

European Health Data Space Consultation

Joint statement on behalf of:

The European Society of Endocrinology (ESE)

The European Society for Paediatric Endocrinology (ESPE)

The European Reference Network on rare endocrine conditions (Endo-ERN)

European Registries for Rare Endocrine Conditions (EuRECa)

The four signatories welcome the European Health Data Space (EHDS) Initiative to further facilitate health-data exchange within and across European countries. If implemented correctly, this will boost innovative medical research, improve patient's access to their personal data, improve the diagnosis and care for patients across Europe and inform European as well as national health related policies.

The societies and networks represent endocrine health and disease across the human lifespan for frequent as well as rare endocrine disorders, while maintaining a strong focus on the integration of basic as well as clinical research towards improved diagnosis and patient care.

With that in mind, the above organisations and networks submitted coordinated individual responses to the most recent [EU consultation](#) on this topic to provide guidance to the EU institutions in making the EHDS a reality.

While generally supportive of the direction the European Commission seems to be taking, we urge the European Commission and other EU institutions involved in the process to take the following points into account for their future deliberations:

- ❖ **The development of EU standards and technical requirements to support exchange of data in healthcare should in first instance be developed by national bodies.** Through a process of exchange of best practices and expertise they should jointly work towards a harmonised EU framework to facilitate the interoperability between the different national data hubs. Hereby also providing support to certain Member States for the creation of these data hubs in the first place. This process will be time-consuming due to its complexity and current fragmentation, and hence should be initiated as soon as possible.
- ❖ **Enhanced patient access and control over personal health data has led to improved health outcomes, for example in people with diabetes¹.** It is of the utmost importance this will be recognised for all future discussions around patient benefits in relation to the EHDS. For this as well as other potential benefits of the EHDS, it is of the utmost importance that nobody is left behind including those with reduced digital access and/or skills such as the elderly population.
- ❖ **In addition to financial compensation, more incentives should be made common practice to stimulate health data sharing across Europe for private entities.** Considerations should be given to involving these entities in the research projects benefitting from the shared data. This could take the form of mere recognition in the final publication of the research as co-author and/or sponsor and/or take the shape of a more active involvement, for example as a member of the steering board.

¹ [Impact of providing patients access to electronic health records on quality and safety of care: a systematic review and meta-analysis | BMJ Quality & Safety](#)

- ❖ **Standard procedures for sharing medical data beyond the EU should be considered by linking in with other data hubs, possibly in coordination with the US and/or other key players in the global health data space.** Better access to other health databases can make an important contribution to medical research in the EU. This is especially true for rare diseases where the amount of available data is currently limited.

Scientific national and European societies, the European Reference Networks as well as infrastructures for health registries like EuRECCa are at the heart of the medical scientific community. The further development of the EHDS will benefit from their engagement.

About ESE and ESPE

The [European Society of Endocrinology \(ESE\)](#) supports and represents 20,000 endocrinologists and [the European Society for Paediatric Endocrinology \(ESPE\)](#) 7,000 pediatric-endocrinologists in Europe. These endocrine health care professionals care for millions of patients with endocrine diseases. Policy and advocacy priorities are summarized in the recently published [White Paper](#) (2021) which was developed by ESE and endorsed by ESPE. Together, our two societies cover endocrine health and disease across the lifespan, from birth over childhood, adolescence, adulthood and ageing

About Endo-ERN

The [European Reference Network on Rare Endocrine Conditions](#) (Endo-ERN) has as main objective to reduce and ultimately abolish health inequalities for patients with rare and/or complex endocrine conditions in Europe, through facilitating knowledge sharing and high-quality healthcare and research. Representing more than 440 rare endocrine diseases and with 78 reference centers in 26 EU member states participating, Endo-ERN at present is the largest ERN. The network and its eight main thematic disease groups of Endo-ERN are chaired both by an adult and paediatric endocrinologist as well as an European patient advocacy group representative (ePAG) and provides expertise from birth to senescence. For further information see also: [Introduction to Endo-ERN-scope and mission](#)

About EuRECCa

The [EuRRECa project](#) was launched in 2018 and includes an e-reporting programme (e-REC) and a core registry that collects a common and condition specific core dataset including clinician and patient reported outcomes. EuRRECa works closely with Endo-ERN, ESPE and ESE and the platforms it has developed have also been adopted by ERN-BOND and its related registry, EuRR-Bone.

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