORMS

The health data collected from mobile and connected devices is highly sensitive.

Thus, it is crucial to obtain an informed consent for the collection, use, and re-use of the data.

In addition, providing for data privacy and cybersecurity is of utmost importance.

DATA OWNERSHIP AND BUSINESS MODEL

As of today, health data ownership is rather blur.
In this context, the health and digital companies still need to define:

- **how to compensate patients** for the use of their data;
- **how to ensure that patient data** can be reused after having been collected several years earlier and/or for another purpose;
- **how to monetize the anonymized and aggregated** connected RWD.

Full patient data anonymization is among the most important stakes in the treatment of connected RWD on the crossroads of the challenges linked to compliance, ethics, and data ownership.

Some of the challenges listed above can also be addressed with emerging technological solutions. Thus, data confidentiality questions can be partially tackled by federated learning, a technology that relies on the distributed storage of data used for machine learning. In other words, patients would not need to provide their data but just grant access to it for an algorithm. Blockchain could also be leveraged to securely store connected patient data, as well as to ensure the transparency of this data use. [42]

Another important topic to address on the way to fully leveraging connected RWD is the consolidation of the data coming from different sources. For instance, more and more insulin pens are connectable with continuous glucose monitoring devices to store and monitor both the insulin intakes and glucose levels in one place. This allows people living with diabetes to see how different factors like dose timing and the amount of insulin taken impact their individual glucose patterns. The two individual pieces of information are valuable but, linked together, they provide an additional insight into the impact of both the dosing and timing of injection on glucose levels. Consolidating different data points provides an additional perspective, much like adding another piece to the puzzle allows seeing the overall picture.

More broadly speaking, the consolidation of connected RWD with other medical data, notably electronic medical records, can be beneficial. An interesting benchmark can be seen in Finland, where patients can connect their wellbeing applications to MyKanta, a public online service allowing citizens to store, view, and share the information on their medical appointments, medication, and laboratory test results. [43]

6 MOVING FORWARD: UNLOCK THE POTENTIAL OF CONNECTED RWD

To conclude, the advent of connected RWD opens considerable opportunities for advancing pharmaceutical research and improving clinical practices. On the one hand, connected RWD can be used to showcase the value of the connected health solutions. Even more importantly, connected RWD provides useful information on the patients' profiles and outcomes, thus facilitating the move toward personalized medicine.

While today tech players appear best positioned to concentrate, anonymize, and leverage most of connected RWD, pharma companies should integrate connected RWD in their agendas and rethink their current organization to be more data oriented. The key topics include the following:

- Consider RWD generation potential when defining product development strategy, as well as when building connected health portfolio.
- Think about connected RWD acquisition strategies.
- Mobilize cross-functional teams to work on the topic.

By further working on these and similar topics, pharmaceutical companies can unleash the opportunities of more efficient and personalized care thanks to getting a 360-degree understanding of the patient by leveraging connected RWD.

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