

## PRESS RELEASE

### **"The European Health Data Space – A moonshot for a true Health Union"**

#### **Creating a living and interconnected organism of data is what will define success of the European Health Data Space when it comes to rare diseases, say experts**

**Gastein, September 27** – *The European Commission's proposal for a European Health Data Space is a major pillar of the European Health Union. It holds the promise to foster a genuine single market for digital health services and products, to the benefit of patients and science. Yet, issues related to ownership, data protection rules, standardization and interoperability of data, alongside the commitment from all stakeholders to collaborate, will be key to allow the EHDS to reach the stars, say experts at the first hybrid European Health Forum Gastein (26-29 September) under the theme "A moonshot for a true European Health Union".*

A beehive, a photograph of neural connections taken by a famous Irish artist, a blue sky mountains lake view generated by artificial intelligence, or a spider web – this is what success of the European Health Data Space (EHDS) would look like to the experts who contributed to the [session](#) "Joining the dots to tackle rare diseases - How can the EHDS connect real world data with health system change?" on 27<sup>th</sup> of September.

Convened by the European Health Forum Gastein and global biotherapeutics company CSL Behring, with participation of the European Hemophilia Consortium, the session looked at the role of the EHDS in building a harmonized European health data ecosystem for rare diseases, and explored opportunities and challenges ahead.

#### **Collaboration is needed to bring health data together in rare diseases**

While there is consensus that the EHDS holds tremendous promise - for the future of health systems, rare disease patients' care, research and innovation - the road to success will necessitate the contributions of all: from patients, health professionals, academics, drugs developers, to regulators and many more. The EHDS will need to be a collaborative, multidisciplinary co-creation process, emphasized the panelists to the debate.

"There are many different sources of data that need to be connected, with different levels of complexity, and from countries with different data systems" outlined Richard Bergström, from the Swedish Ministry of Health

For this reason, "we need common underpinning principles for the EHDS to first function adequately for the Member States", said Jerome de Barros, outlining that ultimately, the EHDS may be a source of inspiration for third countries trying to develop similar systems.

From the patients' standpoint, Amanda Bok from the European Haemophilia Consortium stressed the need for "dynamic collaboration to fully fulfill both the EHDS (the queen bee, who gathers the information) and the patients (who give pieces of data)", describing a beehive as the "closest thing in nature to represent patient demand".

Multi-stakeholder collaboration is at the heart of the EU pilot project on the EHDS, led by the French Health Data Hub. Starting this month, the project gathers sixteen partners from ten EU countries to develop the basis of the EHDS: a common infrastructure for the secondary use of health data, to address the challenges surrounding access to health data throughout the EU and open new perspectives to research and innovation.

However, the issue of data sharing is complex. Emmanuel Bacry from the French Health Data Hub, noted that certain data producers “do not want to share the data they generate”. Despite this, he remains positive about the future: “My belief is that people will eventually understand what data is used for and opt in” he said. Jérôme de Barros from the European Commission, and Prof Niamh O’Connell from the National Coagulation Centre, St. James’ Hospital, Ireland also highlighted the decisive role that cybersecurity safeguards will play when it comes to building patient reassurance and will to share personal health data.

### ***Developing an interoperable, interconnected and sustainable system***

On top of collaboration, the sustainability aspect is critical, said Bacry “we need to be careful about the footprint of the data system we build”.

All concurred in that the EHDS will need to be an interconnected and evolutive system that builds on existing best practices such as the French Health Data Hub or the Irish National Haemophilia Register. Building on Ireland’s experience, Prof O’Connell pointed that accessibility of data 24/7 is key, and that aiming to constantly update and improve a system is what makes it thrive.

Yet financial and management schemes are also important points, noted Bacry. “In France, we advocate for the government to finance the system so that data producers don’t have to look for funding and can continuously produce data”, he explained.

### ***Leveraging the power of data to bring innovation to rare disease patients***

Reflecting on the first use of a type of factor replacement therapy for hemophilia in Ireland years ago, Prof O’Connell highlighted that real world data helped in proving that the treatment was beneficial for patients, and the value it delivered for the health system.

Karen Pinachyan, Head of EU Medical Affairs at CSL Behring added that gene therapy brings a different paradigm to data collection: in gene therapy, data needs to be collected for several years after one single administration. This requires to change parameters as none “wants to enter the same data ten times in different system”, he pointed, stressing the need to ease the burden of data collection for the industry and health professionals, for the system to work.

Taking the example of the data collection process during the COVID-19 vaccine rollout, R. Bergström underlined that “we came to realize that policy making has to be based on some standards of evidence while making the most of new incoming real-world data that does not come from traditional clinical trials”. Real World Evidence now also drives decision-making of novel payment models.

Rare disease patients could be greatly impacted by the EHDS, argued the experts, since data are scarce in the area, and a lot of information can be extracted from small data sets.

Therefore, just like the preparation of the first moon mission, the EHDS is an ambitious project which could be a game changer for patients, our health systems and societies. “It is a crucial and forward-looking proposal, which puts the exchange of data on a new footing. We will only be able to overcome major health challenges of our time together” noted Member of the European Parliament Timmo Wolken.

Yet some important challenges are to be addressed to reach interoperability of data – notably in rare diseases. But just like putting a man on the moon, the EHDS will change the way we view the world, and in this case, how we view data, concluded the moderator Tamsin Rose.

## *NOTE TO THE EDITORS*

### **About the European Health Data Space (EHDS)**

The EHDS proposal was released by the European Commission in March 2022 and provides for rules, common standards and practices, infrastructures and for the primary and secondary use of electronic health data for research, innovation, public health, policy-making and regulatory purposes. The proposal, currently under discussion in the European Parliament and Council, aims to make data work for our health systems and our management and understanding of the latter.

### **About the European Health Forum Gastein**

The European Health Forum Gastein (EHFG) was founded in 1998 as a European health policy conference. It aims to provide a platform for all stakeholders from the fields of public health and beyond. Over the past 25 years, the EHFG has established itself as an indispensable institution in the scope of European health policy. It has made a decisive contribution to the development of guidelines and above all the cross-border exchange of experience, information, and cooperation. Leading experts traditionally participate in the annual conference held in the Gastein Valley in the Austrian Alps in late September.

More information: [www.ehfg.org](http://www.ehfg.org)

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