

# Beyond Compliance: Doing More for Patients in Pharmacovigilance

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# Disclaimer

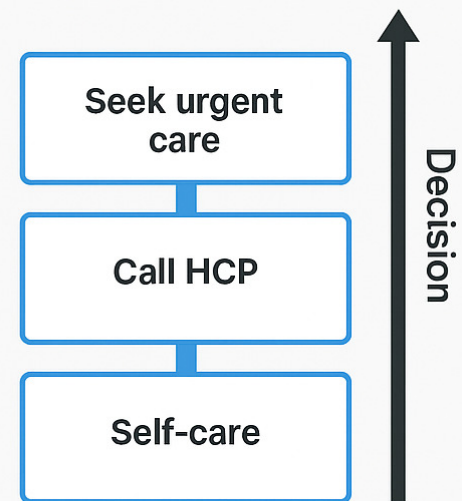
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# The Package Leaflet (PL): “Just words”?

## POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Talk to your HCP if you experience any of the following:

- Muscle pain
- Joint pain
- Back pain



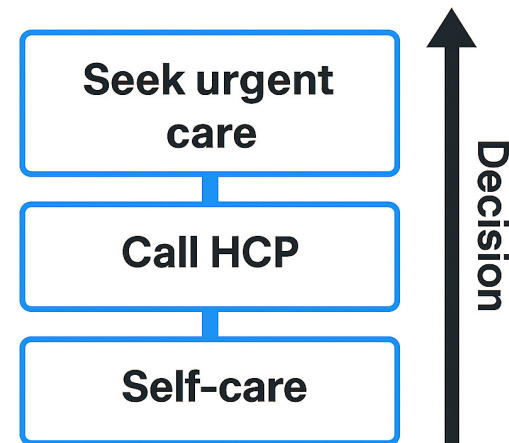
# A Patient Story (Lived experience)

Severe, sudden joint pain during treatment: “what should I do?”



# How well do our materials help patients make decisions in real-world situations?

- Do patients know what's expected vs concerning?
- Do they know when and how to act?



# Trust Matters

**18%**

of people report high  
trust in pharmaceutical  
companies \*

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Many patients start with uncertainty

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Low trust amplifies ambiguity

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Unclear safety language → migration to informal  
sources

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If patients do not know what to do, safety comms  
failed?

\*<https://www.clinicalleader.com/doc/patient-trust-in-pharma-is-low-here-s-how-to-rebuild-it-0001>, accessed on 27-Feb-26.

# Patient Engagement: Being Heard (not just “asked”)



*“Only patients - who live every day with their condition - can really say what causes them the greatest problems and what benefit of a medicine they value most.”*

Meaningful engagement  
= Insight



Decision change

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Understand what matters: experiences, priorities, concerns

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Not validation after decisions, continuous involvement

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*Publications: linking engagement with trust & feeling heard*

# Where patients can shape decisions



R&D



Clinical studies



Regulatory decision making



Post-authorization, PV



Clinical practice

- Study design, endpoints and participation criteria
- **Informed consent** content and design
- Safety communication
- Patient contributors in regulatory committees (PRAC/PDCO/COMP/CAT)
- **EMA** workshops on patient experience data for benefit–risk decisions
- Review and consultation of regulatory documents and public consultations
- Collaborations through EURORDIS, EUPATI, PFMD
- **Direct patient reporting**
- PROs
- Label design
- **PIL** content, user testing
- Workshops, public hearings, and stakeholder engagements for regulatory decision-making
- Patient preference studies
- **ARMM** design, content, user testing
- ARMM dissemination methods
- Awareness and educational activities for patients
- ...

# How can we move beyond tokenism to true listening?

## Tokenism

- Ask once
- Readability
- Sample of convenience

**VS.**

## True Listening

- Engage iteratively
- Actionability
- Representative users

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**Volume of input**

**≠ insight**

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**Aim for  
decision-relevant  
representativeness**

## PLs, Patient Guides... and real life

Available ≠ Accessible

Accessible ≠ Read

Read ≠ Understood

Understood ≠ Effective



# User testing & Global reality

One test, one language, one culture... enough?



