

GlobalSkin-Europe Event

Patient Data for Better Health



13:25 – 14:05:

European Health Data Space (EHDS) by 2035, Patient Registries and Real-World Evidence (RWE).

Today's agenda:

- 1 **Understanding the power of health data**
- 2 **A cornerstone of health data in Europe: The European Health Data Space (EHDS)**
 - a What is the EHDS?
 - b How does the EHDS change patients' rights?
 - c Challenges of the implementation – Patient perspective
- 3 **Unlocking the potential of real-world evidence**
 - a Spotlight on patient-led registries
- 4 **Health data as a foundation for AI systems**
 - a Patients' perspectives on AI in healthcare



Presentation by
Yann Heyer,
Senior Policy Officer at the
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About the European Patients' Forum (EPF)



Independent, non-governmental umbrella



Founded in 2003



81 national coalitions & EU disease-specific organisations



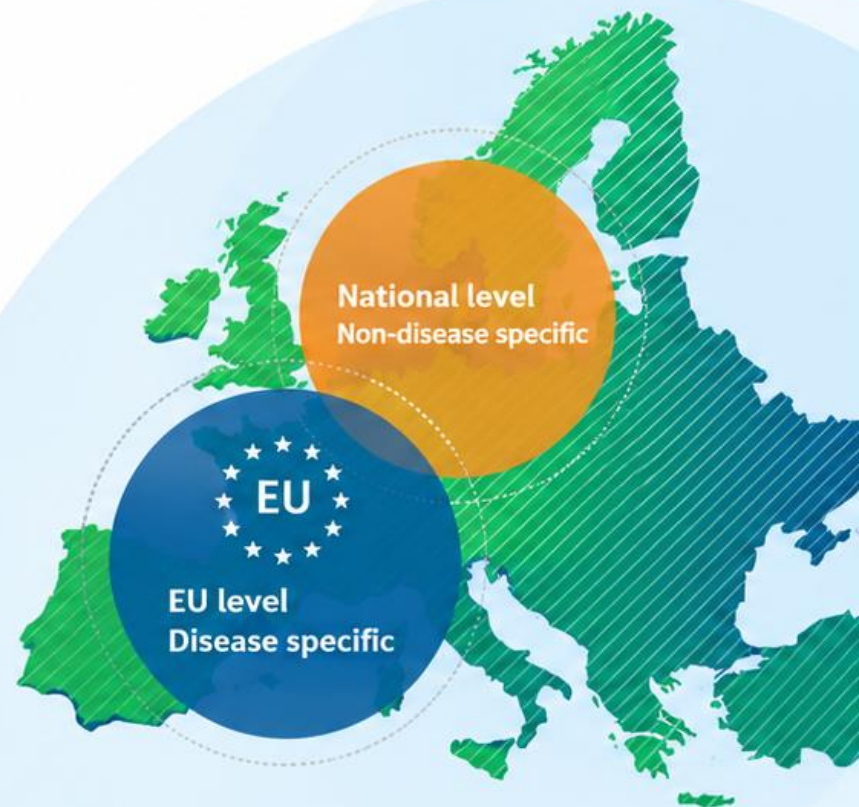
Our vision

A Europe where patient organisations are *valued partners* in creating equitable, person-centred, accessible, and sustainable healthcare systems, based on patients' unique expertise.



Our mission

To advance the interests of patients and patients' communities by strengthening their collective impact across Europe through effective advocacy, education, empowerment and *partnership*



About Data Saves Lives



1

Presenting Data Saves Lives



Data Saves Lives (DSL) is a **multi-stakeholder initiative** aiming to **raise wider patient and public awareness** about the importance of health data.

Created in 2019 and led by the European Patients' Forum.



A tool for **capacity-building and professional development**.



Toolkits and training programmes on:

- The Power of Health Data
- Artificial Intelligence
- Patient-led registries
- EHDS

2

DSL's vision for 2027–2028

Our work is based on three pillars:



Equip patients to generate patient-centred data

Ensure real-world evidence (RWE) and patient experience data (PED) are truly patient-centred, with patients as active contributors.



Strengthen patient representation at all levels

In particular in the context of the EHDS implementation.



Harness Artificial Intelligence literacy

Help patients benefit from AI and online health information, while addressing the risks of misinformation.

3

Localisation of DSL



We will continue to **localise DSL** to strengthen its reach and impact at national level.

