

Real-world data



Real-world data (RWD) is health-related data derived from a diverse human population in real life settings. RWD can be medical health records, registries, biobanks, administrative data, health surveys, observational studies, health insurance data, data generated from mobile applications etc..

The European Commission, through its Framework Programme Horizon 2020 and via the [Innovative Medicines Initiative](#), invests to enable the use of RWD in health and care systems for the benefit of the patients. Notably, the

Innovative Medicines Initiative 2 (IMI2) Programme Big Data for Better Outcomes aims, among other things, at maximising the potential of large-scale, harmonised RWD from variable, quickly-developing digital and non-digital sources, and establishing a health outcomes data ecosystem in Europe (e.g., IMI topic [European Health Data Network](#)).

Two ongoing **Horizon 2020 projects**, [COMED](#) and [IMPACT-HTA](#), will provide methodological guidance on how to use RWD for health economic evaluation as well as for revising the price and reimbursement conditions of a health intervention based on its real-life effectiveness (so-called outcome-based managed entry agreements).

Three ongoing projects of the IMI 2 Programme **Big Data for Better Outcomes**, [ROADMAP](#), [HARMONY](#) and [BigData@Heart](#), will develop the data capacity needed to support the use RWD in three disease areas. Specifically, these projects will develop digital tools and methods to pool, harmonise and analyse heterogeneous sources of RWD to improve care for patients with Alzheimer's disease, blood cancers and heart disease. These projects aim at increasing the value of healthcare delivery by increasing the access to high quality data on patient outcomes, and will help clinical and regulatory decision-making and health economic evaluation.

Why is RWD of interest to medicine? RWD refers to human health-relevant data that is not collected in randomised controlled clinical trials (RCTs). RCTs are the gold standard for ascertaining the efficacy and safety of a therapy. They apply standardised health interventions to patients selected based on strict inclusion and exclusion criteria and are typically restricted to evaluating specific interventions one at a time. This is where RWD has a role to play. Real-world studies document the actual care that patients receive in the clinic and involve a diversity of patient cases (e.g., patients suffering from several diseases at a time) without the limitation of strict inclusion and exclusion criteria. Such studies can generate long-term data on effectiveness and safety of health interventions also providing useful inputs for health economic analyses.

This is why healthcare decision makers are looking to develop strategies to integrate RWD from different sources for different uses in the healthcare systems. There are a number of issues which prevent harnessing the true potential of RWD such as the lack of standardised data collection, the lack of data quality standards and validation processes, the lack of representative databases, the lack of enough studies demonstrating how RWD can be used depending on the purpose in healthcare systems (e.g., for clinical decision-making, regulatory decision-making, health technology assessment, etc.). If these challenges can be addressed RWD can effectively complement RCTs to fill the knowledge gap between clinical trials and clinical practice. RWD can further provide new insights into disease patterns and help improve the safety and effectiveness of medical interventions.

In this context, it was considered relevant and timely, to support an action, within the Commission initiative of the Digital Transformation of Health and Care (DigiCare), that would produce technical guidance documents to enable the effective sharing and use of RWD by different stakeholders (i.e., clinicians, regulators, policy makers, etc.) and for different purposes within the health and care continuum.

Communication on Digitalisation of Health and Care (DigiCare)

The Communication on “enabling the digital transformation of health and care in the digital single market; empowering citizens and building a healthier society” was adopted on 25 April 2018. It focuses on the digital aspects of health and care, and outlines actions under three pillars: 1. Citizens' secure access to their health data, also across borders; 2. Personalised medicine through shared European data infrastructure; 3. Citizen empowerment with digital tools for user feedback and person-centred care.

Pillar 2 is related to research. The case is made for the need for coordination mechanisms between authorities and other stakeholders to share, at EU-level, data and infrastructure for prevention and personalised medicine research and to develop the needed building blocks that would guarantee secure access and the feasibility of cross-border data exchanges for health research purposes. This coordinated effort of pooling data and resources across the EU will further materialise as pilots in three research areas, rare diseases, infectious diseases and the use of real-world data, to ensure that (i) EU citizens affected by life threatening or chronically debilitating rare diseases get faster diagnosis and better care (ii) better anticipate epidemics and accelerate EU-wide identification of infectious threats and (iii) use real world data to ensure that medical products, innovative technologies and therapies meet the patient's needs and lead to outcomes .

Part of the follow-up actions was the establishment of a Member States driven initiative to link national genomic initiatives, and to ensure interoperability between such initiatives. On 10 April 2018, 13 European countries have signed a declaration for delivering cross-border access to their genomic information and committed to access to at least 1 million sequenced genomes in the European Union by 2022. More [here](#).

More information

[Transformation of Health and Care in the Digital Single Market](#)
[European Commission's Digital Single Market mid-term review](#)
[EU Health Research](#)