

Joint EMA HCPWP-PCWP Meeting, 21 – 22 September 2022

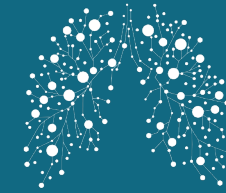
Isabel Proaño

European Federation of Allergies and Airways Diseases Patients'
Organisations (EFA)

- ELHG Policy Brief on medicines for children and rare diseases

- The asthma and COPD patient digital journey in Europe (DIG_IT)

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European Lung Health Group (ELHG) Policy recommendations

*Orphan Medicinal Products and Paediatric
Legislation Review*

September 2022

Respiratory disease on the spotlight



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- **A persistent challenge:** Still today, 1 in 8 deaths in the EU are due to lung diseases, excluding COVID-19
- Between **5,000 and 8,000 distinct rare diseases** exist, affecting between 6% and 8% of the EU population – in other words between 27 and 36 million people.
- Fewer than 1,000 rare diseases benefit from even minimal amounts of scientific knowledge.
- 80% of rare diseases have identified genetic origins and affect between 3 and 4% of births.
- Asthma affects up to 1 in 5 European children
- **1 in 4 primary care consultations are due to respiratory and are among the top causes for hospitalisations among children**

Orphan Medicinal Products and Paediatric Legislation Review – Policy Recommendations



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Improved basic research in respiratory diseases

- Reinforce European Reference Networks (**ERNs**), allocate **EU research funding** for the underlying causes of respiratory diseases and adopt a **Rare Disease Partnership** fund for basic research and early development of medicines.
- Establish disease specific **Centres of Excellence** for paediatric respiratory diseases research and care in Europe .
- Prioritise within the EHDS the collection and use of **Real-World Evidence** (RWE) on the lung diseases spectrum and advance EU-wide research in the area.
- Provide guidance and incentives for **translational basic research** on lung disease.

Framework to steer investment into respiratory unmet medical needs

- **Shape market exclusivity** based on a set of agreed criteria.
- **Reward innovation** on medicines for children, stimulating submission of Paediatric Investigation Plans and introduce **novel financial incentives**
- **Enhance collaboration** by incentivising pharma for taking up academic research and developing it into medicines for rare diseases.
- Prioritise continuous investment in **patient registries** for lung disease and RWE-generation by patients as enablers in defining unmet medical needs

Uniform and transparent regulatory and access pathway focused on delivering innovation quickly and equitably to patients

- Ensure **patient organisations and professional societies** are in all stages of regulatory and access processes at EU and national levels.
- Establish an **iterative early dialogue for OMP and medicines for children developers and EMA-HTA bodies**
- Pilot and adapt the OMP regulatory and access pathways to the specificities of ultra-rare diseases.
- **Incentivise applicants to the new EU HTA** procedure, ensuring homogeneous access to OMPs and medicines for children.
- Adopt **guidelines** on the use of alternative treatments in the presence of approved OMPs.
- Establish rewards of **comparable value for both repurposed and innovative medicines**.

Policy Brief accessible here: https://breathevision.eu/images/ELHG_Brief_Respiratory_Medicine_2022.pdf

Classified as internal/staff & contractors by the European Medicines Agency

Our BREATHE Vision for 2030



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- **European Lung Health Group (ELHG) - formed in 2020** as a collective initiative driven by European level patient groups and healthcare professionals that have come together:
 - **9 partnering organisations** → Alpha-1 Plus Belgium, CFE, EFA, ERS, ELF, LuCE, PHA-E, EU-IPFF, TBEC
 - Representing **half million** respiratory patients & **40,000** health professionals