National DSL initiatives already exist, including in Germany and the Netherlands, and we are in discussions with several others.



A national-led DSL can bring **significant added value**.

We are open to exploring partnerships with patient organisations, Ministries of Health, public bodies, not-for-profit organisations and universities.



Creating a local version of Data Saves Lives mainly means **translating and adapting** our materials (webinars, toolkits and training bootcamps) to the national context and language.



Understanding the power of health data.



Tour de table:

According to you, how and to which extent can health data benefit healthcare systems?

We want your feedback



Understanding the power of health data.



1 What is health data?

- Health data refers to any data describing a person's health, their healthcare or anything affecting any health issues or diseases they may have.
- It can be collected by healthcare organisations and professionals, about individuals ("personal health data") or populations ("population health data").
- There are many different types of personal health data:



Electronic health records (EHR)



National databases of prescriptions and lab tests



Tracking from mobile apps and wearable smart devices



Clinical trial databases

2 Why is health data so valuable?

- People are living for longer, but healthcare budgets are not being increased in line with this rising demand. There is an urgent need for more effective, less costly and smarter medicines.
- Harnessing the power of health data can help us to achieve this and has already led to some significant advances.



3 How is health data shared?

- Data is originally collected by different organisations, for different purposes, most commonly to support the health and care to individuals.
- It can be shared via various means:



Smart device



Central computer database



From one database to another



Even in physical form (although digitisation of data has greatly aided its shareability).

Understanding the power of health data.

Benefits to patients



- Greater insight into own health, making patients more health literate and offering the potential to adapt lifestyle more positively
- Providing data to scientific research speeds up the development of new medical treatments

Benefits to healthcare systems



- Potential to identify at-risk individuals or populations, and speed up diagnosis
- Earlier identification of pathways in disease transmission
- Ability to predict outcomes more accurately and improve patient safety

Benefits to healthcare providers



- Option to participate in more clinical research
- Provides reassurance as recommendations based on more data

Benefits to medical research



- Ability to identify people who may benefit from participation in medical research
- Potential to develop new diagnostics and treatments
- Providing data to accelerate regulatory approval of new diagnostics and treatments

Understanding the power of health data.

Key figures



80%

of health data is 'unstructured' – stored in its native or raw form, in hundreds of formats such as lab results, images and medical transcripts.



878%

The quantity of health data has grown at an explosive rate of 878% since 2016 and is continuing to grow exponentially.



30%

Health data represents the largest segment of data from any industry – estimated at 30% – and is growing faster than any other sector. Yet, the health sector is using **less than 5%** of the data for decision making purposes (World Bank Group, 2023).

Examples of how 'Data Saves Lives'



Cervical cancer

Analysis of the data generated by routine cervical screening of women across Europe revealed the link between HPV and cervical cancer and the need for regular screening. This has the potential to prevent illness and save lives.



Colon cancer

Anonymous patient data from two independent sources (Maccabi Health services in Israel and the UK Health Improvement Network (THIN)) was analysed to develop a new algorithm (computer program) to calculate the risk of people aged over 50 of having colon cancer.



The result: The computer program is now available as part of a colorectal cancer screening system in the UK and Israel, allowing clinicians to encourage patients at greater risk of colorectal cancer to come forward for screening.



A cornerstone of health data in Europe: The European Health Data Space (EHDS).



Tour de table:

Who is familiar with the European Health Data Space, and how do you see the pros and cons of this legislation?

We want your feedback



What is the EHDS?



1

What is the EHDS?



- The **COVID-19 pandemic** provided a very tangible and compelling example of the value of sharing up-to date health data in order to develop effective public health measures and to respond to a crisis. It led to a significant increase in the uptake of digital tools and the sharing of health data, but the full potential of sharing health data has yet to be realised.
- **Definition:** It is a first-ever health-specific data sharing framework that will build on existing legislation to establish:

- clear rules,
- common standards,
- practices,
- and digital infrastructures.



In simple terms, it will clarify how health data can be shared and used throughout the EU Member States.

2

Central issues the EHDS aims to address

1

Continuity of care for patients

This will be of particular benefit to improve coordination of care between different specialists, to ensure a patient's history follows them when changing healthcare providers, if patients become ill while travelling to another part of the country or if they move to a different EU country.



