

## References

1. US Food and Drug Administration. Value and Use of Patient-Reported Outcomes (PROs) in Assessing Effects of Medical Devices: CDRH Strategic Priorities 2016-2017. FDA; 2017.
2. US Food and Drug Administration. Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation. FDA; 2022.
3. US Food and Drug Administration. FDA Patient-Focused Drug Development Guidance Series for Enhancing the Incorporation of the Patient's Voice in Medical Product Development and Regulatory Decision Making. FDA; 2022.
4. US Food and Drug Administration. Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labelling Claims: Guidance for Industry. FDA; 2009.