You report a side effect to your doctor. It disappears into the system somewhere. But what actually happens to it next? Who looks at it, what do they do with it, and could it ever help someone else?

SAFEPOLYMED

SafePolyMed.eu

Improving Safety in Polymedication by Managing Drug-Drug-Gene Interactions

Safety in Polypharmacy training 2026

Session 6 - Video 1/2

Safety Signal Reporting & Digital Health Tools

Pharmacovigilance, Risk Management, and How to Report a Side Effect

Tamika Lang, Joan Jordan, Olga Millán

LeukaNET Leukemia Advocates Network

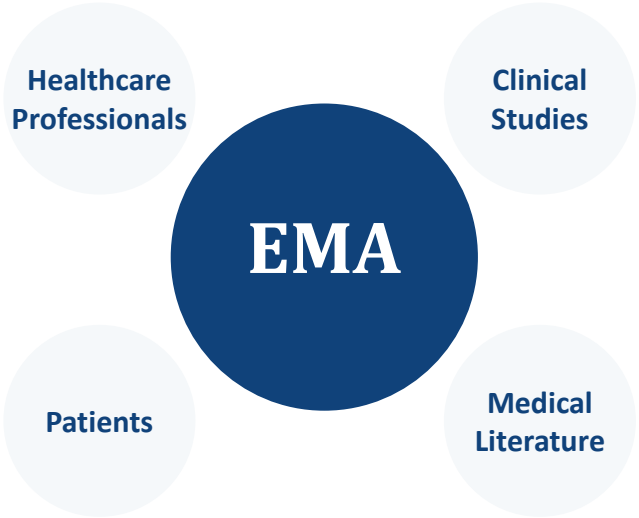
Patvocates PATIENT ENGAGEMENT IS IN OUR DNA

Funded by the European Union

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What Is Pharmacovigilance?

Pharmacovigilance is the science of detecting, assessing, understanding and preventing adverse effects of medicines. Defined by the WHO and put into practice across the EU through Good Pharmacovigilance Practices (GVP).





PRAC

Pharmacovigilance Risk Assessment Committee

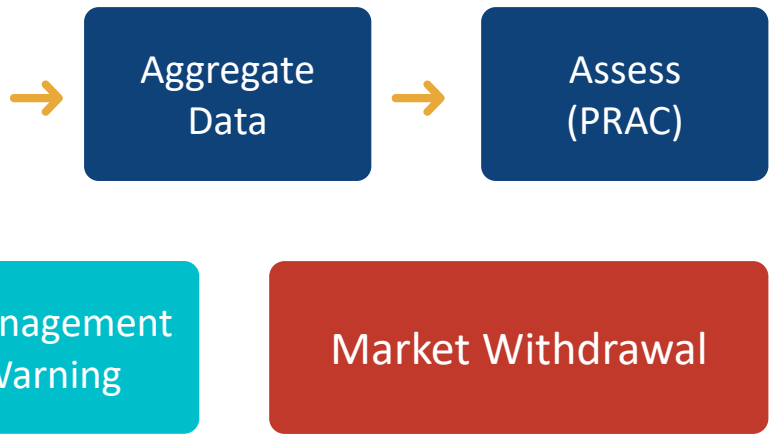
PRAC (patients included) meets monthly to review safety concerns

https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/good-pharmacovigilance-practices

https://www.youtube.com/watch?v=V9TN8nrbGOg

The Goals and Steps of Pharmacovigilance

- Monitor risk-benefit
- Detect ADRs early
- Find risk factors
- Share information

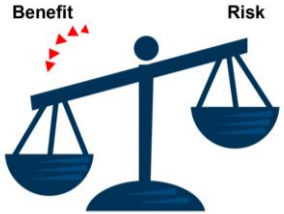


📌 *1990s example: fenfluramine-phentermine (a weight-loss drug combination) was withdrawn from the market after safety signals revealed serious heart valve risks.*

https://ctu.rmi.edu.pk/pharmavigilance/

Understanding Risk Management

No medicine is without risk. Risk and benefit must always be weighed deliberately and never left to chance.



Risk Management

Safety Profile

All identified & potential risks, plus what is still unknown

Risk Assessment

Ongoing pharmacovigilance. Both routine & additional monitoring

Risk Management Plan (RMP)

The plan to minimise risk. Updated across the medicine's lifecycle

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https://ctu.rmi.edu.pk/pharmavigilance

Medicines Under Additional Monitoring



This black, inverted triangle on packaging means the medicine is under additional monitoring, usually for five years. It is a signal to say please report any suspected side effects through your national reporting system.

This reporting is essential and complementary to all other pharmacovigilance activities to better understand the risks and safety profile of a new medicine in a real-life setting.

Example:

Valproate. A generic drug used to treat primarily seizure and bipolar disorder.
Found to cause birth defects when taken during pregnancy, and a black inverted triangle was added.

