

# Patient perspectives on the role of PROMS in the evaluation of medical devices

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Core-MD Webinar

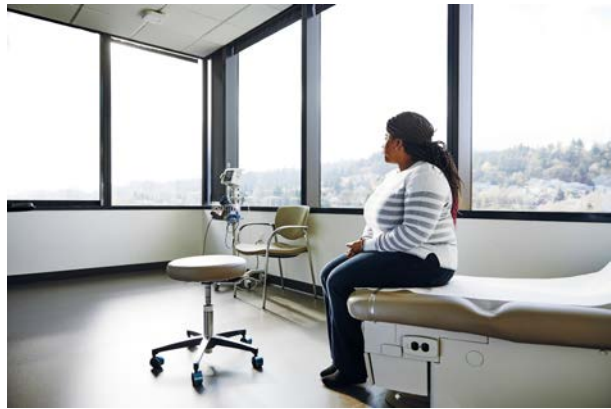


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# Delphi study overview



Patient-centric research

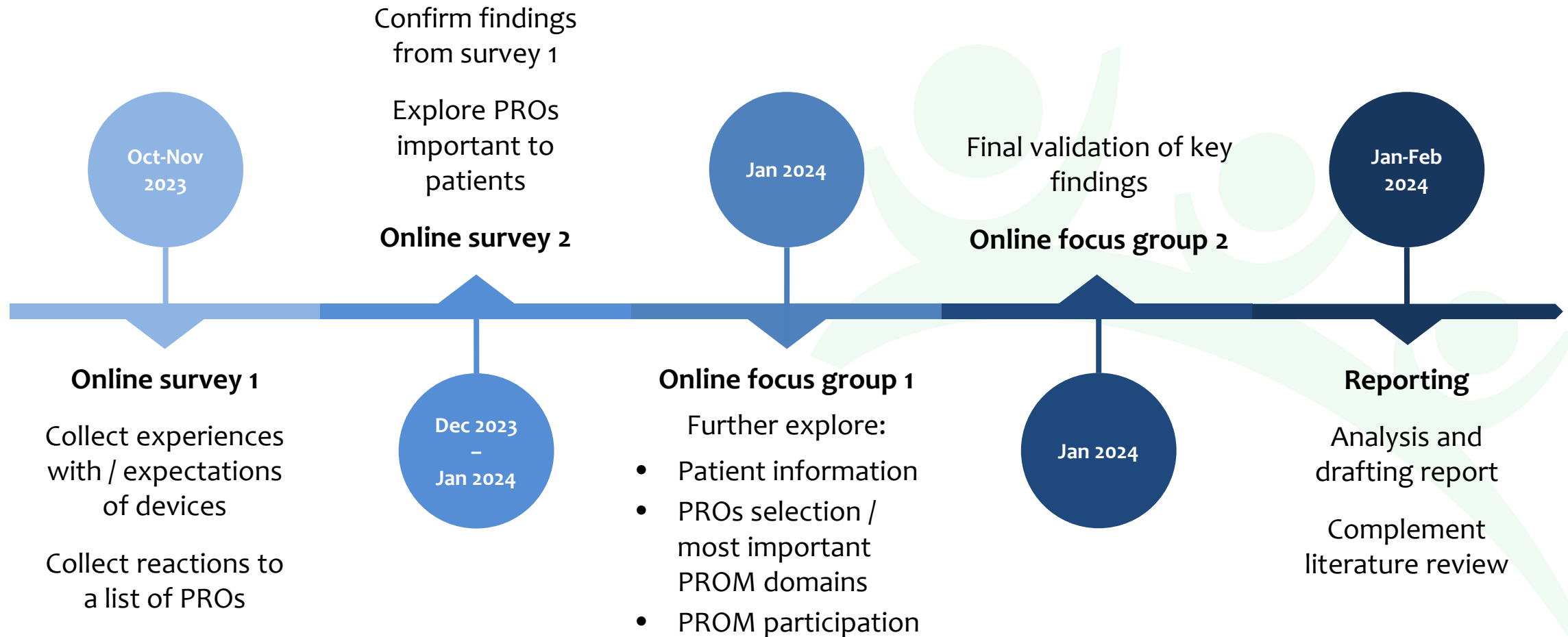


Consensus on PROMs' use and utility

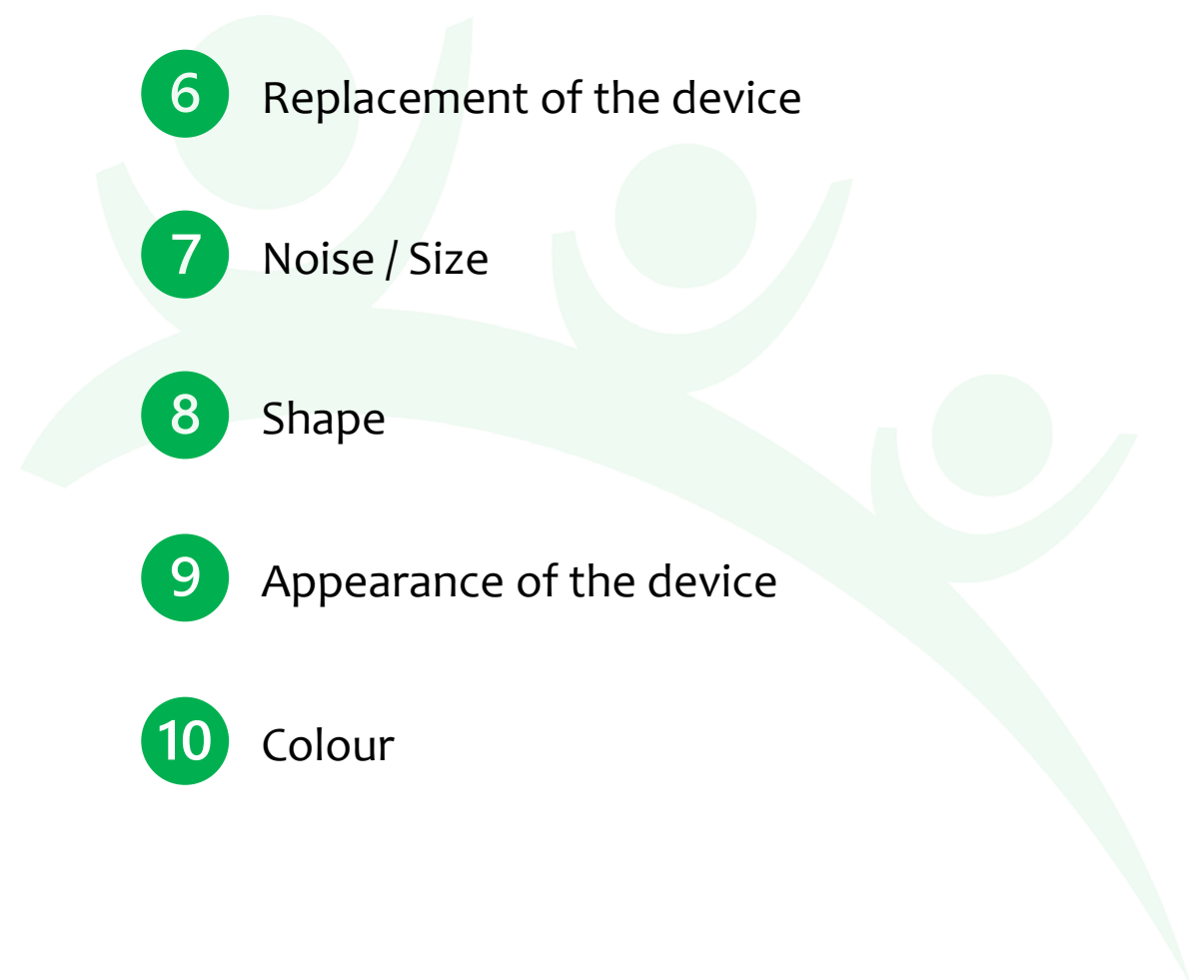


Complementing the literature review

# Approach



# Patient experiences with medical devices

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- 1 Safety and performance of the device
  - 2 Concerns about malfunctioning
  - 3 Security
  - 4 Control of the device
  - 5 Comfort
  - 6 Replacement of the device
  - 7 Noise / Size
  - 8 Shape
  - 9 Appearance of the device
  - 10 Colour

- **Limited familiarity** with PROMs among patients
- **Co-creation and feedback pathways** need to be clearer for patients
- **Frequency of PROM use:** 3-6 months; patients should see why it is important (for them) to participate
- **Detail and format of PROM questionnaires:** online or printed, at clinic or at home

- **Importance of different device choices for patients:** patients want to have a say
- **Desired information and learning materials:** combination of different materials/formats
- **Importance of visual information:** explanatory videos, etc.
- **Role of online communities:** peer-to-peer exchange of experience on social media – moderation needed

# The importance of patient involvement

1. **Develop a set of core indicators for PROMs** per disease area that addresses patients' concerns and capture information that is relevant from their perspective, to inform healthcare decisions and further research needs.
2. **Clearly communicate** the objectives of PROM collection, inform patients about the use of their feedback, and share results/updates with them.
3. **Facilitate PROM collection** (frequency, format) to ensure patients' engagement and willingness to contribute.
4. **Develop ways to integrate PROMs**, and patient experience data more generally, **in the regulatory process** for medical devices and assessment of the risk-benefit.
5. **Involve patients throughout the lifecycle of medical devices**, including in the development of information/communication materials that address their needs.



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