



Improving lung health through the future European Health Data Space

Introduction

The world is undergoing a digital revolution that is influencing all parts of citizen's lives; including social relations, consumption patterns, even governments and democracy. The healthcare sector is a key area of life where huge digital changes are already happening, with more yet to come. The operational setting of healthcare, its public-private nature, and the multiple actors involved in health management make the digital transition of healthcare systems a complex process.

Digital solutions bring great opportunities for health, and especially for patients, as they put them in control of their data and healthcare, and allow for more insights on prevention and care, from treatment decisions to reimbursement.

As stated in the European Lung Health Group (ELHG) BREATHE Vision for 2030¹, **healthcare professionals (HCPs), alongside patients, their data and their needs, should be at the core of the future legislation on the European Health Data Space (EHDS).**

The future of healthcare delivery, medicine and research will greatly depend on how this new space is embedded into patients' lives and clinical practice, and on the value each stakeholder gives to health data. Patients' needs, especially their unmet needs, should be at the centre of any decision on health data, and lead to improving patients-HCPs communication.

The ambition to build a European Health Union (EHU) looks at a stronger European Union health framework where information, prevention and action at national levels are more coordinated. The future EHDS is set to better exchange and access different types of health data across Europe to support the delivery of healthcare (national or cross-border), health research and its outcomes (clinical trials, updated guidelines), and to inform policy making. **Patients should have a pivotal role in the EHDS.**

¹ <https://www.breathevision.eu>

HCPs and patients are collaborating to improve health services for lung health through digital solutions. The lung is an extraordinary primary organ that contains 2,400 kilometres of airways and 300 to 500 million alveoli. As rich as its tissues, the lung is also affected by more than 40 illnesses covering all disease areas:

- **Respiratory infectious diseases:**
such as tuberculosis (TB) or severe acute respiratory syndrome (SARS) like COVID.
- **Respiratory chronic diseases:**
such as asthma, chronic obstructive pulmonary disease (COPD) or lung cancer.
- **Lung rare diseases:**
such as cystic fibrosis, idiopathic pulmonary fibrosis, pulmonary hypertension, or Alpha-1 antitrypsin deficiency (Alpha-1).

With the European Health Data Space, EU governments and regulators aim to develop a common framework for healthcare in virtual settings. The complex legislating process on the rights and obligations of different actors involved should not neglect the main objectives of the future digital space. These objectives, from a lung disease patient and healthcare professional perspective, are clear: facilitate care, increase access, ensure transparency and participation, and enable effective research, all to ultimately improve quality of life.



The European Lung Health Group envisions a European Health Data Space that responds to the following patients and healthcare professionals' expectations:

1. A European Health Data Space to FACILITATE virtual and in-person care for respiratory disease

It is paramount that future digital health data policies aim at strengthening individual care and patient-HCP interactions. Lung diseases are complex conditions affecting the whole health status. To treat them, the patient journey requires multidisciplinary care and the intervention of primary, secondary and tertiary care providers. A health data space should first and foremost benefit the patient and should therefore be conceived as a coordinating tool for patient-centred care. This translates into a European Health Data Space that:

- 1 Supports and enables **HCP-friendly digital services** to improve respiratory HCP-patient communication, co-decision making and building on patient reported outcomes (PROs) through tele-consultations and digital disease trackers.
- 2 Prioritises the **interoperability and interconnectivity** of health data to support the practical, effective and patient-friendly delivery of healthcare, such as sharing electronic health records and electronic prescriptions. This should clearly support the role of digital health technologies as **'early warning systems'** to enable patients and their clinicians to spot problems, such as impending lung exacerbations.
- 3 Creates and promotes **virtual mixed realities** with interactive guidance for respiratory diagnostic procedures and treatment. Respiratory healthcare professionals should be trained in these areas to overcome current limitations.
- 4 Focuses on **early adopters** within lung disease patients and HCPs to advance digital health and continuously assess the behavioural, operational and financial impact of digital tools.
- 5 Leads to **EU funding for pilot projects on digital training for HCPs** involved in respiratory care. For example, setting up a multidisciplinary team making full use of digital tools for better clinical and quality of life outcomes for chronic obstructive pulmonary disease (COPD), which involves respiratory nurses, GPs, specialists, physiotherapists, and of course, patient representatives².



