

# RWE4Decisions welcomes the European Health Data Space

RWE4Decisions welcomes the proposal for a European Health Data Space (EHDS), an ambitious step forward to facilitate the exchange and access to health data in the EU, which will deliver value to patients and to healthcare systems.

The EHDS is a major opportunity as it will promote trust in health data through the creation of a clear governance framework, promoting accessibility whilst ensuring security. It will contribute to a sustainable RWD infrastructure by addressing the current fragmentation across Member States, thereby enabling cross-country and cross-organizational collaboration on health data. Interoperable and high-quality data – which the EHDS aims to achieve – are essential elements to enable a learning healthcare system and support evidence-based decisions by healthcare professionals, patients, policy-makers, regulators, HTA authorities and payers.

Real-world data (data relating to patient health status and/or the delivery of care routinely collected from other sources than traditional clinical trials) are relevant across the entire access life cycle of technologies, from discovery of the medicine to validating its real-world effectiveness and understanding the patients' behaviours, the side effects, and the outcome of a treatment. The EHDS will therefore be an enabler for better patient care, from diagnosis through to access and optimal use of treatments.

RWE4Decisions will be monitoring the development of the proposal through the European Parliament and the Council. We encourage policy-makers to take into account the following aspects in the negotiations:

1. The proposal has to strike the right balance between the rights of patients to control and access their own data, and the needs of clinicians, healthcare providers, industry, research and decision-makers to use health data for care delivery and for scientific, public policy and R&D purposes (so-called 'secondary use'). In the interests of patients, strong safeguards for security and privacy must be put in place, and **the EHDS should look to reconcile the fragmented and differing interpretation of GDPR rules related to RWD across Member States**. The format and context of so-called 'one-time consent' needs to be worked out to enable people to indicate what they want to share and when.
2. Health data access bodies in Member States will be key to promote and facilitate the secondary use of health data by providing access to electronic health data to third parties. One of the challenges will be for Member States to put in place **adequate resources and infrastructures at national level**. Inspiration and good practices can be taken from ongoing national health data initiatives including the Finnish Social and Health Data Permit Authority (Findata) or the French Health Data Hub. Moreover, **it is**

**key that coordination at the European level across these bodies is ensured, based on a robust legal and governance framework.**

3. The EHDS should take a holistic approach, taking into account the use of RWD in the full lifecycle of technologies. **It should enable that high-quality, interoperable data is obtained pre-authorization**, but also consider data generation in the post-authorization phase. This is particularly true for transformative and potentially curative therapies, coming to market early via expedited regulatory approvals to benefit patients and often only limited evidence from traditional clinical development programmes is possible. It is anticipated that RWD should enable the generation of additional evidence post launch to address uncertainties, inform outcomes-based managed entry agreements, and optimize appropriate use in daily practice.
4. The **Commission should endorse a Common Data Model approach, as proposed by EMA's Data Analysis and Real World Interrogation Network (DARWIN EU).**<sup>1</sup> A key hurdle to the harmonization of RWE use is the different requirements for data collection. RWD can come in different formats (payer registry, claims database, company registry etc). The IMI EH DEN consortium has been undertaking a substantial effort in converting RWD in the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM), creating a growing network currently consisting of 140 Data Partners in 26 European countries.<sup>2</sup> DARWIN EU is a federated network of data, expertise and services which can help to support better decision-making throughout the product lifecycle by generating reliable evidence from real-world healthcare data by using the OMOP CDM. A CDM is designed for federated querying and analytics, whereby applications are run locally by the data partners and only aggregated results are shared, thereby complying with data protection requirements. Additionally, it is **important to ensure that provisions to improve data sharing are built on international interoperability standards.**

The EHDS governance model should be transparent, consistent, and inclusive in order to foster trust. In the coming months, legislators should work collaboratively with all stakeholders, to ensure that requirements meet the needs of health professionals, patients, public health bodies, HTA authorities, payers, academia, and industry. Once set up, the European Digital and Health Data Expert Group – in particular the subgroup on secondary use of health data - should consider a strategy for RWD in healthcare in order to support learnings on RWE to enable good decision-making which is based on robust evidence.

#### About RWE4Decisions

*RWE4Decisions is a multi-stakeholder group, which has developed [stakeholder actions](#) that will better enable the use of real-world evidence in HTA/payer decisions about highly innovative technologies. The work has been commissioned by the Belgian National Institute of Health and Disability Insurance (INAMI-RIZIV) and contributors include HTA bodies and payers, regulatory agencies, patient groups, clinicians, industry and academic experts/researchers.*

<sup>1</sup> <https://www.ema.europa.eu/en/about-us/how-we-work/big-data/data-analysis-real-world-interrogation-network-darwin-eu>

<sup>2</sup> <https://www.ehdn.eu/>