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https://eacpt.blogspot.com/2013/10/european-medicines-agency-publishes.html

The Benefits of Risk Management

Challenging and costly but ultimately reassuring.



Enhances the benefit-risk balance



Keeping complex medicines sustainably available on the market.



- Protects Patients
- Avoids Crisis
- Enhance Knowledge
- Builds Trust

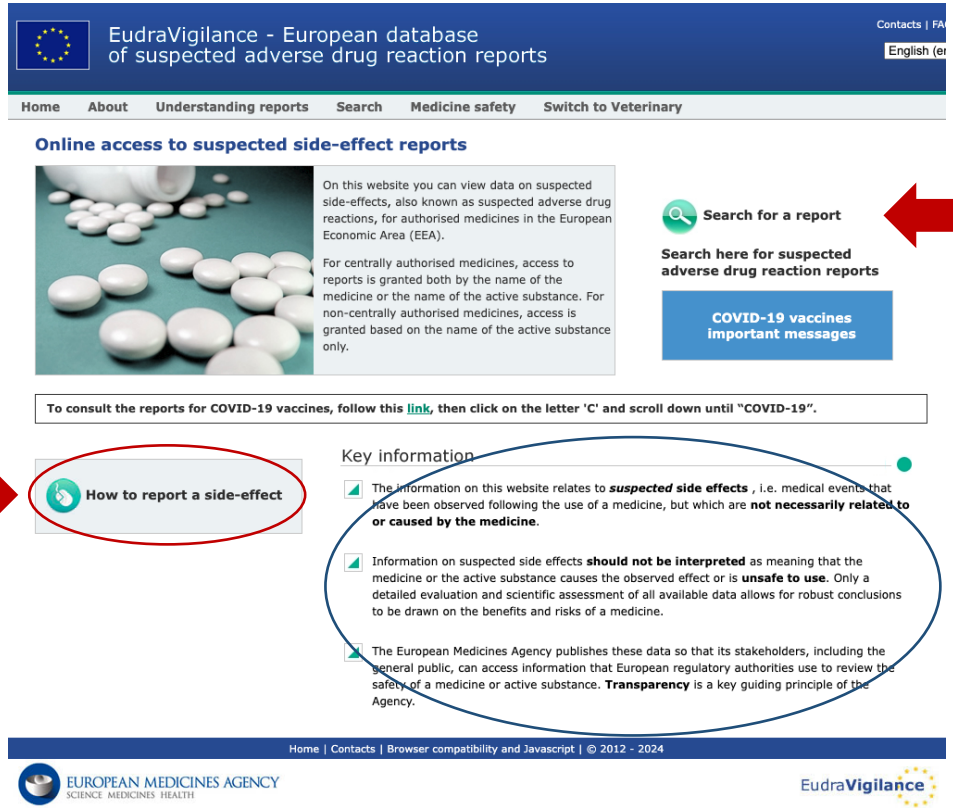
How to Self-Report a Side Effect

- ✓ Sex & age
- ✓ Side-effect description
- ✓ Medicine name & dose
- ✓ Batch number
- ✓ Other medicines taken
- ✓ Other health conditions

Then report via:

- Package Leaflet
- Doctor / Pharmacy
- National Authority
- EudraVigilance (EMA)