2

Consistent and efficient sharing of health data across the EU

- A key issue is the fact that Member States currently use **different Electronic Health Record systems** to store health data, making it difficult to share this efficiently (this is referred to as '**lack of interoperability**').
- Member States also have **different rules on how that data can be accessed and controlled** due to differences in interpretation of the General Data Protection Regulation (GDPR) which governs the collection and processing of personal information in the EU.



Implementation timelines.

2027

Within two years of the entry into force of the regulation (March 2029), the European Commission aims to adopt implementing acts and establish common specifications to ensure interoperability, data quality, and technical standards. Member States will designate *Health Data Access Bodies (HDABs)* and *Digital Health Authorities (DHAs)* within two years.



2029

Within four years (March 2029), certain key types of electronic health information, like patient summaries and electronic prescriptions, will be made accessible for patients and healthcare providers under MyHealth@EU.



2031

Within six years (March 2031), these rules will expand to include more types of health data, such as medical imaging results like X-rays, lab test reports, and hospital discharge summaries.



2033

Within eight years of entry into force (March 2033), the European Commission will conduct an evaluation of the implementation of the Regulation. If necessary, the report of the evaluation will include recommendations or proposals for necessary changes.



2035

Within ten years (March 2035), all the rules about using health data for research and other secondary purposes will be fully in place. The EU will have a fully connected system, called HealthData@EU, to allow countries to share health data securely and effectively. This will mark the complete implementation of the regulation.



Who will benefit from EHDS?



Patients

Able to access and share data more easily, while being reassured that the data will be always protected.



Health professionals

Access a patient's medical history, even when the data were generated in another EU country.



Researchers

Will have faster access to larger amounts of high-quality representative data that will be available in a more efficient and less expensive way.



Regulators and policymakers

Will have easier access to health and epidemiological data. This has the potential to lead to more effective and tailored policymaking.



Industry

Will benefit from improved access to de-identified (anonymised or pseudonymised) health data – vital for the development of innovative medicinal products.

Real life examples.



Primary use

Primary data use relates to information that has been collected about an individual during health care provision and is used by healthcare professionals to make a diagnosis, further assess their health or to treat that individual.

Scenario 1



A Spanish resident is **on holiday in Portugal** when he is involved in a car accident and loses consciousness. The emergency doctor treating him accesses his medical records through the EHDS and MyHealth@EU system and discovers that he has a severe **allergy to penicillin**. With this critical information, the doctor ensures that penicillin is not administered during the surgery, thereby delivering **safe and effective care**. Details of the treatment provided in Portugal are then added to his medical records, making them available to his healthcare providers when he returns to Spain.



Secondary use

Secondary data use refers to data that has already been collected by others, including healthcare professionals in hospitals or in doctor's offices, and that is re-used for a different purpose such as research and innovation, and service planning. Secondary use data is based on data from multiple patients that has been de-identified.

Scenario 1



During a **new flu outbreak**, health authorities across the EU use the EHDS to **monitor the spread of the disease in real-time**. Aggregated and anonymised data from hospitals and clinics are analysed to identify hotspots and predict the trajectory of the outbreak. This data-driven approach allows for timely public health interventions, such as targeted vaccination campaigns, and reallocation of resources to the most affected areas, ultimately **reducing the spread of the flu and saving lives**.

How does the EHDS change patients' rights?

What patient data will be affected?



Patient summaries

(an extensive set of key clinical data including health problems, medication, vaccinations, treatment plans, etc.)



Electronic prescriptions



Electronic dispensations

(information that a prescription has been used).



Medical imaging studies and related imaging reports



Medical test results, including laboratory and other diagnostic results and related reports



Discharge reports

Example

Maarja, a 45-year-old woman from Estonia living with chronic obstructive pulmonary disease (COPD), visits a new pulmonologist after her symptoms worsen. Her **patient summary** gives the specialist an overview of her diagnosis, allergies, vaccinations, current medicines and previous treatments. The doctor orders blood and lung function tests, whose **medical test results and related reports** are recorded electronically, as well as a chest CT scan, with the **medical images and imaging report** stored in her health record.

Following these examinations, Maarja is briefly admitted to hospital for treatment. When she leaves, her **discharge report** records the care she received, changes to her treatment and the follow-up required. Her pulmonologist issues an **electronic prescription** for a new inhaler, which Maarja collects from her local pharmacy. The resulting **electronic dispensation** confirms that the medicine has been supplied, completing a digital record of her care pathway.





