

Patient experience with the use of patient experience data (PED)

Fields marked with * are mandatory.

Introduction and data protection notice

Please note that the terms in **brown** are defined in the [attached glossary](#).

Purpose of the survey

To better understand the use of **Patient Experience Data (PED)** within the different therapeutic areas, the European Medicines Agency (EMA) has launched **four parallel surveys** targeting key stakeholder groups: **patients**, healthcare professionals and academic researchers, pharmaceutical industry, and **assessors**.

PED are data reported directly by patients without the intervention of a clinician or other third party. These data reflect patients' experience of their health status, symptoms, disease course, treatment preferences, quality of life and impact of healthcare.

This survey is specifically intended to patients and carers (individuals or **representatives** of an organisation). Its aim is to gain a clear view on patients' and carers' experiences with the use of PED across all therapeutic areas, and to identify potential gaps and unmet needs. This will also help further develop PED within the European Economic Area (EEA).

The survey takes **10-15 minutes** to complete. If you have any questions, technical or content-related, please use the [contact form](#).

Thank you very much in advance for your contribution.

Data protection notice

In this survey, the EMA does not collect or process personal data. Therefore, please make sure that you do not reveal your identity or include any personal data in the free text answers. The survey is designed to collect the answers only in an aggregate and anonymous format. The results will also be shared in an aggregated form and will not reveal individual responses.

For the collection of data in this survey EMA relies on the EU Survey external system. For more information on how EU Survey processes personal data, please see: <https://ec.europa.eu/eusurvey/home/privacystatement>. The allocation of respective roles, responsibilities, and practical arrangements between controller and processor can be found in the [Data Processing Agreement](#).

The EU Survey external system uses:

- Session "cookies" in order to ensure communication between the client and the server. Therefore, user's browser must be configured to accept "cookies". The cookies disappear once the session has been terminated.
- Local storage to save copies of the inputs of a participant to a survey in order to have a backup if the server is not available during submission or the user's computer is switched off accidentally or any other cause. The local storage contains the IDs of the questions and the draft answers.
- IP of every connection is saved for security reasons for every server request.
- Once a participant has submitted one's answers successfully to the server or has successfully saved a draft on the server, the data is removed from the local storage.

I confirm that I have read and understood the data protection notice.

Who are you?

You may choose to respond to this survey as an individual [patient](#) or [carer](#), or as a [patient organisation representative](#), if relevant.

* 1. In what capacity are you responding to this survey?

- As an individual patient
- As a carer
- As a patient organisation representative at national level
- As a patient organisation representative at EU level

What is your experience with Patient Experience Data (PED)?

Patient Experience Data (PED) are data collected via a variety of [patient \(or carer\) engagement](#) activities and methodologies to reflect patients' experience of their health status, symptoms, disease course, treatment preferences, quality of life, impact of healthcare, etc.

For EU regulators, PED do not only involve quantitative sources of evidence (e.g. [patient reported outcomes](#) or [patient reported experience measures](#)), but also qualitative sources (i.e. any information obtained as part of [patient engagement](#) activities that reflect the wider perspective of patients' experience, for example, the outcome of [focus groups](#), surveys or interviews, [patient preference studies](#), etc.).

PED ensure that medicines development and approval have taken account of patients' perspectives and experience of living with a particular condition, and ultimately lead to more patient-relevant outcomes.

* 2. Please select the main therapeutic area/field that concerns you.

(You will have the option to select a second one further down in the survey.)

Cardiovascular diseases (incl. diabetes and obesity)

* 3. Within the selected therapeutic area/field how would you rate the following aspects:

	Very good	Good	Satisfactory	Unsatisfactory	Nonexistent (unmet medical need)	I'm not sure
* the range of medicines treating diseases	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* the focus on patients and their experiences in the development of medicines	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* the focus on patients and their experiences in the regulatory assessment of medicines	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* the focus on patients and their experiences in cost-benefit analysis and reimbursement decisions of medicines	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

3.1 Please feel free to elaborate on your responses.

While there is a variety of medicines available to treat cardiovascular diseases, it is difficult to fully assess the breadth and effectiveness of the current treatment options due to gaps in research, especially in prevention, early detection, and population-specific therapies. The focus on patient experiences throughout the development, regulatory assessment, and reimbursement of medicines is currently unsatisfactory. The European Heart Network has consistently highlighted the need for a more patient-centered approach across the CVD care pathway. Although the European Medicines Agency (EMA) has taken considerable steps to incorporate patients' feedback—such as through Scientific Advisory Group meetings and engagement opportunities in workshops—patients' perspectives are still not sufficiently integrated into clinical development programs, regulatory decision-making, or cost-benefit analyses. This limits the alignment of therapies with real-world needs and outcomes. Greater involvement of patients and healthcare professionals in all stages—research, regulation, and reimbursement—is essential to ensure treatments not only meet clinical standards but also address patient priorities and improve quality of life. EHN advocates for stronger EU-level policies and funding to support patient-centered innovation and care in cardiovascular health.

* 4. What do you think PED should be mainly used for, in the selected therapeutic area/field?

between 1 and 3 choices

- To understand the patients' needs
- To determine what treatments work better than others
- To explore [patient preferences](#)
- To identify gaps in care
- To improve the quality of care
- To gain insight into the safety profile of the medicine
- To identify treatments that need to be developed
- For regulatory decisions ([benefit/risk assessment](#) for new products/new indications)
- For reimbursement purposes ([HTA outcome](#))
- Other

* 5. Has your organisation ever collected and shared data that would qualify as PED within the selected therapeutic area/field?

