

## ‘RWE4Decisions’ launches call for a Multi-stakeholder Learning Network on Real-World Evidence within the European Health Data Space

At a high-level conference hosted on 10 November 2020 under the associated programme of the German EU Presidency, ‘RWE4Decisions’, a multi-stakeholder group of payers, HTA authorities, health policy decision-makers, patient representatives, clinicians, researchers, industry and academics, led by the Belgian payer and reimbursement authority INAMI-RIZIV – is **calling for a EU multi-stakeholder Learning Network on RWE, to develop practical learnings on the potential use of RWE.**

It is the opportune moment to launch an EU multi-stakeholder Learning Network on RWE, in light of the EU proposals for a European Health Data Space, a renewed European Pharmaceutical Strategy and a Regulation for European collaboration on Health Technology Assessment (HTA).

Jo de Cock, CEO of INAMI-RIZIV, who has been the thought leader behind the initiative, stated that “A ‘*Learning by doing*’ approach is key to realise and clarify the utility of real-world data for HTA/payers decision-making. The proposed EU Learning Network on RWE is looking to finally move the debate from theory to practice through concrete demonstration projects, working collaboratively with stakeholders. It should be designed for Member States to implement evidence-based decision-making, and therefore be supported by EU funding”.

In response to the challenges, healthcare decision-makers are facing with regard to new therapies such as the rising costs, the rapidly increasing number of orphan medications and a growing demand for faster access for patients, this Network should stimulate alignment and collaboration among different ongoing initiatives.

Nearly 200 pilots and initiatives have been launched to examine the potential of the use of real-world data to improve evidence-based and informed decisions related to market access and reimbursement. However there is still a lot of caution for different decision-makers, such as payers, and there are many challenges to overcome (fragmentation and duplication in RWE requests, lack of methodological clarity, uncertainty with regard to data security, lack of patient involvement and under utilisation of digitalized data in health care and medical practice).

There is a need to harness the use of data in the evaluation of the truly added value of pharmaceuticals and to address these operational, technical and methodological gaps. A Learning Network should also support the application of a more outcome based oriented approach, taking into account the effectiveness of pharmaceutical therapies in clinical practice.

This Learning Network should be based on voluntary cooperation, owned and governed by a public initiative of member states (such as the International Horizon Scanning Initiative), based on sharing learnings from other initiatives, be sustainable through long term funding (from EU funds, resources of member states and conflict-checked interventions of industry) and based on a clear and yearly programme which enables sharing and dialogue between member states and stakeholders.

With a focus on innovative therapies - not limited to rare diseases - the Network should engage in early dialogues with the competent authorities to define short and long term evidence development plans, with the work supporting the implementation of outcomes based agreements in the different member states.

Demonstration projects and case studies can contribute to share experience, to pool resources and to build trust. The definition of real world registries or core datasets (epidemiology, natural history of the disease, effectiveness, quality of life, duration of treatment, dose...) is a key element. Also the quality standards to establish them and the analytical methods to evaluate them are of great importance. Datasets should be aligned between and accessible across member states. For rare diseases, European Reference Networks (ERNs) could play an important role in this context.

The EU Learning Network on RWE should be integrated within a European Action Plan on Real World Evidence which:

- ensures the development of a framework for cross country collaboration on analyses;
- supports an infrastructure for sharing of evidence generation plans and post-licensing evidence generation;
- ensures data quality and accessibility as well as data security and privacy;
- develops evidence standards and agree on common data sets;
- promotes comprehensive and aligned guidance across bodies;
- ensures systematic patient involvement in order to capture real world experience;
- promotes the use of digital data in health care.

For more information on RWE4Decision's Call to Action for a Learning Network visit <https://rwe4decisions.com> and follow the initiative on [Twitter](#) and [LinkedIn](#).