How can I control my data?

1

Right to access your own data



You will be able to **access your electronic health data** through a secure health data access service. In some cases, the data will only become available after a healthcare professional has explained it to you.

2

Right to report inaccuracies



If you find incorrect information in your electronic health record, you can **ask your healthcare provider to check and correct it**. However, you cannot change the information yourself.

3

Right to add information



You can **add your own health information** to your electronic health record, such as data from compatible health or wellness apps (including blood glucose, blood pressure, heart rate, physical activity or sleep data). However, the information you add will be marked as provided by you and kept separate from information added by healthcare professionals.

4

Right to restrict access to your own data



You can choose to **restrict healthcare professionals from accessing all or some of your health data**. You can change your decision at any time. In exceptional circumstances, authorized healthcare professionals may temporarily access your restricted data if necessary to provide safe care.

5

Right to opt out of primary use



If your Member State introduces this option through national law, you can **choose to opt out of sharing your health data for primary use** (the provision of healthcare). Healthcare providers will continue to record your health information, but neither you nor your healthcare professionals will be able to access your electronic health data through the EHDS, except in very limited circumstances.

6

Right to manage your proxy authorizations



You can **authorize another person to act on your behalf** in managing your electronic health data. For example, you can allow your spouse, another trusted person, or a legal guardian to access your health records, download prescriptions or help manage your healthcare.

7

Right to opt out of secondary use



You can **choose not to have your identifiable health data used for other purposes**, such as research, innovation or policymaking. This is a separate choice from restricting access to your data for healthcare. If you want to do both, you need to choose each option separately. This right does not apply to anonymised data that can no longer be linked to you. In certain situations of public interest, such as a pandemic, countries may still allow your data to be used.

Challenges of the implementation – Patient perspective.



Definition of ‘public interest’

- One of the central criteria for the delivery of data permit by Health Data Access Bodies. Currently the definition is vague and patient communities fear that it fosters misuse of health data.
- Further define the ‘public interest’ definition included in the EHDS proposal, with common guidance and illustrative examples to ensure clarity and consistency across HDABs.



Ethical and scientific assessments of data permits

- Ethical and scientific assessments within HDABs are important to protect patients’ fundamental rights and prevent the misuse of data.
- Patient organisations of these countries expressed concerns that the ambitious deadlines set out under the EHDS and beyond the EHDS, the general call to simplify and shorten the timeframes for issuing data permits, would place the countries relying of these ethical and scientific assessments in a difficult position.



Patient involvement

- **The EHDS Stakeholder Forum:** we hope this forum will function as a true advisory board, whose feedback and recommendations are actively incorporated.
 - **The EHDS Board:** Where patient organisations can be invited as regular “experts” by the EHDS Board.
 - **At national level, within Health Data Access Bodies (HDABs):** We call for the integration of formalised ‘Patient and Public Advisory Boards’ directly within HDABs.
- We believe it is important that patient involvement is built into HDAB governance structures from the very beginning of EHDS implementation, rather than being added later as a corrective measure once concerns about legitimacy or trust emerge.



Unlocking the potential of real-world evidence.



Tour de table:

Are some of you involved in projects around real-world evidence, and if so, what is the goal of this project?



We want your feedback!

Definition of RWE.



Health-related information generated through routine clinical care, reimbursement activities, or patient interactions with medical devices.

Common sources of RWD include:



electronic health records (EHRs),



administrative claims and billing data,



information collected from devices such as wearable monitors and implantable sensors.



A potential revolution.

In the past, our health data was largely confined to medical records stored personally or in a family doctor's practice or hospital.

Today, while some European countries still rely on paper records, **digital health devices are part of everyday life.**

Many people wear a smartwatch or fitness tracker. These personal wearable devices can be used to monitor our sleep patterns, track levels of activity or calorie consumption or record pulse rate.

Patients with certain health conditions may use sensors to monitor vital signs such as blood sugar or heart rate.



Potential of RWE for patient communities.

1 Unmet medical need (UMN).



- **General Pharmaceutical Legislation:** Advocating for a broader definition of UMN that goes beyond mortality or morbidity and includes also criteria relating to patients' quality of life. Because many lifelong chronic diseases, are not necessarily or no longer life-threatening, impose a significant burden on patients' quality of life.

