1. Specific post-authorisation needs to address remaining uncertainties.

- Approvals with no precedents on regulatory decision making and little CT evidence:

Enhanced post-authorisation obligations needed

- Evidence accepted for a risk-benefit decision is considered insufficient for drug access: **Drugs not reaching patients**

2. Challenges on using RWE

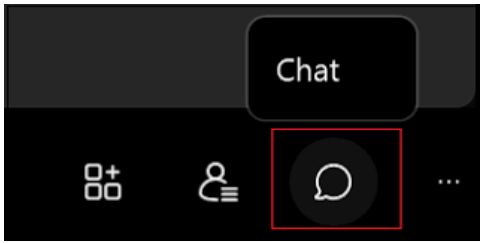
- Quality & fitness for purpose: **Is the RWE collected relevant to patients?**
- Build on lessons learnt & challenges encountered: **Improved RWE strategy**
- Joint stakeholder collaboration & enhanced involvement and communication:

Early involvement of patients, PIs, registry holders, regulators, HTAs

Session 3 panel discussion

- Patricia McGettigan (PRAC)
- Pamela Dobay, Meritxell Sabidó (Industry)
- Lars Wallentin (ESC)
- Kelly Plueschke (EMA)
- Mencía de Lemus (CAT)
- Peter Mol (Chair)

→ **Feel free to include your questions in the Webex chat**



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