

## RWE4Decisions Submission:

### Digital health data and services – the European health data space

RWE4Decisions welcomes the set up of the EHDS to enable the cross-border sharing of real-world data (RWD) by healthcare decision-makers (regulators, HTA authorities, and payers). The EHDS should take into account the potential of RWD for learning healthcare systems and thereby support the development of a multi-stakeholder EU Learning Network on Real-World Evidence (RWE). This Learning Network would be designed for Member States to implement evidence-based decision-making and clarify when, by whom and how RWD should be collected to generate RWE that meets the needs of patients and healthcare systems.

Digital and data are key for improved patient & healthcare systems outcomes. RWD can enable more effective and efficient research and development processes. For example, RWD can help to better characterise diseases, patient populations and understand current needs; it can provide evidence on the real world usage of innovative medicines (dosage, duration) and it may help the assessment of the patient outcomes in real life practice.

In order to ensure that the EHDS takes into account the potential of RWD/RWE for learning healthcare systems, it is key that the EHDS:

1. Puts in place the right legal and governance framework for data security and privacy of individuals, to cover the access to and exchange of health data for secondary use (research, policy & regulatory activities). In the interest of patients, there must be clear communication about the measures that policy-makers take to guarantee data security and privacy. The format and content of a so-called 'one time consent' needs to be worked out to enable people to indicate what they want to share and when.
2. Builds on existing or emerging initiatives such as the eHealth Digital Service Infrastructure (primary data), the Beyond 1+ Million genomes initiative (genomic data), the ERNs (rare diseases) and the EMA's DARWIN (pharmaceutical regulatory data). RWE4Decisions welcomes EMA's ambition to set up DARWIN (Data Analysis and Real World Interrogation Network), which should support better decision-making throughout the product life-cycle via its network of expertise/partnerships and databases. We urge the Commission to work closely with the EMA-HMA and to involve all stakeholders in the design and implementation of DARWIN.
3. Takes into account the use of data in the full lifecycle of technologies, from research to market authorisation. It is expected for instance that RWD should enable the generation of additional evidence post launch, inform dynamic price-setting in relation to the value of medicines, and optimise appropriate use in daily practice. Therefore, the EHDS should take an holistic approach, considering data generation in the post-authorisation phase in addition to data obtained pre-authorisation. This is particularly true when 'highly innovative technologies' - which are potentially transformative such as immunotherapies or cell & gene therapies - come to market early via expedited regulatory approvals to benefit patients and often only limited evidence from traditional clinical development programmes is possible.

4. Supports the quality, accessibility & interoperability of RWD, which involves the establishment of common data standards (in terms of accuracy, completeness and traceability) to ensure validity and consistency across sources. A key hurdle to the harmonisation of RWE use is the different sources and requirements for data collection. RWD can come in different formats (payer registry, claim database, company registry etc). This requires a minimum common data set and interoperability of different applied systems.

5. Supports collaboration and cooperation on RWD. The EHDS can provide the framework for cross-country collaboration on RWD studies underway across different jurisdictions to enable data amalgamation. The EHDS infrastructure should enable cross-organisational sharing of RWE generation plans and post-licensing evidence generation about RWD.