2. A European Health Data Space to increase ACCESS to quality care and information

The digitalisation of healthcare implies the democratisation of digital solutions and the need to make them easily, accessible and to improve digital literacy. The future European Health Data Space has the potential to reduce the unacceptable inequalities in accessing treatment and care within EU Member States, and to bridge the digital poverty gap affecting key players in the healthcare system.

Whether patients or HCPs, the lung health community expects the health data space to respond to crucial unmet needs in lung health prevention (such as early diagnosis or screening), and care (such as prognostics, self-management and access to available medicines and innovation). The respiratory community demands a health data space that is set to:

- 1 Define digital spaces for lung health that are patient and HCPs friendly and affordable. This is achieved by improving the population's **digital literacy** so they can access their secured health data.
- 2 Promote **digital health ecosystems** to enable respiratory disease patients to centralise their care and connect hospitals, HCPs and pharmacists of their choice to manage and improve their own health outcomes, as well as establish a clear legal framework for digital solutions addressed to patient users.
- 3 Improve **access to old and new medicines**, such as personalised treatments, biological drugs and gene therapies for respiratory disease, to ensure respiratory patients have access to the right treatment at the right time.
- 4 Foster systems that enable patients to **generate data** on their needs and preferences. These systems should lead to the establishment and development of patient registries that collect Patient Reported Outcome Measurements (PROMs) in all aspects of care, including daily life treatment outcomes, with a view to improve patients' Quality of Life (QoL). For example, the Severe Heterogeneous Asthma Research collaboration (SHARP) and the European Cystic Fibrosis Society (ECFS-PR) patient registry which is populated with Real World Evidence data.
- 5 Facilitate **healthcare choices, mobility, and transferability** to deepen cross-border healthcare in Europe. Strengthen and widen the current European Reference Networks (ERNs) towards the establishment of lung disease Centres of Excellence in Europe.
- 6 Enable **interconnection between different health spaces and external sources** externally so that the health sector integrates external data sources relevant for public and lung health, such as weather forecasts, activity monitors and air quality data.

² Respiratory diseases often require broad specialised care, which entails competency requirements within the multidisciplinary teams, such as in this example for expert centres treating pulmonary hypertension (PH): <https://ern-lung.eu/inhalt/wp-content/uploads/2020/10/PH-MCC.pdf>

3. A European Health Data Space that functions with **TRANSPARENCY** and fosters **PARTICIPATION**

The prospect of collecting and analysing more health data brings about many opportunities for better health but can create concern and distrust about the potential misuse of data. The lung health community is ready to embrace digital solutions that are co-designed with users and that operate with full transparency. We expect the future European Health Data Space to:

- 1 Establish lung disease **patients as the ultimate controllers of their health data**: they need to know who is using their data, where and how data are stored, monitored, shared, processed, kept safe, how consent is granted and withdrawn, and their digital health footprint, to build trust with the system.
- 2 Invest in **patient education tools** on how health data can serve them and the community. Explain to patients what their role, rights and duties are in an accessible way, to reinforce the need for them to participate in their (digital) care.
- 3 Boost the **creation and sharing of data** that is currently lacking and empower patients to manage and develop their own health data in an easy and not burdensome way. Patients can increase understanding of their health status and improve self-management of their respiratory disease.
- 4 Clarify the **rights and duties** for digital health data collectors and processors (which can also be lung patients), managers and users, ensure the respect and good functioning of the system through independent bodies, and develop solid cyber security policies among health data holders.



4. Health data space to **ENABLE EFFECTIVE RESEARCH** on respiratory disease

Many lung disease patients want their data to be used to further research and policy yet some existing data protection legislation prevents substantial progress. While today health data is shared in many different ways, the legislative frameworks in place can hinder research that uses Big Data (BD) or Artificial Intelligence (AI). We expect the future European Health Data Space to:

- 1 Establish **clear rules for primary, secondary and tertiary use of health data**, prioritising anonymisation to ensure patient privacy. Create strong boundaries guiding the feasibility and ethics standards for big data health research to ultimately serve patients and the society.
- 2 Enable **AI and machine learning** to transform clinical decision support systems. Create new diagnosis and treatment algorithms for patients through simulating interactions and predicting outcomes. This is being studied in the IMI-2 DRAGON⁶ and OPTIMA⁷ projects.
- 3 Serve to develop European Medicine Agency (EMA) guidelines and criteria on **digital tools use and digital health data for clinical trials**. Increase and improve patient samples through (international) remote trials, especially in rare and low prevalence respiratory diseases. Collect patients' RWE data to support strong, evidence-based market authorisation submissions and approvals to facilitate increased innovation at Member State level.
- 4 Incentivise the **medtech and medical devices industries and IT sector to specialise in health**, to facilitate interaction with HCPs and patient groups and to enable partnerships to find digital solutions for respiratory disease prevention and care.

³ SHARP is a project that is building a catalogue of European asthma research centres and improving severe asthma registries with a federated analysis platform for individual national registries and providing infrastructure to expand severe asthma registries where they do not exist. Resulting work will provide a comprehensive description of patient characteristics, phenotypes, treatment strategies, treatment responses and the burden of severe asthma across Europe. <https://www.ersnet.org/science-and-research/clinical-research-collaboration-application-programme/sharp-severe-heterogeneous-asthma-research-collaboration-patient-centred/>

⁴ The ECFS-PR has been collecting clinical data for years and now Cystic Fibrosis Europe is running a pilot in Belgium to populate the registry with Real World Evidence to enrich the data on effectiveness for a CF drug that has been approved under conditional market authorisation. Data and PROMs from patients have a better view on actual patient needs and make patients an active stakeholder: <https://www.ecfs.eu/projects/ecfs-patient-registry/project>

⁵ The European Reference Network - LUNG is a virtual cross-border healthcare networks that provide rare lung disease clinicians with a platform to share knowledge and experiences with the objectives of improving patients' access to diagnosis, care and treatment, establishing common rare disease databases, developing clinical guidelines, thereby facilitating the mobility of expertise rather than patients themselves. <https://ern-lung.eu/>

⁶ "Rapid and secure artificial intelligence (AI) imaging-based diagnosis, stratification, follow-up, and preparedness for coronavirus pandemics" (DRAGON) will draw on new and existing data and sample collection efforts, including CT (computed tomography) scans to carry out detailed profiling of patients and will use AI technology to transform this information into a precision medicine approach that will help clinicians and patients with decision making around treatments. <https://europeanlung.org/dragon/>

⁷ "Optimal treatment for patients with solid tumours in Europe through artificial intelligence" (OPTIMA) will develop Europe's first interoperable, large scale oncology data and evidence generation platform with data from over 200 million people. <https://www.optima-oncology.eu/>

Conclusions

Lung disease patients and healthcare professionals are eager to participate in the future European Health Data Space. There are two clear roles for them: firstly, as **active digital health data providers and collectors**, who have sufficient education and training. Secondly, perhaps more importantly, as the **primary beneficiaries of the health data systems** around them. These roles will ensure that the digital health space will facilitate care, transparency and participation while enabling effective research and increasing access. Such vision will require sufficient investment from Member States and from EU programmes such as EU4Health and the Digital Europe Programme. **We call on Parliament to ensure Council and Commission commit to significant funding of the data space.**

We need an ambitious European Health Data Space to link health data at the EU level with common and understandable rules. We fully support the Commission's target that, by 2025, all citizens should be able to share their health data with the healthcare provider of their choice when travelling abroad in the EU. We would suggest an

additional target that **by 2030 health researchers have sufficient access to controlled data spaces to improve citizen health** and ensure medical research can continue to thrive in Europe.

In Europe, we have vast amounts of data that can improve citizens' health. But the different pockets of data are not accessible due to issues in data transparency, interoperability and uncertainty in Member States on how to ensure both privacy and, at the same time, accessible quality data. Health data is highly sensitive, and cybersecurity is also a critical concern. However, we have seen during the pandemic that barriers can be overcome, and digital solutions can be found when there is a will, such as the opening of the European Reference Networks platform to COVID-19, the EU Digital COVID certificate and the Passenger Locator Form. In that spirit, **we urge Council and Parliament to enthusiastically engage with the proposal, deliver strong political support and not impede the process towards realising an effective health data space.**



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For more information: <https://breathevision.eu/about#acknowledgements>

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