- **Read the BREATHE Vision for 2030** - <https://breathevision.eu/vision-2030>

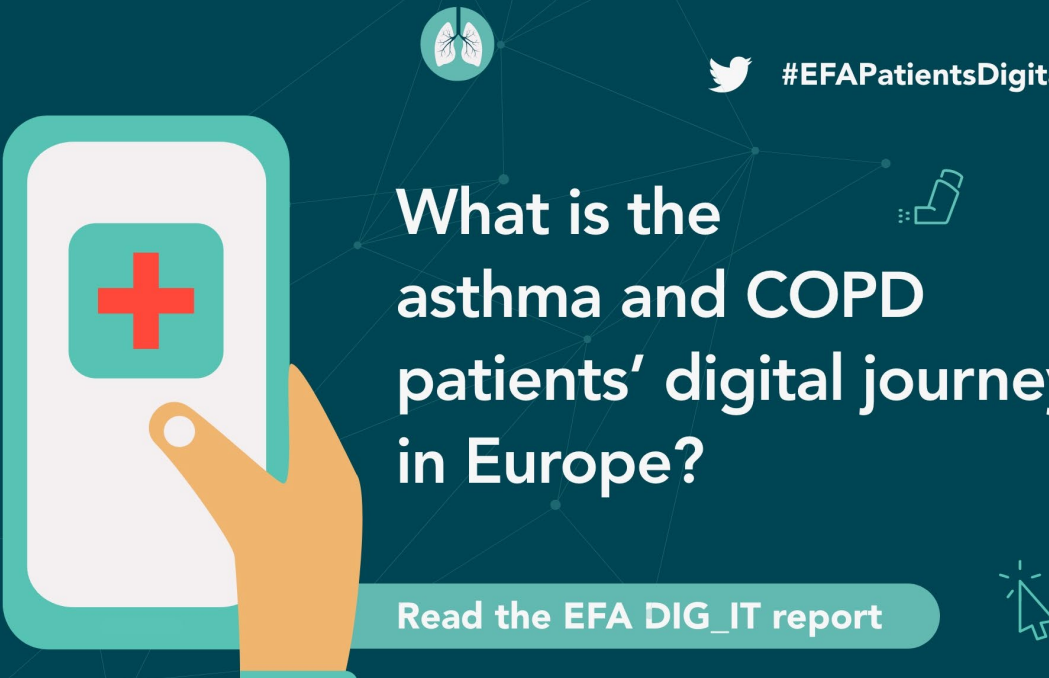


EFA The asthma and COPD patient digital journey

European Federation of Allergy and Airways
Diseases Patients' Associations



European Federation of Allergy and Airways
Diseases Patients' Associations



What is the asthma and COPD patients' digital journey in Europe?

Read the EFA DIG_IT report

#EFAPatientsDigital

- **970 asthma and COPD patients** interviewed in Q2 2021.
- **5 countries:** Belgium, Czech Republic, Ireland, Norway, and Spain.
- **50 questions** on access, diagnosis, treatment, care as well as their views on health data and digital empowerment
- **1 report** including findings & recommendations.
- **5 country-factsheets** including key highlights from each country surveyed.

- Access the DIG_IT Report here – https://efanet.org/images/2022/EFA_DIG_IT_Full_Report.pdf
- Access the DIG_IT factsheets here - <https://efanet.org/inform/patient-evidence/dig-it/country-factsheets>

[#EFAPatientsDigital](https://twitter.com/EFAPatientsDigital)

Asthma and COPD DIG_IT project

What?

- **Access and use** of digital health services
- Digitalisation of **diagnosis, treatment and care**
- Digital use and sharing of **health data**
- **Digital empowerment**
- Impact of **COVID19** on digitalisation for patients

Why?

- To improve the understanding and **confidence pathway** for people with asthma and COPD in the digital health space
- To become **aware of their rights and possibilities.**

Objectives

- Understand the **digital needs, perceptions and use** by asthma and COPD patients, and gather insights on their digital journey
- **Identify existing gaps** in accessing digital solutions
- Identify **potential biases** (age, socio-economic, education, digital literacy)
- Understand the **impact of the COVID crisis** on the use and perception of digital solutions in healthcare

Asthma and COPD DIG_IT findings

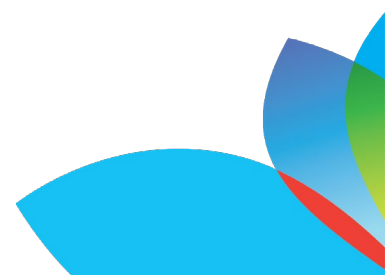
Use of general digital tools (e.g. internet, social media) is high among participants, especially among asthma patients (younger)

Awareness and use of e-health and m-health is overall comparatively low and often limited to simple, general and non-disease-related services and tools

COVID-19 pandemic increased the use of digital services, including e/m-Health, with signs of more positive attitudes towards digitalisation