➤  **RWD** – included through patient-led patients registries, among others – can also help better taking into account the notion UMN and broaden our vision of UMN.

2 RWE can also help compensating certain flaws – not all of them – of CTs.



- **Limited cross-border access to CTs** – including in small Member States and in Eastern Europe.
- **For elderly patients and patients living in rural areas**, have sometimes trouble commuting to the place where will take place the clinical trial.
- **Patient populations that might be underrepresented in CTs:** elderly patients, pregnant women, ethnic minorities, paediatric populations, and patients with multiple chronic conditions.

➤  So, on all of these examples, **RWE could bring an added value** and help better taking into account the needs of these patients.

3 Alignment with patient communities' values.



Equity:
by including patients who are often missing from clinical trials.



Adherence to treatment:
by showing real-life use.



Patient safety:
by looking beyond the short term.



Access and value assessment:
by informing choices of access and funding of new treatment.

Challenges from a patient perspective – Feedback of IDERHA's Patient Advisory Board (PAB).

1 Communication



Lay language

Patients must feel that there is a reliable protocol for using RWE in research. In other words, patients would like to have access to plain language description of the protocol, not necessarily get into the technical details of the protocols.



Informing about the use of data

Patients feel that there is generally a lack of transparency about how their data are used. Proactive communication on research results is one of the main avenues identified by patients to foster health data sharing.



Refocusing RWE in the patient journey

Some proposed to build a journey of patient engagement to make clear and easy-to-understand how and where patients can contribute all the way.

2 Special attention should be dedicated to monitoring



Biases

In every survey we are conducting, this always ranking very high.



Ensuring that the population typically underrepresented in CTs are taken into account in RWE studies.

Spotlight on patient-led registries.



Definition

- Structured databases collect, store, and manage health-related information about individuals with specific health conditions or characteristics in a real-world setting.
- Patient registries are one of the areas covered under the provisions for secondary use of data under the EHDS.
- Certain of our members are pioneers in this field: multiple sclerosis, homophilia, cystic fibrosis, Duchenne.



Potential



Evidence for pharmacovigilance.



Evidence on adherence to medicines.



Identifying meaningful clinical endpoints.



Better assessing the value of medical products.



The example of pharmacovigilance



- If patients are taking medications, most of the time they are doing it at home, when there are no healthcare professionals around. Whether they take them is a well covered secret, whether they have side effects it is difficult to track. Basically, pharmacovigilance happens when patients are in a doctor's office – so **5 days out of 365. It is an enormous data gap.**



- If you help tracking at home, if they are taking their medicines, what they are eating, what side effects they are experiencing – the more you can detail it, the more becomes available to the research to understand these side effects and personalising them. **It is also an enormous research opportunity.**

Toolkit

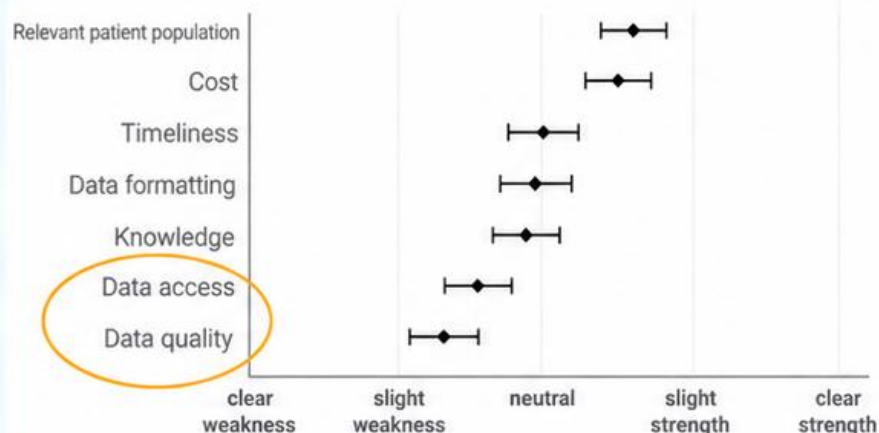


Part Three:
Establishing a
Community-Led
Patient Registry

Strengths and weaknesses of patient-led registries – insights from the More Europa project.