- Yes, several times
- Yes, once
- No

* 5.1 What type of PED has your organisation collected and shared?

Multiple answers possible.

- Patient survey/questionnaire data
- Interviews
- [Focus group](#) discussion data
- [Patient preference studies](#)
- Observational studies designed to capture PED
- Quality of life assessments (e.g. [patient reported outcomes \(PROs\)](#))
- Input into a regulatory procedure (e.g. public hearing, meeting with regulators, [third-party intervention...](#))

- Social media monitoring data
- Other

* 5.2 What were the data about?

Multiple answers possible.

- The therapeutic area/field in general
- A specific disease/condition
- A specific treatment
- General health
- The healthcare system in relation to a specific condition
- Other

* 5.3 Do you believe that, within the selected therapeutic area/field, collecting/sharing PED had an impact on

	Yes	No	I'm not sure
* Understanding the patients' needs	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Improving the quality of care	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Improving treatment development	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Increasing public trust in the healthcare system	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Increasing patient engagement	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Supporting the regulatory decision-making	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Supporting the reimbursement strategy	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Other	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

* If other, please give further details.

Guiding research priorities: Highlighting unmet needs or patient-reported outcomes that influence future clinical studies.

* 5.4 Has your organisation faced any of the below challenges when collecting/sharing PED?

Multiple answers possible.

- Data privacy and confidentiality
- Data quality and accuracy, bias (leading to lack of standardisation and difficulty to use the data)
- Lack of patient engagement
- Technical/linguistic
- No, none
- Other

5.5 Please let us know if you have any further comments about your organisation's experience of collecting /sharing PED in this therapeutic area/field.

Collecting and sharing patient experience data in the CVD field is valuable but challenging. Feedback often comes in different formats and at varying levels of detail, making it hard to standardise or compare. Templates and structured data collection tools can help, but they also risk omitting nuanced patient perspectives or introducing bias. Greater harmonisation of data collection methods, combined with flexible approaches that capture the richness of patient experiences, would improve the utility of PED for research, regulatory, and policy purposes.

* 6. What resources do you believe can facilitate the conception/collection/review and assessment of PED in the selected therapeutic area/field?

between 1 and 3 choices

- Scientific publications
- Clinical guidelines
- EU regulatory bodies guidelines
- International regulatory bodies guidelines
- Initiatives by patient groups
- Training by patient organisations
- Data catalogues (such as the [HMA-EMA Catalogue of real-world data \(RWD\) sources](#))
- All listed above
- None
- I'm not sure

6.1 Please feel free to elaborate on your response.

Not all patient organisations have the resources to implement structured data collection independently, yet they remain an extremely valuable channel for gathering patient experience data. Targeted support for smaller patient organisations, particularly in regions with fewer resources, such as Eastern Europe, is essential to ensure equitable and comprehensive PED collection. Guidance and training from EU regulatory bodies can help standardise approaches and maximize the quality and utility of the data collected.

* 7. Within the selected therapeutic area/field, are you aware of any data sources that include PED which would be useful in medicine development and/or for regulatory decision-making that are currently **not** in the HMA-EMA Catalogue of [real-world data \(RWD\)](#) sources?

The [HMA-EMA Catalogue of RWD sources](#) is a public online repository of information on data sources that facilitates regulators, pharmaceutical companies and researchers to discover adequate data for generating real-world evidence when investigating the use, safety and effectiveness of medicines.

- Yes
- No

* Is there a second therapeutic area/field you would like to input on?

- Yes
- No

Where are PED the most useful?

- * 8. In your opinion, for which therapeutic area/field is the use of PED the most relevant/needed?

Please select only one option. You will be able to select a second one further down.

Cardiovascular diseases (incl. diabetes and obesity)

- * 8.1. What do you think it is the most useful for, in the selected area/field?

between 1 and 3 choices

- To better understand the patients' needs
- To improve the quality of care
- To improve treatment development
- To increase public trust in the healthcare system
- To increase patient engagement
- To support regulatory decisions
- To support the reimbursement strategy
- Other

- * 8b. Please select the second therapeutic area/field for which you think the use of PED is the most relevant /needed.

Pregnancy

- * 8b.1. What do you think it is the most useful for, in the selected area/field?

between 1 and 3 choices

- To better understand the patients' needs
- To improve the quality of care
- To improve treatment development
- To increase public trust in the healthcare system
- To increase patient engagement
- To support regulatory decisions
- To support the reimbursement strategy
- Other

Please let us know if you have any suggestions to improve PED in general, or anything else you would like to share about PED.

Patient experience data (PED) is vital for patient-centered care and decision-making in cardiovascular health. To improve PED, standardisation with flexibility is needed to capture nuanced perspectives, alongside support and training for smaller patient organisations, particularly in under-resourced regions. Collaboration across patient groups, healthcare professionals, regulators, and researchers, as well as secure digital tools and data catalogues, can maximise the quality, accessibility, and impact of PED.

Thank you very much for taking the time to respond.

*Thank
you!*

Background Documents

[Survey on Patient experience data - Glossary.pdf](#)

Contact

[Contact Form](#)