How to Self-Report a Side Effect



You can also search for other reports on suspected ADRs

It guides you

Key information

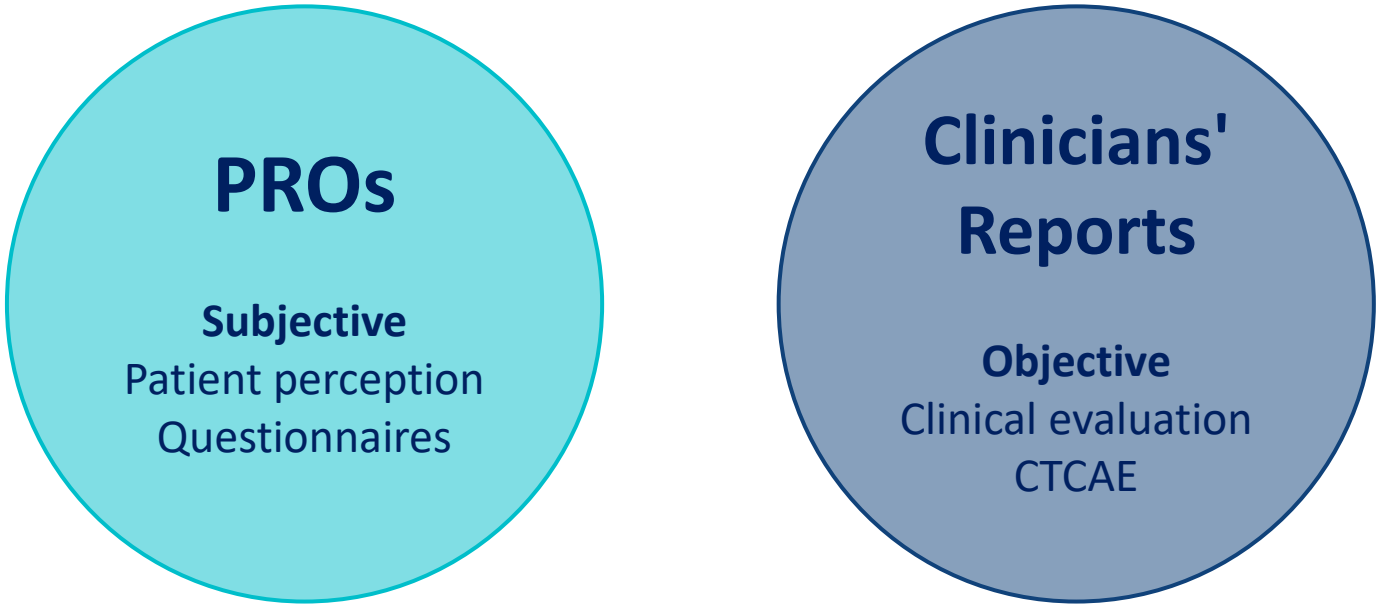
Source: European Medicines Agency, adrreports.eu; screenshot captured [15.09.2026]; annotations added by the authors.
https://www.adrreports.eu/en/index.html

How to Self-Report a Side Effect

💬 ***Real talk**: These systems aren't always easy to navigate. If you are stuck, look for direct contact information, a phone number or email, for your national medicines regulatory agency, and simply ask.*

Two Perspectives, One Fuller Picture

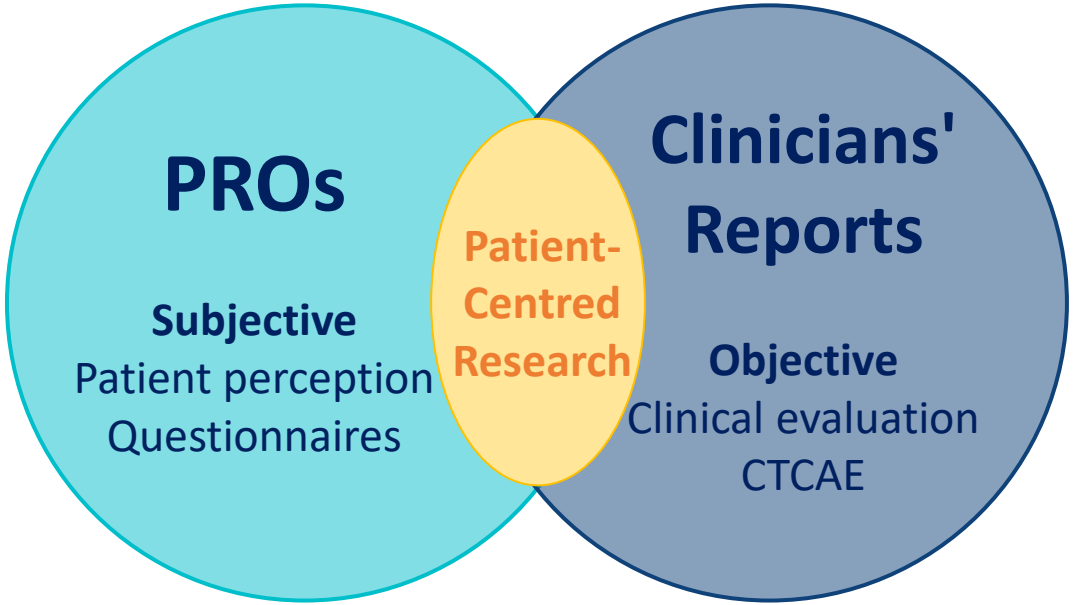
PROs vs. Clinicians' Reports



Neither is more "correct" They are complementary. Together they enable holistic, personalised care.

Two Perspectives, One Fuller Picture

PROs vs. Clinicians' Reports



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Key Takeaways

Pharmacovigilance only works if people participate in it, and that includes you.

- ✓ Know what pharmacovigilance does
- ✓ Understand risk management & additional monitoring
- ✓ Know how to report a side effect yourself

Coming up next: Video 2 — Digital Health Tools

Credits & Attributions

Authors

Tamika Lang | Olga Millán

AI disclosure

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Figures

- Benefit-risk balance scale illustration, adapted (Garbla via CleanPNG). https://www.cleanpng.com/users/@garbla.html
- Website screenshot “Online access to suspected side-effect reports” European Medicines Agency, adrreports.eu; screenshot captured [15.09.2026]; annotations added by the authors. https://www.adrreports.eu/en/index.html

Icons

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