Perceived strengths and weaknesses of registry-based studies



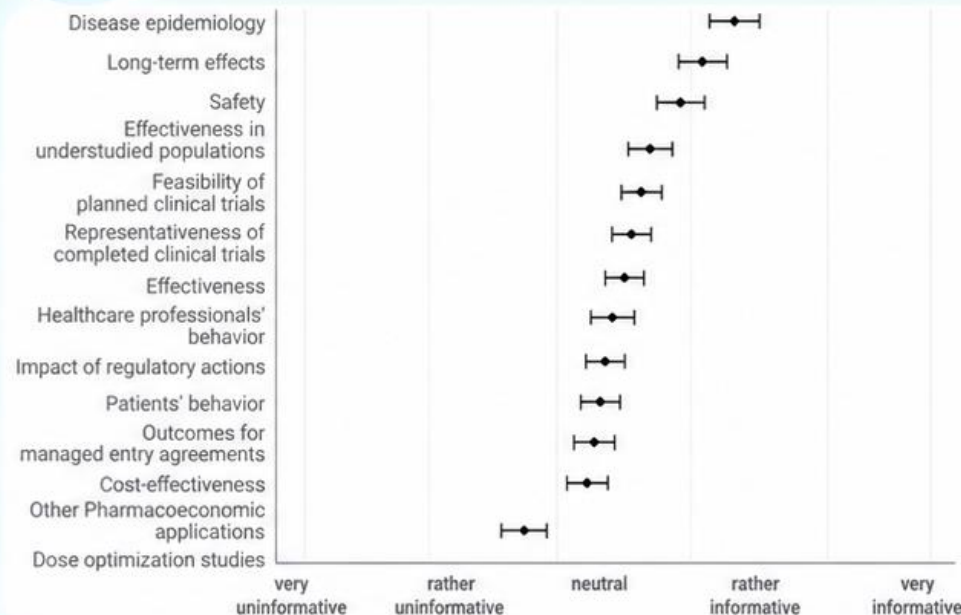
Relevant patient population is the **main asset**.
Cost of registry-based studies is good compared to trial information.



However, **data access** is one of the weaknesses because registries may be quite scattered around.
Data quality is one of stakeholders' concerns in using these data.



How informative are patient registry data for different aspects?



- Main advantage is the **long-term** component (**long-term effects**) but also **safety** – it is a matter of patient safety.
- **Effectiveness in understudied populations** is also seen as informative.
- **It supports clinical trials as well** (feasibility of planned clinical trials, representativeness of completed clinical trials).



Less relevant for **cost-effectiveness** – so less relevant for HTA?



**MORE
EUROPA**



Health data as a foundation for AI systems.

Patients' perspectives on AI in healthcare

Tour de table

What are according to you and from
a patient perspective, the benefits
of AI in healthcare?

What are your concerns about AI?

We want your feedback!

Benefits of AI in healthcare?



Concerns about AI?



The European Patients' Forum's (EPF) survey on Artificial intelligence

Innovation, AI & patient perspectives – enablers & challenges

EUPATI Annual General Meeting (AGM)

24 September 2026

Valentina Strammiello, Executive Director,
European Patients' Forum



Key questions

- Reliability and safety of AI technologies
- Adequacy of the current regulatory framework



Focus on patients

- Understand patient perspectives on AI in healthcare
- Patient acceptance is key for successful implementation



The survey

- Disseminated through our patient organisations members
- Translated into **25 languages**
- **~900** answers analysed with researchers from **KU Leuven**



KU LEUVEN



In partnership with
KU Leuven

Most patients feel hopeful about AI's potential to benefit healthcare



AI can bring important benefits to healthcare

Nearly all respondents (**98%**) believe that AI could bring benefits, particularly in:

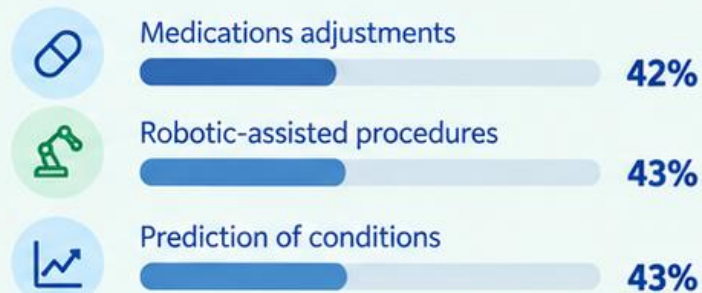


Different levels of comfort across AI applications

Patients reported they would be most comfortable with:



And less comfortable with:



Findings are broadly consistent over time, with one notable increase

Our 2021, 2023 and 2025 surveys show broadly consistent results, with one key difference:



The perception that AI can support patients' **self-management and adherence to treatments** has risen markedly.