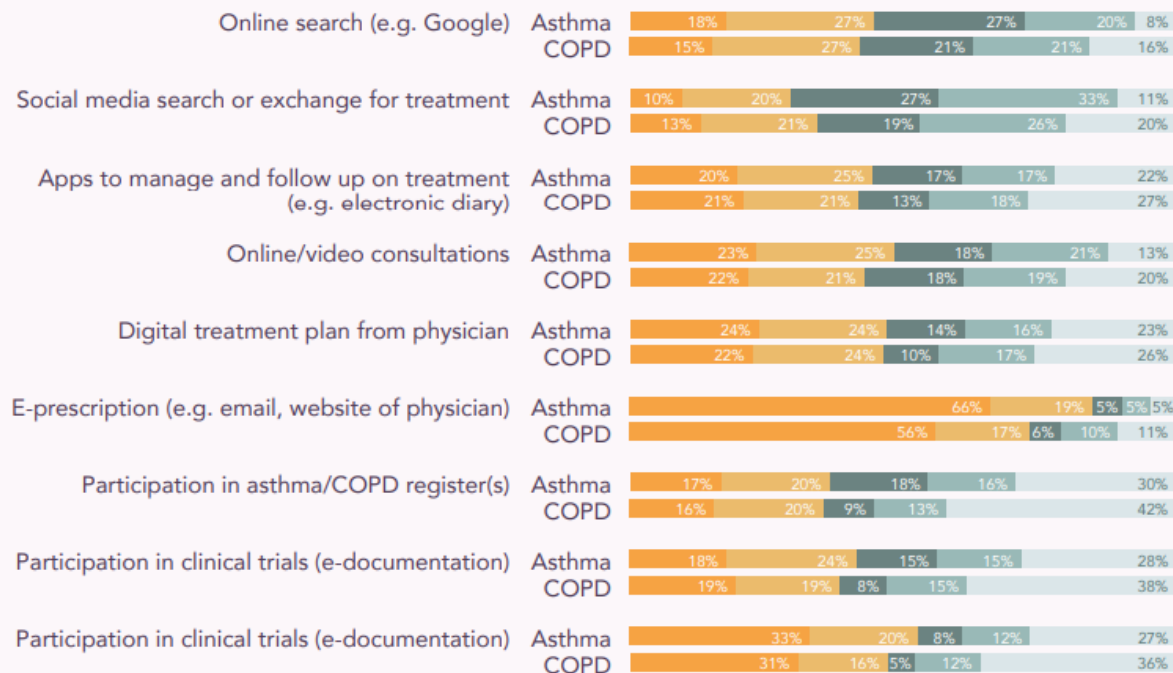
Data privacy and security concerns

Considerable differences among countries in the uptake of digital technologies, due to varying access, investment and reimbursement frameworks



Asthma and COPD DIG_IT findings

Table 14. Perceived usefulness of digital solutions to treat asthma and COPD



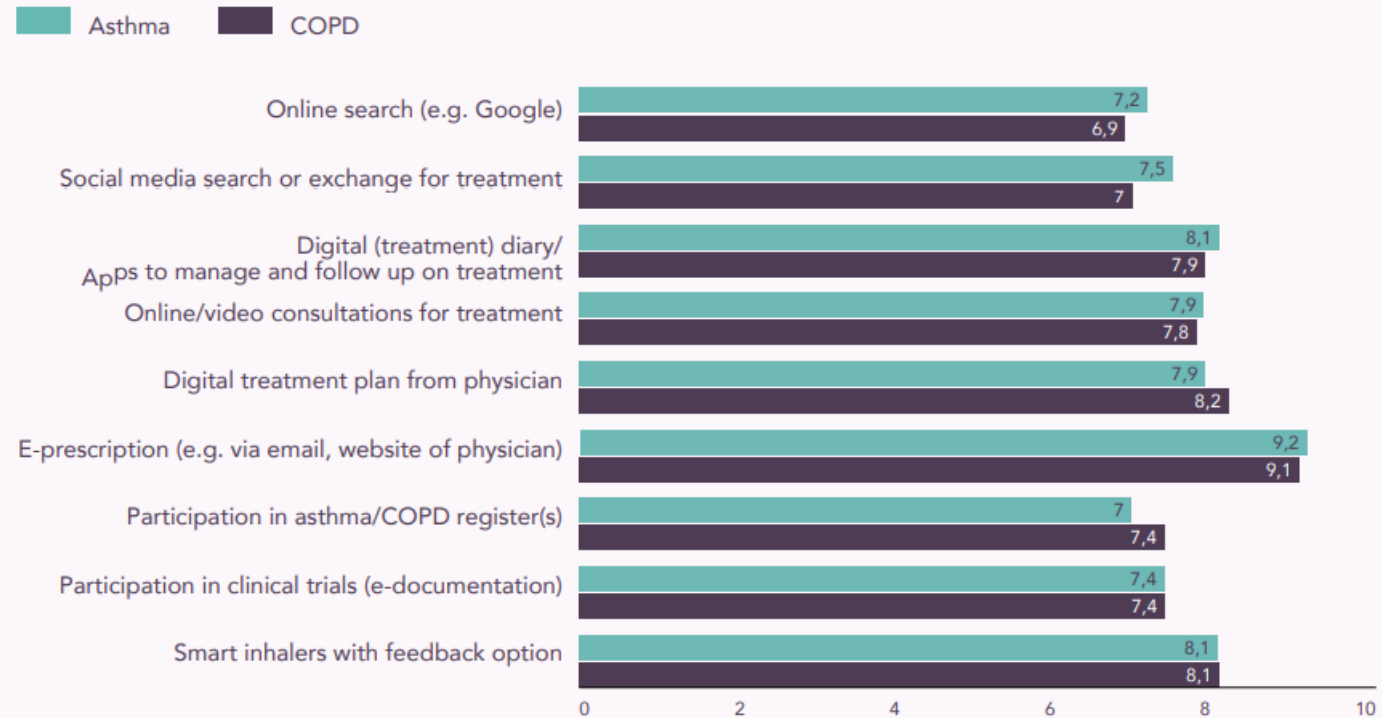
Very Useful Useful Somewhat Useful Not Useful Don't know

Question 25: Where do you feel digital options are specifically useful when it comes to the treatment for asthma/COPD?
Please use a 1-4 scale, where 1 means 'not useful at all' and 4 means 'very useful'

Basis: asthma n=506 COPD n=464

Asthma and COPD DIG_IT findings

Table 15. Patients' satisfaction with digital tools and services used for treatment



Question 24e: How satisfied are you with the tools you have used? Please use a 1-10 scale, where 1 means 'I am not satisfied at all' and 10 'I am extremely satisfied'?

Basis: All patients who declare using the specific healthcare service

THANK YOU

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