Test with intended users (literacy, culture, language)



Assess decision-making, not just recall



Translate for meaning, not words



**User testing should not be a box-ticking exercise**

# Designing with patients: Practical considerations

## Who

- Target population (literacy/background/culture), sampling, representation

## How

- Survey, interview, focus group, user test, ad-board

## Where

- Face-to-face, phone, video, async

## What

- Questions in plain language tied to decisions

## Safeguards

- Confidentiality, privacy, consent, COI

## Ops

- Compensation, data access, costs, reimbursement, documentation

What does  
“muscle  
pain” mean  
in practice?

**Mild**

Manageable  
at home

**Moderate**

Call HCP  
within 24-48h

**Severe**

Seek urgent  
care

*illustrative; always product-specific and regulator-aligned*

Search



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Placeholder text for the second search result, consisting of three horizontal lines of varying lengths.

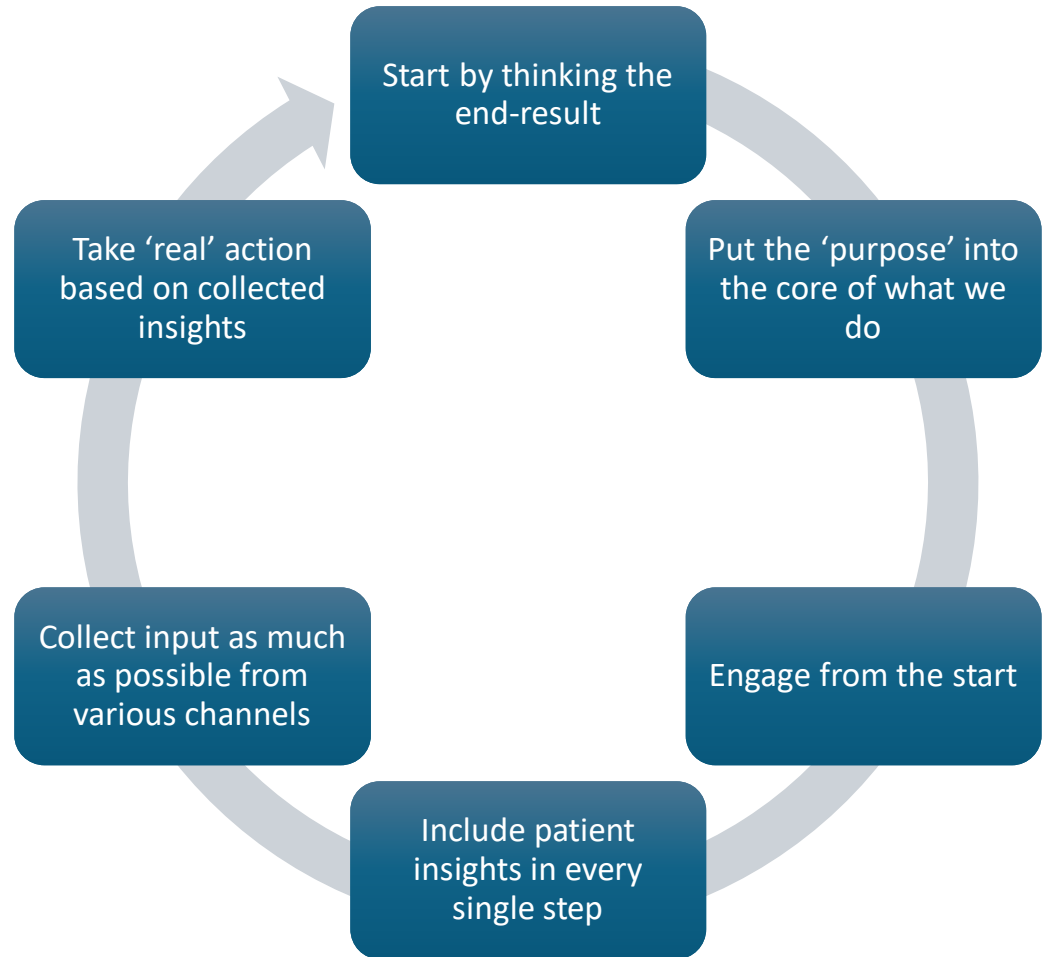


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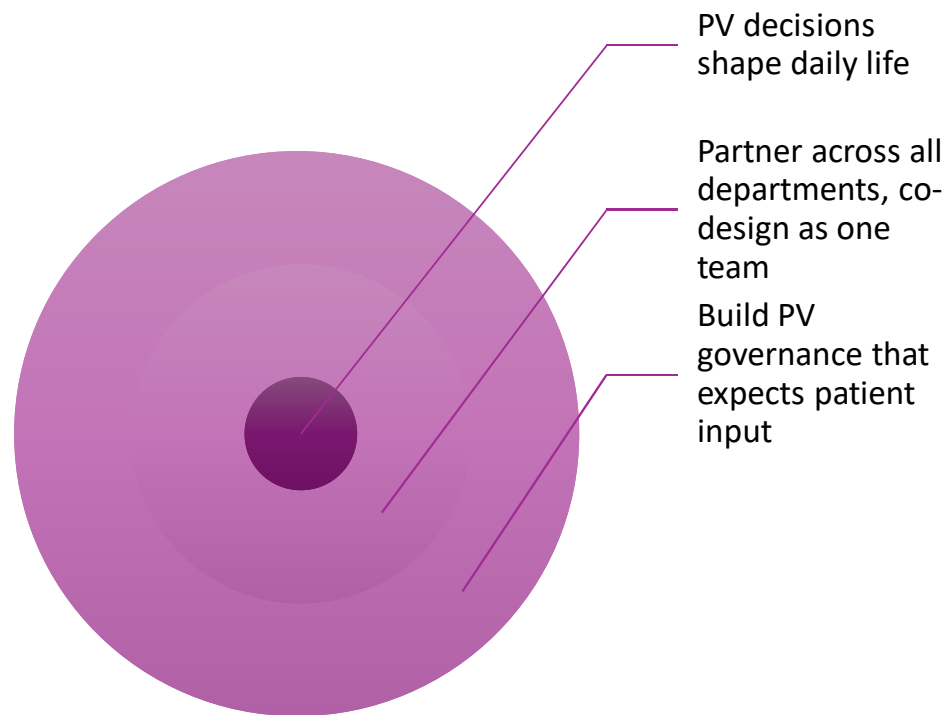
# The “black hole”

**When guidance fails,  
patients go elsewhere**

# Safety Communication That Guides Decisions



# Why not PV as a co-owner of patient engagement



# A Call to Listen, Connect and Do Better

Start with listening  
- truly listening

Ask better  
questions, seek  
meaning, not  
validation

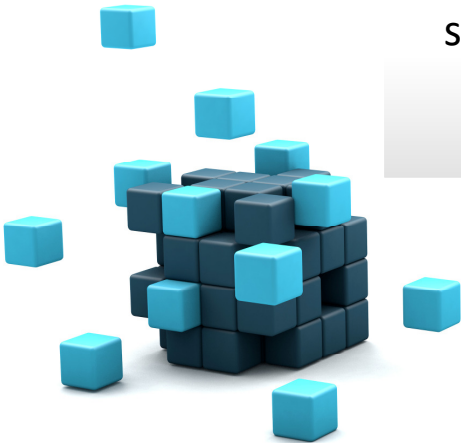
Test materials for  
understanding, not  
just readability

Engage patients  
earlier and  
throughout, not  
only at the end

Step outside the  
silo, talk across  
teams and  
functions

Keep  
communication  
simple, human, and  
useful

Aim to ease  
patients' lives, not  
add burden



# THANK YOU

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**SURVEY: Your one priority action?**

*sli.do*

*#3319005*