This suggests growing awareness of AI-powered digital health tools such as medical devices, apps and wearables.

Positive views on AI in healthcare coexist with significant concerns



Many patients are not yet confident about how AI is applied in healthcare

A significant proportion of patients remain not very confident or not confident at all about how AI is applied in healthcare.



of patients are not very confident or not confident at all.



Main concerns about AI in healthcare



Lack of human empathy and personal touch



Biased AI-driven decisions



A consistent finding over time

These are also consistent findings across our three surveys (2021, 2023 and 2025).



2021 | 2023 | 2025

A strong demand for better patient information



It is not always clear to patients whether they have interacted with AI in their care.



More than 1 in 5 respondents said they were not sure whether AI had been involved in their care.



Patients prefer to receive information through trusted sources



Patients want to be informed early on



An overwhelming majority believe that doctors should inform patients about the use of AI at the **very beginning** of their visit or treatment.

Patients also emphasised the importance of explainable AI



Trust depends on understanding

Concerns about so-called “black box” AI systems were very prominent.



Trust AI only if healthcare professionals are able to **understand and explain its reasoning**.



Require **full transparency** in how AI makes decisions.



Key ways to improve AI literacy

Patients believe the following approaches are important to inform and engage the public:



Accessible educational materials and easy-to-understand resources

73%



Integrating AI literacy into healthcare education

62%



Dedicated support services to help patients understand AI in their care

52%



Media campaigns

47%



Workshops or seminars

40%

What exactly should patient information on AI in healthcare focus on?



France



Patients expect particularly reinforced patient information on **medical imaging** or **biological analysis**.



Netherlands



Focus on cases such as **disagreement between doctors and AI's diagnosis**, and who ultimately holds **responsibility for decisions**.



Czech Republic



Reflection on how patients can be **automatically informed when AI is involved** in their care (e.g. hospital websites, waiting room materials, medical records, physicians).

Healthcare professionals remain by far the most trusted actors to guide patients.



Key concerns about the impact of AI on the patient–doctor relationship

Patients' concerns about AI in healthcare are closely linked to fears that it could weaken or fundamentally change the patient–doctor relationship. The most frequently cited concerns are:



Loss of human empathy and personal touch

70%



Doctors might rely too heavily on AI

51%



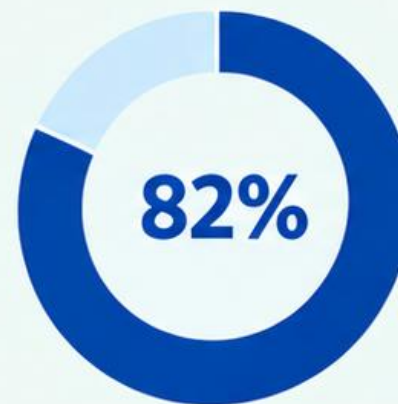
Use of AI tools that are not specifically approved for healthcare purposes

51%



Healthcare professionals are the most trusted source of information

Despite these concerns, healthcare professionals clearly remain by far the most trusted partners to guide patients in this new AI-enabled healthcare environment.



An overwhelming majority of respondents (82%) said they would prefer to be **informed about AI use directly through their doctor or healthcare professional.**

Patients expressed mixed views regarding how much control patients should have over the use of AI in their healthcare



Some (38%) agreed that AI could be used for **background or administrative processes**, but that patients should retain the right to refuse its involvement in medical decision-making.



Nearly one-third of respondents (30%) believed patients should have **full control over any use of AI in healthcare**, including administrative functions such as scheduling or medical record management.



A similar proportion (29%) stated that they **trust AI as long as healthcare professionals oversee the final decisions**.

Access to the full
report here:



A STRONG
PATIENTS'
VOICE
TO DRIVE
BETTER
HEALTH
IN EUROPE



Health data as a foundation for AI systems.

Patients' perspectives on AI in healthcare

Tour de table

What surprised you the most
in the EPF AI survey?

Any other comments?

We want your feedback!

